

Drugs Controller General (India)
Directorate General of Health Services
FDA Bhawan, Kotla Road, New Delhi

NOTICE

File No. 29/Misc./03/2020-DC (193) Part III

Date: 16 MAR 2022

Subject: Classification of medical device pertaining to General Hospital/Orthopaedic Instruments under the provisions of Medical Devices Rules, 2017- Reg.

Safety, quality and performance of medical devices are regulated under the provisions of the Drugs and Cosmetics Act, 1940 and rules made thereunder. For the regulation of medical devices for with respect to the import, manufacture, clinical investigation, sale and distribution, the Central Government, after consultation with the Drugs Technical Advisory Board, has notified Medical Devices Rules, 2017 vide G.S.R. 78 (E) dated 31.01.2017 which are to be commence from 01.01.2018

In this connection, in exercise of the powers conferred under sub-rule (3) of rule 4 of Medical Devices Rules, 2017, the undersigned hereby classifies the medical devices based on the intended use of the device, risk associated with the device and other parameters specified in the First Schedule.

Updated list of medical devices placed at Appendix A subjected to the followings:

1. General intended use given against each of the devices is for guidance to the applicants intends to furnish application of import or manufacture of medical devices under the provisions of Medical Devices Rules, 2017. However, a device may have specific intended use as specified by its manufacturer.
2. This list is dynamic and is subject to revision from time to time under the provisions of the Medical Devices Rules, 2017.

V. G.

(Dr. V. G. Somani)
Drugs Controller General (India)

To,

1. CDSCO Website

File No. 29/Misc./03/2020-DC (193) Part III
Drugs Controller General (India)
Directorate General of Health Services
Central Drugs Standard Control Organisation
FDA Bhawan, Kotla Road, New Delhi

Notice

Classification of Medical Devices Pertaining to General Hospital/Orthopaedic Instruments

S. No.	Device Name	Inteded Use	Risk Class
1	Liquid crystal forehead temperature strip	A liquid crystal forehead temperature strip is a device applied to the forehead that is used to indicate the presence or absence of fever, or to monitor body temperature changes.	B
2	Bed exit monitor, Fall prevention	Inteded to be placed under mattress and used to indicate by an alarm or other signal when a patient attempts to leave the bed.	A
3	Electronic monitor for gravity flow infusion systems	Inteded to electronically monitor the amount of fluid being infused into a patient.	C
4	Electrically powered spinal fluid pressure monitor	Inteded to measure spinal fluid pressure by the use of a transducer which converts spinal fluid pressure into an electrical signal.	B
5	Spinal fluid manometer	A spinal fluid manometer is a device used to measure spinal fluid pressure using needle and graduated column.	B
6	Stand-on patient scale	Inteded for medical purposes that is used to weigh a patient who is able to stand on the scale platform.	A
7	Patient scale	A patient scale is a device intended for medical purposes that is used to measure the weight of a patient who cannot stand on a scaleby placing scale under a bed or chair to weigh both the support and the patient.	A
8	Sterilization process indicator (Biological)	A biological sterilization process indicator is a device intended for use by a health care provider to accompany products being sterilized through a sterilization procedure and to monitor adequacy of sterilization on medical device.	B

