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Product structure and performance 产品主要结构及性能

The product is consist 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, Osteotribe, 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, Trepine, Dissector, Fix Wire, Minimally Invasive Retractor, Laminectomy Punch, Counter Wrench, Ratchet Handle, Template Holder, and Bone Filler.

产品由开路器、扩孔器、丝攻、骨科用扳手、护套、快装手柄、弯棒钳、骨探针、骨科用夹持器、骨定位针、持棒钳、持钩钳、骨科撑开钳、压缩钳、持钉钳、转棒钳、扭断器、试模、量规、弯棒器、骨科复位器、打入器、骨测量器、测深器、断棒器、复位钳、骨锥、植骨器、骨科钻头、骨科撑开器、骨科导向器、取出钳、椎弓根螺钉套管、持板钳、骨膜剥离子、骨锤、骨科定位片、可调式牵开器、多向牵开器、骨科外固定器、持钉夹、撬棒、骨拉钩、吸引管、骨膜剥离器、开口锥、骨刮匙、咬骨钳、髓核钳、骨刀、截骨刀、颈椎撑开器、骨牵引针、钛网剪、椎体撑开器、植骨漏斗、骨铰刀、刮刀、脊柱手术用神经拉钩、导钻、扭力快换接头、骨锉、脊柱牵开器、取钉器、骨导引针、骨科定位杆、骨科用保护器、骨科定位器、骨锯、折弯钳、锥板撑开器、剪断钳、颈椎牵开器、脊柱撑开器、打拔器、骨科用夹持镊、环锯、剥离器、固定针、微创牵开器、椎板咬骨钳、对抗扳手、棘轮手柄、持取器、骨填充器组成。

The devices are manufactured in materials commonly used for surgical instruments for orthopaedic 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.

器械由骨科手术器械常用材料制成，器械金属部分主要由钛合金、不锈钢和铝合金组成。产品标签上提供了材料的完整描述。

Applicable scope 适用范围

For orthopedic spinal fusion surgery 用于骨科脊柱融合手术。

Contraindications 禁忌症

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

骨性结构异常、神经根管的解剖异常、严重神经障碍、严重骨质疏松、金属过敏患者禁止使用。

Attention 注意事项和提示性说明

- Please read this instruction carefully before use 使用前须认真阅读本使用说明书;
- 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 每个组件的包装在收到时应完好无损。使用前, 应仔细检查所有器械包的完整性和无损坏。损坏的包装或产品不得使用, 应退还给富乐;
- 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 手术器械出厂为非灭菌状态, 使用前应灭菌, 建议采用高温压力蒸汽灭菌;
- 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 出于安全性的原因, 未消毒的器械在使用之前必须经过预清洗、清洗和消毒。可重复使用的工具在使用后必须立即进行预清洗、清洗和消毒。清洗及消毒应符合 WS310.2 《医院消毒供应中心第 2 部分: 清洗消毒及灭菌技术操作规范》或 EN ISO 17664 系列标准的规定;
- Avoid collision with other metal parts during sterilization 灭菌中应避免与其他金属件磕碰;
- The operation must be conducted under the guidance of experienced doctors 操作使用必须在有经验医师指导下进行;
- Ensure instruments which incorporate a measuring function are not worn and that any surface markings are clearly visible 确保具有测量功能的器械没有磨损, 并且任何表面标记都清晰可见;
- 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 使用前应仔细检查器械的功能、过度磨损或损坏情况。不得使用损坏的仪器, 因为这可能会增加故障和潜在患者受伤的风险;
- It is recommended that the surgical instruments can be used no more than 20 times 建议手术器械可重复使用次数不超过 20 次;
- The safety of surgical instruments used with implants of other companies was not verified 与其他公司植入产品配合使用的安全性未进行验证。

Warning 警告

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

本系统的产品为非植入物, 术后请勿留置体内。

a. 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 被朊毒体、气体坏疽及突发原因不明的传染病病原体污染的产品的处理应符合 WS310.2 或 EN ISO 17664 系列标准的规定;

b. Reusable products must be pre-cleaned, cleaned and disinfected immediately after use, and the cleaning and

disinfection shall meet the requirements of W310.2 or EN ISO 17664 series standards 可重复使用的组件在使用后必须立即进行预清洗、清洗和消毒，清洗及消毒应符合 WS310.2 或 EN ISO 17664 系列标准的规定；

c. The products are suggested to be sterilized in the high-pressure steam sterilizer according to standard operating procedures of the hospital before use 术前工具进行高温高压灭菌时，建议按照标准医院规程置于高压蒸汽灭菌器中灭菌。














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.






