

English edition of Japanese Medical Device Nomenclature (JMDN) and the definitions is arranged. These are provided for the convenience of users unfamiliar with the Japanese language. These contents are the latest and information except here will be aligned with these contents shortly. When and if any discrepancy arises between the Japanese original and its English translation, the former shall prevail.

As of Oct, 2021(rev. July 2024)

Japanese Medical Device Nomenclature (JMDN)	Definition	JMDN Code	Classification	Rule	QMS Requirements	Designated MDs requiring maintenance
Reusable ultrasound probe for central nerve/central cardiovascular system surgery	A probe used for surgery of the central nerve/central circulatory system. It refers to a hand-held ultrasonic transducer assembly designed to be placed at the surgical site to take images of localized surgery. It is also called a surgical probe or a fingertip probe. It includes the configuration of various transducer assemblies that consist of single or multiple elements that convert voltage into an ultrasonic beam. The assembly determines the direction of the ultrasonic beam mechanically or electronically, focuses, and detects the reflected echo. This category includes ultrasonic transducers used for mode A, mode B, mode M, Doppler, Color Doppler (CD), and dual (combination image, Doppler or color flow) scanning. As a part of the design of transducer casing or housing assembly, the route to introduce the biopsy needle may be incorporated. This device is reusable.	40770004	IV	7-⑤,7-⑥	applicable	applicable
Polygraph with cardiac catheter	A device to test hemodynamics in each site of the heart by inserting the catheter into the heart. The device includes the catheter.	70052004	IV	7-⑥	applicable	applicable
Vessel diameter measuring system with cardiac catheter	A device with a cardiac catheter to measure the balloon diameter and the blood vessel diameter. The catheter is inserted into the coronary artery or other vessel. Then, the balloon located near the tip of catheter is dilated, and the inner pressure obtained by the tip of catheter are sent to the dedicated external measuring device. The data are processed in the measuring device.	70053000	IV	7-⑥	applicable	applicable
Vessel temperature measuring system with cardiac catheter	A device with a cardiac catheter to measure vascular wall temperature. The catheter is inserted into the stenotic segment of the coronary artery or other vessel, and the temperature sensor located near the tip of catheter is pressed against the vascular wall for measurement. The catheter and the temperature measuring device are connected using a dedicated connector.	70054000	IV	7-⑥	applicable	applicable
Cortical electrode	A conductor used on the surface of or deep inside the brain temporarily or for a short period in order to stimulate the brain or record cerebral electrical activity.	32545000	IV	7-⑤	applicable	—
Cardiac/central nerve stimulator	A probe for the heart and central nervous system specifically designed to be used with a stimulator.	36957004	IV	8-②	applicable	—
Flexible angioscope	An endoscope used to observe, diagnose, and treat conditions of the venous or arterial lumen. It is percutaneously inserted. This product is a fiberscope, in which images are transmitted through a fiber optic bundle.	34010000	IV	6-⑤	applicable	applicable
Flexible arterioscope	An endoscope used to observe, diagnose and treat (in some cases) conditions of coronary arteries, peripheral and intracardiac structures. The insertion section, which is made of flexible materials, is inserted into the vessel to be examined. A fiber optic bundle is used for the image transmission system.	34855000	IV	6-⑤	applicable	applicable
Flexible neuroscope	An endoscope used to observe, diagnose, and treat conditions of the central nervous system. The device is inserted through an opening in the skull created in advance. The shape of the insertion section of the product changes according to that of the body cavity. The image transmission system comprises a fiber optic bundle.	37181000	IV	7-⑤	applicable	applicable

Flexible myeloscope	An endoscope used to observe, diagnose, and treat conditions of the spinal cord. The device is inserted through an artificial opening. The insertion section is made of flexible materials, and a fiber optic bundle is used for image transmission.	70105000	IV	7-⑤	applicable	applicable
Flexible lumboscope	An endoscope used to observe, diagnose, and treat conditions of the lumbar spine. The device is inserted through an artificial opening. The insertion section is made of flexible materials, and a fiber optic bundle is used for image transmission.	70108000	IV	7-⑤	applicable	applicable
Flexible spinoscope	An endoscope used to observe, diagnose, and treat conditions of the spine. The device is inserted through an artificial opening. The insertion section is made of flexible materials, and a fiber optic bundle is used for image transmission.	70113000	IV	7-⑤	applicable	applicable
Flexible video myeloscope	An endoscope used to observe, diagnose, and treat spinal cord conditions. Inserted from an artificial opening. The insertion part is flexible, and equipped with a charge coupled device (CCD) chip that serves as an image transmission system.	70122000	IV	7-⑤	applicable	applicable
Flexible video lumboscope	An endoscope used to observe, diagnose, and treat lumbar conditions. Inserted from an artificial opening. The insertion part is flexible, and equipped with a charge coupled device (CCD) chip that serves as an image transmission system.	70125000	IV	7-⑤	applicable	applicable
Flexible video spinoscope	An endoscope used to observe, diagnose, and treat spinal column conditions. Inserted from an artificial opening. The insertion part is flexible, and equipped with a charge coupled device (CCD) chip that serves as an image transmission system.	70130000	IV	7-⑤	applicable	applicable
Flexible video angioscope	An endoscope used to observe, diagnose, and treat conditions of the venous or arterial lumen. Inserted percutaneously. This device is a videoscope that provides images via a charge coupled device (CCD) chip or other imaging components.	70140000	IV	6-⑤	applicable	applicable
Flexible video neuroscope	An endoscope used to observe, diagnose, and treat conditions of the central nervous system. It is inserted through an opening in the skull created in advance. The insertion section changes its shape corresponding to the shape of the body cavity. A videoscope is equipped with a charge-coupled device (CCD) chip for image transmission.	70142000	IV	7-⑤	applicable	applicable
Flexible video arterioscope	An endoscope used to observe, diagnose and treat (in some cases) conditions of coronary arteries, peripheral and intracardiac structures. Inserted into the target vessel. The insertion part is flexible. This is a videoscope equipped with a charge coupled device (CCD) chip that serves as an image transmission system.	70144000	IV	6-⑤	applicable	applicable
Rigid myeloscope	An endoscope used to observe, diagnose, and treat conditions of the spinal cord. The device is inserted through an artificial opening. This product is a rigid endoscope, by which the insertion section resists the body cavity. Relay lens optics are used for image transmission. Some types use a fiber optic bundle for image transmission.	35200000	IV	7-⑤	applicable	applicable
Rigid lumboscope	An endoscope used in direct contact with the central nervous system to observe, diagnose, and treat lumbar conditions. Inserted from an artificial opening. This device is a rigid endoscope, by which the insertion section resists the body cavity, and equipped with relay lens optics as an image transmission system. Some types are equipped with a bundle of optical fibers.	35568009	IV	7-⑤	applicable	applicable
Rigid neuroscope	An endoscope used to observe, diagnose, and treat conditions of the central nervous system. The device is inserted through an opening in the skull created in advance. This product has a rigid insertion section. Relay lens optics are used for image transmission, and some types of products have a fiber optic bundle.	36904000	IV	7-⑤	applicable	applicable

Single-use rigid neuroscope	A single-use endoscope to observe, diagnose, and treat central nervous system conditions. Inserted via a hole opened in the cranium in advance. The insertion part is rigid, and equipped with relay lens optics as an image transmission system. Some types are equipped with a bundle of optical fibers.	70148000	IV	7-⑤	applicable	—
Rigid spinoscope	An endoscope used to observe, diagnose and treat spinal column conditions. Inserted from an artificial opening. The insertion part is rigid, and equipped with relay lens optics as an image transmission system. Some types are equipped with a bundle of optical fibers.	70152000	IV	7-⑤	applicable	applicable
Transseptal needle	A needle for puncturing the atrial septum (oval fossa) in order to form a path through which to insert a catheter for vascular diagnosis/treatment. The needle is to be percutaneously inserted and advanced from the right atrium to the left atrium. This puncture needle is introduced percutaneously into the right atrium using a catheter introducer.	70209000	IV	6-⑤	applicable	—
Reusable cardiac aspiration needle	A long, thin, sharp, hollow needle used to aspirate (remove) fluid from pericardial cavity (pericardiocentesis). Usually it is a rigid needle long enough, i. e. , 10–18 cm, to pierce through the pericardium. It has a short bevel tip. This device is reusable.	44136000	IV	6-⑤	applicable	—
Single-use cardiac aspiration needle	A long, thin, sharp, hollow needle used to aspirate (remove) fluid from pericardial cavity (pericardiocentesis). Usually it is a rigid needle long enough, i. e. , 10–18 cm, to pierce through the pericardium. It has a short bevel tip. This device is for single-use.	44135000	IV	6-⑤	applicable	—
Catheter for central venous	A flexible tube that is usually introduced into a neck or thoracic vein, and inserted into the superior vena cava for purposes that include infusion of substances, aspiration of blood, and monitoring blood pressure. The proximal end of the tube is fixed to the patient for long-term use. Some types of product are cuffed.	10729100	IV	8-②	applicable	—
Catheter for antimicrobial central venous	A flexible antibacterial tube usually insert via a neck or chest vein into the superior vena cava in order to infuse a substance, aspirate blood or monitor blood pressure. The proximal end of the tube is fixed to the patient for long-time use. Some types have a cuff. In some types, antibacterial materials are used only for the cuff.	10729200	IV	7-⑥,13	applicable	—
Catheter for heparin-coated central venous	A flexible heparin-coated tube usually insert via a neck or chest vein into the superior vena cava in order to infuse a substance, aspirate blood or monitor blood pressure. The proximal end of the tube is fixed to the patient for long-time use. Some types have a cuff.	10729300	IV	8-②,14	applicable	—
Urokinase-coated central venous catheter	A flexible tube with urokinase usually insert via a neck or chest vein into the superior vena cava in order to infuse a substance, aspirate blood or monitor blood pressure. The proximal end of the tube is fixed to the patient for long-time use. Some types have a cuff. It contains biological urokinase.	10729400	IV	8-②,14	applicable	—
Central venous catheterization kit	A kit containing equipment for central venous catheterization. Typically, a catheter and an introducer needle are included in a kit.	16615110	IV	8-②	applicable	—
Heparin-coated central venous catheterization kit	A heparin-coated package that contains devices to be used when inserting a central venous catheter. Usually it includes a catheter and an introducer.	16615200	IV	8-②,14	applicable	—
Central venous catheterization kit with urokinase	A package that contains devices to be used when inserting a central venous catheter with urokinase. Usually it includes a catheter and an introducer.	16615300	IV	8-②,14	applicable	—
Antimicrobial central venous catheterization kit	An antibacterial package that contains devices to be used when inserting a central venous catheter. Usually it includes a catheter and an introducer.	16615400	IV	7-⑥,13	applicable	—

Peripheral insertion central venous catheter	A flexible tube that is introduced into a peripheral vein in order to infuse a substance, aspirate blood or monitor blood pressure. For insertion into the upper body, the tube is inserted via the axillary vein into the superior vena cava. For insertion into the lower body, the tube is placed in the inferior vena cava. The proximal end of the tube is fixed to the patient for long-time use.	36257100	IV	7-⑥	applicable	—
Heparin-coated peripheral insertion central venous catheter	A flexible heparin-coated tube that is introduced into a peripheral vein in order to infuse a substance, aspirate blood or monitor blood pressure. For insertion into the upper body, the tube is inserted via the axillary vein into the superior vena cava. For insertion into the lower body, the tube is placed in the inferior vena cava. The proximal end of the tube is fixed to the patient for long-time use.	36257200	IV	7-⑥,14	applicable	—
Peripheral insertion central venous catheterization kit	A kit containing equipment for inserting a peripherally inserted central venous catheter. Usually, a catheter and an introducer needle are included in a kit.	16615120	IV	7-⑥	applicable	—
Vascular perfusion catheter	A flexible tube to supply blood to the vascular bed. The device is used mainly to protect organs (e.g., cerebral and abdominal organs) when circulation is totally or partially suspended, or during surgery or catheterization (e.g., arterial surgery, carotid angioplasty).	10739100	IV	7-⑥	applicable	—
Heparin-coated vascular perfusion catheter	A flexible heparin-coated tube to supply blood to the vascular bed. The device is used mainly to protect organs (e.g., cerebral and abdominal organs) when circulation is totally or partially suspended, or during surgery or catheterization (e.g., arterial surgery, carotid angioplasty).	10739200	IV	7-⑥,14	applicable	—
Coronary artery cannula	A semi-rigid tube to be inserted into the coronary artery and used as a guide path for fluid. Usually, a removable trocar is used for insertion. This device is for single-use.	34896100	IV	6-⑤	applicable	—
Heparin-coated coronary artery cannula	A semi-rigid heparin-coated tube to be inserted into the coronary artery and used as a guide path for fluid. Usually, a removable trocar is used for insertion. This device is for single-use.	34896200	IV	6-⑤	applicable	—
Vena cava cannula	A semi-rigid or rigid tube to be inserted into the venae cavae and used as a guide path for fluid. Usually, a trocar is used for insertion. This device is for single-use.	34904100	IV	7-⑥	applicable	—
Heparin-coated vena cava cannula	A semi-rigid or rigid heparin-coated tube to be inserted into the venae cavae and used as a guide path for fluid. Usually, a trocar is used for insertion. This device is for single-use.	34904200	IV	7-⑥,14	applicable	—
Coronary perfusion catheter	A flexible tube used for coronary perfusion and fluid lavage.	34914100	IV	7-⑥	applicable	—
Heparin-coated coronary perfusion catheter	A flexible heparin-coated tube used for coronary perfusion and fluid lavage.	34914200	IV	7-⑥,14	applicable	—
Aortic cannula	A semi-rigid tube to be inserted into the aorta, and used as a guide path for fluid. Usually, a removable trocar is used for insertion. This device is for single-use.	35565100	IV	7-⑥	applicable	—
Heparin-coated aortic cannula	A semi-rigid heparin-coated tube to be inserted into the aorta, and used as a guide path for fluid. Usually, a removable trocar is used for insertion. This device is for single-use.	35565200	IV	7-⑥,14	applicable	—
Ventricular cannula	A semi-rigid or rigid metal or plastic tubular device to be inserted into the ventricle or atrium usually by using a trocar with a hard pointed tip. After the device is inserted and the trocar is removed, the device is left in situ to be used as the guide path to inject/discharge fluid, or as a guide path through which a catheter or surgical device can be inserted. This device is for single-use.	35891100	IV	6-⑤	applicable	—

Heparin-coated ventricular cannula	A semi-rigid or rigid, heparin-coated metal or plastic tubular device to be inserted into the ventricle or atrium usually by using a trocar with a hard pointed tip. After the device is inserted and the trocar is removed, the device is left in situ to be used as the guide path to inject/discharge fluid, or as a guide path through which a catheter or surgical device can be inserted. This device is for single-use.	35891200	IV	6-⑤,14	applicable	—
Coronary sinus cannula	A semi-rigid tube to be inserted into the coronary sinus in order to perform retrograde coronary perfusion/cardioplegia during cardiopulmonary bypass. The device may be equipped with a self-expandable low pressure balloon, which is usually used to cause retrograde blood flow in the coronary artery in the event of a contingent air embolism in the coronary artery. This device is for single-use.	36109100	IV	6-⑤	applicable	—
Heparin-coated coronary sinus cannula	A semi-rigid heparin-coated tube to be inserted into the coronary sinus in order to perform retrograde coronary perfusion/cardioplegia during cardiopulmonary bypass. The device may be equipped with a self-expandable low pressure balloon, which is usually used to cause retrograde blood flow in the coronary artery in the event of a contingent air embolism in the coronary artery. This device is for single-use.	36109200	IV	6-⑤,14	applicable	—
Cardiac catheter-tip electrode	A conductor installed at one end of a flexible tube which is inserted into the heart in order to detect a specific indicator when measuring cardiac output, or to assess left to right shunt in the heart. Used for cardiac electrophysiologic testing, and recording intracardiac electrocardiograms. This may also be used for temporary pacing and defibrillation.	11434100	IV	7-⑥	applicable	—
Heparin-coated cardiac catheter-tip electrode	A conductor installed at one end of a flexible heparin-coated tube which is inserted into the heart in order to detect a specific indicator when measuring cardiac output, or to assess left to right shunt in the heart. Used for cardiac electrophysiologic testing, and recording intracardiac electrocardiograms. This may also be used for temporary pacing.	11434200	IV	7-⑥,14	applicable	—
Ventricular cardiac catheter	A flexible tube with a specifically shaped tip designed to be inserted into the chambers of the heart such as the left and right ventricles. The distal end may have a hole in the tip or several side holes. The tube is inserted into a peripheral vessel, and the distal end is positioned in the left or right ventricle according to the ventriculography required.	17613000	IV	6-⑤,7-⑥	applicable	—
Thermal dilution catheter	A flexible tube equipped with a probe that monitors cardiac output by using thermodilution method.	34925100	IV	7-⑥	applicable	—
Heparin-coated thermal dilution catheter	A flexible heparin-coated tube equipped with a probe that monitors cardiac output by using thermodilution method.	34925200	IV	7-⑥,14	applicable	—
Pacing cardiac catheter	A flexible tube equipped with an electrode on the distal end. The electrode is inserted into the heart to control the heart rate.	35854110	IV	8-②	applicable	—
Pacing cardiac balloon catheter	A tube with flexible balloon equipped with an electrode on the distal end. The electrode is inserted in the heart to control the heart rate.	35854120	IV	8-②	applicable	—
Heparin-coated pacing cardiac balloon catheter	A flexible heparin-coated tube with balloon equipped with an electrode on the distal end. The electrode is inserted into the heart to control the heart rate.	35854200	IV	8-②	applicable	—
Catheter for central circulatory angiography	A flexible tube designed for injection of a contrast agent into vessels in the central cardiovascular system for vascular imaging in the target section of the body.	10688104	IV	6-⑤	applicable	—

Catheter for central circulatory arterial	A flexible tube designed that is usually inserted through arteries of the central circulatory system for infusion/suction. In order to measure arterial blood pressure continuously, the device is usually connected to an oscilloscope.	10689104	IV	7-⑥	applicable	—
Catheter for heparin-coated central circulatory arterial	A flexible, heparin-coated tube designed that is usually inserted through the arteries of the central circulatory system for infusion/suction. In order to measure arterial blood pressure continuously, the device is usually connected to an oscilloscope.	10689204	IV	7-④,14	applicable	—
Central circulatory arterial microflow catheter	A flexible tube to be inserted into the circulatory system in order to accurately measure the blood flow and pressure in arteries of the central circulatory system.	10691004	IV	7-⑥	applicable	—
Central circulatory transducer-tip catheter	A catheter with a microminiature pressure transducer built into the distal end. When inserted into a blood vessel of the central circulatory system, its mechanical and electrical characteristics change according to the changing pressures. The change is transmitted to the pressure monitor, and displayed.	15071104	IV	7-⑥	applicable	—
Heparin-coated central circulatory transducer-tip catheter	A heparin-coated catheter with a microminiature pressure transducer built into the distal end. When inserted into a blood vessel of the central circulatory system, its mechanical and electrical characteristics change according to the changing pressures. The change is transmitted to the pressure monitor, and displayed.	15071204	IV	7-⑥,14	applicable	—
Guiding intravascular catheter for central circulatory system	A flexible tube for a conduit through which a catheter or a guidewire is inserted to perform percutaneous endovascular surgery in the central circulatory system.	17846104	IV	6-⑤	applicable	—
Heparin-coated central circulatory guiding intravascular catheter	A flexible heparin-coated tube used as a conduit to insert a balloon catheter and guide wire in percutaneous endovascular surgery in the central circulatory system.	17846223	IV	6-⑤,14	applicable	—
Central nervous system transducer-tip catheter	A catheter with a pressure transducer built into the distal end. When inserted into the central nervous system, its mechanical and electrical characteristics change according to the changing pressures. The change is transmitted to the pressure monitor, and displayed.	70271000	IV	7-⑤	applicable	—
Spinal contact pressure monitoring kit	A kit containing devices used to measure blood pressure and cerebrospinal pressure invasively, in particular, devices that include domes and tubes and come into contact with the spinal column.	70272000	IV	7-⑥	applicable	—
Central circulatory cardiac output measurement kit	A kit that includes tube to measure cardiac output based on the changes in arterial pressure wave forms by measuring changes in blood flow in the blood vessels of the central circulatory system.	70274000	IV	7-⑥	applicable	—
Pulmonary artery catheter	A flexible tube with a dilation balloon at the distal end that is advanced from the superior and inferior vena cava into the pulmonary artery to measure pulmonary arterial pressure or perform pulmonary angiography.	35889000	IV	6-⑤,7-⑥	applicable	—
Intravascular optical coherence tomography catheter	A catheter and a guide wire used to observe a cross section of blood vessels using an optical fiber by light. For instance, optical coherence tomography visualizes internal microscopic structure of the tissues without physical invasion of the outer protective layers. This utilizes the nature of light that penetrates and is reflected at various degrees according to the type of the tissue.	70275000	IV	6-⑤,10-④	applicable	—
Valve dilation catheter guidewire and stylet	A guide wire (only the pre-shaped device is included) and a stylet used to guide a catheter for valve dilation or valve replacement to the target site in the heart.	70276000	IV	6-⑤	applicable	—
Coronary sinus blood collection catheter	A tube and a catheter used to collect blood from the coronary sinus (CS). The tip comes in various configurations that allow approaches from the femoral region or superior vena cava etc.	70277000	IV	6-⑤	applicable	—

Cardiac catheterization kit	A kit containing equipment used for inserting a cardiac catheter into the ventricle, atrium, or cardiac blood vessels. The kit includes equipment used for the central cardiovascular system.	10598000	IV	6-⑤	applicable	—
Catheter for central circulatory embolectomy catheter	A flexible tube designed to remove coagulated blood and other cellular components that could occlude the blood vessel of the central circulatory system. The device is not only used to remove occlusions in natural blood vessels, but also to remove occlusions in arteries and access grafts for hemodialysis.	10714004	IV	6-⑤,7-⑥	applicable	—
Central circulatory thrombectomy vibration catheter	A flexible tube with a vibrating tip to disrupt the thrombus in blood vessels of the central circulatory system into pieces small enough to be absorbed and eliminated. Introduced percutaneously or transluminally via the arterial wall.	70283000	IV	7-⑥	applicable	—
Cerebral thrombectomy vibration catheter	A flexible tube with a vibrating tip to disrupt the thrombus in the cerebral artery into pieces small enough to be absorbed and eliminated. Introduced percutaneously or transluminally via the arterial wall.	70284000	IV	7-⑥	applicable	—
Septostomy catheter	A catheter with a balloon or a blade to be used for atrial septostomy.	10747000	IV	6-⑤	applicable	—
Catheter for balloon dilatation angioplasty	A flexible tube for dilation of a narrowed vessel or dilation after stent placement in the vessel (an artery, vein, or shunt), except for coronary blood vessels or intracranial cerebral vessels, by controlled inflation and deflation of a balloon. The device usually consists of a double-lumen catheter with a balloon at the distal end. Some catheters have channels for pressure measurement or delivery of an angiographic agent, or have a balloon with blades, wire, or the like.	17184014	IV	6-⑤	applicable	—
Catheter for coronary balloon dilatation angioplasty	A flexible tube used for dilation of a narrowed coronary artery vessel by controlled inflation of a dilating balloon. The device usually consists of a double-lumen catheter with a balloon at the distal end. Some catheters have channels for pressure measurement or delivery of a contrast agent. Some catheters have a balloon with blades, wire etc.	17184024	IV	6-⑤	applicable	—
Catheter for cerebral balloon dilatation angioplasty	A flexible tube used to dilate stenotic cerebral arteries by controlling the degree of balloon dilation. The device usually consists of dual lumens with a balloon at the distal end. Some have side holes for pressure measurement or delivery of contrast agent.	17184034	IV	6-⑤	applicable	—
Laser angioplasty catheter	A flexible tube equipped with optical fibers for vaporizing atherosclerotic plaques directly by a laser in constricted or occluded blood vessels.	17185000	IV	6-⑤	applicable	—
Balloon dilatation valvuloplasty catheter	A flexible tube with a balloon used for cardiac valvuloplasty and repair surgery.	17453000	IV	6-⑤	applicable	—
Atherectomy angioplasty catheter	A flexible tube and a catheter to remove (resection, perforation, pulverization, or cutting) atherosclerotic plaques percutaneously or transluminally via the arterial wall. The vascular wall becomes smooth after the removal, with the stenosis virtually eliminated.	17519000	IV	6-⑤	applicable	—
Balloon dilatation coronary perfusion angioplasty catheter	A flexible tube to dilate stenotic cerebral arteries by controlling the degree of balloon dilation. The device has holes in the proximal and distal parts of the balloon. In order to prevent circulatory disorders in cardiac muscles, the device ensures blood flow in the distal coronary artery during balloon dilation.	17521000	IV	6-⑤	applicable	—
Catheter guide wire for cardiac/central circulatory system	A device for adjusting the position of, or supporting the delivery of a catheter. The device is commonly made of coated or uncoated stainless steel, and coating facilitates its movement in the cardiovascular and central vascular systems.	35094114	IV	6-⑤	applicable	—

Heparin-coated cardiac/central circulatory catheter guidewire	A device used to adjust the position of the catheter and the lead wire and assist movement. It is made of heparin-coated stainless steel, or plastic. The coating facilitates movement in the heart and central circulatory system, preventing the thrombus formation.	35094214	IV	6-⑤,14	applicable	—
Central nervous system catheter guidewire	A device used to adjust the position of the catheter and lead wire and assist movement. Generally, it is made of stainless steel or plastic either coated or uncoated. The coating facilitates movement in the central nervous system.	35094124	IV	6-⑤,7-⑤	applicable	—
Central circulatory intravascular embolization prosthesis	An artificial device to be used to promote thrombus formation or to block the blood flow in arteries or veins of the central circulatory system for therapeutic purposes.	35449004	IV	8-②	applicable	—
Cardiac catheter-tip flow transducer	A cardiac catheter with a microminiature transducer built into the distal end to detect and measure blood flow. When inserted into a blood vessel, its mechanical and electrical characteristics change according to the changing blood flow. The change is transmitted to the base unit, and displayed.	36040104	IV	7-⑥	applicable	—
Heparin-coated cardiac catheter-tip flow transducer	A heparin-coated cardiac catheter with a microminiature transducer built into the distal end to detect and measure blood flow. When inserted into a blood vessel, its mechanical and electrical characteristics change according to the changing blood flow. The change is transmitted to the base unit, and displayed.	36040204	IV	7-⑥,14	applicable	—
Atherectomy ablative angioplasty catheter	A flexible tube to remove hardened, calcified atherosclerotic plaques percutaneously and transluminally via the arterial wall by means such as pulverizing atheroma into pieces small enough to be absorbed and eliminated through the reticuloendothelial system.	36073000	IV	6-⑤	applicable	—
Cardiovascular catheter guidewire	A device used to adjust the position of a coronary artery catheter and assist movement. Both coated and uncoated devices are available. The coating facilitates movement in the blood vessels. The device is usually made of metal but some are partially made of plastic.	70287009	IV	6-⑤	applicable	—
Central circulatory therapeutic tube and catheter	A tube and catheter used for thrombus removal and vasodilation in the central circulatory system. With an introducer and guide wire, the device is also used for treatment in the blood and lymph vessels.	70288000	IV	7-⑥	applicable	—
Central circulatory intravascular ultrasound catheter	A catheter that incorporates ultrasound for diagnosis in the blood vessels of the central circulatory system. The device is equipped with a transducer at the proximal end of catheter that sends and receives ultrasound signals.	70289004	IV	6-⑤	applicable	—
Cardiovascular suture assist tube	A device temporarily placed in the blood vessel during AC bypass surgery in order to secure blood flow during suturing. Generally, the vessel insertion part is either a shunt or sheet. Inserters made of various materials are used for some devices.	70290100	IV	6-⑤	applicable	—
Heparin-coated cardiovascular suture assist tube	A heparin-coated device temporarily placed in the blood vessel during AC bypass surgery in order to secure blood flow during suturing. Generally, the vessel insertion part is either a shunt or sheet. Inserters made of various materials are used for some devices.	70290200	IV	6-⑤,14	applicable	—
Coronary artery occluder	A device used to temporarily ligate and fix the coronary artery using a snare during the off-pump CABG. This device is for single-use.	70293000	IV	6-⑤	applicable	—
Retractable balloon	A device is inserted into the lower posterior part of the heart, and the balloon is dilated in order to alter the position of the heart and obtain exposure of the coronary artery during the off-pump CABG. This device is for single-use.	70294000	IV	6-⑤	applicable	—

Catheter for coronary wire-support	A catheter for secure a path for inserting a guide wire in percutaneous coronary angioplasty in patients with completely occluded stenosis in the coronary artery through which a guide wire is difficult to pass.	70295000	IV	6-⑤	applicable	—
Central circulatory microcatheter	A small-diameter catheter that can be used for a procedure, such as superselective angiography, which is performed by selecting a particular vessel in the central circulatory system. It has a function at the distal end to improve visibility so that the position can be confirmed under fluoroscopy.	70296004	IV	6-⑤,7-⑥	applicable	—
Fibreoptic oximetry catheter	A flexible tube with a bundle of optical fibers built in that transmits light with a specific wavelength to the blood, and detects the reflected/scattered light at the tip of the tube in order to determine the blood oxygen saturation. This is used with an oximeter.	31659100	IV	7-⑥	applicable	—
Heparin-coated fibreoptic oximetry catheter	A flexible heparin-coated tube with a bundle of optical fibers built in that transmits light with a specific wavelength to the blood, and detects the reflected/scattered light at the tip of the tube in order to determine the blood oxygen saturation. This is used with an oximeter.	31659200	IV	7-⑥,14	applicable	—
Heparin-coated fibreoptic oximetry catheter with thermistor	A flexible heparin-coated tube with a temperature monitoring thermistor and a bundle of optical fibers (that transmits light with a specific wavelength to the blood, and detects the reflected/scattered light at the tip of the tube in order to determine the blood oxygen saturation) built in. This is used with an oximeter.	31659300	IV	7-⑥,14	applicable	—
Intravascular occlusion for central circulatory system	A flexible tube with a dilation balloon at the tip (some are removable) for to block blood vessels of the central circulatory system.	32584004	IV	6-⑤	applicable	—
Balloon dilatation heated angioplasty catheter	A dedicated flexible tube with an expandable balloon designed to provide thermal energy to the site of the angioplasty in the coronary artery.	34109000	IV	6-⑤	applicable	—
Balloon pumping catheter	A catheter for the balloon pump of an auxiliary circulation device, and a balloon catheter to be placed in an artery for auxiliary circulation to the heart. The circulation is assisted by synchronizing the dilation/contraction of the balloon at the tip with the pulse. Used for severe cardiac failure such as cardiogenic shock after acute myocardial infarction, before/during/after high-risk cardiac catheterization and thoracotomy. The device is often used in emergencies in the former cases, and for scheduled use in the latter cases. This device is for single-use.	34919000	IV	7-⑥	applicable	—
Catheter for cardiac ablation	A powered flexible tube designed to surgically remove or partially alter the heart region.	35855000	IV	6-⑤,7-⑥	applicable	—
Oximetry catheter with balloon	A flexible tube with an expandable balloon at the distal end to monitor oxygen saturation in the right heart or pulmonary artery using an optical fiber.	35856100	IV	7-⑥	applicable	—
Heparin-coated oximetry catheter with balloon	A flexible heparin-coated tube with an expandable balloon at the distal end to monitor oxygen saturation in the right heart or pulmonary artery using an optical fiber.	35856200	IV	7-⑥,14	applicable	—
Radio-frequency thermal angioplasty catheter	A flexible tube that uses high frequency energy to heat a metal cap wound around the distal end of the tube or a metal belt around the tube in order to evaporate or melt the atherosclerotic plaque in blood vessels. The high frequency energy is delivered from an electric scalpel unit connected to a device that adjusts the energy level.	36074000	IV	6-⑤	applicable	—

Infusion catheter for coronary artery	A flexible tube for to locally infuse drugs (e.g., heparin) into a coronary vascular structure. Usually, it consists of a dual-lumen tube. While a drug solution being is infused into an artery from one lumen to immerse the vascular wall, the other lumen serves as a path for the guide wire. Furthermore, the device can also be used for thrombolysis in cardiovascular system.	36205000	IV	6-④,6-⑤	applicable	—
Thermal dilution catheter with oxygen saturation monitor	A flexible tube with a dilation balloon at the distal end that floats in the pulmonary artery when measuring pulmonary arterial pressure and mixed venous oxygen saturation.	36218100	IV	7-⑥	applicable	—
Heparin-coated thermal dilution catheter with oxygen saturation monitor	A flexible heparin-coated tube with a dilation balloon at the distal end that floats in the pulmonary artery when measuring pulmonary arterial pressure and mixed venous oxygen saturation.	36218200	IV	7-⑥,14	applicable	—
Cerebral perfusion catheter	A flexible catheter designed for retrograde cerebral perfusion with cool oxygenated blood. The catheter is a 2-lumen type with several side holes and a balloon at the tip. The catheter is percutaneously inserted into the internal jugular vein so that the side holes stay in the vein. In the case of a responsive subclavian venous valve, the balloon at the tip of catheter, which is used for cerebral perfusion, is dilated to occlude the drainage vein (superior vena cava and azygos vein). The catheter is used to protect the brain during deep hypothermic circulatory arrest in thoracic aortic surgery.	37696000	IV	6-⑤	applicable	—
Central nervous multi-lumen catheter	A flexible 2-lumen (or multiple-lumen) tube for the central nervous system used to infuse fluid into the body or drain fluid.	32330314	IV	7-⑤	applicable	—
Central circulatory multi-lumen catheter	A flexible 2-lumen (or multiple-lumen) tube for the central circulatory system used to infuse fluid into the body or drain fluid.	32330324	IV	7-⑥	applicable	—
Cerebrospinal catheter	A flexible tube used to remove and transfer spinal fluid from the central nervous system.	10704000	IV	8-②	applicable	—
Implantable cerebrospinal fluid reservoir	A device to retain spinal fluid when infusing drug solution and collecting spinal fluid. A catheter is connected to access cerebral ventricles and marrow cavity.	15874004	IV	8-⑥	applicable	—
Cerebrospinal fluid catheter	A flexible tube used to drain spinal fluid.	16133000	IV	7-⑤,8-②	applicable	—
Hydrocephalic shunt	A device used to transport excess cerebrospinal fluid from the brain to another absorption site within the body (the atrium or abdominal cavity) of a patient with hydrocephalus.	16244000	IV	8-②	applicable	—
Ventricular neurological catheter	A flexible tube to be surgically inserted from the cranium and through the brain to access cerebral cavity (cerebral ventricles) filled with spinal fluid.	32585010	IV	7-⑤	applicable	—
Implantable ventricular catheter	A semi-rigid or rigid tube designed that is usually placed permanently in order to administer a drug solution into the cerebral ventricle by connecting it to an implantable drug solution infusion pump. This device is for single-use.	32585020	IV	8-⑥	applicable	—
Catheter with measurement transducer	A flexible tube or catheter with a small pressure transducer built in at the distal end. Inserted in order to accurately measure intracranial pressure. Some types drain spinal fluid. When inserted into the cranium, its physical and electrical characteristics change according to the changing pressures. The change is transmitted to the pressure monitor, and displayed.	70301000	IV	7-⑤	applicable	—
Cerebrospinal drain tube	A tubular device used to drain spinal fluid from central nervous system into the cardiovascular system or peritoneal cavity in order to adjust the volume of intracranial fluid and pressure.	34586004	IV	6-⑤,7-⑤,7-⑥,8-②	applicable	—

Brain catheter	A semi-rigid tube to be inserted into the brain and drain fluid to decrease intracranial pressure. This device is for single-use.	34895000	IV	7-⑤	applicable	—
Postcraniotomy drainage kit	A package of sterilized tubes and other devices used to remove fluid from the brain after surgery.	35510000	IV	7-⑤,8-②	applicable	—
Ventricular drainage kit	A kit that containing devices including an externally installed tube attachable to a catheter for the cerebral ventricles to enable sterile drainage and measurement of spinal fluid.	36151000	IV	7-⑤,8-②	applicable	—
Hydrocephalic shunt auxiliary valve for prevention of excessive outflow of cerebrospinal fluid	An auxiliary valve that is concurrently used with a shunt to treat hydrocephalus in order to prevent excessive discharge of spinal fluid due to changes in posture.	70302000	IV	8-②	applicable	—
Hydrocephalic shunt connector	An implantable device used to stabilize the connection when using a hydrocephalus shunt.	70303000	IV	8-②	applicable	—
Hydrocephalic shunt holder	An implantable tool used to stabilize (fix) the hydrocephalus shunt.	70304000	IV	8-②	applicable	—
Peritoneovenous shunt	A plastic tube surgically implanted under the skin. Used to discharge ascitic fluid continuously from the peritoneal cavity to the superior vena cava.	13589000	IV	8-②	applicable	—
Peritoneovenous shunt replacement venous catheter	A silicone rubber tube that replaces a venous side catheter of an implanted ascites shunt when it is occluded.	70311000	IV	8-②	applicable	—
Peritoneovenous shunt valve kit	A kit that consists of a plastic or silicone rubber valved tube that percutaneously returns the excessive ascitic fluid to the venae cavae, a peel away sheath introducer set, and a subcutaneous conduction tunneller.	70312000	IV	8-②	applicable	—
Inferior vena cava filter	A filter placed in the inferior vena cava and used to capture the embolus such as a blood clot in order to prevent pulmonary embolism (e.g., pulmonary artery embolism).	70327000	IV	7-⑥,8-②	applicable	—
Intrathecal catheter	A semi-rigid or rigid tube that is usually designed to be connected to an implantable drug solution infusion pump, and placed permanently to administer a drug solution into the marrow cavity. This device is for single-use.	70336000	IV	8-⑥	applicable	—
Syringomyelia shunt tube	A shunt tube used to direct spinal fluid retained in the lumen of spinal cord (central canal) into the subarachnoid space.	70346000	IV	7-⑤	applicable	—
Programmable implantable infusion pump	A device to be implanted to administer narcotics, short-acting anesthetics, insulin, or antitumor agents. The dose is controlled by drug concentration or radio-frequency (RF) signals from an external programming device. The pump catheter is inserted into the epidural space of the spinal canal, marrow cavity or blood vessel.	35687000	IV	8-⑥	applicable	—
Long-term use implantable infusion port	A metal or non-metal device to be implanted in a patient in order to deliver a liquid or a drug into the vascular system or other anatomical region for a long-term use. It consists of the housing, self-sealing septum and catheter junction. It can be implanted in a range of anatomical sites.	35911104	IV	8-②	applicable	—
Heparin-coated long-term use implantable infusion port	A metal or non-metal heparin-coated device to be implanted in a patient in order to deliver a liquid or a drug into the vascular system or other anatomical region for a long-term use. It consists of the housing, self-sealing septum, catheter junction, and heparin-coated catheter. It can be implanted in a range of anatomical sites.	35911204	IV	8-②,14	applicable	—
Implantable catheter	A catheter to be connected to a metal or non-metal port and implanted in a patient in order to deliver liquid or a drug into the vascular system or other anatomical region for either short-or long-term use.	70384000	IV	7-①,8-②	applicable	—

Heparin-coated implantable catheter	A heparin-coated catheter to be connected to a metal or non-metal port and implanted in a patient in order to deliver liquid or a drug into the vascular system or other anatomical region for either short-or long-term use.	70385000	IV	7-①,8-②,14	applicable	—
Implantable catheter with urokinase	A catheter with urokinase that is to be connected to a metal or non-metal port and implanted in a patient in order to deliver liquid or a drug into the vascular system or other anatomical region for either short-or long-term use.	70386000	IV	7-①,8-②,14	applicable	—
Absorbable suture	A thread (including belt-like or tubular thread and string) made of absorbable material to be used for tissue suture/ligation and fixation of medical devices and tissue. It includes accessories such as needles.	34598000	IV	7-④	applicable	—
Catgut suture	A thread (including belt-like or tubular thread and string) made of absorbable material derived from ruminant to be used for tissue suture/ligation and fixation of medical devices and tissue. It includes accessories such as needles.	13898000	IV	7-④,14	applicable	—
Polyglycolic acid suture	A thread (including belt-like or tubular thread and string) made of polyglycolic acid to be used for tissue suture/ligation and fixation of medical devices and tissue. It includes accessories such as needles.	13908000	IV	7-④	applicable	—
Polydioxanone suture	A thread (including belt-like or tubular thread and string) made of polydioxanone to be used for tissue suture/ligation and fixation of medical devices and tissue. It includes accessories such as needles.	16584000	IV	7-④	applicable	—
Polyglyconate suture	A thread (including belt-like or tubular thread and string) made of polyglyconate to be used for tissue suture/ligation and fixation of medical devices and tissue. It includes accessories such as needles.	17246000	IV	7-④	applicable	—
Polyglactin suture	A thread (including belt-like or tubular thread and string) made of polyglactin to be used for tissue suture/ligation and fixation of medical devices and tissue. It includes accessories such as needles.	17471000	IV	7-④	applicable	—
Poliglecaprone suture	A thread (including belt-like or tubular thread and string) made of poliglecaprone to be used for tissue suture/ligation and fixation of medical devices and tissue. It includes accessories such as needles.	70407000	IV	7-④	applicable	—
Polyglycomer suture	A thread (including belt-like or tubular thread and string) made of polyglycomer to be used for tissue suture/ligation and fixation of medical devices and tissue. It includes accessories such as needles.	70408000	IV	7-④	applicable	—
Synthetic absorbable suture	A thread (including belt-like or tubular thread and string but excluding biological materials) made of absorbable material to be used for tissue suture/ligation and fixation of medical devices and tissue. It includes accessories such as needles.	70409000	IV	7-④	applicable	—
Polyethylene/polydioxanone suture	A thread (including belt-like or tubular thread and string) made of polyethylene/polydioxanone to be used for tissue suture/ligation and fixation of medical devices and tissue. It includes accessories such as needles.	70410000	IV	7-④	applicable	—
Collagen suture	A thread (including belt-like or tubular thread and string) made of collagen to be used for tissue suture/ligation and fixation of medical devices and tissue. It includes accessories such as needles.	13899000	IV	7-④,14	applicable	—
Implantable surgical tape	A sterilized cohesive material used to maintain organs and other internal structures. The material is biodegradable, and naturally decomposes in the body over time.	34046000	IV	7-④	applicable	—
Brachytherapy radiation source spacer	A spacer used to arrange therapeutic radiation sources at the target interval. The material is the same as that of suture thread.	70411000	IV	7-④	applicable	—

Absorbable gastrointestinal anastomosis coupler	A device used to connect/traverse excess tissue of the digestive organs using a joint with 2-ring components inserted into both ends of the junction. This is made of absorbable material, and is also used endoscopically.	18135004	IV	7-④	applicable	—
Absorbable vascular anastomosis coupler	A device used to connect the tissue of blood vessels using a joint with 2-ring components inserted into both ends of the junction. This is made of absorbable material.	18137004	IV	7-④,8	applicable	—
Vena cava clip	An implantable extravascular device used to prevent the passage of blood clots without stopping the blood flow by partially occluding the venae cavae.	34962000	IV	8-②	applicable	—
Intracranial aneurysm surgical clip	A device that, by accessing a blood vessel or another anatomic site, is used to stop blood flow in the aneurysm. A clip used in cerebral aneurysm clipping in which a clip is placed across the neck of the aneurysm or a vessel surrounding the aneurysm.	70421010	IV	8-②	applicable	—
Cerebral arteriovenous malformation surgical clip	A clip (including a type of clip similar to a stapler's staple) used to isolate the arteriovenous vessels in the surgical resection of cerebral arteriovenous malformations or brain tumors.	70421020	IV	8-②	applicable	—
Cerebral blood flow blockade clip	A clip used to temporarily block blood flow around the target site of cerebrovascular anastomosis.	70421030	IV	8-②	applicable	—
Cerebral artery damage restoration sheet	A sheet used with cerebral aneurysm clips to achieve hemostasis by wrapping the damaged blood vessel in the event of tumor artery perforation due to a detached brain tumor.	70422000	IV	8-②	applicable	—
Absorbable suture clip	A device used to close the wound or bundle the end of other tissues, and stop bleeding after resection. This is absorbable, and does not need to be removed.	34606010	IV	7-④,8-⑤	applicable	—
Absorbable implantable ligating clip	An absorbable, implantable device indicated for use in the conduits, blood vessels and other body tissues. It is used to prevent and stop leakage from the tissue. It may be loaded into a cartridge. Some cartridges and appliers have a built-in knife to sever the tissue. The device may be supplied pre-loaded into an applier.	34606020	IV	7-④,8-⑤	applicable	—
Implantable aneurysm clip	An implantable metal device indicated for use in the arteries, veins and the heart. Used to separate an aneurysm from the remaining blood vessel.	34958000	IV	7-⑥,8-②	applicable	—
Absorbable implantable fixation tissue staple	A U-shaped or spiral, absorbable device used to fix the tissue or connect the tissue and devices. The device may be used for suture/anastomosis along with surgical staplers. The staples are usually made of polymer, and may be loaded into a cartridge.	35615004	IV	8-⑤	applicable	—
Absorbable suture set	A set that combines various devices used for suture/ligation of tissues and blood vessels. Usually, it includes an absorbable suture thread, and other devices (e.g., non-absorbable suture thread, suture needle, non-woven fabric, automatic suture device, forceps, and clips) where necessary.	70424000	IV	7-④	applicable	—
Absorbable surgical mesh	An absorbable device used to cover and support soft and hard tissue after damage or degenerative disease. In case the device is made of biodegradable materials such as polyglycolic acid it can be used as a short-term implant.	16048004	IV	8-⑤	applicable	—
Absorbable ligament prosthesis	An implantable device that replaces or repairs the missing or damaged ligament structures, and restores their function. This is made of absorbable prosthesis.	35717004	IV	7-④	applicable	—
Absorbable banded gastroplasty prosthesis	An absorbable device implanted in part of the stomach for reconstruction or functional recovery. This consists of a part to be implanted into a specific site.	36111004	IV	7-④	applicable	—

Absorbable hernia/thoracic wall/abdominal wall prosthesis	An absorbable device used to restore weakened or missing thoracic wall and abdominal wall or hernia. Some contain non-absorbable prosthesis.	70433004	IV	7-④	applicable	—
Absorbable tissue reinforcement material	An absorbable material used to reinforce missing, weakened, and sutured organ/tissue. Automatic suture device may be used in conjunction. This is made of biodegradable substances such as polyglycolic acid, and glycolic acid-lactic acid polyester.	70434000	IV	8-⑤	applicable	—
Absorbable local topical hemostatic material	A device is made of materials to be absorbed in the body, used for local hemostasis, and indicated for surgical openings, and skin wounds or internal structures.	35895100	IV	8-⑤	applicable	—
Absorbable topical hemostatic material with collagen	An absorbable device made of collagen that is applied to a surgical incision, other skin wound, or an internal structure to achieve hemostasis.	35895200	IV	8-⑤,14	applicable	—
Absorbable hemostasis gelatine-containing local topical hemostatic material	An absorbable device coated with gelatin used for local hemostasis in surgical openings, skin wounds or internal structures. Some are adhesive.	35895300	IV	8-⑤,14	applicable	—
Albumin-containing adhesive	An albumin-containing general-purpose reagent that fixes the surface of a tissue onto the surface of another tissue or material.	33492204	IV	8-⑤,14	applicable	—
Aneurysmorrhaphy tissue adhesive	A substance such as glue and resin used to repair an aneurysm by adhering or closing the sac.	33511000	IV	8-⑤	applicable	—
Soft tissue adhesive	A biocompatible adhesive agent used to bond wounds to promote healing. It is made of acrylate or other synthetic substances.	34164100	IV	8-⑤	applicable	—
Collagen-containing soft tissue adhesive	A collagen-containing biocompatible adhesive agent made of acrylate or other synthetic substances used to bond wounds to promote healing.	34164200	IV	8-⑤,14	applicable	—
Central nervous cuff	A device such as silicone rubber sheath that covers the central nerve, and facilitates healing. It is used to prevent epidermal growth on scar tissue, or wrap the nerve end to prevent tumor formation.	33385004	IV	8-②	applicable	—
Absorbable adhesion-prevention dressing	A bioabsorbable device to be surgically implanted. Used to prevent abnormal fibrous adhesion of an organ or a part of the body to another part of the body.	34212000	IV	7-④	applicable	—
Central circulatory vascular cuff	A sheath device used to treat varicose veins that cover blood vessels of the central circulatory system, and prevent further damage. Usually, it is made of polymeric material.	34234004	IV	8-②	applicable	—
Absorbable periodontal tissue regenerative material	An absorbable material applied to lesions in the oral cavity by covering, coating, or filling, to restore periodontal tissues. Some materials contain drugs.	70436004	IV	8-⑤,13	applicable	—
Absorbable bone regeneration material	An absorbable material applied to lesions by covering, coating, or filling, to restore bone tissues. Some materials are intended to have biological effects, contain drugs, or are made of biologically derived materials.	70437204	IV	8-⑤,13,14	applicable	—
Collagen-containing dental bone regeneration material	A collagen-containing material applied to lesions in the oral cavity by covering, coating, or filling, to restore bone tissues.	70437304	IV	8-⑤,14	applicable	—
Porcine dental follicle derivative-containing periodontal tissue regenerative material	A material applied to lesions in the oral cavity by covering, coating, or filling, to restore periodontal tissues. It contains ingredients derived from swine tooth germ tissue.	70439000	IV	8-⑤,14	applicable	—
Soft tissue injection material with collagen	Injectable collagen intended for soft tissue augmentation. It may be partially absorbed.	70440000	IV	8,8-⑤,14	applicable	—

Hyaluronic acid-containing injectable soft tissue	Hyaluronic acid for injection to increase the volume of soft tissues. (Part of it may be absorbed.)	70441000	IV	8,8-⑤,14	applicable	—
Single-use class IV surgical procedure kit	A pre-packaged kit that includes all devices up to Class IV, protective coating materials and drugs that are required for general procedures. This kit is for single-use.	33961004	IV	8-②	applicable	—
Human allograft tissue	Tissues or organs used for transplantation between individuals of the same species but with a different genotype. Some are processed before implantation. Some are sterilized.	35987000	IV	8-④,14	applicable	—
Human autograft tissue	Tissue grafts derived from inside or another site of the recipient's own body.	38745000	IV	8-④,14	applicable	—
Cardiac valve for mechanical artificial	Artificial heart valves (mechanical valve) used for heart valve replacement. Usually, they are used to treat acquired or congenital valvular disease. The types include ball valves, tilting disc valves (single leaflet), tilting disc valves (bi-leaflet), and others. The valves are made of various materials such as silicone rubber, Stellite®, Teflon®, polypropylene, and Dacron®.	35590010	IV	8-②	applicable	—
Mechanical cardiac valve with vascular prosthesis	A device that combines an artificial heart valve (mechanical valve) used for autologous heart valve replacement (including re-replacement) with artificial blood vessels made of artificial materials, and used for repair or replacement of a part of veins and arteries. The artificial valves are usually tilting disc valves (single leaflet) or tilting disc valves (bi-leaflet) that are used to treat acquired or congenital valvular disease. The valves are made of various materials such as silicone rubber, Stellite®, Teflon®, polypropylene, or Dacron®.	35590020	IV	8-②	applicable	—
Bovine pericardium valve	Artificial heart valves (bovine pericardial valves) used for heart valve replacement. Usually, they are used to treat acquired or congenital valvular diseases. They are mostly made of materials derived from bovine pericardium.	35591100	IV	8-②,14	applicable	—
Porcine cardiac valve	Artificial heart valves (porcine heart valves) used for heart valve replacement. Usually, they are used to treat acquired or congenital valvular disease. They are mostly made of materials derived from porcine valves.	35591200	IV	8-②,14	applicable	—
Porcine cardiac valve with vascular prosthesis	A device that combines artificial heart valves (porcine heart valves) used for autogenous heart valve replacement (including re-replacement) with porcine aorta or an artificial blood vessel. Usually, it is used to treat acquired or congenital valvular disease.	35591300	IV	8-②,14	applicable	—
Annuloplasty ring	A rigid or flexible device to be implanted next to the mitral valve or tricuspid valve for reconstructive treatment for valvular insufficiency (valve ring).	35644000	IV	8-②	applicable	—
Implantable cardiac pacemaker	A pacemaker consisting of a pulse generator, which is implanted in a surgically-created pocket under the skin, and an electrode placed inside or on the heart, connected to the pulse generator. An implantable pacing system consists of a sealed pulse generator. A pulse generator contains a battery and an electrical pulse generating circuit board; some types of pulse generator are equipped with an additional circuit to sense cardiac activity. It is also called a permanent pacemaker, a pacer, or an implantable pulse generator.	12913000	IV	8-④	applicable	—

Cardiomyoplasty electrical stimulator	A stimulator to stimulate skeletal muscles (e.g., latissimus dorsi) that surround ventricles during musculoplasty performed in order to increase cardiac output. The stimulator consists of an implantable pulse generator that serves as a heart pacemaker and a neuromuscular stimulator. The pacemaker electrode is placed on cardiac muscle, and the muscle electrode simultaneously stimulates the cardiac muscle and the muscles that surround it. Many of them have such functions as heart pacing that takes over when the heart rate decreases below a set value. A musculoplasty heart stimulator is usually used for patients with ischemic or congestive cardiomyopathy.	18145000	IV	8-⑤	applicable	—
Implantable biventricular pacemaker	An implantable pacemaker for cardiac resynchronization therapy, which has a function to electrically stimulate each left and right ventricles. The pulse generator is sealed in a sealed case, with a built-in battery and electrical pulse generator circuit. Some are equipped with a circuit that senses cardiac activity.	70484009	IV	8-④	applicable	—
Implantable epicardial pacemaker electrode/lead	A lead insulated with non-conductive materials (excluded tip of the electrode), designed to be placed in the epicardium.	35039000	IV	8-④	applicable	—
Implantable endocardial pacemaker electrode/lead	A lead insulated with non-conductive materials (excluded tip of the electrode), designed to be inserted through a vein and placed in a cardiac chamber. The device, which is placed in contact with the endocardial wall, transmits pacing pulses from the pacemaker to the myocardium. The device also transmits the electrical response of the heart to the pacemaker.	35223000	IV	8-④	applicable	—
Transesophageal pacemaker electrode/lead	A flexible lead insulated with non-conductive material and used as conductor. One end is connected to an extracorporeal pacemaker, and the other end is placed in the esophagus to allow cardiac pacing.	36052000	IV	8-④	applicable	—
Implantable pacemaker adaptor	A device used to adapt the connectors of an implantable defibrillator/pacemaker electrode/lead to a defibrillator/a pacemaker (Usually, this device is used in cases where the lead is not designed to be connected to a particular defibrillator/pacemaker). The adapter (including accessories) is implanted with the defibrillator/pacemaker system.	36102000	IV	8-④	applicable	—
Implantable defibrillator/pacemaker electrode/lead	A flexible insulated conductor that connects the implantable cardioverter defibrillator/pacemaker and the heart to transmit signals from the heart to the implanted device, and therapeutic electrical current from defibrillator/pacemaker to the heart.	36241000	IV	8-④	applicable	—
Intracardiac electrode	A conductor to be implanted in the cardiac muscle mainly for diagnosis of cardiac conduction disturbances.	16995000	IV	8-④	applicable	—
Extracorporeal pacemaker electrode wire	An electrode placed in the heart during and after cardiac surgery. It is connected to the extracorporeal pacemaker for temporary pacing.	70485100	IV	7-⑥	applicable	—
Heparin-coated extracorporeal pacemaker electrode wire	A heparin-coated electrode placed in the heart during and after cardiac surgery. It is connected to the extracorporeal pacemaker for temporary pacing.	70485200	IV	7-⑥,14	applicable	—
Collagen-containing myocardial patch	A collagen-containing device used for closure or repair of septal defects and injured cardiac muscle tissue. Usually, it is made of synthetic substances such as polytetrafluoroethylene or polyester. Some are made of animal-derived materials (including collagen).	35273200	IV	8-②,14	applicable	—
Central circulatory vascular prosthesis	A device made of artificial materials, and used for partial repair and replacement of blood vessels such as veins and arteries of the central circulatory system.	35281004	IV	8-②	applicable	—

Central circulatory cardiovascular patch	An implantable extravascular device used to reinforce a zone of vascular fragility, or to close an opening made during surgery in arteries of the central circulatory system. Usually, it is made of polyester or polytetrafluoroethylene.	38572104	IV	8-②	applicable	—
Collagen-containing cardiovascular patch	An implantable, collagen-containing coated extravascular device used to reinforce a zone of vascular fragility, or to close an opening made during surgery in arteries of the central circulatory system. Usually, it is made of polyester or polytetrafluoroethylene.	38572204	IV	8-②,14	applicable	—
Gelatine-containing vascular prosthesis	A gelatin-containing device made of artificial materials, and used for partial repair and replacement of blood vessels such as veins and arteries of the central circulatory system.	35093104	IV	8-②	applicable	—
Collagen-containing coated vascular prosthesis	A collagen-containing device using processed biological tissue as a raw material, and used for partial repair and replacement of blood vessels such as veins and arteries of the central circulatory system.	35093204	IV	8-⑤,14	applicable	—
Albumin-containing vascular prosthesis	An albumin-containing device made of artificial materials, and used for partial repair and replacement of blood vessels such as veins and arteries of the central circulatory system.	35093304	IV	8-②	applicable	—
Heparin-coated vascular prosthesis	A heparin-coated device made of processed biological tissue as a raw material, used for repairing or replacing a part of blood vessels such as the central circulatory vein and arter	35093404	IV	8-⑤,14	applicable	—
Pulmonary arterial shunt	A small vascular graft used for bypassing a stenotic pulmonary artery.	17811000	IV	8-②	applicable	—
Aortic stent graft	A device, in which the inside, outside, or both sides of support structure (stent) placed inside a blood vessel, or between one stent and another are covered with artificial materials. This device is inserted into the thoracic aorta or abdominal aorta in order to maintain the patency of the aorta. The stent graft is inserted through a catheter or other device, and expanded. The stent graft placement is also used to close perforated blood vessels, or to treat aneurysms. After the catheter or other device is removed, the stent graft remains in place as a permanent implant. It is made of stainless steel, Nitinol, polymer, or other substances. It may come as either tubular or branched.	70488000	IV	8-②	applicable	—
Coronary arterial stent graft	A device, in which the inside, outside, or both sides of support structure (stent) placed inside a blood vessel, or between one stent and another are covered with artificial materials. This device is inserted into the coronary vessel in order to maintain the patency of the vessel. The stent graft is inserted through a catheter or other device, and expanded. The stent graft placement is also used to close perforated blood vessels, or to treat aneurysms. After the catheter or other device is removed, the stent graft remains in place as a permanent implant. It is made of stainless steel, Nitinol, polymer, or other substances. It may come as either tubular or branched.	70489000	IV	8-②	applicable	—
Synthetic myocardial patch	A device used for closure and repair of septal defects and damaged cardiac muscle tissue. It is made of polytetrafluoroethylene or polyester.	35273100	IV	8-②	applicable	—
Equine pericardial patch	A device used for closure and repair of septal defects, damaged cardiac muscle tissue, pericardium or a blood vessel opening produced during surgery. It is made of equine pericardium.	35273300	IV	8-②,14	applicable	—
Iliac stent	An expandable tubular device to be implanted in the common iliac artery or external iliac artery of patients with symptomatic atherosclerosis to increase blood vessel diameter.	44279000	IV	8-②	applicable	—

Cardiovascular stent	A stent with a support structure expanded and placed in a cardiac vessel in order to maintain the patency of the vessel. For instance, the stent is delivered by a catheter to an occluded site. By the expansion of the balloon catheter, or the stent itself, the stent expands and supports the blood vessel. After the catheter is removed, the stent remains in place as a permanent implant. It is made of metal, polymer, or other substances. It may come as a continuous tube having a specified length, a tubular scaffold or a tube with a Y-shaped branch.	34179000	IV	8-②	applicable	—
Coronary stent	A stent with a support structure expanded and placed in a coronary vessel in order to maintain the patency of the vessel. For instance, the stent is delivered by a catheter to an occluded site. By the expansion of the balloon catheter, or the stent itself, the stent expands and supports the blood vessel. After the catheter is removed, the stent remains in place as a permanent implant. It is made of metal, polymer, or other substances. It may come as a continuous tube having a specified length, or as a tubular scaffold.	36035004	IV	8-②	applicable	—
Cerebral artery stent	A stent with a support structure expanded and placed in a cerebral artery in order to maintain the patency of the artery. For instance, the stent is delivered by a catheter to an occluded site. By the expansion of the balloon catheter, or the stent itself, the stent expands and supports the blood vessel. After the balloon catheter is deflated and removed, the stent remains in place as a permanent implant. It is made of stainless steel, polymer, or other substances. It may come as a continuous tube having a specified length, or as a tubular scaffold.	70491000	IV	8-②	applicable	—
Absorbable implantable fixation bolt	An absorbable device inserted in bone in order to ensure the safety of a traction device and other similar devices. It is fixed with nuts. Some are equipped with washers.	16077004	IV	8-⑤	applicable	—
Absorbable implantable fixation screw	An absorbable device to fix bones by applying plates or nails to the bone, fixing soft tissue to the bone, or stabilizing bone fragments. This is used for orthopedic surgery and maxillofacial surgery, etc. The screws come in various types such as cortex bone screws, cancellous bone screws, ankle bone screws, navicular bone screws, screws with a partial thread and screws where the thread occupies the entire shaft. Lag screws are used in a special way in order to compress the entire bone fragments.	16101004	IV	8-⑤	applicable	—
Absorbable implantable fixation staple	A U-or other shaped absorbable device to be implanted in a fractured bone for fixation or repair in cases of Orthopedic surgical bone fracture or fracture of the mandible. It may also be used to fix ligament/tendons or other structure to the bone.	16103004	IV	8-⑤	applicable	—
Absorbable implantable fixation nut	An absorbable device used with bone fixation devices such as bone screws and bone bolts to enhance fixation. It may also be used when the bone hole is larger than the screw diameter.	32847004	IV	8-⑤	applicable	—
Absorbable implantable fixation pin	An absorbable device used to support an internal/external fixation or the traction device, to fix soft tissue and ligament onto the bone, and to stabilize bone fragments.	32854004	IV	8-⑤	applicable	—
Absorbable implantable fixation button	A button-shaped absorbable device used as fixing material for joint reconstruction.	70497000	IV	8-⑤	applicable	—
Absorbable vertebral body prosthesis	A device that is replaced or repair one or multiple vertebral bodies or spinal columns which are lost due to trauma, deformation or degenerative disease. It is made of absorbable materials.	34170004	IV	8-⑤	applicable	—

Absorbable implantable fixation plate	An absorbable implantable, fixation device that is fixed to fractured bone fragments with screws in order to fill the fracture gap and protect the fractured part from stress in cases of bone deformities and treatment for bone fracture. It is also used for bone lengthening for pathologically fractured bone, as a reinforcement in cranial or maxillofacial surgery, or for fusion of joints where fixation is required.	35241004	IV	8-⑤	applicable	—
Absorbable implantable fixation tack	An absorbable device for bone fixations, used to fix plates, etc. which are used for bone fracture treatment, or the like.	70498000	IV	8-⑤	applicable	—
Absorbable implantable sheet	An absorbable device used to cover and support the missing bone part, etc. Some have multiple holes.	70499000	IV	8-⑤	applicable	—
Absorbable implantable fixation system	An absorbable device that consists of a case and multiple trays. It includes various implants and special surgical devices. This system is designed for specific surgeries for bone fracture and the spinal column, corrective surgery and ligament reconstruction. In order to maintain this system, implants are restocked after use.	35642004	IV	8-⑤	applicable	—
Absorbable implantable fixation wire	An absorbable, implantable device used to fix bones. This is used for various purposes – e.g., as fastening wire that assists bone fixation; as figure-eight loop for re-joining the olecranon, tibial tubercle or greater trochanter; as reinforcement for bone screws and bone plate fixation; as a Kirschner wire that supports the toes and fingers (joint fixation). It comes in various materials. Some are expandable to be elongated or coiled, and others are rigid.	35685004	IV	8-⑤	applicable	—
Absorbable ligament fixation anchor	An absorbable, implantable device used to connect one or both ends of a ligament, tendon or artificial ligament onto the bone.	36174004	IV	8-⑤	applicable	—
Absorbable implantable fixation washer	An absorbable device used along with bone fixation devices such as bone screws and bone bolts in order to enhance fixation or prevent soft tissue injury.	36198004	IV	8-⑤	applicable	—
Absorbable intraspinal fixation system	A device that consists of rods, plates, hooks, screws (including pedicle screws), connectors, wires, cables and other tools. It is used for fixation, support, or alignment correction of the spinal column. Usually, it is made of metals, polymers, or other materials that include absorbable materials. It may also be used for fracture fixation, degenerative or congenital anomalies.	37272004	IV	8-⑤	applicable	—
Absorbable spinal cage	A device used to add, correct or repair the height of the spinal column as a substitution for a part of the intervertebral disk or spinal column. Usually, it is made of absorbable materials.	38161004	IV	8-⑤	applicable	—
Absorbable bone fixation band	An absorbable wires, cables, and bands used to fasten/suture bone and soft tissue, fix bone to an implant, fix bone to bone etc. Usually, it is made of a polymeric material.	70502000	IV	8-⑤	applicable	—
Absorbable implantable fixation cable	An absorbable cable (made up of stranded wire) used for bone fixation. It is used as an internal fixation device. It is used to reunite fractured bones or an osteotomy section in the olecranon, patella, medial malleolus, or greater trochanter, and to fix the spinal column, generally through the use of a fastening apparatus. It includes an implant used with cables. Usually, it is made of a polymeric material.	70505000	IV	8-⑤	applicable	—
Natural bone graft	A bone to be transplanted from the donor to the recipient for reinforcement in plasty or reconstruction, for bone formation or for mechanical support. The bone is collected from another site of the recipient, or collected from other patients and undergone pretreatment.	11910000	IV	8-④,14	applicable	—
Collagen-based bone matrix implant	A collagen-containing material inserted or transplanted into the body to be replaced with bone lost due to trauma, osteoporosis or morbidity.	17756000	IV	8-⑤,14	applicable	—

Absorbable tendon prosthesis	An implantable device for replacement or repair in order to restore the function of a lost or damaged tendon. It is made of absorbable materials.	32869004	IV	8,8-④	applicable	—
Absorbable cement spacer	An absorbable device used to secure the thickness of bone cement (e.g., polymethyl methacrylate [PMMA]) between the embedded artificial joint and the bone.	33982004	IV	8-⑤	applicable	—
Absorbable cement bone plug	An absorbable device used as closure to seal the marrow cavity to limit the passage of bone cement (used as cement restrictor). It is made of absorbable materials.	34031004	IV	8-⑤	applicable	—
Absorbable tendon spacer	An absorbable device used to separate tissues and prevent physical contact. This prevents the tendon from adhering to adjoining tissues, and allows it to move freely.	35671004	IV	8-⑤	applicable	—
Drug-containing radial head prosthesis	A device used for total or partial replacement of the proximal radius (radial head). Some use bone cement for fixation while others do not. Usually, it is made of metals, ceramics, carbon, polymers or a combination of these substances are used as the raw material. It may be absorbed partially. It contains drugs.	35966004	IV	8,8-⑤,13	applicable	—
Scleral buckling device	An absorbable device to be inserted in the sclera in order to assist retinopexy.	15794000	IV	8-⑤	applicable	—
Implantable vagus nerve stimulator electrode/lead	A lead insulated with non-conductive material except for the electrode which is implanted in nerve tissue. Used to establish electrical connection between stimulator and vagus nerve.	44041000	IV	8-②	applicable	—
Implantable myoplasty stimulator electrode/lead	A lead insulated with non-conductive material except for the electrode which is attached to the heart. Used to establish electrical connection between stimulator and cardiac muscle in order to assist the pumping function of the heart.	44044000	IV	8-②	applicable	—
Skin graft	A graft used to treat skin defects for the purpose of repair, reconstruction, or treatment.	11912100	IV	8-⑤	applicable	—
Collagen-based skin graft	A collagen-containing graft used to treat skin defects for the purpose of repair, reconstruction or treatment.	11912200	IV	8-⑤,14	applicable	—
Intracardiac patch	A device made of synthetic materials to be used for reinforcement or repair of damaged membrane of the heart. It may also be used as a pledget.	31744000	IV	8-②	applicable	—
Absorbable ENT polymer hemostat synthetic tissue reconstructive prosthesis	An absorbable device used for soft tissue replacement or repair in the ear, nose or throat (ENT) surgery. Some are made of collagen or absorbable natural gelatin etc.	33310204	IV	7-④,14	applicable	—
Implantable absorbable synthetic/carbon fibre tissue reconstructive prosthesis	A material made of polytetrafluoroethylene (PTFE) reinforced with carbon fiber used to produce composite materials for absorbable implants. In cosmetic surgery, it is used to restore the structure of bones and tissues around the jaw, nose, and eye.	33473204	IV	8-⑤,14	applicable	—
Meningeal prosthesis	A biological or artificial device used to repair meninges.	35614000	IV	8-②	applicable	—
Nerve sheath prosthesis	A device used for replacement or repair to restore functionality to the nerve sheath.	35650000	IV	8-②	applicable	—
Nipple prosthesis	A device to be replaced with or repair natural nipples lost or resected by surgery. Although this has the "outer" surface, it is considered as implant because it is embedded in tissue for connection.	35681000	IV	8-⑧	applicable	—
Implantable contraceptive drug delivery device	A device such as a small, hollow rubber rod. Loaded with a contraceptive agent such as the contraceptive hormone levonorgestrel, and embedded under the skin of the upper arm to steadily release the contraceptive agent into the whole body.	35945000	IV	8-⑥	applicable	—

Human dura mater graft	An allograft made of the cadaveric dura mater. Usually, it is processed, sterilized, and used for reconstruction or replacement of the recipient's dura mater. Since the dura mater is vital to maintain the integrity of the spinal cord, this device is efficacious when it is used to obtain the integrity of the spinal cord. It is important for the spinal cord to be constantly protected from damage and excessive pressure.	36036000	IV	8-②,14	applicable	—
Artificial pericardial prosthesis	A combination device that introduces sheet prosthesis (conical dual layered fibroserous sac that wraps the heart and the root of large blood vessels) or embolization implant into the part of pericardial defect to compensate for the pericardial defect. Sheet material and embolization implants are made of biological or artificial materials. It consists of the sheet materials, embolization implant, and inserter. Some kits include other items that are necessary for surgery.	36182000	IV	8-②	applicable	—
Mammary prosthesis	An implantable device used for breast reconstruction or breast implantation. Expanded with sterile solution.	36196000	IV	8-⑧	applicable	—
Gel-filled mammary prosthesis	An implantable device used for breast reconstruction or breast implantation. The shell is fully or partially filled with silicone gel in advance, or filled during surgery.	36197000	IV	8-⑧	applicable	—
Xenograft	A tissue graft that is used for heterologous transplantation between different species (including humans).	38746000	IV	8-④,14	applicable	—
Artificial dura mater	An artificial membrane used to supply or replace the dura mater when the dura mater is lost after an open head injury or traumatic spinal fluid fistula, or when the dura mater is partially resected during craniotomy. It is either absorbable or non-absorbable. The non-absorbable membrane may be used to prevent adhesion of the brain surface to the dura mater.	70510000	IV	8-②	applicable	—
Synthetic artificial dura mater	An artificial membrane used to supplement, or be replaced with the dura mater when the dura mater is lost after an open head injury or traumatic spinal fluid fistula, or when the dura mater is partially resected during craniotomy. It is either absorbable or non-absorbable. The non-absorbable membrane may be used to prevent adhesion of the brain surface to the dura mater.	70511000	IV	8-②	applicable	—
Implantable biventricular pacing pulse generator with defibrillation feature	An implantable pulse generator mainly used to treat cardiac failure, which has a function to electrically stimulate each left and right ventricles. It is sealed in a sealed case, with a built-in battery and electrical pulse generator circuit, and is equipped with a circuit that senses cardiac activity. The device delivers an appropriate defibrillation pulse to the cardiac muscles as necessary when tachycardia is detected so as to decrease the heart rate to the normal range, and delivers a pacemaker pulse when bradycardia is detected so as to increase the heart rate to the normal range.	70514000	IV	8-④	applicable	—
Implantable biventricular pacing pulse generator without defibrillation feature	An implantable pulse generator mainly used to treat cardiac failure, which has a function to electrically stimulate each left and right ventricles. It is sealed in a sealed case, with a built-in battery and electrical pulse generator circuit, and is equipped with a circuit that senses the cardiac activity. The device delivers a pacemaker pulse when bradycardia is detected so as to increase the heart rate to the normal range.	70515000	IV	8-④	applicable	—
Circulatory assist centrifugal pump	A special centrifugal pump used to maintain blood circulation in the event of cardiac failure. It assists blood circulation (support of blood circulation in the event of cardiac failure) in patients who depend on artificial support to maintain cardiac function. The dependency on artificial support is due to the absence of normal cardiac function. This is used to support the recovery of cardiac function for a short period during and after cardiotomy.	36379100	IV	7-⑥,8-②	applicable	applicable

Heparin-coated circulatory assist centrifugal pump	A special, heparin-coated centrifugal pump used to maintain blood circulation in case of cardiac failure. It assists blood circulation (support of blood circulation in case of cardiac failure) in patients who depend on artificial support to maintain cardiac function. Dependency of artificial support is due to the lack of normal cardiac function. This is used to support the recovery of cardiac function for a short period during and after cardiectomy.	36379209	IV	7-⑥,14	applicable	applicable
Circulatory assist spiral pump	A dedicated spiral pump placed in left ventricles in order to maintain blood circulation in the event of cardiac failure. It assists blood circulation (support of blood circulation in the event of cardiac failure) in patients who depend on artificial support to maintain cardiac function. Dependency on artificial support is due to the absence of normal cardiac function (Usually, after open chest cardiac surgery).	36382000	IV	8-②	applicable	applicable
Circulatory assist manually-operated crank pump	A manual centrifugal pump operated by a qualified person or operator and which is used to replace an electrically powered pump when there is an outage of the main power supply. A special pump used for circulation support (support of blood circulation in the event of cardiac failure) in patients who depend on artificial support to maintain cardiac function.	36858000	IV	7-⑥	applicable	applicable
Single-use centrifugal pump	A pump that delivers blood by using centrifugal force to assist the recovery of cardiac function for a short period during and after cardiectomy. This device is for single-use. This is used with a dedicated driving device.	70521100	IV	7-⑥,8-②	applicable	N/A
Single-use heparin-coated centrifugal pump	A heparin-coated pump that delivers blood by using centrifugal force to assist the recovery of cardiac function for a short period during and after cardiectomy. This device is for single-use. This is used with a dedicated driving device.	70521200	IV	7-⑥,8-②,14	applicable	N/A
Extracorporeal assistant artificial cardiac pump	An extracorporeal auxiliary artificial heart pump.	70522010	IV	7-⑥	applicable	applicable
Intravascular membrane oxygenator	A type of membrane artificial lung designed to support internal gas exchange for a long-term use.	18133000	IV	8-③	applicable	—
Assistant artificial heart driving unit	An extracorporeal device that drives and controls an extracorporeal assistant artificial heart blood pump that supports circulation in patients with severe cardiac failure.	70560000	IV	7-⑥	applicable	applicable
Single-use extracorporeal assistant artificial cardiac pump	An extracorporeal auxiliary artificial heart pump. This device is for single-use.	70522020	IV	7-⑥	applicable	—
Automatic implantable defibrillator	A device to be implanted in the body to monitor the electrocardiogram (ECG), deliver a defibrillation pulse to the cardiac muscles when tachycardia is detected so as to decrease the heart rate to the normal range.	35852000	IV	8-④	applicable	—
Implantable automatic dual-chamber defibrillator	A device to be implanted in the body to monitor the electrocardiogram (ECG), deliver a defibrillation pulse to the cardiac muscles when tachycardia is detected so as to decrease the heart rate to the normal range, and deliver a pacemaker pulse when bradycardia is detected so as to increase the heart rate to the normal range.	37265000	IV	8-④	applicable	—
Fibrillator	A device that induces fibrillation by delivering a weak electrical shock. Ventricular fibrillation is caused by an MF sine wave from an electrode applied to the surface of the heart. Used for open chest cardiac surgery at normal body temperature (37°C), or treatment for arrhythmia.	11700000	IV	6-⑤	applicable	applicable

Implantable defibrillation electrode	A conductor used to deliver a controlled electrical shock from the defibrillator to patients so as to restore normal heart rate. A set of cables equipped with electrode is connected to the defibrillator. The internal electrode (spoon or small paddle) is directly applied to the exposed cardiac muscles (Usually, in open chest cardiac surgery).	15033004	IV	6-⑤	applicable	—
Artificial endocrine pancreas	A device that automatically infuses insulin, and controls blood glucose levels to treat diabetes mellitus.	70585000	IV	8-⑥	applicable	applicable
Implantable assistant artificial heart system	A complete ventricle bypass system that supports the left or right ventricle so as to maintain circulatory blood flow. This is implanted in the body. Usually, it is used for patients with weakening cardiac function who need support for circulation while waiting for a heart transplant. It consists of an implantable artificial heart, and extracorporeal power supply device etc. The patient may leave the hospital and stay at home while wearing the system until a suitable organ for transplantation becomes available.	34941000	IV	8-③	applicable	applicable
Implantable assistant artificial cardiac pump	An implantable artificial heart pump that supports the left or right ventricle so as to maintain circulatory blood flow. Usually, it is used for patients with weakening cardiac function who need support for circulation while waiting for a heart transplant. The energy is supplied from an extracorporeal power supply device.	35266000	IV	8-③	applicable	applicable
Implantable assistant artificial heart power supply unit	A device that supplies electric power to an artificial heart pump. It is implanted systemically or locally along with the energy source so as to support the maintenance of appropriate circulatory blood flow.	37315000	IV	8-③	applicable	applicable
Carotid sinus nerve electrical stimulator	An electric peripheral nerve stimulator that stimulates carotid artery branches (Hering's nerve) in order to decrease arterial blood pressure. Usually, the stimulator is completely implantable, and used for controlling hypertension.	35369000	IV	8-④	applicable	N/A
Antiseizure brain electrical stimulator	A type of stimulator that stimulates a specific region of the patient's brain (e.g., cerebrum, cerebellum) in order to prevent or mitigate an attack. It is either an implantable lead/electrode system connected to the passive electronic circuit (Usually, signals or energy is guided and delivered from outside the body via radio-frequency wave) or a self-contained stimulator implantable at any site in the body (It has its own energy source, and has no specific dependency on external devices except for activating the stimulus and changing the settings). Used for treatment of epilepsy, spasmodic disorder, and dyskinesia (e.g., cerebral palsy).	36222000	IV	8-④	applicable	N/A
Coma arousal vagus nerve electrical stimulator	An electrical nerve stimulator that continuously stimulates the vagus nerve to arouse the patient from vegetative state (e.g., severe coma). The stimulator consists of a pulse generator, and a lead wire connected to an electrode implanted under the skin near the left vagus nerve.	37310000	IV	8-②	applicable	applicable
Psychiatric therapy vagus nerve electrical stimulator	An electrical brain stimulator that stimulates a specific region of the vagus nerve during psychotherapy. The stimulator usually consists of an extracorporeal pulse generator and an electrode.	37311000	IV	8-②	applicable	applicable
Implantable gait neuromuscular electrical stimulator	An electrical neuromuscular ambulation stimulator to be implanted in one or both legs. The stimulator usually consists of an implantable receiver with an electrode placed around the nerve and an extracorporeal transmitter that sends stimulation pulses percutaneously to the implanted receiver. The extracorporeal transmitter is usually operated by a switch located in the heel of the shoe.	37856000	IV	8-④	applicable	applicable

Absorbable peritoneum catheter cuff	A cuff that consists of biodegradable porous material to be attached to the peritoneal dialysis catheter. It is embedded subcutaneously at the outlet of the peritoneal dialysis catheter. It helps to maintain stable contact between the skin and the catheter, and prevents bacterial invasion from the outlet.	70589100	IV	8-⑤	applicable	—
Collagen-containing peritoneum absorbable catheter cuff	A cuff that consists of biodegradable porous material containing collagen to be attached to the peritoneal dialysis catheter. It is embedded subcutaneously at the outlet of the peritoneal dialysis catheter. It helps to maintain stable contact between the skin and the catheter, and prevents bacterial invasion from the outlet.	70589200	IV	8-⑤,14	applicable	—
Antiseizure vagus nerve electrical stimulator	An electrical nerve stimulator that intermittently stimulates the vagus nerve to control seizures. Usually, the stimulator consists of a pulse generator to be implanted in the anterior thoracic wall, and a lead wire connected to an electrode implanted subcutaneously near the left vagus nerve. The vagus nerve stimulator can be programmed extracorporeally after implantation. The stimulator is used to treat epilepsy by resolving seizures and reducing the frequency of seizures.	34210000	IV	8-④	applicable	N/A
Bladder/bowel evacuation neuromuscular electrical stimulator	A type of stimulator which is usually used to stimulate the conical end of the spinal cord (medullary cone) to induce urination and defecation. Usually, it consists of an implantable receiver equipped with an electrode (placed near the sacral nerve root), and an external transmitter (percutaneously transmits stimulation pulses to the implanted receiver). Some can induce an erection in males by adjusting the controller to stimulate a specific pair of nerve roots. Used for patients with lower body paralysis whose spinal cord is completely degenerated, and who have difficulty with urination and defecation either by voluntary reflex or by using a catheter.	35641000	IV	8-④	applicable	applicable
Analgesic electrical stimulator	A type of stimulator that stimulates part of or the entire spinal cord for pain relief (analgesia). An implantable lead and electrode system are built in. The implantable lead and the electrode system are placed in the epidural cavity, and connected to either a passive electronic circuit (Usually, signals or energy is guided and delivered from outside the body via radio-frequency waves [RF]) or implantable stimulator (It has its own energy source, and has no specific dependency on external devices). Used for treatment of acute or chronic refractory pain in patients for whom drug therapy is not desirable or ineffective.	36007000	IV	7-⑤	applicable	applicable
Implantable incontinence neuromuscular electrical stimulator	An electrical neuromuscular stimulator to treat urinary and fecal incontinence. Implanted in the abdomen with an electrode placed on the wall of urinary bladder or pelvic floor. Stimulation pulses are percutaneously transmitted from the extracorporeal transmitter to the implanted receiver.	36175000	IV	8-④	applicable	N/A
Tremor brain electrical stimulator	A stimulator that stimulates a specific region of the deep brain (e.g., thalamus) to control tremors. The tremor-controlling brain stimulator consists of an electrode implanted in the brain by stereotaxicotomy, and a lead connected to the pulse generator. The pulse generator is usually implanted near the clavicle. The stimulator is used to control various types of tremors (tremor of patients with essential tremor, tremor associated with Parkinson's disease), and symptoms of Parkinson's disease.	37307000	IV	8-④	applicable	N/A
Implantable bladder/bowel evacuation control stimulator	A type of implantable stimulator – i. e. , an electrical neuromuscular stimulator-which is usually used to treat urinary and fecal incontinence by means such as stimulating the conical end of the spinal cord (medullary cone) to induce urination and defecation. Usually, the stimulator is implanted in the abdomen, and the electrode is placed on the wall of the urinary bladder or pelvic floor. Some can induce an erection in males by stimulating a specific pair of nerve roots. Used also for patients with lower body paralysis whose spinal cord is completely degenerated, and who have difficulty with urination and defecation either by voluntary reflex or by using a catheter.	70599000	IV	8-④	applicable	N/A

Implantable stimulator for pain relief	A type of implantable stimulator system that stimulates part of or the entire brain or spinal cord for pain relief (analgesia). An implantable lead and electrode are built in. They are placed in the epidural cavity or in the skull, and connected to the implantable stimulator (It has its own energy source, and has no specific dependency on external devices). Used for treatment of acute or chronic refractory pain in patients for whom drug therapy is not desirable or ineffective.	70600000	IV	8-④	applicable	N/A
Pacemaker/defibrillator lead extraction kit	A kit that includes devices used to remove an implanted pacemaker or defibrillator lead. The devices in the kit are usually used in combination in order to remove the implanted lead. Usually, a stylet, an expansion sheath, a snare, and a collection basket are included.	18111000	IV	6-⑤	applicable	—
Central circulatory remote afterloading brachytherapy therapeutic radionuclide system	A device that places a radiation source temporarily at the treatment site in the central circulatory system for providing a required radiation dose during radiotherapy. This device equips a remotely controlled radiation source transporter.	38300004	IV	7-⑥	applicable	applicable
Central circulatory manual brachytherapy therapeutic radionuclide system	A device that places a radiation source manually or automatically at the treatment site in the central circulatory system for providing a required radiation dose during radiotherapy. This device does not equip a remotely controlled radiation source transporter.	38299004	IV	7-⑥	applicable	applicable
Central circulatory remote afterloading brachytherapy therapeutic radionuclide source	A device for the central circulatory system used as radiation source to deliver a high or low dose rate with an after-loading brachytherapy device designed for radiotherapy which is necessary for treatment and symptomatic therapy, and uses natural radioisotopes or radioisotopes produced by an accelerator or a nuclear reactor. The radiation source used for the after-loading brachytherapy device is provided in various physical configurations –e.g., a single encapsulated radiation source (sealed radiation source), ribbon radiation source, plated, foiled, or embedded radiation source, and encapsulated liquid or gel. The radiation source is contained in a sealed storage container installed in the after-loading device, and transferred to the treatment site via guide tube in various structures.	38302004	IV	7-⑥	applicable	—
Central circulatory permanent implant manual brachytherapy therapeutic radionuclide source	A device for the central circulatory system to be placed permanently in the body for radiotherapy which is necessary for treatment and symptomatic therapy, and uses natural radioisotopes or radioisotopes produced by an accelerator or a nuclear reactor. Generally, it is placed in the body by an applicator under X - ray fluoroscopy or endoscopy. The radiation source, which is permanently placed manually, is designed to achieve compatibility with tissues. The radiation source can be selected from the following forms – e.g., microsphere, globe, stent, seed, and wire-in order to generate low-energy photons, beta particles, or alpha particles.	38303004	IV	7-⑥	applicable	—
Central circulatory temporary placement manual brachytherapy therapeutic radionuclide source	A device for the central circulatory system that uses natural radioisotopes or radioisotopes produced by an accelerator or a nuclear reactor, and is placed in the body temporarily, and removed after the pre-determined treatment period. It is used for brachytherapy treatment, inserted and removed manually or under endoscopy. The radiation source, which is temporarily inserted manually, is supplied in various forms – e.g., encapsulated, sealed, plated, foiled, or embedded. The radiation sources directly inserted in the body, or inserted using a catheter or an applicator include the following forms: a needle, globe, ovoid, seed, or wire, or liquid sealed in the cuff of a catheter.	38304004	IV	7-⑥	applicable	—

Brain manual brachytherapy applicator	An applicator specifically designed for brain radiotherapy. A single or module applicator designed to facilitate manual placement (puncture, placement under endoscopy, or placement and removal using an image diagnostic system) of single or multiple therapeutic radiation sources in the brain. Some applicators are designed in a standard configuration, and others are designed so as to handle specific radiation sources. This category includes associated devices such as brain applicator, positioner, template, and catheter guide which are used for manual administration of the radiation source in short-distance irradiation such as hollow needles, tubes, and catheters.	38412000	IV	7-⑤	applicable	applicable
Brain remote afterloading brachytherapy applicator	A remote controlled brachytherapy applicator designed exclusively for brain radiotherapy for temporary implantation in the body. It serves as a computer-controlled guide for temporary placement and removal of a single or multiple therapeutic radiation sources in the brain. This category includes various applicators such as hollow needles, tubes, and catheters and associated devices and connectors.	38413000	IV	7-⑤	applicable	applicable
Blood vessel manual brachytherapy applicator	A manual brachytherapy applicator designed exclusively for blood vessel radiotherapy. Most commonly, it is used to prevent formation of plaque, stenosis and restenosis in blood vessels after surgery. A single or module device designed to facilitate manual placement (placement and removal under endoscopy or using an image diagnostic system) of single or multiple therapeutic radiation sources in the treatment site. Some applicators are designed in a standard configuration, and others are designed so as to handle specific radiation sources.	38432000	IV	7-③,7-⑥	applicable	applicable
Blood vessel remote afterloading brachytherapy applicator	A remote controlled brachytherapy applicator designed exclusively for radiotherapy in blood vessels. This treatment is used to prevent plaque formation. and stenosis in blood vessels after surgery. It is designed for temporary implantation in a blood vessel, and serves as a guide for computer-controlled temporary placement and removal of single or multiple therapeutic radiation sources at treatment sites. The category includes various applicators such as hollow needles, tubes, and catheters, associated devices and connectors.	38433000	IV	7-③,7-⑥	applicable	applicable
Central circulatory general-purpose manual brachytherapy applicator	A general-purpose brachytherapy applicator used to facilitate radiotherapy. A single or module applicator designed to facilitate manual placement (puncture, local placement, placement under endoscopy or placement and removal using an image diagnostic system) of single or multiple therapeutic radiation sources in treatment sites in the central circulatory system. Some applicator are designed in a standard configuration, and others are designed in various physical configurations, or designed so as to be easily processed into a configuration that can handle specific radiation sources. It comes in hollow needles, tubes, catheters, ovoid, and tandem.	38435004	IV	7-⑥	applicable	applicable
Central circulatory general-purpose remote afterloading brachytherapy applicator	A general-purpose remote controlled brachytherapy applicator used to facilitate radiotherapy. It is designed to be temporarily implanted in the body. It serves as a guide for computer-controlled temporary placement and removal of a single or multiple therapeutic radiation sources at treatment sites in the central circulatory system. This category includes various applicators such as hollow needles, tubes, and catheters, as well as associated devices and connectors.	38436004	IV	7-⑥	applicable	applicable
Brain analgesic electrical stimulator	A type of stimulator that stimulates the brain's internal structures for pain relief. It is either an implantable lead/electrode system connected to a passive electronic circuit (Usually, signals or energy is guided and delivered from outside the body via radio-frequency wave [RF]) or a self-contained stimulator implantable at any site in the body (It has its own energy source, and has no specific dependency on external devices). It is used for treatment of severe chronic refractory pain for which drug therapy is not desirable or ineffective.	35653000	IV	8-④	applicable	applicable

Implantable bone fracture healing promotion electrical stimulator	A device that electrically stimulates bone formation (osteogenesis). It is used for refractory bone fractures (the end of the fractured bone remains disunited) as an alternative therapy to bone transplantation and as adjuvant therapy for spinal fusion. This device sends a weak electric current around a bone fracture or fixed part, or develops an electromagnetic field (the effect of concomitant induced voltage). Also known as an osteogenic stimulator.	70615000	IV	8-④	applicable	N/A
Phrenic nerve electrical stimulator	A type of stimulator that provides electrical stimulation to the phrenic nerve to rhythmically contract the diaphragm and induce breathing in patients suffering from hypoventilation. It consists of an implantable receiver (placed next to the patients' phrenic nerve) with an electrode, and an external transmitter (delivering stimulation pulses to the implanted receiver via the patient's skin).	35652000	IV	8-④	applicable	applicable
Implantable analgesic peripheral nerve electrical stimulator	A type of stimulator that provides stimulation from electrodes placed next to the peripheral nerve. Usually, it is either an implantable lead/electrode system connected to a passive electronic circuit (energy is guided and delivered from outside the body) or a self-contained stimulator implantable at any site in the body (It has its own energy source, and has no specific dependency on external devices). It is used for treatment of severe chronic refractory pain for which drug therapy is not desirable or ineffective.	38474000	IV	8-④	applicable	applicable
Craniotomy surgical drill	A perforator used to open a hole in the vault of the cranial. When the inner table is penetrated, the clutch system releases the drill bit so as to prevent the brain surface being damaged. Usually, it is used to remove skull fragments to ensure access to the brain. (See the automatic trepan).	44404000	IV	6-⑤	applicable	N/A
Craniotomy surgical drill attachment	A device connected to a hand piece, or used with a motor, and connected to a drill to open a hole in the vault of the skull (calvaria). When the inner table is penetrated, the clutch system releases the drill bit to prevent the brain surface being damaged. It uses air, nitrogen, battery or electric power as a power source. It may be inserted to allow the use of a guide wire. It comes in either a micro or macro design (See the automatic trepan).	42981000	IV	7-⑤	applicable	N/A
Absorbable dental bone reconstruction implant materials	An absorbable biomaterial used for dental treatment by filling the missing part of jaw bone and building up jaw bone (reinforcement).	34006004	IV	8-⑤	applicable	—
Endomyocardial biopsy forceps	A catheter that is used to collect or remove a small amount of cardiac muscle, tumor sample or other tissue for biopsy (histological/pathological diagnosis). Usually, it consists of a catheter with a set of forceps and the operation handle.	70937000	IV	6-⑤	applicable	—
Spinal surgical injector	An injector-like manual device used to infuse orthopedic surgical (bone) cement and artificial bone etc. into a surgical site (including the spinal column). This device is for manual operation only.	70957000	IV	6-④,6-⑤	applicable	N/A
Bone absorptiometer radionuclide source	Radioisotopes used as radiation sources of devices for osteoabsorptiometry (bone densitometry), which are produced by either an accelerator or nuclear reactor, or exist in nature. The radiation sources used in these devices are designed to deliver multiple photon radiation beams to the target sites for the purpose of collecting information about energy attenuation based on the bone density parameters obtained from the images or by calculation. The radiation sources of devices for radiation osteoabsorptiometry are provided in the physical form of a capsule or as sealed radiation. Commonly used radioisotopes include iodine-125 (I-125), americium-241 (AM-241), gadolinium-57 (Gd-57), and cobalt-57 (Co-57).	38315000	III	10-④	applicable	—

Radioactive compound synthesizing facilities	A small-scale production facility for radioactive drugs for nuclear medicine or radiopharmaceuticals used in examinations of malignant tumors, metabolic functions, etc. For instance, these facilities include one that synthesizes positron nuclide-labeled compounds that are used in PET scanning.	70009000	Ⅲ	10-②,13	applicable	applicable
Intravascular diagnostic ultrasound probe	An ultrasonic transducer assembly using a catheter, reusable or for single-use. It is designed to be positioned and inserted into the veins or arteries by an operator. It is water-resistant or waterproof, and sealed in a housing with sound and electrical insulation. It is also called a vascular probe or vascular transducer, and often integrated into or concurrently used with the devices that need ultrasonic guidance and ultrasonic placement, such as endoscopic devices or biopsy needles. It consists of a single or multiple transducer element array(s) (called a piezoelectric element, active element or crystal element), attenuation materials, relining materials, and matching materials.	37895000	Ⅲ	10-④	applicable	applicable
Reusable vascular surgical ultrasound probe	A probe used in vascular surgery. It refers to a hand-held ultrasonic transducer assembly designed to be placed at the surgical site to take local images during surgery. It is also called a surgical probe or a fingertip probe. It includes the configuration of various transducer assemblies that consist of single or multiple elements that convert voltage into an ultrasonic beam. The assembly determines the direction of the ultrasonic beam mechanically or electronically, focuses, and detects the reflected echo. This category includes ultrasonic transducers used for mode A, mode B, mode M, Doppler, Color Doppler (CD), and dual (combination image, Doppler or color flow) scanning. This device is reusable.	40770003	Ⅲ	10-④	applicable	applicable
Reusable temporary use intracorporeal central nervous system ultrasound probe	An ultrasonic probe used temporarily in central nervous system surgery. It refers to a hand-held ultrasonic transducer assembly designed to be placed at the surgical site to take local images during surgery. It is also called a surgical probe or a fingertip probe. It includes the configuration of various transducer assemblies that consist of single or multiple elements that convert voltage into an ultrasonic beam. The assembly determines the direction of the ultrasonic beam mechanically or electronically, focuses, and detects the reflected echo. This category includes ultrasonic transducers used for mode A, mode B, mode M, Doppler, Color Doppler (CD), and dual (combination image, Doppler or color flow) scanning. As a part of the design of transducer casing or housing assembly, the route to introduce the biopsy needle may be incorporated. This device is reusable.	70021000	Ⅲ	10-④	applicable	applicable
Pathogen inactivation/reduction system	A system that selectively changes the pathogenic surface structures, or irreversibly modifies the pathogenic nucleic acids with radiation in order to prevent proliferation of pathogens in blood products.	44185000	Ⅲ	3	applicable	applicable
Blood irradiator	A device that irradiates the blood and blood components with ionizing radiation sources in order to inactivate the lymphocytes. Available sources for irradiation include cesium-137. The device is used in ordinary laboratory environments, therefore, it is designed as a self-blocking unit.	17437000	Ⅲ	3	applicable	applicable
Cardiac catheter polygraph	A device that is connected to a catheter inserted into the heart and examines the hemodynamics of each part of the heart. The catheter is not included.	70052003	Ⅲ	10-④	applicable	applicable
Intracranial pressure gauge	A device that measures intracranial pressure intermittently or continuously. Usually, intracranial pressure is determined when it is necessary to monitor increases in pressure postoperatively, or when measurement of intracranial pressure is important.	35249000	Ⅲ	10-④	applicable	applicable

Anaesthesia depth monitor	A device that shows the state of consciousness of an unconscious (anesthetized) patient by detecting, processing, and displaying biological signals from the patient. The device is capable of detecting the level of sedation, unconsciousness, and awakening based on the bispectral analyses of electroencephalography (EEG) and other EEG variables. It is used during anesthetic management or cases subject to trauma.	41920000	III	10-④	applicable	applicable
Heparin-coated body surface electric stimulator electrode	A heparin-coated conductor to be applied to the body surface so that an electric current can be passed into the tissue. It may have both negative and positive electrodes.	34374203	III	1,14	applicable	—
Intramuscular stimulator probe	An intramuscular probe specifically designed to be used with a stimulator. It is inserted into the body and probes the nerves, etc. in less invasive surgery.	36957003	III	7,8	applicable	N/A
Central monitor with analytic capability	A unit designed to collect, process, or display vital signs and other patient data from a single or multiple bedside monitoring units. The unit is designed to actuate visual or audible signals/alarms if adverse conditions are recorded. The device is usually placed in an intensive care unit, or the central patient monitoring station in a cardiology ward, to allow healthcare professionals to simultaneously monitor biological data of a number of patients. Some devices are equipped with additional functions including Holter monitoring or ST-segment monitoring. Only devices capable of detecting arrhythmia or apnea are included in this category.	38470003	III	10-④	applicable	applicable
Cardiac arrhythmia monitoring system	A device consisting of units, modules, or components (e.g., a monitor, recording device, and amplifier) for the uninterrupted detection, measurement, and display of electrical activity of the heart to generate visual or audible signals or alarms when atrial arrhythmia or ventricular arrhythmia, such as premature contraction or ventricular fibrillation, has been detected.	43239000	III	10-④	applicable	applicable
Multiparameter monitor with critical parameters	A unit that collects monitoring parameters using an embedded function kit, module, or other devices to display data, by bed or by patient. The bedside unit can be connected to the central monitor; it can also be operated alone. Monitoring parameters include an electrocardiogram (ECG), blood pressure, body temperature, cardiac output, and respiratory gases; in addition, other critical parameters (supporting detection of arrhythmia or apnea; and in the case of anesthesia, determination of dose levels of a relaxant or local anaesthesia) are included.	33586003	III	10-④	applicable	applicable
Apnoea monitor	A device designed to detect cessation of breathing (apnea) of a patient, and to record, process, and display the respiratory status. Some devices are capable of printing data.	35194003	III	10-④	applicable	applicable
Apnoea alarm	A device that records a patient's respiratory rate, and generates alarm signals when the respiratory rate has exceeded the preset value. The device is usually used to detect the cessation of breathing (apnea) in an infant, and to generate a warning for a parent or a caregiver in a serious situation that may become life-threatening. The device utilizes a variety of methods for monitoring (e.g., a sensor pad on which an infant lies, and a sensor chest belt).	36319000	III	10-④	applicable	applicable
Electrocardiographic module with arrhythmia analysis function	A type of plug-in module intended to be used with a multimodal-monitor, used for the detection and recording of electrocardiogram (ECG) signals with an arrhythmia analysis function.	36349003	III	10-④	applicable	applicable
Electrocardiographic/respiratory module	A type of plug-in module usually intended to be used with a multimodal-monitor, used for the monitoring of electrocardiogram (ECG) signals and respiration to detect arrhythmia or apnea. Some devices have functionality that includes calculation of the frequency of respiration and frequency of obstructive respiratory events based on the measured ECG.	36548000	III	10-④	applicable	applicable

Nerve detection module	A type of plug-in module, usually intended to be used with a multimodal-monitor, used for the detection of a nerve center in a certain part of the body. The device is used when performing anesthesia or the like, to aid determination of the dose of a relaxant or a local anesthetic. The device consists of a nerve stimulation device and a receiver that records nerve action potentials.	37246003	Ⅲ	10-④	applicable	applicable
Oximetry catheter	A special catheter to be inserted through the inguinal or cervical vein to determine oxygen saturation (venous oxygen saturation: SvO2) in the blood flowing from the heart to the lungs.	15200009	Ⅲ	10-④	applicable	—
Cerebral oximeter	A device for the continuous measurement and monitoring of oxygen saturation in the cerebral blood. The measurement and monitoring is performed with the probe placed on the head.	17942000	Ⅲ	10-④	applicable	applicable
Intracranial pressure monitor	A device that gives a warning about increased intracranial pressure (ICP) with an alert sounded ideally before increased ICP can cause neurological disorders. In addition, the device performs continuous monitoring and early warning, neither of which can be performed with other diagnostic devices. Some types can record and display ICP waves on the strip chart so that the long-term tendency of ICP can be observed.	16763010	Ⅲ	10-④	applicable	applicable
Intracranial pressure module	A type of plug-in module usually intended to be used with a multimodal-monitor, used for the detection and recording of intracranial pressure (ICP).	16763020	Ⅲ	10-④	applicable	applicable
Nerve detector stimulator	A device that detects the nerves intermittently to monitor the relative position of the nerves to surgical devices (e.g., a scalpel). It may be used to determine the dose of a muscle relaxant or anesthetic. It consists of a neural stimulator and a receiver that records nerve signal activity.	35723003	Ⅲ	10-④	applicable	applicable
Self monitoring glucose meter	A device for self monitoring blood glucose or ketones. The device is dedicated for patient use at home.	30854000	Ⅲ	—	applicable	applicable
Heparin-coated intra-arterial needle	A thin, sharp, hollow device used for arterial puncture. Usually, it is made of metal and coated with heparin to prevent blood coagulation.	12747203	Ⅲ	6,14	applicable	—
Insulin hypodermic syringe	A device consisting of a graduated cylinder and a plunger, used for subcutaneous injection of insulin.	35389010	Ⅲ	2-①,6-④	applicable	—
Insulin hypodermic syringe with needle	A device consisting of a graduated cylinder and a plunger, with an appropriate needle, used for subcutaneous injection of insulin.	35389020	Ⅲ	2-①,6-④	applicable	—
Spinal anaesthesia needle	A device with a sharp beveled tip, used for purposes that include administration of an anesthetic or analgesic into the subarachnoid space. The device is usually sterilized, and intended for single-use.	35212000	Ⅲ	7-①	applicable	—
Epidural injection needle	A device with a sharp tip, used for administration of an anesthetic or analgesic into the epidural space. The device is sometimes used to insert a catheter into the epidural space for continuous anesthetic delivery.	36191010	Ⅲ	7-①	applicable	—

Spinal/epidural anaesthesia needle	A puncture device kit for combined spinal and epidural anesthesia, used for administration of an anesthetic or analgesic into the epidural space or subarachnoid space. The device consists of a catheter, which delivers a local anesthetic into the epidural space continuously or repeatedly, a filter, and other components. Needles for combined spinal anaesthesia administered into the subarachnoid space and epidural anesthesia has a sharp tip used for administration of an anesthetic or analgesic. The device is sometimes used to insert a catheter into the epidural space for continuous anesthetic delivery.	36191020	Ⅲ	7-①	applicable	—
Sterile anesthesia needle	A device with a hollow tube used for percutaneous nerve block. Some devices have an insulated tube, others have a terminal which is connected to an electrode, and others have sharp and hollow tube. The device is sterilized and intended for single-use.	70203003	Ⅲ	7-①	applicable	—
Heparin-coated cardiovascular/thoracic troca	A heparin-coated surgical device with an acute, pyramidal or conical tip. It is used to puncture the body cavity in cardiovascular and thoracic surgery. Combined with a compatible sleeve that fits into the lumen of this device, the device can be introduced into the body cavity. With the removal of the device after puncture, a working channel is created in the body cavity.	42401203	Ⅲ	6-①,14	applicable	—
Long-term use jejunostomy catheter	A flexible tube to be used to form a fistula from the abdominal wall to the jejunum. It is for long-term use.	10731003	Ⅲ	8	applicable	—
Long-term use enteral feeding kit	A package of items used in combination to provide enteral nutrition to patients. It is for long-term use.	11677003	Ⅲ	5-④	applicable	—
Long-term use enterostomy feeding tube	A hollow device to be placed surgically in the stomach, duodenum or jejunum to provide enteral nutrition. It is for long-term use.	16799003	Ⅲ	8	applicable	—
Gastrostomy tube for long-term use	A hollow device to be placed surgically in the stomach, duodenum or jejunum for enteral nutrition, etc. It is for long-term use.	35419003	Ⅲ	8	applicable	—
Long-term use gastrostomy button	A short tube to be percutaneously inserted into the stomach to enable enteral nutrition. It is for long-term use. The device does not cause regurgitation, and the external tip is flat and placed at the same height as the abdominal skin.	38565003	Ⅲ	8	applicable	—
Long-term use nasogastric tube	A flexible, plastic tube to be inserted through the nasopharynx and esophagus and placed in the stomach for removal of gastric contents, drug administration or enteral nutrition. It is for long-term use.	14221003	Ⅲ	5-④	applicable	—
Long-term use esophageal tube	A hollow device used to achieve hemostasis of varices. It is for long-term use. Usually, it has two balloons: one for the stomach, the other for the esophagus. It may have only one balloon.	35416003	Ⅲ	5-④	applicable	—
Long-term use infant enteral feeding kit	A kit of items used in combination to provide enteral nutrition to infants. It is for long-term use.	36044003	Ⅲ	5-④	applicable	—
Long-term use biliary catheter	A flexible tube that is used for biliary drainage, splinting of the bile duct during treatment, or preventing narrowing of the bile duct, intended for long-term use.	10696013	Ⅲ	8	applicable	—
Biliary tube	A tube used for endoscopy of, injection of drug solutions into, and drainage from the bile duct.	10696023	Ⅲ	7-①	applicable	—
Long-term use tracheal tube cuff	A balloon-like cuff attached around the endotracheal tube. It is for long-term use. It is placed inferior to the vocal cords during mechanical ventilation of the lungs so as to create a seal between the tube and the tracheal walls.	14082003	Ⅲ	5-④	applicable	—

Long-term use ventilation tracheal tube	A cylindrical tube to be inserted into the trachea through the oral cavity or the nose for securing an airway, administering inhalational anesthetics or medical gas, or to provide ventilation. It is made of plastic, rubber, etc. and designed for long-term use. It may be packaged with a connector to connect to the breathing circuit or a manual resuscitator. There are dedicated types for pediatric and adult patients. These are different in terms of size, length, cuff, protective device, or radiolucency.	14085003	Ⅲ	5-④	applicable	—
Long-term use jet ventilation tracheal tube	A cylindrical, hollow tube to be inserted into the trachea for ventilation in patients during jet (high flow) ventilation. It is used for ventilation in patients, and designed for long-term use. Usually, a tube with no cuff is used so that the ventilated gas can be easily discharged to around the tube.	17935003	Ⅲ	5-④	applicable	—
Long-term use laser-resistant ventilation tracheal tube	A cylindrical, hollow tube to be inserted into the trachea to secure airway patency and administer anesthetics. It is for long-term use. It cannot be broken or ignited easily by laser beams even if it is accidentally exposed to them during brain, throat or neck surgery.	36064003	Ⅲ	5-④	applicable	—
Reusable long-term use nasopharyngeal tracheal tube	A rubber or plastic tube to be inserted through a nostril into the pharynx to maintain airway patency. It is for long-term use. It may be equipped with a 15 mm connector at the tip for oxygen supplementation. This device is reusable.	42421000	Ⅲ	5-④	applicable	—
Long-term use oropharyngeal tracheal tube	A curved tube made of metal or plastic, to be inserted through the oral cavity in order to maintain airway patency at the time of gas exchange or aspiration. It is for long-term use. It is useful for preventing airflow being blocked by the tongue.	42424003	Ⅲ	5-④	applicable	—
Long-term use esophageal/tracheal double-lumen tube	A dual-lumen tube that enables an airway to be secured or perform artificial respiration, ventilation, etc. , regardless of whether it is inserted into either the trachea or esophagus. It has two cuffs (a cuff at the proximal end of the tube is for the trachea or esophagus, and the other in the middle of the tube is for the pharynx). It may be packaged with a connector connecting to the breathing circuit or a manual resuscitator. It is for long-term use.	70250003	Ⅲ	5-④	applicable	—
Long-term use ureteral tube stent	A flexible tube inserted and placed in the ureter for purposes such as drainage or irrigation. It is for long-term use.	34926003	Ⅲ	5-④	applicable	—
Antimicrobial urological catheter	A flexible tube to be inserted into the urethra to access the urinary tract for introduction, drainage, etc. of fluid. It is mixed or coated with drug or material such as antibiotics to prevent urinary tract infection.	34096000	Ⅲ	5-②,13	applicable	—
Long-term use self-retained urological catheter	A flexible tube to be placed in the bladder. It is for long-term use. It has an inflatable balloon at the distal end. It is usually used for urination, hemostasis, etc.	34917003	Ⅲ	5-④	applicable	—
Long-term use nephrostomy catheter	A flexible tube to be inserted percutaneously into the renal pelvis to access the upper urinary tract. It is for long-term use.	10735003	Ⅲ	8	applicable	—
Long-term use nephrostomy tube	A tube used to perform nephrostomy from the body surface area of the pelvis to the kidney. It is for long-term use.	14224003	Ⅲ	8	applicable	—
Stoma drainage urological catheter	A flexible tube to be inserted into a urological fistula for urination on a long-term basis.	31074009	Ⅲ	8	applicable	—
Suprapubic urological catheter	A flexible tube to be inserted directly into the bladder through an incision made above the pubis (above the pubic arch) in a male or female patient for urination.	34924003	Ⅲ	8	applicable	—
Kidney stone filter	A filter to be placed in the urinary duct to prevent a renal stone from moving from the kidney into the bladder.	11717000	Ⅲ	8	applicable	—

Heparin-coated arterial cannula	A semi-rigid heparin-coated tube to be inserted into an artery and utilized as a guidepath for solutions. Usually, it is inserted with a removable trocar. This device is for single-use.	34893203	III	6,14	applicable	—
Heparin-coated femoral cannula	A semi-rigid or rigid heparin-coated tube inserted into the femoral blood vessel and utilized as a guidepath for solutions. This device is for single-use.	34902203	III	6,14	applicable	—
Heparin-coated venous cannula	A semi-rigid or rigid heparin-coated tube to be inserted into a vein and utilized as a guidepath for solutions. Usually, it is inserted with a removable trocar. This device is for single-use.	34905203	III	6,14	applicable	—
Catheter for drug administration angiography	A flexible tube designed to inject contrast media into a visceral organ or the peripheral vascular system for visualization of the vascular system in the target body site. It is also used for administration of pharmaceuticals.	10688103	III	6-④,13	applicable	—
Catheter for heparin-coated drug administration angiography	A flexible heparin-coated tube designed to inject contrast media into a visceral organ or the peripheral vascular system for visualization of the vascular system in the target body site. It is also used for administration of pharmaceuticals.	10688203	III	6-④,14	applicable	—
Drug administration angiographic kit	A kit of devices and instruments used for preparation for radiographic visualization of the arteries in specific organs or body parts, or for administration of pharmaceuticals.	16545003	III	6-④	applicable	—
Heparin-coated guiding intravascular catheter	A flexible heparin-coated tube used as a conduit to insert a balloon catheter and guide wire in percutaneous vascular surgery.	17846213	III	6,14	applicable	—
Heparin-coated vascular indwelling sensor	A heparin-coated sensor that is inserted into the peripheral blood vessel, and determines blood pressure, partial pressure in the blood, temperature, etc.	70273000	III	6,14	applicable	—
Heparin-coated catheter introducer	A heparin-coated sheath to be used in a vein or artery to facilitate percutaneous placement of a catheter.	10678203	III	6,14	applicable	—
Introducer catheter	A catheter used with a guiding catheter with a lumen of 9 Fr or wider. It is used to narrow the lumen of the guiding catheter when it is inserted, for better lubrication between the catheter and guide wire and to facilitate insertion.	70281000	III	6,6-④	applicable	—
Non-central circulatory thrombectomy vibration catheter	A flexible tube that breaks up a thrombus in the blood vessel of the non-central vascular system. The device fragments the thrombus percutaneously and through the inner cavity. The tip of the catheter vibrates to make fragments small enough to be suctioned or removed.	70282000	III	6-④	applicable	—
Transjuglar intrahepatic portal vein access set	A set used to access the intrahepatic portal vein from the jugular vein percutaneously. The set contains devices for imaging of the hepatic vein, portal vein, bile duct and for liver biopsy, and a balloon catheter to dilate a shunt for performing shunting with the stent.	70285000	III	6-④	applicable	—
Heparin-coated intravenous catheterization kit	A heparin-coated kit containing devices to be used for inserting a catheter through the vein.	12161203	III	6,14	applicable	—
General-purpose vascular catheter cuff	A device mainly has effects on the growth of subcutaneous tissue. It is applied to the insertion site of a vascular catheter in order to support the prevention of infection.	17470000	III	8	applicable	—
Vascular catheter guidewire	A device used for adjusting the position of, and supporting the delivery of a catheter. It is generally made of coated or uncoated stainless steel. The coating makes it easier to move in the blood vessel.	35094103	III	6-④	applicable	—

Heparin-coated vascular catheter guidewire	A device used for adjustment of positions of a catheter, a lead wire, etc. and support moving them. It is made of heparin-coated stainless steel, plastic, etc. The coating makes the wire move easily in the blood vessel and prevents thrombus formation.	35094203	Ⅲ	6,14	applicable	—
Vascular embolization prosthesis	An artificial device used therapeutically for promoting thrombus formation in the vein or blocking the blood flow.	35449003	Ⅲ	8	applicable	—
Non-central circulatory intravascular ultrasound catheter	A catheter that ultrasonically diagnoses the interior of the blood vessel in the non-central circulatory system. It is equipped with a transducer that sends and receives ultrasonic at the proximal end.	70289003	Ⅲ	10-④	applicable	—
Microcatheter	A catheter with a small diameter used for selection of blood vessels having a diameter of 1 to 2 mm and for treatment in highly selective angiography and embolization. The tip is equipped with a function that enhances visibility so that the position can be confirmed under fluoroscopy.	70296013	Ⅲ	6-④	applicable	—
Ophthalmic microcatheter	A catheter with a small diameter used for treatment in the ophthalmic therapeutic area. The tip may be equipped with a function to enhance visibility so that the position can be confirmed under fluoroscopy.	70296023	Ⅲ	6-④	applicable	—
Catheter for microdialysis	A catheter with a small diameter having a dialysis membrane around the tip. It collects components of the body fluid from the tissues at the insertion site via dialysis fluid supplied to the lumen of the catheter.	70297000	Ⅲ	6-③,7-④	applicable	—
Catheter for peripheral intravascular	A flexible tube inserted into the peripheral blood vessels (the peripheral vascular system) which are percutaneously accessible. It is short in length so that its distal end can be held near the insertion site. Usually, this device contains a plastic tube 2 to 8 cm long (1 to 3 inch), and a metal stylet is installed inside the lumen (catheter-over-introducer-needle). This is an injection device most commonly used for short-term placement (usually no longer than a week), for administration of nonirritating solutions, electrolytes, vitamins and drugs, and for injection of certain kinds of anesthetics to the patients having good intravenous access.	34920000	Ⅲ	7-①	applicable	—
Lymphangiography kit	A kit of devices and materials used to inject a contrast material into the lymphatic vessel for the purpose of visualization in radiography. This unit provides one or more devices as a single unit for the intended purpose of the devices.	35168000	Ⅲ	6-④	applicable	—
Myelography kit	A kit, tray or set of devices and materials used to inject contrast media into the subarachnoid space (usually, the lumbar vertebra) for the purpose of visualization of the spinal cord in radiography.	35199000	Ⅲ	6-④	applicable	—
Catheter for pericardial drainage with urokinase	A flexible tube used to drain fluid from the periphery of the heart. It contains urokinase, a biological material.	10741203	Ⅲ	6,14	applicable	—
Drug administration multi-lumen catheter	A flexible, dual-lumen (or multiple-lumen) tube used to inject fluid into the body cavity or drain it from the body cavity. It is also used to administer drugs. Tubes used for the central circulatory system or for the central nervous system are excluded.	32330203	Ⅲ	5-②,7-①,13	applicable	—
General-purpose suction catheter for heparin-coated	A flexible heparin-coated tube used for removal of fluid and evacuation of air through a natural opening of the body, surgical incision or wound site. It is usually designed to be connected to a collecting can or bottle when connected to a vacuum aspiration unit.	34923203	Ⅲ	3,7,14	applicable	—
General-purpose suction catheter with urokinase	A flexible tube with urokinase used for removal of fluid and evacuation of air through a natural opening of the body, surgical incision or wound site. It is usually designed to be connected to a collecting can or bottle when connected to a vacuum aspiration unit.	34923303	Ⅲ	3,7,14	applicable	—

Heparin-coated thoracic drainage tube	A heparin-coated single-lumen or dual-lumen straight or angular tube. It is used for removal of secretions or irrigation of the thoracic cavity after thoracic surgery or cardiac surgery.	11308203	Ⅲ	7,14	applicable	—
Urokinase-coated thoracic drainage tube	A single-lumen or dual-lumen straight or angular tube with urokinase. It is used for removal of secretions or irrigation of the thoracic cavity after thoracic surgery or cardiac surgery.	11308303	Ⅲ	7,14	applicable	—
Heparin-coated drainage tube	A heparin-coated plastic or metal tube used for removal of exudate or purulent substances from a cavity, wound site, or infection site.	14191203	Ⅲ	5-②,14	applicable	—
Drainage tube with urokinase	A plastic or metal tube with urokinase used for removal of exudate or purulent substances from a cavity, wound site, or infection site.	14191303	Ⅲ	5-②,14	applicable	—
Heparin-coated wound drainage kit	A package containing heparin-coated devices including plastic bags or bottles and a trocar to be used for draining fluid and pus from a wound.	35824203	Ⅲ	4-②,14	applicable	—
Peritoneovenous shunt peritoneal replacement catheter	A tube made of perforated silicone rubber with holes to be exchanged when the abdominal side of the implanted peritoneovenous shunt is occluded.	70310000	Ⅲ	8	applicable	—
Abdominal side exchange catheter for pleural shunt	A tube made of perforated silicone rubber with holes to be exchanged when the abdominal side of the implanted pleural effusion shunt is occluded.	70313000	Ⅲ	8	applicable	—
Thoracic side exchange catheter for pleural shunt	A tube made of perforated silicone rubber with holes to be exchanged when the thoracic side catheter of the implanted pleural shunt is occluded.	70314000	Ⅲ	8	applicable	—
Pleural shunt valve	An implantable device with a valve, made of plastic or silicone rubber, which continuously drains excessive pleural effusion from the thoracic cavity to the abdominal cavity, placed surgically or percutaneously.	70315000	Ⅲ	8	applicable	—
Hydrocephalic valve prosthesis	A device used for adjusting the intraventricular cerebrospinal fluid pressure.	35965000	Ⅲ	8	applicable	—
Arteriovenous shunt	A U-shaped plastic tube to be inserted between the artery and the vein and to bypass the capillary system. It is often used for arteriovenous access in hemodialysis.	13586000	Ⅲ	8	applicable	—
Catheter for arteriovenous shunt	A blood access device consisting of various rigid or semi-rigid tubes. It is surgically implanted in the adjoining artery and vein, and connected externally, and forms a shunt through which blood flows continuously. This device is used for hemodialysis. The connecting part of the arterial side of the shunt to the venous side is removed when a patient is connected to a set for hemodialysis blood tube, and the part is replaced to restore the shunt after the hemodialysis is completed. This device is for single-use.	32121000	Ⅲ	8	applicable	—
Haemodialysis co-axial flow catheterization kit	A kit of tubes and needles (coaxial flow) to be used to provide blood access for hemodialysis or other purposes. It is for long-term use.	33799100	Ⅲ	8	applicable	—
Hemodialysis co-axial flow catheterization kit with urokinase	A kit of tubes and needles (coaxial flow) with urokinase to be used to provide blood access for hemodialysis or other purposes. It is for long-term use.	33799200	Ⅲ	8	applicable	—
Implantable haemodialysis catheter	An implantable flexible tube for short-or long-term use, designed for extracorporeal circulation of hemodialysis. It is used to withdraw and infuse blood. The blood circulates through the extracorporeal blood circulation circuit of the dialyzer, and returns to the body after loop closure. Usually, it is implanted to perform standard hemodialysis in a patient with an inadequate peripheral vascular system, or with cardiovascular disease as primary disease, for whom the use of an arteriovenous fistula is not indicated.	37278000	Ⅲ	8	applicable	—

Closed loop haemodialysis catheter	A conduit catheter designed for extracorporeal circulation during hemodialysis.	42452000	III	8	applicable	—
Heparin-coated emergency blood access indwelling catheter	A heparin-coated catheter that is implanted in the veins including the internal jugular vein and femoral vein when a blood portal (blood access) is needed urgently for extracorporeal circulation in blood purification therapy.	70320300	III	8,14	applicable	—
Urokinase-coated emergency blood access indwelling catheter	An urokinase-coated catheter that is implanted in the veins including the internal jugular vein and femoral vein when a blood portal (blood access) is needed urgently for extracorporeal circulation in blood purification therapy.	70320400	III	8,14	applicable	—
Emergency blood access indwelling catheter	A catheter intended to be placed in veins such as the internal jugular vein or femoral vein when urgent vascular access is required to perform extracorporeal circulation in the process of blood purification. Delivery of an infusion fluid or agent external to the circuitry that is used to remove and return blood, and measurement of venous pressure may be performed.	70320100	III	8	applicable	—
Antibacterial emergency blood access indwelling catheter	An antibacterial catheter that is implanted in the veins including the internal jugular vein and the femoral vein when a blood portal (blood access) is needed urgently for extracorporeal circulation in blood purification therapy. Some types have a cuff. In some types, antibacterial materials are used only for the cuff.	70320200	III	8,13	applicable	—
Long-term use catheter balloon repair kit	A kit containing adhesives, balloons, and other items to be used for repair or replacement of balloon catheters. It is for long-term use.	31665003	III	5-④	applicable	—
Urokinase-coated obturator	A device to be inserted into the lumen of a catheter introducer or a catheter to prevent bending and lumen occlusion during long-term placement, etc. It contains urokinase, a biological material.	70323203	III	6,14	applicable	—
Peritoneal catheter	A flexible tube to be inserted into the cavity that is surrounded by a bilayer sac, which lines the abdominal wall, covering most of the viscera contained inside the wall (the peritoneum).	16433000	III	3	applicable	—
Epidural catheter	A semi-rigid or rigid tube usually designed to be placed in the epidural space for infusion of drugs for pain management. This device is for single-use.	34898000	III	6-④,7-①	applicable	—
Anaesthetic conduction catheter	A flexible tube to be used for continuously and repeatedly infusing local anesthetics to the wound area or the vicinity of the peripheral nerve. A flexible tube used for infusion into the epidural space may be included. It is used in surgical procedures. It may be used in diagnosis or temporary relief of chronic pain in the extremities, pelvis, abdomen and lumbar spine.	35795009	III	7-①	applicable	—
Heparin-coated single-use general-purpose suction tip	A heparin-coated device to be attached to the aspirator for adjustment and management of aspiration in surgical procedures and treatment. It is a general-purpose aspiration tip for single-use.	35917203	III	6,14	applicable	—
Long-term use thoracic catheter	A semi-rigid or rigid tube to be inserted into the chest (the pleural cavity) to facilitate placement of a chest tube. It is for long-term use.	36247003	III	8	applicable	—
Heparin-coated lacrimal fluid/passage silicone tube	A heparin-coated silicone tube to be inserted and placed in the canaliculus, or to dilate the lacrimal passage for treatment of epiphora resulting from lacrimal punctum obstruction, canalicular obstruction, nasolacrimal duct obstruction, etc.	70337203	III	5-②,14	applicable	—
Blood component separation bag with filter	A plastic bag that is used for collecting, separating, storing, processing, transporting and administering blood and blood components, and is connected to a leukapheresis filter. It does not contain blood stock solutions.	70358000	III	3	applicable	—

Leukocyte removal blood filter	A filter to be inserted into a transfusion line, etc. for removal of leukocytes from blood to be infused into a patient.	70365000	III	3	applicable	—
Potassium absorption blood filter	A filter to be used for adsorptive removal of excessive potassium from blood to be infused into a patient.	70367000	III	3	applicable	—
Anaesthetic infusion administration set	A transfusion set to be used for infusing an anesthetic solution into the infusion site of a patient or a recipient of the solution. Some types provide transfusion gravitationally without using an active device. Other types provide transfusion using an infusion pump or a transfusion device. It may have a transfusion filter, a T-shaped stopcock, a connection for co-infusion, etc.	70375000	III	7-①	applicable	—
Infusion pressure regulator	A device to adjust supply of transfusion, liquid or blood by adding pressure to the infusion bag inserted in this device. The pressure is generated mechanically, pneumatically (with pressurized air), or manually (with a hand pump).	13100013	III	11-①	applicable	applicable
Enteral feeding infusion pump	A special pump designed to provide nutrition directly into the stomach of patients who are unable to maintain appropriate food intake or have no appetite.	13209000	III	11-①	applicable	applicable
General-purpose infusion pump	A device that facilitates accurate and constant intravenous administration of a medication or solution. The device is used to provide pressure that is higher than that for an infusion kit with a manual control clamp or a medication infusion controller. The flow rate usually ranges from 1 to 999 mL per hour, and solutions or drugs are delivered from a standard fluid bag or a bottle.	13215000	III	11-①	applicable	applicable
Syringe infusion pump	A device designed to be used in cases where there is a requirement for delivery of a highly accurate volume of solution at a constant rate. With the capability for a low flow rate setting and flow rate conversion, the device is suitable for uses where a small amount of highly concentrated drug is administered for a long duration in the treatment of neonates, infants, or patients in a critical condition. The device can also be used for administration of epidural anesthesia.	13217000	III	11-①	applicable	applicable
Oxytocin syringe infusion pump	A dedicated transfusion syringe pump for administration of oxytocin. It is calibrated in the unit specifically for this use.	16167000	III	11-①	applicable	applicable
Multichannel infusion pump	A device that is designed to deliver 2 or more drugs or solutions continuously or intermittently into the vein, and is capable of controlling the delivery on a channel-by-channel basis. A syringe and a bag or a bottle can be used.	17634000	III	11-①	applicable	applicable
Warming high-flow infusion pump	A device to be used for heating and rapidly infusing blood or other fluids during surgical procedures involving major bleeding, or for burns or injuries. The maximum flow rate of the device may exceed 1 liter/min.	17907010	III	11-①	applicable	applicable
Nonprogrammable implantable infusion pump	A non-programmable device to be implanted for bolus administration of narcotics or therapeutic drugs for intractable pain.	34071000	III	8	applicable	—
Patient-controlled analgesic infusion pump	A device that delivers a prescribed amount of intravenous or epidural anesthesia/analgesic when actuated by the patient. Agents can be administered either in on-demand (bolus) mode or continuous mode.	35932000	III	11-①	applicable	applicable
Portable insulin infusion pump	A device for continuous subcutaneous insulin infusion in patients with diabetes mellitus type 1. The device can also be used for intermittent administration of insulin for the treatment of patients with insulin-independent (type 2) diabetes mellitus or gestational diabetes.	35983000	III	11-①	applicable	applicable

Syringe infusion pump control unit	A device designed to be used with its dedicated syringe pump to support delivery of intravenous anesthesia. The infusion volume, set in advance based on the patient's (target) body weight, height, and age, and medications to be administered, can be controlled and monitored. This technique is usually called "target controlled infusion" (TCI).	37217000	III	11-①	applicable	applicable
High-flow blood transfusion pump	A device to be used for rapidly infusing blood or other fluids during surgical procedures involving major bleeding, or for burns or injuries. The maximum flow rate of the device may exceed 1 liter/min.	17907020	III	11-①	applicable	applicable
Active infusion pressure regulator	A device to adjust supply of transfusion, liquid or blood by adding pressure to the infusion bag inserted in this device. The pressure is generated mechanically, or pneumatically (with pressurized air).	13100023	III	11-①	applicable	applicable
Drug infusion controller	A drug infusion device utilizing gravity and the height of the liquid container as the only pressure source for infusion (administration) of liquid. The device may incorporate an electronic stalagmometer.	11010000	III	11-①	applicable	applicable
Catheter drug injection port	A device used as an infusion site. It is located at the luer end of a catheter or an intravenous (IV) tube. This device is also used for heparin immobilization by maintaining heparin lavage in the catheter.	16858000	III	8	applicable	—
Subcutaneous port/catheter	A device that can be implanted for a short or long period and consists of a metal or plastic port with a self-sealing septum. It is connected to a catheter and used to deliver drugs or other liquids to the various anatomical areas or blood vessels. It is subcutaneously implanted and can deliver drugs and liquids through a medical supply pump (for drugs and liquids), or bolus administration. A catheter is included.	33923100	III	7-①,8	applicable	—
Heparin-coated subcutaneous port/catheter	A heparin-coated device that can be implanted for a short or long period and consists of a metal or plastic port with a self-sealing septum. It is connected to a catheter and used to deliver drugs or other liquids to the various anatomical areas or blood vessels. It is subcutaneously implanted and can deliver drugs and liquids through a medical supply pump (for drugs and liquids), or bolus administration. A heparin-coated catheter is included.	33923200	III	7-①,14	applicable	—
Short-term use implantable infusion port	A metal or non-metal device to be implanted in a patient in order to deliver liquid or drugs to the vascular system or other anatomical areas; for short-term use. It consists of a housing, a self-sealing septum, and a catheter connection. It can be implanted in various anatomical areas.	35911003	III	7-①	applicable	—
Drug solution injection nozzle	A device basically consisting of a needle tube and a needle hub for spraying, injecting and applying drug solutions to the surgical area.	70388000	III	7-①	applicable	—
Reusable insulin pen injector	A manual device for subcutaneous insulin injection in humans. The devices are reusable (many are pen-type devices), and each injection requires a dedicated, replaceable needle tip to be attached. The device mechanism varies depending on the purpose. A cartridge, pre-filled with insulin to be injected, is inserted in the pen, and the insulin is injected by a healthcare professional or the patient, depending on the circumstances. The device is not a subcutaneous syringe.	70392000	III	6-④	applicable	—
Portable continuous anaesthesia unit	A unit that houses filters, catheters, and connectors in the assembly case for continuous anesthesia after epidural anesthesia. A needle is not included.	70395000	III	3	applicable	—

Pressurized drug injector	A portable pump that uses non-electric power sources such as a balloon, atmospheric pressure, or a spring to administer an agent continuously at a constant rate. Some examples of this type of devices include: those that allow selection of agent infusion rate; those equipped with an injector for patient controlled analgesia (PCA); and those designed to be connected to a PCA device.	12504003	Ⅲ	3,11	applicable	—
Subarachnoid/epidural anaesthesia kit	A kit containing a set of devices necessary for injecting anesthetics into the epidural space and the spinal subarachnoid space.	34842003	Ⅲ	7-①	applicable	—
Subarachnoid anaesthesia kit	A kit containing a set of devices necessary for injecting local anesthetics into the subarachnoid space around the spinal cord.	34845000	Ⅲ	6-④	applicable	—
Infusion pump management unit	A unit to be used for operating, managing and monitoring many infusion pumps, and supplying electricity to them at the bedside of a patient. The infusion pumps take various forms and are used simultaneously for one patient. It is used in an intensive care unit and is useful for high-level management of the various infusion pumps, infusion set and line, drugs to be infused, etc.	36179010	Ⅲ	11-①	applicable	applicable
Mobile infusion pump management unit	A mobile unit to be used for operating, managing and monitoring many infusion pumps, and supplying electricity to them at the bedside of a patient. The infusion pumps take various forms and are used simultaneously for one patient. It is used in an intensive care unit and is useful for high-level management of the various infusion pumps, infusion set and line, drugs to be infused, etc.	36179020	Ⅲ	11-①	applicable	applicable
Hemostatics infusion kit	A kit consisting of injection tubes, a spray mechanism, syringes, etc. to be used for injection of hemostatic drugs.	70397000	Ⅲ	11-①	applicable	—
Epidural anaesthesia catheter	A soft tube through which a local anesthetic or analgesic is injected into the epidural cavity.	35795000	Ⅲ	7-①	applicable	—
Heparin-coated apheresis set	Devices used in a centrifugal apheresis system. The system may contain heparin.	70405000	Ⅲ	11-①,14	applicable	—
Ligature wire	A wire to be used for tightening and fixing the blood vessels, the pedicle of a tumor, other tissues and bones.	14457000	Ⅲ	8	applicable	—
Implantable ligating clip	An implantable metal device indicated for use in the conduits, blood vessels, and other body tissues. It is used to prevent and stop leakage from the tissue.	35649000	Ⅲ	8	applicable	—
Non-sterile silk suture	Non-sterile packaged, fine silk thread (including belt-or tube-shaped thread, and string). The device, which is required to be sterilized prior to use to prevent infection, is intended for suturing or ligation of tissues, or securing a medical device and a tissue. Needles and other accessories are also included.	34601000	Ⅲ	8	applicable	—
Sterile silk suture	Sterile silk thread intended for suturing or ligation of tissues, or securing a medical device and tissue (including belt-or tube-shaped thread, and string). Needles and other accessories are also included.	13910000	Ⅲ	8	applicable	—
Polyester suture	Polyester thread intended for suturing or ligation of tissues, or securing a medical device and tissue (including belt-or tube-shaped thread, and string). Needles and other accessories are also included.	13906000	Ⅲ	8	applicable	—
Polyethylene suture	Polyethylene thread intended for suturing or ligation of tissues, or securing a medical device and tissue (including belt-or tube-shaped thread, and string). Needles and other accessories are also included.	13907000	Ⅲ	8	applicable	—

Polypropylene suture	Polypropylene thread intended for suturing or ligation of tissues, or securing a medical device and tissue (including belt-or tube-shaped thread, and string). Needles and other accessories are also included.	13909000	III	8	applicable	—
Polybutester suture	Polybutester thread intended for suturing or ligation of tissues, or securing a medical device and tissue (including belt-or tube-shaped thread, and string). Needles and other accessories are also included.	17245000	III	8	applicable	—
Polytetrafluoroethylene suture	A polytetrafluoroethylene thread (including belt-or tube-shaped thread, and string). intended for suturing or ligation of tissues, or securing a medical device and tissue. Needles or other accessories are also included.	17467000	III	8	applicable	—
Plastic suture	Plastic thread intended for suturing or ligation of tissues, or securing a medical device and tissue (including belt-or tube-shaped thread, and string). Needles and other accessories are also included.	34602000	III	8	applicable	—
Polyamide suture	Polyamide thread intended for suturing or ligation of tissues, or securing a medical device and tissue (including belt-or tube-shaped thread, and string). Needles and other accessories are also included.	38847000	III	8	applicable	—
Polyvinylidene fluoride suture	Polyvinylidene fluoride thread intended for suturing or ligation of tissues, or securing a medical device and tissue (including belt-or tube-shaped thread, and string). Needles and other accessories are also included.	38873000	III	8	applicable	—
Polyurethane suture	Polyurethane thread intended for suturing or ligation of tissues, or securing a medical device and tissue (including belt-or tube-shaped thread, and string). Needles and other accessories are also included.	70412000	III	8	applicable	—
Vinylidene fluoride/hexafluoropropene copolymer suture	Poly (hexafluoropropylene-vdf) thread intended for suturing or ligation of tissues, or securing a medical device and tissue (including belt-or tube-shaped thread, and string). Needles and other accessories are also included.	70413000	III	8	applicable	—
Stainless steel suture	Stainless steel thread intended for suturing or ligation of tissues, or securing a medical device and tissue (including belt-or tube-shaped thread, and string). Needles and other accessories are also included.	35383000	III	8	applicable	—
Urinary incontinence treatment tape	A tape made of a synthetic material used to raise the midurethra for treatment of urinary incontinence.	70414000	III	8	applicable	—
Titanium suture	Titanium thread intended for suturing or ligation of tissues, or securing a medical device and tissue (including belt-or tube-shaped thread, and string). Needles and other accessories are also included.	70415000	III	8	applicable	—
Injection needle type suture unit	A sterile device with a non-absorbable suture that is built into a needle-like device. It is used to repair skin damage or muscle lacerations. After removal of the needle inserted into the wound site with the suture left in situ, ligation is performed. This device is for single-use.	70416000	III	8	applicable	—
Non-absorbable vascular anastomosis coupler	A device used to connect the tissue of blood vessels using a joint with components inserted into the ends of the junction. This is made of non-absorbable materials.	18137003	III	8	applicable	—
Implantable vascular clip	An implantable device designed to block the blood flow in small vessels by compression.	35640003	III	8	applicable	—
Contraceptive fallopian tube clip/band	An implantable device applied to the fallopian tubes, and used to ligate them to prevent an ovum from passing through. Usually, it is used in tubal ligation, and considered a contraceptive device.	33598000	III	8	applicable	—

