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

The Trauma Surgical Instrument is composed of Angle Ruler, Annular Tubes, Arch Drill, Bending Clamp, Bone Awl, Bone Chisel, Bone Cutter, Bone Drill, Bone Funnel, Bone Hammer, Bone Holding Forceps, Bone Hook, Bone Knife, Bone Lever, Bone Measurer, Bone Probe, Bone Reamer, Bone Retractor, Bone Rongeur, Bone Saw, Bone Scissors, Bone Wire Clamp, Burr, Casing, Clamp Forceps, Compression Clamp, Connector, Countersink Drill, Crowbar, C-Shaped Drill, Curette, Depth Finder, Diameter Gauge, Dissector, Drill, Driver-Extractor, Expanding Awl, Extractor, Femoral Intramedullary Alignment Handle Sleeve, Fix Wire, Flexible Reamer, Guide Device, Guide Needle, Guide Pin, Hollow Drill, Iliac Bone Extractor, Impactor, Intramedullary Reamer, Locking Needle Press, Medical Ruler, Medullary Cavity Reamer, Metal Cable Tensioner, Broken Nail Extractor, Nail Holding Forceps, Open Drill, Orthopedic Distraction Forceps, Orthopedic Distractor, Orthopedic Drill Guide, Orthopedic Holder, Orthopedic Nail Holder, Orthopedic Protector, Orthopedic Suture Passer, Osteotomy Plate, Osteotome, Pelvic Reduction Forceps, Periosteal Dissector, Pin Hole Reamer, Plate Holding Forceps, Positioning Device, Positioning Frame, Positioning Pin, Positioning Rod, Pressure Clamp, Quick Connect Rod, Quick-Change Handle, Reduction Forceps, Remove Clamp, Rod Bender, Screw Extractor, Screw Holder, Screw Holding Forceps, Screw Remove Device, Shearing Clamp, Shet Metal Bending Clamp, Sleeve, Steel Needle Scissors, Steel Plate Bender, Steel Plate Molding Sheet, Surgical Tendon Sorting Frame, Tap, Template, Tendon Distractor, Tendon Forceps, Torque Handle, Torque Quick-Change Connector, Torque Wrench, Wire Passer, Wire Tap, and Wrench.

创伤手术器械由角度尺、套管、弓形钻、折弯钳、骨锥、骨凿、剪断器、骨科钻头、植骨漏斗、骨锤、持骨钳、骨拉钩、骨刀、骨撬、骨测量器、骨探针、骨铰刀、骨用牵开器、咬骨钳、骨锯、骨剪、骨克丝钳、磨头、套筒、夹持钳、压缩钳、转接头、埋头钻、撬棒、C型导钻、刮匙、测深器、直径尺、剥离器、导钻、打拔器、开口锥、拔出器、股骨髓腔对线手柄套、固定针、柔性扩髓器、骨科导向器、导针、骨导引针、空心钻、髌骨取出器、打入器、髓腔扩大钻、锁针加压器、医用尺、髓腔铰刀、金属缆线收紧器、断钉取出器、持钉镊、开路器、骨科撑开钳、骨科撑开器、骨科钻孔瞄准器、骨科用夹持器、骨科用持钉器、骨科用保护器、骨科用穿线器、截骨板、骨锉、骨盆复位钳、骨膜剥离器、钉孔清除器、持板钳、骨科定位器、骨科定位架、骨定位针、骨科定位杆、加压钳、快速连接杆、快装手柄、复位钳、取出钳、弯棒器、螺钉取出器、持钉夹、持钉钳、取钉器、剪切钳、钢板弯曲钳、护套、钢针剪、钢板弯曲器、钢板塑型片、手术肌腱整理架、丝攻、模板、试模、肌腱分张器、肌腱钳、扭力手柄、扭力快换接头、骨科用扭力扳手、钢丝穿引器、丝锥、骨科用扳手组成。

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 upper limb internal fixation surgery or lower limb internal fixation surgery.  
用于骨科上肢内固定手术或下肢内固定手术。

