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Product structure and performance

The product consists of Open Drill, Reamer, Tap, Wrench, Sleeve, Quick-Change Handle, Rod Bending Forceps, Bone Probe, Orthopedic Holder, Positioning Pin, Rod Holder, Hook Holder, Orthopedic Distraction Forceps, Compression Clamp, Screw Holding Forceps, Rotating Rod Clamp, Brokeback Device, Template, Depth Gauge, Rod Bender, Orthopedic Reductor, Impactor, Bone Measurer, Depth Finder, Rod Cutter, Reduction Forceps, Bone Awl, Bone Graft Apparatus, Bone Drill, Orthopedic Distractor, Guide Device, Remove Clamp, Pedicle Screw Sleeve, Plate Holding Forceps, Periosteal Stripping, Bone Hammer, Orthopedic Positioning Piece, Adjustable Retractor, Multidirectional Retractor, Orthopedic External Fixator, Screw Holder, Crowbar, Bone Hook, Suction Tube, Periosteal Dissector, Expanding Awl, Curette, Bone Rongeur, Nucleus Pulposus Forceps, Bone Knife, Osteotomy, Cervical Distractor, Bone Traction Pin, Titanium Mesh Scissors, Vertebral Distractor, Bone Funnel, Bone Reamer, Scraper, Nerve Retractor for Spinal Surgery, Drill, Torque Quick-Change Connector, Osteotome, Spinal Retractor, Screw Remove Device, Guide Pin, Positioning Rod, Orthopedic Protector, Positioning Device, Bone Saw, Bending Clamp, Cone-plate Distractor, Cutting Clamp, Cervical Retractor, Spinal Distractor, Driver-Extractor, Forceps, Trephine, Dissector, Fix Wire, Minimally Invasive Retractor, Laminectomy Punch, Counter Wrench, Ratchet Handle, Template Holder, and Bone Filler.

The devices are manufactured in materials commonly used for surgical instruments for orthopedic surgery. The metal parts of the instruments are mainly made of titanium alloy, stainless steel and aluminum alloy. The complete description of materials is available on the labelling of products.

Applicable scope

For orthopedic spinal fusion surgery.

Contraindications

Patients with abnormal bone structure, anatomical abnormality of nerve root canal, severe neurological disorder, severe osteoporosis and metal allergy are forbidden to use.

Attention

- Please read this instruction carefully before use;
- Packages for each of the components shall be intact upon receipt. All instrument sets shall be carefully examined for completeness, and for lack of damage, prior to use. Damaged packages or products shall not be used, and shall be returned to Fule;
- Surgical instruments are not sterilized when they leave the factory, the surgical instruments shall be sterilized before

use, and it is recommended to use high temperature and pressure steam sterilization;

- For safety reasons, instruments that are not disinfected must be pre-cleaned, cleaned and disinfected before use. Reusable tools must be pre-cleaned, cleaned and disinfected immediately after use. Cleaning and disinfection shall meet the requirements of WS310.2 "Central sterile supply department (CSSD) — Part 2: Standard for operating procedure of cleaning, disinfection and sterilization" or EN ISO 17664 series standards;
- Avoid collision with other metal parts during sterilization;
- The operation must be conducted under the guidance of experienced doctors;
- Ensure instruments which incorporate a measuring function are not worn and that any surface markings are clearly visible;
- The instruments shall be carefully examined prior to use for functionality, excessive wear, or damage. A damaged instrument shall not be used as this may increase the risk of malfunction and potential patient injury;
- It is recommended that the surgical instruments can be used no more than 20 times;
- The safety of surgical instruments used with implants of other companies was not verified.

Warning

The products in this system are non-implants. Do not detain them in the body after operation.

- The treatment of products contaminated by prion, gas gangrene and infectious disease pathogens of unknown cause shall meet the requirements of WS310.2 or EN ISO 17664 series standards;
- Reusable products must be pre-cleaned, cleaned and disinfected immediately after use, and the cleaning and disinfection shall meet the requirements of WS310.2 or EN ISO 17664 series standards;
- The products are suggested to be sterilized in the high-pressure steam sterilizer according to standard operating procedures of the hospital before use.

The hospital must confirm that high-pressure steam sterilizer be reliable and effective, and be checked regularly, to ensure that the instruments can reach the suggested sterilization temperature during the exposure.

Label graphs, symbols and abbreviations

For the explanation of general graphs and symbols, please refer to EN ISO 15223-1, Symbol for Use in the Label of Medical Devices.