Contraceptive vas deferens clip/band	An implantable device, usually a minute clamp made of plastic placed in the vas deferens to stop the flow of sperm permanently. It is used for male sterilization instead of vasectomy.	42927000	III	8	applicable	—
Non-biodegradable tissue fixation staple	A U-shaped or spiral, non-absorbable device used for fixation of the tissues or fixation between the tissue and device. It may be used for suture, anastomosis, etc. with a surgical stapler. Usually, it is made of polymer, and may be loaded into a cartridge.	35615003	III	8	applicable	—
Non-absorbable suture set	A set combining various devices used for suture and anastomosis of tissues and blood vessels. Usually the set contains non-absorbable surgical sutures, and other devices (e.g., suture needles, nonwoven fabrics, an automatic suture device, forceps, clips) are included, where necessary.	70425000	III	8	applicable	—
Implantable suture retention device	An implantable device such as a fixed bridge, a surgical button, a thread holder. It is used to support wound healing by distributing the tension of the suture more widely. The distribution of the tension of the suture helps to prevent the suture from cutting the skin or the tissue.	70426000	III	8	applicable	—
Hydrogel wound dressing for secondary healing	Secondary healing wound care dressings, made of hydrophilic-polymer, used to absorb exudate, reduce bleeding or body-fluid loss, and protect wounds from scraping, friction, drying, and contamination.	34082003	III	4-①	applicable	—
Secondary healing saline solution-containing dressing	Secondary wound care dressings saturated with saline solution, intended to promote biological cleaning and the autolytic debridement process in wounds.	37298003	III	4-①	applicable	—
Secondary healing hydrophilic gel-forming dressing	A secondary wound care dressings, usually in sheet or ribbon form, made of hydrophilic fiber, chitin, or alginate (salt and acid) or the like, which absorbs exudate and maintains a moist environment, aiding autolytic debridement.	43186003	III	4-①	applicable	—
Antimicrobial dressing	A sterile fabric or narrow slip impregnated with an infectant and an antibacterial agent used for dressing wounds.	34614000	III	4-①,13	applicable	—
Puncture protection patch	A patch impregnated with antimicrobials. It is used to protect the skin puncture site to suppress bleeding, absorb fluid, and protect from contamination. The antimicrobials are used to prevent microbial growth in the patch.	70432000	III	4,13	applicable	—
Absorbable gauze	Sterile, light gauze made of oxidized cellulose, with a loose weave. It is used during surgery and absorbed into the body.	32376000	III	6-③	applicable	—
Absorbable dressing	A wound dressing and a protective dressing made of a bioengineered material. It protects wounds and is absorbed into the skin as they heal.	34615100	III	4-①,14	applicable	—
Collagen-containing absorbable dressing	A wound dressing and a protective dressing made of a bioengineered material. It contains collagen, protects wounds and is absorbed into the skin as they heal.	34615200	III	4-①,14	applicable	—
Foam wound dressing for secondary healing	A secondary healing wound care dressings, made of hydrophilic foam, a superabsorbent pad, intended to cover wounds with a high volume of exudate.	11323003	III	4-①	applicable	—
Skin graft/donor-site dressing	Non-absorbable, non-adherent sheet made of mylar or other materials to dress or protect burns and various wounds including a skin graft and skin donor sites.	15319000	III	4-①	applicable	—
Wound dressing kit	A kit, tray, or set of pre-packaged various devices, wound dressings and protective dressings, drugs, etc. necessary for dressing wounds.	34059000	III	4-①	applicable	—
Interactive wound dressing	A sterile wound dressing and a protective dressing of a synthetic or natural material. It is used to actively promote healing of wounds or burns by interacting directly and indirectly with the body tissues.	34083000	III	4-①,14	applicable	—

Deep-cavity wound dressing	A wound dressing and a protective dressing made of a natural or synthetic material. It is used for management of deep wounds involving muscle or bone.	36226000	Ⅲ	4-①	applicable	—
Heated occlusive dressing	A wound dressing and a protective dressing to seal wounds to prevent exposure to the air and bacteria in the environment. This is heated to promote healing of wounds.	37275000	Ⅲ	4-①	applicable	—
Surgical mesh	A non-absorbable device to be used for dressing and supporting of the soft tissues or the hard tissues after idamaged or onset of degenerative disease. It may be made of metal, or a polymeric material.	16048003	Ⅲ	8	applicable	—
Non-absorbable ligament prosthesis	An implantable device used for replacement or repair in order to restore the function of a deficient or damaged ligamentous structure. It is made of a non-absorbable material.	35717003	Ⅲ	8	applicable	—
Non-absorbable banded gastroplasty prosthesis	A non-absorbable device implanted in part of the stomach for reconstruction or functional recovery. This consists of a part to be implanted into a specific site.	36111003	Ⅲ	8	applicable	—
Non-absorbable hernia/thoracic wall/abdominal wall prosthesis	A device made of a non-absorbable, synthetic fiber used for repairing a weakened or deficient chest wall, abdominal wall or a hernia.	70433013	Ⅲ	8	applicable	—
Non-absorbable antimicrobial hernia/thoracic wall/abdominal wall prosthesis	A device made of a non-absorbable, synthetic fiber used for repairing a weakened or deficient chest wall, abdominal wall or a hernia. It contains substances with antibacterial properties.	70433023	Ⅲ	8,13	applicable	—
Non-absorbable staple line reinforcement prosthesis	Materials made of non-absorbable synthetics including polytetrafluoroethylene. They are used to reinforce tissue defects, suture sites or junctions in combination with an automatic suture device.	70435000	Ⅲ	8	applicable	—
Endocapsular ring	An annular band used to reinforce the mechanical safety of subluxation of the lens capsule when the zonular is weak or absent. The device is implanted in the lens capsule, generates tension and keeps the lens capsule stretched.	42839000	Ⅲ	5-④	applicable	—
Collagen-containing burn dressing	A wide layered gauze pad used to dress and protect burned skin, and absorb exudates from the burns. It contains collagen.	11322203	Ⅲ	4,14	applicable	—
Symblepharon ring	A device used to prevent the eyelid from adhering to the eyeball. For instance, it may be used to keep the wound surfaces separated in a patient with glaucoma. It may be made of a polymeric material, or a simple mucosal graft may be used.	16073000	Ⅲ	5-④	applicable	—
Ophthalmic clip	An ophthalmic clasp permanently or temporarily implanted to promote healing or prevent bleeding from the ocular small vessel. Malleable metals including tantalum may be used.	32814000	Ⅲ	8	applicable	—
Nerve cuff	A device such as a silicone rubber sheath used to encase the nerve, and promote repair of the encased nerve. It is used to cover the end of the nerve to prevent tumor formation as well as epidermal growth in the scar tissue.	33385003	Ⅲ	8	applicable	—
Implantable vascular cuff	A sheath device that covers the blood vessel in order to prevent further damage in treatment for varicose, etc. Usually, it is made of polymeric materials.	34234003	Ⅲ	8	applicable	—
Eye muscle sleeve	A device made of synthetic materials to be used for encasing or separating the eye muscles.	35660000	Ⅲ	8	applicable	—
Lacrimal punctum plug	A device to be inserted into the opening of the punctum to prevent lacrimation. For instance, it may be used in patients with dry eyes.	36237100	Ⅲ	8	applicable	—

Collagen-containing lacrimal punctum plug	A collagen-containing device, inserted into the opening of the punctum to prevent lacrimation. For instance, it may be used in patients with dry eyes.	36237200	III	8,14	applicable	—
Non-absorbable periodontal tissue regenerative material	A non-absorbable material to be applied to the affected area in the oral cavity by covering, application, filling, etc. for the purpose of periodontal tissue regeneration. It may contain drugs.	70436003	III	8,13	applicable	—
Non-absorbable bone regeneration material	A non-absorbable material to be applied to the affected area by covering, application, filling, etc. for the purpose of bone tissue regeneration. Absorbable materials or those intended to produce biological effects are excluded. It may contain drugs, or use a biological material.	70437103	III	8,13,14	applicable	—
Extra-ocular orbital implant	A device made of synthetic materials to be used for compressing the eyeball where retinal detachment is caused by injuries, etc.	70442000	III	8	applicable	—
Dermal dilator	A device to be temporarily implanted subcutaneously to dilate the surrounding skin. Usually, a balloon is implanted subcutaneously where solutions including saline solution are infused.	70443003	III	8	applicable	N/A
Hydrophilic-bead dressing	A bead made of porous spherical polymer, such as a dextranomer bead, in which sugar chains have a network structure cross-linked with epichlorohydrin, a cross-linking agent. It is applied to skin defects with exudates in leg ulcers or severe burns to promote granulation.	33616000	III	4-①	applicable	—
Gastroplasty band	A belt or strip placed around the upper stomach (inside the body) to form a small sac with a narrow outlet in order to reduce food intake for weight loss. It may be surgically placed, or adjustable.	17649000	III	8	applicable	—
Single-use class III surgical procedure kit	A kit containing all items (Class I to Class III) necessary for general surgical treatment, including various devices, dressings, and drugs. This kit is for single-use.	33961003	III	6-④	applicable	—
Peritoneal irrigation kit	A package containing syringes and other devices for the peritoneal lavage.	12996009	III	3	applicable	—
Invasive external cardiac pacemaker	A device that generates pacing impulses from an external pulse generator through an electrode inserted into the heart from the major vein (e.g., subclavian electrode), or by contacting directly with the heart wall. An external temporary pacemaker is used to generate electrical impulses to the heart when sinus node (SA node) abnormalities or cardiac conduction abnormalities occur.	35224000	III	9-①	applicable	applicable
Noninvasive external cardiac pacemaker	A device that generates electrical impulses to stimulate the entire heart for resuscitation, treatment for arrhythmias, or temporary pacing during invasive procedures possibly causing cardiac arrhythmia or ventricular asystole (cardiac arrest) in contrast to invasive, single chamber, or dual chamber pacing. The pulses from this device are usually applied to the chest surface via an electrode. However, the device may be connected to an implanted lead.	35822000	III	9-①	applicable	applicable
Transesophageal external cardiac pacemaker	A non-invasive device to provide electrical impulses (pacing stimulation) that stimulate the entire heart through one or more electrode(s) placed in the esophagus. It is for temporary use.	36046000	III	9-①	applicable	applicable
Pacemaker programmer	A device to be used to change one or more electrical operating characteristics non-invasively. The programmer can read out parameters stored in the pacemaker and provide information about the patient status.	15993000	III	9-②	applicable	applicable
Implantable pacemaker bag	An implantable device to be used to fix a pacemaker. This is intended to provide a stable environment for pacemaker implantation. Usually, it is made of polymer mesh.	16038000	III	8	applicable	—

Pacemaker electrode analyzer	A device that is connected to an implanted pacemaker lead, and provides variable pacing pulses to determine the pacing threshold and voltage of cardiac R waves, etc. in a patient.	31699000	Ⅲ	9-②	applicable	applicable
Pacemaker charger	A device to be percutaneously used to recharge the battery of a rechargeable pacemaker.	33658000	Ⅲ	9-①	applicable	applicable
Non-central circulatory vascular prosthesis	A device made of artificial materials, and used for partial repair and replacement of blood vessels such as veins and arteries of the non-central circulatory system.	35281003	Ⅲ	8	applicable	—
Non-central circulatory cardiovascular patch	An implantable extravascular device used to reinforce a zone of vascular fragility, or to close an opening made during surgery in arteries of the non-central circulatory system. Usually, it is made of polyester or polytetrafluoroethylene.	38572103	Ⅲ	8	applicable	—
Collagen-containing non-central circulatory cardiovascular patch	An implantable extravascular device used to reinforce a zone of vascular fragility, or to close an opening made during surgery in arteries of the non-central circulatory system. Usually, it is made of polyester or polytetrafluoroethylene. A device impregnated with biological substances such as collagen is included.	38572203	Ⅲ	8	applicable	—
Heparin-coated temporary use indwelling vascular prosthesis	A heparin-coated device made of synthetic resin. It is used for the temporary bypass of blood from vessels including veins and arteries.	70487103	Ⅲ	8	applicable	—
Gelatine-containing non-central circulatory vascular prosthesis	A gelatin-coated device made of artificial materials, and used for partial repair and replacement of blood vessels such as veins and arteries of the non-central circulatory system.	35093103	Ⅲ	8	applicable	—
Collagen-containing non-central circulatory vascular prosthesis	A collagen-coated device made of artificial materials, and used for partial repair and replacement of blood vessels such as veins and arteries of the non-central circulatory system.	35093203	Ⅲ	8	applicable	—
Albumin-containing non-central circulatory vascular prosthesis	An albumin-coated device made of artificial materials, and used for partial repair and replacement of blood vessels such as veins and arteries of the non-central circulatory system.	35093303	Ⅲ	8	applicable	—
Vascular prosthesis with heparin for non-central circulatory system	A heparin-coated device made of artificial materials, and used for partial repair and replacement of blood vessels such as veins and arteries of the non-central circulatory system.	35093403	Ⅲ	8	applicable	—
Blood vessel stent graft	A device, in which the inside, outside, or both sides of support structure (stent) placed inside a blood vessel, or between one stent and another are covered with artificial materials. This device is inserted into the peripheral blood vessel in order to maintain the vascular patency. The stent graft is inserted through a catheter or other device, and expanded. The stent graft placement is also used to close perforated blood vessels, or to treat aneurysms. After the catheter or other device is deflated and removed, the stent graft remains in place as a permanent implant. It is made of stainless steel, Nitinol, polymer, or other substances. It may come as either tubular or branched.	70487000	Ⅲ	8	applicable	—
Biliary stent	A stent with supporting structures, designed to be placed into the bile duct to maintain its patency. The stent can be delivered to the blocked area of the bile duct by the delivery system. Stents support the bile duct, for example by self-expanding properties, or by inflation of a balloon catheter to expand the stent. After deflating and removing the balloon catheter, just the stent stays in place. Stents are made of materials including stainless steel or resin. The stent may be a tube with a certain length, or have a tube-like scaffold structure.	17672000	Ⅲ	8	applicable	—

Bronchial stent	A stent with a support structure expanded and placed in the bronchus in order to maintain the patency of the bronchus. For instance, the stent is delivered to an occluded site by being expanded, or with a balloon or catheter. By the expansion of the balloon catheter, the stent expands and supports the blood vessel. After the balloon catheter is deflated and removed, the stent remains in place as a permanent implant. It is made of stainless steel, polymer, or other substances. It may come as a continuous tube having a specified length, or as a tubular scaffold.	17957000	III	5-④	applicable	—
Hand tendon prosthesis	An implantable device used to reconstruct the flexor tendon of the hand surgically. It is implanted and left for 2 to 6 months to help the new tendon sheath to grow. It is made of silicone elastomer or medical, polyester-reinforced, silicone elastomer.	35276000	III	8	applicable	—
Ureteral stent	A stent with a support structure expanded and placed in the ureter in order to maintain the patency of the urethra. For instance, the stent is delivered to an occluded site by being expanded, or with a balloon or catheter. By the expansion of the balloon catheter, the stent expands and supports the lumen of the duct. After the balloon catheter is deflated and removed, the stent remains in place as a permanent implant. It is made of stainless steel, polymer, or other substances. It may come as a continuous tube having a specified length, or as a tubular scaffold.	35645000	III	5-④	applicable	—
Vaginal stent	A stent with a support structure expanded and placed in the vagina in order to maintain the patency of the vagina. It is made of stainless steel, polymer, or other substances. It may come as a continuous tube having a specified length, or as a tubular scaffold.	35646000	III	5-④	applicable	—
Tracheal stent	A stent with a support structure expanded and placed in the trachea in order to maintain the patency of the trachea. For instance, the stent is delivered to an occluded site by being expanded, or with a balloon or catheter. By the expansion of the balloon catheter, the stent expands and supports the lumen of the duct. After the balloon catheter is deflated and removed, the stent remains in place as a permanent implant. It is made of stainless steel, polymer, or other substances. It may come as a continuous tube having a specified length, or as a tubular scaffold.	36029000	III	5-④	applicable	—
Vascular stent	A stent with a support structure expanded and placed the blood vessel excluding the coronary vessel and the iliac artery in order to maintain the patency of the vessel. For instance, the stent is delivered by a catheter to an occluded site. By the expansion of the balloon catheter, or the stent itself, the stent expands and supports the blood vessel. After the catheter is removed, the stent remains in place as a permanent implant. It is made of metal, polymer, or other substances. It may come as a continuous tube having a specified length, or as a tubular scaffold.	36035003	III	8	applicable	—
Pancreatic stent	A stent with supporting structures, designed to be placed into the pancreatic duct to maintain its patency. The stent can be delivered to the blocked area of the bile duct by the delivery system. Stents support the pancreatic duct, for example by inflating a balloon catheter to expand the stent. After deflating and removing the balloon catheter, just the stent stays in place. Stents are made of materials including stainless steel or resin. The stent may be a tube with a certain length, or have a tube-like scaffold structure.	36143000	III	8	applicable	—
Urethral stent	A stent with a support structure expanded and placed in the urethra in order to maintain the patency of the urethra. For instance, the stent is delivered to an occluded site by being expanded, or with a balloon or catheter. By the expansion of the balloon catheter, the stent expands and supports the lumen of the duct. After the balloon catheter is deflated and removed, the stent remains in place as a permanent implant. It is made of stainless steel, polymer, or other substances. It may come as a continuous tube having a specified length, or as a tubular scaffold.	36211000	III	5-④	applicable	—

Stent for esophageal	A stent with a support structure expanded and placed in the lumen. This is used to treat esophageal atresia or gastroesophageal atresia, or to maintain the patency of these passages. For instance, the stent is delivered to an occluded site by being expanded, or with a balloon catheter. By the expansion of the balloon catheter, the stent expands and supports the lumen of the duct. After the balloon catheter is deflated and removed, the stent remains in place as a permanent implant. It is made of stainless steel, polymer, or other substances. It may come as a continuous tube having a specified length, or as a tubular scaffold.	36227000	III	5-④	applicable	—
Colorectal stent	A stent with a support structure expanded and placed in the lumen of the large intestine. This is used to treat colonic atresia or colorectal atresia, or to maintain the patency of these passages. For instance, the stent is delivered to an occluded site by being expanded, or with a balloon catheter. By the expansion of the balloon catheter, the stent expands and supports the lumen of the duct. After the balloon catheter is deflated and removed, the stent remains in place as a permanent implant. It is made of stainless steel, polymer, or other substances. It may come as a continuous tube having a specified length, or as a tubular scaffold.	70493000	III	5-④	applicable	—
Gastroduodenal stent	A stent with a support structure expanded and placed in the duodenal lumen. This is used to treat duodenal atresia or gastroduodenal atresia, or to maintain the patency of these passages. For instance, the stent is delivered to an occluded site by being expanded, or with a balloon catheter. By the expansion of the balloon catheter, the stent expands and supports the lumen of the duct. After the balloon catheter is deflated and removed, the stent remains in place as a permanent implant. It is made of stainless steel, polymer, or other substances. It may come as a continuous tube having a specified length, or as a tubular scaffold.	70494000	III	5-④	applicable	—
Hemi hip prosthesis	A prosthetic joint used in femoral head or neck replacement. The device is used for patients with conditions including proximal hip fracture and arthritis. The device may comprise an integral component, or consist of a stem equipped with a trunnion and the femoral head. The femoral head component (the ball-shaped piece of bone) is either composed of a single piece, or formed from an outer shell, inner liner, and other parts. The devices are made of materials including metal, carbon, polymer or ceramic. There are different types of fixation: with cement and cementless.	33704000	III	8	applicable	—
Resurfacing hip prosthesis	A prosthetic joint used for resurfacing the joint surfaces of the femoral head and acetabulum. The devices are made of materials including metals, polymer, carbon, and ceramic. Some types of device have an insertion part in the femoral component.	33717000	III	8	applicable	—
Hip prosthesis acetabular component	A prosthetic hip joint used for replacement or repair of the acetabulum. The device may be composed of an integral component, or consist of an outer shell made of metal, ceramic, or other material, and an inner liner made of metal, polymer, ceramic, or other material. Some types of device have screws or other parts to reinforce fixation within the body. There are constrained and unconstrained types.	35661000	III	8	applicable	—
Femoral component for hip prosthesis	A prosthetic hip component used for femoral head replacement. Some devices are used for replacement of the femoral neck. The device is usually equipped with a trunnion or a femoral head at the proximal end. The device is usually made of metals, carbon, or ceramic, and composed of many parts. Some types of device have screws or other parts to reinforce fixation within the body. There are constrained and unconstrained types. There are different types of fixation: with cement and cementless.	35666000	III	8	applicable	—

Total hip prosthesis	A prosthetic joint for replacement of the joint part of the hip joint. The device usually consists of components that fit into the femur and acetabulum. Some devices are equipped with screws, bolts, blocks, or other parts depending on the prosthetic hip joint designs. The device is usually made of metals, polymer or ceramic. When implanting components, cement may be or may not be used.	36315000	III	8	applicable	—
Unicondylar knee prosthesis	Prosthetic joints used for replacement of one of the femoral condyles and the supporting surface of the corresponding tibial condyle.	32833000	III	8	applicable	—
Tibial resurfacing knee prosthesis	A prosthetic joint used for replacement of the surface and missing bone at the proximal end of the tibia. The device is designed to form a joint, with the femoral condyle alone. It is generally known as an amphiarthrosis or a prosthetic tibial plateau.	32836000	III	8	applicable	—
Total knee prosthesis	A prosthetic joint used for replacement of the entire joint surfaces of a damaged/degenerating knee joint. There are constrained, semi-constrained, and unconstrained types. Some types of device consist of parts, which are designed to be connected to each other by a hinge to form a joint. The device is usually made of metal, carbon, ceramic, polymers, or other materials; and any or all of such materials are used in the components. There are different types of fixation: with cement and cementless.	35667000	III	8	applicable	—
Knee prosthesis femoral component	A prosthetic joint component used for repair or replacement of the femoral part of the knee joint. The device is designed to form a joint with the tibial component, and to form a joint with the prosthetic patellar component as needed. The device is usually made of metal, ceramic, or polymer, fixed with bone cement. Some types of device are equipped with a stem or a fixation mechanism.	35668000	III	8	applicable	—
Knee prosthesis tibial component	A prosthetic joint component used for repair or replacement of the tibial plateau of the knee joint. The device is designed to form a joint with a prosthetic femoral component. The device is usually made of metal, ceramic, or polymer, fixed with bone cement. Some types of device comprise a stem, fixation screws, and a metal tray with polymer insert.	35669000	III	8	applicable	—
Knee prosthesis patellar component	A prosthetic joint component used for patellar replacement. The device is designed to form a joint with the distal end of the prosthetic femoral component, and bone cement is used in some types of such devices. The device is usually made of materials including metal, ceramic, polymer, and carbon.	35679000	III	8	applicable	—
Shoulder prosthesis humeral component	A component of an artificial shoulder joint. It is attached to the proximal humerus for replacement, or repair of the articular surface. Usually, it is made of metal, ceramic, carbon, polymer, or a combination of these materials. A cement fixation type or cement-less type is available.	32835000	III	8	applicable	—
Total shoulder prosthesis	An artificial joint used to reinforce or replace the joint surface of the shoulder. Usually, it is made of metal, ceramic, carbon, polymer, or a combination of these materials. It is unconstrained, constrained or semi-constrained. A cement fixation type or cement-less type is available.	35670000	III	8	applicable	—
Shoulder prosthesis glenoid component	A component of an artificial shoulder joint. It is attached to the glenoid for replacement, or repair of the articular surface. Usually, it is made of metal, ceramic, carbon, polymer, or a these combinations. A cement fixation type or cement-less type is available.	36259000	III	8	applicable	—

Elbow prosthesis radial component	An artificial joint made of metal, polymer, etc. to reinforce or replace the joint surface of the proximal radius. It may be a portion of a constrained or unconstrained artificial joint.	33701000	III	8	applicable	—
Elbow prosthesis humeral component	A humeral component made of metal, polymer, ceramic, etc. It is used to reinforce or replace a portion of or the entire distal humeral joint surface. A cement fixation type or cement-less type is available. It may be a portion of a constrained or unconstrained artificial joint.	35664000	III	8	applicable	—
Elbow prosthesis ulnar component	An ulnar component device made of metal, polymeric materials, etc. It is used to reinforce or replace a portion of or the entire proximal ulnar joint surface. A cement fixation type or cement-less type is available. It may be a portion of a constrained or unconstrained artificial joint.	70495000	III	8	applicable	—
Total elbow prosthesis	An artificial joint used to replace or substitute the entire surface of an damaged or deformed elbow joint. Constrained, semi-constrained, or non-constrained types are available. Some types consist of multiple parts connected by hinges and designed to form the joint in combination. Usually, it is made of metal, ceramic, carbon, polymer (the parts are made of either or all of these materials), or of a combination of these materials. A cement or cementless fixation type is available.	70496000	III	8	applicable	—
Artificial bone matrix implant	A device made of synthetic bone matrix to be inserted or placed inside the body to replace a bone defect caused by morbid conditions including injury or osteoporosis. Powder, liquid or paste types are included.	17751000	III	8	applicable	—
Implantable fixation bolt	A non-biodegradable device to be inserted in bone to improve safety of a traction device or a similar device. The device uses a nut for fixation; some devices are equipped with washers. The device may be made of metal or polymer.	16077003	III	8	applicable	—
Implantable fixation screw	A non-absorbable bone fixation device used to fix a plate or a nail onto bone, fix soft tissues, a sheet or non-woven fiber onto bone, or stabilize fractured bone fragments. The device is used for orthopedic and maxillofacial surgery, etc. The screws come in various types such as cortical bone screws, cancellous bone screws, ankle bone screws, or navicular bone screws, with a partial or fully threaded. Lag screws are used for special case in order to compresses all of the fracture fragments. The device is usually made of metal, etc.	16101003	III	8	applicable	—
Implantable fixation staple	A non-absorbable device, including a U-shaped type, to be implanted in a fractured bone for fixation or repair of an orthopedic fracture, mandibular fracture, etc. This is also used for connecting a ligament, tendon, etc. to the bone to be fixed. Usually, it is made of metal.	16103003	III	8	applicable	—
Implantable fixation nut	A non-biodegradable device that is to be used with bone fixation devices such as bone screws and bolts, to enhance fixation. The device may be used when the bone hole is larger than the screw diameter.	32847003	III	8	applicable	—
Implantable fixation pin	A non-absorbable device used for internal/external fixation, a support of traction device, or fixation of bone, soft tissues, and ligaments onto bone.	32854003	III	8	applicable	—
Implantable femur intramedullary fixation nail	A rod made of metal or other material. The device is inserted into the femoral medullary cavity, serving as a fixation device that keeps both ends of fractured/diseased bone in the right position. The device may be used to extend and correct bone when missing bone or pathological displacement of bone is observed. The device is equipped with many components; and some devices are of the locking-type which improves fixation of bone fragments both proximally and distally; some are of the non-locking-type.	33187000	III	8	applicable	—

Implantable fixation compression hip plate	A device used for fixation of the head of the femur, fractured at its proximal end. The device usually consists of a plate, and is designed to be used with a partially threaded, large screw that is inserted into the guide hole located in the proximal end of the plate. The device is fixed to the femur using cortex bone screws.	34003000	III	8	applicable	—
Spine disc prosthesis	A device used to replace or repair the plate-like structure between two movable vertebral bodies. Usually, it is made from metal, polymer, other artificial materials or biological materials, or a combination of these materials.	34163000	III	8	applicable	—
Artificial vertebral body	A device used to replace or repair one or more defects of the vertebral body or the spine caused by injury, deformation or degenerative disease. Usually, it is made of metal, polymer, other artificial materials or a combination of these materials.	34170003	III	8	applicable	—
Rib prosthesis	A device used to replace or repair the entire rib or a portion of it. Usually, it is made of metal, polymer, other artificial or biological materials, or a combination of these materials.	34219000	III	8	applicable	—
Implantable fixation plate	A non-absorbable implantable fixation device that is fixed to fractured fragments with screws or the like, in order to fill the fracture gap and protect the fractured part from stress in cases of bone deformities and treatment for bone fracture. It is also used for bone lengthening for pathologically fractured bone, as a reinforcement in cranial or maxillofacial surgery, or for fusion of joints where fixation is required. The bone plate is usually made of metals and carbon, etc.	35241003	III	8	applicable	—
Implantable fixation system	A non-absorbable device consisting of a container and multiple trays. There are many implants and dedicated surgical devices. This system is designed for specific operations including fracture surgery, spinal surgery, corrective surgery or ligament reconstruction. To maintain this system, any implant that has been used needs to be replenished.	35642003	III	8	applicable	—
Clamp for cranial fixation	A non-absorbable, implantable fixation device for cranial closure after craniotomy, or to clamp cranial fragments together for fixation in order to restore dislocation after complicated fracture of skull. Plates, discs, and auxiliary pins, etc. are used for fixation. Usually, it is made of metal, stainless steel, titanium, etc.	70500000	III	8	applicable	—
Extrasomatic fixation system	A device that consists of a container or multiple trays. There are many implants (e.g., pins, screws, wires) and dedicated surgical devices. This system is designed for specific surgery including fracture surgery, spinal surgery, or corrective surgery. To maintain this system, any implant that has been used needs to be replenished. The external fixator can be reused by following the instructions.	35647003	III	8	applicable	—
Implantable fixation wire	A non-absorbable, implantable device used for bone fixation. It is used for various purposes. For instance, it is used as a fastening wire that supports bone fixation, an 8-shaped loop that reattaches the olecranon, the tibial tubercle, the greater trochanter, etc., a Kirschner wire that reinforces the toe or the finger (joint fixation) for reinforcement of bone screw fixation and bone plate fixation. Usually, it is made of metal. Some types are made of malleable materials that are elongated, or formed into a coil shape. Other types are made of inflexible and rigid materials.	35685003	III	8	applicable	—
Temporomandibular joint prosthesis	An implantable, artificial joint used for reconstruction of the temporomandibular joint. Usually, it is made of artificial materials including metal and polymer.	35943000	III	8	applicable	—
Ligament fixation anchor	A non-absorbable, implantable device used for bonding one end or both ends of the ligament, the tendon or an artificial ligament to the bone(s). Usually, it is made of metal or ceramic.	36174003	III	8	applicable	—

Implantable fixation washer	A non-absorbable device intended to be used with bone fixation devices such as bone screws and bolts to enhance fixation or prevent soft tissue damages. The device is usually made of metals, polymer or reinforced polymer.	36198003	III	8	applicable	—
Spinal internal fixation system	A device consisting of rods, plates, hooks, screws (including pedicle screws), connectors, wire, cables, and the other components. The device is used for spinal fixation, support, or alignment correction. The device is usually made of metals, polymer and the other materials. The device may be used for fixation of bone fractures, degenerative disease, or congenital anomalies.	37272003	III	8	applicable	—
Implantable tibia intramedullary fixation nail	A rod made of metal or other material. The device is intended to be inserted into the tibial medullary cavity, serving as a fixation device to keep both ends of the fractured/diseased bone in the right position. The device may be used to extend and correct bone when missing bone or pathological displacement of bone is observed. The device is equipped with many components; and some devices are of the locking-type which improves fixation of bone fragments both proximally and distally; some are of the non-locking-type.	38152000	III	8	applicable	—
Implantable humerus intramedullary fixation nail	A rod made of metal or other material. The device is intended to be inserted in the medullary cavity of the humerus, forearm bones, clavicle, etc., serving as a fixation device to keep the both ends of the fractured/diseased bone in the right position. The device may be used to extend and correct bone when missing bone or pathological displacement of bone is observed. In addition, some types are locking devices with many components that support fixation of proximal and distal fractured bone, while others are non-locking devices.	38153000	III	8	applicable	—
Intracorporeal fixation device set	A device dedicatedly manufactured for specific patients. The sizes, designs or materials are different from those of an ordinary device. Typical examples include a dedicated-order device of which only one is produced, such as an intramedullary rod to reinforce the knee joint long enough to reach from the femur (proximal end) to the tibia (distal end). It is manufactured in compliance with the present regulations. This is not included in the category of custom-made, artificial joint sets.	38159000	III	8	applicable	—
Spinal cage	A device used to replace, correct or repair the height of the spinal column instead of a intervertebral disc or a portion of the intervertebral body. Usually, it is made of metal, polymer, absorbable materials, other artificial materials, biological materials, or a combination of these materials.	38161003	III	8	applicable	—
Bone fixation band	A wire, cable or band, etc. used to bind and suture the bone and the soft tissue, to fix the bone and an implant(s), and to fix bone to bone. It is made of metal or polymer.	70501000	III	8	applicable	—
Head prosthesis fixation material	Materials used to fix head prostheses (a facial prosthesis) to the face, including an eye prosthesis, nasal prosthesis, and ear prosthesis. They are composed of plates to be fixed to the cranial, screws, a support (an anchor) for fixation, etc.	70503000	III	8	applicable	—
Implantable fixation cable	A non-absorbable cable used for bone fixation (twisted or braided). The cable is used as an internal fixation device. In principle, fastening is performed using clamps in order to recombine fractures or osteotomies such as olecranon, patella, medial malleolus and greater trochanter, or to fix the spine. The device also includes components such as implants used in combination with cables. The device is usually made of a metal or polymer.	70504000	III	8	applicable	—
Sacral hemostasis pin	An implantable device used to control excessive hemorrhage from the presacral blood vessels. This device has a thumbtack-like shape and made of metal (mainly titanium).	70506000	III	8	applicable	—
Cranial resinous compound	A resin-like substance used to reconstruct the cranial after a neurosurgical procedure.	16131000	III	8	applicable	—

Orthopedic bone cement	A substance usually made of methyl methacrylate, polymethyl methacrylate (PMMA), methacrylic acid ester, or copolymers containing PMMA and polystyrene. It is used in arthroplasty to fix artificial joints made of polymer, metal or ceramic to the in vivo bone. It may be used as a filling material in the damaged site of bone lesions. It may contain an antibiotic.	35217000	III	8	applicable	—
Total joint arthroplasty cement spacer	A device made of cement usually placed in the articular cavity temporarily to prevent bone-to-bone contact and contraction of the soft tissues after surgical repair of all joints.	44267000	III	8	applicable	—
Artificial bone cap	An implantable device used to cover the amputation stump of the bone such as the humerus or the tibia to suppress bony overgrowth after amputation in young patients.	16082000	III	8	applicable	—
Total ankle prostheses	An artificial joint used to replace the major articular surface of the foot joint. Usually, it is made of metal, ceramic, carbon, polymer or of a combination of these materials. A constrained, semi-constrained, or non-constrained type is available. A cement or cementless fixation type is available.	32837000	III	8	applicable	—
Non-absorbable tendon prosthesis	An implantable device to replace or repair loss or damage of the tendon to restore its function. This is made of non-absorbable materials.	32869003	III	8	applicable	—
Maxillofacial prosthesis	A device used to repair or replace the maxilla. It is usually made of metal, but it may also be made of polymer.	33168000	III	8	applicable	—
Hip prosthesis acetabular support component	A device that may be in the form of an acetabular support ring, sheet or mesh. The device is used to support the prosthetic acetabular component where there has been an acetabular damage. The device is usually made of metal or polymer.	33179000	III	8	applicable	—
Hip prosthesis bone cement restrictor	A device used in the distal femoral cavity, or with an acetabular component, in order to limit leakage of bone cement. The device is usually made of polymer containing polymethyl methacrylate (PMMA).	33180000	III	8	applicable	—
Total wrist prosthesis	An artificial joint to replace or substitute for the surface of the finger joint. A constrained, semi-constrained, or non-constrained type is available. Usually, it is made of metal, ceramic, carbon, polymer, or a combination of these materials. A cement or cementless fixation type is available.	33705000	III	8	applicable	—
Cement spacer	A non-absorbable device used to maintain the thickness of bone cement (e.g., polymethyl methacrylate [PMMA]) between the implanted artificial joint, etc. and the bone. Usually, it is molded with polymer or bone cement materials (PMMA).	33982003	III	8	applicable	—
Cement bone plug	A non-absorbable device used as the blocker (used as a cement restrictor) to seal the medullary cavity in order to limit the pathway of bone cement. It is made of polymethyl methacrylate (PMMA), polyethylene (UHMWPE), etc. A metal marker may be incorporated into it.	34031003	III	8	applicable	—
Ankle prostheses talar component	An artificial foot joint component attached to the talus in order to replace or repair the articular surface. Usually, it is made of metal, ceramic, carbon, polymer, or a combination of these materials. A cement or cementless fixation type is available.	34108000	III	8	applicable	—
Chin prosthesis	A device implanted in the soft tissue of the lower jaw bone to correct deformation of the lower jaw or improve appearance. Usually, it is made of polymer.	35261000	III	8	applicable	—
Ankle prostheses tibial component	An artificial foot joint component attached to the distal tibia in order to replace or repair the articular surface. Usually, it is made of metal, ceramic, carbon, polymer, or a combination of these materials. A cement or cementless fixation type is available.	35662000	III	8	applicable	—

Wrist prosthesis carpal component	An artificial joint component that replaces the support surface of the carpal bone and forms an artificial joint between an artificial radius and ulna. Usually, it is made of metal, ceramic, carbon, polymer, or a combination of these materials. A cement or cementless fixation type is available.	35663000	III	8	applicable	—
Tendon spacer	A non-absorbable device used to separate tissues and prevent physical contact. This prevents the tendon from adhering to adjoining tissues, and allows it to move freely.	35671003	III	8	applicable	—
Total ossicular prosthesis	A device or system consisting of multiple devices that are intended to replace the ear ossicle for correction or restoration of hearing. Usually, it is made of biological or synthetic materials.	35674000	III	8	applicable	—
Orbital rim prosthesis	A device used to reconstruct the orbital floor or the orbital margin. Usually, it is made of stainless steel, titanium or titanium alloy. It may be made of other materials.	35677000	III	8	applicable	—
Zygomatic prosthesis	A device used to replace or repair the cheekbone. Usually, it is made of metal. It may also be made of polymer.	35678000	III	8	applicable	—
Local ossicular prosthesis	A biological or synthetic device used for replacement of the ossicle in the middle ear, etc.	35690000	III	8,14	applicable	—
Wrist prosthesis radial/ulnar component	An artificial joint component to replace the support surface of the carpal bone and the articular support surface between the distal radius and ulna and the carpal bones. Usually, it is made of metal, ceramic, carbon, polymer, or a combination of these materials. A cement or cementless fixation type is available.	35727000	III	8	applicable	—
Radial head prosthesis	A device used to replace the entire or a portion of the proximal radius (radial head). A cement or cementless fixation type is available. Usually, it is made of metal, ceramic, carbon, polymer, or a combination of these materials.	35966003	III	8	applicable	—
Total temporomandibular joint prosthesis	An implantable artificial joint used to reconstruct the bilateral temporomandibular joint. Usually, it is made of artificial materials including metal and polymer.	36042000	III	8	applicable	—
Temporomandibular disk prosthesis	An implant or articular disk inserted as an interposition material in order to form a contact between the mandibular condyle and the glenoid fossa in the temporomandibular joint. Usually, it is made of artificial materials including metal and polymer	36260000	III	8	applicable	—
Digit prosthesis	An artificial joint used to replace the finger joint, thumb joint or toe joint. Usually, it is made of metal, ceramic, carbon, polymer, or a combination of these materials. A constrained, semi-constrained, or non-constrained type is available. A cement or cementless fixation type is available.	37845000	III	8	applicable	—
Joint prosthesis set	An artificial joint device manufactured specifically for an individual patient. The sizes, designs or materials are different from those of an ordinary device.	38158000	III	8	applicable	—
Lower limb reconstruction artificial material	An implant used to repair bone loss, or to reconstruct the lower extremity function in patients with extensive bone resection due to malignant tumors, etc. This includes artificial joints or the articulating parts and accessories.	70508000	III	8	applicable	—
Upper limb reconstruction artificial material	An implant used to repair bone loss, or to reconstruct the upper extremity function in patients with extensive bone resection due to malignant tumors, etc. This includes artificial joints or the articulating parts and accessories.	70509000	III	8	applicable	—

Anterior chamber lens	A device intended to be permanently implanted into the ocular cavity that is in contact with a portion of the cornea and a portion of sclera anteriorly and with a portion of the ciliary body and the iris as well as a portion of the crystalline lens from end to end of the pupil posteriorly. It is intended to replace the opecified crystalline lens. Usually, it is a plastic lens and inserted into the anterior chamber of the eye after the removal of the cataractous crystalline lens.	35655000	III	8	applicable	—
Posterior chamber lens	A device intended to be permanently implanted into the posterior chamber of the eye to replace the opecified crystalline lens and to restore vision. Usually, it is a plastic lens and which is inserted into the posterior chamber of eye after the removal of a cataractous crystalline lens.	35658100	III	8	applicable	—
Heparin-coated posterior chamber lens	A heparin-coated device intended to be permanently implanted into in the posterior chamber of the eye to replace the opecified crystalline lens and to restore vision. Usually, it is a plastic lens and inserted into the posterior chamber of the eye after the removal of the cataractous crystalline lens. i	35658200	III	8,14	applicable	—
Multifocal posterior chamber lens	A device intended to be permanently implanted into in the posterior chamber of the eye to replace the opecified crystalline lens and to restore vision. Usually, it is a plastic lens and inserted into the posterior chamber of the eye after the removal of the cataractous crystalline lens. is It has the multifocal mechanism.	35658300	III	8	applicable	—
Posterior chamber lens with inserter	A posterior chamber lens or a multifocal posterior chamber lens that is pre-loaded on a single-use lens inserter.	35658400	III	8	applicable	—
Tympanostomy tube	A device used to replace or repair the function of the tympanic membrane.	33794000	III	8	applicable	—
Tympanic membrane implant	A device used to replace or repair the function of the tympanic membrane of the middle ear. It may be made of synthetic materials.	34410000	III	8	applicable	—
Auditory electrical stimulator	A device used to partially restore hearing in a patient with high-frequency sensorineural hearing loss or severe hearing impairment. It consists of an electrode array (inserted into the cochlea on one side), a receiver and stimulator (implanted near the ear inside the skull), a speech processor (it is attached to the outside of the body, converts sounds to electric signals and sends the signals to the receiver and stimulator.). The device equipped with the sonic stimulation function contains an acoustic unit which amplifies sounds, adjusts tone quality, and transmits the sounds to the ear mold.	35643000	III	8	applicable	—
Tracheoesophageal speech valve	A device equipped with a companion flange inserted into the surgically formed tracheoesophageal fistula. It has a slit along the diameter on the esophagus surface of the device. It is used to utterance function rehabilitation after laryngectomy.	36245000	III	5-④	applicable	—
Liquid tissue reconstructive material	A synthetic liquid substance to be injected or infused to fill a space for cosmetic or reconstruction purposes.	17876000	III	8	applicable	—
Tympanostomy semi-permeable membrane tube	A small, cylindrical, hollow device to be implanted for ventilation and drainage of the middle ear, and for to prevent the inflow of liquid into the middle ear cavity. It is inserted through the tympanic membrane to allow the free passage of air between the external ear and middle ear. The tube is made of silicone elastomer or porous polyethylene, and the membrane is made of polytetrafluoroethylene.	33643000	III	8	applicable	—
Implantable neurological stimulator electrode/lead	A lead insulated with non-conductive materials except in the electrode portion, designed to be implanted into the nerve tissue. It is used to establish an electrical connection between a stimulator and the tissue.	44040000	III	8	applicable	—

Implantable incontinence stimulator electrode/lead	A lead insulated with non-conductive materials, designed to be implanted into the sphincter. The electrode portion is not insulated. It is used to establish an electrical connection between a stimulator and the sphincter.	44045000	III	8	applicable	—
Implantable eyelid weight	An ophthalmic device that weights the eyelid or compresses the eyelid for functional recovery of the upper eyelid. It is intended to be implanted in the upper eyelid.	18074000	III	8	applicable	—
Nose prosthesis	A device to be inserted into the facial tissues (nose) for cosmetic or reconstruction. Usually it is made of polymeric materials.	31038000	III	8	applicable	—
Endolymphatic vessel prosthesis	A device used to repair or replace a portion of the endolymphatic vessel. It may be equipped with valves that send materials to one direction.	31931000	III	8	applicable	—
Implantable middle ear mold	A device that is implanted for reconstruction of the middle ear cavity in eardrum repair, and works as a mold. It keeps the middle ear cavity filled with sufficient air and promotes regeneration of the middle ear mucosa. It is made of polyamide, polytetrafluoroethylene, silicone elastomer, or polyethylene.	31934000	III	8	applicable	—
Implantable mechanical/hydraulic incontinence device	An implantable device used to treat urinary incontinence by adding pressure continuously or intermittently to occlude the urethra. The completely implantable type may have a static pressure pad, or consist of a system comprising a container with radiopaque liquid implanted into the abdomen, and a manual pump and valves implanted under the skin surface and connected with a tube to the adjustable pressure pad or to the cuff surrounding the urethra. It sends the radiopaque liquid from the container as needed, and it inflates the pad or cuff to compress the urethra.	31994000	III	8	applicable	—
Vas deferens prosthesis	A device used to repair the site of damage or obstruction in the vas deferens that sends sperm from the epididymis to the urethra. Devices for temporary use are not included.	31995003	III	8	applicable	—
Ureterovesical prosthesis	An internal device that is implanted into the ureteral wall. The function of the sphincter is supported by increasing the volume and tensile strength of the ureteral wall. Usually, it is made of non-absorbable polymers including silicone rubber and teflon. It is applied with a catheter.	31998000	III	8	applicable	—
Ear, nose, and throat (ENT) prosthesis	A non-absorbable device used for soft tissue replacement or repair in the ear, nose, and throat (ENT) surgery. It is made of polymers including porous polyethylene, silicone elastomer, polyurethane, and polyamide.	33310103	III	8	applicable	—
Implantable synthetic/carbon fibre prosthesis	A material made of polytetrafluoroethylene (PTFE) reinforced with carbon fiber used to produce composite materials for non-absorbable implants. In cosmetic surgery, it is used to restore the structure of bones and tissues around the jaw, nose, and eye.	33473103	III	8	applicable	—
Intestinal splinting prosthesis	A rigid or flexible device used to maintain a part of the intestinal tract in situ, or maintain the damaged site of the intestinal tract in situ and protect it.	33806000	III	8	applicable	—
Ocular sclera prosthesis	A device used to reinforce or repair a scleral defect.	34000000	III	8	applicable	—
Anal sphincter prosthesis	A device used to restore the function of defecation by re-controlling fecal incontinence.	34092000	III	5-④	applicable	—
Implantable incontinence prosthesis	An implantable device used to correct or control the excretory function including defecation and urination in a patient who has lost control of the excretory function.	34214100	III	8	applicable	—
Collagen-containing implantable incontinence prosthesis	An implantable collagen-containing device used to correct or control the excretory function including defecation and urination in a patient who has lost control of the excretory function. It may be used for treatment of vesicoureteral reflux or a skin test.	34214200	III	8,14	applicable	—

Bile duct prosthesis	A device used to replace or repair the duct that carries bile from the gallbladder to restore function.	35258000	III	8	applicable	—
Bladder mesh prosthesis	A device used to support the walls of the bladder or other replaced tissues. It is made of polymeric materials, and may have a butterfly-like shape or be V-shaped so that it fits the anatomical structure(s).	35259000	III	8	applicable	—
Cervical cerclage prosthesis	A device used for the support or functional recovery of the uterine cervix.	35260000	III	8	applicable	—
Ear prosthesis	A device intended to implant into the tissues for external ear reconstruction usually for cosmetic reasons. It may also be used to reinforce the hearing mechanism. The external component is usually made of polymeric materials. The internal component may be fixed with screws.	35262000	III	8	applicable	—
Esophageal prosthesis	A tubular device to be inserted into the esophagus for replacement or repair to restore function.	35263000	III	8	applicable	—
Fallopian tube prosthesis	A device that replaces or restores the function of the fallopian tube.	35264000	III	8	applicable	—
Larynx prosthesis	A device used for replacement and restoration of the laryngeal function, or for maintenance of patency of the larynx. It is made of stainless steel, polymer, etc.	35268000	III	8	applicable	—
Muscle prosthesis	A device a part or the whole of which is inserted into the body to replace muscle tissue for prosthetic, therapeutic or experimental purposes.	35272000	III	8	applicable	—
Testicular prosthesis	A device in the shape of a testicle. It is implanted into the scrotum to restore cosmetic appearance of the testicle. It works aesthetically and prevents psychogenic sequelae. It may be entirely made of polymer including silicone rubber, or it may be in the form of a silicone membrane sac filled with silicone oil. It may be made of metal.	35277000	III	8	applicable	—
Tracheobronchial prosthesis	A device used to replace the whole or a part of the trachea and bronchus for functional recovery.	35278000	III	8	applicable	—
Urethral prosthesis	A device used to replace or repair the urethra.	35279000	III	8	applicable	—
Urethral sphincter prosthesis	An internal device that is indicated for incontinence. It is intended to support or replace the natural urethral sphincter. Usually, it consists of a single cuff or double cuff surrounding the urethra, a reservoir containing a hydraulic liquid including saline solution (or the reservoir may contain a radiopaque agent), and a manual pump. It is mainly made of non-absorbable polymer materials.	35280000	III	8	applicable	—
Tracheal prosthesis	A tubular device used to replace the natural trachea in airway reconstruction.	35458000	III	8	applicable	—
Eustachian tube prosthesis	A device used to replace or repair the eustachian tube from the middle ear to the pharynx.	35512000	III	8	applicable	—
Gastroesophageal antireflux prosthesis	A device used to treat severe gastroesophageal reflux disease.	35695000	III	5-④	applicable	—
Intraocular drain	An artificial drain to be implanted into the eye to lower elevated intraocular pressure.	36099000	III	8	applicable	—

Penile prosthesis	An internal device that is indicated for erectile dysfunction. It is used to obtain expansion and stiffness of the penis. This is a hydraulic device, and made of silicone rubber or other polymers. It is implanted in the penis. It consists of a reservoir containing liquids including saline solution (a radiopaque agent may be added) to be implanted in the abdomen and one or multiple inflatable cylinders connected to a manual pump to be implanted beneath the scrotal skin.	36250000	III	8	applicable	—
Rod penile prosthesis	An internal device that is indicated for erectile dysfunction. It is used to obtain permanent expansion and stiffness of the penis. It is made of silicone rubber or other polymers, and has one or multiple rod-shaped bodies. It may be rigid or semi-rigid and reinforced with metal.	36251000	III	8	applicable	—
Intracorneal ring	A ring-shaped device that is inserted into the cornea to correct refractive error including myopia by flattening the corneal curvature.	36291000	III	8	applicable	—
Corneal prosthesis	A device used to replace the cornea and to restore vision.	42525000	III	8	applicable	—
Eye valve prosthesis	An artificial, membrane-like device used to replace the valves in the human eye.	42526000	III	8	applicable	—
Implantable lesion identification marker	A device in the form of a wire, needle, clip or bead intended to be implanted in the body temporarily or permanently in order to make an identification mark that can be confirmed on a film or digital image. It is used for position determination and visualization of sites of interest such as tumors or lesions. It is made of materials compatible with those used with the imaging system including a magnetic resonance imaging (MRI) system, X-ray system and nuclear medicine system.	40808000	III	8	applicable	—
Non-central circulatory embolization implant kit	A device or a collection of devices used in combination to implant an embolization implant that forms a permanent or temporary embolus (to stop blood flow) in the artery or the vein in the non-central circulatory system. Usually, it consists of an embolization implant, an inserter, and a dedicated syringe(s). It may contain other devices necessary for the surgery. This device is for single-use.	70512000	III	8	applicable	—
Retinopexy prosthesis	A sterile ophthalmic implant device used to locally reshape and fix the eyeball in order to reattach a detached retina onto the choroid.	70513000	III	8	applicable	—
Hemodialysis system	A system used to perform hemodialysis with a dialyzer.	34995000	III	11-①	applicable	applicable
Control/monitor for dialysis system	A device for monitoring parameters including dialysis fluid flow rate, temperature, and venous pressure during hemodialysis by artificial kidney.	36424000	III	11-①	applicable	applicable
Multi-patient dialysis fluid delivery system	A device that prepares dialysis fluid for hemodialysis using an artificial kidney, capable of supplying dialysis fluid for two or more patients.	34993000	III	11-①	applicable	applicable
Individual dialysis console	A device with functions necessary to perform hemodialysis on one patient. Adsorbent-based devices that recirculate dialysis fluid are also included.	34994010	III	11-①	applicable	applicable
Multipurpose dialysis system	A device for blood dialysis monitoring or a single-patient blood dialysis filter system that may be capable of performing hemodialysis, hemodiafiltration, hemofiltration, or slow continuous hemofiltration.	34994020	III	11-①	applicable	applicable
Dialysis fluid flowmeter for dialysis system	An essential component of a dialyzer. It measures the flow rate of dialysis fluid in the dialyzer to confirm that the flow rate is appropriate.	32123000	III	11-①	applicable	applicable
Dialysis fluid level detector for dialysis system	An essential unit of a dialyzer. It detects the volume of dialysis fluid in the dialyzer and gives a warning sound when the volume is inappropriate.	32126000	III	11-①	applicable	applicable

Blood level detector for dialysis system	An essential unit of a dialyzer. It detects the blood volume in arterial and venous chambers in the extracorporeal circulation circuit during dialysis and gives a warning sound when the volume is inappropriate.	32127000	Ⅲ	11-①	applicable	applicable
Blood leak detector for dialysis system	An essential unit of a dialyzer. It detects a blood leak into the dialysis fluid discharging line in the dialyzer and gives a warning sound when blood is detected in the discharging line.	32128000	Ⅲ	11-①	applicable	applicable
Dialysis fluid temperature monitor for dialysis system	An essential unit of a dialyzer. It monitors the temperature of the dialysis fluid in the extracorporeal circulation circuit and gives a warning sound when an abnormal temperature is detected.	32156000	Ⅲ	11-①	applicable	applicable
Pillow pressure alarm for hemodialysis system	A device that gives a warning sound or a visual signal when a decrease in the arterial blood volume is detected in the arterial blood tube set connected to a hemodialysis system based on a decrease in the blood flow rate. It consists of a small-sized pillow that detects a decrease in blood pressure caused by a decrease in the blood flow rate. These devices can employ existing techniques.	32124000	Ⅲ	11-①	applicable	applicable
Electrical conductivity measuring instrument for dialysis fluid	A device used to determine the concentration of dialysis fluid supplied to a dialyzer based on the measurement of electrical conductivity of dialysis fluid (usually, it is electrically measured.). It may be a component of a dialyzer or an independent device.	34998000	Ⅲ	11-①	applicable	applicable
Blood line clamp for dialysis system	A unit used to handle the blood line clamp during dialysis. Usually, this unit is installed in a complete dialysis system.	35684000	Ⅲ	11-①	applicable	applicable
Blood circulation unit for dialysis system	A unit used to handle the blood circulation during dialysis. Usually, this unit is installed in a complete dialysis system.	36428000	Ⅲ	11-①	applicable	applicable
Air bubble/foam guard for dialysis system	A dedicated device that works with a dialyzer. It is intended to give a warning to stop the connected pump mechanism when a bubble is detected in the blood before the blood is returned to the patient.	36437000	Ⅲ	11-①	applicable	applicable
Replenisher pump	A device that injects replenishing fluid in hemodiafiltration, hemofiltration, or slow continuous hemofiltration.	70517000	Ⅲ	11-①	applicable	applicable
Extracorporeal circulation hematocrit monitor	A device that measures the hematocrit level in the blood (the percentage of erythrocytes) invasively during extracorporeal circulation during dialysis or open heart surgery.	70518000	Ⅲ	10-④	applicable	applicable
Hemodiafiltration system	A device used for blood purification with a hemodiafilter. Functionality for controlling ultrafiltration volume and infusion volume is incorporated into a regular hemodialysis system.	70520000	Ⅲ	11-①	applicable	applicable
Hollow fiber dialyser	A device used for removing wastes that have accumulated in blood due to abnormal renal function or renal failure. Removal of wastes works by moving wastes from blood into the dialysis fluid across a semi-permeable membrane capable of allowing blood and dialysis fluid to circulate in separate compartments. The membrane consists of hollow fibers. The blood passes through the lumen of hollow fibers, while the dialysis fluid passes outside the hollow fibers, removing impurities.	35004000	Ⅲ	3	applicable	—

Parallel-plate dialyser	A medical device used for removing wastes that have accumulated in blood due to abnormal renal function or renal failure. Removal of wastes works by moving wastes from blood into the dialysis fluid across a semi-permeable membrane capable of allowing blood and dialysis fluid to circulate in separate compartments. The membrane consists of flat-sheet membranes. With the blood and dialysis fluid flowing separately in a space between the flat-sheet membranes, waste products are removed from the blood.	35005000	III	3	applicable	—
Heart-lung bypass system	A set of devices that perform mechanical circulatory assist and make cardiac surgery easier by by-passing the heart during open heart surgery. Its fundamental function is to add oxygen to the venous blood and return the oxygenated blood to the arterial circuit with a pump. Usually, it has a few functions including intracardiac aspiration, filtration, and temperature management. The important modules and components of this set include a pump, a temperature regulator, various types of monitors. This is manufactured as a single unit or a device consisting of modules is also available.	35099000	III	9-①	applicable	applicable
Roller pump for heart-lung bypass	A unit of components of a heart-lung bypass system. It injects (circulates) the extracorporeal blood flow through a roller-like mechanism that injects blood into an extracorporeal tube set connected to the other parts of the oxygenator or the artificial heart-lung system for the purpose of gas exchange and reinjection.	36347000	III	9-②	applicable	applicable
Console for heart-lung bypass	One of the modules of a heart-lung bypass system, or a primary mounting unit. With other units being installed in this unit, a complete system is formed. This will work as the basic workstation that can control and monitor all functions.	36373000	III	9-②	applicable	applicable
Driving unit for extracorporeal circulation assist centrifugal pump	A specifically manufactured centrifugal pump that is used to maintain blood circulation in a patient with heart failure. It supports circulation (blood circulation support during heart failure) in a patient who is dependent on artificial support in order to maintain cardiac function. The dependence on artificial support is due to impaired cardiac function. This device is used to temporarily support recovery of cardiac function during or after open heart surgery. There is a type that has various monitoring functions.	70523000	III	9-②	applicable	applicable
Heparin-coated heart-lung bypass heat exchange	A heparin-coated device that consists of a heat exchange system used during extracorporeal circulation. This device is intended to heat or cool the blood or perfusate in cardiopulmonary bypass surgery or for treatment.	11973213	III	3-①,14	applicable	applicable
Heparin-coated heart-lung bypass blood reservoir	A heparin-coated device used as a part of a heart-lung bypass unit or in conjunction with other devices during temporary extracorporeal circulation. It maintains a blood reserved for extracorporeal circulation. It may have a filtering function. This device is for single-use.	31710203	III	2-①,14	applicable	—
Heparin-coated heart-lung bypass defoamer	A heparin-coated device used to remove bubbles from the blood during cardiopulmonary bypass surgery. It is used with an oxygenator that adds the required amount of oxygen to the blood before it is returned to the patient.	31711213	III	3-①,14	applicable	applicable
Heart-lung bypass gas control unit	One of the modules of a heart-lung bypass system. It controls and measures the rate of gas flow that is supplied to an oxygenator. It is calibrated for a specific gas, and has high precision at a low flow rate. It may work as a flowmeter.	31714000	III	9-②	applicable	applicable
Heparin-coated heart-lung bypass circuit filter	A heparin-coated filter to prevent particles and blood clots from entering the circulation, which may block extracorporeal circulation. This filter may be used for trapping air bubbles.	33309203	III	3-①,14	applicable	—

Filter for heart-lung bypass hemoconcentration	A filter used to remove crystalline particles from a priming solution and to concentrate the patient's blood before the cardiopulmonary bypass device is removed from the patient in a heart-lung bypass system.	36089000	III	3	applicable	—
Heart-lung bypass pressure gauge	One of the modules of a heart-lung bypass system. It electrically or mechanically measures the blood pressure in the tube circuit.	36356000	III	10-④	applicable	applicable
Heart-lung bypass temperature control unit	One of the modules of a cardiopulmonary bypass device. It measures and displays the temperature of the fluid and the blood with various temperature probes connected to the device in order to monitor the temperature of the fluid and the blood at various points. It may control the temperature (e.g., the temperature of the fluid that flows in and out from the heat exchanger).	36374000	III	9-②	applicable	applicable
Heart-lung bypass circuit system	A packed, sterile set of a heart-lung bypass circuit system used in cardiopulmonary bypass surgery and for assisting circulation. Usually, it consists of a tube, a bubble-removing device, a venous and intracardiac blood reservoir, an oxygenator, a blood filter, a priming solution filter, an in-line blood gas sensor, a heat exchanger, safety valves, a centrifugal pump, and catheters, etc.	70524100	III	3	applicable	—
Heparin-coated heart-lung bypass circuit system	A packed, sterile, heparin-coated set of a heart-lung bypass circuit system used in cardiopulmonary bypass surgery and for assisting circulation. Usually, it consists of a tube, a bubble-removing device, a venous and intracardiac blood reservoir, an oxygenator, a blood filter, a priming solution filter, an in-line blood gas sensor, a heat exchanger, safety valves, a centrifugal pump, and catheters, etc.	70524200	III	3,14	applicable	—
Heparin-coated single-use heart-lung bypass defoamer	A heparin-coated system used to remove air bubbles from blood during cardiopulmonary bypass procedures. The device is used with an oxygenator, which adds necessary oxygen to blood before returning blood to the patient. The device is intended for single-use.	31711223	III	3-①,14	applicable	—
Heparin-coated single-use heart-lung bypass heat exchange	A heparin-coated device consisting of a heat exchange system used during extracorporeal circulation. It heats or cools the blood or perfusate during cardiopulmonary bypass surgery or for treatment. This device is for single-use.	11973223	III	3-①,14	applicable	—
Heart-lung bypass in-line gas monitor	One of the modules of a heart-lung bypass system. It is used to measure and monitor the gas concentration(s) in the circulating blood. It is used with an appropriate sensor.	31685000	III	10-④	applicable	applicable
Heparin-coated heart-lung bypass in-line gas monitor	One of the heparin-coated modules of a heart-lung bypass system. It is used to measure and monitor the gas concentration(s) in the circulating blood. It is used with an appropriate sensor.	31685009	III	10-④,14	applicable	applicable
Heart-lung bypass in-line blood gas sensor	A device used concurrently with a heart-lung bypass system for detection and transmission of certain measurable signals. The signals are displayed on the base unit, which shows the amount of gas in the blood.	31715100	III	10-④	applicable	N/A
Heparin-coated heart-lung bypass in-line blood gas sensor	A heparin-coated device used concurrently with a heart-lung bypass system for detection and transmission of certain measurable signals. The signals are displayed on the base unit, which shows the amount of gas in the blood.	31715200	III	10-④,14	applicable	N/A
Heart-lung bypass pulsatile pressure generator	One of the components of a heart-lung bypass system. It is an electronic device that provides electricity to the roller pump of the system and controls the pump. The roller pump functions in a pulsatile manner. Therefore, it imitates the natural movement of the heart.	35101000	III	9-②	applicable	applicable

Heart-lung bypass air/fluid level detector	A device that gives a warning or stops the roller pump connected to the device when air (e.g., bubbles) is detected in the perfusion line or when the fluid level in the reservoir of a heart-lung bypass system is too low.	35440000	III	10-④	applicable	applicable
Extracorporeal circulation blood parameter monitor	A device that measures substances in the blood or the temperature of the blood during extracorporeal circulation in open heart surgery.	70526000	III	10-④	applicable	applicable
Extracorporeal circulation blood parameter monitor measuring cell	A cell that measures substances in the blood or the temperature of the blood during extracorporeal circulation in dialysis and open heart surgery. Usually, it is installed in the extracorporeal circulation circuit before use. It is used in combination with the hematological parameter monitor for extracorporeal circulation.	70527000	III	10-④	applicable	—
Heparin-coated extracorporeal circulation blood parameter monitor measuring cell	A heparin-containing cell that measures substances in the blood or the temperature of the blood during extracorporeal circulation in dialysis and open heart surgery. Usually, it is installed in the extracorporeal circulation circuit before use. It is used in combination with the hematological parameter monitor for extracorporeal circulation.	70528000	III	10-④,14	applicable	—
Extracorporeal bubble oxygenator	A device used for gas exchange between the blood and gas environment in order to meet the gas exchange requirements in the patient. Usually, it is used in open heart surgery.	35100000	III	3	applicable	—
Extracorporeal membrane oxygenator	A device used during open heart surgery, in the treatment of respiratory failure or cardiorespiratory failure (in adults), or for the care of high risk newborns in whom conventional respiratory/medical management procedures are not effective. Extracorporeal oxygenation of blood is performed using a special membrane oxygenator, and the procedure requires a catheter to be placed into a peripheral vessel.	17643100	III	3	applicable	—
Heparin-coated extracorporeal membrane oxygenator	A heparin-coated device used in open heart surgery, to treat a patient (adults) with respiratory failure or cardiopulmonary failure, or in a high-risk neonate for whom conventional pulmonary and medical management is ineffective. Addition of oxygen to the blood outside the body is performed with a special membrane oxygenator. A catheter needs to be inserted into a peripheral vessel.	17643200	III	3,14	applicable	—
Hemofilter	A device to remove excess metabolic products or water from blood, without using dialysis fluid, based primarily on the principle of ultrafiltration using a semi-permeable membrane. The device is intended for single-use.	70529000	III	3	applicable	—
Adsorption hemoperfusion column	A device used with a dedicated device that removes toxins, etc. from the blood of a patient. This is a column, and usually used exclusively for removal of a specific toxin or a series of toxins. It is made of absorbable or adsorptive materials. This device is for single-use.	34422000	III	3	applicable	—
Membrane plasma separator	A device that separates the plasma from the whole blood using a membrane. It does not allow blood cells to pass. This device is for single-use.	70530000	III	3	applicable	—
Membrane plasma component separator	A device that separates the components in the plasma using a membrane. This device is for single-use.	70531000	III	3	applicable	—
Adsorption plasma perfusion column	A device that removes pathogenic substances, etc. using adsorbents from the plasma previously separated. This device is for single-use.	70532000	III	3	applicable	—
Haemoconcentrator	A device for concentrating blood components usually through the removal of water and electrolytes, used in the treatment of fluid overload or during heart surgery that utilizes extracorporeal circulation.	44602000	III	3	applicable	—

Blood cell washer bag	A bag used for blood washing or separation of a cell component from a mixture of blood cells. This device is for single-use. It is installed in an appropriate base unit before use.	16752000	Ⅲ	3	applicable	—
Autotransfusion blood cell wash set	A disposable set used to process the autologous blood with an autologous blood recovery system before reinjection of the blood. This device is for single-use.	17605000	Ⅲ	3	applicable	—
Apheresis filter	A filter used to separate and trap blood components. This device is for single-use.	36194000	Ⅲ	3	applicable	—
Selective plasma component adsorber	A device that selectively adsorbs and removes pathogenic substances from the plasma previously separated in a patient. Usually it is used with a membrane plasma separator during extracorporeal circulation. After the pathogenic substances are adsorbed and removed, the remaining plasma is returned to the patient. This device is for single-use.	70533000	Ⅲ	3	applicable	—
Slow continuous hemofilter	A device that performs slow continuous hemofiltration, hemodialysis, or hemodiafiltration over a longer period of time than normal hemodialysis treatment. This device is intended for single-use.	70534000	Ⅲ	3	applicable	—
Endotoxin removal adsorption hemoperfusion column	A device that selectively adsorbs and removes blood endotoxins from the blood. This device is for single-use.	70535000	Ⅲ	3	applicable	—
Hemodiafilter	A device to remove body fluids and wastes from blood using a semi-permeable membrane, based on the principles of ultrafiltration and diffusion using a perfusate. The amount of water lost by ultrafiltration is compensated by fluid replacement. The device is intended for single-use.	70536000	Ⅲ	3	applicable	—
Cytapheresis column	A device that removes blood cells from patient's blood. This device is for single-use.	70537000	Ⅲ	3	applicable	—
Hemofiltration system	A device used to perform blood purification using hemofilter.	35453000	Ⅲ	11-①	applicable	applicable
Blood purifier for adsorption hemoperfusion	A device used to remove toxins from the blood by passing the blood through materials (adsorption hemoperfusion column) that absorb (or adsorb) a specific toxin or a series of toxins.	35104010	Ⅲ	11-①	applicable	applicable
Unit for endotoxin removal adsorption hemoperfusion	A device used for blood purification with an adsorption type blood purification device for endotoxin removal.	35104020	Ⅲ	11-①	applicable	applicable
Plasma separation unit	A device used for blood purification with a membrane plasma separator, a membrane plasma fractionator, or a selective plasma component adsorber.	36426000	Ⅲ	11-①	applicable	applicable
Albumin apheresis unit	A device used to separate the blood collected from a donor or a patient into its various components. It mixes the collected blood with anticoagulants and performs processing including separation of plasma, platelets, erythrocytes, and leukocytes. Usually, this processing is performed while the device is connected to the donor or patient, and the unprocessed components are returned to the patient.	16405000	Ⅲ	11-①,14	applicable	applicable
Centrifugal apheresis unit	A device that collects the whole blood in a person, centrifugally separates specific blood components, and returns the remaining blood to the person. It performs collection, separation and return of blood.	70538000	Ⅲ	11-①,14	applicable	applicable
Centrifugal hemoperfusion unit	A centrifugal-type blood purifier that performs processing such as washing and concentration of blood components, etc.	70539000	Ⅲ	11-①,14	applicable	applicable

Centrifugal blood component sampling unit	A device that centrifugally separates specific blood components from human whole blood collected. In this process, the unprocessed components are usually disposed of and not returned to the person.	70540000	Ⅲ	11-①,14	applicable	applicable
Slow continuous hemofiltration system	A device used for blood purification with extracorporeal circulation using slow continuous hemofilter.	70541000	Ⅲ	11-①	applicable	applicable
Blood cell removal unit	A device used to remove blood cells using a cytapheresis column.	70542000	Ⅲ	11-①	applicable	applicable
Ascites filtration and reinfusion system	A device that withdraws ascitic fluid or pleural effusion from a patient in advance, filtrates and concentrates it with an ascites filter or an ascites concentration device, circulates the body fluid extracorporeally, and returns it to the blood.	70543000	Ⅲ	11-①	applicable	applicable
Multipurpose blood treatment unit	A device used for multi-purpose processing of the blood or body fluid including blood purification or blood cell removal using a membrane plasma separator, a slow continuous hemofilter, cytapheresis column or ascites filter, etc.	70544000	Ⅲ	11-①	applicable	applicable
Heparin-coated hemodialysis blood tubing	A single-use sterilized set using heparin intended for hemodialysis. Usually, it consists of a tube assembly (connectors, clamps, etc.) necessary for introducing the blood or other solutions through a vascular access device into an appropriate dialyzer/dialysis system and for circulating.	34999203	Ⅲ	2-①,14	applicable	—
Heparin-coated tube connector	A device used to mutually couple and connect 2 tubes. It is a heparin-coated connector.	70545203	Ⅲ	2-②,14	applicable	—
Pump driving unit for circulatory assist balloon	A dedicated pumping device that controls an inflatable balloon that is inserted into the descending aorta. Precisely synchronized with the cardiac rhythm, this device supports cardiac function by mitigating the so-called "cardiac afterload" that occurs subsequent to the increase of coronary blood flow. It supports the circulation (supporting the blood circulation in cardiac insufficiency) in a patient who is dependent on artificial support for maintenance of cardiac function. Artificial support is required because of a deteriorating cardiac function (usually, after open heart surgery).	36340000	Ⅲ	9-①	applicable	applicable
Dialysis apheresis unit	A device that is connected with a dialyzer during dialysis. It filtrates the blood and separates the plasma, and extracts specific substances in the plasma (e.g., LDL-cholesterol). Then, the plasma is passed through the filtration column in the device and the specific substances that are combined with various substrates are extracted.	36344000	Ⅲ	3	applicable	—
Gas-powered pulmonary resuscitator	A portable device used for ventilation or assisted ventilation in a patient with apnea or respiratory failure. Usually, it is used in an ambulance or an emergency department. It is connected to a compressed oxygen supplier. It is equipped with a compressed gas tube, a breathing circuit and a mask, or a connector for endotracheal tube attachment. The gas model may have a manual or automatic pressure cycling function.	13366000	Ⅲ	9-①	applicable	applicable
Ventilator for general-purpose	A device equipped with an automatic circulatory function that supports and manages alveolar ventilation by supplying an appropriate amount of gas to the respiratory airway. The respiratory gas is supplied to the airway of a patient via a mouthpiece, a mask, and an endotracheal tube. It can provide respiratory support in multiple and various situations (e.g., anesthesia, intensive care, neonate care, transportation, high frequency ventilation, special purposes related to specific disease). It is used with a breathing circuit.	70561000	Ⅲ	9-①	applicable	applicable

Ventilator for high-frequency	An automatic circulator used to support or manage alveolar ventilation at rate considerably higher than the physiological respiratory rate and with a tidal volume less than the anatomical dead space. Usually, it functions independently. The high frequency ventilation is superimposed on normal ventilation frequency with this device. Therefore, some types are used with an intensive care ventilator, and others are used in a patient with ventilation complications.	15783000	Ⅲ	9-①	applicable	applicable
Manually-operated jet ventilator	A hand-held device used for ventilation in an emergency when complete or partial airway obstruction occurs, or when a rigid bronchoscope is used. The patient is ventilated with air or oxygen using jet ventilation (gas is discharged in small amounts, rapidly and continuously) via a dedicated catheter cannula. The device can be operated with compressed air.	17865000	Ⅲ	9-①	applicable	applicable
Negative-pressure ventilator	An automatic circulator used to support or manage vesicular breathing. It puts a negative pressure on the exterior surface of the chest wall and expands the chest to allow air to flow into the lungs. There are two types as follows: One. a rigid container that accommodates the whole body below the neck of a patient (i. e. , oxygenator); Two. a container that accommodates the thoracoabdominal region only (cuirass respirator). Both of them make the pressure in each container lower than atmospheric pressure in the oral cavity or the nasal cavity of the patient.	17877000	Ⅲ	9-①	applicable	applicable
Adult ventilator	An automatic circulator that manages and supports alveolar breathing. It is equipped with the functions needed to perform long-term respiratory support in compliance with various breathing requirements. This is intended to be used in adult patients, but it can be used for pediatric patients as well. There is a type that can be used to support ventilation in neonates, which is an extreme case. Usually, it is equipped with pressure and volume modes of ventilation. Patients with apnea can breathe spontaneously and receive the minimum minute volume of ventilation. It has a monitor and alarm specifically designed to be used in an intensive care unit.	42411000	Ⅲ	9-①	applicable	applicable
Reusable manually-operated pulmonary resuscitator	A reusable manually-operated reusable device, used for ventilation or assisted-ventilation of patients who are not breathing or breathing insufficiently. The devices are usually used in an ambulance, emergency room, or the intensive care unit of a hospital. The device is equipped with an oxygen reservoir, tube, and mask, or a connector for a tracheal tube attachment.	17591000	Ⅲ	9-①	applicable	applicable
Manually-operated cardiac pump resuscitator	A manually operated pump (operated and controlled with air pressure) used to apply a rhythmical compression to the chest (cardiac compression) in cardiopulmonary resuscitation (CPR). The same compression is gained at each compression, and the compression can be adjusted to the originally set load level in order to prevent damage to the ribs and the viscera.	35308000	Ⅲ	9-①	applicable	applicable
Single-use manually-operated pulmonary resuscitator	A manually-operated single-use device used for ventilation or assisted-ventilation of patients who are not breathing or breathing insufficiently. The devices are usually used in an ambulance, emergency room, or the intensive care unit of a hospital. The device is equipped with an oxygen reservoir, tube, and mask, or a connector for a tracheal tube attachment.	36086000	Ⅲ	9-①	applicable	—
Reusable active device-breathing circuit connector	A reusable device used to connect a breathing circuit with an endotracheal tube, a face mask, and other components in the breathing circuit. The device has standardized external and internal dimensions of 22 mm and 15 mm, respectively, based on the ISO standards. Therefore, there are types that come in other sizes to comply with respiratory tubes for pediatric and adults. It is made of plastic or metal. Some types are designed to allow partial rotation at the connection point. This device is connected to an active device before use. It can be reused after being subjected to an appropriate cleaning process.	34838003	Ⅲ	9-①	applicable	N/A

Neonatal/pediatric ventilator	A dedicated automatic cycle device used to control and support alveolar ventilation that has sufficient function to provide long-term respiratory support to neonates and pediatric patients who have changeable respiratory requirements. The device is not suitable for children and adults. However, it has been designed to be particularly suitable for assisting respiration in premature babies. Usually, it has a pressure cycle mode. It enables natural respiration with a minimum minute volume when apnea occurs in a patient. This device is equipped with a monitor and an alarm designed for a high-care unit.	14361000	III	9-①	applicable	applicable
Exhaled air pulmonary resuscitator	A device used to provide respiratory support for a patient who has a patent airway but has shallow breathing or apnea. Usually, it consists of a mouthpiece, a non-rebreathing valve or filter, and a mask. The non-rebreathing valve or one-way valve is designed to protect healthcare professionals from coming into contact with the patient's fluids, droplets and expired air.	17141000	III	9-①	applicable	applicable
Ventilator for anaesthesia	An independent-type, automatic circulator used to support and manage alveolar ventilation during general anesthesia. This device is suitable for inhalation anesthetics. It has fewer functions compared with an intensive care ventilator, and its operation is simple. However, it appropriately copes with the requirements for exchange between oxygen and carbon dioxide in order to maintain normal blood gas concentrations. This device works as a mechanical means to provide a patient with respiratory gas under control. It is equipped with an alarm that warns of the occurrences of respiratory changes or dangerous operating conditions.	34851000	III	11-①	applicable	applicable
Ventilator for transportable	A device used to support or manage alveolar ventilation. It is equipped with a self-contained gas supply mechanism designed to be operated while moving. Usually, it is portable, and it may work with a battery power source or with an air pressure source. However, it may need an external power source to use for long hours. It is mainly used for treatment in an alternate location and for emergency care during transportation or outside a hospital.	36289000	III	9-①	applicable	N/A
Continuous positive airway pressure unit	This device is sometimes called continuous positive airway pressure (CPAP). A device that supplies a constant amount of oxygen/air at a prescribed pressure to patients, making the lungs at a state of slightly positive pressure and thereby accelerating gas exchange. The device is used, under a physician's guidance, for adult patients with sleep apnea due to airway obstruction.	36700000	III	9-①	applicable	applicable
Ventilator for home use	An automatic circulator that supports and manages alveolar ventilation. It is used by the patient at home where the patient is dependent on long-term or permanent respiratory support under the directions of a doctor. The patient or patient's family can operate. There is a gas type or an electric type.	36943000	III	9-①	applicable	N/A
Bi-level positive airway pressure unit	A device often called BIPAP (bilevel positive airway pressure) ventilator. It provides oxygen or air at a constant flow rate, and provides the maximum and minimum airway pressure during spontaneous respiration.	36990000	III	9-①	applicable	applicable
Converter for ventilator	A device used to connect a certain type of electrically operated ventilator to a certain type of breathing circuit system, and to ensure compatibility. With this device, a ventilator and a breathing circuit manufactured by different manufacturers can be combined in an innovative way. It is useful as it allows a hospital, etc. to flexibly select a breathing circuit or breathing circuit system that makes it possible to create a new type of breathing circuit or system using the same ventilator.	37038000	III	9-①	applicable	applicable

Continuous-automatic positive airway pressure unit	A device used to provide continuous positive airway pressure in spontaneously breathing patients, to accelerate alveolar ventilation. The device is sometimes called automatic continuous positive airway pressure (CPAP). The device is usually used for adult patients with sleep apnea due to airway obstruction, under a physician's guidance. The airway pressure is automatically controlled with a sensor at an appropriate level for CPAP.	37234000	III	9-①	applicable	applicable
Anaesthesia system	A general anesthesia supplier completely integrated for oxygen, nitrous oxide, and other medical gases. The main components include a gas supply system of high, middle, and low pressure gases, a breathing circuit (with or without a ventilator), and a gas scavenger system. It has built-in devices such as an alarm, analysis equipment, and a monitor (with an integrated circuit and display).	37710000	III	11-①	applicable	applicable
Closed-circuit anaesthesia system	An anesthesia system specifically designed for gases that continuously come in contact with the airway in a patient. This device reuses the expired gas of a patient that has passed through carbon dioxide absorbents and returns it to the patient. To maintain equilibrium, a very small amount of fresh gas is required. This method is known as closed circulation. However, a small amount of used gas is exhausted from the closed circuit.	34432000	III	11-①	applicable	applicable
Ventilator for anaesthesia system	A type of module of an anesthesia system used to support or manage alveolar ventilation during general anesthesia. This device is suitable for inhalation anesthetics. It is able to cope well with the need to exchange oxygen with carbon dioxide in order to maintain normal blood gas concentrations while the exact amount of anesthetics is administered. This device works as the mechanical means to provide respiratory gas under control for a patient. It is equipped with an alarm that warns of the occurrence of respiratory changes or dangerous operating conditions.	42330000	III	11-①	applicable	applicable
Dental anaesthesia gas delivery unit	A unit consisting of a fresh gas supply module and a protection module for the purpose of administration of oxygen and nitrous oxide, or air in dental surgery.	36193000	III	11-①	applicable	applicable
Mixed gas anaesthesia apparatus	A device that supplies a mixture of nitrous oxide and oxygen based on non-rebreathing anesthesia (e.g., with a demand valve mask) for painless delivery, dental surgery, postoperative pain relief, or delivery with little pain (i. e. , use of pain-reducing drugs).	70573000	III	11-①	applicable	applicable
Regulator for medical gas	A device that adjusts multiple types of medical gas to constant concentrations to deliver these gases to patients. Usually, the mixed gas is a mixture of oxygen (O ₂) and air or a mixture of O ₂ and nitrous oxide (laughing gas). In special cases, nitric oxide (NO) or nitrogen (N ₂) may be mixed. Adjusting to the specified concentration of one component (usually, O ₂), the mixed gas is precisely made, and delivered to patients through various breathing circuits/tubes.	36327000	III	11-①	applicable	applicable
Vaporizer for Ethrane anaesthesia	A device that vaporizes an anesthetic ethrane and administers the gas to a patient before surgery in a controlled way. This is usually attached to an anesthesia system or a ventilator.	36316000	III	11-①	applicable	applicable
Vaporizer for Isoflurane anaesthesia	A device that vaporizes an anesthetic isoflurane and administers the gas to a patient in a controlled way. This is usually attached to an anesthesia system or a ventilator.	36890000	III	11-①	applicable	applicable
Vaporizer for Ether anaesthesia	A device that vaporizes an anesthetic ether and administers the gas to a patient before surgery in a controlled way. This is usually attached to an anesthesia system or a ventilator.	36892000	III	11-①	applicable	applicable

Vaporizer for desflurane anaesthesia	A device that vaporizes an anesthetic desflurane and administers the gas to a patient before surgery in a controlled way. This is usually attached to an anesthesia system or a ventilator.	36979000	Ⅲ	11-①	applicable	applicable
Vaporizer for Sevoflurane anaesthesia	A device that vaporizes an anesthetic sevoflurane and administers the gas to a patient before surgery in a controlled way. This is usually attached to an anesthesia system or a ventilator.	36980000	Ⅲ	11-①	applicable	applicable
Portable anaesthesia gas delivery unit	A portable independent unit that delivers mixed gases (oxygen, nitrous oxide, volatile inhalation anesthetics) continuously, or intermittently and monitors delivery to support the maintenance of an adequate level of anesthesia. Usually, it is used in the military or surgery under unconventional conditions.	44469000	Ⅲ	7-①	applicable	applicable
Inhalation analgesia unit	A device designed mainly to deliver anesthetic gas to patients or generate anesthetic vapor for inhalation. Usually, it has a built-in demand valve. It may be connected to a vaporizer calibrated for control of the volatile anesthetic concentration.	16953000	Ⅲ	11-①	applicable	applicable
Stimulator for electrical anaesthesia	A device that introduces and maintains anesthesia in patients by applying an electric current to the nerve tissue (e.g., an electrode placed on the patient's head). It may be used in minor surgery.	31268000	Ⅲ	9-①	applicable	applicable
Anaesthesia gas delivery unit	An independent unit that delivers mixed gases (oxygen, nitrous oxide, volatile inhalation anesthetics) continuously, or intermittently and monitors delivery to support the maintenance of an adequate level of anesthesia.	34846000	Ⅲ	11-①	applicable	applicable
Hyperbaric patient chamber	A housing apparatus with air and gas pressures higher than standard atmospheric pressure (e.g., 2-3ATM). It is used for treatment of diseases including gas gangrene, decompression sickness and anaerobic infections, or where a condition requires a high concentration of oxygen. It may also be used to investigate the effects of compression and decompression on humans and animals.	12061000	Ⅲ	9-①	applicable	applicable
Hypobaric patient chamber	A housing apparatus with air pressure lower than standard atmospheric pressure.	35115000	Ⅲ	9-①	applicable	applicable
Oxygen therapy activator	A device that produces active oxygen (energy excited species of oxygen) in the form of a mixture with room air. Active water is produced as a byproduct. Inhalation of this mixed gas (together with having water as necessary) is considered useful to relieve symptoms of chronic or serious diseases (e.g., some cancers, diabetes mellitus, rheumatism, cardiovascular disease). Some physiological processes are activated.	37230000	Ⅲ	11-①	applicable	applicable
Nitric oxide gas administration system	A dedicated system used to deliver nitric oxide to patients. It incorporates a monitor and an analyzer that can adjust the flow rate and volume of gas delivery.	37266000	Ⅲ	11-①	applicable	applicable
Oxygen therapy delivery system	A system consisting of multiple devices that are used simultaneously to deliver oxygen based on various methods, concentrations, duration, and flow rates. It is equipped with an oxygen delivery device. It may have a flowmeter, a mask, a tube and a nasal cannula.	37498000	Ⅲ	11-①	applicable	applicable
Active device oxygen condenser	A device that separates nitrogen from room air using an adsorption column or membrane with a large surface area. The device for a medical gas pipeline system (JIST7101) is excluded. The components of this device include a compressor, a filter and a reservoir. The oxygen concentration is adjusted according to the flow rate used. It is connected to a ventilator, etc. before it is used. Those to be simply and physically	12873003	Ⅲ	9-②	applicable	applicable
Stationary infant incubator	A stationary type neonatal incubator. It may have wheels but is stationed in a ward or clinical department to perform the original purpose of this device.	36025000	Ⅲ	9-①	applicable	applicable

Mobile infant heater	A device that has a built-in infrared heating element. It is controlled so as to emit heat uniformly to neonatal and infant patients who require the thermal environment control. It has wheels and is easily movable to various places including patient rooms, wards, clinical departments, and floors.	17433000	Ⅲ	9-①	applicable	applicable
Transportable infant incubator	A neonatal incubator specifically designed to carry a neonate to or from a medical facility.	35121000	Ⅲ	9-①	applicable	applicable
Temporary defibrillator with pacing function	A device which incorporates a non-invasive, temporary pacemaker, or to which an optional pacing attachment can be connected later. It administers an electric shock and displays the electrocardiogram (ECG) to establish normal cardiac rhythm in patients with ventricular fibrillation. It has a function to administer an electrical impulse that stimulates the entire heart simultaneously for resuscitation of patients, arrhythmia treatment and temporary pacing. The ECG is displayed by the electrocardiograph monitor of the device to confirm arrhythmia and therapeutic effects.	17882000	Ⅲ	9-①	applicable	applicable
Automated defibrillator	A device that analyzes the electrocardiogram (ECG) to determine delivery of a defibrillation shock. It is placed on a patient via adhesive defibrillation electrodes with both functions of ECG monitoring and defibrillator discharge. It provides the shock for the patient without the help of an operator.	35972010	Ⅲ	9-①	applicable	applicable
Semi-automated defibrillator	A device that analyzes the electrocardiogram (ECG) to determine delivery of a defibrillation shock. It is placed on a patient via adhesive defibrillation electrodes with both functions of ECG monitoring and defibrillator discharge. It informs the operator of the timing for providing the shock.	37805000	Ⅲ	9-①	applicable	applicable
Manual defibrillator	A medical, electrical device designed to defibrillate the heart by delivering an electric pulse shock via internal or external electrodes. Usually, it has an ECG monitor, or may have a synchronizing function. ECG analysis and delivery of the shock are performed manually by the operator.	37806000	Ⅲ	9-①	applicable	applicable
Defibrillator for non-medical professionals	An automated or semi-automated defibrillator in which manual mode setting is difficult.	35972020	Ⅲ	9-①	applicable	applicable
Transtelephonic defibrillator	A system that enables a physician to read the electrocardiogram (ECG) for diagnosis and control the defibrillator via a telephone connection at a place distant from the patient. It is composed of a base station (a base where the physician is present) consisting of a portable defibrillator with the function of an electrocardiograph (ECG), a microphone, a battery, a mobile phone (usually cellular phone), a control panel and an ECG display with a recording function.	17579000	Ⅲ	9-①	applicable	applicable
Invasive implantable defibrillator system analyzer	A device used to assess and monitor the performance of an automatic implantable defibrillator placed in a patient.	36078000	Ⅲ	9-②	applicable	applicable
Programmer for active implantable device	A program for transmit one or more electrical operating characteristics noninvasively to the active base unit and change the characteristics. The program does not control the entire therapeutic system. It can change a certain range of the characteristics which are selected by a physician or under a physician's direction within a pre-specified range in the implantable, programmable base unit. It may read out parameter values stored in active devices and provides information about patient status.	70586000	Ⅲ	9-②	applicable	—
Automated peritoneal dialysis system	A device that utilizes automated peritoneal lavage, in which, after dialysis conditions are specified, perfusate is injected intraperitoneally and then allowed to drain.	11226000	Ⅲ	3	applicable	applicable

Peritoneal dialysis catheter	A device used to infuse fluid (dialysate) into the peritoneal cavity and utilize the peritoneum as the dialysis membrane. It diffuses metabolic wastes and water out of the blood. Usually, it uses a Dacron cuff, which promotes cell proliferation, for sealing this device to prevent bacterial invasion and fluid leakage. Usually, it is inserted percutaneously for both continuous use and temporary use. It may be surgically implanted or used for a limited period. It is used in manual peritoneal dialysis (continuously performed on an outpatient basis) or automated peritoneal dialysis (continuously and periodically performed), intra-peritoneal chemotherapy or removal of fluid overload resulting from congestive heart failure.	34921000	III	8	applicable	—
Titanium adaptor	An adapter made of titanium. It is used to connect a catheter for peritoneal dialysis to a tube set for peritoneal lavage. An adapter that extends the catheter for peritoneal dialysis is included.	70588000	III	3	applicable	—
Peritoneal dialysis catheterization kit	A package of devices to be used for insertion of a catheter for peritoneal lavage.	16992000	III	3	applicable	—
Peritoneal dialysis tube set	A set of sterile devices intended for peritoneal lavage. The set is for single-use. Usually, the set consists of tubes, a reservoir bag as an option, and appropriate connectors. It may have a peritoneal perfusate filter to capture and remove contaminated substances.	35000000	III	3	applicable	—
Peritoneal dialysis catheter adaptor	A connecting device (usually, it is a small part) that is used to connect a catheter for peritoneal lavage to an external device that manages dialysates. This device is used to connect devices of different makers and makes devices compatible with each other. This device is for single-use.	35944000	III	3	applicable	—
Portable continuous peritoneal dialysis transfer set	A set of devices including tubes to be used in continuous ambulatory peritoneal dialysis (CAPD) that infuses perfusate into and discharges it from the peritoneal cavity.	35986000	III	3	applicable	—
Automated peritoneal dialysis unit circuit and related device set	A dedicated device that is attached to an automated peritoneal dialysis system and used for peritoneal dialysis. The dialysis conditions are set in the device, and the infusion, reservoir and drainage of dialysis fluid are repeatedly performed under automatic operation and control.	70590000	III	3	applicable	—
Peritoneal perfusate infusion/drainage tube and related device set	A set of sterile devices used for peritoneal lavage. The set is for single-use. Usually, the set consists of a transfer set for infusion and drainage of peritoneal dialysis fluid, a reservoir bag, and fixing connectors.	70591000	III	3	applicable	—
Peritoneal dialysis circuit and related device set	A set of sterile devices used for peritoneal lavage. The set is for single-use. Usually, the set consists of a peritoneal dialysis tube, a reservoir bag as an option, and appropriate connectors.	70592000	III	3	applicable	—
Powered cardiopulmonary resuscitator	A device that electrically simulates manual closed chest compression, open chest cardiac massage, and artificial respiration to normalize cardiac output and pulmonary ventilation after cardiac arrest or apnea.	35309000	III	9-①	applicable	applicable
Manually-operated cardiac pump	A device that performs closed chest cardiac massage with manual chest compression to normalize cardiac output after cardiac arrest.	70593000	III	9-①	applicable	—
Mechanical cardiopulmonary resuscitator	A device that simulates manual closed chest compression, open chest cardiac massage, and artificial respiration to normalize cardiac output and pulmonary ventilation after cardiac arrest or apnea. It may use compressed oxygen or air as a drive source.	70594000	III	9-①	applicable	applicable

Ascites filtration and reinfusion set	A set of devices used to filtrate and concentrate the ascites or a pleural effusion that is drained out of the body in advance, and return it to the blood. The device may be directly connected to the patient in the extracorporeal circulation. The set is for single-use.	70595009	Ⅲ	3	applicable	applicable
Ascites filter	A device used to filtrate the ascites or a pleural effusion that is drained out of the body in advance, and return it to the blood. The device may be directly connected to the patient in the extracorporeal circulation. This device is for single-use.	70596010	Ⅲ	3	applicable	—
Ascites concentrator	A device used to concentrate the ascites or a pleural effusion that is drained out of the body in advance, and return it to the blood. The device may be directly connected to the patient in the extracorporeal circulation. This device is for single-use.	70596020	Ⅲ	3	applicable	—
Blood recovery autotransfusion unit	A device used to collect and cleanse the blood for immediate or subsequent re-transfusion of the patient's blood lost during surgery or due to trauma. The device centrifugally separates erythrocytes and cleanses them in saline solution(NaCl) as a part of the recycling process. This device reinfuses the blood directly into the patient after collection and cleansing.	34863003	Ⅲ	11-①	applicable	applicable
Autotransfusion blood collection unit	A device used to collect the blood in a patient who will undergo major surgery. An autologous transfusion unit cleanses the blood before it is returned to the patient, or before it is stored in preparation for the later use.	36966000	Ⅲ	11-①	applicable	applicable
Incontinence neuromuscular electrical stimulator	A nonimplantable neuromuscular stimulator used to treat urinary incontinence or fecal incontinence. It is integrated into a plug or pessary, and consists of a pair of electrodes connected to a battery-powered pulse supplier. A plug or pessary is inserted into the rectum or vagina and used to stimulate the pelvic floor muscle.	36784000	Ⅲ	5-④,8	applicable	applicable
Middle ear implant hearing aid	A kind of hearing aid designed to transmit output signals by vibrating the ear ossicles, etc. directly.	30084000	Ⅲ	8	applicable	—
Radionuclide system contour detector for remote irradiation therapy	A therapeutic device that can be controlled by software or a mechanical structure. It is used to precisely determine the outline of the area of the body to be irradiated. It may be manually operated, use a laser for positioning, or use slice images obtained by computed tomography. Usually, the information obtained from this device is entered into a radiotherapy planning system and utilized for the radiotherapy plan.	36499000	Ⅲ	9-①	applicable	applicable
Radionuclide system for remote irradiation therapy	A device that delivers a therapeutic radiation dose from a single external radiation beam generated from a radiation source to an anatomical area. The standard equipment configuration is as follows: 1. a therapeutic head (this is positioned in a movable housing and a shielded radiation source storage container with a built-in single radiation source.). 2. a rotary or fixed gantry that has a therapeutic head at one end and a counterweight at the other end. The counterweight also functions as a beam breaker. 3. a collimator device installed in the gantry for adjusting the position of therapeutic beam. 4. a movable patient table used to adjust the posture of the patient exposed to the radiation beam. 5. an operator console with a control part.	38297000	Ⅲ	9-①	applicable	applicable
Non-central circulatory remote afterloading brachytherapy therapeutic radionuclide system	A device that places a radiation source temporarily at the treatment site in the non-central circulatory system for providing a required radiation dose during radiotherapy. This device equips a remotely controlled radiation source transporter.	38300003	Ⅲ	9-①	applicable	applicable
Non-central circulatory manual brachytherapy therapeutic radionuclide system	A device that places a radiation source manually or automatically at the treatment site in the non-central circulatory system for providing a required radiation dose during radiotherapy. This device does not equip a remotely controlled radiation source transporter.	38299003	Ⅲ	9-①	applicable	applicable

Radionuclide source for remote irradiation therapy	Radiation sources generated in a reactor and used as in a remote afterloading system designed to deliver a therapeutic radiation beam to a target anatomical area. The radiation sources incorporated as a component of the remote afterloading system are generally sealed. The radioisotopes most usually used to remote radiation therapy are cobalt 60 (Co-60), cesium 137 (Cs-137) and iridium 192 (Ir-192).	38305000	III	9-①	applicable	—
Non-central circulatory remote afterloading brachytherapy therapeutic radionuclide source	A device for the non-central circulatory system used as radiation source to deliver a high or low dose rate with an after-loading brachytherapy device designed for radiotherapy which is necessary for treatment and symptomatic therapy, and uses natural radioisotopes or radioisotopes produced by an accelerator or a nuclear reactor. The radiation source used for the after-loading brachytherapy device is provided in various physical configurations —e.g., a single encapsulated radiation source (sealed radiation source), ribbon radiation source, plated, foiled, or embedded radiation source, and encapsulated liquid or gel. The radiation source is contained in a sealed storage container installed in the after-loading device, and transferred to the treatment site via guide tube in various structures.	38302003	III	9-①	applicable	—
Non-central circulatory permanent implant manual brachytherapy therapeutic radionuclide source	A non-central cardiovascular device containing an isotope naturally occurring or produced by an accelerator or a nuclear reactor, intended to be permanently implanted in the body for radiation therapy requiring treatment or symptomatic treatment. In general, the device is placed in the body using an applicator with the assistance of a fluoroscope or an endoscope. The radiation source for manual permanent implantation is designed so that histocompatibility can be achieved. Morphological types of radiation sources include microsphere, sphere, stent, seed, and wire, which are used to generate low-energy photons, beta particles, or alpha particles.	38303003	III	9-①	applicable	—
Non-central circulatory temporary placement manual brachytherapy therapeutic radionuclide source	A non-central cardiovascular device containing an isotope naturally occurring or produced by an accelerator or a nuclear reactor, intended to be temporarily implanted in the body and to be removed after a prescribed duration of treatment. Used in brachytherapy, the device is placed and removed manually or under endoscopic observation. Radiation sources to be placed manually for temporary implantation are provided in a variety of forms, including encapsulated, sealed, plated, foiled, and embedded. Some devices may be directly inserted into the body, and others may be implanted using a catheter or an applicator. Morphological types of radiation sources include needle, sphere, ovoid, seed, wire, and fluid filled in a cuff of a catheter.	38304003	III	9-①	applicable	—
Radionuclide system for Stereotactic radiotherapy	A device for delivering a therapeutic dose from external beams to an anatomical area. The external beams are generated with multiple radiation sources collimated and arranged to reach one specified focus. The standard equipment configuration is as follows: 1. a stereotactic positioning device attached to the patient for determination of the 3D coordinates of the anatomical area to be treated, 2. a set of a helmet with a fixed diameter and a collimator, 3. a high-density plug that is attached to the hole of the helmet to function as a beam breaker, 4. a shielded hole to store the radiation sources and reduce radiation in the room. 5. radiation sources precisely arranged so that beams from all radiation sources cross at a single point, 6. a movable patient table.	38298000	III	9-①	applicable	applicable

Radionuclide source for Stereotactic radiosurgery therapeutic	A radioisotopes generated in a reactor and used as one of a series of radiation sources incorporated into a stereotaxic radiosurgery system designed to deliver precisely focused radiation beams required in symptomatic or other treatment to a target anatomical area. The radiation source used in a stereotaxic radiosurgery system is generally sealed (sealed radiation source). Different from other therapeutic radiation sources, multiple radiation sources are used in a stereotaxic radiosurgery system. And multiple external radiation beams which are focused and fixed on a single point are simultaneously generated. The radioisotope most commonly used for stereotaxic radiosurgery is cobalt 60 (Co-60).	38306000	Ⅲ	9-①	applicable	—
Applicator for vaginal manual brachytherapy	A manual brachytherapy applicator specifically designed for vaginal or transvaginal radiation therapy. A single or module applicator designed to facilitate manual placement (puncture, local placement, endoscopic placement or placement and removal using a diagnostic imaging system) of single or multiple therapeutic radiation sources in treatment sites. It may be designed to be standard in configuration or to handle specific radiation sources. The device contains various vaginal applicators including hollow needles, tubes and catheters. It is used when brachytherapy sources are manually delivered.	38406000	Ⅲ	7-③	applicable	applicable
Applicator for vaginal remote afterloading brachytherapy	A remote controlled brachytherapy applicator specifically designed for vaginal or transvaginal radiation therapy. It is designed to be temporarily implanted in the body. It serves as a guide for computer-controlled temporary placement and removal of a single or multiple therapeutic radiation sources in the vagina. This device group includes various applicators such as hollow needles, tubes, and catheters, as well as associated devices and connectors.	38407000	Ⅲ	7-③	applicable	applicable
Applicator for manual cervical/endometrial brachytherapy	A manual brachytherapy applicator specifically designed for uterine cervix or intrauterine radiation therapy. A single or module applicator designed to facilitate manual placement (puncture, placement with an endoscope or a diagnostic imaging system) of single or multiple therapeutic radiation sources in treatment sites. It may be designed to be standard in configuration or to handle specific radiation sources. The device contains various uterine cervical or endometrial applicators including hollow needles, tubes and catheters. It is used when brachytherapy sources are manually delivered.	38408000	Ⅲ	7-③	applicable	applicable
Applicator for brachytherapy Cervical/endometrial remote afterloading	A remote controlled brachytherapy applicator specifically designed for uterine cervical or intrauterine radiation therapy. It is designed to be temporarily implanted in the body. It serves as a guide for computer-controlled temporary placement and removal of a single or multiple therapeutic radiation sources in the uterine cervix and endometrium. This device group includes various applicators such as hollow needles, tubes, and catheters, as well as associated devices and connectors.	38409000	Ⅲ	7-③	applicable	applicable
Applicator for bronchial manual brachytherapy applicator	A manual brachytherapy applicator specifically designed for temporarily use in bronchial radiation therapy. A single or module applicator designed to facilitate manual placement (placement using an endoscope or positioning, placement and removal using a diagnostic imaging system) of single or multiple therapeutic radiation sources in treatment sites. It may be designed to be standard in configuration or to handle specific radiation sources. The device contains various bronchial applicators including hollow needles, tubes and catheters. It is used when brachytherapy sources are manually delivered.	38410000	Ⅲ	7-③	applicable	applicable

Applicator for bronchial remote afterloading brachytherapy	A remote controlled brachytherapy applicator specifically designed for bronchial radiation therapy. It is designed to be temporarily implanted in the body. It serves as a guide for computer-controlled temporary placement and removal of a single or multiple therapeutic radiation sources in the bronchus. This device group includes various applicators such as hollow needles, tubes, and catheters, as well as associated devices and connectors.	38411000	III	7-③	applicable	applicable
Applicator for nasopharynx manual brachytherapy	A manual brachytherapy applicator specifically designed for nasopharyngeal radiation therapy. A single or module applicator designed to facilitate manual placement (puncture, endoscopic placement or placement and removal using a diagnostic imaging system) of single or multiple therapeutic radiation sources in treatment sites in the nasopharynx. It may be designed to be standard in configuration or to handle specific radiation sources. The device contains various nasopharyngeal applicators including hollow needles, tubes and catheters. It is used when brachytherapy sources are manually delivered.	38414000	III	7-③	applicable	applicable
Applicator for nasopharynx remote afterloading brachytherapy	A remote controlled brachytherapy applicator specifically designed for nasopharyngeal radiation therapy. It is designed to be temporarily implanted in the body. It serves as a guide for computer-controlled temporary placement and removal of a single or multiple therapeutic radiation sources in the nasopharynx. This device group includes various applicators such as hollow needles, tubes, and catheters, as well as associated devices and connectors.	38415000	III	7-③	applicable	applicable
Applicator for tongue manual brachytherapy	A manual brachytherapy applicator specifically designed for lingual radiation therapy. A single or module applicator designed to facilitate manual placement (puncture, local placement or placement and removal using a diagnostic imaging system) of single or multiple therapeutic radiation sources in treatment sites in the tongue and the surrounding tissues. It may be designed to be standard in configuration or to handle specific radiation sources. The device contains various lingual applicators including hollow needles, tubes and catheters. It is used when brachytherapy sources are manually delivered.	38416000	III	7-③	applicable	applicable
Applicator for tongue remote afterloading brachytherapy	A remote controlled brachytherapy applicator specifically designed for tongue or oral cavity radiation therapy. It is designed to be temporarily implanted in the tongue or the surrounding tissues. It serves as a guide for computer-controlled temporary placement and removal of a single or multiple therapeutic radiation sources. This device group includes various applicators such as hollow needles, tubes, and catheters, as well as associated devices and connectors.	38417000	III	7-③	applicable	applicable
Applicator for neck manual brachytherapy	A manual brachytherapy applicator specifically designed for neck radiation therapy. A single or module applicator designed to facilitate manual placement (puncture, local placement or placement and removal using a diagnostic imaging system) of single or multiple therapeutic radiation sources in treatment sites in the neck tissues. It may be designed to be standard in configuration or to handle specific radiation sources. The device contains various neck applicators including hollow needles, tubes and catheters. It is used when brachytherapy sources are manually delivered.	38418000	III	7-③	applicable	applicable
Applicator for neck remote afterloading brachytherapy	A remote controlled brachytherapy applicator specifically designed for neck radiation therapy. It is designed to be temporarily implanted in the neck tissues. It serves as a guide for computer-controlled temporary placement and removal of a single or multiple therapeutic radiation sources. This device group includes various applicators such as hollow needles, tubes, and catheters, as well as associated devices and connectors.	38419000	III	7-③	applicable	applicable

Applicator for esophagus manual brachytherapy	A manual brachytherapy applicator specifically designed for esophagus radiation therapy. A single or module applicator designed to facilitate manual placement (puncture or placement and removal using an endoscope or a diagnostic imaging system) of single or multiple therapeutic radiation sources in treatment sites in the esophagus. It may be designed to be standard in configuration or to handle specific radiation sources. The device contains various esophageal applicators including hollow needles, tubes and catheters. It is used when brachytherapy sources are manually delivered.	38420000	III	7-③	applicable	applicable
Applicator for esophagus remote afterloading brachytherapy	A remote controlled brachytherapy applicator specifically designed for esophagus radiation therapy. It is designed to be temporarily implanted in the esophagus. It serves as a guide for computer-controlled temporary placement and removal of a single or multiple therapeutic radiation sources. This device group includes various applicators such as hollow needles, tubes, and catheters, as well as associated devices and connectors.	38421000	III	7-③	applicable	applicable
Applicator for bile duct manual brachytherapy	A manual brachytherapy applicator specifically designed for bile duct radiation therapy. An applicator designed to have a configuration that facilitates manual placement (puncture or placement and removal using an endoscope or a diagnostic imaging system) of single or multiple therapeutic radiation sources in treatment sites in the bile duct. It may be designed to be standard in configuration or to handle specific radiation sources. The device contains various bile duct applicators including hollow needles, tubes and catheters. It is used when brachytherapy sources are manually delivered.	38422000	III	7-③	applicable	applicable
Applicator for brachytherapy bile duct remote afterloading	A remote controlled brachytherapy applicator specifically designed for bile duct radiation therapy. It is designed to be temporarily implanted in the bile duct. It serves as a guide for computer-controlled temporary placement and removal of a single or multiple therapeutic radiation sources at treatment sites This device group contains hollow needles, tubes, and catheters, as well as associated devices and connectors.	38423000	III	7-③	applicable	applicable
Applicator for pancreas manual brachytherapy	A manual brachytherapy applicator specifically designed for pancreatic radiation therapy. A single or module applicator designed to facilitate manual placement (puncture, endoscopic placement, or placement and removal using a diagnostic imaging system) of single or multiple therapeutic radiation sources in treatment sites in the pancreas. It may be designed to be standard in configuration or to handle specific radiation sources. The device contains various pancreatic applicators including hollow needles, tubes and catheters. It is used when brachytherapy sources are manually delivered.	38424000	III	7-③	applicable	applicable
Applicator for pancreas remote afterloading brachytherapy	A remote controlled brachytherapy applicator specifically designed for pancreatic radiation therapy. It is designed to be temporarily implanted in the pancreas. It serves as a guide for computer-controlled temporary placement and removal of a single or multiple therapeutic radiation sources at treatment sites. This device group includes various applicators such as hollow needles, tubes, and catheters, as well as associated devices and connectors.	38425000	III	7-③	applicable	applicable
Applicator for prostate manual brachytherapy	A manual brachytherapy applicator specifically designed for prostate radiation therapy. A single or module applicator designed to facilitate manual placement (puncture or placement or removal with a trigger loading device, an endoscope or a diagnostic imaging system) of single or multiple therapeutic radiation sources in treatment sites in the prostate gland. It may be designed to be standard in configuration or to handle specific radiation sources. It contains various prostate applicators including hollow needles, tubes and catheters. It is used when brachytherapy sources are manually delivered.	38426000	III	7-③	applicable	applicable

Applicator for prostate remote afterloading brachytherapy	A remote controlled brachytherapy applicator specifically designed for prostate radiation therapy. It is designed to be temporarily implanted in the prostate gland. It serves as a guide for computer-controlled temporary placement and removal of a single or multiple therapeutic radiation sources. This device group includes various applicators such as hollow needles, tubes, and catheters, as well as associated devices and connectors.	38427000	III	7-③	applicable	applicable
Applicator for bladder manual brachytherapy	A manual brachytherapy applicator specifically designed for bladder radiation therapy. An applicator designed to facilitate manual placement (puncture or placement and removal using an endoscope or a diagnostic imaging system) of single or multiple therapeutic radiation sources in treatment sites in the bladder. It may be designed to be standard in configuration or to handle specific radiation sources. It contains bladder applicators including hollow needles, tubes and catheters. It is used when brachytherapy sources are manually delivered.	38428000	III	7-③	applicable	applicable
Applicator for bladder remote afterloading brachytherapy	A remote controlled brachytherapy applicator specifically designed for bladder radiation therapy. It is designed to be temporarily implanted in the bladder. It serves as a guide for computer-controlled temporary placement and removal of a single or multiple therapeutic radiation sources at treatment sites. This device group includes various applicators such as hollow needles, tubes, and catheters, as well as associated devices and connectors.	38429000	III	7-③	applicable	applicable
Applicator for manual rectal/anal brachytherapy	A manual brachytherapy applicator specifically designed for rectal and/or anal radiation therapy. A single or module applicator designed to facilitate manual placement (puncture or placement and removal using an endoscope or a diagnostic imaging system) of single or multiple therapeutic radiation sources in treatment sites in the rectum and/or anus. It may be designed to be standard in configuration or to handle specific radiation sources. It contains rectal or anal applicators including hollow needles, tubes and catheters. It is used when brachytherapy sources are manually delivered.	38430000	III	7-③	applicable	applicable
Applicator for rectal/anal remote afterloading brachytherapy	A remote controlled brachytherapy applicator specifically designed for rectal or anal radiation therapy. It is designed to be temporarily implanted in the rectum or anus. It serves as a guide for computer-controlled temporary placement and removal of a single or multiple therapeutic radiation sources. This device group includes various applicators such as hollow needles, tubes, and catheters, as well as associated devices and connectors.	38431000	III	7-③	applicable	applicable
Applicator for eye manual brachytherapy	A template with a groove on the one side. The groove shows the position of the brachytherapy source that is manually, temporarily delivered to the eye surface. The other side is shielded.	38434000	III	7-③	applicable	applicable
Applicator for brachytherapy non-central circulatory general-purpose manual	A general-purpose brachytherapy applicator used to facilitate radiotherapy. A single or module applicator designed to facilitate manual placement (puncture, local placement, placement under endoscopy, and placement and removal using an image diagnostic system) of single or multiple therapeutic radiation sources in treatment sites in the non-central circulatory system. Some are designed in a standard configuration, and others are designed in various physical configurations, or designed so as to be easily processed into a configuration that can handle specific radiation sources. It comes in hollow needles, tubes, catheters, ovoid, and tandem.	38435003	III	7-③	applicable	applicable

Applicator for brachytherapy non-central circulatory general-purpose remote afterloading	A general-purpose remote controlled brachytherapy applicator used to facilitate radiotherapy. It is designed to be temporarily implanted in the body. It serves as a guide for computer-controlled temporary placement and removal of a single or multiple therapeutic radiation sources at treatment sites in the non-central circulatory system. This device group includes various applicators such as hollow needles, tubes, and catheters, as well as associated devices and connectors.	38436003	Ⅲ	7-③	applicable	applicable
Stereotactic radiotherapy accelerator system	A stereotactic radiation therapy system for treatment based on a linear accelerator (or microtron). Output is limited to a narrow, high-energy beam. The gantry allows radiation from a wide range of angles and positions. The device may be used to inactivate lymphocytes.	18054000	Ⅲ	9-①	applicable	applicable
Linear accelerator system	A treatment system capable of producing high-energy electrons, which can produce high-energy X-rays (or electron beams). The system provides a radiation field of uniform intensity and predictable energy level in a beam with well-defined dimensions. The operating principle is linear acceleration of electrons by means of microwaves. The output is used as therapeutic beam, either directly or after allowing it to pass through a suitable target. The system is often used in the treatment of cancer. The device may be used to inactivate lymphocytes.	35159000	Ⅲ	9-①	applicable	applicable
X-ray/CT combined linear accelerator system	A combined system of a linear accelerator system and an X-ray CT system for radiotherapy planning.	70602000	Ⅲ	9-①	applicable	applicable
Non-linear accelerator system	A therapeutic particle accelerator system using a strong magnetic field to produce a non-linear acceleration path for particles accelerated in an alternating electric field. The acceleration path is mostly spiral or circular. The output is used as therapeutic beam, either directly or after allowing it to pass through a suitable target. The device may be used to inactivate lymphocytes.	33073000	Ⅲ	9-①	applicable	applicable
Particle radiotherapy equipment	A system that generates a high energy beam consisting of particles including protons, neutrons and carbon ions and radiates this particle beam to deliver the therapeutic dose to the affected area. It is mainly used in cancer treatment. It consists of an accelerator which accelerates the main particles to high energies, an irradiation nozzle which forms the beam (output of the high energy) and radiates it to a patient, and a device which very precisely locates the affected area. Generally, it is equipped with an ion source, an accelerator, a rotary or fixed gantry, a positioning device, a movable table, an operator console, etc.	70603010	Ⅲ	9-①	applicable	applicable
Living tissue radiotherapy system	A low energy X-ray therapy system designed to treat adjacent tumor lesions with high dose X-rays by placing soft X-ray beams from 5 to 50 kV inside the tumor tissue. The energy range of these X-ray beams are higher in the Grenz Ray therapy system and lower in the orthovoltage X-ray treatment system. It is not used for superficial skin tumors for which a low voltage X-ray therapy system is indicated. It is used in both intraoperative radiation and stereotactic localized radiation therapy. The former is performed for residual tumor after surgical resection of the neoplasm. In the latter, interstitial radiation is performed after diagnosis of tumor tissues obtained by biopsy.	70604000	Ⅲ	9-①	applicable	applicable
X-ray/CT combined particle radiotherapy equipment	A combined system of particle radiotherapy equipment and an X-ray CT system for radiotherapy planning.	70603020	Ⅲ	9-①	applicable	applicable

Radiation therapy simulator	Special configuration of a diagnostic radiography system used for radiation treatment planning, consisting of a fluoroscope, a radiographic device, and associated hardware and software. It is used to determine the radiation field size and position based on a generated series of parameters. The system may include equipment for signal analysis and display, and supporting apparatus relevant to the patient and other equipment. Generally, measured parameters are received and transmitted to the radiation treatment planning system to be used for therapeutic calculations.	35294000	Ⅲ	9-②	applicable	applicable
X-ray CT system for radiotherapy planning	A X-ray CT system that has a special configuration, containing hardware, software, etc. used in radiotherapy planning. It is used to determine the size and positioning of the therapeutic radiation field based on a series of treatment parameters to be generated. It may contain a device for signal analysis and display, a supporting device for the patient and the system and a device for moving the patient and the system. Generally, it receives measured parameters and sends the data to the radiotherapy planning system for therapeutic calculation.	70605000	Ⅲ	9-②	applicable	applicable
Motorized automatic aperture control accelerator system collimator	A beam control device with a motor. It is a collimator assembly. The function to adjust the jaw or leaf positioning is controlled by computer. It is placed in the beam projection port of the accelerator housing and used to adjust the form of the radiation beam that is delivered to the therapeutic target area of the body. It is made of a highly attenuating material or alloy including lead and tungsten, and protects patients by controlling or avoiding delivery of radiation to non-target areas of the body. Usually, the collimator is designed to contain a light localizer that displays the position of the radiation beam and helps to adjust the position of the patient to be treated.	38138000	Ⅲ	9-②	applicable	applicable
Psychiatric therapy brain electrical stimulator	A type of stimulator that stimulates a specific area (e.g., cerebrum, cerebellum) of a patient undergoing psychotherapy. Usually, it consists of an external pulse generator and electrodes. Stimulation pulses are provided via the electrode array placed in the cortex or the electrode tip with a very thin lead, implanted in the deep cerebellar nucleus. It is used for treatment of psychological disorders (e.g., depression, anxiety, mania, and insomnia).	36164000	Ⅲ	9-①	applicable	applicable
Convulsive therapy brain electrical stimulator	A device that treats depression by inducing a convulsion (a seizure) with an electric current applied to the brain via externally placed electrodes.	11484000	Ⅲ	9-①	applicable	applicable
Helium/neon laser	A gas laser used in surgical procedures, etc. It utilizes a mixed gas of helium (He) and neon (Ne) as the substrate. Visualization of beams is easy. Therefore, it is used as a beam for sighting or positioning the target (pilot/lead beam).	36531010	Ⅲ	9-①	applicable	applicable
Helium/neon laser therapy equipment	A gas laser used in treatment for remission of pain resulting from chronic, noninfectious inflammation of the muscle or joint or in treatment of hyperesthesia. It uses a mixed gas of helium and neon as the substrate.	36531020	Ⅲ	9-①	applicable	applicable
Semiconductor laser therapy equipment	A semiconductor laser used in photodynamic therapy which is performed in combination with a photosensitizer excited at specific wavelengths and pain remission treatment. It utilizes a semiconductor (e.g., aluminum, gallium, indium, phosphorus) as the substrate. A semiconductor laser used in pain remission treatment and photodynamic therapy which is performed in combination with a photosensitizer excited at specific wavelengths. It utilizes a semiconductor (e.g., aluminum, gallium, indium, phosphorus) as the substrate.	70630000	Ⅲ	9-①	applicable	applicable
PDT excimer laser	An excimer laser used in photodynamic therapy which is performed in combination with a photosensitizer excited at specific wavelengths. It utilizes an excited dimer as the active substance.	35984020	Ⅲ	9-①	applicable	applicable
Alexandrite laser	A laser that is used in surgical procedures and utilizes alexandrite as the substrate.	70631000	Ⅲ	9-①	applicable	applicable

PDT semiconductor laser	A semiconductor laser used in photodynamic therapy which is performed in combination with a photosensitizer excited at specific wavelengths. It utilizes a semiconductor (e.g., aluminum, gallium, indium, phosphorus) as the substrate.	70632000	Ⅲ	9-①	applicable	applicable
Carbon dioxide laser	A gas laser that is used in surgical procedures. It utilizes carbon dioxide as the substrate. It is widely used in several clinical fields (e.g., gynecology, neuroscience, dermatology).	35939000	Ⅲ	9-①	applicable	applicable
Nd:YAG laser	A laser that is used for surgical procedures. It utilizes a crystal consisting of neodymium (Nd), and yttrium, aluminum and garnet (YAG) as the substrate. It is widely used in peritoneoscopic and endoscopic procedures. A special type of device is used in ophthalmology.	35940000	Ⅲ	9-①	applicable	applicable
Nd:YAG doubled frequency laser	A type of double frequency laser. Usually, it is operated in continuous mode or pulse mode and used in surgical procedures which require precise resection, evaporation and photocoagulation with minimal damage to the surrounding tissue. It utilizes a crystal consisting of neodymium (Nd), and yttrium, aluminum and garnet (YAG) as the substrate. The tissue interaction in the surgical site is determined by the power density selected for the specific use.	36150000	Ⅲ	9-①	applicable	applicable
Erbium:YAG laser	A laser that is used for surgical procedures, etc. and utilizes a crystal consisting of erbium, and yttrium, aluminum and garnet (YAG) as the substrate.	36169000	Ⅲ	9-①	applicable	applicable
Holmium:YAG laser	A laser that is used in surgical procedures, etc. and utilizes a crystal consisting of holmium, and yttrium, aluminum and garnet (YAG) as the substrate. It is used in peritoneoscopic and endoscopic procedures.	36170010	Ⅲ	9-①	applicable	applicable
Pulsed holmium:YAG laser	A laser that is used for surgical procedures, etc. and utilizes a crystal consisting of holmium (Ho), and yttrium, aluminum and garnet (YAG) as the substrate.	36170020	Ⅲ	9-①	applicable	applicable
Argon laser	A gas laser that is used for surgical procedures, etc. and utilizes argon gas as the substrate. It is used in some clinical fields (e.g., neuroscience, otology, ophthalmology).	35938000	Ⅲ	9-①	applicable	applicable
Diode laser	A laser that is used in surgical procedures etc. It utilizes a solid state substance (e.g., gallium arsenide) as the substrate. It may be used in ophthalmology, etc.	36546000	Ⅲ	9-①	applicable	applicable
Single-use laser guide contact probe	A device dedicated for use with a laser. This device is for single-use. It is used to deliver the laser output energy for the ultimate target area (e.g., surgical area). It is made of flexible optical fibers and the operator can move and induce it easily. Usually, it is connected to a laser delivery device.	17193000	Ⅲ	9-①	applicable	—
Excimer laser	A gas laser that is used in surgical procedures, etc. and utilizes an excited dimer (EXCIteddiMER) as the substrate. The substrate most commonly used is a noble gas halide (e.g., argon fluoride, xenon chloride).	35984010	Ⅲ	9-①	applicable	applicable
Dye laser	A liquid laser that is used in surgical procedures, etc. and utilizes an organic compound (pigment) with a strong absorption band as the active medium. In luminescence, the pigment is required to be optically excited by another light source (e.g., another laser, flash lamp).	36043000	Ⅲ	9-①	applicable	applicable
Carbon monoxide laser	A gas laser that is used in surgical procedures, etc. It utilizes carbon monoxide as the substrate.	36168000	Ⅲ	9-①	applicable	applicable
Argon/krypton laser	A gas laser that is used in surgical procedures, etc. It utilizes argon krypton gas as the substrate. It is used in ophthalmology, etc.	36171000	Ⅲ	9-①	applicable	applicable

Ruby laser	A laser that utilizes ruby as the substrate. It is used in dermatology, etc.	36189000	Ⅲ	9-①	applicable	applicable
Laser delivery unit waveguide	A device consisting of a rigid hollow tube with multiple connections that can be flexed freely. Through this device, laser energy generated from the laser output source is transmitted to near the target area. Usually, it is used with an infrared laser. To deliver laser beams ultimately to the target area, a laser fiber probe that is for single-use can be connected. A refractor system is employed in the joint so that laser beams can be refracted while passing through the device.	36203000	Ⅲ	9-①	applicable	applicable
Copper vapour laser	A gas laser used in surgical procedures, etc. It utilizes copper vapor as the substrate. It is used in dermatology, etc. for treatment of cutaneous vascular lesions (e.g., port-wine stains, telangiectasia).	36238000	Ⅲ	9-①	applicable	applicable
Endotherapy laser guide	A dedicated device used with an endoscope in endoscopic therapy. It is used to guide or direct a laser beam during endoscopic laser treatment. Usually, it is made of quartz fibers and connected to the laser power supply arm.	36288000	Ⅲ	9-①	applicable	applicable
Dye/alexandrite laser	A liquid laser used in surgical procedures, etc. It utilizes dye and alexandrite as the substrate.	36301000	Ⅲ	9-①	applicable	applicable
Krypton laser	A gas laser that utilizes krypton (Kr) as the substrate.	36532000	Ⅲ	9-①	applicable	applicable
Helium/cadmium laser	A gas laser used in surgical procedures, etc. It utilizes a mixed gas of helium (He) and cadmium (Cd) as the substrate.	37051000	Ⅲ	9-①	applicable	applicable
KTP laser	A laser that is used for surgical procedures, etc. and utilizes a crystal consisting of potassium, titanium and phosphoric acid (KTP) as the substrate. An infrared beam (YAG) generated from the neodymium/yttrium, aluminum and garnet source pass the KTP crystal and some of the infrared light is converted into visible light at the green end of the spectrum. It is used in some clinical fields (e.g., neuroscience, otology, ophthalmology, dermatology).	37202000	Ⅲ	9-①	applicable	applicable
Ophthalmic PDT laser system	An ophthalmic laser system used in combination with a photosensitizer in photodynamic therapy. For instance, it is used in treatment of age-related macular degeneration.	70633000	Ⅲ	9-①	applicable	applicable
Ophthalmic laser photocoagulation system	A device used for the treatment of eye diseases, utilizing the thermal effect of lasers. For instance, the device may be used for photocoagulation of the retina, iris, ciliary body, or chamber angle.	70634000	Ⅲ	9-①	applicable	applicable
Ophthalmic pulsed laser surgical system	A device used for the treatment of eye diseases or incision of eye tissue, utilizing the destructive or thermal effect of the pulsed laser-induced shock-waves. For example, the device may be used for posterior capsulotomy or photocoagulation of the iris or chamber angle.	70635000	Ⅲ	9-①	applicable	applicable
Ophthalmic laser photocoagulation/pulsed laser surgery system	A composite system consisting of an ophthalmic laser photocoagulation system and an ophthalmic pulse laser surgical system.	70636000	Ⅲ	9-①	applicable	applicable
Excimer laser angioplasty unit	A gas laser that is used in percutaneous transluminal angioplasty. It utilizes an excited dimer (EXCIteddiMER) as the substrate. The substrate most commonly used is a noble gas halide (e.g., argon fluoride, xenon chloride).	70637000	Ⅲ	9-①	applicable	applicable
Ophthalmic corneal surgery laser system	A device that utilizes the ablation function of the laser and used in keratectomy. For instance, it is used in corneal surface resection, corneal refractive surgery, etc.	70638000	Ⅲ	9-①	applicable	applicable

Ophthalmic laser photocoagulation system probe	A probe-type delivery system designed to be used after connection to a laser photocoagulation system. Some devices are capable of illumination or suction. The device may be for single-use or reusable.	70639000	Ⅲ	9-①	applicable	—
Ophthalmic laser photocoagulation system sterile probe	A probe-shaped delivery system to be connected to an ophthalmologic laser photocoagulation system before use. It may have an illumination function or the aspiration function. This device is sterile and for single-use.	70640000	Ⅲ	9-①	applicable	—
Fibreoptic laser delivery unit	A flexible optical fiber cable used to provide visible and near-infrared wavelength laser energies. With this device, the laser output source is transmitted to near the target area. To deliver laser beams ultimately to the target area, a laser fiber probe that is for single-use can be connected.	36185000	Ⅲ	9-①	applicable	applicable
Skin laser scanner	A device that scans a wide area uniformly with a laser beam generated from an appropriate laser. A laser beam is focused intensively on a very small lesion at each scanning. Therefore, in order to treat a wide area, a scanner should be used to deliver the laser beam back and forth to scan the entire target area. This device is used for removal of nevi, pigmentation, tattoos, etc.	36775000	Ⅲ	9-①	applicable	applicable
Laser delivery unit holder	A device used in conjunction with a laser delivery device. This device supports the laser delivery device when the laser is operated. It supports positioning of the final output of laser beam, prevents unwanted movement and improves safety.	41707000	Ⅲ	9-②	applicable	applicable
Dental hard/soft tissue ablation laser	A dental device with the function of a carbon dioxide laser or Er:YAG laser part as well as that of a tooth surface cleaner to remove carbonized tooth substance. It is used for vaporization/resection of oral cavity soft tissues and for coagulation/carbonization of the affected dentin (only C2).	70641000	Ⅲ	9-①	applicable	applicable
Reusable laser contact tip	A reusable solid tip. A laser passes through the tip and is converted into heat on the tissue. Usually, the tip is used in contact with the tissue.	70642000	Ⅲ	9-①	applicable	—
Reusable laser delivery unit handpiece	A reusable handpiece that is connected to an optical fiber or a waveguide of a laser delivery device and used. Usually, it is used held in hand.	70643000	Ⅲ	9-①	applicable	—
General-purpose electrosurgical unit	A unit used to resect/ablate the tissue or to coagulate the incision/wound site with high-frequency waves. The high-frequency waves are emitted between the active and neutral electrodes or between two active electrodes and applied to the patient's body. The thermic effects associated with tissue destruction in electrosurgery are generated by the resistance of the tissue to high-frequency or high-dense waves rather than that to heat as in electrocautery. This treatment method is usually known as surgical diathermy.	11490000	Ⅲ	9-①	applicable	applicable
Electrosurgical system electrode with return alarm	A conductor that establishes an electrical connection between the output terminal of the generator of an electrosurgical unit and the patient who receives the electrosurgical effect. (It may be used with cables.) It is fixed to the patient's body. (Usually, it is positioned in such a way that the contact of made with the entire plate is the most appropriate for the specific procedure.)	11500013	Ⅲ	9-①	applicable	N/A
Electrosurgical patient plate	An electrode with a relatively wide surface area used to make current density in the high-frequency return circuit low enough to avoid damage to living tissue, such as burns. It is closely attached to the patient body when used. It has a relatively larger surface area than an operational return electrode. It contains electrodes, conductive cords, and their related accessories. It is used with a therapeutic electrosurgical unit and an active therapeutic device.	11500023	Ⅲ	9-①	applicable	N/A

Electrosurgical system with electrode disconnection alarm	A device used with an electrosurgical unit for detection of blockage of the return electrode cable between the electrosurgical unit and the return electrode (an electrode suspected of electric current leakage). This device functions as a special type of patient circuit safety monitor and gives a warning if any safety limit is exceeded. This function is pre-incorporated in the latest electrosurgical units. Therefore, this device may reflect conventional techniques.	35632000	Ⅲ	9-①	applicable	applicable
Argon gas delivery electrosurgical unit	A unit that provides argon gas for an electrosurgical unit. The argon gas is provided via the active electrode of the electrocautery attached to the unit and forms the protective layer to prevent oxidation around the surgical site during incision and coagulation, which keeps the tissue surface clean. This device is installed in the mount and connected to the electrosurgical unit. Thereby, both the device and unit can be integrally operated.	36154000	Ⅲ	9-①	applicable	applicable
Argon-enhanced electrosurgical unit	A monopolar electrosurgical unit (ESU) equipped with a certain system (usually, it is housed in an individual transfer trolley or incorporated in the generator chassis of the ESU) for providing argon gas. The electrosurgical current forms the ionized channel (arch) which reduces tissue carbonization and coagulates a large bleeding surface (e.g., capillary bed) rapidly and uniformly. This method is also called surgical diathermy.	36155000	Ⅲ	9-①	applicable	applicable
Mechanical vibration electrosurgical unit	An electrosurgical unit used for ablation and coagulation of the soft tissues of the body with a high-frequency current during surgery. The high-frequency energy is converted to mechanical vibrations of the two blade edges at the tip of the ablation device. These blade edges vibrate with a high-frequency mechanical movement, ablate and fracture collagen molecules in the tissue. Thereby, vibration and degeneration of collagen occur resulting in coagulation. This mechanical movement can be generated with ultrasound as an energy source.	36273000	Ⅲ	9-①	applicable	applicable
Radio-frequency ablation system	A system that heats and cauterizes malignant or benign tumors, etc. with radio wave energy.	36070000	Ⅲ	9-①	applicable	applicable
Percutaneous cardiac coagulation/ablation electrosurgical unit	A unit used to percutaneously cauterize/coagulate the cardiac muscle/myocardial tissue with high-frequency waves. It is used with catheter electrodes. The high-frequency waves are emitted between the active and neutral electrodes.	70644000	Ⅲ	9-①	applicable	applicable
Electrosurgical unit for cardiac ablation	A unit for percutaneously cauterize/coagulate the cardiac muscle/myocardial tissue with high-frequency waves. It is used with a probe. The high-frequency waves are emitted between the active and neutral electrodes. The thermic effects associated with tissue destruction in electrosurgery are provided by the resistance of the tissue to high-frequency or high-dense waves rather than that to heat as in electrocautery.	70645000	Ⅲ	9-①	applicable	applicable
Cauterization probe	A probe that is connected to an ablation electrosurgery unit and used to cauterize/coagulate the tissue.	70646000	Ⅲ	9-①	applicable	—
Non-visual non-endoscopic electrosurgical unit	A base unit and its related accessories that perform incision and coagulation of the tissue with high-frequency current non-visually and non-endoscopically.	70648000	Ⅲ	9-①	applicable	applicable
Material combined electrosurgical unit	A system consists of the main unit and its accessories, which is used for incision/coagulation of tissues, using high-frequency current, in combination with argon gas (plasma) or other materials that have specific actions.	70649000	Ⅲ	9-①	applicable	applicable
Battery-powered electrosurgical cautery unit	A battery-powered supply device used in hemostasis, treatment of superficial skin lesions and minor surgery (e.g., removal of warts). It uses electricity but the electric current is not applied to the patient; the tip of the incision device or wire loop is heated. It may have a built-in thermocoupler for temperature control of the tip.	35029000	Ⅲ	9-①	applicable	applicable

Line-powered cauter	A line-powered device designed to ablate or coagulate the tissue using a probe or blade heated with electricity. The electric current is not applied to the patient; the tip of the incision device is heated. It prevents loss of body fluid in the patient and makes observation of the surgical field easier. It is used for removal of warts or superficial skin lesions. It may be used with an endoscopic treatment system for endoscopic removal of gastrointestinal polyps, tubal ligation in contraceptive surgery, etc.	35030000	Ⅲ	9-①	applicable	applicable
Ophthalmic electrosurgical unit	A dedicated electrosurgical device used for ablation and coagulation of eye tissue and surrounding tissues during ophthalmic surgery. For instance, some types may use a high-frequency electric current. The strength of the energy source is limited to a level suitable for the intended use to ensure advanced safety.	41645000	Ⅲ	9-①	applicable	N/A
Phacoemulsification cataract extraction unit	An ophthalmic device designed to convey ultrasonic energy to the probe connected to the device for removal of the lens with phacoemulsification in cataract surgery.	17596000	Ⅲ	6-③	applicable	applicable
Microwave surgical unit	A microwave generating device and its accessories that are used for resection (partial resection), hemostasis and coagulation of body tissue utilizing microwaves.	70650000	Ⅲ	9-①	applicable	applicable
Ultrasonic knife handpiece	A hand-held surgical device usually used to ablate delicate tissues including tumors, utilizing ultrasonic energy. It is connected to the device to generate the necessary ultrasonic energy.	39837000	Ⅲ	9-①	applicable	applicable
Ultrasonic knife unit	A surgical device used to incise soft tissues including tumors, utilizing ultrasonic energy. It introduces fluid to the incision site for washing or aspiration to keep the surgical area clean and remove fragments.	36540000	Ⅲ	9-①	applicable	applicable
Ultrasonic suction system	A device that pulverizes tissues and tumors having a high water content and removes them from various portions of the body, by utilizing mechanical ultrasonic vibration and combining perfusion and aspiration. It is used in neurosurgery, general surgery and gynecologic and orthopedic procedures.	37776000	Ⅲ	11-①	applicable	applicable
Ultrasonic surgical unit	An ultrasonic surgery device and its accessories that coagulate, incise, and fragment body tissues. The high-frequency energy is converted into mechanical vibration, and vibrates the molecules in the body tissues by vibration of the blade edge, which causes degeneration of the proteins. Thereby, the body tissue is incised, fragmented, and coagulated. It may have an aspiration function.	70651000	Ⅲ	9-①	applicable	applicable
Cataract/vitreous surgical unit	A composite system for intraocular surgery used in cataract surgery or intravitreal surgery. It has some or all of the functions of perfusion, aspiration, phacofragmentation, vitrectomy, intraocular illumination, intraocular ventilation, diathermy, intraocular scissors, injection and removal of viscous, elastic substances, etc. It contains the accessories corresponding to the functions.	70652000	Ⅲ	9-①	applicable	applicable
General-purpose cryosurgical unit	A unit supplying refrigerant gas or liquid for heat dissipation in the target tissue, either by direct supply of refrigerant or indirectly by contact of a probe cooled with refrigerant. The device is usually used for general surgical treatment (e.g., dermatology, oral cavity surgery, gynecology, urology, otorhinolaryngology, and proctology).	11067000	Ⅲ	9-①	applicable	applicable
Ophthalmic cryosurgical unit	An ophthalmic surgical device for cataract extraction and other ophthalmic surgery to cool the target tissue by means of applying gas or liquid refrigerant either directly or indirectly by contact of a cryogenic probe.	11068000	Ⅲ	6-③	applicable	applicable

Single-use hand-controlled electrosurgical unit active electrode	A conductor that establishes an electrical connection between the output terminal of the electrosurgical device generator and the patient who receives the electrosurgical effect. It may be used with cables. The power switch of this device is the main part of the electrode and can be operated manually by an operator. Usually, it is in the shape of a pen or pencil and often referred to by either one of these names. This device is for single-use.	35044000	III	9-②	applicable	—
Single-use foot-controlled electrosurgical unit active electrode	A conductor that establishes an electrical connection between the output terminal of the electrosurgical device generator and the patient who receives the electrosurgical effect. It may be used with cables. The power switch of this device is incorporated into the foot pedal. The ablation mechanism can be adjusted by operating the pedal. Usually, it is in the shape of a pen, a pencil, scissors, a knife or forceps and often referred to by one of these names. This device is for single-use.	70656000	III	9-②	applicable	N/A
Reusable hand-controlled electrosurgical unit active electrode	A conductor that establishes an electrical connection between the output terminal of the electrosurgical device generator and the patient who receives the electrosurgical effect. It may be used with cables. The power switch of this device is the main part of the electrode and can be operated manually by the surgeon. Usually, it is in the shape of a pen or pencil and often referred to by either one of these names. This device is reusable.	42552000	III	9-②	applicable	N/A
Reusable foot-controlled	A conductor that establishes an electrical connection between the output terminal of	42553000	III	9-②	applicable	N/A
Driving unit for angioplasty athelctomy catheter	A drive unit used to remove hardened, calcified atherosclerotic plaques from the arterial wall percutaneously and transluminally.	70659000	III	9-①	applicable	applicable
Hair root electrolyser	A device that destroys the hair roots by electrolysis. For instance, it is used in the treatment of ingrowing eyelashes.	70660000	III	9-①	applicable	applicable
Diathermy unit	A composite apparatus of an ophthalmic electrosurgical unit and a hair root electrolyser.	70661000	III	9-①	applicable	applicable
Laser procedure active instrument	A probe, light-guiding fibers, conductive cords, and their related accessories. They are used for incision and coagulation of the tissue with a laser.	70663000	III	9-①	applicable	N/A
Ultrasound procedure active instrument	A probe, conductive cords, and their related accessories. They are used for incision, coagulation, and fragmentation of the tissue with ultrasound.	70664000	III	9-①	applicable	N/A
Non-visual non-endoscopic procedure active instrument	Active electrodes, conductive cords and their related accessories. They are used for incision and coagulation of the tissue non-visually and non-endoscopically with a high-frequency electric current.	70665000	III	9-①	applicable	N/A
Therapeutic active instrument	Active electrodes, conductive cords and their related accessories. They are used in specific treatment with a high-frequency electric current.	70666000	III	9-①	applicable	N/A
Multiple energy sources active instrument	Active electrodes, conductive cords and their related accessories. They are used for incision and coagulation of the tissue with different forms of energy such as a high-frequency electric current, electromagnetism, ultrasound, a laser and other energy sources.	70667000	III	9-①	applicable	N/A
Material-combined procedure active instrument	Active electrodes, electrically conductive cables and their accessories used for incision/coagulation of tissues using high-frequency current, in combination with argon gas (plasma) or other materials that have specific actions.	70668000	III	9-①	applicable	N/A