高压蒸汽灭菌器必须经医院证实可靠有效，并且定期检查，以确保器械在暴露时间内都能达到推荐的灭菌温度。

Label graphs, symbols and abbreviations 标签图形、符号及缩写

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

关于一般图形和符号的解释，请参考 EN ISO 15223-1，医疗器械标签中使用的符号

Symbol 符号	Explanation 释义	Symbol 符号	Explanation 释义
	Humidity limitation 湿度限制		Caution 注意事项
	Catalogue number 产品代码		Manufacturer 制造商
	Batch code 批号		Temperature limitation 温度限制
	Date of manufacture 制造日期		Authorised representative in the European Union 欧盟授权代表
	Non-sterile 非灭菌		Unique device identifier 唯一器械标识
	Medical device 医疗器械		CE mark CE 标识
	Consult instructions for use or consult electronic instructions for use 查阅使用说明书或查阅电 子使用说明书		

Transportation packaging identification 运输包装标签			
Symbol 符号	Explanation 释义	Symbol 符号	Explanation 释义
	Country of manufacture 生产制造国家		This way up 此面向上
	Keep away from sunlight 防晒		Keep dry 保持干燥
	Fragile, handle with care 易碎，小心轻放		

Preparation for decontamination and cleaning 去污和清洗的准备

- Reprocess instrument as soon as is reasonably practical following use 使用后，在合理可行的情况下尽快对仪器进行再处理;
- As required, disassemble any instrument according to disassembly instructions 根据需要，按照拆卸说明拆卸任何器械;
- All cleaning agents shall be prepared as recommended by the manufacturer 所有清洁剂应按照制造商的建议进行制备.

Cleaning and decontamination 清洗和去污

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

手术器械灭菌前需进行清洗，推荐清洗方法：

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 手动清洗：用洁净水对产品进行冲洗，除去表面可见污染物。将产品浸泡在酶清洁剂或洗涤剂中，用软毛刷反复刷洗器械表面。用洁净水全面冲洗器械表面，用一次性无绒软布全面擦拭器械外表面。对器械进行目视检测，检查是否清洗干净以及有无损坏。如果清洗不彻底，重复清洗步骤。

b) Automatic cleaning: It is recommended to use clean or purified water for ultrasonic cleaning (cleaning agent: neutral detergent) 自动清洗：建议采用洁净水或纯化水进行超声清洗（清洗剂：中性清洁剂）。

Automatic ultrasonic cleaning parameters 自动超声波清洗参数：

Ultrasonic cleaning 超声波清洗: temperature 温度 60-70°C, cleaning time 清洗时间: 20-30min;

Ultrasonic rinsing 超声波漂洗: temperature 温度 40-60°C, rinsing time 漂洗时间: 5-10min;

Drying 烘干: temperature 温度 80-100°C, drying time 干燥时间: 20-30min.

Packaging 包装

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

灭菌包装要求：手术器械干燥后用单层手术包布双层包裹，用于后续压力蒸汽灭菌。

Sterilisation 灭菌

Pressure steam sterilisation is the recommended method of sterilization, with the following recommended conditions:
灭菌方式建议采用压力蒸汽灭菌，推荐条件如下：

Lower exhaust pressure steam sterilization 下排气式压力蒸汽灭菌：

Temperature 温度	Minimum sterilization time 最短灭菌时间	Pressure reference range 压力参考范围
121°C	30min	102.8kPa~122.9kPa

Pre-vacuum pressure steam sterilization 预真空式压力蒸汽灭菌：

Temperature 温度	Minimum sterilization time 最短灭菌时间	Pressure reference range 压力参考范围
132°C	10min	184.4kPa~210.7kPa
134°C	10min	201.7kPa~229.3kPa

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

对于管腔器械推荐使用预真空式压力蒸汽灭菌。

Pressure steam sterilisers 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.

