CE0123

Instruction for Use

General Spinal System

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1. Product Name

General Spinal System

2. Performance, Structure and Components.

General Spinal System is used for spinal internal fixation and designed according to structural features of human spine bone. It is composed of Z MIS,Z6, Z5,AF/RF series spinal system(Reduction screw,U-screws, fixing rods, crosslink, set screw), Anterior cervical system(Anterior cervical plate and Anterior Vertebral Screw),Laminoplasty system(Laminoplasty plate,Laminoplasty screw) etc. According to the different clinical indications, spinal internal fixators can be used as a combination of different types. There are multiple specifications and models to be selected according to different patients and segments. The product are provided non-sterile and should be sterilized before use.

During the surgery, general spinal system is implanted according to the physiological curvature of spine, which not only maintains the integrity and fusion of active segments, but also need to maintain spinal three-dimensional form and balance, until the spine surgical site get total fusion.

Anterior cervical plate and Laminoplasty plate are made of pure titanium (TA3), which are strictly in

accordance with the requirements of EN ISO 5832–2:2018 Implants for surgery –– Metallic materials –– Part 2: Unalloyed titanium.

Z MIS,Z6, Z5,AF/RF series spinal system, anterior vertebral screw and Laminoplasty screw are made of Titanium Alloy (TC4), which is strictly meet the ISO 5832–3 Implants for surgery — Metallic materials — Part 3: Wrought titanium 6–aluminium 4–vanadium alloy.

3. Type&Specifications

Component Name	Specification
Z MIS series spinal system	**Z MIS:** U–Screw(Mono–axial) Diameter:4.5~8.0mm(0.5mm increments) Length:20~60mm(5mm increments) U–Screw(Poly–axial) Diameter:4.5~8.0mm(0.5mm increments) Length:20~60mm(5mm increments) Fixing Rod Diameter:5.0~6.0mm(0.5mm increments) Length:30~160mm(5mm increments) Setscrew:Break off

Z 6 series spinal system	**Z 6:** U-Screw(Mono-axial) Diameter:4.0~8.0mm(0.5mm increments) Length:20~70mm(5mm increments) U-Screw(Poly-axial) Diameter:4.0~8.0mm(0.5mm increments) Length:20~70mm(5mm increments) Fixing Rod Diameter:5.5~7.5mm(0.5mm increments) Length:40~200/300/500mm(5mm increments) Crosslinks: Diameter:5.0~6.0mm(0.5mm increments) Length:50~80mm(5mm increments)
Z 5 series spinal system	**Z 5:** U-Screw(Mono-axial) Diameter:4.0~8.0mm(0.5mm increments) Length:25~70mm(5mm increments) U-Screw(Poly-axial) Diameter:4.0~8.0mm(0.5mm increments) Length:25~70mm(5mm increments) Fixing Rod Diameter:5.0~6.0mm(0.5mm increments) Length:40~200/300/500mm(5mm increments)

AF/RF series spinal system	AF: Reduction Screw Diameter:3.0~8.0mm(0.5mm increments) Length:6~80mm(2mm increments) Fixing Rod Diameter:3.0~7.0mm(0.1mm increments) Length:30~240mm(5mm increments) 250~600mm(50mm increments) Setscrew Crosslink(Transverse connector) Diameter:3.0~7.0mm(0.1mm increments) Laminar hook Height:4.0~6.0mm(0.5mm increments) Length:14–16mm(0.5mm increments) Occipital plates Length:20~40mm RF: U–Screw(Mono–axial) Diameter:3.0~8.0mm(0.5mm increments) Length:25~70mm(5mm increments) U–Screw(Poly–axial) Diameter:3.0~8.0mm(0.5mm increments) Length:25~60mm(5mm increments) Fixing Rod Diameter:4.0~6.0mm(0.1mm increments) Length:40~300/400/500/600mm(5mm increments) Crosslink
Anterior cervical system	Anterior Cervical Plate 4Holes,6Hole,8Holes,10Holes Anterior Vertebral Screw Diameter:3.5,4.0,5.0mm

Laminoplasty system	Laminoplasty Plate Height:10~18mm(2mm increments) Laminoplasty Screw Diameter:2.0,2.5,3.0mm Length:4~12mm(2mm increments)

4. Intended Use

The General Spine System is used for spinal Internal fixation.

5. Indication

The General Spine System is used for thoracolumbar fractures, spondylolisthesis and lumbar instability, etc.