High-frequency current procedure active instrument with automatic function	Active electrodes, conductive cords and their related accessories. They are used for incision and coagulation of the tissue with a high-frequency electric current. They have neither a switch that converts a mode to an automatic control mode (an impedance detection mode) nor an indicator. They have a function of automatically starting output (on) or increasing power output.	70669000	Ⅲ	9-①	applicable	N/A
Electrosurgical unit with automatic function	A body of the device and related accessories that are used for incision and coagulation of the tissue with a high-frequency electric current. They have neither a switch that converts a mode to an automatic control mode (an impedance detection mode) nor an indicator. They have a function that automatically starts output (on) or increases power output.	70670000	Ⅲ	9-①	applicable	applicable
Therapeutic electrosurgical unit	A body of the device and related accessories that are used in specific treatment with a high-frequency electric current.	70671000	Ⅲ	9-①	applicable	applicable
Radio-frequency lesion probe	A device that is connected to a radio frequency (RF) lesion generator and provides RF energy for a specific site in the nervous system where a therapeutic lesion is to be generated.	32531000	Ⅲ	9-①	applicable	N/A
Radio-frequency lesion generator	A device that administers a high-frequency electric current (radio frequency) to the internal nerves in order to increase temperature in a controlled way to create a therapeutic lesion. A dedicated probe equipped with an electrode and a temperature sensing element at the tip is connected to this device, and energy is provided to the site to be treated. It may be used in sensitive sites including those in the brain.	35156000	Ⅲ	9-①	applicable	applicable
Microwave hyperthermia system	A system used to generate high temperatures and to control the provision of heat to the body in the treatment of malignant and benign tumors, or other diseases. Usually, it is computer-controlled, and heats the whole body or heats tissues or internal organs in a localized manner using a microwave energy source. The energy a patient receives is provided via a component attached to the main unit or a catheter-type or probe-type applicator separately inserted into the local site endoscopically or surgically.	40783000	Ⅲ	9-①	applicable	applicable
High-frequency hyperthermia system	A system used to generate high-temperatures and to control the provision of heat to the body in the treatment of malignant and benign tumors, or other diseases. Usually, it is computer-controlled and heats the whole body or heats tissues or internal organs in a localized manner using a radio-frequency wave (RF) energy source. The energy a patient receives is provided via a component attached to the main unit or a catheter-type or probe-type applicator separately inserted into the local site endoscopically or surgically.	40782000	Ⅲ	9-①	applicable	applicable
Ultrasound hyperthermia system	A system used to generate high-temperatures (higher than 43°C) and to control the provision of heat to the body in the treatment of malignant and benign tumors, or other diseases. Usually, it is computer-controlled and it heats the whole body or tissues or internal organs in a localized manner using an ultrasonic energy source. The energy a patient receives is provided via a component attached to the main unit or a catheter-type or probe-type applicator inserted into a local site endoscopically or surgically. Unlike an ultrasonic diathermy system, an ultrasonic hyperthermia system is not used in physiotherapy.	40781000	Ⅲ	9-①	applicable	applicable
Heated fluid hyperthermia system	A system that generates high-temperature fluids and controls fluid circulation in the vest, mattress, jacket, band, pad, bodywrap, catheter probe and other parts of the system in order to generate heating effects over the whole body or at localized sites in the treatment of malignant and benign tumors or other diseases. Usually, it is computer-controlled and used to perform radical or palliative treatment by increasing the temperature to 43°C or higher over the whole body, or to localized tissues or organs in a controlled way while controlling the effects on the non-target tissues.	40784000	Ⅲ	9-①	applicable	applicable

Laser hyperthermia system	A system that heats the targeted living tissue to a high temperature in order to treat malignant or benign tumors and other diseases. The system heats the whole body or tissues and internal organs in a localized manner with laser light energy. The energy a patient receives is provided via a component attached to the main unit or a catheter-type or probe type applicator separately inserted into the local site endoscopically or surgically.	70672000	Ⅲ	9-①	applicable	applicable
Combination hyperthermia system	A system used to generate high temperatures (higher than 43°C) and to control the provision of heat to the body in the treatment of malignant and benign tumors, or other diseases. Usually, it is computer-controlled and heats the whole body or tissues or internal organs in a localized manner using 2 or more energy sources (or individually) including ultrasonic, radio-frequency (RF) wave and microwave sources, and the heated circulating liquid. The energy a patient receives is provided via a component attached to the main unit or a catheter-type or probe-type applicator inserted into the local site endoscopically or surgically.	40785000	Ⅲ	9-①	applicable	applicable
Intracorporeal shock wave lithotripter	A lithotripter that is used in combination with a pyeloscope or an ureteroscope and has a probe. The handpiece consists of a shock wave source and a steel probe. A shock wave source consists of a projectile accelerated by the energy source (e.g., compressed air, electromagnetic coils). The shock wave is transmitted to the steel probe through a collision between the projectile and the steel probe, and a stone is fragmented by the mechanical vibration. The devices corresponding to an intracorporeal laser lithotripter, an intracorporeal ultrasonic lithotripter, and an intracorporeal electrohydraulic lithotripter are excluded.	70673000	Ⅲ	9-①	applicable	applicable
Intracorporeal laser lithotripter	A system consisting of a special ureteroscope, a laser-resistant catheter, a dedicated laser (presently, dye laser with a green light), etc. It is used to fragment a ureteral stone. The calculus is irradiated with laser energy to fragment it. Then, the fragmented calculi are removed forcibly or eliminated spontaneously.	36037000	Ⅲ	9-①	applicable	applicable
Intracorporeal ultrasonic lithotripter	A system consisting of rigid tubular devices including an operating sheath, a pyeloscope or ureterorenoscope, and an ultrasonic lithotripsy probe. The lithotripsy probe consists of an ultrasonic transducer and a steel probe. The ultrasonic transducer converts sound waves to horizontal and vertical vibrations. These vibrations are transmitted along the hollow probe contacted with the stone, which is fragmented by the mechanical vibrations. The probe can be connected to a suction pump, and fragmented calculus are sucked through the lumen of the probe.	35712000	Ⅲ	9-①	applicable	applicable
Intracorporeal electrohydraulic lithotripter	A device that fragments a stone located in the kidney, ureter, bladder, or bile duct utilizing plasma-induced shock waves. Usually, it consists of a generator-driven probe that emits energy pulses to the center of the calculus while circulating saline solution in a probe. The impact of water pressure (the shock wave occurring when the bubble bursts), which is produced by the plasma bubble generated, fragments the calculus into a number of pieces. The fragments are removed with surgical devices (e.g., a grasper, stone basket).	35711000	Ⅲ	9-①	applicable	applicable
Ballistic lithotripter	A device that generates shock waves with the air-compressed tip operated continuously and fragments the targeted stone.	70674000	Ⅲ	9-①	applicable	applicable
Micro-explosive shock wave lithotripter	A device equipped with a pin hammer for lithotripsy at the tip of the insertion part of the device. It operates the pin hammer by the explosion of a minute amount of powder loaded at the rear end of the insertion part, and fragments a stone.	70675000	Ⅲ	9-①	applicable	applicable

Single-use intracorporeal lithotripsy ultrasound transducer assembly	A transducer assembly enclosed in a catheter designed to be inserted into the body via a blood vessel, surgically or endoscopically in order to perform local lithotripsy (fragmentation of a stone). It consists of a single or multiple transducer element array(s) (also called a piezoelectric element, active element, or crystal element), attenuation materials, relining materials, and matching materials.	44138000	III	9-①	applicable	—
Renal water jet catheter system	A system used to remove a stone from the depth of the renal pelvis by water injection under pressure through a catheter. It is used to remove a renal calculus surgically.	32070000	III	9-①	applicable	applicable
Intracorporeal puncture lithotripter	A device equipped with a drill for lithotripsy at the tip of the device. With the drill, it makes a hole in a stone and implements perforation and fragmentation of the stone. Usually, the drill for lithotripsy is passed through a rigid endoscope inserted into the body and introduced to a vesical or ureteral stone and makes a perforation that allows the stone to be fragmented through rotation of the drill. The drilling part is thin and long, but it does not oscillate with the rotation. The drill can be changed according to the form and hardness of the stone. The fragments are removed forcibly or eliminated spontaneously later.	70676000	III	9-①	applicable	applicable
Fluoroscopic X-ray intracorporeal lithotripter	A device equipped with a pin hammer for lithotripsy at the tip of the part inserted into the body. It fragments a stone with a shock delivered by the protrusion of the pin hammer. Usually, the pin hammer-shaped operating part is passed through a rigid endoscope which is inserted via the urethra under lumbar anesthesia and introduced to the stone in the urethra. Then, the pin hammer-shaped operating part is activated, and the pin hammer is protruded and fragments the stone. The operating part is introduced and operated under fluoroscopy. The operating part is internally loaded with a minute amount of powder. The pin hammer is protruded by the explosion of the powder, and the stone is fragmented by the shock. The fragmented stones are eliminated from the body during urination.	70677000	III	9-①	applicable	applicable
Extracorporeal lithotripter	A device that sends noninvasive shock waves extracorporeally to fragment and pulverize a stone internally produced. This technique is called extracorporeal shock wave lithotripsy (ESWL). The methods employed by the device include a method using submersible electrodes (to emit shock waves that target a stone) or a method using a cylinder containing pressurized water, etc. and a shock wave generator (to use shock waves focused on pulverizing a stone). Usually, the cylinder is positioned so as to be protruded from a cushioned treatment table that touches the patient skin. The sand-like fragments produced are eliminated from the body through natural excretion.	36032000	III	9-①	applicable	applicable
Atmocautery	A device used for hemostasis by supplying of superheated steam directly to a vessel. Usually, it is used for non-malignant uterine lesions.	34862000	III	9-①	applicable	applicable
Water jet knife unit	A surgical device utilizing high-pressure water jetting technology to incise the body tissues. It can make an extremely delicate and precise incision such as a low-pressure incision of the soft tissue without giving damage to the hard, elastic structure. It makes the surgical site clearly visible and allows the structure to be cleaned with water. It is used in various situations including treatment of skin burns or malignant tumors, resection of tumors or varicose veins. It may be used with a standard endoscope.	36961000	III	9-①	applicable	N/A
Water jet knife handpiece	A dedicated surgical device used as the cutting handpiece of a water jet cutting device. The surgeon holds it in his/her hand and uses it as a severing device.	37570000	III	9-①	applicable	N/A

Surgical robot unit	An operation support device that performs treatment of tissues including suturing, detaching and severing, and installing a prosthesis. It is used in open surgery or endoscopic surgery. The control system is based on computer technology. It usually consists of a series of systems including an operator console, arms for device operation. It may be used as a supporting device for training of surgeons.	38678000	Ⅲ	9-①	applicable	applicable
Surgical robot navigation unit	A unit used for navigation (e.g., for placement of pedicle screws in spinal surgery) during surgery. This unit is based on computer technology and consists of an operator console, an image processing analyzer, etc. A position-detecting device, which is used to follow the surgical devices, is connected to the unit. Usually, information to be entered into the computer includes that related to CT or MRI, ultrasound, fluoroscopy, and anatomical landmarks. However, in some cases, preoperative images may not be used. The unit uses space coordinates obtained from the information mentioned above as a template, and follows the movement of the surgical device also by means of reading the location point in order to obtain precise 3D images showing the device and its angle. It is also used as a device to assist in the training of surgeons.	38723013	Ⅲ	9-①	applicable	applicable
Neurolosurgical navigation unit	A device that provides spatial positioning information about apparatus used during neurosurgery, neurosurgery/orthopedic surgery, and other types of surgery. This device is based on computer technology, and usually consists of a surgeon's console and an apparatus positioning detector. Usually, preoperative CT and MRI scans are used to input an image into a computer, and information from the positioning detector is overlaid on the image in the surgeon's console to keep track of correct spatial positioning information regarding the probe and other apparatus.	38723023	Ⅲ	6,7-⑤	applicable	applicable
Drug-containing dental tooth surface cleaner auxiliary material	An auxiliary cleaning material containing pharmaceutical agents. It is applied to the stained tooth after mechanical cleaning of the tooth surface.	70709000	Ⅲ	5-②,13	applicable	—
Dental multi-purpose ultrasonic therapy/general-purpose electrosurgery combined unit	An integrated system combining an ultrasonic instrument and an electrosurgical unit. It is used in dental treatment.	70721000	Ⅲ	9-①	applicable	applicable
Drug-containing dental zinc phosphate cement	A material made from the reaction of oxide powder (the main material: zinc oxide) with a phosphoric acid aqueous solution (it may contain metal ions). It contains pharmaceutical ingredients. It is used as a cementing agent that bonds a dental restoration to the hard tissue of oral cavity or other devices, a lining of a restoration and a temporary restorative material.	16710003	Ⅲ	8-①,13	applicable	—
Drug-containing dental polycarboxylate cement	A cement made from the reaction of zinc oxide with an aqueous solution of polyacrylic acid or of a similar polycarboxylic acid compound, or from the reaction of zinc oxide and polycarboxylic acid powder with water. It contains pharmaceutical ingredients. It is used as a cementing agent that bonds a dental restoration to the hard tissue of oral cavity or other devices, a lining of a restorative material and a temporary restorative material.	16705003	Ⅲ	8-①,13	applicable	—
Drug-containing dental adhesive resin-modified cement	A material mainly made of resin or a resin containing inorganic powder. It contains pharmaceutical ingredients. It is used to bond a dental prosthesis, etc. It may contain a dental dentin adhesive, a dental etching material, etc.	70836003	Ⅲ	8-①,13	applicable	—
Drug-containing dental composite resin-modified cement	A cementing material for a dental prosthesis, etc. It is mainly made of resin or a resin-containing inorganic powder. It contains pharmaceutical ingredients. It does not adhere to the tooth substance.	70837003	Ⅲ	8-①,13	applicable	—

Drug-containing dental zinc oxide eugenol cement	A hydrophobic material containing eugenol that reacts with zinc oxide, an accelerant, rubber, resin and an inactive inorganic filler. It contains pharmaceutical ingredients. It is used as a temporary restorative material, a lining (of a restorative material) and a material for relining a cavity in operative dentistry.	16709003	Ⅲ	8-①,13	applicable	—
Drug-containing dental zinc oxide non-eugenol cement	A cementing material for a dental prosthesis. It is mainly made of zinc oxide and fatty acids and contains pharmaceutical ingredients. It is called non-eugenol since it does not contain eugenol.	70838003	Ⅲ	8-①,13	applicable	—
Drug-containing dental glass polyalkenoate luting cement	A cementing material for a dental prosthesis. It contains pharmaceutical ingredients. It derives from the reaction of aluminosilicate glass powder with an alkenoic acid aqueous solution, or from the reaction of a mixture of aluminosilicate glass and polyacid powder with water or an organic solution.	70839003	Ⅲ	8-①,13	applicable	—
Drug-containing resin-modified dental glass-polyalkenoate/resin combined luting cement	A luting and bonding material for a dental restoration, dental prosthesis, orthodontic appliance, etc. It is resin-modified glass polyalkenoate cement component for dental luting applications. It contains pharmaceutical ingredients.	70841003	Ⅲ	8-①,13	applicable	—
Drug-containing dental filling composite resin for indirect restoration	A material for mixing or polymerizing (with external energy). It is made mainly of resin and an inorganic or composite filler. It contains pharmaceutical ingredients. It is used mainly in filling and restoration of the dental cavity or in repair of an artificial crown.	70847003	Ⅲ	8-①,13	applicable	—
Drug-containing polymer-based bracket adhesive and tooth conditioner	A bracket adhesive resin and a tooth surface conditioning material are the bonding materials made of polymethyl methacrylate, etc. They are used to bond an orthodontic bracket to the tooth surface. It contains pharmaceutical ingredients.	31750003	Ⅲ	8-①,13	applicable	—
Drug-containing dental dentin adhesive	A material mainly used to accelerate dentin bonding of composite resins, restorations or cementing agents. It contains pharmaceutical ingredients. It can be used as an enamel bonding agent.	42483003	Ⅲ	8-①,13	applicable	—
Drug-containing dental filling glass polyalkenoate cement	A cement made from the reaction of aluminosilicate glass powder with an alkenoic acid aqueous solution, or a mixture of aluminosilicate glass and polyacid powder with water or an organic solution. It contains pharmaceutical ingredients. It is used for filling and restoration of the tooth.	70848003	Ⅲ	8-①,13	applicable	—
Drug-containing dental core build-up glass polyalkenoate cement	A cement made from the reaction of aluminosilicate glass powder or powder of melted glass and metal with an alkenoic acid aqueous solution, or from the reaction of a mixture of aluminosilicate glass and polyacid powder with water or an organic solution. It contains pharmaceutical ingredients and may contain metal powder. It is used for core build-up.	70849013	Ⅲ	8-①,13	applicable	—
Drug-containing dental core build-up resin-modified glass-polyalkenoate cement	A material for core build-up. It is a combination of a resin component and a glass polyalkenoate cement component. It contains drug.	70849023	Ⅲ	8-①,13	applicable	—
Drug-containing dental lining/basing glass polyalkenoate cement	A cement made from the reaction of aluminosilicate glass powder with an alkenoic acid aqueous solution, or from the reaction of a mixture of aluminosilicate glass and polyacid powder with water or an organic solution. It contains pharmaceutical ingredients. It is used for lining or relining.	70850003	Ⅲ	8-①,13	applicable	—
Drug-containing dental polymer-based pit/fissure sealing material	A resin material suitable for sealing dental pits and fissures. It contains pharmaceutical ingredients. This material cures by chemical polymerization or polymerization by external energy.	31780003	Ⅲ	8-①,13	applicable	—

Drug-containing dental pit/fissure sealing resin-modified glass polyalkenoate-based cement	A cement made from the reaction of aluminosilicate glass powder with an alkenoic acid aqueous solution, or from the reaction of a mixture of aluminosilicate glass and polyacid powder with water or an organic solution. It contains pharmaceutical ingredients. It is used for sealing pits and fissures.	70851013	Ⅲ	8-①,13	applicable	—
Drug-containing dental pit/fissure sealing resin-modified glass-polyalkenoate cement	A sealing material for pits and fissures. It is a combination of a resin component and glass polyalkenoate cement for dental sealing of pits and fissures. It contains pharmaceutical ingredients.	70851023	Ⅲ	8-①,13	applicable	—
Calcium hydroxide-based cavity-lining dental material	A material containing calcium hydroxide. It is used mainly for pulp capping.	16182000	Ⅲ	8-①,13	applicable	—
Drug-containing dental pulp-capping material	A material used for pulp capping of a deep cavity. It contains pharmaceutical ingredients. It contains zinc oxide eugenol cement for pulp capping.	70852000	Ⅲ	8-①,13	applicable	—
Drug-containing dental filling material kit	A kit for dental restorations. It consists of dental composite resins for restoration, etching materials, adhesives, etc. It contains pharmaceutical ingredients.	70853003	Ⅲ	8-①,13	applicable	—
Drug-containing dental filling resin-modified glass-polyalkenoate cement	A dental filling material. It is a combination of a resin component and a polyalkenoate cement component for dental filling. It contains pharmaceutical ingredients.	70854003	Ⅲ	8-①,13	applicable	—
Drug-containing dental composite resins for indirect restoration	A material for polymerizing with external energy. It is made mainly of resin and an inorganic or composite filler. It contains pharmaceutical ingredients. It is used to fabricate a crown or inlay on the tooth in cavity preparation or on its model, and to create a dental restoration by polymerization.	70855003	Ⅲ	8-①,13	applicable	—
Drug-containing tooth surface coating material	A low viscosity resin material used for tooth surface coating. It contains pharmaceutical ingredients. A kit of this material and other materials is included.	70861003	Ⅲ	8-①,13	applicable	—
Drug-containing tooth surface conditioning material	A material used to treat the tooth surface after cavity preparation or root canal preparation. It contains pharmaceutical ingredients.	70862000	Ⅲ	6,13	applicable	—
Drug-containing dental polymer-based cavity lining/basing material	A polymer-based lining material such as glass polyalkenoate cement. It contains drug.	70863003	Ⅲ	8-①,13	applicable	—
Kit for drug-containing dental composite resins for indirect restoration	A kit consisting of a dental composite resin for indirect dental restoration, dental cement and an etching material which are used concurrently. It has components containing pharmaceutical ingredients.	70864003	Ⅲ	8-①,13	applicable	—
Drug-containing dental core build-up material kit	A kit for dental restoration consisting of materials for dental core build-up, dental etching material, dental dentin adhesive, etc. It has components containing pharmaceutical ingredients.	70865003	Ⅲ	8-①,13	applicable	—
Drug-containing dental dentin adhesive kit	A kit consisting of materials for dental dentin adhesive and dental etching material. It may contain other pertinent devices. It has components containing pharmaceutical ingredients.	70866003	Ⅲ	8-①,13	applicable	—
Drug-containing dental polymer-based temporary sealing material	A material for temporary sealing. It mainly consists of polymeric materials. It contains pharmaceutical ingredients.	70870003	Ⅲ	8-①,13	applicable	—
Drug-containing dental temporary sealing material	A material for temporary sealing. It contains pharmaceutical ingredients.	70871003	Ⅲ	8-①,13	applicable	—
Drug-containing dental periodontal dressing	A material used to cover and protect the periodontal tissue after surgery. It contains pharmaceutical ingredients.	70872000	Ⅲ	7-①,13	applicable	—

Drug-containing dental root canal sealing material	A material used for permanent sealing of the root canal. It contains pharmaceutical ingredients. Some of the material may cure without the assistance of water. A root canal filling point may be used concurrently. It is used for positive root filling, and root canal filling from the side of a crown.	70874000	Ⅲ	8-①,13	applicable	—
Calcium hydroxide-based dental root canal filling material	A material used for root canal filling. It contains calcium hydroxide.	70876000	Ⅲ	8-①,13	applicable	—
Iodoform root canal filling dental material	A material used for root canal filling. It contains iodoform.	70877000	Ⅲ	8-①,13	applicable	—
Drug-containing dental multipurpose glass polyalkenoate cement	A cement made from the reaction of aluminosilicate glass powder with an alkenoic acid aqueous solution, or from the reaction of a mixture of aluminosilicate glass and polyacid powder with water or an organic aqueous solution. It contains pharmaceutical ingredients. It is used for restoration, luting and bonding, relining, core build-up, etc.	70879000	Ⅲ	8-①,13	applicable	—
Drug-containing gingival retraction cord	A cotton thread containing drugs that is used temporarily for gingival retraction during abutment tooth preparation.	35861003	Ⅲ	5-①,13	applicable	—
Drug-containing gingival retraction material	A material containing pharmaceutical ingredients that is used temporarily for gingival retraction during abutment tooth preparation and impression taking. A gingival retraction cord containing pharmaceutical ingredients is excluded. It is a liquid or paste containing drugs that is used temporarily for clarification of impression during impression taking by shrinkage and retraction of the gum. Some types come as a kit that contains application syringes, chips, etc.	70884000	Ⅲ	5-①,13	applicable	—
Drug-containing tooth polishing abrasive	A semi-solid abrasive in the form of powder, paste, cream or gel. It is used by dental hygienists and dentists to clean and polish the tooth surface. The tooth surface is polished with a preventive treatment brush, a toothpaste cup, etc. It contains pharmaceutical ingredients.	70905000	Ⅲ	7-①	applicable	—
Dental bone reconstruction implant materials	An absorbable or non-absorbable biomaterial used for filling of defects in the jawbone or building up (reinforcement) of the jawbone in dental treatment. However, a non-absorbable dental bone reconstruction implant materials, and an absorbable dental bone reconstruction implant materials are excluded.	34006009	Ⅲ	8	applicable	—
Non-absorbable dental bone reconstruction implant materials	A non-absorbable biomaterial used to fill (filling) defects in the lower jaw bone or to build up (reinforce) the jaw bone in dental treatment.	34006003	Ⅲ	8	applicable	—
Dental endosseous implant	A dental implant to be implanted partially or fully in the jaw bone.	42347000	Ⅲ	8	applicable	—
Dental implant fixture	A part of dental implant to be surgically implanted in the bone.	42348000	Ⅲ	8	applicable	—
Dental submucosal implant	A dental implant that is completely covered by the gum or mucosa.	42349000	Ⅲ	8	applicable	—
Dental intramucosal implant	A dental implant to be implanted in the soft tissue in the oral cavity.	42350000	Ⅲ	8	applicable	—
Dental subperiosteal implant	A dental implant to be implanted between the periosteum and the bone surface.	42352000	Ⅲ	8	applicable	—
Dental transendodontic and transradicular implant	A rod-shaped implant to be inserted into the bone through the root canal or the root.	42353000	Ⅲ	8	applicable	—
Dental transgingival implant	A dental implant used to prevent detachment of a dental prosthesis. It has an abutment structure extending into the oral cavity via the mucosa.	42354000	Ⅲ	8	applicable	—

Dental implant system	A system consisting of dental implants, dental implant abutments, surgical instruments for implants, and dental laboratory tools used for fabrication of the superstructure of an implant.	70909000	III	8	applicable	—
Dental implant abutment	A device to be fixed to a dental implant fixture to serve as a support for the superstructure, or to be used temporarily until the gingiva is healed.	70910000	III	8	applicable	—
Dental caries removal solution	A liquid used to detect and remove dental caries in the tissue of the affected tooth.	38783000	III	6,13	applicable	—
Dental bleaching agent	A dental liquid or paste used to whiten the teeth for treatment or cosmetic purposes.	38785000	III	6,13	applicable	—
Drug-containing dental hypersensitive dentine desensitizer	A material applied to the tooth surface in order to control hyperesthesia of the dentin (including the molded surface). It contains pharmaceutical ingredients.	70913000	III	8-①,13	applicable	—
Drug-containing dental adhesive material kit	A kit consisting of devices used for standard dental adhesion. It contains pharmaceutical ingredients. Devices with other specified names are excluded.	70920003	III	8-①,13	applicable	—
Drug-containing endodontic instrumentation aid dental material	A material used to demineralize and soften the dental hard tissues in the cavity and the root canal wall. It contains pharmaceutical ingredients. It is also used to assist root canal enlargement with a reamer or a file, to float cutting debris with foams and to clean the root canal wall. There is a kit that contains the devices used to apply the materials.	70928003	III	5-①,13	applicable	—
Orthopedic spine external fixation system	An orthopedic system designed for a specific surgical procedure. It is used to correct vertebral misalignment and fix vertebrae in their proper position and adjust extracorporeally to promote cure. Usually, it contains a case tray, external components and a large number of implants (e.g., Steinmann pins, Schanz screws, Kirschner wires) as well as appropriate measuring devices. Implants are replenished when used in order to maintain this system. The external fixation device contained in this system is reusable in accordance with instructions provided by the manufacturer.	42848000	III	8	applicable	—
Reusable colored vision corrective contact lens	A vision-correcting ophthalmic lens containing colorants and/or ultraviolet absorbing agents, to be worn directly on the surface of the eye. Usually, lenses should be used under the instruction of a physician. The device is reusable.	32803000	III	5-③'	applicable	—
Reusable vision corrective contact lens	A vision-correcting ophthalmic lens which does not contain either colorants or ultraviolet absorbing agents, to be worn directly on the surface of the eye. Usually, lenses should be used under the instruction of a physician. The device is reusable.	36055000	III	5-③'	applicable	—
Single-use vision corrective contact lens	A vision-correcting ophthalmic lens which does not contain either colorants or ultraviolet absorbing agents, to be worn directly on the surface of the eye. Usually, lenses should be used under the instruction of a physician. The device is intended for single-use.	37581000	III	5-③'	applicable	—
Single-use colored vision corrective contact lens	A vision-correcting ophthalmic lens containing colorants and/or ultraviolet absorbing agents, to be worn directly on the surface of the eye. Usually, lenses should be used under the instruction of a physician. The device is intended for single-use.	37583000	III	5-③'	applicable	—
Therapeutic contact lens	A device designed to be worn over the front surface of the eye. It is used to protect the eye, to seal the anterior chamber, to deliver drugs, to change the corneal curvature, or to treat the retina in a special way.	36054000	III	5-③'	applicable	—
Collagen-containing eye protector	A mechanical eye shield (a corneal shield) placed over the eye surface to protect the cornea. It is made of collagen. For instance, it may allow clinical observation during regeneration of the corneal epithelium, and the patient's field of vision can be partially restored.	17652000	III	5-③',14	applicable	N/A

Intra-uterine contraceptive device	A device used to avoid pregnancy during sexual intercourse. It is placed in the upper uterine fundus and a thread extending from the device is inserted into the vagina through the orifice of the uterus.	35125000	Ⅲ	5-④	applicable	—
Contraceptive fallopian tube insert	An implantable device applied to the fallopian tube in tubal ligation to prevent an ovum from passing through. This device is a plug or valve inserted into the fallopian tube and considered to be a kind of contraceptive device.	32678000	Ⅲ	5-④	applicable	—
Implantable bone-conduction hearing aid	A hearing aid that uses bone conduction output via a transducer. Its vibrating part is installed directly on the cranial.	34180000	Ⅲ	8	applicable	N/A
Endoscopy submucosal injection material	A solution, etc. , that is injected into the submucosa in the lesion site in endoscopic mucosal resection. It separates and lifts the mucosal layer and muscular layer, and maintains this state to improve the operability of resection and detachment in the lesion site.	71028000	Ⅲ	6-③	applicable	—
Carotid artery stent	A stent with a support structure expanded and placed in a carotid artery in order to maintain the patency of the artery. For instance, the stent is delivered by a catheter to an occluded site. By the expansion of the balloon catheter, or the stent itself, the stent expands and supports the blood vessel. After the catheter is removed, the stent remains in the place as a permanent implant. It is made of metals, polymers, or other substances. It may come as a continuous tube having a specified length, or as a tubular scaffold.	45851000	Ⅳ	8-②	applicable	—
Central circulatory catheter for trapping embolus	A catheter system for blood vessels of the central circulatory system for capture and remove emboli (blood clots and fragments) during blood vessel plasty and stent placement. It is equipped with an embolus capturing filter or an occlusion balloon at the tip. This device is for single-use.	44841004	Ⅳ	6-⑤	applicable	—
Extracorporeal shockwave pain treatment device	A device that delivers a shock wave from outside the body to eliminate pain and for palliative treatment. An extracorporeal lithotripter is excluded.	71029000	Ⅲ	9-①	applicable	applicable
Implantable electrocardiographic data recorder	A device implanted under skin to measure and record cardiac activity and biological functional phenomena. It contains a battery and a circuit that senses cardiac activity and biological functional phenomena. The data are stored in the device. Generally, a non-invasive programmer is used for programming and displaying stored data.	71030000	Ⅳ	8-④	applicable	—
Reusable orthokeratology contact lens	A gas-permeable hard contact lens for orthokeratology. It is directly worn on the front surface of the eye, and changes the corneal shape to correct the uncorrected vision after the lens is removed. Usually, it is used under medical supervision. This device is reusable.	47926000	Ⅲ	5-③'	applicable	—
Radiation therapy synchronizer	A physiological monitoring device used as one of the components of radiotherapy equipment. It produces signals that enable synchronization of radiotherapy with measurable physiological parameters (such as respiration information or heart rate information of a patient). It is used for respiratory-gated treatment. A device used for respiratory-gated imaging as one of the components of a diagnostic imaging system is included.	47928000	Ⅲ	9-②	applicable	applicable
Catheter for penetrating vascular stenosis	A catheter used to secure a passage for a guide wire in percutaneous blood vessel plasty for patients where passage of the guide wire is difficult due to stenosis in arteries, veins or shunts except for the coronary artery and intracranial cerebral blood vessels.	46916000	Ⅳ	6-⑤	applicable	—

Glucose monitor system	A system that continuously measures the glucose level in the blood or body fluid. Usually it consists of an electrochemical sensor inserted subcutaneously and a portable receiver, which receives an electrical signal derive from the sensor electrodes, converts it to the glucose level, and stores and displays the level.	44611003	Ⅲ	—	applicable	applicable
Negative pressure wound therapy system	A system that adds controlled negative pressure, helps protect wounds, promotes granuloma formation, and removes exudates and infectious wastes to promote wound healing. Usually, it consists of a monitoring unit for negative pressure maintenance, a foam dressing, a film drape, a connecting tube and an exudate reservoir.	20395000	Ⅲ	4-①	applicable	applicable
Reusable decorative contact lens	An ophthalmic lens that is not vision-correcting, to be worn directly on the surface of the eye. Lenses for vision corrective purposes are not included. Lenses are included that are intended to change the appearance of the iris or pupil (color, pattern, or shape) when they are worn. Normally, lenses should be used under the instruction of a physician. The device is reusable.	47837000	Ⅲ	5-③'	applicable	—
Single-use decorative contact lens	An ophthalmic lens that is not vision-correcting, to be worn directly on the surface of the eye. Lenses for sight corrective purposes are not included. Lenses are included that are intended to change the appearance of the iris or pupil (color, pattern, or shape) when they are worn. Usually, lenses should be used under the instruction of a physician. The device is intended for single-use.	47836000	Ⅲ	5-③'	applicable	—
Vesicoureteral reflux treatment injectable material	An injection material containing dextranomer beads, etc. as a main component, a swelling formation material. It is cystoscopically and transurethrally inserted into the submucosa near the ureteral orifice or of the intramural ureter in the bladder for treatment of vesicoureteral reflux.	17876013	Ⅲ	8	applicable	—
Posterior chamber lens with crystalline lens	A device that is permanently implanted into the posterior chamber of the eye for vision correction in a patient with refractive error. It is inserted into the posterior chamber of the phakic eye. Generally, it is a lens made of plastic/synthetic resin.	47413000	Ⅲ	8	applicable	—
Vibrating peripheral vessel penetration catheter system	A system that generates or transmits oscillation in the catheter tip in order to penetrate completely occluded sites in peripheral vessels.	46850004	Ⅳ	6-⑤	applicable	applicable
Antimicrobial catheter cover material	A sterilized cover/protective material such as adhesive film materials impregnated with a disinfectant and an antibacterial agent. Directly applied to the injection needle or catheter puncture site to fix them. Non-woven cloth may be added in order to strengthen the fixation and retention.	47937003	Ⅲ	13	applicable	—
Antimicrobial ventilation tracheal tube	A cylindrical tube to be inserted into the trachea from the oral cavity or nasal cavity for securing the airway, administration of inhalational anesthetics or medical gases and ventilation. It is coated with substances having antibacterial properties for prevention of infection. It may be packaged with a connector that connects to the breathing circuit or a manual resuscitator.	46877003	Ⅲ	13	applicable	—
Single-use interspinous placement	A device to be placed between the spinous processes to relieve lower lim pain and leg pain. With the placement, it holds the lumbar spine in the flexed position and prevents it from being in the extended position whenever possible.	47023003	Ⅲ	8	applicable	—
Bovine pericardial patch	A device used for closure and repair of septal defects, damaged cardiac muscle 、tissue, pericardium or a blood vessel opening produced during surgery. It is made of bovine pericardium.	35273404	Ⅳ	8-②,14	applicable	—

Blood component separation kit	A kit consisting of a blood component processor, collecting bags, a sprayer, etc. The blood component processor is used with a system such as an apheresis system for separating, collecting and administering specific blood components. The kit is for single-use.	58331003	Ⅲ	3	applicable	—
Shunt for fetal pleural effusion	A shunt tube and delivery system used to continuously drain fetal pleural effusion to the maternal amniotic cavity.	71031000	Ⅲ	8	applicable	—
Non-absorbable local hemostatic material for central circulation system	A non-absorbable local hemostatic device used for surgical openings, skin wounds or internal structures to achieve hemostasis in blood vessels of the central circulatory system.	31744024	Ⅳ	8-②	applicable	—
Absorbable clamp for cranial fixation	An absorbable, implantable fixation device that is used for cranial closure after craniotomy, or to pinch cranial fragments together for fixation in order to restore dislocation after complicated fracture of skull. Plates, discs, and auxiliary pins are used for fixation.	70500004	Ⅳ	8-⑤	applicable	—
Drug-eluting stent for femoral artery	A drug-eluting stent with a support structure expanded and placed in a femoral artery in order to maintain the patency of the artery. For instance, the stent is delivered by a catheter to an occluded site. By the expansion of the balloon catheter, or the stent itself, the stent expands and supports the blood vessel. After the catheter is removed, the stent remains in the place as a permanent implant. It is made of metals, polymers, or other substances. It may come as a continuous tube having a specified length, or as a tubular scaffold.	46919004	Ⅳ	13	applicable	—
Percutaneous central venous temperature control device	A control system that adjust body temperature by heat exchange with the blood via a reflux catheter placed in the central veins of patients who need body temperature control. It consists of a catheter through which reflux liquid circulates, and a control unit for temperature control, circulation, a body temperature monitor, and an alarm etc.	44710004	Ⅳ	8-②	applicable	applicable
Balloon catheter for neuroendoscopy	A balloon catheter used with a dedicated endoscope for endoscopic nerve treatment. The catheter is inserted into the cerebral ventricles etc. via an endoscope channel. It operates without electricity (e.g., radio-frequency waves, electromagnetic energy, ultrasound and laser energy). This device is for single-use.	71032000	Ⅳ	6-⑥	applicable	—
Blood coagulation analyzer for self monitoring	An automatic or semi-automatic device dedicated for self monitoring including qualitative and quantitative analyses of hemostatic components (suppression of bleeding) such as fibrinogen, fibrin and platelet, and the time to hemostasis.	56687003	Ⅲ	—	applicable	applicable
Orthodontic anchor screw	A small, metal screw used as an anchorage unit to provide the orthodontic force in orthodontic therapy. The screw is planted and fixed in the oral cavity jawbone, and an orthodontic tool is connected to the head of the screw. It is used as the anchorage unit to provide the orthodontic force for movement of the teeth. A self-tapping type and a self-drilling type are available. The screw is removed after orthodontic therapy. This device is for single-use.	46536003	Ⅲ	8	applicable	—
Vascular graft with bovine-derived valve	A device that combines a bovine-derived valve with a bovine cervical vein or artificial blood vessel used for pulmonary artery replacement (including re-replacement). Usually, used for treatment of congenital heart abnormalities.	46422014	Ⅳ	8-②,14	applicable	—
Catheter for replacement of coronary catheter	A flexible tube with a balloon at the distal end. The device is used to fix the guide wire in the guiding catheter by controlling the dilation of the balloon when replacing the catheters.	17846124	Ⅳ	6-⑤	applicable	—

Arteriovenous cannula for central circulatory system	A semi-rigid or rigid tube to be inserted into a blood vessel other than in a thoracotomy site, and used as a guide path for fluid in the blood vessel in areas including the central circulatory system. This device is for single-use.	47733104	IV	7-⑥	applicable	—
Single-use negative pressure wound therapy system	A system that adds controlled negative pressure, helps to protect wounds, promotes granuloma formation, and removes exudate and infectious wastes to promote wound healing. Usually, it consists of a monitoring unit for negative pressure maintenance, a foam dressing, a film drape, a connecting tube and an exudate reservoir. It is for single-use.	58202003	III	4-①	applicable	—
Filling material for tracheobronchial	An occlusion plug made of resin that is filled to the bronchus. It is used to maintain occlusion for the purpose of stopping air leakage or closure of a fistula. Held with straight grasping forceps bronchoscopically, the usually filler is usually placed in the bronchus where air leakage or a fistula is confirmed.	35458113	III	5-④	applicable	—
Collagen-containing absorbable nerve regeneration inducing material	An absorbable, collagen-containing device that is inserted in the site of laceration or defect of peripheral nerve due to trauma or other causes in order to induce nerve regeneration and restore function by giving continuity to the both nerve stumps,	71034004	IV	8-⑤	applicable	—
Transcatheter bovine cardiac valve	An artificial heart valve (bovine pericardial valve) placed using a catheter. Usually, it is used for treatment of acquired or congenital valvular diseases, and mainly made of bovine pericardium. Some valves include a delivery system.	60245004	IV	8-②,14	applicable	—
Wearable automatic defibrillator	A wearable device that continuously monitors the ECG with electrodes placed on the body surface for restoration of normal heart rate. When tachycardia is detected, it automatically delivers defibrillation pulses from the defibrillation electrodes on the body surface to the cardiac muscle.	48051003	III	9-①	applicable	applicable
Heparin-coated central circulatory arteriovenous cannula	A semi-rigid or rigid heparin-coated tube to be inserted into a blood vessel other than in a thoracotomy site, and used as a guide path for fluid in the blood vessel in areas including the central circulatory system. This device is for single-use.	47733204	IV	7 -⑥,14	applicable	—
Local hemostasis material using gelatin containing human thrombin	A gelatin-based device with human thrombin applied to the surgical incision openings, the skin wound and the internal structure for local hemostasis that is made of a material absorbed in the body, optionally with adhesive effect.	35895324	IV	8-⑤,14	applicable	—
Equine cardiac valve	An artificial heart valve (equine pericardial valve) used for heart valve replacement. Usually, it is used for treatment of acquired or congenital valvular diseases, and is mainly made of equine pericardium.	35591404	IV	8-②,14	applicable	—
Patient-adaptive implantable fixation plate	A non-absorbable, implantable fixation device that fills the space between the fractured bones in the treatment of bone deformity or fracture. It is attached to the fractured bone with screws, etc. to protect the fracture site from stress. It is custom designed and manufactured to fit an individual patient. It may be used in distraction osteogenesis of pathological fractures and for reinforcement in cranial and maxillofacial surgical procedures and articular fusion requiring fusion surgery. Usually, the bone plate is made of metal, carbon, etc.	35241023	III	8	applicable	—
Catheter system for bronchial thermoplasty	A catheter system that delivers a high-frequency current via a catheter that is placed in contact with the bronchial area. It consists of a catheter, a main unit that generates a high-frequency current and the related accessories.	44775003	III	9-①	applicable	applicable
Thulium/YAG laser	A laser used in surgical procedures, etc. It utilizes a crystal consisting of thulium (Tm) and yttrium, aluminum and garnet (YAG) as the substrate.	71037003	III	9-①	applicable	applicable

Transcatheter porcine pericardial valve	An artificial heart valve (porcine pericardial valve) placed using a catheter. Usually, it is used for treatment of acquired or congenital valvular diseases, and consists mainly of porcine pericardium. Some include a delivery system.	60245114	IV	8-②,14	applicable	—
Malignant tumors treatment using alternating electric field	A portable device that exposes a specific body site to an alternating electric field by means of externally placed electrodes. It treats malignant tumors, etc. by inhibiting cell division.	58845003	III	9-①	applicable	applicable
Single-use probe for PDT semiconductor laser	A device dedicated for use with a PDT semi-conductor laser. This device is for single-use. It is connected to the PDT semi-conductor laser system and used to apply a laser having a specific wavelength to the tumor tissue where photosensitizers accumulate.	61471003	III	9-①	applicable	—
Control unit for central venous placement temperature management system	A control unit that controls temperature and circulation of the perfusate circulating in the circulatory catheter of a temperature management system with percutaneously placed central venous catheters. It also monitors the body temperature and gives a warning, etc.	44709003	III	9-①	applicable	applicable
Software for high risk pharmacokinetic analyzer	A software that performs pharmacokinetic analysis based on measurements of the blood concentrations of drugs which should be administered with caution, and supports determination of the dose and regimen of the drugs. This term may include recording media where the software are stored.	61215003	III	11,11-①	applicable	—
Software for peritoneal dialysis treatment	A software that performs prescription simulation of peritoneal dialysis based on the results obtained from a peritoneal function test (PFT), a peritoneal equilibration test (PET) and a body composition analyzer. It supports preparation of a dialysis treatment plan. The dialysis conditions that are determined based on the simulation are set in an automated peritoneal dialysis system. This term may involve the recording media where the software are stored.	41049003	III	3	applicable	—
Software for radiation planning	A software that calculates and displays the area to be treated with radiation and the internal dose distribution based on the results obtained with CT systems etc. , and supports the radiotherapy planning. This term may involve the recording media where the software are stored. The dose distribution may be not calculated.	40887003	III	9-②	applicable	—
Software for radiotherapy QA/QC planning	A software that verifies the validity of the radiotherapy plan by recalculation of the dose and the MU value calculated with the radiotherapy planning system software and radiotherapy planning system. This term may involve the recording media where the software are stored.	40887013	III	9-②	applicable	—
Software for ophthalmic surgery treatment planning	A software for intended to aid ophthalmic surgical planning based on measurement of the eye prior to the surgery. It simulates surgical results. This term may involve the recording media where the software are stored.	71039003	III	9-②	applicable	—
Implantable clip for heart	An implantable metal device. It is indicated for use in the heart, and is used to prevent blood flow in such anatomical sites as the left atrial appendage.	35649004	IV	8-②	applicable	—
Heparin-coated stent-graft for blood vessels	A heparin-coated device, in which the inside, outside, or both sides of support structure (stent) placed inside a blood vessel, or between one stent and another are covered with artificial materials. This device is inserted into the peripheral blood vessel in order to maintain the patency of the vessel. The stent-graft is inserted through a catheter or other device, and expanded. It is also used to close perforated blood vessels, or to treat aneurysms. After the catheter or other device is removed, the stent-graft remains in place as a permanent implant. It is made of stainless steel, Nitinol, polymer, or other substances. It may come as either tubular or branched.	47932003	III	8,14	applicable	—

Heparin-coated stent-graft for central circulatory system	A heparin-coted device with artificial material inside, outside, or both sides of support structure (stent) or between stents, that remains inside a blood vessel. This device is inserted into the blood vessel of the central circulatory system in order to maintain the patency of the vessel. The stent graft is inserted through a catheter or other device, and expanded. It is also used to close perforated blood vessels, or to treat aneurysms. After the catheter or other device is removed, the stent graft remains in place as a permanent implant. It is made of stainless steel, Nitinol, polymer, or other substances. Some are tubular or branched.	47932014	IV	8-②,14	applicable	—
Reusable limbal supported Contact lens for abnormal cornea shape	A contact lens that can correct vision in the eye having an irregularly shaped cornea. The lens is directly worn on the front surface of the eye. The lens has a special shape that allows it to be retained between the corneal limbus and conjunctiva, and to make the artificial tear exchangeable. Usually, it is used under medical supervision. This device is reusable.	71050003	III	5-③'	applicable	—
Software for parameter selection of electrical stimulator	A software used to transmit electrical operating characteristics noninvasively to the base therapeutic system and change the characteristics. The software does not control the entire therapeutic system. It can change a certain range of the characteristics which are selected by a physician or under a physician's direction within a pre-specified range in the implantable or extracorporeal base electrical stimulator. It may provide patient information stored in the electric simulator. This term may involve the recording media where the software are stored.	71051003	III	9-②	applicable	—
Cardiac electrosurgical unit	A unit used to cauterize/coagulate cardiac muscle tissue by direct contact using high frequency radio waves. It consists of a generator, and a probe etc.	60784004	IV	6-⑤,9-①	applicable	applicable
Cardiac cryosurgical unit	A unit used for cryocoagulation of the cardiac tissue by direct contact with a chilled probe. It consists of a generator and a probe etc.	60721004	IV	6-⑤,9-①	applicable	applicable
Heparin-coated drain for intraocular	A heparin-coated artificial drain that is implanted intraocularly to mitigate increased intraocular pressure.	61127003	III	8,14	applicable	—
Implantable accessoryfor implanted cardiac pacemake	An accessories used in the implantation procedure of an implantable cardioverter-defibrillator and pacemaker system. The accessories consist of a sleeve used for lead fixation, a plug used to occlude the unused connector port, a cap used to insulate an unused lead connector, and other non-active devices implanted with the implantable cardioverter-defibrillator and pacemaker system.	44900003	III	8	applicable	—
Controler for temporary non-roller type cardiac support blood pump	A drive unit that operates and monitors an implantable, intracardiac pump catheter for circulatory assistance. The pump catheter provides circulatory assistance in emergency care of patients with acute cardiac failure, such as cardiogenic shock, or in patients in whom normal cardiac function is impaired during cardiac catheterization or surgical treatment, by bypassing the aortic valve and expelling the blood. It may have various monitoring functions.	57808003	III	9-①	applicable	applicable
Catheter for temporary non-roller type cardiac support blood pump	A pump catheter for emergency use that supports circulation by bypassing the aortic valve and delivering the blood in patients with acute cardiac failure such as cardiogenic shock, and patients whose normal cardiac function is lost in cardiac catheter treatment or surgical treatment. It is inserted in the heart percutaneously or via blood vessel to implant, and used with a dedicated driving device.	56732004	IV	7-⑥	applicable	—

Software for active implanted device control	A software used to transmit one or more electrical operating characteristics noninvasively to the active base unit and change the characteristics. The software does not control the entire therapeutic system. It can change a certain range of the characteristics which are selected by a physician or under a physician's direction within a pre-specified range in the implantable, programmable base unit. It may read out parameter values stored in active devices, transmit them to external devices and provide information about patient status. This term may involve the recording media where the software are stored.	71052003	Ⅲ	9-①	applicable	—
Bioabsorbable coronary stent	A stent with an absorbable support structure expanded and placed in a coronary vessel in order to maintain the patency of the coronary vessel. This device is delivered by a catheter to an occluded site. By the inflation of the balloon catheter, or self-expansion of the stent itself, this device expands and supports the blood vessel.	61535004	Ⅳ	8-②,8-⑤	applicable	—
Catheter for replacement of pulmonary artery catheter	A flexible tube with a balloon at the distal end. The device is used to fix the guide wire in the guiding catheter by controlling the dilation of balloon when replacing the catheter. The device is used for the pulmonary artery.	17846134	Ⅳ	6-⑤	applicable	—
Focused ultrasound surgical system	A system used to cauterize/coagulate the target tissue by heat of focused ultrasonic energy. The ultrasonic energy is supplied from transducer placed outside the patient's body or inserted into the local site. It may have a temperature monitor of target tissue or function of imaging monitor in addition to a control mechanism of transducer.	57888003	Ⅲ	9-①	applicable	applicable
Implantable leadless cardiac pacemaker	An electrode-integrated pacemaker which is placed inside the heart percutaneously by catheter. It is sealed in a sealed case, with a built-in battery, electrical pulse generating circuit, and electrodes, etc. , and is equipped with a circuit that senses cardiac activity. Some include a delivery system.	60789004	Ⅳ	8-④	applicable	—
Suture site reinforcement material	A non-absorbable synthetic material used to reinforce suture site. The one to use in combination with an automatic suture unit is excluded.	70435013	Ⅲ	8	applicable	—
Halothane anaesthesia vaporizer	A device used to vaporize the anesthetic halothane (also called Fluothane) and administer the gas to the patient before surgery, at a controlled rate. The device is usually attached to an anesthesia system or respirator.	36891000	Ⅲ	11-①	applicable	applicable
Methoxyflurane anaesthesia vaporizer	A device that vaporizes an anesthetic methoxyflurane and administers the gas to a patient before surgery in a controlled way. This is usually attached to an anesthesia system or a ventilator.	36984000	Ⅲ	11-①	applicable	applicable
Absorbable tissue spacer for radiotherapy	An absorbable material used to reduce radiation exposure of normal tissue during radiotherapy by implanting surgically or percutaneously between tissue, internal organs, etc. , to make a space between the malignant tumor and normal tissue.	60424004	Ⅳ	8-⑤	applicable	—
Magnetic stimulator for transcranial treatment	A magnetic stimulator for treatment used to continuously stimulate the local region of cerebral cortex transcranially.	61124003	Ⅲ	9-①	applicable	applicable
Control device for cardiac/central circulatory catheter	A device to hold the catheter for applying cardiac or central circulatory region and to control it by magnetic or mechanical power. It is used to be controlled remotely by the operator.	71056003	Ⅲ	6,7,9-①	applicable	applicable
Thyroid cartilage fixation device	A fixation device used for maintaining dilatation of dissectedthyroid cartilage during plastic surgery of pharynx for patient with vocal cord dysfunction. Usually, it is made of metal.	71057003	Ⅲ	8	applicable	—
Percutaneous repair system for mitral valve coaptation failure	An implantable device that is inserted percutaneously to repair the coaptation failure of mitral valve. Some include a delivery system.	56280004	Ⅳ	8-②	applicable	—

Fistula formation prosthesis for pancreas	A prosthetic device used to pull the walls of gastrointestinal tract and neighboring pancreas cyst and form a fistula between them, through the gastrointestinal tranct under endoscopic ultrasonographic guidance for therapeutic purpose. For example, indwelling part of the prosthesis is made of metal, and has double-walled flanges on the both side of edges that have gripping force to hold the two tissue walls.	62611003	Ⅲ	8	applicable	—
Software for analysis of germline gene variants (for eligibility identification of antineoplastic agents)	A software for medical device, which is used to identify eligibility for treatment with antineoplastic agents, based on information of variants derived from germline gene obtained from whole blood specimens. This term may include the recording media, etc. where the software are stored.	71058003	Ⅲ	—	applicable	—
System for analysis of somatic cell gene variants (for eligibility identification of antineoplastic agents)	A system for analysis of gene variants used to conduct eligibility identification for treatment with antineoplastic agents, based on information of gene variants derived from somatic cell obtained from body tissue samples. This system consists of DNA sequencer, preparation reagents for sequencing sample, and software for analyzing, and may contain template preparation reagents as a component.	71059003	Ⅲ	—	applicable	applicable
Absorbable spacer for implantable device	An absorbable device used in combination with an apparatus placed in the body temporarily or permanently. This device is used to place the apparatuses in intended intervals, and may be used to intend for enhancing visibility, etc. Devices identified elsewhere are excluded.	71062004	Ⅳ	7-④,8-⑤	applicable	—
Information collating software for radiotherapy	A software that has function of collating the information such as irradiation parameter specified by a radiation planning software, and the condition that a radiotherapy equipment irradiates, on the occasion of the irradiation of X-ray in the radiotherapy. This term may involve the recording media where the software are stored.	40887023	Ⅲ	9-②	applicable	—
Hypoglossal nerve electrical stimulator	An electrical nerve stimulator that induces contraction of muscles of tongue to improve airway patency by stimulating hypoglossal nerve. Usually, the stimulator consists of a pulse generator to be implanted in the anterior thoracic wall, an electrode to be implanted around hypoglossal nerve, and a lead connected to the pulse generator. Some include respiratory monitoring sensor and lead to be implanted in the intercostal muscles to stimulate in synchronization with the respiratory.	60360004	Ⅳ	8-④	applicable	N/A
Corneal curvature fluctuation meter	A device used to detect changes in corneal curvature, to be worn directly on the surface of the eye.	62111003	Ⅲ	5-③'	applicable	—
Absorbable bone regeneration material containing human demineralized bone matrix	An absorbable material containing demineralized bone matrix derived from human allogeneic bone applied to lesions by covering, coating, or filling, to restore bone tissues.	47257004	Ⅳ	8-⑤,14	applicable	—
Adipose tissue separation kit	A dedicated kit used to separate and process adipose tissues for infusion of specific cells or tissues. This device may be used in combination with a cytology centrifuge, etc. This device is for single-use.	47501003	Ⅲ	3	applicable	—
Gene variants analysis set (for cancer genome profiling)	A gene variants analysis set used for cancer genome profiling based on information of gene variants obtained from body tissue samples. This set consists of software for analysis and preparation reagents for template DNA.	60943013	Ⅲ	—	applicable	—
Implantable prostatic tissue retractor system	A system used for transurethral placement of an implant to retract the prostate tissue to maintain the patency of the urethra. This system consists of an implant made of suture threads and metal parts, an implant delivery device, etc.	58882003	Ⅲ	8	applicable	—

Orthodontic anchorage device	A device consists of components of orthodontic appliance system such as a screw, a wire connected to the screw, and attachments which are used as an anchorage unit to provide an orthodontic force for movement of the teeth in orthodontic therapy. This device is removed after orthodontic treatment. This device is for single-use.	71065003	III	8	applicable	—
Open abdominal wound dressing kit	A dressing kit that covers an open abdominal wound with controlled negative pressure, helps protect the abdominal organs from outside the body, provides efficient drainage, suppresses inflammation, and reduces the edema to enable early peritoneal closure. Usually, it consists of a form dressing, drape, tubing set, and protection layers.	47406003	III	4-①	applicable	—
Software for gene variants analysis (for cancer genome profiling)	A software for gene variants analysis which is designed to perform cancer genome profiling based on information of gene variants obtained from body tissue samples. This term may involve recording media, etc. where the software are stored.	60943023	III	—	applicable	—
Supporting software for differential diagnosis with endoscopic imaging	A software, which is designed to process data obtained from an endoscopic image. The resultant data are provided for diagnostic, etc. It has functions to output numeric values and graphs based on quantitative data such as benign/malignant differentiation of lesion candidates, presenting candidates of diagnostic outcomes, and stage of disease progression. This term may involve recording media where the software are stored.	71066003	III	10-④b	applicable	—
Software for analysis of somatic cell gene variants (for eligibility identification of antineoplastic agents)	A software, which is used to identify eligibility for treatment with antineoplastic agents based on the information of gene variants derived from somatic cell obtained from body tissue samples. This term may involve recording media where the software are stored.	70159013	III	—	applicable	—
Intracardiac prosthesis	An implantable artificial device to block the intracardiac blood flow to reduce thromboembolism. Clips or a devices used on pericardial defect lesions are excluded.	45418004	IV	8-②	applicable	—
Collagen-containing absorbable artificial dura mater	A collagen-containing artificial membrane, which is made of materials to be absorbed in the body, used to supply or replace the dura mater when the dura mater is lost after an open head injury or traumatic spinal fluid fistula, or when the dura mater is partially resected during craniotomy.	45829004	IV	8-②,8-⑤,14	applicable	—
Murine antibody-coated coronary stent	A stent with a support structure coated with a murine antibody expanded and placed in a coronary vessel in order to maintain the patency of the vessel. This device is delivered by a catheter to an occluded site. By the expansion of the balloon catheter, or the stent itself, this device expands and supports the blood vessel. After the catheter is removed, the stent remains in place as a permanent implant.	47826004	IV	8-②,14	applicable	—
Gene variants analysis system (for cancer genome profiling)	A system for gene variants analysis which is designed to perform cancer genome profiling based on the information of gene variants obtained from body tissue samples. This system consists of DNA sequencer, preparation reagents for sequencing sample, and software for analyzing, and may contain template preparation reagents as a component.	60943033	III	—	applicable	applicable
Gastronomy drug administration tube for long-term use	A hollow device to be placed surgically in the stomach, the duodenum or the jejunum for administration of drugs needing appropriate management about dosage, the rate of administration, etc. It is for long-term use.	71068004	IV	8-⑥	applicable	—
Enteral drug administration pump	A portable pump used to administer drugs needing appropriate management about dosage, the rate of administration, etc., into the stomach, the duodenum or the jejunum.	13215013	III	11-①	applicable	applicable

Vena cava stent	A stent with a support structure expanded and placed in the vena cava in order to maintain the patency of the vessel. For instance, the stent is delivered by a catheter to an occluded site. By the expansion of the balloon catheter, or the stent itself, the stent expands and supports the blood vessel. After the catheter is removed, the stent remains in place as a permanent implant. It is made of metal, polymer, or other substances. It may come as a continuous tube having a specified length, or as a tubular scaffold.	71070004	IV	8-②	applicable	—
Reprocessed cardiac catheter-tip electrode	A conductor installed at one end of a flexible tube which is inserted into the heart in order to detect a specific indicator when measuring cardiac output, or to assess left to right shunt in the heart. Used for cardiac electrophysiologic testing, and recording intracardiac electrocardiograms. This may also be used for temporary pacing and defibrillation. This product is a reprocessed single-use device.	46359004	IV	7-⑥	applicable	—
Software for analysis of germline gene variants (for identification of morbid risk)	A software for a medical device which is used to determine pathological variants and identify morbid risk based on information on variants derived from germline gene obtained from whole blood specimens. This term may include the recording media, etc. where the software is stored.	71058013	III	—	applicable	—
Neutron irradiator for boron neutron capture therapy	A device that irradiates the affected area by producing high-energy protons and causing them to collide with a suitable target to emit the neutrons used in boron neutron capture therapy. It is mainly used in the treatment of cancer. It consists of an accelerator that accelerates protons to high energy and a neutron radiating device, etc. and may have a proton transport device. Generally, it is equipped with an ion source, a target, a moderator, a collimator, a positioning device, a movable table, an operator console, etc.	71077003	III	9-①	applicable	applicable
Software for boron neutron capture therapy treatment planning	A software that calculates and displays the area to be treated and internal dose distribution, based on the results obtained from CT systems, etc., and supports the treatment planning when boron neutron capture therapy is performed. This term may involve the recording media where the software are stored.	71078003	III	9-②	applicable	—
Somatic cell gene variants analysis set (for eligibility identification of antineoplastic agents)	A gene variants analysis set used to identify eligibility for treatment with antineoplastic agents, based on information on gene variants derived from somatic cell obtained from body tissue samples. It consists of software for analysis and preparation reagents for template DNA.	71059023	III	—	applicable	—
Malaria diagnostic system	A device that, when used in combination with nuclei staining reagents, counts the number of red blood cells containing protozoa and the number of normal red blood cells to inspect whether or not protozoan infections of which malaria is typical are present.	71081003	III	—	applicable	applicable
Active instrument for microwave surgical unit	Probes, conductive cords, and their related accessories used for resection (partial resection), hemostasis and coagulation of body tissue utilizing microwaves.	71082003	III	9-①	applicable	—
Erbium, chromium, YSGG lasers	A laser that is used for surgical procedures, etc., and utilizes crystals consisting of erbium (Er), chromium (Cr) and yttrium-scandium-gallium-garnet (YSGG) as the substrate.	36170033	III	9-①	applicable	applicable
Prosthesis for eustachian tube	A device to be placed to maintain an appropriate lumen diameter in eustachian tube.	71083003	III	8	applicable	—

Heparin-coated percutaneous cardiopulmonary support system	A heparin-coated extracorporeal circulation system that is used for periods of several days to several weeks to support cardiopulmonary function. It consists of oxygenator, blood pump, cannula, etc. Usually, the cannula is inserted and placed into the femoral artery or vein, vena cava, or the right atrium, etc., and the system is used with a dedicated driving device. This system is for single use.	70524304	IV	7-⑥,14	applicable	—
Stent-graft for central circulatory system	A device with artificial material inside, outside, or both sides of support structure (stent) or between multiple stents, that remains inside a blood vessel. This device is inserted into the blood vessel of the central circulatory system in order to maintain their patency of the vessel. The stent graft is inserted through a catheter or other device, and expanded. It is also used to close perforated blood vessel or to treat aneurysms. After the catheter or other device is removed, the stent graft remains in place as a permanent implant. It is made of stainless steel, Nitinol, polymer, or other substances. Some are tubular or branched.	47932114	IV	8-②	applicable	—
Absorbable implantable suture retention device	An absorbable implantable device including a fixation bridge, surgical button and thread support used to ensure wider distribution of suture thread and assist the healing of the wound. Wider distribution of the tension of suture threads protects the skin or tissue from being cut by the suture thread.	45061004	IV	8-⑤	applicable	—
Vertebral body support material	A support material with a support structure expanded and placed in a vertebral body in order to restore the vertebral height at the fracture point and form a cavity for injecting orthopedic bone cement into the vertebral body. For example, it is delivered to the fractured vertebral body by a catheter, after which the support material is expanded by a balloon catheter or by itself to support the fractured vertebral body. After the catheter is removed, the support material remains in place as a permanent implant.	47021003	III	8	applicable	—
Software for central monitor with analytic capability	A software, which configures a central monitor with analytic capability and is designed to process obtained data. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	38470013	III	10-④	applicable	—
Extracorporeal photopheresis system	A system that injects a photoactive agent into leukocytes etc. separated from human whole blood, exposes the leukocytes to ultraviolet light and returns them to the human body in order to perform extracorporeal photopheresis. Usually, it is composed of a machine for separating blood components, blood tubing, UVA lamp, and other parts., and may include the photoactive agent.	46912003	III	11-①,13	applicable	applicable
Artificial cardiac valve ligator	An implantable metal device used to suture an artificial valve or artificial valve annulus to the autogenous valve annulus. In some cases, it may also include appliers and other instruments for implanting the device.	61353004	IV	8-②	applicable	—
Titanium-sapphire laser	A laser used for surgical procedures, etc., that utilizes titanium sapphire as a substrate.	36170043	III	9-①	applicable	applicable
Transseptal active puncture instrument	A device used to create a passageway for catheter introduction, etc., by puncturing the atrial septum (fossa ovalis).This device is available in a needle or a wire type and is introduced percutaneously into the right atrium using a catheter introducer.It is also used together with a high-frequency generator and other devices.	61875004	IV	6-⑤	applicable	—
Single-use colored vision corrective drug-containing contact lens	A ophthalmic lens for vision correction that is worn directly on the front surface of the eye and contains a coloring agent or ultraviolet absorber. It contains a drug in the lens or in the preservation solution with the intention of producing a medicinal effect. Usually used under the direction of a physician. The device is for single-use.	71089003	III	5-③',13	applicable	—

Single-use vision corrective drug-containing contact lens	A ophthalmic lens for vision correction that is worn directly on the front surface of the eye and do not contain either colorants or ultraviolet absorbers. It contains a drug in the lens or in the preservation solution with the intention of producing a medicinal effect. Usually used under the direction of a physician. This product is for single use.	71090003	Ⅲ	5-③',13	applicable	—
Single-use gas-powered pulmonary resuscitator	A portable device used for ventilation or assisted ventilation in a patient with apnea or respiratory failure. Usually, it is used in an ambulance or an emergency department. It is connected to a compressed air supplier and/or compressed oxygen supplier. Some devices are equipped with a compressed gas tube, a breathing circuit, a mask, or a connector for endotracheal tube attachment, etc.	57981003	Ⅲ	9-①	applicable	—
Delivery system for implantation of cardiac prosthetic materials	A delivery system used to introduce and implant prosthetic materials and other materials into defects and blood vessels in the heart by percutaneous insertion for the treatment of cardiac disease.	45419004	Ⅳ	6-⑤	applicable	—
Healing promoting material using human amnion	An allograft derived from human amnion applied to the affected area to promote tissue healing. Some of them contain other tissues such as chorionic membrane other than amnion.	65105004	Ⅳ	8-⑤,14	applicable	—
Software program to support tumor malignancy determination	A software for medical device used to support the identification/determination of malignancy of a tumor based on gene expression information, etc. obtained from body tissue samples. It may also include a recording media, etc. on which the software is recorded.	61231003	Ⅲ	—	applicable	—
Water vapour delivery system for prostatic tissue	A system used to treat enlarged prostate tissue using water vapour generated by high-frequency current. The system consists of a water vapor delivery device, a device that generates high-frequency current, and accessories.	71095003	Ⅲ	9-①	applicable	applicable
Remanufactured central circulatory intravascular ultrasound catheter	A catheter that uses ultrasound for diagnosis in the blood vessels of the central circulatory system. The device is equipped with a transducer at the proximal end of the catheter that sends and receives ultrasound signals. This product is a remanufactured single-use medical device.	64174004	Ⅳ	6-⑤	applicable	—
Collagen-containing absorbable tendon regeneration material	An absorbable material containing collagen applied to the affected area by covering or other means, to promote regeneration of tendon tissues.	60907004	Ⅳ	8-⑤	applicable	—
Mobile analogue general-purpose diagnostic X-ray system	A general-purpose mobile analog radiography system, intended for use in a variety of common planar imaging applications. This is typically an X-ray film based system that uses analog or analog-to-digital conversion technology for image capture and display. The mobile design allows it to operate on utility power or battery power, and the device can be pushed by one person to various locations within a building. The device is commonly used for bedside radiography, and imaging during interventions or operations. The device consists of modules that are upgradable by adding hardware or software. Devices that are capable of fluoroscopy are not included in this category.	37626010	Ⅱ	10	applicable	applicable
Mobile analogue general-purpose integral diagnostic X-ray system	A general-purpose mobile analog radiography system, intended for use in a variety of common planar imaging applications. This is typically an X-ray film based system that uses analog or analog-to-digital conversion technology for image capture and display. The mobile design allows it to operate on utility power or battery power, and the device can be pushed by one person to various locations within a building. The device is commonly used for bedside radiography, and imaging during interventions or operations. The device consists of modules that are upgradable by adding hardware or software. Devices that are capable of fluoroscopy are not included in this category. The X-ray generator is integrated with the system.	37626020	Ⅱ	10	applicable	applicable

Portable analogue general-purpose diagnostic X-ray system	A general-purpose portable diagnostic analog radiography system intended for use in a variety of common planar imaging applications. This is typically an X-ray film based system that uses analog or analog-to-digital conversion technology for image capture and display. The portable design allows the device to operate on utility power or battery power; it can easily be disassembled, moved to another location, and re-assembled for use. The device consists of modules that are upgradable by adding hardware or software. Devices that are capable of fluoroscopy are not included in this category.	37642010	II	10	applicable	applicable
Portable analogue general-purpose integral diagnostic X-ray system	A general-purpose portable diagnostic analog radiography system intended for use in a variety of common planar imaging applications. This is typically an X-ray film based system that uses analog or analog-to-digital conversion technology for image capture and display. The portable design allows the device to operate on utility power or battery power; it can easily be disassembled, moved to another location, and re-assembled for use. The device consists of modules that are upgradable by adding hardware or software. Devices that are capable of fluoroscopy are not included in this category. The X-ray generator is integrated with the system.	37642020	II	10	applicable	applicable
Portable digital general-purpose diagnostic X-ray system	A general-purpose portable diagnostic radiography system intended for use in a variety of common planar imaging applications. The system uses digital technology for image capture, display, and manipulation. The portable design allows the device to operate on utility power or battery power; it can easily be disassembled, moved to another location, and re-assembled for use. The device consists of modules that are upgradable by adding hardware or software. Devices that are capable of fluoroscopy are not included in this category.	37643010	II	10	applicable	applicable
Portable digital general-purpose integral diagnostic X-ray system	A general-purpose portable diagnostic radiography system intended for use in a variety of common planar imaging applications. The system uses digital technology for image capture, display, and manipulation. The portable design allows the device to operate on utility power or battery power; it can easily be disassembled, moved to another location, and re-assembled for use. The device consists of modules that are upgradable by adding hardware or software. Devices that are capable of fluoroscopy are not included in this category. The X-ray generator is integrated with the system.	37643020	II	10	applicable	applicable
Stationary analogue general-purpose diagnostic X-ray system	A general-purpose stationary diagnostic radiography system intended for use in a variety of common planar imaging applications. This is typically an X-ray film based system that uses analog or analog-to-digital conversion technology for image capture and display. The device, which has a stationary design, requires installation work, and is used in a specific location of a building or in an X-ray inspection vehicle. The device consists of modules that are upgradable by adding hardware, software, or accessories. Devices that are capable of fluoroscopy are not included in this category.	37644010	II	10	applicable	applicable

Stationary analogue general-purpose integral diagnostic X-ray system	A general-purpose stationary diagnostic radiography system intended for use in a variety of common planar imaging applications. This is typically an X-ray film based system that uses analog or analog-to-digital conversion technology for image capture and display. The device, which has a stationary design, requires installation work, and is used in a specific location of a building or in an X-ray inspection vehicle. The device consists of modules that are upgradable by adding hardware, software, or accessories. Devices that are capable of fluoroscopy are not included in this category. The X-ray generator is integrated with the system.	37644020	II	10	applicable	applicable
Stationary digital general-purpose diagnostic X-ray system	A general-purpose stationary diagnostic radiography system intended for use in a variety of common planar imaging applications. The system uses digital technology for image capture, display, and manipulation. The device, which has a stationary design, requires installation work, and is used in a specific location of a building or in an X-ray inspection vehicle. The device consists of modules that are upgradable by adding hardware, software, or accessories. Devices that are capable of fluoroscopy are not included in this category.	37645010	II	10	applicable	applicable
Stationary digital general-purpose integral diagnostic X-ray system	A general-purpose stationary diagnostic radiography system intended for use in a variety of common planar imaging applications. The system uses digital technology for image capture, display, and manipulation. The device, which has a stationary design, requires installation work, and is used in a specific location of a building or in an X-ray inspection vehicle. The device consists of modules that are upgradable by adding hardware, software, or accessories. Devices that are capable of fluoroscopy are not included in this category. The X-ray generator is integrated with the system.	37645020	II	10	applicable	applicable
Mobile digital general-purpose diagnostic X-ray system	A general-purpose mobile digital radiography system intended for use in a variety of common planar imaging applications. The system uses digital technology for image capture, display, and manipulation, and its mobile design allows it to operate on utility power or battery power; the device can be pushed by one person to various locations within a building. The device is commonly used for bedside radiography, and imaging during interventions or operations. The device consists of modules that are upgradable by adding hardware or software. Devices that are capable of fluoroscopy are not included in this category.	37647010	II	10	applicable	applicable
Mobile digital general-purpose integral diagnostic X-ray system	A general-purpose mobile digital radiography system intended for use in a variety of common planar imaging applications. The system uses digital technology for image capture, display, and manipulation, and its mobile design allows it to operate on utility power or battery power; the device can be pushed by one person to various locations within a building. The device is commonly used for bedside radiography, and imaging during interventions or operations. The device consists of modules that are upgradable by adding hardware or software. Devices that are capable of fluoroscopy are not included in this category. The X-ray generator is integrated with the system.	37647020	II	10	applicable	applicable

Mammography combined diagnostic X-ray system	A system comprising a diagnostic mammography device and a general-purpose diagnostic radiography device.	70001000	II	10	applicable	applicable
Stationary analogue general-purpose fluoroscopic diagnostic X-ray system	A general-purpose stationary diagnostic fluoroscopy system that uses real-time analog or analog-to-digital conversion technology for image capture, display, and manipulation, designed for use in a variety of general-purpose applications requiring real-time fluoroscopic images. The system typically has a radiographic function in addition to fluoroscopic function, optimizing the macroscopic or quantitative evaluation of the anatomy and physiology of the targeted body areas. The device is often used with an X-ray contrast medium, which is to be administered orally or injected using a syringe. Images can be viewed in both real-time and delayed formats.	37621010	II	10	applicable	applicable
Stationary analogue general-purpose integral fluoroscopic diagnostic X-ray system	A general-purpose stationary diagnostic fluoroscopy system—a device typically comprising a pickup tube that uses real-time analog or analog-to-digital conversion technology for image capture, display, and manipulation, designed for use in a variety of general-purpose applications requiring real-time fluoroscopy. The system typically has a radiographic function in addition to fluoroscopic function, optimizing the macroscopic or quantitative evaluation of the anatomy and physiology of the targeted body areas. The device is often used with an X-ray contrast medium, which is to be administered orally or injected using a syringe. Images can be viewed in both real-time and delayed formats. The X-ray generator is integrated with the system.	37621020	II	10	applicable	applicable
Mobile analogue general-purpose fluoroscopic diagnostic X-ray system	A general-purpose mobile diagnostic fluoroscopy system (moving within an X-ray imaging facility) that uses real-time analog or analog-to-digital conversion technology for image capture, display, and manipulation, designed for use in a variety of general-purpose applications requiring real-time fluoroscopic images. The system typically has a radiographic function in addition to fluoroscopic function, optimizing the macroscopic or quantitative evaluation of the anatomy and physiology of the targeted body areas. The device is often used with an X-ray contrast medium, which is to be administered orally or injected using a syringe.	37622010	II	10	applicable	applicable
Mobile analogue general-purpose integral fluoroscopic diagnostic X-ray system	A general-purpose mobile diagnostic fluoroscopy system (moving within an X-ray imaging facility)—a device typically comprising a pickup tube that uses real-time analog or analog-to-digital conversion technology for image capture, display, and manipulation, designed for use in a variety of general-purpose applications requiring real-time fluoroscopic images. The system typically has a radiographic function in addition to fluoroscopic function, optimizing the macroscopic or quantitative evaluation of the anatomy and physiology of the targeted body areas. The device is often used with an X-ray contrast medium, which is to be administered orally or	37622020	II	10	applicable	applicable

Portable analogue general-purpose fluoroscopic diagnostic X-ray system	A general-purpose portable diagnostic fluoroscopy system (the device can be moved to another location where it can be easily re-assembled) that uses real-time analog or analog-to-digital conversion technology for image capture, display, and manipulation, designed for use in a variety of general-purpose applications requiring real-time fluoroscopic images. The system typically has a radiographic function in addition to fluoroscopic function, optimizing the macroscopic or quantitative evaluation of the anatomy and physiology of the targeted body areas. The device is often used with an X-ray contrast medium, which is to be administered orally or injected using a syringe.	37631010	II	10	applicable	applicable
Portable analogue general-purpose integral fluoroscopic diagnostic X-ray system	A general-purpose portable diagnostic fluoroscopy system (the device can be moved to another location where it can be easily re-assembled)—a device typically comprising a pickup tube that uses real-time analog or analog-to-digital conversion technology for image capture, display, and manipulation, designed for use in a variety of general-purpose applications requiring real-time fluoroscopic images. The system typically has a radiographic function in addition to fluoroscopic function, optimizing the macroscopic or quantitative evaluation of the anatomy and physiology of the targeted body areas. The device is often used with an X-ray contrast medium, which is to be administered	37631020	II	10	applicable	applicable
Mobile digital general-purpose fluoroscopic diagnostic X-ray system	A general-purpose mobile diagnostic fluoroscopy system (moving within an X-ray imaging facility) that uses digital conversion technology for image capture, display, and manipulation, designed for use in a variety of general-purpose applications requiring real-time fluoroscopic images. The system typically has a radiographic function in addition to fluoroscopic function, optimizing the macroscopic or quantitative evaluation of the anatomy and physiology of the targeted body areas. The device is often used with an X-ray contrast medium, which is to be administered orally or injected using a syringe. Images can be viewed in both real-time and delayed	37646010	II	10	applicable	applicable
Mobile digital general-purpose integral fluoroscopic diagnostic X-ray system	A general-purpose mobile diagnostic fluoroscopy system (moving within an X-ray imaging facility) that uses digital conversion technology for image capture, display, and manipulation, designed for use in a variety of general-purpose applications requiring real-time fluoroscopic images. The system typically has a radiographic function in addition to fluoroscopic function, optimizing the macroscopic or quantitative evaluation of the anatomy and physiology of the targeted body areas. The device is often used with an X-ray contrast medium, which is to be administered orally or injected using a syringe. Images can be viewed in both real-time and delayed	37646020	II	10	applicable	applicable
Portable digital general-purpose fluoroscopic diagnostic X-ray system	A general-purpose portable diagnostic fluoroscopy system (the device can be moved to another location where it can be easily re-assembled) that uses real-time digital technology for image capture, display, and manipulation, designed for use in a variety of general-purpose applications requiring real-time fluoroscopic images. The system typically has a radiographic function in addition to fluoroscopic function, optimizing the macroscopic or quantitative evaluation of the anatomy and physiology of the targeted body areas. The device is often used with an X-ray contrast medium, which is to be administered orally or injected using a syringe.	37649010	II	10	applicable	applicable
Portable digital general-purpose integral fluoroscopic diagnostic X-ray system	A general-purpose portable diagnostic fluoroscopy system (the device can be moved to another location where it can be easily re-assembled) that uses real-time digital technology for image capture, display, and manipulation, designed for use in a variety of general-purpose applications requiring real-time fluoroscopic images. The system typically has a radiographic function in addition to fluoroscopic function, optimizing the macroscopic or quantitative evaluation of the anatomy and physiology of the targeted body areas. The device is often used with an X-ray contrast medium, which is to be administered orally or injected using a syringe. The X-ray generator is integrated with the system.	37649020	II	10	applicable	applicable

Stationary digital general-purpose fluoroscopic diagnostic X-ray system	A general-purpose stationary diagnostic fluoroscopy system that uses real-time digital technology for image capture, display, and manipulation, designed for use in a variety of general-purpose applications requiring real-time fluoroscopic images. The system typically has a radiographic function in addition to fluoroscopic function, optimizing the macroscopic or quantitative evaluation of the anatomy and physiology of the targeted body areas. The device is often used with an X-ray contrast medium, which is to be administered orally or injected using a syringe. Images can be viewed in both real-time and delayed formats.	37679010	II	10	applicable	applicable
Stationary digital general-purpose integral fluoroscopic diagnostic X-ray system	A general-purpose stationary diagnostic fluoroscopy system that uses real-time digital technology for image capture, display, and manipulation, designed for use in a variety of general-purpose applications requiring real-time fluoroscopic images. The system typically has a radiographic function in addition to fluoroscopic function, optimizing the macroscopic or quantitative evaluation of the anatomy and physiology of the targeted body areas. The device is often used with an X-ray contrast medium, which is to be administered orally or injected using a syringe. Images can be viewed in both real-time and delayed formats. The X-ray generator is integrated with the system.	37679020	II	10	applicable	applicable
Linear tomography diagnostic X-ray system	A medical X-ray system used to produce two-dimensional cross-sectional images (tomography) on the X-ray films placed at an angle and depth that is fixed relative to the body position by adjusting the rectilinear movement of the X-ray tube, which is synchronized with irradiation but moves in the opposite direction to the recording plate and film, while irradiation is in progress. The X-ray tube moves in parallel with the film but in the opposite direction. Thereby, the shadow of the selected image remains on the film in motion, and the shadows of other images fade or disappear because of the effect of the relative displacement. This device group uses conventional	37648000	II	10	applicable	applicable
Multi-directional tomography diagnostic X-ray system	A medical X-ray system used to produce two-dimensional cross-sectional images (tomography) on X-ray films placed at an angle and depth that is fixed relative to the body position by adjusting the fixed patterns of nonlinear movement of the X-ray tube (linear, elliptical, round, cloverleaf, or helical patterns depending on the system design), while irradiation is in progress. Thereby, the shadow of the selected image remains on the film in motion, and the shadows of other images fade or disappear because of the effect of the relative displacement. This product group uses conventional technologies and the majority of the devices have been replaced with X-	37660000	II	10	applicable	applicable
Mobile digital angiographic fluoroscopic diagnostic X-ray system	A mobile digital diagnostic fluoroscopy system (moving within an X-ray imaging facility), designed to optimize the macroscopic or quantitative evaluation of the anatomy and function of the blood and lymphatic systems in the heart, brain, or other organs. The device uses digital technology for real-time image capture, display, and manipulation, and typically has a radiographic function in addition to fluoroscopic function. The device is often used with an X-ray contrast medium, which is administered into blood vessels for imaging, or during surgery or other interventions performed with the aid of imaging. Images can be viewed in both real-time and delayed	37612000	II	10	applicable	applicable
Mobile analogue angiographic fluoroscopic diagnostic X-ray system	A mobile diagnostic fluoroscopy system (moving within an X-ray imaging facility), designed to optimize the macroscopic or quantitative evaluation of the anatomy and function of the blood and lymphatic systems in the heart, brain, or other organs. The device uses analog or analog-to-digital conversion technology for real-time image	37614000	II	10	applicable	applicable

Stationary analogue angiographic fluoroscopic diagnostic X-ray system	A stationary diagnostic fluoroscopy system, designed to optimize the macroscopic or quantitative evaluation of the anatomy and function of the blood and lymphatic systems in the heart, brain, or other organs. The device uses analog or analog-to-digital conversion technology for real-time image capture, display, and manipulation, and typically has a radiographic function in addition to fluoroscopic function. The device is often used with an X-ray contrast medium, which is administered into blood vessels for imaging, or during surgery or other interventions performed with the aid of imaging. Images can be viewed in both real-time and delayed formats.	37616000	II	10	applicable	applicable
Stationary digital angiographic fluoroscopic diagnostic X-ray system	A stationary diagnostic fluoroscopy system, designed to optimize the macroscopic or quantitative evaluation of the anatomy and function of the blood and lymphatic systems in the heart, brain, or other organs. The device uses digital technology for real-time image capture, display, and manipulation, and typically has a radiographic function in addition to fluoroscopic function. The device is often used with an X-ray contrast medium, which is administered into blood vessels for imaging, or during surgery or other interventions performed with the aid of imaging. Images can be viewed in both real-time and delayed formats.	37623000	II	10	applicable	applicable
Stationary analogue mammographic diagnostic X-ray system	A piece of equipment designed for compression and imaging of the breast, installed in a specific location in a radiography facility or an X-ray inspection vehicle. The device is primarily used for the purpose of optimizing macroscopic evaluation of X-ray films, which indicate the anatomy and function of the blood and lymphatic vessels in the breast of humans. The system uses analog or analog-to-digital conversion technology for image capture and display. This device is used for breast cancer examination, biopsy site marking requiring X-ray guidance, stereotactic biopsy, and identification of lesion area.	37630000	II	10	applicable	applicable
Portable analogue mammographic diagnostic X-ray system	A portable radiography system (the device can be disassembled, and moved to another location where it can be easily reassembled for use), designed for compression and imaging of the breast. The device is primarily used for the purpose of optimizing macroscopic evaluation of X-ray film images, which indicate the anatomy and function of the blood and lymphatic vessels in the breast of humans. The system uses analog or analog-to-digital conversion technology for image capture and display. The breast imaging device is used for breast cancer examination, biopsy site marking requiring X-ray guidance, stereotactic biopsy, and identification of lesion area.	37632000	II	10	applicable	applicable
Mobile analogue mammographic diagnostic X-ray system	A mobile radiography system (the device can be pushed by one person to various locations within a radiography facility) designed for compression and imaging of the breast. The device is primarily used for the purpose of optimizing macroscopic evaluation of X-ray films, which indicate the anatomy and function of the blood and lymphatic vessels in the breast of humans. The system uses analog or analog-to-digital conversion technology for image capture and display. The breast imaging device is used for breast cancer examination, biopsy site marking requiring X-ray guidance, stereotactic biopsy, and identification of lesion area.	37671000	II	10	applicable	applicable

Stationary digital mammographic diagnostic X-ray system	A set of equipment designed for compression and imaging of the breast, installed in a specific location in a radiography facility or an X-ray inspection vehicle. A digital mammographic system (DMS) is used for recording absorption patterns of X-ray beams that have passed through the breast on film, paper, digital, video format, or other various recording media. It is used to optimize the macroscopic evaluation of the anatomy and function of the blood and lymphatic systems in the breast. The system uses digital technology for image capture, display, and manipulation. The DMS is used for breast cancer examination, biopsy site marking requiring X-ray guidance, stereotactic biopsy, and identification of the lesion area.	37672000	II	10	applicable	applicable
Mobile digital mammographic diagnostic X-ray system	A mobile radiography system (the device can be pushed by one person to various locations within a radiography facility) designed for compression and imaging of the breast. A digital mammographic system (DMS) is used for recording absorption patterns of X-ray beams that have passed through the breast on film, paper, digital, video format, or other various recording media. It is used to optimize the macroscopic	37673000	II	10	applicable	applicable
Portable digital mammographic diagnostic X-ray system	A portable radiography system (the device can be disassembled, and moved to another location where it can be easily reassembled for use), designed for compression and imaging of the breast. A digital mammographic system (DMS) is used for recording absorption patterns of X-ray beams that have passed through the breast on film, paper, digital, video format, or other various recording media. It is used to optimize the	37674000	II	10	applicable	applicable
Mobile digital uro/gynaecological fluoroscopic diagnostic X-ray system	A mobile diagnostic fluoroscopy system (moving within the radiography facility) with fluoroscopic capabilities specifically designed for use in urological or gynecological surgical and interventional procedures requiring real-time imaging of the pelvic area. The device uses digital technology for real-time image capture, display and manipulation, and generally has spot-film capabilities as well as fluoroscopic capabilities. The device is widely used for imaging and X-ray guided surgical or	37615000	II	10	applicable	applicable
Mobile analogue uro/gynaecological fluoroscopic diagnostic X-ray system	A mobile diagnostic fluoroscopy system (moving within the radiography facility) with fluoroscopic capabilities specifically designed for use in urological or gynecological surgical and interventional procedures requiring real-time imaging of the pelvic area. It uses analog or analog-to-digital conversion technology for real-time image capture, display and manipulation, and generally has spot-film capabilities as well as fluoroscopic capabilities. The device is widely used for imaging and X-ray guided	37624000	II	10	applicable	applicable
Stationary digital uro/gynaecological fluoroscopic diagnostic X-ray system	A stationary diagnostic fluoroscopy system with fluoroscopic capabilities specifically designed for use in urological or gynecological surgical and interventional procedures requiring real-time imaging of the pelvic area. The device uses digital technology for real-time image capture, display and manipulation, and generally has spot-film capabilities as well as fluoroscopic capabilities. The device is widely used for imaging and X-ray guided surgical or interventional procedures. The images can be viewed in both real-time and delayed formats, and has various levels of image processing and	37633000	II	10	applicable	applicable
Stationary analogue uro/gynaecological fluoroscopic diagnostic X-ray system	A stationary diagnostic fluoroscopy system with fluoroscopic capabilities specifically designed for use in urological or gynecological surgical and interventional procedures requiring real-time imaging of the pelvic area. It uses analog or analog-to-digital	37634000	II	10	applicable	applicable

Pneumoencephalograph diagnostic X-ray system	A diagnostic X-ray system used in radiography of the cerebral ventricle and the subarachnoid space visualized with the sterilization gas or air injected through lumbar puncture. This product group uses conventional technologies, and the majority of the devices have been replaced with X-ray computed tomography.	37680000	II	10	applicable	applicable
Abdominal public health screening diagnostic X-ray system	A diagnostic radiography system specifically designed for brief radiography of the stomach or other gastrointestinal areas of a large number of people. Generally, it has a simple structure, the device generates and controls X-ray beams, and records absorption patterns of X-ray beams that have passed through the targeted area. This is also called a mass screening device, and is used for optimizing macroscopic evaluation of gastrointestinal radiographic images, using various viewing and recording media including film, paper, and fluorescent screens. The device is often used in the mobile radiography environment; it is installed in a vehicle used for medical checks, which goes from town to town.	37675010	II	10	applicable	applicable
Abdominal public health screening integral diagnostic X-ray system	A diagnostic radiography system specifically designed for brief radiography of the stomach or other gastrointestinal areas of a large number of people. Generally, it has a simple structure, the device generates and controls X-ray beams, and records absorption patterns of X-ray beams that have passed through the targeted area. This is also called a mass screening device, and is used for optimizing macroscopic evaluation of gastrointestinal radiographic images, using various viewing and recording media including film, paper, and fluorescent screens. The device is often used in the mobile radiography environment; it is installed in a vehicle used for medical checks, which	37675020	II	10	applicable	applicable
Thoracic public health screening diagnostic X-ray system	A diagnostic radiography system specifically designed for brief radiography of the chests of a large number of people. Generally, it has a simple structure, the device generates and controls X-ray beams, and records absorption patterns of X-ray beams that have passed through the targeted area. This is also called a mass screening device, and is used for optimizing macroscopic evaluation of radiographic images of the lung and other thoracic organs, using various viewing and recording media including film, paper, fluorescent screens, and digital or video formats. The device is often used in the mobile radiography environment; it is installed in a vehicle used for medical	37627010	II	10	applicable	applicable
Thoracic public health screening integral diagnostic X-ray system	A diagnostic radiography system specifically designed for brief radiography of the chests of a large number of people. Generally, it has a simple structure, the device generates and controls X-ray beams, and records absorption patterns of X-ray beams that have passed through the targeted area. This is also called a mass screening device, and is used for optimizing macroscopic evaluation of radiographic images of the	37627020	II	10	applicable	applicable
Thoracic and abdominal public health screening diagnostic X-ray system	A diagnostic radiography system specifically designed for brief radiography of the chests and abdomens (stomach or other areas of the gastrointestinal tract) of a large number of people. Generally, it has a simple structure, the device generates and controls X-ray beams, and records absorption patterns of X-ray beams that have passed through the targeted area. This is also called a mass screening device, and is	37627030	II	10	applicable	applicable

Thoracic and abdominal public health screening integral diagnostic X-ray system	A diagnostic radiography system specifically designed for brief radiography of the chests and abdomens (stomach or other areas of the gastrointestinal tract) of a large number of people. Generally, it has a simple structure, the device generates and controls X-ray beams, and records absorption patterns of X-ray beams that have passed through the targeted area. This is also called a mass screening device, and is used for optimizing macroscopic evaluation of radiographic images of the lung and other thoracic organs, using various viewing and recording media including film, paper, fluorescent screens, and digital or video formats. The device is often used in the mobile radiography environment; it is installed in a vehicle used for medical checks,	37627040	II	10	applicable	applicable
Dental public health screening panoramic X-ray system	A X-ray dental diagnostic system with an extra-oral X-ray source used to generate and control X-ray beams for advanced brief dental imaging, involving the teeth, jaw, oral cavity, sinus and other maxillofacial structures of a large number of people; the device is used for panoramic imaging of signals amplified by an imaging tube with a spot camera that uses a roll film.	70002000	II	10	applicable	applicable
Single-energy X-ray bone absorptiometer	A single-energy X-ray absorptiometry device designed for calculating bone density based on data obtained from peaks of a single photon energy. The device uses 1 or more X-ray tubes as a radiation source. In the device, the X-ray tube and photon detector are geometrically arranged, and X-rays are irradiated to the object of interest; the X-ray absorption coefficient at each site is measured.	37625010	II	10	applicable	applicable
Single-energy integral X-ray bone absorptiometer	A single-energy X-ray absorptiometry device designed for calculating bone density based on data obtained from peaks of a single photon energy. The device uses 1 or more X-ray tubes as a radiation source. In the device, the X-ray tube and photon detector are geometrically arranged, and X-rays are irradiated to the object of interest; the X-ray absorption coefficient at each site is measured. The X-ray generator is integrated with the system.	37625020	II	10	applicable	applicable
Dual-energy X-ray bone absorptiometer	A dual-energy X-ray absorptiometry device designed for calculating bone density based on data obtained from peaks of 2 types of photon energy. The device uses 1 or more X-ray tubes as a radiation source. In the device, the X-ray tube and photon detector are geometrically arranged, and X-rays are irradiated to the object of interest; the X-ray absorption coefficient at each site is measured. Using this information, some devices	37661010	II	10	applicable	applicable
Dual-energy integral X-ray bone absorptiometer	A dual-energy X-ray absorptiometry device designed for calculating bone density based on data obtained from peaks of 2 types of photon energy. The device uses 1 or more X-ray tubes as a radiation source. In the device, the X-ray tube and photon detector are geometrically arranged, and X-rays are irradiated to the object of interest; the X-ray absorption coefficient at each site is measured. Using this information, some devices	37661020	II	10	applicable	applicable
X-ray/CT combined cardiovascular diagnostic X-ray system	A system combining a diagnostic X-ray computed tomography (CT) and a diagnostic cardiovascular fluoroscopy system.	70003000	II	10	applicable	applicable

Digital general-purpose dental intraoral X-ray system	A diagnostic, digital, dental (intraoral), general-purpose X-ray system used to produce and control an X-ray beam. Digital techniques are employed to record the absorption patterns of the X-ray beam used for a general dental examination or routine dental radiography associated with diagnosis and treatment (surgery and intervention) of diseases related to the tooth, jaw, and oral structures. In dental radiography, the X-ray source (X-ray tube) is placed inside the patient's mouth. This system group includes fixed, movable and portable devices, and consists of basic modular devices which can be upgraded by adding hardware or software.	37617000	II	10	applicable	applicable
Analogue general-purpose dental intraoral X-ray system	A diagnostic analog, dental (intraoral), general-purpose X-ray system used to produce and control an X-ray beam. Analog techniques or analog-to-digital conversion technology are employed to record the absorption patterns of the x-ray beam used for a general dental examination or routine dental radiography associated with diagnosis and treatment (surgery and intervention) of diseases related to the tooth, jaw, and oral structures. In radiography, the X-ray source (X-ray tube) is placed inside the patient's mouth. This system group includes fixed, movable and portable devices, and consists of basic modular devices which can be upgraded by additional hardware or software.	37635000	II	10	applicable	applicable
Analogue general-purpose dental extraoral X-ray system	A general-purpose extraoral diagnostic analog radiography system for dentistry used to generate and control X-ray beams. The device uses analog or analog-to-digital conversion technology to record the absorption pattern of X-ray beams used for general dental examination or routine dental radiography examination involving the diagnosis and treatment (surgical or interventional) of diseases of the teeth, jaw, and oral structures. The X-ray source (X-ray tube) is placed outside the patient's mouth during imaging procedures. This category includes stationary, mobile, and portable devices; the device consists of upgradable basic modules.	37636000	II	10	applicable	applicable
Digital general-purpose dental extraoral X-ray system	A general-purpose extraoral diagnostic digital radiography system for dentistry used to generate and control X-ray beams. The device uses digital technology to record the absorption pattern of X-ray beams used for general dental examination or routine dental radiography involving the diagnosis and treatment (surgical or interventional) of diseases of the teeth, jaw, and oral structures. The X-ray source (X-ray tube) is placed outside the patient's mouth during imaging procedures. This category includes stationary, mobile, and portable devices; the device consists of upgradable basic modules.	37667000	II	10	applicable	applicable
Analogue dental panoramic X-ray system	An extraoral diagnostic analog radiography system for dentistry used to generate and control X-ray beams. The device is specifically designed to produce panoramic X-ray images of teeth, jaw and oral structures. This category includes stationary, mobile, and portable devices; the device consists of basic modules that are upgradable by adding hardware or software.	37637000	II	10	applicable	applicable
Digital dental panoramic X-ray system	A diagnostic digital radiography system for dentistry equipped with an extraoral X-ray source specifically designed for panoramic imaging of teeth, jaw, and oral structures; used to generate and control X-ray beams. This category includes stationary, mobile, and portable devices; the device consists of basic modules that are upgradable by adding hardware or software.	37640000	II	10	applicable	applicable

Analogue dental panoramic/tomographic X-ray system	A diagnostic analog radiography system for dentistry equipped with an extraoral X-ray source used to generate and control X-ray beams used in advanced dental imaging involving the teeth, jaw, oral cavity, sinuses and other maxillofacial structures. The device uses analog or analog-to-digital conversion technology for image capture and display, and may have various image processing and analysis capabilities. This system is designed to provide the capability to produce two or more special-purpose dental radiography including linear scan, panoramic, cephalometry, linear tomography, spiral tomography, scanography, and zonography. This category includes stationary, mobile,	37668000	II	10	applicable	applicable
Digital dental panoramic/tomographic X-ray system	A diagnostic digital radiography system for dentistry equipped with an extraoral X-ray source used to generate and control X-ray beams used in advanced dental imaging involving the teeth, jaw, oral cavity, sinuses and other maxillofacial structures. The device uses digital technology for image capture, manipulation, and display, and may have various image processing and analysis capabilities. This system is designed to provide the capability to produce two or more special-purpose dental radiography including linear scan, panoramic, cephalometry, linear tomography, spiral tomography, scanography, and zonography. This category includes stationary, mobile, and portable devices.	37669000	II	10	applicable	applicable
Cephalometric diagnostic X-ray system	A diagnostic radiography system specifically designed for the radiographic visualization and measurement of the dimensions of the human head (skull). The device may be used in various dental X-ray applications, such as orthodontics. The device is used to generate and control X-ray beams and to record the absorption patterns of X-rays passing through the head, and is intended to optimize macroscopic evaluation of the resultant image. In some devices, images can be recorded using various viewing and archive media, including film, paper, fluorescent screens, digital, and video formats. This category includes stationary, mobile, and portable devices.	37677010	II	10	applicable	applicable
Cephalometric integral diagnostic X-ray system	A diagnostic radiography system specifically designed for the radiographic visualization and measurement of the dimensions of the human head (skull). The device may be used in various dental X-ray applications, such as orthodontics. The device is used to generate and control X-ray beams and to record the absorption patterns of X-rays passing through the head, and is intended to optimize macroscopic evaluation of the resultant image. In some devices, images can be recorded using various viewing and archive media, including film, paper, fluorescent screens, digital, and video formats. This category includes stationary, mobile, and portable devices. The	37677020	II	10	applicable	applicable
Dental digital X-ray imaging sensor	A digital dental X-ray sensor used in the oral cavity, in combination with a general-purpose dental X-ray imaging device. The sensor consists of a CCD or other components, and comprises a sensor drive circuit and a signal processing circuit.	70004010	II	10	applicable	N/A

Panoramic digital X-ray sensor	A sensor used in combination with a diagnostic digital dental X-ray imaging device that is specifically designed for panoramic imaging of teeth, jaw, and oral structures. The sensor consists of a CCD and other components, and comprises a sensor drive circuit and a signal processing circuit.	70004020	II	10	applicable	N/A
Cephalometric digital X-ray sensor	A sensor for a digital X-ray image processing system combined with a diagnostic X-ray system designed for visualization and size measurement of the human head (skull) using radiation. The sensor consists of the charge coupled devices (CCDs) and contains a sensor driving circuit and signal processing circuit.	70004030	II	10	applicable	N/A
Limited view field X-ray computed tomography system	A diagnostic X-ray computed tomography (CT) system equipped with a gantry designed exclusively for taking images of the area from the head to the neck or the extremities. The system is designed to have at least 1 fixed circular arrangement of multiple X-ray tubes and detectors, or designed to have an assembly where single or multiple X-ray tube(s) and detector(s) rotate around an axis at high speed within the area that the gantry can take images. Using this system, 2D or 3D images are produced. In addition, spiral CT and special radiography can be performed at multiple angles set relative to the position of the body. Various digital techniques are employed for information	37619000	II	10	applicable	applicable
Whole body X-ray computed tomography system	A diagnostic X-ray computed tomography (CT) system with a sufficiently large gantry that allows imaging of any desired region of the body. It includes designs with one or more fixed annular arrays of X-ray tubes and detectors, or those with X-ray tube(s) and detector assemblies that rotate rapidly around a central axis within the gantry imaging area. It can produce 2D or 3D images; in addition, spiral CT or other special imaging can be performed at multiple specified angles in relation to body position. It uses a variety of digital technology for information capture, image reconstruction, and display.	37618010	II	10	applicable	applicable
Body rotational whole body X-ray computed tomography system	A diagnostic X-ray computed tomography (CT) system used for irradiating a patient in a cone beam X-ray CT system, which is comprised of an X-ray tube and an X-ray flat panel detector, while the patient is rotated on a rotating photographing table, and collecting X-ray transmission signals related to the patient from multiple directions. The signals are processed on a computer to produce 2D and 3D images. This system can also be used to obtain a digital image as a digital radiography device (code: 70018000) that reads the output from an X-ray flat panel detector as an X-ray flat	37618020	II	10	applicable	applicable
Whole body electron beam X-ray computed tomography system	A diagnostic X-ray computed tomography (CT) system equipped with a gantry large enough to take X-rays of any part of the body. Scanning electron beam technology is used in the X-ray tube. The system mainly consists of focus and deflection coils that scan the electron beam emitted from the electron gun, a target ring to which the electron beam is led, and a detector that detects the X-rays emitted from the target ring. With the apparatus, 2D or 3D images are produced. In addition, spiral CT and special radiography can be performed at multiple angles set relative to the body position. Various digital techniques are utilized for information uptake, and reconstruction and display of images.	70005000	II	10	applicable	applicable

Arm type X-ray computed tomography system	A diagnostic X-ray computed tomography (CT) system for hard tissues such as bone and teeth, designed to acquire X-ray transmission signals from multiple angles in relation to the patient's position through the rotation of the supporting structure (arm) on which the X-ray tube and detector are mounted at both ends, and to produce 2D or 3D images by computer processing of the signals.	70006000	II	10	applicable	applicable
Stationary nuclear medicine gamma camera system	An analog or digital diagnostic-detector based, planar (2-dimensional) nuclear medicine (NM) imaging system intended to be used in only one location within a radiographic facility or fixed in a mobile/portable imaging environment. The device uses Anger or non-Anger detection methods to record, quantify and analyze radionuclide emissions (primarily gamma rays) produced during the decay of injected/orally administered radiopharmaceuticals or other radiation emitting materials.	40640000	II	10-②	applicable	applicable
Mobile nuclear medicine gamma camera system	An analog or digital diagnostic-detector based, planar nuclear medicine (NM) imaging system equipped with a motorized or electromechanical control system, which allows the user to move the device within a facility. The device uses Anger or non-Anger	40641000	II	10-②	applicable	applicable
Nuclear medicine rotating detector SPECT system	A single photon emission computed tomography (SPECT) stationary diagnostic system is a 3-dimensional (tomography) imaging camera-based system, used to detect, record, quantify and analyze radionuclide emissions (primarily gamma rays) produced during the decay of injected/orally administered radiopharmaceuticals or other radiation emitting materials. The system is designed so that the detector head fitted with a	40642000	II	10-②	applicable	applicable
Nuclear medicine annular SPECT system	Single photon emission computed tomography (SPECT) of a stationary diagnostic system specifically designed for tomographic imaging. It is used to detect, record, quantify and analyze radionuclide emissions produced during the decay of injected or orally administered radiopharmaceuticals or other radiation-emitting materials. The position of the system is typically fixed; the system is imaging table, which is controlled	40643000	II	10-②	applicable	applicable
Nuclear medicine positron emission tomography system	A positron emission tomography (PET) system specifically designed to detect, record, quantify, and analyze the pattern of 511-keV photon emissions generated by annihilation from the decay of positron-emitting radiopharmaceuticals. The device creates physiological images of 3-dimensional tomographic imaging digital sections, showing the distribution pattern of positrons emitted by the injected or orally administered radiopharmaceutical. Typically, lead collimators are used. Special software and reconstruction technology allow mapping of the metabolic patterns and metabolic rate related to the targeted physiological processes.	40644000	II	10-②	applicable	applicable
Nuclear medicine data processing system	A data processing system specifically dedicated for nuclear medicine. The system is used for various types of filter processing, image display, clinical analysis, management of image storage, etc. The system differs from a nuclear medicine system workstation in the sense that the former has a control system for directly operating a diagnostic imaging unit. This system can deliver or receive data online or offline, and has a configuration that can provide functions such as processing, manipulating, and displaying a patient's images and information collected with the nuclear medicine	70007000	II	10-②	applicable	applicable
Bone absorptiometer diagnostic radionuclide system	A diagnostic system that uses multiple radiation sources which store different types of radionuclide to produce a single radiation beam with multiple pieces of energy. This beam is passed through the anatomical area, and records the information about differences in the photon absorption rate using parameters obtained with digital images and through calculation. With this information, bone mineral density	38314000	II	10-②	applicable	applicable

Radionuclide dynamic function testing equipment	A device used to measure and record temporal variations of radioisotope concentrations in the body. Specialized devices, such as devices for thyroid uptake measurement, renograms, and radioisotope blood volume measurement, are included.	70008000	II	10-②	applicable	applicable
Nuclear medicine rectilinear scanner system	A rectilinear scanner is a device for detecting, recording and imaging the gamma-rays emitted from a radiopharmaceutical or other radioactive materials injected or orally administered. The gantry is designed to traverse the targeting part of the body in narrow and parallel increments pre-determined by the highly collimated scintillation detector(s) (single or multiple). The detector head moves only bi-dimensionally relative	40645000	II	10-②	applicable	applicable
Nuclear medicine hand-held detector	A hand-held non-imaging system used to detect, record, quantify, and analyze radionuclide emissions (e.g., gamma rays, alpha rays, and beta rays) by injected or orally administered radiopharmaceuticals, radiation-emitting devices or materials. The device is frequently used to monitor and detect deep vein thrombosis related to by surgical procedures requiring radionuclide positioning and some radiolabeled monoclonal antibody applications. The device is likely to have special kinds of software or auxiliary functions that are different from those of similar devices intended for radiation protection.	40646000	II	10-②	applicable	applicable
Thyroid uptake measurement nuclear medicine system	A diagnostic nuclear medicine system (non-imaging) designed mainly for testing and analyzing thyroid radioiodine uptake. The system can be upgraded by adding software or hardware modules to be used for various quantitative tests including a wipe test or a Schilling test, and radioimmunoassay. Generally, this system is equipped with a multichannel analyzer, a computer, a scintillation detector, a detector support device, a control console, a video display, a well counter detector, a collimator, shield materials and application software module.	40648000	II	10-②	applicable	applicable
Nuclear medicine system workstation	A standalone imaging workstation specifically designed to create network connection with one or more nuclear imaging devices, such as gamma camera, PET device, and SPECT device. The workstation may have any type of hardware, or any type of configuration. The device may be regarded as a component of a picture archiving and communication system (PACS). It differs from an operator console in that the workstation does not have controls for the direct manipulation of the imaging device. The device allows data transfer either on-line or off-line, and is typically situated away from the operator console. The device has a configuration in which the patient's images	40937000	II	10-②	applicable	applicable
X-ray/CT combined positron CT system	A combined system of positron emission tomography (PET) and X-ray computed tomography (CT). The device is a 3-dimensional (tomographic) imaging device, showing the distribution pattern of positrons emitted by the injected or orally administered radiopharmaceutical; in addition, it has one or more fixed annular arrays of X-ray tubes and detectors, or X-ray tube(s) and detector assemblies that rotate around a central axis within the gantry imaging area, allowing 2-dimensional or 3-dimensional X-ray imaging. The device uses a variety of digital technology for information capture,	70010010	II	10	applicable	applicable

X-ray/CT combined SPECT system	A system comprises both imaging capabilities of single photon emission computed tomography (SPECT) and X-ray computed tomography (CT). The device is a 3-dimensional (tomographic) imaging device used to detect, record, quantify and analyze radionuclide emissions (primarily gamma rays) produced during the decay of injected or orally administered radiopharmaceuticals or other radiation-emitting materials; in addition, it has one or more fixed annular arrays of X-ray tubes and detectors, or X-ray tube(s) and detector assemblies that rotate around a central axis within the gantry imaging area, allowing 2-dimensional or 3-dimensional X-ray imaging.	70010020	II	10	applicable	applicable
Positron CT combined SPECT system	A system capable of performing both SPECT examination and positron CT (PET) examination.	70010030	II	10-②	applicable	applicable
Nuclear medicine equipment and related system absorption compensation sealed source	A sealed radioisotope equipped dedicated for the correction of absorption of radiation from a diagnostic radioisotope by organs and tissues to improve quantitative capability of diagnostic imaging of the nuclear imaging system (PET or SPECT devices), thereby improving accuracy of diagnosis.	70011000	II	10-②	applicable	—
Pulmonary ventilatory function technegas generator	Technegas is composed of ultrafine gas-like aerosols of carbon-coated technetium 99-m, which enters the lungs with inhaled air, and reaches the alveolar wall. The technegas generator is a device that heats technetium 99-m together with carbon at high temperature under argon gas to form technegas by evaporation.	70012000	II	11	applicable	applicable
Mobile ultrasound imaging system	A vehicle such as a van, truck or car, or a mobile storage device equipped with at least one instance of an ultrasound diagnostic system and related devices. The device is moved to many locations by driving or being hauled by a vehicle and used as a	36208000	II	10	applicable	applicable
Ultrasound imaging system for general-purpose	A general-purpose ultrasound imaging system intended for use in a wide variety of both extracorporeal or intracorporeal (endosonographic or endoscopic) imaging. The general-purpose system is intended to support a wide variety of transducers and	40761000	II	10	applicable	applicable
Computer system for ultrasound imaging system	A mainframe computer, a personal computer (PC) or a PC-based platform, and related hardware, software and operating system software dedicated used for controlling and monitoring performance of a diagnostic ultrasound system and related image processing, display and analytical functions.	40845000	II	10	applicable	applicable
Operator console for ultrasound imaging system	A console for an operator functions as the main control panel for the diagnostic ultrasound system. This is equipped with hardware and software that enable display, processing and analysis of images as well as image archiving including storage and retrieval of images. It is one of the components of a diagnostic ultrasound system, and has connectivity to the general PACS, local area network, RIS or HIS system. Equipped with only the main control for direct operation, it is different from the workstation, but is generally incorporated into the integrated design of an imaging unit as seen in the mobile or portable ultrasound system.	40971000	II	10	applicable	applicable

Echoencephalograph	A graphic recorder used for recording the reflection (echo) of ultrasound in the head. With the transducer to generate and receive ultrasonic waves, the sound properties are graphically reproduced (echogram). This device is used to record the boundaries between each side of the cranium and midline structures, and detect the presence of mass lesions (e.g., brain tumor, subdural hematoma).	11387000	II	10	applicable	applicable
Ultrasound imaging system for Obstetrics/gynaecological	An obstetric/gynecological ultrasound imaging system intended for use in both extracorporeal or intracorporeal (endosonographic or endoscopic) imaging. The system includes software packages supporting for various still imaging and real-time imaging related to fetal imaging, amniocentesis, and imaging of the uterus. The device is used to produce and send ultrasonic pulses to targeted parts, detect ultrasonic echoes, process information obtained, and produce 2D or 3D still or dynamic images of anatomic structures or blood flow. The device is also used for guiding or placing other medical devices.	40762000	II	10	applicable	applicable
Ultrasound imaging system for mammography	A breast ultrasound imaging system intended for use in extracorporeal or intracorporeal (endosonographic or endoscopic) imaging. The system generally comprises a special patient table for diagnostic imaging, to obtain reproducible breast images. The system contains a software package to support a variety of still and real-time imaging of the breast, used primarily for cancer diagnosis. The device is also called an ultrasound breast imaging system. The device is used to produce ultrasonic pulses, send the pulses to the target sites, detect ultrasonic echoes, process obtained information, and produce 2D or 3D still or dynamic images.	40764000	II	10	applicable	applicable
Ultrasound imaging system for cardiovascular	An ultrasound imaging system intended for use in extracorporeal or intracorporeal (endosonographic or endoscopic) imaging procedures involving the heart and blood vessels. The system contains a software package to support a variety of still and real-time imaging of the heart, used to diagnose anatomic anomalies of the heart, and to identify blood flow characteristics and functional and anatomical problems associated with myocardial infarction. The device is used to produce and send ultrasonic pulses to targeted parts, detect ultrasonic echoes, process information obtained, and produce 2D or 3D still or dynamic images of anatomic structures or blood flow.	40763000	II	10	applicable	applicable
Ultrasound imaging system for bladder	An dedicated ultrasound imaging system used for diagnostic imaging of the bladder. The device is used to produce and send ultrasonic pulses to targeted parts, detect ultrasonic echoes, process information obtained, and produce 2D or 3D still or dynamic images of anatomic structures or blood flow. Information is obtained about the morphology of the bladder and lesions inside, by processing images to obtain bladder wall thickness, bladder weight, and other measurements. The system can measure urine volume in the bladder.	70013000	II	10	applicable	applicable
Ophthalmic ultrasound imaging system	An dedicated ultrasound imaging system used in ophthalmic diagnostic imaging. The system contains software that supports a variety of stationary or real-time imaging applications for the eye and orbit, including physical measurement and cancer treatment. The device produces ultrasonic pulses, guides the pulses to the target	11389000	II	10	applicable	applicable

Ultrasound pachometer	An ophthalmic device that uses ultrasound technology to measure the thickness of the cornea.	16330012	II	10-①	applicable	applicable
Ultrasonic amplifier	A unit used to amplify signals transmitted from the probe of an ultrasound imaging system. This is used with an ultrasound system in the event the quality of original data transfer is lowered by the distance between the console and the imaging probe in the ultrasound system. Signal amplification is often required in association with insertion of small handheld ultrasound probe into the blood vessel and tissue	36370000	II	10	applicable	applicable
Axial length measuring ultrasound system	An ophthalmic device that uses ultrasound technology to measure axial length of the eye (distance along the axis of the eye between the anterior corneal surface and the anterior retinal surface).	16330022	II	10	applicable	applicable
Ophthalmic ultrasound imaging/axial length measuring system	A multifunctional device combining the functions of ophthalmic ultrasound imaging system and axial length measuring ultrasound system.	16330032	II	10	applicable	applicable
Ultrasound corneal thickness/axial length measuring system	A multifunctional device combining the functions of ultrasound pachometer and axial length measuring ultrasound system.	16330042	II	10	applicable	applicable
Esophageal ultrasound probe	A reusable or single-use ultrasound transducer assembly enclosed in a water-resistant, acoustically and electrically insulated housing that is intended to be inserted into and positioned in the esophagus by the operator. The device is also called an endoscopic ultrasound probe or an ultrasound endoscopic transducer to be used in the esophagus; the device is often incorporated in or used in combination with a device that requires ultrasonography guidance or ultrasonic wave generation, such as an endoscopic device	37891000	II	10	applicable	applicable
Paranasal ultrasound probe	A reusable or single-use ultrasound transducer assembly enclosed in a fluid-resistant, acoustically and electrically insulated housing that is intended to be inserted into and positioned in the paranasal sinuses by the operator. The device is also called an endoscopic ultrasound probe or ultrasound endoscopic transducer to be used in the paranasal sinuses; the device is typically incorporated in or used in combination with a device that requires ultrasonography guidance or ultrasonic wave generation, such as an endoscopic device or a needle biopsy device. The device is composed of either a single transducer element or an array of transducer elements (also called piezoelectric elements, active elements, or crystals), damping, backing, and matching materials.	37894000	II	10	applicable	applicable

Stationary extracorporeal ultrasound probe	An ultrasound transducer assembly that is installed in the housing of an ultrasonography scanner device, such as a breast scanner, Doppler flow system, ultrasound bone absorptiometry device, or ultrasound bone densitometer; it is floor-or wall-mounted, or ceiling-mounted so that the operator can place the transducer assembly outside the patient's body. The assembly includes single or multiple element transducer assembly configurations that convert electric voltages into an ultrasound	40767000	II	10	applicable	applicable
hand-held extracorporeal ultrasound probe	An extracorporeal diagnostic ultrasound transducer assembly that is designed to be moved manually over the intact surface of a patient's body, during imaging applications. The assembly includes single or multiple element transducer assembly configurations that convert electric voltages into an ultrasound beam. The assembly steers the beam direction, focusing and detecting the reflected echoes mechanically or electronically. The device is typically used with coupling gels to ensure adequate contact with the patient. This category includes ultrasound transducers used with A-mode, B-mode, M-mode, Doppler, color Doppler (CD), and duplex (combined imaging, Doppler or color flow Doppler) scanning capabilities.	40768000	II	10	applicable	applicable
Non-vascular surgical ultrasound probe	A probe that is used for non-vascular surgery. A hand-held ultrasound transducer assembly designed to be positioned within a surgical site for localized intraoperative imaging applications. The device is sometimes called a surgical probe or fingertip probe. The device includes various single or multiple element transducer assembly configurations that convert electric voltages into an ultrasound beam. The assembly steers the beam direction, focusing and detecting the reflected echoes mechanically or electronically. This category includes ultrasound transducers used with A-mode, B-mode, M-mode, Doppler, color Doppler (CD), and duplex (combined imaging, Doppler or color flow Doppler) scanning capabilities. The device may incorporate a biopsy	40770002	II	10	applicable	applicable
Vaginal ultrasound probe	An ultrasound transducer assembly specifically designed to be positioned within the vagina either manually or under endoscopic guidance. The device includes various single or multiple element transducer assembly configurations that convert electric voltages into an ultrasound beam. The assembly steers the beam direction, focusing and detecting the reflected echoes mechanically or electronically. This category includes ultrasound transducers used with A-mode, B-mode, M-mode, Doppler, color Doppler (CD), and duplex (combined imaging, Doppler or color flow Doppler) scanning capabilities. The device may incorporate a biopsy needle guide channel as a part of the	40771000	II	10	applicable	applicable
Rectal ultrasound probe	An ultrasound transducer assembly specifically designed to be positioned within the rectum either manually or under endoscopic guidance. The assembly includes single or multiple element transducer assembly configurations that convert electric voltages into an ultrasound beam. The assembly steers the beam direction, focusing and detecting the reflected echoes mechanically or electronically. The device is also known as a rectal, transrectal, or prostate probe; the device may incorporate a biopsy needle guide channel as a part of the transducer casing or housing assembly designs. The device is reusable.	40772000	II	10	applicable	applicable

Body orifice ultrasonic probe cover	A protective cover designed to be put on an ultrasound probe to protect the probe from the patient's body fluids, stains, etc. , when a probe is inserted into a body orifice (e.g., transvaginal, transrectal, or transesophageal applications).	70015000	II	5-⑥	applicable	—
Intraoperative ultrasonic probe cover	A protective cover designed to be put on a device including an ultrasound probe or gamma probe in surgical procedures to protect the probe from the patient's body fluids, stains, etc.	70016000	II	6	applicable	—
Puncture kit for ultrasonic probe	A tool for biopsies that are performed during monitoring with an ultrasound imaging system. The kit contains covers to be placed on a device such as an ultrasound probe, and tools to guide the direction of a puncture needle. The category does not include a puncture needle.	70017000	II	5-⑥	applicable	—
Body cavity ultrasound probe	An ultrasound transducer assembly specifically designed to be positioned within a body cavity, either manually or under endoscopic guidance. The assembly includes single or multiple element transducer assembly configurations that convert electric voltages into an ultrasound beam. The assembly steers the beam direction, focusing and detecting the reflected echoes mechanically or electronically. The device may incorporate a biopsy needle guide channel as a part of the transducer casing or housing assembly designs. The device is reusable.	70018000	II	10	applicable	applicable
Bladder ultrasound probe	An ultrasound transducer assembly specifically designed to be positioned within the bladder, either manually or under endoscopic guidance. The assembly includes single or multiple element transducer assembly configurations that convert electric voltages into an ultrasound beam. The assembly steers the beam direction, focusing and detecting the reflected echoes mechanically or electronically. Also known as a bladder, or transurethral probe, the device may incorporate a biopsy needle guide channel as a part of the transducer casing or housing assembly designs. The device is reusable.	70019000	II	10	applicable	applicable
Stationary extracorporeal water tank coupler diagnostic ultrasound probe	An ultrasound transducer assembly that is installed in the housing of an ultrasonography scanner device, such as a breast scanner, Doppler flow system, ultrasound bone absorptiometry device, or ultrasound bone densitometer; this may be floor-or wall-mounted, hand-held (including the desktop type), or ceiling-mounted, so that the operator can place the transducer assembly outside the patient's body. The assembly includes a water tank, water bag, or other ultrasound medium. The assembly includes single or multiple element transducer assembly configurations that convert electric voltages into an ultrasound beam. The assembly steers the beam direction, focusing and detecting the reflected echoes mechanically or electronically.	70020000	II	10	applicable	applicable

Ultrasound system synchronizer	A physiological monitoring device used as one component in a diagnostic ultrasound system. This device produces signals which can synchronize imaging acquisition and data collection with specific measurable, physiological parameters, such as the starting point of a patient's respiratory or cardiac cycle. It is used mainly to reduce artifacts and to increase the signal-to-noise ratio in real-time ultrasonic imaging and in video imaging.	35460000	II	10	applicable	applicable
Bone absorptiometer ultrasound system	A device is used to perform calculation of bone mineral density and other values based on data related to the transmitted or reflected portion of ultrasonic waves after emission. The device is also called a bone densitometer. An integrated type of ultrasound transducer is used to deliver an ultrasound beam to an anatomical area of interest. Data obtained from the detection and analysis of ultrasound waves are used for estimation of bone mineral density and subcutaneous fat, or other quantitative assessment including bone fracture risks. The system generally consists of an ultrasound transducer, electronic device for detection, control panel, computer, application software, video display, and patient positioning system.	40779000	II	10	applicable	applicable
Ultrasound probe positioning unit	A unit used to position an ultrasonic transducer assembly to be inserted through an endoscope. This device is an accessory of a diagnostic ultrasound imaging system, and transmits signals that can display the position of the transducer assembly enclosed within the catheter after processing the image. This device helps to position a transducer assembly (a probe) during endoscopy, and enables movement observation after placement.	40786000	II	10	applicable	applicable
Resistive magnet mammographic MRI system	A magnetic resonance (MR) diagnostic imaging device specifically designed for breast imaging. The device uses a resistive magnet, and can be stationary, mobile, or portable. The gantry designs include closed bore, open bore, and a variety of designs to allow the elements to be close to the patient. In addition to the conventional magnetic resonance imaging, the device can be designed to perform magnetic resonance (MR) spectroscopy and a variety of real-time imaging capabilities required in interventions, treatments, and surgical interventions involving MRI. The MR device for mammography is typically equipped with a dedicated patient support bed for the purpose of controlling the positioning of the patient's body to optimize visualization of the breast.	37611000	II	10-①	applicable	applicable
Resistive magnet whole body MRI system	A general-purpose diagnostic magnetic resonance imaging (MRI) system designed for the imaging of any targeted area of the body (whole body imaging). The system includes a resistive magnet, and can be stationary, mobile, or portable. In addition to conventional magnetic resonance imaging, the device can be designed to perform magnetic resonance (MR) spectroscopy, a variety of real-time imaging capabilities required in physiologically synchronized imaging, MRI mammography imaging, and	37653000	II	10-①	applicable	applicable
Resistive magnet head/extremity imaging MRI system	A magnetic resonance (MR) diagnostic imaging device specifically designed to visualize the head, neck, or limbs using a resistive magnet. The devices for head or limb imaging are commonly of closed-bore designs with a cylindrical or rectangular opening; while some devices have open-bore designs. This category includes MRI devices with conventional head or limb imaging capabilities, conventional devices with the ability to perform MR spectroscopy and other real-time imaging capabilities required in interventions and treatments involving MRI; and it is dedicated for MR spectroscopy.	37655000	II	10-①	applicable	applicable

Resistive magnet cardiovascular MRI system	A magnetic resonance (MR) diagnostic imaging device specifically designed to visualize the cardiovascular system. The device uses a resistive magnet, and can be stationary, mobile, or portable. The gantry designs include closed bore, open bore, and a variety of designs to allow the elements to be close to the patient. Some types of device have MR spectroscopy and a variety of real-time imaging capabilities required in interventions, treatments, and surgical interventions involving MRI. The device is equipped with a patient support bed specifically designed to control the positioning of the patient's body, to optimize visualization of the cardiovascular system at rest and during exercise	37681000	II	10-①	applicable	applicable
Superconducting magnet mammographic MRI system	A magnetic resonance (MR) diagnostic imaging device specifically designed for breast imaging. The device uses a superconducting magnet, and can be stationary, mobile, or portable. The gantry designs include closed bore, open bore, and a variety of designs to allow the elements to be close to the patient. In addition to the conventional magnetic resonance imaging, the device can be designed to perform magnetic resonance (MR) spectroscopy and a variety of real-time imaging capabilities required in interventions,	37609000	II	10-①	applicable	applicable
Superconducting magnet whole body MRI system	A general-purpose magnetic resonance (MR) diagnostic imaging system (MRI) designed to scan any targeted area of the body (whole body imaging). The device uses a superconducting magnet, and can be stationary, mobile, or portable. Some types of device have MR spectroscopy and a variety of real-time imaging capabilities required in interventions, treatment, and surgical interventions involving MRI. The gantry designs include closed bore, open bore, semi-open, and a variety of designs to allow the elements to be close to the patient.	37654000	II	10-①	applicable	applicable
Superconducting magnet head/extremity imaging MRI system	A magnetic resonance (MR) diagnostic imaging device specifically designed to visualize the head, neck, or limbs using superconducting magnet technology. The devices for head or limb imaging are commonly of closed-bore designs with a cylindrical or rectangular opening; while some devices have open-bore designs. This category includes MR devices with conventional head or limb imaging capabilities, conventional devices with the ability to perform MR spectroscopy and other real-time imaging capabilities required in interventions and treatments involving MRI; and it is dedicated for MR spectroscopy.	37656000	II	10-①	applicable	applicable
Superconducting magnet cardiovascular MRI system	A magnetic resonance (MR) diagnostic imaging device specifically designed to visualize the cardiovascular system. The device uses a superconducting magnet, and can be stationary, mobile, or portable. The gantry designs include closed bore, open bore, and a variety of designs to allow the elements to be close to the patient. Some types of device have MR spectroscopy and a variety of real-time imaging capabilities required in interventions, treatment, and surgical interventions involving MRI. The device is equipped with a patient support bed specifically designed to control the positioning of the patient's body, to optimize visualization of the cardiovascular system at rest and during exercise stress tests, or during interventions.	37676000	II	10-①	applicable	applicable
Permanent magnet head/extremity imaging MRI system	A magnetic resonance (MR) diagnostic imaging device specifically designed to visualize the head, neck, or limbs using a permanent magnet. The devices for head or limb imaging are commonly of closed-bore designs with a cylindrical or rectangular opening; while some devices have open-bore designs. This category includes MR devices with conventional head or limb imaging capabilities, conventional devices with the ability to perform MR spectroscopy and other real-time imaging capabilities required in interventions and treatments involving MRI; and it is dedicated for MR spectroscopy.	37651000	II	10-①	applicable	applicable

Permanent magnet whole body MRI system	A general-purpose magnetic resonance (MR) diagnostic imaging system (MRI) designed to scan any targeted area of the body (whole body imaging). The device uses a permanent magnet, and can be stationary, mobile, or portable. In addition to conventional magnetic resonance imaging, the device can be designed to perform magnetic resonance (MR) spectroscopy, a variety of real-time imaging capabilities required in physiologically synchronized imaging, MRI mammography imaging, and other MRI-based interventions, treatment, and surgical interventions by adding software/hardware modules. The gantry designs include closed bore, open bore, semi-open, and a variety of designs to allow the elements to be close to the patient.	37652000	II	10-①	applicable	applicable
Permanent magnet mammographic MRI system	A magnetic resonance (MR) diagnostic imaging device specifically designed for breast imaging. The device uses a permanent magnet, and can be stationary, mobile, or portable. The gantry designs include closed bore, open bore, and a variety of designs to allow the elements to be close to the patient. In addition to conventional magnetic resonance imaging, the device can be designed to perform magnetic resonance (MR) spectroscopy and a variety of real-time imaging capabilities required in interventions, treatments, and surgical interventions involving MRI. The MR device for mammography is typically equipped with a dedicated patient support bed specifically for the purpose of controlling the positioning of the patient's body to optimize	37659000	II	10-①	applicable	applicable
Permanent magnet cardiovascular MRI system	A magnetic resonance (MR) diagnostic imaging device specifically designed to visualize the cardiovascular system. The device uses a permanent magnet, and can be stationary, mobile, or portable. The gantry designs include closed bore, open bore, and a variety of designs to allow the elements to be close to the patient. Some types of device have MR spectroscopy and a variety of real-time imaging capabilities required in interventions, treatment, and surgical interventions involving MRI. The device is equipped with a patient support bed specifically designed to control the positioning of the patient's body, to optimize visualization of the cardiovascular system at rest and during exercise stress tests, or during interventions.	37682000	II	10-①	applicable	applicable
MRI system radio-frequency coil	Radiofrequency (RF) coils can be transmitters, receivers, or transceivers of RF pulses required for magnetic resonance imaging (MRI). The device is used to improve signal-to-noise characteristics, thereby improving image resolution. RF coils can roughly be divided into two types: volume coil (a coil surrounding the part of body to be imaged), and surface coil (a coil that is placed directly on the surface of a region of interest, or under the region and is fixed). This category includes RF coils with a variety of designs and shapes, including surface coil, phased-array coil, saddle coil, Helmholtz coil, and	40749000	II	10-①	applicable	applicable
MRI system workstation	A standalone image-processing workstation that is designed to be networked with one or more magnetic resonance imaging (MRI) systems. The workstation may have any type of hardware, or any type of configuration. The MRI workstation differs from an operator console in that it does not have a control to directly manipulate the diagnostic imaging device. The device allows data transfer either on-line or off-line, and is typically situated away from the MRI operator console. The device has a configuration in which the patient's images and information collected by the MRI system are further processed to provide viewing capabilities. Only those devices capable of providing information that allows decision-making, evaluation, or diagnosis of the patient's	40940000	II	10	applicable	applicable

Computed radiography	A device that acquires an X-ray image stored in a photostimulable phosphor screen by laser beam scanning or the like; the data are then processed by a computer and converted into digital data to be output. The digital data are transmitted to an image-processing device or image recording device and used as images for diagnosis. The device uses photostimulable phosphor screens. In some cases, photo-stimulable fluorescent screen cassette may be used in combination.	70023000	II	10	applicable	applicable
Film-recorded digital radiography	An image input device that reads out medical images recorded on X-ray film to produce digital images in an indirect manner. The device, which consists of the film transport system, a stabilized light source such as a laser or halogen lamp, an optical system including a polygonal mirror, and a photoelectric conversion sensor, has higher precision and higher density readout capabilities compared to consumer electronics image readout devices. Generated digital images can include additional information such as the patient's ID, and can be stored in the image server, allowing the user to	70024000	II	10	applicable	applicable
Electronically recorded digital radiography	A digital image acquisition system in which X-rays passed through a human body are captured by an X-ray image intensifier/TV camera, and analog output signals are captured after analog-to-digital conversion to an image processing device to receive digital images. Digital images can be optimized by image processing technology including gamma correction and edge enhancement. The real-time capability allows video image capture. When recorded on the media, image data are also distributed through the network as needed, facilitating viewing, storing, and retrieving image data.	70025000	II	10	applicable	applicable
X-ray flat panel detector-recorded digital radiography	A digital image acquisition system in which X-rays passed through a human body are captured by an X-ray flat panel detector, and digital output signals are supplied to an image processing device to receive digital images. If necessary, image processing technology including gamma correction and edge enhancement are applied to digital images. Image data are either recorded on the media, or output to a server or other external devices for recording.	70026000	II	10	applicable	applicable
X-ray tube housing assembly	A component consisting of an X-ray device for diagnostic or treatment purposes. The housing is a container made of steel, cast aluminum, or aluminum alloy and part of the interior wall is lined with lead to provide shielding against X-ray leakage occurring during patient examination or treatment procedures. This housing assembly is intended to be at ground potential, and is filled with insulated oil. This prevents electrical arcs from the high-voltage applying electrodes of the X-ray tube and high-voltage cables to surrounding objects, including the patient and operator. The housing	35618000	II	10	applicable	applicable

Stationary diagnostic X-ray generator	A generator which is an essential component of a stationary diagnostic X-ray system intended to be operated at a fixed location within a facility or an X-ray inspection vehicle. The device regulates incoming voltage and current to provide an X-ray tube with the electric power needed to produce an X-ray beam at the desired voltage (kV) and current (mA). Typically, the device may be composed of a control assembly (console) and high-voltage transformer assembly; alternatively, the device may use a mono-tank type design for high-voltage devices. Designs for transformers, constant-voltage inverters, and capacitor-discharge high-voltage devices are incorporated. Devices for treatment are excluded.	37604010	II	10	applicable	applicable
Stationary integral diagnostic X-ray generator	A generator which is an essential component of a stationary diagnostic X-ray system operated from a fixed place in a facility or an X-ray inspection vehicle. The device adjusts the received voltage and electric current, and supplies the X-ray tube with the electricity necessary for generating X-ray beams at the required voltage (kV) and current (mA). Generally, the device consists of a control assembly (console) and a high-voltage transformer, or sometimes it incorporates a mono-tank high-voltage generator in the design. It incorporates a transformer, constant voltage, an inverter, and a capacitor discharge high-voltage generator in the design. The type for therapeutic use is excluded. An X-ray generator is integrated into the device.	37604020	II	10	applicable	applicable
Mobile diagnostic X-ray generator	A X-ray generator with special size, weight, and power requirements, suitable for use in a mobile radiography system, which is intended to be operated at different locations within a facility. The device regulates incoming voltage and current to provide an X-ray tube with the electric power needed to produce an X-ray beam at the desired voltage (kV) and current (mA). Designs for transformers, inverters, and capacitor-	37605010	II	10	applicable	applicable
Mobile integral diagnostic X-ray generator	A X-ray generator satisfying the requirements of special size, weight and power source appropriate for mobile X-ray equipment which is designed so that it can be moved to various places within the facility. The device adjusts the received voltage and electric current, and supplies the X-ray tube with that electricity necessary for generating X-ray beams at the required voltage (kV) and current (mA). It incorporates a transformer, an inverter and a high-voltage generator (capacity discharge type) in the design. Generally, the device consists of a control assembly (console), and a high-voltage transformer. However, it incorporates a mono-tank high-voltage generator in the design. This device is an essential component of mobile diagnostic X-ray	37605020	II	10	applicable	applicable
Portable diagnostic X-ray generator	A X-ray generator with special size, weight, and power requirements, suitable for use in a portable radiography system, which is intended to be disassembled, and then re-assembled after moving to different locations. The device regulates incoming voltage and current to provide an X-ray tube with the electric power needed to produce an X-ray beam of desired voltage (kV) and current (mA). Designs for high-voltage devices for this category include transformer and inverter types. Typically, the device may be composed of a control assembly (console) and high-voltage transformer assembly; alternatively, the device may use a mono-tank type design for high-voltage devices.	37606010	II	10	applicable	applicable
Portable integral diagnostic X-ray generator	A X-ray generator satisfying the requirements of the special size, weight and power source appropriate for portable X-ray equipment which can be taken apart and reassembled in various places. The device adjusts the received voltage and electric	37606020	II	10	applicable	applicable
Infrared thermography system	A system that utilizes infrared photography techniques and other infrared techniques to produce images and graphs of body surface temperature distribution in order to diagnose and evaluate various conditions and diseases. This device is also called a	40803000	II	10-③	applicable	applicable

