C:\Users\FG01\Desktop\捕获.JPGBeijing Fule Science & Technology Development Co., Ltd

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**Product Structure and Performance**

The system is composed of pedicle screw, pedicle hook, pedicle rod, connector etc. The materials aretitanium alloy Ti6Al4V which meet the requirement of ISO 5832-3.The surface oftitanium productis treated by anodic oxidation coloring. The products are supplied non-sterile.

**Applicable Scope and Major Indications**

Applicable scope: the system is applicable to posterior cervical, thoracolumbar internal fixation of the trauma, orthopedics, and degenerative pathological changes. The device isintended for skeletally mature patients.

**Contraindications**

Bony structure defect; anatomy abnormality of nerve root canal;serious nerve dysfunction; obedity;serious osteoporosis;metal sensitivity;patients with severe infection; patients with serious primary diseases such as heart, brain, liver, kidney, hematopoietic system and endocrine system or psychiatric patients; severe osteoporosis; allergic to implants, allergic constitution or allergic to multiple drugs; the spine is obviously unstable due to the destruction of spine caused by tumor, fracture and infection with anterior column defect; peripheral vascular disease, long-term alcoholism, metabolic disorder of body tissue, immune function disorder, drug abuse and other medical history; pregnant and lactating women; patients in critical condition.

**Attentions**

1. Please carefully read the instruction before use.

2. Before the surgery, determine the surgery plan according to the symptom, sign and the image check.

3. MR examination can be carried out onTi6Al4V product according to routine parameters of the hospital.

4. Choose the products and special matching tools with suitable specification and model according to the symptom and the position of patients.

5. Perform the surgery under the directions of an experienced surgeon.

6. The surgeon shall describe the relevant precautions in details to the patients before the surgery.

7. At the delivery time, if the product is found scratched, damaged, and bended or cracked, it cannot be used anymore.

8. The implants and tools provided by our company are not sterilized but the devices must be sterilized before the surgery. We recommend the method of high pressure steaming for sterilization.

9. Any activities in the early post-operation period, if being conducted improperly in method or extent, would possibly cause the invalidation of the metal implant, such as fixation loosening, broken or bending, etc. For this reason, the time, method and extent of activity in the early post-operation period shall be conducted strictly under the correct instruction of the surgeon, and shall be implemented step by step.

10. Before healing of bone grafting in early post-operation period, the external fixation shall be used for 6 to 12 weeks.

11. The product is disposable.

12. And it is forbidden to be used with products of other materials and model or from other companies.

13. To avoid contamination, this product should be disposed as infectious medical waste disposal method.

**Warning**:

1. The products and instruments should be sterilized before use.Recommended to meet the EN ISO 17665-1 related requirements of the high pressure steam sterilization method.Recommended sterilization conditions:

Down-draining steam sterilizer: temperature: 121℃; duration of exposure: 30 minutes; barometric pressure: 102.9kPa(1.05kg/cm2);drying time:45 minutes.High pressure steam sterilizer must be approved by the hospital and inspection regularly to ensure the medical device can reach the recommended sterilization temperature during the exposure period.

1. The product is disposable and should not be reused under any circumstances.Used implants may contain many acquired flaws, or the integrity of itself may be damaged, which will shorten the service life or cause cross infection. Whether the appearance of used implants is good or not, it's strictly prohibited to be reused.

**Installation and Operating Instructions**

Standard operating points of the system:

1. Use awl to drill a puncture point on cortical bone, use probe to check the depth and the wall, expand the hole widely if necessary.
2. Use spinal screw spanner inserts the screw, follow the same direction.
3. Use rod bender pre-bend the rod and insert to the U shape of screws by rod-holding pliers.
4. Use rod-compressor and screw-holding pliers together, press in the connection rod into the pedicle screw slot, use hex spanner to rotate the screws slightly (rotate counter-clockwise one or two circles before insert in order to match the screws completely), place nut by screw-holding plier and lock well.
5. Use both pulling-offpliers and locking pliers to extend, rotate the rod, install the transverse connector after reduction.

Standard operating point

The description of the clinical operation of the typical system:

1. At first, an opening in the cortical bone is opened with the awl (for drilling hole) at the punctured point, then the hole is expanded with the expanding bit if needed, the depth and wall of the canal is probed with the probe.
2. Spinal screw is inserted with the spinal screw spanner, and all the screws should have the openingsin the same direction.
3. Spinal rod is pre-bended with the rod bender, and then it is put into the openings of the screws with the rod-holding pliers.
4. Rod-compressor and screw-holding pliers are used together to press the connection rod into the pedicle screw slot, and thejack screwsare inserted slightly with the internal hexagonal spanner (they are rotated counter-clockwise one or two full circles before inserted, so as to be matched with the screws). Outer nuts are placed with screw-holding pliers on the screws, and then the jack screws are locked.
5. Pulling-off pliers and locking pliers are used to spread and rotate the rods, after the restoration, the transverse connector is installed.