### Contraindications 禁忌症

- People with metal allergies shall use with caution 金属过敏者慎用;
- Individuals with severe infected or metabolic disorders in calcified tissues shall use with caution 严重感染、钙化组织代谢紊乱者慎用;
- Severe comminuted fracture patients 严重粉碎性骨折者;
- Severe osteoporosis patients 严重骨质疏松者;
- Patients may not follow medical advice 病者可能不遵医嘱者;
- Pathological fractures caused by bone diseases (benign or malignant tumors, osteomyelitis, endocrine metabolism, degenerative diseases, deformities, etc.)由骨病(良性或恶性肿瘤、骨髓炎、内分泌代谢、退行性疾病、畸形等因素)所导致的病理性骨折;
- Autoimmune diseases or severe fatal diseases 自身免疫性疾病或严重致命性疾病;
- Preoperative diabetes patients with poor blood sugar control 术前糖尿病患者血糖控制不好者;
- Individuals allergic to multiple medications 对多种药物过敏者;
- Patients with mental illnesses who lack self-control and cannot express themselves accurately 无自制力、不能确切表达的精神性疾病患者;
- Pregnant and lactating women 妊娠、哺乳期妇女;
- Severe heart and lung dysfunction patients 严重心肺功能异常者.

### 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 被朊病毒、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、符合及缩写

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 Community/European Union

Symbol 符号	Explanation 释义	Symbol 符号	Explanation 释义
			欧洲共同体授权代表
	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:

- 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 Trauma Surgical Instrument is used, it shall cooperate with our company's orthopedic implants product 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；
- Bone Knife is used to cut off bone 骨刀用于切除、截断骨；
- Bone Reamer, Bone Reamer (I), Bone Reamer (III), Bone Reamer (Double-Kinfe), Bone Reamer (Single-Kinfe), Medullary Cavity Reamer (I), and Medullary Cavity Reamer (II) are used for reaming or reaming, medullary cavity

- reconstruction and expansion in orthopedic surgery 骨铰刀、骨铰刀（I）、骨铰刀（III）、骨铰刀（双刀）、骨铰刀（单刀）、髓腔铰刀（I）、髓腔铰刀（II）用于骨科手术中扩孔或铰孔、髓腔再造及扩大；
- Steel Needle Scissors are used to cut implants or plaster 钢针剪用于剪断植入物或石膏；
  - Bone Holding Forceps (II), Bone Holding Forceps (Big), Bone Holding Forceps (Small), Screw Holding Forceps, Plate Holding Forceps (II), Reduction Forceps (IV), Reduction Forceps (C-Shape), Reduction Forceps (Elbow I), Reduction Forceps (Pointed End IV), Pelvic Reduction Forceps (Acetabulum), Pelvic Reduction Forceps (Arc clamp head), Pelvic Reduction Forceps (Double Claws), Pelvic Reduction Forceps (Flat clamp head), Pelvic Reduction Forceps (High and Low Claws), Pelvic Reduction Forceps (Lateral Long), Pelvic Reduction Forceps (Lateral Short), Pelvic Reduction