压力蒸汽灭菌器必须经医院证实可靠有效，并且定期检查，以确保器械在暴露时间内都能达到推荐的灭菌温度。

Operating instructions 操作说明

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

创伤手术器械使用时，与本公司骨科植入产品配合使用，完成整个临床手术。

Typical clinical operation instructions 典型临床操作说明：

- Sterilize the tools with pressure steam before use 使用前对工具进行压力蒸汽灭菌处理；
- 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 开路器、开路器（I）、开路器（II）、开路器（III）、开路器（IV）、开路器（V）、开路器（VI）、开路器（VII）、扩孔器用于骨科手术时打孔、钻孔、扩孔；
- 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 丝攻（I）、丝攻（II）、丝攻（III）、丝攻（IV）、丝攻（V）、丝攻（VI）、丝攻（VII）用于骨科手术时在骨骼上攻螺纹孔；
- Wrench (Star), Wrench (StarQuick-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 骨科用扳手（梅花）、骨科用扳手（梅花快换）、骨科用扳手（六角）、骨科用扳手（六角预紧）、骨科用扳手（断螺塞）、骨科用扳手（梅花I）、骨科用扳手（六角T型）、骨科用扳手（预紧）、骨科用扳手（预紧I）、骨科用扳手（调节套）、骨科用扳手（万向）、骨科用扳手（组合）、骨科用扳手（锁棒）、骨科用扳手（万向I）、骨科用扳手（转棒）、骨科用扳手（I）、骨科用扳手（II）、骨科用扳手（III）、骨科用扳手（IV）、骨科用扳手（V）、骨科用扳手（VI）、骨科用扳手（VII）、骨科用扳手（VIII）、骨科用扳手（IX）、骨科用扳手（X）、骨科用扳手（XI）、骨科用扳手（XII）、骨科用扳手（XIII）、骨科用扳手（XIV）、骨科用扳手（XV）、骨科用扳手（XVI）、骨科用扳手（XVII）、骨科用扳手（XVIII）、骨科用扳手（XIX）、骨科用扳手（XX）、骨科用扳手（XXI）、骨科用扳手（XXII）、骨科用扳手（XXXIII）、骨科用扳手（XXIV）、骨科用扳手（XXV）、骨科用扳手（XXVI）、骨科用扳手（XXVII）、骨科用扳手（XXVIII）、骨科用扳手（XXIX）、骨科用扳手（XXX）、骨科用扳手（XXXI）、骨科用扳手（XXXII）、骨科用扳手（XXXIII）、骨科用扳手（XXXIV）、骨科用扳手（XXXV）、骨科用扳手（XXXVI）、骨科用扳手（XXXVII）、骨科用扳手（XXXVIII）、打入器（I）、打入器（T型）、打入器（II）、打入器（IV）、打入器（V）、打入器（VI）、打入器（VII）、打入器（VIII）、打入器（IX）、打入器（X）、打入器（XI）、打入器（XII）、打入器（XIII）、打入器（螺旋压棒器I）、打入器（椎弓根钩）、打入器（单手柄压棒器）、打入器（螺旋压棒器II）、打入器（螺旋压棒器III）、打入器（推进器）、打入器（注射器）、打拔器、对抗扳手用于辅助将植入物或骨植入体内或者从体内取出；

- 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 护套(I)、护套（短）、护套（矫正）、护套（II）、护套（III）、护套（IV）、护套（V）、护套（VI）、护套（套管）、护套（VII）、快装手柄（I）、快装手柄（II）、快装手柄（III）、快装手柄（IV）、快装手柄（V）、快装手柄（VII）、快装手柄（VIII）、快装手柄（IX）、快装手柄（X）、快装手柄（XI）、棘轮手柄与手术器械配合使用，用于辅助完成植入物安装；
- Rod Bending Forceps, Bending Clamp, Cutting Clamp are used for cutting, bending and ligation in orthopedic surgery 弯棒钳、折弯钳、剪断钳用于骨科手术时剪断、弯曲、结扎；
- 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 骨探针（I）、骨探针（II）、骨探针（III）、骨探针（IV）、骨探针（V）用于骨科手术中探测方向和深度；
- 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 骨科用夹持器（I）、骨科用夹持器（II）、骨科用夹持器（III）、骨科用夹持器（IV）、骨科用夹持器（V）、骨科用夹持器（VI）、骨科用夹持器（VII）、骨科用夹持器（VIII）、骨科用夹持器（IX）、骨科用夹持器（X）、骨科用夹持器（XI）、骨科用夹持器（XII）、骨科用夹持器（XIII）、骨科用夹持器（XIV）、骨科用