9	Sterilization process indicator (Physical/chemical)	A physical/chemical sterilization process indicator is a device intended for use by a health care provider to accompany products being sterilized through a sterilization procedure and to monitor one or more parameters of the sterilization process on medical device.	B
10	Clinical color change thermometer.	A clinical color change thermometer is a disposable device used to measure a patient's oral, rectal, or axillary (armpit) body temperature.	A
11	Apgar timer.	The Apgar timer is a device intended to alert a health care provider to take the Apgar score of a newborn infant.	A
12	Hydraulic adjustable hospital bed.	Intended for medical purposes that consists of a bed with a hydraulic mechanism operated by an attendant to adjust the height and surface contour of the bed.	A
13	Manual adjustable hospital bed.	A manual adjustable hospital bed is a device intended for medical purposes that consists of a bed with a manual mechanism operated by an attendant to adjust the height and surface contour of the bed.	A
14	Pediatric medical crib.	Intended for medical purposes for use with a pediatric patient.	B
15	Medical bassinet.	Intended for medical purposes in hospital for use (birth to approximately 5 months of age) in a nursery, labor and delivery unit, or patient room.	B
16	Nonpowered flotation therapy mattress.	A nonpowered flotation therapy mattress is a mattress intended for medical purposes which contains air, fluid, or other materials, to treat or prevent decubitus ulcers (bed sores).	A
17	Therapeutic medical binder.	Intended for medical purposes and that can be secured by ties so that it supports the underlying part of the body or holds a dressing in place like abdominal, breast and perineal binder.	A
18	Burn sheet.	Inteded to wrap around a burn victim to retain body heat, to absorb wound exudate, and to serve as a barrier against contaminants	A
19	Neonatal eye pad.	A neonatal eye pad is an opaque device used to cover and protect the eye of an infant during therapeutic procedures, such as phototherapy.	A
20	Pressure infusor for an I.V. bag.	Device inteded to inflate and increases the pressure on the I.V. bag to assist the infusion of the fluid	B

21	Intravascular administration set, automated air removal system.	Inteded to detect and automatically remove air from an intravascular administration set with minimal to no interruption in the flow of the intravascular fluid.	B
22	Patient care reverse isolation chamber.	Device inteded protects a patient who is undergoing treatment for burns or is lacking a normal immunosuppressive defense due to therapy or congenital abnormality.	B
23	Jet lavage.	A jet lavage is a device used to clean a wound by a pulsatile jet of sterile fluid.	B
24	Patient lift, Electricially powered	Inteded to lift and transport patients in hsoptial in the horizontal or other required position from one place to another, as from a bed to a bath.	B
25	Nipple shield.	A nipple shield is a device consisting of a cover used to protect the nipple of a nursing woman.	A
26	Lamb feeding nipple.	A lamb feeding nipple is a device intended for use as a feeding nipple for infants with oral or facial abnormalities	A
27	Suction snakebite kit.	Intended for removing venom from the wound.	A
28	Chemical cold pack snakebite kit.	Intended for first-aid treatment of snakebites	D
29	Therapeutic scrotal support.	Intended for medical purposes to support the scrotum (the sac that contains the testicles)	A
30	Cardiopulmonary resuscitation board.	Intended to be placed under a patient to act as a support during cardiopulmonary resuscitation.	A
31	Ultrasonic cleaner for medical instruments.	Intended for cleaning medical instruments by the emission of high frequency soundwaves	B
32	Medical insole.	Intended for medical purposes that is placed inside a shoe to relieve the symptoms of athlete's foot infection by absorbing moisture.	A
33	Ingestible event marker.	An ingestible event marker is a prescription device used to record time-stamped, patient-logged events. The ingestible component links wirelessly through intrabody communication to an external recorder which records the date and time of ingestion as well as the unique serial number of the ingestible device.	C