Forceps (Straight), Pelvic Reduction Forceps (Three Claws), Remove Clamp, Clamp Forceps (I), Clamp Forceps I, Clamp Forceps II, and Clamp Forceps III are used to clamp and fix bones, implants, or instruments in orthopedic surgery 持骨钳（II）、持骨钳（大）、持骨钳（小）、持钉钳、持板钳（II）、复位钳（IV）、复位钳（C型）、复位钳（弯头I）、复位钳（尖头IV）、骨盆复位钳（髌臼）、骨盆复位钳（弧钳头）、骨盆复位钳（双爪）、骨盆复位钳（平钳头）、骨盆复位钳（高低双爪）、骨盆复位钳（侧向长）、骨盆复位钳（侧向短）、骨盆复位钳（直）、骨盆复位钳（三爪）、取出钳、夹持钳（I）、夹持钳I、夹持钳II、夹持钳III用于骨科手术中夹持并固定骨骼、植入物，或夹持器械；
  - Bone Rongeur (Bent Lengthening), Bone Rongeur (Bent), Bone Rongeur (Gun Type), and Bone Rongeur (Straight) are used for biting dead bone or repairing bone stump 咬骨钳（弯加长）、咬骨钳（弯）、咬骨钳（枪式）、咬骨钳（直）用于咬取死骨或修整骨残端；
  - Orthopedic Distraction Forceps (I), Orthopedic Distraction Forceps (II), Orthopedic Distraction Forceps (Double Holes), Orthopedic Distraction Forceps (MeasureI), Orthopedic Distraction Forceps (Single Hook), Orthopedic Distraction Forceps (Square Blade), and Orthopedic Distractor 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（双孔）、骨科撑开钳（测量I）、骨科撑开钳（单钩）、骨科撑开钳（方叶片）、骨科撑开器用于骨科手术中撑开椎体、组织或植入物；
  - Compression Clamp, Compression Clamp (Double Holes), and Pressure Clamp (Ball Pin) are used to compress and fix metal hook and nail in orthopedic operation or to compress between vertebrae in spinal operation 压缩钳、压缩钳（双孔）、加压钳（球头针）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；
  - Bone Wire Clamp (I), Shet Metal Bending Clamp (I), Shet Metal Bending Clamp (II), Shearing Clamp, Bending Clamp, Bending Clamp (I), Bending Clamp (II), Bending Clamp (III), and Bending Clamp (Gun Type) are used for cutting, bending and ligation in orthopedic surgery 骨克丝钳（I）、钢板弯曲钳（I）、钢板弯曲钳（II）、剪切钳、折弯钳、折弯钳（I）、折弯钳（II）、折弯钳（III）、折弯钳（枪式）用于骨科手术时剪断、弯曲、结扎；
  - Bone Hook, Bone Hook (I), Bone Hook (II), and Bone Hook (Universal) 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、骨拉钩（I）、骨拉钩（II）、骨拉钩（通用）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；
  - Bone Retractor and Bone Retractor (Small) are used in orthopedic surgery to expose the operation field, make the operation easy, protect the tissue and avoid accidental injury 骨用牵开器和骨用牵开器（小）用于骨科手术中暴露手术视野，使手术易于进行，并保护组织，避免意外损伤；
  - Guide Pin, Guide Pin (I), Guide Pin (Ball Head), Guide Pin (Clean I), Guide Pin (Hook), Positioning Pin (Ball Head), Positioning Pin (Polish Rod I), Positioning Pin (Polish Rod), Positioning Pin (Right Angle), Positioning Pin (Thread I), Positioning Pin (Thread), and Positioning Pin I are used for guiding, directing, or positioning during orthopedic surgery 骨导引针、骨导引针（I）、骨导引针（球头）、骨导引针（清洁I）、骨导引针（钩型）、