Thermography system operator console	A console for an operator functions as the main control panel for a thermography system. Depending on the configuration of the system, this is equipped with hardware and software that enable display, processing and analysis of images as well as image archiving including storage and retrieval of images. It is one of the components of a thermography system, and has connectivity to the general PACS, local area network, DICOM, etc.	40972000	II	10	applicable	applicable
Powered liquid crystal thermography system	An electric device that produces, displays, and analyzes images or graphs of the distribution of body surface temperature for the purpose of diagnosis and evaluation of clinical status or medical conditions. Sheets made from a cholesteric liquid crystal based material are enclosed in the outer layer of a blanket, pillow, mattress, or other materials placed surrounding the body. Cholesteric liquid crystals change in color with surface temperature of the body area that is in contact with the material containing	40798002	II	10	applicable	applicable
Microwave thermography system	A system that utilizes microwave generation and detection technologies to produce images and graphs of body temperature distribution in order to diagnose and evaluate various conditions and diseases. This device is sometimes called a microwave thermography probe or microwave scanning system. Generally, this thermography system consists of a microwave generator (probe), a microwave detector, a thermal	40802000	II	10-①	applicable	applicable
Diagnostic X-ray imaging system workstation	A standalone image processing workstation specifically designed for use with X-ray based diagnostic imaging system, such as digital radiography systems, X-ray computed tomography (CT) systems or fluoroscopy systems. The workstation may have any type of hardware, or any type of configuration. The device may be regarded as a component of a picture archiving and communication system (PACS). The workstation differs from	40935000	II	10	applicable	applicable
Ultrasound imaging system workstation	A standalone image-processing workstation that is designed to be networked with one or more ultrasound imaging systems. The device may be regarded as a component of a picture archiving and communication system (PACS). The ultrasound workstation differs from an operator console in that it does not have a control to directly	40936000	II	10	applicable	applicable
Electrical impedance scanner	An electrical impedance scanner (EIS), also referred to an impedance imaging system, is a real-time 2D multi-frequency imaging system. This device is generally designed to be a movable. Extremely low-voltage electric signals are sent via reference electrode attached to the body surface, which generates impedance. The device is used to map	42183000	II	10-①	applicable	N/A
General-purpose imaging system workstation	A standalone imaging workstation specifically designed to use with diagnostic imaging devices, including digital X-ray, X-ray computed tomography (CT), fluoroscopy, magnetic resonance imaging (MRI), gamma camera, PET, and SPECT devices. The workstation may have any type of hardware, or any type of configuration. The device may be regarded as a component of a picture archiving and communication system	70030000	II	10	applicable	applicable
Optical coherence tomography (OCT) imaging system	An OCT (optical coherence tomography) diagnostic imaging system which diagnostically represents the images of tissue characteristics and shapes of various sites (e.g., heart, blood vessel, abdomen, lung) using near-infrared rays, without the need to obtain tissues surgically. This system contains a software package that supports the taking of both still and real-time images, and is used to diagnose anatomic abnormalities in tissues and to examine functional and anatomic	70031000	II	10-①	applicable	applicable
Manually-operated contrast medium injector system	A manually-operated mechanical system used to control the volume and speed of the contrast media infused into the blood or lymph vessels under pressure in imaging diagnosis. Generally, this system consists of a calibrated syringe, a syringe holder and a housing unit. The housing unit is placed on a table or floor stand, or permanently installed in the system.	40721000	II	11	applicable	applicable

Powered multiphase contrast medium injector system	A device operated by line- or battery-powered, low- or high-pressure contrast medium injector intended to allow the operator to specify a baseline contrast medium injection flow rate, to program sequential changes in the flow rate during injection, and to determine the total volume of contrast medium to be injected. The system is typically	40723000	II	11	applicable	applicable
Powered single-phase contrast medium injector system	A device operated by line- or battery-powered low- or high-pressure contrast medium injector intended to allow the operator to determine the total contrast medium volume to be injected, and to specify a constant flow rate for a particular injection of the contrast medium. The system is typically used in X-ray CT, fluoroscopy/angiography, magnetic resonance imaging (MRI), ultrasound, and other examinations. Only nonmagnetic materials are used to make fixed-type contrast medium injection devices	40724000	II	11	applicable	applicable
Barium enema contrast medium delivery/evacuation kit	A device intended to inject or discharge barium sulfate suspension (contrast medium) or air into the digestive tract during a lower gastrointestinal tract examination, consisting of a container and a tube.	40725000	II	11	applicable	applicable
Radioactive compound injector	A device intended to inject a radioactive agent or radiopharmaceutical into the subject for PET examination.	70032000	II	11	applicable	applicable
Electronic thermometer	A measurement device for determining the patient's body temperature. The device consists of a display unit, sensor, and other elements, and is intended to detect body temperature and convert it to some electric characteristic (e.g., resistance or voltage). These electric characteristics are processed in the electronic circuits, and the highest temperature value is retained and then digitally displayed as a temperature reading.	14032010	II	10-③	applicable	N/A
Continuous measurement electronic thermometer	A measurement device for determining the patient's body temperature. The device consists of a display unit, attached sensor, and other elements, and is intended to detect changes in body temperature and convert these values to some electric characteristic (e.g., resistance or voltage). These variations in the electric characteristics are processed in the electronic circuits, and are displayed continuously as temperature readings.	14032020	II	10-③	applicable	applicable
Zero heat flow method thermometer	A thermometer intended to continuously determine the deep body temperature to the area of the body on which the measuring probe is placed. The heater, located inside the probe, is controlled in such a way that no heat flow exists between the deep tissue and the body surface, enabling temperature measurement of the deep tissue below the surface site	70043000	II	10-③	applicable	applicable
Ear infrared thermometer	A measurement device for determining the patient's body temperature. The device is typically designed to estimate deep body (core) temperature by measuring infrared of the auditory canal. Some types of devices indicate temperature readings by directly measuring infrared radiation from the eardrum. The device may indicate corrected readings (offsets) of axillary, oral cavity, or rectal temperature readings.	17887000	II	10-③	applicable	N/A
Skin infrared thermometer	A measurement device for determining the patient's body temperature. This device is designed to measure the infrared emissions from the skin of specific site (e.g., armpit or forehead) to estimate the temperature at the site. Some types of devices have capabilities to convert a temperature into an oral cavity or rectal temperature	17888000	II	10-③	applicable	N/A
Phosphorescent/fibreoptic thermometer	A measurement device to measure a patient's body temperature. This device usually utilizes a fiber-optic probe which incorporates a small temperature sensor based on physical properties (e.g., liquid crystal structure, polarization rotation) which change depending on phosphorescence decay time or other temperature	35942000	II	10-③	applicable	applicable
Reusable active device connected thermometer probe	A device intended to connect to a thermometer, which is usually inserted into a body opening for temperature measurement. The device is intended for short-term use in body orifices (excluding the oral cavity up to the pharynx, external auditory canal up to the eardrum, and nasal cavity) and can be cleaned, disinfected, or sterilized for	37340002	II	5-⑥	applicable	—

Automatic electronic sphygmomanometer	An electronic device to be used in indirect (noninvasive) measurement of blood pressure. The device is intended for self-measurement of blood pressure at home under a physician's supervision, for the purpose of self-management of blood pressure by the user. The user must be informed of the maximum allowable cycles, which are 30,000.	16173000	II	10-③	applicable	N/A
Medical electronic sphygmomanometer	An electronic device to be used in indirect (noninvasive) measurement of blood pressure. Appropriate capabilities, automated or manual cuff pressurization, and the like are performed using a stored software. In addition to systolic and diastolic pressures, it also usually displays heart rate and mean arterial pressure. Automatic electronic sphygmomanometers are not included.	16173010	II	10-③	applicable	applicable
Manually-operated electronic sphygmomanometer	An electronic device to be used in indirect (noninvasive) measurement of arterial blood pressure. The arm cuff pressurizes manually. The measurement reading is usually displayed on the electronic monitor.	16174000	II	10-③	applicable	N/A
Counterpressure sphygmomanometer	An automatic electronic sphygmomanometer that measures the change in blood volume taking place in a single finger. The device uses a cuff wrapped around a finger, which exerts counter pressure just sufficient to equal the arterial pressure (so that there is no change in arterial volume), or a sensor placed on the tip of a finger, which emits visible light and detects pulse waves, thereby detecting subtle changes in	16986000	II	10-③	applicable	applicable
Central/peripheral venous pressure monitor	A device that measures and records invasive central or peripheral venous blood pressure measurements, or the difference between the central and peripheral venous pressures of the patient using an indwelling catheter and a pressure manometer.	34931000	II	10	applicable	applicable
Long-term sphygmomanometer data recorder	A device intended to be carried by the patient to record long-term (24 hours) blood pressure. Recorded data are downloaded to the analyzer at the hospital for analysis.	36888000	II	10	applicable	applicable
Ocular plethysmograph	A device intended for the evaluation of changes in blood flow rate in the eye. Obtained data may be used for the calculation of ophthalmic artery pressure. Some devices may contain suction or air-filled eye cups or a contact lens-type testing device with a pulse sensor or pressure sensor such as a transducer. Some devices are intended for detection and evaluation of stenosis or occlusion of carotid artery in stroke prevention programs, or evaluation of other diseases associated with the blood flow state in the internal carotid artery.	33384000	II	10	applicable	N/A
Pressure/pulse wave testing equipment	A device intended to measure noninvasive blood pressure in the extremities, and to analyze by measuring once, multiple times, or simultaneously the electrocardiogram, phonocardiogram, carotid sphygmogram, finger plethysmogram, sphygmogram of the femoral artery, anhydromogram of the extremities, etc. Some include apparatuses, etc. to	70045000	II	10-①	applicable	applicable
Single-use intravenous line manometer set	A set consisting of a manometer, 3-way stopcock, and extension tubing, intended to measure central venous pressure by the water manometer method. One end is connected to the central venous catheter, and the other end is connected to the IV solution set.	70046002	II	2-①	applicable	—
Electronic stethoscope	An electronic listening device that detects and amplifies very weak internal body sounds that cannot be detected with ordinary acoustic stethoscopes. Some types of device are capable of distinguishing heart sounds and intensified sounds (e.g. blood	13754000	II	10	applicable	N/A
Ultrasonic stethoscope	A portable device specifically designed for detecting blood flow using sound waves. The device usually has built-in earpieces, and uses ultrasound waves used to assess arterial and venous blood flow in patients with circulatory disturbance.	13756000	II	10	applicable	N/A
Magnetocardiograph	A device that uses superconducting sensor technology (a SQUID fluxmeter) to measure noninvasively the weak magnetic field generated on the surface of the chest in association with cardiac activity and analyze the data.	70047000	II	10	applicable	applicable

Magnetoencephalograph	A device that uses superconducting sensor technology (a SQUID fluxmeter) to measure noninvasively the weak magnetic field generated on the scalp-surface in association with by neural activity and analyze the data.	70048000	II	10	applicable	applicable
Magnetomyograph	A device that uses superconducting sensor technology (a SQUID fluxmeter) to measure noninvasively the weak magnetic field generated on the surface of the body in association with muscle neural activity and analyze the data.	70049000	II	10	applicable	applicable
Thermal dilution cardiac output unit	A unit for measurement of cardiac output using the indicator dilution method. A thermal indicator (cold saline solution or other solution) is injected into the blood entering the heart, and the change in temperature of the blood ejected from the heart	10615010	II	10	applicable	applicable
Thermal dilution cardiac output unit with thermal coil	A device designed for the cardiac output measurement using a catheter with a thermal coil. The thermal coil heats the blood entering the heart, and the change in temperature of the blood ejected from the heart is monitored using a flow-directed balloon catheter equipped with a temperature probe at its tip. The measured results are displayed on the device.	10615020	II	10	applicable	applicable
Dye dilution cardiac output unit	A unit for measurement of cardiac output using the indicator dilution method. An indicator dye is injected into the blood entering the heart, and the change in the concentration of dye in the blood ejected from the heart is monitored using a flow-directed balloon catheter. The measured results are displayed on the device.	16177000	II	10	applicable	applicable
Impedance cardiac output unit	A unit that determines cardiac output based on measurement of thoracic impedance changes associated with cardiac activity. The measured results are displayed on the device.	17496000	II	10	applicable	applicable
Ballistocardiograph cardiac output unit	A device used to record the body movement (toward the head and feet) caused by cardiac protrusion when blood is ejected by cardiac contraction. A patient is placed on a special table carefully balanced so that the transducer, which reproduces the properties of a ballistocardiogram, can sense vibrations of the body. This device is used	10266000	II	10	applicable	applicable
Direct Fick cardiac output unit	A unit to measure blood flow from the heart according to the Fick method. With this method, cardiac output is calculated as the value obtained by dividing total oxygen consumption by the difference in the oxygen content between arterial blood and mixed venous blood. This device can measure all parameters (including the mixed venous oxygen content) and display the measured values. Note: Fick's law of diffusion: A principle that the material added in a solution tends to diffuse in the way that the concentration of the entire solution becomes uniform.	10614000	II	10	applicable	applicable

Thermal dilution cardiac output unit infusion/withdrawal pump	A dedicated pump used with a thermal dilution cardiac output flowmeter. With this pump, the appropriate pharmaceuticals or pigments are injected exactly as planned and a blood sample is collected for measuring cardiac output.	13220000	II	11	applicable	applicable
Radioisotope cardiac output unit	A unit to measure blood flow from the heart using the indicator dilution method. This unit injects a radioisotope into the blood flowing to the heart, and monitors the blood from the heart. The measurement results are displayed on the unit.	15795000	II	10	applicable	applicable
Ultrasonic cardiac output unit	A unit that measures the blood flow from the heart using the ultrasonic Doppler effect. The measurement results are displayed on the unit.	17190000	II	10-①	applicable	applicable
Arterial waveform cardiac output unit	A unit that determines cardiac output from the change in arterial pressure waveforms. The measured results are displayed on the device.	70050000	II	10	applicable	applicable
Pulse contour cardiac output unit	A device that determines cardiac output continuously through pulse contour analysis. The device is used with a dedicated arterial catheter.	70051000	II	10	applicable	applicable
Polygraph	A physiological recorder used to record physiological parameters including the electrocardiogram, blood pressure, electroencephalogram, body temperature, and respiration.	13085000	II	10	applicable	applicable
Sleep assessment device	A device that usually records biological signals detectable during sleep, used in the evaluation of sleep disorders (e.g., insomnia, snoring, and sleep apnea). While the majority of devices are computerized, some are only used for the purpose of graphical	33843000	II	10	applicable	applicable
Non-central circulatory angiopolygraph	A device to examine vascular hemodynamics except in the heart.	70055000	II	7	applicable	applicable
Electromagnetic blood flowmeter	A device that provides confirmation and measurement of the blood flow velocity after coronary artery bypass surgery, organ transplantation and other forms of revascularization. This device utilizes invasive techniques; it uses a catheter inserted into the blood vessel or a probe encompassing the blood vessel exposed surgically without penetrating the vascular wall. It is also called an EM flowmeter.	10431000	II	10	applicable	applicable
Ultrasonic blood flowmeter	A noninvasive, or invasive ultrasonic Doppler device for blood flow measurement, intended for the identification of various blood flow disorders, e.g., thrombosis.	10432000	II	10-①	applicable	applicable
Doppler blood-flow measurement ultrasound system	A portable or stationary ultrasonic device that does not produce 2-dimensional or 3-dimensional images, and is intended to be used for determining various blood-flow related parameters of the heart, artery, or vein. The device is used to output audible data, or display the Doppler shift as a function of time, allowing comparison of normal and abnormal blood flow patterns for diagnosis. The continuous wave Doppler and	40759000	II	10	applicable	applicable
Laser blood flowmeter	A device that measures blood flow velocity using laser techniques, noninvasively or invasively, to identify impairment of blood flow (e.g., thrombus, stenosis, mechanical injury), and supports evaluation of the degree of the impairment.	16903000	II	10-①	applicable	applicable
Magnetic resonance blood flowmeter	A device that applies a quantitative method to check the adequacy of blood flow in patients with symptoms of peripheral vascular disease. This device senses a magnetic	18019000	II	10-①	applicable	applicable

Non-indwelling blood flow transducer	A device for measuring blood flow externally (extravascularly). The device is used together with a blood flowmeter. The device may measure the blood flow either inside the heart or over the outside of a blood vessel (formed as an open circle which is slid over the vessel, available in different diameters to fit the size of individual blood vessel). Some devices employ ultrasound or electromagnetic technology.	31657000	II	10-①	applicable	applicable
Spinal fluid pressure monitor	A device to measure direct spinal fluid pressure in the patient concerned when necessary as a result of hospitalization, treatment or diagnosis. It is a mechanical measuring device.	31319010	II	6	applicable	applicable
Electronic spinal fluid pressure monitor	A device to measure direct spinal fluid pressure in the patient concerned when necessary as the result of hospitalization, treatment or diagnosis. It is an electronic measuring device.	31319020	II	10	applicable	applicable
Intrauterine pressure monitor	A device used during treatment or diagnosis to measure directly intrauterine pressure which influences a patient.	33727000	II	10	applicable	applicable
Esophageal pressure monitor	A device used for the diagnosis related to the esophageal function and postoperative evaluation in esophageal manometry. This device may be the main component of the esophageal stethoscope.	35248000	II	10	applicable	applicable
Single-use pressure transducer	A device used to convert pressure into electric signals to display on the base unit. The device is intended for single-use.	35927000	II	2-①	applicable	—
Reusable pressure transducer	A device used to convert pressure into electric signals to display on the base unit. The device is reusable.	14119000	II	2-①	applicable	N/A
Reusable pressure transducer dome	A device (dome) to be connected with a pressure transducer to form a measurement system, for invasive blood pressure measurement or cerebrospinal fluid pressure measurement. Some types of device incorporate a stopcock and flushing device. The	37312000	II	2-①,2-②	applicable	N/A
Single-use pressure transducer dome	A device (dome) to be connected with a pressure transducer to form a measurement system, for invasive blood pressure measurement or cerebrospinal fluid pressure measurement. Some types of device incorporate a stopcock and flushing device. The pressure transducer is influenced by pressure in the medium that enters the measurement system through the device. The device is intended for single-use.	37257000	II	2-①,2-②	applicable	—
Fascial pressure monitor	An internal pressure meter that measures intrafascial pressure.	70056000	II	10	applicable	—
Barostat	A device that pumps air into a balloon inserted into the gastrointestinal tract including the esophagus, stomach, small intestine, large intestine, and rectum at a constant rate to measure the pressure changes associated with pumping as internal pressure data.	70057000	II	10	applicable	—
Infusion pump	A device that pumps a constant volume of water into a catheter in manometry of the gastrointestinal tract including esophagus, stomach, small intestine, large intestine, and rectum, when the pressure is measured with a transducer. In monitoring esophageal and gastrointestinal motility, measurement is made using the open-chip method.	70058000	II	10	applicable	—

Ophthalmic tonometer	A device specifically designed for intraocular pressure measurement.	16809000	II	10	applicable	applicable
Tonograph	A device for recording a graph of the change in intra-ocular pressure as the applied force is varied. A variety of tension recording systems are used, such as an air-puff tension recording system, which records deflections of the cornea in reaction to a puff of pressurized air; and an applanation tonometry recording system and the like, which records the force necessary to impress or flatten the cornea surface.	35399000	II	10	applicable	N/A
Single-use applanation tonometer measuring prism	A single-use sterile device designed to be used in combination with an applanation tonometer for evaluation of the contact area of the cornea.	70059000	II	10	applicable	—
Phonocardiograph	A device that records heart sounds on the body surface. Vibrations caused by cardiac activity are transmitted to the body surface via the organs and tissues and are detected by a microphone. The vibrations are processed with an electric filter, and the sound properties of the phonocardiograms are obtained. The device is used to evaluate lower frequencies (atrial or ventricular gallop) and higher frequencies (mitral	13017000	II	10	applicable	applicable
Fetal heart phonodetector	A device that detects fetal heart sounds sonically, utilizing ECG with a function to capture heart sounds.	35067000	II	10	applicable	applicable
Ultrasonic fetal heart detector	A device that uses ultrasonic waves to transduce the data of fetal heart beat into audible sound.	35068000	II	10-①	applicable	applicable
Heart rate monitor	A device that measures and displays a patient's heart rate (beats/min). This device is usually used during exercise stress testing.	35197000	II	10	applicable	applicable
Pulse rate meter	A device that measures the pulse rate per minute when a change in intravascular pressure, which is generated when the blood is pumped out to the aortic root by cardiac contraction, propagates itself peripherally. Measurement is made using methods related to pressure, photoelectrical strain gauge, and impedance.	70061000	II	10	applicable	applicable
Heart sound transducer	A device intended to be placed on the chest to detect sounds coming from the heart valves.	33315000	II	10	applicable	applicable
Single-use body orifice thermometer probe	A device intended to connect to a thermometer, which is usually inserted into a body opening for temperature measurement. The device is intended for short-term use in body orifices (excluding the oral cavity up to the pharynx, external auditory canal up	35254002	II	5-⑥	applicable	—

Electroacoustic transducer	A device used to detect oscillations that are generated by the activity of the heart and transmitted to the body surface via organs and tissues. The device generally consists of a microphone and signal-transmitting components. The device is used together with other devices including a phonocardiograph.	37336000	II	10	applicable	applicable
Ultrasound probe for cystometer	An ultrasonic probe used with a cystometer utilizing ultrasound technology. This device generates ultrasounds of relatively low frequencies.	37804000	II	5-⑥	applicable	applicable
Cystometer	A device used for examination of the bladder to obtain measurement data related to pressure and volume. These data are used for diagnostic evaluation of the neuromuscular mechanism of the bladder. It can also measure postvoid residual volume. The operation modes include mechanical, ultrasonic, or combined modes.	11111000	II	10-①	applicable	applicable
Partial-body plethysmograph	A device that measures and records the change in the volume of the organ, the body part, or the limb. This is also used to record the blood volume present in the area examined and the volume passing through the area. Many measuring techniques may	13056000	II	10	applicable	applicable
Urodynamic measurement system	A system intended for diagnosis and testing of urinary bladder function. The device is used to identify causes of micturition abnormalities (including incontinence). The device is useful for the diagnosis of conditions including neurogenic bladder, urinary stress incontinence, urinary obstruction, and a spastic urinary sphincter. A diagnostic	14307000	II	10-①	applicable	applicable
Portable penile tumescence data recorder	A device that monitors the erection of the penis (erection tendency). The patient carries the device and records the erectile function (e.g., length, thickness, duration). The recorded data are used to diagnose penile dysfunction (e.g., impotence).	33890000	II	10	applicable	N/A
Whole body plethysmograph	A device that measures and records volume changes in the body. The device is usually constructed of metal, plastic, and glass, and is often used for pulmonary function studies. The unit consists of an airtight chamber in which the patient is placed, and a spirometer, which is used to determine lung volume changes of the patient and airway resistance.	35242000	II	10	applicable	applicable
Compartmental pressure monitor	A device used to measure increased intramuscular pressure caused by compartmental syndrome. Compartment syndrome is disease attributable to swelling in the muscular compartment and the myelin sheath.	35997000	II	10	applicable	applicable
Pressure amplifier	An amplifier used to measure pressure (e.g., blood pressure). This device group may reflect conventional techniques.	36748000	II	10	applicable	applicable

Phonocardiograph/pulse wave unit	A heart sound/pulse wave unit to obtain a recording of heart sounds and pulse waves by connecting to the electrocardiograph or the electrocardiographic analysis system. In order to comprehensively diagnose cardiac function, this unit simultaneously records the electrocardiogram, combined with the carotid pulse wave, apex beat, digital pulse volume, phonocardiogram, etc.	70062000	II	10	applicable	applicable
General-purpose electrocardiograph	A device used to detect, register, and record electric signals generated as a result of activities of the heart, and to reproduce such signals (voltage versus time) as an electrocardiogram (ECG) for later use. The ECG is usually reproduced in the form of a printout; however, in some types of device, it is displayed on a monitor, or using digital media. The device may have other capabilities (e.g., single channel or multi-channel	11407010	II	10	applicable	applicable
Long-term electrocardiographic data recorder	A device that records cardiac activity over 24 hours. During recording, the device is connected to and carried by the patient. Signals are stored on a cassette tape (magnetic tape) or digital media (non-movable parts). Recorded data are analyzed at	35162000	II	10	applicable	applicable
ECG recorder with real-time analysis	A device that performs real-time analysis of measured electrocardiogram (ECG) signals, and records abnormal waveforms present on ECG.	70063000	II	10	applicable	applicable
Holter analyzer	A device used to analyze a patient's long-term (usually, 24-hour) cardiac activity, previously recorded using an ambulatory monitoring device connected to the patient. The device is used with an ambulatory long-term electrocardiogram (ECC) monitoring	36827000	II	10	applicable	applicable
Computer for electrocardiogram interpretation	A dedicated computer with special cardiac software installed. It is used to read waves obtained in the electrocardiograph (ECG). The pre-specified pattern recognition technology is utilized to read the waves. Electrocardiographic signals registered are compared with the pre-defined diagnostic criteria.	34972000	II	10	applicable	applicable
Cardiac stress exercise monitoring system	A stress exercise device designed to record electrocardiogram (ECG) signals from electrodes placed on the patient's limbs and chest while the patient exercises in varying amounts, using a treadmill, ergometer, or other device. The device usually analyzes recorded data, displays results, monitors functions, controls patient workload and prints out results, thereby providing physicians with a representation of general	36145000	II	10	applicable	applicable
ECG telephonic transmission equipment	A device that uses communication methods (e.g., phone) to transmit electrocardiogram (ECG) signals measured on the patient.	70064000	II	10	applicable	applicable
Apex cardiograph	A device used to record pulsations at the left ventricular apex in the precordium. This device senses motion (vibration) of the soft tissues within the intercostal spaces with a non-invasive transducer, and reproduces the properties on the apex cardiogram. It is used to assess left ventricular function.	10164000	II	10	applicable	applicable
His bundle detector	A device to detect disorders of impulse conduction in the bundle of His (atrioventricular) from the atrium to the cardiac ventricle. The bundle of His is a collection of electrical fibers in the heart that conduct the electrical impulses that regulate the heartbeat	12009000	II	10	applicable	applicable

Impedance cardiograph	An electrocardiograph used to record variations in chest electric impedance generated by myocardial activity. Usually, detection is performed on the body surface. A graph of sequential variations in impedance (impedance cardiograph) is recorded. This electrocardiograph is used to examine myocardial activity to diagnose specific cardiac abnormalities and to detect trends and variations in cardiac function.	12103000	II	10	applicable	applicable
Vector cardiograph	An electrocardiograph (ECG) device used to record a series of changes in the magnitude and direction (vector) of the potential in a complete cardiac cycle. Some devices display electric signals as a loop (representing the 2-dimensional projection of	14345000	II	10	applicable	applicable
Cardiokymograph	An electrocardiograph that records heart wall motion (mainly motion of the left ventricular anterior wall) on an amplitude vs. time graph (heart kymograph). The device utilizes a transducer (e.g., a flat coil) fixed to the chest by a strap as a part of	16522000	II	10	applicable	applicable
Ischemia monitoring system module	A small dedicated device used for measurement of ischemia (a decrease in blood supply to a part of the body) detected through connected cables/lead codes including 12-lead ECG cables placed on the body based on the vector method. It is designed to work as a	37249000	II	10	applicable	applicable
Exercise stress test computer	A dedicated computer used to interpret various physiological parameters, wave forms obtained during stress testing (exercise stress testing), and a special software package is installed in it. Using pre-specified pattern recognition technology, signals are transmitted from exercise testing devices, such as an ergometer, connected to the	35447000	II	10	applicable	applicable
Electrocardiograph amplifier	An amplifier used in conjunction with an electrocardiograph (ECG). This device group may reflect conventional techniques.	36719000	II	10-③	applicable	applicable
Multi-function electrocardiograph	A device that records and displays electrocardiograms either manually or automatically, and is also capable of analyzing recorded electrocardiograms, recording	11407020	II	10-①	applicable	applicable
ECG and blood pressure Holter recorder	A device that records electrocardiograms and noninvasive intermittent blood pressure measurements continuously, for a long period of time.	70066000	II	10-①	applicable	applicable
Cardiac event recorder	A device that is carried or worn by the patient, and records or transmits cardiac activity (e.g., electrocardiogram and heartbeat) upon activation by the patient. Recorded data are analyzed using an analyzer or computer with special software at the medical institution.	70067000	II	10	applicable	applicable
Electrocardiograph with ultrasound diagnostic system	A system integrates an electrocardiograph, which is capable of recording the standard 12-lead electrocardiogram (ECG) and analyzing the ECG, and devices such as a general-purpose ultrasound diagnostic device. In addition to ECG recording and analysis capabilities, the device is capable of ultrasound diagnosis of the abdomen, the	11407030	II	10-①	applicable	applicable
Electroencephalograph	A device used to record potential changes that are generated as a result of electrical activity of the brain, usually detected on the surface of the scalp. Electric signals are transmitted to the recorder from leads placed on the scalp and the ear lobes, reproducing their characteristics as an electroencephalogram (EEG). The device is	11467010	II	10-①	applicable	applicable
Visual evoked response stimulator	A stimulation device that provides visual stimulation to the eye of a patient (e.g., pattern change). Usually, it is either an optical stimulator in which the stimulus is transmitted through an optical system to the eye or a direct-view stimulator in which	35373000	II	10-①	applicable	applicable
Auditory evoked response stimulator	A stimulation device that provides appropriate stimulation of the auditory system. The device is used for the measurement of evoked responses, activation of the electroencephalogram (EEG), and other purposes.	35368000	II	10-①	applicable	applicable

Fetal auditory evoked response stimulator	A stimulation device that uses acoustic stimuli to evaluate fetal health. The device, which consists of a sound source providing vibroacoustic pulse stimulation, is placed on the abdominal region of the pregnant woman corresponding to the top of the head of the fetus. The device is used in prenatal tests or monitoring of the labor to evaluate the condition of the fetus based on the change in fetal heartbeat, acid-base balance and other factors.	36159000	II	10-①	applicable	applicable
Electroencephalographic spectrum analyzer	A device used to display frequency components of electroencephalogram (EEG) signals and power spectral density.	35777000	II	10	applicable	applicable
Brain electric activity mapping equipment	A device used to analyze and display the action potential distribution map of measured electroencephalogram signals.	11467020	II	10	applicable	applicable
Magnetic stimulator	A device that uses magnetic fields to stimulate certain areas of the central or peripheral nervous system.	36902000	II	10-①	applicable	applicable
Scalp electroencephalographic electrode	A conductor placed in the scalp to record changes in electrical potential in various areas in the brain. This electrical activity is generally recorded by an	11440002	II	6	applicable	—
Long-term electroencephalograph data recorder	A device carried by the patient for long-term electroencephalogram (EEG) recording (24 hour-recording). The data are deciphered by the long-term EEG analysis device for detailed assessment	35163000	II	10	applicable	applicable
Epilepsy alarm	A device that sends out an alarm signal as a warning for signs of epileptic seizure.	36693000	II	10	applicable	applicable
Electroencephalograph amplifier	An amplifier used in the electroencephalograph (EEG). This device group may reflect conventional techniques.	36740000	II	10	applicable	applicable
Long-term recording electroencephalographic analyzer	A device used to analyze the long-term neural activity (usually brain activity for 24 hours) previously recorded with a recording device that is attached to a patient and carried by the patient	36901000	II	10	applicable	applicable
Electromyograph	A graphic recorder that is used for the measurement and recording of the intrinsic electrical potential of skeletal muscle. The device is usually used in the clinical diagnosis of myopathy, to evaluate muscle weakness, and to determine whether weakness is related to the muscle itself or nerves connected to the muscle.	11474000	II	10-①	applicable	applicable
Electromyograph electrode	A conductor that is inserted into the muscle or nervous tissue to detect bioelectric signals. These devices are usually needle electrodes. The electrical activity detected by the device is generally called an electromyography (EMG).	11441002	II	6	applicable	—

Electrically-evoked response stimulator	A device used to provide electrical stimulation using skin electrodes to measure the evoked response.	32516000	II	10-①	applicable	applicable
Facial nerve stimulator	A device used to test the viability of facial nerve branches during the diagnostic and clinical assessment of facial paralysis (e.g., Bell's palsy), or when facial nerves have been damaged due to surgical procedures. Some devices can test muscle contractility independent of innervation. During facial surgery, the device is useful in locating nerve branches and identifying potential damage to facial nerve	35724000	II	10-①	applicable	applicable
Somatosensory nerve electrical stimulator	An electrical stimulator used to apply precisely timed and repeatable stimuli to the peripheral nerves. The device is usually a multiple-channel external stimulator that uses external surface electrodes or invasive (i. e. , needle) electrodes. The device is used for evoked-potential procedures and also for other research procedures (e.g.,	35726000	II	10-①	applicable	applicable
Diagnostic neuromuscular electrical stimulator	A stimulator designed to apply stimuli to a peripheral region while monitoring the response in a different peripheral region. The device usually has simpler design and capabilities than a treatment neuromuscular stimulator does. Most diagnostic neuromuscular stimulators use external electrodes (e.g., hand-held bipolar electrodes, ring electrodes, and needle electrodes) to stimulate highly localized areas. These devices are used to stimulate a peripheral nerve or muscle during motor-nerve conduction studies (e.g., posterior tibial nerve) or sensory-nerve conduction studies	35729000	II	10-①	applicable	applicable
Cardiac electrophysiology stimulation system for diagnostic	A programmable stimulator that delivers precisely timed electrical impulses to the heart at the time of spontaneous rhythm or pacing. This device can be used in asynchronous or synchronous mode to provide various stimulations. For pacing, a wide range of cycle lengths (usually 150 to 1500 ms) can be applied. The device is used for cardiac physiological testing, such as for determining the function of each component of atrioventricular conduction, assessing factors necessary to induce and stop tachycardia, and the sinus node function.	35974000	II	10-①	applicable	applicable
Electric stimulator needle electrode	A conductor used to apply electrical current to tissue. In using, a pair of cathode and anode is needed. These are usually called needle electrodes.	34374102	II	6	applicable	—
Subcutaneous stimulator probe	A subcutaneous probe specifically designed to be used with a stimulator.	36957002	II	6,6-①	applicable	—
Electromyograph amplifier	An amplifier intended to be used to perform electromyography (EMG). Devices in this category may reflect conventional technology.	36728000	II	10	applicable	applicable
Physiological signal conditioner	A device used to record, process, or display biological signals (e.g., integrator and differentiator). Only devices intended to be used off-line are included.	32520000	II	10	applicable	applicable
Auditory evoked response audiometer	An electronic acoustic device used to evaluate the activity of the auditory nervous system in response to an acoustic signal at the ear. Signals (detected via scalp electrodes) may be measured only by computer averaging and signal processing	35747010	II	10	applicable	N/A

Evoked response computer	A device that measures biological signals generated in response to stimuli, and performs averaging and other data analysis processing.	70068000	II	10-①	applicable	applicable
Obstetric perinatal physiologic data analyzer	A device used during labor to analyze electronic signal data obtained from a maternal/fetal monitor. With this device, the condition of the fetus can be clinically diagnosed, and recommendations are provided regarding delivery management and clinical intervention. This device may be equipped with a signal analyzer, an indicator and an electronic interface with another device.	32626000	II	10	applicable	applicable
Obstetrical prenatal physiologic data analyzer	A device that uses a microcomputer to assess and report fetal growth based on information obtained from ultrasonography. A hand-held pocket-type with a built-in computer (a programmed calculator) is available. Data are entered manually in this type. On the other hand, a large desk-top type can provide hard-copy reports, enter data automatically, and store reports for later data search and review.	43007000	II	10	applicable	applicable
Cystoscopic electrode	A conductor to record the electrical activity of the bladder. It is placed in direct contact with the bladder so that it can stimulate the bladder to generate the electrical activity.	11436000	II	5-⑥	applicable	—
Electroglottograph	A graphic recorder to record changes in electric potential or impedance caused by vocal cord movement during respiration and speech. An appropriate sensor is utilized. It is used in dysphonia treatment to assess the severity of vocal cord obstruction and to examine the pharyngeal mechanism.	16034000	II	10	applicable	applicable
Cardiac imaging system	A device that captures and analyzes cardiac image signals from an ultrasound imaging system. With this device, chamber volume calculation, ventricular wall motion analysis and coronary stenosis analysis can be performed.	70069000	II	10	applicable	applicable
Electronystagmograph	A graphic recorder that is used to detect electrical potential generated by eye movement. The device is equipped with electrodes for each eye to allow measurement of both eyes simultaneously and for the forehead (for multi-channel recording).	11479000	II	10	applicable	applicable
Electroretinograph	A graphic recorder of the changes in electrical potential on or near the surface of the cornea when compared to a reference point on the body, following stimulation of the retina by light (e.g., flashes of white light). These recorders include a primary electrode (generally gold, platinum, or silver) and a reference electrode, which are	11482000	II	10	applicable	applicable
Esophageal electrode	A conductor used to stimulate contraction of the esophageal muscle.	35037000	II	5-⑥	applicable	—
Fetal scalp electrode	An electric signal conductor that is placed directly on the scalp of the fetus in the uterus, to monitor fetal vital signs. They are usually spiral electrodes.	35038002	II	6	applicable	—

Visual evoked response computer	A device used to measure the changes in bioelectrical potentials evoked by visual stimuli (e.g., brightness change or graphical change).	70071000	II	10-①	applicable	applicable
Electrooculograph	A device is intended to record potential difference between the retina and cornea during eye movement in response to visual stimuli. These devices may include surface electrodes, which are placed at the inner and outer canthi of each eye, and an amplifier that boosts the bioelectrical potential. Some types of recorder have a built-in processor that collects the signals from the electrodes, processes them, and displays them.	11480000	II	10	applicable	N/A
Physiological signal amplifier	An amplifier to adjust the signal level and impedance between two or more medical devices that transmit biological signals.	32521000	II	10	applicable	applicable
Block monitoring peripheral nerve electrical stimulator	A type of electrical nerve stimulator that stimulates the nerves to assess the adequacy of surgical neuromuscular block (e.g., ulnar nerve, facial nerve, lower leg nerve) and the disappearance of the neuromuscular block during the recovery period. The device is battery-powered or line-powered, and usually the following 4 types of stimulation: 1. Single twitch stimulation 2. Train of four stimulation 3. Tetanic stimulation 4. Post-tetanic facilitation	35722000	II	9	applicable	N/A
Patient monitoring system	A system consisting of various devices used for detecting, processing and displaying the vital signs of multiple patients at the same time. The system is designed to emit a signal or an alarm visually or audibly in the event any harmful condition is detected and recorded; this provides healthcare practitioners with a high-level monitoring system. It collects the signals from the patient's monitoring units and other devices, processes them, and displays them.	37595000	II	10	applicable	applicable
Central monitor	A unit designed to collect, process, or display vital signs and other patient data from a single or multiple bedside monitoring units. The unit is designed to actuate visual or audible signals/alarms if adverse conditions are recorded. The device is usually placed within an intensive care unit or the central patient monitoring station in a cardiology ward.	38470002	II	10	applicable	applicable
Breathing frequency monitor	A noninvasive device that measures respiratory rate. Some types of device have additional capabilities such as respiratory volume measurement or alarm notification.	12662000	II	10	applicable	applicable
Ventilation monitor	A device that continuously monitors the breathing circuit by means of various respiratory parameters in the respiratory cycle, such as respiratory rate, pressure, flow rate, and lung volume. Respiratory rate indicator and I:E ratio indicator may be equipped. The device gives an alarm at onset of abnormal ventilatory function.	12678000	II	10	applicable	applicable
Noninvasive blood pressure monitor	A device that measures blood pressure noninvasively outside the patient's body, and processes and displays the data. The device may have the capability to initiate a visual or audible signal or alarm, when adverse conditions are registered. Some types of device use an external transducer.	31681000	II	10	applicable	applicable
Blood-pressure alarm	A device that monitors a patient's blood pressure and sends out alarm signals in the event it exceeds a pre-defined limit.	31691000	II	10	applicable	applicable
Invasive blood pressure monitor	A device that measures blood pressure invasively in an artery, and processes and displays the data. The device may have the capability to initiate a visual or audible signal or alarm, when adverse conditions are registered.	31692000	II	10	applicable	applicable
Multiparameter monitor	A unit that collects data of several monitoring parameters using an embedded function kit, module, or other devices and displays the data by bed or by patient. The bedside unit can be connected to the central monitor; it can also be operated alone. Monitoring parameters include electrocardiogram (ECG), blood pressure, body temperature, pulse oximetry, and respiratory rate.	33586002	II	10	applicable	applicable

ST-segment monitor	A device that measures and displays the ST-segment of the electrocardiogram (ECG) signals.	34115000	II	10	applicable	applicable
Respiration monitor	A device intended to monitor the respiratory function of the patient. The device measures the flow rate of an inhaled or exhaled breath, and airway pressure (Paw). Some types of device measure carbon dioxide (CO2), oxygen (O2) and esophageal pressure (Pes).	35194002	II	10	applicable	applicable
Electrocardiographic monitor	A device that processes and displays the patient's electrocardiogram (ECG). Some types of device display heart rate. The device may have the capability to initiate a visual or audible signal or alarm, when adverse conditions are registered.	35195000	II	10	applicable	applicable
Electroencephalographic monitor	A device that processes and displays electric signals generated in the brain, and presents them, typically in the form of an electroencephalogram (EEG).	35196000	II	10	applicable	applicable
Electrocardiographic module	A type of plug-in module intended for use with a multiparameter monitor and used for the detection and recording of electrocardiogram (ECG) signals; those with arrhythmia analysis functionality are excluded.	36349002	II	10	applicable	applicable
Respiration module	A type of plug-in module intended for use with a multiparameter monitor, and used to measure the flow rate of an inhaled or exhaled breath, and airway pressure (Paw). Some types of device measure carbon dioxide (CO2), oxygen (O2) and esophageal pressure (Pes).	70076000	II	10	applicable	applicable
Invasive blood pressure module	A type of plug-in module intended for use with a multimodal-monitor, and used for measurement of blood pressure (at single or multiple sites) using a pressure transducer directly inserted into a blood vessel via a catheter.	36550000	II	10	applicable	applicable
Noninvasive blood pressure module	A type of plug-in module intended for use with a multimodal-monitor, and used for measurement of blood pressure with a cuff wrapped around the arm or leg (noninvasive method).	36551000	II	10	applicable	applicable
Carbon dioxide module	A type of plug-in module usually intended for use with a multimodal-monitor, and used for measurement of carbon dioxide (CO2) content in an exhaled breath. Carbon dioxide content can be measured from the mainstream or sidestream.	36552000	II	10	applicable	applicable
Multifunction module	A type of plug-in module intended for use with a multimodal-monitor, and used for the measurement and monitoring of two or more functional indicators (e.g., electrocardiogram [ECG], respiratory rate, temperature, blood pressure, pulse or oximetry).	36553000	II	10	applicable	applicable
Pulse oximeter module	A type of plug-in module usually intended for use with a multimodal-monitor, and used for the percutaneous measurement of oxygen saturation in blood (SpO2) by photodetection with a special probe. Light emitted from the light-emitting diode (LED) reaches arterial blood, is received by the detector, and is measured by the principle of	36554000	II	10	applicable	applicable

Cardiac output module	A type of plug-in module intended for use with a multimodal-monitor, and used for the measurement of cardiac output (blood volume pumped out from the heart per minute). The device is usually used for bedside monitoring.	36561000	II	10	applicable	applicable
Body temperature module	A type of plug-in module intended for use with a multimodal-monitor, and used for the measurement and monitoring of the patient's body temperature (single or multiple sites). Usually, a probe (cutaneous or rectal) is used for measurement.	36562000	II	10	applicable	applicable
Transportable multiparameter monitor	A monitoring unit specifically designed for use while the patient is in transit (from some other place to hospital, from hospital to another hospital, or to another department within the hospital). Parameters that can be monitored include electrocardiogram (ECG), blood pressure, temperature and pulse oximetry. This device can be used as an ordinary bedside unit.	36872000	II	10	applicable	applicable
Multi-gas module	A type of plug-in module usually intended for use with a multimodal-monitor, and used for anesthesia to measure the concentrations of gases such as anesthetic gas, oxygen (O ₂) and carbon dioxide (CO ₂) in an exhaled or inhaled breath. Either the mainstream or sidestream can be used for gas sampling.	37061000	II	10	applicable	applicable
Intracardiac oximeter module	A type of plug-in module intended for use with a multimodal-monitor, and used for the measurement of the ratio of oxyhemoglobin to oxyhemoglobin consumed in the heart (SvO ₂ : venous oxygen saturation) by comparing the absorptions of red light and infrared light of blood. The probe is inserted via a catheter (a Swan-Ganz catheter is often used).	37172000	II	10	applicable	applicable
Long-term recording electrocardiograph module	A type of plug-in module intended for use with a multimodal-monitor, used for the detection and recording of the patient's cardiac activity for 24 hours. Recording is performed while the patient is lying down (in the department of cardiology), and signals are stored on a cassette (magnetic tape), digital medium (with no movable parts), or other media and subsequently analyzed by electrocardiogram machine equipment.	37175000	II	10	applicable	applicable
Electromyographic module	A type of plug-in unit used for monitoring multiple items, and detecting and recording electromyogram signals (EMG signals). Measurement of electrical activity occurring in the muscle tissues may lead to diagnosis of muscular disorders.	37208000	II	10	applicable	applicable
Nerve location module	A type of plug-in unit usually used for monitoring multiple items and detecting the neural center in a certain body area. It consists of a neurostimulator and a receiver to record neural action potentials.	37246002	II	10-①	applicable	applicable
Electroencephalographic module	A type of plug-in module intended for use with a multimodal-monitor, and used for the detection and recording of electroencephalogram (EEG) signals, produced as a result of electrical activity of the brain and detected by electrodes placed on the patient's forehead or scalp. Some types of device record auditory evoked potential (AEP) signals. The device is used for anesthesia, critical care, or other procedures.	37323000	II	10	applicable	applicable
Intracardiac oximeter	A device that measures the oxygen saturation of blood pumped from the heart to the lungs (SvO ₂ -venous oxygen saturation). Measurement is performed by inserting a special catheter from a vein in the groin or neck. Catheters are not part of the device.	15200000	II	10-③	applicable	applicable
Pulse oximeter	A device that percutaneously measures oxygen saturation in blood (SpO ₂) by photodetection with a special probe. Light is generated within and irradiated from a light-emitting diode to pass through arterial blood, is received by the detector, and is measured by the principle of spectrophotometry. Some types of device have pulse rate, electrocardiogram (ECG), and respiration monitoring capabilities.	17148010	II	10	applicable	applicable

Pulse oximeter/capnometer	A device used to monitor oxygen saturation (SpO2) and carbon dioxide (CO2). Parameters that can be monitored include end tidal carbon dioxide (EtCO2), fractional concentration of inspired carbon dioxide (FiCO2), arterial oxygen saturation (SpO2), pulse rate, and respiratory rate measurements.	17148020	II	10	applicable	applicable
Transcutaneous blood gas analyzer/pulse oximeter combined biophenomena monitoring equipment	A single device that has the ability to perform transcutaneous blood gas monitoring and pulse oximetry. (See the definitions of transcutaneous blood gas analyzer and of pulse oximeter.)	17148030	II	10	applicable	applicable
Transcutaneous blood gas sensor/pulse oximeter probe combined biophenomena monitoring equipment	A single sensor that can act as a transcutaneous blood gas sensor and pulse oximetry probe. (See the definitions of transcutaneous blood gas sensor and of pulse oximeter probe.)	17148040	II	10	applicable	N/A
Neonatal monitor	A dedicated device that detects, processes and displays multiple vital sign parameters in newborns.	35569000	II	10	applicable	applicable
Fetal cardiac monitor	A device used for detecting, measuring and displaying fetal cardiac activity. Usually it measures fetal heart rate and also assesses heart valve movement. This device works non-invasively as follows: 1) It records fetal heart sounds electronically and graphically, 2) It discerns fetal electrocardiogram signals from maternal ones which are obtained from the maternal abdomen with the external electrode.	43958000	II	10	applicable	applicable
Uterine contraction monitor	A device used for monitoring progress in labor (early uterine contraction). Through a transducer fixed on the abdomen of the woman during childbirth, this device measures the duration, frequency and relative pressure of uterine contractions. It usually has an alarm. Fetal parameters are not monitored.	17922000	II	10	applicable	applicable
Cardiotocographic monitoring system	A cardiotocograph (a device that records fetal heart rate and uterine contraction simultaneously). Usually, uterine contraction is measured by a tocometer, which is placed on the maternal abdomen. This device has a pressure transducer plate which	37796000	II	10	applicable	applicable
Telemetry cardiotocograph system	A set of systems for transmitting and receiving signals (usually electric signals) remotely, and for recording them. The system is intended for use in radio-telemetry for the continuous and ambulatory recording of fetal heart rate and uterine contractions.	38479000	II	10	applicable	applicable
Telemetry cardiotocograph receiver	A part of the wireless telemeter system. It receives wireless signals from the transmitter that senses fetal heart rate and uterine contractions during labor.	38480000	II	10	applicable	applicable
Telemetry cardiotocograph transmitter	A part of a wireless telemeter system. It transmits signals related to fetal heart rate and uterine contractions to the receiver.	38481000	II	10	applicable	applicable
Transcutaneous blood gas analyzer	An automated or semi-automated device used to transcutaneously measure the oxygen (pO2) and carbon dioxide (pCO2) partial pressures in blood by using a special heating sensor which increases blood flow rate at the application site. The device is mainly	36346000	II	10-①	applicable	applicable
Transcutaneous blood gas module	A type of plug-in module usually intended for use with a multimodal monitor, and used for the measurement of partial pressure of the gases (pO2, pCO2) in blood using a gas- sensitive membrane electrode and a heating sensor placed on the skin. Heating causes	36898000	II	10	applicable	applicable
Transcutaneous blood gas sensor	A device used to measure partial pressure of the gases (partial pressure of oxygen [pO2] and carbon dioxide [pCO2]) in blood transcutaneously. Electric signals are transmitted to the base unit where signals are analyzed, and results are usually	37178000	II	10-①	applicable	applicable

Subcutaneous blood gas analyser	An automated or semi-automated device used to measure oxygen partial pressure (pO ₂) in the blood by inserting a special catheter, cannula or probe into the subcutaneous tissue. It has graph output and data output functions.	37199000	II	10-①	applicable	applicable
Airway pressure monitor	A dedicated device used to measure and display the pressure values monitored at the upper respiratory tract in a patient (e.g., average maximal expiratory pressure and inspiratory static oral cavity pressure). The information obtained with this device is used for diagnosis. Usually, it incorporates a pressure indicator and a built-in alarm.	31318000	II	10	applicable	applicable
Gastrointestinal/esophageal motility monitor	A system that monitors the gastrointestinal system and the esophagus to obtain data to be used for diagnosis. Usually, the system measures peristaltic movement, pressure, acidity, etc. in the stomach or the esophagus. Time series measurements of peristalsis.	32081000	II	5-⑥,10	applicable	applicable
Fetal electroencephalographic monitor	A device that detects, processes and displays electric signals occurring in the fetal brain. It shows the signals on an electroencephalogram (EEG).	32660000	II	10	applicable	applicable
Hypopnea alarm	A device used to diagnose insomnia accompanying hypopnea. The device records the phase difference between thoracic movement and abdominal movement to find slow and shallow respiration leading to decreased oxygen uptake. It gives alarm signals in the event the pre-specified limit is exceeded.	36974000	II	10	applicable	applicable
Telemetry electrocardiograph	A set of system for transmission, reception, and recording of signals (usually, electric signals) to a remote device. The system is intended for use particularly in radio-telemetry for the continuous and ambulatory recording of electrocardiogram (ECG) signals. Functions of these devices include the telephonic transmission and recording function of ECG data.	31733000	II	10	applicable	applicable
Telemetry electromyograph receiver	A part of a wireless telemeter system. This device receives wireless signals from the electromyogram (EMG) transmitter.	35556000	II	10	applicable	applicable
Telemetry electroencephalograph	A set of system for transmission, reception, and recording of signals (usually, electric signals) to a remote device. The system is intended for use particularly in radio-telemetry for the continuous and ambulatory recording of electroencephalogram (EEG) signals. Functions of these devices include the telephonic transmission and recording function of EEG data.	35626000	II	10	applicable	applicable
Telemetry pulse oximeter	A system that measures hemoglobin oxygen saturation and utilizes wireless communication in a part of the signal transmission pathway to eliminate hard-wired or other cable connections. This system is often employed to allow the patient to move freely.	36118000	II	10	applicable	applicable
Telemetry electrocardiograph receiver	A part of a radio-telemetry system, intended to receive radio signals from an electrocardiogram (ECG) transmitter.	36365000	II	10	applicable	applicable
Telemetry electroencephalograph transmitter	A part of a wireless telemeter system. This device transmits electroencephalogram (EEG) signals to the receiver.	36366000	II	10	applicable	applicable
Telemetry electrocardiograph transmitter	A part of a radio-telemetry system, intended to transmit electrocardiogram (ECG) signals to a receiver.	36367000	II	10	applicable	applicable

Telemetry electroencephalograph receiver	A part of a wireless telemeter system. This device receives wireless signals from the electroencephalogram (EEG) transmitter.	36381000	II	10	applicable	applicable
Telemetry pulse oximeter transmitter	A part of a radio-telemetry system, intended to transmit arterial oxygen saturation (SpO2) signals.	37353000	II	10	applicable	applicable
Telemetry electromyograph	A set of systems to transmit and receive signals (usually electric signals) remotely, and to record them. The system is intended for use particularly in radio-telemetry for continuous and ambulatory recording of electromyogram (EMG) signals. Functions for	37794000	II	10	applicable	applicable
Telemetry electromyograph transmitter	A part of a wireless telemeter system. It transmits electromyogram (EMG) signals to the receiver.	38443000	II	10	applicable	applicable
Telemetry pulse oximeter receiver	A part of a radio-telemetry system, intended to receive radio signals from a pulse oximetry transmitter.	38557000	II	10	applicable	applicable
Telemetry physiological signal system	A set of system for transmission, reception, and recording of signals (usually, electric signals) to a remote device. The device is intended for use particularly in radio-telemetry for the continuous and ambulatory recording of biological signals except electrocardiograms (ECG), electroencephalograms (EEG), electromyograms (EMG), and fetal signals.	32547000	II	10	applicable	applicable
Telemetry ECG receiver module	Usually, a type of plug-in unit used for a multiparameter monitor and to receive (wireless) ECG signals transmitted through the air via the patient's receiver (remotely). When it is used by a patient walking in the hospital room or ward within	37176000	II	10	applicable	applicable
Telemetry data transmitter	A part of a radio-telemetry system, intended to transmit data measured by an instrument (e.g., standalone multigas analyzer) to the central monitor.	37206000	II	10	applicable	applicable
Long-term respiration pulmonary function data recorder	A device that records lung function (e.g., respiratory rate) as the carrying information for diagnosis over a long period (usually for 24 hours or longer). It is attached to a patient's body and carried by the patient. The recorded measured values (data) are downloaded to an appropriate analysis system in the hospital for analysis.	16305000	II	10	applicable	applicable
Long-term body temperature data recorder	A device that records temperature as the trend information for diagnosis over a long period (usually for 24 hours or longer). It is attached to a patient's body and may be carried by the patient. The recorded measured values (data) are used as the	17572000	II	10	applicable	applicable
Pneumographic data recorder	A device that graphically displays chest movement during respiration. Utilizing a sensor (e.g., electrical impedance), the device detects and transduces chest movement during respiration. Both the speed and waveform of the movement may be displayed	35244000	II	10	applicable	applicable
Pneumotachographic data recorder	A device that graphically records the air volume per one respiration during inspiration or expiration based on the momentary air flow (velocity) in the oral cavity and	35245000	II	10	applicable	applicable
Nerve function monitor	A device used to monitor the function of individual nerves or nerve bundles. The functional integrity of nerves may change during surgery due to trauma, anesthesia, or other factors; therefore, it is important to know whether any change has occurred, and the timing of the occurrence.	36081000	II	10	applicable	applicable
Long-term physical activity data recorder	An automatic device that measures and records patient movement over a long period during the day. Usually, the patient carries this device attached to his/her limb and performs daily activities. Physical activities are detected by a transducer and signals are transmitted to the counting and timer circuits. Activities are recorded for several	36252000	II	10	applicable	applicable
Long-term urodynamic data recorder	A device that records urinary dynamics for 24 hours. It is carried by the patient. Data obtained are analyzed in the hospital.	36964000	II	10	applicable	applicable

Esophageal catheter with pH sensor	A catheter with a pH sensor at the tip. It is mainly used to determine the pH in the stomach and the esophagus.	70077000	II	10	applicable	—
Icterometer	A device used to noninvasively measure serum bilirubin concentrations by the absorption spectrophotometry method in which absorption of light irradiation by	70078000	II	10	applicable	—
Pediatric pulmonary function analyser	A device used to measure and record neonatal or pediatric respiratory function (usually based on tidal volume, ventilation frequency, minute ventilation, airway compliance, airway resistance).	36134000	II	10	applicable	applicable
Peak flow spirometer	A device used to measure the maximal ventilation flow rate (maximal expiratory volume per unit time) for comparison with the normal value or previous value. The device helps to detect diseases including asthma, emphysema and bronchitis. It is	31300000	II	10	applicable	applicable
Respiratory flow meter	A device that determines the expiratory flow rate based on airflow velocity measured with a respiratory transducer.	70079010	II	10	applicable	applicable
Respiratory resistance meter	A device that measures respiratory resistance based on the external air pressure and respiratory flow rate as measured by the respiratory transducer.	70079020	II	10	applicable	applicable
Powered diagnostic spirometer	An electric device used to measure the air volume and airflow velocity in the lungs, for diagnosis or investigation of lung diseases. The measurements provide information about the patient's lung function, allowing comparison with a normal value or	13680002	II	10	applicable	applicable
Oxyhemoglobin analyzer	An automated or semi-automated device that measures the concentration of hemoglobin bound to oxygen in the blood.	33275000	II	10-①	applicable	applicable
Functional oximeter	A device used to measure the changes in the hemoglobin concentration in the blood by detecting infrared light irradiated to the body.	70080000	II	10-①	applicable	applicable
Basal metabolism measuring system	A device to determine basal metabolism. It may be used with a ventilator.	70081000	II	10	applicable	applicable
Nitrogen gas analyzer	A device that measures the concentration of nitrogen in expired or inspired air using an electrochemical method, mass spectrum method, ultraviolet absorption method, or infrared absorption method.	31338000	II	10	applicable	applicable
Carbon dioxide gas analyser	A device designed to measure the concentration of carbon dioxide in a mixed gas by the electrochemical method, infrared absorption, gas chromatography, or mass spectrometry to assess ventilation, circulation, and metabolic conditions.	31339000	II	10	applicable	applicable
Hydrogen gas analyzer	Usually, a device to measure the exhaled hydrogen (H ₂) concentration.	37252000	II	10	applicable	applicable

Nitrogen dioxide gas analyzer	A device that measures the concentration of nitrogen dioxide (NO ₂) in expired or inspired air using an electrochemical method, mass spectrum method, ultraviolet absorption method, or infrared absorption method.	37269000	II	10	applicable	applicable
Capnometer	A device intended to monitor carbon dioxide.	17148050	II	10	applicable	applicable
Carbon dioxide carbon isotope ratio analyzer	A device that measures changes in the carbon dioxide (CO ₂) concentration in mixed gas, the carbon isotope ratio (13C/12C) in exhaled carbon dioxide, or others using an electrochemical method, infrared absorption method, gas chromatography method, or mass spectrum method to determine ventilation, circulatory and metabolic conditions.	70082000	II	10	applicable	applicable
Adult pulmonary function analyzer	A device used to measure pulmonary function and efficiency (usually, ventilation, diffusion, and distribution of a gas in the lungs) in adult patients.	35282010	II	10	applicable	applicable
Respiratory function measuring system	A device intended to measure gas exchange (ventilation, diffusion, and distribution), respiratory center function, respiratory muscle function, and other lung function as well as pulmonary efficiency and the condition of the bronchi.	35282020	II	10	applicable	applicable
Nasal resistance unit	A device used for the measurement of the air flow and pressure change in the nasal cavity in order to determine the state of the nasal cavity. The device is used to determine the degree of nasal obstruction or nasal congestion. These devices may be	17228000	II	10	applicable	applicable
Water vapour gas analyzer	A dedicated device to measure the water vapor level in the air expired from the lungs using mass spectrometry.	31271000	II	10	applicable	applicable
Differential gas pressure transducer	A medical 2-chamber device often used for pulmonary function tests. Electric signals are generated in proportion to the difference in gas pressure between the 2 chambers. Next, measured values are processed and displayed with the base unit.	31293000	II	10	applicable	applicable
Long-term monitoring spirometer	A device that continuously measures the tidal volume and minute volume rates in a patient to assess the ventilation function. An alarm system for the high tidal volume and low tidal volume may be installed in the device.	35353000	II	10	applicable	applicable
Carbon monoxide gas analyzer	A device that measures the carbon monoxide concentration in mixed gas to be used as a reference for assessment of metabolic and respiratory conditions. Techniques including electrochemical analysis, infrared absorption, gas chromatography, or mass	35467000	II	10	applicable	applicable
Pulmonary exercise stress monitoring system	A device for exercise tolerance test that measures respiratory gases by using oxygen (O ₂) and carbon dioxide (CO ₂) analyzers, in addition to other pulmonary function parameters during exercise. The device measures and calculates the patient's respiratory parameters with a mask, mouthpiece, or hood attached to a tube that	36146000	II	10	applicable	applicable
Diagnostic positive airway pressure unit	A unit used to examine a patient suspected of having sleep apnea and its complications. By analyzing the recorded data, the patient's condition can be assessed, and the appropriate medication can be prescribed.	37235000	II	10	applicable	applicable
Nitric oxide gas analyzer	A device to measure and assay the nitrogen oxide (NO) concentration in mixed gas. This device is used to measure the NO concentrations in expired and inspired air during special respiratory treatment. NO gas is effective only when a very small amount of the gas is used. Therefore, the data obtained with this device is important.	37268000	II	10	applicable	applicable

X-ray computed tomography system xenon gas administration system	A component of an X-ray computed tomography system. The xenon gas delivery device used for diagnostic radiography systems is designed to supply xenon gas (via inhalation or injection) when a real-time imaging examination of physical or physiological parameters, such as blood flow, is performed.	40907000	II	11	applicable	applicable
Nuclear medicine xenon gas administration system	A component of a nuclear medicine imaging device such as a gamma camera or SPECT. A xenon gas re-breathing device is used to deliver xenon gas to the patient or to collect the radioactive xenon gas in expired gas in a real-time imaging examination of physical or physiological parameters such as pulmonary function or blood flow. The device is designed to reduce the emission of radioactive gases into the atmosphere during	40908000	II	11	applicable	applicable
Single-use nuclear medicine xenon gas inhalation set	A device used to deliver xenon gas to the patient, and to collect radioactive xenon in expired gas following an imaging examination of physical or physiological parameters, such as pulmonary function or blood flow. The device is designed to suppress emission of radioactive gases into the atmosphere	70084000	II	11	applicable	N/A
Multi-gas monitor	A multi-gas monitor intended to monitor the concentrations of oxygen, carbon dioxide, nitrous oxide, or anesthetic gas in expired or inspired air of the patient, and respiratory rate or other parameters.	70085000	II	10-①	applicable	applicable
Pulmonary function testing filter	A device used to remove saliva, sputum, and other contaminating microdroplets produced by the patient during pulmonary function tests. The device is intended for single-use.	70086000	II	3-①	applicable	—
Respiratory circulation testing equipment	A testing device that can perform at least 2 types of tests out of a respiratory function test, a basal metabolism test and a pulmonary exercise test.	70088000	II	10	applicable	applicable
Automatic perimeter/ophthalmic camera	A multifunctional device that functions as an ophthalmic camera and performs automated perimetry.	16918002	II	10	applicable	N/A
Refractometer/tonometer	A multifunctional device with the capabilities of tonometer and refractor/keratometer.	36387060	II	10	applicable	N/A
Ophthalmic interferometer	A device to determine the retinal visual acuity with interference fringes. For example, the device is sometimes used to measure light wavelength during eye surgery. The device is often used for cataract surgery.	36397000	II	10	applicable	N/A
Aqueous/flame cell analyzer	A device that measures anterior chamber flare (protein content) and the number of cells in the aqueous humor.	37948000	II	10	applicable	applicable

Eye movement testing equipment	A device that measures eye movement by processing images of the eye captured by the camera. Some types of device have a built-in angular velocity sensor, with the ability to analyze the data.	70093000	II	10	applicable	N/A
Optical intraocular measuring instrument	A device that optically measures dimensions of components of the eye such as corneal radius of curvature, corneal thickness, anterior chamber depth, and axial length.	70096000	II	10	applicable	applicable
Temograph	A device to record involuntary shaking or tremulousness (tremor). This has a built-in sensor that senses movements of the finger, hand and arm in various resting positions. The movements are directly recorded with a recording pen or electrical transducer (in a highly sensitive recording).	14144000	II	10	applicable	N/A
Neuropathological diagnostic quantitative sensory tester	A device used to test and determine the level of vibration required to measure the vibration perception threshold of a certain area of the skin. The device is used for the diagnosis of neuropathological conditions, and to detect conditions, such as suspected diabetes, exposure to neurotoxic substances (e.g., solvents and heavy metals), poor working conditions, and early symptoms of disorders caused by traffic accidents or other events.	37349000	II	10-①	applicable	N/A
Noise generating audiometer	A device consisting of an electronic generator, amplifier, and earphone. The device is used to make masking noise for the non-tested ear during an audiometric test. The device is used to minimize the non-test ear's perception of the test sound, which is generated at the test ear.	31939000	II	10-①	applicable	N/A
Visual reinforcement audiometer	An electroacoustic device intended for use in audiometric tests on infants. With appropriate responses to test signals, pictures attractive to infants are displayed as a reward.	34013000	II	10-①	applicable	N/A
Pure-tone audiometer	An audiometer capable of both air conduction and bone conduction measurements. Usually, the device is equipped with earphones and a headband, which provide a pure tone of specified frequency at known sound pressure levels to one ear at a time. Some devices are equipped with a bone conduction vibrator. For clinical use, in addition to the both capabilities, a function of generating calibrated masking noise is necessary.	37503000	II	10-①	applicable	N/A
Manually-operated audiometer	An electroacoustic device that manually presents signals, allows selection of frequency and hearing level, and records the subject's response. Devices with speech audiometry capability are excluded.	41184000	II	10-①	applicable	N/A
Automatic-recording audiometer	An electroacoustic device that automatically presents signals, selects or modifies frequency, modifies hearing level, and records the subject's response. Change in the hearing level is controlled by the patient. The devices may have the ability to generate a fixed frequency, or a continuously changing sweep frequency. Some devices generate both continuous and pulsed test tones. Devices with speech audiometry capability are excluded.	41185000	II	10-①	applicable	N/A

Computer-controlled audiometer	An electroacoustic device in which test procedures are controlled by a computer or microprocessor. Unlike an automatic recording audiometer, test signal levels are not controlled by the patient. Usually, calculation of hearing levels according to the patient's response and displaying are also performed. Devices with speech audiometry capability are excluded.	41187000	II	10-①	applicable	N/A
Speech audiometer	An electroacoustic device for audiometry using speech testing materials. Pure tone audiometers are often equipped with the capability to be used as speech testing audiometers, by connecting a device that supplies pre-recorded speech material via the external input port.	41188000	II	10-①	applicable	N/A
Impedance audiometer	An electroacoustic device that evaluates the acoustic impedance/admittance of the human ear by means of acoustic probe signals. The practical use of this device involves measuring the changes in acoustic impedance/admittance caused either by varying the air pressure in the external acoustic meatus or by activating the middle ear muscle.	36717010	II	10-①	applicable	N/A
Impedance audiometer with pure-tone and speech audiometric functions	An electroacoustic device that evaluates the acoustic impedance/admittance of the human ear by means of acoustic probe signals. The device has both pure-tone threshold audiometry and speech audiometry capabilities.	36717020	II	10-①	applicable	N/A
Objective audiometry device	A device used in audiometry to detect and record local potentials generated in the brain or spinal cord in response to stimuli (e.g., visual, acoustic, and somatic sensation) applied to a sense organ or at a point in the afferent tract of a sense organ, or in the central nervous system. The characteristics of recorded electrical potentials differ depending on the recording site, form and amount of stimulation (evoked response), level of consciousness, and anesthetic levels. Obtained waveforms may be used for the evaluation of the function and integrity of the brain and its sensory system.	11614000	II	10	applicable	applicable
Oto-acoustic emission instrument	A device used to record and analyze weak sounds coming from the ear. Types of stimuli that generate such sounds include spontaneous otoacoustic emission, a click stimulus (otoacoustic emission evoked by transient stimuli), or a tone-burst stimulus (distortion product otoacoustic emission).	36908000	II	10-①	applicable	N/A
Eustachian tube function testing instrument	A device intended for the diagnosis of conditions such as patulous Eustachian tube or stenosis of the Eustachian tube, used to observe or record the changes in the characteristics of sound passing between the nasal cavity and external acoustic meatus associated with swallowing movements, and the process of releasing pressure in the middle ear cavity by swallowing.	70097000	II	10-①	applicable	N/A
Auditory evoked response audiometer with oto-acoustic emission measurement function	An electronic acoustic device used to evaluate the activity of the auditory nervous system with the response to an acoustic signal at the ear. The response is detected via a scalp electrode. The device also has the ability to record and analyze weak sounds from the ear. Types of stimuli that generate sounds include spontaneous otoacoustic	35747020	II	10	applicable	N/A
Rotational/pendular/linear motions stimulator	An electric motor-driven chair that provides quantitatively reproducible, acceleratory stimulation to the otolith organ of the inner ear. This chair can perform rotary movement, pendular movement or linear movement.	70098000	II	10	applicable	N/A
Biomechanic platform system	A system that uses a tilting balance platform consisting of a sensor, computer and special software to test the balance of a patient. The patient controls the center of gravity (tilting in one direction) following the instructions of the physician or	17242002	II	10	applicable	N/A

Quantitative sensory test odorimeter	A device used to assess the sense of smell in a patient quantitatively and qualitatively. There are a variety of components to the device, such as a rack of vials with various types of odor, and a sliding device for test tubes. Usually, the device is used for patients with head injuries which may change the sense of smell.	12796000	II	10-①	applicable	N/A
Tonoscope	A device used to visualize sounds by recording vibrations on the screen. This is used to examine the head or the brain using sounds.	14069000	II	10	applicable	applicable
Vestibular function caloric stimulator	A type of stimulator that applies a stream of air or water as a thermal stimulus to the external acoustic meatus. A vestibular function stimulator consisting of a perfusion system that includes a pump, valves, heaters, and regulators to control the flow rate and temperature of the medium. Stimulation of the semicircular canal induces involuntary eye movements, which can be measured using a nystagmograph. These	34891000	II	10-①	applicable	applicable
Touch discrimination quantitative sensory tester	A device used to examine the area of the skin with normal, increased or reduced sensitivity, and to determine the threshold of the sense of touch during a neurological examination. The examination is performed by means of various methods as follows: 1	35056000	II	10-①	applicable	N/A
Electromagnetic stimulator	A type of stimulator that delivers electromagnetic energy to tissues at the levels below the heat sensation threshold. Usually, the device increases the temperature of the target tissue by less than 1°C utilizing high-frequency energy with a short pulse.	35169000	II	10-①	applicable	applicable
Nerve locator stimulator	A device used to locate a nerve intermittently, in order to monitor the positional relationship between the nerve and surgical instruments (e.g., scalpel). The device consists of a nerve stimulator and a receiver that records nerve signal activity.	35723002	II	10-①	applicable	applicable
Local anesthesia nerve stimulator	A battery powered nerve stimulator used to locate an appropriate nerve in a particular area of the body before a local anesthetic is administered. By stimulating the area with electric current, a muscle reflex is activated and can be monitored. Muscle reflexes can	37042000	II	10-①	applicable	applicable
Quantitative sensory test thermal analysis system	A device that quantitatively assesses and diagnoses responses to heat stimulation (usually, responses on the skin surface) in order to obtain information about the hot-cold sensation threshold. The device can be either invasive or non-invasive. The device is used for detection of early diabetes mellitus or a phantom pain, diagnostic tests including neurological examination related to nerve fibers, and a pain threshold test.	37350000	II	10-①	applicable	N/A
Temperature discrimination quantitative sensory tester	A quick testing device used to determine the area where thermal perception is impaired. Tests are performed by applying a charged roller heated to pre-specified temperatures, e.g., 25°C and 49°C (normal skin temperature is 30°C to 32°C). The patient distinguishes corresponding sensations, and sites with normal and abnormal sensation are marked.	38826000	II	10-①	applicable	N/A
Single-use nerve locator	A single-use nerve locator used for distinguishing or locating a motor nerve, or for electromyography during surgery. The device consists of a needle electrode, which will be inserted subcutaneously, a probe electrode, which will be in contact with skin.	70099000	II	10	applicable	N/A
Electrogustometer	A device used to test the sense of taste. Electrical stimuli are applied by allowing the electrode to contact the tongue, and the electric current threshold of taste perception is measured.	70100000	II	10-①	applicable	N/A
Optokinetic stimulator	A device used to stimulate the nerves associated with equilibrium such as the vestibular nerve with visual stimuli, to evoke eye movements by the vestibulo-ocular reflex, in order to measure the degree of equilibration disturbance.	70101000	II	10	applicable	N/A

Powered cutaneous pain gauge	An electric device used to determine sensitivity to pain (such as a sharp pin prick). The device is also called an algometer.	12950002	II	10	applicable	N/A
Physiologic neuromuscular function analyzer	A device used to determine and assess physical or joint movement for the purpose of graphic display of the body and bionic analysis such as spine analysis or joint movement testing. The device can be also used to determine the severity of ataxia (disturbance of muscle coordination). It is usually used for testing mechanisms/tasks related to sport, work and rehabilitation. The device may contain a variety components including a unit utilizing optoelectronics or electricity and magnetism, a marker, a	17929000	II	10	applicable	applicable
Myograph	A device that determines and records various phases of muscle contraction including strength or velocity. It has a built-in sensor to detect and graphically reproduce displacement or power related to muscle contraction (myogram). The device is used to assess the muscle under some conditions including displacement under continuous	12692000	II	10-①	applicable	N/A
Perineometer	A device consisting of a bag connected to an external pressure gauge. The bag contains liquid to be injected into the vagina. The device determines perineal muscle strength through resistance to spontaneous contraction of the perineal muscle. The device is used to diagnose and treat urinary incontinence and sexual dysfunction through	32686000	II	10	applicable	N/A
Spine curvature monitor	A device that detects, displays, and records the position of several vertebrae adjacent to each other.	34037000	II	10-①	applicable	N/A
Quantitative sensory test palpometer	A device that inspects and determines the threshold of pain perception in patients suspected of having disorders. Some types of device utilize multiple measurement techniques. The device usually detects the initial phase of the reflex escape response, which is called the pressure pain threshold.	40817000	II	10	applicable	N/A
Cruciate ligament function testing equipment	A device used to evaluate cruciate ligament function.	70102000	II	10	applicable	—
Fundus camera	A device used to take images of the ocular fundus (inside the eyeball, the posterior fundus) through the pupil.	10551000	II	10	applicable	applicable
Ophthalmic camera	A camera specifically designed to record still images of the eye and ocular fundus (when fluorescein angiography technique is used, angiographic images). In some devices, light may be illuminated from the objective lens, and take retinal images (at 1 second intervals) by adjusting the position with the eye, or may document pathology of	16419000	II	10	applicable	applicable
Laryngostroboscope unit	A device used to observe phonation within the pharynx. The device is usually used in conjunction with other devices constituting the system, and an appropriate laryngoscope. The device is used for the testing of phonation (glottic) function, and assessment of dysphonia.	31923000	II	10	applicable	N/A
Fat/lean analyzer	A device used to measure body fat and fat-free mass. The measurement results are shown by weight.	36022010	II	10	applicable	N/A
Body composition analyzer	A device used to measure body water content (intra- and extracellular fluid volume), lean body mass and other parameters by using bioelectrical impedance analysis (BIA).	36022020	II	10	applicable	N/A

Phonatory function testing equipment	A device that monitors and records the strength of phonation, fundamental frequency, expiratory flow, and other physical quantities, used for the diagnosis of dysfunction of the vocal organs. Some devices include the ability to calculate the correlation between these physical quantities and their stability.	70103000	II	10	applicable	N/A
Tongue pressure measuring instrument	A device to determine lingual pressure electrically.	70104000	II	10	applicable	—
Endoscopic telescope	One of the components of an endoscopic system that consists of a variety of components to function. The device consists of a rigid or flexible endoscope with an image transmission system based on a relay lens, optical fiber, or solid-state image sensing device. It is usually connected to a fiber cable to provide light from the light source. The device may be inserted through a sheath. The device is used to examine a	37084000	II	5-⑥,6	applicable	applicable
Flexible duodenoscope	An endoscope used for visual examination, diagnosis, and treatment of the duodenum (upper gastrointestinal tract up to the proximal duodenum). The device is intended to examine the mucous membranes, gallbladder, pancreas, stomach and other organs. A fiber optic bundle is used for image transmission.	35020000	II	5-⑥	applicable	applicable
Flexible gastroduodenoscope	An endoscope used for visual examination, diagnosis, and treatment of that part of the gastrointestinal tract that extends from the stomach to the duodenum. The device is a flexible endoscope, which changes its shape depending on the shape of the body cavity. A fiber optic bundle is used for the image transmission system.	35087000	II	5-⑥	applicable	applicable
Gastroscope	An endoscope used for visual examination, diagnosis, and treatment of the stomach. It is inserted through the mouth, or an artificial opening. The insertion section is flexible, and a fiber optic bundle is used for image transmission.	35088000	II	5-⑤	applicable	applicable
Flexible esophagoscope	An endoscope used for visual examination, diagnosis, and treatment of the esophagus. The insertion section changes its shape corresponding to the shape of the body cavity. The device is inserted through the oral cavity. The image transmission system comprises a fiber optic bundle.	36631000	II	5-⑥	applicable	applicable
Flexible sigmoidoscope	An endoscope used for visual examination, diagnosis, and treatment of the colon and rectum. It is a fiberscope in which the insertion section is flexible allowing modification of the shape depending on the shape of the cavity; a fiber optic bundle is used for image transmission.	15057000	II	5-⑥	applicable	applicable
Flexible colonoscope	An endoscope used for visual examination, diagnosis, and treatment of the colon. The insertion section is flexible, and is inserted through the anus. A fiber optic bundle is used for image transmission.	34966000	II	5-⑥	applicable	applicable
Flexible pancreatoscope	An endoscope used for visual examination, diagnosis, and treatment of the pancreas. A fiber optic bundle is used for image transmission, and the insertion section is flexible. The device is usually inserted into the working channel of a duodenoscope, and is inserted through the papilla of Vater.	32253000	II	5-⑥	applicable	applicable
Flexible choledochoscope	An endoscope used for visual examination, diagnosis, and treatment of the biliary tract. The insertion section is flexible, is inserted through the incised part of the abdomen, and can also be inserted through a flexible duodenoscope. The device is a fiberscope in which a fiber optic bundle is used for image transmission.	34939000	II	5-⑥	applicable	applicable

Flexible nasopharyngoscope	An endoscope used for visual examination, diagnosis, and treatment of the nasopharynx (upper portion of the pharynx, behind the nose). The device is a flexible endoscope, which changes its shape depending on the shape of the body cavity. The image transmission system comprises a fiber optic bundle.	35204000	II	5-⑥	applicable	applicable
Flexible bronchoscope	An endoscope used for visual examination, diagnosis, and treatment of the bronchi and lungs. The insertion section is flexible. The device is a fiberscope with a fiber optic bundle for image transmission.	35461000	II	5-⑥	applicable	applicable
Flexible nephroscope	An endoscope used for visual examination, diagnosis, and treatment of the kidney. The device is percutaneously inserted into the renal pelvis. The device is a flexible endoscope, which changes its shape depending on the shape of the body cavity. The image transmission system comprises a fiber optic bundle.	35502000	II	6	applicable	applicable
Flexible cystoscope	An endoscope used for visual examination, diagnosis, and treatment of the urinary bladder from via the urethra (or the upper urinary tract). The insertion section is flexible, and changes the shape corresponding to the shape of the cavity. The device is a fiberscope with a fiber optic bundle for image transmission.	35980000	II	5-⑥	applicable	applicable
Flexible enteroscope	An endoscope used for visual examination, diagnosis, and treatment of the small intestine. The device is used during surgery of the small intestine. The device may be of push type (introduced by guidance under direct vision) or probe type (having an insertion section which changes its shape corresponding to the shape of the cavity).	36298000	II	5-⑥	applicable	applicable
Flexible culdoscope	An endoscope used for visual examination, diagnosis, and treatment of the uterus, ovary, uterine tube, pelvis and pelvic cavity via the posterior vaginal fornix. The device is a flexible endoscope, and a fiber optic bundle is used for image transmission.	36624000	II	6	applicable	applicable
Flexible cystourethroscope	An endoscope used for visual examination, diagnosis, and treatment of the urinary bladder and the urethra (including the prostate area) in male patients. The insertion section is flexible. The device is a fiberscope with a fiber optic bundle for image transmission.	36632000	II	5-⑥	applicable	applicable
Flexible thoracoscope	An endoscope used for visual examination, diagnosis, and treatment of the thoracic cavity. The device is inserted into the body cavity through the intercostal space. The device is a flexible endoscope, and a fiber optic bundle is used for image transmission.	36639000	II	6	applicable	applicable
Flexible ureteroscope	An endoscope used for visual examination, diagnosis, and treatment of the ureter (a tube through which urine passes from the kidney to the bladder), and renal pelvis through the external urethral orifice. The insertion section is flexible, and the shape changes corresponding to the shape of the cavity. The device is a fiberscope with a fiber optic bundle for image transmission.	36640000	II	5-⑥	applicable	applicable
Flexible laryngoscope	An endoscope used for visual examination, diagnosis, and treatment of the larynx. The insertion section is flexible, and the shape changes corresponding to the shape of the cavity. The device is a fiberscope with a fiber optic bundle for image transmission.	36645000	II	5-⑥	applicable	applicable
Flexible intubation laryngoscope	An endoscope used to assist the insertion and placement of a special tracheal tube in the trachea (the human airway) for the maintenance of this airway during anesthesia or in emergency medical care. The insertion section is flexible, and the shape changes corresponding to the shape of the cavity.	36706010	II	5-⑥	applicable	applicable
Flexible pharyngoscope	An endoscope used for visual examination, diagnosis, and treatment of the pharynx. The insertion section is flexible, and the shape changes corresponding to the shape of the cavity. The device is a fiberscope with a fiber optic bundle for image transmission.	36709000	II	5-⑥	applicable	applicable
Flexible ureterorenoscope	An endoscope used for visual examination, diagnosis, and treatment of the ureter and the renal pelvis through the external urethral orifice. The insertion section is flexible, and the shape changes corresponding to the shape of the cavity. The image transmission system comprises a fiber optic bundle.	37111000	II	5-⑥	applicable	applicable
Flexible hysteroscope	An endoscope used for visual examination, diagnosis, and treatment of the uterine cavity (uterus). The device is inserted through the vagina or uterine cervix. The device is a flexible endoscope which changes its shape corresponding to the shape of the body cavity.	37152000	II	5-⑥	applicable	applicable

Flexible laparoscope	An endoscope used for visual examination, diagnosis, and treatment of the abdominal cavity or retroperitoneum. It is inserted through an artificial opening on the abdominal wall (usually, immediately below the navel). The insertion section is made of flexible materials, and a fiber optic bundle is used for image transmission.	70106000	II	6	applicable	applicable
Flexible stomatoscope	An endoscope used for visual examination of the oral cavity. The insertion section is flexible, and comprises an optical system such as an image fiber.	70107000	II	5-⑥	applicable	applicable
Flexible antroscope	An endoscope mainly used for visual examination, diagnosis, and treatment of the maxillary sinus. This device is a flexible endoscope.	70109000	II	5-⑥	applicable	applicable
Flexible lacrimal passage endoscope	An endoscope used for visual examination, diagnosis, and treatment of the lacrimal duct. The insertion section is flexible with a fiber optic bundle.	70110000	II	5-⑥	applicable	applicable
Flexible mammary ductoscope	An endoscope used for visual examination, diagnosis, and treatment of mammary ducts. The insertion section is flexible with a fiber optic bundle.	70111000	II	5-⑥	applicable	applicable
Flexible plastic surgery endoscope	An endoscope used for aspiration of subcutaneous tissues or reconstructive surgery in the field of plastic surgery. The insertion section is flexible with a fiber optic bundle.	70112000	II	6	applicable	applicable
Flexible ear endoscope	An endoscope used for visual examination, diagnosis, and treatment in the field of otology, mainly in the middle ear. This device is a flexible endoscope.	70114000	II	5-⑥	applicable	applicable
Flexible salpingoscope	An endoscope used for visual examination, diagnosis, and treatment of the uterine tube, as well as for ovum collection or implantation of fertilized ovum. The device is inserted through the abdominal cavity, vagina, or uterine cervix. The insertion section is flexible, and changes its shape corresponding to the shape of the body cavity. A fiber optic bundle is used in the image transmission system.	70115000	II	5-⑥	applicable	applicable
Flexible arthroscope	An endoscope used for visual examination, diagnosis, and treatment of the joints (e.g., knee joint and shoulder joint). It is inserted into the joint through an artificial opening. Usually, the insertion section is flexible, and has a fiber optic bundle.	70116000	II	6	applicable	applicable
Flexible mediastinoscope	An endoscope used for visual examination, diagnosis, and treatment of the mediastinum (the central part of the thoracic cavity, between the right and left pleural cavities, behind the sternum). The insertion section is flexible, and has an optical fiber tube bundle as an image transmission system.	70117000	II	6	applicable	applicable

Flexible urethroscope	An endoscope used for visual examination, diagnosis, and treatment of the urinary tract. The insertion section is flexible, and changes its shape corresponding to the shape of the body cavity. The device is a fiberscope with a fiber optic bundle for image transmission.	70118000	II	5-⑥	applicable	applicable
Flexible rhinoscope	An endoscope used for visual examination, diagnosis, and treatment of the nasal cavity through the external naris. The device is a flexible endoscope, and has a fiber optic bundle.	70119000	II	5-⑥	applicable	applicable
Flexible sinoscope	An endoscope used for visual examination, diagnosis, and treatment of the paranasal sinuses. The device is a flexible endoscope, and has an optic fiber imaging system.	70120000	II	5-⑥	applicable	applicable
Flexible rhino-laryngoscope	An endoscope used for visual examination, diagnosis, and treatment of the larynx through the nasal cavity. The insertion section is flexible, and changes its shape corresponding to the shape of the body cavity. The device is a fiberscope with a fiber optic bundle for image transmission.	70121000	II	5-⑥	applicable	applicable
Flexible video bronchoscope	An endoscope used for visual examination, diagnosis, and treatment of the bronchi and lungs. The insertion section is flexible, and changes the shape corresponding to the shape of the cavity. A solid-state image sensing device is used for the image transmission system.	17662000	II	5-⑥	applicable	applicable
Flexible video gastroscope	An endoscope used for visual examination, diagnosis, and treatment of the stomach. The device is inserted through the oral cavity or an artificial opening on the stomach wall. A solid-state image sensing device is used for the image transmission system. The insertion section is usually flexible.	17663000	II	5-⑥	applicable	applicable
Flexible video sigmoidoscope	An endoscope used for visual examination, diagnosis, and treatment of the colon and rectum. The device is a videoscope in which the insertion section is flexible and changes its shape corresponding to the shape of the body cavity; a solid-state image sensing device is used for image transmission.	17664000	II	5-⑥	applicable	applicable
Flexible video cystourethroscope	An endoscope used for visual examination, diagnosis, and treatment of the urinary bladder, and the ureter (including the prostate area) in male patients. The insertion section is flexible. The device is a videoscope in which a solid-state image sensing device is used for image transmission.	32019000	II	5-⑥	applicable	applicable
Flexible video laryngoscope	An endoscope used for visual examination, diagnosis, and treatment of the larynx. The insertion section is flexible, and the shape changes corresponding to the shape of the cavity. The device is a videoscope in which a solid-state image sensing device is used for image transmission.	35462000	II	5-⑥	applicable	applicable
Endoscopic video imaging system	A system that displays a video image transmitted from the videoscope to the display screen. The operator and assistant can observe the treated site with this system. It usually consists of a videoscope, an endoscopic camera, a camera control unit, a light source and light source cable, a video recorder, an image processor (sometimes with color calibration), a visual display unit (e.g., television monitor manufactured for medical use).	35616000	II	5-⑥	applicable	applicable

Flexible video duodenoscope	An endoscope used for visual examination, diagnosis, and treatment of the duodenum (upper gastrointestinal tract up to the proximal duodenum). The device is intended to examine the mucous membranes, gallbladder, pancreas, stomach and other organs. A solid-state image sensing device is used for the image transmission system.	36112000	II	5-⑥	applicable	applicable
Flexible video colonoscope	An endoscope used for visual examination, diagnosis, and treatment of the colon. The insertion section is flexible, and is inserted through the anus. A solid-state image sensing device is used for the image transmission system.	36117000	II	5-⑥	applicable	applicable
Flexible video laparoscope	An endoscope used for visual examination, diagnosis, and treatment of the abdominal cavity or retroperitoneum. The device is inserted through an artificial opening in the abdominal wall (usually immediately below the navel). A solid-state image sensing device is used for the image transmission system.	36283000	II	6	applicable	applicable
Rigid video laparoscope	An endoscope used for visual examination, diagnosis, and treatment of the abdominal cavity or retroperitoneum. The device is inserted through an artificial opening in the abdominal wall (usually immediately below the navel). The insertion section is either	43053000	II	6	applicable	applicable
Flexible video enteroscope	An endoscope used for visual examination, diagnosis, and treatment of the small intestine. The device is used during surgery of the small intestine. The device may be of a push type (introduced by guidance under direct vision) or probe type (having an	36299000	II	5-⑥	applicable	applicable
Flexible video choledochoscope	An endoscope used for visual examination, diagnosis, and treatment of the biliary tract. The insertion section is flexible, is inserted through the incised part of the abdomen, and can also be inserted through a flexible duodenoscope. A solid-state image sensing device is used for image transmission.	36626000	II	5-⑥	applicable	applicable
Flexible video nephroscope	An endoscope used for visual examination, diagnosis, and treatment of the kidney. The device is percutaneously inserted into the renal pelvis. The device is a flexible endoscope, which changes its shape depending on the shape of the body cavity. This is	38663000	II	6	applicable	applicable
Flexible video esophagoscope	An endoscope used for visual examination, diagnosis, and treatment of the esophagus. The insertion section is flexible, and the shape changes corresponding to the shape of the cavity. The device is inserted through the oral cavity. This is a video device in which a solid-state image sensor is used for image transmission.	38666000	II	5-⑥	applicable	applicable
Flexible video ureteroscope	An endoscope used for visual examination, diagnosis, and treatment of the ureter (a tube through which urine passes from the kidney to the bladder), and renal pelvis through the external urethral orifice. The insertion section is flexible, and the shape changes corresponding to the shape of the cavity. The device is a videoscope in which a solid-state image sensing device is used for image transmission.	38689000	II	5-⑥	applicable	applicable
Flexible video pharyngoscope	An endoscope used for visual examination, diagnosis, and treatment of the pharynx. The insertion section is flexible, and the shape changes corresponding to the shape of the cavity. The device is a videoscope in which a solid-state image sensing device is used for image transmission.	38691000	II	5-⑥	applicable	applicable
Flexible video ureterorenoscope	An endoscope used for visual examination, diagnosis, and treatment of the ureter and the renal pelvis through the external urethral orifice. The insertion section is flexible, and the shape changes corresponding to the shape of the cavity. The device is a videoscope in which a solid-state image sensing device is used for image transmission.	38703000	II	5-⑥	applicable	applicable
Flexible video gastroduodenoscope	An endoscope used for visual examination, diagnosis, and treatment of that part of the gastrointestinal tract that extends from the stomach to the duodenum. The device is a flexible endoscope, which changes its shape depending on the shape of the body cavity. A solid-state image sensing device is used for the image transmission system.	38805000	II	5-⑥	applicable	applicable
Flexible video intubation laryngoscope	An endoscope used to assist the insertion and placement of a special tracheal tube in the trachea (the human airway) for the maintenance of this airway during anesthesia or in emergency medical care. The insertion section is flexible, and changes its shape corresponding to the shape of the body cavity. The device is a videoscope in which a	70123010	II	5-⑥	applicable	applicable

Rigid video intubation laryngoscope	An endoscope used to assist the insertion and placement of a special tracheal tube in the trachea (the human airway) for the maintenance of this airway during anesthesia or in emergency medical care. In some devices, the insertion section is rigid, and the	70123020	II	5-⑥	applicable	applicable
Flexible video stomatoscope	An endoscope used for visual examination of the oral cavity. The insertion section is flexible, and uses a solid-state image sensing device.	70124000	II	5-⑥	applicable	applicable
Flexible video antroscope	An endoscope mainly used for visual examination, diagnosis, and treatment of the maxillary sinus. The device is a flexible videoscope.	70126000	II	5-⑥	applicable	applicable
Flexible video lacrimal passage endoscope	An endoscope used for visual examination, diagnosis, and treatment of the lacrimal duct. The insertion section is flexible, and uses a solid-state image sensing device.	70127000	II	5-⑥	applicable	applicable
Flexible video mammary ductoscope	An endoscope used for visual examination, diagnosis, and treatment of mammary ducts. The insertion section is flexible, and uses a solid-state image sensing device.	70128000	II	5-⑥	applicable	applicable
Flexible video plastic surgery endoscope	An endoscope used for aspiration of subcutaneous tissues or reconstructive surgery in the field of plastic surgery. The insertion section is flexible, and uses a solid-state image sensing device.	70129000	II	6	applicable	applicable
Flexible video ear endoscope	An endoscope used for visual examination, diagnosis, and treatment in the field of otology, mainly in the middle ear. The device is a flexible videoscope.	70131000	II	5-⑥	applicable	applicable
Flexible video salpingoscope	An endoscope used for visual examination, diagnosis, and treatment of the uterine tube, as well as for ovum collection or implantation of fertilized ovum. The device is inserted through the abdominal cavity, vagina, or uterine cervix. The insertion section is flexible, and changes its shape corresponding to the shape of the body cavity. The device is a videoscope in which a solid-state image sensing device is used for image transmission.	70132000	II	5-⑥	applicable	applicable
Flexible video arthroscope	An endoscope used for visual examination, diagnosis, and treatment of the joints (e.g., knee joint and shoulder joint). It is inserted into the joint through an artificial opening. Usually, the insertion section is flexible, and uses a solid-state image sensing device.	70133000	II	6	applicable	applicable
Flexible video mediastinoscope	An endoscope used for visual examination, diagnosis, and treatment of the mediastinum (the central part of the thoracic cavity, between the right and left pleural cavities, behind the sternum). The insertion section is flexible, and uses a solid-state image sensing device.	70134000	II	6	applicable	applicable
Flexible video urethroscope	An endoscope used for visual examination, diagnosis, and treatment of the urinary tract. The insertion section is flexible, and changes its shape corresponding to the shape of the body cavity. The device is a videoscope in which a solid-state image sensing device is used for image transmission.	70135000	II	5-⑥	applicable	applicable

Flexible video rhino-laryngoscope	An endoscope used for visual examination, diagnosis, and treatment of the larynx through the nasal cavity. The insertion section is flexible, and changes its shape corresponding to the shape of the body cavity. The device is a videoscope in which a solid-state image sensing device is used for image transmission.	70136000	II	5-⑥	applicable	applicable
Flexible video rhinoscope	An endoscope used for visual examination, diagnosis, and treatment of the nasal cavity through the external naris. The device is a videoscope with a solid-state image sensing device.	70137000	II	5-⑥	applicable	applicable
Flexible video sinoscope	An endoscope used for visual examination, diagnosis, and treatment of the paranasal sinuses. The device is a videoscope with a solid-state image sensing device.	70138000	II	5-⑥	applicable	applicable
Flexible video thoracoscope	An endoscope used for visual examination, diagnosis, and treatment of the thoracic cavity. The device is inserted into the body cavity through the intercostal space. The device is a flexible videoscope in which a solid-state image sensing device is used for image transmission.	70139000	II	6	applicable	applicable
Flexible video hysteroscope	An endoscope used for visual examination, diagnosis, and treatment of the uterine cavity (uterus). The device is inserted through the vagina or uterine cervix. The device is a flexible endoscope which changes its shape corresponding to the shape of the body cavity or the lumen of a device. A solid-state image sensing device is used for image transmission.	70141000	II	5-⑥	applicable	applicable
Flexible video pancreatoscope	An endoscope used for visual examination and diagnosis of the pancreas. The device is usually connected to the working channel of a duodenoscope, and is inserted through the papilla of Vater. The insertion section is flexible, and uses a solid-state image sensing device for image transmission.	70143000	II	5-⑥	applicable	applicable
Flexible video nasopharyngoscope	An endoscope used for visual examination, diagnosis, and treatment of the nasopharynx (upper portion of the pharynx, behind the nose). The device is a flexible endoscope that changes its shape corresponding to the shape of the body cavity. The device is a videoscope in which a solid-state image sensing device is used for image transmission.	70145000	II	5-⑥	applicable	applicable
Flexible video cystoscope	An endoscope used for visual examination, diagnosis, and treatment of the urinary bladder from via the urethra (or the upper ureter). The insertion section is flexible, and changes its shape corresponding to the shape of the body cavity. The device is a videoscope in which a solid-state image sensing device is used for image transmission.	70146000	II	5-⑥	applicable	applicable
Flexible video culdoscope	An endoscope used for visual examination, diagnosis, and treatment of the uterus, ovary, uterine tube, pelvis and pelvic cavity via the posterior vaginal fornix. The device consists of a flexible endoscope and a videoscope in which a solid-state image sensing device is used for image transmission.	70147000	II	6	applicable	applicable
Rigid nephroscope	An endoscope used for visual examination, diagnosis, and treatment of the kidney, renal pelvis, major calyces, and minor calyces. The device is percutaneously inserted into the renal pelvis. The insertion section is rigid, and certain resistance is experienced in inserting the device into the body cavity or through the outer cylinder.	15290000	II	6	applicable	applicable
Rigid cystoscope	An endoscope used for visual examination, diagnosis, and treatment of the urinary bladder from via the urethra (or the upper urinary tract). The insertion section is rigid. Relay lens optics are used for image transmission.	17145000	II	5-⑥	applicable	applicable

Pyeloscopy kit	A kit of packaged tools including devices, instruments, and other accessories necessary for pyeloscopic procedures. An endoscopic device necessary for the pyeloscopic procedures may be included. The kit is considered to be reusable even if some of the	32083000	II	6,9	applicable	applicable
Rigid resectoscope	An endoscope used for visual examination, diagnosis, and treatment, especially for resection of tissues (e.g., enlarged prostate gland or endometrium). The device usually	35301000	II	5-⑥,9	applicable	applicable
Rigid urethroscope	An endoscope used for visual examination, diagnosis, and treatment of the urethra. The insertion section is rigid, and certain resistance is experienced in inserting the device into the body cavity. Relay lens optics are used for image transmission.	35423000	II	5-⑥	applicable	applicable
Rigid cystourethroscope	An endoscope used for visual examination, diagnosis, and treatment of the urinary bladder and the urethra (including the prostate area) in male patients. The insertion section is rigid.	36652000	II	5-⑥	applicable	applicable
Rigid ureteroscope	An endoscope used for visual examination, diagnosis, and treatment of the ureter (a tube through which urine passes from the kidney to the bladder) and renal pelvis through the external urethral orifice. The insertion section is rigid, and certain resistance is experienced in inserting the device into the body cavity. Relay lens optics	36654000	II	5-⑥	applicable	applicable
Rigid ureterorenoscope	An endoscope used for visual examination, diagnosis, and treatment of the ureter and the renal pelvis through the external urethral orifice. The insertion section is rigid, and certain resistance is experienced in inserting the device into the body cavity. Relay lens optics are used for image transmission. Some times use a fiber optic bundle for	37112000	II	5-⑥	applicable	applicable
Rigid urethrotome	An endoscope used for visual examination, diagnosis, and treatment, especially for incision, of a narrowed part of the urethra. The device usually consists of a rigid outer cylinder, optical telescope, working element, and scalpel for incision.	17633000	II	5-⑥	applicable	applicable
Rigid anoscope	An endoscope used for visual examination, diagnosis, and treatment of the anal canal and lower rectum. The device is a rigid endoscope, and has relay lens optics for image transmission	10156002	II	5-⑥	applicable	applicable
Rigid gastroscope	An endoscope used for visual examination, diagnosis, and treatment of the stomach. The device is inserted through the oral cavity or an artificial opening on the stomach wall. The device is a rigid endoscope. A relay lens optics system is used for image transmission.	11858000	II	5-⑥	applicable	applicable
Rigid laparoscope	An endoscope used for visual examination, diagnosis, and treatment of the abdominal cavity or retroperitoneum. The device is inserted through an artificial opening in the abdominal wall (usually, immediately below the navel). The device is a rigid endoscope and certain resistance is experienced in inserting the device into the body cavity or through the lumen of the device. Relay lens optics are used for image transmission.	12291000	II	6	applicable	applicable
Rigid sigmoidoscope	An endoscope used for visual examination, diagnosis, and treatment of the colon and rectum. The insertion section is rigid, and certain resistance is experienced in inserting the device into the body cavity. Relay lens optics are used for image transmission	15058000	II	5-⑥	applicable	applicable
Rigid bronchoscope	An endoscope used for visual examination, diagnosis, and treatment of the bronchi and lungs. The insertion section is rigid, and relay lens optics are used for image transmission.	15074000	II	5-⑥	applicable	applicable
Rigid intubation laryngoscope	An endoscope used to assist the insertion and placement of a tracheal tube in the trachea (human airway) for the maintenance of this airway during anesthesia or in emergency medical care. The insertion section is rigid, and either relay lens optics or a	36706020	II	5-⑥	applicable	applicable
Rigid laryngoscope	An endoscope used for visual examination, diagnosis, and treatment of the larynx. The device is a rigid endoscope, and has relay lens optics for image transmission.	15076000	II	5-⑥	applicable	applicable

Sphincteroscope	An endoscope used for examination of the anal sphincter.	15787002	II	5-⑥	applicable	applicable
Laparoscopy kit	A kit of packaged tools including devices, instruments, and other accessories necessary for laparoscopic procedures. An endoscopic device necessary for the laparoscopic procedures may be included. The kit is considered to be reusable, even if some of the accessories need to be replenished.	32043000	II	6,9	applicable	applicable
Transcervical rigid amnioscope	An endoscope inserted through the cervix and used for direct visual examination, diagnosis, and treatment of the fetus or for visual examination of the color and volume of amniotic fluid.	32631000	II	5-⑥	applicable	applicable
Transabdominal rigid amnioscope	An endoscope used for visual examination, diagnosis, and treatment of the amnion. The device is inserted into the amniotic cavity through an artificial opening in the maternal abdominal wall.	34837000	II	5-⑥	applicable	applicable
Rigid arthroscope	An endoscope used for visual examination, diagnosis, and treatment of the joints (e.g., knee joint and shoulder joint). It is inserted into the joint through an artificial opening. Usually, the insertion section is rigid.	34856000	II	6	applicable	applicable
Rigid culdoscope	An endoscope used for visual examination, diagnosis, and treatment of the uterus, ovary, uterine tube, pelvis and pelvic cavity via the posterior vaginal fornix. The device is a rigid endoscope, and relay lens optics are used for image transmission.	34979000	II	6	applicable	applicable
Rigid directoscope	An endoscope used for visual examination and diagnosis of the larynx. The device is a rigid endoscope, and has relay lens optics.	35011000	II	5-⑥	applicable	applicable
Rigid mediastinoscope	An endoscope used for visual examination, diagnosis, and treatment of the mediastinum (the central part of the thoracic cavity, between the right and left pleural cavities, behind the sternum). The insertion section is rigid, and relay lens optics are used for image transmission.	35187000	II	6	applicable	applicable
Rigid nasopharyngoscope	An endoscope used for visual examination, diagnosis, and treatment of the nasopharynx (upper portion of the pharynx, behind the nose). The device is a rigid endoscope and certain resistance is experienced in inserting the device into the body cavity or through the lumen of the device. Relay lens optics are used for image transmission.	35205000	II	6	applicable	applicable
Rigid pelviscope	An endoscope used for visual examination and diagnosis of the pelvis. The device is inserted transcutaneously through an artificial opening. The device is a rigid endoscope with relay lens optics.	35233000	II	6	applicable	applicable
Rigid proctoscope	An endoscope used for visual examination, diagnosis, and treatment of the rectum and anus. The device is a rigid endoscope which comprises relay lens optics and a mirror with a light source at the tip.	35255000	II	5-⑥	applicable	applicable
Rigid rhinoscope	An endoscope used for visual examination, diagnosis, and treatment of the nasal cavity through the external naris. The device is a rigid endoscope with relay lens optics.	35316000	II	5-⑥	applicable	applicable

Rigid thoracoscope	An endoscope used for visual examination, diagnosis, and treatment of the thoracic cavity. The device is inserted into the body cavity through the intercostal space. The device is a rigid endoscope with relay lens optics for image transmission. Some types of device use a fiber optic bundle for image transmission, and the tip may be bent.	35398000	II	6	applicable	applicable
Rigid surgical lumbolescope	An endoscope used for visual examination, diagnosis, and treatment of the vertebrae, primarily the lumbar vertebrae, inserted through an artificial opening. However, devices used on the central nervous system are excluded. This product is a rigid endoscope, by which the insertion section resists the body cavity. Relay lens optics are	35568000	II	7	applicable	applicable
Rigid hysteroscope	An endoscope used for visual examination, diagnosis, and treatment of the uterine cavity (uterus). The device is inserted through the vagina or uterine cervix. The device is a rigid endoscope and certain resistance is experienced in inserting the device into	36628000	II	5-⑥	applicable	applicable
Rigid rhino-laryngoscope	An endoscope used for visual examination, diagnosis, and treatment of the larynx through the nasal cavity. The device is a rigid endoscope with relay lens optics.	36637000	II	5-⑥	applicable	applicable
Rigid antroscope	An endoscope mainly used for visual examination, diagnosis, and treatment of the maxillary sinus. The device is a rigid endoscope.	36647000	II	5-⑥	applicable	applicable
Rigid esophagoscope	An endoscope used for visual examination, diagnosis, and treatment of the esophagus. The insertion section is rigid, and certain resistance is experienced in inserting the device into the body cavity. Relay lens optics are used for image transmission. These	36653000	II	5-⑥	applicable	applicable
Rigid pharyngoscope	An endoscope used for visual examination, diagnosis, and treatment of the pharynx. The insertion section is rigid, and relay lens optics are used for image transmission.	36708000	II	5-⑥	applicable	applicable
Rigid auditory canal endoscope	An extremely short endoscope used for visual examination, diagnosis, and treatment of the auditory acoustic meatus (a tube between the opening part of the ear and the eardrum). The device is usually rigid.	36903000	II	5-⑥	applicable	applicable
Rigid adenoscope	An endoscope used for visual examination, diagnosis, and treatment of the nasal cavity, used, for instance, during adenoidectomy. The device is a rigid endoscope.	36906000	II	5-⑥	applicable	applicable
Rigid sinoscope	An endoscope used for visual examination, diagnosis, and treatment of the paranasal sinuses. The device is a rigid endoscope with relay lens optics for image transmission. Some devices have a fiber optic bundle.	37180000	II	5-⑥	applicable	applicable

TEM rectoscope	A device used for microscopic procedures and treatment of the lower intestine accessed via the anus with a special proctoscope tube (transanal endoscopic microsurgery [TEM]). It is a rigid endoscope system, and is equipped with a device to send gas to inflate the observation site and dedicated surgical devices as well as an optical observation telescope.	37182000	II	5-⑥	applicable	applicable
ESDP endoscope	A device dedicated for the treatment of varices, such as in endoscopic subfascial dissection of incompetent perforating veins (ESDP). The device is inserted transcutaneously along the outer side of the perforating veins, through an artificial opening. The device is usually a rigid endoscope and certain resistance is experienced in inserting the device into the body cavity or through the lumen of the device. The image transmission system used is one of the relay lens optics technology.	37183000	II	5-⑥	applicable	applicable
Rigid lacrimal passage endoscope	An endoscope used for visual examination, diagnosis, and treatment of the lacrimal duct. The insertion section is rigid, and relay lens optics or a fiber optic bundle are used for image transmission.	70149000	II	5-⑥	applicable	applicable
Rigid mammary ductoscope	An endoscope used for visual examination, diagnosis, and treatment of mammary ducts. The insertion section is rigid, and relay lens optics or a fiber optic bundle are used for image transmission.	70150000	II	5-⑥	applicable	applicable
Rigid plastic surgery endoscope	An endoscope used for aspiration of subcutaneous tissues or reconstructive surgery in the field of plastic surgery. The insertion section is rigid, and relay lens optics or a fiber optic bundle are used for image transmission.	70151000	II	6	applicable	applicable
Rigid ear endoscope	An endoscope used for visual examination, diagnosis, and treatment in the field of otology, mainly in the middle ear. The device is a rigid endoscope.	70153000	II	5-⑥	applicable	applicable
Rigid salpingoscope	An endoscope used for visual examination, diagnosis, and treatment of the uterine tube, as well as for ovum collection or implantation of fertilized ovum. The device is inserted through the abdominal cavity, vagina, or uterine cervix. The insertion section is rigid, and certain resistance is experienced in inserting the device into the body cavity. Relay lens optics are used for image transmission. Some devices have a fiber optic bundle for image transmission.	70154000	II	5-⑥	applicable	applicable
Rigid stomatoscope	An endoscope used for visual examination of the oral cavity. The insertion section is rigid, and relay lens optics or an image fiber may be used for image transmission.	70155000	II	5-⑥	applicable	applicable

Ophthalmic endoscope	An endoscope used for visual examination, diagnosis, and treatment of the eye and appendages of the eye.	70156000	II	6	applicable	applicable
Ultrasonic flexible gastroduodenoscope	An endoscope with a build-in ultrasound probe; the endoscope is used for visual examination, diagnosis, and treatment of the upper gastrointestinal tract extending from the esophagus via the stomach to the duodenum, and the ultrasound probe is used for the examination of mucous membranes, the gall bladder, pancreas, stomach, and surrounding organs. The device is classified as Class II.	36951000	II	5-⑥	applicable	applicable
Ultrasonic rigid laparoscope	An endoscope with a build-in ultrasound probe; the endoscope is used for visual examination, diagnosis, and treatment of the abdominal area, and the ultrasound probe for the examination of the abdominal area. The device is inserted through an artificial opening in the abdominal wall. The insertion section is rigid, and certain resistance is experienced in inserting the device into the body cavity. The device is a Class II device.	36963000	II	6	applicable	applicable
Ultrasonic flexible duodenoscope	An endoscope with a build-in ultrasound probe; the endoscope is used for visual examination, diagnosis, and treatment of the upper gastrointestinal tract extending from the esophagus via the stomach to the duodenum, and the ultrasound probe is used for the examination of mucous membranes, the gall bladder, pancreas, stomach, and surrounding organs. The device is classified as Class II.	37223000	II	5-⑥	applicable	applicable
Ultrasonic flexible colonoscope	An endoscope with a build-in ultrasound probe; the endoscope is used for visual examination, diagnosis, and treatment of the lower gastrointestinal tract, from the rectum, via the colon, to the cecum, and the ultrasound probe is used for the examination of mucous membranes and other organs. The device is a fiberscope with a fiber optic bundle, or a videoscope with a solid-state image sensing device.	38807000	II	5-⑥	applicable	applicable
Ultrasonic flexible laparoscope	An endoscope with a build-in ultrasound probe; the endoscope is used for visual examination, diagnosis, and treatment of the abdominal area, and the ultrasound probe for the examination of the abdominal area. The device is inserted through an artificial opening in the abdominal wall. The device is a fiberscope with a fiber optic bundle, or a videoscope with a solid-state image sensing device.	70157000	II	6	applicable	applicable
Ultrasonic flexible bronchoscope	An endoscope with a build-in ultrasound probe; the endoscope is used for visual examination, diagnosis, and treatment of the bronchi and lungs, and the ultrasound probe for examination of the bronchi, lungs, and surrounding organs. The device is a fiberscope with a fiber optic bundle, or a videoscope with a solid-state image sensing device.	70158000	II	5-⑥	applicable	applicable
Ultrasound endoscopic observation system	A dedicated system used for endosonographic imaging. The device consists of an endoscopic ultrasound device and ultrasound imaging device. The system supports a variety of transducers and associated application software packages, used for the collection, display and analysis of ultrasonographic information. Typical uses include:	70159000	II	5-⑥	applicable	applicable
Endoscope light source/processing unit with air/water supply function	A dedicated external power source device, designed to function as both a light source and a processing unit intended for use together with endoscopes (primarily video endoscopes). This device provides light for viewing the surgical fields and body cavities, and receives the electronic image signals for processing into signals that can be displayed on a monitor.	34540002	II	11	applicable	applicable
Line-powered endoscope light source with air/water supply function	A dedicated, external power source that provides light for viewing body cavities when using rigid or flexible endoscopes (e.g., laparoscopes and gastroscopes) and their accessories. The device transmits its light through a fiber-optic cable that connects the endoscope to the site of observation and intervention, while minimizing tissue heating.	35158002	II	11	applicable	applicable
Battery-powered endoscope light source with air/water supply function	A dedicated battery-powered device that provides light for viewing surgical field and body cavities when using rigid or flexible endoscopes, (e.g., laparoscopes and gastroscopes) and their accessories. The device transmits its light through a fiber-optic cable that connects the endoscope to the site of observation and intervention, while minimizing tissue heating. Depending on the built-in optical filters, some devices may generate infrared light, ultraviolet light, or visible light within a specific wavelength range. The device can supply air or water.	35906002	II	11	applicable	applicable

Hysteroscopic gas distension unit	A dedicated device used to inject pressure-adjusted gas into the uterine cavity to distend the uterus. This device makes it possible to secure a wide area in the uterine cavity for examinations and surgery. It maintains gas pressure in equilibrium through gas leakage correction.	12144000	II	11	applicable	applicable
Bipolar endotherapy coagulator	A special electrosurgical unit used during endoscopy in high-frequency endoscopic electrosurgery. This device destroys the tissue between 2 contact faces of the device with high temperature by detecting the high-frequency current in that tissue.	32684000	II	6,9	applicable	applicable
Unipolar endotherapy coagulator	A special electrosurgical unit used during endoscopy in high-frequency electrosurgery. This device destroys the tissue between the electrode tip of the device and the plate attached to the patient's external body surface with high temperature by detecting the high-frequency current in that tissue.	33596000	II	6,9	applicable	applicable
Endoscopic electrosurgical unit	A dedicated electrosurgical unit designed to be used with an endoscope and dedicated endoscopic devices in endoscopic treatment. It is specifically designed to generate high-frequency energy inside the body via the endoscope or the endoscope system when used with the endoscopic electrode.	33602000	II	6,9	applicable	applicable
Arthroscopic fluid distension unit	A dedicated device used to distend the tissue around the joint where an arthroscopy is being performed (e.g., the knee or shoulder joint). The cavity is filled with fluid to extend the tissue around the site, which facilitates viewing and intervention with an arthroscope. The device may usually be used to irrigate surgically removed bone, cartilage, and other tissue debris, and remove body fluids from the site.	36003000	II	11	applicable	applicable
Endoscope irrigation/aspiration unit	A dedicated endoscopy device intended for perfusion and aspiration (washing effect) with fluids to facilitate endoscopic viewing and intervention in body cavities or the lumen of a device. The device should be used with a suitable endoscope and its accessories.	36023000	II	6,11	applicable	applicable
Hysteroscopic fluid distension unit	A dedicated endoscopy device intended to inject fluids into the uterine cavity to dilate the uterus, in order to facilitate hysteroscopic viewing and intervention. The device also helps to provide a wide space for intervention. The device may also be used to wash resected tissues and remove body fluid from around the intervention site.	36122000	II	2,11	applicable	applicable

Electrosurgical unit with endotherapy monitor/shield	A dedicated device designed to be connected to an appropriate electrosurgical unit in order to manage leakage of high frequency current from the active electrode used with the endoscope, the endoscope system or dedicated endoscopic treatment device in endoscopic treatment (e.g., laparoscopic surgery). It is specifically designed to monitor and manage the leakage current during high-frequency endoscopic electrosurgery.	36152000	II	6,9	applicable	applicable
Arthroscopic gas distension unit	A dedicated device used to inflate the tissues around the joint (e.g., knee joint, shoulder joint) for arthroscopy. With this device, inert gas is injected into the space to inflate the tissues around the treatment site, which makes observation and treatment easier with an arthroscope.	36677000	II	11	applicable	applicable
Endoscope air supply pump	A device that supplies air via the endoscope to prevent condensation/dew condensation on the lens, or to extend the space at the tip of the endoscope, in order to provide the desired field of view, and visibility to allow intervention.	36750012	II	11	applicable	applicable
Endoscope water supply system	An endoscopic device intended to supply water to facilitate endoscopic viewing in body cavities, or the lumen of another device. The device should be used with a suitable endoscope and its accessories.	36500022	II	2,11	applicable	applicable
Endoscope air and water supply system	An endoscopic device intended to supply air or water to facilitate endoscopic viewing, or intervention in body cavities, or the lumen of another device. The device should be used with a suitable endoscope and its accessories.	36500032	II	2,11	applicable	applicable
Endoscope contour detector device	A device intended for use in displaying on the monitor screen the 3-dimensional morphology of the endoscope inserted in the lumen, to aid endoscope insertion. This display is achieved by extracorporeally detecting the magnetic field generated by the endoscope using a built-in magnetic generator or from a probe that includes a built-in magnetic generator.	70161000	II	10-①	applicable	applicable
Endoscopic irrigation/aspiration probe	A probe intended to be connected to a dedicated device for perfusion and aspiration (washing effect) with fluids to facilitate endoscopic viewing and intervention in body cavities or within the lumen of a device. Some devices may have electrocautery capabilities. The device is intended for single-use.	70162000	II	9,11	applicable	—
Reusable electrosurgical endoscopic snare	A device intended for use in ligating, cauterizing, and severing tissue and polyps, employing a high frequency current during endotherapy. The device consists of an insulated introducer sheath, snare loop (attached to the tip of the sheath), manipulating wire (connected to the loop and handle), and a handle (controlling the manipulating wire). The proximal end of the manipulating wire is connected to a high frequency electrosurgical unit.	35623000	II	6-①,9	applicable	N/A
Endoscopic working guide	An endoscopy component which consists of several elements that are needed for it to function. The device is used to assist the entry of the endoscopic electrode into an appropriate endoscope. The device can activate the electrode's cutting path actively or	37085000	II	6,9	applicable	N/A

Reusable active endotherapy device	A device used for endoscopic treatment (e.g., ablation and coagulation of the tissues) utilizing electricity (including energy sources such as high-frequency, electromagnetism, ultrasound and laser) or external driving forces. Generally the device consists of probe electrodes inserted through the working channel or other route, and a generator supplying energy to be transmitted to the tip of this device. It	38816000	II	6-①,9	applicable	N/A
Single-use active endotherapy device	A device used for endoscopic treatment (e.g., ablation and coagulation of the tissues, smoke emission) utilizing high-frequency, electromagnetism, ultrasound, laser and other energy. The device consists of probe electrodes inserted through the working channel or other route, a generator supplying energy and others. This device is for single-use.	38817000	II	6,9	applicable	—
Single-use electrosurgical endoscopic snare	A device intended for use in ligating, cauterizing, and severing tissue and polyps, employing a high frequency current during endotherapy. The device consists of an insulated introducer sheath, snare loop (attached to the tip of the sheath), manipulating wire (connected to the loop and handle), and a handle (controlling the manipulation wire). The proximal end of the manipulation wire is connected to a high	38827000	II	6,9	applicable	—
Reusable high-frequency current procedure endoscopic active instrument	Active electrodes that perform incision and coagulation of tissues are deployed within the endoscope, making use of high-frequency current; a probe is used to perform incision and coagulation, conducting electricity and heating up a heating element; together with electrically conductive cables, as well as associated accessories. A device	70164010	II	9	applicable	N/A
Single-use high-frequency current procedure endoscopic active instrument	Active electrodes that perform incision and coagulation of tissues are deployed within the endoscope, making use of high-frequency current; a probe is used to perform incision and coagulation, conducting electricity and heating up a heating element; together with electrically conductive cables, as well as associated accessories. A device intended for performing incision and coagulation of tissues by a physician under direct vision or with an endoscope. The device is not intended for specific therapeutic effect. The device should only be used with high-frequency energy. The device should not be	70164020	II	9	applicable	—
Electrosurgical endoscopic thermal diode	A dedicated device intended for use with an endoscope during endotherapy. The device has a built-in thermal diode at the distal tip. The device is used for occluding the uterine tubes for female sterilization, or coagulation of bleeding tissues. Some devices	37155000	II	6,9	applicable	N/A
Endoscopic active resection device	A device that is inserted into a body cavity together with an endoscope or on its own, to cut or resect tissues using an electrically powered or pneumatically powered rotating/sliding severing blade. Some devices may be used under direct vision, or under the operating microscope, or have perfusion/suction capabilities.	35326002	II	6,9	applicable	applicable
Single-use artificial orifices endotherapy cannula	A device used to deliver agents or contrast media into body cavities through an artificial opening during endoscopic examination, for the purpose of either diagnosis or treatment. The device is intended for single-use.	38814002	II	6	applicable	—
Single-use artificial orifices endotherapy dilator	A device, either rigid rod or flexible tube, used to dilate lumens or body cavities, to enable or facilitate insertion of endoscopic devices. Such dilation may be performed transcutaneously (through the cutaneous layers) via an artificial opening into the human body. The device is intended for single-use.	38821002	II	6	applicable	—
Fetal blood sampler	A device used to collect fetal blood with an endoscope through the uterine cervix. The fetal skin is punctured with a small blade and blood is collected into a heparin-coated tube.	32662000	II	6	applicable	N/A
Single-use artificial orifices non-active endotherapy device	A device used together with special endoscopes for endotherapy; this device is used via an artificial opening into the human body for mechanical work such as holding, collecting, resecting, clipping, or ligating tissues or foreign objects; delivering liquid	38819002	II	6	applicable	—
Single-use infection-prevention endoscopic sheath for artificial orifices	A covering (sheath) that is attached to an endoscope to protect the insertion section of the endoscope and prevent it from coming into direct contact with mucous membranes, blood, or body fluids when in use. This single-use device is intended for use in an	70173000	II	6	applicable	—
Bronchoscope ventilation sheath	A device used for ventilation in the trachea or the bronchus. It has a channel for ventilation and is inserted into the trachea with the bronchoscope.	70174000	II	5-②	applicable	N/A

Laryngostroboscope	A system that monitors phonation in the larynx. The system, consisting of a variety of devices, including a nasal laryngeal stroboscope unit, camera, video recorder, computer, and software, is usually used together with a suitable endoscope. The device	12294000	II	10	applicable	applicable
Laparoscopic lesion lifting device	A device used to elevate the stomach in order to perform local resection in laparoscopic partial gastrectomy. The device is intended for single-use.	70175000	II	6	applicable	—
Artificial orifices endoscope defroster	A device made from liquid or solid that is applied to the surface of the lens of an endoscope, which is to be inserted through an artificial opening, to prevent dew condensation which occurs due to temperature differences between the endoscope and internal body.	70177000	II	6	applicable	N/A
Multiphasic health testing system	A system that measures biological information (e.g., blood pressure, electrocardiogram), collects information utilizing a means of communication (e.g., phone line) and comprehensively checks the patient's health status.	70178000	II	10	applicable	applicable
Biofeedback system	A system usually consisting of a set of devices that generate visual or auditory signals, corresponding to at least one physiological function, such as electroencephalographic activity, muscle activity, blood pressure, skin temperature and balance so that the patient can control involuntary functions consciously to some extent. The system can	10396000	II	10-③	applicable	applicable
Penile tumescence transducer	A device to detect an erection, process related measured values and display them on the screen of the base unit.	17442000	II	10	applicable	N/A
Long-term gastric pH data recorder	A device to record acidity in the stomach with a sensor over a 24-hour period. It is carried by the patient. Recorded results are later analyzed with an appropriate device.	36965000	II	10	applicable	applicable
Dental diagnostic intraoral camera	A device used for taking video or still images of the oral cavity for diagnostic purposes.	70180000	II	10	applicable	N/A
Pelvic examination kit	A prepackaged tray, kit, or set containing everything necessary for performing a pelvic examination, such as various devices, materials for sample collection, and drugs.	34122000	II	6	applicable	—
Single-use tissue biopsy needle	A cylindrical hollow container specifically used to collect a biopsy sample. The devices come in varying diameters, and the tip is formed in various geometric shapes to enable collection of samples for analysis. The device is intended for single-use.	12734010	II	6	applicable	—
Aspiration tissue biopsy needle kit	A kit containing biopsy needles, in which tissue is resected by mechanical aspiration, and other necessary tools.	12734020	II	6	applicable	—
Single-use cholangiographic needle	An elongated, edged instrument used in injection of contrast media for cholangiography. The device is intended for single-use.	12739002	II	6	applicable	—
Single-use subcutaneous needle	An elongated, edged, hollow tube used together with an injector, secondary pharmacotherapy kit, or venous access kit (for example, blood collection adapter and holder) for administration or withdrawal of liquids. The device is intended for single-	12745002	II	6	applicable	—
Single-use intra-arterial needle	An elongated, edged, hollow tube used to puncture an artery. The device is usually made of metal and for single-use.	12747102	II	6	applicable	—
Single-use tine test needle	An elongated, sharp needle used to make multiple punctures simultaneously during tests (for example, the tine test for tuberculosis). The device is intended for single-use.	15679012	II	6	applicable	—
Tine test/vaccine needle	A elongated, sharp needle or needles with different tip shapes (for example, bifurcated) that are used to make multiple punctures simultaneously (e.g., the tine test for tuberculosis or during smallpox vaccination). The device is intended for single-use.	15679022	II	6	applicable	—

Single-use filter needle	An elongated, edged instrument with an integrated filter for filtration of the injection solution. The device is intended for single-use.	16266002	II	6	applicable	—
Single-use subcutaneous injection/infusion port needle	An elongated, edged, hollow tube that is attached to a syringe and inserted subcutaneously for drug injection or used to inject drugs into a line. The device is intended for single-use.	17180002	II	6	applicable	—
Single-use injection needle	An elongated, sharp metal needle inserted into the skin to inject or withdraw fluids. The device is intended for single-use.	30889000	II	6	applicable	—
Single-use fistula needle	A long, thin, sharp, hollow device for single-use to drain fluids from a fistula.	32111002	II	6	applicable	—
Single-use ophthalmic cannula	A sterilized tube used to collect/aspirate intraocular contents or to inject perfusate into the eye in ophthalmic surgery. The device is intended for single-use.	34899012	II	6	applicable	—
Single-use ophthalmic surgery cannula with tube	A cylindrical device that is equipped with a tube and used to inject perfusate (e.g., irrigation fluid) or aspirate intraocular contents in ophthalmic surgery. The device is intended for single-use.	34899022	II	6	applicable	—
Single-use ophthalmic surgical cannula	A cylindrical device used to inject perfusate (e.g., irrigation fluid) or aspirate intraocular contents in ophthalmic surgery. The device is intended for single-use. Some of these devices have a round, flat, or hook-shaped tip. There may also be a sleeve at the tip.	34899032	II	6	applicable	—
Single-use blood collecting needle	A single-use needle that constitutes part of a blood collection kit. The needle is attached to a holder and has a shape that punctures directly into the human body to collect blood and a shape that connects to a winged needle without having a needle that punctures into the human body.	35209002	II	6	applicable	—
Single-use blunt needle	A long, thin device with a blunt curved tip so as to prevent damage to delicate structures during probing inside the body.	35210000	II	6	applicable	—
Single-use aspiration needle	An elongated, edged, hollow tube used to withdraw fluids from a body cavity or collect biopsy specimens. The device is intended for single-use.	35886000	II	6	applicable	—
Single-use manually-operated lancet	A small, sharp-tipped instrument for skin puncture, used to collect blood or to drain the content of pus (Note 1) or furuncle (Note 2). The device may be shaped like a needle or sword. The device is intended for single-use.	37466000	II	6	applicable	—
Introduction needle	A puncture device that aids insertion of a needle, catheter, or wire into the body for therapy or diagnosis.	70194000	II	6	applicable	—

Prefilled syringe double-edged needle	An instrument that has a metal or plastic needle on both ends and is used to penetrate a rubber stopper (e.g., of a prefilled syringe) for administration or mixing of drug solutions in the container. The device is intended for single-use.	70195000	II	6	applicable	—
Single-use intrabone injection needle	A needle with an elongated lumen used to puncture bone to collect tissue or inject drug solutions. The device is commonly made of metal or plastic and for single-use.	70197000	II	6	applicable	—
Single-use infusion/drainage needle	A long, thin, sharp, metal needle used to pierce the skin in order to inject or drain fluids. Besides a long, thin, sharp, hollow needle, needles with various configurations such as bifurcated tip are available. This device is for single-use.	70198000	II	6	applicable	—
Ophthalmic needle	A hollow needle used to inject drug solutions into the eye or to aspirate intraocular fluids into the syringe during eye surgery (for example, cataract surgery). The device is either straight or curved. The device is intended for single-use.	70200000	II	6	applicable	—
Dental injection needles	A device that is made up of an elongated, hollow metal tube with a sharp tip and a needle hub and is primarily used with a dental cartridge syringe for administration of local anesthetic agents.	12740000	II	6	applicable	—
Drug/vaccine injection needle	A device used for parenteral administration of a drug in a cartridge. The cartridge may be integrated with a pen injector, or is either attached or inserted into a pen-injector for use. The device is used by patients who regularly self-administer drugs such as	44127010	II	6	applicable	—
Single-use endoscopic sclerotherapy injection needle	A device that is used with a special endoscope for endoscopic sclerotherapy to inject a drug into the mucosa or a blood vessel. The tip of the soft tube has an injection needle and a syringe connector at the other end. The device is intended for single-use.	36076002	II	6	applicable	—
Single-use endoscopic injection needle	A device that is used with a special endoscope in endoscopic surgery to inject a drug into the mucosa or a blood vessel, for purposes such as hemostasis and sclerotherapy. The tip of the flexible tube has an injection needle and a syringe connector at the other	38825000	II	6	applicable	—
Percutaneous ethanol injection needle	An elongated, edged, hollow tube used to inject ethanol percutaneously into hepatocellular carcinoma tumors to induce necrosis. The device comes as a kit with a	44127020	II	6	applicable	—
Contrast medium injection needle	A thin, edged instrument that is connected with a contrast-filled syringe for injection of contrast media used in computerized tomography (CT). The device is sterilized and intended for single-use.	44127030	II	6	applicable	—
Syringe with general-purpose needle	A device used to inject or withdraw a fluid or gas. The device is normally made of glass or plastic and consists of a container with a scale and a plunger. The device is often used to administer drugs or collect blood.	13929002	II	2,6,6-①	applicable	—
Blood gas syringe	An instrument comprising a tube and plunger and used with a needle to collect arterial blood. The device is usually made of plastic or glass and can collect blood without exposing it to the air.	16785000	II	2,6,6-①	applicable	—
Active device connected anaesthesia syringe	A hollow, plastic cylinder-shaped device with an injection plunger. The device is used for administration (injection) of substances such as anesthetics. The device is connected to an active device.	35387002	II	2-①	applicable	—
Needleless cartridge hypodermic syringe	A device consisting of a metal tube and a plunger. Before using the device, a sealed glass cartridge containing medication is loaded into the device from its proximal end. The device has a dedicated nozzle that pushes in the contents of the cartridge.	36279000	II	6	applicable	—

Hypodermic syringe with safety-needle cartridge	A device consisting of a metal tube and a plunger. Before using the device, a sealed glass cartridge containing medication is loaded into the device from its proximal end. The device uses a non-exposed needle with protection for subcutaneous injection protection	36280000	II	6	applicable	—
Drug/vaccine injection syringe	A device used for intramuscular (IM) or subcutaneous injection of a pharmaceutical or vaccine into the human body using a standard plunger syringe with an appropriate needle. A pharmaceutical or vaccine for injection is drawn into a prefilled syringe	12132000	II	6	applicable	—
Loss of resistance epidural localization syringe	A device used in the loss of resistance (LOR) method in epidural anesthesia. It consists of a syringe and a plunger, and is usually made of plastic or glass.	70201002	II	2,6-①	applicable	—
Temporary use anesthesia puncture needle	A hollow device for percutaneous nerve block. Some needles have an insulated shaft, others have a terminal which is connected to an electrode, and others are sharp and hollow. The device is for temporary placement and also for single-use. The device cannot be used on the central nervous system	70203012	II	6	applicable	—
Puncture needle with port	A puncture needle with a side port for the guidewire channel, used to insert a vascular catheter.	70203022	II	6	applicable	—
Plastic cannula sterile puncture needle	An arterial or venous indwelling needle made up of a plastic cannula and a metal needle.	70204010	II	7	applicable	—
Plastic cannula abdominal puncture needle	A device comprising a plastic cannula and a metal needle, used to puncture a body cavity or organ to drain fluids or inject drug solutions.	70204020	II	6	applicable	—
Dialysis indwelling needle	A non-metal indwelling needle placed at the puncture site for hemodialysis.	70204030	II	2-②	applicable	—
Ultrasonic aspiration biopsy kit	The biopsy needle and other supplies required for image-guided aspiration biopsy of a tissue. The distal tip of the needle must remain clearly visible on the image.	10403000	II	6	applicable	—
Injection needle set	A device made up of an injection needle, syringe, and tube or three-way stopcock and used for percutaneous injection of solutions (e.g., into an organ) or for mixing of drug	70205000	II	6	applicable	—
Nerve exploration set	A set of needles used for nerve search guided by muscle contraction and for local injection of drug solutions, and electrode catheters, etc.	70206000	II	6	applicable	—
Marker insertion set	A device consisting of a puncture needle, an introducer needle, and a marker and used for placement of a metal marker or pigment injection into a tumor or other tissues. Not all of the components are included in some products	70207000	II	6	applicable	—
Laser irradiation therapy set	A set of puncture needles, a metal wire(s), a metal pipe(s), etc. which are used for laser irradiation therapy.	70208010	II	6	applicable	—
Laser irradiation therapy kit	A kit includes a puncture needle, a guide wire, and a guiding sheath for guiding probes (used for laser irradiation therapy, for example). Not all of the components are included; in some products, two or more of components are integrated into one	70208020	II	6	applicable	—
Transvaginal drug solution injection needle	A device consisting of a needle and a tube used to inject a drug solution transvaginally.	70210000	II	6	applicable	—
Brachytherapy puncture set	A device is a puncture needle for insertion of a radiation source into the body (e.g., a tumor) and made up of a stylet and cannula.	70211000	II	6	applicable	—

Electromagnetic wave coagulation therapy needle	A puncture needle used in microwave coagulation therapy to protect electrodes, etc. The device has a hollow metal or plastic tube. This tube may be insulated and have a sharp tip. The device may come with an extension tube.	70212000	II	6	applicable	—
Electromagnetic wave coagulation therapy kit	A package containing a puncture needle and other necessary tools, such as an extension tube, for protection of electrodes, etc. during microwave coagulation therapy. The device has a hollow metal or plastic tube. This tube may be insulated and have a sharp tip. The device may come with an extension tube.	70213000	II	6	applicable	—
Thermotherapy needle	A puncture needle used for protection of an internal temperature sensor, etc. during heat therapy. The device has a hollow metal or plastic tube, with or without a closed end. The device may also come with a stylet or some other tools.	70214000	II	6	applicable	—
Thermotherapy kit	A package consisting of devices necessary for thermotherapy, including puncture needles and a stylet used as a protective device for the sensor for measurement of deep temperature. It has a metal or plastic hollow tube, and the tip may be closed.	70215000	II	6	applicable	—
Single-use arthrogram kit	A kit of single-use devices and supplies used to visualize the joint radiographically after injection of contrast media into the joint space.	15316002	II	6	applicable	—
Bone marrow biopsy kit	A kit used for aspiration of tissue during a bone marrow biopsy. The kit includes a single-use biopsy needle and other necessary tools.	16833000	II	6	applicable	—
Renal biopsy kit	A kit for renal biopsy. The kit includes a biopsy needle and other necessary tools.	16834000	II	6	applicable	—
Endometrial sampling kit	A kit consisting of the appropriate devices to create sample slides and smear preparations, including syringes, needles, and aspirators, swabs, sample collectors for obtaining endometrial tissue. This is used to collect and prepare Pap smears samples in a medical institution. This kit is for single-use.	11531000	II	6	applicable	—
Soft tissue biopsy kit	A kit for collection of soft biological tissues. The kit includes a biopsy needle and other necessary tools.	16835010	II	6	applicable	—
Powered soft tissue biopsy kit	A kit consisting of various components including biopsy needles and other necessary items that are used to collect the biological soft tissue of the target site. This device has an electrically operated control unit.	16835020	II	6,9	applicable	N/A
Single-use bone marrow collection/transfusion set	A kit containing a bag, filter, tube and adapter that are to be combined for collection or filtration of bone marrow. The device is intended for single-use.	33984002	II	6	applicable	—
Lung biopsy kit	A kit consisting of various instruments, including single-use biopsy needles, and other necessary items that are used to aspirate tissue samples during transdermal lung biopsy.	38562000	II	6	applicable	—
Brain biopsy kit	A kit consisting of various components, including a single-use brain biopsy needle(s), and other necessary items that are used to perform brain stereotactic biopsy.	38563000	II	6	applicable	—

Single-use lumbar puncture kit	A kit used for puncture of the lumbar spine and collection of spinal fluid. The kit includes single-use instruments and other materials. The package usually contains a spinal needle and tube for spinal fluid.	12404002	II	6	applicable	—
Single-use lumbar puncture needle	A needle with a stylet used during a lumbar puncture to collect spinal fluid for diagnostic testing. The device is intended for single-use.	34583002	II	6	applicable	—
Single-use pneumoperitoneal needle	An elongated needle that is used to inject or drain gas from the peritoneal cavity. The device is intended for single-use.	12750002	II	6	applicable	—
Single-use automatic lancet	An instrument for collection of blood from capillary vessels in the fingertip or ear lobe. The built-in needle automatically pops out and pierces the skin to the preset depth. This enables sampling of a small amount of blood for testing. The device is intended for single-use.	37243002	II	6	applicable	—
Reusable manually-operated lancet	A small device with a sharp tip (needle-like) used to puncture the skin for blood sampling or drainage of the bursa or ganglion. This device is reusable.	37244000	II	6	applicable	N/A
Esophageal varices sclerotherapy injector	A puncture instrument used together with an endoscope for injection of a sclerosing agent in sclerotherapy of esophageal varices. It consists of a needle, syringe, flexible tube, and connector among others.	70217000	II	6	applicable	—
Thoracic trocar	A cone-shaped or cylindrical surgical instrument with a sharp tip used to puncture the chest cavity during chest surgery. A trocar assembly can be introduced in combination with a compatible sleeve filling lumen of the trocar. Removing the trocar after	70218000	II	6	applicable	—
Abdominal trocar	A cone-shaped or cylindrical surgical instrument with a sharp tip used to puncture the abdominal wall. A trocar assembly can be introduced in combination with a sleeve filling lumen of the trocar. Removing the trocar after puncture creates a working	14155000	II	7	applicable	—
Amniotic trocar	A cone-shaped or cylindrical surgical instrument with a sharp tip used to puncture the abdominal wall and amniotic cavity of a pregnant woman for endoscopic observation of	14156000	II	7	applicable	—
Gallbladder trocar	A cone-shaped or cylindrical surgical instrument with a sharp tip used to puncture the abdominal wall to access the gallbladder. A trocar assembly can be introduced in combination with a sleeve filling lumen of the trocar. Removing the trocar after	14159000	II	7	applicable	—
Gastro-urology trocar	A cone-shaped or cylindrical surgical instrument with a sharp tip used to puncture the abdominal wall. The device is normally used with a sleeve. Removing the trocar after puncture creates a working channel into the body cavity.	32021000	II	7	applicable	—
Gastrostomy trocar	A cone-shaped or cylindrical surgical instrument with a sharp tip used to puncture the abdominal wall and perform gastrostomy. A trocar assembly can be introduced in combination with a sleeve filling lumen of the trocar. Removing the trocar after	70219000	II	6	applicable	—
Single-use amniocentesis needle	A needle used for transabdominal surgical puncture, for collection of amniotic fluid or the fluid contained in the umbilical cord. The device is intended for single-use.	70220000	II	6	applicable	—
Single-use amniocentesis kit	A pre-packaged kit for transabdominal surgical puncture, used for collection of amniotic fluid or the fluid contained in the umbilical cord. The kit contains a needle, syringe, blood collection tube, and disinfection materials, etc.	35496000	II	6	applicable	—
Single-use trocar sleeve	A plastic sleeve used together with a trocar during puncture of a body cavity. Removing the trocar after puncture creates a working channel into the body cavity. The sleeve may have a shut-off valve or port for supplying gas or fluid. Some products	37148002	II	6	applicable	—