34	Remote Medication Management System.	The system is intended to store the patient's prescribed medications in a delivery unit, to permit a health care professional to remotely schedule the patient's prescribed medications, to notify the patient when the prescribed medications are due to be taken, to release the prescribed medications to a tray of the delivery unit accessible to the patient on the patient's command, and to record a history of the event for the health care professional.	B
35	Medical examination light, AC powered or Battery	Intended for medical purposes that is used to illuminate body surfaces and cavities during a medical examination.	A
36	Skin pressure protectors.	A skin pressure protector is a device intended to reduce pressure on the skin over a bony prominence to reduce the likelihood of the patient's developing decubitus ulcers (bedsores)	A
37	Ultraviolet (UV) radiation environmental disinfection device	A medical ultraviolet air purifier is a device intended for medical purposes in hospital/clinic to destroy bacteria in the air by exposure to ultraviolet radiation.	B
38	Ultraviolet (UV) radiation chamber disinfection device.	An ultraviolet (UV) radiation chamber disinfection device is intended for the low-level surface disinfection of non-porous medical device surfaces by close-controlled UV irradiation.	C
39	Body waste receptacle.	A body waste receptacle is a device intended for medical purposes that is not attached to the body and that is used to collect the body wastes of a bed patient.	A
40	Vacuum-powered body fluid suction apparatus.	A vacuum-powered body fluid suction apparatus is a device used to aspirate, remove, or sample body fluids.	B
41	Washers for body waste receptacles.	A washer for body waste receptacles is a device intended for medical purposes that is used to clean and sanitize a body waste receptacle, such as a bedpan.	A
42	Sterilization wrap.	It is intended to allow sterilization of the enclosed medical device and also to maintain sterility of the enclosed device until used	B
43	Ethylene oxide gas sterilizer.	Intended for use by a health care provider that uses ethylene oxide (ETO) to sterilize medical devices.	C
44	Dry-heat sterilizer.	A dry-heat sterilizer is a device that is intended for use by a health care provider to sterilize medical devices by means of dry heat.	C

45	Steam sterilizer.	A steam sterilizer (autoclave) is a device that is intended for use by a health care provider to sterilize medical devices by means of pressurized steam.	C
46	Liquid chemical sterilants/high level disinfectants.	A liquid chemical sterilant/high level disinfectant is a germicide that is intended for use as the terminal step in processing critical and semicritical medical devices prior to patient use.	C
47	Hand-carried stretcher.	A hand-carried stretcher is a device intended to carry patient as an assistance for injury or disability.	A
48	Manual Wheeled stretcher.	A manual wheeled stretcher is a device intended to transport patients in a horizontal position as an assistance to injury or disability.	A
49	Motorised Wheeled stretcher.	A motorised wheeled stretcher is a device intended to transport patients in a horizontal position as an assistance to injury or disability with a motorised mechanism.	B
50	Liquid crystal vein locator.	Inteded to indicate the location of a vein by revealing variations in the surface temperature of the skin.	A
51	Medical washer.	Intended for general medical purposes to clean and dry medical devices, which later undergo sterilization or disinfection before use on patient.	B
52	Medical washer-disinfector.	A medical washer-disinfector is a device that is intended for general medical purposes to clean, decontaminate, disinfect, and dry surgical instruments, anesthesia equipment, hollowware, and other medical devices.	B
53	Hydrogen Peroxide Gas Plasma Sterilization System	Intended for sterilization/disinfection of both metal and nonmetal/polymer based medical devices.	C
54	Blood bank centrifuge	Intended to separate blood components of a suspension by application of centrifugal force.	A
55	Environmental chamber for storage of platelet concentrate	A refrigerated environmental chamber for storage of platelet concentrate is a device used to hold platelet-rich plasma within a preselected temperature range	B
56	Blood storage refrigerator	Thsesse are devices intended for medical purposes that are used to preserve blood and blood products by storing them at cold or freezing temperatures.	B
57	Heat-sealing device	A heat-sealing device is a device intended for medical purposes that uses heat to seal plastic bags containing blood or blood components.	A

58	Templates	A single use, sterile surgical instrument intended to be used to correctly position an implant. It can be used before making the incision to mark the implant shape, after making the incision, to check the implant position and during the coil pocket creation to check for its size. The product does not include orthopaedic implants.	A
59	X- ray marker for strut	Intended to be used in Six axis correction apparatus with software.	A
60	Clamp	Resuable Handheld Surgical Instrument for clamping tissues or materials or bone. These include Clamp for holding pins.	A
61	Container for orthopaedic cement dispenser	A sterile device in which an orthopaedic cement dispenser is placed to maintain the sterility of the dispenser and its contents when it is taken out of the sterile field to be mixed. The product does not include orthopaedic implants.	A
62	Box Wrench for Nut/Bolt	A minimally invasive, reusable surgical instrument intended to grip, twist or turn nut & bolt.	A
63	Instrument set for external fixation system	The instrument used for external fixation system. These include screw guide, allen key, half pin introducer, jig for fixator, minimally invasive spine surgery access tube, access tube holding handle, hex tightener, retractor blade, light source cable, optic fiber cable.	A