- 骨定位针（球头）、骨定位针(光杆 I)、骨定位针（光杆）、骨定位针（直角）、骨定位针(螺纹 I)、骨定位针（螺纹）、定位针 I 用于在骨科手术过程中导向、导引或定位；
- Orthopedic Suture Passer, Orthopedic Suture Passer (Bent), Orthopedic Suture Passer (Straight), Orthopedic Suture Passer I, Orthopedic Suture Passer II, and Orthopedic Suture Passer III are used for perforation or threading during non-spinal surgery 骨科用穿线器、骨科用穿线器（弯）、骨科用穿线器（直）、骨科用穿线器 I、骨科用穿线器 II、骨科用穿线器 III 用于非脊柱手术时穿孔或穿线；
  - Curette, Curette (I), Curette (Elbow), Curette (Elliptical Elbow), and Curette I are used to scrape the focus, scar, granulation tissue in sinus, dead bone or pathological tissue in bone cavity and potential cavity 刮匙、刮匙（I）、刮匙（弯头）、刮匙（椭圆弯头）、刮匙 I 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；
  - Bone Awl, Bone Awl (I), Bone Awl (Positioning Rod), Expanding Awl, and Expanding Awl (Straight) are used to open a hole in the bone in orthopedic surgery 骨锥、骨锥（I）、骨锥（定位杆）、开口锥、开口锥（直形）用于骨科手术中在骨骼上开孔；
  - Tap (I), Tap (II), Tap (IV), Tap (Hollow Combination), Tap (Hollow), Tap (LCP), and Wire Tap are used for tapping screw holes on bones during orthopedic operation 丝攻（I）、丝攻（II）、丝攻（IV）、丝攻（空心组合）、丝攻（空心）、丝攻（LCP）、丝锥用于骨科手术时在骨骼上攻螺纹孔；
  - Bone Drill, Bone Drill (V), Bone Drill (VI), Bone Drill (Compression Opening), Bone Drill (Compression), Bone Drill (Countersunk), Bone Drill (Depth Limited), Bone Drill (Flat Head), Bone Drill (Limited Hollow), Bone Drill (Limiter), Bone Drill (Multi-use), Bone Drill (Soft Drill), Bone Drill(I), Bone Drill(II), Bone Drill(III), Bone Drill(Hollow Combination), Bone Drill(Soft), Arch Drill, Arch Drill (Chuck), Countersink Drill, Countersink Drill (Hollow I), Countersink Drill (Hollow II), Countersink Drill (Hollow III), Burr (Concave), and Burr (Convex) are used for drilling, tapping, or embedding the nail head into the bone 骨科钻头、骨科钻头（V）、骨科钻头（VI）、骨科钻头（加压开口）、骨科钻头（加压）、骨科钻头（埋头）、骨科钻头（限深）、骨科钻头（平头）、骨科钻头（限位空心）、骨科钻头（限位器）、骨科钻头（多用）、骨科钻头（软钻）、骨科钻头（I）、骨科钻头（II）、骨科钻头（III）、骨科钻头（空心组合）、骨科钻头（软）、弓形钻、弓形钻（夹头）、埋头钻、埋头钻（空心 I）、埋头钻（空心 II）、埋头钻（空心 III）、磨头（凹）、磨头（凸）用于钻孔、攻螺纹；或用于将钉头埋入骨内；
  - C-Shaped Drill, Drill (I), Drill (II), Drill (III), and Drill (Handle) are used for guiding and positioning of drill or tap C 型导钻、导钻（I）、导钻（II）、导钻（III）、导钻（手柄）用于钻头或丝锥导向定位；
  - Bone Saw (Hollow I) and Bone Saw (Hollow) is used to cut bones 骨锯（空心 I）和骨锯（空心）用于截锯骨骼；
  - Bone Chisel, Bone Chisel (I), Bone Chisel (Opening), Bone Chisel (Yang I), and Bone Chisel (Yin I) are used for bone trimming, bone extraction, and bone chiseling during orthopedic surgery 骨凿、骨凿（I）、骨凿（开口）、骨凿（阳 I）、骨凿（阴 I）用于骨科手术时修整骨骼、取骨和凿骨；
  - Bone Funnel (II) and Bone Funnel (III) are used to convey and stir bone defects and cavity fillers in bone grafting surgery 植骨漏斗（II）和植骨漏斗（III）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；
  - Medical Ruler (I), Medical Ruler (II), Medical Ruler (III), Angle Ruler (I), Angle Ruler (II), Depth Finder, Depth Finder (I), Depth Finder (II), Depth Finder (X), Depth Finder (i), Depth Finder (III), Depth Finder (IV), Depth Finder (V), Depth Finder (VI), Depth Finder (VII), Depth Finder (VIII), Depth Finder (Screw), Template, Template (I), Template (II), Template (Development), Bone Measurer (I), Bone Measurer (II), and Diameter Gauge I are used to measure the diameter, depth, aperture, angle, radian, etc. 医用尺（I）、医用尺（II）、医用尺（III）、角度尺（I）、角度尺（II）、测深器、测深器（I）、测深器（II）、测深器（X）、测深器（i）、测深器(III)、测深器（IV）、测深器（V）、测深器（VI）、测深器（VII）、测深器(VIII)、测深器（螺钉）、