Invasive single-use trocar sleeve fixation device	A device that is attached to a trocar sleeve for invasive fixation of the sleeve to the abdominal wall. The device is intended for single-use.	70222000	II	6	applicable	—
Single-use trocar guide rod	A small metal or plastic rod guiding a large (10 to 20 mm in diameter) trocar sleeve, in order to expand the working channel created in the body. This rod is inserted into a trocar sleeve, and the sleeve is withdrawn while keeping airtightness of the opening. A special dilator to which a large sleeve is attached is inserted outside the rod, and this	37149002	II	6	applicable	—
Single-use trocar sleeve dilator	A hollow dilator with a tapered tip. It is used for a significant dilatation of the working channel (10 to 20 mm in diameter). The tapered tip enables smooth insertion of a large trocar sleeve. The dilator is inserted outside the guide rod and used to displace the	37151002	II	6	applicable	—
Single-use subcutaneous tunneller	A surgical instrument that is usually made of metal including stainless or polymeric material and used to create an interconnected channel or a tunnel under the skin for insertion of a tube or catheter. The device is intended for single-use.	35950002	II	6	applicable	—
Urological needle guide	A device used to assist needle insertion into the urinary tract for treatment or diagnosis.	70227000	II	6	applicable	—
Short-term use jejunostomy catheter	A flexible tube used for a short term to create a fistula between the abdominal wall and jejunum.	10731002	II	7	applicable	—
Short-term use enteral feeding kit	A package of materials used for a short term for enteral nutrition.	11677002	II	5-②	applicable	—
Transesophageal enteral feeding tube	A long, flexible, radiopaque tube (or non-opaque tube with a separate radiopaque line) to be placed in the stomach via the nasopharynx or esophagus, for enteral nutrition.	16798000	II	5-②	applicable	—
Short-term use enterostomy feeding tube	A hollow tube to be surgically placed in the stomach, duodenum, or jejunum for short-term enteral nutrition.	16799002	II	7	applicable	—
Short-term use gastrostomy feeding tube	A hollow tube to be surgically placed in the stomach for short-term enteral nutrition.	35419002	II	7	applicable	—
Jejunostomy feeding tube	A hollow tube to be surgically placed in the jejunum for enteral nutrition.	38564000	II	7	applicable	—
Short-term use gastrostomy button	A short tube inserted into the stomach percutaneously, for short-term enteral nutrition. This device does not allow back-flow, and its proximal tip remains flat to the abdominal skin and creates no protrusion.	38565002	II	7	applicable	—
Gastrointestinal tube	A single-lumen or double-lumen, flexible plastic tube to be placed in the stomach, duodenum, or jejunum for aspiration or enteral nutrition.	14202000	II	5-②	applicable	—
Short-term use nasogastric tube	A flexible, plastic tube to be placed for a short term in the stomach via the nasopharynx or esophagus for removal of gastric contents, administration of drugs, or enteral nutrition.	14221012	II	5-②	applicable	—
Short-term use nasal/oral gastric tube	A flexible, plastic tube to be placed for a short term in the stomach, duodenum, or jejunum via the nasopharynx or mouth and esophagus, for administration of drugs or enteral nutrition.	14221022	II	5-②,5-⑥	applicable	—
Stomach evacuator tube	A single-lumen tube inserted into the stomach via the mouth, for removal of gastric contents.	14230000	II	5-②	applicable	—
Appetite-suppressing gastric balloon	A balloon to be inserted into the stomach and inflated there to suppress appetite. The indwelling balloon creates a false sense that the stomach is almost full. The balloon is inserted through a catheter, and placed until the desirable effect is obtained. Usually it is made of polymeric materials and deteriorates over time.	17202000	II	5-②	applicable	—

Mercury balloon single lumen tube	A tube used for infusion of solutions, drainage, splinting and bleeding compression in the gastrointestinal tract.	32058000	II	5-②,7	applicable	—
Short-term use esophageal tube	A hollow tube used for a short term to achieve hemostasis of a bleeding varix. The device usually comes with two balloons (one for the stomach and the other for the esophagus). Some may only come with just one or three or more balloons.	35416002	II	5-②	applicable	—
Short-term use sterile gastroesophageal tube and catheter	A set comprising a tube and catheter inserted into the esophagus or stomach for a short period for sampling of gastric juice, injection of drug solutions, lavage, or diagnosis.	70232000	II	5-②	applicable	—
Esophageal varices sclerotherapy endoscopic fixation balloon	A balloon catheters used to fix an endoscope in the esophagus during sclerotherapy for esophageal varices. The device consists of a balloon and flexible tube. Some products also include a syringe and connector, etc.	70233000	II	5-②	applicable	—
Esophageal varices sclerotherapy hemostatic balloon	A balloon catheter used to achieve hemostasis of the puncture site during sclerotherapy for esophageal varices.	70234000	II	5-②	applicable	—
Suture anchor	A device used to approximate the gastric wall to the abdominal wall to facilitate gastrostomy.	70235000	II	7	applicable	—
Rectal tube	A tube inserted into the rectum for diagnosis or therapy.	14227000	II	5-②	applicable	—
Barium enema kit	A kit consisting of items used for injecting a barium suspension via the rectum into the large intestine for performing enema examination.	16514000	II	5-②	applicable	—
Intestinal decompression tube	A hollow tube to be placed in the intestine to reduce the increased pressure that may occur before and following bowel obstruction.	35415010	II	6	applicable	—
Short-term use infant enteral feeding kit	A kit of parts to be assembled for short-term enteral nutrition in infants.	36044002	II	5-②	applicable	—
Gastrointestinal guidewire	A guidewire used in gastrointestinal (including bile duct) procedures (excluding probes).	70236000	II	6	applicable	—
Intestinal balloon catheter	A balloon used to dilate a narrowed area of the gastrointestinal tract (duodenum and lower GI tract) or to fix the distal end of an endoscope.	70237000	II	6	applicable	—
Intestinal tube	A hollow tube to be placed in the gastrointestinal tract (intestine, for example) for a variety of purposes such as depressurization, draining, lavage, and injection of drug solutions.	35415020	II	6	applicable	—
Short-term use biliary/pancreatic duct catheter	A flexible tube used for a short term for biliary tract drainage, splinting of the bile duct during therapy, or supporting the bile duct to prevent stenosis. The device is sometimes used for pancreatic duct drainage.	10696012	II	7	applicable	—
Short-term use biliary catheter	A flexible tube used for a short term for biliary tract drainage, splinting of the bile duct during therapy, or supporting the bile duct to prevent stenosis.	10696022	II	7	applicable	—
Biliary drain	A flexible tube made of natural rubber or silicone and used to drain bile during biliary tract surgery. The device may have a side hole(s).	11307000	II	7	applicable	—
Cholangiography catheter	A flexible tube used to inject contrast media into the gallbladder, bile duct, or pancreatic duct for enhanced radiography.	16429000	II	6	applicable	—

Biliary manometric catheter	A flexible tube designed to measure pressure in the biliary system.	36181000	II	6	applicable	—
Introducer for bile duct stent	An introducer used to insert a biliary stent. The device is intended for single-use.	70238000	II	6	applicable	—
Single-use endoscopic lithectomy forceps	A device that is used with a dedicated endoscope to hold and remove stones during endoscopic therapy. The device is made of an elongated shaft and a wire basket at the	37141002	II	6	applicable	—
Biliary dilatation catheter	A catheter used to dilate a narrowed bile duct.	70239000	II	6	applicable	—
Gallstone removal catheter set	A catheter or a set of devices used in combination of the catheter which inserted into the biliary tract together with an endoscope, for removal of bile duct stones. The catheter inserted into the biliary tract device consists of a sheath, and a wire basket to capture bile duct stones, etc.	70240000	II	5-②	applicable	—
Lithectomy balloon catheter	A device used alone or with an endoscope for removal of stones. It comprises an elongated sheath and a balloon at the tip, designed to trap stones.	70241000	II	6	applicable	N/A
Lithotripsy forceps	A device used alone or with an endoscope for crushing and removal of stones. The device consists of an elongated sheath and a wire basket at the tip that crushes and captures stones.	70242000	II	6	applicable	N/A
Barium enema rectal catheter	A flexible tube used to inject barium into the lower GI tract via the rectum, for enhanced radiography. Rubber or plastic variants are also used in colonoscopy. There are other variants that come with an indwelling balloon made of silicone, used for testing incontinence.	34912000	II	5-⑥	applicable	—
Gastric decompression tube	A hollow tube that is connected to another tube (e.g., gastric feeding tube) to reduce the gastric pressure of patients with a gastrostomy.	70243000	II	6	applicable	—
Over tube	A tube that is used with an endoscope to secure a channel for catheters and other tubes in the gastrointestinal tract.	70244000	II	5-②	applicable	—
Biliary tract catheter	A balloon catheter used for bile duct drainage following biliary anastomosis.	70245000	II	5-②	applicable	—
Endoscopic dilation catheter	A catheter that is inserted to dilate a narrowed area by inflating the balloon under the endoscope. The device is intended for single-use.	70246000	II	5-②,6	applicable	—

Tracheal suction catheter	A soft tube used to aspirate fluid and semisolid materials from the trachea. The device is intended for single-use.	10749000	II	5-⑥	applicable	—
Suction kit	A kit used for aspiration of secreta, consisting of sterilized gloves, aspiration catheter, and container for the aspirate. Some variants may not include gloves.	13846000	II	5-⑥,6	applicable	—
Bronchial suction catheter	A flexible tube used for aspiration of fluid and semisolid materials from the pharynx, trachea, and bronchus.	31249000	II	5-②	applicable	—
Bronchial drug infusion catheter	A flexible tube used for injection of drugs into the pharynx, trachea, and bronchus.	70248000	II	5-②	applicable	—
Short-term use tracheal tube cuff	A short-term use balloon-like cuff attached to around an endotracheal tube. This is placed below the vocal cords to seal the space between the tube and the tracheal wall during mechanical ventilation of the lungs.	14082012	II	5-②	applicable	—
Ventilation tracheal tube cuff	A balloon-like cuff attached to around a tracheal tube. This is placed below the vocal cords to seal the space between the tube and the tracheal wall during mechanical ventilation of the lungs.	14082022	II	5-②	applicable	—
Short-term use ventilation tracheal tube	A cylindrical tube made of plastic or rubber inserted into the trachea via oral cavity or nose to secure the airway, administer inhalation anesthetics or medical gas, or maintain ventilation. The tube may be packaged with a connector for a respiratory circuit or manual resuscitator. The tubes, Cole-type, may come in different internal/external diameters.	14085012	II	5-②,5-⑥	applicable	—
Cole ventilation tracheal tube	A cylindrical tube inserted into the trachea via oral cavity or nose to secure the airway, administer inhalation anesthetics or medical gas, or maintain ventilation. The tube may be packaged with a connector for a respiratory circuit or manual resuscitator. The tubes, non-Cole type, may come in different internal/external diameters.	14085022	II	5-②,5-⑥	applicable	—
Non-cole type ventilation tracheal tube	A cylindrical tube inserted into the trachea via oral cavity or nose to secure the airway, administer inhalation anesthetics or medical gas, or maintain ventilation. The tube may be packaged with a connector for a respiratory circuit or manual resuscitator. The tubes, non-Cole type, may come in different internal/external diameters.	14085032	II	5-②,5-⑥	applicable	—
Short-term use jet ventilation tracheal tube	A hollow, cylindrical device that is inserted into the trachea for jet (high-flow) ventilation. It is designed for short-term use. The device usually lacks a cuff so that the ventilated gas may be exhaled quickly.	17935002	II	5-②	applicable	—
Short-term use laser-resistant ventilation tracheal tube	A hollow, cylindrical device that is inserted into the trachea to secure the airway patency or to administer anesthetics. It is intended for short-term use. The tube does not rupture or catch fire easily when it is exposed to a laser beam during head, throat, or neck surgery.	36064002	II	5-②,5-⑥	applicable	—
Reinforced ventilation tracheal tube	The hollow, cylindrical tube with a metal or plastic reinforcement on the internal surface, inserted into the trachea to secure the airway patency or to administer anesthetics.	14085042	II	5-②,5-⑥	applicable	—
Short-term use nasopharyngeal tracheal tube	A rubber or plastic tube inserted into the pharynx via a nostril to secure the airway patency. The device may have a connector (diameter: 15 mm or 22 mm) at the tip for oxygen insufflation. The device is intended for single-use.	42422000	II	5-②	applicable	—

Short-term use oropharyngeal tracheal tube	A curved, metal or plastic tube inserted from the oral cavity to secure the airway patency in ventilation or aspiration. It is intended for short-term use. The device is useful to prevent airway obstruction by the tongue.	42424012	II	5-②	applicable	—
Sterile suction tube and catheter	A device inserted into the trachea via the nasal or oral cavity to maintain the airway or for other purposes.	70249000	II	5-②	applicable	—
Short-term use esophageal/tracheal double-lumen tube	A double-lumen tube that can be used for artificial respiration or ventilation after securing the airway, regardless of whether it is inserted into the trachea or esophagus. The device has two cuffs (one closer to the distal end for the esophagus or trachea, and	70250002	II	5-②,5-⑥	applicable	—
Short-term use oropharyngeal tube	A curved, metal, plastic, or rubber tube inserted via the oral cavity to secure the airway patency for ventilation or aspiration. It is intended for short-term use. The device is useful to prevent airway obstruction by the tongue.	42424022	II	5-②	applicable	—
Saliva suction tube	A flexible tube connected to an aspirator and an aspirate container and used for aspiration of saliva and other substances from the oral cavity. The shape of the tip may	70252000	II	5-②	applicable	—
Neonatal oropharyngeal suction catheter	A flexible tube used to suction amniotic fluids out of the neonatal oral cavity and the pharynx.	70253000	II	5-②	applicable	—
Tracheobronchial introducer	A device used to insert a stent or catheter into the trachea or bronchus.	70254000	II	5-②	applicable	—
Tracheostomy cannula	A hollow, cylindrical device (cannula) used to secure the airway in the area of cricothyroid ligament in an emergency procedure. The device may contain a needle. The device is intended for single-use	14089000	II	7	applicable	—
Tracheostomy tube cuff	An inflatable cuff attached around the tracheostomy tube. The cuff is used to fill the space between the tube and trachea for artificial ventilation in patients with subglottic stenosis.	14094000	II	5-②	applicable	—
Upper respiratory tract tracheotomy kit	A kit of surgical instruments and other accessories used when a tube is inserted or placed by puncturing the trachea or creating an opening in it to relieve upper airway occlusion and facilitate respiration. The kit may include a tube used to secure the airway patency after tracheotomy.	14099000	II	7	applicable	—
Cricothyrotomy kit	A package kit, set, or tray containing instruments and tools required to cut or puncture the skin and cricothyroid membrane in an emergency procedure for upper airway obstruction.	15028000	II	6	applicable	—
Tracheotomy kit	A kit that contains a set of devices and other supplies (e.g., towels, gauze, a suction, swabs) to be used in tracheostomy.	35403000	II	7	applicable	—
Single-use tracheostomy tube	A device inserted through an artificial opening into the trachea to secure patency after tracheotomy. The device is intended for patients who have undergone surgery for respiratory stenosis, etc. and is designed to secure the airway patency and facilitate	35404010	II	7	applicable	—

Tracheostomy tube for adults	A device inserted through an artificial opening into the trachea to secure patency after tracheotomy. The device is intended for patients who have undergone surgery for respiratory stenosis, etc. and is designed to secure the airway patency and facilitate prompt aspiration of secretions. The device is usually made of plastic and may come with a plunger. The device also comes with/without a cuff, with/without an opening, and in various sizes to meet the need of each patient. The device is intended for single-use. The device is not intended for pediatric patients only.	35404020	II	7	applicable	—
Pediatric tracheostomy tube	A device inserted through an artificial opening into the trachea to secure patency after tracheotomy in infants. The device is intended for patients who have undergone surgery for respiratory stenosis, etc. and is designed to secure the airway patency and facilitate prompt aspiration of secretions. The device is usually made of plastic and may come with a plunger. The device also comes with/without a cuff, with/without an opening, and in various sizes to meet the need of each patient. The device is intended for single-use. The device is not intended for pediatric patients only.	35404030	II	7	applicable	—
Reinforced ventilation tracheostomy tube	A device inserted through an artificial opening into the larynx to secure the airway patency. The tube is reinforced with metal or plastic.	35404040	II	7	applicable	—
Tracheostomy tube inner tube	An inner cylinder that protects the inside of the tube from adhesion of secretions. The device is removable and can be washed outside the patient's body. The device is commonly there are types with or without holes in the inner cylinder to meet the need	70255000	II	7	applicable	—
Laryngectomy tube	A tube used to secure the airway patency in partial or total laryngectomy.	12292010	II	6	applicable	—
Post-laryngectomy tube	A tube used to secure the airway patency in patients who have undergone partial or total laryngectomy.	12292020	II	6	applicable	—
Nasopharyngeal catheter	A flexible tube to be inserted into the nasopharyngeal cavity to suction or inject a drug.	16432002	II	5-②	applicable	—
Bronchial balloon catheter	A flexible indwelling tube to be inserted into the bronchus. An inflatable balloon is attached to the distal end of the tube.	17827000	II	5-②	applicable	—
Ventilation bronchial tube	A double-lumen cylindrical tube inserted into the trachea to administer anesthetics or used during pulmonary function tests. The device is equipped with two cuffs separately	31329000	II	5-②,5-⑥	applicable	—
Aerosol delivery tube	A flexible large-bore tube (usually diameter: 22 mm) to deliver aerosol usually connected to an oxygen mask, tracheal tube, humidifier, or nebulizer. The tube is usually supplied excessively long and cut into an appropriate length by healthcare	32202000	II	5-⑥	applicable	—
Nasal cavity catheter	A semi-rigid or rigid, plastic or metal tubular surgical instrument inserted nasally into the nasal sinuses. This instrument is intended for injection/drainage of fluids or insertion of a catheter or surgical tools. The device is intended for single-use	34903010	II	5-①,5-②	applicable	—
Nasal cavity irrigation catheter	A catheter that is inserted through the nose for hemostasis with balloon, lavage, or draining.	34903020	II	5-②	applicable	—
Oxygen delivery transtracheal catheter	A flexible tube to be inserted via the tracheal wall to supply oxygen when breathing through the nose or the mouth is impossible because of obstruction.	36231000	II	5-②	applicable	—
Oxygen supply-carbon dioxide collection transnasal catheter	A semi-rigid tube used to deliver oxygen or collect carbon dioxide (exhaled gas). Monitoring is done through prongs inserted separately into the nostrils. The device	36306000	II	5-⑤	applicable	—

Single-use airway-esophageal obturator	A tube that is inserted into the esophagus from the oral cavity and has two lumina and two cuffs to support respiration. There is a hole for breathing between the pharyngeal and esophageal cuffs. When both cuffs are inflated, the pharyngeal cuff prevents air	42420000	II	5-②	applicable	—
Esophagus closing airway	A tube that secures the airway patency and performs artificial respiration or ventilation by occluding the esophagus with its cuff. The device may have two cuffs (one for the esophagus and the other for the pharynx)	70256000	II	5-②	applicable	—
Oropharynx tube	A tube used to secure ventilation (orally and transnasally) in the event of upper airway obstruction. Sterilized and non-sterilized products are included.	70257000	II	5-②	applicable	—
Ventilation bronchial obstruction catheter	A bronchial catheter used to limit ventilation in one lung to administer anesthetics or perform pulmonary function tests. The device is intended for single-use.	70258000	II	5-②,5-⑥	applicable	—
Reusable mouthpiece connector	A hard, small device inserted into the patient's mouth and connected, usually through a tube, to a therapeutic or diagnostic ventilator. The mouthpiece easily fits the respiratory system only by holding it with his/her lips. It can be reusable after cleaned	43467000	II	5-②	applicable	—
Single-use mouthpiece connector	A hard, small device inserted into the patient's mouth and connected, usually through a tube, to a therapeutic or diagnostic ventilator. The mouthpiece easily fits the	44545000	II	5-②	applicable	—
Body orifice obstruction balloon catheter	A balloon catheter used, for therapy or diagnosis, to fill an organ with a fluid or keep foreign bodies from entering the organ by partially occluding the organ. It is intended for short-term use.	70261000	II	5-②	applicable	—
Nelaton catheter	A red, flexible rubber tube used for urinary catheterization.	10734000	II	5-②	applicable	—
Urological catheter insertion/urine sampling kit	A kit that contains a sterilized urinary catheter and other accessories (e.g., urine collection bag) required for urinary catheterization or voiding.	14292000	II	5-②	applicable	—
Intermittent urological catheterization kit	A kit that contains a urinary catheter and other accessories that is used for urination from the bladder for sampling or other purposes.	16321000	II	5-②	applicable	—
Coude urological catheter	A flexible tube with a curved tip inserted in the bladder for injection or drainage of fluids for medical or surgical procedure. The tube is used to easily pass fluids to the bladder	31981000	II	5-②	applicable	—
Urological catheterization kit	A kit of materials necessary for urinary catheterization. The device is intended for single-use.	32030000	II	5-②	applicable	—
Ureteral catheter	A flexible tube used to pass fluids to or from the ureter.	34926012	II	5-②	applicable	—
Short-term use ureteral tube stent	A flexible tube inserted and placed in the ureter to drain pus and fluids or to perform lavage. It is intended for short-term use.	34926022	II	5-②	applicable	—
Intermittent urological catheter	A flexible tube inserted and placed in the bladder or ureter, for a relatively short term, for voiding, urine collection, or urodynamic testing.	36125000	II	5-②	applicable	—
Urinary irrigation kit	A kit including a syringe(s) combined with other items that are used to cleanse the urethra and the bladder.	14301000	II	5-②	applicable	—
Continuous irrigation urological catheter	A flexible tube used for successive lavage of the bladder and its surroundings.	32331000	II	5-②	applicable	—
Short-term use self-retained urological catheter	A flexible tube placed in the bladder for a short term. The device has an inflatable balloon at the distal end. The device is usually used for voiding or hemostasis.	34917002	II	5-②	applicable	—
Irrigation urological catheter	A flexible tube used for lavage of the bladder and its surroundings.	34930010	II	5-②	applicable	—

Percutaneous irrigation urological catheter	A flexible tube used to cleanse the bladder and related structures percutaneously.	34930020	II	6	applicable	—
Short-term use nephrostomy catheter	A flexible tube percutaneously inserted into the renal pelvis to access the upper urinary tract. It is intended for short-term use.	10735002	II	7	applicable	—
Short-term use nephrostomy tube	A tube used for nephrostomy connecting the body surface near the pelvis and the kidney. It is intended for short-term use.	14224002	II	7	applicable	—
Short-term use stoma drainage urological catheter	A flexible tube inserted into a urinary stoma for voiding. It is intended for short-term use.	31074000	II	5-②,7	applicable	—
Male urethrographic urological catheter	A flexible tube used to inject a contrast medium into a male urethra for enhanced radiography.	32089000	II	5-②	applicable	—
Short-term use suprapubic urological catheter	A flexible tube inserted into the urinary bladder of a male or female patient from an incision above the pubic bone (pubic arch) for voiding. It is intended for short-term use.	34924002	II	7	applicable	—
Ureterolithotomy tube and catheter	A catheter inserted into the urinary tract to remove urinary stones. The device has a part such as basket to capture stones.	70263000	II	5-②	applicable	—
Olive-shaped tip catheter	A flexible tube with an olive-shaped tip used for dilatation of ureteral stricture.	10737000	II	5-②	applicable	—
Filiform/filiform follower urological catheter	A flexible tube with a very thin or filamentous tip used to identify stenosis or sites with irregular shape or to widen the passage.	32022000	II	5-②	applicable	—
Single-use fibreoptic light ureteral catheter	A fiber catheter illuminator, etc. that is inserted into the urinary tract during lower abdominal or pelvic surgery to make the passage visible. This device consists of a bundle of optical fibers, etc. that radiates light along the entire length of the fibers and	32035000	II	5-②	applicable	—
Percutaneous urological catheter	A catheter used for percutaneous or endoscopic dilatation of the urinary tract.	70264000	II	6	applicable	—
Ureteral locator	A tubular instrument made of vinyl or other materials with multiple valves. The device is inserted into the ureter to make palpation easier during laparotomy.	70265000	II	5-②	applicable	—
Urological extractor	A device inserted percutaneously or transurethrally into the urinary system for removal of foreign bodies such as intraureteral stones.	70266000	II	6	applicable	—
Central venous catheter repair tube	A tube used to repair or replace a damaged portion of the external part of a central venous catheter. A sleeve and an adhesive to ensure a tight bond may be including.	70268000	II	2-①	applicable	—
Arterial cannula	A semi-rigid tube to be inserted into an artery and used as a guide path for fluid. Usually, a removable trocar is used for insertion. This device is for single - use.	34893102	II	6	applicable	—
Femoral cannula	A semi-rigid or rigid tube to be inserted into a femoral vessel and used as a guide path for fluid. This device is for single-use.	34902102	II	6	applicable	—
Venous cannula	A semi-rigid or rigid tube to be inserted into a vein and used as a guide path for fluid. Usually, a trocar is used for insertion. This device is for single-use.	34905102	II	6	applicable	—

Catheter for angiographic	A flexible tube to inject contrast media into an organ or peripheral vascular system for visualization of vascular structure of the targeted area.	10688102	II	6	applicable	—
Imaging pressure tube	A pressure-resistant tube used to inject contrast media into the heart, great vessels, or coronary arteries for cardiac or vascular radiography.	70269000	II	2-①	applicable	—
Non-central circulatory arterial catheter	A flexible tube usually designed to pass through a non-central artery for injection or aspiration. The device is normally connected to a transducer or other apparatus for continuous measurement of arterial pressure.	10689002	II	7	applicable	—
Non-central circulatory arterial microflow catheter	A flexible tube to be inserted into the circulatory system to exactly measure the blood flow and pressure of the artery in the non-central circulatory system.	10691002	II	7	applicable	—
Non-central circulatory transducer-tip catheter	A catheter incorporating a built-in micro miniature pressure transducer at its distal end. When the catheter is inserted into the blood vessel of the non-central circulatory	15071002	II	7	applicable	—
Angiographic kit	A kit of devices and instruments for radiographic visualization of blood vessels. The kit excludes catheters inserted into a blood vessel or introducers.	16545002	II	6	applicable	—
Manometric balloon catheter	A flexible tube used to measure the pressure of each visceral organ. The catheter has a balloon at the distal end.	17745000	II	6	applicable	—
Guiding catheter for intravascular	A flexible tube used as a guide for a balloon catheter or guidewire during percutaneous vascular surgery.	17846102	II	6	applicable	—
Pressure monitoring tube set	A set of tubes to be connected ex vivo (directly or via a valve) to a catheter transducer for invasive blood pressure measurement or cerebrospinal fluid pressure measurement. The device has physical characteristics suitable for maintaining the blood pressure waveform and its precision.	35529000	II	2-①,2-②	applicable	—
Pressure monitoring damping device	A device for adjusting the damping coefficient during invasive blood pressure measurement.	70270000	II	2-①	applicable	—
Non-central circulatory intravascular catheter	A flexible tube inserted into a blood vessel for blood collection, blood pressure monitoring, or intravenous fluid administration.	40601000	II	7	applicable	—
Sialography catheter	A catheter inserted into a salivary gland for dilatation or contrast medium injection.	70278000	II	6	applicable	—
Embolization implant inserter	A long, thin surgical device used to advance an embolization implant such as an embolization coil through an appropriate catheter. When this catheter is placed in the target site of the artery or vein, the embolization implant is ready to be delivered (to be implanted). This device, also known as "pusher, " is removed before the implant is advanced. This device is for single-use.	43978000	II	6	applicable	—
Catheter introducer	A sheath that facilitates percutaneous catheter placement in a vein or artery. The device may come with a puncture needle.	10678102	II	6	applicable	—
Hemostasis valve	A valve used with a catheter or catheter introducer to stop the outflow of blood.	70279000	II	6	applicable	—
Catehter for non-central circulatory embolectomy	A flexible tube designed to remove coagulation of blood and other substances that may lead to non-central vascular occlusion. The device is also used to remove occlusion of natural vessels, arterial access grafts, and access grafts for hemodialysis.	10714002	II	6,7	applicable	—

Intravenous catheterization kit	A kit of tools used to insert a catheter into a vein.	12161102	II	6	applicable	—
Introducer	A device used to help insertion of a needle into the skin for treatment or diagnosis.	12727010	II	6	applicable	—
Introducer needle	A needle that is inserted into a patient's body for placement/manipulation of catheters and guidewires. The device may have a hemostasis valve.	12727020	II	6	applicable	—
Balloon dilatation angioplasty catheter for non-central circulatory	A flexible tube that achieves dilatation of a stenotic non-central vessel by controlling balloon inflation. The device usually consists of a double-lumen catheter with a balloon at the distal end. The device may have a side hole for pressure recording or contrast	17184002	II	6	applicable	—
Snare catheter	A flexible tube or wire that is used to capture foreign bodies in a blood vessel or other ducts and used for retrieval or manipulation of these foreign bodies.	17927000	II	6	applicable	—
Aspiration catheter	A catheter that is used to improve patency of the junction between the blood vessel and the manometer by being inserted into the vessel connected to the manometer. This device is intended for single-use.	34894000	II	2-①	applicable	—
Temporary use catheter guidewire	A device used temporarily to facilitate adjustment or transfer of a catheter in a blood vessel.	35094012	II	5-①,6	applicable	—
Non-vascular guidewire	A guidewire (excluding probes) used in ducts other than blood vessels, such as urinary tracts, trachea/bronchi, bile duct, pancreatic duct, and gastrointestinal tract.	35094022	II	6	applicable	—
Peritoneal dialysis catheter guidewire	A guidewire used temporarily for correction of the position of a peritoneal dialysis catheter.	35094032	II	6	applicable	—
Catheter tip flow transducer	A catheter incorporating a built-in micro miniature transducer at its distal end. The miniature transducer detects and measures the blood flow rate. When the catheter is	36040002	II	7	applicable	—
Vessel suturing lumen retention catheter	A catheter that is used for maintaining the inner diameter in angiorrhaphy.	70291000	II	6	applicable	—
Saphenous vein dilation system	A system used in a coronary artery bypass grafting to inject saline solution into a removed blood vessel. Injection of saline solution confirms that the blood vessel is	70292000	II	6	applicable	—
Measure guide	A device used to check for a change in the distance between the double markers compared with the distance before the tip of the micro catheter with the markers was reshaped.	70298000	II	6	applicable	—
Autologous blood transfusion system tubing	A soft, hollow, cylindrical device usually used as an extension tube to pass blood between the bellows and the autotransfusion bag. This tube is made of a synthetic material. It can be also used to maintain a closed circuit during recovery and	42924000	II	2-②	applicable	—
Non-central circulatory intravascular occluding catheter	A flexible tube with a balloon (which may be detachable) at the tip used to block a non-central blood vessel.	32584002	II	6	applicable	—
Bartholin's gland catheter	A flexible tube used to drain an inflamed Bartholin duct and Bartholin's gland.	10695000	II	6	applicable	—
Pericardial drainage catheter	A flexible tube used to drain fluids or gases from a body cavity such as the pericardial cavity and pleural cavity.	10741102	II	6	applicable	—

Wound drain	A device, usually made of rubber or silicone, for removal of fluids or pus from a wound or infected area.	11305000	II	4-②	applicable	—
Single-use multi-lumen catheter	A flexible, double-lumen (or multilumen) tube used for injection or drainage of fluids to or from inside the body (excluding those used for administration of drugs or in the central cardiovascular or central nervous system). The device is intended for single-	32330102	II	5-②,7	applicable	—
General-purpose suction catheter	A flexible tube used to drain fluids and gases from a body orifice, surgical incision, or wound. When used with an aspiration unit, the device is usually be connected to a collecting can or bottle .	34923102	II	4-②,5-②,7	applicable	—
Cerebrospinal fluid reservoir	A system connecting with the ventricle in a closed system for drainage or collection of the cerebrospinal fluid to decrease intracranial pressure.	15974002	II	7	applicable	—
Shunt valve programmer	A device used to non-invasively (from outside the body) check or change the pressure setting of a pressure-adjustable shunt valve (for hydrocephalus). The valve pressure setting is controlled with an electrically generated magnetic power or dynamic power .	70305009	II	2-①	applicable	—
DePezzer catheter	A catheter with a bulbous tip, used to drain fluid from the body cavity.	10709000	II	5-②	applicable	—
Catheter for eustachian	A tube used to drain fluid from the middle ear.	10718000	II	5-②	applicable	—
Rectal catheter	A flexible tube placed in the rectum for purposes such as irrigation.	10746000	II	5-②	applicable	—
Ileostomy rectal catheter	A flexible tube used as a template in continent ileostomy and used for postoperative drainage. In some cases, the tube is inserted by the patient on a regular basis to drain the contents of an ileal fistula. This device is for single-use .	40099000	II	5-②	applicable	—
Thoracic drainage tube	A straight or angled, single-or double-lumen tube used to drain secretions or irrigate the thoracic cavity after chest or heart surgery.	11308102	II	7	applicable	—
Drainage tube	A plastic or metal tube used to remove exudate or purulent material from a body cavity, wound, or infected area.	14191102	II	5-②,7	applicable	—
Sump drain	A double-or multi-lumen tube used to inject air via the smaller lumen and drain fluids from the larger lumen.	15270000	II	6	applicable	—
Hydrocephalic shunt filter	A device made of a cellulose-like material and used with a shunt to drain fluid from the brain. This device prevents cellular materials or foreign substances from escaping from the shunt system.	15688000	II	3-①	applicable	—
Endolymphatic shunt	A tube to be inserted surgically into the inner ear to drain liquid from the membranous labyrinth.	16033000	II	7	applicable	—
Pleuroperitoneal shunt	A tube made of plastic to be implanted surgically in the pleural cavity or the peritoneal cavity for drainage.	17218000	II	7	applicable	—
Menstrual fluid collector	A cup-shaped container designed to be placed inside the vagina for collecting menstrual blood samples.	18132000	II	5-②	applicable	—
Wound drainage kit	A package containing a plastic bag or bottle, trocar, and other tools used to drain fluids or pus from wounds.	35824102	II	4-②	applicable	—
Sterile intracorporeal indwelling drain tube and catheter	A tube and catheter placed in the body to drain unnecessary fluids after a surgery. It is also called a drain.	70306000	II	7	applicable	—

Wound suction catheter	A catheter connected to an evacuating source such as portable aspirator and mainly used to aspirate exudate such as blood and lymph retained in a dead space after surgery.	70307000	II	4-②	applicable	—
Irrigation catheter	A flexible tube used to inject or drain fluids (saline solution, for example) to or from body cavities excluding blood vessels (e.g., the stomach of a patient with bleeding esophageal varices).	10730000	II	5-②,7	applicable	—
Short-term use umbrella catheter	A flexible tube where the diaphragm at the distal end opens when a catheter (e.g., an umbrella catheter for barium enema) is inserted into a body opening. It is for short-term use.	10760002	II	5-②	applicable	—
Infusion catheter	A flexible tube used to inject solutions into the vein, subcutaneous tissue, or other tissues.	33172000	II	6	applicable	—
Peritoneal dialysis catheter hole button	A button-shaped instrument used for a short term to maintain an opening from the skin to the peritoneal cavity for insertion of a peritoneal dialysis catheter.	70309000	II	7	applicable	—
Peritoneal/pleural cavity catheterization kit	A toolkit used for percutaneous placement of a peritoneovenous shunt (in the peritoneal cavity) or pleurovenous shunt (in the pleural cavity).	70316000	II	6	applicable	—
Mushroom catheter	A flexible aspiration tube with a flared tip that is used to minimize the harm to the aspiration site.	10732000	II	6	applicable	—
Dental suction tube	A tubular dental instrument connected to an externally powered aspiration device (usually one dedicated for use in dentistry) and used for removal of fluids and cutting debris in the oral cavity.	70317000	II	5-⑥	applicable	—
External shunt connector	A connector to an external shunt for hemodialysis. It is intended for short-term use. The device may have a side branch for injection of drugs such as anticoagulants.	70318000	II	2-②	applicable	—
Shunt thrombus suction set	A set used to suction a thrombus developing inside an arteriovenous shunt (external shunt) during procedures including hemodialysis.	70319000	II	2-①	applicable	—
Single-use dialysis needle	An elongated, edged instrument used as a canal for the blood to go out and come in during hemodialysis. The device is intended for single-use.	12741002	II	6	applicable	—
Haemodialysis single needle with catheter	A flexible, double-lumen tube used with a single-needle. The device is used for hemodialysis via a single puncture.	34922000	II	6	applicable	—
Emergency blood access indwelling catheter repair tube	A tube used to repair or replace the damaged portion of the external part of a catheter for hemodialysis, etc. A sleeve and an adhesive to ensure a tight bond may be included.	70321000	II	2-①	applicable	—
Catheter needle	An elongated, edged, hollow device inserted into the patient's body for placement/manipulation of catheters.	32337000	II	6	applicable	—
Adaptor for intravenous catheter	An instrument (usually small) used to connect an external apparatus for infusion or blood transfusion to a catheter. The device is intended for single-use.	44036000	II	2-①	applicable	—

Cerebral introducer	A kit containing an instrument for facilitating insertion of a drainage catheter or endoscope into the body (catheter introducer), dilator, and endoscope cover. The device is intended for single-use. Not all of the components are included in some products.	70322000	II	6	applicable	N/A
catheter for radiography Uterine	A flexible tube through which milky white contrast media is injected into the uterus to facilitate radiography of the uterus (salpingography) or the uterus and fallopian tubes (hysterosalpingography). Usually the tube has one balloon (two in some cases) at or near the distal end, and the central lumen through which the contrast media is injected.	18746000	II	5-②	applicable	—
Injection needle stylet	A wire or a thin, flexible rod to be inserted into the lumen of an injection needle to reinforce the needle and maintain the shape and patency of the needle.	13836000	II	1,6,7	applicable	—
Short-term use catheter balloon repair kit	A kit containing adhesives and balloons used for repair or replacement. It is for short-term use.	31665002	II	5-②	applicable	—
Ureteral catheter adaptor	An accessory that facilitates ureteral catheter placement. The device is intended for single-use.	31973000	II	5-②	applicable	—
Angiography infusion stopcock	A switching device controlling the flow route of a contrast medium into the heart, great vessels, or coronary arteries for cardiac or vascular radiography.	32172002	II	2-①	applicable	—
General-purpose blood flow circuit stopcock	A device used to control the flow route of blood and other fluids. The device is usually made of a durable material (plastic, metal, etc.). The device is intended for single-use.	35375012	II	2-①	applicable	—
Continuous flow catheter flush valve	A dedicated Y-shaped part that is connected to an indwelling catheter in the injection line and is connectable to a second injection source. The second injection source usually provides liquid to flow inside the catheter at a low flow rate called the "keep-vein-open" rate.	35511000	II	2-①	applicable	—
Introducer for catheter with hemostasis valve	A sheath that facilitates percutaneous catheter placement in a vein or artery. The device is equipped with a hemostasis valve.	36079000	II	6	applicable	—
Connector for angioplasty balloon dilatation catheter	Connected to an introducing catheter, etc. and providing a bifurcation for pressure monitoring, injection of drug solutions, and flushing of the catheter during a percutaneous vascular (therapeutic or investigational) intervention (e.g. balloon angioplasty).	36177000	II	2-②	applicable	—
Obturator	A device inserted inside a catheter or catheter introducer to protect it from kinking and blockage during long-term placement.	70323102	II	6	applicable	—
Balloon inflation gauge	A pressure gauge used to measure the degree of inflation of the balloon including that of the balloon catheter for PTCA. This is used with a compression device (a syringe or small pump) to inflate the balloon.	70325000	II	2-①	applicable	—
Infusion pump stopcock	A device used with an infusion pump or infusion set, etc. to control the flow route of fluid or the gas flow. The device is usually made of a durable material (plastic, metal, etc.) and used for varying purposes.	35375022	II	2-①	applicable	—
Enteral nutrition pump gastrointestinal stopcock	A device used with an enteral nutrition set, etc. to control the flow route of fluid or the gas flow. The device is usually made of a durable material (plastic, metal, etc.) and used for varying purposes.	35375032	II	2-①	applicable	—
Transfusion/catheter stopcock	A device used with a transfusion set, etc. to control the flow route of fluid or the gas flow. The device is usually made of a durable material (plastic, metal, etc.) and used for varying purposes.	35375042	II	2-②	applicable	—
Pressure monitoring stopcock	A device used with a tube set for invasive pressure measurement, to control the flow route of fluid or the gas flow.	35375052	II	2-②	applicable	—

Infusion/catheter accessory set	A set of an infusion set. It contains a cap for a catheter, a connector (either with or without an injection port), and a check valve.	70326009	II	2-①	applicable	—
Transfusion/catheter accessory set	A set of a transfusion set. It contains a blood purifier circuit, a cap for a catheter, a connector (either with or without an injection port), and a check valve.	70326002	II	2-②	applicable	—
Gastrointestinal catheter introducer	An introducer used for percutaneous insertion of a catheter into the gastrointestinal tract or bile duct.	70329000	II	6	applicable	—
Catheter positioner	A device used for insertion and placement of an indwelling catheter at an appropriate position in the ureter.	70330000	II	5-②	applicable	—
Intrauterine balloon	A balloon to be inserted into the uterus and inflated with air, gas, a sterile solution, etc. for suppression of bleeding from the inner wall in the uterus.	12155000	II	5-②	applicable	—
Single-use arthroscopy catheter	A flexible tube used in arthroscopy to examine the interior of a joint. This device is for single-use.	15983002	II	6	applicable	—
Intrauterine catheter	A flexible tube used for detection and measurement of intrauterine and amniotic pressure.	16431000	II	5-②	applicable	—
Rectosphincteric balloon	A hollow rubber balloon connected to a manometer to assess the function of the rectal sphincter. The balloon is inflated with air or liquid.	17781000	II	5-②	applicable	—
Suction/insufflation catheter	A soft catheter used for aspirating or aerating air to the body cavity in order to remove or transfer substances in the cavity.	17795000	II	6	applicable	—
Carotid artery shunt	A device used to prevent any interruption to the cerebral blood supply during surgery such as carotid endarterectomy.	17797000	II	7	applicable	—
Chorionic villi sampling catheter	A soft catheter designed to collect in utero samples of filamentous process growing in the extraembryonic membrane (chorionic villi) in the outermost layer for genetic testing during the first trimester. Usually this device has a malleable, pre-shaped stylet which is inserted by ultrasonic induction. Sample suction is performed with an external syringe.	18105000	II	5-②	applicable	—
Manipulation/injection uterine catheter	A rigid plastic or metal surgical instrument inserted into the uterus via the uterine cervix. The device is used to manipulate the position of the uterus, provide a route for other devices, and inject or drain drug solutions/fluids. The device may be inserted using a trocar. The device is intended for single-use.	33911010	II	5-②	applicable	—

Uterine manipulation set	A set that is used to secure visibility during laparoscopic surgery by manipulating the position of the uterus, and to inject or drain drug solutions/fluids in or from the uterus. The set consists of a balloon catheter, syringe, tube, and catheter, etc.	33911020	II	5-②	applicable	—
Salpingography catheter	A flexible tube used to inject contrast medium into the uterine tube during radiography.	34157000	II	5-②	applicable	—
Intrafallopian uterine catheter	A semi-rigid or rigid, plastic or metal tubular surgical instrument inserted using a hard, pointed trocar into the uterine tube via the uterine cervix and the corpus uteri. After the trocar is removed following the insertion procedure, the catheter is left in the uterine tube for subsequent procedures inside the tube or to guide other devices that are used to manipulate tissues. The device is intended for single-use.	34217000	II	5-②	applicable	—
Preterm membrane rupture catheter	A flexible tube to be inserted into the uterus to induce rupture of the membrane surrounding the fetus before the 37th week of pregnancy.	34218000	II	5-②	applicable	—
Hemostatic catheter	A flexible tube to be inserted into the various sites of the body to stop blood flow. The device has a inflatable balloon and may be used with an endoscope.	34918000	II	5-②	applicable	—
Arthroscopy drainage catheter	A rigid or semi-rigid pipe inserted into a joint to inject or drain perfusion during or after arthroscopic surgery. The device may come with a trocar, obturator, or tube. The device is intended for single-use.	35620000	II	6	applicable	—
Bronchial catheter	A semi-rigid or rigid plastic or metal tubular surgical device to be inserted into the tracheal lumen usually by using a trocar with a hard pointed tip. After the device is inserted and the trocar is removed, the device is left in situ to be used as the guide.	35673000	II	5-②	applicable	—
Suprapubic catheter	A semi-rigid or rigid, plastic or metal tubular instrument inserted into the bladder from the suprapubic region. When the trocar with a hard tip (used for insertion of the catheter) is withdrawn, the catheter is left for voiding or guiding of another catheter or surgical instruments. The device is intended for single-use.	35789000	II	6	applicable	—
Single-use general-purpose suction tip	A device attached to an aspirator used for adjustment/control of aspiration during a surgical procedure or treatment. This device is a general-purpose suction tip for single-use.	35917102	II	6	applicable	—
Short-term use thoracic catheter	A semi-rigid or rigid tube to be inserted into the chest (the pleural space) to facilitate placement of a chest drain. It is for short-term use.	36247002	II	6	applicable	—
Percutaneous drainage peritoneal catheter	A flexible tube used for nonsurgical and transdermal drainage from abdominal tumors and for collecting fluids (infectious and noninfectious). This is mainly used for drainage of hepatic, subphrenic, subhepatic and pancreatic tumors or fluids.	37701000	II	6	applicable	—
Reusable tracheostomy tube	A device inserted into the tracheostoma to secure the airway patency. The device is intended for patients who have undergone tracheal surgery (e.g., for respiratory stenosis) and designed to secure the airway patency, facilitate prompt aspiration of	38792000	II	7	applicable	N/A

Reusable fibreoptic light ureteral catheter	An optical fiber catheter to be inserted into the urinary tract to confirm that the pathway is established in lower abdominal or pelvic surgery. This device consists of a bundle of optical fibers that radiate light along the entire length of the fibers and is	41605000	II	5-②	applicable	N/A
Reusable airway-esophageal obturator	A tube that is inserted into the esophagus from the oral cavity and has two lumina and two cuffs to support respiration. There is a hole for breathing between the pharyngeal and esophageal cuffs. When both cuffs are inflated, the pharyngeal cuff prevents air from flowing into the stomach, and the esophageal cuff prevents air from escaping	42419000	II	5-②	applicable	—
Reusable oropharyngeal tracheal tube	A curved plastic or metal tube to be inserted into the airway via the oral cavity to maintain airway patency during gas exchange or suction. This is useful to prevent the tongue from obstructing airflow. This device is reusable.	42423000	II	5-②	applicable	—
Thoracic cavity drainage system with blood collection bag	A combination of a plastic device and a blood collection bag. The plastic device consists of at least one chamber connected to the suction tube. This device is connected to the chest drain to be used for removal of air and purulent secretions as well as for blood collection. The blood collection bag can be treated in the same way as the usual blood bag and blood collected in the bag can be transfused back into the patient	70332010	II	2-①,2-②	applicable	—
Orthopedic drain set with blood collection bag	A set that contains an aspiration tube and either a plastic tool, connected to the aspiration tube and having one or multiple chambers, or a blood collection bag. The	70332020	II	2-①,2-②	applicable	—
Extension tube	A tube used to extend the lines for transfusion, blood transfusion, blood collection, fluid collection and administration of contrast media, etc. The tube has connectors at both ends.	70333009	II	2-①	applicable	—
Transfusion/catheter extension tube	A tube used to extend a line used for blood transfusion, blood collection, fluid collection, contrast medium injection (excluding a pressure-resistant line), or infusion using a pump. The device has a connector at one or both ends. The device may also have a port for blood collection or injection	12170012	II	2-②	applicable	—
Auxiliary extension tube for blood tubing	A tube used to extend the main or additional line of blood tubing. This extension tube is a blood tubing component.	12170022	II	2-①	applicable	—
Intravenous tubing extension kit	A kit containing tubes and a connector(s) used to extend a standard venous line (IV) set. This kit is used when a tube included in an existing standard infusion set is too short to reach the infusion IV line or when the IV line is located too far away. This kit	12170032	II	2-②	applicable	—
Enteral nutrition pump extension tube	An extension tube connected to a compatible enteral nutrition set, used to deliver enteral nutrients from a pump. The device's connector is designed to be incompatible with an infusion line	12170042	II	2-②	applicable	—
Infusion pump extension tube	A tube used to extend a line connected to an infusion pump. The device has a connector at one or both ends. The device may have an injection port.	12170052	II	2-②	applicable	—
Blood transfusion set extension tube	A tube used to extend a line such as a blood transfusion line or the line of a blood collection set. The device has a connector at one or both ends. The device may have an injection port	12170062	II	2-②	applicable	—
Needle-less contrast medium infusion set extension tube	A tube used to extend a line of needle-free contrast media infusion set. The device has a connector at one or both ends. The device may have an injection port.	12170072	II	2-②	applicable	—
Protective overtube	A flexible tube used to prevent injury by devices inserted into the body such as sensors, guidewires, and indwelling cannulas. The device is intended for single-use.	70334000	II	6	applicable	—
Ovarian cyst evacuation set	A set of metal pipes and needles used in aspiration/drainage of contents of ovarian cysts or in subsequent lavage. The needle included in the set may have a balloon attached. Not all of the components are included in some products	70335000	II	5-②	applicable	—
Reusable bronchial cannula	A semi-rigid or rigid plastic or metal tubular surgical device to be inserted into the tracheal lumen by using a trocar with a hard pointed tip. After the device is inserted and the trocar is removed, the device is left in situ to be used as the guide path for	70338000	II	5-②	applicable	N/A

Lacrimal fluid/passage silicone tube	A tube made of silicone or polyurethane, etc. used to treat epiphora induced by occlusion of the lacrimal punctum, lacrimal canaliculus, or nasolacrimal duct, etc. This tube is inserted or placed in the lacrimal canaliculus, etc. to dilate the lacrimal passage. It usually comes with a device(s) used for insertion of the tube.	70337102	II	5-②	applicable	—
Tubal patency catheter	A catheter inserted into the uterus for tubal patency test.	70340000	II	6	applicable	—
Dialysis priming /fluid replacement set	A single-use, sterilized set used for flushing of the blood tubing, fluid replacement, or drainage. In using, the set may be integrated with a blood tubing. One end is connected to the drug solution or drain while the other is connected to the tubing.	70341000	II	2-②	applicable	—
Non-sterile bronchial tube	A cylindrical tube with two cavities to be inserted into the trachea for anesthetic administration or pulmonary function testing. It has tracheal and bronchial cuffs, which regulate ventilation to one of the two lungs, when necessary. It is not sterile.	70342000	II	2-②	applicable	—
Artificial insemination catheter	A flexible tube used in artificial insemination, i. e. , delivery of sperm or fertilized ovum into the uterus. The device is intended for single-use.	70345010	II	5-②	applicable	—
Embryo transfer catheter	A flexible tube used in in vitro fertilization or embryo transfer. The device is intended for single-use.	70345020	II	5-②	applicable	—
Electromagnetic thermotherapy set	A set that contains a catheter used as protective material during electromagnetic hyperthermia, needle, and tube, etc.	70347000	II	6	applicable	—
Urinary tract pressure measurement catheter	A device connected to a pressure gauge and inserted via the urethral orifice to measure the pressure inside the ureter, bladder, or urethra.	70348000	II	5-②	applicable	—
Female urethral imaging urological catheter	A tube through which contrast media is injected or a metal chain is inserted into the female urethra for radiography.	70349000	II	5-②	applicable	—
Sealed small radiation source catheter	A device used during brachytherapy to place the radioactive seed or source within a body cavity. It is designed to fix a catheter in place.	38437000	II	6	applicable	—
Salpingoplasty catheter	A catheter inserted through the uterus into the uterine tube to recover tubal patency. The balloon attached to the catheter tip dilates the uterine tube under salpingoscopy. By progressing into the uterine tube, the lumen of uterine tube can be observed, and	70350000	II	5-②	applicable	—

Trocar application cuff	A flexible rubber cuff that is placed inside the incision to protect the tissue when an instrument such as trocar and forceps, or a hand is inserted into the body cavity.	70351000	II	5-②	applicable	—
Blood component separation bag	A plastic bag used to collect, isolate, preserve, treat, transport, or infuse blood or blood components. The bag is blood preservative-free.	70357000	II	2-②	applicable	—
Frozen bag	A plastic bag used to collect, isolate, preserve, discard, transport, or infuse blood or blood components, including those which can be frozen. The bag is blood preservative-free.	70359000	II	2-①	applicable	—
Blood donor set	A set of flexible plastic bag(s) (at least one soft bag), a tube, and a hollow needle attached to the tube (to be inserted into the donor's vein). After the blood is collected, the blood is kept in one bag, or separated blood components (for example, red blood cell, plasma) are kept in multiple bags. Usually collected blood and blood components are analyzed, stored, or used as needed. The device is intended for single-use.	10426000	II	6	applicable	—
Exchange blood transfusion set	A vascular injection set used to withdraw blood from a sick neonate/infant and simultaneously replace it with a donor's blood or plasma. Usually the set includes a needle, catheter, tube, flow regulator, drip chamber, injection filter, stopcock for an intravenous infusion set, injection tube, connectors, side tube with a cap that can be used as an injection port, and a tube to connect the tube to a container such as an intravenous infusion bag.	35405000	II	7	applicable	—
Blood transfusion set	A vascular injection set used to inject blood from a container into the blood vessel of a patient via a needle or catheter. This set may include a needle, catheter, tube, flow regulator, drip chamber, injection filter, stopcock for an intravenous infusion set, injection tube, connectors, side tube with a cap that can be used as an injection port, and a tube to connect the tube to a container such as an intravenous infusion bag.	38569000	II	7	applicable	—
Arterial blood sampling kit	A kit containing a syringe, needle, and plug, etc. for sampling of arterial blood. The device is usually used for blood gas analysis.	31336000	II	6	applicable	—
Blood collection kit with blood sampling port	A tube equipped with a reservoir and blood sampling port for collection of blood in a closed circuit. The device is connected to another device (e.g., catheter) by a connector, and the blood is aspirated via the blood sampling port on manipulation of the reservoir.	70360000	II	2-②	applicable	—
Fetal scalp blood sampling kit	A kit containing items used to collect blood from the fetal scalp transvaginally at delivery. Usually, the kit has a device used to puncture the scalp for blood sampling, such as syringes, needles, plastic cones and thin blood collection tubes as well as swabs and antiseptic solutions. This kit is for single use.	16873000	II	2-②	applicable	—
Single-pack blood donor set	A set of a flexible plastic bag(s) (one soft bag), tube, and hollow needle attached to the tube (to be inserted into the donor's vein). Collected blood is analyzed, stored, or used as needed. The device is intended for single-use.	44033000	II	2-②	applicable	—
Double-pack blood donor set	A set of flexible plastic bags (two soft bags), tube, and hollow needle attached to the tube (to be inserted into the donor's vein). After the device collected the blood, blood components (e.g., red blood cell, plasma) are isolated and kept in separate bags.	44034000	II	2-②	applicable	—
Triple-pack blood donor set	A set of flexible plastic bags (three soft bags), tube, and hollow needle attached to the tube (to be inserted into the donor's vein). After the device collected the blood, blood components (e.g., red blood cell, plasma) are isolated and kept in separate bags. Collected blood and blood components are analyzed, stored, or used as needed. The	44037000	II	2-②	applicable	—

Blood bag negative pressure blood sampling device	A device used with a blood bag to support vacuum blood sampling.	70361000	II	11	applicable	—
Specific gravity test kit	A set of sterilized items including a tube and hollow needle attached to the tube (to be inserted into the donor's vein). It may come as a tube integrated with the needle. Usually, blood drawn into the tube is used to determine specific gravity, blood type, or	70363000	II	6	applicable	—
Open blood collecting tube	A tube used during blood collection. The tube ends are open, and the blood coming through an inserted tube is filled in this device. Some products can be sealed with a cap or plug. The device is intended for single-use	34590000	II	2-②	applicable	—
Testing evacuated sealed blood collecting tube	A tube used in the laboratory together with a blood collection tube adapter and blood collection needle. It is partially evacuated and sealed when provided. The blood comes into the tube because of vacuum. The device allows pretreatment of blood with various chemicals depending on the purpose without transfer of blood to other containers	35414009	II	2-②	applicable	—
Evacuated sealed blood collecting tube	A tube used in blood collection together with a blood collection tube adapter and blood collection needle. It is partially evacuated and sealed when provided. The blood comes into the tube because of vacuum. The device allows pretreatment of blood with various chemicals depending on the purpose without transfer of blood to other containers	35414000	II	2-②	applicable	—
Blood filter	A filter inserted inside a blood transfusion line to remove impurities from blood that enters the patient's body. The device may also be used to capture bubbles in arterial blood.	35071000	II	3-①	applicable	—
Blood/solution warmer	An apparatus used to warm preserved blood, blood products, or drugs before administration. Usually the device warms the bag directly or in a special set or a plastic tube (e.g., with a heating coil for blood/drug solution). The device does not include single-use accessories (e.g., tubes)	10447000	II	3-①	applicable	applicable
High-flow blood/solution warmer	An apparatus used to warm blood or other fluids for rapid infusion when severe bleeding occurs during surgery or in the event of burns/scalds or trauma. The maximum flow rate exceeds 1 liter/min in some products. The heating medium may be water or a heat-transfer surface (that transmits heat to the single-use set used in a specific type of heater). The device does not have a function of infusing fluids	38446000	II	9	applicable	applicable
Arteriotomy kit	A kit consisting of the tools needed for blood collection, such as test tubes, a rack(s), needles, bandages, gauze pads and a needle container.	18026000	II	6	applicable	—
Portable blood sampling pump	A device used to continuously perform controlled blood sampling for a predefined period (usually for 24 hours). This device is attached to the patient's body, and the patient has to carry the device for the predefined period. After use, the device is	36997000	II	6	applicable	—
Blood/solution warming coil	A plastic tube used with devices that warm preserved blood, blood products, or drugs (fluid warmer for blood and therapeutic solution, fast-flow fluid warmer-pump, and fast-flow fluid warmer for blood and therapeutic solution) before injection. The device	70368000	II	3-①	applicable	—
Infusion start kit	A package that includes a needle, tube, and other instruments used to establish venous access for intravenous infusion.	33963000	II	7	applicable	—
Intravenous administration set with noncoring needle	A set of tools used for intravenous fluid administration. The device includes a tube, clamp, and needle (solid with a side hole). The device is used in an implanted injection/infusion port.	17701000	II	2,5-②	applicable	—
Intravenous administration set for scalp vein	A set of devices used to administer a solution intravenously. The set includes tubes, clamps, and needles and needle holders appropriate for scalp intravenous injection. The set is usually used for pediatric patients (in particular for infants)	17825000	II	2,6	applicable	—
Infusion pump infusion administration set	An infusion set specifically used for transfer of the infusion solution from the pump to the infusion site.	35833000	II	2-②	applicable	—
Insulin pump infusion administration set	An infusion set specifically designed for injection of drugs from an insulin pump.	35838000	II	2-②	applicable	—
Infusion administration set controller	A dedicated infusion set used to deliver an infusion solution from the infusion controller to the infusion site. Usually it consists of tubes, a clamp(s), a protective rack(s), and placebo group, etc.	36244000	II	2-②	applicable	—

Intravenous administration set with heat exchange function	A type of set for intravenous administration. It is designed to directly warm an infusion solution to be administered.	41609000	II	2-①	applicable	—
Gravity pour/infusion pump infusion administration set	An infusion set used to inject infusion solution into the infusion site of the patient or recipient. The device transfers solution either by gravity (without an active device) or with an active device such as an infusion pump.	70371000	II	2-②	applicable	—
Infusion administration set with venous pressure measurement function	An infusion set that is used to inject infusion solution into the infusion site of the patient or recipient and is also capable of measuring venous pressure.	70372000	II	2-②	applicable	—
Contrast media infusion administration set	An infusion set used to inject contrast media into the infusion site of the patient or recipient. The device transfers contrast media either by gravity (without an active device) or with an active device such as infusion pump. The device may come with a filter, three-way stopcock, and connector for mixed injection, etc.	70373000	II	7	applicable	—
Contrast media infusion administration set without needle	An infusion set that contains no puncture needle and is used to transfer contrast medium from its bottle to the syringe, for catheter-based angiography. The device may come with a three-way stopcock and burette, etc.	70374000	II	2-①	applicable	—
Enteral nutrition pump infusion set	An enteral nutrition set specifically for delivery of enteral nutrients from a pump. The connector of the device is designed to be incompatible with an infusion line.	70376000	II	2-②	applicable	—
Syringe filter	An instrument connected to a syringe for removal of foreign bodies from the injection solution.	15283000	II	3-①	applicable	—
Intravenous line filter	An instrument used with an infusion line to remove microorganisms and other foreign bodies from the infusion. The device may also be used to remove air.	35072000	II	2-①	applicable	—
Single-use winged needle for general veins	A very thin, edged instrument commonly used for venipuncture. The device is intended for single-use.	70378000	II	6	applicable	—

Single-use winged scalp vein needle	A very thin, edged instrument used in a scalp vein or other small veins (especially for pediatric patients). The device is intended for single-use.	35211002	II	6	applicable	—
Single-use blood preservation in-line backflow check valve	A device used to prevent reflux of gas or liquid in a medical tube or pipeline. This is used for blood preservation. This device is for single-use.	34099002	II	2-②	applicable	—
Reusable active device connected backflow check valve	A device used to prevent reflux of gas or liquid in a medical tube or pipeline. This device is connected to the active device, and is reusable.	42548002	II	2-①	applicable	N/A
Reusable intravenous infusion set	A set containing tubes, a clamp(s), needles, etc. which are used to infuse the solution for intravenous administration. This set is not sterilized and reusable.	70382000	II	6	applicable	—
Continuous flow flush device	A device with a channel that allows a constant infusion rate to be maintained in order to assist arterial pressure measurement and retain patency. A fixing valve of the device has a manual mechanism that enables flushing of the line at a rate about the	70383000	II	2-①	applicable	—
Prefilled syringe with needles	A single-use glass or plastic syringe with a needle, used to administer drug. Usually, the syringe is designed to contain single dose of drugs,	70390000	II	2,6	applicable	—
Pen-type medication injector	A manually operated pen-type device used for intramuscular or subcutaneous injection of drugs (excluding insulin) into the human body. The device is reusable (mostly pen-type) and each injection requires a new, replaceable needle to be attached. The	70391000	II	6	applicable	—
Single-use ophthalmic medication injector	A device for infusion of a drug solution (e.g., of a viscoelastic substance) into the eye in ophthalmic surgery. The device is usually made of glass or plastic and consists of a container and plunger. The device is intended for single-use.	70393000	II	6	applicable	—
Reusable medication/vaccine injector	A device used for intramuscular (IM) or subcutaneous injection of drugs/vaccines into the human body. The device is usually reusable and comes in varying forms depending on the purpose. The device is either manually operated or powered (e.g., by spring	12504002	II	11	applicable	—
Reusable mechanically-powered needleless medication/vaccine injector	A hand-held mechanical device (spring type) used for transdermal injection of drugs (particularly, of a local anesthetic) or vaccines into the human body. This is needleless and reusable, and structured in various ways according to use. Usually, it is a gun-type plunger-driven syringe with one or more holes on the syringe from which a drug or a vaccine is extruded under high pressure. A drug or vaccine to be injected is loaded	18069000	II	11	applicable	—
Reusable gas-powered needleless medication/vaccine injector	A hand-held gas-driven device used for transdermal injection of drugs (particularly, of a local anesthetic) or vaccines into the human body. This is needleless and reusable, and structured in various ways according to use. Usually, it is a gun-type plunger-driven syringe with one or more holes on the syringe from which a drug or a vaccine	42949000	II	11	applicable	—
Non-intravenous infusion pump	A device used for injection of drugs and solutions into the patient's body (other than blood vessels) in an accurate and constant manner. The device may require a syringe for use. The device is not used for subcutaneous injection of insulin or vaccines or	70394000	II	11	applicable	N/A
Single-use dye injector	An injector for promoting pigmentation by skin penetration. It is used by a physician to cover scars and burns, to make artificial eyebrows, to make a nipple appear natural after breast reconstruction, and to improve the aesthetic appearance of other body	17660002	II	6	applicable	—
Single-use indicator injector	A syringe-like device used to accurately perform bolus injection of an indicator (e.g., cold saline solution) into the bloodstream. The device is usually used for delivery of the indicator to the heart, for evaluation of blood flow through the heart. The device's variants are used with a densitometer or thermal dilution cardiac output flowmeter for	31736002	II	6	applicable	—
Obstetric anaesthesia kit	A kit containing a set of items including injection needles, catheters, syringes, sterilized gauze, skin disinfectants, local anesthetics which are used for local block during labor and delivery.	33595000	II	6	applicable	—

Brachial plexus anaesthesia kit	A kit containing a set of items including injection needles, syringes, sterilized gauze, and skin disinfectants used for upper extremity nerve block (supraclavicular nerve, interscapular nerve, subclavian nerve, axillary nerve, brachial plexus). Some types are	34840000	II	6	applicable	—
Caudal anesthesia kit	A kit containing a set of items used for injecting local anesthetics into the sacrum and the sacral canal.	34841000	II	6	applicable	—
Epidural anaesthesia kit	A kit containing a set of items necessary for injecting anesthetics into the epidural space.	34842002	II	6	applicable	—
Glossopharyngeal anaesthesia kit	A kit containing a set of items necessary for administering anesthetics to the tongue and the pharynx.	34843000	II	6	applicable	—
Pudendal anaesthesia kit	A kit containing a set of items necessary for injecting anesthetics into the external genitalia.	34844000	II	6	applicable	—
Saddle block anaesthesia kit	A kit containing a set of items necessary for injecting anesthetics into the dural sac in the areas corresponding to the buttocks, the perineum, and the medial thigh.	35888000	II	6	applicable	—
Laryngotracheal anaesthesia kit	A kit containing a set of items necessary for injecting anesthetics into the upper trachea and the sublingual structure.	35905000	II	6	applicable	—
Paracervical anaesthesia kit	A kit of items including antiseptic solutions, injection needles, needle guides, syringes, and other accessories used with anesthetics. This set is used for local block (e.g., paracervical block, uterosacral block, genital block) in labor, delivery, or both of these events.	42325000	II	6	applicable	—
Blood/body fluid transfusion/enteral nutrition infusion set	A device that is connected to a catheter inserted into the stomach or intestine, for administration of enteral nutrition. The device can be used for transfusion of blood and other bodily fluids.	70398000	II	2-②	applicable	—
Implantable port drug injection device	A device consisting of a needle (for injection of drugs into an implanted port), tube, etc.	70401000	II	2-②	applicable	—
Powered syringe for dental anaesthesia	An electric injector (with a cartridge filled with anesthetic solution and a sterilized needle) for dental anesthesia. The anesthetic is injected on operating the switch.	70402000	II	11	applicable	applicable
Single-use manually-operated barium enema contrast medium delivery/evacuation kit	A pre-packaged kit made up of a bag, cap, tube, baffle, and enema tip used to inject or remove barium sulfate solution (contrast agent) or air for lower GI tract examination. The device is intended for single use.	70403000	II	5-②,11	applicable	—
Blood transfusion connecting tube	A connection tube with a connector for a blood bag or other devices at each end. The device is used to transfer blood from a blood bag during transfusion.	70404000	II	2-②	applicable	—

Single-use hemostatic clip applier	A surgical device designed to apply a hemostatic clip for ligation of a blood vessel. The device is for single-use. Some devices are used with an endoscope.	36126000	II	6	applicable	—
Umbilical tape	A narrow, flat strip made of a synthetic material used for binding or suturing around the umbilical cord after delivery.	13983000	II	7	applicable	—
Single-use suture needle	A needle used to insert or remove sutures into/from tissues. There are specific-and general-purpose variants. The device is intended for single-use.	70417002	II	6	applicable	—
Single-use automatic suturing device	A device that automatically sutures a damaged parts or a ruptured muscle with sterile suture. The device is intended for single-use.	15065002	II	6	applicable	—
Single-use arthroscopic suture unit	A device that is used to repair a wound or ruptured muscle. The surgeon's desired number of stitches are applied at the wounded or ruptured site using the suture punch system in controlled arthroscopy. The device is intended for single-use.	17735002	II	6	applicable	—
Non-absorbable gastrointestinal anastomosis coupler	A device designed to join the two ends of gastrointestinal tracts by connecting the residual tissues with a ring-shaped component inserted to each open end before anastomosis. The device is made of non-absorbable materials. The device is also used	18135002	II	6	applicable	—
Vascular anastomosis coupler	A device used for inserting the component into the end of the binding site so as to bind the vascular tissues to this joint. This device is made of non-absorbable materials except for "non-absorbable vascular anastomosis coupler" and "absorbable vascular	18137002	II	7	applicable	—
Surgical stapler	A surgical instrument used to place surgical staples (including a variant that can be used for transection of tissues). The device may be pistol-shaped. The device is either for single-use or reusable. "Reusable surgical stapler" and "single-use surgical stapler"	32369009	II	6,7,9	applicable	—
Single-use surgical stapler	A surgical instrument used to place surgical staples (including a variant that can be used for transection of tissues). The device may be pistol-shaped. The device is for single-use. Some devices are used with an endoscope.	32369002	II	6,7	applicable	—
Single-use wire/ligature passer	A surgical instrument used to pass wires or ligatures through body tissue. Usually it is a flexible or firm rod with a handle and a clasp, catch, or clasp to pass the material through tissue. The device may have a ring-shaped handle and a long and linear or curved blade. The device is intended for single-use.	32864002	II	6	applicable	—
Implantable hemostatic clip (exclude reusable use)	A device used to stop blood flow in tissues (e.g., a blood vessel). The device is not reusable. Variants that are implanted in the patient's body are excluded.	34050000	II	6	applicable	—
Surgical vascular clamp (exclude reusable use)	A surgical instrument used to temporarily stop blood flow in an anastomosed vessel. The vascular clamp usually includes peripheral vessel clamps and iliac clamps. The reusable device is excluded.	35596000	II	6	applicable	—
Removable skin staple (exclude reusable and absorbable use)	A metal (e.g., stainless steel or titanium) device with a pistol-like applicator to close or approximate a wound or edges of an incision. The edges of a wound or incision are approximated by the applier, and staples are applied to hold the edges together. Staples are removed when the wound or incision is cured. Reusable and absorbable	35884002	II	6,7	applicable	—
Single-use suture passer	A surgical instrument used to pass sutures and suture needles through body tissue. Usually it is a flexible or firm rod with a handle and a hook, catch, or clasp to pass the material through tissue. The device may have a ring-shaped handle and a linear or curved blade. The device is intended for single-use.	37839002	II	6	applicable	—

Single-use staple remover	A metal or plastic surgical instrument used to remove staples from a surgical wound or incision that no longer requires stapling to stay closed. The device is intended for single-use	16787002	II	6	applicable	—
Umbilical occlusion clip	A device used to ligate/close the umbilical blood vessels of a neonate. It is intended for single-use and discarded after healing.	32192000	II	6	applicable	—
Single-use surgical umbilical clamp	A surgical instrument used to compress (constrict) the umbilical cord after childbirth. The device is used before transection or ligation of the umbilical cord to achieve hemostasis essentially and facilitate healing. The device may have a security lock with	43998000	II	7	applicable	—
Surgical aortic clamp (exclude reusable use)	A surgical instrument used to compress an aorta temporarily in an atraumatic manner. The device may use an inserter made of varying materials. It includes anastomosis clamps for aorta and clamps for aortic aneurysm. The reusable device is	34947000	II	6	applicable	—
General-purpose artery clamp (exclude reusable use)	A surgical instrument used to compress an artery temporarily in an atraumatic manner. The reusable device is excluded.	34948000	II	6	applicable	—
Surgical intestinal clamp (exclude reusable use)	A surgical instrument used to hold, join, compress, or support the intestine in an atraumatic manner during gastrointestinal surgery. The reusable device is excluded.	34953000	II	6	applicable	—
Surgical rectal clamp	A surgical instrument used to hold, join, compress, or support the rectum, rectal valve, or anal canal in an atraumatic manner. The device is intended for single-use.	35542002	II	6	applicable	—
Surgical carotid clamp	A surgical instrument used to compress the carotid artery. The device is intended for single-use.	35593002	II	6	applicable	—
Endoscopic esophageal varices ligation therapy ligator set	A set used together with an endoscope for ligation of esophageal varices (in endoscopic variceal ligation). The device consists of a transparent hood to be attached to the endoscopic tip and an O-ring-shaped band made of rubber or elastomer used to ligate a varix	70420002	II	5-②	applicable	—
Ligating tape	A band-shaped or tubular thread or tape for temporary ligation of a blood vessel or other tissues. A needle may be attached to it.	70423000	II	6	applicable	—
Reusable scalp clip	A sterilized surgical instrument with two blades joined at the middle or consisting of one α-shaped part. It is used to achieve hemostasis during scalp surgery. (Excluding a non-sterilized instrument.) This instrument is reusable.	34959002	II	6	applicable	—
Single-use skin clip	A surgical instrument with two blades joined at the middle or consisting of one α-shaped part. The device is used to pull skin incision edges closer during a procedure or to fix an object (e.g., electrode) to the skin. The device is intended for single-use	34960000	II	6	applicable	—
Endoscopic loop ligator	A device used with a special endoscope during endoscopic therapy. It is used to ligate a polyp with a loop of wire to achieve hemostasis or induce necrosis and sloughing. The device comes with an insertion sheath, a loop of wire attached to the sheath tip, a	36176000	II	7	applicable	N/A
Surgical clip	A surgical instrument having two blades joined at the middle or consisting of one α-shaped part. It temporarily holds or fixates another instrument, device, or tissue.	37406000	II	6	applicable	—
Single-use scalp clip	A surgical instrument having two blades joined at the middle or consisting of one α-shaped part. The device is used to achieve hemostasis during scalp surgery. The device is intended for single-use.	37458000	II	6	applicable	—
Single-use surgical punch	A surgical instrument used to create a hole for suturing or anastomosis of a tissue, blood vessel, etc. The device is intended for single-use.	35285012	II	6	applicable	—
Surgical aortic punch	A surgical instrument used to resect tissues and create a hole in the aorta for anastomosis during vascular surgery. The device is intended for single-use.	35285022	II	6	applicable	—

Single-use urinary incontinence suturing needle	A device for elevating the female bladder neck to treat urinary incontinence. This device is for single-use.	70430002	II	6	applicable	—
Urinary incontinence prevention prosthesis	A device for elevating the bladder neck to prevent urinary incontinence.	70431000	II	5-②	applicable	—
Transparent adhesive dressing	A transparent film (made of polyurethane, etc.) having an adhesive area (e.g., margin) used to cover and protect a wound yielding a small amount of exudate.	17428000	II	4-②	applicable	—
Non-adhesive dressing	A gauze or pad-like dressing coated with or soaked in an emulsion of silicone or white petrolatum for protection of wounds without adhesion.	11325000	II	4-②	applicable	—
Local control hydrogel dressing	A local wound dressing made of hydrophilic polymer for absorption of exudate, reduced blood/body fluid loss, and protection of wounds from scratching, abrasion, dryness, and contamination.	34082002	II	4-②	applicable	—
Local control saline solution-containing dressing	A local wound dressing containing hypertonic saline solution used for accelerating biological cleaning of wounds and autolytic debridement.	37298002	II	4-②	applicable	—
Local control hydrophilic gel-forming dressing	A local wound dressing, usually appearing like a sheet or ribbon, made of hydrophilic fiber, chitin, or alginate (salt and acid), etc. that accelerates autolytic debridement by absorbing exudate and maintaining wet microenvironment.	43186002	II	4-②	applicable	—
Burn kit	A package of required items used in combination for treatment of first-or second-degree burns, including dressings and antibiotics.	10516000	II	4-②	applicable	—
Local control foam dressing	A local wound dressing comprising a superabsorbent pad made of hydrophilic foam for covering wounds with a large amount of exudate.	11323002	II	4-②	applicable	—
Surgical packing	A cylindrical gauze. The gauze comes in various widths and is soaked with vaseline, povidone iodine, etc. and is used for filling surgical incisions.	13886000	II	4-②	applicable	—
Wound protecting ring	A round, plastic cover with a hole at its center. The dressing is affixed to the skin around the surgical wound or placed over the wound for protection. The dressing may also be used to hold a surgical drape.	44273000	II	6	applicable	—
Single-use first aid emergency kit without medication	A convenient kit containing devices and materials for first aid treatment in emergency situations. Usually, it is used in the home, in a car, for emergency services in an ambulance or in crowded venues. This kit does not contain drugs. This kit is for single-use.	44047000	II	6	applicable	—
Bone wax	A waxy stick, paste, source or ointment used for arresting bleeding from the bone during surgery. Previously, the product was produced from refined beeswax as the raw material. Nowadays, this can be produced from synthetic wax.	10459000	II	7	applicable	—
Incision/drainage kit	A package of devices including surgical scalpels and tubes used for creating an opening in the body and placing a drain. This device is for single-use.	35118000	II	6	applicable	—

Uterine operation set	A set used for injection and excretion of drug solutions, etc. into the uterus while manipulating the uterus. The device consists of a balloon catheter, syringe, tube, and catheter, etc.	70224002	II	5-②	applicable	—
Abdominal hypobaric patient chamber	A hood-like device used to reduce abdominal pressure in a pregnant woman in order to alleviate abdominal pain during pregnancy or delivery.	32620000	II	9	applicable	applicable
Obstetrical decompression pump	A dedicated pump used with a hood-like device to control and reduce pressure on a pregnant woman. It is used for alleviating abdominal pain during pregnancy or labor.	35283000	II	9	applicable	applicable
Laparoscopy gas pneumoperitoneum device	A dedicated device used to inject pressure-controlled gas into the peritoneal cavity for dilation. The device assists in securing the area under examination or surgery. The device may be capable of maintaining gas pressure in equilibrium by correcting for leakage.	70447000	II	11	applicable	applicable
Ophthalmic conformer	An ophthalmic device usually made of molded plastic to be inserted temporarily between the eyeball and palpebra in order to secure space in the orbit and to prevent closure or adhesion during healing after eye enucleation.	16065000	II	7	applicable	N/A
Emergency kit for anaphylaxis	A dedicated kit of the items necessary for emergency care (e.g., drugs, endotracheal tubes) when a patient is in anaphylactic shock. In anaphylactic shock, allergic reactions (shortness of breath, rash, wheezing, and hypotension) are usually observed.	16160000	II	5-②	applicable	—
Dialysis start/stop set	A pre-packaged set of single-use instruments and materials (gauze, compress cotton, tweezers, etc.) required at the beginning and end of a dialysis session.	32142000	II	2-①	applicable	—
Surgical tamp	A hand-held surgical device consisting of a handle at the proximal end, an axis, and usually a rectangle, obtuse tip at the distal end. This device is intended to wrap tissues or other substances during surgical procedures.	32873000	II	6	applicable	N/A
Single-use class II surgical procedure kit	A pre-packaged kit that contains all items necessary for ordinary treatment (Class I or Class II), such as various devices, covering protective materials and drugs. This kit is for single-use.	33961002	II	6	applicable	—
Single-use circumcision kit	A pre-packaged kit, set or tray that contains all items necessary for circumcision, such as various devices, covering protective materials and drugs. It usually includes antiseptics, a circumcision clamp(s), scissors and a scalpel(s). This kit is for single-use.	34945000	II	6	applicable	—
Emergency kit for cardiopulmonary resuscitation	A kit containing a set of items necessary for performing cardiopulmonary resuscitation (CPR). This kit contains first-aid medicines, endotracheal tubes, face masks, and manual resuscitation bags. This kit is for single-use.	35693000	II	6	applicable	—
General-purpose emergency kit for resuscitation	A kit packaged in a portable case containing emergency items (e.g., drugs, endotracheal tubes, face masks, manual resuscitation bags) which are stored so as to be ready for use in case of emergency. This kit is strategically located in a hospital. It may also be located in a vehicle that belongs to an emergency department.	36690000	II	6	applicable	—
Ophthalmic insufflator	An apparatus used to inject a small volume of air into the eye for retinal reattachment or removal of subretinal fluid in ophthalmic surgery.	37069000	II	6	applicable	N/A

Reusable surgical procedure kit	A packaged kit, set or tray that contains all items necessary for general surgical treatment, such as various devices, wound covering, protective materials and drugs. This is reusable after being cleansed properly.	37547000	II	6	applicable	—
Puncture needle setting device for ultrasonic probe	A fixation device used to mount a puncture needle onto an ultrasonic probe, etc.	70448000	II	5-⑥	applicable	—
Skin grafting peeler	A surgical device used to collect skin for skin grafting. It can be used either manually or automatically.	70449000	II	6	applicable	—
Skin grafting dilator	A device used to expand a skin graft in order to cover an area larger than the graft. The device enables enlargement at various ratios by making a mesh-like incision on the graft.	70443002	II	6	applicable	—
Anaesthetic filter	A device used to remove microorganisms and other foreign bodies from anesthetics and analgesics, etc. The device may also be used to remove air.	70450000	II	2-①	applicable	—
Water for oxygen inhalation warming humidifier	Bottled sterilized water used to administer aerosolized water to patients.	70452002	II	5-⑥	applicable	N/A
General-purpose surgical irrigation/aspiration unit	A device used to perfuse or aspirate fluids in/from a body cavity or any other desired area during surgery for gaining cleaning effect continuously. The device can remove tissue/tissue fragments and fluids, etc. from the cavity/area and keep the cavity/area clean and visible. The device may also be used to facilitate access to a desired area.	41643000	II	11	applicable	applicable
Ophthalmic irrigation/aspiration unit	A device used for perfusion with or aspiration of fluids from the eye and orbital cavity in ophthalmic surgery. For example, this device can help the operator by removing fragments, tissues, and fluids from the intervention site, keeping the site clean, and facilitating observation. The device is often used during cataract surgery. The device	36586000	II	6	applicable	applicable
Powered suction unit	An apparatus that can generate negative pressure. It is made up of a vacuum pump, electric motor, gauge, microbiological/moisture filter, overflow trap, and collection bottle or canister. The device is used to aspirate fluids or particulate materials. The device operates on electricity and is usually used when heavy work is required such as	36777000	II	11	applicable	applicable
Liposuction unit	An apparatus equipped with a powerful pump that can achieve the desired negative pressure and is used with a special cannula for aspirating subcutaneous fat during liposuction. Liposuction is often considered cosmetic surgery.	36894000	II	11	applicable	applicable
Thrombus suction unit	A device for providing negative pressure used during thrombectomy in the heart and the pericoronary artery. This device is used to send controlled low pressure generated	37232000	II	11	applicable	applicable
Thrombectomy device	A thrombectomy device used to remove a thrombus from the central circulatory system. The device enables aspiration of a thrombus near the tip of the catheter connected to the device by generating negative pressure.	70454000	II	11	applicable	applicable
Nasal irrigation/aspiration unit	A device for perfusion and aspiration of the nasal cavity with solutions to enhance the cleaning effect. It is used for removing tissue cores, tissues, fluid, etc. from the treated area, keeping the treated area clean and supporting clearer observation. It may also be used to facilitate easy access to the target area during the procedure.	33579000	II	11	applicable	applicable

Dental bone dust collector	A device used to collect bone debris generated by drilling, etc. during oral surgery.	70455000	II	5-⑥	applicable	N/A
Thoracic suction unit	A device that provides negative pressure for removing a large quantity of accumulated body fluid from the thorax (pleural cavity) which is located between the lungs and the chest wall. A large quantity of body fluid is often produced in association with serious internal trauma, damage, surgery, etc.	36787010	II	11	applicable	applicable
Powered thoracic suction unit	An electric apparatus that provides negative pressure for removal of a large amount of body fluids or air in the chest cavity between the lung and thoracic wall (pleural cavity). A large amount of body fluid is often produced by serious internal trauma, damage, or surgery, etc.	36787020	II	11	applicable	N/A
Low pressure suction unit	An apparatus that generates weak negative pressure used in interventions such as aspiration of fluids or particulate materials. Careful pressure control is necessary to avoid accidental injury when it is used to remove an object blocking the airway in a neonate. The device may run on pressurized gas or other mechanisms.	34860010	II	11	applicable	applicable
Powered low pressure suction unit	An electric apparatus that generates weak negative pressure (low negative pressure) used to aspirate fluids, gases, and particulate materials, etc. The device may be used to continuously remove from the body (for drainage) fluids, gases, or particulate materials within the thoracic cavity, abdominal cavity, etc. Careful pressure control must be exercised to avoid accidental injury in neonatal or neonatal-like patients	34860020	II	11	applicable	N/A
Manually-operated transportable suction unit	An apparatus that is powered by hand, foot, or both and generates weak negative pressure used in interventions such as aspiration of fluids or particulate materials. The device may be designed for portable or emergency use. The device may also be designed to be integrated into electrical equipment	36616010	II	11	applicable	N/A
Pressurized gas-powered transportable suction unit	An apparatus that generates negative pressure by the power of pressurized gas (e.g., air, oxygen) and is used in interventions such as aspiration of fluids or particulate materials. The device is designed for portable or emergency use.	36616020	II	11	applicable	N/A
Powered transportable suction unit	An electric apparatus that generates negative pressure and is used in interventions such as aspiration of fluids or particulate materials. The device may be designed for portable or emergency use. The device may be battery-powered.	36616030	II	11	applicable	N/A
Powered suction pump	An electrical diaphragm suction pump used in acupuncture/moxibustion. It is connected to a glass or plastic cup that is pressed against the body surface for suction of waste.	36616040	II	11	applicable	applicable
Powered ovum collection suction unit	An electric apparatus that generates a low flow rate, high suction pressure and is used with a tube, needle, or catheter for aspiration and collection of ovum or oocyte. The device may have an integrated suction pressure regulator.	70456000	II	11	applicable	N/A
Fetal vacuum extractor	A device used to extract the head of a fetus with a vacuum cup.	32596010	II	11	applicable	applicable

Manually-operated fetal vacuum extractor	A manually operated device used to extract the head of a fetus with a vacuum cup.	32596020	II	11	applicable	N/A
Abortion suction unit	A device specifically designed for suctioning substances related to conception or menstruation through the cervical duct with the cannula connected to the suction source by using negative pressure. It is designed to remove a fetus and the placenta easily in early abortion (usually, less than 12 weeks' gestation).	32671000	II	11	applicable	N/A
Aspiration tissue biopsy needle unit	A device to which a biopsy needle and other necessary tools are connected for use in resecting tissues by mechanical suction, accompanied by relevant accessories.	70457000	II	11	applicable	N/A
Uterine suction catheter	A semi-rigid or rigid, plastic or metal tubular surgical device inserted into the uterus via cervix using a hard, pointed catheter. The device serves as an aspirator by pulling the piston inside the catheter. The device is intended for single-use.	32655000	II	6	applicable	—
Electrosurgical suction tip	A dedicated tip attachment to perform suction in the operative site, specifically designed for electrosurgery. It can be electrically insulated and is usually made of material resistant to the heat generated at the tip. Usually, this device is for single-	35509000	II	2-②	applicable	—
Reusable fibreoptic illuminated suction tip	A device connected to a suction device during surgery or treatment. This device controls or guides the suction, and usually has a built-in optical fiber illuminator for clearer observation of the surgical site. It may have an additional perfusion function	35528000	II	2-②	applicable	N/A
Surgical suction unit regulator	A device used for adjusting the level of negative pressure by controlling the suction device. Usually, at least two values are set and the operator (a surgeon) selects the level using a foot switch. It is usually used in neurosurgery in order to avoid	37003000	II	2-②	applicable	applicable
Thoracic suction unit regulator	A device that controls the suction flow rate by the suction device which is used with a chest drainage system. It is usually made of metal and equipped with a regulatory function and a pressure gauge	37782000	II	2-②	applicable	N/A
Tracheal suction unit regulator	A device that controls the level of negative pressure to be applied for removing tracheal secretions. It usually allows continuous suction at various levels of pressure. It is made of metal or plastic. A pressure gauge is built-in to monitor suction pressure.	37783000	II	2-②	applicable	applicable
Single-use fibreoptic illuminated suction tip	A device attached to an aspirator during a surgical procedure or treatment, used to adjust and control suction. The device usually has an integrated fiber optic light bulb to provide an enhanced view of the surgical site. The device may also have integrated	38518000	II	7	applicable	—
Orthopedic cement extractor system	A set of devices usually used in combination for removing orthopedic cement from the site to which the cement has been applied during replacement of a cement-fixated artificial joint. It may contain a suction tube, a vacuum trap, and a vacuum source unit	34036000	II	6	applicable	applicable
Airway mucus clearing device	A device for removal of excess secretions (mucus and sputum) from the lungs or airway of a patient who is unable to expel them on his/her own. The device facilitates spitting up of secretions by changing the airway pressure. The device is normally used in just one	43947000	II	5-⑥	applicable	applicable
Liposuction catheter	A rigid tube inserted into the subcutaneous layer transdermally for removal of fatty deposits. Aspiration is performed with an appropriate unit. This device is for single-use.	36107000	II	6	applicable	—

Single-use suction kit	A packaged kit, tray or set that contains various devices, bandages and drugs necessary for the suction procedure. It usually has a few compartments to hold various tools necessary for needle biopsy, suction, and drainage. The tray usually has foamed adhesives applied to the floor of the tray and notches into which sharp devices and needles can be placed. This kit is for single-use.	36142000	II	6	applicable	—
Transportable suction unit	A device that generates negative pressure used for treatment procedures including suction of fluid or particulate matter. It is operated by pressurized gas such as air or oxygen, by battery, or by hand and foot. It is designed to be used during transportation or in an emergency. "Manually-operated transportable suction unit, " "powered transportable suction unit," and "powered and gas-powered transportable suction unit"	36616009	II	11	applicable	—
Urethral catheter suction unit	A device to suction the dedicated catheter along the urethra at a constant low flow rate using a motor or gear chain. Some types may have a pressure transducer around the catheter tip. Others may record data through a catheter side hole using an external	36808000	II	11	applicable	—
Reusable suction kit	A packaged kit, tray, or set that contains various devices, bandages and drugs necessary for suction procedures. It usually has a few compartments to store various tools necessary for needle biopsy, suction, and drainage. It usually has foamed adhesives applied to the floor of the tray and notches into which sharp devices and needles can be placed. This device is reusable after being cleansed properly. Some of the accessories need to be replenished.	37447000	II	6	applicable	—
Enteral suction tube	A hollow device made of plastic or metal with a single or multiple holes. This is used for aspiration of the gastrointestinal tract.	38561000	II	7	applicable	—
Heart-lung bypass negative-pressure controller	A device used for adjusting the level of negative pressure when vacuum assisted techniques are employed.	70458000	II	2-①	applicable	N/A
Short-term use bladder irrigation kit	A package containing syringes and other devices used for cleansing the urinary bladder. This is for short-term use.	10406002	II	2,5-②	applicable	—
Active device connected dental syringe	An invasive dental device connected to active equipment for cleaning the oral cavity, pulp cavity, and root canal, for removal of foreign bodies and cutting debris.	35970012	II	2-①,6,12	applicable	N/A
Single-use dental syringe	A single-use, invasive, non-active dental device for cleaning the oral cavity, pulp cavity, and root canal, for removal of foreign bodies and cutting debris. Active devices or those requiring connection to active equipment are excluded	35970022	II	2,6	applicable	—
Dental irrigation probe	A device attached to a handpiece for cleaning (including removal of plaque) of tooth surface and periodontal pockets with mechanical vibration, etc.	70460000	II	5-⑥	applicable	N/A
Periodontal pocket irrigation probe	A device attached to a handpiece for cleaning of periodontal pockets, removal of plaque, or measurement of periodontal pocket depth with mechanical vibration, etc.	70461000	II	5-⑥	applicable	N/A

Uterine irrigation unit	A device usually specifically designed for the uterus to facilitate collection of a fertilized egg from the uterus.	17520000	II	2,5-②	applicable	applicable
Surgical mist irrigation tip	A device that produces a mist of air or of a mixture of carbon dioxide and air, for washing off blood from a specific surgical area. The device is a chip with a special hole that enables mounting on a suitable tube for delivery of cleaning solution.	18033000	II	2,5-②,12	applicable	—
Gastric/colonic lavage unit	A device specifically designed for cleansing the stomach or the colon to remove stimulants or toxic substances, or to clean the cavities before surgery. This is usually operated by a pulsatile flow of sterile water including saline solution.	35994000	II	2,5-②,12	applicable	—
Orthopedic lavage unit	A device used to clean the surgical area for removal of bone tissue and cement during orthopedic surgery. The device usually runs on pulsatile flow of a sterile liquid (e.g., saline solution). The device is usually used in surgery such as artificial joint replacement, bone resection, and surgical fracture fixation.	37026000	II	2,5-②,12	applicable	applicable
Short-term use douche kit	A package of a liquid container, connector, flexible catheter, etc. for use in bowel irrigation.	11297002	II	2,5-②	applicable	—
Ear/nose/throat treatment unit	A unit that supports the patient's body during an otorhinolaryngology (ENT) examination or treatment. The device provides special functions for examination or treatment. Usually it has a table or chair as a part of the system or equipment.	11585000	II	11	applicable	N/A
Air fluidized bed	A bed designed for use in patients who receive treatment for severe and extensive burns. It is also used for the treatment of decubitus ulcers or in patients who have low body fat and need frequent pressure relief. In the bed, a large number of microspheres	35921000	II	9	applicable	applicable
Air pressure alleviation pad	A device used mainly for pressure ulcer prevention. It consists of a pump to send air and a mattress to be inflated with air. Some types may prevent pressure from concentrating in one point of the body lying on the mattress filled with air. Other types	35226000	II	9	applicable	applicable
Reusable decontamination and sterilization washer	A washer used for washing and sterilization of reusable medical apparatuses or devices that are contaminated by organic matter such as blood and necrotic cell fragments. The device usually runs a cleaning cycle that uses either warm or cold water together	14413000	II	15	applicable	applicable
Agar sterilizer	A sterilizer dedicated for agar sterilization and tapping. Agar is a gelatin-like substance obtained from algae and used as a stabilizer or growth medium for microbial culture. The filling and drainage components require sterilization. Steam is usually used for the sterilization medium.	35929000	II	15	applicable	applicable

Moist heat sterilizer for wrapped goods	An apparatus for sterilization of packaged medical devices (e.g., surgical instruments) using steam as an inactivator (sterilizing agent) of microorganisms.	38671010	II	15	applicable	applicable
Moist heat sterilizer for unwrapped goods	An apparatus for sterilization of non-packaged medical devices (for example, surgical instruments) using steam as an inactivator (sterilizing agent) of microorganisms.	40547010	II	15	applicable	applicable
Moist heat sterilizer for fluids	An apparatus for sterilization of liquids in hermetic containers using wet heat (usually steam) as sterilizing agent for inactivation of microorganisms.	41450010	II	15	applicable	applicable
Small agar sterilizer	A medical sterilizer that uses wet heat (usually steam) as sterilizing agent for inactivation of microorganisms, and offers a cycle for sterilization of agar (culture medium) as the main function. The device may also offer a sterilization cycle(s) for	70471000	II	15	applicable	applicable
Small wrapped goods moist heat sterilizer	A medical sterilizer that uses wet heat (usually steam) as sterilizing agent for inactivation of microorganisms, and offers a sterilization cycle for packaged surgical instruments, etc. as the main function. The device may offer a sterilization cycle(s) for other materials such as non-packaged surgical instruments, agar (culture medium)	38671020	II	15	applicable	applicable
Small moist heat sterilizer for unwrapped goods	A medical sterilizer that uses wet heat (usually steam) as sterilizing agent for inactivation of microorganisms, and offers a sterilization cycle for non-packaged surgical instruments, etc. as the main function. The device may offer a sterilization	40547020	II	15	applicable	applicable
Small moist heat sterilizer for fluids	A medical sterilizer using wet heat (usually steam) as sterilizing agent for inactivation of microorganisms, and offers a cycle for sterilization of liquids such as drug solutions as the main function. The device may also offer a sterilization cycle(s) for packaged/non-packaged surgical instruments and agar (culture medium). The pressure vessel, the main component of the apparatus, must conform to requirements for a	41450020	II	15	applicable	applicable
Dry heat sterilizer	An apparatus for sterilization of medical devices such as surgical instruments using heat in the absence of humidity for inactivation of microorganisms.	35364000	II	15	applicable	applicable
Ethylene oxide gas sterilizer	An apparatus for sterilization of medical devices (e.g., surgical instruments) using ethylene oxide gas as sterilizing agent for inactivation of microorganisms.	13740000	II	15	applicable	applicable
Formaldehyde gas disinfectant	An apparatus that disinfects/sterilizes medical devices and facilities, etc. using formaldehyde gas as disinfecting agent for inactivation of microorganisms.	70472000	II	15	applicable	N/A
Chlorine dioxide gas disinfectant	An apparatus that disinfects or sterilizes medical devices or medical facilities, etc. using chlorine dioxide gas as disinfecting agent for inactivation of microorganisms.	70473000	II	15	applicable	N/A
Disinfectant for reusable contact lens	A device usually disinfects reusable contact lenses with heat.	10995000	II	15	applicable	N/A
Boiled water sterilizer	An apparatus used for disinfection of medical devices such as surgical instruments using boiled water for a specified period as the medium for inactivation of microorganisms.	31793000	II	15	applicable	N/A
Flexible endoscope disinfectant	A disinfectant designed for decontamination and disinfection of a flexible endoscope. The device houses a processor that allows circulation of disinfectant inside the endoscope lumen. The device may also be capable of drying the cleaned endoscope.	35628000	II	15	applicable	applicable

Reusable rigid endoscope decontamination disinfectant	A disinfectant designed for decontamination and disinfection of a reusable, rigid endoscope. The device has a function to circulate disinfectant inside the endoscope lumen. The device may also be capable of drying the cleaned endoscope.	35981000	II	15	applicable	applicable
Cold liquid sterilizer	An apparatus used for disinfection of medical devices such as surgical instruments and flexible/rigid endoscopes using solutions, etc. that inactivate microorganisms. The goods to be disinfected are placed in a tray or bucket and immersed in the cleaning solution, etc. for a specified period.	36253000	II	15	applicable	applicable
Formaldehyde gas sterilizer	An apparatus used for sterilization of medical devices such as surgical instruments using formaldehyde gas as sterilizing agent for inactivation of microorganisms.	40583000	II	15	applicable	applicable
Ultraviolet water purification unit	An apparatus for water purification using a UV disinfection lamp that generates short-wavelength radiation and kills bacteria, viruses, and other microorganisms in water.	35435000	II	15	applicable	N/A
Water sterilizer	An apparatus that produces sterile water used by surgeons and surgical assistants for handwashing.	70475000	II	15	applicable	applicable
Plasma gas sterilizer	An apparatus used for sterilization of medical devices such as surgical instruments using plasma gas as sterilizing agent for inactivation of microorganisms. Plasma refers to a group of reaction products generated by excitation of ions, electrons, and free	36305000	II	15	applicable	applicable
Microwave sterilizer for unwrapped goods	A device used for sterilizing individual surgical devices, etc. unpackaged as a set. It utilizes microwaves as the heating source to inactivate microorganisms.	37494000	II	15	applicable	applicable
Microwave sterilizer for wrapped goods	A device used for sterilizing surgical devices, etc. packaged as a set. It utilizes microwaves as the heating source to inactivate microorganisms.	37495000	II	15	applicable	applicable
Microwave sterilizer for fluid	A device used for sterilizing solutions, etc. filled into hermetic containers, etc. It utilizes microwaves as the heating source to inactivate microorganisms.	37509000	II	15	applicable	applicable
Hydrogen peroxide gas sterilizer	An apparatus used for sterilization of medical devices such as surgical instruments using hydrogen peroxide gas as sterilizing agent for inactivation of microorganisms.	40567000	II	15	applicable	applicable
Chlorine dioxide gas sterilizer	A device that uses chlorine dioxide gas as a sterilant to inactivate microorganisms and sterilizes medical devices including surgical devices.	40571000	II	15	applicable	applicable
Heat bone disinfectant	An apparatus that can disinfect bone grafts for human femoral head replacement by heating at a specified temperature (80°C to 90°C) for a specified period (10 minutes) in a hermetic airtight container using sterile water (e.g., saline solution) as the (thermal)	70476000	II	15	applicable	applicable
Strongly acidic water electrolyzer	An apparatus that can continuously produce an acidic aqueous solution (strongly acidic electrolyzed water) containing hypochlorous acid derived from the anode by electrolysis of tap water, after addition of a small amount of sodium chloride, in a	70477000	II	15	applicable	applicable
Blood refrigerator	A cooling apparatus specifically designed to preserve blood and blood components such as whole blood, blood cells, and plasma at a constant temperature. The device has an integrated alarm that tells an unexpected temperature elevation. The device may also	35486000	II	2-①	applicable	applicable

Blood donation blood rocker	A device that can keep blood homogeneous by continuous shaking. The device is usually used at blood donation centers. It keeps blood in motion during transfer from the donor to the blood bag placed inside the cradle of the device.	36405000	II	2-②	applicable	applicable
Heart preservation/transport system	A special container that holds and preserves the heart donated during transportation to the hospital where the recipient awaits heart transplantation. The technical support unit responsible for transportation can keep the organ in an almost physiological state with this device.	37276000	II	2-②	applicable	N/A
Kidney preservation/transport system	A special container that holds and preserves the kidney donated during transportation to the hospital where the recipient awaits kidney transplantation. The technical support unit responsible for transportation can keep the organ in an almost physiological state with this device.	33479000	II	2-②	applicable	N/A
Liver preservation/transport system	A special container that holds and preserves the liver donated during transportation to the hospital where the recipient awaits liver transplantation. The technical support unit responsible for transportation can keep the organ in an almost physiological state with this device.	42919000	II	2-②	applicable	N/A
Intestine bag	A flexible container used temporarily during surgery to protect the intestine from water loss.	33522000	II	2-②	applicable	—
Portable continuous peritoneal perfusate thermal conditioner	A device that heats the peritoneal perfusate before injection into the peritoneal cavity. The perfusate is usually heated through direct contact of the dialysis fluid bag with the radiant heat source.	70478002	II	9	applicable	—
Tissue culture vessel	A culture vessel or a polymeric or metallic material to be a scaffold for cells that is used for tissue culture.	70480000	II	2-②	applicable	—
Valve prosthesis rotator	A surgical device used for heart valve replacement. It is used for changing direction of the flow in an artificial valve.	70483009	II	6	applicable	—
Percutaneous pacemaker electrode extractor	A composite device used for removal of a pacemaker electrode by making a small incision in the skin. This device incorporates a small clamp holding an electrode and a device designed to remove tissue adhering to the electrode. The device may have a loop that slides along the electrode to remove the adhering tissue or a lever to assist the	34235000	II	6	applicable	N/A
External cardiac pacemaker transesophageal electrode	An electrode placed in the esophagus to establish an electric connection for the purpose of delivery of electrical impulses sent from a transesophageal external cardiac pacemaker. This is a non-invasive device for temporary use.	41474000	II	5-⑥	applicable	—
Steerable stylet	A movable device temporarily used for assistance in positioning the leads of pulse generator or in moving their positions.	70486000	II	6	applicable	—
Urological stent repositioning catheter	A catheter used to make a small adjustment in the position of a ureteral stent after its placement.	70492000	II	6	applicable	—
Orthopedic rotator	A transplant device or accessories of the brace used to support, protect or assist the use of the cast, brace or transplant device for the purpose of medical care.	35487000	II	6	applicable	—

Positioning sensor	A device that detects movement or reacts to movement and sends signals that are proportional to the level of movement. The base unit reacts to the signal sent from the sensor or the signal indicating the location of the object to which the sensor is attached, and displays or controls the target object for monitoring. It can be attached to the leg of a patient as an aid to determining precise positioning of a prosthetic hip	43267000	II	10	applicable	applicable
Tracheostomy speech valve	A device connected to an endotracheal tube to enable the patient to speak without the use of a hand/finger for closing the opening. The device enables patients with tracheostoma to speak more easily and clearly.	36071000	II	5-⑤	applicable	—
Syringe for implantaion	A hollow tube with a threaded plunger and pressure gauge, used to implant other instruments such as embolization implant. After surgically positioned at the target site	43989000	II	5-①,6	applicable	—
Short-term use vas deferens prosthesis	A device used to repair the site of an injury or obstruction of the duct that transports sperm from the epididymis to the urethra. This is for short-term use.	31995002	II	7	applicable	—
Dialyser connector	A connector between a dialysis fluid circuit and dialyzer, etc.	70516000	II	2-①	applicable	N/A
Extracorporeal circulation hematocrit monitor measuring cell	A cell used to determine the hematocrit level (percentage of red blood cells) invasively during extracorporeal circulation in hemodialysis or open heart surgery. It is usually attached to an extracorporeal circulation device	70519000	II	2-②	applicable	—
Heat exchanger for heart-lung bypass	A heat exchange system used during extracorporeal circulation for heating or cooling the blood or the perfusate for cardiopulmonary bypass or treatment.	11973112	II	3-①	applicable	applicable
Heart-lung bypass system blood reservoir	A device used as part of the heart-lung bypass pump or used together with other devices during short-term extracorporeal circulation to maintain blood reserve for extracorporeal circulation. The device may have a filter. The device is intended for	31710102	II	2-①,2-②	applicable	—
Heart-lung bypass defoamer	A device used to remove bubbles from the blood during cardiopulmonary bypass. This is used with an oxygenator that adds the required amount of oxygen to the blood before the blood returns to the patient	31711112	II	3-①	applicable	applicable
Heart-lung bypass filter	A filter used to prevent particles and blood clots from entering the bloodstream and obstructing extracorporeal circulation. This filter may be used for trapping air bubbles.	33309102	II	3-①	applicable	—
Cardioplegic solution filter	A filter used to remove foreign bodies from cardioplegic solution and to prevent their obstructing extracorporeal circulation. The device may also be capable of removing microaggregates and bubbles from blood cardioplegic solution	70525000	II	3-①	applicable	—
Single-use defoamer for heart-lung bypass	A device used to remove bubbles from blood during cardiopulmonary bypass. The device is used with an oxygenator, which adds the required amount of oxygen to blood before the blood returning to the patient. The device is intended for single-use	31711122	II	3-①	applicable	—
Single-use heart exchanger for heart-lung bypass	An apparatus incorporating a heat exchange system used during extracorporeal circulation. The device warms or cools blood or the perfusate for cardiopulmonary bypass or treatment. The device is intended for single-use.	11973122	II	3-①	applicable	—
Hemodialysis blood tubing	A single-use sterilized blood tubing intended for hemodialysis (including hemofiltration and hemodiafiltration). Usually, it consists of a tube assembly (connectors, clamps, etc.) necessary for introducing blood or other solutions through a vascular access device	34999102	II	2-①	applicable	—
Ventricular vent suction control valve	An adjustable or non-adjustable valve designed to be attached to the left ventricular (LV) line to maintain weak suction so that the line remains in place. The device is used to decrease left ventricular pressure during cardiopulmonary bypass.	17581000	II	6	applicable	—
Connector for tube for blood tubing	A connector that is used to join two tubes. The device is used in a blood tubing, etc.	70545102	II	2-②	applicable	—

Plasma separation blood tubing	A blood tubing used with a membrane plasma separator, plasma fractionation membrane, or selective adsorption column for plasma fractionation, etc. for blood purification through extracorporeal circulation. The device is intended for single-use.	70546000	II	2-①	applicable	—
Transducer protection filter	A device for removal of foreign bodies from the gas line during pressure monitoring.	70547000	II	3-①	applicable	—
Blood tubing for slow continuous hemofiltration	A blood tubing for slow continuous hemofilter which purifies the blood through extracorporeal circulation. The device is intended for single-use.	70549000	II	2-①	applicable	—
Ascites filtration and reinfusion system blood tubing	A blood tubing used with concentrated ascites reinfusion system to drain ascites or pleural effusion and return fluid to the bloodstream after filtration and concentration. The device is intended for single-use.	70550000	II	2-①	applicable	—
Blood tubing for blood cells removal	A blood tubing used with a cytapheeresis column for removal of blood cells through extracorporeal circulation. The device is intended for single-use.	70551000	II	2-①	applicable	—
Hemofiltration blood tubing	A blood tubing used with a hemofilter for blood purification through extracorporeal circulation. The device is intended for single-use.	70552000	II	2-①	applicable	—
Blood tubing for adsorption hemoperfusion	A blood tubing used with an adsorption blood purification device. The device is intended for single-use.	70553000	II	2-①	applicable	—
Blood tubing for endotoxin removal adsorption hemoperfusion	A blood tubing used with an adsorption blood purification device for endotoxin removal through extracorporeal circulation. The device is intended for single-use.	70554000	II	2-①	applicable	—
Blood tubing for centrifugal apheresis unit	A blood tubing used with a centrifugal apheresis system for separation and collection of blood components. The device is intended for single-use.	70555000	II	2-①	applicable	—
Circuit for centrifugal hemoperfusion unit	A blood tubing attached to a centrifugal blood purification device for purification concentration or other process of blood components, etc. The device is intended for single-use.	70556000	II	2-①	applicable	—
Blood tubing for centrifugal blood component sampling unit	A blood tubing through which blood components are separated and collected with a centrifugal blood component collection device. This device is for single-use.	70557000	II	2-①	applicable	—

Blood tubing for multipurpose blood treatment	A blood tubing used with a membrane plasma separator, slow continuous hemofilter, or cytapheeresis column etc. for multi-purpose processing of blood such as blood cell removal or blood purification etc. through extracorporeal circulation. The device is intended for single-use.	70558000	II	2-①	applicable	—
Priming solution filter for heart-lung bypass system	A single-use device for filtration of non-heme priming solution for a heart-lung circuit system.	36080000	II	3-①	applicable	—
Blood tubing for monitoring set	A tube connecting a blood tubing and sphygmomanometer. The device is sometimes integrated into a blood tubing. The end connected to a blood tubing may have a Luer taper, or it may be a needle.	70559000	II	2-①	applicable	—
Breathing circuit filter	A sieve placed in a gas supply line. The device captures bacterial pathogens by the pore size or electrostatic charge. The device is usually used in ventilation systems or a gas	35070000	II	2-①	applicable	—
Gas delivery line filter	A fine-pore (<100 µm) membrane that is capable of capturing fine particles present in gases, and is connected to a gas line. The device can minimize the risk of transmission	35534000	II	2-①	applicable	—
Suction unit filter	A sieve installed in or connected to an aspirator. The pore size in the membrane is small enough to capture bacterial pathogens. Therefore, the device prevents environmental infection and reduces the risk of cross infection to another patient.	37798000	II	2-①	applicable	—
Warmer humidifier	A device used to warm and humidify gases in a patient circuit that are delivered from a ventilator, etc.	70562000	II	2-①	applicable	applicable
IMV supplement ventilator breathing circuit	A device comprising a tube and one-way valve, designed for mandatory ventilation for patients with a ventilator in order to supplement the spontaneous respiratory rate. The device may be used as an attachment to an old respirator without the capability for intermittent mandatory ventilation (IMV).	16803000	II	5-⑥	applicable	—
Reusable IMV supplement ventilator breathing circuit	A device designed to provide mandatory ventilation for a patient with a ventilator in order to supplement the spontaneous respiratory rate. It is usually made of durable materials and consists of tubes and one-way valves. This device is reusable after being cleansed and sterilized as recommended.	42909000	II	5-⑥	applicable	—
Single-use breathing circuit connector	A single-use device used to connect a respiratory circuit to an endotracheal tube, face mask, and other components of the respiratory circuit. Because the outer and inner diameters of the tube are standardized respectively to 22 mm and 15 mm by ISO, it may be used to adjust the size of respiratory tubes for pediatric and adult patients. The device is made of plastic or metal. Some design variants enable partial rotation at the	34838012	II	5-⑥	applicable	—
Reusable breathing circuit connector	A device used to connect a respiratory circuit with an endotracheal tube, face mask, and other components of the ventilator circuit. Because the outer and inner diameters of the tube are standardized respectively to 22 mm and 15 mm by ISO, it may be used to adjust the size of respiratory tubes for pediatric and adult patients. The device is	34838022	II	5-⑥	applicable	—
Tracheal tube adaptor	A connecting device, which is usually a small part, used for connecting the endotracheal tube to the breathing circuit or manual resuscitator in order to make them mutually compatible and establish a connection between them.	35400000	II	5-⑥	applicable	—

Reusable ventilator breathing circuit	A device for transmission of air or oxygen-rich gas from a ventilator to the patient. The device may be connected to devices for humidification, drug administration, and monitoring of gas concentration/pressure in a respiratory circuit. The device is reusable.	37705000	II	5-⑥	applicable	—
Single-use ventilator breathing circuit	A single-use device for transmission of air or oxygen-rich gas from a ventilator to the patient. The device may be connected to devices for humidification, drug administration, and monitoring of gas concentration/pressure in the respiratory circuit.	37706000	II	5-⑥	applicable	—
Breathing circuit set	A ventilator set including a ventilator circuit, water trap, nebulizer, filter, mask, pressure-regulating valve, connector, rebreathing bag, etc. Heated humidifier itself is excluded.	70566000	II	5-⑥	applicable	—
Anesthetic breathing circuit set	An anesthetic breathing circuit set including a ventilator circuit, water trap, nebulizer, filter, mask, pressure-regulating valve, connector, anesthetic bag, etc. Heated humidifier itself is excluded.	70567000	II	5-⑥	applicable	—
Non-anaesthetic breathing circuit bag	A bag that houses breathing gas in the breathing circuit.	70568000	II	5-⑥	applicable	—
Gas delivery tube for breathing circuit	A tube for supplying gases into a breathing circuit, connected to a mask, etc.	70569000	II	5-⑥	applicable	—
Aerosol non-rebreathing mask	A flexible, cone-shaped device placed over the patient's nose and mouth to deliver air, oxygen, or a mixture of air and oxygen, which contains aerosolized particles, to the airway. The device has two one-way valves, one that closes during inspiration so that room air does not get mixed with oxygen inside the reservoir bag, and the other that closes during expiration so that exhaled gas does not enter the reservoir bag. The device is intended for single-use.	35172000	II	5-⑥	applicable	—
Air/oxygen non-rebreathing mask	A flexible, cone-shaped device placed over the patient's nose and mouth to deliver high-concentration oxygen mixed with air to the airway. The device has two one-way valves, one that closes during inspiration so that room air does not get mixed with oxygen inside the reservoir bag, and the other that closes during expiration so that exhaled gas does not enter the reservoir bag. The device is intended for single-use.	35173000	II	5-⑥	applicable	—
Partial rebreathing mask	A device used to deliver a mixture of air and oxygen to the patient's airway. The device is equipped with a reservoir bag that allows the patient to inhale a mixture of exhaled and fresh gases. The device is usually connected to the oxygen source via a tube. The device has a head strap for fixation. The device is made of plastic.	35174000	II	5-⑥	applicable	—
Venturi mask	A flexible, cone-shaped device placed over the patient's nose and mouth to deliver a mixture of an almost precise ratio of air and oxygen to the patient's airway. The device usually has a replaceable part (Venturi tube) to change the mixture ratio of air and oxygen.	35175000	II	5-⑥	applicable	—
Resuscitation mask	A flexible, cone-shaped device placed over the patient's nose and mouth to deliver oxygen during cardiopulmonary resuscitation (CPR). The device is designed to substitute mouth-to-mouth resuscitation to prevent cross-infection. The device is also used with manikins during CPR training. The device may come with an airway, one-	36066000	II	5-⑥	applicable	—

Heated humidifier	An apparatus that is connected to the inspiratory line and increases the humidity and temperature of gases that enter the patient's lungs by delivering warmed vapor to the line.	12050000	II	2-①	applicable	applicable
Single-use heat/moisture exchange humidifier	A device that captures the heat and moisture from a patient, and heats and moisturizes the inspired gas by utilizing the heat and moisture of the patient, when connected to the patient's artificial airway through the line. It is a passive canister type device and also called an artificial nose.	35530000	II	5-⑥	applicable	—
Artificial nose	A passive, canister-shaped apparatus (artificial nose) that captures and uses the heat and moisture in exhaled air to heat and humidify inspiratory air, when connected in line with the patient's artificial airway. This device has one port each for the patient and the ventilator and is connected to a respirator/anesthetic apparatus.	70570000	II	5-⑥	applicable	—
Artificial nose for tracheostomised patients	A passive, canister-shaped apparatus (artificial nose) that captures and uses the heat and moisture in exhaled air to heat and humidify inspiratory air, when connected in line with the patient's artificial airway. This device has only one port for the patient (no port for any apparatus), and is connected to the tracheostoma of a patient breathing spontaneously.	70571000	II	5-⑥	applicable	—
Single-use artificial nose filter	A passive, single-use, canister-shaped apparatus that is connected by tube in line with the patient's artificial airway and is designed to remove foreign bodies and captures and use heat and moisture in exhaled air to heat and humidify inspiratory air. The device is connected to the patient's artificial airway through the line. It is a passive canister type device and also called an artificial nose.	70572000	II	3-①	applicable	—
Reusable heat/moisture exchange humidifier	A device that captures the heat and moisture from a patient, and heats and moisturizes the inspired gas by utilizing the heat and moisture of the patient, when connected to the patient's artificial airway through the line. It is a passive canister type device and also called an artificial nose.	41189000	II	5-⑥	applicable	—
Single-use anaesthesia breathing circuit	A device used to deliver medical gas to the patient from the fresh gas feeder of an anaesthesia system. The respiratory system may connect the patient, ventilator, circle absorber and a connector of monitor. The device usually has two passages for gas flow.	37704000	II	2-①	applicable	—
Scavenging anaesthesia mask	A cylinder-shaped device placed over the patient's nose and mouth to deliver anesthetic or analgesic gas to the patient. The device has soft edges fitted to the anatomical form of the patient's face to eliminate the gap and an outer casing or other device to prevent the escape of gas.	33523000	II	2-①	applicable	—
Reusable to-and-fro absorption anaesthesia breathing circuit	A respiratory system connected between the reservoir bag and the patient port. This device divides the air flow passing through a carbon dioxide absorber in two directions. This device is reusable.	34433000	II	2-①	applicable	—
Single-use anaesthesia breathing circuit bag	A single-use, reservoir bag made of elastomer and used to preserve respiratory air in the respiratory circuit. The device is set to the inspiratory or expiratory limb of the respiratory circuit, depending on the circuit design. The device may function as a maximum pressure limiter during spontaneous breathing or manually assisted ventilation.	34877000	II	2-①	applicable	—
Anaesthesia mask	A flexible, cone-shaped device that is made of conductive or non-conductive rubber or other materials and placed over the patient's nose or mouth for delivery of anesthetic gas to the upper airway. The device is sometimes used with a resuscitator.	35176000	II	2-①	applicable	—
Halogenated vapour absorber	A canister containing absorbents (e.g., activated charcoal) that remove halogenated steam from the respiratory system or expired gas.	36096000	II	2-①	applicable	applicable
Reusable carbon dioxide absorber	A refillable container, used with the respiratory circuit of an anaesthesia system for removal of carbon dioxide on expiration. The device is reusable after refilling of the carbon dioxide absorbent inside and subsequent steps necessary for hygiene.	37022000	II	2-①	applicable	applicable
Reusable anaesthesia breathing circuit bag	A reservoir bag made of elastomer and used to retain respiratory gas in the respiratory circuit. The device is set to the inspiratory or expiratory limb of the respiratory circuit, depending on the circuit design. The device may function as a maximum pressure limiter during spontaneous breathing or manually assisted ventilation. This device is reusable.	37709000	II	2-①	applicable	—

Single-use carbon dioxide absorber	A pre-packaged container of carbon dioxide absorbent used with the respiratory circuit of an anesthesia system. The device is used with a respiratory circuit for removal of carbon dioxide on expiration. The device is intended for single-use.	42414000	II	2-①	applicable	—
Reusable anaesthesia breathing circuit	A device used to deliver medical gas from the fresh gas feeder of an anesthesia system to the patient. The respiratory system may connect the patient, ventilator, circle absorber, and a connector of monitor. The device usually provides two passages for inspiration and expiration. There are rebreathing and non-rebreathing systems. The	37021000	II	2-①	applicable	—
Tympanic membrane anaesthesia apparatus	A device for applying weak electric current in the target site during otorhinolaryngology (ENT) surgery to facilitate absorption of anesthetic into the tympanic membrane. The device includes electrodes for the ear and arm as accessories.	70574000	II	9	applicable	N/A
Iontophoretic tympanic membrane anaesthesia apparatus	An apparatus that facilitates absorption of anesthetic solution into the tympanic membrane by applying weak electric current to the human body (iontophoresis).	70575000	II	6,9	applicable	N/A
Nasal oxygen cannula	A semi-rigid tube and prongs used to deliver oxygen to the patient via nostrils. The device is intended for single-use.	35201000	II	5-⑥	applicable	—
Continuous positive airway pressure nasal cannula	The semi-rigid tube and prongs used for delivery of oxygen during continuous positive airway pressure (CPAP).	35202000	II	5-⑥	applicable	—
Nasal oxygen delivery cannula	A flexible tube inserted into the nostrils to deliver supplementary oxygen into the nasopharynx.	35203000	II	5-⑥	applicable	—
Air/oxygen mask	A flexible, cone-shaped device placed over the patient's nose and mouth to deliver air and oxygen gas to the airway. The device is usually non-conductive. The device may have a strap, a connector(s), a valve(s), etc.	35171000	II	2-①	applicable	—
Air/oxygen tracheostomy mask	A device used for delivery of oxygen or a mixture of air and oxygen to a patient with a tracheostomy tube. The device is usually connected to the oxygen source via a tube, a breathing tube, etc.	35178000	II	2-①	applicable	—
Aerosol tracheostomy mask	A device used for delivery of air, oxygen, or a mixture gas of air and oxygen mixed with aerosolized water to a patient with a tracheostomy tube. The device is usually connected to the oxygen source or nebulizer via a breathing tube, etc.	35179000	II	2-①	applicable	—
Oxygen administration kit	A kit that includes devices for oxygen administration. The devices include a mask, nasal prongs, oxygen tubing, and a connector.	12855000	II	5-⑥	applicable	—

Oxygen therapy flowmeter	A device used for administration of pure oxygen (O ₂). The device is used to treat critically ill patients (e.g., those with myocardial infarction, hypoxia, or postoperative deterioration). The device may have a function of humidification and is connected to	37132000	II	2-①,11	applicable	N/A
Synchronised respiration oxygen conserving regulator	A device used to regulate the rate of flow of oxygen delivered from an apparatus, such as a medical oxygen cylinder and oxygen delivery system, to the patient through nasal cannulas.	70576000	II	9	applicable	N/A
Oxygen controller	A device used to measure and regulate oxygen concentration during oxygen therapy.	70577000	II	11	applicable	N/A
CPAP kit	A kit that includes devices used do provide continuous positive airway pressure (CPAP), allowing delivery of oxygen and air to the patient at a controlled rate. The devices include a mask, nasal prongs, a respiratory circuit, and connector.	70579000	II	5-⑥	applicable	—
Set for synchronised respiration oxygen conserving regulator	A device used to regulate the rate of flow of oxygen delivered from an apparatus, such as a medical oxygen cylinder and oxygen delivery system, to the patient through nasal cannulas. This may also include a regulator, oxygen tube, and nasal cannulas.	70580000	II	9	applicable	—
Single-use oxygen generating oxygen supply unit	A device used for first aid. The device supplies a constant quantity of oxygen for a short time (for around 12 minutes) by chemically generating oxygen. This consists of a mask, a tube and an oxygen generator, and may have an oxygen generation indicator. This device is for single-use.	70581000	II	11	applicable	—
Oxygen concentrator	An apparatus that removes nitrogen from room air by passing air through an adsorption column or a membrane with a large surface area. Apparatuses for medical gas pipeline systems (JIS T7101) are excluded. The components of the apparatus include a compressor, filter, and reservoir. Oxygen concentration is regulated based on	12873002	II	9	applicable	applicable
Liquid oxygen vaporization unit set	A device that vaporizes liquid oxygen, depressurizes the oxygen and supplies it to a patient. This incorporates a liquid oxygen container, a heating coil, a relief economizer valve, a pressure regulator, etc. The oxygen concentration varies according to the applied flow rate. This device may have an oxygen supply tube, a nose cannula, etc. to supply oxygen	70582000	II	9	applicable	applicable
Liquid oxygen vapor unit	An apparatus that vaporizes liquid oxygen and delivers oxygen to the patient at a reduced pressure. Apparatuses for medical gas pipeline systems (JIS T7101) are excluded. The components include a liquid oxygen container, heating coil, relief/economizer valve, pressure regulator, etc.	70583000	II	9	applicable	applicable
Open infant incubator	A unit that functions like a standard incubator but has lower side walls and no hood, allowing contact with the infant inside. The unit is intended not for premature babies but for infants with a disease which requires as intensive a care as that in an incubator. The unit has an overhead heating lamp, oxygen flowmeter, gas mixer, aspiration unit, unit for an infusion pump, etc. This differs from a closed incubator in that the infant is not completely enclosed in the unit	36742000	II	9	applicable	applicable
Stationary infant radiant warmer	An apparatus that has an integrated infrared heating element and is designed to irradiate heat evenly over a neonate or infant who needs a controlled heat environment. The device is normally kept in a ward or treatment room. Although the	17956000	II	9	applicable	applicable

Infant regional heating unit	A device designed to utilize radiant heat, to be used alone or with other devices (e.g., a treatment table for a patient in respiratory arrest) to supply heat to the patient concerned from above. This is usually used for warming a newborn baby or a neonate	36812000	II	9	applicable	N/A
Peritoneal dialysis ultraviolet irradiation unit	A device that provides ultraviolet irradiation for disinfection of connection area when components of peritoneal dialysis transfer tube set are connected. The device may have a connecting function	17434000	II	9	applicable	applicable
Regional perfusion heat exchanger	A special device that warms the blood by transmitting heat through the membrane. This is used for perfusion of the limbs or the organs except the heart.	13318000	II	3-①	applicable	N/A
Peritoneal perfusate filter	A device that has pores through which contaminated particles in the peritoneal perfusate are captured before it is injected into the peritoneal cavity.	33627000	II	3-①	applicable	—
Blood recovery unit	A blood salvage machine with the ability to wash cells, for immediate or subsequent re-transfusion of the patient's blood lost during surgery or due to trauma. The blood salvage process commonly involves separation of red blood cells and subsequent washing with saline solution (NaCl), etc. The machine is used for blood collection and cell washing only.	34863002	II	11	applicable	applicable
Single-use autotransfusion kit	A single-use set consisting of a centrifuge bowl, blood bag, etc. that are specifically designed to be used with a blood salvage machine with the ability to wash cells, for immediate or subsequent re-transfusion of the patient's blood lost during surgery or	70597000	II	3-①	applicable	N/A
Gait neuromuscular electrical stimulator	A type of electrical neuromuscular stimulator that stimulates the lower extremity nerves (e.g., peroneal nerve, femoral nerve), and induces muscular contraction in the lower extremities to improve the locomotor function in patients with partial paralysis of the lower limbs.	35725000	II	9	applicable	applicable
Scoliosis neuromuscular electrical stimulator	A type of stimulator that increases strength by stimulating the muscular tissues of the back to stabilize a scoliotic spine (scoliosis) or to delay disease progression. Some types may utilize an embedded receiver with electrodes and an external transmitter. However, the majority of stimulators are external types and utilize surface electrodes	36006000	II	9	applicable	applicable
Multifunctional muscle electrical stimulator	A device that assists and controls biological functions through electrically stimulating the peripheral muscles paralyzed by neurological disorders. Stimulation methods include a method with surface electrodes, and a method with embedded electrodes.	70598000	II	9	applicable	applicable

Breathing circuit gas sensor	A device that detects gases inside the respiratory circuit. The device is usually mounted on an anesthetic ventilator, etc. The device is designed for monitoring of gas inflow and outflow, to or from a patient. The base unit displays incoming signals and controls monitored parameters in response.	36849000	II	2-①	applicable	applicable
Infrared light therapy unit	An apparatus used for the treatment of rigors, pain, and inflammation by providing warmth. The device transmits infrared light at a wavelength of 600 to 1200 nanometers (nm). The device is sometimes used for disease management/treatment in	35147000	II	9	applicable	applicable
Ultraviolet light therapy unit	An apparatus with a special lamp that irradiates ultraviolet light. The device is usually used for the treatment of skin disorders (psoriasis). The device has a ceiling light like a sunbed or an enclosure (chamber, cabinet, etc.) with UV light tubes that irradiate UV light evenly for systemic exposure. The device is often used with neoralon for neoralon	35149000	II	9	applicable	applicable
Carbon arc light therapy unit	A device used for skin treatment (e.g., heliotherapy), equipped with special carbon rods that generate ultraviolet light; this device uses conventional techniques.	34476000	II	9	applicable	applicable
Neonatal jaundice light therapy unit	An apparatus that transmits a blue, green, or white light and is used to treat neonatal jaundice, etc.	35239000	II	9	applicable	applicable
Seasonal affective disorder light therapy unit	A device used for patients with seasonal affective disorder (SAD). This device imitates ordinary daylight to improve the patient's mental state.	34091000	II	9	applicable	N/A
Xenon beam light therapy unit	An apparatus that improves neural reflexes, enhances blood flow by warming, activates tissues, and relieves pain/inflammation, etc. by irradiation with a continuous spectrum of UV light, visible light, and infrared light generated by a xenon discharge tube. The device provides preset control options for emission pulse, duration, etc.	70606000	II	9	applicable	applicable
Low frequency therapy equipment	An apparatus that stimulates nerves and muscles percutaneously for relief of pain and muscle atrophy. The device consists of a stimulus generator and electrodes. Electrodes are placed on the skin (not inserted). Electrical stimulation is delivered through the skin (percutaneously) to the area of pain or muscle abnormality. Usually, electrical stimulation is delivered using constant current (pulse frequency, duration,	35372000	II	9	applicable	applicable
Interference low frequency therapy equipment	An apparatus intended for the treatment of muscular and painful disorders. The device delivers 2 types of medium-frequency (MF) current, designed to provoke interference from multiple pairs of skin electrodes. The currents produce a beat frequency, commonly used in the treatment of muscle disorders, at the difference of the frequencies. A beat frequency is a difference frequency produced at higher frequencies	36737000	II	9	applicable	applicable
Low frequency therapy equipment electrode	A conductor used with a low-frequency therapy device. It is placed on the patient's body to transmit electromagnetic energy from a base unit.	34479000	II	5-⑥	applicable	—
Strength-duration measurement low frequency therapy equipment	A device for nerve/muscle stimulation that is used percutaneously for the relief of pain and muscle atrophy and can display an intensity-duration curve. An intensity-duration curve is obtained by plotting the minimum electrical current that induces muscle	70607000	II	9	applicable	applicable
Microwave therapy system	A therapeutic apparatus that transmits a beam of high-frequency microwaves for heating body tissue at a depth of 1 to 2 cm under the skin, to facilitate cure or relieve pain. Unlike surgical diathermy, the tissue is heated but not damaged.	11245000	II	9	applicable	applicable

Ultra-short wave therapy unit	A therapeutic apparatus that delivers radiofrequency (13 to 27. 12 MHz) electromagnetic radiation to a specific body area and causes heat in the tissues deep inside the skin for the treatment of specific disorders (pain, muscle spasm, joint contracture, etc.). The device is not used for the treatment of malignancies. Unlike medical diathermy, the tissue is heated but not damaged	11246000	II	9	applicable	applicable
Ultrasound physical therapy system	An apparatus used for the relief of muscle pain. The device converts electromagnetic energy into ultrasonic waves that penetrate the target tissue and achieve pain relief by thermal and non-thermal physiological responses. The ultrasonic energy is transmitted via a special probe	11248000	II	9	applicable	applicable
Ultrasonic bone growth stimulator	An apparatus that facilitates bone growth (osteogenesis) by applying pulsed low-intensity ultrasound.	18154000	II	9	applicable	applicable
Canopy heating unit	A device used to warm the whole body of a patient with radiant heat from above. The heat is provided to a specific area of the canopy. Therefore, warming can be controlled also with a control unit. It is usually used in a burn care unit or intensive care unit.	36855000	II	9	applicable	N/A
Canopy heating unit control unit	A unit used for controlling the temperature of radiant heat generated in the canopy of the warming device and radiated.	36953000	II	9	applicable	N/A
Canopy heating unit system	A system used for warming the body of a patient by providing controlled radiant heat. It consists of a canopy as the heat source and a control unit with heat control, heat monitoring and alarm functions.	37327000	II	9	applicable	N/A
Bath for hydro-massage therapy	A bathtub equipped with catheter nozzles that emit a large amount of water jet for massage effect. The device is also called a non-invasive hydrotherapy unit. The device can be used for pain relief in patients with rheumatism, etc. The device is designed to	14450000	II	9	applicable	applicable
Bath for arm	A warm-bath apparatus for thermal therapy of the upper limbs. Usually electricity is the medium used for heating. The device may have additional therapeutic features such as massaging. The device may also utilize physical properties of ultrasound that occur when bubbles are injected into water.	10182000	II	9	applicable	applicable
Bath for leg	A warm-bath apparatus for use in treatment of the lower limbs. Usually electricity is the medium used for heating. The device may have additional therapeutic features such as massaging. The device may also utilize physical properties of ultrasound that	12313000	II	9	applicable	applicable
Bath for foot	A warm-bath apparatus used in treating the feet. Usually electricity is the medium used for heating. The device may have additional therapeutic features such as massaging. The device may also utilize physical properties of ultrasound that occur when bubbles are injected into water	36557010	II	9	applicable	applicable
Bath for whole body	A warm-bath apparatus used for thermal therapy of the upper/lower limbs or the whole body. Usually electricity is the medium used for heating. The device may have additional therapeutic features such as massaging. The device may also utilize physical properties of ultrasound that occur when bubbles are injected into water	36557020	II	9	applicable	applicable
Water pad heating control unit	A unit that controls temperature and circulation of the liquid inside the water pad heating system. An antimicrobial agent(s) is usually added to the liquid used.	36956010	II	9	applicable	N/A
Water pad specific heating control unit	A unit that controls temperature and circulation of the liquid inside a water pad heating system. Antibacterial agents are usually added to the liquid used. Devices that do not need maintenance management are excluded	36956020	II	9	applicable	applicable

Dry heating pad system	A system used to warm the human body by heat generated from the power source. The device usually consists of a pad with an integrated thermogenic material/device such as heating wire or cable and a control unit for temperature control, monitoring, and alerting, etc.	37329000	II	9	applicable	applicable
Water pad heating system	A system used to warm the human body by circulation of heated water. The device consists of a pad in which warm water is circulated and a control unit for water heating/circulation, monitoring, and alerting, etc.	37330010	II	9	applicable	N/A
Water pad specific heating unit system	A system used for warming the human body with preheated circulating water. This consists of pads in which heated water circulates, and a control unit which performs preheating and circulation of water, monitoring, and can set off an alarm. Devices that do not need maintenance management are excluded.	37330020	II	9	applicable	applicable
Paraffin bath	An apparatus for relieving pain like arthralgia by immersing the patient's body part(s) such as hands and fingers in the bath filled with melted paraffin (wax) at a specified temperature.	35232000	II	9	applicable	applicable
Cold air therapy unit	A unit designed for treatment to relieve pain, etc. in patients with rheumatism, arthritis, neuralgia, etc. by cold air. The device delivers cold air to the area of inflammation or pain.	36758000	II	9	applicable	applicable
Cryogenic analgesia unit	A device used for obtaining analgesia (pain relief) by applying extremely low temperature (freezing temperature) to the body tissues. The device consists of a cryostat and a cooling probe, and may have a peripheral nerve block stimulator (nerve stimulator). It employs several methods, including a natural melting cycle, to protect tissues from permanent damage. Low-temperature analgesia is a therapy to block the pain transmission (nerve conduction).	17140000	II	9	applicable	applicable
Electric pad heating unit	A pad electrically heated to warm the hypothermic patient. Both an adult size and a pediatric size are available. The device is usually used during prolonged surgery.	11989000	II	9	applicable	N/A
Perineal heating unit	A device that provides heat to the surface of perineum (the area between the vulva and the anus) by means of direct or indirect contact with the radiant heat source. It is useful for pain relief in the vulva after episiotomy (surgical incision of the vulva and the vagina to prevent laceration during delivery).	33594000	II	9	applicable	applicable
Water pad heating unit	A blanket or mattress used to warm or cool the body. It uses water for heat exchange. A pediatric size or an adult size may be available.	36854010	II	9	applicable	applicable
Water pad non-specific heating unit	A blanket or mattress for warming or cooling the body. Heat exchange is achieved using water. A pediatric size or an adult size may be available. Devices that require maintenance management are excluded.	36854020	II	9	applicable	N/A