Symbol	Explanation	Symbol	Explanation
	Humidity limitation		Caution
	Catalogue number		Manufacturer
	Batch code		Temperature limitation

Symbol	Explanation	Symbol	Explanation
	Date of manufacture		Authorised representative in the European Union
	Non-sterile		Unique device identifier
	Medical device		CE mark
	Consult instructions for use or consult electronic instructions for use		

Transportation packaging identification			
Symbol	Explanation	Symbol	Explanation
	Country of manufacture		This way up
	Keep away from sunlight		Keep dry
	Fragile, handle with care		

Preparation for decontamination and cleaning

- Reprocess instrument as soon as is reasonably practical following use;
- As required, disassemble any instrument according to disassembly instructions;
- All cleaning agents shall be prepared as recommended by the manufacturer.

Cleaning and decontamination

The surgical instruments need to be cleaned before sterilization. Recommended cleaning methods:

a) Manual cleaning: Rinse the product with clean water to remove visible contaminants from the surface. Soak the product in an enzyme cleaner or detergent and brush the surface of the instruments repeatedly with a soft bristle brush. Rinse the surface of the instrument thoroughly with clean water and wipe the outer surface of the instruments thoroughly with a soft disposable lint-free cloth. The instruments are visually inspected for cleanliness and damage. If the cleaning is

not complete, repeat the cleaning procedure.

b) Automatic cleaning: It is recommended to use clean or purified water for ultrasonic cleaning (cleaning agent: neutral detergent) .

Automatic ultrasonic cleaning parameters:

Ultrasonic cleaning: temperature 60-70°C, cleaning time: 20-30min;

Ultrasonic rinsing: temperature 40-60°C, rinsing time: 5-10min;

Drying: temperature 80-100°C, drying time: 20-30min.

Packaging

Sterilization packaging requirements: Surgical instruments are dried and double wrapped in a single layer of surgical wrap for subsequent pressure steam sterilization.

Sterilization

Pressure steam sterilization is the recommended method of sterilization, with the following recommended conditions:

Lower exhaust pressure steam sterilization:

Temperature	Minimum sterilization time	Pressure reference range
121°C	30min	102.8kPa~122.9kPa

Pre-vacuum pressure steam sterilization:

Temperature	Minimum sterilization time	Pressure reference range
132°C	10min	184.4kPa~210.7kPa
134°C	10min	201.7kPa~229.3kPa

Pre-vacuum pressure steam sterilization is recommended for tubular instruments.

Pressure steam sterilizers must be proven reliable and effective by the hospital and checked regularly to ensure that the recommended sterilization temperature is achieved throughout the exposure time of the instruments.

Operating instructions

When the Spinal Fixation Surgical Instrument is used, it cooperates with our company's spinal implants products to complete the whole clinical operation.

Typical clinical operation instructions:

- Sterilize the tools with pressure steam before use;
- Open Drill, Open Drill (I), Open Drill (II), Open Drill (III), Open Drill (IV), Open Drill (V), Open Drill (VI), Open Drill (VII), Reamer are used to punch, drill, and ream holes in orthopedic surgery;
- Tap (I), Tap (II), Tap (III), Tap (IV), Tap (V), Tap (VI), Tap (VII) are used for tapping screw holes on bones during orthopedic operation;
- Wrench (Star), Wrench (Star Quick-Change), Wrench (Hex), Wrench (Hex Pre-load), Wrench (Plug Cutting), Wrench (Star I), Wrench (Hex T-shape), Wrench (Pre-load), Wrench (Pre-load I), Wrench (Regulating Sleeve), Wrench (Polyaxial), Wrench (Combination), Wrench (Lock Rod), Wrench (Polyaxial I), Wrench (Rotating