- 夹持器 (XV)、骨科用夹持镊 (I)、骨科用夹持镊 (II) 用于骨科手术时夹持植入物、器械或组织，手术结束前取出；
- 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, guiding or positioning during orthopedic surgery 骨定位针 (I)、骨定位针 (II)、骨定位针 (盒)、骨定位针 (III)、骨定位针 (IV)、骨定位针 (V)、骨定位针 (VI)、骨定位针 (VII)、骨定位针 (VIII)、骨定位针 (IX)、骨定位针 (X)、骨定位针 (XI)、骨导引针用于在骨科手术过程中导向、导引或定位；
 - 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 持棒钳 (I)、持棒钳 (II)、持棒钳 (III)、持钩钳 (I)、持钩钳 (II)、持钉钳 (I)、持钉钳 (II)、持钉钳 (III)、转棒钳 (I)、转棒钳 (II)、复位钳 (I)、取出钳 (I)、取出钳 (II)、取出钳 (III)、持板钳 (I)、持板钳 (II)、持板钳 (III)、持板钳 (IV)、持板钳 (V) 用于骨科手术中夹持并固定骨骼、植入物，或夹持器械；
 - 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 骨科撑开钳 (I)、骨科撑开钳 (II)、骨科撑开钳 (III) 骨科撑开钳 (IV) 用于骨科手术中撑开椎体、组织或植入物；
 - 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 压缩钳 (I)、压缩钳 (II)、压缩钳 (III)、压缩钳 (IV) 用于骨科手术时压缩固定金属钩、钉或脊柱手术时在椎体间加压用；
 - 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 扭断器 (I)、扭断器 (II)、扭断器 (III)、扭断器 (IV)、扭断器 (V)、弯棒器 (I)、弯棒器 (II)、弯棒器 (III)、断棒器 (I)、断棒器 (II)、断棒器 (III)、断棒器 (IV) 用于骨科融合手术时弯折钢板或棒，或截断植入物；
 - 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 试模 (I)、试模 (II)、试模 (III)、试模 (IV)、试模 (V)、试模 (VI)、试模 (VII)、试模 (VIII)、试模 (IX)、试模 (X)、试模 (XI)、试模 (XII)、试模 (XIII)、试模 (XIV)、试模 (撑开式)、试模 (肾形)、量规 (I)、量规 (II)、骨测量器 (I)、骨测量器 (II)、骨测量器、测深器、测深器 (I) 用于骨科手术时测量直径、深度、孔径、角度、弧度等；
 - Orthopedic Reductor (I), Orthopedic Reductor (II), Orthopedic Reductor (III) are used for fracture reduction in orthopedic fusion surgery 骨科复位器 (I)、骨科复位器 (II)、骨科复位器 (III) 用于骨科融合手术骨折复位；