Air pad heating unit	A blanket or mattress that can deliver warm air evenly, to offset normal body heat loss. It may cover the whole body or a part(s) of the body, may be designed for a specific body part, or may come in different sizes to suit the patient's build.	36931000	II	9	applicable	N/A
Air pad heating control unit	A device that filters room air, warms it to a preset temperature, and delivers it to the interior of a pad or blanket.	36954010	II	9	applicable	N/A
Control unit for air pad specific heating unit	A device that filters room air, warms it to a preset temperature, and delivers it to the interior of a pad or blanket. Equipment that requires no maintenance is excluded.	36954020	II	9	applicable	applicable
Electric pad heating control unit	A device for regulation/control of the temperature of an electrically heated pad.	36955000	II	9	applicable	N/A
Insulating pad heating unit	A mattress that transforms itself in response to the characteristics of a patient body and completely alleviates pressure on the skin tissue. This device is made of insulating materials, and prevents temperature loss (hypothermia) by stopping any loss in body temperature.	37044000	II	9	applicable	N/A
Air pad heating system	A system used to warm the human body with clean, heated air, to offset normal body heat loss. The device consists of a pad designed to receive warm air and a unit that controls air supply, heating, monitoring, etc.	37328010	II	9	applicable	N/A
Air pad specific heating system	A system used to warm the human body with clean, heated air, to offset normal body heat loss. The device consists of a pad designed to receive warm air and a unit that controls air supply, heating, and monitoring, etc. Equipment that requires no maintenance is excluded.	37328020	II	9	applicable	applicable
Magnetic vibration heat therapy equipment	A system for heating the patient's body with the heat by the vibration and magnetism generated by a magnetic coil, etc. The device is composed of a component that delivers heat and a control unit for managing temperature, failure, etc.	70608000	II	9	applicable	applicable
Bed type massager	An electric device dedicated to be used on a bed or chair. The device may be integrated into a bed or chair and have additional features. The device massages someone lying on	34488000	II	9	applicable	applicable
Pneumatically-powered intermittent massager	A device used for non-invasive treatment of venous disorders. It is used to apply counter pressure to the arms or the legs. The device is used to apply external pressure on the patient's arm or leg. Usually, the device is used for the treatment of leg edema.	10969000	II	9	applicable	applicable
Pneumatically-powered sequential massager	A device used for non-invasive treatment of venous disorders. The device facilitates venous blood flow by applying stimuli that stimulate muscle contraction. It is used to apply counter pressure to the arms or the legs. The device is a multiple-chamber	16837000	II	9	applicable	applicable
Pneumatically-powered pressurizing massager	A device for non-invasive treatment of venous disease. The device is used with a dedicated compression unit. It exerts a counter pressure to the arms or the legs of a patient to improve blood circulation in the veins, and imitates muscular activity. The	30877000	II	9	applicable	applicable
Pneumatically-powered massager with vibrating head	A hand-held pneumatic device that has a vibrating head mechanism and moves on the part of the body to be treated. The vibrating head (or pad) can be removed and exchanged for vibrating heads of various sizes and shapes. It is also used for	34489000	II	9	applicable	applicable
Plunger-like joint manipulator	A special plunger-like device used for joint manipulation and massage in chiropractic therapy.	33999000	II	9	applicable	—

Physiotherapy massager	An electric device (usually motorized) to provide an extensive range of effects in massage treatment. It utilizes a vibrating belt or other mechanism that comes into contact with the body. It is used for stimulating and massaging the muscular.	35538000	II	9	applicable	applicable
Joint/spinal manipulator	A special device used for the joint manipulation and massage in chiropractic therapy.	36229000	II	9	applicable	—
Massager with vibrating head	A hand-held electric device that has a vibrating head (or a pad) and moves on the part of the body to be treated. The vibrating head can be removed and exchanged for vibrating heads of various sizes and shapes. It is also used for stimulating and massaging the muscular structures of the body. There are times used for respiratory.	36560000	II	9	applicable	applicable
Massager for ear drum	An electric device used in otolaryngological therapy to massage the tympanic membrane by air vibration. The device is usually composed of a crank and piston connected to a gear motor, the main unit, and bifurcated rubber tube that connects the	70609000	II	9	applicable	N/A
Active extension/traction rotary motion equipment	An active device for training, reinforcement, and rehabilitation of muscles. Strength of muscles in the upper/lower limb, back, etc. is maintained, enhanced, and recovered.	70611000	II	9	applicable	applicable
Active automatic traction unit	An active device used to widen the intervertebral space by applying tractional force on a body part (e.g., cervical spine or lumbar spine) with a harness worn on the head or at the pelvis. The device usually comprises a unit that controls tractional force, a motor, and a cord attached to the harness. An adjustable rod is used to change the angle of	14105002	II	9	applicable	applicable
Active automatic intermittent traction unit	An active device that applies tractional force during traction therapy, in an intermittent or periodic manner according to the preset minimum/maximum force and duration.	14106002	II	9	applicable	applicable
Active simplified traction unit	An active device that generates tractional (stationary) force during therapy.	35519002	II	9	applicable	applicable
Active hand passive motion exerciser	An active device that realizes joint movement without exerting muscle power by continuously making the finger bend and stretch.	17137002	II	9	applicable	applicable
Active lower extremity passive motion exerciser	An active device that realizes joint movement without exerting muscle power by continuously making the leg bend and stretch.	35977002	II	9	applicable	applicable
Active upper limb passive motion exerciser	An active device that realizes joint movement without exerting muscle power by continuously making the arm bend and stretch.	35978002	II	9	applicable	applicable
Active respiratory exerciser	An active device that indicates respiratory volume or flow rate for a patient and improves ventilation by delivering a stimulus to the patient.	11634002	II	9	applicable	N/A
Single-use acupuncture needle	A single-use, elongated, pointed, unsterilized instrument that is used to stimulate peripheral nerves for anesthesia, pain relief, or other therapeutic effects.	35207002	II	6,7	applicable	—

Sterile acupuncture needle	A single-use, elongated, pointed, sterilized instrument that is used to stimulate peripheral nerves for anesthesia, pain relief, or other therapeutic effects.	34175000	II	6,7	applicable	—
Reusable contact needle	A device that stimulates the peripheral nerves through contact with the skin without insertion into the skin for surgical anesthesia, pain alleviation, or production of other treatment effects. This device is active and reusable.	70613002	II	9	applicable	—
Acupuncture electrical stimulator	A device used for electrical stimulation in acupuncture. The device consists of an apparatus for external stimulation and needle electrodes. Needle electrodes used for this device refer to single-use acupuncture needles.	13763000	II	9	applicable	applicable
Skin electrical conductivity measuring instrument	An instrument used to measure conductivity of the patient's skin based on skin thickness, moisture, electric conduction, etc.	31109000	II	9	applicable	applicable
Acupuncture kit	A kit, tray or set of packaged devices or products used for acupuncture. It usually contains acupuncture needles and an acupuncture point detector.	10014000	II	6	applicable	applicable
Electroshock electrode	A conductor placed on a patient's head in electroshock therapy for treatment of depression. It transmits electrical charges to the brain from the stimulator for electroconvulsive therapy.	11444000	II	9	applicable	N/A
Neuromuscular electrical stimulator for ejaculation	A type of electrical neuromuscular stimulator used for stimulating the nerves that control the ejaculatory function. It is usually inserted into the rectum of a male patient. It consists of an electrode probe connected to an electrical pulse provider. It is used in male patients with neurological disorders to obtain sperm in assisted reproductive technology.	17912000	II	9	applicable	N/A
Transcutaneous peripheral nerve electrical stimulation electrode	An electrode attached to the skin of a patient that provides electrical stimulation to reduce or resolve pain.	35995000	II	9	applicable	N/A
Electric potential therapy apparatus	A device that generates an alternating current of hundreds to tens of thousands of volts or a continuous current of hundreds to about a thousand volts and applies it to the patient's body, insulated from ground to achieve a holistic effect.	70614000	II	9	applicable	applicable
Electrical stimulator for soft tissue	An electrical stimulator that provides stimulation (usually, direct current) to damaged tissue from outside the body in order to promote cure.	35046000	II	9	applicable	applicable
Electrical bone growth stimulator	An apparatus that applies electric stimuli for bone growth (osteogenesis). The device is used as alternative to bone grafting, for the treatment of intractable (unknitted) fracture or as adjunctive therapy for spinal fusion. The device applies a weak electric current to the fracture or around the fusion site, or generates an electromagnetic field	35463000	II	9	applicable	applicable

Tubal patency insufflator	A device that sends gas or liquid (pigment for the tubal patency test) into the fallopian tubes (the tubes or oviducts leading from the ovary to the uterus or womb) to maintain the patency of the tubes.	36772000	II	10	applicable	applicable
Hydrotubation instrument	An operative device for performing hydrotubation using water or a drug solution (contrast media) during laparoscopic surgery in fertility treatment for diagnosis or treatment of tubal patency.	70616000	II	6	applicable	—
Behavior therapy electrical stimulator	A type of stimulator used to provide an electrical impulse, harmless but uncomfortable, to a patient (the arm, leg, etc.) in order to correct undesirable behavioral characteristics. It is usually used in aversion therapy by a therapist or in aversion therapy under a home-based clinical treatment program. Some types may provide	34875000	II	9	applicable	N/A
Chiropractic treatment unit	A unit that can be equipped with the functions of devices including aspirators for foot care and for treatment, a perfusion unit, a compressor, an electrical abrader. It is used for treatment of indurated skin, corns, ingrown nails, and other disorders of the leg.	37212000	II	9	applicable	N/A
Combined physical therapy equipment	A physiotherapy apparatus that integrates a massage bed, active automatic traction unit, etc. into one unit and enables the use of one feature without others. "Active automatic traction unit, etc. " refers to active automatic traction units, active automatic intermittent traction units, and active simplified traction units.	70618000	II	9	applicable	applicable
Constant current treatment unit	An apparatus that always applies a weak direct current to the human body through the skin at a constant amount by automatically adjusting the voltage according to the fluctuation in the biological impedance. The device is commonly used to get rid of or treat pain, etc.	70619000	II	9	applicable	applicable
Low frequency therapy equipment/interference low frequency therapy equipment combined physical therapy equipment	An apparatus that has functions of low frequency therapy equipment and interference low frequency therapy equipment. (See definitions of low frequency therapy equipment and interference low frequency therapy equipment.)	70620000	II	9	applicable	applicable
Low frequency therapy equipment/skin electrical conductivity measuring instrument combined physical therapy equipment	An apparatus that has functions of low frequency therapy equipment and skin electrical conductivity measuring instrument. (See definitions of low frequency therapy equipment and skin electrical conductivity measuring instrument.)	70621000	II	9	applicable	applicable
Low frequency therapy equipment/acupuncture electrical stimulator/skin electrical conductivity measuring instrument combined physical therapy equipment	An apparatus that has functions of low frequency therapy equipment, acupuncture electrical stimulator, and skin electrical conductivity measuring instrument. (See definitions of low frequency therapy equipment, acupuncture electrical stimulator, and skin electrical conductivity measuring instrument.)	70622000	II	9	applicable	applicable
Low frequency therapy equipment/ultrasound physical therapy system combined physical therapy equipment	An apparatus that has functions of low frequency therapy equipment and ultrasound physical therapy system. (See definitions of low frequency therapy equipment and ultrasound physical therapy system.)	70623000	II	9	applicable	applicable

Low frequency therapy equipment/interference low frequency therapy equipment/ultrasound physical therapy system combined physical therapy equipment	An apparatus that has functions of low frequency therapy equipment, interference low frequency therapy equipment, and ultrasound physical therapy system. (See definitions of low frequency therapy equipment, interference low frequency therapy equipment, and ultrasound physical therapy system.)	70624000	II	9	applicable	applicable
Electric potential therapy apparatus/infrared light therapy unit combined physical therapy equipment	An apparatus that has functions of electric potential therapy apparatus and infrared light therapy unit. (See definitions of electric potential therapy apparatus and infrared light therapy unit.)	70625000	II	9	applicable	applicable
Ultraviolet light therapy unit/infrared light therapy unit combined physical therapy equipment	An apparatus that has functions of ultraviolet light therapy unit and infrared light therapy unit. (See definitions of ultraviolet light therapy unit and infrared light therapy unit.)	70626000	II	9	applicable	applicable
Low frequency therapy equipment/dry heating pad system combined physical therapy equipment	An apparatus that has functions of low frequency therapy equipment and dry heating pad system. (See definitions of low frequency therapy equipment and dry heating pad system.)	70627000	II	9	applicable	applicable
Low frequency therapy equipment/xenon beam light therapy unit combined physical therapy equipment	An apparatus that has functions of low frequency therapy equipment and xenon beam light therapy unit. (See definitions of low frequency therapy equipment and xenon beam light therapy unit.)	70628000	II	9	applicable	applicable
Water pad heating system/air pad heating system combined physical therapy equipment	An apparatus that has functions of water pad heating system and air pad heating system. (See the definitions of water pad heating system and air pad heating system).	70629000	II	9	applicable	applicable
Treatment electrosurgical plate	A relatively large electrode used to decrease the density of returning high-frequency current to a level that does not burn human tissue. The device is pasted on the patient's body. The device comes with conductive cords and other accessories. The device is not intended for a specific treatment.	11500002	II	9	applicable	N/A
General electrosurgical unit	A device accompanied by accessories that cuts/coagulates tissues with a high-frequency current or with the electricity/heat of the heating element. The device is used by a physician to confirm that an incision or coagulation is made as intended, macroscopically or microscopically. The device is not intended for specific therapeutic purposes.	70647000	II	9	applicable	applicable
Powered dermatome	An electric surgical device used for removal of the fragment of damaged skin or for thinly slicing the skin of a donor for skin graft. A dedicated blade should be used for these purposes.	11179000	II	11	applicable	N/A

Trephine system control unit	A part of the trephine system used to control the motorized trephine device when particular attention is required when adjusting the cutting speed in ophthalmic surgery including corneal transplantation. It is used for adjustment of the trephine speed (rpm).	43928000	II	9	applicable	N/A
Gas-powered trephine system	A rotary surgical device consisting of a motor (an engine) and a cylindrical or trephine insertion portion. It usually has an extremely sharp-edged saw blade or a cutting blade with a thin saw blade. The blade is beveled on one side. It is used for removal of the intervertebral disc, other hard tissues, or soft tissues. It may have a speed control device. This is a gas-driven device.	32724000	II	9	applicable	N/A
Battery-powered trephine system	A rotary surgical device consisting of a motor (an engine) and a cylindrical or trephine insertion portion. It usually has an extremely sharp-edged saw blade or a cutting blade with a thin saw blade. The blade is beveled on one side. It is used for removal of the intervertebral disc, other hard tissues, or soft tissues. It may have a speed control device. This is a battery-driven device.	32820000	II	9	applicable	N/A
Electrically-powered trephine system	A rotary surgical device consisting of a motor (an engine) and a cylindrical or trephine insertion portion. It usually has an extremely sharp-edged saw blade or a cutting blade with a thin saw blade. The blade is beveled on one side. It is used for removal of the intervertebral disc, other hard soft tissues, or soft tissues. It may have a speed control device. This is an AC-powered device.	32821000	II	9	applicable	N/A
Powered corneal trephine	An electric cylindrical device for ophthalmic surgery equipped with a blade for resection/removal of a ring-shaped piece of corneal tissue (corneal button). For example, when a healthy corneal graft is obtained from a cadaver, the recipient's morbid cornea is resected and removed to allow transplantation of the graft.	14148022	II	6	applicable	N/A
Vitrectomy unit	An apparatus used in ophthalmic surgery for partial resection of the vitreous body. For example, the device may be used to control a cutter handpiece (usually with a vibrating blade) that sever excess tissue (piece by piece) and removes the cut pieces by suction.	14386000	II	11	applicable	applicable
Vitrectomy unit cutter handpiece	A device used with a base unit in ophthalmic surgery such as vitrectomy. For example, it may be a vibrating knife (nibbler) controlled by a base unit through a cable.	34125000	II	11	applicable	applicable
Bipolar electrode	A bipolar electrode, conductive cords, and accessories used for incision/coagulation of tissues with a high-frequency current. A bipolar electrode is made up of one supporting part equipped with two active electrodes between which a high-frequency current runs. A device intended for performing incision and coagulation of tissues by a physician.	70655000	II	9	applicable	N/A
Automated percutaneous discectomy system	A system for automated, percutaneous removal of the nucleus pulposus from the intervertebral disc. The system enables single-step removal and suction of the nucleus pulposus without repeated Nucleotome insertion. The system is used as an alternative to discectomy. The system is usually operated under local anesthesia.	36077000	II	6	applicable	N/A
Hemostatic knife	A surgical severing instrument that is similar to a scalpel, excluding the fact that its blade is designed to be heated with an electric current. The blade transmits heat directly to body tissues to achieve hemostasis. The instrument uses thermal energy for	36136000	II	9	applicable	N/A

Reusable epilator tweezers electrode	A tweezer-type electrode used with an epilator. It is used to destroy the dermal hair papillae with an electric current supplied from the base unit to around the hair shaft for hair removal. This device is reusable.	37485000	II	6	applicable	N/A
Reusable epilator needle electrode	A needle type electrode used with an epilator. It is used to destroy the dermal hair papillae with an electric current supplied from the base unit to around the hair shaft, and subcutaneous and dermal papillae for hair removal. This device is reusable.	38798000	II	9	applicable	N/A
High-frequency current procedure active instrument	A set of instruments comprising an active electrode that incises/coagulates tissues with a high-frequency current, a probe that achieves incision/coagulation by the electricity/heat of the heater element, conductive cords, and other accessories. Sets	70662000	II	9	applicable	N/A
Single-use catheter for rectal prostatic hypertrophy hyperthermia unit	A dedicated catheter used with microwave hyperthermia equipment for prostatic hyperplasia or a cooler for hyperthermia equipment for prostatic hyperplasia. A cooling medium (e.g., water) is provided from the main equipment or individual cooling	42454000	II	5-⑥	applicable	—
Reusable catheter for microwave urethral prostatic hypertrophy hyperthermia unit	A dedicated catheter used with microwave hyperthermia equipment for prostatic hyperplasia. The device is used for treatment of prostatic hyperplasia or prostatic carcinoma using microwaves as the heat source. The catheter is inserted transurethrally. The surrounding sites and organs may need cooling during the treatment procedure. See the section of microwave hyperthermia system. This device	36921000	II	5-⑥	applicable	—
Single-use catheter for microwave urethral prostatic hypertrophy hyperthermia unit	A dedicated catheter used with microwave hyperthermia equipment for prostatic hyperplasia. The device is used for treatment of prostatic hyperplasia or prostatic carcinoma using microwaves as the heat source. The catheter is inserted	42455010	II	5-⑥	applicable	—
Single-use high-frequency/radio-frequency urethrostrophic hypertrophy hyperthermia unit catheter	A dedicated information system consisting of computers and software. This uses the data related to diagnostic images (e.g., X-ray, CT scan, MRI, or two-or three-dimensional images) obtained through virtual simulation using a positioning device for radiation therapy or the data related to specific radiation therapies (e.g., brachytherapy, external radiation therapy, and so on), and calculates the setting	42455020	II	5-⑥	applicable	—
Surgical navigation unit	An apparatus that displays the location of instrument to assist the surgeon during stereotactic surgery. The device is based on computer technology and usually includes a console that is operated by the surgeon. There are other devices (e.g., a locating device) attached to it for tracking the instrument used. Input into the computer	38723002	II	6,7	applicable	applicable
Single-use dental root canal reamer	A hand-held rotary dental surgical instrument used to enlarge and clean the root canal by performing a lateral cut. The device is sterilized and intended for single-use.	31875012	II	6	applicable	—
Powered dental root canal reamer	A rotary dental surgical instrument connected to an active device to enlarge and clean the root canal by performing a lateral cut.	31875022	II	6	applicable	—
Single-use dental file	A hand-held dental surgical instrument used to enlarge the root canal and smooth out the root canal wall by scratching/scraping with vertical reciprocating motion or plucking motion. The instrument is sterilized and intended for single-use.	31878012	II	6	applicable	—
Powered dental file	A dental instrument connected to active medical equipment to enlarge the root canal and smooth out the root canal wall by scratching/scraping with vertical reciprocating motion or plucking motion.	31878022	II	6	applicable	—
Powered drill for dental use	A rotary tool connected to a dental drill handpiece. The device makes a hole in the tooth to fixate a ready-made or cast pin, which holds a restoration.	43311000	II	9	applicable	—
Powered dental drill system	An electrical dental drilling system consisting of a powered dental drill handpiece and a complete set of various attachments. The power source is electricity, gas pressure or remote drives. This device can be configured according to the purpose of use, and used	44015000	II	9	applicable	applicable
Dental root canal orifice enlargement drill	A device connected to an active medical device to obtain access to and enlarge an opening of root canal.	70686000	II	6	applicable	—

Powered dental root canal filling paste remover	An electric dental instrument with a spiral/conical coil spring as a working tip for removal of the filling material inside a root canal.	70688000	II	6	applicable	—
Dental air-powered rotary unit	A device that runs equipment for cutting/polishing teeth, denture, dental crowns, etc. by compressed air. Dental gas-powered handpiece are excluded.	70689000	II	9	applicable	applicable
Dental electrically-powered rotary unit	An electric dental device that runs equipment for cutting/polishing teeth, denture, dental crowns, etc. Electrictrically-powered dental handpiece are excluded. The device may include instruments used for peeling/removal of prostheses, foreign bodies, etc.	70690000	II	5-⑥,9	applicable	applicable
Dental jet cutting instrument	A device that cuts teeth by blowing powder on them. The device is sometimes used for cleaning/polishing of teeth. The device comes with polishing powder.	70691000	II	6	applicable	applicable
Dental gas-powered handpiece	A surgical handpiece with a chuck to connect a rotary device such as dental burs and reamers. The device usually contains a small turbine powered by compressed air and a water spray for cooling the rotary grinding instrument. The device may be connected	40958000	II	9	applicable	applicable
Electrically-powered dental handpiece	An electrically-powered dental handpiece with a chuck used to connect a dental device, such as dental burs and reamers, which rotates, vibrates, repeats rotation, reciprocates, or moves in combination of these motions. The device has an integrated electric motor.	38347000	II	9	applicable	applicable
Straight and geared angle handpiece	A device driven by air-powered rotary unit, electrically-powered rotary unit, etc. for dental burs, reamers, etc. to rotate, vibrate, repeat rotation, reciprocate, or move in combination of these motions. The device may have a linear or angled shape.	70692000	II	9	applicable	applicable
Dental practice electric engine and related instrument	A dental device includes a dental electric motor, a motor stand, a belt for the motor, a bracket arm for the motor, and a K4 pulley used for dental treatment. Dental air-powered rotary unit and dental electrically-powered rotary unit are excluded.	70694000	II	9	applicable	applicable
Powered dental endodontic paste carrier	An electronic endodontic instrument with a spiral or conical coil-like spring on its working tip. The device is used to deliver filling materials and drugs to the root canal.	41539000	II	9	applicable	N/A
Dental multipurpose treatment motor	An electric dental drill handpiece capable of measuring the root canal length. It includes the battery-operated type.	70695000	II	9	applicable	applicable
Dental pulp testing electrical stimulator	An electrical dental pulp examiner, which applies a high-frequency current from its electrode to stimulate the nerve tissue of dental pulp for assessment of the pain reaction.	13187000	II	10	applicable	applicable
Endodontic apex locator	An electrical dental device to determine the location of the root canal tip for endodontic care.	16355000	II	10	applicable	applicable
Dental occlusal sound analyzer	A device that electrically measures occlusal sound (or vibration) generated by teeth contacts in chewing cycles. The device is used to test for premature contact that may cause occlusal interference.	70696000	II	10	applicable	applicable
Periodontal probe	A device that electrically measures the depth of periodontal pockets.	70697000	II	10	applicable	applicable
Dental mandibular movement analyzer	A device that electrically measures mandibular movement to detect abnormalities of the temporomandibular joint. The device may also be used for measurement of temporomandibular joint sounds or muscle action potentials.	70698000	II	10	applicable	applicable
Optical calculus/plaque detector	A dental calculus/plaque detector. The device uses the optical property of calculus and plaque for detection.	33995010	II	10	applicable	N/A
Optical caries detector	A dental caries detector. The device uses the optical property of caries for detection.	33995020	II	10	applicable	N/A

Electric caries detector	A dental caries detector. The device uses the electrical property of caries for detection.	33995030	II	10	applicable	N/A
Tooth mobility analyzer	A device that vibrates a tooth and electrically measures its mobility. The device can detect an abnormal load on a specific tooth or evaluate the severity of periodontal disease.	70701000	II	10	applicable	applicable
Dental iontophoreser	An apparatus that introduces fluoride ion, etc. into the tooth substance using potential difference. The device is used for prevention of dental caries or treatment of root canal.	70703000	II	9	applicable	applicable
Rotary periodontal scaler	A power-driven device used for removal of deposits such as dental calculi from the tooth surface in dental cleaning and periodontal treatment. The oscillation type is included in this group.	31885000	II	9	applicable	applicable
Ultrasonic periodontal scaler	A powered device that uses an ultrasonic tip for removal of deposits (e.g., calculus) from the tooth surface in tooth cleaning or periodontic treatment.	36047000	II	9	applicable	applicable
Air-powered scaler	An air-powered device that, by mechanical vibration, removes deposits (e.g., calculus) from the tooth surface, enlarges the root canal, abrades teeth, or cleans periodontal tissue, etc. in tooth cleaning or periodontic treatment.	70704000	II	9	applicable	applicable
Powered dental endodontic enlarger	A device that has a sharply machined protrusion in the working part used to enlarge the root canal by grinding. It is driven by ultrasound waves or a dental handpiece that makes a rotatory or reciprocating motion.	40529000	II	9	applicable	applicable
Ultrasonic dental endodontic enlarger	An electrically powered device that enlarges the root canal by abrasion using the ultrasonic tip.	43076000	II	9	applicable	applicable
Dental endodontic enlarger	A device for enlarging and preparing the root canal, which probes, enlarges, and cleans the root canal by dental file, etc. The motion of the file includes vibrating, rotating, repeating rotation, reciprocating, and a combination of these motions.	70705000	II	9	applicable	applicable
Dental bilateral neuromuscular electrical stimulator	A device that applies electrical stimulation to relieve pain or relax muscles in the head/neck.	70706000	II	9	applicable	applicable
Powered tooth surface cleaner	A device that runs on external energy and is intended for cleaning and polishing the tooth surface by blowing powder mixed with water or air.	70707012	II	9	applicable	N/A
Active device connected tooth surface cleaner	A device that blows powder mixed with water or air against the tooth surface for cleaning/polishing and is connected to an active medical device.	70707022	II	5-⑥	applicable	N/A
Dental tooth surface cleaner auxiliary material	Cleaning adjuvants used for a stained tooth surface after mechanical cleaning of the tooth surface. Products containing pharmaceutical ingredients are excluded.	70708000	II	5-②	applicable	—

Dental root canal irrigator	A device that cleans the root canal by mechanical vibration of an oscillator, etc.	70710000	II	9	applicable	applicable
Root canal suction dryer	A handpiece used to clear cutting debris and blood in the root canal by water flow, etc. and aspiration, and to dry the root canal by suction.	70711000	II	6	applicable	N/A
Dental endodontic material electric heating injector	A device used to inject gutta-percha, etc. , which was previously heated/softened in the heating chamber attached to a handpiece, into the root canal. The device may run on battery.	70712009	II	9	applicable	N/A
Active device dental root canal cleanser	A device attached to a handpiece for removal of cutting debris from the root canal and for cleaning of the root canal wall. The device is attached to an active medical device.	70714002	II	6	applicable	N/A
Electrothermal endodontic plugger	A dental device with a cylindrical or tapered working tip that is heated to melt and insert filling material. The device is commonly used to compress the filling material in the root canal in the direction of tooth axis.	70716000	II	9	applicable	applicable
Tooth bleach activation apparatus	An optical or electrical heat source that activates a dental bleaching agent or drug-containing dental tooth surface cleaner auxiliary material for tooth surface cleaning applied on the tooth.	70717000	II	9	applicable	applicable
Chairside dental CAD/CAM unit	An apparatus using a complex software system, installed in a clinic or a dental office. It is used for computer-aided design (CAD) or computer-aided manufacturing (CAM) of dental restorations.	38597000	II	10	applicable	applicable
Ultrasonic instruments for multi-purpose treatment	An ultrasonic apparatus used for multi-purposes, such as removal of calculi/plaque, root canal preparation (enlargement, washing, cleaning), filling with gutta-percha, and root canal length measurement.	70719000	II	9	applicable	applicable
Dental unit	A unit equipped with utilities used in ordinary dental treatment/procedures such as compressed air, water, suction, electricity, tabletop (or bracket table), and cuspidor (spittoon). It may also be equipped with the operating light. The device usually comes with a chair for the patient receiving examination or treatment.	34991010	II	9	applicable	applicable
Dental optional additive unit	A dental unit into which optional devices are incorporated. It includes units used for orthodontic treatment, pediatric treatment, and preventive dental treatment. The optional devices incorporated into the unit include a photopolymerization irradiator for dental treatment, a microwave scalpel, and an ultrasonic scaler for periodontal treatment. Dental X-ray units are excluded.	34991020	II	9	applicable	applicable
Orthodontic supply unit	A dental unit equipped with utilities used in ordinary orthodontic treatment such as compressed air, water, suction, electricity, tabletop (or bracket table), and cuspidor.	70723000	II	9	applicable	applicable
Pediatric dental unit	A dental unit equipped with utilities used in ordinary pediatric dentistry such as compressed air, water, suction, electricity, tabletop (or bracket table), and cuspidor (spittoon). It may also be equipped with the operating light. The device usually comes with a chair for the patient receiving examination or treatment.	70724000	II	9	applicable	applicable
Prophylactic dental unit	A dental unit equipped with utilities used in ordinary preventive dentistry such as water, suction, electricity, tabletop (or bracket table), and cuspidor (spittoon). It may also be equipped with a compressed air unit and the operating light. The device usually comes with a chair for the patient receiving examination or treatment.	16692000	II	9	applicable	applicable
Portable dental unit	A portable dental unit with integrated tools for suction and oral cavity cleaning. The device may be used in orthodontics, pediatric dentistry, or preventive dentistry. The device is portable.	70725000	II	9	applicable	applicable
Portable dental optional additive unit	A portable dental unit in which optional devices are incorporated. It includes units used for orthodontic treatment, pediatric treatment, and preventive dental treatment. The optional devices incorporated into the unit include a photopolymerization irradiator for dental treatment, a microwave scalpel, and an ultrasonic scaler for periodontal treatment. Dental X-ray units are excluded.	70726000	II	9	applicable	applicable

Dental suction unit	A suction device specifically designed for dental use that can remove water, blood, saliva, and particles that may be present in the oral cavity during dental treatment/procedures and droplets scattered from the oral cavity. The device may be a stand-alone device with a suction pump or have an electrically powered shutter for suction control.	34859000	II	9	applicable	N/A
Dental suction unit pump	An electrically-powered dental suction pump used as the suction source of a dental suction system, dental treatment unit, etc.	70727000	II	9	applicable	N/A
Dental water line filter	A filter used for removal of foreign substances from dental water used in dental treatment.	70728000	II	3-①	applicable	—
Orthodontic wire	A wire component of an orthodontic appliance system, coming in varying sizes and grades. This wire is used to apply pressure to a tooth to alter its position.	16204000	II	5-⑤	applicable	—
Orthodontic tube	A component of an orthodontic appliance system, used as an attachment holding a wire to maintain the desired teeth alignment.	31759000	II	5-⑤	applicable	—
Orthodontic spring	A device used to generate orthodontic force as a part of an orthodontic system. The device is usually a coiled thin metallic wire.	31797000	II	5-⑤	applicable	—
Orthodontic magnet	A small magnet used to assist orthodontic treatment with functional orthodontic appliances and to achieve aligned teeth using traction by enlargement of the palate, depression of molars, distal shift of molars, and forced eruption of impacted teeth.	37601000	II	5-⑤	applicable	—
Orthodontic band	A metal band commonly made of stainless steel sheet and used to keep an orthodontic attachment in contact with the teeth. The attachment is (hard) soldered to the band. The band is shaped to conform exactly to the shape of the tooth and cemented to a	38734000	II	5-⑤	applicable	—
Orthodontic lock	An appliance such as Gurin lock used to fix an orthodontic arch wire to a bracket.	38741000	II	5-⑤	applicable	—
Orthodontic attachment	A precision device welded or soldered to a band or glued to the tooth or other instruments. This device is used in orthodontic treatment to strengthen orthodontic force. Brackets, tubes, buttons, eyelets, cleats, hooks, and sheaths are included in this	41059000	II	5-⑤	applicable	—
Orthodontic clasp	A removable elastic retainer that is a component of orthodontic appliances. The device may be manufactured from clasp wire or cast or ready - made/prefabricated alloy	41068000	II	5-⑤	applicable	—
Orthodontic archwire	A dental wire used with an orthodontic attachment. This wire is fixed to the crowns of 2 or more teeth to shift the teeth and guide them to a desired position.	41397000	II	5-⑤	applicable	—
Orthodontic material kit	A kit made up of wire, attachment, etc. that comprise an orthodontic appliance system. Devices with drug-containing component(s) are excluded.	70729000	II	5-⑤	applicable	—
Orthodontic teeth positioner	A plastic appliance shaped to conform to the corrected bite impression, which is used to prevent shifting of the teeth or to shift the teeth to its final position after removal of orthodontic appliances (prosthetics). The patient continually bites the appliance for	33592000	II	5-⑤	applicable	—
Orthodontic resin material	A material deriving from silicone rubber, plastics, or resins used to make orthodontic appliances and occlusal splints. Dental occlusal splint material is excluded.	70730000	II	5-⑤	applicable	—
Orthodontic elastomer	An elastic material in varying shapes (structures) such as small ring (for binding), chain-like, or filamentous. This material is used with a variety of other orthodontic appliances. Elastic bands (polymer or rubber bands or sutures) are used in	38733000	II	5-⑤	applicable	—

Orthodontic appliance elastic material	An elastic material and auxiliary materials used to fabricate removable, orthodontic elastic appliances.	70731000	II	5-⑤	applicable	—
Orthodontic face bow	An appliance used concurrently for extraoral traction that places an anchor on the head or posterior neck. The device is an elongated metal arch wire inserted into the orthodontic appliance in the oral cavity and commonly used to shift the teeth or jawbone posteriorly or to keep it from shifting anteriorly.	40468000	II	5-⑤	applicable	—
Orthodontic ligation material	A wire that secures the orthodontic arch wire or other appliances to the bracket slot.	41677000	II	5-⑤	applicable	—
Orthodontic bite guidance	A removable functional appliance used for treatment of early malocclusion, etc. The patient places the device in the oral cavity for a designated hours per day for the treatment of malocclusion, deep overbite, open bite, overlap etc.	70732000	II	5-⑤	applicable	—
Dental lip bumper	An orthodontic appliance used to block the movement of the mandibular molar (etc.) with the force deriving from the lips.	70737000	II	5-⑤	applicable	—
Long-term orthodontic oral mucosa protector	A covering material on an orthodontic appliance, used to reduce stimulation to the oral mucosa. It is intended for long-term use.	70738000	II	5-⑤	applicable	—
Dental plating kit	A kit that contains plating solutions and dental plating devices for dental use.	70761000	II	8-①	applicable	N/A
Dental noble metal foil	A foil made of precious metal (gold, silver, platinum, or palladium) and mainly used to manufacture crown restoration.	70762000	II	8-①	applicable	—
Dental direct gold filling material	A gilt, sintered gold powder, or a combination of both used for gold filling inside the oral cavity directly. The filling material is plugged by a hammer or filling instrument, and cold welding occurs through plugging.	11159000	II	8-①	applicable	—
Dental gold bullion	Gold bullion used as a raw material for dental alloys. It is mainly used for fabrication of dental restorations and appliances.	70763000	II	8-①	applicable	—
Dental silver bullion	Silver bullion used as a raw material for dental alloys. It is mainly used for fabrication of dental restorations and appliances.	70764000	II	8-①	applicable	—
Dental platinum bullion	Platinum bullion used as a raw material for dental alloys. It is mainly used for fabrication of dental restorations and appliances.	70765000	II	8-①	applicable	—
Dental palladium bullion	Palladium bullion used as a raw material for dental alloys. It is mainly used for fabrication of dental restorations and appliances.	70766000	II	8-①	applicable	—
Dental casting gold alloy	An alloy for casting in which the proportion of gold is not less than 65% and that of a combination of gold and platinum group metals is not less than 75%. It is mainly used for fabrication of dental restorations and appliances.	70767000	II	8-①	applicable	—

Dental casting low carat gold alloy	An alloy for casting in which the proportion of a combination of gold and platinum group metals is not less than 25% and less than 75%. Dental casting gold-silver-palladium alloy and dental casting 14-carat gold alloy are excluded. It is mainly used for fabrication of dental restorations and appliances.	70768000	II	8-①	applicable	—
Dental casting 14-carat gold alloy	An alloy for casting in which the proportion of gold is 58. 33% to 60. 00%. It is used for fabrication of dental restorations and appliances.	70769000	II	8-①	applicable	—
Noble metal materials for dental metal-ceramic restorations	An alloy for casting in which the proportion of either gold or platinum group metals is not less than 35%, or that of a combination of gold and platinum group metals is not less than 35%. It is used to fabricate dental metal-ceramic restorations.	70770000	II	8-①	applicable	—
Dental wrought gold alloy	An alloy not intended for casting in which the proportion of gold is not less than 65%, and that of a combination of gold and platinum group metals is not less than 75%. It is mainly used for fabrication of dental restorations and appliances.	70771000	II	8-①	applicable	—
Dental wrought low gold content alloys	An alloy not intended for casting in which the proportion of a combination of gold and platinum group metals is not less than 25% and less than 75%. It is mainly used for fabrication of dental restorations and appliances.	70772000	II	8-①	applicable	—
Dental gold alloy brazing materials	A hard soldering material in which the proportion of gold is not less than 30%, and that of a combination of gold and platinum group metals is not less than 35%. It is mainly used for fabrication of dental restorations and appliances.	70773000	II	8-①	applicable	—
Dental casting gold-silver-palladium alloy	An alloy for casting in which the proportion of gold is not less than 12%, that of palladium is not less than 20%, and that of silver is not less than 40%. It is mainly used for fabrication of dental restorations and appliances.	70774000	II	8-①	applicable	—
Dental wrought gold-silver-palladium alloy	An alloy not intended for casting and having a form of wire, plate, bar, or cap. The proportion of gold in this alloy is not less than 12%, that of palladium is not less than 25%, and that of silver is not less than 40%. It is mainly used for fabrication of dental restorations and appliances.	70775000	II	8-①	applicable	—
Dental gold-silver-palladium alloy solders	A hard soldering material in which the proportion of gold is not less than 15%, that of a combination of gold and palladium is not less than 30%, and that of silver is not less than 30%. It is mainly used for fabrication of dental restorations and appliances.	70776000	II	8-①	applicable	—
Dental casting silver alloy type 1	An alloy for casting free of gold and platinum group metals. The proportion of silver in this alloy is not less than 60% and that of indium is less than 5%. It is mainly used for fabrication of dental restorations and appliances.	70777000	II	8-①	applicable	—
Dental casting silver alloy type 2	An alloy for casting free of gold. The proportion of silver in this alloy is not less than 60%, that of indium is not less than 5%, and that of platinum group metals is not more than 10%. It is mainly used for fabrication of dental restorations and appliances.	70778000	II	8-①	applicable	—
Dental silver alloy brazing materials	A hard soldering material in which the proportion of silver is not less than 35%. It is mainly used for fabrication of dental restorations and appliances.	70779000	II	8-①	applicable	—
Plus metal for dental casting 14-carat gold alloy	An alloy added to gold bullion for fabrication of dental casting 14-carat gold alloy. It is used for fabrication of dental restorations and appliances.	70780000	II	8-①	applicable	—
Plus metal for dental casting gold alloys	An alloy added to dental gold bullion for fabrication of dental casting gold alloy. Plus metals for dental casting 14-carat gold alloys are excluded. It is mainly used for fabrication of dental restorations and appliances.	70781000	II	8-①	applicable	—
Dental silver-palladium alloy solders	A hard soldering material primarily composed of silver and palladium. It is mainly used for fabrication of dental restorations and appliances.	70782000	II	8-①	applicable	—

Dental casting nickel-chromium alloy	An alloy for casting in which the proportion of a combination of nickel and chromium is not less than 50%. It is mainly used for fabrication of dental restorations and appliances.	70783000	II	8-①	applicable	—
Nickel-chromium alloy wires for dental use	A wire-shaped alloy not intended for casting. The proportion of nickel in this alloy is not less than 70%, that of chromium is not less than 7%, and that of copper is not more than 7%. It is mainly used for fabrication of dental restorations and appliances.	70784000	II	8-①	applicable	—
Dental wrought nickel-chromium alloy plate	A plate shaped alloy not intended for casting. The proportion of nickel in this alloy is not less than 80%, that of chromium is not less than 5%, and that of copper is not more than 7%. It is mainly used for fabrication of dental restorations and appliances.	70785000	II	8-①	applicable	—
Dental wrought nickel-chromium alloy	An alloy not intended for casting primarily composed of nickel and chromium. Dental nickel-chromium alloy wire and dental nickel-chromium alloy plate are excluded. It is mainly used for fabrication of dental restorations and appliances.	70786000	II	8-①	applicable	—
Dental nickel-chromium alloy solder	A hard soldering material primarily composed of nickel and chromium. It is mainly used in fabrication of dental restorations and appliances made from dental nickel-chromium alloy, dental stainless steel wire, dental cobalt-chromium alloy, etc.	70787000	II	8-①	applicable	—
Dental casting cobalt-chromium alloy	An alloy for casting in which the proportion of cobalt is not less than 40% and that of chromium is not less than 20%. It is mainly used for fabrication of dental restorations and appliances.	70788000	II	8-①	applicable	—
Dental wrought cobalt-chromium alloy wire	A wire-shaped alloy not intended for casting with the following compositions: for clasps and orthodontic appliances, cobalt, not less than 25%, chromium, not less than 15%; for burs, cobalt, not less than 20%, chromium, not less than 15%. It is mainly used for fabrication of dental restorations and appliances.	70789000	II	8-①	applicable	—
Dental wrought cobalt-chromium alloys	An alloy not intended for casting and primarily composed of cobalt and chromium. Dental cobalt-chromium alloy wire is excluded. It is mainly used for fabrication of dental restorations and appliances.	70790000	II	8-①	applicable	—
Dental cobalt-chromium alloy solder	A hard soldering material primarily composed of cobalt and chromium. It is mainly used in fabrication of dental restorations and appliances made from dental nickel-chromium alloy, dental stainless steel wire, dental cobalt-chromium alloy, etc.	70791000	II	8-①	applicable	—
Dental stainless steel wire	A stainless steel wire used to fabricate dental clasps, burs, dowels, and orthodontic appliances.	70792000	II	8-①	applicable	—
Dental stainless steel alloy	A dental stainless alloy processed with dental stainless alloy plate or dental stainless steel wire. It is mainly used for fabrication of dental restorations and appliances.	70793000	II	8-①	applicable	—
Dental casting titanium alloy	An alloy for casting composed of pure titanium or primarily composed of titanium. It is mainly used for fabrication of dental restorations and appliances.	70794000	II	8-①	applicable	—
Dental wrought titanium alloys	An alloy not intended for casting and composed of pure titanium or primarily composed of titanium. It is mainly used for fabrication of dental restorations and appliances.	70795000	II	8-①	applicable	—
Alloys for dental amalgam	A particulate alloy primarily composed of silver, tin, and copper. It is mixed with mercury to form dental amalgam. This alloy is in powder or tablet form, or comes in a capsule in which known amounts of the alloy and mercury are sealed by the	34836000	II	8-①	applicable	—
Dental mercury	A high-purity mercury used as a component of dental amalgam for restoration of caries or fractured teeth.	35767000	II	8-①	applicable	—
Dental gallium alloy filling material	A filling material made of liquid gallium-tin-indium alloy. It turns into paste when mixed with a suitable alloy powder and hardens in the oral cavity.	38762000	II	8-①	applicable	—

Base metal materials for dental metal-ceramic restorations	A metal material used in dental metal-ceramic restoration, excluding metals of noble metal materials for dental metal-ceramic restorations. It is mainly used for fabrication of dental restorations and appliances.	70796000	II	8-①	applicable	—
Dental wrought alloys	A metal material not intended for casting and provided in various shapes, sizes, and materials. Metals identified elsewhere are excluded. It is mainly used for fabrication of dental restorations and appliances.	70797000	II	8-①	applicable	—
Dental casting alloy	An alloy for casting used for fabrication of dental restorations and appliances. Metals identified elsewhere are excluded.	70798000	II	8-①	applicable	—
Dental brazing alloy	A hard soldering material used for dental cast restorations. Metals identified elsewhere are excluded. It is mainly used for fabrication of dental restorations and appliances.	70799000	II	8-①	applicable	—
Dental soldering material	A material suitable for soldering of dental cast restorations. It is a soluble alloy used for low temperature soldering of materials hard to melt (metal, wire, etc.).	38779000	II	8-①	applicable	—
Ceramic tooth	A ready-made, ceramic (dental porcelain) prosthetic tooth mounted on a removable or fixed denture. It normally comes as a set of anterior teeth (separately for maxilla and mandible) or posterior teeth (separately for maxilla and mandible) in various sizes.	38644000	II	5-⑤	applicable	—
Dental porcelain	A porcelain firing for fabrication of dental restorations such as inlays, prosthetic teeth, crowns, and bridges. It comes as a powder or paste. Dental metal/ceramic restoration porcelain is excluded.	70801000	II	8-①	applicable	—
Dental ceramic fused to metal restorative materials	A porcelain applied on a metallic crown frame and fired for fabrication of dental metal-ceramic restorations. It comes as a powder or paste.	70802000	II	8-①	applicable	—
Dental castable ceramic	A dental porcelain injected into a mold by centrifugal force or pressure to form dental restorations such as inlays, prosthetic teeth, crowns, and bridges. It may crystallize after casting.	70803000	II	8-①	applicable	—
Dental injectable ceramic	A dental porcelain fabricated by injection molding and firing to fabricate dental restorations such as inlays, artificial teeth, crowns, and bridges.	70804000	II	8-①	applicable	—
Dental porcelain for machinable ceramic block	A ceramic block machined by a dental CAD/CAM unit to fabricate dental restorations such as inlays, prosthetic teeth, crowns, and bridges.	70805000	II	8-①	applicable	—
Dental porcelain kit	A kit composed of ceramic materials (porcelain dental ceramic, dental metal/ceramic restoration porcelain, dental casting ceramic, dental injection molding ceramic, and dental machinable ceramic block) and related appliances.	70806010	II	8-①	applicable	—
Dental pressable ceramic	A dental porcelain molded by compression to fabricate dental restorations such as inlays, artificial teeth, crowns, and bridges.	70806020	II	8-①	applicable	—
Acrylic resin tooth	A ready-made artificial tooth composed of acrylic resin and mounted on a denture. It usually comes as a set of anterior teeth (separately for maxilla and mandible) or posterior teeth (separately for maxilla and mandible) in various sizes, shapes, and colors.	70807000	II	5-⑤	applicable	—
Synthetic hard resin tooth	A ready-made artificial tooth, made of hard resin and mounted on a denture. It usually comes as a set of anterior teeth (separately for maxilla and mandible) or posterior teeth (separately for maxilla and mandible) in various sizes, shapes, and colors.	70808000	II	5-⑤	applicable	—
Dental molded temporary crown	An artificial crown commonly made of stainless steel, aluminum, or resin. It is placed over a damaged tooth or abutment tooth for temporary protective restoration.	34976000	II	7	applicable	—

Thermoplastic resin tooth	A ready-made artificial tooth made of thermoplastic resin and mounted on a denture. It usually comes as a set of anterior teeth (separately for maxilla and mandible) or posterior teeth (separately for maxilla and mandible) in various sizes, shapes, and	70809000	II	5-⑤	applicable	—
Metal cusp molar	An artificial posterior tooth with metal blade (metal cusp and occlusal surface) and resin body. The metal blade and resin components may be integrated or separate.	70810010	II	5-⑤	applicable	—
Separable resin molar	An artificial tooth made of resin and separable into occlusal and base components. The separate occlusal component can be used as a casting pattern.	70810020	II	5-⑤	applicable	—
Dental acrylic resins for crown and bridge	A material primarily made of methacrylate ester monomer and polymer, etc. and used for restoration of crowns and fabrication of temporary veneer crowns, etc. under various polymerization conditions.	70811010	II	8-①	applicable	—
Dental synthetic resins for crown and bridge	A type of resin (harder than dental acrylic resin for crown and bridge) in powder, liquid, or paste containing at least one of methacrylate monomer, methacrylate polymer, inorganic filler, and composite filler. This material is used for restoration of	70811020	II	8-①	applicable	—
Temporary dental polymeric crown/bridge	A material made of polymethylmethacrylate, etc. for fabrication of temporary prosthetic appliances such as crowns and bridges that are used until permanent restorations are placed.	31783000	II	8-①	applicable	—
Crown/bridge thermoplastic resin	A thermoplastic material used to fabricate crowns, inlays, or temporary veneer crowns by injection molding, etc.	70811030	II	8-①	applicable	—
Dental cusp	A material used to fabricate a cusp on the occlusal surface for improved occlusion.	16464000	II	5-⑤	applicable	—
Accessories for dental synthetic resins for crown and bridge	Accessories used to fabricate dental laboratory items with dental synthetic resins for crown and bridge.	70812000	II	8-①	applicable	—
Kit for dental synthetic resins for crown and bridge	A kit composed of dental synthetic resins for crown and bridge, building up tools, abrasive, and other related appliances.	70813000	II	8-①	applicable	—
Dental polymer-based crown/bridge staining material	A resin-based coloring material, etc. used to harmonize the color of polymer-based dental crowns with that of natural teeth.	70814000	II	8-①	applicable	—
Dental ceramics adhesive	A material used to bond a dental restorations (made of dental porcelain, ceramic, or resin-based material containing inorganic filler) or appliance to a resin-based material.	70815000	II	8-①	applicable	—
Dental resin adhesive	A material used to bond a resin-based prosthetic appliance or orthodontic bracket.	70816000	II	8-①	applicable	—
Dental tooth splint	A reinforcing material used for stabilization of a loose tooth or retention of orthodontic appliances, etc.	70817000	II	5-⑤	applicable	—
Repair kit for dental synthetic resins for crown and bridge	A kit used for color adjustment or repair of crown restorations made of dental synthetic resins for crown and bridge or dental acrylic resins for crown and bridge. It is	70818000	II	8-①	applicable	—
Dental implant suprastructure	A dental prosthetic appliance to be secured to an abutment protruding from an implant and its retainer.	70819000	II	8-①	applicable	—
Dental inlay kit	A kit that contains combinations of a ready-made prosthesis or restoration, a chip for formation, an etching material, a bonding agent, dental composite resin for	70820000	II	8-①	applicable	—
Dental machinable resin block	A resin-based block to be machined using a dental CAD/CAM unit to fabricate dental restorations such as inlays, prosthetic teeth, crowns, and bridges.	70821000	II	8-①	applicable	—
Dental preformed crown	A ready-made, artificial preformed crown commonly made of stainless steel, aluminum, or resin. Crowns designed for temporary use are excluded.	70822000	II	8-①	applicable	—

Dental ceramics staining material	A material used for color adjustment of dental ceramic materials.	70823000	II	8-①	applicable	—
Acrylic denture base resins	A material primarily made of methacrylate ester monomer and polymer, etc. and used for fabrication of a denture base under various polymerization conditions.	70824000	II	5-⑤	applicable	—
Denture base thermoplastic resin	A thermoplastic material used to fabricate denture bases, trial denture, bite plates, individualized trays, night guards, splints, etc. by injection, mechanical compression, air compression, or suction molding, etc.	70825000	II	5-⑤	applicable	—
Short-term soft lining materials for removable dentures	A soft lining elastic relining material for denture base designed for short-term use.	34769000	II	5-⑤	applicable	—
Long-term soft lining materials for removable dentures	A soft lining elastic relining material for denture base designed for long-term use.	34770000	II	5-⑤	applicable	—
Dental resin surface glazing/hardening material	A material applied to the surface of a resin-based prosthetic appliance. After hardening, this material enhances lubrication and abrasion resistance of the surface.	70826000	II	5-⑤	applicable	—
Denture base soft reliner	A relining material for denture base which remains soft after hardening.	17610000	II	5-⑤	applicable	—
Denture base resin accessories	Materials used to fabricate dental laboratory items with resin for a denture base.	70827000	II	5-⑤	applicable	—
Temporary denture base resin	A type of resin used to fabricate duplicate dentures, temporary dentures, etc.	70828000	II	5-⑤	applicable	—
Denture base reliner kit	A kit of materials used to reline/rebase a denture base or repair a broken denture base under various polymerization conditions.	70829000	II	5-⑤	applicable	—
Denture base soft resin	A soft resin material used for a part of denture base for patients with cleft palate.	70830000	II	5-⑤	applicable	—
Denture repair kit	A kit containing materials necessary for repairing cracks or chips of denture. It usually comes with resin/bonding material, a mixing jar, and an applicator.	11171000	II	5-⑤	applicable	—
Denture base hard relining materials	A relining material for denture base which turns hard after hardening.	17609000	II	5-⑤	applicable	—

Denture base relining/rebase/repair resin	A type of resin used to reline/rebase a denture base or repair a broken denture base under various polymerization conditions.	70831000	II	5-⑤	applicable	—
Denture base adhesive	A bonding material used for fabrication/repair of denture bases. It is also called resin primer, denture primer, etc.	70834000	II	5-⑤	applicable	—
Dental zinc phosphate cement	A material that cures by a reaction between oxide powder (primarily zinc oxide) and phosphoric acid aqueous solution (may contain metal ions). It is used as a cementing agent to keep a dental prosthetic appliance in touch with hard tissue of oral cavity or	16710002	II	8-①	applicable	—
Dental silicophosphate cement	A material that cures by a reaction between powder of acid-degradable aluminosilicate glass and metal oxide (primarily zinc oxide) and phosphoric acid aqueous solution (may	16708000	II	8-①	applicable	—
Dental zinc polycarboxylate cements	A type of cement that cures by a reaction between zinc oxide and an aqueous solution of polyacrylic acid or of similar polycarboxylic compound, or from a reaction induced by mixing a powder of zinc oxide and polycarboxylic acid with water. It is used as a	16705002	II	8-①	applicable	—
Dental resin-modified cement for denture reliner	A material primarily made of plain resin or resin containing inorganic powder and used for bonding a prosthetic appliance, tooth, etc. It may include a dental dentin adhesive, dental etching material, etc. Ones containing drugs are excluded.	70836002	II	8-①	applicable	—
Dental composite resin-modified cement	A cementing material for prosthetic appliances, etc. primarily made of plain resin or resin containing inorganic powder and not adhering to the tooth substance. Ones containing drugs are excluded.	70837002	II	8-①	applicable	—
Dental zinc oxide eugenol cement	A hydrophobic material containing eugenol that reacts with zinc oxide, an accelerant of the reaction, rubber, resin, and an inactive inorganic filler. It is used for temporary cementation, cementation, temporary restoration, lining, relining, or temporary sealing. Ones containing drugs are excluded.	16709002	II	8-①	applicable	—
Dental zinc oxide non-eugenol cement	A material primarily composed of zinc oxide and fatty acids and used for cementation, temporary cementation, or temporary sealing. Not containing eugenol, this material is called non-eugenol. Ones containing drugs are excluded.	70838002	II	8-①	applicable	—
Dental glass polyalkenoate luting cement	A cement for cementing prosthetic appliances. This cement derives from a reaction between aluminosilicate glass powder and alkenoic acid aqueous solution or between a mixture of aluminosilicate glass-polyacid powder and water or organic acid aqueous	70839002	II	8-①	applicable	—
Dental ethoxy benzoic acid cement	A hydrophobic cement containing a compound of ethoxybenzoic acid that reacts with zinc oxide, an accelerant of the reaction, rubber, resin, and inactive inorganic filler. It is used as material for temporary restoration, lining, and cavity relining in	16703000	II	8-①	applicable	—
Dental zinc oxysulfate cement	A temporary restorative material primarily composed of zinc sulfate.	38776000	II	8-①	applicable	—
Dental aluminic acid cement	A lining/capping cement primarily composed of aluminum hydroxide powder and polycarboxylic acid aqueous solution.	70840000	II	8-①	applicable	—
Dental resin-modified glass-polyalkenoate luting cement	A cementing and bonding material used for dental restorations, prosthetic appliances, and orthodontic appliances. It is a combination of a resin component and glass polyalkenoate cement for dental cementation. Ones containing drugs are excluded.	70841002	II	8-①	applicable	—
Dental cement kit	A kit consist of dental cement and other appliances, etc. that are used for mixing and condensation. Kits with drug-containing components are excluded.	70842000	II	8-①	applicable	—

Dental cyanoacrylate cement	A cementing and bonding material primarily composed of cyanoacrylate monomer and used for dental prosthetic appliances.	70843000	II	8-①	applicable	—
Dental colour matching test material	A material used to examine the color compatibility of restorations, etc. with the teeth.	70844000	II	6	applicable	—
Dental trial colour matching test material	A try-in material used for color compatibility assessment of dental cement.	70845000	II	6	applicable	—
Dental loose teeth fixation adhesive	A resin-based bonding material used to fix a loose tooth, etc. Ones containing drugs are excluded.	70846000	II	8-①	applicable	—
Dental restorative composite resin kit	A package containing composite resin materials for dental fillings polymerized by mechanical mixing, by hand mixing, or by external energy. The materials are used mainly for direct or indirect restoration of a tooth cavity.	35876000	II	8-①	applicable	—
Dental composite resins for restoration	Materials primarily composed of resin, inorganic filler or resin and composite filler. They are polymerized chemically by mixing or by external energy. They are used for filling of a tooth cavity or repair of artificial crowns. Drug containing materials are	70847002	II	8-①	applicable	—
Polymer-based bracket adhesive and tooth conditioner	A bracket bonding resin/tooth conditioner is a bonding material made of polymethylmethacrylate, etc. used to cement an orthodontic bracket to the tooth surface. Ones containing drugs are excluded.	31750002	II	8-①	applicable	—
Dental polymer-based adhesive	A filler-free resin used to support mechanical adhesion of a composite restorative material to acid-treated enamel.	34782000	II	8-①	applicable	—
Dental etching material	An acid aqueous solution or a gelled acid used to treat the adherend surface for sustained adhesion of composite resin, bonding material, or pit and fissure sealant.	36153000	II	6	applicable	—
Dental dentin adhesive	A filling material used primarily to facilitate adhesion of composite resins, restorations, or bonding material to dentin. It may also be used as a bonding material for enamel. Ones containing drugs are excluded.	42483002	II	8-①	applicable	—
Dental filling glass polyalkenoate cement	A type of cement that cures by a reaction between aluminosilicate glass powder and alkenoic acid aqueous solution or between a mixture of aluminosilicate glass-polyacid powder and water or organic acid aqueous solution. It is used for tooth filling and restoration. Ones containing drugs are excluded.	70848002	II	8-①	applicable	—
Dental core build-up glass polyalkenoate cement	A type of cement that cures by a reaction of either aluminosilicate glass powder or a powder of melted glass and metal with alkenoic acid aqueous solution or between a mixture of aluminosilicate glass-polyacid powder and water or organic acid aqueous solution. It may contain metal powder. It is used for core build-up. Drug containing materials are excluded.	70849012	II	8-①	applicable	—
Dental core build-up resin-modified glass-polyalkenoate cement	A cement material composed of a resin component and a glass polyalkenoate cement for core build-up. Drug containing materials are excluded.	70849022	II	8-①	applicable	—
Dental lining/basing glass polyalkenoate cement	A type of cement that cures by a reaction between aluminosilicate glass powder and alkenoic acid aqueous solution or between a mixture of aluminosilicate glass-polyacid powder and water or organic acid aqueous solution. It is used for lining or relining.	70850002	II	8-①	applicable	—
Dental silicate cement	A material that cures by a reaction between aluminosilicate glass powder and phosphoric acid aqueous solution (may contain metal ions). It is used for esthetic restoration of frontal teeth.	34784000	II	8-①	applicable	—

Polymer-based pit and fissure sealants	A resin material suitable for sealing dental pits and fissures. It cures by chemical polymerization or polymerization by external energy. Ones containing drugs are excluded.	31780002	II	8-①	applicable	—
Dental pit/fissure sealing glass polyalkenoate-based cement	A type of cement that cures by a reaction between aluminosilicate glass powder and alkenoic acid aqueous solution or between a mixture of aluminosilicate glass-polyacid powder and water or organic acid aqueous solution. It may contain resin components. It is used for sealing dental pits and fissures. Ones containing drugs are excluded.	70851012	II	8-①	applicable	—
Dental pit/fissure sealing resin-modified glass-polyalkenoate cement	A dental pit and fissure sealant composed of a resin component and glass polyalkenoate cement for pit and fissure sealing. Ones containing drugs are excluded.	70851022	II	8-①	applicable	—
Dental glazing/hardening material	A dental glazing/hardening material is intended to smooth out and glaze the surface of a restorative filling material.	34771000	II	8-①	applicable	—
Dental ceramic repair kit	A pre-packaged kit for repair of broken ceramic restorations or prosthetic appliances. The kit includes etching gel/solution, bonding material, silane-based solution, polymer restorative (composite) material, and other accessories.	35877000	II	8-①	applicable	—
Dental pulp-capping material	Materials of various compositions used for capping deep cavities. Materials intended for absorptivity or biological effects, or containing drugs or biological raw materials are excluded.	38770000	II	8-①	applicable	—
Material for dental core build-up	A polymeric material used for core build-up on the root canal post.	38789000	II	8-①	applicable	—
Dental filling material kit	A dental restoration kit containing dental composite resins for restoration, an etching material, bonding material, etc. Those with drug-containing components are excluded.	70853002	II	8-①	applicable	—
Dental filling resin-modified glass-polyalkenoate cement	A dental filling material composed of a resin component and glass polyalkenoate cement for dental filling material. It may be used in the repair of artificial crowns. Ones containing drugs are excluded.	70854002	II	8-①	applicable	—
Dental composite resins for indirect restoration	A material composed primarily of resin and inorganic filler or of composite filler and polymerized by external energy. A crown, inlay, etc. is fabricated on a tooth with a cavity or on a model of the tooth and polymerized to fabricate a restoration. Ones	70855002	II	8-①	applicable	—
Dental filling acrylic resin	A material made primarily of acrylic ester monomer and polymer. It is polymerized chemically by mixing or by external energy. It is mainly used for filling of a tooth cavity or repair of artificial crowns. Drug containing materials are excluded.	70856000	II	8-①	applicable	—
Dental polymer-based restoratives modifier	A material used to adjust the viscosity or color of resin-based dental filler.	70857000	II	8-①	applicable	—
Dental adhesive/filling material surface hardening protection material	A material used to facilitate curing of the surface of dental resin-based cement, glass polyalkenoate cement for dental filling, or dental composite resins for restoration. This material is also used for protection of such surface.	70858000	II	8-①	applicable	—
Tooth surface conditioning material	A material used to process the tooth surface after cavity or root canal preparation. Materials with absorptivity or biological effects, or containing drugs or biological raw materials are excluded.	70859000	II	6	applicable	—
Dental sealing/coating material	A material used to seal the dentinal tubule or cavity margin. It is applied on the surface or interface of the tooth substance, restorative filling material, prosthetic appliances, etc.	70860000	II	8-①	applicable	—
Tooth surface coating material	A low-viscosity resin-based material for coating of tooth surface. It may be included in a kit containing other materials. Ones containing drugs are excluded.	70861002	II	8-①	applicable	—

Dental polymer-based cavity lining/basing material	A polymer-based lining material such as glass polyalkenoate resin cement. Ones containing drugs are excluded.	70863002	II	8-①	applicable	—
Dental composite resin kit for indirect restoration	A kit containing composite resin for dental indirect restoration, dental cement used together with a composite resin, and other related substances such as etching	70864002	II	8-①	applicable	—
Dental core build-up material kit	A dental restoration kit containing material for dental core build-up, a dental etching material, and dental dentin adhesive, etc. Kits with drug-containing components are excluded.	70865002	II	8-①	applicable	—
Dental dentin adhesive kit	A kit containing a dental dentin adhesive and a dental etching material. It may contain other appliances. Kits with drug-containing components are excluded.	70866002	II	8-①	applicable	—
Dental temporary stopping	A temporary sealant composed primarily of polymeric material (such as gutta-percha), wax, zinc oxide, etc.	70867000	II	7	applicable	—
Dental zinc oxide eugenol temporary sealing material	A temporary sealant primarily made of zinc oxide and eugenol.	70868000	II	8-①	applicable	—
Dental temporary sealing material kit	A kit made up of dental temporary sealants and related appliances. Kits with drug-containing components are excluded.	70869000	II	8-①	applicable	—
Dental polymer-based temporary sealing material	A temporary sealant composed primarily of polymeric material. Ones containing drugs are excluded.	70870002	II	8-①	applicable	—
Dental temporary sealing material	Materials used for temporary sealing. Materials identified elsewhere or containing drugs are excluded.	70871002	II	8-①	applicable	—
Dental periodontal dressing	A paste material usually applied around periodontal tissue for covering and protection after surgery. Materials intended for absorptivity or biological effects, or containing drugs or biological raw materials are excluded.	35573000	II	7	applicable	—
Dental gutta-percha points	A material made from sap condensate of certain tropical tree and used as root canal filling. Gutta-percha softens on heating and cures on cooling after filled in a root canal.	31872000	II	8-①	applicable	—
Dental root canal obturating point	A metal or polymer point/cone suitable for filling of root canals. It is not intended for abutment of prostheses or repair of crowns.	34791000	II	8-①	applicable	—
Dental solid root canal filling material	A solid material used for filling of root canals.	70873000	II	8-①	applicable	—
Dental root canal sealing material	A material that cures without water and is intended for permanent sealing of the root canal, regardless of whether an obturating point is concurrently used. Materials intended for biological effects, or containing drugs or biological raw materials are	36095000	II	8-①	applicable	—
Root canal filling solvent	A material used to soften filling materials such as gutta-percha.	70875000	II	6	applicable	—

Dental emergency kit	A kit of devices and materials to be used when an unexpected accident occurs in dental treatment. It contains the products needed by a general user to make a temporary restoration in an emergency without support from a dentist. Reinstallation and recovery of appearance and functions of a fallen crown, bridge, filling material and	44406000	II	8-①	applicable	—
Dental cavity varnish	A solution of single or multiple resin components dissolved in an organic solvent, used for protection of the dental pulp and sealing of the periphery during filling with amalgam restorations	35698000	II	8-①	applicable	—
Dental multipurpose glass polyalkenoate cement	A type of cement that cures by a reaction between aluminosilicate glass powder and alkenoic acid aqueous solution or between a mixture of aluminosilicate glass-polyacid powder and water or organic acid aqueous solution. Cements containing	70878000	II	8-①	applicable	—
Dental resin-modified glass-polyalkenoate cement for temporary restoration	A material that composed of a resin component and glass polyalkenoate cement for dental filling, and intended for temporary restoration. Ones containing drugs are excluded	70880000	II	8-①	applicable	—
Dental alginate impression material	An impression material containing alginate as the primary component for gelation.	35863000	II	4-②	applicable	—
Dental polyether impression material	An elastic material primarily made of polyether, which forms a rubber-like material suitable for taking impressions after reaction.	35864000	II	4-②	applicable	—
Dental polysulfide impression material	An elastic material primarily made of polysulfide, which forms a rubber-like material suitable for taking impressions after reaction.	35865000	II	4-②	applicable	—
Dental silicone impression material	An elastic material primarily made of polysiloxane, which forms a rubber-like material suitable for taking impression after reaction.	35866000	II	4-②	applicable	—
Dental agar impression material	An impression material containing reversible agar hydrocolloid as a component for gelation.	35862000	II	4-②	applicable	—
Dental impression compound	A thermoplastic impression material used to take an impression of the oral cavity. It is a mixture of natural resin, filler, and lubricant.	34799000	II	4-②	applicable	—
Dental zinc oxide eugenol-based impression material	An impression material primarily made of zinc oxide and eugenol.	70885000	II	4-②	applicable	—
Dental impression material kit	A kit that combines a dental impression material, setting time regulator, mixing instrument, etc.	70886000	II	4-②	applicable	—
Dental optical impression auxiliary material	A material used to prevent diffuse reflection, etc. during optical impression-taking using a chairside dental CAD/CAM unit.	70888000	II	4-②	applicable	—
Dental resin-based impression material	A resin-based material used to take an impression of the oral cavity. (Dental polyether impression material, dental polysulfide impression material, and dental silicone impression material are excluded.)	70889000	II	4-②	applicable	—
Denture adhesive	Powder-like or paste-like materials used for stabilizing a denture (removable denture) in the oral cavity. Materials defined by other names are excluded.	16388009	II	5-⑤	applicable	—
Glue type denture adhesives	Powder, paste, or sheet-like material used to maintain adhesion of a removable denture to the oral mucosa.	16388010	II	5-⑤	applicable	—
Liner type denture adhesives	An insoluble paste used to maintain sticking (by negative pressure) of a removable denture to the oral mucosa.	16388020	II	5-⑤	applicable	—

Dental retention pin	An appliance implanted permanently in a tooth to retain or stabilize a dental restoration.	35868000	II	8-①	applicable	—
Dental precision ball attachment	An attachment composed of a bulbar (male) component and a ringed (female) component.	38576000	II	8-①	applicable	—
Dental precision bur attachment	A device comprising a ready-made metal bur, hook, sleeve, screw, etc. and used to secure a removable prosthetic appliance to a bar shaped appliance.	38577000	II	8-①	applicable	—
Dental precision magnetic attachment	A device that holds a removable prosthetic appliance by magnetic attraction.	38578000	II	8-①	applicable	—
Dental precision slide attachment	A device which is designed to fit the male component along the precision groove of the female component.	38580000	II	8-①	applicable	—
Dental precision elastic attachment	An attachment designed to allow enough play that can accommodate tooth-borne or mucosa-borne denture displacement caused by deformation of the basal seat mucosa so that excessive force is not exerted on the base.	38603000	II	8-①	applicable	—
Prefabricated root canal post	A ready-made post or rod inserted into the prepared root canal for retention or reinforcement. The post may come in various shapes and sizes and may be made of an alloy, ceramic, fiber-reinforced plastic, etc.	38609000	II	8-①	applicable	—
Dental general-purpose acrylic resin	An acrylic resin used for a multi-purposes such as fabrication of temporary inlays, crowns, and bridges or repair of denture bases. It includes adjusting materials of curing time, etc.	70916010	II	8-①,7,5-⑤	applicable	—
General-purpose dental acrylic resin kit	A kit containing dental, general-purpose acrylic resins and related appliances.	70916020	II	8-①,7,5-⑤	applicable	—
Dental laboratory metal surface treatment material	A dental laboratory surface treatment agent used to make a surface of cast metal frames adherent or to reinforce its adhesiveness.	70917010	II	8-①	applicable	—
Dental laboratory colour improvement metal surface treatment material	A dental laboratory surface treatment agent used to improve the color of surface of cast metal frames. It is not used for surface treatment by plating.	70917020	II	8-①	applicable	—
Dental color masking material	A resin-based material used to mask the color of teeth, crown restorations, and metal bases. (Materials identified elsewhere as in "Tooth surface coating material" and "Dental adhesive kit".)	70919000	II	8-①	applicable	—
Dental adhesive kit	A kit containing appliances used for routine adhesion operations in dental treatment. Those defined with other names and those that have pharmaceutical ingredients are excluded.	70920012	II	8-①	applicable	—
Dental laboratory adhesive material	A resin-based material for bonding/repair, used in fabrication of crown restorations and dentures and implanted in the oral cavity. It does not contain drugs. (Materials identified elsewhere as in "dental ceramic adhesive" and "dental metal adhesive" are excluded.)	70920022	II	8-①	applicable	—
Dental metal adhesive material	A material used to bond metal to a resin-based dental material.	70921000	II	8-①	applicable	—

Dental metal adhesive kit	A kit that contains dental metal adhesive materials and related tools.	70922000	II	8-①	applicable	—
Prefabricated root canal post kit	A kit comprising a ready-made post/rod, drill, wrench, gauge, etc. The post or rod is inserted into the prepared root canal for reinforcement. The drill, wrench, gauge, etc. are used for pretreatment before insertion of the post/rod.	70924000	II	8-①	applicable	—
Dental hypersensitive dentine desensitizer	A material applied to the tooth surface to reduce hyperesthesia of dentin (including prepared dentin). Materials with absorptivity or biological effects, or containing drugs or biological raw materials are excluded.	70926000	II	8-①	applicable	—
Long-term use occlusal splint dental material	A material used to fabricate dental occlusal splints that can be used for over 30 days.	70929000	II	5-⑤	applicable	—
Long-term use dental occlusal splint	A rigid or flexible appliance that covers the occlusal surface. It is used for over 30 days for retention of a displaced or loose tooth, treatment of clenching (habitual contraction of the jaw muscles), bruxism and their sequelae, and for temporary analgesia of pain in the muscle or temporomandibular joint (for example, temporomandibular joint).	70930000	II	5-⑤	applicable	—
Long-term use dental molded polymer clasp	A ready-made dental clasp made of polymeric material that can be used for over 30 days.	70931000	II	5-⑤	applicable	—
Long-term use dental preformed metal clasp	A ready-made elastic metal clasp for removable partial dentures. This clasp can be used for over 30 days.	70932000	II	5-⑤	applicable	—
Dental lubricating material	Materials that provide lubricity by application to the surface of the denture base, artificial tooth or oral mucosa for the purpose of controlling discomfort caused by lack of lubrication between the denture and the oral mucosa. Those containing drugs and biological products are excluded.	70933000	II	5-⑤	applicable	—
Powered keratome	An electric device for making lamellar incisions in the cornea in ophthalmic surgery.	12222002	II	6	applicable	N/A
Powered keratome blade	A spare blade for powered keratome. This is for single-use.	35137000	II	6	applicable	—
Water jet keratome	An ophthalmic surgery device used for shaving off the corneal tissue utilizing high-pressure water in nonpenetrating keratoplasty.	44249000	II	6	applicable	—

Bone cutter	A surgical device for penetrating the bone or separating one bone into two parts with a sharp blade(s). It usually consists of a manual or non-electrical device with one or more sharp blades. It may have two blades rotating around a central shaft and two short handles like forceps or cutting pliers. It is mainly used in orthopedic surgery and oral surgery.	10455000	II	6	applicable	applicable
Single-use sclerotome	An ophthalmic surgical instrument used in sclerotomy. The device is for single-use.	13507002	II	6	applicable	—
Single-use manual corneal trephine	A manual cylindrical device for ophthalmic surgery equipped with a blade for resection/removal of a ring-shaped piece of corneal tissue (corneal button). For example, when a healthy corneal graft is obtained from a cadaver, the recipient's morbid cornea is resected and removed to allow transplantation of the graft. The	14148012	II	6	applicable	—
Single-use ophthalmic knife	A severing instrument with a handle and a blade of various shapes and sizes, used in surgery of the eye and surrounding area. The device includes a spare blade that is used after attachment to the reusable handle. The device is intended for single-use.	32764002	II	6	applicable	—
Single-use scalpel	An instrument used to sever and separate body tissues during surgery. The device is a surgical instrument that usually has a handle and a blade of various shapes and sizes. Instruments categorized as a knife may be designed for other technological approaches. The device may be designed for sever specimens or objects other than body tissues. The device is intended for single-use.	35130002	II	6	applicable	—
Single-use scalpel blade	A component of a surgical instrument (scalpel) that is attached to the handle. It can cut through tissues by exerting downward pressure. The device is intended for single-use.	37445000	II	6	applicable	—
Single-use adenotome blade	A surgical blade designed to be attached to the guillotine of an adenotome, an instrument specifically designed for severing/resection of adenoid tissues. The device is intended for single-use.	37446000	II	6	applicable	—
Single-use scissors	An instrument that is usually used for severing tissues, cloth, sutures, etc. during surgery. The device has a pair of pivoted blades (usually a hole on each handle through which the thumb and another finger are inserted for use) and the object placed between the blades is severed by closing them. The device is intended for single-use.	35325002	II	6	applicable	—
Single-use ophthalmic scissors	An ocular surgical instrument used to sever tissues in ophthalmic surgery. The device may have a pair of rotary blades and a handle that can be grasped with the thumb and another finger. The blade shape may vary. The device is intended for single-use.	35327002	II	6	applicable	N/A
Single-use surgical saw	A manually operated or powered (by air, nitrogen, battery, AC power, etc.) device, which may be used alone or with a variety of attachments such as a vibrating blade or reciprocating blade. The device is usually designed for use in a specific field. The device may be used microscopically or macroscopically. The device can be used in many	13448012	II	6	applicable	N/A
Powered surgical saw	A handpiece and its attachment that enables vibration or reciprocal motion. The device may be used microscopically or macroscopically. The device is electrically powered.	13448022	II	9	applicable	N/A
Single-use saw	A device manually operated or powered (by air, nitrogen, battery, AC power, etc.) and used to sever or separate an anatomical structure or part of the human body. The device is used alone or with a variety of attachments. The device is usually designed for use in a specific field. The device is intended for single-use.	34821002	II	6	applicable	N/A

Single-use file	A manually operated, hand-held surgical instrument with a series of bumps or teeth on its surface that is used to smooth out, grind off, or sever tissues. The device is intended for single-use.	11701002	II	6	applicable	N/A
Single-use ophthalmic snare	A surgical instrument with a loop (made of flexible wire, for example) that is positioned around the target tissue and constricts it. The device is usually used for enucleation of the eye. For example, the composition of this ocular surgical device may be 1 channel/cannula, 2 fastening rings, 1 sliding ring, etc. The device is intended for single-use.	32755002	II	6	applicable	N/A
Single-use cranial bur	A small rotary shaft usually made of hard metal such as steel. It has grooves or a severing plane on one end and is used to excavate soft or hard tissue from the cranial. It is attached to a suitable electrically powered apparatus and rotated for use. The device is intended for single-use.	10520002	II	6	applicable	—
Airway needle	A single-use instrument with a thin, sharp tip used to establish airway patency. It is usually hollow and made of metal. Typically, it is used in emergency cricothyroidotomy in patients with respiratory obstruction.	12732002	II	6	applicable	N/A
Single-use perforator	A metal instrument that will be passed through soft tissue or bone. It has a handle at the proximal end and a spear-or cone-shaped distal end, or is pincer-shaped with an operating handle. It may be a hollow/cylindrical drill with sawtooth. The device is intended for single-use.	12989002	II	6	applicable	N/A
Single-use nucleus pulposus resection device	A special medical device that is used in percutaneous nucleotomy. Access to the intervertebral disc is created percutaneously using a bushing, and a probe is inserted inside the bushing to cut and remove the nucleus pulposus. The device usually consists of a bushing, probe, suction device, etc. The device is intended for single-use.	70934000	II	6	applicable	—
Powered corneal bur	A hand-held, small rotary shaft that is made of a hard alloy (for example, steel), has grooves of various shapes or a severing plane at one end, and is used in surgery to scrape off corneal tissue. The device is attached to a suitable electrically powered apparatus for rotation. The device may come with an electrically powered apparatus.	32812000	II	6,9	applicable	N/A
Single-use dermatome blade	A blade, available in various sizes, attached to a dermatome for collection of skin grafts. The device is intended for single-use.	35134000	II	6	applicable	—
Single-use blood vessel surgical stripper	A surgical instrument used for complete or partial vascular resection. The device may be specifically designed for partial resection of a vein or artery. The device is intended for single-use.	35377002	II	6	applicable	—
Single-use ophthalmic forceps	A device used to hold, manipulate, compress, pull, or join ocular and surrounding tissues. For example, the device may have a pair of blades with attached handles. The handles may be permanently integrated with the blades or attached (usually by a screw).	16209002	II	6	applicable	N/A
Single-use forceps	A surgical instrument with two tips that are closed to hold objects. The device's handles are permanently integrated. This category contains all types of surgical forceps, microforceps and surgical tweezers. The device is intended for single-use.	35079002	II	6	applicable	N/A
Single-use surgical clamp	A surgical instrument used to hold, join, compress, or support an organ, tissue, or blood vessel in a nontraumatic manner. The device is intended for single-use.	10861002	II	6	applicable	—
Single-use surgical probe	A thin, rod-shaped surgical instrument made of metal and soft materials. The device is used to explore sinuses, fistulae, and other cavities and wounds. The probe tip is designed for insertion into specific anatomical structures (e.g., for exploration of the mastoid process) and may be bent at right angles where it joins the shaft. The device is intended for single-use.	32870002	II	6	applicable	N/A

Single-use eye speculum	A device to keep the eyelids open in ophthalmic surgery or examination. For example, the device is a surgical instrument with two arms connected at a pivot. It may come in various sizes, shapes, and contours. The distal end may be round and is used to dilate or stretch the tissue around the eye sockets when the instrument is used. The device is used during examination or eye surgery. The device is usually made of stainless steel and equipped with an automatic eyelid-opening/-retaining mechanism. The device is	35349002	II	6	applicable	—
Single-use intraocular lens inserter	An instrument inserted into the eye to guide insertion/placement of an intraocular lens in surgery. The device is removed after insertion of the lens. The device is intended for single-use.	36061002	II	6	applicable	—
Single-use tongue scraper	A wooden or metal instrument used to collect scrapings from the top of the tongue for diagnosis. The device is intended for single-use.	16308000	II	6	applicable	—
Single-use ophthalmic curette	An ophthalmic abrasive instrument with a tip that is fenestrated, spoon-shaped, or ring-shaped, etc. The tip may be either pointed or round. The device is used to collect or resect ocular tissues. The device is for single-use.	32772002	II	6	applicable	—
Single-use lens surgical spoon	A manually operated instrument used in treatment, resection, etc. of the lens in ophthalmic surgery. The device is for single-use.	35153002	II	6	applicable	—
Single-use spoon	A instrument with handles and a spoon-shaped (dish-shaped) distal tip. The device is used in surgery, administration of drugs, or for some other purposes related to healthcare. The device is intended for single-use.	41716002	II	6	applicable	N/A
Single-use ophthalmic hook	A surgical instrument that has a rod-shaped handle with a tapered distal tip. The shape of distal end varies: it may be curved or bent with a round or pointed tip. The device is intended for single-use.	35314002	II	6	applicable	N/A
Single-use orbit retractor	An ophthalmic surgical instrument used to open up the incision on the eye or surrounding structures, or to fixate the eyeball. The device is intended for single-use.	13381002	II	6	applicable	—
Cardiac insulation pad	A thin, flexible pad that is placed around the heart for hypothermic cardioplegia in heart surgery using extracorporeal circulation. The device helps prevent a rapid return of the cardiac temperature. The device is intended for single-use.	35973000	II	6	applicable	N/A
Single-use sclereal plug	A nail-like plug inserted into the wound opening after removal of a chip, etc. in vitreous surgery. The device is intended for single-use.	70946000	II	6	applicable	—
Single-use retractor	A surgical device used to separate tissues or anatomical structures. The device establishes access to an organ or tissue by exposing the target and enables examination or treatment. The device is intended for single-use. The device may have	13373002	II	6	applicable	—
Single-use organ fixation pelotte	A device used in therapy or examination to fixate or retain an organ to its original position. The device is intended for single-use.	70954000	II	6	applicable	—
Single-use ophthalmic surgical spatula	A surgical instrument shaped like a spatula, etc. , that is usually made of stainless steel, etc. and used for application of a substance to the eye, treatment of ocular tissue, or removal of substances from the eye or surrounding structures. The device may have	32754002	II	6	applicable	N/A

Surgical cannulated drill	A device that establishes a passageway with the same diameter as that of the drill bit when the device is attached to a surgical drilling and reaming machine and rotated at the recommended speed to cut through the bone and tissue. It is usually flexible and has a hollow shaft so that it fits into the guide pin placed in the precise location prior	11332000	II	6	applicable	applicable
Biopsy drill	A drilling device (a drill bit) used for extracting (cutting off) a small piece of bone or cartilage for microscopy. Necessary operations can be performed when it is attached to a manual or electric surgical perforator and rotated at an appropriate speed.	11330000	II	6	applicable	N/A
Powered Orthopedic reamer	An electric orthopedic device used to open or enlarge a medullary cavity for insertion of other instruments in artificial joint replacement or fracture fixation.	35297002	II	9	applicable	N/A
Manually-operated Orthopedic injector	A manually operated syringe-like device used to inject orthopedic (bone) cement, artificial bone, etc. into the surgical site excluding the spine) Single-use components may be included.	70956000	II	6	applicable	N/A
Single-use instrument for osteosynthesis	A manually operated instruments such as a manual bone drill, calcaneal retractor, and pelvic claps used mainly in orthopedic osteosynthesis. Only manually operated devices are included. The device is intended for single-use	70958002	II	6	applicable	—
Powered Orthopedic cement dispenser	An electric syringe-like device used to inject orthopedic (bone) cement into the surgical site. The device may be attached to an integrated power unit that pushes the plunger.	35809002	II	11	applicable	—
Battery-powered surgical drill handpiece	A handpiece with a chuck used with drill bits, bone tap, or wire. The device runs on rechargeable batteries. A cannula may be inserted in the device so that it may be used over a guide wire. The device is designed for microscopic or macroscopic use.	37867010	II	9	applicable	N/A
Electrically-powered surgical drill	A handpiece with a chuck used with drill bits, bone tap, or wire. The device is electrically powered. The device may have a hollow center for use over a guide wire. The device is designed for microscopic or macroscopic use.	37867020	II	9	applicable	N/A
Powered surgical drill motor	A device that transmits rotation force from the surgical drilling motor to a surgical drill via a rotating cable (Bowden cable). Electricity is usually provided by the main power supply. The general type of this device group appears to reflect conventional	43915000	II	6	applicable	N/A
Powered bone operating instrument	An instrument used in bone surgery. This device is electrically powered.	70959010	II	9	applicable	N/A
Battery-powered bone operating instrument	A surgical device used in bone surgery such as osteosynthesis. The device runs on rechargeable batteries.	70959020	II	9	applicable	—
Single-use intramedullary canal cleaning brush	A surgical instrument used to remove blood clots and bone fragments from the medullary canal before injection of orthopedic cement. The device commonly has a handle on one side and stinging hair, fiber, or thorns on the other. The stinging hair, fiber, or thorns may be planted on a plane or radially from the instrument axis. The handle and stinging hair may be either soft or rigid. The device is intended for single-use.	35589002	II	6	applicable	N/A
Single-use Orthopedic file	A long tapered surgical cutting tool with teeth that is used to cut and enlarge a hole in bone tissue. The device is sterilized and intended for single-use.	36167002	II	6	applicable	—

Single-use manually-operated surgical drill handpiece	A manually operated handpiece with a chuck, used with drill bits, bone tap, or wire, etc. The device is also called a retainer and bit. A cannula may be inserted in the device so that it may be used over a guide wire. The device is intended for single-use.	36235002	II	6	applicable	—
Single-use Orthopedic bur	A small rotary shaft made of hard-metal such as steel with grooves of various shapes or a cutting plane on one end, used to cut or shape a hole in bone in maxillofacial surgery, spinal surgery, or other major or minor bone surgery. The device is intended for single-use.	36249002	II	6	applicable	—
Single-use surgical drill attachment	An appliance connected to a manually operated or powered handpiece to perform specific task, drilling, and reaming, and to introduce or guide a wire, etc. The device comes with a reduction gear that enables fine speed control for specific tasks. A	37870002	II	6	applicable	—
Single-use surgical crown drill bit	A hollow boring tool used as a crown drill or hollow mill. The device is used to remove the shaft of a broken screw without head, or to collect the central portion of the bone in biopsy. The device is intended for single-use.	37871002	II	6	applicable	—
Single-use bone operating instrument	A surgical device used in bone surgery such as osteosynthesis. The device is manually operated. The device is intended for single-use.	70962012	II	6	applicable	N/A
Single-use instrument for spinal surgery	An instrument used for spinal surgery such as spinal fusion. The device is manually operated. The device is intended for single-use.	70963012	II	6	applicable	—
Battery-powered spinal cord operating instrument	An instrument used in spinal surgery such as spinal fusion. The device runs on rechargeable batteries.	70963022	II	9	applicable	N/A
Single-use instrument for joint surgery	An instrument used in joint surgery such as artificial joint replacement. The device is manually operated. The device is intended for single-use.	70964012	II	6	applicable	N/A
Battery-powered joint operating instrument	An instrument used in joint surgery such as artificial joint replacement. The device runs on rechargeable batteries.	70964022	II	9	applicable	—
Powered dental implant surgical device	A device used while connected to an active equipment in dental implant surgery. The device may be designed for single-use only.	70965002	II	6	applicable	—
Single-use instrument for ligament/tendon surgery	A device used in surgery on tendons/ligaments such as ligament reconstruction. The device is manually operated. The device may come with a suture needle. The device is intended for single-use.	70966002	II	6	applicable	N/A
Power tool torque control unit	A device that is connected with an electrical device or electrical device system and used for adjusting the torque of the electrical device. It provides power to perform the treatment by weakening or strengthening the torque of the electrical device, such as by inserting or by fastening an orthopedic fixation screw or a denture fixation screw.	43894000	II	9	applicable	applicable
Orthopedic prosthesis implantation instrument	A tool specifically designed to be used for insertion of an orthopedic artificial implant or a prosthesis. It may work as a standard interface between the parts of the prosthesis when it is inserted, or it may be used for confirming appropriate spatial localization, fixing the location for a device (a sensor), holding parts during cement	13180000	II	6	applicable	—
Powered Orthopedic cement extractor	A set of electric surgical instruments usually used in artificial joint replacement to remove orthopedic (bone) cement, which was used to implant an artificial joint. The set may include a slap hammer, chisel, comparable electric devices to crack and remove	44598000	II	9,12	applicable	N/A
Dilator for catheter	A device used to dilate or enlarge a lumen or opening for catheter insertion. (usually used in surgery)	32338000	II	6	applicable	N/A

Single-use medical dilator	A non-electrical dilating instrument. The device is intended for single-use. Electrical devices are excluded.	70969002	II	6	applicable	—
Lens for ophthalmic surgical laser	A lens used with an ophthalmic surgical laser. It is usually transparent and guides the laser beam to the eye, eye socket, or surrounding skin for coagulation/cutting.	40238000	II	5-①'	applicable	N/A
Reusable diagnostic contact lens	A contact lens worn by a patient to help diagnosis of specific eye disorders/conditions. The device is reusable.	34651010	II	5-①'	applicable	N/A
Single-use diagnostic contact lens	A contact lens worn by a patient to help diagnosis of specific eye disorders/conditions. The device is intended for single-use.	34651020	II	5-①'	applicable	—
Electroretinograph corneal electrode	An electrode used in contact with the corneal surface or the mucosa near the cornea for transmission of potential signals in electroretinography. It may contain a conductor for measurement of the reference potential of the cornea in addition to that for corneal	70972000	II	5-①'	applicable	applicable
Gonioscope	A device used in gonioscopy.	11894000	II	5-①'	applicable	N/A
Intraocular pressure reducer	A manually operated ophthalmic surgical device for reducing intraocular pressure in ophthalmic surgery.	15048000	II	6	applicable	N/A
Aesthesiometer	An apparatus used to measure the corneal perceptual sensitivity by applying a nylon filament to the cornea.	70974000	II	5-①'	applicable	N/A
Reusable contraceptive pessary	A circular device made of silicone or plastic material, etc. that is placed in the vagina and used to mechanically prevent conception. This may be a reusable device.	35237000	II	5-②	applicable	—
Contraceptive cervical cap	A device that is inserted into the cervix and works as a physical barrier to prevent spermatoc invasion into the uterus. It consists of a cup with a round edge made of elastic rubber. A medical professional adjusts the size to make it fit the perimeter of	32608000	II	5-②	applicable	—
Contraceptive sponge	A bubble-like device that works as a physical barrier to prevent spermatoc invasion into the uterus when it is inserted into the vagina. This device absorbs semen. The one containing spermicides destroys sperm	35931000	II	5-②	applicable	—
Latex surgical glove	A natural rubber garment, designed to protect the patient and wearer from cross infection when used in medical or dental surgery.	40548000	II	6	applicable	—
Non-latex surgical glove	A garment made of synthetic material and designed to protect the patient and wearer from cross infection when used in medical or dental surgery.	40549000	II	6	applicable	—
Delivery procedure set	A set of materials and tools such as gauze and catheter used for disinfection, hemostasis, draining, etc. of the mother and neonate during parturition.	70978000	II	5-②	applicable	—

Home use electric massager	An electrically powered massager designed especially for home use. For instance, its head or other specifically shaped component vibrates and is applied to the desired body part for massage. The vibrating head can be changed to another of a different size or shape. Other variants are used to compress or massage a body part using pneumatic pressure. The device is also used to stimulate or massage muscles.	34662000	II	9	applicable	N/A
Home use pneumatically-powered massager	A massager designed especially for home use and operates only with pneumatic pressure.	34663000	II	9	applicable	N/A
Home use suction massager	A massager designed to induce tactile sensation especially for home use. The user can operate it on his/her own for therapeutic stimulation and massage of muscles. The device includes suction cups or variants. The device is not suitable for hospital or clinic use.	34664000	II	9	applicable	N/A
Electric massager with needles and a protection pipe	A device used by applying a vibrating pipe tip and needle points perpendicularly to the skin. The device contains multiple needles inside the protective pipe.	70979000	II	9	applicable	N/A
Home use heating digital compressor	Home use therapy equipment with round protrusions heated electrically, etc. , imitating acupressure therapy with its own weight or under compression.	70980000	II	9	applicable	N/A
Home use digital compressor with rollers	Home use therapy equipment with protruding rollers imitating acupressure therapy with its own weight or under compression.	70981000	II	9	applicable	N/A
Home use pneumatic digital compressor	Pneumatic equipment imitating acupressure therapy which is designed especially for home use. For example, rounded protrusions pneumatically press the user's body and imitates acupressure therapy. The protrusions can be changed to another of different shape.	70982000	II	9	applicable	N/A
Home use ultrasonic bubble bath	An apparatus that generates bubbles by blowing pressurized warm water with air into the bath, producing ultrasonic waves from the bubbles. It does not use electrical oscillation to generate ultrasonic waves.	70983000	II	9	applicable	N/A
Home use air bubble bath	Home use equipment that blows bubbles into warm water by mechanisms such as passing air through a porous board.	70984000	II	9	applicable	N/A
Home use whirlpool bath	Home use equipment that blows warm water inside a bathtub so that the water flow rotates in the bathtub and forms a vortex.	70985000	II	9	applicable	N/A
Home use hydro-massage therapy bath	A bathtub equipped with a nozzle that generates a large quantity of jetted water to thereby provide treatment massaging effects. This device can be used for a patient with rheumatism in pain relief therapy, which is also known as non-invasive water jet therapy.	34667000	II	9	applicable	N/A
Home use low-frequency therapy equipment	Home use equipment that applies a mild, low-frequency electric current to the skin surface for treatment.	70986000	II	9	applicable	N/A
Home use electric potential therapy apparatus	Home use equipment that puts the body on an alternating electric field or direct electric field, or applies an electric potential to the body in an insulated state, for treatment.	70987000	II	9	applicable	N/A
Home use shortwave diathermy unit	Home use treatment equipment that radiates high-frequency (from 13 to 27. 12 MHz) electromagnetic energy to a specific site of the body. It is operated for the purpose of providing deep tissue-heating for the tissues inside the body for mitigation of selected conditions.	34668000	II	9	applicable	N/A
Home use short wave therapy unit	Home use equipment that irradiates a desired body surface with electromagnetic energy in the high-frequency band (from 13 MHz to 2450 MHz) to heat the tissue deep inside the irradiated area for treatment.	70988000	II	9	applicable	N/A
Home use high frequency therapy equipment	Home use equipment hat irradiates a desired body surface with electromagnetic energy in high-frequency band (about 9 MHz) to achieve vasodilation or improve blood flow.	70989000	II	9	applicable	N/A

Home use combination electric therapy apparatus	Home use therapeutic equipment combining low-frequency therapy equipment and an electric potential therapy apparatus, or an electric massager and an electric potential therapy apparatus, etc.	70990000	II	9	applicable	N/A
Electric potential/heat/electromassage combined home use medical device	Home use therapeutic equipment combining an electric potential therapy apparatus, heat therapy equipment, and an electric massager.	70991000	II	9	applicable	N/A
Low-frequency/electric potential/ultrashort wave combined home use medical device	Home use therapeutic equipment combining low-frequency therapy equipment, an electric potential therapy apparatus, and an ultra-short wave therapy unit.	70992000	II	9	applicable	N/A
Low-frequency/electric potential/heat combined home use medical device	Home use therapeutic equipment combining low-frequency therapy equipment, an electric potential therapy apparatus, and heat therapy equipment.	70993000	II	9	applicable	N/A
Low-frequency/heat/electromassage combined home use medical device	Home use therapeutic equipment combining low-frequency therapy equipment, heat therapy equipment, and an electric massager.	70994000	II	9	applicable	N/A
Low-frequency/electric potential combined home use medical device	Home use therapeutic equipment combining low-frequency therapy equipment and an electric potential therapy apparatus.	70995000	II	9	applicable	N/A
Low-frequency/ultrashort wave combined home use medical device	Home use therapeutic equipment combining low-frequency therapy equipment and an ultra-short wave therapy unit.	70996000	II	9	applicable	N/A
Low-frequency/electromassage combined home use medical device	Home use therapeutic equipment combining low-frequency therapy equipment and an electric massager.	70997000	II	9	applicable	N/A
Low-frequency/heat combined home use medical device	Home use therapeutic equipment combining low-frequency therapy equipment and heat therapy equipment.	70998000	II	9	applicable	N/A
Low-frequency/moxibustion combined home use medical device	Home use therapeutic equipment combining low-frequency therapy equipment and a moxibustion apparatus.	70999000	II	9	applicable	N/A
Electric potential/ultrashort wave combined home use medical device	Home use therapeutic equipment combining an electric potential therapy apparatus and an ultra-short wave therapy unit.	71000000	II	9	applicable	N/A
Electric potential/heat combined home use medical device	Home use therapeutic equipment combining an electric potential therapy apparatus and heat therapy equipment.	71001000	II	9	applicable	N/A
Home use electric potential/moxibustion combined medical device	Home use therapeutic equipment combining an electric potential therapy apparatus and a moxibustion apparatus.	71002000	II	9	applicable	N/A
Electric potential/electromassage combined home use medical device	Home use therapeutic equipment combining an electric potential therapy apparatus and an electric massager.	71003000	II	9	applicable	N/A
Electric potential/air massage combined home use medical device	Home use therapeutic equipment combining an electric potential therapy apparatus and a pneumatically-powered massager.	71004000	II	9	applicable	N/A
Heat/moxibustion combined home use medical device	Home use therapeutic equipment combining a heat therapy equipment and a moxibustion apparatus.	71005000	II	9	applicable	N/A
Heat/electromassage combined home use medical device	Home use therapeutic equipment combining a heat therapy equipment and an electric massager.	71006000	II	9	applicable	N/A
Moxibustion/electromassage combined home use medical device	Home use therapeutic equipment combining a moxibustion apparatus and an electric massager.	71007000	II	9	applicable	N/A

Electric sleep inducer	An apparatus that induces sleep by application of a weak electric pulse patterned for a sympathoinhibitory effect to the head.	71010000	II	9	applicable	N/A
Home use electric needle	A home use electrical needle that generates voltage from the piezoelectric element to provide electrical stimulation to an affected site of the body.	71011000	II	9	applicable	N/A
Home use infrared light therapy unit	A home use therapy device using for infrared radiation.	71012000	II	9	applicable	N/A
Home use ultraviolet light therapy unit	A home use therapy device for ultraviolet radiation.	71013000	II	9	applicable	N/A
Home use carbon arc light therapy unit	Home use phototherapy equipment to treat an affected site using a carbon arc generated by arc discharge with a carbon rod as the electrode.	71014000	II	9	applicable	N/A
Home use electromagnetic induction therapy apparatus	Home use therapy equipment that generates a magnetic field with the use of alternating current and uses magnetism for treatment.	71015000	II	9	applicable	N/A
Home use magnetic induction therapy apparatus with permanent magnet	Home use therapy equipment that uses the magnetism of a permanent magnet for treatment.	71016000	II	9	applicable	N/A
Home use heat therapy equipment	Home use therapy equipment that applies thermal stimulation using electric heat for treatment (excluding moxibustion apparatus).	71017000	II	9	applicable	N/A
Moxibustion apparatus	A home use therapy apparatus that applies thermal stimulation to a target area for treatment.	71018000	II	9	applicable	N/A
Home use ultrasonic inhaler	A home use apparatus that atomizes a solution by ultrasonic vibration for inhalation.	71020000	II	11	applicable	N/A
Home use electrically-powered inhaler	A home use apparatus that atomizes a solution by compressed air for inhalation.	71021000	II	11	applicable	N/A
Home use electrically-heated inhaler	A home use apparatus that generates steam by electric heat and atomizes a solution using a steam blast for inhalation.	71022000	II	11	applicable	N/A
Batch process water electrolyzer	A home use apparatus that stores drinkable water containing calcium ions for a period and electrolyzes it to produce drinkable alkaline electrolyzed water and undrinkable acidic electrolyzed water.	71023000	II	11	applicable	N/A
Continuous flow water electrolyzer	A home use apparatus connected to a water outlet that electrolyzes drinkable water containing calcium ions to produce drinkable alkaline electrolyzed water and undrinkable acidic electrolyzed water.	71024000	II	11	applicable	N/A
Pocket-size hearing aid	A sound amplifier to assist hearing of patients with hearing loss. This device is composed of a part worn somewhere other than the head, and an ear mold, which is connected to the other part, inserted in the ear canal, and reproduces amplified sound.	30082000	II	9	applicable	N/A
Behind-the-ear hearing aid	A sound amplifier to assist hearing of patients with hearing loss. This device is composed of a part placed behind the ear lobe, and an ear mold, which is connected to the other part, inserted in the ear canal, and reproduces amplified sound.	34671000	II	9	applicable	N/A

Face-plate hearing aid	A hearing aid composed of an amplifier, controller, and battery holder. The device may have an integrated earphone and microphone or come with separate earphone and microphone. The device is attached to a case or shell which is shaped according to the	33953000	II	9	applicable	N/A
In-the-ear hearing aid	A sound amplifier to assist hearing of patients with hearing loss. This device in its entirety fits within the ear canal and ear lobe. The amplified sound is reproduced in the ear canal.	34672000	II	9	applicable	N/A
Modular in-the-ear hearing aid	A hearing aid with a uniform external case not designed to fit individual user's ear.	41193000	II	9	applicable	N/A
Custom-made in-the-ear hearing aid	An in-the-ear hearing aid with a case or shell made to fit individual user's ear and with the internal circuit also adjusted to meet their needs.	41208000	II	9	applicable	N/A
Canal hearing aid	A small hearing aid that is worn almost completely in the ear canal. The device is a smaller version of the in-the-ear hearing aid.	41209000	II	9	applicable	N/A
Completely-in-the-canal hearing aid	A hearing aid that is smaller than canal hearing aids and placed very close to the tympanic membrane.	41211000	II	9	applicable	N/A
Spectacle hearing aid	A hearing aid with all of its components placed inside the temple (or temples) of spectacles. The sound is propagated from the spectacles by air conduction.	34673000	II	9	applicable	N/A
Programmable hearing aid	A device that aids persons with hearing impairment. Its properties are configured by software.	17666000	II	9	applicable	N/A
Tinnitus masker	A device that delivers noise to the wearer's ears to mask ear noise. The device is typically worn like a hearing aid.	30899000	II	9	applicable	N/A
Bone-conduction hearing aid	A hearing aid worn on the head that is attached to spectacles or headband and propagates the sound through the bone conduction receiver.	33993000	II	9	applicable	N/A
Digital hearing aid	A device that is designed to aid persons with hearing impairment by digitalization of sound signals, which are processed in a digital circuit using a digital processing algorithm.	41207000	II	9	applicable	N/A
Headband hearing aid	A hearing aid that is mostly housed in a case attached to a headband. The amplified sound is propagated to the ear via an earphone or sound tube.	41212000	II	9	applicable	N/A

Wound pad for home use	A pad made by materials such as hydrocolloid, which is used to protect wounds at home. It is used to protect wounds such as mild cut, abrasion, puncture, scratch, and shoe sore, as well as mild burn. It maintains a moist environment to promote pain relief and healing.	71025000	II	4-②	applicable	—
Home use acupuncture unit	An acupuncture device designed to be used by a user who performs acupuncture at home.	34675002	II	6	applicable	—
Vaginal douche	An apparatus designed to deliver a liquid (usually solution) directly into the vaginal cavity as a douche. The device is composed of a bag or bottle with an attached tube or nozzle for manual use. The device may be designed for a single-use with a prefilled cleaning solution.	32616000	II	5-②	applicable	—
Contraceptive micro-condom	A small sheath made of latex or a synthetic material to cover the glans penis for the purpose of contraception.	34030000	II	5-②	applicable	—
Contraceptive, condom, female	A sheath type device with rings at both ends that is inserted into the vagina and kept during coitus to prevent sperm invasion into female reproductive tract or prevent transmission among sex partners of microorganisms causing sexually transmitted diseases.	36281000	II	5-②	applicable	—
Contraceptive, condom, male	A sheath type device that cover the penis during coitus to prevent sperm invasion into female reproductive tract or prevent transmission among sex partners of microorganisms causing sexually transmitted diseases.	36282000	II	5-②	applicable	—
Capsule imaging and tracking device	A capsule-shaped medical device used for observation and diagnosis of the gastrointestinal tract. It contains a radio transmitter that records image data while moving inside the gastrointestinal tract peristaltically and sends the data wirelessly and non-invasively to the receiver outside the body while moving inside the body.	71027000	II	10-③	applicable	—
Single-use vertebral orthotic	A device used for the balloon kyphoplasty which is intended to restore the vertebral height at a bone fracture site and to form a cavity inside the trabecular bone for orthopedic bone cement injection. An expandable balloon is attached to the distal end of the device.	47021002	II	6	applicable	N/A
Dental air-powered drill handpiece	A pneumatically driven handpiece with a chuck to connect a dental device, such as dental burs and reamers, which rotates, vibrates, repeats rotation, reciprocates, or moves in combination of these motions. The device has an integrated pneumatic motor.	40958032	II	9	applicable	applicable
Ion penetration percutaneous local anaesthesia apparatus	A device for percutaneously promoting penetration of an anesthetic solution by passing a weak electric current through the human body in ionized local anesthesia.	70575022	II	6,9	applicable	N/A
Blood component separation apparatus	A device used for separation of specific blood components with a blood component separation kit.	58329002	II	3-①	applicable	applicable
Patient-adaptive, single-use device for joint surgery	A surgical device used for joint surgery including arthroplasty with prosthetic joint replacement. It is a manual machine designed and manufactured to fit an individual patient. Only manually operated types are included. This device is for single-use.	70964212	II	6	applicable	—

Balloon-guided small-intestine endoscopy system	A system consisting of an endoscope, an over-tube with a balloon, a balloon and a balloon controller installed on an endoscope, etc. It is inserted into the upper or lower gastrointestinal tract orally or via the anus, and fixes the endoscope and over-tube in the intestinal tract by inflating the balloon. The endoscope and over-tube fixed in the	71033002	II	5-②,5-⑥	applicable	applicable
Workstation for cardiac mapping system	An operational unit that percutaneously navigates (advances in the right direction and to the right location) devices including a catheter applies to the heart, to the target of the heart by using dedicated software. This unit operates the catheter in combination with a device that supplies magnetic force or mechanical power, etc.	31742002	II	9	applicable	applicable
Single-use infusion/drainage blunt needle	A device that has a long, thin, hollow tube for administration of solutions including drugs to a patient or for draining solutions from the body. This device has a blunt tip to prevent damage to the insertion site. This device is for single-use.	30889012	II	6	applicable	—
Electronic urine glucose meter	A urine glucose meter specifically dedicated for healthcare. It is a dedicated automatic or semi-automatic healthcare device with a sensor for measurement of the urine glucose level in daily life.	70188012	II	—	applicable	N/A
Urine chemistry for self monitoring	An automatic or semi-automatic device dedicated to self monitoring to identify and measure chemical substances in the urine with a test strip or a sensor.	70186000	II	—	applicable	applicable
Urine glucose meter for self monitoring	An automatic or semi-automatic device dedicated to self monitoring to identify and measure urine glucose with a test strip or a sensor.	70188000	II	—	applicable	applicable
Magnetic stimulator for urinary incontinence treatment	A non-implantable magnetic stimulator used for treatment of urinary incontinence. It usually consists of a main body equipped with a power supply part and a stimulation unit that provides magnetic energy.	71035002	II	9	applicable	applicable

Patient-adaptive, single-use device for bone surgery	A surgical device used for bone surgery including osteosynthesis surgery. It is designed and manufactured to fit each individual patient. It should be a manually operated device. This device is for single-use.	70962212	II	6	applicable	—
MRI-combined positron CT system	An integrated system combining systems for positron emission tomography computed tomography and magnetic resonance imaging. This system is both a three-dimensional (tomographic) imaging system that generates images of the distribution of positron released from positron-emitting radiopharmaceuticals administered orally or intravenously, and a magnetic resonance imaging system capable of generating two-dimensional or three-dimensional magnetic resonance images. Either system can be used independently. The system uses a variety of digital technologies for scanning and	58250002	II	10-①,10-②	applicable	applicable
Thermoregulation system	A system for temporary use that adjusts body temperature by heat exchange with the human body via a cuff placed in the pharynx or esophagus of a patient who needs temperature control. It consists of the cuff, where the perfusate circulates, and the control unit, where perfusate temperature is controlled, circulation and body	71036002	II	5-⑥,9	applicable	applicable
Decontamination disinfectant for ultrasound probe	A disinfectant that removes wastes or stains from, and disinfects the lumen and surface of an ultrasonic probe.	45058002	II	15	applicable	applicable
Digital impression taking apparatus	A device used for collecting three-dimensional shape data with digital methods to be provided for computer-aided design (CAD) and computer-aided manufacturing (CAM) of dental restorations, etc.	38597012	II	10	applicable	applicable
Transcutaneous catheter with intravascular valve cutter	A flexible tube with a blade used in revascularization by bypass grafting. A peripheral vein is diverted to an artery in bypass grafting. This tube is inserted percutaneously into the vein, with the vein left under the skin without being removed or collected, and incises the venous valve without causing damage, and lose its function.	14339002	II	6	applicable	N/A
Valve function assessment balloon catheter for valvuloplasty	A flexible tube used for postoperative assessment of valve regurgitation before restart of the heartbeat in valvuloplasty with synthetic Vascular prosthesis replacement in the root of the ascending aorta.	71038002	II	6	applicable	—
Software for using with general-purpose X-ray diagnostic system	A software, which is designed to process data obtained from the following devices: mobile analogue general-purpose diagnostic X-ray system, portable analogue general-purpose diagnostic X-ray system, portable digital general-purpose diagnostic X-ray system, stationary analogue general-purpose diagnostic X-ray system, stationary digital general-purpose diagnostic X-ray system, and mobile digital general-purpose diagnostic X-ray system.	37626032	II	10	applicable	—
Software for general-purpose integral diagnostic X-ray system	A software for medical device, which is intended to process data obtained from the following devices: mobile analogue general-purpose integral diagnostic X-ray system, portable analogue general-purpose integral diagnostic X-ray system, portable digital general-purpose integral diagnostic X-ray system, stationary analogue general-purpose integral diagnostic X-ray system, stationary digital general-purpose integral diagnostic X-ray system, and mobile digital general-purpose integral diagnostic X-ray system.	37626042	II	10	applicable	—
Software for using with mammography-combined diagnostic X-ray system	A software, which is designed to process data obtained from a combined diagnostic mammography-radiography system. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	70001012	II	10	applicable	—

Software for using with general-purpose fluoroscopic diagnostic X-ray system	A software, which is designed to process data obtained from the following devices: stationary analogue general-purpose fluoroscopic diagnostic X-ray system, mobile analogue general-purpose fluoroscopic diagnostic X-ray system, portable analogue general-purpose fluoroscopic diagnostic X-ray system, mobile digital general-purpose fluoroscopic diagnostic X-ray system, and stationary digital general-purpose fluoroscopic diagnostic X-ray system.	37621032	II	10	applicable	—
Software for general-purpose integral fluoroscopic diagnostic X-ray system	A software which is designed to process data obtained from the following devices: stationary analogue general-purpose integral fluoroscopic diagnostic X-ray system, mobile analogue general-purpose integral fluoroscopic diagnostic X-ray system, portable analogue general-purpose integral fluoroscopic diagnostic X-ray system, mobile digital general-purpose integral fluoroscopic diagnostic X-ray system, and stationary digital general-purpose integral fluoroscopic diagnostic X-ray system.	37621042	II	10	applicable	—
Software for using with cardiovascular fluoroscopic diagnostic X-ray system	A software, which is designed to process data obtained from the following devices: mobile digital angiographic fluoroscopic diagnostic X-ray system, mobile analogue angiographic fluoroscopic diagnostic X-ray system, stationary analogue angiographic fluoroscopic diagnostic X-ray system, and stationary digital angiographic fluoroscopic diagnostic X-ray system.	37612012	II	10	applicable	—
Software for mammographic diagnostic X-ray system	A software which is designed to process data obtained from the following devices: stationary analogue mammographic diagnostic X-ray system, portable analogue mammographic diagnostic X-ray system, mobile analogue mammographic diagnostic X-ray system, stationary digital mammographic diagnostic X-ray system, mobile digital mammographic diagnostic X-ray system, and portable digital mammographic diagnostic X-ray system.	37630012	II	10	applicable	—
Software for using with uro/gynaecological fluoroscopic diagnostic X-ray system	A software, which is designed to process data obtained from the following devices: mobile digital uro/gynaecological fluoroscopic diagnostic X-ray system, mobile analogue uro/gynaecological fluoroscopic diagnostic X-ray system, stationary digital uro/gynaecological fluoroscopic diagnostic X-ray system, and stationary analogue uro/gynaecological fluoroscopic diagnostic X-ray system.	37615012	II	10	applicable	—
Software for public abdominal health screening diagnostic X-ray system	A software, which is designed to process data obtained from an abdominal public health screening diagnostic X-ray system. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	37675032	II	10	applicable	—
Software for public thoracic health screening diagnostic X-ray system	A software which is designed to process data obtained from a thoracic public health screening diagnostic X-ray system. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	37627052	II	10	applicable	—
Software for public thoracic and abdominal health screening diagnostic X-ray system	A software, which is designed to process data obtained from a thoracic and abdominal public health screening diagnostic X-ray system. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	37627062	II	10	applicable	—
Software for abdominal health screening integral diagnostic X-ray system	A software for medical device, which is designed to process data obtained from an abdominal public health screening integral diagnostic X-ray system. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	37675042	II	10	applicable	—
Software for thoracic public health screening integral diagnostic X-ray system	A software, which is designed to process data obtained from a thoracic public health screening integral diagnostic X-ray system. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	37627072	II	10	applicable	—
Software for integral thoracic and abdominal public health screening integral diagnostic X-ray system	A software, which is designed to process data obtained from a thoracic and abdominal public health screening integral diagnostic X-ray system. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	37627082	II	10	applicable	—

Software for dental panoramic X-ray system	A software for medical device, which is designed to process data obtained from a dental public health screening panoramic X-ray system, an analogue dental panoramic X-ray system, or a digital dental panoramic X-ray system. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	70002012	II	10	applicable	—
Software for dental panoramic/tomographic X-ray system	A software for medical device, which is designed to process data obtained from an analogue dental panoramic/tomographic X-ray system or a digital dental panoramic/tomographic X-ray system. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	37668012	II	10	applicable	—
Software for general-purpose dental extraoral X-ray system	A software, which is designed to process data obtained from an analogue general-purpose dental extraoral X-ray system or a digital general-purpose dental extraoral X-ray system. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	37636012	II	10	applicable	—
Software for cephalometric diagnostic X-ray system	A software, which is designed to process data obtained from a cephalometric diagnostic X-ray system. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	37677032	II	10	applicable	—
Software for cephalometric integral diagnostic X-ray system	A software, which is designed to process data obtained from a cephalometric integral diagnostic X-ray system. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	37677042	II	10	applicable	—
Software for X-ray computed tomography system	A software, which is designed to process data obtained from a limited view field X-ray computed tomography system or a whole body X-ray computed tomography system. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	37619012	II	10	applicable	—
Software for arm type X-ray computed tomography system	A software, which is designed to process data obtained from an arm type X-ray computed tomography system. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	70006012	II	10	applicable	—
Software for nuclear medicine gamma camera	A software, which is designed to process data obtained from a stationary nuclear medicine gamma camera system or a mobile nuclear medicine gamma camera system. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	40640012	II	10	applicable	—
Software for SPECT system	A software, which is designed to process data obtained from a nuclear medicine rotating detector SPECT system. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	40642012	II	10	applicable	—
Software for nuclear medicine positron emission tomography system	A software, which is designed to process data obtained from a nuclear medicine positron emission tomography system. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	40644012	II	10	applicable	—
Software for ultrasound imaging system	A software, which is designed to process data obtained from an ultrasound imaging system. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	36208012	II	10	applicable	—
Software for bone absorptiometer ultrasound system	A software, which is designed to process data obtained from a bone absorptiometer ultrasound system. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	40779012	II	10	applicable	—
Software for MRI system	A software, which is designed to process data obtained from the following devices: resistive magnet mammographic MRI system, resistive magnet whole body MRI system, resistive magnet head/extremity imaging MRI system, resistive magnet cardiovascular MRI system, superconducting magnet mammographic MRI system,	37611012	II	10	applicable	—

Software for computed radiography	A software, which is designed to process data obtained from a computed radiography. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	70023012	II	10	applicable	—
Software for X-ray flat-panel detector-recorded digital radiography	A software, which is designed to process data obtained from an X-ray flat-panel detector-recorded digital radiography. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored used by the software.	70026012	II	10	applicable	—
Software for continuous measurement electronic thermometer	A software for medical device, which is designed to process data obtained from a continuous measurement electronic thermometer. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	14032032	II	10	applicable	—
Software for zero heat flow method thermometer	A software, which is designed to process data obtained from a zero heat flow method thermometer. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	70043012	II	10	applicable	—
Software for ear infrared thermometer	A software, which is designed to process data obtained from an ear infrared thermometer. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	17887012	II	10	applicable	—
Software for automatic electronic sphygmomanometer	A software for medical device, which is designed to process data obtained from a automatic electronic sphygmomanometer or a manually-operated electronic sphygmomanometer. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	16173022	II	10	applicable	—
Software for medical electronic sphygmomanometer	A software, which is designed to process data obtained from a medical electronic sphygmomanometer. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	16173032	II	10	applicable	—
Software for ultrasonic fetal heart detector	A software, which is designed to process data obtained from an ultrasonic fetal heart detector. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	35068012	II	10	applicable	—
Software for general-purpose electrocardiograph	A software, which is designed to process data obtained from a general-purpose electrocardiograph or a multi-function electrocardiograph. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	11407042	II	10	applicable	—
Software for visual evoked response stimulator	A software, which is designed to process data obtained from a visual evoked response stimulator. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	11407052	II	10	applicable	—
Software for auditory evoked response stimulator	A software for medical device, which is designed to process data obtained from an auditory evoked response stimulator. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	35368012	II	10	applicable	—
Software for auditory-evoked response audiometer	A software for medical device, which is designed to process data obtained from an auditory evoked response audiometer. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	35747032	II	10	applicable	—
Software for electromyograph	A software, which is designed to process data obtained from an electromyograph. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	11474012	II	10	applicable	—

Software for electrically-evoked response stimulator	A software for medical device, which is designed to process data obtained from an electrically-evoked response stimulator. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	32516012	II	10	applicable	—
Software for facial nerve stimulator	A software, which is designed to process data obtained from a facial nerve stimulator. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	35724012	II	10	applicable	—
Software for somatosensory nerve electrical stimulator	A software, which is designed to process data obtained from a somatosensory nerve electrical stimulator. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	35726012	II	10	applicable	—
Software for diagnostic neuromuscular electrical stimulator	A software, which is designed to process data obtained from a diagnostic neuromuscular electrical stimulator. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	35729012	II	10	applicable	—
Software for evoked response computer	A software, which is designed to process data obtained from an evoked response computer. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	70068012	II	10	applicable	—
Software for electronystagmograph	A software, which is designed to process data obtained from an electronystagmograph. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	11479012	II	10	applicable	—
Software for electroretinograph	A software, which is designed to process data obtained from an electroretinograph. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	11482012	II	10	applicable	—
Software for visual evoked response computer	A software, which is designed to process data obtained from a visual evoked response computer. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	70071012	II	10	applicable	—
Software for electrooculograph	A software, which is designed to process data obtained from an electrooculograph. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	11480012	II	10	applicable	—
Software for nerve function monitor	A software for medical device, which is designed to process data obtained from a nerve function monitor. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	36081012	II	10	applicable	—
Software for objective audiometry device	A software, which is designed to process data obtained from an objective audiometry device. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	11614012	II	10	applicable	—
Software for auditory evoked response audiometer with oto-acoustic emission measurement function	A software for medical device, which is designed to process data obtained from an auditory evoked response audiometer with oto-acoustic emission measurement function. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	35747042	II	10	applicable	—
Software for nerve locator/stimulator	A software, which is designed to process data obtained from a nerve locator stimulator. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	35723012	II	10	applicable	—
Software for optokinetic stimulator	A software, which is designed to process data obtained from an optokinetic stimulator. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	70101012	II	10	applicable	—

Software for carbon dioxide gas analyser	A software, which is designed to process data obtained from a carbon dioxide gas analyzer. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	31339012	II	10	applicable	—
Software for capnometer	A software, which is designed to process data obtained from a capnometer. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	17148062	II	10	applicable	—
Software for pulse oximeter	A software, which is designed to process data obtained from a pulse oximeter. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	17148072	II	10	applicable	—
Software for multi-gas monitor	A software for medical device, which is designed to process data obtained from a multi-gas monitor. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	70085012	II	10	applicable	—
Software for pulse oximeter/capnometer	A software, which is designed to process data obtained from a pulse oximeter/capnometer. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	17148082	II	10	applicable	—
Software for functional oximeter	A software, which is designed to process data obtained from a functional oximeter. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	70080012	II	10	applicable	—
Software for adult pulmonary function analyser	A software, which is designed to process data obtained from an adult pulmonary function analyzer. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	35282032	II	10	applicable	—
Software for pulmonary exercise stress monitoring system	A software, which is designed to process data obtained from a pulmonary exercise stress monitoring system. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	36146012	II	10	applicable	—
Software for noise generating audiometer	A software, which is designed to process data obtained from a noise generating audiometer. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	31939012	II	10	applicable	—
Software for visual reinforcement audiometer	A software, which is designed to process data obtained from a visual reinforcement audiometer. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	34013012	II	10	applicable	—
Software for pure-tone audiometer	A software for medical device, which is designed to process data obtained from a pure-tone audiometer. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	37503012	II	10	applicable	—
Software for speech audiometer	A software, which is designed to process data obtained from a speech audiometer. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	41188012	II	10	applicable	—
Software for audiometer	A software, which is designed to process data obtained from a manually-operated audiometer, automatic-recording audiometer, or computer-controlled audiometer. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	41184012	II	10	applicable	—

Software for impedance audiometer	A software, which is designed to process data obtained from an impedance audiometer. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	36717032	II	10	applicable	—
Software for impedance audiometer with pure-tone and speech audiometric functions	A software for medical device, which is designed to process data obtained from an impedance audiometer with pure-tone and speech audiometric functions. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	36717042	II	10	applicable	—
Software for fundus camera	A software, which is designed to process data obtained from a fundus camera. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	10551012	II	10	applicable	—
Software for ophthalmic camera	A software, which is designed to process data obtained from an ophthalmic camera. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	16419012	II	10	applicable	—
Software for ultrasound endoscopic observation system	A software, which is designed to process data obtained from an ultrasound endoscopic observation system. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	70159012	II	10	applicable	—
Software for home use massager	A software, which is designed to process data obtained from a home use electric massager, a home use pneumatically-powered massager, or a home use suction massager. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	34662012	II	10	applicable	—
Software for electric massager with needles and a protection pipe	A software, which is designed to process data obtained from an electric massager with needles and a protective pipe. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	70979012	II	10	applicable	—
Software for home use low-frequency therapy equipment	A software, which is designed to process data obtained from home use low-frequency therapy equipment. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	70986012	II	10	applicable	—
Software for X-ray/CT combined cardiovascular diagnostic X-ray system	A software, which is designed to process data obtained from an X-ray/CT combined cardiovascular diagnostic X-ray system. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	70003012	II	10	applicable	—
Software for long-term electrocardiographic data recorder	A software, which is designed to process data obtained from a long-term electrocardiographic data recorder. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	35162012	II	10	applicable	—
Software for ECG recorder with real-time analysis	A software, which is designed to process data obtained from an ECG recorder with real-time analysis. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	70063012	II	10	applicable	—
Software for transcutaneous blood gas analyzer	A software, which is designed to process data obtained from a transcutaneous blood gas analyzer. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	36346012	II	10	applicable	—
Software for oto-acoustic emission instrument	A software, which is designed to process data obtained from an oto-acoustic emission instrument. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	36908012	II	10	applicable	—

Software for phonatory function testing equipment	A software, which is designed to process data obtained from phonatory function testing equipment. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	70103012	II	10	applicable	—
Software for cardiac event recorder	A software, which is designed to process data obtained from a cardiac event recorder. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	70067012	II	10	applicable	—
Software for electroencephalograph	A software, which is designed to process data obtained from an electroencephalograph. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	11467032	II	10	applicable	—
Software for transcutaneous blood gas analyzer/pulse oximeter combined biophenomena monitoring equipment	A software, which is designed to process data obtained from transcutaneous blood gas analyzer/pulse oximeter combined biophenomena monitoring equipment. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	17148092	II	10	applicable	—
Software for transcutaneous blood gas sensor/pulse oximeter probe combined biophenomena monitoring equipment	A software, which is designed to process data obtained from transcutaneous blood gas sensor/pulse oximeter probe combined biophenomena monitoring equipment. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	17148002	II	10	applicable	—
Software for Eustachian tube function testing instrument	A software, which is designed to process data obtained from an Eustachian tube function testing instrument. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	70097012	II	10	applicable	—
Software for X-ray/CT combined positron CT system	A software, which is designed to process data obtained from an X-ray/CT combined positron CT system. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	70010042	II	10	applicable	—
Software for positron CT combined SPECT system	A software, which is designed to process data obtained from a positron CT combined SPECT system. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	70010052	II	10	applicable	—
Software for Holter analyser	A software, which is designed to process data obtained from a Holter analyzer. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	36827012	II	10	applicable	—
Software for powered liquid crystal thermography system	A software, which is designed to process data obtained from a powered liquid crystal thermography system. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	40798012	II	10	applicable	—
Software for nuclear medicine system workstation	A software, which configures a nuclear medicine system workstation and further processes the data obtained. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	40937012	II	10	applicable	—
Software for MRI system workstation	A software, which configures an MRI system workstation and further processes the data obtained. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	40940012	II	10	applicable	—
Software for diagnostic X-ray imaging system workstation	A software, which configures an X-ray imaging system workstation and further processes the data obtained. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	40935012	II	10	applicable	—
Software for ultrasound imaging system workstation	A software, which configures an ultrasound imaging system workstation and further processes the data obtained. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	40936012	II	10	applicable	—

Software for general-purpose imaging system workstation	A software, which configures a general-purpose imaging system workstation and further processes the data obtained. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	70030012	II	10	applicable	—
Software for X-ray/CT combined SPECT system	A software, which is designed to process data obtained from an X-ray/CT combined SPECT system. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	70010062	II	10	applicable	—
Software for electronic stethoscope	A software, which is designed to process data obtained from an electronic stethoscope. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	13754012	II	10	applicable	—
Software for ECG telephonic transmission equipment	A software, which is designed to process data obtained from ECG telephonic transmission equipment. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	70064012	II	10	applicable	—
Software for fetal auditory evoked response stimulator	A software, which is designed to process data obtained from a fetal auditory evoked response stimulator. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	36159012	II	10	applicable	—
Software for nasal resistance unit	A software for medical device, which is designed to process data obtained from a nasal resistance unit. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	17228012	II	10	applicable	—
Software for biomechanic platform system	A software, which is designed to process data obtained from a biomechanical platform system. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	17242012	II	10	applicable	—
Software for laryngostroboscope	A software, which is designed to process data obtained from a laryngostroboscope unit or a laryngostroboscope. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	31923012	II	10	applicable	—
Software for nuclear medicine annular SPECT system	A software, which is designed to process data obtained from a nuclear medicine annular SPECT system. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	40643012	II	10	applicable	—
Software for radionuclide dynamic function testing equipment	A software, which is designed to process data obtained from radionuclide dynamic function testing equipment. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	70008012	II	10	applicable	—
Software for film-recorded digital radiography	A software, which is designed to process data obtained from a film-recorded digital radiography. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	70024012	II	10	applicable	—
Software for electronically recorded digital radiography	A software for medical device, which is designed to process data obtained from an electronically recorded digital radiography. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	70025012	II	10	applicable	—
Software for counterpressure sphygmomanometer	A software, which is designed to process data obtained from a counterpressure sphygmomanometer. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	16986012	II	10	applicable	—
Software for pressure/pulse wave testing equipment	A software, which is designed to process data obtained from pressure/pulse wave equipment for use in diagnosis. This term may involve the recording media where the software are stored.	70045012	II	10	applicable	—

Software for magnetoencephalograph	A software for medical device, which is designed to process data obtained from a magnetoencephalograph. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	70048012	II	10	applicable	—
Software for thermal dilution cardiac output unit	A software, which is designed to process data obtained from a thermal dilution cardiac output unit and a thermal dilution cardiac output unit with thermal coil. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	10615032	II	10	applicable	—
Software for dye dilution cardiac output calculator	A software, which is designed to process data obtained from a dye dilution cardiac output unit. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	16177012	II	10	applicable	—
Software for impedance cardiac output unit	A software, which is designed to process data obtained from an impedance cardiac output unit. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	17496012	II	10	applicable	—
Software for arterial waveform cardiac output unit	A software, which is designed to process data obtained from an arterial waveform cardiac output unit. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	70050012	II	10	applicable	—
Software for pulse contour cardiac output unit	A software, which is designed to process data obtained from a pulse contour cardiac output unit. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	70051012	II	10	applicable	—
Software for pulse contour cardiac output unit	A software, which is designed to process data obtained from a sleep assessment device. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	33843012	II	10	applicable	—
Software for ultrasonic blood flowmeter	A software, which is designed to process data obtained from an ultrasonic blood flowmeter. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	10432012	II	10	applicable	—
Software for urodynamic measurement system	A software, which is designed to process data obtained from a urodynamic measurement system. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	14307012	II	10	applicable	—
Software for whole body plethysmograph	A software for medical device, which is designed to process data obtained from a whole body plethysmograph. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	35242012	II	10	applicable	—
Software for cardiac stress exercise monitoring system	A software, which is designed to process data obtained from a cardiac stress exercise monitoring system. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	36145012	II	10	applicable	—
Software for ECG and blood pressure Holter recorder	A software, which is designed to process data obtained from an ECG and blood pressure Holter recorder. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	70066012	II	10	applicable	—
Software for magnetic stimulator	A software, which is designed to process data obtained from a magnetic stimulator. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	36902012	II	10	applicable	—
Software for central monitor	A software, which is designed to process data obtained from a central monitor. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	38470012	II	10	applicable	—

Software for noninvasive blood pressure monitor	A software, which is designed to process data obtained from a noninvasive blood pressure monitor. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	31681012	II	10	applicable	—
Software for multiparameter monitor	A software for medical device, which is designed to process data obtained from a multiparameter monitor. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	33586012	II	10	applicable	—
Software for respiration monitor	A software, which is designed to process data obtained from a respiration monitor. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	35194012	II	10	applicable	—
Software for electrocardiographic monitor	A software, which is designed to process data obtained from an electrocardiographic monitor. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	35195012	II	10	applicable	—
Software for electroencephalographic monitor	A software for medical device, which is designed to process data obtained from an electroencephalographic monitor. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	35196012	II	10	applicable	—
Software for transportable multiparameter monitor	A software, which is designed to process data obtained from a transportable multiparameter monitor. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	36872012	II	10	applicable	—
Software for intracardiac oximeter	A software for medical device, which is designed to process data obtained from an intracardiac oximeter. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	15200012	II	10	applicable	—
Software for invasive blood pressure monitor	A software, which is designed to process data obtained from an invasive blood pressure monitor. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	31692012	II	10	applicable	—
Software for telemetry electrocardiograph	A software, which is designed to process data obtained from a telemetry electrocardiograph. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	31733012	II	10	applicable	—
Software for telemetry electroencephalograph	A software, which is designed to process data obtained from a telemetry electroencephalograph. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	35626012	II	10	applicable	—
Software for telemetry physiological signal system	A software, which is designed to process data obtained from a telemetry physiological signal system. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	32547012	II	10	applicable	—
Software for respiratory resistance meter	A software which is designed to process data obtained from a respiratory resistance meter. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	70079032	II	10	applicable	—
Software for powered diagnostic spirometer	A software, which is designed to process data obtained from a powered diagnostic spirometer. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	13680012	II	10	applicable	—

Software for respiratory function measuring system	A software, which is designed to process data obtained from a respiratory function measuring system. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	35282042	II	10	applicable	—
Software for automatic perimeter/ophthalmic camera	A software, which is designed to process data obtained from an automatic perimeter/ophthalmic camera. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	16918012	II	10	applicable	—
Software for neuropathological diagnostic quantitative sensory tester	A software, which is designed to process data obtained from a neuropathological diagnostic quantitative sensory tester. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	37349012	II	10	applicable	—
Software for vestibular function caloric stimulator	A software, which is designed to process data obtained from a vestibular function caloric stimulator. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	34891012	II	10	applicable	—
Software for electrogustometer	A software, which is designed to process data obtained from an electrogustometer. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	70100012	II	10	applicable	—
Software for body composition analyser	A software for medical device, which is designed to process data obtained from a body composition analyzer. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	36022032	II	10	applicable	—
Software for endoscope contour detector device	A software, which is designed to process data obtained from an endoscope contour detector device. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	70161012	II	10	applicable	—
Software for dental diagnostic intraoral camera	A software for medical device, which is designed to process data obtained from a dental diagnostic intraoral camera. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	70180012	II	10	applicable	—
Software for X-ray bone absorptiometer	A software, which is designed to process data obtained from the following devices: single-energy X-ray bone absorptiometer, single-energy integral X-ray bone absorptiometer, dual-energy X-ray bone absorptiometer, and dual-energy integral X-ray bone absorptiometer. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	37625032	II	10	applicable	—
Software for skin infrared thermometer	A software, which is designed to process data obtained from a skin infrared thermometer. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	17888012	II	10	applicable	—
Software for vector cardiograph	A software for medical device, which is designed to process data obtained from a vector cardiograph. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	14345012	II	10	applicable	—
Software for electrocardiograph with ultrasonic diagnostic system	A software, which is designed to process data obtained from an electrocardiograph with ultrasound diagnostic system. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	11407062	II	10	applicable	—
Software for eye movement testing equipment	A software, which is designed to process data obtained from eye movement testing equipment. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	70093012	II	10	applicable	—

Software for surgical navigation unit	A software, which is designed to process data obtained from a surgical navigation unit. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	38723032	II	10	applicable	—
Software for MRI-combined positron CT system	A software, which is designed to process data obtained from an MRI-combined positron CT system. The resultant data are provided for diagnosis, etc. This term may involve the recording media where the software are stored.	58250012	II	10	applicable	—
Feeding tube supporting system	A device that follows the location of a tip of the intestinal feeding tube inserted into the body and displays the location on a monitor screen in order to support insertion and placement of the feeding tube. It detects magnetism generated from the intestinal feeding tube or from a magnetic field generation unit connected to a stylet inserted in the feeding tube and follows the location of the tube.	59078002	II	10-①	applicable	applicable
Ozone gas disinfectant	A device that disinfects or sterilizes medical devices and medical facilities using ozone gas as a disinfectant to deactivate microorganisms.	46087002	II	15	applicable	N/A
Single-use intradermal injection needle SUD	A device with a sharp, hollow needle specifically designed to facilitate and secure the intradermal injection of drugs including vaccines. This device is for single-use.	12745012	II	6	applicable	—
Stop cock bulb for active device	A device used with a medical tube or pipeline that controls the direction of the flow of a liquid or gas. This product is connected to an active device.	37357002	II	2-①	applicable	N/A
Supporting software for respiratory treatment	A software that collects and stores the treatment information obtained from a ventilator, etc. and assists a physician to assess the treatment effect on the patient, or prepare or change a prescription. This term may involve the recording media where	71040002	II	10	applicable	—
Software for bone density	A software that calculates bone density, etc. in order to obtain bone-related information based on the information collected from CT system, etc. This term may involve the recording media where the software are stored.	71041002	II	10	applicable	—
Supporting software for selecting CL	A software that derives values to establish a standard for contact lenses, etc. based on information collected from a refractometer, a keratometer, a corneal topography system, etc. and supports contact lens selection by a physician. This term may involve	71042002	II	10	applicable	—
Supporting software for dental implant treatment	A software that supports preparation of a dental implant treatment plan based on information collected from diagnostic imaging systems in dental implant treatment. This term may involve the recording media where the software are stored.	71043002	II	10	applicable	—
Supporting software for dental orthodontics treatment	A software, that assists diagnosis in orthodontics and supports preparation of an orthodontics plan based on information collected from diagnostic imaging systems in dental orthodontic treatment. This term may involve the recording media where the software are stored.	71044002	II	10	applicable	—
Supporting software for external fixators treatment plan	A software that analyzes information useful for bone fracture and for correction of bone deformities based on information collected from diagnostic X-ray systems, etc. or based on information entered in a therapeutic apparatus, and supports preparation of a treatment plan with external fixators. This term may involve the recording media	58120002	II	10	applicable	—
Diagnostic supporting software for diabetes	A software that supports analysis and assessment of therapeutic effects of diabetes treatment by processing information collected from a blood glucose meter, etc into the data related to changes or trends in blood glucose levels. This term may involve the recording media where the software are stored.	71045002	II	10	applicable	—