**Postoperative Complications and Treatment**

**Infection:** For the infection of the superficial layer of the fascia, the processing method is early debridement and open (or close) drainage. For deep infected patients, should immediately lead incision debridement and lavage drainageonce found, to retain bone graft block as much as possible and metal implants, in the incision depth were placed flush tube and drainage tube, suture incision layer by layer. If the infection cannot be controlled, consider to re-conduct debridement and remove the bone graft block and metal implants when necessary.

■**Broken, bend or loosening:** Fractures occur in poor segment fusion**;** Excess load of screw for expanding and recovery; Vertebral height loss caused by intervertebral disc degeneration; Late removal the implant; No support was used; Patients disobey surgeon’s instruction and overexertion; Treatment method:

To choose a propermetallic implants in bone graft fusion according to patient’s condition

It is necessary to select a proper operation plan for patients with intervertebral disc trauma and use support after the surgery for reducing the stress arising from the metal implant.

The effective way to prevent screw breakage and bending loose is to remove the implant as early as possible.

■**Spinal cord and nerve injury:**Nerve tissues injuryis mostly related to the excess traction and compression of the spine as well as the direct damages of the medical devices or the restoration of the fracture.Each pedicle of vertebral arch surround by nerve tissue, especially centralizing inside and below the pedicle of vertebral arch, thus the nerve tissue are more easy to be effected by the abnormality of structure of the pedicle of vertebral arch.In addition, if the implanted screws are too long, it is possible to penetrate the anterior cortex and vascular.In order to reduce the nerve injury, the surgeon must be familiarwith the anatomy and positioning of the spine, and identify the direction of the screw through the C arm machine

**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 Labelling of Medical Devices.

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| Symbol | Explanation | Symbol | Explanation |
|  | HUMIDITY  LIMITATION |  | CAUTION, see instructions for use |
|  | DO NOT REUSE |  | MANUFACTURER |
|  | BATCH CODE |  | TEMPERATURE LIMITATION |
|  | DATE OF MANUFACTURE |  | AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY |
|  | NON-STERILE |
|  | MEDICAL DEVICE |  | UNIQUE DEVICE IDENTIFIER |

**Maintenance and Storage Methods of Product**

The product shall be stored in a ventilated, non-corrosive gas room with the relative humidity between 35% to 80% and temperature between 10℃ to 25℃.

**Time Limit for the Implants**

All metal implants aretemporary, implants only play as a fixed role in bone healing, there will be no more effect on bone healing after the implant totally completed, instead may lead to implant loosening, fracture or bending. According to the related literature, fracture healing time is generally from 4 to 6 months; we consider the aged group and severe trauma cases and suggest the healing time to be extended from 8 to 12 months then to remove the implants for non- long term implant. For those long-term implant products are required to be kept until the function is useless. Patients are recommended to remove the implants under the surgeon’s advice after complete healing.

### Product Specifications and Model

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| Name | Type | Description | Remark |
| U Monoaxial Expandable Pedicle Screw | FJD5 | D：4.0～7.5  L：20～80 | Screws include self tapping and non-self tapping  Types of thread include single thread and double threads ;  Interval between D and l is: 0.5 ;  Interval of L is: 5 |
| U Monoaxial Reduction Expandable Pedicle Screw | D：4.5～7.5  L：20～60 |
| Monoaxial Reduction Minimally-invasive Cement Pedicle Screw | D：4.5～7.5  L：20～60 |
| UG Monoaxial Pedicle Screw | D：4.0～7.5  L：20～80 |
| UG Monoaxial Reduction Pedicle Screw | D：4.5～7.5  L：20～60 |
| US Monoaxial Pedicle Screw | D：4.0～7.5  L：20～80 |
| US Monoaxial Reduction Pedicle Screw | D：4.5～7.5  L：20～60 |
| Polyaxial Minimally-invasive Cement Pedicle Screw | D：5.5～7.5  L：35～55 |
| Polyaxial Reduction Minimally-invasive Cement Pedicle Screw | D：4.5～8.5  L：25～90 |
| UG Polyaxial Pedicle Screw | D：4.0～7.5  L：20～80 |
| UG Polyaxial Reduction Pedicle Screw | D：4.5～7.5  L：20～60 |
| US Polyaxial Pedicle Screw | D：4.0～7.5  L：20～80 |
| US Polyaxial Reduction Pedicle Screw | D：4.5～7.5  L：20～60 |
| B Screw Plug | D1：5～14 | Interval of D1: 0.5 |
| US Screw Plug |
| Adjustable connector | FJG4 | D：3.5, 5.5, 6.0  L：24～60 | Interval of L: 1 |
| Parallel Connector | D1：3.5～6.0  D2：3.5～6.0 | The connectors include trapezoidal type and square type;  Interval between D1 and D2 is: 0.5 |
| Extend Connector | Interval between D1 and D2 is: 0.5 |
| Screw Plug for Connector | D：4～12 | Interval between D1 and D is: 0.5 |
| Laminar Hook | FJG5 | D：5.0,5.5,6.0  L：6.5,7.0,8.0 | - |
| B Screw Plug | D1：5～14 | Interval of D1is: 0.5 |
| Pedicle Hook | FJG6 | D：5.0,5.5,6.0  L：6.5,7.0,8.0 | - |
| B Screw Plug | D1：5～14 | Interval of D1is: 0.5 |
| Connecting Rod (Bent) | FJB1 | D：3.5, 5.5, 6.0  L：40～200 | Interval of L is: 5 |
| Note: Rotating parts of screw plug include hexagon and torx.US screw plugs include normal type, reduction type and self cutting type. Reduction parts of screws include normal reduction and extendable reduction. The head parts of polyaxial screws include polyaxial, uniaxial and uniplanar. | | | |