模板、模板/试板（I）、模板/试板（II）、模板（显影）、骨测量器（I）、骨测量器（II）、直径尺 I 用于骨科手术时测量直径、深度、孔径、角度、弧度等；

- Positioning Device, Positioning Device (I), Positioning Device (II), Positioning Device I, Positioning Device II, Positioning Device III, Positioning Device IV, Positioning Device (Anti-Rotation), Positioning Device (Limit I), Orthopedic Drill Guide, Orthopedic Drill Guide (I), Orthopedic Drill Guide (II), Orthopedic Drill Guide (IV), Orthopedic Drill Guide (V), Orthopedic Drill Guide (DCS), Orthopedic Drill Guide (DHS), Orthopedic Drill Guide (Distal End I), Orthopedic Drill Guide (Multiholes I), Orthopedic Drill Guide (Multiholes II), Orthopedic Drill Guide I, Orthopedic Drill Guide II, Guide Device, Guide Device (I), Guide Device (i), Guide Device (II), Guide Device (ii), Guide Device (III), Guide Device (iii), Guide Device (IV), Guide Device (iv), Guide Device (V), Guide Device (VI), Guide Device (VII), Guide Device (VIII), Guide Device (Double Head I), Guide Device (Double Head II), Guide Device (Double Head III), Guide Device (Double Head), Guide Device (For Soft Drills), Guide Device (LC-DCP Base), Guide Device (LC-DCP Universal II), Guide Device (LC-DCP Universal), Guide Device (LC-DCP), Guide Device (LCP IV), Guide Device (LCP V), Guide Device (LCP I), Guide Device (LCP II), Guide Device (LCP IV), Guide Device (Multihole), Guide Device (Polyaxial), Guide Device (Porous I), Guide Device (VA-LCP II), Guide Device I, Positioning Frame, Positioning Frame (V), Positioning Frame (VI), Positioning Frame (Connecting Guide Block), Positioning Frame (Distal End IV), Positioning Frame (Distal End I), Positioning Frame (Distal Guide Rod II), Positioning Frame (Distal Guide Rod I), Positioning Frame (Distal Sight I), Positioning Frame (Distal Sight II), Positioning Frame (Distal Sight IV), Positioning Frame (Guide Rod), Positioning Frame (Handle I), Positioning Frame (Handle II), Positioning Frame (Handle III), Positioning Frame (Handle IV), Positioning Frame (Handle V), Positioning Frame (Handle), Positioning Frame (Mobile Aiming Block), Positioning Frame (Positioner I), Positioning Frame (Positioning Pin), Positioning Frame (Proximal Cancellous Bone), Positioning Frame (Proximal End III), Positioning Frame (Proximal End IV), Positioning Frame (Proximal End I), Positioning Frame (Proximal Guide Rod II), Positioning Frame (Proximal Guide Rod I), Positioning Frame (Proximal Sight I), Positioning Frame (Sleeve), Positioning Frame (Ultra Distal End), Guide Needle, Positioning Rod (Distal End), and Positioning Rod (Proximal End) are used for positioning, guiding and protection 骨科定位器、骨科定位器（I）、骨科定位器（II）、骨科定位器 I、骨科定位器 II、骨科定位器 III、骨科定位器 IV、骨科定位器（抗旋）、骨科定位器（限位 I）、骨科钻孔瞄准器、骨科钻孔瞄准器（I）、骨科钻孔瞄准器（II）、骨科钻孔瞄准器（IV）、骨科钻孔瞄准器（V）、骨科钻孔瞄准器（DCS）、骨科钻孔瞄准器（DHS）、骨科钻孔瞄准器（远端 I）、骨科钻孔瞄准器（多孔 I）、骨科钻孔瞄准器（多孔 II）、骨科钻孔瞄准器 I、骨科钻孔瞄准器 II、骨科导向器、骨科导向器（I）、骨科导向器（i）、骨科导向器（II）、骨科导向器（ii）、骨科导向器（III）、骨科导向器（iii）、骨科导向器（IV）、骨科导向器（iv）、骨科导向器（V）、骨科导向器（VI）、骨科导向器（VII）、骨科导向器（VIII）、骨科导向器（双头 I）、骨科导向器（双头 II）、骨科导向器（双头 III）、骨科导向器（双头）、骨科导向器（软钻用）、骨科导向器（LC-DCP 基础）、骨科导向器（LC-DCP 通用 II）、骨科导向器（LC-DCP 通用）、骨科导向器（LC-DCP）、骨科导向器（LCP IV）、骨科导向器（LCP V）、骨科导向器（LCP I）、骨科导向器（LCP II）、骨科导向器（LCP IV）、骨科导向器（多孔）、骨科导向器（万向）、骨科导向器（多孔 I）、骨科导向器（VA-LCP II）、骨科导向器 I、骨科定位架、骨科定位架（V）、骨科定位架（VI）、骨科定位架（连接导向块）、骨科定位架（远端 IV）、骨科定位架（远端 I）、骨科定位架（远端导杆 II）、骨科定位架（远端导杆 I）、骨科定位架（远端瞄准器 I）、骨科定位架（远端瞄准器 II）、骨科定位架（远端瞄准器 IV）、骨科定位架（导向杆）、骨科定位架（手把 I）、骨科定位架（手把 II）、骨科定位架（手把 III）、骨科定位架（手把 IV）、骨科定位架（手把 V）、骨科定位架（手把）、骨科定位架（移动瞄准块）、骨科定位架（定位器 I）、骨科定位架（定位针）、骨科定位架（近端松质骨）、骨科定位架（近端 III）、骨科定位架（近端 IV）、骨科定位架（近端 I）、骨科定位架（近端导杆 II）、骨科定位架（近端