Evaluation software for peripheral blood flow	A software that supports assessment of the presence or absence of impairment of peripheral blood flow, and the severity of the impairment, based on information collected from a rheometer, etc. This term may involve the recording media where the	71046002	II	10	applicable	—
Quantitative calculation software for IGC test	A software that performs quantitative calculation of blood flow in relation to a brightness time change based on information obtained from video images of indocyanine green angiography. This term may involve the recording media where the software are stored. However, it excludes those that correspond to the "software for	71047002	II	10	applicable	—
Navigation system for intravenous catheter placement	A navigation apparatus for supporting percutaneous insertion and placement of a central intravenous catheter by indicating the direction of movement and the last location of placement of the catheter based on the magnetic field and information	61667002	II	6,7	applicable	applicable
Single-use electrical tissue peeling in general surgery	An electric device used for tissue peeling in general surgery. This device is for single-use.	71048002	II	6	applicable	—
Physiological signal use motion function improvement supporting system	An active device that exercises the joints based on biological signals to obtain functional improvement.	71049002	II	9	applicable	applicable
Safety valve for heart-lung bypass	A safety valve, which is one of the components of a heart-lung bypass system, connected to the blood delivery side of the centrifugal pump when the pump is operated, to prevent blood regurgitation from occurring in association with stopping of centrifugal pump operation. This device is for single-use.	17581012	II	2-①	applicable	—
Single-use auxiliary tool for valvuloplasty	A surgical device used in valvuloplasty. It is used as a template when an artificial tendinous cord is formed. This device is for single-use.	71053002	II	7	applicable	—
Single-use guides for automatic suture	A device that is connected to an automatic suture device and guides the needle to the correct location, such as the dorsal side of the cleavage site, without causing damage to the vessel. This device is for single-use.	71054002	II	6,7	applicable	—
Washing catheter for bronchovesicular lavage	A flexible tube used for specimen collection from bronchoalveolar lavage fluid.	32158002	II	5-②	applicable	—
Analyzing software for hemodynamics or cardiac function	A medical device program that analyzes hemodynamics or cardiac function based on information obtained from diagnostic imaging systems, etc. and uses the results for diagnosis. This term may involve the recording media where the software are stored	61213002	II	10	applicable	—
Closed drug transfer system	A system used to prevent scatter or leakage of a drug including carcinostatic agent from environment by connecting containers when transferring the drug from one container to another drug solution container. It has a mechanism to control the differential pressure of inside and outside the container.	71055002	II	2-①	applicable	—

Compression device for transtympanic micropressure	An electric device used to pressurize the middle ear by air vibration. This device is mainly used by the patient at home under the direction of a doctor, to reduce vertiginous attack arising from delayed endolymphatic hydrops or Ménière's disease.	47542002	II	9	applicable	N/A
Diagnostic assistant device for pathological whole slide image	A device used to process the pathological images that assist pathological diagnosis and support preparation of a treatment plan through the storage, display, and capture of high magnification images of whole pathological slide samples (pathological whole slide images).	15132012	II	10	applicable	applicable
Cranial reshaping orthotic helmet	A helmet-shaped device used to correct deformed cranial bone of infant. It is designed and manufactured to fit an individual patient.	62265003	II	—	applicable	—
Rectal plug	A device inserted into the rectum via the anus, to prevent leakage of intestinal contents to the outside the body. It is used for a patient with fecal incontinence or gas incontinence.	46193002	II	5-②	applicable	—
Metal material for dental three-dimensional additive manufacturing	A metal material for three-dimensional additive manufacturing mainly used for fabrication of dental restorations and appliances.	71060002	II	8-①	applicable	—
Artificial nose for inhalational anesthetic administration	A passive, non-active, canister-shaped apparatus used to administer the vaporized inhalational anesthetic via inspiratory air in addition to remove foreign bodies and captures and use heat and moisture in exhaled air to heat and humidify inspiratory air when it is connected in line with the patient's artificial airway.	71064002	II	5-⑥	applicable	—

Load sensor unit for artificial joint replacement	An instrument used to assist surgeon during artificial joint replacement. Usually it consists of sensor computer system, etc., and the sensor is placed directly into a surgical site during surgery. It displays the location of loads and dynamics in proportion to the level of movement.	58988002	II	6	applicable	—
Invasive head fixation device for neurosurgery	A device used for fixation or support the patient's head during a neurosurgical surgery or radiotherapy. It is equipped with functions to perform procedure such as stereotaxic craniotomy with precision. It consists of a frame to which surgical device, etc. are attached, and bolts to fix the patient's head invasively to the frame.	35361002	II	7	applicable	N/A
Eyelid heating pressure device	A device used to heat or pressurize on the eyelid or the periocular with, for instance, electric heat and air pressure.	71072002	II	9	applicable	applicable
Supporting software for root canal	A software for medical device, which is used to support preparation of a treatment	71073002	II	10	applicable	—
Analyzer for hemodynamics or cardiac function	A device that analyzes hemodynamics or cardiac function based on information obtained from diagnostic imaging systems, etc., and uses the result for diagnosis.	71075002	II	10	applicable	applicable
ICG fluorescence imaging view box	A device used in fluorescence imaging offered to make a diagnosis, etc. during indocyanine green angiography. Some have a near infrared camera to take fluorescent images or device for projecting contrast images.	71076002	II	10	applicable	applicable
Retinal scanning laser glasses	A device that corrects vision by scanning retina and projecting images onto the retina using laser light. For example, it consists of a light source that outputs laser light and an optical scanning unit that scans the retina with laser light.	71079002	II	9	applicable	applicable
Supporting software for detecting lesion with endoscopic imaging	A software, which is designed to process data obtained from endoscopic image. The resultant data are provided for diagnostics, etc. It has a function for detecting lesion candidates. This term may involve the recording media where the software are stored.	71080002	II	10	applicable	—
Reprocessed cuff for pneumatically-powered massager	A cuff for a pneumatically-powered massager used for the non-invasive treatment of venous disorders. The device facilitates venous blood flow by applying stimuli that stimulate muscle contraction. It is used to apply counter pressure to the arms or legs of patients. Usually, the device is used for the treatment of leg edema. The device is a single-chamber, pneumatic stocking system. The entire chamber regularly inflates and deflates to provide rhythmic compression of a limb. This product is a reprocessed single-use device of cuff for pneumatically-powered massager that is intended to be used only once.	71084002	II	1	applicable	—
Pelvic-organ-supporting pessary	A circular device made of silicone or plastic material, etc. that is placed in the vagina and used to mechanically support pelvic organs. This may be a reusable device.	34149002	II	5-②	applicable	—
Reprocessed single-use natural orifices endoscopic dilator	A device used to dilate the tube cavity, body cavity and lumen in order to secure or facilitate the insertion of an endoscopic device. Dilation is performed from a natural orifice of the human body, in the urethra or urinary tract, for example. It is a flexible or rigid rod or tube. This product is a reprocessed single-use device.	38821102	II	5-①	applicable	—
Visual field securing gel for natural orifices endoscope	A transparent gel that secures the visual field during endoscopic treatment or endoscopy by being injected through an endoscope inserted into a natural orifice of the human body. It assists endoscopic viewing and intervention.	71085002	II	5-②	applicable	—

Design support software for dental restorations	A software, which supports design of dental restorations by a dentist based on information collected from diagnostic imaging systems, etc. This term may involve the recording media where the software are stored.	50484002	II	10	applicable	—
Smoking cessation treatment support system	A system that includes an analyzer for measuring expired carbon monoxide concentration and a software that assists smoking cessation treatment by promoting behavioral modification.	71087002	II	10	applicable	applicable
Software for home use electrocardiograph	A software for home use, which is designed to process ECG information obtained from general-purpose devices. The resultant data are provided for supporting the detection of signs of disease. This term may involve the recording media where the software are stored.	47699002	II	10	applicable	—
Software for home use heart rate monitor	A software for home use, which is designed to process heart rate information obtained from general-purpose devices. The resultant data are provided for supporting the detection of signs of disease. This term may involve the recording media where the software are stored.	58884002	II	10	applicable	—
Amyloid β mass spectrometry set	A set of mass spectrometry testing that measures peptides (amyloid β peptides, etc.) derived from amyloid precursor proteins from samples of biological materials. It consists of pretreatment reagents and analyzing software.	71088002	II	10	applicable	—
Reprocessed thoracic trocar	A surgical device with a sharp pyramidal or conical tip used to puncture the body cavity during chest surgery. A trocar assembly can be introduced in combination with a compatible sleeve filling lumen of the trocar. Removing the trocar after puncture creates a working channel into the body cavity. This product is a reprocessed single-use device.	70218002	II	6	applicable	—
Reprocessed single-use trocar sleeve	A plastic sleeve used together with a trocar during puncture of a body cavity. Removing the trocar after puncture creates a working channel into the body cavity. The sleeve may have a shut-off valve or port for supplying gas or liquid. Some products do not require a trocar for use. The sizes and designs vary. The sleeve comes with accessories that are required for it to function. This product is a reprocessed single-use medical device.	61813002	II	6	applicable	—
Reprocessed abdominal trocar	A surgical device with a sharp pyramidal or conical tip used to puncture the abdominal wall. A trocar assembly can be introduced in combination with a sleeve filling lumen of the trocar. Removing the trocar after the puncture creates a working channel into the body cavity. This product is a reprocessed single-use device.	61814002	II	7	applicable	—
Reprocessed reducer for trocar	A device to be attached to a trocar sleeve. It reduces gas leakage during the procedure, and keeps the body cavity airtight. This product is a reprocessed single-use device.	70225002	II	—	applicable	—
Supporting software for size estimation with endoscopic imaging	A software for a medical device used for diagnosis, etc. by computing endoscopic image information to measure or estimate the size of objects in the endoscopic image. It has a function of indicating the size of the objects in numeric values. It may also include a recording media, etc. on which the software is recorded.	71092002	II	10	applicable	—
Endoscope tissue diagnostic information processing unit	A device that processes image information obtained from a video endoscope or endoscopic video camera and uses it for diagnosis and other purposes. It has a function to calculate and display tissue diagnostic information such as tissue oxygen saturation from endoscopic images.	71096002	II	10	applicable	applicable
Home-use nasal mucosal protector	A poorly absorbable material to protect nasal mucosa from antigens, etc. It is intended for long-term use.	60371002	II	5-⑤	applicable	—

Probe cover for body surface ultrasonic	A device applied to an ultrasonic probe to protect it from body fluid and dirt when the probe is used on the body surface. It includes a device applied to the ultrasonic probe to confirm the insertion direction of puncture needle, or a device used for attaching instruments for guiding the insertion direction of puncture needle to the ultrasonic probe or the like.	70014000	I	1	applicable	—
Grid for MRI	A grid used for position the puncture site etc. when biopsying under the magnetic resonance imaging (MRI) guide.	70022000	I	1	applicable	N/A
Collimator for motorized automatic aperture control diagnostic X-ray system	A beam forming/limiting device equipped with a shutter system with an automatic control motor. It is designed to adjust the shutter and limit the X-ray beam to the size of the film cassette in the holder. A collimator assembly can be attached to the beam emission port of the X - ray tube housing assembly. Generally, it is equipped with a light localizer which projects a light field consistent with the X-ray beam onto the patient's body, and places the X - ray tube on the center of the film cassette. The X - ray collimator reduce the impact of scattered radiation that could affect the quality of	33136000	I	12	applicable	applicable
Collimator for motorized manual aperture control diagnostic X-ray system	A X-ray beam forming/limiting device equipped with a motor-equipped shutter/length control system. The operator should manually adjust the length of the collimator shutter or the cone, and limit the size and the configuration of X-ray beam to the size of the X - ray cassette to be used prior to irradiation. Most of the motor-equipped collimator assemblies are equipped with a light localizer. The X - ray collimator reduce the impact of scattered radiation that could affect the quality of image, and to protect patients, it inhibits or eliminates the radiation reaching body parts other than the	42252000	I	12	applicable	applicable
Collimator for non-motorized manual aperture control diagnostic X-ray system	A X-ray beam limiting device without a motor. Aperture size/length/shutter assembly should be manually adjusted to limit the size of the X-ray beam to the size of the X - ray cassette to be used. The device has been designed to allow manual control to operate more than a pair of shutters. It has also been designed to allow the addition or removal of an accessory device and an extension device so that the operator can change	42253000	I	1	applicable	applicable
X-ray tube support floor stand	A hardware assembly consisting of a floor support stand and associated mechanical, electronic, or software control. It constitutes the structure used for installation, retention, and position adjustment of the X - ray tube device, an accessory of the X -	37076000	I	12	applicable	applicable
Ceiling mount X-ray tube support	A ceiling-mounted metal fitting assembly and associated mechanical, electronic, or software control. It constitutes the structure used for the installation, retention, and position adjustment of the X - ray tube device, an accessory of the X - ray device designed for diagnostic X - ray, a therapeutic X - ray device, and a device for positioning the radiotherapy plan. Some are designed to support the radiation cassette or image receptor assembly, and adjust the movement and position to the position of X - ray tube (e.g., C-arm assembly). This device group is categorized as parts or	40946000	I	12	applicable	applicable
Wall mounting X-ray tube support	A wall-mounted metal fitting assembly and associated mechanical, electronic, or software control. It constitutes the structure used for the installation, retention, and position adjustment of the X - ray tube device, an accessory of the X - ray device designed for diagnostic X - ray, a therapeutic X - ray device, and a device for positioning the radiotherapy plan. Some are designed to support the radiation cassette	40947000	I	12	applicable	applicable
Non-powered patient table for general-purpose diagnostic X-ray system	A non-electric patient platform equipped with a fixed posture table or non-electric patient platform equipped with mechanical table positioning control and table height control such as pneumatic control, magnetic lock, crank, and lever. This is designed to adjust and keep the patient's general/plane images that require a general-purpose X	40654000	I	1	applicable	applicable

Powered patient table for general-purpose diagnostic X-ray system	A programmable electric patient platform which is designed to adjust and keep the patient's posture when taking general/planar images that require a general-purpose X-ray device and special diagnostic photography. It is equipped with an electronic control or software control function that controls the height and position of the table. It is	40655000	I	12	applicable	applicable
Non-powered patient table for fluoroscopic diagnostic X-ray system	A non-electric patient platform equipped with a fixed posture table, or a non-electric patient platform equipped with mechanical table top positioning control and table height control such as a pneumatic control magnetic lock, crank, and lever. Designed to position and keep the patient's posture for imaging or intervention that requires a general-purpose X-ray fluoroscopy system. It is either fixed, movable, or incorporated into the design of the general-purpose X-ray system. The device is used only for X-ray	40657000	I	1	applicable	applicable
Powered patient table for fluoroscopic diagnostic X-ray system	A electrically powered patient table to position and keep the patient's posture for imaging or intervention that requires a general-purpose X-ray fluoroscopy system. A programmable electric patient platform equipped with an electronic control or software control function that controls the position, height and movement of the table relative to the X-ray beam. Some are fixed, movable, or incorporated into the design of	40658000	I	12	applicable	applicable
Non-powered patient table for bedside diagnostic X-ray system	A type of non-electric patient bed equipped with a mattress that serves as an X-ray table for bedside X-ray photography. Generally, it is used for controlling severely ill patients and for intensive treatment. Some are equipped with a fixed posture table, and others are equipped with a mechanical table positioning control and table height control such as pneumatic control, magnetic lock, crank, and lever. Made of	40665000	I	1	applicable	applicable
Powered patient table for bedside diagnostic X-ray system	A type of programmable electric patient bed equipped with a mattress that serves as an X-ray table for bedside X-ray photography. Generally, it is used for controlling severely ill patients and for intensive treatment. It is specifically designed to allow bedside X-ray photography for various types of imaging and easy installation of the C-arm, an opening and a mattress. Some are equipped with an electronic control or	40666000	I	12	applicable	applicable
Non-powered patient table for planar tomography diagnostic X-ray system	A non-electric patient platform equipped with a fixed posture table, or a non-electronic patient platform equipped with mechanical table positioning control and table height control such as pneumatic control, magnetic lock, crank, and lever. Designed to position and keep the patient's posture for plane tomography. Either fixed or movable, and made of radiotranslucent materials with a low X-ray attenuation coefficient.	40661000	I	1	applicable	applicable
Powered patient table for planar tomography diagnostic X-ray system	A programmable patient platform for electric X-ray mammography which is equipped with an electronic control or software control function that controls the height and position of the table. It is designed to position and keep the patient's posture for plane tomography. Either fixed or movable, and made of radiotranslucent materials with a low X-ray attenuation coefficient.	40662000	I	12	applicable	applicable
Non-powered patient table for cardiovascular diagnostic X-ray system	A non-electric patient platform equipped with a fixed posture table, or a non-electric patient platform equipped with mechanical table positioning control and table height control such as pneumatic control, magnetic lock, crank, and lever. Designed to position and keep the patient's posture for examinations of the heart and blood vessels	40659000	I	1	applicable	applicable

Powered patient table for cardiovascular diagnostic X-ray system	A programmable electric patient platform equipped with electronic control or software control function that controls the position, height and movement of the table relative to the X-ray beam. Designed to position and retain the patient's posture for examinations of the heart and blood vessels or intervention that requires an X - ray angiography device. Various accessories used for treatment of the heart and other organs (e.g., brain and kidney angiography and intervention under angiography) can be incorporated. Fixed or movable patient platform is available.	40660000	I	12	applicable	applicable
Non-powered patient table for X-ray mammography system	A non-electric patient platform equipped with a fixed posture table top or a non-electric patient platform equipped with mechanical table top positioning control and table height control such as pneumatic control, magnetic lock, crank, and lever. Designed to adjust and keep the patient's posture for X-ray mammography. Fixed or movable, and made of radiotranslucent materials with a low X-ray attenuation coefficient. Some are designed to incorporate various accessories such as an	40663000	I	1	applicable	applicable
Powered patient table for X-ray mammography system	A programmable patient platform for electric X-ray mammography is equipped with electronic control or software control that controls the height and position of the table top, and designed to adjust and keep the patient's posture for X-ray mammography. Fixed or movable, and made of radiotranslucent materials with a low X - ray attenuation coefficient Generally, equipped with special openings and metal clamps for	40664000	I	12	applicable	applicable
X-ray image intensifier	An X-ray image intensifier that converts an X-ray image into an optical image, and further into and electron image, and finally into a size-reduced brightness optical image. It consists of a large vacuum glass container equipped with 4 fundamental sub-systems. The sub-systems comprise an input fluorescent body/fluorescent X-ray	15963000	I	12	applicable	applicable
X-ray television system	A TV camera designed to capture image output using an output fluorescent body of an X-ray image intensifier. It consists of image sensor elements and an electronic circuit, and converts optical images into analog signals or digital signals, etc. Mainly used for a general-purpose fluoroscopic diagnostic device and cardiovascular fluoroscopic diagnostic device.	70027000	I	12	applicable	applicable
X-ray fluoroscopy image recording system photospot camera	A photo camera with an installation/support structure and film magazine designed to directly capture images on photosensitive film from the output fluorescent body of an image intensifier of an X-ray fluoroscopy system. Most photo spot cameras are able to advance frames at short intervals while continuously taking a certain number of images. Generally, 70, 90, or 105 mm film is used.	40964000	I	12	applicable	applicable
Cinefluorographic X-ray fluoroscopy image recording system	A sub-system of an X-ray fluoroscopy system that uses a movie or video camera designed to record continuous X-ray fluoroscopic images using a cinefluorography system, on movie film (Generally 16 mm or 35 mm film) or other media. The cinefluorography system is part of an X-ray fluoroscopy system, and consists of a cinefluorography system (movie camera or video camera), an optomechanical device, film, a developing processor, a projector, and electric machine control video display software.	40965000	I	12	applicable	applicable

X-ray indirect roentgenography camera	A device that converts a subject's fluorescence image generated on the fluorescent plate by X - ray into a reduced image on fluoroscopic film using a mirror and lens.	70028000	I	12	N/A	N/A
X-ray flat panel detector	An X - ray detector with a planar X - ray entry face that detects X - rays that pass through the body and converts them into electric signals. The entering X - rays are absorbed by a fluorescent body or photoconductor, converted into electric signals by pixels inside, and digitally output sequentially. The detector is smaller than an	70029000	I	12	applicable	applicable
Liquid crystal thermography sheet	A non-electric device that generates, displays and analyzes images and graphs of body surface temperature distribution in order to diagnose and evaluate various conditions and symptoms. Sheets made of cholesteric liquid crystal-based material is buried in the outer layer of a blanket, pillow and mattress that surround the body. The material	40798001	I	1	applicable	—
Automatic X-ray film changer	An automatic X - ray film changer is generally one of the components of a diagnostic X - ray device. It is designed to send a cassette, a sheet of X - ray film, or a film roll having a specific size from a supply magazine to a pair of sensitization screens for exposure, and then send it to the receiving bin. Some are controlled by an electric machine or software. Typical main components of an automatic changer for sheet film or roll film include a cassette holder, installation stand, control panel, change mechanism, supply magazine, receiving magazine, control, program selector and other components.	35831000	I	12	applicable	applicable
Bucky device	A device that effectively absorbs scattered X - ray film emitted from an X - ray film subject (patient) by using a grid, and eliminates the stripes by moving the grid to improve the quality of images in diagnostic X - ray photography. The device consists of the main case, grid, grid transfer mechanism and a cassette tray.	70033000	I	12	applicable	applicable
Motorized diagnostic imaging view box	A device equipped with an electric mechanical or software controlled motor that retains, retrieves, and projects light for direct observation of medical images taken using a variety of methods such as X - ray, magnetic resonance (MR), CT, and	35823000	I	12	N/A	N/A
Non-motorized diagnostic imaging view box	A non-motorized device that retains, fixes, and projects light for medical images taken using a variety of methods such as X - ray, magnetic resonance (MR), CT, ultrasound, or nuclear medicine, and recorded in films. A simple structure without a motor, it is	36488000	I	12	N/A	N/A
Diagnostic imaging view box with densitometer	A device to assist interpretation of medical images recorded on X - ray film, and analyzes film density information. The device consists of a film transportation system, stabilized light source, CCD sensor and other optical systems and photoelectric conversion sensors. The device reads bone contrast information from the film, and	70034000	I	1	N/A	N/A
Darkroom automatic radiographic film developer	An automatic film development device that requires manual removal of X - ray film or radiographic film from a cassette and manual installation into a development device in a darkroom. The device is designed to send X - ray film or radiographic film to the liquid developer, and does not require any work other than inserting the film in the film development process. Generally, the device consists of 6 main sub-systems – i. e. , controls for film transfer, temperature, circulation, supplementation, drying, and electricity.	41011000	I	12	applicable	applicable

Darkless automatic radiographic film developer	A bright room development device designed to eliminate the need for a darkroom. The automatic development device is for X - ray film or radiographic film. It automatically loads unused film into a cassette, and sends used film into the automatic film developer of the device. The device consists of the following 6 main sub-systems – i. e. , controls for film transfer, temperature, circulation, supplementation, drying, and electricity– as well as a cassette loader and unloader. Generally, it is designed to be installed on the floor or desk.	41012000	I	12	applicable	applicable
Automatic cine film radiographic film developer	An automatic photographic film development device for 16 mm or 35 mm film rolls used for X-ray fluoroscopic examination (cinefluorography) which are necessary for a movie camera that records the fluorescent body discharged from an image intensifier as a continuous X-ray fluoroscopic image in movie format. Also known as a cine film development device.	41014000	I	12	applicable	applicable
Automatic film developing processor for dental X-Ray film	An automatic Dental X - ray film developing processor. Manual types are excluded.	70035000	I	1	applicable	applicable
Multi-format diagnostic imaging camera	Usually, a camera-based image device that adopts a laser scanning technique. The device captures digital images generated using image diagnosis systems such as CT, MRI, PET, gamma camera, and ultrasound, and reproduces the captured digital image on film in various image formats. It is usually equipped with a function that allows the operator to designate the number of images recorded on one film (multi-formatting). Usually, 1 to 128 images in even numbers can be selected for the number of images recorded on one film.	35580000	I	12	applicable	applicable
Diagnostic imager	An image diagnostic imager captures digital image signals such as CT, MRI, ultrasound, and CR, and reproduces the captured images on image recording film. The image is reproduced on film using a laser beam, or thermal head. The imager generally consists of the image signal processor, a laser scanner and a film developer etc. The multiple image information can be recorded on one film.	70036000	I	12	applicable	applicable
X-ray exposure reduction device	An X-ray control function that is intended to reduce X-ray exposure, including a pulse fluoroscope. It provides an auxiliary function added to an X-ray control device as the component.	70037000	I	12	applicable	applicable

X-ray automatic exposure control	An automatic exposure controller is a software control or electronic control sub-system of a diagnostic X-ray system. It automatically monitors X-ray beams that pass through the body during an examination, and terminates the irradiation when radiation reaches the density sufficient for radiation imaging.	34311000	I	12	applicable	applicable
Patient positioning device for head/neck diagnostic imaging and radiotherapy	A device that consists of fixed or adjustable positioning devices such as frames and plates, and is specifically designed to properly position and fix the patient's head, neck, and cervical spine for image diagnosis and dental X-ray photography. In image-guided surgery, interventional therapy, or radiotherapy, the device is used to easily implement reproducible positioning for continuous image examination or continuous	40898000	I	1	N/A	N/A
Patient positioning device for breast diagnostic imaging and radiotherapy	A device that is specifically designed to properly position and fix a female patient's breasts and chest for image diagnosis, image-guided surgery, interventional therapy, or radiotherapy. The device may come in frames or plates, and is used to facilitate reproducible positioning for continuous image examination or continuous radiotherapy.	40899000	I	1	N/A	N/A
Patient positioning device for extremity diagnostic imaging and radiotherapy	A device that is specifically designed to properly position and fix a patient's arms and legs for image diagnosis, image-guided surgery, interventional therapy, or radiotherapy. The device may come in frames or plates, and is used to facilitate reproducible positioning for continuous image examination or continuous radiotherapy.	40900000	I	1	N/A	N/A
Patient positioning device for pelvis diagnostic imaging and radiotherapy	The device that consists of frames, plates, or other parts, and is specifically designed to properly position and fix the patient's abdomen and pelvic region for image diagnosis, image-guided surgery, interventional therapy, or radiotherapy. The device is also used to facilitate reproducible positioning for continuous image examination or continuous radiotherapy.	40901000	I	1	N/A	N/A
Patient positioning device for whole body diagnostic imaging and radiotherapy	A device that consists of fixed or adjustable parts (e.g., frames and plates), and is specifically designed to properly position and fix the patient's whole body for image diagnosis, image-guided surgery, interventional therapy, or radiotherapy. The device is also used to facilitate reproducible positioning for continuous image examination or continuous radiotherapy.	40902000	I	1	N/A	N/A
X-ray fluorescent screen	A fluorescent screen for an X-ray device and is one of the component of an X-ray fluoroscopy system, and used to allow the observer to directly observe an X - ray image of the patient in real time. It is similar to X-ray intensifying screens, and just like intensifying screen, it consists of relining materials (cardboard, plastic, or metal), reflection layer materials such as titanium dioxide, active layers (calcium tungstate, barium sulfate, or rare-earth materials) and protective layers of the fluorescent body. The light emitted for image formation should have wavelengths that can be seen by the human eye.	37684000	I	1	N/A	—

Photo-stimulable fluorescent screen	A fluorescent screen that stores X - ray energy, and generates fluorescence equivalent to the energy by irradiation of laser beam. Some photostimulable fluorescent screens are combined with a cassette. Usually, the screen is used in combination with a computed radiograph, and a cassette for a photostimulable fluorescent screen.	70038000	I	1	N/A	—
X-ray intensifying screen	A device generally considered as a component of an X - ray film cassette used for X - ray image diagnosis. Used concurrently with emulsion X - ray film. The device consists of a relining material (cardboard, plastic, or metal), a reflection layer made of such materials as titanium dioxide, an active layer made of a fluorescent body (calcium tungstate, barium sulfate, or rare earth), and a protective layer (generally, plastic coating) that prevents static electricity and allows cleaning. It is used to reduce the exposure dose to the patient and shorten the exposure period to minimize motion artifacts on film images.	34317000	I	1	N/A	—
Manually-operated X-ray film cassette	A tool that seals X - ray film and protects it from exposure to room lights when transported to and inserted into an image diagnostic device, film formatting device, or film development device for medical imaging. Generally, it is designed to be used in combination with a specific imaging device and image formatting unit, and consists of	35437000	I	1	N/A	N/A
Automatic film changing X-ray film cassette	An X - ray film cassette designed to be used with an automatic X - ray film changer, and function as a part of the film changer. The cassette is, under specified darkroom conditions, loaded with X - ray film, and attached to the loading magazine of the film changer. The cassette remains inserted into the magazine after exposure until detached by the operator for final processing.	35839000	I	12	N/A	N/A
Photo-stimulable fluorescent screen cassette	A photostimulable fluorescent screen cassette used for X - ray photography. Usually, it is concurrently used with a computed radiograph, or a photostimulable fluorescent screen.	70039000	I	12	N/A	N/A
X-ray grid	A stationary or moving (reciprocating or rotating) grid used for diagnostic X-ray photography such as plain X-ray imaging and mammography. Generally, it consists of a housing (box) that is divided by radiotranslucent spacers (intermediates) and which is filled with aluminum or radiotranslucent organic compounds, and contains pieces of	40914000	I	1	applicable	applicable
Stationary X-ray grid	A component of an X-ray device used for diagnostic X-ray photography such as plain X - ray imaging and mammography. Generally, it consists of a housing (box) that is divided by radiotranslucent spacers (intermediates), and contains pieces of lead foil. These spacers (intermediates) are filled with aluminum or radiotranslucent organic compounds. An X-ray photography grid is placed between the X-ray subject (patient)	40915000	I	1	applicable	applicable
Moving X-ray grid	A component of an X-ray device used for diagnostic X-ray photography. The moving grid is designed to automatically move back and forth in linear or reciprocal movement during one X-ray irradiation or continuous irradiation. Generally, it consists of pieces of lead foil divided by radiotranslucent spacers (intermediates). It is used to absorb scattered X-rays, minimize artifacts, and improve the contrast of X-ray images. Some	40916000	I	1	applicable	applicable

Rotating X-ray grid	A component of an X-ray device used for diagnostic X-ray photography. The rotating X-ray grid is mainly used for continuous photography. It is designed to rotate automatically and continuously during a series of X-ray irradiations. This continuous rotational motion erases shadows caused by lead pieces. It is used to absorb scattered X-rays and reduce artifacts and improve the contrast of X-ray images. It consists of a lead grid and a rotating mechanism.	40917000	I	1	applicable	applicable
Dental X-ray beam alignment device	A mechanical device used to support and place dental X-ray film. In the case of dental X-ray imaging, it is used as a guide for proper physical positioning of the X-ray tube relative to the placed dental X-ray film. Some are designed to serve as a guide for a dental X-ray device used inside or outside the oral cavity.	31828000	I	5-①	N/A	N/A
Dental digital X-ray sensor	An intraoral digital dental X-ray sensor used in combination with a general-purpose dental X-ray imaging device. This category excludes a sensor equipped with a sensor driving circuit or signal processing circuit, and a sensor connected to an active medical device.	70040009	I	5-①	applicable	N/A
Screen medical X-ray/diagnostic imaging film	An X-ray film designed for medical imaging. The film is sensitive to the wavelengths of the light emitted from an intensifying screen or other visible light sources. It is a sheet coated with a photosensitive emulsion composed of particles having sensitivity to X-rays and visible light.	40979000	I	1	N/A	—
Non-screen medical X-ray/diagnostic imaging film	A non-screen type X-ray film designed for medical imaging. Non-screen type films are designed to be exposed directly to X-rays. The sensitivity to visible light emitted from an intensifying screen is relatively low. It is a sheet coated with a photosensitive emulsion that is sensitive to X-rays.	40980000	I	1	N/A	—
Diagnostic imaging cine film	A movie or movie film in various sizes (e.g., 16 mm, 35 mm) specifically designed for medical or dental image diagnosis. In medical image diagnosis, film of this type is often called cine-film.	40982000	I	1	N/A	—
Non-self-developing diagnostic imaging film	A sheet or roll of film (e.g., 70 mm, 90 mm, 100 mm, or 105 mm) specifically designed for medical or dental image diagnosis. A film of this type requires a photo developer in order to develop the images captured in the film.	40984000	I	1	N/A	—
Self-developing diagnostic imaging film	Self-developing photographic films (e.g., instant, Polaroid) specifically designed for medical or dental image diagnosis, which is used with a dedicated camera, and in particular, for the cases where it is useful to confirm whether the obtained result exactly reflects the situation.	40983000	I	1	N/A	—
Screen dental diagnostic imaging X-ray film	Screen-type X-ray film of a predetermined size to be used specifically for a dental X-ray device. Screen type films are designed to be sensitive mainly to the wavelength of light emitted from an intensifying screen. It is a sheet made of a single-sided (single-sided emulsion film) or dual-sided (dual-sided emulsion film) transparent film base.	40977000	I	1	N/A	—
Non-screen dental diagnostic imaging X-ray film	Non-screen type X-ray film of a predetermined size to be used specifically for a dental X-ray device. The non-screen type film is designed to be exposed directly to X-rays, and has relatively weak photosensitivity to visible light emitted from an intensifying screen.	40978000	I	1	N/A	—
Radiation protection apron	A standard length or half-length apron to protect the patient, the operator, and other personnel from radiation exposure during a medical or dental procedure. Some have a fixed or removable collar to protect the neck and thyroid. The apron generally consists of a liquid resistant outer cover that covers a thin sheet made of lead or other materials comparable to lead. For neutron attenuation, the apron is made of hydrogenic materials. For use in beta/gamma-mixed radiation fields, the apron is made of layers of a hydrogenic material and a materials comparable to lead.	38355000	I	1	applicable	N/A
Radiation protection bib	A personal protection device that protects the chest of the patient, the operator, and other personnel from unnecessary radiation exposure during a medical/dental procedure for diagnosis and treatment. Some have a fixed or removable collar to protect the neck and thyroid.	38356000	I	1	applicable	N/A
Radiation protection gloves	A personal protection device that completely protects the hands of the operator and other personnel from unnecessary exposure to primary radiation and scattered radiation associated with diagnosis and therapeutic measures. Each finger is individually protected. Generally, the gloves used for diagnostic X-ray and nuclear medicine are made of lead or other materials comparable to lead.	38364000	I	1	applicable	N/A

Radiation protection mitten	A personal protection device that protects the hands of the operator and other personnel from unnecessary exposure to primary radiation and scattered radiation associated with diagnosis and therapeutic measures. The mittens are also called mitts, and protect the thumb and other fingers individually or together. Generally, the	38365000	I	1	applicable	N/A
Partial hand radiation protector	A flat pad with straps or partial gloves that protect part of hands and fingers from unnecessary exposure to primary radiation and scattered radiation associated with	38366000	I	1	applicable	N/A
Radiation protection goggles	A personal protection device that protects the eyes of the operator and other personnel from unnecessary exposure to primary radiation and scattered radiation associated with medical/dental procedures for diagnosis and treatment. Generally, the device comes in the form of goggles that constitute a single unit equipped with a lenses, side shield, top shield, bottom shield made of glass, plastic, and other materials comparable to lead. The lens and shields serve as a physical barrier that protect the wearer from the radiation emitted from the radiation emitting device.	38360000	I	1	applicable	N/A
Patient radiation protection spectacles	A personal protection device that covers a patient's eyes and protects them from unnecessary exposure to primary radiation and scattered radiation associated with diagnosis and treatment. The protective goggles come in various configurations. Goggles that attenuate photons are made of lead glass, lead, or tungsten. Goggles that attenuate neutrons are made of hydrogenous materials.	38361000	I	1	applicable	N/A
Radiation face protector	A transparent or opaque personal protection device that protects the face and eyes of medical personnel and other personnel from unnecessary exposure to primary radiation and scattered radiation associated with diagnosis and treatment. The device	38363000	I	1	applicable	N/A
Operator radiation protection spectacles	A personal protection device that protects the eyes of the operator and other personnel from unnecessary exposure to primary radiation and scattered radiation associated with diagnosis and treatment. The glasses generally consist of a frame with lenses and side shields made of materials comparable to lead such as glass and plastic. The lenses and the shield also serve as a physical barrier that protects from liquid radioactive	38884000	I	1	applicable	N/A
Gonadal radiation protector	A personal protection device that attenuates unnecessary radiation exposure in diagnostic, medical or dental procedures, and shields the gonad of the patient and the operator. The device comes in various types – e.g. 1). In an anatomical design indicated for the gonad; 2). Directly worn on the body; 3). Installed on the wall or in the radiation emitting device with multi-joint arm. The protectors for the male gonad and female gonad are made of lead or other materials comparable to lead.	38367000	I	1	applicable	N/A
Radiation protection blanket	A personal protection device that protects specific body parts of the patient, operator, and other personnel from unnecessary radiation exposure in medical/dental procedures for diagnosis and treatment. Generally, the blanket used for diagnostic X-ray and nuclear medicine consists of a liquid resistant outer cover that covers a thin sheet made of lead or other materials comparable to lead. The blanket functions	38357000	I	1	applicable	N/A
Radiation protection collar	A personal protection device that protects the neck or thyroid of the patient, the operator, and other personnel from unnecessary radiation exposure in medical/dental procedures for diagnosis and treatment. Some can be used alone or some are designed	38358000	I	1	applicable	N/A
Thyroid gland radiation protector	A radiation protection device specifically designed to shield the thyroid of the patient and the operator etc. from unnecessary radiation exposure from diagnostic drugs or dental procedure. The device forms an attenuation barrier between thyroid and primary radiation source or scattered radiation source. In order to shield the thyroid region of the throat, a structural thyroid protector is also available which is to be	38362000	I	1	applicable	N/A
Stationary radiation protection barrier	A device for permanent installation that forms a structural barrier that shields or attenuates radiation emitted from primary radiation source or scattered radiation source. Usually, the device is equipped with a solid or transparent barrier that protects the patients from unnecessary exposure to radiation emitted from diagnostic and therapeutic radiation emitting devices. The device is also used to protect patients	38374000	I	1	applicable	N/A
Radiation protection cap	A personal protection device that protects the head of the operator and other personnel from unnecessary exposure to primary radiation and scattered radiation associated with medical procedures for diagnosis and treatment.	70041000	I	1	applicable	N/A

Mobile radiation protection barrier	A stand-alone, movable barrier that protects the operator etc. from unnecessary exposure to radiation used for medical diagnosis, treatment and dental procedures. The device forms a physical radiation attenuation barrier between the person and the primary radiation source or scattered radiation source. Most of them have an insertion	38373000	I	1	applicable	N/A
Radiation protection curtain	A flexible radiation protection tool that protects the operator etc. from unnecessary exposure to radiation emitted from the patient and the radiation used for medical or dental procedures. The tool is a flexible radiation shield/attenuation barrier installed between the person and primary radiation source or scattered radiation source. It is	38375000	I	1	applicable	N/A
Chest X-ray photofluorographic protective box	A protective box that surrounds the X - ray source, the mirror camera entry face, and the patient positioned between them so as to protect the operator from radiation scattered from the patient and leaked from the X - ray source during a chest X - ray.	70042000	I	1	applicable	N/A
Compact thermoluminescent dosimetry electrometer	A stand-alone, external detection unit that reads the radiation absorbed by a thermoluminescence dosimeter (TLD) brick. TLD brick is used to measure the radiation dose emitted to the phantom, eyes and other organs with high	37110000	I	1	applicable	N/A
Mercury capillary thermometer	A measuring device that measures the body temperature of the patient. The device is a thin hollow glass tube with both ends sealed. The bulb at the bottom is filled with mercury. The device functions based on the capillary principle. The medium filled in	35397000	I	1	N/A	—
Alcohol capillary thermometer	A measuring device that measures the body temperature of the patient. The device is a thin hollow glass tube with both ends sealed. The bulb at the bottom is filled with colored alcohol. The device functions based on the capillary principle. The medium	34343000	I	1	N/A	—
Colour-indicating thermometer	A measuring device that measures the body temperature of the patient. The device is sealed in the tip of a plastic or metal strip, and indicates the body temperature by using an array of thermochemical cells (dots) that change in color tone according to the recorded body temperature.	35899000	I	1	N/A	—
Reusable thermometer probe	A device is connected to a clinical thermometer, and usually inserted into a body orifice or placed on the body surface to measure the body temperature. The device is indicated for temporary use, and short-term use in the oral cavity up to the pharynx,	37340001	I	5-③	applicable	—
Thermometer sensor conversion adapter	An adaptor that converts thermocouple input signals into thermistor thermometer input signals.	70044000	I	12	applicable	applicable
Aneroid sphygmomanometer	A device that consists of a pressurizable cuff that is wrapped around the arm, a pneumatic pressure adjuster valve for the cuff, and an aneroid manometer.	16156000	I	1	N/A	N/A
Mercury sphygmomanometer	A device that measures the arterial blood pressure indirectly (non-invasively). It consists of an expandable cuff to be wrapped around the arm, and a valve that	16158000	I	1	N/A	N/A
Single-use intravenous line manometer	A sterilized plastic pressure stick connected to an infusion line to measure venous blood pressure using the water manometer method. This device is for single-use.	70046001	I	2	applicable	—
Mechanical stethoscope	A mechanical hearing device used to hear the sound of heart and lungs. Usually, the listening head has a membrane which is connected to the head gear equipped with ear	13755000	I	1	N/A	N/A
Fetal stethoscope	A mechanical hearing device used to listen to the fetal heartbeat. Usually, it is a hollow tube (trumpet shape), and transmits the fetal heartbeat via an inner channel by aerial conduction.	32659000	I	1	N/A	N/A

Esophageal stethoscope	A type of mechanical stethoscope designed to be inserted into the patient's esophagus to listen to the sound of the heart and lungs.	35054000	I	1	N/A	N/A
Percussion hammer	A metal (usually, stainless steel) or wooden device that consists of a handle, a shaft, and a head. Used to transmit a force to the body in order to test a reflex. The handle is designed to fit in the palm, usually round, and tapered to the top. The head is placed at	11950000	I	1	N/A	N/A
Powered percussion hammer	A spring type percussion hammer with a lock and release spring stopper at the piston head. Used to transmit a measured force to the body in order to test a reflex.	32953000	I	12	N/A	N/A
Ploss switching valve	A three-way switching valve installed between the stethoscope applied over the heart, the blood pressure measurement cuff, and ear piece. It eliminates other sounds to focus on one sound (heartbeats or blood pressure).	33213000	I	1	N/A	—
Powered chest percussor	An electric device used to transmit vibrations to the patient's thoracic wall in order to assist elimination of retained mucosa from the lungs and improve fluid discharge from bronchus. It is operated by electricity or compressed gas.	35235000	I	12	N/A	N/A
Intrauterine pressure transducer	A transducer used to measure the pressure in the uterine cavity.	32643000	I	12	applicable	applicable
Sphygmograph	A graphic printer of arterial pulse waveforms. Usually, it is equipped with a lever. The shorter end of the lever is placed on the radial artery on the wrist, and the longer end is equipped with a stylus that records the changing pulses (usually on a moving sheet).	13671000	I	12	applicable	applicable
Pulse wave meter	The device adopts such means as pressure, photoelectricity, strain gauge, and impedance, and displays the waveforms of wave motions that represent the changes of pressure in the blood vessels conveyed toward the periphery when cardiac contraction	70060000	I	12	applicable	applicable
Gas flow transducer	A conductor that converts gas flow rate into electric signals, and sends the signals to a measurement/display device.	31279000	I	12	applicable	N/A
Single-use pulse oximeter probe	A device that is used on the fingers, ear lobes, bridge of the nose, feet, or other parts of pediatric and adult patients, irradiates light via skin, and detects the amount of light absorbed by oxyhemoglobin and deoxyhemoglobin in arterial tissue blood. The base unit receives the signals, and indicates the result. This device is for single-use.	31658000	I	1	applicable	—
Single-use thermometer probe	A device is connected to a clinical thermometer, and usually inserted into a body orifice or placed on the body surface to measure the body temperature. The device is intended for temporary use, and short-term use in the oral cavity up to the pharynx, ear canal up to the tympanic membrane or nasal cavity only. This device is for single-	35254001	I	1	applicable	—
Reusable pulse oximeter probe	A device that is used on the fingers, ear lobes, bridge of the nose, feet, or other parts of pediatric and adult patients, irradiates light via skin, and detects the amount of light absorbed by oxyhemoglobin and deoxyhemoglobin in arterial tissue blood. The base	37808000	I	1	applicable	N/A
Tremor transducer	A device that measures the degree of tremor caused by some diseases.	32546000	I	12	N/A	N/A
Reusable electrocardiograph electrode	A conductor to be placed on the body surface (usually, strapped by a belt using contact gel). It transmits electric signals detected on the body surface to a processing device (cardiac electrical activity is represented as a graph). A general device that records	42489000	I	1	applicable	N/A
Single-use electrocardiograph electrode	A conductor to be placed on the body surface. It transmits electric signals detected on the body surface to a processing device (cardiac electrical activity is represented as a graph). A general device that records this electrical activity is called an electrocardiograph (ECG). This device is for single-use.	35035000	I	1	applicable	—

Electrocardiograph cable or lead	A device that transmits a patient's electrocardiogram signals to an electrocardiograph (ECG). The device is placed on the chest using electrodes according to a specific pattern.	35562010	I	1	N/A	N/A
Radiolucent electrocardiograph cable/lead	A device that transmits a patient's electrocardiogram signals to an electrocardiograph (ECG). The device is placed on the chest using electrodes according to a specific pattern. Some are specifically designed so as to project subtle X - ray images for	36038000	I	1	N/A	N/A
Intracardiac electrocardiograph cable or switch	Cables or switches are externally connected to a guide wire and catheter inserted into the central vein, and transmit cardiac electric signals from the patient to an external monitor (e.g., electrocardiograph). Some transmit a stimulating electric current to the heart temporarily for examination mainly.	35562020	I	1	N/A	—
Neonatal electrocardiograph electrode	A conductor for neonates to be placed on the body surface, and transmit electric signals detected on the body surface to a processing device (cardiac electrical activity is represented in a graph). A general device that records this electrical activity is called	17460000	I	1	applicable	—
Apex cardiograph transducer	A device that detects cardiac motions (e.g., acceleration, speed, and displacement) according to the change in mechanical or electrical characteristics. The results are displayed on the base unit.	33314000	I	12	applicable	applicable
Self-suction ECG electrode system	An automatic vacuum type electrode device that is used to attach electrodes to subjects in an electrocardiogram examination.	70065000	I	12	applicable	applicable
Electroencephalograph electrode	A conductor that records the changes in electric potential in various cerebral regions from the scalp. A general device that records this electrical activity is called an electroencephalograph (EEG).	11440001	I	1	applicable	—
Electroencephalographic electrode head cap	A special type of patient cap used for electroencephalogram (EEG) recording. Electrodes suitable for measuring electroencephalogram potential are installed around the inner surface of the cap. The cap eliminates the process of pasting individual electrodes to the patient's scalp.	17554000	I	1	applicable	—
Electromyograph body surface electrode	A conductor that detects biological electric signals in muscles and neural tissues on the body surface. A general device that records the electrical activity detected by the conductor is an electromyograph (EMG).	11441001	I	1	applicable	—
Reusable body surface electric stimulator electrode	An electrodes placed on the body surface, and used along with an electrostimulator to transmit electricity to tissues. Both cathodes and anodes are necessary. The electrodes are reusable after proper cleaning.	43441000	I	1	applicable	—
Body surface electric stimulator electrode	A conductor placed on body surface, and used to transmit electricity to tissues. Both cathodes and anodes are necessary.	34374001	I	1	applicable	—
Body surface stimulator probe	Probes for the body surface specifically designed for use in combination with a stimulator.	36957001	I	1	applicable	—

Electronystagmograph electrode	Conductors that are placed above and below the eye sockets, and transmit electric signal for the evaluation of rapid eye movement (ocular nystagmus). A general device that records this electrical activity is called an electronystagmograph (ENG).	11442000	I	1	applicable	—
Nasopharyngeal electrode	A conductor that is temporarily placed on the nasopharynx for recording electrical activity.	11452000	I	5-③	applicable	—
Electroretinograph electrode	A conductor that is placed near the eyes and transmits electric signals for retinal evaluation. A general device that records this electrical activity is called an electroretinograph (ERG).	11460000	I	1	applicable	—
Sweat test electrode	A conductor that is placed on the skin of the arm or leg, and measures sodium and chlorine concentration in sweat to diagnose cystic fibrosis.	11461000	I	1	applicable	—
Electrooculograph electrode	A conductor attached near the eye to transmit signals to diagnose and evaluate extraocular neuromuscular system.	35036000	I	1	applicable	—
Fetal scalp surface electrode	A conductor that is attached to the scalp of fetus in utero, and transmits electric signals to allow fetal vital signs to be monitored.	35038001	I	1	applicable	—
Fetal scalp clip electrode	An electrical conductor designed to establish an electrical connection between fetal skin and an external monitoring device by pinching the skin using a single-use clip.	42560000	I	1	applicable	—
Visual evoked response electrode	A conductor that transmits changes in electric potential from the skin surface in order to measure visual evoked response.	70070000	I	1	applicable	—
Respiration sensor	A sensor used to detect nasal and oral flow and pressure. Usually, used to evaluate sleep disorders (e.g., insomnia, snoring, and sleep apnea).	70072000	I	1,12	applicable	—
Thoracic and abdominal respiration sensor	A sensor used to detect chest and abdominal activity. Usually, used to evaluate sleep disorders (e.g., insomnia, snoring, and sleep apnea).	70073000	I	1,12	applicable	—
Body motion sensor	A sensor used to detect body movement. Usually, used to evaluate sleep disorders (e.g., insomnia, snoring, and sleep apnea).	70074000	I	1,12	applicable	—
Sleep assessment sensor	Electrodes and sensors that are connected to a sleep evaluation device, and measures the patient's bio-physical phenomena. Parameters measured by the sleep evaluation device are electrocardiogram, electroencephalogram, thoracic wall movement, nasal and oral cavity air flow, eye movement, oxygen saturation, and electromyogram.	70075000	I	1,12	applicable	N/A
Toco transducer	A device that converts uterine contractions into electric signals during delivery, and is used with a fetal heart monitor (the results are displayed). Obstetrics is the field of medicine that covers obstetrical technique and midwifery (the medical field that deals with childbirth).	37258000	I	12	applicable	applicable
Reusable urine flowmeter	A device that directly or indirectly measures urinary flow rate and urine volume during normal urination or urethral catheterization. Measurement is mechanical, electrical or a combination of both. This is reusable use.	36337000	I	12	applicable	applicable
Urine flow transducer	A device that measures the patient's urine volume by time unit. The measurement unit is liter/minute.	36799000	I	12	applicable	N/A
Petechiometer	Usually, it refers to a device that causes petechia (bleeding) of diameter < 3 mm on the skin surface. The depth of this bleeding can be measures for evaluation of fragility of a capillary blood vessel. Other methods of measurement are preferred in some cases.	16932000	I	1	applicable	N/A

Rotary spirometer	A mechanical device that measures pulmonary capacity based on exhaled air blown into a rotating drum.	70083000	I	1	applicable	N/A
Manually-operated diagnostic spirometer	A mechanical device that measures pulmonary air volume and air flow for diagnosis or examination of pulmonary diseases. These measurement values provide information on the patient's pulmonary functions, enabling comparison with normal values or previous	13680001	I	1	applicable	N/A
Exhalation gas detector	A device that detects the carbon dioxide level in the air exhaled by the patient. A test paper to be used for detection contains a chemical substance whose color changes with the carbon dioxide level in the exhaled gas. The unit includes a color chart for	70087000	I	1	applicable	—
SAS screener	A device that monitors presence/absence of the air flow from the nose and oral cavity when the patient is asleep. Some are made for single-use.	70089000	I	12	applicable	N/A
Direct ophthalmoscope	A hand-held ophthalmoscope (power source or battery-operated) used for intraocular examination. It consists of a light, a mirror with a hole (the examiner looks through this hole) and a dial to select lenses with different degrees. Some provide a normal	12817000	I	12	applicable	N/A
Monocular indirect ophthalmoscope	An ophthalmoscope used for intraocular examination. It consists of a light source and a hand-held lens. Some provide an inverted image magnified approximately 2-5 times.	35216000	I	12	applicable	N/A
Pleoptophor	An ophthalmic device used for training for foveal fixation. It is also used to treat eccentric fixation (strabismus) by dazzling the vicinity of the macula lutea, and relatively enhancing the visual capability of the central fovea of retina.	36390000	I	1	applicable	N/A
Binocular indirect ophthalmoscope	An ophthalmoscope used for intraocular examination. It provides a stereoscopic image for examination. It is held by hand, fixed by a head belt, or installed on a special spectacles frame.	37067000	I	12	applicable	N/A
Euthyscope	A device used to examine and correct the fundus oculi. The improved funduscope (a mirror with a hole used for intraocular examination) projects bright light that traces a 30° arc of the fundus oculi. The center of this light flux is blocked by a black disc that covers the fovea centralis (a depression in the center of the yellow spot of the retina where only cones are seen, and there are no blood vessels). It is also used to treat amblyopia (a state where one or more eyes fails to achieve normal visual acuity even if	37864000	I	1	applicable	N/A
Visual field plotter	An ophthalmic device used to measure and record the visual field and the sensitivity of a fixed eye. Used for examination of the photosensitivity, color sensitivity, and the ability to detect/identify an object and pattern	14380000	I	1	applicable	N/A
Automatic perimeter	A device that measures the visual field by recording the patient's response to small light spots (dots) automatically displayed at various positions. Some print out the measured visual field	16918001	I	1	applicable	N/A
Manually-operated perimeter	A device that measures the visual field by recording the patient's response to small light spots (dots) manually displayed at various positions. Some record the visual field curve on a pre-printed card (chart)	16919000	I	1	applicable	N/A
Campimeter	A device used to measure the central visual field. A hand-held device that displays a white spot is moved from the periphery to the center of a black background (tangent screen). The patient stares at the center from a distance of approximately 2 meters, and tells when the target is seen. This is Tangent Screen Testing, a simple measurement of the visual field. Some use a dedicated tool that projects bright light	34968000	I	1	applicable	N/A
Scotometer	A device that measures the site of deteriorated sensitivity in the visual field (relative scotoma), absolute scotoma and blind spot.	36385000	I	1	applicable	N/A

Retinoscope	An ophthalmic device used for examination, diagnosis and evaluation of refractive error by projecting a beam, and observing the movement of the region of the retinal surface illuminated and the reflection of the released beam.	13372000	I	12	applicable	N/A
Keratoscope	An ophthalmic diagnostic device used for cornea examination. Some have a circular plate with white and black concentric circles printed on it (Placido disk). Where there is astigmatism, the rings look distorted.	16347000	I	10-①	applicable	N/A
Corneal topography system	A system used to measure the curvature of the anterior corneal surface at an ophthalmology department. Some include a videokeratoscope and a computer equipped with an image processing function. Some are equipped with patient data management.	18038010	I	10-①	applicable	N/A
Corneal topography system with pupillometer function	A system used to measure the curvature of the anterior corneal surface at an ophthalmology department. Some include a videokeratoscope and a computer equipped with an image processing function. Some are equipped with patient data management.	18038020	I	10-①	applicable	N/A
Refractometer	A device that measures the degree of ocular refractive error. Recent devices automatically measure the degree and print out the result.	36387010	I	10-①	applicable	N/A
Refractometer with subjective refraction measurement function	A refractometer that examines subjective refraction.	36387020	I	10-①	applicable	N/A
Refractokeratometer	A refractometer that can measure the radius of the cornea curvature, or has a corneal topography function.	36387030	I	10-①	applicable	N/A
Refractokeratometer with subjective refraction measurement function	A refractometer that examines subjective refraction, and can measure the radius of the cornea curvature, or has a corneal topography function.	36387040	I	10-①	applicable	N/A
Refractokeratometer with axial length measurement function	A refractometer that can measure the eye axial length and the radius of the cornea curvature, or has a corneal topography function.	36387050	I	10-①	applicable	N/A
Rotary prism	Prisms with various powers used to evaluate the ocular muscle in a visual function test.	32715000	I	1	applicable	N/A
Refractor	A device installed lenses with various powers in order to measure ocular refraction. A set of trial lenses that function mechanically.	35299000	I	1	applicable	N/A
Binocular vision test unit	An ophthalmic device used to examine visual function. A patient wears red/green glasses, looks at 4 light spots (one each of white and red spot and two green spots), and answers how they look. From the result, inhibition is assessed.	37071000	I	10-①	applicable	N/A
Retinometer	A hand-held diagnostic device (power source or battery-operated) used to examine potential acuity. It is used, for example, in a visual acuity test for patients with an opacified lens.	70090000	I	10-①	applicable	N/A

Adaptometer	A device that measures the time required for retinal adaptation and minimum light threshold by varying the intensity of a stimulus light source.	10024000	I	10-①	applicable	N/A
Ophthalmotropometer	An ophthalmic device used to measure eye movement.	12820000	I	10-①	applicable	N/A
Optometer	An ophthalmic device used to measure the near point distance.	12821000	I	10-①	applicable	N/A
Optomyometer	An ophthalmic device used to measure the relative strength of the ocular muscle.	12822000	I	1	applicable	N/A
Pupillograph	A device used to record the pupil's response to reflected light.	13235000	I	10-①	applicable	N/A
Diplopiometer	An ophthalmic device used for the diagnosis of diplopia (visual symptom where two images of a single object are perceived in the visual cortex).	15826000	I	10-①	applicable	N/A
Anomaloscope	A device used to detect color vision defects by allowing the patient to mix the spectrum of colors and obtain the same color as the presented sample.	16342000	I	10-①	applicable	N/A
Phorometer	An ophthalmic device used to test ocular balance.	17119000	I	10-①	applicable	N/A
Haploscope	A device used to assess binocular visual function and for examination, treatment and training for amblyopia and strabismus. It consists of 2 movable observation tubes. Each tube has a slide carrier, a weak light source to illuminate the slide and a strong light source to produce a residual image. Some are used to measure the strabismus (imbalance in the strength of extraocular muscles), and assess binocular vision (seeing with both eyes simultaneously).	32700000	I	10-①	applicable	N/A
Nystagmus inducing tape	An ophthalmic device with a long, narrow belt made of flexible material such as cloth, with a series of pattern printed on it. The belt crosses the patient's visual field so as to induce optokinetic nystagmus (abnormal and irregular eye movement), and examine loss of sight.	32706000	I	1	applicable	N/A

Distometer	A device used to measure the distance between the cornea and lens for vision correction. It is also used to facilitate measurement of the lens position and change of image for refraction.	32741000	I	1	applicable	N/A
Synoptophor	An ophthalmic device used for assessment and training of the binocular visual function (capacity to focus on one object with both eyes). Usually, it is used for diagnosis of strabismus (ocular deviation that cannot be controlled by the patients themselves). There are different forms of strabismus such as stereopsis (stereoscopic vision), amblyopia (poor visual acuity), and anisometropia (unequal refractive error).	36058000	I	10-①	applicable	N/A
Central critical flicker fusion frequency meter	A device that measures the central flicker value.	70091000	I	10-①	applicable	N/A
Contrast sensitivity meter	A device that measures contrast sensitivity.	70092000	I	10-①	applicable	N/A
Pupillography device with optometric function	A device with multiple functions-i. e. , a near point ruler, and a function for recording the response of the pupil to reflected light or a visual target.	70094000	I	10-①	applicable	N/A
Ophthalmoscopic diagnostic set	A set consisting of combination of ophthalmoscopic diagnostic devices that are categorized into different types. A mirror body of the direct ophthalmoscope is detachable from the handle. By utilizing this structure, this set is intended to be used in a way that the mirror bodies of the direct ophthalmoscope and an otoscope speculum are interchangeably attached to the handle.	70095000	I	12	applicable	N/A
Equilibrium function test equipment	A device that indicates the position and movement of the center of gravity of a human body standing upright on a scale, and performs quantitative analysis.	17242001	I	12	applicable	N/A
Tuning fork	A U-shaped device usually made of stainless steel with a handle at the bottom of the U-shape. The vertical part at the top of "U" is cut to a length that makes a sound having a specific wavelength when hit by a hard object (usually, rubber). Used for audiometry	32526000	I	1	N/A	N/A
Gait physiologic analyser	A device used to test the gait and gait pattern. It utilizes a platform that measures the reaction force from the ground, takes an image, assesses the motion of the knees, ankles and hip joints, and measures the force and torque. It is used to support diagnosis and planning of corrective measures for the gait and gait-related problems.	35757000	I	1	applicable	N/A
Hand dynamometer	A device that measures, examines, and coordinates the strength of the muscles of the hands and forearms of the patient. Usually it is used for rehabilitation after stroke.	35021000	I	1	N/A	N/A
Manually-operated cutaneous pain gauge	A manually-operated device used to measure the sensitivity to pain (e.g., puncture with a pin). Also known as an algometer.	12950001	I	1	N/A	N/A
Tropometer	A device that measures the amount of rotation of the axis of the eyeball or a long bone.	35408000	I	1	N/A	N/A
Joint movement tester	A tester is used to assess the characteristics of joints. Usually, the assessment is performed before and after surgery of an abnormal joint (e.g., arthroplasty, arthroscopic procedure). It assesses the range of joint movement and normal function	36148000	I	1	N/A	N/A

Bone-angle scaler	A device used to measure the angle of bones for X-ray examination or surgery. Usually, it is known as a protractor.	37529000	I	1	N/A	N/A
Back dynamometer	A device/instrument used to measure the strength (muscle strength generated when bending the back muscle, in particular). Usually, it is used to control the muscle strength for rehabilitation.	34395000	I	1	N/A	N/A
Slit lamp microscope	A slit-lamp biomicroscope used for observation, examination and photography of the eyeball. It is also used for measurement of intraocular pressure, corneal thickness, and anterior chamber depth. A slit light is projected on the eyeball from an oblique direction, and the movable microscope is aligned to the light in order to observe and measure the reflected surface.	35148000	I	12	applicable	N/A
Ophthalmic light microscope	An optical microscope used for examination, observation, and photography of the eyeball. Some are designed to examine the anterior part of the eye (cornea, aqueous humor, lens, anterior chamber, vitreous body) with a stereoscope. Others are used for fitting contact lenses, follow-up and detection of corneal damage, foreign objects, and diseases. It is usually used with a light source specifically designed for the system.	35190000	I	12	applicable	N/A
Colposcope	A special microscope used for examination of the female genital organs (e.g., vagina, cervix).	10960000	I	12	applicable	applicable
Urethrometer	A device specifically designed to be inserted into the urethra, dilate it, and measure the degree of dilation. Usually, the measurement is indicated on the dial.	14288000	I	5-①	applicable	N/A
Vaginometer	A device that measures the length and diameter of the vagina or the external orifice of the uterus.	14323000	I	5-①	applicable	N/A
Endoscopic video image processor	A unit designed to receive electronic signals transmitted from a video endoscope or endoscopic video camera for processing. Some are equipped with a function to correct/enhance the color and light quality, or a function to generate stereoscopic images. The image is reproduced by a visual display unit (VDU), recorded by a video recorder, and stored as computerized media. Some are also hand-cam images using a monitor.	18034000	I	12	applicable	applicable
Endoscope light source/processing unit	A device relying on an external power source which is designed to be used in conjunction with an endoscope (mainly video endoscope) and functions as the light source and processing unit. The device serves as the light source for observation of the surgical field and body cavity when using a rigid or flexible endoscope (e.g., laparoscope, gastroscope) and its accessories. It illuminates the site being observed/treated via an optical fiber light source cable connected to the endoscope.	34540001	I	12	applicable	applicable
Line-powered endoscope light source	An external powered, dedicated device that provides light for observation of the surgical field and body cavity when using a rigid or flexible endoscope (e.g., laparoscope, gastroscope) and its accessories. It illuminates the site being observed/treated via an optical fiber light source cable connected to the endoscope.	35158001	I	12	applicable	applicable
Battery-powered endoscope light source	A battery-powered, dedicated device that provides the light for observation of the surgical field and body cavity when using a rigid or flexible endoscope (e.g., laparoscope, gastroscope) and its accessories. It illuminates the site being observed/treated via an optical fiber light source cable connected to the endoscope.	35906001	I	12	applicable	applicable
Endoscopic video camera	A camera specifically designed to be used with an endoscope. Some are equipped with voice function. In order to convert optical images into electronic video images, it is connected to a flexible or rigid endoscope directly or via an adaptor.	35958000	I	12	applicable	applicable
Endoscope peripheral equipment controller	An item connected to an endoscope or other devices to be used in combination with the endoscope, and performs a centralized switching for the devices connected to it.	70160000	I	12	applicable	applicable
Endoscopic balloon pump	A balloon pump that inflates and deflates the balloon attached to an endoscope or an overtube. It assists the insertion of the endoscope.	36500001	I	12	applicable	applicable

Endoscope water supply tank	A water storage tank to be connected to the water supply unit of an endoscope, and supply water.	36500042	I	2	N/A	N/A
Ultrasonic probe driving unit	An externally installed unit that mechanically drives or holds/moves an ultrasonic transducer, and controls the direction of ultrasonic beams. It may be connected to an ultrasonic endoscope that does not have a driving source or an ultrasonic probe. It may include the motor that generates the driving power, motor control circuit, and	70163000	I	12	applicable	applicable
Flexible bronchoscope curette	A device used with a specific endoscope to collect bronchial samples for histological/pathological diagnosis during a bronchoscopic examination. It is a type of biopsy forceps that has a flexible insertion part such as a metal coil or a plastic tube	31248000	I	6-①	N/A	N/A
Cystoscopic rongeur	A device used with a dedicated endoscope for endoscopic treatment. It has sturdy blades and powerful force for scraping and cutting hard tissue during endoscopic treatment.	32015000	I	6-①	N/A	N/A
Rigid bronchoscope curette	A device used with a specific rigid endoscope. It is used to collect bronchial samples for histological/pathological diagnosis during a bronchoscopic examination. Usually, it is a type of metal biopsy forceps. To exactly perform the biopsy, it is equipped with a sharp curette like a nail. It is a rigid device.	33202000	I	6-①	N/A	N/A
Laparoscopic rigid biopsy forceps	An endoscopic device to be used with a dedicated rigid laparoscope. It is used to collect samples during laparoscopic examination. Usually, the insertion part is made of a metal tube, and inserted into an endoscope.	35080000	I	6-①	N/A	N/A
Endoscopic scissor forceps	A device used with a dedicated endoscope for endoscopic treatment. It is used to sever tissue or suture threads. Usually, it consists of a flexible metal coil or plastic tube. It has scissors at the end, and is operated by handles at the other end. It is inserted into a body cavity via the working channel of the endoscope.	35326001	I	6-①	N/A	N/A
Endoscopic flexible grasping forceps	A device used with a dedicated endoscope for endoscopic treatment. It is used to hold tissue or foreign matter. Usually, the insertion part is made of a flexible metal coil or plastic tube.	35524000	I	5-①	N/A	N/A
Endoscopic rigid biopsy forceps	An endoscopic forceps used with a dedicated endoscope. Used to collect samples for histological/pathological diagnosis during endoscopic examination. Usually, the forceps are made of rigid metal tubes. They have a pair of cups at one end, and are operated by handles at the other end. They are inserted into a body cavity via an artificial orifice or	35732000	I	6-①	N/A	N/A
Endoscopic sponge grasping forceps	A device used with a dedicated endoscope for endoscopic treatment and used for transferring folded gauze or an absorbent cotton pad to the site being treated.	35792000	I	5-①,6-①	N/A	N/A
Laparoscopic spatula	A device used with a dedicated endoscope for endoscopic treatment. It is used for blunt dissection of tissue adhesions embedded in a wide area. It is used for laparoscopic treatment.	36083000	I	6-①	N/A	N/A
Endoscopic flexible biopsy forceps	An endoscopic forceps used with a dedicated endoscope. Used to collect samples for histological/pathological diagnosis during endoscopic examination. Usually, the forceps are made of rigid metal tubes. They have a pair of cups at one end, and are operated by handles at the other end. They are inserted into a body cavity via an artificial orifice or	38810000	I	6-①	N/A	N/A
Reusable endoscopic cytology brush	A brush used to collect mucosal cells for pathological diagnosis during endoscopic examination. It has a flexible insertion part made of a metal coil or plastic tube, and has a plastic brush at the end to collect mucosa for bronchoscopic examination. This device is reusable.	38833000	I	5-①	N/A	N/A

Single-use endoscopic cytology brush	A brush used to collect mucosal cells for pathological diagnosis during endoscopic examination. It has a flexible insertion part made of a metal coil or plastic tube, and has a plastic brush at the end to collect mucosa for bronchoscopic examination. This	38834000	I	5-①	N/A	—
Endoscopic periosteal elevator and raspatory	Used with an endoscope for endoscopic treatment. It has a swab (folded gauze or absorbent cotton pad) at the end of the shaft.	70165000	I	5-①,6-①	N/A	N/A
Endoscopic non-active knife	A non-active knife used for dissecting the urinary tract via the forceps outlet of the endoscope.	70166000	I	6-①	N/A	N/A
Bronchoscopic aspiration tube	A device used with a dedicated endoscope for endoscopic treatment and used to aspirate waste matter from the respiratory tract and bronchus. Made of a plastic tube.	16399000	I	5-①	N/A	N/A
Reusable endoscopic sclerotherapy injection needle	A device used with a dedicated endoscope for endoscopic treatment. It is used to inject drugs into the mucosa or a blood vessel for sclerotherapy. It has an injection needle at the end of the flexible tube, and a connector of the syringe at the other end. This	36076001	I	6-①	N/A	N/A
Reusable rigid endotherapy lithectomy forceps	A device used with a dedicated endoscope. It is intended to be used to grasp and remove stones during endotherapy. It consists of a thin shaft and a wire basket at the distal end in which the stones are caught (picked up) for extraction. This device is reusable.	37141001	I	6-①	N/A	N/A
Resectoscope suction apparatus	A device used with an endoscope and its direct application to assist the use of the endoscope. The dedicated glass bottle is equipped with a rubber ball that is manually operated. Connected to a resectoscope and used to wash off residual tissue and coagulated matter using the cleaning solution during surgery.	37143000	I	1	N/A	N/A
Reusable endoscopic cannula	A cannula used to convey a drug solution or contrast medium into the body cavity for diagnosis and treatment during endoscopic examination. This device is reusable.	38813000	I	5-①,6-①	N/A	N/A
Single-use natural orifices endoscopic cannula	A cannula used to convey a drug solution or contrast medium into a body cavity via a natural orifice of human body for diagnosis or treatment during endoscopic examination. This device is for single-use.	38814001	I	5-①	N/A	—
Reusable endoscopic injection needle	A device used with a dedicated endoscope for endoscopic treatment. It is used to inject drugs into the mucosa or a blood vessel for hemostasis, sclerosis, or other purposes. It has an injection needle at the end of the flexible tube, and a connector of the syringe at the other end. This device is reusable.	38824000	I	6-①	N/A	N/A

Endoscope lens cleaner	A device that supplies the air or fluid onto the lens surface in order to eliminate blood and foreign matter. It is made of metal or plastic and has a tubular configuration. It is attached to the insertion part of endoscope. The device that transfers the air or fluid is a manual pump or gravity dependent infusion bag.	70167000	I	5-①	N/A	N/A
Endoscopic colonoscope stiffener	A special cable that is inserted into a flexible colonoscope in order to adjust the rigidity of the colonoscope in a colonoscopic examination.	17826000	I	5-①	N/A	N/A
Endoscopic measuring device	A dedicated device used with an endoscope and its direct applications to measure the size of objects in the visual field during an endoscopic examination. It is made of a flexible metal coil or plastic tube, and has a scale at the distal end.	32053000	I	5-①,6-①	N/A	N/A
Arthroscopic surgical probe	A surgical device used for examination, probing, and treatment inside the joint.	35948000	I	6-①	N/A	N/A
Endoscopic obturator	This device is a component of an endoscope that consists of several parts required to achieve its function. At the distal end, it has a round head or tip which is inserted into a sheath in order to fill the lumen of the sheath (open end) of the rigid endoscope. It makes it easy to insert the sheath into the body and prevents injury to the patient.	35692000	I	5-①,6-①	N/A	N/A
Endoscopic inflation bulb	A device used with an endoscope and its direct applications that assists the use of the endoscope. The rubber ball-like device is used to transfer the air via the endoscope in order to secure the endoscopic visual field.	35800000	I	1	N/A	N/A
Reusable endoscopic dilator	A device used to dilate the tube cavity, body cavity and lumen in order to secure or facilitate the insertion of an endoscopic device. It is made of a flexible or rigid rod or tube. The device is inserted via the skin (subcutaneously) and used, for example, in the urethra and urinary tract. This device is reusable.	37142000	I	5-①,6-①	N/A	N/A
Single-use natural orifices endoscopic dilator	A device used to dilate the tube cavity, body cavity and lumen in order to secure or facilitate the insertion of an endoscopic device. Dilation is performed from a natural orifice of the human body, in the urethra or urinary tract, for example. It is a flexible or rigid rod or tube. This device is for single-use.	38821001	I	5-①	N/A	—
Ultrasound balloon	A balloon that seals an ultrasonic medium. Used in combination with an ultrasonic endoscope or a probe used for an ultrasound image diagnostic device. This device is for single-use.	70168000	I	5-①	N/A	—
Endoscopic ligation instrument	A device or tool used to close internal wounds by tying the end of suture threads in endoscopic treatment. Known as a thread ligator.	36243000	I	5-①,6-①	N/A	N/A

Endoscopic sheath	This device is a component of an endoscope that consists of several parts required to achieve its function. This device is a thin metal tube, and other parts are inserted into this device, and assembled so as to complete the surgical endoscopic device.	37086000	I	5-①,6-①	N/A	N/A
Reusable non-active endotherapy device	A device used with a dedicated endoscope for endoscopic treatment for mechanical operations such as holding, collecting, resecting, clipping, ligating the tissue or foreign matter, sending drug solutions, suctioning, dilating lumens, and probing. It functions without electricity (e.g., high-frequency waves, electromagnetism, ultrasound, laser energy). This device is reusable.	38818000	I	6-①	N/A	N/A
Single-use natural orifices non-active endotherapy device	A device used with a dedicated endoscope for endoscopic treatment. It is inserted via a natural orifice of the human body for mechanical operations such as holding, collecting, resecting, clipping, and ligating the tissue or foreign matter, sending drug solutions, suctioning, dilating lumens, and probing, or for illuminating tissue, etc., by light supplied from the light source via the optical fiber bundle, etc. The mechanical operations function without electricity (e.g., high-frequency waves, electromagnetism, ultrasound, laser energy). This device is for single-use.	38819001	I	5-①	N/A	—
Tissue storage pouch	A device that is inserted into the abdominal cavity in endoscopic surgery to prevent the dispersion of separated tissues, and isolate/store the tissues. This device is sterilized and for single-use.	70169000	I	1	applicable	—
Reusable tissue storage pouch introducer	A device that assists the insertion of a tissue retrieval sac into a body cavity. This is sterilized before use, and reusable after sterilization or cleaning.	70170000	I	1	applicable	—
Resected organ remover	A device use to hold or fix an organ in its original position, or remove it from the body.	70171000	I	6-①	N/A	N/A
Single-use infection-prevention endoscopic sheath for natural orifices	A cover (sheath) applied to an endoscope to protect the insertion part from direct contact with the mucosa, blood or body fluids. This device is for single-use for a natural orifice.	70172000	I	5-①	N/A	—
Laser/laparoscope adaptor	The adaptor is used to connect the laparoscope to the laser or the laser arm for laparoscopic laser treatment.	18027000	I	1	N/A	N/A
Endoscopic laser filter	A component of an endoscope that requires the addition of a filter to the optical device as an eyepiece. Used to protect the operator's eyes from laser energy generated from the optical unit during laser treatment.	36308000	I	1	N/A	N/A
Adaptor for endoscope element	Connectors that enable to complete an endoscopic assembly by connecting or integrating single or multiple endoscopic parts, and the connections to other devices (e.g., laser), as well as parts used to add functions. Some are connected to the stopcock or tool port in order to introduce a device or catheter, or aspirate/introduce fluid.	37090010	I	1	N/A	N/A
Multiport adaptor	An adaptor that has a port for connecting a tracheal tube and respiratory circuit with an insertion port for a bronchoscope or a balloon catheter.	37090020	I	1	N/A	—

Natural orifices endoscope defroster	Applied to the surface of an endoscopic lens that is inserted via a natural orifice. Anti-fogging liquid or solid that prevents dew condensation caused by the difference of the temperature between the endoscope and inner body.	70176000	I	5-①	N/A	N/A
Endoscope fixation device	A device that holds and adjusts a laparoscope, various types of endoscopes, and other tools for procedures at the desired position during surgery. It consists of joints and rigid or semi-rigid arms. It simply holds an endoscope.	37090030	I	1	N/A	—
Gas pressure transducer	A device used to convert gas pressure into an electric signal for subsequent display or processing by the base unit.	31278000	I	12	applicable	applicable
Dental intraoral camera	A device that displays oral cavity information on a monitor for treatment and explanation to the patient.	70179000	I	12	N/A	N/A
Flow clinical chemistry analyser	An automatic or semi-automatic device used for qualitative/quantitative analysis of chemical substances and human tissue samples. With this device, a chemical reaction	35745010	I	—	applicable	applicable
Mobile flow clinical chemistry analyser	An automatic or semi-automatic device used for qualitative/quantitative analysis of chemical substances and human tissue samples. With this device, a chemical reaction occurs in a continuous flow of fluid. Samples are picked up from the sample cup on the turntable at designated intervals, and introduced into the flow of reagents. Through	35745020	I	—	applicable	applicable
Discrete automated clinical chemistry analyzer	A device that certainly enables to automate or mechanize manual processes of clinical chemistry analyses without having any significant change from the conventional method. Measurement is done using individual test tubes or cuvettes while they are transferred by a conveyer or turntable. Samples, diluents and reagents are dispensed at each station. The time for mixture, incubation and coloration is secured, and then	35743010	I	—	applicable	applicable
Portable discrete automated clinical chemistry analyzer	A device that certainly enables to automate or mechanize manual processes of clinical chemistry analyses without having any significant change from the conventional method. Measurement is done using individual test tubes or cuvettes while they are	35743020	I	—	applicable	applicable
Centrifugal clinical chemistry analyser	An automatic or semi-automatic device that transfers and mixes liquids by centrifugal force. The reaction that occurs in the centrifuge is monitored by a photometer. A separate module is required for preparation of the sample and reagents. Portable types are excluded.	35744010	I	—	applicable	applicable
Mobile centrifugal clinical chemistry analyser	An automatic or semi-automatic device that transfers and mixes liquids by centrifugal force. The reaction that occurs in the centrifuge is monitored by a photometer. A	35744020	I	—	applicable	applicable
Dry clinical chemistry analyser	An automatic or semi-automatic device used for qualitative/quantitative analysis of chemical substances that occur in a reaction between chemical substances, human tissue samples, or reagents and human tissue. It measures the amount of light reflected by a reagent-impregnated test strip or multi-layer film, into which the	34549000	I	—	applicable	applicable
Packed clinical chemistry analyser	An automatic or semi-automatic device used for qualitative/quantitative analysis of chemical substances or human tissue samples. It performs photometric analysis of samples bonded with reagents and contained in a bag etc. The device can output	34550000	I	—	applicable	applicable
General-purpose spectrophotometric analyser	A device that quantifies the concentration of substances by measuring the luminous (optical) characteristics of the substance in gas or liquid. Used for diagnosis and	36910000	I	—	applicable	applicable
Sweat test iontophoreser	A device that induces perspiration, collects sweat, and analyzes chlorides or the presence/absence of chlorides and sodium. The analysis results serve as an indicator of cystic fibrosis.	15128000	I	—	applicable	N/A
Flame photometer electrolyte analyser	An automatic or semi-automatic device that measures electrolytes such as sodium, potassium, lithium and calcium based on the fact that several metal elements absorb	35826000	I	—	applicable	applicable

Blood potassium analyser	A device that measures blood potassium ion (K+) concentration. The blood sample is placed on the K+ sensor osmosis membrane, and K+ spreads over the entire membrane, and permeates the ion selective electrode. The change in membrane potential is fed into the computer. The computer calculates the ion activity, and	35566000	I	—	applicable	applicable
Ion selective analyser	An automatic or semi-automatic device for various measurements based on electric potential difference using ion selective electrodes (ISE) that include external and internal reference electrodes. Some are incorporated into a general-purpose analyzer	35902000	I	—	applicable	applicable
Calcium analyser	A device that measures the calcium concentration of liquid samples such as whole blood, plasma, serum and urine. A calcium ion selective electrode or fluorescence quenching titration may be used.	35937000	I	—	applicable	applicable
Coulometric electrolyte analyser	An automatic or semi-automatic device that measures the chloride ion concentration in whole blood, plasma, serum or urine samples. Some are incorporated into a general-purpose analyzer, and others are used on their own. The device measures the chloride concentration of clinical samples by coulometric titration.	35903000	I	—	applicable	applicable
Fluorometric electrolyte analyser	An automatic or semi-automatic device that measures the concentration of specific electrolyte solutions such as ferrous ion by fluorometry. Some are incorporated into a general-purpose analyzer, and others are used on their own.	34555000	I	—	applicable	applicable
Protein fractionation electrophoresis analyser	An automatic or semi-automatic device that measures the fractionation of protein in blood, urine, cerebrospinal fluid and other body fluids. The fractionation of protein is used to assist the detection of abnormal proteins in body fluids, and genetically variant protein caused by diseases associated with tissue destruction.	31365000	I	—	applicable	applicable
Densitometry analyser	An automatic or semi-automatic device that measures transmitted light or reflected light from the pattern in a support medium that occurs in electrophoresis, thin - layer chromatography or immunoassay blotting sample separation for serum sample	15129000	I	—	applicable	applicable
Protein analyser	An automatic or semi-automatic special device used to measure concentration and to identify specific proteins generated by an immunological response. Some use the immunological response to latex.	30857000	I	—	applicable	applicable
Enzyme immunoassay analyser	An automatic or semi-automatic device that identifies substances in body fluids and measures their concentration by an enzymatic reaction in the presence of antigen/antibody conjugate. Portable types are excluded.	35706010	I	—	applicable	applicable
Mobile enzyme immunoassay analyser	An automatic or semi-automatic device that identifies substances in body fluids and measures their concentration by an enzymatic reaction in the presence of antigen/antibody conjugate. This device is a portable type	35706020	I	—	applicable	applicable
Microtitre plate reader	A device used to read the test result indicated on the microtiter plate. The result can be printed out or displayed on the screen. Test samples are blood, reagents or mixtures. The process is also known as enzyme-linked immunosorbent assay (ELISA).	37036000	I	—	applicable	applicable
Immunoturbidimetric analyser	An automatic or semi-automatic light scattering analyzer that quantifies the analytes in the body fluid by measuring the light scattering intensity from the immune complex generated in the reaction between analyte and antibody. Dedicated reagents are used	35926010	I	—	applicable	applicable

Mobile immunoturbidimetric analyser	An automatic or semi-automatic light scattering analyzer that quantifies the analytes in body fluids by measuring the light scattering intensity from the immune complex generated in the reaction between analyte and antibody. Dedicated reagents are used. The device is also called a laser nephelometer. This device is a portable type.	35926020	I	—	applicable	applicable
Immunofluorescent analyser	A device adopts a method that uses fluorescent markers in order to measure the activity of antigen/antibody. When the components of body fluids react with reagents, the device detects the intensity of fluorescence emitted from the fluorescent reagents, and measures automatically or semi-automatically the volume of antigen/antibody.	35707010	I	—	applicable	applicable
Mobile immunofluorescent analyser	A device adopts a method that uses fluorescent markers in order to measure the activity of antigen/antibody. When the components of body fluids react with reagents, the device detects the intensity of fluorescence emitted from the fluorescent reagents, and measures automatically or semi-automatically the volume of antigen/antibody.	35707020	I	—	applicable	applicable
Chemiluminescent immunoassay analyser	An automatic or semi-automatic device that identifies and quantifies the substances in body fluids such as drugs, proteins and hormones by measuring the intensity of light emitted from the chemiluminescent substance used as a marker. Portable types are available.	36223010	I	—	applicable	applicable
Mobile chemiluminescent immunoassay analyser	An automatic or semi-automatic device that identifies and quantifies the substances in body fluids such as drugs, proteins and hormones by measuring the intensity of light emitted from the chemiluminescent substance used as a marker. This device is a portable type.	36223020	I	—	applicable	applicable
Particle-counting immunoassay analyser	An automatic or semi-automatic device for immunological measurement by counting latex aggregates based on the light scattering.	70181000	I	—	applicable	applicable
Fecal occult blood test equipment	An automatic or semi-automatic device that detects fecal hemoglobin by checking the light reflected by the coloration in the result of an assay such as immunochromatography.	70182000	I	—	applicable	applicable
Glucose analyzer	A device used in a laboratory to measure blood sugar (glucose) concentration.	36730000	I	—	applicable	applicable
Lactate analyser	A device that measures lactate (waste matter from muscle metabolism) concentration in biological fluids using a lactate oxidase fixed electrode and test paper, instead of using perchloric acid which is harmful in manual methods.	35885000	I	—	applicable	applicable
High performance liquid chromatography analyser	An automatic or semi-automatic device that isolates, identifies and quantifies liquid sample components such as amino acids and hormones using high performance liquid chromatography.	36420000	I	—	applicable	applicable
Osmometric analyser	A device that measures the osmolar concentration (quantity of solute per unit volume) of solutions.	36458000	I	—	applicable	applicable
Laboratory refractometer	A device used in a laboratory to measure the refractive index (light refraction) of solutions to quantify the solute concentration in an examination sample. Usually, clinical devices have been calibrated in advance with total solids. This device indicates the concentration of total solids.	15169000	I	—	applicable	N/A
Cholesterol analyser	A device that measures the cholesterol in serum/whole blood.	30855000	I	—	applicable	applicable
Bilirubinometry analyser	A device that measures directly or indirectly the bilirubin concentration in blood or other samples using one of 3 methods (i. e., spectrophotometry, blood fluorometry, and colorimetry).	35475000	I	—	applicable	applicable
Glycohemoglobin analyser	A special device that measures the concentration of glycohemoglobin in human blood (HbA1c) using such methods as HPLC, electrophoresis and immunoassay.	35968000	I	—	applicable	applicable
Catecholamines analyser	A device that measures catecholamine concentration in biological samples.	35989000	I	—	applicable	applicable

Creatinine analyser	A device that measures creatinine concentration in urine or serum sample. The device measures the rate of reaction to alkaline materials by using a photodetector, and converts the rate into the concentration.	35991000	I	—	applicable	applicable
Nitrogen analyser	A special device that analyzes the quantity of nitrogen (N2) in biological fluids.	36741000	I	—	applicable	applicable
Portable clinical refractometer	A portable device used in laboratory tests to measure the optical refractive index against the light emitted to a solid/liquid. Used for measurement of blood glucose and alcohol concentration of specific urine samples.	37034000	I	—	applicable	N/A
Blood gas oxygen analyser	A special device used to continuously measure, monitor and display the partial oxygen pressure in human blood by using an electrochemical sensor.	12590000	I	—	applicable	applicable
General-purpose blood gas analyser	An automatic or semi-automatic device that identifies and quantifies 2 or more gases or electrolytes in whole blood using multiple electrodes. The device can output graphics and data.	30847000	I	—	applicable	applicable
Coulometric carbon dioxide measuring instrument	A device used to measure bicarbonates/carbon dioxide in plasma, serum, or whole blood. The measurement of bicarbonates/carbon dioxide is used for diagnosis and treatment of a number of potentially serious diseases that are associated with changes in the balance of internal acidity.	31407000	I	—	applicable	applicable
Extracorporeal blood gas analyser	An automatic or semi-automatic device that continuously controls and monitors partial oxygen pressure in extracorporeal circulation blood (e.g., blood circulating in a closed extracorporeal circuit). Used with a cardiopulmonary bypass unit during open chest cardiac surgery.	37238000	I	—	applicable	applicable
Methane gas analyser	An analyzer that measures methane content in exhaled air samples. Usually, parts per million (ppm) is adopted. It utilizes electrochemical chromatography or gas chromatography. Most of these analyzers can also measure the content of hydrogen or carbon dioxide in exhaled air samples. They are used to detect an incomplete carbohydrate degradation by bacteria and dysfunction of the small intestine due to intestinal bacterial overgrowth.	17477000	I	—	applicable	applicable

In vitro oximeter	A photoelectronic device used to measure oxygen concentration and hemoglobin in blood samples collected from patients.	15201000	I	—	applicable	applicable
Heparin analyser	An automatic device that measures heparin concentration in blood samples by mixing the sample and protamine (heparin neutralizer), and quantifying the subsequent air activation coagulation by photometric measurement.	33321000	I	—	applicable	applicable
Enzyme analyser	An automatic or semi-automatic device that measures the enzymatic activity of the sample for diagnosis. Some are equipped with a temperature controller and other devices in order to process more than one sample sequentially by adding reagents and samples. Some are equipped with a microcomputer that calculates enzymatic activity.	35470000	I	—	applicable	applicable
Microbial component analyser	A device that optically measures microbially derived components such as endotoxins in plasma and serum.	70183000	I	—	applicable	applicable
Blood cell count analyser	An automatic or semi-automatic device that quantifies the formed elements in the blood (i. e. , erythrocytes, leukocytes, and platelets) by electroimpedance, optical scattering or dye binding. The device measures the absolute numbers of erythrocytes.	35476000	I	—	applicable	applicable
Hematocrit analyser	A device that measures hematocrit (proportion of erythrocytes) in blood samples.	33328000	I	—	applicable	N/A
Manually-operated blood cell count analyser	A device that functions as a manual blood cell counting chamber. The device consists of a thick glass slide with a dent of a specific depth and a grid of perpendicular lines. The blood cells of the known volume in the square covered with the cover glass are counted microscopically.	35103000	I	—	applicable	N/A
Reticulocyte analyser	An automatic or semi-automatic device used for quantitative and qualitative analysis of stained undifferentiated erythrocytes. It assists the diagnosis of certain types of hematopoietic diseases.	30863000	I	—	applicable	applicable
Automatic blood cell differential analyser	An automatic or semi-automatic device that classifies blood cells such as erythrocytes, leukocytes or platelets, and identifies the characteristics and the count of microcytes and macrocytes.	35479000	I	—	applicable	applicable
Coagulation timer	A device used to measure and indicate coagulation time. It automatically indicates and records the time required for coagulation of whole blood.	35505000	I	—	applicable	N/A
Blood coagulation analyser	An automatic or semi-automatic device that performs qualitative and quantitative analysis of hemostatic (reduce of bleeding) components such as fibrinogen, fibrin, and platelets, and measures the time taken for bleeding to stop.	35514000	I	—	applicable	applicable
Thrombosis analyser	A device that detects the presence of blood aggregation such as thrombus formation and coagulation in blood vessels by photometric measurement.	36746000	I	—	applicable	applicable
Erythrocyte sedimentation rate analyser	An automatic or semi-automatic device that measures the rate of erythrocyte sedimentation (sinking), which is known as the erythrocyte sedimentation rate (ESR), in whole blood samples.	35488000	I	—	applicable	applicable
Platelet aggregation analyser	A device that measures the change in the shape of platelets and platelet aggregation in blood coagulation.	35473000	I	—	applicable	applicable

Platelet aggregation record analyser	An automatic device that records the change in the shape of platelets and aggregation over time. The device is connected to a platelet aggregation analyzer suitable for the method adopted (e.g. optical density, electroimpedance), and stores the data.	35769000	I	—	applicable	applicable
Cell analyser	A device that analyzes the physiological function of cells such as blood cells.	70184000	I	—	applicable	applicable
Blood smear maker	An automatic device used to produce blood sample film (blood smear sample) on a glass slide. It collects the sample from a test tube, transfers the microscopic slide, and adjusts the length and width of the smear sample. Some stain the blood films. Used to prepare samples optimal for laboratory analysis by avoiding contact with pathogen-contaminated blood samples.	15110000	I	—	applicable	N/A
Cartidge for blood coagulation test	A dedicated cartridge for an analyzer that measures the time taken for blood coagulation.	70185000	I	—	applicable	N/A
Chromosome analyser	An automatic device that indicates the blood cells in peripheral blood samples, and enables the operator to identify individual cells by type.	33936000	I	—	applicable	N/A
Hemoglobin analyser	A device that measures the hemoglobin in the blood by spectrophotometry.	35481000	I	—	applicable	applicable
Viscosimetric analyser	A device that measures the resistance of fluid against the flow by intermolecular force. It is also used for the analysis of whole blood, serum or plasma.	36823000	I	—	applicable	N/A
Hemoximetric analyser	A device that measures oxygen saturation (SaO2), and the concentrations of oxidized hemoglobin (HbO2), carbon monoxide hemoglobin (COHb), methemoglobin (MetHb), and reduced hemoglobin (RHb) by using the differential absorption of light in hemolyzed blood.	37078000	I	—	applicable	applicable
Radioimmunoassay analyser	An automatic or semi-automatic device that quantifies such substances as hormones, vitamins, drugs, cancer antigens, enzymes, receptors, viruses, antibodies, and polypeptides in biological fluids by radioisotope labelling. The method of quantification provides the method of binding between the ligand (analyte, usually an antigen), and the ligand-specific binder (usually an antibody). The radioimmunoassay measures the	35506000	I	—	applicable	applicable
Immunoassay scintillation counter	A device that measures the radiation emitted from a radioactive indicator used to label biochemical samples. The radiation converted into photons by a scintillator is measured by the photomultiplier tube. Generally, the counter is used as a detector of radioimmunoassay or immunoradiometric assay for clinical use.	34567000	I	—	applicable	applicable
Hematocrit centrifuge	A device used in a laboratory to separate components of a suspension by application of centrifugal force. Usually, it consists of an electrically powered unit, a vertical shaft as a part of the unit, and a horizontal rotor attached to the top end of the vertical shaft. It is a desktop device that spins at 10000 rpm or faster, rapidly processes the blood.	32429000	I	—	N/A	N/A
Blood bank centrifuge	A device usually used by a blood donor facility to separate components of a suspension by application of centrifugal force. It consists of an electrically powered unit, a vertical shaft as a part of the unit, and a horizontal rotor attached to the top end of the vertical shaft. Usually, it is a large low-speed device that can dispose a large volume of donated	15115000	I	—	N/A	N/A

Ultracentrifuge	A centrifuge used in a general-purpose laboratory to separate components of a suspension by application of centrifugal force. Usually, it consists of an electrically powered unit, a vertical shaft as a part of the unit, and a horizontal rotor attached to the top end of the vertical shaft. This is a special centrifuge that processes a relatively small number of samples at much higher speed (Usually, up to 100000 rpm and 100G).	15193000	I	—	N/A	N/A
Cytology centrifuge	A device used in a clinical laboratory to separate components of suspended solids by application of centrifugal force. Usually, it consists of an electrically powered drive, a vertical shaft as a part of the drive, and a horizontal rotor attached to the top end of the vertical shaft.	35881000	I	—	N/A	N/A
Cell washing centrifuge	A device used in a laboratory to separate components of a suspension by application of centrifugal force. Usually, it consists of an electrically powered unit, a vertical shaft as a part of the unit, and a horizontal rotor attached to the top end of the vertical shaft. The device is used for separating erythrocytes from a whole blood sample, and cleaning platelets.	35901000	I	—	N/A	N/A
Laboratory general-purpose centrifuge	A centrifuge used in a general-purpose laboratory to separate components of a suspension by application of centrifugal force. Usually, it consists of an electrically powered unit, a vertical shaft as a part of the unit, and a horizontal rotor attached to the top end of the vertical shaft. The device centrifuges a sample – e.g., body fluid- plasma, serum, etc. which has been centrifuged at a lower speed.	36465000	I	—	N/A	N/A
Cell disrupter	A device used in a laboratory for breaking the membrane to allow direct contact with the cellular contents. Usually, a high-voltage current or an ultrasonic shock wave is used to destroy cell membranes.	17123000	I	1	N/A	N/A
Hematological separator	A device used in a laboratory to separate target blood cells before the selection of stem cells. One method involves using paramagnetic microspheres coated with the selected antibody. These paramagnetic microspheres, in combination with selected cells, form aggregates and separate the cells. Through various pretreatments in combination with centrifugation, the cells are separated.	15113000	I	1	N/A	—
Cell/plasma haematological separator	Usually, an examination device used to separate various blood components such as blood cells and plasma for storage at a blood bank. It utilizes various processes such as centrifugal force, pressure, and membranes.	16901000	I	1	N/A	—
Serum separator	An examination device that separates a certain type of plasma in the primary sample, and further separates the separated matter to be used as a secondary sample.	17106000	I	1	N/A	—
Immunoassay sample processor	A device or instrument that homogenizes the sample collected from human tissue, or produces samples for analysis using an immunoassay analyzer.	30870000	I	—	applicable	applicable
Sample processor	A device for pre-treatment of samples. The automatic system is equipped with various examination devices such as a control computer that pre-treats samples for sample analysis, a sample handler, a processor or a robot. It does exclude just a simple analysis.	38757000	I	—	applicable	applicable
Blood grouping haematology analyser	An automatic or semi-automatic device used for examination prior to blood transfusion (determination of ABO types and subtypes, Rh and other erythrocyte phenotypes, detection of antibodies, syphilis examination and hepatitis examination).	35635000	I	—	applicable	applicable
Urine analyser	An automatic or semi-automatic, dedicated device that identifies and measures chemical substances in the urine by photometric measurement or granule pattern recognition.	35918000	I	—	applicable	applicable
Urine gravimeter	A device that measures the specific gravity of urine.	70187000	I	—	applicable	N/A
Automated urine screening system	An automatic urine screening system that consists of microbiology (culture media), bacteriological culture media, and urine screening (bacteriology).	30648000	I	—	applicable	N/A
Single-use urine flowmeter	A device used to measure the flow rate of urine excreted from a patient. This device is for single-use.	32072000	I	1	applicable	—
Urinary sediment analyser	An automatic or semi-automatic special device that recognizes, and counts the pattern of urinary sediment by flow cytometry or the smear method.	33915000	I	—	applicable	applicable
Nephelometric analyser	A device that detects scattered light only using a photodetector that is installed in the direction to form a certain angle with the incident beam coming from the light source shone toward the suspension that contains cells. Bacterial particles in a suspension can	15163000	I	—	applicable	applicable

Yeast/fungi analyser	A device or a (device) system used to confirm the presence of yeast/fungi in biological samples.	30667000	I	—	applicable	applicable
Automated blood culture analyser	An automatic or semi-automatic device that detects the microbial growth in a blood culture medium. Some identify microorganisms. To identify pathogens, use the growth curve calculated by measuring the production rate of metabolites in a sample-containing bottle, tube, or vial. To measure the production rate of metabolites, various	35617000	I	—	applicable	applicable
Colony quantitative analyser	A device that reflects the light surface to allow an accurate count of bacterial colonies. The light surface divides the agar medium dish by a grid of perpendicular lines, and the operator can count the colonies in each grid, and check the counted grids.	15126000	I	—	applicable	applicable
Microbe identification analyser	An automatic or semi-automatic device that identifies infectious or pathogenic microorganisms that are isolated from biological samples such as blood, urine, cerebrospinal fluid, sputum and feces by specifying the characteristics of morphology.	34573000	I	—	applicable	applicable
Antibiotic susceptibility analyser	An automatic or semi-automatic device that identifies infectious/pathogenic microorganisms by photometry such as absorption, fluorescence and luminescence, and measures the susceptibility to therapeutic drugs.	34574000	I	—	applicable	applicable
Bacteriological incubator	A device that cultivates microorganisms for examination.	70189000	I	—	applicable	applicable
Automated cytological analysis device	A device that utilizes the morphology and stainability of cells, and performs cytodiagnosis by image analysis.	70190000	I	—	applicable	applicable
Cryostat microtome	A device that consists of microtomes contained in a temperature controlled cabinet called a cryostat. The device enables the preparation of sections of frozen tissue samples rather than using a time-consuming fixed procedure. This leads to rapid	15157000	I	1	N/A	N/A
Rotary microtome	A microtome used to shave sections of tissue samples into thin slices. Usually, the sample is stabilized (fixed) with paraffin wax before being shaved off. The section is shaved off by each round of the pulley.	15158000	I	1	N/A	N/A
Sliding microtome	A microtome used to shave celloidin section and large section tissue into thin slices. Usually, the sample is stabilized (fixed) with paraffin wax before being shaved off. When the sliding sledge that supports the sample holder is pushed to the top of the	15159000	I	1	N/A	N/A
Reusable microtome blade	A flat, wedge - shaped blade with a very sharp cutting edge. Usually, it is attached to a microtome which is used to prepare ultra-thin slices from paraffin-fixed tissue. This device is reusable.	42439000	I	1	N/A	N/A
Single-use microtome blade	A flat, wedge - shaped blade with a very sharp cutting edge. Usually, it is attached to a microtome which is used to prepare ultra-thin slices from paraffin-fixed tissue. This device is for single-use.	42440000	I	1	N/A	—
Automated staining device	A device that prepares tissue samples for pathological examination and samples for cytodiagnosis and blood examination. It includes a device for staining or a device for smearing only.	70191000	I	—	applicable	applicable
Cryogenic temperature control unit	A device that maintains a constant, extremely low temperature such as -200°C. Usually, it consists of a temperature sensor, a thermometer and electronic components. Used in a cryosurgery treatment unit and other base units to preserve	16538000	I	1	N/A	N/A
Sperm/ semen analyser	A device that measures the sperm concentration in a sample, and shows quality of the sperm activity (motility).	36744000	I	—	applicable	N/A
Gene analyser	A device that analyzes the sequence information of nucleic acid molecules extracted from biological samples. Usually, nucleic acid molecules are amplified in order to ensure secure analysis.	70192000	I	—	applicable	applicable
Flow cytometer	A device that passes cells in a flow cell, irradiates the cells with a laser beam, etc. and identifies/quantifies the cells based on the scattered light intensity and type of	70193000	I	—	applicable	applicable
Reusable cholangiographic needle	A long, thin needle used to infuse a contrast medium into the bile duct for cholangiography. This device is reusable.	12739001	I	6-①	N/A	N/A

Reusable hypodermic needle	A long, thin, hollow needle used with a syringe, secondary drug therapy set or venous dissection set (e.g., blood collection adaptor and holder) to administer liquid to patients and draw liquid from patients. This device is reusable.	12745001	I	6-①	N/A	N/A
Reusable intra-arterial needle	A long, thin, hollow needle for puncturing an artery. Usually, it is made of metal. This device is reusable.	12747001	I	6-①	N/A	N/A
Reusable tine test needle	Long, thin needles for making simultaneous multiple punctures in a tine test for tuberculosis. This device is reusable.	15679001	I	6-①	N/A	N/A
Reusable filter needle	A long, thin, needle with a filter installed in order to filtrate the injection fluid during administration. This device is reusable.	16266001	I	6-①	N/A	N/A
Reusable subcutaneous injection/infusion port needle	A long, thin, hollow needle attached to a syringe to directly inject or infuse a drug intravenously for treatment. This device is reusable.	17180001	I	6-①	N/A	N/A
Reusable fistula needle	A long, thin, hollow, reusable needle used for drainage from a fistula. This device is reusable.	32111001	I	6-①	N/A	N/A
Reusable ophthalmic cannula	A nonsterile cylindrical device used for the drainage and suction of intraocular substances, and infusion of perfusate in ophthalmic surgery. This device is reusable. Tips connecting to device to generate ultrasonic energy are not included.	34899011	I	6-①	N/A	N/A
Reusable ophthalmic surgery cannula with tube	A cylindrical device with tube used for infusion of perfusate and suction of intraocular substances in ophthalmic surgery. This device is reusable.	34899021	I	6-①	N/A	—
Reusable ophthalmic surgical cannula	A cylindrical device used for infusion of perfusate and suction of intraocular substances in ophthalmic surgery. This device is reusable. Some have a round, flat or hook tip, and in others, the end of needle is covered with a sleeve.	34899031	I	6-①	N/A	—
Reusable blood collecting needle	A needle used as part of a blood collection set in order to collect blood. The dedicated needle is attached to a blood collection adaptor. This device is reusable.	35209001	I	6-①	N/A	N/A
Drug solutions double-edged needle	A needle sharp at both ends used to mix drug solutions in containers sealed with a rubber stopper. This device is for single-use.	70196000	I	2	N/A	—
Aeration needle	Usually, a needle used to feed air into the infusion solution bottle during drip infusion. Some have a tube and filter.	70199000	I	1	N/A	—
Reusable injection needle	A thin metal tube with a pointed tip which is inserted through the skin to infuse or remove liquid. This device is reusable after sterilization.	30890000	I	6-①	N/A	N/A

Reusable biopsy needle	A hollow cylindrical needle used to collect biopsy samples. Various diameters and tip configurations are available. Used to collect tissue samples for analysis. Some are straight and others are curved. This device is reusable after sterilization	31730000	I	6-①	N/A	N/A
Reusable aspiration needle	A long, thin, hollow needle with a pointed tip used to remove fluid from the body cavity or collect a biopsy sample. This device is reusable.	37462000	I	6-①	N/A	N/A
Reusable blunt needle	A thin needle with a curved tip. It is designed to prevent damage to delicate anatomical regions during internal probing. This device is reusable.	37463000	I	6-①	N/A	N/A
Generalpurpose syringe	A syringe used to inject or extract liquid or gas. Usually it is made of glass or plastic, and consists of a scaled container and a plunger. In many cases it is used with an injection needle for drug administration or blood collection	13929001	I	2	N/A	—
Angiography syringe	A device consists of a cylinder and plunger, and is connected to a needle or catheter which is used to inject (infuse) a contrast medium into the heart, a great vessel or coronary artery in order to examine the heart and vessels by X-ray radiography	15286000	I	2	N/A	—
Syringe tip cap	A cap that covers the end of a syringe. The cap is made of plastic, prevents the contents of the syringe from leaking, and maintains its sterility until the syringe is used	16825000	I	1	N/A	—
Anaesthesia syringe	A hollow, cylindrical, plastic device with an injection plunger. Used with an injection needle to administer (infuse) anesthetic.	35387001	I	2	N/A	—
General-purpose irrigation syringe	Mainly used for cleaning and flushing the body cavity. It is a hard plastic cylinder that has a rubber ball fixed at one end, and a nozzle at the other end.	35390000	I	2	N/A	—
Metered-delivery hypodermic syringe	A device consists of a scaled cylinder and a plunger, and is used to administer (inject) an accurately measured substance.	35904000	I	2	N/A	—
Periodontium anaesthesia syringe	A dental cartridge syringe specifically designed to administer a local anesthetic to the periodontal ligament or bone by gradual pressurization.	35869000	I	2	applicable	N/A
Reusable dental anaesthesia syringe	A dental device used in dentistry to administer a local dental anesthetic using a prefilled cartridge and sterilized needle. This device is reusable.	35969000	I	2	applicable	N/A
Tuberculin hypodermic syringe	A device consists of a small cylinder and a plunger, has a fixed capacity, and is used for a tuberculin test.	35391000	I	2	applicable	—
Needle-less loss of resistance epidural localization syringe	A device used for the loss of resistance (LOR) technique in epidural anesthesia. It consists of a needleless cylinder and a plunger. Usually, made of plastic or glass.	70201001	I	2	N/A	—
Glass injection syringe	An injection syringe made of glass.	70202000	I	2	N/A	—
Reusable arthrogram kit	A kit used to visualize the joint by X-ray radiography after a contrast medium has been injected into the joint space. This kit is reusable.	15316001	I	6-①	N/A	N/A

Biopsy puncture instrument	A puncture device used with a biopsy needle to collect tissue samples.	70216000	I	1	applicable	—
Reusable bone marrow collection/transfusion set	A kit used in combination in order to collect and transfer bone marrow. This kit is reusable.	33984001	I	6-①	N/A	N/A
Reusable lumbar puncture kit	A kit used for lumbar puncture to collect spinal fluid. Usually, a spinal needle and a spinal fluid tube are included. This kit is reusable.	12404001	I	6-①	applicable	N/A
Reusable lumbar puncture needle	A sharp needle with stylet is used for spinal puncture to collect spinal fluid for diagnosis and examination. This device is reusable.	34583001	I	6-①	applicable	N/A
Reusable pneumoperitoneal needle	A long, thin, sharp, hollow, needle used to infuse gas into the peritoneal cavity or remove gas from it. This needle is reusable.	12750001	I	6-①	applicable	N/A
Reusable automatic lancet	A pen-shaped device used to collect blood from a capillary at a fingertip or earlobe. A pre-loaded needle protrudes automatically, and pricks the skin to a desired depth so as to yield a small amount of blood for analysis. This device is reusable.	37243001	I	6-①	N/A	N/A
ENT trocar	A surgical device with a sharp pyramidal or conical point. Used to make a puncture into a body cavity during ear, nose and throat (ENT) surgery. The assembled device is inserted in combination with a compatible sleeve that fits the lumen of the device. The trocar is removed after the puncture is made so as to create a working channel in the body cavity. Some are equipped with a dilator with a large sleeve inserted along the outer surface of this guide rod, and	33678000	I	6-①	N/A	—
Reusable amniocentesis kit	A packaged kit, tray or set that includes all of the devices and dressings necessary for collecting an amniotic fluid sample from pregnant women. This device is reusable after proper cleaning.	32685000	I	6-①	N/A	—
Endoscopic trocar	This device is a component of an endoscope that consists of several parts required to achieve its function. Connected to an endoscope to make a puncture into a body cavity. It has a pyramidal or conical point and can be used in combination with a compatible	37144000	I	6-①	N/A	N/A
Trocar sleeve	A metal or plastic sleeve. It serves as a small tool that makes a puncture into the body cavity in combination with a trocar. The trocar is removed from the sleeve after the puncture is made to create a working channel in the body cavity. Some are equipped	37148001	I	6-①	N/A	N/A
Reusable invasive trocar sleeve fixation device	A device to be attached to a trocar sleeve in order to invasively fix the sleeve onto the abdominal wall. This device is reusable.	70221000	I	6-①	N/A	—
Noninvasive trocar sleeve fixation device	A device to be attached to a trocar sleeve in order to non-invasively fix the sleeve onto the abdominal wall.	70223000	I	1	N/A	—
Trocar guide rod	A small metal rod used to expand the working channel created in the body by inserting a large trocar sleeve of approximately 10-20 mm. This guide rod is inserted into a trocar sleeve, and the sleeve is removed while keeping the orifice airtight. A special dilator with a large sleeve is inserted along the outer surface of this guide rod, and	37149001	I	6-①	N/A	N/A

Trocar sleeve dilator	A hollow dilator with a tapered point used to smoothly insert a large trocar sleeve required for significantly dilating the lumen of the working channel of approximately 10-20 mm. This dilator is inserted along the outer surface of the guide rod so as to	37151001	I	6-①	N/A	N/A
Trocar housing	A device to be attached to a trocar sleeve. A shut - off valve or port is used to introduce gas or liquid. Some have various sizes and designs.	70224000	I	1	N/A	—
Reducer for torocar	A device to be attached to a trocar sleeve. It reduces gas leakage during the procedure, and keeps the body cavity airtight.	70225000	I	1	N/A	—
Trocar for cardiovascular/thoracic	A surgical device with a sharp pyramidal or conical point that is used to make a puncture into a body cavity during cardiovascular and thoracic surgery. The assembled device is introduced in combination with a compatible sleeve that fits the lumen of the device. The trocar is removed after the puncture is made so as to create a working	42401001	I	6-①	N/A	—
Reusable subcutaneous tunneller	A surgical device usually made of metals such as stainless steel, or a polymeric material. It is used to create a communicating channel or a tunnel under the skin, which is intended to provide a guide path for a tube or catheter. This device is	35950001	I	6-①	N/A	N/A
Blood collecting puncture instrument	A puncture device used with a blood lancet to collect trace blood for self-measurement of blood glucose.	70226000	I	1	N/A	—
Needle guard	A cap pulled out to cover the used needle in order to prevent accidental needle stick injuries.	17812000	I	1	N/A	—
Dental syringe	A device used in dentistry to rinse the oral cavity, dental pulp cavity and root canal to remove excised fragments. It does not have a needle.	35970011	I	2	N/A	—
Single-use needle recapping device	A device that enables to hold the needle cap and to easily cover the needle by user so as to prevent accidental needle stick injuries. This device is for single-use.	36187000	I	1	N/A	—
Reusable needle recapping device	A device that has needle cap and enables to easily cover the needle by user so as to prevent accidental needle stick injuries. This device is reusable.	37461000	I	1	N/A	N/A
Fistula length measuring instrument	A device that measures the depth and width of the fistula. Some are used for a gastric fistula produced for tube feeding.	70228000	I	5-①	applicable	—
Fistula indwelling tube replacement device	A support device used to assist the retention of a device that has been placed in a fistula when it is removed or inserted.	70229000	I	5-①	applicable	—
Gastrostomy tube measuring kit	A kit used to measure the length from the bolster to the part held with the forceps of a gastic flstula tube with a bolster placed in the body by pulling the part remained outside the body surface with forcens	70230000	I	1	applicable	—
Esophageal balloon catheter	A flexible tube with an inflatable balloon at the distal end. Used for access to the esophagus in diagnostic or therapeutic procedure.	34915000	I	5-①	applicable	—
Temporary use gastroesophageal sterile tube and catheter	A tube and catheter for temporary use to collect gastric juices, infuse drug solutions, and for cleaning and diagnosis. Inserted into the esophagus or stomach. Some are fiber-form.	70231000	I	5-①	applicable	—

Ostomy irrigation kit	A kit consists of a tube with conical end, or a soft, flexible catheter with an indwelling needle and a container of liquid for infusion. It is used to clean the colon via a colostomy.	37716000	I	5-①	applicable	—
Artificial esophageal tube	Tubes that are inserted into an artificial esophagus.	70247000	I	5-①	applicable	—
Laryngotracheal anaesthesia spray kit	The kit is used to spray an anesthetic agent into the larynx or trachea. It consists of a needle and syringe used to draw up the anesthetic, and a cannula with many small holes for spraying the anesthetic. The anesthetic is drawn up into the syringe, the needle is removed from the syringe, and attached to the cannula. This cannula is	70251000	I	2	applicable	—
Hemostatic nasal catheter	A nasal catheter used to stop nasal bleeding. Usually, it consists of a single lumen tube with sponge attached at the distal end. Some have a built-in air way used for nasal breathing during sponge and catheter insertion. Some have a dual-lumen tube with a balloon at each distal end for simultaneous insertion into both nasal cavities. It is also used to stabilize the zygomatic arch.	18716000	I	5-③	applicable	—
Reusable tube disconnecting wedge	A device used to disconnect the connector of the respirator from the connector of such tubes as a tracheal tube and a tracheostomy tube. It is wedge - shaped, and has an opening in the center of the slot. It is applied gently to the connection part to separate the connector of the respirator from the tube connector. Usually, it is included in the	44345000	I	2	applicable	—
Nasal balloon	A rubber balloon inflated with air or liquid to maintain the structure and patency of the nasal cavity.	12699000	I	5-①	applicable	—
Reusable ENT catheter	A tubal surgical device that secures a passage for aspiration, perfusion, and the insertion of other surgical devices. This device is reusable after cleaning and sterilization.	16432001	I	5-①	applicable	—
Short-term use oropharyngeal airway	A curved tube made of metal, plastic or rubber inserted only for oral cavity use to maintain the patency of the respiratory tract for gas exchange or aspiration, which is intended for short-term use. This device is useful for preventing the tongue from	70259000	I	5-③	applicable	—
Short-term use nasopharyngeal airway	A rubber or plastic airway inserted via the nostril into the pharynx in order to maintain the patency of the respiratory tract. No connector. This device is for single-use.	70260000	I	5-③	applicable	—
Temporary use metallic urethral catheter	A metal tube used to drain urine retained in the urinary bladder.	70262000	I	5-①	applicable	—
Endoscope/arthroscope connection tube	A tube connected to an endoscope or arthroscope during endoscopic surgery or examination.	70267000	I	2	N/A	—
Protective stopcock	A lid-like plastic item used to prevent content leakage from the tool, and maintain sterility of the contents until use. This item is for single-use.	70280000	I	1	N/A	—
Vascular catheter cuff	A device applied to the insertion site of a vascular catheter in order to support the prevention of infection by the effect mainly on the growth of subcutaneous tissue. General-purpose types are excluded.	17470009	I	1	applicable	—

Guidewire insertion connector	A guidewire connected to the connector of a catheter, etc. and assists the insertion of a guidewire into the body. This is not inserted into the body, nor used for the administration of drug solutions	70286000	I	1	N/A	—
Intravascular catheter with valve cutter	A flexible tube with a blade that is inserted into the resected vein, and used to dissect the venous valve without any damage, and eliminate its function in revascularization by bypass transplantation in which peripheral veins are used for arteries.	70299000	I	2	N/A	—
Renal auxiliary cooling catheter	A catheter used to infuse the chilled perfusate into the kidney from the renal artery via the catheter in order to preserve the kidney after cardiac arrest.	70300000	I	2	applicable	—
Cerebrospinal fluid drainage circuit	A drainage circuit connected to the drain tube placed for discharging cerebrospinal fluid.	34586001	I	1	N/A	—
Shunt valve adjustment tool	A tool used to noninvasively confirm or change non-invasively from outside the body the pressure of the pressure-adjustable shunt valve used for hydrocephalus treatment. Usually, a permanent magnet is used to select the pressure of the adjustable valve. It	70305000	I	1	applicable	—
Drainage bag	A plastic drainage bag that consists of 1 or 2 chambers, and is connected to a drain tube. It is connected to a thoracic or abdominal cavity drain, and used to eliminate blood, air, and purulent matter from the thoracic or abdominal cavity.	70308000	I	1	N/A	—
Temporary use umbrella catheter	A flexible tube with a diaphragm at the distal end that opens when a catheter (e.g., barium enema umbrella catheter) is inserted into a body orifice for temporary use.	10760001	I	5-①	N/A	—
Single-use nasal dropper	A hollow tube used for aspiration of a small amount of liquid, and to administer the liquid drop by drop into the nasal tube. Both ends are open, and an aspiration valve is usually attached to one end. Usually, made of glass or plastic. This device is for single-	35215000	I	5-①	N/A	—
Single-use dental suction cannula	A tubal dental device to be connected to a non-active aspiration device (usually, a dentistry dedicated device). Used to eliminate water and cutting debris that have accumulated in the oral cavity. This device is for single-use	37434000	I	5-①	N/A	—
Reusable dental suction cannula	A tubal dental device to be connected to a non-active aspiration device (usually, a dentistry dedicated device). Used to eliminate water and cutting debris that have	38759000	I	5-①	N/A	—
Reusable dialysis needle	A long, thin, sharp needle used to infuse/drain blood during hemodialysis. This device is reusable.	12741001	I	6-①	applicable	N/A
Catheter holder	An extracorporeal tool that is attached to a venous catheter or injection needle to protect the insertion part and prevent the venous tool from falling accidentally.	15735000	I	1	N/A	—
Shunt holder	A holder used to stabilize (fix) the blood access tool for hemodialysis or other purposes.	32133000	I	1	N/A	—
Crimp for plier	A manual tool that consists of two rods having a handle at each proximal end extending to the distal end through a pivot point. The tips serve as pliers, and are used to manipulate the arteriovenous shunt of patients required hemodialysis	32139000	I	1	N/A	—
Catheter connector	A tool used to connect the catheter to another object such as a container, or insert the catheter into the body for irrigation or drainage.	32339000	I	1	applicable	—
Esophageal intubation detector	A device that detects esophageal intubation by using a syringe or valve in order to suck through the tracheal tube inserted into the patient via a tube piece (e.g., other small	36290000	I	5-①	applicable	—
Angioplasty balloon inflator	A hand-held device (e.g., syringe or small pump) with a manometer used for balloon pressurization when a balloon catheter for angioplasty is placed in the body. The pressure occurring during coronary artery dilation (also known as percutaneous	17541010	I	1	applicable	—
Non-vascular balloon inflator	A hand-held device (e.g., syringe or small pump) with a manometer used for balloon pressurization when a balloon catheter is placed in the body.	17541020	I	1	applicable	—

Reusable tracheal tube stylet	A device used to stabilize a tracheal tube, and facilitate passage through the vocal cords. Usually, made of flexible metal. It is inserted into the tracheal tube before intubation. In order to prevent damage to the trachea during insertion, it is removed	35402000	I	5-①	applicable	—
Reusable tracheal introducer tube	A device used to introduce a tracheal tube for intubation. A long, thin, rod-like device with a curved tip that usually allows adjustment of the tube in a favorable direction for routine or difficult oral intubation. This device is reusable	36131000	I	5-①	applicable	—
Single-use tracheal tube stylet	A device used to stabilize a tracheal tube, and facilitate passage through the vocal cords. Usually made of flexible metal. It is inserted into the tracheal tube before intubation. In order to prevent damage to the trachea during insertion, it is shorter	37469000	I	5-①	applicable	—
Single-use tracheal introducer tube	A device used to introduce a tracheal tube for intubation. A long, thin, rod-like device with a curved tip that usually allows adjustment of the tube in a favorable direction for routine or difficult oral intubation. This device is for single-use	41829000	I	5-①	applicable	—
Reusable tracheal tube guide	A device used as a guide when replacing a tracheal tube placed in the patient. The guide is inserted into inside of the tube placed in the body, and the tube is removed by sliding it along the guide. In order to facilitate the correct insertion of the new tracheal	42075000	I	5-①	applicable	—
Single-use tracheal tube guide	A device used as a guide when replacing a tracheal tube placed in the patient. The guide is inserted into inside of the tube placed in the body, and the tube is removed by sliding it along the guide. In order to facilitate the correct insertion of the new tracheal tube, the new tracheal tube is inserted by sliding it along the guide. The guide is	42084000	I	5-①	applicable	—
Catheter clamp	A device that is used to hold or pressurize the catheter. The pressure is applied until the catheter is closed.	16449000	I	1	N/A	—
Reusable tubing clamp	A device that is used to block or pinch the tube. Usually, it is used in laboratories. Some are for general-purpose use and are used in medical institutions. This device is reusable.	43223000	I	1	N/A	—
Tube cuff spreader	A device that is used in to attach the tracheal tube cuff to the tracheal tube or tracheal cannula.	31327000	I	6-①	N/A	—
Temporary use catheter balloon repair kit	A kit that contains adhesives and balloons used temporarily for repair or replacement of a catheter balloon.	31665001	I	5-①	applicable	—
Reusable catheter controller steering unit	A unit that is connected to the proximal end of an operable guidewire in order to control an operable catheter. This device is reusable after proper cleaning and sterilization.	31742000	I	12	applicable	—
Infusion stopcock	A stopcock that is used to adjust the infusion of fluid into the vascular system. It is included in a vascular administration kit. This item is for single-use.	32172011	I	2	N/A	—
Enteral nutrition infusion stopcock	A stopcock that is used to adjust the infusion of fluid into the gastrointestinal tract. It is connected to a catheter for enteral feeding.	32172021	I	2	N/A	—
General-purpose stopcock valve	A valve that is used to control the direction of flow of a liquid or gas. Usually, it is made of durable materials (e.g., plastic, metal) and is used for various purposes. It is not connected to an active device	35375001	I	2	N/A	—
Tracheal tube cuff inflator	A device that supplies air to the cuff of a tube when a tracheal tube is placed in the body. Usually, it is equipped with a rubber ball that supplies the air. Most of them are equipped with a manometer that indicates the pressure so as to prevent overinflation	35401000	I	1	applicable	—
Drug solution needle	A liquid collection needle that is attached to a syringe, and used to draw up a drug solution from a container. Usually made of plastic or metal. Some have a filter.	70324000	I	1	N/A	—

Infusion accessory set	A set of accessories used with an infusion set. It contains caps, connectors, and adaptors.	70326001	I	2	N/A	—
Catheter fixation patch	A patch having adhesive on one side, and a catheter holder on the other side, and which is used to allow an arterial, central venous, or epidural catheter to be fixed easily.	70328000	I	1	applicable	—
Catheter sterile sleeve	A device that covers a sheath to make it easier to perform an aseptic procedure with an imaging tool in this device.	70331000	I	1	N/A	—
Reusable arthroscopy catheter	A flexible tube used for arthroscope examination in the joint. This device is reusable.	15983001	I	6-①	applicable	N/A
Tubing for suction	A plastic tube used to connect an aspirator or a drain tube to a collection container when aspirating effusions that need to be removed.	16779000	I	1	N/A	—
Lacrimal tube	A tube used to collect tears for diagnosis and examination.	17003000	I	5-①	applicable	—
Balloon hemostasis	An inflatable balloon to be inserted into the nasal cavity and expanded to stop blood by pressure. This balloon is inflated with air or liquid. This device is for single-use.	31911000	I	5-③	applicable	—
Insemination uterine catheter	A semi-rigid or rigid tube used to inject seminal fluid into the uterus. This device is for single-use.	34077000	I	5-①	applicable	—
Single-use ear catheter	A semi-rigid or rigid, plastic tubal surgical device inserted into the ear canal. This catheter is left in the place as a guide path for aspiration, irrigation, or insertion of other surgical devices. This device is for single-use.	34897000	I	5-③	applicable	—
Hemostatic transnasal catheter	A curved tube including a stylet that is used to block the choana for stopping nasal bleeding by attaching a spring.	35790000	I	5-①	applicable	—
Infusion extension tube	A tube used to extend a drip infusion line.	12170001	I	2	N/A	—
Ophthalmic perfusion/aspiration tube	A set of tubes used for perfusion/aspiration devices in ophthalmic surgery.	70339000	I	2	applicable	—
Temporary use laryngotomy tube	A tube that is temporarily used to secure the airway of patients undergoing partial or total laryngectomy. This is nonsterile.	70343000	I	5-①	applicable	—
Cervical dilator	A catheter that is used to dilate the cervical canal with a balloon when the uterine does not dilate enough due to inertia uteri.	70344000	I	5-①	applicable	—
Orthopedic drainage cannula	An orthopedic drainage cannula. This does not fall under the classification of other cannulas.	70352000	I	5-①	N/A	N/A
Insufflation tube	A flexible tube used to connect the insufflation device and insufflation needle or trocar. Some include a filter.	70353000	I	2	N/A	—

Exhaust tube	A flexible tube used to connect a gas suction unit of an insufflation device and an endoscopic treatment tool or trocar.	70354000	I	2	N/A	—
Water supply or suction tube for endoscope	A flexible tube used to connect the water feed unit or aspiration unit to the endoscope or endoscopic treatment tool.	70355000	I	2	N/A	—
Air and water supply tube	A flexible tube used to connect the water feed unit or air supply unit to the endoscope or endoscopic treatment tool.	70356000	I	2	N/A	—
Blood sampling suction unit	A simple auxiliary aspirator that consists of a housing, plunger and gasket. Usually, it assists trace bleeding by generating negative pressure on a puncture site so that patients can measure their blood glucose levels themselves.	70362000	I	1	applicable	—
Evacuated blood collecting tube holder	A holder that is included in a vacuum blood collection system. It is used for fixation and stabilization upon puncturing blood collection needle etc. After fitting and fixing the blood collection needle, the vacuum blood collection tube is inserted into this.	70364000	I	1	applicable	—
Blood sampling/transfusion tube heat fusion joint device	A device used in a way that a blood collection set or blood transfusion tube set and the tube to be connected to those tube sets are severed with a heated blade and the tubes are moved while the severed section is still touching the blade. The heated blade is then	70366000	I	1	applicable	—
Tissue culture sample preparation container	A container used to prepare the blood components which are necessary for tissue cultivation. The containers also refer to It has the bags for storing and separating plasma and serum derived from human and animal	70369000	I	2	applicable	—
Gravity pour infusion administration set without needle	An infusion set (no needle) used to administer for fluid infusion by gravity without using any active device. A needle or butterfly needle is connected to the head.	70370000	I	2	applicable	—
Reusable winged needle for general veins	A very thin, sharp needle used for veins in general. This device is reusable.	70377000	I	6-①	applicable	—
Reusable winged scalp vein needle	A very thin, sharp needle used for scalp veins or other small veins (pediatric use in particular). This device is reusable.	35211001	I	6-①	applicable	N/A
Container adaptor	An adaptor (usually, a small part) used to connect a container to an extracorporeal component (usually, infusion line) for infusing a drug solution or draining body fluid. Usually, it is used to connect components from different manufacturers. This device is	44035000	I	2	applicable	—
Fluid transfer tube set	A set of devices used to transfer an infusion solution from a container to an intravenous infusion bag or other containers for infusion solution.	16610000	I	2	applicable	—
Intravenous line connector	A device that is inserted into a Y-shaped connection site on the venous line for drug administration or blood collection.	17501000	I	2	applicable	—
Drug solution preparation needle	A device used to transfer a drug from one container to another container. Some are equipped with a tube, plastic or metal needle for connecting or inserting into the container.	70379000	I	2	applicable	—
Liquid transfer device set	A set of devices used to transfer an infusion solution from a container to an intravenous infusion bag or other containers for infusion solution.	70380000	I	2	applicable	—

Drug solution preparation instrument	A device used to transfer a drug solution from one container to another container. Some are equipped with a tube or spike for connection/insertion into the container.	70381000	I	2	applicable	—
Infusion line clamp	A tool used to block or pinch a tube line (e.g., infusion set, aspirator tube) in order to stop the passage of a substance in the line. This tool is reusable.	32146000	I	1	applicable	—
Single-use in-line backflow check valve	A device used to prevent reflux of gas or liquid in a medical tube or pipe line. This device is for single-use.	34099001	I	2	applicable	—
Single-use infusion solution container	A plastic or glass container used to hold an infusion solution mixture to be administered using an intravascular infusion set. This tool is for single-use.	35127000	I	2	applicable	—
Dial-calibrated infusion line clamp	A tool that is used to block or pinch the line of an infusion set to control the passage of liquid in the line. Equipped with a scaled dial that indicates the infusion rate. Used for drug infusion by gravity. This tool is for single-use.	35894000	I	1	applicable	—
Reusable in-line backflow check valve	A device used to prevent reflux of gas or liquid in a medical tube or pipe line. This device is reusable.	42548001	I	2	applicable	N/A
Reusable uterine injector	A device used to inject liquid, a drug, or other substance into the uterus. Usually, it has a structure suitable for the uterus, and is reusable. Usually, it is manually operated.	15622000	I	5-①	N/A	—
Intraosseous drug infusion kit	A kit intended to inject drugs into the bone. Usually, it consists of an injection needle (some are specifically designed) and other items (e.g., insertion handle and scalpel necessary for accessing the marrow cavity in order to administer first aid drugs and other liquids).	18009000	I	1	N/A	—
Dental medication injector	A root canal injector made of synthetic resin that is used to clean the root canal, or apply or insert a root canal treatment agent in dental treatment. It consists of an outer cylinder with a needle, and a plunger. It is also used to insert dental root canal filler.	70387000	I	1	N/A	—
Laryngeal injection kit	A package kit, a set or a tray that contains devices, wound cover/protection materials and drugs needed for larynx injection.	33427000	I	5-①	N/A	—
Single-use syringe for prefilled drugs	A glass or plastic syringe used to administer drug. Usually, the syringe is designed to contain single dose of drugs. This device is for single-use.	70389000	I	2	N/A	—
Manually-operated infusion pressure regulator	A bag that externally applies a constant pressure on a soft bag for infusion in order to adjust the rate of infusion. Pressure is manually generated (using a hand pump).	13100001	I	1	N/A	—
Enema kit	A package that consists of items used to inject a solution into the rectum. It promotes bowel movements.	11582000	I	5-①	N/A	—

Enema tip	A single-use tool attached to the head of an enema tube to make it easy to inject enema into the rectum.	11583000	I	5-①	N/A	—
Reusable dye injector	An injector used to pigment the skin by permeation. It is used by a medical doctor to cover a scar or burn, create an artificial eyebrow, natural appearance of nipples after	17660001	I	6-①	applicable	N/A
Reusable indicator injector	A device used to ensure accurate bolus injection of the indicator drug (e.g., chilled saline solution) into the bloodstream. Usually, used to infuse an indicator drug into the heart in order to assess blood flow in the heart. Some are used with a densitometer or thermodilution device to measure cardiac output. This device is reusable.	31736001	I	6-①	applicable	N/A
Preparation drug solution injection connector	A device attached to a blood bag or drug solution container to infuse/drain a drug solution in the bag or drug solution container.	70396000	I	2	N/A	—
Drug injector testing equipment	A device/instrument used to confirm that drug injectors (e.g., infusion pump, syringe pump, infusion controller) are functioning normally. Usually, used to check the flow rate, bolus, and alarm function.	36794000	I	1	applicable	—
Infusion connecting tube	A coupling tube that has a connection part at both ends to be connected to a drug solution bottle or other items. It is used to transfer the solution in the bottle for infusion.	70399000	I	2	applicable	—
Set for nutrition infusion	A device that is connected to a catheter inserted into the stomach or intestine for infusion of enteral nutrition.	70400000	I	2	N/A	—
Plasma thawing unit	A device used to thaw the frozen plasma stored by the blood bank, etc. under control before use. Various means such as a microwave oven and warming bath can be utilized.	43434000	I	1	applicable	—
Single-use luer adaptor	An adaptor used to hold multiple components used in combination in a fixed position or to connect multiple components. This device is for single-use.	35075000	I	1	applicable	—
Adaptor for syringe/needle	An adaptor that is used to connect a syringe or injection needle to a tube, stopcock, or other structure. Some are luer lock type, others are luer slip type. Some are equipped with a tube or syringe.	35384000	I	1	applicable	—
Single-use pin-indexed system adaptor	An adaptor that locks two components which are mutually compatible. The pin index is a system that consists of coded pins and holes, and serves as a safety system that allows the connection to be made only when they match and prevents inadvertent	35897000	I	2	applicable	—
Reusable hemostatic clip applier	A surgical device used to allow the use of hemostasis clips for blood vessel ligation. This device is reused after cleaning and sterilization. Some are used for endoscopy.	35798000	I	6-①	N/A	N/A
Reusable ligation/fixation clip applier	A surgical device used to allow the use of clips for luminal tissue ligation and fixation. This device is reused after cleaning and sterilization. Some are used for endoscopy.	70406000	I	6-①	N/A	N/A
Needle holder	A surgical device with handles, that is designed to hold the suture needle when suturing. The edge of the blade from the distal end to the pivot point comes in various configurations.	12726010	I	6-①	N/A	N/A
Single-use needle holder	A surgical device with handles, that is designed to hold the suture needle when suturing. The edge of the blade from the distal end to the pivot point comes in various configurations. This device is for single-use.	12726020	I	1	N/A	—
Umbilical ligator	A surgical device used for umbilical cord ligation. Usually, it consists of a long shaft or cannula with a clamp or grip at the distal end that holds the ligation thread. It has a handle with moving parts at the proximal end that mechanically operate the clamp or grip at the distal end.	15041000	I	6-①	N/A	N/A

Ophthalmic suture needle	An ophthalmic needle used to suture ocular tissues.	32763000	I	6-①	N/A	—
Suture needle	A needle used to insert and pull out a suture thread from the tissue. Some are designed for special functions, and other are for general-purpose.	70417001	I	6-①	N/A	—
Cervical cerclage needle	A solid cylindrical device that comes in various diameters. It has various configurations at the distal end. The solid cylindrical device is used for reefing around the cervical canal with suture materials of various types. It comes in various diameters.	32600000	I	6-①	N/A	N/A
Clincher	A device that automatically makes a surgical knot, and can move the knot.	70418000	I	1	N/A	N/A
Ligator	A surgical device used for ligation of a blood vessel or other physical structures. It consists of a long shaft or cannula with a clamp or grip at the distal end that holds the ligation thread. It has a handle with moving parts at the proximal end that	12332000	I	6-①	N/A	N/A
Reusable automatic suture unit	A device that performs automatic suturing with a sterilized thread and repairs the damaged site or muscular damage. This device is reusable.	15065001	I	6-①	N/A	N/A
Reusable arthroscopic suture unit	A device used to repair a damaged site or muscular damage. Under a controlled arthroscope, its suture punch system makes the number of stitches that the surgeon desires at the injured or damaged site. This device is reusable.	17735001	I	6-①	N/A	N/A
Reusable surgical stapler	A surgical device used for surgical stapling (some have tear-off function). Some are designed like a pistol. Some are used for endoscopy. Active types are excluded. This	32369001	I	6-①	N/A	—
Wire/ligature passer	A surgical device used to pass wire or ligation thread through tissue. Usually, it is either a flexible or rigid rod with a handle that has a hook, catch or clasp that holds the material to be passed through the tissue. It is tapered and has a button or acorn-	32864001	I	6-①	N/A	N/A
Endotherapy suturing device	A device used with a special endoscope for endoscopic treatment. Used for mechanical work such as closure of wounds and cuts with various materials (e.g., silk, catgut).	34078000	I	5-①,6-①	N/A	N/A
Surgical coarctation clamp	A scissor-like surgical device with ring handles. The two cutting blades from the distal end to the pivot point are either straight or curved. The center of the cutting blade has a groove from one end to the other end that does not have teeth in order to prevent damage to the blood vessel held by the device.	35594000	I	6-①	N/A	—
Removable reusable skin staple handle	A reusable handle used in combination with a pistol-like mechanism and detachable skin staples with single-use.	35884001	I	1	N/A	—
Suture passer	A surgical device used to pass the suture thread and suture needle through the tissue. Usually, it is a flexible or rigid rod with a handle that has a hook, catch or clasp that holds the material to be passed through the tissue. It is tapered and has a button or	37839001	I	6-①	N/A	N/A
Reusable staple remover	A metal or plastic surgical device used to remove staples from a surgical wound or dissected site. This device is reusable.	16787001	I	6-①	N/A	N/A
Clip remover	A surgical device that looks like scissors or tweezers, and has two blades fixed at the proximal end or in the middle. The blades are designed to hold the clip and release	10895000	I	6-①	N/A	N/A
Surgical bronchus clamp	A surgical device used to place pressure on the bronchus nontraumatically.	34950000	I	6-①	N/A	—
Surgical bulldog clamp	A surgical device that has a saw-like bite that is either linear, oblique or curved. Used to hold, connect, press or support the organs, blood vessel or tissue. The handles are either straight or ring in shape.	34951000	I	6-①	N/A	—
Reusable surgical hemorrhoid clamp	A scissor-like surgical device that has ring handles. The two blades from the distal end to the pivot point have a saw-like bite and a triangular point. This device is reusable after sterilization.	34952000	I	6-①	N/A	N/A