- Bone Awl (I), Bone Awl (II), Bone Awl (III) are used to open a hole in the bone in orthopedic surgery 骨锥 (I)、骨锥 (II)、骨锥 (III) 用于骨科手术中在骨骼上开孔;
- 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 植骨器 (漏斗)、植骨器 (捣棒)、植骨器 (I)、植骨器 (II)、植骨器 (III)、植骨器 (IV)、植骨器 (V)、植骨器 (VI)、植骨器 (VII)、植骨器 (VIII)、植骨器 (IX)、植骨器 (X)、植骨器 (XI)、植骨器 (XII)、植骨器 (XIII)、植骨器 (XIV)、植骨器 (XV)、植骨器 (XVI)、植骨器 (XVII)、植骨漏斗 (I)、植骨漏斗 (II)、植骨漏斗 (III)、植骨漏斗 (IV)、植骨漏斗 (V)、植骨漏斗 (VI)、植骨漏斗 (VII)、植骨漏斗 (漏斗)、植骨漏斗 (捣棒)、骨填充器用于植骨手术中完成骨骼系统的骨缺损和骨空腔填充物的输送、搅拌等操作;
- 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 骨科钻头 (限深)、骨科钻头 (II)、骨科钻头 (万向)、骨科钻头 (空心)、骨科钻头 (III)、骨科钻头 (IV)、骨科钻头 (V)、骨科钻头 (VI)、骨科钻头 (VII)、骨科钻头 (VIII)、骨科钻头 (IX)、骨科钻头 (X)、骨科钻头 (XI) 用于钻孔、攻螺纹; 或用于将钉头埋入骨内;
- 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 骨科导向器 (I)、骨科导向器 (II)、骨科导向器 (III)、骨科导向器、骨科定位片 (I)、骨科定位片 (II)、骨科定位片 (III)、骨科定位杆、骨科用保护器 (I)、骨科用保护器 (II)、骨科用保护器、骨科定位器、骨定位针 (I)、骨定位针 (II)、骨定位针 (盒)、骨定位针 (III)、骨定位针 (IV)、骨定位针 (V)、骨定位针 (VI)、骨定位针 (VII)、骨定位针 (VIII)、骨定位针 (IX)、骨定位针 (X)、骨定位针 (XI)、骨定位针 (光杆) 用于定位、导向和保护;
- Pedicle Screw Sleeve is used in the process of spinal surgery, with other surgical tools 椎弓根螺钉套管脊柱手术过程中, 配合其他手术工具使用;
- 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 骨膜剥离子 (I)、骨膜剥离子 (II)、骨膜剥离子 (III)、骨膜剥离子 (IV)、骨膜剥离子 (V)、骨膜剥离子 (小)、骨膜剥离器、剥离器用于剥离或分开附着于骨面上的骨膜及软组织;
- Bone Hammer, Crowbar (I), Crowbar (II) are used for knocking and prying in orthopedic operation 骨锤、撬棒 (I)、撬棒 (II) 用于骨科手术时作敲击、撬拨;
- 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 可调式牵开器 (I)、可调式牵开器 (II)、可调式牵开器 (III)、可调式牵开器 (IV)、多向牵开器、多向牵开器 (撑开瓣)、颈椎牵开器、脊柱牵开器 (I)、脊柱牵开器 (II) 用于骨科手术中显露手术视野, 使手术易于进行, 并保护组织, 避免意外损伤;
- 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 骨科外固定器 (I)、骨科外固定器 (II)、骨科外固定器 (III) 连接体内骨针使用, 通过固定、加压或牵拉骨端, 实现骨科畸形矫正、骨折复位等治疗目的;
 - Screw Holder is used to clamp implants, instruments or tissues in orthopedic surgery and take them out before the end of surgery 持钉夹用于骨科手术时夹持植入物、器械或组织, 手术结束前取出;
 - 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 骨拉钩 (I)、骨拉钩 (II)、骨拉钩 (III)、骨拉钩 (IV)、骨拉钩 (V)、骨拉钩 (VI)、骨拉钩 (VII)、骨拉钩 (VIII)、骨拉钩 (IX) 用于骨科手术中显露手术视野, 使手术易于进行, 并保护组织, 避免意外损伤; 或用于骨科手术中剥离、牵开或遮挡神经根;
 - Suction Tube is used to flush tissue or aspirate 吸引管用于冲洗组织或吸液;
 - Expanding Awl is used to open a hole in the bone in orthopedic surgery 开口锥用于骨科手术中在骨骼上开孔;
 - 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 骨刮匙 (I)、骨刮匙 (II)、骨刮匙 (III)、骨刮匙 (IV)、骨刮匙 (V)、骨刮匙 (VI)、刮刀 (I)、刮刀 (II)、刮刀 (III)、刮刀 (IV)、刮刀 (V)、刮刀 (VI)、刮刀 (圆头)、刮刀 (弧形)、刮刀 (三角形)、刮刀 (环形快换)、刮刀 (方形快换)、刮刀 (实心) 用于刮除病灶、窦道内的瘢痕、肉芽组织, 以及骨腔和潜在腔隙的死骨或病理组织等;
 - 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 咬骨钳 (I)、咬骨钳 (II)、咬骨钳 (III)、椎板咬骨钳 (钳柄)、椎板咬骨钳 (钳头-直型)、椎板咬骨钳 (钳头-弧型) 用于咬取死骨或修整骨残端;
 - 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 髓核钳 (I)、髓核钳 (II)、髓核钳 (带齿)、髓核钳 (钳头--直型)、髓核钳 (钳头--弯型) 用于骨科手术中咬除组织或息肉;
 - 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 骨刀 (I)、骨刀 (II)、骨刀 (III)、骨刀、骨刀 (后壁刀)、骨刀 (尖头)、骨刀 (平头)、骨刀 (上弯)、骨刀 (方角刀)、截骨刀用于切除、截断骨;
 - Bone Traction Pin (I), Bone Traction Pin (II) are used for traction, positioning or fixation during fracture