- 导杆 I)、骨科定位架(近端瞄准器 I)、骨科定位架(护套)、骨科定位架(超远端)、导针、骨科定位杆(远端)、骨科定位杆(近端)用于定位、导向和保护;
- Screw Holder (HA II), Screw Holder (HA I), Screw Holder (LCP I), Screw Holder (LCP II), Nail Holding Forceps, Orthopedic Holder, Orthopedic Holder (II), Orthopedic Holder (III), Orthopedic Nail Holder, and Tendon Distractor are used to clamp implants, instruments or tissues in orthopedic surgery and take them out before the end of surgery 持钉夹(HA II)、持钉夹(HA I)、持钉夹(LCP I)、持钉夹(LCP II)、持钉镊、骨科用夹持器、骨科用夹持器(II)、骨科用夹持器(III)、骨科用持钉器、肌腱分张器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 Hammer (I), Bone Lever, Bone Lever (I), Bone Lever (II), Crowbar, Crowbar (Reset Plate), and Crowbar (Reset Rod) are used for knocking and prying in orthopedic operation 骨锤(I)、骨撬、骨撬(I)、骨撬(II)、撬棒、撬棒(复位板)、撬棒(复位杆)用于骨科手术时作敲击、撬拨;
  - Wrench, Wrench (Ball), Wrench (Combination), Wrench (Compression Screw Holding Rod), Wrench (Compression Screw), Wrench (Cross I), Wrench (Cylindrical), Wrench (Double Head II), Wrench (Hexagon I), Wrench (Hexagon II), Wrench (Hexagon Quick-change), Wrench (Hexagon), Wrench (Hexagonal Polyaxial Quick-Change), Wrench (Hexagonal Tail Cap), Wrench (Hollow Cross), Wrench (Hollow Hexagon I), Wrench (Hollow Hexagon), Wrench (Hollow Star Quick-change), Wrench (Hollow Star), Wrench (Locked Handle I), Wrench (Locked Handle II), Wrench (Locking), Wrench (L-Shaped Hexagon), Wrench (Nail Removal), Wrench (One Character), Wrench (Opening), Wrench (Polyaxial Hexagon), Wrench (Polyaxial Star), Wrench (Polyaxial Tail Cap), Wrench (Polyaxial), Wrench (Rod), Wrench (Spiral Blade), Wrench (Star I), Wrench (Star Quick-change), Wrench (Star Screwdriver), Wrench (Star Self Holding), Wrench (Star), Wrench (Tension Screw Holding Rod), Wrench (Tension Screw), Wrench (Tightening Rod), Wrench (T-Shape I), Wrench (T-Shaped Polyaxial Socket), Wrench (T-shaped Quick-change), Wrench (T-Shaped Socket), Impactor, Impactor (I), Impactor (III), Impactor (Angled), Impactor (Ball Head), Impactor (DCS), Impactor (DHS), Impactor (L-shape), Impactor (Round Head), Impactor (Round Head I), Impactor (Straight), Extractor, Extractor (Spiral Blade), Driver-Extractor, Driver-Extractor (Compression), Driver-Extractor (Connecting Rod), Driver-Extractor (Guide Pin I), Driver-Extractor (Guide Pin II), Driver-Extractor (Slide Hammer I), Driver-Extractor (Slide Hammer), Driver-Extractor (Spiral Blade I), Broken Nail Extractor (I), Screw Extractor (Slipping I), Screw Extractor (Slipping II), Screw Remove Device (I), Iliac Bone Extractor (I), Iliac Bone Extractor (II), Torque Wrench (Star II), and Torque Wrench (Star) are used to assist the implantation or removal of implants or bone from the body 骨科用扳手、骨科用扳手(球型)、骨科用扳手(组合)、骨科用扳手(加压螺钉持杆)、骨科用扳手(加压螺钉)、骨科用扳手(十字 I)、骨科用扳手(柱形)、骨科用扳手(双头 II)、骨科用扳手(六方 I)、骨科用扳手(六方 II)、骨科用扳手(六方快换)、骨科用扳手(六方)、骨科用扳手(六方万向快换)、骨科用扳手(六方尾帽)、骨科用扳手(空心十字)、骨科用扳手(空心六方 I)、骨科用扳手(空心六方)、骨科用扳手(空心梅花快换)、骨科用扳手(空心梅花)、骨科用扳手(手柄锁定 I)、骨科用扳手(手柄锁定 II)、骨科用扳手(锁紧)、骨科用扳手(L型六方)、骨科用扳手(卸钉)、骨科用扳手(一字)、骨科用扳手(开口)、骨科用扳手(六方万向)、骨科用扳手(梅花万向)、骨科用扳手(尾帽万向)、骨科用扳手(万向)、骨科用扳手(杆型)、骨科用扳手(螺旋刀片)、骨科用扳手(梅花 I)、骨科用扳手(梅花快换)、骨科用扳手(梅花起子)、骨科用扳手(梅花自持)、骨科用扳手(梅花)、骨科用扳手(拉力螺钉持杆)、骨科用扳手(拉力螺钉)、骨科用扳手(拉紧杆)、骨科用扳手(T型 I)、骨科用扳手(套筒 T型万向)、骨科用扳手(快装 T型)、骨科用扳手(套筒 T型)、打入器、打入器(I)、打入器(III)、打入器(斜形)、打入器(球头)、打入器(DCS)、打入器(DHS)、打入器(L型)、打入器(圆头)、打入器(圆头 I)、打入器(直形)、拔出器、拔出器(螺旋刀片)、打拔器、打拔器(加压)、打拔器(连接块)、打拔器(导针 I)、打拔器(导针 II)、打拔器(滑锤 I)、打拔器(滑锤)、打拔器(螺旋刀片 I)、断钉取出器(I)、螺钉