64	Spinal cage system instruments	The spinal cage system instruments are used by surgeon for spinal implants, devices or hardware, uses surgical procedures to implant titanium, titanium-alloy, stainless steel, or non-metallic devices into the spine. The instrument set includes rasp for cervical disc spacer, bone graft compactor, bone tamp for cervical disc spacer, cage support block, cervical distractor pin, cutter for cage, funnel, graft, seat holder for cervical disc spacer, introducer for cervical disc spacer, left angled curette, quick change, quick change for box chisel, spreader, tap handle - quick coupling, threaded inserter for droner peek cage, tlif cage guide, tlif cage holder, tommy bar for cages, trial for droner peek/plif /radial tlif cage, Cervical Distractor, Rasp For Radial Tlif/Plif Cage, Right Angled Curette, Screw Tighter, Pin Introducer For Vertebral Distractor, Plif Cage Holder, Dura, Curette. The system does not include orthopaedic implants.	A
65	Cervical plate system instruments	The Cervical plate system instruments is a comprehensive system of instruments for stabilization of the spine in the cervical regions. The instruments used by surgeon includes pin fixation, plate bender, supporting pin for cervical plate, Screw Tightner for Cervical Plate Screw, Knob Aligner for Cervical Lock Plate, Plate Holder for Cervical Lock Plate, Threaded Pin. The system does not include orthopaedic implants.	A
66	Mesh system instruments	The instrument used by surgeon include mesh holder, mesh pusher, curved mesh pusher, mesh cutter. The instrument is intended to aid surgeon in placing mesh.(Mesh is not apart of the system.). Mesh is used to provide mechanical support for weakened tissues of the pelvic floor.	A
67	Cervical disc spacer instruments for Spine	Intended to be used in cervical disc surgery. The products include Rasp for cervical disc spacer, Graft seat holder for cervical disc spacer, Bone tamp for cervical disc spacer & Lateral mass system & small anatomical system instruments. The product does not include orthopaedic implants.	A

68	Spinal Instrument	The instruments used in spinal surgery. These include Bone Cutter, Bone Nibbler Single / Double Action, Bone Nibbler Single Action, Hijack Punch, Disc Punch, Chisel with Detachable Handle Gouge with fiber handle, Plate holding forcep for C1-C2 spacer, Rounger Right Angle, Sargent Rounger, Rounger Kiliner, Olecrona Rounger, Lacksell Rounger, Kerrison Punch, Rib Rasperactory, Mastroid Retractor, Kochar's Bone hook, Micro cob elevator, Elevator Cobs, Chisel with attached fiber handle, Bone Lever, Micro Curettes, Meatal Curette, Curette, Gauge, Atraumatic Micro Force, Plate holding forcep for C1-C2 spacer, Introducer for C1-C2 spacer.	A
69	Instrument set for Bone Screws & Plates	The instrument set fore bone screw & plates includes Tap, Countersink shaft, Tension device Muller type, handle for quick coupling, holding clip, Dynamic Compression Plate/Limited Contact Dynamic Compression Plate neutral & load guide, bending iron for plates, bending iron for k-wires, Direct measuring device, threaded plate holder , Push pull reduction device, Tension device Muller type, Bending pin, Refractor. The product does not include orthopaedic implants.	A
70	Electronic Drive Instruments & Accessories	The electronic instruments used as orhtopaedic instruemnts. This includes Battery, Battery charger, Tubes for connecting to cuffs, Single cuffs for tourniquet, Double cuffs for tourniquet, High speed Motor control unit, Cutters & Burrs, Straight and Angled Handpieces, Craniotome, Perforator, light source cable, optic fibre cable. The system does not include orthopaedic implants.	A