- surgery 骨牵引针 (I)、骨牵引针 (II) 用于在骨折手术过程中牵引、定位或固定;
- Titanium Mesh Scissors (I) and Titanium Mesh Scissors (II) is used to cut implants or plaster 钛网剪 (I) 和钛网剪 (II) 用于剪断植入物或石膏;
 - 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 椎体撑开器 (I)、椎体撑开器 (II)、椎体撑开器 (III)、椎体撑开器 (IV)、椎体撑开器 (V)、椎体撑开器 (快换)、锥板撑开器、脊柱撑开器 (I)、脊柱撑开器 (II)、脊柱撑开器、骨科撑开器 (I)、骨科撑开器 (II)、骨科撑开器 (III)、骨科撑开器、颈椎撑开器用于骨科手术中撑开椎体、组织或植入物;
 - 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 or reaming, medullary cavity reconstruction and expansion in orthopedic surgery 骨铰刀 (I)、骨铰刀 (II)、骨铰刀 (III)、骨铰刀 (IV)、骨铰刀 (片形)、骨铰刀 (撑开式)、骨铰刀 (快换)、骨铰刀 (圆形)、骨铰刀 (方形) 用于骨科手术中扩孔或铰孔、髓腔再造及扩大;
 - 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 脊柱手术用神经拉钩 (I)、脊柱手术用神经拉钩 (II)、脊柱手术用神经拉钩 (III) 用于骨科手术中显露手术视野, 使手术易于进行, 并保护组织, 避免意外损伤; 或用于骨科手术中剥离、牵开或遮挡神经根;
 - 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 导钻 (I)、导钻 (II)、导钻 (III)、导钻 (IV)、导钻 (V)、导钻 (VI)、导钻 (VII)、导钻 (VIII) 用于钻头或丝锥导向定位;
 - 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 扭力快换接头、快换手柄 (I)、快换手柄 (II)、快换手柄 (III)、快换手柄 (IV)、快换手柄 (V)、快换手柄 (VII)、快换手柄 (VIII)、快换手柄 (IX)、快换手柄 (X)、快换手柄与手术器械配合使用, 用于辅助完成植入物安装;
 - Osteotribe, Osteotribe (Quick-Change), Osteotribe (Straight), Osteotribe (Bent) are used to file bone and level the broken end of bone in orthopedic surgery 骨锉、骨锉 (快换)、骨锉 (直)、骨锉 (弯) 用于骨科手术时锉削骨骼、锉平骨断端;
 - Screw Remove Device is used to assist in the implantation or removal of implants or bone from the body 取钉器用于辅助将植入物或骨植入体内或者从体内取出;
 - 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 骨科用保护器 (I)、骨科用保护器 (II) 用于骨科手术中, 放入到手术部位, 减少手术过程对相关组织的损害;
 - Bone Saw (I), Bone Saw (II) are used to cut bones 骨锯 (I)、骨锯 (II) 用于截锯骨骼;
 - Minimally Invasive Retractor, Minimally Invasive Retractor (Open Flap) are used to stretch the soft tissue to expose the surgical field 微创牵开器、微创牵开器 (撑开瓣) 将软组织牵拉, 暴露手术视野;
 - Minimally Invasive Retractor (Connecting piece) is used to connect the retractor to the fixture 微创牵开器 (连

接片) 连接牵开器与固定装置;

- Template (Kidney-shaped) is used to measure the intervertebral size and select the appropriate fusion cage 试模 (肾形) 用于测量椎间尺寸, 挑选合适的融合器;
- Template Holder (Temple) is used to hold Template (Kidney-shaped) 持取器 (试模) 用于持取试模 (肾形);
- Trephine is used for drilling and decompression during removal and correction of rotting bone or orthopedic spine surgery 用于切除和修正腐骨或骨科脊柱手术时钻孔、减压;
- Fix Wire is used to fix a template or other instruments in orthopedic surgery 用于骨科手术中固定试模或其他器械;

Maintenance and storage methods 保养与储存方式

- 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 产品储运和运输过程中应轻拿轻放, 严禁相互碰撞、划刻、防止包装破坏, 造成产品损伤, 否则禁止使用.
- The product should be stored in room temperature, avoid direct sunlight, relative humidity not more than 80%, no corrosive gas and good ventilated room 产品应储存在常温下, 避免阳光直射、相对湿度不大于 80%, 无腐蚀气体和通风良好的室内.
- The product should be protected from rain, corrosion and sun during transportation 产品运输过程中应防雨、防腐、防晒.

Production date 生产日期

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

产品生产日期详见产品标签。

Electronic instruction website: 电子说明书网址

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