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| Product Name | Type | Description | Remark |
| Adjustable Iliac Screw | FJD3 | D：4.0～10.0  L：20～100 | Screws include self tapping and non-self tapping.  Types of thread include single thread and double threads.  Interval between D is: 0.5  Interval of L is: 5  Interval of D1 is: 0.5 |
| COX Monoaxial Pedicle Screw | D：4.0～7.5  L：20～80 |
| COX Monoaxial Reduction Pedicle Screw | D：4.5～7.5  L：20～60 |
| COX Polyaxial Pedicle Screw | D：4.0～7.5  L：20～80 |
| COX Polyaxial Reduction Pedicle Screw | D：4.5～7.5  L：20～60 |
| X Transverse connector | FJG4 | D：5.5,6.0 | - |
| Connecting Rod | FJB1 | D：3.5,5.5,6.0  L：40～500 | Include straight, bent, single hex head and double hex heads  Interval of L is : 5 |
| Transverse Connecting Rod | FJB4 | D：3.0,4.0  L：30～100 | Round，flat  Interval of L is: 5 |
| Note: Rotating parts of screw plugs include hexagon and torx. Reduction screws include normal reduction and extendable reduction. The thread head types of polyaxial screws include polyaxial, uniaxial and uniplanar. | | | |

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| Product Name | Type | Description | Remark |
| SCHANZ Pedicle Screw | FJD4 | D：5.0,5.5, 6.0,6.5, 7.0,7.5  L：30～60 | Screw types include self tapping and non-self tapping  Types of thread include single thread and double threads.  Interval of L is: 5 |
| SCHANZ Pedicle Screw Ⅰ |
| Sleeve Chuck | FJB5 | Include anteroposterior, lateral, deviation | —— |
| Note: Rotating parts of screw plug include hexagon and torx.Reduction screws include normal reduction and extendable reduction. The types of polyaxial screw heads include polyaxial, uniaxial and uniplanar. | | | |

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| System Model | No. | Product Name | Specification | Material | Remark |
| CFS | 03 | Pressurization Polyaxial Pedicle Screw | D：3.5～7.5  L：20～80 | Ti6AL4V | Include self tapping and non-self tapping; single thread and double threads.  Interval between D and D1 is: 0.5  interval of L is: 0.5 |
| Pressurization Polyaxial Reduction Pedicle Screw | D：3.5～7.5  L：20～60 |
| Pressurization Monoaxial Pedicle Screw | D：3.5～7.5  L：20～80 |
| Pressurization Monoaxial Reduction Pedicle Screw | D：3.5～7.5  L：20～60 |
| Note: screw plug, fixation screw, locking device,set screw and locking screw include cross, hexagon and torx types.Reduction type screws include normal reduction and extendable reduction type. The head types of polyaxial screws include polyaxial, uniaxial and uniplanar. | | | | | |

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| Name | Sub-model | Description | | Material | Remark |
| Diameter | Length |
| Fix Monoaxial  Screw | ZJX-D4 | D：3、3.5、4、4.5、5、5.5 | L：6～60 | Ti6AL4V | Include tapping and non tapping type  L interval：1 |
| Fix Polyaxial  Screw | ZJX-D5 |
| Compression  Screw | ZJX-D4 | D：3.5、5、5.5、6、6.5、7、7.5、8、9 | —— | —— |

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| Name | Sub-model | Description | | Material | Remark |
| Diameter | Length |
| Connecting hook | ZJX-G1 | D：3、3.2、3.5、4、4.5、5、5.5 | —— | Ti6AL4V | —— |
| Compression  Screw | D：5、5.5、6、6.5、7、7.5、8、9 |
| Shift connector | ZJX-G3 | D：3、3.2、3.5、4、4.5、5、5.5、6 | L：10～30 | Ti6AL4V | L interval：1 |
| Vertebra hook | ZJX-G7 | D：3、3.2、3.5、4、4.5、5 | —— | Ti6AL4V | Left and right deviation |
| L：16、19 | Straight |
| Connecting Rod | ZJX-B3 | D：2、2.5、3、3.2、3.5、4 | L：20～100 |  | Include round and flat  L interval：5 |