71	Instrument system for bipolar hip system	The instrument system for bipolar hip system used in surgical procedure includes Advanced Muller Rasp handle for cemented stem, Long scoop for Hip for cemented stem, Rasp for cemented stem, Inserter for cemented stem, Head trail, Tommy bar, Long scoop for Hip for cemented stem, Tommy bar for rasp handle for cemented stem, Trial locating pin for cemented stem, Positioning bar for cemented stem, Head, dismantler for cemented stem, Introducer for cement restrictor, Head trial adaptor, Set of gauges, Ruller for uncemented stem, Rasp handle for uncemented stem, Trial neck for uncemented stem, Rasp for uncemented stem, Repositioning Lever for uncemented stem, Double Curved Gauge for uncemented stem, Proximal Trial Stem for uncemented stem, Gauge for medullary Cavity for uncemented stem, Reduction Lever for uncemented stem, Positioning bar for uncemented stem, Hammer for uncemented stem, Hex wrench for uncemented stem, Distal trial stem for uncemented stem, Proximal trial neck for uncemented stem, Ruller for uncemented stem, Hip head dismenteler for uncemented, Trial adaptor for cemented stem.	A
72	Plaster Instruments/Saw	A instrument used to cut or shave or put plaster. The instruments include plaster sawengle type & heavy duty type, plaster bender, plaster spreader, plaster shear.	A
73	Wire tensioner	An orthopaedic, manual hand-held surgical instrument used during orthopaedic surgery to apply an appropriate tension to a wire that is being implanted, usually as part of a system to provide corrective surgery to the spine. The product does not include orthopaedic implants.	A
74	Thick /Thin Guide Pin	The guide pin is to be used facilitate precise placement of a cannulated screw during orthopaedic surgery.	A
75	Depth Gauge	Device intended to aid surgeon in determining the appropriate length retractor blade to use based on surgical site depth through a color-coded system.	A
76	Vice Grip	The product used to hold pliers.	A

77	Bone Tap	A metal surgical instrument designed for cutting internal threads into bone so that the threads facilitate the insertion of bone screws. The screws anchor bone fragments, fixtures and/or other devices to the bone. The product does not include orthopaedic implants.	A
78	Reamer & its attachment	A hand hold instrument used to enlarge. It includes pedicle reamer, reamer for cemented stem, Distal reamer for uncemented stem, adaptors for reamers & Quick Change. The product does not include orthopaedic implants.	A
79	Torque Wrench	The torque wrench is used to tighten the setscrew on the connector assemblies of the implantable pulse generator and extension.	A
80	Pedical Screw Instruments	The instruments include rocker, Tap breaker, Persuader, Sound, Quick Change. These instruments used to aid surgeon in placing pedical screw in spinal fusion surgery.	A
81	Surgical Probe	It includes curved/straight probe, thorasic probe, Depuy Probe Curved.	A
82	Rod Cutter/Reducer	A reusable surgical instrument used to reduce or seat an implantable rod into the saddle of the implant.	A
83	Alignment Guide	A reusable manual surgical instrument designed to facilitate the correct orientation (alignment) of another medical device or implant during orthopaedic surgery.	A
84	Retractor Holder	A mechanism to which surgical retractors are mounted to, in order for the retractors to hold back tissues.	A
85	Extractor	An instrument, commonly known as a splinter probe, used to aid in the removal of foreign objects from superficial skin tissue. The device is single-use. These include Extractor rod, Extractor hammer, Extractor rod handle, Head extractor for cemented stem, Head extractor.	A
86	Retractor	Handheld surgical device used to hold soft tissues retracted from the field of view. These include Self-Retaining Retractor,	A