- Rod), Wrench (I), Wrench (II), Wrench (III), Wrench (IV), Wrench (V), Wrench (VI), Wrench (VII), Wrench (VIII), Wrench (IX), Wrench (X), Wrench (XI), Wrench (XII), Wrench (XIII), Wrench (XIV), Wrench (XV), Wrench (XVI), Wrench (XVII), Wrench (XVIII), Wrench (XIX), Wrench (XX), Wrench (XXI), Wrench (XXII), Wrench (XXIII), Wrench (XXIV), Wrench (XXV), Wrench (XXVI), Wrench (XXVII), Wrench (XXVIII), Wrench (XXIX), Wrench (XXX), Wrench (XXXI), Wrench (XXXII), Wrench (XXXIII), Wrench (XXXIV), Wrench (XXXV), Wrench (XXXVI), Wrench (XXXVII), Wrench (XXXVIII), Wrench (Polyaxial/Self Holding), Impactor (I), Impactor (T Shape), Impactor (II), Impactor (IV), Impactor (V), Impactor (VI), Impactor (VII), Impactor (VIII), Impactor (IX), Impactor (X), Impactor (XI), Impactor (XII), Impactor (XIII), Impactor (Helix Rod Pusher I), Impactor (Pedicule Hook), Impactor (Single Handle Rod Pusher), Impactor (Helix Rod Pusher II), Impactor (Helix Rod Pusher III), Impactor (Pusher), Impactor (Injector), Driver-Extractor, Counter Wrench are used to assist the implantation or removal of implants or bone from the body;
- Sleeve (I), Sleeve (Short), Sleeve (Rectify), Sleeve (II), Sleeve (III), Sleeve (IV), Sleeve (V), Sleeve (VI), Sleeve (Annular Tubes), Sleeve (VII), Sleeve, Quick-Change Handle (I), Quick-Change Handle (II), Quick-Change Handle (III), Quick-Change Handle (IV), Quick-Change Handle (V), Quick-Change Handle (VII), Quick-Change Handle (VIII), Quick-Change Handle (IX), Quick-Change Handle (X), Quick-Change Handle (XI), Ratchet Handle are used with surgical instruments to assist in the installation of implants;
 - Rod Bending Forceps, Bending Clamp, Cutting Clamp are used for cutting, bending and ligation in orthopedic surgery;
 - Bone Probe (I), Bone Probe (II), Bone Probe (III), Bone Probe (IV), Bone Probe (V) are used to detect direction and depth in orthopedic operation;
 - Orthopedic Holder (I), Orthopedic Holder (II), Orthopedic Holder (III), Orthopedic Holder (IV), Orthopedic Holder (V), Orthopedic Holder (VI), Orthopedic Holder (VII), Orthopedic Holder (VIII), Orthopedic Holder (IX), Orthopedic Holder (X), Orthopedic Holder (XI), Orthopedic Holder (XII), Orthopedic Holder (XIII), Orthopedic Holder (XIV), Orthopedic Holder (XV), Forceps (I), Forceps (II) are used to clamp implants, instruments or tissues in orthopedic surgery and take them out before the end of surgery;
 - Positioning Pin (I), Positioning Pin (II), Positioning Pin (box), Positioning Pin (III), Positioning Pin (IV), Positioning Pin (V), Positioning Pin (VI), Positioning Pin (VII), Positioning Pin (VIII), Positioning Pin (IX), Positioning Pin (X), Guide Pin are used for guiding or positioning during orthopedic surgery;
 - Rod Holder (I), Rod Holder (II), Rod Holder (III), Hook Holder (I), Hook Holder (II), Screw Holding Forceps (I), Screw Holding Forceps (II), Screw Holding Forceps (III), Rotating Rod Clamp (I), Rotating Rod Clamp (II), Reduction Forceps (I), Remove Clamp (I), Remove Clamp (II), Remove Clamp (III), Plate Holding Forceps (I), Plate Holding Forceps (II), Plate Holding Forceps (III), Plate Holding Forceps (IV), Plate Holding Forceps (V) are used to clamp and fix bones, implants, or instruments in orthopedic surgery;
 - Orthopedic Distraction Forceps (I), Orthopedic Distraction Forceps (II), Orthopedic Distraction Forceps (III), Orthopedic Distraction Forceps (IV) are used to open vertebral body, tissue or implant in orthopedic surgery;
 - Compression Clamp (I), Compression Clamp (II), Compression Clamp (III), Compression Clamp (IV) are used to compress and fix metal hook and nail in orthopedic operation or to compress between vertebrae in spinal operation;
 - Brokeback Device (I), Brokeback Device (II), Brokeback Device (III), Brokeback Device (IV), Brokeback Device (V), Rod Bender (I), Rod Bender (II), Rod Bender (III), Rod Cutter (I), Rod Cutter (II), Rod Cutter (III), Rod Cutter (IV) are used to bend the plate or rod, or cut off the implant in orthopedic fusion surgery;