- 取出器（打滑 I）、螺钉取出器（打滑 II）、取钉器（I）、髌骨取出器（I）、髌骨取出器（II）、骨科用扭力扳手（梅花 II）、骨科用扭力扳手（梅花）用于辅助将植入物或骨植入体内或者从体内取出；
- Quick-Change Handle (Ratchet), Quick-Change Handle (Straight IV), Quick-Change Handle (Straight V), Quick-Change Handle (Straight VI), Quick-Change Handle (Straight), Quick-Change Handle (T-Shape I), Quick-Change Handle (T-Shape II), Quick-Change Handle (T-Shape III), Quick-Change Handle (T-Shape IV), Quick-Change Handle (T-Shaped Hollow), Quick-Change Handle I, Quick-Change Handle II, Quick Connect Rod (Aiming Frame Lock Wheel), Quick Connect Rod (Compression), Quick Connect Rod (Distal End of Long Nail), Quick Connect Rod (Distal End), Quick Connect Rod (Handle), Quick Connect Rod (Proximal End of Long Nail), Quick Connect Rod (Proximal End), Quick Connect Rod (Short Rod), Torque Quick-Change Connector, Torque Handle, Connector (I), Connector (II), Sleeve, Sleeve (I), Sleeve (II), Sleeve (III), Sleeve (IV), Sleeve (VI), Sleeve (VIII), and Sleeve (Tail Cap) are used with surgical instruments to assist in the installation of implants 快装手柄（棘轮）、快装手柄（直型 IV）、快装手柄（直型 V）、快装手柄（直型 VI）、快装手柄（直型）、快装手柄（T 型 I）、快装手柄（T 型 II）、快装手柄（T 型 III）、快装手柄（T 型 IV）、快装手柄（T 型空心）、快装手柄 I、快装手柄 II、快速连接杆（瞄准架锁轮）、快速连接杆（加压）、快速连接杆（长钉远端）、快速连接杆（远端）、快速连接杆（手把）、快速连接杆（长钉近端）、快速连接杆（近端）、快速连接杆（短杆）、扭力快换接头、扭力手柄、转接头（I）、转接头（II）、护套、护套（I）、护套（II）、护套（III）、护套（IV）、护套（VI）、护套（VIII）、护套（尾帽）与手术器械配合使用，用于辅助完成植入物安装；
  - Steel Plate Bender (I), Steel Plate Bender (III), Steel Plate Bender (IV), Steel Plate Molding Sheet, Steel Plate Molding Sheet (Arc), Steel Plate Molding Sheet (Stright), Bone Cutter, Bone Cutter (Main Body), Bone Cutter (Wrench), and Rod Bender are used to bend the plate or rod, or cut off the implant in orthopedic fusion surgery 钢板弯曲器（I）、钢板弯曲器（III）、钢板弯曲器（IV）、钢板塑型片、钢板塑型片（弧形）、钢板塑型片（直形）、剪断器、剪断器（主体）、剪断器（扳手）、弯棒器用于骨科融合手术时弯折钢板或棒，或截断植入物；
  - Locking Needle Press, Locking Needle Press (I), Locking Needle Press (II), Pin Hole Reamer, Metal Cable Tensioner (Connector), Metal Cable Tensioner (Main Body), Wire Passer, Casing, and Annular Tubes (Ball Head Positioning Pin) are used in orthopedic trauma surgery, in conjunction with other surgical instruments 锁针加压器、锁针加压器（I）、锁针加压器（II）、钉孔清除器、金属缆线收紧器（接头）、金属缆线收紧器（主体）、钢丝穿引器、套筒、套管（球头定位针）用于骨科创伤手术中，配合其他手术器械使用；
  - Periosteal Dissector (I), Periosteal Dissector (II), Periosteal Dissector (Flat), and Periosteal Dissector (Round) are used to peel off or separate periosteum and soft tissue attached to bone surface 骨膜剥离器（I）、骨膜剥离器（II）、骨膜剥离器（平）、骨膜剥离器（圆）用于剥离或分开附着于骨面上的骨膜及软组织；
  - Dissector is used to peel or separate mucous membranes and tissues 剥离器用于剥离或分离粘膜、组织；
  - Osteotomy Plate (I), Osteotomy Plate (II), and Femoral Intramedullary Alignment Handle Sleeve (II) are used for positioning, detection, guidance, evaluation or providing reference in joint surgery; or used for supporting and positioning distal femoral osteotomy blocks during joint replacement surgery 截骨板（I）、截骨板（II）、股骨髓腔对线手柄套（II）用于关节手术中定位、探测、导向、评估或提供基准用；或用于关节置换手术中股骨远端截骨块的支撑及定位；
  - Bone Probe is used to detect direction and depth in orthopedic operation 骨探针用于骨科手术中探测方向和深度；
  - Bone Scissors are used for cutting bones, ligaments, or tissues 骨剪用于剪断骨、韧带或组织；
  - Fix Wire (Compression) is used to fix templates/trial molds or other instruments during joint replacement surgery 固定针（加压）用于关节置换手术中固定试模或其他器械；
  - Flexible Reamer (One-way II) and Flexible Reamer (Two-way II) are used to expend the medullary cavity in