87	Bone Curette	A hand held manual surgical instrument used for cutting and excising bone tissue typically during orthopaedic surgery. It is typically a long, slender instrument with a handle at the proximal end and a concave, spoon-like tip which has a sharp edge, at the distal end. The bowl may be open (ring curette) or it may be double-ended, and is used to facilitate the removal of the bone tissue without causing trauma to the surrounding muscles. This is a reusable device.	A
88	Bone Cutter	A surgical instrument used to cut bone to penetrate/separate bone, during orthopaedic surgical procedures.	A
89	Surgical Punch/Bone Punch	A surgical instrument used to punch holes in bone, typically for the purposes of biopsy procedures or for fixation procedures. The instrument can be ring handled, pistol grip or shaft-like in design. Ring handled or pistol grip designs feature extended shafts which terminate in a punch-like or mechanical jaw mechanism at the distal tip. The shaft-like instrument is a hollow tube, sharpened on one end, and is usually used with a trocar.	A
90	Surgical Mallet	A hand held surgical instrument that is used by a surgeon to manually impart a force on another device during surgical intervention.	A
91	Hook	A handheld reusable instrument used to hold tissues or to pull tissues around.	A
92	Dissector	A hand-held surgical instrument, usually spoon shaped or rounded at the working end made of stainless steel, used to separate a soft tissue or body structure from another. It comes in various shapes and sizes but usually has a handle proximally which continues into a shaft as one moves distally. The shaft terminates in a tip which may be pointed or flat, sharp or blunt and angled or straight from the shaft. These include tear drop dissector set & pen field dissector.	A
93	Surgical Spatula	It is reusable surgical instrument designed to rotate and /or dissect tissues, bone fragments & other instruments.	A

94	Osteotome	A handheld surgical instrument with a flat cutting edge that can be hit with a hammer used to trim bone. These include box osteotome for uncemented stem & Box osteotomy for cemented stem.	A
95	Surgical Elevator	A Handheld Surgical Instrument that is a long flat piece of metal, with a blunt end and an optional hook end, used to lift organs or tissues; with lifting force normally supplied by an assistant.	A
96	Needle Holder	Needle holders intended to secure needles during suturing.	A
97	Scissor	Intended to used for cutting various materials, ie gauze.	A
98	Approximator	A surgical instrument having a shaft-like handle, which tapers as it approaches its distal end. The distal portion of the instrument is curved towards its tip which culminates in a pointed end that is intended to grasp tissue and retract it during a surgical procedure. These include Tibia /femur distal approximator.	A
99	Pliers	The purpose of these instruments is to hold, bend or cut commonly used orthodontic materials such as wires. These include Wire bending pliers, Cerclip plier & locking plier.	A
100	Tamp, Surgical	Inserted into the disc space to pack and fill the disc space with bone graft/bone substitute at the end of surgery. End of shaft is normally impacted with a mallet supplied by the hospital to further pack the bone into the disc space. Not an implantable device.	A
101	Orthopaedic Countersink	The countersinks are bone profilers which are bone-cutting instruments used for bone preparation to enable the placement of gingival part of components during dental procedures in the mouth.	A

102	Wrench	A heavy-duty, surgical instrument with specially designed sturdy handles and gripping jaws (typically parallel) used to grip and hold an object during a surgical intervention. It has a scissors-like design with curved handles and is made of high-grade stainless steel. It is available in various sizes and the jaws (typically broad with serrations) at the working end are activated through a single pivot or a double ratio-lever exchange pivot to provide greater gripping force. This is a reusable device. This include combination wrench.	A
103	Periostic elevator	A sterile, single use dental instrument shaped as a kind of a lever designed to lift, separate, or displace teeth &/or soft tissues during dental procedures.	A
104	Pneumatic Tourniquet & its attachment	The tourniquet used for stopping flow of blood through artery by compression. The attachment includes Consol unit & cuffs.	A
105	Electronically operated Tourniquet Single & Double Cuff Consol	Electronically operated Tourniquet used for stopping flow of blood through artery by compression. This unit include consol.	B
106	Forceps	Forceps are used to grasp, manipulate, compress, pull or join tissue, equipment or supplies. It includes burns for radius, modified burns, martins cartilage forcep, sequestum forcep, reduction forcep, self centering forcep, Fergussons Type Bone Holding forcep, Haygrooves Type Bone- Holding Forcep, Lanes Type Bone – Holding Forcep, Patella with Single Pronge, Patella Double Pronge, Patella with Eye, Rocker Forcep, Plate & Bone Holding Forcep.	A
107	Plaster Knife	A flat-bladed instrument with a cutting edge used to cut or shave plaster.	A
108	Plaster Spreader – Modified & Hanning Type	A manual surgical instrument with specially designed blades used to separate and spread hardened plaster, i.e., that which has already been used to form a cast.	A
109	Surgical Drill & its attachment	The surgical drilling machine that, when rotated at an appropriate speed, will cut into bone creating a hole of the same dimension as the diameter of the bit. The attachment includes drill bit, drill guides, burr & handpiece.	B