- Template (I), Template (II), Template (III), Template (IV), Template (V), Template (VI), Template (VII), Template (VIII), Template (IX), Template (X), Template (XI), Template (XII), Template (XIII), Template (XIV), Template (Distraction), Template (Kidney-shaped), Template, Depth Gauge (I), Depth Gauge (II), Bone Measurer (I), Bone Measurer (II), Bone Measurer, Depth Finder, Depth Finder (I) are used to measure the diameter, depth, aperture, angle, radian, etc;
- Orthopedic Reductor (I), Orthopedic Reductor (II), Orthopedic Reductor (III) are used for fracture reduction in orthopedic fusion surgery;
- Bone Awl (I), Bone Awl (II), Bone Awl (III) are used to open a hole in the bone in orthopedic surgery;
- Bone Graft Apparatus (Funnel), Bone Graft Apparatus (Tamper), Bone Graft Apparatus (I), Bone Graft Apparatus (II), Bone Graft Apparatus (III), Bone Graft Apparatus (IV), Bone Graft Apparatus (V), Bone Graft Apparatus (VI), Bone Graft Apparatus (VII), Bone Graft Apparatus (VIII), Bone Graft Apparatus (IX), Bone Graft Apparatus (X), Bone Graft Apparatus (XI), Bone Graft Apparatus (XII), Bone Graft Apparatus (XIII), Bone Graft Apparatus (XIV), Bone Graft Apparatus (XV), Bone Graft Apparatus (XVI), Bone Graft Apparatus (XVII), Bone Funnel (I), Bone Funnel (II), Bone Funnel (III), Bone Funnel (IV), Bone Funnel (V), Bone Funnel (VI), Bone Funnel (VII), Bone Funnel (Funnel), Bone Funnel (Tamper), Bone Filler are used to convey and stir bone defects and cavity fillers in bone grafting surgery;
- Bone Drill (Depth Limited), Bone Drill (II), Bone Drill (Polyaxial), Bone Drill (Hollow), Bone Drill (III), Bone Drill (IV), Bone Drill (V), Bone Drill (VI), Bone Drill (VII), Bone Drill (VIII), Bone Drill (IX), Bone Drill (X), Bone Drill (XI) are used for drilling, tapping, or embedding the nail head into the bone;
- Guide Device (I), Guide Device (II), Guide Device (III), Guide Device, Orthopedic Positioning Piece (I), Orthopedic Positioning Piece (II), Orthopedic Positioning Piece (III), Positioning Rod, Orthopedic Protector (I), Orthopedic Protector (II), Orthopedic Protector, Positioning Device, Positioning Pin (I), Positioning Pin (II), Positioning Pin (Box), Positioning Pin (III), Positioning Pin (IV), Positioning Pin (V), Positioning Pin (VI), Positioning Pin (VII), Positioning Pin (VIII), Positioning Pin (IX), Positioning Pin (X), Positioning Pin (Polish Rod) are used for positioning, guiding and protection;
- Pedicle Screw Sleeve is used in the process of spinal surgery, with other surgical tools;
- Periosteal Stripping (I), Periosteal Stripping (II), Periosteal Stripping (III), Periosteal Stripping (IV), Periosteal Stripping (V), Periosteal Stripping (Small), Periosteal Dissector, Dissector are used to peel off or separate periosteum and soft tissue attached to bone surface;
- Bone Hammer, Crowbar (I), Crowbar (II) are used for knocking and prying in orthopedic operation;
- Adjustable Retractor (I), Adjustable Retractor (II), Adjustable Retractor (III), Adjustable Retractor (IV), Multidirectional Retractor, Multidirectional Retractor (Open Flap), Cervical Retractor, Spinal Retractor (I), Spinal Retractor (II) can be used in orthopedic surgery to expose the operation field, make the operation easy, protect the tissue and avoid accidental injury;
- Orthopedic External Fixator (I), Orthopedic External Fixator (II), Orthopedic External Fixator (III) are connected with the internal bone pin to achieve orthopedic deformity correction, fracture reduction and other treatment purposes through fixation, compression or traction of the bone end;
- Screw Holder is used to clamp implants, instruments or tissues in orthopedic surgery and take them out before the end of surgery;
- Bone Hook (I), Bone Hook (II), Bone Hook (III), Bone Hook (IV), Bone Hook (V), Bone Hook (VI), Bone Hook (VII), Bone Hook (VIII), Bone Hook (IX) are used in orthopedic surgery to expose the operation field, make the operation easy, and protect the tissue from accidental injury; or it can be used in orthopedic surgery to