- orthopedic surgery 柔性扩髓器(单向II)和柔性扩髓器(双向II)用于骨科手术中髓腔内的扩髓;
- Hollow Drill (I), Hollow Drill (II), Hollow Drill (IV), Hollow Drill I, Hollow Drill II, and Hollow Drill III are used for bone resection or extraction in orthopedic surgery 空心钻(I)、空心钻(II)、空心钻(IV)、空心钻I、空心钻II、空心钻III用于骨科手术中切除骨或取骨用;
  - Intramedullary Reamer (I), Intramedullary Reamer (II), Intramedullary Reamer (Proximal End I), and Intramedullary Reamer (Proximal End II) are used to expand the medullary cavity 髓腔扩大钻(I), 髓腔扩大钻(II), 髓腔扩大钻(近端I), 髓腔扩大钻(近端II)用于扩大髓腔;
  - Open Drill I and Open Drill II are used to punch, drill, and ream holes in orthopedic surgery 开路器I和开路器II用于骨科手术时打孔、钻孔、扩孔;
  - Orthopedic Protector is used in orthopedic surgery, placed at the surgical site to reduce damage to related tissues during the surgical process 骨科用保护器用于骨科手术中,放入到手术部位,减少手术过程对相关组织的损害;
  - Osteotribe is used to file bone and level the broken end of bone in orthopedic surgery 骨锉用于骨科手术时锉削骨骼、锉平骨断端;
  - Surgical Tendon Sorting Frame is used to assist in measuring, clamping, and fixing tendon soft tissue before implantation of soft tissue implants in orthopedic surgery to prepare specific soft tissue implants 手术肌腱整理架用于在骨科手术中软组织植入物植入前,辅助测量、夹持和固定肌腱软组织以准备特定的软组织植入物;
  - Tendon Forceps is used to bite off tissue or polyp in orthopedic surgery 肌腱钳用于骨科手术中咬除组织或息肉;

#### Maintenance and storage methods 保养和储存方式

- 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。