110	Surgical Trays	Trays are containers intended to provide a suitable platform for containing many medical/surgical instruments and related items during a clinical procedure. They might in addition be used during reprocessing/sterilization procedures. They are non-invasive, reusable devices.	A
111	Implant Trials	Trials are temporary sizing guides which are used by surgeons to check the size and fit of orthopaedic implants before actual implantation of device. The product does not include orthopaedic implants.	B
112	Computer Assisted Surgery System	Image guided instruments are intended for planning and intraoperative navigation during surgical procedures where the use of stereotactic surgery may be appropriate, and where a reference to a rigid anatomical structure such as a long bone can be identified relative to a CT or MR based model or fluroscopy images of the anatomy. The instruments when used in conjunction with the navigational software allo real time tracking with three-dimensional visualization of the surgical field.	B
113	Knee System Instruments	These are surgically invasive instruments which are used manually to assist during total knee arthroplasty. The devices are single use/reusable. The product does not include orthopaedic implants.	B
114	Hip System Instrument	These are surgically invasive instruments which are used manually to assist in the implantation of the femoral or acetabular components in total or hemiarthroplasty. The devices are single use/reusable. The product does not include orthopaedic implants.	B
115	Insertion and removal instruments	Reusable surgical instruments to facilitate the manipulation, implantation and removal of various orthopaedic devices during orthopaedic surgeries.	A

116	Bone cement accessories	Cement Accessories are devices used in conjunction with bone cement to facilitate its handling and penetration into a bone site. Accessories include devices for scrubbing and drying a bone cavity, plugging the cavity to contain the cement in the desired location, hand- or vacuum-mixing the cement, inserting the cement into the prepared cavity, pressurizing the cement to ensure adhesion to the bone, and removing excess soft cement after implantation of prosthetic components. Bone cement/implant not included.	B
117	Sleeves and its attachment	Manual surgical instruments that aid in the placement of bone cuts when preparing site to accept the implant components. These include Sleeve for Block for Half Pin, locking sleeve.	A
118	Arthroscopes	An arthroscope is an electrically powered endoscope intended to make visible the interior of a joint. The arthroscope and accessories also is intended to perform surgery within a joint.	B
119	Arthroscopic Instruments	These are surgically invasive instruments for manipulating and removing bone and bone fragments. Intended to used in orthoscopic surgical procedure.	B
120	Shaver System	Surgical device intended for the resection of soft and osseous tissues during a surgical procedure.	B
121	Visualization system for arthroscopic and endoscopic procedure	They are used in diagnostic and operative arthroscopic and endoscopic procedures to provide illumination, visualization and capture of still and motion pictures of surgical sites.	A
122	Fluid Management System	Irrigation pump with accessories for diagnostic and/or surgical arthroscopic procedures. It pumps medically sterile irrigation fluids through a sterile tube. These fluids are used to distend and irrigate corresponding body cavities to provide space and improve visibility for the surgeon. The products does not include implants.	B
123	Bone Chisel	A single bladed surgical instrument, bevelled on one side, that is intended for use in cutting or contouring bone. Widely used in orthopaedic surgery.	A
124	Pusher	A hand-held dental instrument designed for positioning & adapting metal bands on teeth in orthodontics.	A