6.Contraindications

a) Abnormal bone structure.
b) Abnormal root canal anatomy.
c) Serious mental disorder or Severe osteoporosis.
d) Allergic to metal.

7. Complications

a) Dural rupture and nerve injury.
b) The discomfort or pain caused by the implant.
c) Infection, metal allergy or rejection.
d) The nonunion or delayed union caused the implant to loosen or even break.

8.Notes

a) The delivery status of the spinal internal fixation system is non-sterilization, and the sterilization cycle is 30 minutes for 121℃.

b) Preoperative examination of packaging integrity shall be performed. The implants damage during the operation, shall not be used continuously.

c) The Doctors should evaluated the patients conditions such as: weight, occupation, activity intensity, mental status, foreign body allergy preoperative, and decision if the patients applicable to use the products; if applicable, should be according to the patient's own situation, choose the applicable specifications of products, before surgery prepare the different types and specifications of products.

d) Unless explicitly stated in the design permit and technical manual, the implant is not processed or changed in any way, avoiding the modification, bending or scratching of the product contour to prevent product failure.

e) The doctor should realize the risk and limitation of the product and the operation, and let the patients known the importance of the doctor's advice before the operation.

f) Surgeons should be qualified, and familiar with the product implantation technology, use of related surgical instruments。

g) Scratches and bending of the products during the operation procedure will affect their service life.

h) The internal fixation is unable to bear alone the normal body weight. Early activity or heavy load may lead to implant loosening, dislocation or fracture if the patient do not follow the doctor's advice.

i) The time to remove the implants should be determined by the rehabilitation of the patients after surgery, and it is generally about 12 months after surgery.

j) The X-ray examination should be done regularly after the operation, follow the doctor's advice

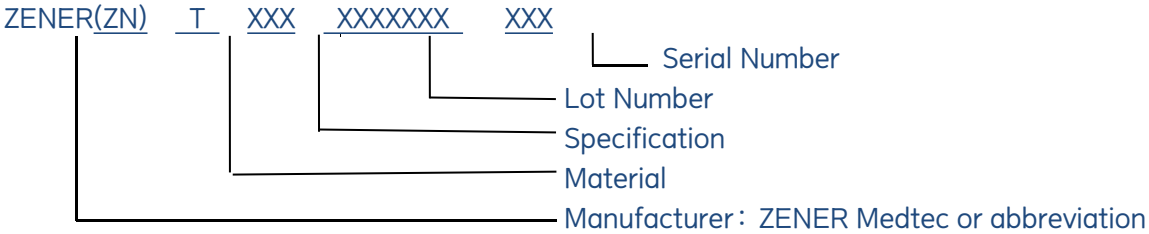
9.Warning

a)The product is for single-use, not reusable.

b) No heavy load before the trauma site was completing healing.

10. Packaging Identification

10.1Packaging Identification:



10.2 The packaging provides at least following information:

a) Manufacturer name, address, trademark

b) European representatives name, address

c) CE identification and code of Notified Body

d) Material name or represent

e) Product name, model and specification

f) Sterilization valid period(or non sterile product warning information)

g) "Do not reuse" should be marked

h) Lot number and date of production

11. Application Methods

Detailed preoperative planning is demanded according to symptoms and signs of patient and imaging examination. The full range of surgical instruments must be confirmed.

Operation should be under general anesthesia with endotracheal intubation. Choose the right position and incision. Expose the vertebral segments need fixation to do parallel drilling and tapping.

Select the appropriate specifications and types of Z MIS,Z6,Z5, AF/RF series spinal system(Reduction screw,U-screws, fixing rods, crosslink, set screw etc.), Anterior cervical system(Anterior cervical plate and Anterior Vertebral Screw),Laminoplasty system(Laminoplasty plate,Laminoplasty screw). Install internal fixation system in the reduction of spondylolisthesis or fracture, and the operation procedure refers to "*Orthopaedic Surgery*".

12. Storage Condition.

If the implants are scratched and be collision during transportation and operation, it would weaken the strength and fatigue resistance performance, so it is necessary to properly maintain and use the implant, otherwise, there will be risks cannot be ignored.

The implant should be stored in the relative humidity of no more than 80%, no corrosive gas and well ventilated indoor。

13. Service Life

The Internal fixation is the main load before bone fracture healing. The implants should be removed after one year when the fracture is healed. Otherwise, the risk of re-fracture may happen if the doctor's advice is not followed.

14. Revision Date: September 22, 2023