Reusable surgical tube clamp	A surgical device used to press a tube. This device is reusable after sterilization.	34954000	I	1	N/A	N/A
Reusable surgical rectal clamp	A surgical device used to hold, connect, press or support the rectum, rectal valve or anal tube nontraumatically. This device is reusable.	35542001	I	6-①	N/A	N/A
Reusable surgical carotid clamp	A surgical device used to press the carotid artery. This device is reusable.	35593001	I	6-①	N/A	N/A
Reusable implantable vascular clip	A device designed to block the blood flow of a small vessel by pressurization. This device is reusable after sterilization.	35640001	I	6-①	N/A	—
Surgical tape	Belt-like or tubal threads and strings used to temporarily hold organs. Some have a needle.	70419000	I	4	N/A	—
Non-surgical esophageal varices ligation therapy ligator set	A set used for esophageal varix ligation in non-surgical esophagoscopic variceal ligation. It consists of a transparent hood and a rubber or elastomer O-ring band which is connected to the end of esophagoscope for variceal ligation.	70420001	I	5-①	N/A	—
Reusable non-sterilized scalp clip	A nonsterile surgical device that consists of two blades fixed in the center or an alpha-shaped unit. Used for hemostasis on the scalp during surgery. This device is reusable.	34959001	I	6-①	N/A	—
Reusable skin clip	A surgical device that consists of two blades fixed in the center or an alpha-shaped unit. Used to connect the edges of dissected skin or fix electrodes on the skin during surgery. This device is reusable.	37699000	I	6-①	N/A	—
Surgical wound clip	A metal device used to temporarily gather the edges of a wound together.	38144000	I	6-①	N/A	—
Reusable aneurysmal suture needle	A metal device with a sharp point that has a handle, and used to ligate blood vessels. This device is reusable.	34608000	I	6-①	N/A	N/A
Suture retention device	Devices including a fixation bridge, surgical button and thread support used to ensure wider distribution of the tension of suture thread and assist the healing of the wound.	33519000	I	6-①	N/A	N/A
Esophageal ligator	A surgical device used for esophageal ligation. It consists of a long shaft or catheter with a clamp or grip at the distal end that holds the ligation thread. It has a handle with moving parts at the proximal end that mechanically operates the clamp or grip at the distal end.	34137000	I	1	N/A	—
Haemorrhoid ligator	A surgical device for hemorrhoid ligation. Usually, it consists of a long shaft or catheter with a clamp or grip at the distal end that holds the ligation thread. It has a handle with moving parts at the proximal end that mechanically operates the clamp or grip at the distal end.	35157000	I	5-①	N/A	—
Reusable surgical punch	A surgical device used to create a hole for suturing or connecting tissues or blood vessels. This device is reusable.	35285001	I	6-①	N/A	—
Suture guide	A device placed on an open wound to guide the surgeon when deciding on the suture position. It is pulled tight to ensure that the suture threads are connected.	36129000	I	6-①	N/A	N/A

Needle driver	A device used to manipulate the suture needle in abdominal surgery. The curve of the suture needle at the shaft end is controlled by the handle.	70427000	I	1	N/A	—
Vasovasostomy set	A set of needle and plates that is used to fix the end of vas deferens to the plate using the needle in the (microscopic) vasovasostomy.	70428000	I	6-①	N/A	—
Prostatectomy urinary suture guide	A metal device that is used to facilitate positioning of the suture after prostatectomy. Some have a balloon catheter for single-use.	70429000	I	5-①	N/A	N/A
Urinary incontinence suturing needle	A device used to lift up the female urinary bladder neck with a thread in order to treat urinary incontinence.	70430001	I	1	N/A	—
Surgical dressing	Cover and protective materials in suitable sizes used for post-operative wounds.	34654000	I	4	applicable	—
Skin adhesive	A skin adhesive used for closure, connection or reinforcement of skin wounds. Made of acrylate or other synthetic substances.	33492101	I	4	applicable	—
Angiography surgical drape	A cover used exclusively for angiography. This device is for single-use.	16006000	I	1	N/A	—
Single-use general-purpose surgical drape	A drape made of non-woven fabric used as a protective cover or curtain in order to isolate the surgical dissection site and surgical site from contamination in the operating room and catheter room (surface of devices and tables). This is also used to protect the patient from heat, flame or other morphological energy during surgery.	35531000	I	1	N/A	—
Laser-resistant surgical drape	A surgical drape that is specifically processed or coated with materials for protection against laser energy at the typical surgical level. This can be used to protect devices, instruments, and the patient.	36008000	I	4	N/A	—
Cast construction material	A tool that consists of hard protection materials (cast) made of plastic, glass fiber, or plaster for fixation of fractures, diseased joints or painful sprains.	33056000	I	1	N/A	—
Toe separator	A device that consists of U-shaped channels attached to a frame or a plate, or a U-shaped channel set. Used to hold individual phalanges at desired positions.	13544000	I	1	N/A	—
Bunion shield	A pad used to protect a bunion that has formed at the root of the big toe.	13565000	I	1	N/A	—
Hand/finger splint	A splint used to fix a damaged hand or finger.	16210000	I	1	N/A	—
Inflatable extremity splint	A sleeve to be placed around the arm or leg and inflated to support and protect the arm or leg.	32302000	I	1	N/A	—
Splint for intranasal septal	A device made of biomaterial or synthetic material. Used for replacement or repair of the septum that separates the nasal cavities at the middle surface.	34005000	I	1	N/A	—

Moulded splint	A splint that is used to support and protect a damaged body part. It is formed in advance to fit to the body part concerned.	35354000	I	1	N/A	—
Single-use padded splint	A padded splint that is used to support a damaged body part. This device is for single-use.	35357000	I	1	N/A	—
Vacuum mouldable splint	A splint that is used to support and protect an injured body part. The splint is placed around the affected site. The air is deflated in order to support and protect the affected site.	35358000	I	1	N/A	—
External nasal splint	A splint that is used to support a fractured or treated nasal bone. It is placed outside the nose, functions like a truss and supports the nose.	35411000	I	1	N/A	—
Mouldable splint	A splint that is used to support and protect a damaged body part. It is formed so as to fit the affected body part.	36204000	I	1	N/A	—
Reusable first aid emergency kit without medication	A kit that consists of emergency items and materials for first aid treatment. Usually, it is used at a facility, in the home, in a car, in an ambulance, and at places where crowds gather. The kit does not include drugs. This kit is reusable after properly washing the reusable items, and replenishing consumables.	43000000	I	6-①	applicable	N/A
Reusable first aid emergency kit with medication	A kit that consists of emergency items and materials for first aid treatment. Usually, it is used at a facility, in the home, in a car, in an ambulance, and at places where crowds gather. The kit includes drugs and components that can work as	44039000	I	4,6-①	applicable	applicable
Burn dressing	A wide, layered gauze pad used to cover and protect burned skin, and absorb the exudate from the burn.	11322101	I	4	applicable	—
Flocculent dressing	A pad made of cotton, synthetic fiber, hydrophilic polymer, etc. used to cover wound of skin or oral mucosa. The pad for wounds of oral mucosa can be used temporarily or in short term.	11751000	I	4	applicable	—
Visceral retainer	A wide, thin, flat pad or net with a string or a cord at one end, usually made of flexible plastic. This device is used to hold an organ at the proper position. It is also implanted into a surgical site temporarily. This device is for single-use.	13371000	I	6-①	applicable	N/A
Skin barrier adhesive plate	An adhesive plate that is placed on the skin to protect it from external contamination.	31071000	I	4	N/A	—
Compression dressing	A covering material that is used to apply pressure to an affected site and prevent the body from retaining fluid. Most commonly, it is used for transplanted skin and the treatment of burns.	34084000	I	1	N/A	—
Burn wrap	A nonsterile covering material used to cover a wound and maintain the condition of a burn patient being transferred to a burn center or hospital. The material is used at the site of an emergency. It cools the burn, moisturizes the affected site, prevents exacerbation of the burn, minimizes trauma, and prevents contamination. The material can be coated with a gel. It comes in various sizes (towel to bed sheet size).	36093000	I	4	applicable	—

Skin approximation tape	A cloth or plastic tape coated with adhesive on one side. Used for closure, connection and reinforcement of a skin wound.	70438000	I	4	applicable	—
Catheter dressing	A sterilized cover/protective material such as adhesive film materials, which is directly applied to the puncture site of needle or catheter for fixation. Non-woven cloth may be added for enhanced fixation and retention.	70444000	I	1	applicable	—
Wound depth measuring instrument	A non-invasive probe which is applied to the body surface for a short period in order to measure the size (width) and depth (difference between the normal skin and wound) of the wound or socket. For contact with an open wound on the skin, it should be	70445000	I	12	applicable	—
Wound area measuring instrument	A device used to measure and record the area of a wound. It includes recording sheets to record the size of the wound. The recording sheets may be used in combination with the area calculator to calculate the area of the wound. For contact with an open wound on the skin, it should be sterilized and used only once.	70446000	I	12	applicable	—
Single-use class I surgical procedure kit	A prepackaged kit that contains all the Class I devices, cover and protection materials and drugs which are necessary for general treatment. This kit is for single-use.	33961001	I	5-①	applicable	—
Ophthalmic foreign body extractor magnet	A device used to remove magnetic, metal foreign objects from the eye. It contains a permanent magnet.	35495000	I	6-①	N/A	N/A
Ultrasonic nebulizer	A device that supplies aerosolized water or drugs generated by mechanical oscillation. It consists of an aerosol generator, reservoir, and baffle.	12719000	I	2	applicable	N/A
Heated nebulizer	A device that supplies aerosolized water or drugs generated by heating. It consists of an aerosol generator, reservoir, and baffle.	12716000	I	2	applicable	N/A
Medication spray bottle	A container with a spray nozzle used to spray a drug (e.g., nasal spray)	16529000	I	5-①	applicable	N/A
Non-heated humidifier	A unit used to add vapor to a dry gas. Usually, it has a reservoir and tube (to bring a gas flow and water into contact with each other). Generally, it is used with a nasal cannula.	35113000	I	5-③	applicable	N/A
Non-heated nebulizer	A device that supplies aerosolized water or drugs generated without heating (excluding mechanical oscillation). It consists of an aerosol generator, reservoir, and baffle.	35457000	I	2	applicable	N/A
ENT nebulizer	A device that supplies aerosolized water or drugs for the patient to inhale.	70451000	I	2	applicable	N/A
Gas warmer	A device that warms the gas used to administer oxygen or drugs to the lungs in oxygen therapy or compressed air therapy.	70452000	I	2	applicable	—
Reusable vaginal applicator	A device used to apply drugs, pharmaceutical products for vaginal treatment, or to attach or apply other medical tools in the vagina. The hand-held valve (e.g., manual	32652000	I	5-①	N/A	N/A
Reusable pneumatically-powered ENT applicator	An applicator used to administer a powdered drug into the ear, nose or throat (ENT) by blowing the air. This device is reusable.	33466000	I	5-①	N/A	N/A

Breathing gas mixer	A device used to spray aerosolized liquid drugs into the air that the patient inhales. Usually, manually operated. Different from nebulizers, it does not have a baffle, and the particle size of aerosols is not homogenous.	36327009	I	2	N/A	N/A
ENT drug solution spray	A sprayer with a hand-held valve (manual pump) that blows the drug into the ear, nose or throat (ENT).	70453000	I	2	N/A	N/A
Diagnostic nebulizer	A device used for asthma assessment. It generates cold air (–10°C to –20°C), and the patient inhales this air via a mouth piece to induce an asthma attack. The severity of respiratory tract occlusion is assessed so that the attending physician can prescribe appropriate treatment.	37072000	I	5-①	applicable	N/A
Pleural drainage system	A plastic device that consists of 1 or 2 chambers connected to an aspiration tube. Connected to a thoracic cavity drain to eliminate blood, air, and purulent discharge from the thoracic cavity.	10817000	I	1	applicable	—
Suction system operated by gas	A device that generates negative pressure used for such treatment as the aspiration of liquid or granular substances. Operated by compressed gas (air or oxygen) fed via a nozzle. Usually used at the bedside, in an operating room, and anesthesia room.	36607000	I	1	applicable	applicable
Suction system operated by vacuum	A device used for such treatment as the aspiration of liquid or granular substances by using negative pressure supplied by the hospital's medical gas supply system. Usually used at bedside, or in an operating room.	36778000	I	1	applicable	applicable
Reusable ear catheter	A tubal surgical device made of rigid plastic or metal. Inserted into the ear canal, and used to secure a passage for aspiration, perfusion, and the insertion of surgical devices. This device is reusable after cleaning and sterilization.	33395000	I	5-①	applicable	N/A
Canister for suction system	A canister used with an aspirator to collect body fluids. This device is for single-use. Usually made of plastic, stored as folded individually in a package, and assembled before use. Some are provided as a finished canister. Dispose of it in accordance with the applicable local environment laws and regulations. Some have a non-return valve that prevents contamination.	34858000	I	1	applicable	N/A
Reusable suction unit bottle	A glass or plastic bottle used with an aspirator to collect body fluids. It forms an airtight seal using a top or a lid. This device is reusable.	38476000	I	1	applicable	N/A
Reusable general-purpose suction tip	A tool connected to an aspirator to adjust or indicate the aspiration for surgery or treatment. This is a reusable aspiration tip for general-purpose.	38749000	I	1	applicable	N/A
Powered douche	A device that squirts liquid into a body part. Used to maintain hygiene or for treatment. Electrically operated.	34628000	I	2,12	applicable	applicable
Sterile manually-operated douche	A device that squirts liquid into a body part. Used to maintain hygiene or treatment. Uses sterilized liquid and is operated manually.	34629009	I	2	applicable	N/A
Manually-operated douche	A device that squirts liquid into a body part. Used to maintain hygiene or for treatment. Operated manually.	34630000	I	2	N/A	N/A

Needle douche	A needle without a blade point. Used to clean inside the oral cavity, dental pulp cavity, and root canal, remove fragments, suction and wash off foreign substance or contamination during surgery, and suction a drug solution.	70459000	I	1	N/A	—
Urological irrigation system	A device used to infuse water for washing into the urinary tract via a nozzle inserted into the urinary tract. It consists of a liquid container connected to the nozzle via a tube, and components that control the water pressure released from the nozzle, temperature and flow rate.	43415000	I	2,5-①,12	N/A	—
Colonic irrigation system	A device used to infuse water into the large intestine via a nozzle inserted into the rectum to expel the contents of the lower section of the large intestine. It consists of a liquid container connected to the nozzle via a tube, and components that control the water pressure released from the nozzle, temperature and flow rate. Some have connections for connecting to anal tubes to facilitate manual insertion and removal	43827000	I	2,5-①,12	N/A	—
Temporary use bladder irrigation kit	A package for temporary use that contains injection syringes and other components used for cleaning the urinary bladder.	10406001	I	2,5-①	applicable	—
Ear irrigation kit	A package that contains injection syringes and other components used for cleaning the ear canal.	11371000	I	2,5-①,12	N/A	—
Oral lavage unit	A dental device specifically designed for dental treatment. Used to wash the site to be treated (e.g., cavity, carious cavity) to ensure cleanliness and remove tooth fragments, remaining filler, necrotic cell debris and infectious agents. It basically utilizes the	12304019	I	2,5-①,12	N/A	N/A
Dental oral lavage unit	A dental device specifically designed for dental treatment. Used to wash the site to be treated (e.g., cavity, carious cavity) to ensure cleanliness and remove tooth fragments, remaining filler, necrotic cell debris and infectious agents. Connected to an active	12304020	I	2,5-①,12	N/A	N/A
Powered dental oral lavage unit	An apparatus comprising a syringe that is connected to a compressor and which squirts saline solution by air pressure from a handpiece to wash the affected site after oral surgery. Some are connected to a small gas cylinder.	12304030	I	2,5-①,12	applicable	N/A
Reusable dental syringe	A invasive, dental devices used to wash the inside of the oral cavity, dental pulp cavity and root canal, and remove foreign substances and cutting debris. Active devices and instruments connected to an active device are excluded. This device is reusable	35970021	I	2,6-①	N/A	—
Perineal irrigation kit	A package that consists of injection syringes and other items used for cleaning the perineum.	12996000	I	2,5-①	N/A	—
Wound irrigation kit	A package that consists of injection syringes and other items used for cleaning the wound.	14462000	I	2	applicable	—
Ear irrigation syringe	A syringe with a plunger used to flush perfusate into the ear canal.	35025000	I	2,5-①	N/A	N/A

ENT lavage unit	A device specifically designed to clean the treatment site in order to remove necrotic cell debris, infectious agents or foreign materials in ear, nose and throat (ENT) treatment. Usually, it is operated by the pulsatile flow of sterilized water such as physiological saline used to cleaning the treatment site.	35152000	I	2,5-①,12	applicable	N/A
Nose applicator	A device used to directly administer a drug into the nasal cavity. It consists of a horn-like cup and holder. The device is inserted into the nasal cavity, and filled with warm salt water or other treatment solution for washing and treating the nasal passages and mucosa.	41599000	I	2,5-①	N/A	N/A
Disinfectant injector	A device used to inject disinfectant.	70462000	I	1	N/A	—
Cleaning agent injector	A device used to inject a cleaning agent.	70463000	I	1	N/A	—
Powered dental douche	A device used to squirt saline solution using air pressure from a small gas cylinder or compressor for cleaning the affected site after oral surgery.	70464000	I	2,5-①,12	applicable	N/A
Endoscopic irrigation/aspiration unit	A perfusion/aspiration device for perfusion/aspiration (for washing) with liquid for better endoscopic observation in a body cavity or lumen. Used with an endoscope. It is sterilized.	70465000	I	2,12	N/A	N/A
Utensil decontamination washer	A washer used for (chemical or heating) decontamination/disinfection of reusable surgical devices, anesthetic tools, shoes, and other surgical tools. Some have a built-in drier.	35424000	I	1,12	N/A	N/A
Powered endoscope lens cleaner	A device that supplies liquid or gas to the end surface of the lens to eliminate blood and foreign materials adhering to the lens. A metal or plastic sheath is attached to the endoscope before use. The device that supplies liquid or gas is electrically operated.	70466000	I	2,12	applicable	—
Douche kit	A kit containing items used with the washer unit for washing a specific site or part of the patient/operator.	11297001	I	2,12	applicable	—
Bone particle collector	A container used to collect bone fragments generated by sawing, reaming, perforation, and rasping in orthopedic surgery. It is not good to leave bone fragments in the joint region because the fragments could cause osteohypertrophy and the joint cannot move.	17131000	I	1	N/A	—
Powered pinch valve	A device that is used to support for body cleaning that closes and opens the cleaning tube with an electrically operated pinch valve, and releases and stops the supply of cleaning solution that flows down from the cleaning solution bag by gravity.	70467000	I	2,12	applicable	applicable

Irrigation/aspiration volume measuring unit	A device that measures the balance (between the volume released from the cleaning pump and the volume collected into the collection bottle) of the volume (weight) of a cleaning solution that is released from an electrically operated body washer, and collected by the aspiration device.	70468000	I	12	applicable	applicable
Orthopedic operation table	An adjustable table equipped with an elevatable top that supports the patient's body, and special device that assists and performs the traction of the patient's limbs for orthopedic procedures on an upper or lower limb. The special functions of this device	35394000	I	1,12	N/A	N/A
Gynaecological operation table	A surgical table used for gynecological surgery.	36618000	I	1,12	N/A	N/A
General-purpose manually-operated operation table	A completely mobile surgical table (general-purpose) that has been improved to make it usable for almost all parts of the body that require surgery. Manual or hydraulic operation.	36867010	I	1	applicable	applicable
Operation table accessories	Accessories that come with the surgical table.	70469000	I	1	N/A	N/A
Column operation table system	A permanent or semi-permanent column installed in an operating room, and used to introduce and install a removable tabletop (brought in by a compatible trolley).	36611000	I	1,12	applicable	applicable
Battery-powered mobile operation table top column	A semi-permanent tabletop column installed in an operating room and used to introduce and install a removable tabletop which carries the patient when preparing for surgery. This can be moved around the operating room to allow the operator to perform all types of surgery smoothly. It is battery - operated, and has no permanent electrical connection. The battery should be charged by the main power supply. The	44145000	I	12	applicable	—
Powered general-purpose operation table	A completely mobile surgical table (general-purpose) that has been improved to make it useable for almost all parts of the body that require surgery. Electrically line or battery operated.	36867020	I	12	applicable	applicable
Ophthalmic operation table	A device specifically designed to support the patient's body in ophthalmic surgery. Proper support and fixation of the patient's body allows the surgeon to adopt the optimal approach. A narrow table top allows the surgeon to reach the center line. This is not suitable for general surgery.	37225000	I	1,12	applicable	N/A
Operation table system	A system that consists of several components that form a complete surgical table system. It is used to replace tabletops, change the patient's position, and transfer the patient to and from the operating room. Usually, it consists of columns, a removable tabletop, remote controller for the trolley, and a trolley.	37325000	I	1,12	applicable	applicable
Delivery table	An adjustable table for examination/treatment. Used to support the female patient's body in an appropriate position for labor, delivery, and other pregnancy-related examination/treatment. Usually, it is equipped with leg holders, handles, a container for the placenta, and other items.	13960000	I	1,12	N/A	N/A
Urological table	An adjustable table for examination/treatment equipped with an appropriate (e.g., metal, plastic) table top supported by a fixed base. It has a knee clutch and handle. Operated manually or by electrical control for lowering/raising and tilting using a	13969000	I	1,12	N/A	N/A
Birthing bed	A bed designed for the use during labor and delivery. Accessories can be attached to the bed.	15732000	I	1,12	N/A	N/A
Gynaecological examination/treatment table	An adjustable table for examination/treatment. Used to support the female patient's body in an appropriate position for gynecological examination/treatment.	36065000	I	1,12	N/A	N/A

Proctological table	An adjustable table for examination/treatment. Usually, equipped with knee/elbow holders and heel stirrups. Used to support the patient's body in an appropriate position that the patient's back is exposed during perianal examination/treatment	36165000	I	1,12	N/A	N/A
Brachytherapy template	A template used to guide the direction of insertion of a puncture needle when inserting the radiation source next to the tumor guided by ultrasound.	70470000	I	1	N/A	N/A
General-purpose diagnosis/treatment table	A table for general diagnosis and procedures. This may be suitable for performing several basic functions (e.g., lifting up and down or tilting the patient). Used in examination and operating rooms. This does exclude tables that fall under "tables for	13958009	I	1,12	applicable	N/A
General-purpose examination/treatment table	A table for general examination/treatment. Some are equipped with several basic functions (e.g., lowering/raising, tilting). Used in examination and operating rooms. Electrically or manually operated.	13958000	I	1,12	applicable	applicable
Ophthalmic examination/treatment chair	A chair used for ophthalmic examinations, treatment or surgery. The chair facilitates such postures as sitting, semi-sitting, or semi-recumbency that allow easy access to the patient and comfort for the patient. The chair can be lifted up and down. Some are standalone, others are connected to a diagnostic table unit.	15723000	I	1,12	applicable	N/A
Asphyxia treatment table	A table equipped with an aspirator, oxygen supply device, heater (e.g., infrared lamp on the top, or infant warmer pad at the bottom). Used for resuscitation of a neonate who cannot breathe spontaneously at birth and is in a hypoxic state.	36685000	I	12	applicable	applicable
Physical therapy table	A table for examination/treatment that is equipped with foot support, and the height and position are adjustable (e.g., vertical tilt from recumbent to upright position). Some are equipped with exercise training devices (e.g., pulley, turntable) and other accessories (e.g., cervical vertebral bar, arm suspenders). Used to improve the blood circulation of the lower extremities of patients with neurological diseases (e.g., spinal	13964000	I	1,12	applicable	N/A
Rotating vestibulo-ocular function chair	By assessing the deviation of optical response to rhythm exercise (nystagmus) by angular acceleration or angular deceleration or stimulation to the vestibular system.	17217000	I	12	applicable	—
Examination/treatment chair	A chair operated manually or electrically, and used for blood collection and dialysis. Also used for transferring the patient.	16437000	I	1,12	applicable	N/A
Non-powered dental examination/treatment chair	A chair for examination that supports the patient at the desired position for specific dental treatment and examination. This exclude electrically operated one. The height and angle of the back rest are adjustable, and the chair can be tilted with the body axis.	34935020	I	1	N/A	N/A
Surgical light system	An illuminator that consists of 2 or more light heads individually installed on rotary arms. Some have light heads of the same size and others have different sizes. Some have a combination of operating room illuminator and examination room illuminator. Some have a mount to install a camera or other device.	37332000	I	1	N/A	N/A
Operating light	A operating light that illuminates the surgical site for a long period for the optimal visualization of small objects with low contrast at various depths or in small incisions. This reduces shadows and minimizes the misperception of colors. Usually, the light source at the lamp head sheds light. The light source is a valve that reflects the light	12282000	I	1	applicable	applicable
Examination light	An illuminator used for medical consultation and treatment. Installed on the ceiling or floor. Some serve as a part of the illumination system that consists of several light heads.	12276000	I	1	N/A	N/A
Ophthalmodiaphanoscope	An ophthalmic device used to examine the back surface of the eye (retina) via oral vestibule by transillumination.	12804000	I	12	N/A	N/A
Entoptoscope	An ophthalmic device used to examine the light transmitting parts of the eye.	15288000	I	12	N/A	N/A
Mobile examination light	An illuminator that has all the characteristics of the medical illuminators. Most of them are equipped with a pantograph-type counter balance assembly. Usually used for medical consultation and treatment of minor diseases. It is designed to allow easy movement from one place to another.	36843000	I	1	N/A	N/A

Head-worn light	An apparatus (lamp) designed to be attached to the head of the operator. The lamp is attached to a band or helmet frame so that it is placed on the forehead of the operator, and directly illuminates the visual field during surgery, diagnosis, or treatment. Usually, it consists of a magnifying lens, reflector, and a component connected to an optical fiber cable (to transmit cold light or supply electric power from a battery pack).	11963000	I	1	N/A	N/A
General/plastic surgery mirror	A device that displays the virtual image of an object placed in front of it. Used to assist the surgeon during general surgery and plastic surgery.	32261000	I	1	N/A	N/A
Ophthalmic mirror	An ophthalmic device with a mirror that reflects the beam during examination of the eyes and associated structures. Some have a round or concave mirror attached to the headband.	32707000	I	1	N/A	N/A
ENT mirror	The mirror has the surface sufficiently polished so as to form the virtual image of an object placed in front of it by reflecting non-diffusing light. Used for medical treatment of the ear, nose and throat (ENT). A thin handle is attached to the opposite side of the headband.	33431000	I	1	N/A	N/A
ENT headband mirror	A device with a round concave mirror on the headband so as to project luminous flux into the nasal cavity or throat during clinical examination.	34637000	I	1	N/A	N/A
General-purpose light source	An apparatus that generates intense light (known as cold light) used for general surgery or medical treatment. The light is transmitted to the treatment apparatus (e.g., head light, microscope, and endoscope) directly or more usually via an optical	32037000	I	1	N/A	N/A
Fibreoptic operating light with/without Illuminator	A operating light that illuminates the surgical site for a long time in order to optimally visualize small objects with low contrast from small incisions of various depths. Usually, it functions with the light supplied from the light source outside the surgical site via the optical fiber tube bundle. Installed on the ceiling or an appropriate floor device.	32241000	I	1	N/A	N/A
Transilluminator light	A lamp equipped with an intense light source. It illuminates the skin and soft tissue to make it semitransparent for examination, and for direct observation of soft tissue (e.g., content of the breast or penis) by a healthcare professional.	36761000	I	1	N/A	N/A
Ear light	An apparatus that illuminates the auditory canal to confirm the position of a plug inserted into the auditory canal in order to restrict the passage of the ear impression material.	41238000	I	12	N/A	N/A
Alcohol disinfectant	An apparatus that sprays alcohol mist which is a disinfectant to inactivate microorganisms, and disinfect and sterilize the patient's bed, Japanese bedding (Futon), and mattress.	70474000	I	12	applicable	N/A

Hot water pasteurization device	A warming bath that is usually small, and heats water to 70-75°C for at least 20 minutes, and kills almost all infectants. This method is indicated only for the cases that do not need complete sterilization.	44555000	I	12	applicable	N/A
Peritoneal perfusate thermal conditioner	An apparatus for storage at a constant temperature. This is used for heating and storage of perfusate before infusion.	70478001	I	12	applicable	—
Nursing bottle incubator	A device to keep feeding bottles warm.	70479000	I	12	N/A	—
Human tissue incubator	An apparatus for human tissue cultivation that maintains a stable, appropriate environment where oxygen does not exist.	70481000	I	12	applicable	N/A
Cardiac valve prosthesis sizer	A surgical device manually operated during heart valve replacement. It measures the size of an orifice used for implantation of an artificial heart valve.	17703010	I	6-①	N/A	—
Annuloplasty ring sizer	A surgical device manually operated during valvuloplasty. It measures the size of orifice used for implantation of a valvuloplasty ring in an appropriate size. It includes handles used for the sizer and holder.	17703020	I	6-①	N/A	—
Valve prosthesis tester	A surgical device manually operated during heart valve replacement. Used to confirm the mobility of the artificial valve lobes.	70482000	I	5-①	N/A	—
Valve prosthesis holder and handle	A surgical device manually operated during heart valve replacement. Used to hold the artificial valve or change the direction of the artificial valve.	70483000	I	5-①	N/A	—
Measuring device for vascular graft	A surgical device that measures the patient's vascular diameter in order to select an appropriately sized artificial vascular graft to be used for blood vessel prosthesis implantation or nerve regeneration inducing material placement.	70490000	I	5-①	N/A	—
Orthopedic bone cement mixer	A device that kneads or mixes (bone) cement or an artificial bone implant used for Orthopedic surgery. It includes a mixing spatula, deaeration tube, and other accessory devices. This device is for single-use.	33191000	I	2	N/A	—
Reusable powered Orthopedic cement mixer	An electric device used to mix polymethyl methacrylate powder and methyl methacrylate monomer to produce polymer bone cement. Usually, it includes a bowl with an electric spatula (a mixing device made of wire). Connected to a vacuum fume exhaustor. This device is reusable after proper cleaning and sterilization.	42982000	I	12	applicable	N/A

Bone cement deaeration tube	A tube that is used to remove the gas generated when using bone cement.	70507000	I	1	applicable	—
Dialysis set holder	A device that is used to hold and fix a dialysis set when dialysis is performed.	32144000	I	1	N/A	—
Breaker for blood tubing	A device that shuts off the extracorporeal hemodialysis circuit in the event of an emergency.	70548000	I	1	applicable	—
Shunt adaptor	An adaptor (usually, a small part) that is used for connecting the tubes to shunts for hemodialysis or other purposes. It enables those items to be used in combination by making them mutually compatible. This device is for single-use.	35338000	I	2	applicable	—
Ventilator filter	A sieve used to prevent particles and microorganisms from entering the gas line of a artificial respirator. The filter is made of paper, fiber or copper strips, and is usually installed in a plastic container.	14352000	I	1	applicable	—
Mixer hem Breathing gas	An apparatus that adjusts several different types of medical gases supplied to a patient in order to maintain them at a constant concentration.	70563000	I	2	applicable	N/A
Ventilator mask	A mask that is connected to the respiratory circuit of an artificial respirator, covers the patient's nose and mouth, and supplies gases from the artificial respirator. Some are a mouthpiece type.	70564000	I	2	applicable	N/A
Ventilator pressure monitor	A monitor that measures the pressure of an artificial respirator circuit during treatment or diagnosis. Some are the latest electronic measurement devices, and other are simple mechanical devices.	70565000	I	12	applicable	N/A
Reusable general-purpose water trap	A water trap that is used inside a circuit or connected to the circuit, when highly humid gas or air passes through the circuit (respirator), condensation forms rapidly. It eliminates the accumulated liquid periodically and drains it without interrupting the	31286000	I	2	applicable	—

Single-use ventilator water trap	A water trap used for the respiratory circuit of an artificial respirator. It collects condensation accumulated during heating or humidifying. Usually, it uses a 22 mm tapered connector, and is connected to the exhalation rim of a respiratory circuit. In	36276000	I	2	applicable	—
Reusable ventilator water trap	A water trap used for the respiratory circuit of an artificial respirator. It collects condensation accumulated during heating or humidifying. Usually, it uses a 22 mm tapered connector, and is connected to the exhalation rim of a respiratory circuit. In order to prevent liquid leakage when disconnecting it from the circuit, some are	36277000	I	1,12	applicable	—
Single-use general-purpose water trap	A water trap that is used inside a circuit or connected to the circuit, when highly humid gas or air passes through the circuit (respirator), condensation forms rapidly. It eliminates the accumulated liquid periodically, and drains it without interrupting the	41679000	I	2	applicable	—
Gas extraction tubing	A hollow cylindrical device used to extract unnecessary gases from the source of an anesthesia apparatus or system under its control. Used to protect the work environment from contamination. Usually, the inner diameter is larger than that of the tube of the compressed gas. The tube has low resistance to the extraction process, and connects the gas extraction apparatus to the duct system at the hospital or facility. Some are a color-coded polymer tube which is reinforced with woven polyester.	16821000	I	1	applicable	—
Oxygen tent	A flexible tent installed on the upper side of the bed or around the head of the patient in order to increase the oxygen tension. Some use humidification and temperature control. Designed for patients who cannot tolerate a nasal prong or face mask.	12893000	I	2	applicable	applicable
Topical oxygen therapy sleeve	A flexible sheath used to apply an oxygen-enriched gas to the skin. The sleeve covers the hand or the leg, or the lower part of the body below the head.	13620000	I	2	applicable	applicable
Mist tent	A canopy that is hung on the patient's bed or a mask that is placed on the patient's chin for aerosol drug therapy. Some are used in a highly humid environment or for	12554000	I	2	applicable	—
Oxygen gas analyser	An apparatus that measures the oxygen concentration of a gas or liquid (blood) by paramagnetism, mass spectrometry, polarography, thermal conductivity, or gas chromatography.	35219000	I	12	applicable	N/A
Air and oxygen mixer	An apparatus that mixes oxygen and air, selects the arbitrary oxygen concentration (21-100%), and supplies it to the peripheral respiration assisting apparatus such as an	70578000	I	12	applicable	N/A
High-pressure gas regulator	A pressure reducing valve that decreases the pressure to a low constant operation pressure. The valves for medical gas pipeline systems (JIST7101) are excluded. This is	35300000	I	2	applicable	applicable
Radiant heat shield hood	A hood used to cover a baby in an infant incubator who cannot maintain body temperature in equilibrium due to the loss of radiant heat, and prevent the loss of	70584000	I	1	applicable	—
Defibrillation body surface electrode	A conductor used to transmit a controlled electrical shock from a defibrillator to the patient in order to restore normal heartbeat. A cable set includes electrodes to be connected to the defibrillator. Used on the chest which is not opened (normal).	15033001	I	1	applicable	—
Peritoneal dialysis circuit welder	An apparatus that automatically connects thermoplastic tubes aseptically used for peritoneal dialysis hemodialysis. The tubes to be connected are laid in parallel, and cut with a heated blade. The cut sections are pressed together without contacting the	70587000	I	1	applicable	N/A

One-piece urostomy bag	A plastic bag used as a urine collector for urinary tract control. It is temporarily invasive via the stoma.	31068009	I	1	applicable	—
Multiple-piece urostomy bag	It consists of two or more plastic bags attached to the skin as a urine collector for urinary tract control. It is temporarily invasive via the stoma. It is equipped with a non-return valve that prevents the urine from remaining at the bottom of the stoma, and a drain tap to allow the urine to be discharged.	31069009	I	1	applicable	—
Reusable manually-operated radioactive source placement auxiliary device	A manually operated brachytherapy assisting auxiliary device designed for radiotherapy that does not specify treatment site. A single or module device designed to assist the manual, percutaneous placement of single or multiple radiation sources for treatment, which is performed by using an applicator resembling a puncture needle (hollow needle), to the treatment site. Some have a standard configuration, and other	70601000	I	1	N/A	N/A
Non-powered X-rays radiation therapy table	A bed for radiotherapy designed to adjust the patient's posture and immobilize the patient for treatment that uses an X-ray therapy apparatus. It is equipped with a table top that fixes the posture, pneumatic control, magnetic lock, crank, and lever for mechanical tabletop positioning and table height control. Either fixed or mobile. Some	40682000	I	1	applicable	applicable
Powered X-rays radiation therapy table	A programmable electrically operated bed for radiotherapy designed to adjust the patient's posture and immobilize the patient for treatment that uses an X-ray therapy apparatus. The height and position of the tabletop is adjusted by electronic or software control. Either fixed or mobile. Some are integrated with an X-ray therapy system.	40683000	I	12	applicable	applicable
Non-powered remote irradiation therapy table	A bed for radiotherapy designed to adjust the patient's posture and immobilize the patient for treatment that uses a remote radionuclide radiotherapy apparatus. It is equipped with a table top that fixes the posture, pneumatic control, magnetic lock, crank, and lever for mechanical tabletop positioning control and table height control. Either fixed or mobile. Some are integrated with an X-ray therapy system.	40684000	I	1	applicable	applicable
Powered remote irradiation therapy table	A programmable electrically operated bed for radiotherapy designed to adjust the patient's posture and immobilize the patient for treatment that uses a remote cobalt 60 radiotherapy apparatus and other remote radionuclide radiotherapy apparatuses. The	40685000	I	12	applicable	applicable
Non-powered accelerator system table	A mechanically-operated bed for radiotherapy designed to adjust the patient's posture and immobilize the patient for radiotherapy that uses a medical linear accelerator or non-linear accelerator. It is equipped with a table top that fixes the posture, pneumatic control, magnetic lock, crank, and lever for mechanical tabletop positioning control and	40686000	I	1	applicable	applicable
Powered patient table for accelerator	A bed operate by programmable for electric radiotherapy designed to adjust the patient's posture and immobilize the patient for radiotherapy that uses medical linear accelerator or non-linear accelerator. The height and position of the tabletop is	40687000	I	12	applicable	applicable
Non-powered neutron therapy table	A bed for radiotherapy designed to adjust the patient's posture and immobilize the patient for treatment that uses neutron rays that are generated from a nuclear	40690000	I	1	applicable	applicable
Powered neutron therapy table	A programmable bed for radiotherapy designed to adjust the patient's posture and immobilize the patient for treatment that uses neutron rays that are generated from the nuclear reactor, etc. In order to prevent or eliminate an accidental activation during treatment, the bed is made of hydrogenic materials with low molecular weight. The height and position of the tabletop is adjusted by electronic or software control.	40691000	I	12	applicable	applicable
Non-powered radionuclide brachytherapy table	A programmable bed for electric radiotherapy to adjust the patient's posture and immobilize the patient for treatment that uses an after loading short-distance irradiation treatment apparatus that is operated manually or electrically. It is	40692000	I	1	applicable	applicable
Powered radionuclide brachytherapy table	A programmable bed for radiotherapy designed to adjust the patient's posture and immobilize the patient for treatment that uses an after loading short-distance irradiation treatment apparatus that is operated manually or electrically. The height	40693000	I	12	applicable	applicable

Accelerator system collimator electron applicator	The electron applicator is a collimator accessory of an accelerator for treatment. It is attached between the beam emission port of the accelerator's collimator housing and the subject. This is used as the final collimation before the electron beam reaches the subject. Placed near the skin, and used to decrease the amount of scattering of electrons that reach the target treatment site. The function of the final part of	42268000	I	1	N/A	N/A
Wet hot pack unit	An apparatus that stores a reusable hot pack in warm water or other appropriate medium at the desired temperature so it can be used whenever necessary.	38469000	I	12	applicable	N/A
Hot pack	A pack that contains a heating medium is warmed by a heating apparatus. The warmed pack is applied to the affected site as an antiphlogistic procedure (thermotherapy). Some are also used as a cooling pack after being chilled by a cooling apparatus. This device is reusable.	37240010	I	1	applicable	—
Cold pack unit	An apparatus that cools the content of a reusable hot/cold pack before applying the pack (wet dressing). Usually, it can cool more than one pack at a time.	36034000	I	12	applicable	—
Cold pack	A pack used for an antiphlogistic procedure (cryotherapy). A pack that contains a cooling medium is chilled by a cooling apparatus, and applied to the affected site.	37240020	I	1	applicable	—
Elastic stocking	Medical elastic stockings etc. (including elastic sleeves for arms) used for the purpose of promoting venous return, such as alleviation or prevention of the venous blood and lymph fluid in the extremities. It has a function to gradually apply compression from	31724000	I	1	applicable	—
Non-active extension/traction rotary motion equipment	A non-active apparatus for training, enhancement, and rehabilitation. It is used to strengthen, sustain, develop or restore the muscle strength of the upper and lower extremities and back muscles.	70610000	I	1	applicable	applicable
Non-active automatic traction unit	A non-active apparatus with a harness which is worn on the head or the pelvis, and used to stretch a part of body (e.g., cervical spine, vertebra). Usually, it consists of a	14105001	I	1	applicable	applicable
Non-active automatic intermittent traction unit	A non-active apparatus for traction therapy. Designed to intensify or release a force either in an intermittent or cyclic mode according to the pre-selected minimum/maximum levels and duration.	14106001	I	1	applicable	applicable
Non-active simplified traction unit	Non-active traction apparatuses for treatment (e.g., head halter, pelvis belt, traction splint or harness, beam structure) that generate the traction force without any motion (stationary)	35519001	I	1	applicable	applicable
Non-powered exercising equipment with measuring functions	An apparatus used for rehabilitation training that indicates the measurement to be referred to for diagnosis and treatment. This apparatus does not use external power.	70612000	I	1	applicable	applicable
Non-active hand passive motion exerciser	A non-active apparatus for joint exercise of the continuous bending and stretching of fingers without using muscles.	17137001	I	1	applicable	applicable
Non-active leg passive motion exerciser	A non-active apparatus for joint exercise of the continuous bending and stretching of legs without using muscles	35977001	I	1	applicable	applicable
Non-active upper limb passive motion exerciser	A non-active apparatus for joint exercise of the continuous bending and stretching of arms without using muscles.	35978001	I	1	applicable	applicable
Non-active respiratory exerciser	A non-active apparatus that indicates the patient's respiratory volume or flow rate, stimulates the patient, and improves ventilation.	11634001	I	1	applicable	N/A
Reusable acupuncture needle	A long, thin, pointed device used to stimulate the peripheral nerves so as to promote the effect of surgical anesthesia, pain relief, or other treatment. This device is reusable. Exclude the sterilized one	35207001	I	6-①	N/A	—

Reusable non-active contact needle	A non-active device used to stimulate the peripheral nerves by touching, not inserting in the skin so as to promote the effect of surgical anesthesia, pain relief, or other treatment. This device is reusable.	70613001	I	1	applicable	—
Venous return circulatory assist system	Usually, an apparatus designed to facilitate blood circulation through veins to the heart using an electric air compression pump, a pressure adjustment mechanism, and a timing mechanism. It works by pressurizing/depressurizing the arms or legs. It consists of a tube that supplies the air from the pump to the cuff or air pressure.	10849000	I	1	applicable	applicable
Skin abrasion unit	An electric apparatus that scrapes and removes the skin surface during plastic surgery. This unit enhances the function of rotary polishing devices (e.g., wire brush, emery disc) and is used to remove scars, tattoos, birthmarks, fine wrinkles and sites.	11177000	I	12	applicable	N/A
Impactor	A metal device used to subject a specific body part to an impact. The distal end has a shape that controls the position, distribution and volume of the force to be applied to the tissue. The distal end is a rough flat disk that looks like a chisel, or has an anatomical curve. The proximal end is a handle, which is designed to absorb the shock.	32856000	I	1	applicable	—
Hemostasis pressure device	A device used to compress the site of catheter insertion on the thigh or forearm (radial artery) to achieve hemostasis at the end of angiography, or other diagnostic procedures.	70617000	I	4	applicable	—
Binocular loupe	A system that consists of lenses that the operator wears during a surgical procedure. It functions as a small telescope, providing a magnified image of the work field. Usually, it is used as binocular, and it can be connected to an external light source that provides.	32692000	I	1	applicable	N/A
Surgical microscope	An optical microscope used for treatment and examination but primarily for surgical procedures, and installed on the structure of the facility (ceiling or wall). They are designed for various specialty areas such as ophthalmic surgery, brain surgery, and	36354010	I	12	applicable	applicable
Transportable surgical microscope	A surgical microscope that is not installed on the ceiling, wall, or other structure of the facility.	36354020	I	12	applicable	applicable
Microscope accessory	Accessories used with a microscope in order to add functions to the microscope. All the accessories fall under this device group regardless of the type and model of the	37294000	I	12	applicable	applicable
Frenzel glasses	Glasses used to observe the movement of a subject's eyeball. Some are equipped with a light, infrared light, or infrared CCD camera.	70653000	I	1	applicable	N/A
Mounted surgical microscope	A surgical microscope to be installed on the ceiling.	36354030	I	12	applicable	applicable
Endoscopy holder	A holder that supports and adjusts a laparoscope, or other endoscope, and surgical devices to a desired position during surgery. It consists of joints and rigid or semi-rigid arms. Some are equipped with such functions as braking, balancing, minute positioning, and position detection.	16240000	I	1	applicable	applicable
Electrosurgery electrode holder	A holder that temporarily holds a hand-control, electric surgical electrode (pencil electrode) which is activated, but not used during surgery.	35043000	I	1	N/A	N/A
Single-use electrode cleaner	A single-use cleaner that is used to eliminate carbides that have accumulated on the surface of an active electrode after use.	70654000	I	1	N/A	—
Cable or switch for electrosurgical unit	Cables, switches or adaptors used to transmit signals, supply electric power, for extending the connection between an electric surgical device and the apparatuses connected to them for control. This category does exclude extensions connected to the primary power source.	70657000	I	12	N/A	—
Connection cable or switch for ablation device	Cables, switches or adaptors used to transmit signals, supply electric power, for extending the connection between the medical device used as a probe and the apparatuses connected to them for control, during atheroablation angioplasty or other procedures. This category does exclude to use as extensions connected to the primary	70658000	I	12	N/A	—

Reusable tourniquet	A band-like device applied to the extremities (arm or leg) so as to inhibit circulation, and block the normal blood flow to and from the distal part. Used with a tourniquet that adjusts the pressure. The cuff usually consists of two parts, and can change the pressure. An unit transmits the air to the reusable tourniquet, select/control/maintain the tourniquet pressure during surgery.	17230000	I	1	N/A	—
Hemostatic unit	An unit transmits the air to the reusable tourniquet, select/control/maintain the tourniquet pressure during surgery.	70678000	I	12	applicable	N/A
Dental mirror	A dental device that usually consists of a mirror head and a handle, and is used for oral examination or retraction.	31776000	I	5-①	N/A	—
Periodontal pocket probe	A hand-held dental instrument used for measuring the depth of periodontal pocket in order to observe the severity of periodontal diseases.	31848000	I	5-①	N/A	—
Dental explorer	A hand-held device (probe) used for palpation in dental treatment. The tapered working part of the shaft comes in a needle, hook, or blunt configuration according to the purpose of use.	35812000	I	5-①	N/A	—
Dental gingival applicator	A dental instrument used to apply a plaster in the periodontal pocket.	70679000	I	5-①	N/A	—
Dental rubber dam clamp	A dental device with a buccal and lingual wing, or flange, used to anchor a rubber dam down to the cervical region of an exposed tooth. It is also used to retain a simple vapor barrier.	15712000	I	5-①	N/A	—
Dental rubber dam frame	A flexible frame that holds the expanded rubber dam for easy access to the surgical site.	31849000	I	1	N/A	N/A
Dental rubber dam punch	A hand-held dental instrument used to open holes of various sizes on the rubber dam.	35553000	I	1	N/A	N/A
Dental rubber dam clamp forceps	A hand-held dental instrument used to apply and remove the rubber dam clamp.	35851000	I	5-①	N/A	N/A
Dental amalgam filling instrument	A hand-held dental filling instrument used to fill amalgam. The end is either flat or has saw-like configuration. The entire device is either straight or curved.	16460000	I	5-①	N/A	—
Dental amalgam carrier	A dental instrument specifically designed to be used for collecting and carrying the plastic amalgam, and packing it into a prepared cavity (cavity which has been formed).	35696000	I	5-①	N/A	N/A
Dental burnisher	A rotary dental device that has a working tip with a smooth or rippled surface. To achieve the glossy, smooth metal surface, it spreads and forms the cold work material or the corners of the cavity into a thin edge. It is also used to polish the surface of the restoration.	35785000	I	5-①	N/A	—
Dental amalgam carver	A dental instrument used to create the anatomical form of the dental restorations for complete finishing. Used to give the amalgam a smooth finish.	35793000	I	5-①	N/A	—
Dental wax carver	A dental instrument used to carve the wax patterns. Usually, it has a dull blade edge in various sizes and shapes. It can be heated so as to soften the wax when forming the wax pattern.	35794000	I	1	N/A	—
Dental filling/restorative material applicator	A dental instrument used to apply the filler or restorative material in the oral cavity. It excludes reusable devices that come into direct contact with fillers and devices operated by an external energy source.	38782000	I	5-①	N/A	—
Dental plastic filling carver	A dental instrument with a blade or a nail used for severing, scraping or scratching the surface of plastic filler to form a smooth surface.	41861000	I	5-①	N/A	—

Dental automatic mallet	A hand-operated, spring-type device used to apply gold foil and inlay. The power is adjustable. A mallet used to remove prosthesis or foreign matter in oral cavity is included.	42395000	I	5-①	N/A	N/A
Dental filling instrument	A reusable hand-held dental filling instrument used to fill and apply dental materials such as dental cement, dental composite resin, dental core build-up materials, dental pit and fissure filler, dental cavity lining materials, dental pulp capping materials, and material for temporary dental sealing, as well as dental dressings such as capping .	70680000	I	5-①	N/A	—
Dental compressed filling instrument	An instrument used for compressed filling of dental direct gold filler, gingival retraction cord, and dental periodontal dressing.	70681000	I	5-①	N/A	N/A
Dental mixing spatula	A spatula-shaped device used to knead or mix dental material (impression material, cement, etc).	38530000	I	1	N/A	—
Dental mixing instrument	A dental instrument used to knead or mix dental materials (e.g., impression materials, cement). Some are equipped with an injection function. Impression material kneading device and cement mixers are included. Spatula-like devices are excluded.	70682000	I	1	N/A	—
Dental curette	A dental instrument with a spoon-like working tip. Used for the tissue curettage.	31904000	I	6-①	N/A	—
Periodontic hoe	A hand-held dental instrument with a small blade that forms a right angle with the axis. It is operated by exerting a pulling motion.	31908000	I	6-①	N/A	—
Dental scaler	A hand-held dental instrument used to remove deposits such as tartar from the tooth surface for oral cleaning and periodontal treatment.	35320000	I	6-①	N/A	—
Periodontal curette	A dental instrument is usually a round shape, has a sharp blade with the surface ground into a concave shape, and has a half-round section view. Used for curettage of the periodontal pocket and root surface.	41660000	I	6-①	N/A	—
Dental excavator	A hand-held dental instrument with a curved blade to sever and remove carious dentin.	35811000	I	6-①	N/A	—
Tooth separator	A dental instrument used to move a tooth from the position where it is in contact with an adjacent tooth.	42340000	I	5-①	N/A	N/A
Dental rubber dam	A latex rubber sheet used to isolate the surgical field during dental treatment. After a hole is made in the sheet with a punch, the sheet is spread over the surgical site. Some	11155010	I	5-①	applicable	—
Dental rubber dam moisture barrier kit	A kit consists of a dental rubber dam, dental rubber dam clamp, dental rubber dam punch, and dental rubber dam frame. Used to prevent contamination with saliva and for damp proofing during dental treatment. (Consists of Class I items only.)	11155020	I	5-①	applicable	—
Dental impression tray	When an impression is taken, the impression material is packed into the tray, which retains the material for pressure fitting.	16350000	I	5-①	N/A	—
Dental impression material syringe	This dental injection syringe is used to inject the impression material onto the impression tray.	35860000	I	5-①	N/A	N/A

Dental elevator/raspatory	A dental instrument is used to peel off tissues such as periosteum and mucosa, and remove prosthesis and foreign matter in the oral cavity during oral surgery. Electrical devices are excluded.	70683000	I	6-①	N/A	N/A
Dental elevator	A dental instrument with lever-like shape used to extract a tooth or remove a tooth root.	16480000	I	6-①	N/A	N/A
Dental carbide bur	A rotary cutting device has a working component made of tungsten carbide, is attached to the dental handpiece, and used to grind such hard tissues as teeth and bones. It can be also used to grind metal, plastic, porcelain, and other similar materials.	16668000	I	6-①	N/A	—
Dental steel bur	A rotary cutting device is made of carbon steel or stainless steel to grind such hard tissues as teeth and bones. It can be also used to grind metal, plastic, porcelain, and other similar materials used to produce dental workpieces.	16669000	I	6-①	N/A	—
Dental diamond bur	A rotary cutting device has a steel working component coated with minute diamond crystals, is attached to a dental handpiece, and used to grind such hard tissues as teeth and bones. It can also be used to grind metal, plastic, porcelain, and other similar materials.	16670000	I	6-①	N/A	—
Dental plastic bur	A rotary cutting device has a plastic working component, is attached to a dental handpiece, and used to grind soft dentin in particular.	70684000	I	6-①	N/A	—
Dental root canal reamer	A hand-held rotary dental instrument is used to wipe the wound of the root canal or to expand the root canal by performing a lateral cut.	31875001	I	6-①	N/A	—
Endodontic enlarger	A dental instrument is used to secure access to the root canal or to expand the root canal orifice.	31876000	I	6-①	N/A	—
Dental file rasp	A dental instrument has a working component that expands the root canal, and smooths the wall by severing or grinding when moved vertically.	31878011	I	6-①	N/A	—
Dental file	A hand-held dental instrument expands the root canal, and smooths the wall of the root canal when reciprocally moved vertically, or lifted up.	31878021	I	6-①	N/A	—
Dental endodontic rasp	A dental instrument for the root canal has a sharp protrusion on the working component. Used to grind and expand the root canal.	41878000	I	6-①	N/A	—
Dental broach	A dental instrument has a smooth working component at the end, and the round or polygonal section. Used to examine the root canal.	41865000	I	6-①	N/A	—
Dental endodontic applicator	A sharp-pointed dental instrument has a round cross section and a coarse working component at the end. Used to hold cotton or liquid when it is inserted into the root canal.	42334000	I	6-①	N/A	—
Dental cleanser	A long tapered dental severing instrument with a blade used to form/expand a hole in the root canal, or extract the pulp.	35784000	I	6-①	N/A	—
Dental drill	A dental instrument that is mainly used to open a hole in the cavity. Electrical devices are excluded.	70685000	I	6-①	N/A	—

Dental endodontic paste carrier	A hand-held rotary dental instrument has a working component equipped with a spiral or conical coil-like spring. Used to deliver filler or a drug to the root canal.	42336000	I	6-①	N/A	—
Dental root canal filling paste remover	A hand-held rotary dental instrument has a working component equipped with a spiral or conical coil-like spring, and is used to remove the filler from the root canal. Electrical devices are excluded.	70687000	I	6-①	N/A	—
Dental endodontic spreader	A dental instrument has a tapered working component, a round section view, and a sharp point. Used to pressure fit (mainly from the side) the filler into the root canal.	37678000	I	6-①	N/A	—
Endodontic plugger	A hand-held rotary dental instrument has a cylindrical or tapered working component, a round section view, and a flat point. Used to pack the filler into the root canal mainly in the direction of the axis.	41876000	I	6-①	N/A	—
Dental mandrels for rotary instruments	A shaft holds rotary dental severing devices such as a grindstone, grinding disk, circular saw, drill bit, lathe head stock, as well as disks, stones, and cups used for grinding.	35170000	I	1	N/A	—
Dental abrasive disk	A rotary dental instrument consists of a round flat sheet or slightly conical sheet that contains abrasive. It is fixed or made to be fixed to the mandrel in the center.	35807000	I	6-①	N/A	—
Dental engine and related instrument	An electric dental engine, engine stand, engine belt, engine bracket arm, and K4 pulley. Dental air-powered rotary unit and dental electrically-powered rotary unit are excluded.	70693000	I	1	N/A	N/A
Dental bite force analyser	This device measures the bite force (pressure) of the upper and lower teeth using an oral sensor without transmitting any energy to the human body. It detects abnormal distribution and imbalance of bite pressure due to neuromuscular function disorders.	70699000	I	12	applicable	applicable
Occlusal contact analyser	This apparatus measures and analyzes the distribution, chronological order of the teeth contact using an oral sensor without transmitting any energy to the human body. It examines premature contact that could cause bite pressure imbalance and occlusal interference.	70700000	I	12	applicable	applicable
Gingival fluid measurer	This device measures the exudate from the gingival groove (groove between teeth and gum) to check for gingivitis.	33203000	I	4	applicable	N/A
Dental temporomandibular joint sound-noise analyser	A device that measures the sound-noise of jaw joints when they are moving by using a microphone placed outside the oral cavity. This detects abnormal behavior of the soft tissue around the joint – e.g., articular disc – that disturbs smooth movement of the temporomandibular joint.	70702000	I	12	applicable	applicable
Dental polymerization activator	An electric light used to polymerize dental resin materials.	35775000	I	12	applicable	applicable
Dental cleaner	A device that cleans and grinds the tooth surface by polishing powder using a water jet or air jet. The devices corresponding to the active device connected tooth surface cleaner are excluded.	70707001	I	1	N/A	N/A
Dental amalgam mixer	A device that shakes the amalgam plate in order to mix mercury and alloy powder placed in the dish. Usually, electrically powered. The plate is either attached or detachable.	10082000	I	1	N/A	N/A
Dental amalgam capsule	A capsule used to mix alloy and mercury which are individual weighed. It can be reused several times.	35791000	I	1	N/A	—
Tooth bleaching heating unit	A light and electric heat source used to heat the teeth after applying a dental bleaching agent or a drug-containing dental tooth surface cleaner auxiliary material to the teeth. Apparatuses that activate dental bleaching agents or drug-containing tooth surface cleaner auxiliary materials are excluded.	31806009	I	12	applicable	applicable

Dental impression material mixer	An electric device used to mix impression materials immediately before use at the chair side.	38790000	I	1	N/A	N/A
Dental endodontic materials heating injector	A device heats and softens a root canal filling material, e.g. gutta-percha in the heating chamber attached to the handpiece, and injects it into the root canal. It is also used to soften agar impression material. Devices operated by an external energy are excluded.	70712001	I	5-①	N/A	N/A
Dental root canal obstacle remover set	A set of devices used to remove foreign matter from the root canal such as fragments of broken root canal treatment devices.	70713000	I	6-①	N/A	N/A
Dental root canal cleanser	A dental instrument that is attached to a handpiece, and used to remove cutting debris from the root canal, and clean the root canal. A dental instrument connected to an active device is not included.	70174001	I	6-①	N/A	N/A
Dental burner	A burner that uses butane gas as fuel, and is used to heat or disinfect dental devices. Burners incorporated into a dental unit are excluded.	70715000	I	1	N/A	N/A
Massaging pick	A oral hygiene device with a sharp point that is used to manually stimulate and massage the gums and improve the periodontal (gum) condition.	33208000	I	5-①	N/A	—
Dental injector	A device that is used to inject dental materials inside the oral cavity or onto a tray.	70718000	I	5-①	N/A	N/A
Dental material thermal conditioner	A heating apparatus for maintaining agar impression material and other materials in the desired condition for use.	70720000	I	1	N/A	N/A
Dental implant prosthesis instrument	A device that is used to design, produce, dress, and fix a prosthesis used a dental implant.	70722000	I	5-①	N/A	N/A
Dental examination/treatment chair	A chair for dental treatment that secures the patient in the correct posture for dental treatment and examination. Non-electrical devices are excluded. Some allow the height and back rest to be adjusted, or have a tilting function with the body axis as pivot to optimize oral access and the visual field for the dentist. This chair is a	34935010	I	12	applicable	applicable
General-purpose dental light	A dedicated illuminator for general dental use that illuminates targeting a specific part such as a dental surgery site, the site of an examination, or procedures (usually, inside the oral cavity).	12351000	I	12	N/A	N/A
Dental intraoral surgical light	A light that is used to illuminate the cavity, or a very small area.	12352000	I	12	N/A	N/A
Orthodontic ligator	A dental device that pushes a ligature under the arch wire or bracket wing for guiding, or pushes the arch wire or auxiliary device into a predetermined position.	37413000	I	5-①	applicable	N/A
Orthodontic headgear	A device that is used in conjunction with an orthodontic device to apply pressure to the teeth or jaw from outside the oral cavity. A typical example of orthodontic head gear has a strap that holds the patient's neck or head, and an inner bow that is fixed to the	31757000	I	1	N/A	N/A
Orthodontic chin cap	This chin cap is part of an orthodontic device placed outside the jaw, and applies a force to the chin toward the upper rear side.	41067000	I	1	N/A	N/A
Orthodontic band pusher	A manual dental device that aligns the metal band to the teeth position.	31801000	I	5-①	N/A	N/A

Orthodontic positioning instrument	A device that is used for positioning to align an orthodontic apparatus with the orthodontic band or tooth surface. Calipers used for positioning are also included.	70733000	I	5-①	N/A	N/A
Standardised cephalofacial photography appliance	An apparatus that is used to take a standard photo of the head or face. Used for diagnosis for orthodontic treatment.	70734000	I	1	N/A	N/A
Short-term use orthodontic oral mucosa protector	A material that is used to coat an orthodontic apparatus for a short period in order to mitigate irritation to the oral mucosa caused by the apparatus.	70735000	I	5-③	applicable	—
Orthodontic labial muscle fixator	An apparatus that is used to strengthen the oral muscles, and maintain tooth alignment after the orthodontic treatment.	70736000	I	5-③	applicable	—
Electric lathe for dental laboratory	A dental laboratory use low-speed rotation apparatus that is connected to an electric motor, and cut/grind prosthesis.	70739000	I	1	N/A	N/A
High speed lathe for dental laboratory	A dental laboratory use high-speed rotation apparatus that is connected to an electric motor, and cut/grind prosthesis.	70740000	I	1	N/A	N/A
Motor for dental laboratory	A motor that is used with a flexible drive system in dental laboratories in order to provide a rotational force to a handpiece for dental laboratory. It is either an electric or air motor used in combination with various speed control apparatuses.	34699000	I	1	N/A	N/A
Dental drill remote drive	A device that is used to transmit a rotational force to a dental handpiece from a dental remote motor. This is designed to allow the handpiece to be operated flexibly. Designed based on a cable and pulley system or metal rotary span cable such as metal spiral	37708000	I	1	N/A	N/A
Engine for dental laboratory	A hand-held dental device consists of one handpiece that has a chuck to connect to a rotating device such as a dental bur and reamer. This is usually placed away from the power source and connected to a flexible drive system. Electric engines for dental	38611009	I	1	applicable	applicable
Electric engine for dental laboratory	A hand-held dental device for dental laboratory that consists of one handpiece that has a chuck to connect to a rotating device such as a rotary tungsten carbide cutting instrument for dental laboratory. This is usually placed away from the power source	38611000	I	1	N/A	N/A
Engine motor for dental laboratory	A dental device that has a built-in motor, and is used with a flexible drive system that provides a rotational force to the dental handpiece. Electrically-powered motors for dental laboratory are excluded.	38763009	I	1	applicable	applicable
Electrically-powered motor for dental laboratory	A dental device that has a built-in motor, and is used with a flexible drive system that provides a rotational force to an electric engine and handpiece for dental laboratory.	38763000	I	1	N/A	N/A
Trimmer for dental laboratory	A device that is used to trim an unsized dental plaster/stone model such as that for gnathostatic models and parallel models. Usually, it is equipped with a motor-driven grinding disk.	70741000	I	1	N/A	N/A
Vacuum mixer for dental laboratory	A stirring-kneading apparatus that is used to mixes gypsum or casting investment material with liquid, e.g. water under reduced pressure. Usually, it is equipped with a	70742000	I	1	N/A	N/A
Remote drive drill handpiece for dental laboratory	A hand-held device consists of one handpiece that has a chuck to connect to a rotating device such as a bur and grinding wheel. Used at a dental laboratory. The device is placed away usually remote from the power source	34700000	I	1	N/A	N/A
Dental laboratory rotary steel cutting instrument	A rotary cutting device has a steel working component, is attached to a dental laboratory handpiece, and is used to grind metal, plastic, porcelain, or other similar materials	70743000	I	1	N/A	N/A
Rotary tungsten carbide cutting instrument for dental laboratory	A rotary cutting device has a tungsten carbide working component, is attached to a dental laboratory handpiece, and is used to grind metal, plastic, porcelain, or other similar materials	70744000	I	1	N/A	N/A

Gas-powered dental laboratory handpiece	A dental laboratory device consists of one handpiece that has a chuck to connect to a rotating device such as a bur. Usually, a small turbine driven by compressed air is built in.	70745000	I	1	N/A	N/A
Dental laboratory electrically-powered handpiece	A dental laboratory device consists of one handpiece that has a chuck to connect to a rotating device such as a dental bur and reamer. A motor is built in.	70746000	I	1	N/A	N/A
Dental laboratory air motor	A dental laboratory air motor device consists of one handpiece that has a chuck to connect to a rotating device such as a bur. Usually, a small motor driven by compressed air is built in.	70747000	I	1	N/A	N/A
Welding/soldering instrument for dental laboratory	This device is used in dental laboratory to weld dental metal or metal dental crown restoration, or brazing using soldering material.	70748000	I	1	N/A	N/A
Curing unit for dental laboratory	This device is used in dental laboratory to polymerize polymeric materials at a dental laboratory. Polymerization is performed by heating, heating and pressurization, irradiation of light or a combination of these.	35761000	I	1	N/A	N/A
Dental flask	A container that retains the mold used to make polymer prosthesis.	42343000	I	1	N/A	—
Press for dental laboratory	This apparatus is used for pressing together two halves of a mould for forming and polymerization of base material when producing a removable denture in a dental laboratory.	34705000	I	1	N/A	N/A
Heating press for dental laboratory	This apparatus is used for pressing and heating together two halves of a mould for forming and polymerization of base material when producing a removable denture in a dental laboratory.	70749000	I	1	N/A	N/A
Moulding unit for dental laboratory	This apparatus is used to mold thermoplastic material by injection/pressurization, and produce a denture base or prosthesis.	70750010	I	1	N/A	N/A
Dental electrodeposition moulding unit	This apparatus is used to accumulate and mold metal or fine particles by using electrical attraction, and produce dental laboratory items.	70750020	I	1	N/A	N/A
High-frequency casting unit for dental laboratory	A device that melts and casts dental alloys using high frequency melting system.	70751000	I	1	N/A	N/A
Arc heating casting unit for dental laboratory	A device that melts and casts dental alloys using arc discharge melting system.	70752000	I	1	N/A	N/A
Furnace casting unit for dental laboratory	A device that melts and casts dental alloy using a heating furnace melting system.	70753000	I	1	N/A	N/A
Casting furnace for dental laboratory	A device used to keep the investment in a specific state and at a specific temperature in order to burn off the wax from the inlay and molds of the crown and bridge, and	36180000	I	1	N/A	N/A
Casting auxiliaries for dental laboratory	A casting flask and casting ring used to produce dental laboratory items.	70754000	I	1	N/A	N/A
Porcelain furnace for dental laboratory	A dedicated furnace used to fire porcelain used in dental laboratory.	35762000	I	1	N/A	N/A
Dental articulator	A hinged dental device. The upper and lower jaw models are attached to this according to the intermaxillary relationship recorded in advance. Designed to simulate part or all of the movement of the lower jaw.	10201000	I	1	N/A	N/A

Dental facebow	A calipers-like dental device used to record the position of maxillary arch relative to the temporal lower temporomandibular joint (or open mouth movement axis), and align the oral model in relation to the axis of open mouth movement.	35700000	I	1	N/A	N/A
CAD/CAM unit for dental laboratory	This apparatus utilizes complex software, is installed in a workshop or dental laboratory, and used for computer aided design (CAD) or computer aided manufacturing (CAM) for dental restoration.	34713000	I	1	N/A	N/A
Metal surface treatment device for dental laboratory	A surface processor for dental laboratory that is used to add and enhance adhesion by processing the surface of dental metal. (Metal surface processing device for dental	70755009	I	1	applicable	applicable
Metal surface processing device for dental laboratory	A surface processor for dental laboratory that is used to add and enhance adhesion by processing the surface of dental metal.	70755000	I	1	N/A	N/A
Pressure investing unit for dental laboratory	A device that is used to the lost wax casting, and is equipped with a pressurizer in order to reduce the generation of air bubbles.	70756000	I	1	N/A	N/A
Implant instrument/material for dental laboratory	Devices and materials for dental laboratory. Used to produce the upper structure of the dental implant.	70757000	I	1	N/A	N/A
Dental precision attachment fixation kit	Dental devices and materials used to obtain precision attachment at a desired position when producing a dental prosthesis.	70758000	I	1	N/A	N/A
Ceramics heating pressure molding device for dental laboratory	A device for dental laboratory used to pressurize and mold the heated dental ceramic material. Joint cast or cast is used. Some have the function of firing dental porcelain.	70759000	I	1	N/A	N/A
Carver for dental laboratory	A device that is used to build up or sculpt the wax, plaster, resin or ceramic. In order to make the work process easier, various other materials can be supplementarily used	70760000	I	1	N/A	N/A
Dental fusible alloy	An alloy used in dental laboratory that is a mixture of bismuth ($\geq 40\%$), tin and lead.	70800000	I	1	N/A	—
Dental impression tray resin	A powder and liquid self-curing resin, a paste-like self-curing resin or a thermoplastic resin that is used for a custom-made tray and base plate, etc.	70832000	I	5-①	N/A	—
Dental pattern resin	A resin is used to produce casting patterns such as inlays and crowns. Some are used for temporary adhesion in dental technical work.	70833000	I	1	N/A	—
Dental occlusal diagnosis material	A material mainly made of resin, and used to evaluate the strength of a facet or assess the state of occlusion.	70835000	I	5-③	N/A	—
Dental impression plaster	This material is primarily made of calcium sulphate hemihydrate, and used to take an oral impression.	34800000	I	5-①	applicable	—
Dental fit checking material	A material used to check the compatibility of the plate denture or prosthesis to the mucosal surface or abutment tooth.	70881000	I	5-①	applicable	—
Gingival retraction kit	A prepackaged kit that includes devices used for gingival retraction during abutment tooth preparation. The kit is provided as a single unit that consists of single or multiple items according to the purpose of use. Kits that include drugs are excluded.	16352000	I	5-①	applicable	—
Gingival retraction cord	A cotton thread containing no drugs that is used temporarily for gingival retraction during abutment tooth preparation.	35861001	I	5-①	applicable	—
Gingival retraction material	A material that is used temporarily for gingival retraction during abutment tooth preparation and impression taking. Gingival retraction cord and materials that contain drugs are excluded.	70882000	I	5-①	applicable	—

Dental bite registration material	This material is used to record teeth occlusion, and the positional relationship between the upper and lower jaws in order to produce crowns, bridges, and denture. Dental casting wax materials are excluded.	70883000	I	5-①	N/A	—
Dental spacer	A thin plate made of wax or plastic. It covers the surface of an edentulous jaw ridge and teeth structure to take the primary impression. The spacer is removed from the hardened primary impression. This creates a space of a certain thickness between the	44575000	I	5-①	N/A	—
Dental impression taking instrument	Devices and materials used to take the impression. Impression trays are excluded.	70887000	I	5-①	N/A	—
Dental model duplicating agar impression material	This impression material is mainly made of agar, and used to produce the duplicated model.	70890000	I	1	N/A	—
Dental model duplicating elastomeric impression material	This impression material is mainly made of silicone or other types of synthetic rubber, and used to produce the duplicated model.	70891000	I	1	N/A	—
Optical impression auxiliary material for dental laboratory	A material that is used to prevent irregular reflection when taking an optical impression using dental laboratory CAD/CAM unit. This is used to take the impression from the model.	70892000	I	1	N/A	—
Dental casting wax	A dental casting wax is used to produce the wax mold for fixed prosthesis restoration by the lost wax casting method.	16189000	I	5-①	N/A	—
Dental paraffin wax	This casting wax is mainly used for a trial denture and arrangement of artificial teeth.	70893000	I	5-①	N/A	—
Dental casting sheet wax	A wax is used to produce a cast wax pattern of denture base, bar and clasp.	70894000	I	1	N/A	—
Dental sticky wax	A wax for temporary adhesion is used to produce dental laboratory items.	70895000	I	1	N/A	—
Bite registration rim	A preliminary model of the dental arch is attached to the trial denture or the permanent base in order to record the relationship between the upper and lower jaws. The occlusal rim is produced and adjusted for individual patient based on the existing	18083000	I	5-①	N/A	—
Dental impression wax	This material is used to take an oral impression. Made of wax. Some materials are mixed with resin having a low melting point.	34807000	I	5-①	N/A	—
Bite registration rim wax plate	Dental materials (model wax) used to record the relationship between the upper and lower jaws. Molded like a plate, and used to produce the occlusal rim. Some are reinforced with foil (metal, plastic).	38584000	I	5-①	N/A	—
Bite registration rim wax	Dental materials (model wax) used to record the relationship between the upper and lower jaws. Used to produce the occlusal rim. Some are reinforced with foil (metal, plastic).	38602000	I	5-①	N/A	—
Dental utility wax	This multipurpose wax is supplementarily used for producing dental laboratory items.	70896000	I	5-①	N/A	—
Dental base plate	This base plate is used as the foundation when build up the occlusal rim, or producing denture for trial application. The dental base plate is made of wax, shellac or polymer, and produced for individual patients (individual production)	34808000	I	5-①	N/A	—

Dental general-purpose wax	A wax is used to take an oral impression, wax pattern of a trial application, and produce the pattern of the inlay and the crown. Waxes that are given other names are excluded.	31836010	I	5-①	N/A	—
Molded dental wax	This material is used to produce a device that maintains a removable partial denture. It is molded with wax to a prescribed configuration, and may be replaced with metal by casting.	31836020	I	1	N/A	—
Dental pattern cast	A ready - made pattern used to produce restorations. Made of wax or resin. Molded dental wax are excluded.	31836030	I	1	N/A	—
Dental baked plaster	Calcined gypsum is used as a model material to produce dental laboratory items.	70897010	I	1	N/A	—
Dental stone	A dental stone used as a model material to produce dental laboratory items.	70897020	I	1	N/A	—
Dental refractory modelling material	This model material for high-temperature processing is primarily made of anhydrous silicic acid, phosphate, colloidal silica, and ethyl silicate.	70898000	I	1	N/A	—
Dental refractory modelling auxiliary material	This material is used to enhance the strength of a dental refractory model.	70899000	I	1	N/A	—
Dental polymer-based modelling material	This material is made of various polymers, and is used in the production of dental models and restorations.	34811000	I	1	N/A	—
Dental gypsum-bonded casting investments	This casting investment material is primarily made of anhydrous silicic acid and gypsum.	70900010	I	1	N/A	—
Dental casting investments for high-fusing alloy	This casting investment material is primarily made of anhydrous silicic acid, alumina, magnesia, phosphate, colloidal silica, ethyl silicate, and gypsum.	70900020	I	1	N/A	—
Dental brazing investment material	This brazing investment soldering material is primarily made of quartz and binders.	70900030	I	1	N/A	—
Reusable dental abrasive point	A device that is used to remove excessive filler such as dental composite resins for restoration, and to grind or polish the restorations such as a crown. This device is reusable.	31833000	I	6-①	N/A	—
Abrasive point for dental laboratory	A silicon carbide, and alumina, etc. are used as the material for grinding in dental laboratory. The point, wheel, and disk are included.	70901000	I	1	N/A	—
Diamond abrasive point for dental laboratory	Diamond is used as the material for grinding in dental laboratory. The point, wheel, and disk are included.	70902000	I	1	N/A	—
Dental prophylaxis cup	A cup usually made of rubber, and used when a grinding material is used for dental abrasive (cleaning). The cup attached to the dental handpiece is rotated when the grinding material is applied to the teeth.	16184000	I	6-①	N/A	—
Dental rubber abrasive	A dental abrasive with various grinding components on the rubber base material. The point, wheel, and disk are included.	70903000	I	6-①	N/A	—

Dental abrasive strip	A dental strip with grinding particles coated on one or both sides. Used to grind the surface of teeth or restorations.	35702000	I	5-①	N/A	—
Dental-professional teeth cleaning brush	A rotary dental brush used for cleaning and polishing by a dental hygienist or a dentist.	35768000	I	5-①	N/A	—
Tooth abrasive	A powder, paste, cream or gel-like semi-solid abrasive used for cleaning and grinding the tooth surface by a dental hygienist and a dentist. A prophylaxis and treatment brush and tooth polishing cup are used to grind the tooth surface. Materials intended	70904000	I	5-①	N/A	—
Abrasive/polishing device kit for dental laboratory	A kit that consists of grinding materials and abrasive for dental laboratory.	70906000	I	1	N/A	—
Dental polishing device	A material used for polishing the prosthesis. Items that are given different names are excluded.	70907000	I	1	N/A	—
Dental abrasive device	A material used for grinding the prosthesis. Items that are given different names are excluded.	70908000	I	1	N/A	—
Dental glove	Rubber or plastic gloves used when performing dental examinations, treatments or other procedures. Surgical gloves are excluded.	70911000	I	5-①	applicable	—
Dental matrix band	A band or short tube that is made of stainless steel or polyester. It provides the general outline of the restorative material, and holds the restorative material. The band is attached to the desired position by the matrix retainer (a device that fits this band around the teeth without any gap). The outline is formed according to the	16195000	I	5-③	N/A	—
Dental matrix wedge	A dental device that is inserted into the tooth cervix so as to slightly separate the teeth when inserting the filling material.	16370000	I	5-③	N/A	—
Dental matrix retainer	This retainer retains the matrix band at the desired position on the teeth.	33204000	I	5-③	N/A	N/A
Dental occlusal splint	A rigid or flexible material that covers the occlusal surface. Used to retain the position of a malpositioned tooth or loose tooth, to treat clenching (habitual clenching), bruxism and its aftereffects, and for temporary analgesia of pain in the muscles or temporomandibular joint, e.g., temporomandibular joint disorder. It should not be used for a period exceeding 30 days.	36311000	I	5-③	applicable	—
Dental molded polymer clasp	A ready - made dental clasp made of polymeric materials. It should not be used for a period exceeding 30 days.	38625000	I	5-③	applicable	—
Dental molded metal clasp	A ready-made, elastic metal clasp used for removable partial denture. It should not be used for a period exceeding 30 days.	70912000	I	5-③	applicable	—

Dental occlusal splint material	Materials used to produce dental occlusal splint. They should not be used for a period exceeding 30 days.	70914000	I	5-③	applicable	—
Retention bead for dental laboratory	Minute synthetic resin beads used for casting patterns. The beads form minute protrusions on the metal coping surface in order to retain the resin surface when producing a resin facing crown.	70915000	I	1	N/A	—
Ceramic surface treatment material for dental laboratory	A technical material for surface treatment that is used to provide or enhance the adhesiveness of the dental ceramic surface. Materials do not stay on the surface of a dental crown restoration, etc.	70918000	I	1	N/A	—
Dental material separator	A separator used in the oral cavity. Used for the separation of the denture base or artificial/natural teeth and dental material, or between dental materials.	70923000	I	5-①	applicable	—
Dental marker	A marker used to assess the strength of the facet, and for positioning.	70925000	I	5-③	applicable	—
Dental oral cavity cleaning kit	A kit that contains a prophylactic treatment brush, prophylactic cup, dental floss, and abrasive. The kit is used by a dentist and dental hygienist for tooth surface cleaning.	70927000	I	5-①	N/A	—
Dental endodontic instrumentation aid material	A material used to soften and neutralize the calcified root canal wall during dental treatment. Some are provided as a set that includes the devices used with materials. Drug-containing materials are excluded.	70928001	I	5-①	applicable	—
Ear knife	A special surgical severing device used in surgery of anatomical structures of the ear. The handle comes in various configurations. The handle is tapered, forming a thin shaft to which a small blade is attached.	12245000	I	6-①	N/A	—
Manually-operated keratome	A manually operated ophthalmic surgical device used for incision of cornea.	12222001	I	6-①	N/A	N/A
Knife handle	A metal (usually, stainless steel) surgical device to which a blade for tissue severing or resection is attached.	12235000	I	6-①	N/A	N/A
Orthopedic osteotome	A surgical device with a cutting blade. Used for osteotomy (surgical cutting of bones). The severed bone is usually used for transplantation. This device is also used for osteoplasty.	12844000	I	6-①	N/A	N/A
Sclerotome	An ophthalmic surgical device used for incision of sclera.	13507001	I	6-①	N/A	N/A
Bone trephine	A device used to sever and remove an intervertebral disk.	14147000	I	6-①	N/A	N/A
Manual corneal trephine	A cylindrical, manual ophthalmic surgical device that has a blade at the end, and is used to sever and remove ring-like pieces of corneal tissue (corneal button). If healthy tissues are collected from a deceased person for transplantation, cornea displaying signs of abnormality is cut off and removed.	14148001	I	6-①	N/A	N/A

Sacculotomy tack	A device that is used to puncture the sacculle in order to remove the labyrinth lymph node from the inner ear.	16080000	I	6-①	N/A	N/A
Ophthalmic knife	A surgical severing device that has a handle and a blade and comes in various configurations and sizes. Used for the surgery of the eye and surrounding structures.	32764001	I	6-①	N/A	N/A
Ophthalmic cystitome	An ophthalmic surgical device used to cut the ocular crystalline lens capsule.	34984000	I	6-①	N/A	N/A
Knife	A device used for severing and resecting tissue during surgery. Usually, it is designed as a surgical device with a handle and a blade that come in various configurations and sizes. The devices classified as a knife are designed to sever by using other techniques. Some are used to cut samples and other objects as well as tissues.	35130001	I	6-①	N/A	N/A
Gingivectomy knife	A severing instrument used to resect the soft tissue wall of the pocket.	41544000	I	6-①	N/A	N/A
Syndesmotome	A dental surgical device used to sever the ligament fibers and separate the alveolar part.	42338000	I	6-①	N/A	N/A
Dental surgical tissue scissors	Scissors specifically designed for dental surgery.	31822000	I	6-①	N/A	N/A
Dental collar/crown scissors	A dental scissors have straight or curved short blades designed to sever metal band.	31847000	I	1	N/A	N/A
Scissors	Scissors usually used to sever tissue, cloth, or sutures during surgery. The two blades meet at the pivot (Usually, they have a hole at each handle for the thumb and other fingers respectively). The blades are closed to sever the material.	35325001	I	6-①	N/A	N/A
Ophthalmic scissors	An ophthalmic surgical device used to sever tissue in ophthalmic surgery. Some have two rotary blades or handles gripped by the thumb and other fingers. The blade comes in various configurations.	35327001	I	6-①	N/A	N/A
Line operated autopsy saw	A hand-held saw has a round rotary blade, and is connected by a cable to a power source or a battery. It is usually used to cut/dissect the upper cranial bone. Some are equipped with a removal unit that has a container for collecting tissue and bone.	44142000	I	6-①	applicable	—
Manually-operated autopsy saw	A manually operated hand-held device that has a saw-like blade. Used to sever bone during an autopsy.	44143000	I	6-①	N/A	—

Gas-powered autopsy saw	A gas-powered hand-held device that has a round rotary blade. Usually used to dissect the upper cranial bone during an autopsy. Some are equipped with a removal unit that has a container for collecting tissue and bone fragments. Usually, compressed air is the power source.	44144000	I	6-①	applicable	—
Surgical saw	A manual or power-operated (e.g., air, nitrogen, battery or power source) device. Used as a single unit, or with various attachments such as a vibrating blade and reciprocating blade. Usually used exclusively for a specific purpose. It adopts either a	13448001	I	6-①	N/A	N/A
Cast cutter blade	A surgical blade that comes with a cast removal device (cast cutting saw), and is used to cut the cast material.	15774000	I	6-①	N/A	—
Powered cast cutter	Usually, a hand-held electric device that has a cylindrical handle at the proximal end, and a semi-circular blade at the distal end which is used to cut a cast made of plaster or synthetic material. The blade electrically cuts by a motor installed in the handle.	16340000	I	12	N/A	N/A
Manually-operated cast cutter	A hand-held scissors-like device has two blades. The distal end to the pivot of the blades forms various jaw-like structures. Used to cut a cast made of plaster or synthetic materials. The tip of one blade is made blunt so as not to cause damage to	16341000	I	6-①	N/A	N/A
Saw	A manual or power-operated (e.g., air, nitrogen, battery or power source) device that is used to cut or separate an anatomical structure or object. Used as a single unit, or with various attachments. Usually used for a specific purpose.	34821001	I	6-①	N/A	N/A
Chisel	A surgical device that has a blade with an oblique angle on one side. Used to sever bone and other hard tissues or sever out the outline.	10824000	I	6-①	N/A	N/A
File	A hand-held manual surgical device that has a rough surface and which comes in various configurations. Used to smooth, grind or sever tissue.	11701001	I	6-①	N/A	N/A
Dental margin finishing file	This finishing file is a metal manual dental device that has a fine mesh surface which is used to finish the margins of the tooth or other dental restorations.	31863000	I	5-①	N/A	N/A
Corneal bur instrument	A small hand-held rotary surgical device that consists of a steel or other hard alloy shaft that has a groove cutter or cutter in various configurations at the end. Used for curettage of corneal tissue.	35786000	I	6-①	N/A	N/A
Dental plastic filling material file	A dental instrument that has grooves on one side. Used to finish the margins of plastic filling material.	37629000	I	5-①	N/A	N/A
Ophthalmic snare	A surgical device that is used to arrange a flexible wire loop around tissue for resection, and snare it. Usually used for eyeball removal. Some consist of a channel or cannula. 2 fixed rings and a sliding ring, and used in ophthalmic surgery.	32755001	I	6-①	N/A	N/A
Snare	A device usually consists of a channel or cannula, 2 fixed rings and a sliding ring. It is used to arrange a flexible wire loop around tissue, and snare it. The sliding ring is moved relative to the fixed rings so as to control the length of the wire extended from the channel.	34822000	I	6-①	N/A	N/A
Adenotome	A surgical device used to dissect the adenoids.	10025000	I	6-①	N/A	N/A
Tonsillectome	A manually operated surgical device used to dissect the tonsils. It comes in a flexible loop that holds the tonsil, or a metal frame with a sliding blade. The loop type holds the tonsil, allowing an incision to be made with a manual knife. The frame type has a	14070000	I	6-①	N/A	N/A

Reusable resection blade	A surgical blade that is used to push the adenoid tissue into the guillotine cutter of the adenoid dissector. This device is reusable.	35836000	I	6-①	N/A	N/A
Cranial bur	Usually a small rotary shaft made of steel or other hard metal. It has a groove cutter or cutter in various configurations on one end. Used to open a hole in soft or hard cranial tissues. Attached to an appropriate electric device to effect rotation.	10520001	I	6-①	N/A	N/A
Reusable airway needle	A device with a sharp point which is used to open the airway. Usually, made of hollow metal. Used for emergency cricothyroidectomy in patients with respiratory occlusion. This device is reusable.	12732001	I	6-①	N/A	N/A
Perforator	Usually a stainless steel device is used to pierce through soft tissue or bone. The spear-shaped shaft has a handle at the proximal end, and a spear or conical configuration at the distal end. Some have a tong-like configuration that is moved when the handle is	12989001	I	6-①	N/A	N/A
Skin graft mesh dilation dermatome	A manual device used to form patterned cuts on the donor's skin piece before grafting. Usually, when the skin is fed into the cutting wheels (the skin is stretched to a certain extent) small slit-like holes are formed. This procedure ensures better skin grafting.	13614000	I	6-①	N/A	N/A
Guide	A trocar guide rod, which is used for trocar sleeve replacement, and other apparatuses, devices or accessories used to guide an object in a desired direction. This guide is used in the following cases: 1. Slow introduction or operation on a site difficult to access.	37150000	I	6-①	N/A	N/A
Pneumatically-powered cast cutter	A hand-held pneumatic saw. Usually it has a cylindrical handle at the proximal end, and a semi-circular blade at the distal end that cuts a cast made of plaster or synthetic materials. The blade performs the cutting movement by means of an air motor installed in the handle that vibrates the blade. Cutting is effected by vibration, not by	17523000	I	12	N/A	N/A
Wire cutter	A scissors-like surgical device that has 2 blades. Used to cut the wire, pins or connected parts.	32885000	I	6-①	N/A	N/A
Surgical guillotine	A cutter that consists of a metal frame. The cutter slides through the frame. It comes in various configurations and sizes according to the type of tissue to be severed. Various cranks or shaft driver mechanisms generate the power.	35096000	I	6-①	N/A	N/A
Malleus cutter	A cutter has ring handles. One blade from the distal end to the pivot slides back and forth, and manipulates the cutting part. Some have a sharp anvil or clasp at the end of the fixed blade. The one with an anvil at the end has a sliding blade that opens and closes the other sharp blade to the anvil. The one with a clasp at the end has a sliding blade that touches the clasp.	35213000	I	6-①	N/A	N/A
Blood vessel surgical stripper	A surgical device used to resect part of a blood vessel. Some strippers are designed to sever part of a vein or artery. There are two kinds of surgical blood vessel stripper: One is a flexible stainless steel cable that has a stripping cup or disk on one end, and a	35377001	I	6-①	N/A	N/A
Dermatome	A surgical knife used to harvest the skin for grafting. Either manual or electric-powered.	36432000	I	6-①	N/A	N/A
Reusable dermatome blade	A blade that comes in various sizes, attached to the skin graft knife, and is used to harvest the skin graft. This device is reusable after sterilization. Usually, the blade point should be sharpened periodically.	37472000	I	6-①	N/A	N/A
Gas-powered dermatome	A gas pressure-operated surgical device used to cut a thin piece of skin for grafting, or to resect a small skin lesion. A dedicated blade is required for this purpose.	37473000	I	12	applicable	N/A
Gas-powered surgical saw	A saw has a handpiece with an attachment that generates vibration or reciprocal movements. It adopts either a micro or macro design. Rechargeable batteries are used. Usually, compressed air or compressed nitrogen is used.	37841000	I	12	applicable	N/A
Soft tissue trephine	A cylindrical or coronary saw used to resect discs of tissues other than bones. It comes in various sizes and configurations according to the size and hardness of the tissue to be resected.	38440000	I	6-①	N/A	N/A

Manually-operated dermatome	A hand-held surgical device used to sever a thin piece of skin for grafting, or to resect a small skin lesion. A dedicated blade is required for this purpose.	38797000	I	6-①	N/A	N/A
Reusable ophthalmic forceps	A forcep used to hold, operate, press, pull or connect the ocular tissue and the surrounding tissue. Some have two blades and two handles connected to the blades, and are used for surgery. Usually, other have detachable handles which are attached	16209001	I	6-①	N/A	N/A
Dental articulation paper tweezers	A dental forceps have a spring at each point, and are used to hold the occluding paper.	31813000	I	5-①	N/A	N/A
Dental tweezers	A manual dental forcep have a tapered spring at each point. These points are to hold the wound cover or protection material used in the earl cavity.	31814000	I	5-①	N/A	N/A
Forceps	A surgical device that has two blades which are closed to hold an object. The handles are permanently connected to the forceps. This category includes all surgical forceps, micro-forceps and surgical tweezers	35079001	I	6-①	N/A	N/A
Pylorus separator	A set of forceps used to separate the gastrointestinal tissue such as pylorus (distal end of the stomach) from the neighboring tissues during surgery. Usually, this device is made of stainless steel	13543000	I	6-①	N/A	N/A
Tonsil forceps	A surgical device that has two blades which are connected at the proximal end to the handles (some are used like scissors which have a pivot). Usually, it is used to hold and manually operate the tonsils during tonsillectomy	15672000	I	1	N/A	N/A
Reusable forceps	A surgical device that is used to hold, connect, press and support an organ, tissue or blood vessel non-traumatically. This device is reusable.	10861001	I	6-①	N/A	N/A
Reusable circumcision surgical clamp	A surgical device that is used to press the foreskin of the penis during preputiotomy. This device is reusable after sterilization.	10869000	I	6-①	N/A	N/A
Single-use nose clip	A device that is used to block the passage of air through the nostrils. The clip is usually made of rubber, plastic or foam tips, and used to test the pulmonary function. The clips are used to ensure that air flows through the mouthpiece for accurate measurement. This device is for single-use	10907000	I	1	N/A	—
Dental forceps	A dental forcep used to remove the alveolar crest after tooth extraction.	15713000	I	6-①	N/A	N/A
Tube introduction forceps	A scissors-like device with ring handles. The distal end of the blade forms a ring with a saw blade, which is used to insert an endotracheal tube. The blade at the center is S-shaped, or curved.	31264000	I	6-①	N/A	N/A
Surgical forceps	A surgical or dental device that is used to clamp and sever the cartilage, bone and other hard tissues. Usually, it is sturdy enough to withstand the force required to clamp the tissue. They come in various designs such as a plier type, pistol grip type	32853000	I	6-①	N/A	N/A
Orthodontic plier	A small pliers have a point that takes various configurations according to the purpose of use. Used to hold a small object, bend and cut a metal piece or wire.	33209000	I	1	N/A	N/A
Stone removal forceps	A surgical device that is used to hold, handle and remove a urinary stone or gallstones. It consists of two blades that have a handle at each end. Some have permanently connected handles, and others have handles that are attached by pressure before use. Other devices can also be used for lithotomy	35083000	I	6-①	N/A	N/A
Dental extraction forceps	A surgical device that is used to hold, connect, press or support the ocular tissue or the surrounding tissue non-traumatically.	35552000	I	6-①	N/A	N/A
Forceps for dental laboratory surgical	A dental laboratory instrument used to bend, sever and create a bulge in metal strips and wire, and break plaster or other. Electricall instrument are excluded.	70935000	I	1	N/A	—

Ophthalmic surgical clamp	A surgical device used to hold, connect, press or support the ocular tissue or the surrounding tissue non-traumatically.	35801000	I	6-①	N/A	N/A
Dental root separator	A separator is a dental surgical instrument specifically designed to be inserted between the mandibular teeth, and create a gap between them.	42339000	I	6-①	N/A	N/A
ENT cupped forceps	A forcep with a spoon-(dish) like configuration at the distal end, and is used to treat the ear, nose, and throat (ENT), and remove tissue from the body.	70936000	I	6-①	N/A	N/A
Percutaneous tracheostomy forceps	A forcep used to bluntly dilate the gap between tracheal cartilages, and create an orifice for percutaneous tracheostomy. The guide wire can be inserted into their tip to achieve an accurate approach to the tracheostomy site.	70938000	I	6-①	N/A	—
Tongue depressor	A surgical instrument used to move the tongue to facilitate examination of surrounding organs and tissue.	14066000	I	6-①	N/A	N/A
Trabeculotomy surgical probe	A thin metal rod used for trabecular meshwork surgery. Some are used to incise the trabecular meshwork from outside the eye.	32761000	I	6-①	N/A	N/A
Reusable surgical probe	A surgical device is a thin rod made of metal or flexible material. It is used to examine cavities, fistulas, and other hollow structures and wounds. Design of its tip of probe varies depending on the specific anatomical purpose (e.g., examination of mastoid). Some bend and form a right angle with the shaft. This device is reusable.	32870001	I	6-①	N/A	N/A
Ophthalmic probe	This device is a thin rod made of flexible metal, and has a round point. Used to examine the eyes and related structures.	35251000	I	6-①	N/A	N/A
Urinary tract sizer	A device used to measure the internal diameter of the urinary tract in order to select a device of a suitable size.	70939000	I	5-①	N/A	N/A
Ophthalmic Flieringa ring	A loop-like band usually made of stainless steel that is sutured onto the sclera to prevent the eyeball from being crushed during difficult ocular surgery.	32758000	I	6-①	N/A	N/A
Fornixscope	An ophthalmic device used to lift the eyelid and keep the eye open during a conjunctiva examination.	32708000	I	5-①	N/A	N/A
Eye speculum	A device used to lift the eyelid and keep the eye open in ophthalmic surgery or examination. Some are a surgical device that consists of 2 arms connected at the pivot, and comes in various sizes, configurations and profiles. Some have a round distal end which is inserted in order to dilate and stretch the tissue around the ocular cavity.	35349001	I	6-①	N/A	N/A
Applier	This surgical device is used to apply surgical clips, staples or other medical devices to the tissue.	16446000	I	6-①	N/A	N/A
Incontinence surgical clamp	A surgical device designed to press the urethra non-traumatically from outside to cause enuresis. It consists of a malleable metal frame, and is partially coated with sponge rubber.	35119000	I	6-①	N/A	N/A

Skull surgical clamp	A surgical device used to hold the skull during surgery in order to fix the head and neck at the desired position during surgery. Usually used for neurosurgery.	35446000	I	6-①	N/A	N/A
Intraocular lens inserter	A device inserted into the eye to guide the insertion and positioning of the intraocular lens during surgery. The device is removed after the intraocular lens is inserted.	36061001	I	6-①	N/A	N/A
Single-use penile surgical clamp	A surgical device used to pinch and handle the penis during surgery. This device is for single-use.	38523000	I	6-①	N/A	N/A
Single-use circumcision surgical clamp	A surgical device used to pinch the foreskin of penis during posthymectomy. This device is for single-use.	38525000	I	6-①	N/A	N/A
Single-use hemorrhoid surgical clamp	A surgical device that resembles scissors and has ring handles. The blade from the pivot to the end has a triangular jaw with saw-like teeth. This device is for single-use.	38526000	I	6-①	N/A	—
Endoscopic surgery introducer and extractor	A cylindrical device that is used to insert devices and remove resected tissue during endoscopic surgery.	70940000	I	6-①	N/A	N/A
Surgical clamp cover material	A device that is made of plastic to cover the clamp jaw to protect body during temporary non-traumatic compression and hemostasis. The device is for single-use.	70941000	I	4	N/A	—
Lens expressor	A manual ophthalmic surgical device used to remove the nucleus lentis from the eye.	12318000	I	6-①	N/A	N/A
Reusable ophthalmic curette	An ophthalmic surgical device has an end with a fenestrated, spoon, or ring in shape, and is used for abrasion. Some have a sharp point and others have a round point. Used to collect and resect the ocular tissue. This device is reusable.	32772001	I	6-①	N/A	N/A
Reusable lens surgical spoon	A manual ophthalmic surgical device used to handle and resect the eye lens during eye lens surgery. This device is reusable.	35153001	I	6-①	N/A	N/A
Stone extractor	A surgical device used to remove stones (e.g., kidney stones, gallstones) from the body. According to the surgical method adopted, it comes in various configurations and designs. Usually, it has the long, flexible distal end equipped with a dilation mechanism (e.g., basket at the distal end). It comes in a spoon-like configuration and various other configurations .	35808000	I	6-①	N/A	N/A
Reusable cornea mill	An ophthalmic surgical device that is used to remove the "rust ring" from the cornea. This device is reusable.	37241000	I	6-①	N/A	N/A
Reusable spoon	A device with a handle that has a spoon-(dish) like configuration at the distal end, and a handle. Used as a surgical device, a device to administer a drug, or another function at medical departments. This device is reusable.	41716001	I	6-①	N/A	N/A

Reusable ring curette	A device with a handle that has a hollow configurations like a ring at the distal end, and a handle. Used to curette lesion tissue and other body tissues. This device is reusable.	70942000	I	6-①	N/A	N/A
Reusable orbit retractor	An ophthalmic surgical device used to push aside the edge of a dissected eye and other structures, or fix the eyeball. This device is reusable.	13381001	I	6-①	N/A	N/A
Orbital depressor	An ophthalmic surgical device used to push aside the tissue so as to make it easy to test the site around the orbital cavity in ophthalmic surgery.	16465000	I	6-①	N/A	N/A
Reusable ophthalmic hook	A surgical device comes in various configurations, and has a shaft-like handle that tapers towards the distal end. Some have a distal end with curved or bent, and have a tip with round or sharp. This device is reusable.	32767000	I	6-①	N/A	N/A
Surgical claps	A surgical device has a shaft-like handle. The handle comes in various configurations, and tapers towards the distal end. The distal end is either a round point, curved toward the sharp point, or bent.	35105000	I	6-①	N/A	N/A
Orbital retractor	An ophthalmic surgical device has 2 broad clasps with a curved point at the handle. The edge of the clasp is not sharp, and is notched so as to push aside the tissue around the orbit during examination or treatment.	35314001	I	6-①	N/A	N/A
Ophthalmic retractor	An ophthalmic surgical device used to push aside the edges of an incision of the eye and related structures.	70943000	I	6-①	N/A	N/A
Ophthalmic surgical lid plate	A lid plate that is inserted between the cornea and eyelid so as to protect the cornea during eyelid surgery. Made of plastic or metal.	70944000	I	6-①	N/A	N/A
Sclereal plug	A nail-like plug used to be inserted into a wound temporarily to close the wound when the tip inserted into the wound is removed during vitreous body surgery.	70945000	I	6-①	N/A	—
Reusable retractor	A surgical device used to separate the tissues or other anatomical sites. It exposes the organ or tissue concerned, and enables access to them for examination or treatment. This device is reusable.	13373001	I	6-①	N/A	N/A
Dental retractor	A manual dental instrument used to push aside and protect the soft tissue to provide better visibility and access during surgery.	13380000	I	6-①	N/A	N/A
Urological retractor	A retractor designed to retain the anatomical structure of the bladder, and have a frame-like structure in which a retractor blade is installed. Some are not sharp, and others have a clasp like appearance (or have more than one clasp). Used to push aside the edges of the incised wound, organ or tissue during surgery.	35311000	I	6-①	N/A	N/A

Laparoscope mechanical distension unit	An apparatus used to mechanically lift up the abdominal wall so as to make a space in the abdominal cavity for a laparoscopic procedure. The abdominal wall is lifted up by an extracorporeal lifting mechanism (e.g. manual traction device, support arm, winch	36302000	I	6-①	N/A	N/A
Rigid direct anoscope	An autoscope used to observe, diagnose, and treat the anal canal and the lower part of the rectum. Some are equipped with a light and dilation apparatus.	10156001	I	5-①	N/A	N/A
Vaginoscope	An autoscope usually used for pediatric vaginal examination. It consists of a coloscope, cold light device, and dilation apparatus. Usually used to search for foreign matter or bleeding site.	15630000	I	5-①	N/A	N/A
Direct sphincteroscope	An autoscope used for anal sphincter examination. Some are used to examine up to the rectum.	15787001	I	5-①	N/A	N/A
Speculum	A surgical device consists of 2 arms connected at the pivot. It comes in various sizes, configurations and profiles. It has a round distal end which is inserted, dilates and extends the body cavity, orifice and lumen in order to open a hole. Used for examination or insertion of other devices. Usually, it is made of stainless steel, or plastic. The arms near the pivot usually form handles. The arms away from the pivot	35517000	I	6-①	N/A	N/A
Vascular tunneller	A stainless steel surgical device usually used to produce tunnels along the vascular tissue in order to produce connected channels. Usually, it is a flexible or rigid rod with a handle tapered to the rod. It has a button or an acorn-shaped knob at the distal end. Some have the pivot near the distal end, slightly curved long blades, and ring handles.	35950009	I	6-①	N/A	—
Indirect laryngoscope	A device consists of a rod-like holder with a tilted mirror at the end. Used for observation, diagnosis, and treatment of the pharynx and surrounding tissues.	70947000	I	5-①	N/A	N/A
Intubation laryngoscope	A laryngoscope used to assist the insertion and placement of an endotracheal tube into the trachea, or eliminate foreign matter in order to secure the airway (human airway) for anesthesia or emergency medical care. Used for observation, diagnosis, and treatment of the larynx and surrounding tissues. It consists of a handle and a blade.	70948009	I	5-①	N/A	N/A
Occlusal retractor	Some are equipped with a lighting apparatus. The “Gillie’s lumenscope for A dental instrument used to keep the patient's mouth open during dental treatment.	70949000	I	5-①	N/A	N/A
Nasal breath mirror	A polished metal piece fogs up due to the water vapor emitted from the nasal cavity when placed near the nasal cavity. The device is used to assess ventilation via the nasal cavity.	70950000	I	1	N/A	N/A
Endoscopic mouthpiece	A device that is used to keep the patient's mouth open during the use of endoscope.	70951000	I	5-①	N/A	N/A
Metreurynter	An inflatable bag used to dilate the uterine cervix.	12524000	I	5-①	N/A	N/A
Colostomy rod	A rod that is placed through the colon loop in order to temporarily keep the colon loop pulled out of the abdominal wall via the surgical orifice, and prevent the colon loop from returning to the inside during loop colostomy.	31987000	I	6-①	N/A	N/A
Salivary gland dilator	A surgical device used to dilate the cavity, tube and orifice of the salivary gland during ear, nose and throat (ENT) surgery.	35830000	I	6-①	N/A	N/A

Dissector	A hand-held surgical device usually has a spoon-like or round cutting component made of stainless steel. Used to separate the soft tissue or body structure from other tissue or structures. It comes in various configurations and sizes. Usually, it has a handle at the proximal end, and a shaft at the other end. The end of the shaft is pointed, flat, sharp or blunt. Some are bent away from the shaft, and others are straight.	11290000	I	6-①	N/A	N/A
Levator	A surgical device that is used to lift, place, and push up with a lever the tissue or other anatomical structure, surgical material or device. It has a handle at the proximal end, and a blunt blade, or a clasp with no blade at the end of the handle. It comes in various	11504000	I	6-①	N/A	N/A
Tendon surgical stripper	A surgical device consists of a semi-circular groove that has a handle and a blade with a sharp point. The stripper is used to resect the whole length of the ligament, tendon and myelin used as biological graft.	35380000	I	6-①	N/A	N/A
Elevator	A device that is used to strip off the tissue during general surgery. Electrical devices are excluded.	70952000	I	6-①	N/A	N/A
Reusable organ fixation pelotte	A device that is used to fix or maintain the organ in situ during a procedure or examination. This device is reusable.	70953000	I	6-①	N/A	—
Ophthalmic surgical spatula	A surgical device in spatulated shape usually made of stainless steel, and used to apply a drug onto the surface of the eye, treat the ocular tissue, and remove substances from the surface of the eye and surrounding structures. Some have a handle at the proximal end, and a flat blade without sharp angles at the distal end. Some shaft or blade is twisted, some is curved, bent, forming angles from the handle to the distal end	32754001	I	6-①	N/A	N/A
ENT surgical probe	A surgical probe that is made of flexible metal, has a ball-like or a pointed thin, long stick-like end. Used to search for a fistula, cavity or wound during otorhinological treatment. Some have a distal end (before the ball or sharp point) that bends forming a	33433000	I	6-①	N/A	N/A
Eye brush	A brush used to collect tissue samples, or apply drugs onto the surface of the eye or related structures. Some have a handle on one end, and bristles, fibers, or spikes on the other end. Bristles, fibers, or spikes are inserted evenly in a plane surface, or radially around the axis. The shaft handle is flexible or rigid, and bristles are soft or hard	34880000	I	6-①	N/A	N/A
Evisceration prosthesis	A device that is used to hold or fix the abdominal organs in situ.	35654000	I	6-①	N/A	N/A
Gynaecological dissector	A device that is used to, for example, collect mucosal tissue from the uterus for cytological diagnosis. This device is for single-use.	70955000	I	5-①	N/A	—
Surgical drill handpiece	This manual or power-operated (e.g., air, nitrogen, battery, power source) device is used on its own, or used as a motor-driven device equipped with various attachments (e.g., chuck, reaming attachment, wire inserter/guide, percussor). Some can be cannulated so as to be used over a guide wire. It adopts either a micro or macro design	37146000	I	6-①	N/A	N/A
Distractor	A surgical device used to separate connected surfaces, and to retain their positions to allow a surgical operation to be performed. Some are used for long bones in lengthening procedures (limb lengthening for patients with legs of different lengths). For the lengthening, the device is usually connected to the bone with pins. External fixation may be used. Some are used for spinal fusion or maxillofacial (in the oral	11291000	I	6-①	N/A	N/A

Bone tap	A metal surgical device that is used to cut threads on the bone surface in order to apply bone screws. The bone screws fix the bone fragments, fixture or other device to the bone.	17507000	I	6-①	N/A	N/A
Bone mill	A mill used to crush the bone into slurry or powder which is used as bone matrix for bone regeneration or bone transplantation.	18129000	I	1	N/A	N/A
Bone screw starter	A surgical device that is used to start the insertion of the bone screw into the bone. It cuts the bone to form a desired angle to which the bone screw can be applied tightly or loosely.	32859000	I	6-①	N/A	N/A
Surgical drill bit guide	A hand-held surgical device used to determine the position and angle of the drill hole, and protect the surrounding tissues. This is inserted into a tube so as to fit the dedicated drill bit size. It has a saw-like configuration at the distal end so as to secure	35095000	I	6-①	N/A	N/A
Orthopedic reamer	A manual Orthopedic device used to cut and expand the marrow cavity before inserting an artificial joint, or other devices in order to fix the bone fracture.	35297001	I	6-①	N/A	N/A
Manual Orthopedic cement dispenser	A manually operated injection syringe-like device used to inject Orthopedic (bone) cement into a surgical site. "Orthopedic injectors" are excluded.	35809001	I	2	N/A	—
Reusable bone setting instrument	A surgical device used to connect bones in Orthopedic surgery, and refer to the manual bone drill, calcaneus compressor and innominate bone clasp. It is manually operated. This device is reusable.	70958001	I	6-①	N/A	N/A
Countersink	A rotary surgical device used to expand the outer diameter of the drill hole to prevent the screw or bolt head protruding from the surface.	16462000	I	6-①	applicable	N/A
Shaver system	A special system or a device used for percutaneous surgery of the joints (e.g., knee joint, shoulder joint). Some systems are exclusively used for other sites (e.g., nasal cavity). Usually used in conjunction with a dedicated endoscope so that the operator	36436000	I	12	applicable	N/A
Gas-powered surgical drill handpiece	A drill consists of a single handpiece that includes a chuck which is used in combination with a drill bit, bone tap or wire. Some have a hollow structure into which a guide wire can be inserted. It adopts either a micro or macro design. It has a system powered by compressed air and compressed nitrogen can be used as a power source.	37876000	I	12	applicable	N/A
Pneumatic bone operating instrument	A pneumatic surgical device used for bone surgery.	70960000	I	6-①	applicable	N/A
Bone staple driver	A hand-held surgical device designed to provide force to other devices to facilitate the insertion of a bone staple into tissue. The distal end has a configuration to be connected to a device which is to be inserted into the tissue. The proximal end is designed to absorb and transmit the impact.	10458000	I	6-①	N/A	N/A
Driver/extractor	A surgical device used in combination with other devices when inserting or removing pins, screws or other devices during surgery.	11345000	I	6-①	N/A	N/A
Reusable surgical drill bit	A drill bit connected to a manual or powered surgical perforator. With an appropriate rate of revolution, it produces a hole in the bone having the same diameter as itself. Usually, it is a "twist drill" type (spiral type). Some have a flat, angled blade. This device is reusable.	32390000	I	6-①	N/A	N/A
Prosthesis driver	A hand-held surgical device designed to provide force to other devices to allow an Orthopedic prosthesis to be inserted into tissue. The distal end has a configuration to be connected to a device which is to be inserted into the tissue. The proximal end is	32865000	I	6-①	N/A	N/A
Surgical wrench	A manually operated surgical device that has a fixed mating part, and is used to hold, turn or twist the nuts, bolts, and wire.	32871000	I	6-①	N/A	N/A

Acetabular socket pusher	A rod-like surgical device that has a grip and is designed to hold the acetabular cup or shell at the distal end. By using the socket pusher, the acetabulum of a hip prosthesis is inserted into an appropriate position in the acetabular roof of the pelvis.	32878000	I	6-①	N/A	N/A
Wire crimper	A manual orthopedic device, which has similar functions to the wire pressing forceps, that is used to bend a wire or fastener.	32879000	I	6-①	N/A	N/A
Surgical screwdriver	A surgical device has a shaft, and is designed to fit the screw threads so as to tighten or loosen the screw at one end by using torque. The head has either a single slot, cross slot, Phillips, Allen or hexagram configuration, etc. The other end of the shaft is	33968000	I	6-①	N/A	N/A
Surgical bone clamp	A surgical device used to hold the bone, or connect the proximal or distal end of the fractured bone during surgery.	34949000	I	6-①	N/A	N/A
Surgical gouge	A heavy surgical device made of stainless steel, and used to resect bone and other hard tissue. It has a handle at the proximal end which is connected to a shaft. The distal end has a sharp, semi-circular configuration that ensures easy resection of tissue.	35090000	I	6-①	N/A	N/A
Intramedullary nail driver	A hand-held surgical device designed to provide force to other devices in order to insert an intramedullary rod into the tissue. The distal end has a configuration to be	35166000	I	6-①	N/A	N/A
Reusable intramedullary canal cleaning brush	connected to a device which is to be inserted into the tissue. The proximal end is A brush used to remove blood clots and bone fragments from the medullary canal before injecting Orthopedic cement. Usually, it has a handle on one end, and bristles, fibers, or spikes on the other end. Bristles, fibers, or spikes are inserted evenly in a plane surface, or radially around the axis. The shaft handle is flexible or rigid, and bristles can be soft or hard. This device is reusable.	35589001	I	6-①	N/A	N/A
Reusable external fixation system	A special surgical system that consists of a case and several trays. The system is designed to be used for specific surgery such as bone fracture surgery, spinal surgery and orthodontic surgery. The external fixtures of this system can be reused in	35647001	I	6-①	N/A	N/A
Orthopedic caliper	A surgical measuring instrument that consists of 2 legs connected by a hinge to one shaft. Used to measure the diameter and length of the bone.	35788000	I	1	N/A	N/A
Prosthetic joint facsimile	Copies of artificial joint components used to determine the size of the permanent artificial joint, or confirm that the part to be implanted has appropriate dimensions. (Trial components used for other types of Orthopedic surgery are included in this	36135000	I	6-①	N/A	N/A
Orthopedic file	A surgical device designed as a long, tapered trimming device with teeth which make holes in the bone tissue, and expand the holes.	36167001	I	6-①	N/A	N/A
Manually-operated surgical drill handpiece	A device consists of a manual handpiece including a chuck which is used with a drill bit, bone tap or wire. It is also known as a fixator or a bit. Some are inserted into a tube so that a guide wire can be inserted.	36235001	I	6-①	N/A	N/A
Orthopedic bur	A small rotary shaft made of steel or other hard metal. It has a grooved surfaces or cut surfaces of various configurations on one end. Used for boring and forming of the bone tissue during maxillofacial surgery, spinal surgery and other bone surgery procedures.	36249001	I	6-①	N/A	N/A

Reusable surgical drill attachment	This device is connected to a manual, electric or pneumatic handpiece, and used for specific tasks, drilling, reaming, severing and trimming, introducing and guiding the wire. Some have a decelerating gear to achieve the desired speed for specific	37870001	I	6-①	N/A	N/A
Surgical crown drill bit	A hollow boring device used as a crown (crown type) drill or hollow mill. Before removing the screw that has lost its screw head, it is used for overdrilling the part including the shaft, and is also used to collect a sample from the center of the bone for biopsy.	37871001	I	6-①	N/A	N/A
Reusable extention fixator	A fixator used to fix the pins, etc. inserted into bone or soft tissue for bone fracture treatment or bone lengthening out side the body. Usually, this device is reusable.	70961000	I	1	N/A	—
Reusable instrument for bone surgery	A surgical device used for bone surgery such as osteosynthesis. The device is manually operated. This device is reusable.	70962001	I	6-①	N/A	N/A
Reusable instrument for spinal surgery	A surgical device used for spinal fusion and the other spinal surgeries. The device is manually operated. This device is reusable	70963001	I	6-①	N/A	N/A
Reusable joint operating instrument	A surgical device used for artificial joint replacement and other joint surgery procedures. Manually operated devices only. This device is reusable.	70964001	I	6-①	N/A	N/A
Reusable dental implant surgical instrument	A surgical hand-held instrument used for dental implants and other surgical procedures. Manually operated. Some are used non-invasively. This device is reusable.	70965001	I	1,6-①	N/A	N/A
Ligament/tendon reconstruction instrument	A stainless steel surgical device used to produce tunnels along the ligament or tendon tissue to produce connected channels. Usually, it is a flexible or hard rod that has a tapered handle towards the rod. It has a button or an acorn-shaped knob at the distal end. Some have the pivot near the distal end, or wing handles with slightly curved legs	34827000	I	6-①	N/A	N/A
Ligament/tendon operating instrument	A surgical device used for ligament reconstruction and other forms of ligament and tendon surgery. Manually operated devices only.	70966001	I	6-①	N/A	N/A
Reusable Orthopedic implant extractor	A surgical device used to remove a hip prosthesis, intramedullary rods and other Orthopedic implants. This device is reusable.	12696000	I	6-①	N/A	N/A
Surgical depth gauge	A depth measuring instrument used to measure the length of a screw used to tighten the edges of bone fracture, determine the appropriate length, and for many other medical purposes.	32845000	I	1	N/A	—
Orthopedic fixation forceps	Surgical forceps have specifically designed blades, and are used to hold an Orthopedic implant or device. Used by a surgeon or the operator for implanting a prosthesis to handle it safely during surgery	42894000	I	6-①	N/A	—
Temporal bone holder	A bone holder for a surgical use to clamp and hold the bone fragments from the outside the surgical field so as to assist the operator and assistant. Used for bone reconstruction and production of graft materials. It has sturdy legs. Some have a dish-	43956000	I	6-①	N/A	N/A
Awl	A manual Orthopedic surgical device has a spike-like configuration, and has no blade. Used to make holes in the bone.	15275000	I	6-①	N/A	N/A

Bone skid	A long flat surgical device has a cradle at both ends. The cradles are formed to fit the outline of a specific bone. The skid is designed to slide under a specific region of the bone so that the bone can be moved, and the position can be decided.	32862000	I	1	N/A	N/A
Orthopedic tape	A fabric or plastic (adhesive) tape used to fix a catheter, IV tube and other medical devices. (Tapes used for secondary fixation are excluded.)	32882000	I	1	N/A	N/A
Orthopedic cerclage applier	A surgical device used to arrange, fix and connect an Orthopedic fastening loop, clamp or wire.	35797000	I	6-①	N/A	N/A
Orthopedic cement extractor	A device or a set of devices used to remove Orthopedic (bone) cement from the affected site. It may include a "slap hammer" used to crush bone cement, a chisel (electric or	37065009	I	12	applicable	N/A
Manually-operated Orthopedic cement extractor	Usually, a set of manual surgical devices used to remove Orthopedic (bone) cement from the affected site when replacing an artificial joint fixed with cement. The group of these general devices may include the "slap hammer" used to crush bone cement for removal, a chisel or other manual instruments.	44597000	I	6-①	N/A	N/A
Dermatome skin approximation tape	A tape that comes in various sizes with adhesive on both sides. It is attached onto a skin graft knife to collect a skin graft tissue. This device is for single-use.	70967000	I	2	applicable	—
Vaginoplasty instrument	A device that is inserted into the abdominal cavity in order to prevent the restenosis of the abdominal cavity for patients who do not have a vagina after construction of the vagina by skin valve transplantation, use of the peritoneum, or other procedures (e.g.	70968000	I	5-①	N/A	—
Hammer	A metal (Usually stainless steel) device that consists of a handle, shaft and head. The handle is usually round, and designed to fit into the palm. The handle is tapered towards the shaft. The head is placed at the end of this shaft usually with cylindrical	11947010	I	6-①	N/A	N/A
Wooden hammer	A wooden hammer.	11947020	I	6-①	N/A	N/A
Spatula	A spatula usually made of stainless steel, and used to apply a drug to the surface, fill drugs into a cavity, treat the tissue, and remove substances from the surface or blood vessels. It has a handle at the proximal end, and a flat blade without a sharp angle at the distal end. The shaft or blade is straight, curved or bent in various angles from the	13645000	I	6-①	N/A	N/A
Dilator	A surgical device that is used to dilate the inner diameter (caliber) of an orifice, lumens or blood vessels.	11254000	I	6-①	N/A	N/A
Nasal dilator	A flexible, thin cylindrical, hollow or rod-like device made of metal or plastic, and that comes in various sizes. Used to dilate the nasal structure and nasal cavity.	11260000	I	5-①	N/A	N/A
Rectal dilator	A device used to dilate the anal sphincter and anus to allow the smooth insertion of a device for examination of anal function.	11262000	I	5-①	N/A	N/A
Tracheal dilator	ThisA flexible, thin cylindrical, hollow or rod-like device that is made of metal or plastic, and comes in various sizes. Used to dilate the tracheal structure and tracheal passageway.	11263000	I	5-①	N/A	N/A
Reusable urinary duct dilator	A flexible, thin cylindrical, hollow or rod-like device that is made of metal or plastic with various sizes. Some have a mechanism to dilate the urethra and its degree is indicated on the dial. This device is reusable.	11265000	I	5-①	N/A	N/A
Vaginal dilator	A device that is inserted into the vagina, and placed there for a certain period. The insertion part has a round end for smooth insertion. It is used to dilate a narrow vaginal opening due to a congenital defect. It may interfere with sexual conduct.	11267000	I	5-①	N/A	N/A

Reusable urethral bougie	A flexible, cylindrical, hollow or solid device that is used to diagnose urethral stenosis. It is made of metal or plastic and comes in various diameters. This device is reusable.	14286000	I	5-①	N/A	N/A
Esophageal dilator	A thin hollow or solid cylindrical device (usually, a surgical device) is made of iron, plastic, or other appropriate materials, and comes in various sizes and flexibilities. Used to dilate the esophageal structure and passageway.	35009000	I	5-①	N/A	—
Lachrymal eye dilator	An ophthalmic device used to dilate the lacrimal punctum.	35010000	I	6-①	N/A	N/A
ENT bougie	A rod-type surgical device used to examine or dilate a stenosis during otologic surgery.	35022000	I	5-①	N/A	—
Esophageal bougie	A hollow cylindrical surgical device with an olive-shaped metal weight. It slides over a string or wire guide, and is used to dilate an esophageal stenosis. (Some are made of tapered plastic.)	35052000	I	5-①	N/A	—
Reusable medical dilator	A device used for dilation. Electrical devices are excluded. This device is reusable.	70969001	I	6-①	N/A	—
Applicator for medical use	A device used to apply drugs on the body or in the body, perform treatment, collect samples for examination, or clean the apparatus place in the body by a method that has possibility to contact the body tissue. The applicator comes in various types, each of which usually has a specific function: 1. A simple thin rod made of wood, flexible	10172000	I	5-①	N/A	—
Eye applicator	A thin ophthalmic rod made of wood, flexible metal or synthetic material with lint or synthetic fiber at one end. Some have a sponge-like absorber made of lint or synthetic fiber molded into a stick shape.	10175000	I	6-①	N/A	—
Single-use laryngotracheal topical anaesthesia applicator	A thin stick used to apply local anesthesia to the larynx and trachea. This item is for single-use.	31343000	I	5-①	N/A	—
Non-sterile absorbent tipped applicator	A thin, long stick made of wood, flexible metal or synthetic material with a non-sterile absorber at one end. It is used to absorb a material from any accessible surface and	33721000	I	4	N/A	—
Sterile absorbent tipped applicator	A thin, long stick that is made of wood, flexible metal or synthetic material with a sterilized absorber at one end. It is used to absorb a material from any accessible surface and internal area of the body. Sometimes, the absorbed material is used as a	33722000	I	4	applicable	—
Superficial tissue foreign body extractor	A magnetic or mechanical forceps used to remove foreign matter from the skin, superficial fascia, and other superficial tissue for minimizing tissue injury.	15580000	I	6-①	N/A	N/A
Eyes spud	A thin, long, probe-like device used to catch and remove foreign matter from the ocular surface.	16025000	I	6-①	N/A	—
Cerebral surgery mirror	A neurosurgical device used to observe the surgical site during neurosurgery. Inserted through a surgical opening of the cranial. Usually, it consists of a mirror, shaft, and handle.	70970000	I	6-①	N/A	N/A
Gastrointestinal sizer	A device used to measure the size of a digestive organ. Some measure the size of the lumen, and others measure the depth of a fistula.	70971000	I	5-①	N/A	—
Spectacles	A device that consists of a pair of lenses and a frame to hold the lenses.	35065000	I	1	N/A	—
High magnification lens system	A lens system used for visual magnification of patients with a visual disorder. It comes in a scope for distant or near view, or a magnifying lens for near view.	30047000	I	1	N/A	—

Tinted lens	A lens that weakens radiated light by its absorption or reflection.	30048000	I	1	N/A	—
Spectacle lens	A glass or plastic device used to correct a refraction error of the eye according to a prescription, or protect the eyes from radiation and mechanical hazard. Some are worn on top of the eye glasses for its protection.	35957000	I	1	applicable	—
Eikonometer	An ophthalmic device used to diagnose aniseikonia.	11391000	I	1	N/A	N/A
Tachistoscope	An ophthalmic device used to illuminate letters and images at various speeds for ophthalmic diagnosis and examination.	13970000	I	1	N/A	N/A
Nystagmus inducing optokinetic drum	A drum-like ophthalmic device covered with black and white strips or patterns. Used to induce and assess nystagmus (involuntary rapid eyeball movement).	16476000	I	1	N/A	N/A
Visual acuity eye chart	A visual acuity chart used to test visual acuity. Some have a visual target inside a box with the background illuminated and a letter or symbol is selectively shown.	16800000	I	1	N/A	—
Amsler chart	An ophthalmic device used to detect disorders in the center or near-center of the visual field. Some are a series of charts with a grid in various sizes, and placed at a distance of 30 cm from the patient.	32786000	I	1	N/A	N/A
Visual acuity projector	A projection-type examination device for testing visual acuity and visual sense. Some use black letters or other symbols which are reduced step wise according to the distance, and projected on the screen or wall to test visual acuity.	35922000	I	1	N/A	N/A
Polatest	A device used to assess latent strabismus. When the patient does not recognize it, and it cannot be confirmed visually, the visual target that is polarized by the phoropter cannot be recognized as a proper cross shape by the patient. The phoropter is adjusted.	37070000	I	1	N/A	N/A
Visual acuity testing equipment	A visual acuity test apparatus that presents optically far or near visual targets.	70973000	I	1	N/A	N/A
Ophthalmoleukoscope	A color perception test device that uses polarized light.	12810000	I	1	N/A	N/A
Colour discrimination tester	A color perception test device that uses color threads or color perception plates. Color perception is assessed using an ophthalmic device that consists of various color materials such as multi-color plates, which are perceived as one color by patients with defective color vision.	32687000	I	1	N/A	N/A
Colour discrimination chart	An ophthalmic chart that consists of color patterns printed on a colored (including white) background. Used for a color perception test.	35898000	I	1	N/A	N/A
Colour discrimination quick-test	A color perception test device used to rapidly assess the ability to recognize various colors. Used for pilots and sailors. It consists of one or several disks. Some have colored glasses which can be manually replaced, and are used to indicate a selected color.	37066000	I	1	N/A	N/A
Fresnel lens	A thin flexible ophthalmic lens or prism that is worn temporarily on top of the lenses of eye glasses, usually for the purpose of diagnosis.	32693000	I	1	N/A	—
Prism bar	A device that consists of prisms having various reflective indexes, and is used to assess the function of the ocular muscles during a visual acuity test.	32719000	I	1	N/A	N/A
Trial lens frame	A lens frame that is used to hold the trial lens in front of the eye during a refraction test.	32791000	I	1	N/A	N/A

Ophthalmic spectacle clip	A clip used to hold a prism, spherical, cylindrical piece or shield on a trial glass frame or glass frame during a visual acuity test.	32792000	I	1	N/A	N/A
Trial lens	A lens that is used for optometry.	34653000	I	1	N/A	N/A
Manual pupillometer	A manual ophthalmic device used to measure the width and diameter of the pupil. In order to assess the pupil, the diameter and other measured values of the pupil relative to the parameters of the device are measured.	32727000	I	1	N/A	—
Ophthalmodiastimeter	A device used to measure the distance between the eyes in order to fit prescribed lenses properly.	12805000	I	1	N/A	N/A
Pupillometer	An ophthalmic device used to measure the width and diameter of the pupil.	13236000	I	1	N/A	N/A
Pachometer	A device used to measure the thickness of the cornea using an optical technique.	16330001	I	12	applicable	applicable
Exophthalmometer	An ophthalmic device used to measure the degree of abnormal protrusion of the eyeball.	16345000	I	1	applicable	N/A
Haidinger brush	An apparatus (usually, having an AC power source) creates the image of 2 conical brushes connected at their tops. Some are used to examine the visual function and the function of the macula lutea by showing an image through a Nicol prism.	32688000	I	1	N/A	N/A
Extracorporeal eyelid weight	An ophthalmic device used to place a weight on the upper eyelid, or compress the eyelid in order to restore its function. Some are worn on the outside of the upper eyelid so as to place a load (place a force on the eyelid). It is also used to treat transient paralysis, or measure the size of an eyelid weight to be implanted before surgery.	18142000	I	1	applicable	N/A
Recumbent spectacles	Prism eyeglasses used by bed-ridden patients so they can read books in the supine position.	30143000	I	1	N/A	—
Ocular pressure applicator	A device used to apply pressure on the eye during ophthalmic surgery. Some are a manual apparatus that has a valve that compresses the site just like a sphygmomanometer. Some are equipped with a dial gauge, band and bellows.	33804000	I	6-①	applicable	N/A
Cotton ball	A cotton ball used to apply drugs to the various site of body or wipe off liquid.	11028000	I	4	N/A	—

Eye pad	A pad made of gauze, cotton or various other materials. Used to protect the eye or absorb secretions.	11661000	I	4	N/A	—
Gauze sponge	A gauze that is intended to apply to surgical incisions and other skin wounds or an internal structure in order to stop bleeding, absorb liquid, and protect the organs from abrasion, dryness, or contamination.	13700000	I	4	N/A	—
X-ray detectable sponge	A sponge that contains an X-ray detectable agent, and is intended to apply to surgical incisions and other skin wounds or an internal structure in order to stop bleeding, absorb liquid, and protect the organs from abrasion, dryness, or contamination.	13705000	I	4	N/A	—
Laparotomy sponge	A sponge used inside the body during laparotomy in order to stop bleeding, absorb liquid, and protect the organs from abrasion.	15085000	I	4	N/A	—
X-ray detectable gauze	A cotton or cellulose absorbent does not contain any drug, and is used inside the body or for surgical incisions in order to stop bleeding, absorb liquid, and protect the organ from abrasion, dryness or contamination. It contains an X-ray detectable agent.	32374000	I	4	N/A	—
Cottonoid pad	A pad made from cotton or synthetic fiber, used during surgery in order to protect nerve tissues, absorb liquid, or hemostasis.	32572000	I	4/5-③	N/A	—
Non-woven gauze	A cover/protection material made of non - woven fabric, and used to treat wounds or surgical incisions.	34655000	I	4	N/A	—
Medical absorbent cotton	A medical pad, is made from cotton fiber, used to apply drugs, absorb a small amount of body fluid from the body surface, or for other medical purposes	70975000	I	4	N/A	—
Medical sponge	A sponge made of a polymeric material, and used to apply drugs to various body parts, or remove liquid. Wound cover and protection materials are excluded.	13695000	I	4	N/A	—
Latex sheet drape with self-retaining finger cot	A latex cover with self-retaining finger cot. The surgeon wears it when he/she inserts his/her finger into the rectum during transurethral prostatectomy.	31978000	I	5-①	N/A	—
Single-use finger protector	A device used to protect an damaged finger from further injuries during the healing process. It is worn on the injured finger, stops bleeding from the finger without any contact with the injured site, and protects it. Usually, made of plastic, rubber, reinforced metal or other durable materials. This device is for single-use.	35073000	I	1	N/A	—
Reusable finger protector	A device used to protect an injured finger from further injuries during the healing process. Usually, made of plastic, rubber, reinforced metal or other durable materials. This device is reusable.	42050000	I	1	N/A	—
Non-latex medical examination glove	Gloves made of synthetic materials, and used to protect the patient and users from cross infection during examination, check-up, treatment and handling of contaminated medical materials except for surgery. Dental gloves are excluded.	70976000	I	1	N/A	—
Latex medical examination glove	Natural rubber gloves used to protect the patient and users from cross infection during examination, check-up, treatment and handling of contaminated medical materials except for surgery. Dental gloves are excluded.	70977000	I	1	N/A	—
Hernia aid strap	A strap wrapped around the pelvis and abdomen in order to retain an abdominal hernia in the normal position. It comes in pediatric and adult sizes.	30883000	I	1	N/A	—
Hernia aid girdle	A girdle designed to trap a spinal hernia and place it in the right position.	30884000	I	1	N/A	—
Hernia aid band	A band designed to trap a spinal hernia and place it in the right position.	35409000	I	1	N/A	—
Infant hernia aid strap	A bandage-like strap made of worsted yarn, worn by an infant in order to treat an	35410000	I	1	N/A	—
Home use low frequency therapy electrode	An electric conductor used in conjunction with a low frequency therapy device for home use. Worn by the user and the electric energy is non-invasively transmitted from	71008000	I	1	applicable	N/A

Home use electric potential therapy apparatus electrode	An electrode used in conjunction with an electric potential therapy apparatus for home use. It directs electric potential or an electric field onto the body.	71009000	I	1	applicable	—
Home use hot pack	The single-use pack contains a special chemical substance that generates heat. This pack generates heat when activated, and is applied to the affected site in an antiphlogistic procedure (thermotherapy). It is for home use.	71019000	I	1	applicable	N/A
Menstrual tampon	A plug made of cellulose or synthetic material, or a cup-like plug made of synthetic materials, that is inserted into the vagina to absorb menstrual or other vaginal discharge. It is non-scented or scented for aesthetic and deodorizing.	35694000	I	5-③	applicable	—
Adhesive bandage	An adhesive tape that is made of cloth or plastic, has adhesive on one side, and is used for the body surface. It comes in various shapes. Some have pads. Used to cover and protect a wound, draw wounded skin together, and support a wounded site in the body.	34864000	I	4	applicable	—
Liquid bandage	A bandage made of liquid, or semi-liquid material or materials in combination of powder and liquid. Used to protect or draw wounded skin or oral mucosa together, or protect a burn. The bandage for wounds of oral mucosa can be used temporarily or in	33584000	I	4	applicable	—
Home use contact granule patch	A home use equipment grain-like hard object placed in the center of an adhesive tape. When the tape is applied to a body part that is stiff, the object compresses the site, and "relieves the stiffness." It is for home use only.	71026000	I	1	applicable	—
Home use noninvasive acupuncture equipment	A home use equipment used for acupuncture at home. Pasted on the skin, instead of inserting a needle into the body.	34675001	I	1	applicable	N/A
Mass spectrometric analyzer	An automatic or semi-automatic device that ionize inorganic or organic compounds in human samples, then identifies and quantifies by mass analyzer based on the effect of an electric and a magnetic field. The device consists of ionizer that converts the compound into ions, mass analyzer that sorts the ions by their mass-to-charge ratio, and detector that detects the presence of arrived ions. The device may include separation analyzer, e.g., a liquid chromatography analyzer, gas chromatography analyzer. The device also has functions to output graphics and data. Devices equipped with diagnostic function are included.	57848001	I	—	applicable	applicable
Storage and display device for pathological whole slide image	A device used to capture of high magnification images of whole pathological slide samples (pathological whole slide images), and to display and store the images into recording media in the device.	15132021	I	12	applicable	applicable
External pacemaker cable or adaptor	A cable or adaptor used to connect cardiac electrodes and external pacemaker which are used for temporary pacing, and transmit a stimulating electric current to the heart and action potential signals of the heart.	71061001	I	1	applicable	—
Electronic tourniquet	An electronic device used to pressurize the upper and lower extremities for avascularization. It is used to overswell the vein for puncturing. The cuff pressurizes	71063001	I	12	N/A	N/A
Intra-vaginal organ positioning device for diagnostic imaging and radiotherapy	A device that is specifically designed to be inserted in the vagina to properly position and fix the surrounding organs such as uterine cervix, rectum, and urinary bladder for image diagnosis or radiotherapy. This device is used to facilitate reproducible positioning for continuous image examination or continuous radiotherapy.	71067001	I	5-①	N/A	N/A
3D organ phantom	A model reproducing the individual patient's actual organ structures based on his/her imaging data such as CT and MRI. It is complementarily used for medical treatment with other diagnostic information, as a purpose of confirmation of the organ structure,	62215001	I	1	N/A	—
Dry pasteurization device	A warming device that is small, and usually heats to no less than 62°C for at least 30 minutes without use of warm water, and kills almost all infectants. This method is indicated only for the cases that do not need complete sterilization.	71069001	I	12	applicable	N/A
Erythrocyte sedimentation rate measuring instrument	A device that manually measures the rate of erythrocyte sedimentation (sinking), which is known as the erythrocyte sedimentation rate (ESR), in whole blood samples.	55974001	I	—	N/A	N/A
Oral/swallowing function exerciser	A non-active device used under the instruction of a doctor, etc. for rehabilitation of deterioration in oral or swallowing functions.	63278001	I	5-①	N/A	—

Reusable drainage flowmeter	A device that directly or indirectly measures the amount of drainage from the thoracic or abdominal cavity when it is connected with the thoracic or abdominal cavity drain. Measurement is mechanical, electrical or a combination of both. This is reusable use.	71071001	I	12	applicable	applicable
Surgery instrument for root canal treatment	A surgical instrument used for root canal treatment. Manually operated. Some are used non-invasively. This device is reusable.	71074001	I	1,6-①	N/A	N/A
Sizer for valvuloplasty	A surgical device manually operated during valve reconstruction and valvuloplasty. It can measure the size of the valve cusp for heart valve surgery using autologous pericardium, etc. of the appropriate size. Some include handle used in sizer and holder. This device is reusable.	47684001	I	6-①	N/A	—
Motorless fixed-aperture accelerator system collimator	Fixed-aperture collimator assembly that is not equipped with a motor. It is positioned between the subject and the beam projection port of the accelerator's collimator housing and is used to adjust the form of the radiation beam that is delivered to the therapeutic target area of the body. It is made of a highly attenuating material or alloy including lead or tungsten, and protects patients by controlling or avoiding delivery of radiation to non-target area of the body.	42265001	I	1	N/A	N/A
Microbial quantitative analyser	An automatic or semiautomatic device that uses electrical impedance to quantify microorganisms in biological samples. For example, it is used to quantify microorganisms in samples collected from the oral cavity for examination.	71086001	I	—	applicable	applicable
Liquid metal capillary thermometer	A measurement device used to measure the patient's body temperature. The device is a thin hollow glass tube with both ends sealed. The bulb at the bottom is filled with liquid metals such as gallium alloy (excluding mercury). The device functions based on the capillary principle. The medium filled in the notched column expands in proportion	71091001	I	1	N/A	—
Ostium uteri cap	A cap that is placed at the uterine opening to reduce semen outflow. ItThe device is intended for temporary use only and it is not sterilized.	46969001	I	5-①	N/A	—
Material for masticatory ability test	A reference material used to test the masticatory ability. For example, masticatory ability is tested by measuring the number of particles, etc. that are chewed and subsequently expelled by the patient. It may include a camera to capture the spat material and a program to measure the number of particles.	71093001	I	1	N/A	—
Surgical aid sheets	A sterilized single-use sheet used temporarily during surgery to improve visibility of tissues, surgical instruments, etc. in the surgical field. Some sheets have a scale.	61448001	I	1	applicable	—
Non-active extension/traction motion training assisting device	A non-active device used to assist in joint rehabilitation under the instruction of a doctor, etc.. This product has a shape suitable for training the target joint.	71094001	I	1	N/A	—