125	Bender	A reusable surgical instrument used to bend medical device, typically those for implantation to the appropriate anatomical fit.	A
126	Dilator & accessories	A surgical instrument used for enlarging cavities or openings during surgical procedures. This include dilator incision.	A
127	Surgical Screw Driver	A metal instrument designed to impart force on another instrument. The distal end is shaped to mate with the instrument being driven into some form of tissue. The proximal end is designed to absorb & transmit an impact force.	A
128	Orthopaedic implant impactor	A minimally invasive surgical instrument used in arthroscopy to transmit an impact force on bone and measure the depth of impact.	A
129	Rail Fixation System	The Rail Fixation System consists of series of external fixators intended to be used to stabilize bone segment in a broad range of indications,including fractures, joint fusion, bone transport, lengthening & angular corrections. The system contains rail, Sandwich Plate, Dyna Ring, Bolt For Sandwich Plate, compression-distraction Unit.	B
130	External Ring fixation system	The Ring Fixation System consists of series of external fixators intended to be used to stabilize bone segment in a broad range of indications,including fractures, joint fusion, bone transport, lengthening & angular corrections. The system includes Half Rings 5/8 Ring, Rings With Curved Extremities, Italian Femoral Arches, Arches With Holes, Threaded Rods, Telescopic Rods, Post-Male/ Female, Hinges-Male/ Female/Standard, Long/Short Connection Plates, Connected Plates With Threaded Ends, Twisted/Curved Plates, Bushing Threaded Sockets, Connection Bolts, Nut, Washers, Bolt, Multiple, Wire Fixation Buckle, Blocks for Half Pins, Universal Joint, Rotational and Translational Device, Oblique Support, Set Screw, Foot Rings, Knurling post male. Implants not included.	B
131	Six axis correction apparatus with software	The software along with apparatus used to correct multi plane deformity or bone fracture. The system include struts, C/Y plate connector, Labels for strut, clamps, rings, wires & screws.	B

132	Unilateral External Fixation System	A collection of instruments used for the placement of external fixation system into or onto bone that may involve external fixation. The instruments include Rods for holding clamps, Spanners, Compressors, Spanners, Screw Guide.	B
133	Intramedullary Locking Nail Instrument Sets	The Intramedullary locking nail instrument sets includes Awl, Tissue Protector, Nut for coupling bolt, Proximal Jig, Distal Jig, Knob, Proximal Arm for Jig, Coupling bolt, Measuring device, T handle, Universal Spanner, Tommy Bar, Ram, Ram Rod, Jig cover ,Detachable Slide Hammer,F-Tool, Spanner Wrench, Standard Tamp, Screw Tightner,Medullary tube Polyamide.	B
134	Adhesive Plaster B.P.' 88 (Zinc Oxide Adhesive Plaster)	It is intended to secure dressings and for strapping on intact skin.	A
135	Adhesive Tape USP	It is intended to secure dressings and for strapping on intact skin .	A
136	Elasticated Cohesive Bandage	It is intended to secure dressings and for strapping on intact skin .	A
137	Cotton and Rubber Elastic Bandage	It is intended for sprains, strains and painful joints on intact skin.	A
138	Cotton Crepe Bandage	It is intended for sprains, strains and painful joints on intact skin.	A
139	Elastic Adhesive Bandage	It is intended to secure dressings and for strapping on intact skin.	A
140	Extension Plaster –width wise stretchable	It is intended to secure dressings and for strapping on intact skin.	A
141	Microporous surgical tape	It is intended to secure dressings and for strapping on intact skin.	A
142	Orthopedic cast padding	It is intended to protect long prominences under the plaster on intact skin .	A
143	Plaster of Paris Bandage	It is intended for support of fractured body part.	A
144	Tearable adhesive plaster	It is intended to secure dressings and for strapping on intact skin.	A
145	Skin traction kit	It is intended to provide traction for fractured femur.	A
146	Tearable Adhesive Tape	It is intended to secure dressings and for strapping on intact skin.	A