- peel, pull or block the nerve root;
- Suction Tube is used to flush tissue or aspirate;
- Expanding Awl is used to open a hole in the bone in orthopedic surgery;
- Curette (I), Curette (II), Curette (III), Curette (IV), Curette (V), Curette (VI), Scraper (I), Scraper (II), Scraper (III), Scraper (IV), Scraper (V), Scraper (VI), Scraper (Round), Scraper (Arc), Scraper (Triangle), Scraper (Loop Quick-Change), Scraper (Square Quick-Change), Scraper (Solid) are used to scrape the focus, scar, granulation tissue in sinus, dead bone or pathological tissue in bone cavity and potential cavity;
- Bone Rongeur (I), Bone Rongeur (II), Bone Rongeur (III), Laminectomy Punch (Clamp Handle), Laminectomy Punch (Tong Head-Straight), Laminectomy Punch (Tong Head-Arc) are used for biting dead bone or repairing bone stump;
- Nucleus Pulposus Forceps (I), Nucleus Pulposus Forceps (II), Nucleus Pulposus Forceps (Toothed), Nucleus Pulposus Forceps (Tong Head-Straight), Nucleus Pulposus Forceps (Bent) is used to bite off tissue or polyp in orthopedic surgery;
- Bone Knife (I), Bone Knife (II), Bone Knife (III), Bone Knife, Bone Knife (Rear Wall Knife), Bone Knife (Sharp), Bone Knife (Flathead), Bone Knife (Up Bend), Bone Knife (Square), Osteotomy are used to cut off bone;
- Bone Traction Pin (I), Bone Traction Pin (II) are used for traction, positioning or fixation during fracture surgery;
- Titanium Mesh Scissors (I) and Titanium Mesh Scissors (II) are used to cut implants or plaster;
- Vertebral Distractor (I), Vertebral Distractor (II), Vertebral Distractor (III), Vertebral Distractor (IV), Vertebral Distractor (V), Vertebral Distractor (Quick-Change), Cone-plate Distractor, Spinal Distractor (I), Spinal Distractor (II), Spinal Distractor, Orthopedic Distractor (I), Orthopedic Distractor (II), Orthopedic Distractor (III), Orthopedic Distractor, Cervical Distractor are used to open vertebral body, tissue or implant in orthopedic surgery;
- Bone Reamer (I), Bone Reamer (II), Bone Reamer (III), Bone Reamer (IV), Bone Reamer (Sheet Shape), Bone Reamer (Distraction), Bone Reamer (Quick-Change), Bone Reamer (Round), Bone Reamer (Square) are used for reaming, medullary cavity reconstruction and expansion in orthopedic surgery;
- Nerve Retractor for Spinal Surgery (I), Nerve Retractor for Spinal Surgery (II), Nerve Retractor for Spinal Surgery (III) are used in orthopedic surgery to expose the surgical field, make the operation easy, protect the tissue and avoid accidental injury, or to peel, pull or block the nerve root in orthopedic surgery;
- Drill (I), Drill (II), Drill (III), Drill (IV), Drill (V), Drill (VI), Drill (VII), Drill (VIII) are used for guiding and positioning of drill or tap;
- Torque Quick-Change Connector, Quick-Change Handle (I), Quick-Change Handle (II), Quick-Change Handle (III), Quick-Change Handle (IV), Quick-Change Handle (V), Quick-Change Handle (VII), Quick-Change Handle (VIII), Quick-Change Handle (IX), Quick-Change Handle (X), Quick-Change Handle are used with surgical instruments to assist in the installation of implants;
- Osteotribe, Osteotribe (Quick-Change), Osteotribe (Straight), Osteotribe (Bent) are used to file bone and level the broken end of bone in orthopedic surgery;
- Screw Remove Device is used to assist in the implantation or removal of implants or bone from the body;
- Orthopedic Protector (I), Orthopedic Protector (II) are used in orthopedic surgery, which can be placed in the surgical site to reduce the damage to related tissues;

- Bone Saw (I), Bone Saw (II) are used to cut bones;
- Minimally Invasive Retractor, Minimally Invasive Retractor (Open Flap) are used to stretch the soft tissue to expose the surgical field;
- Minimally Invasive Retractor (Connecting piece) is used to connect the retractor to the fixture;
- Template (Kidney-shaped) is used to measure the intervertebral size and select the appropriate fusion cage;
- Template Holder (Template) is used to hold Template (Kidney-shaped) ;
- Trephine is used for drilling and decompression during removal and correction of rotting bone or orthopedic spine surgery;
- Fix Wire is used to fix a template or other instruments in orthopedic surgery;

Maintenance and storage methods

- The product should be handled with care during storage, transportation and transportation. Collision, scratching and packaging damage are strictly prohibited, otherwise, it is forbidden to use.
- The product should be stored in room temperature, avoid direct sunlight, relative humidity not more than 80%, no corrosive gas and good ventilated room.
- The product should be protected from rain, corrosion and sun during transportation.

Production date

Please refer to the product label for the production date of the product.

Electronic instruction website:

<https://www.fuleorthopedics.com/>