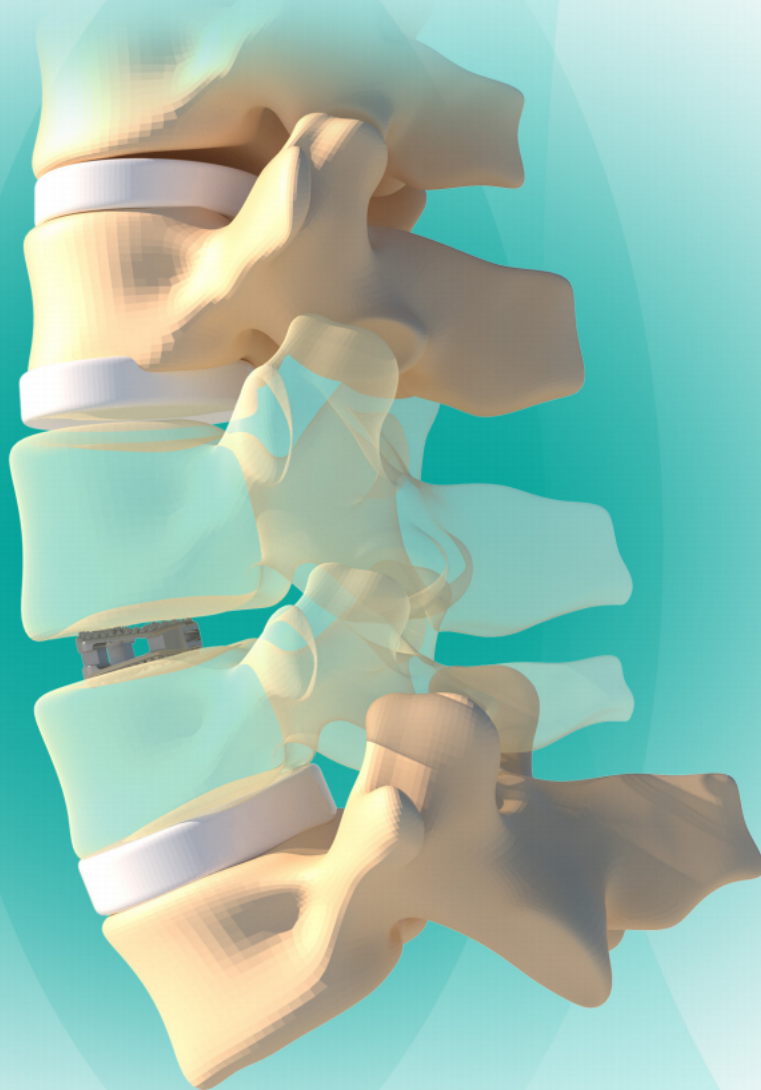


Anterior Lumbar Interbody Fusion Cage

Operation Manual





Why choose Fule?

Our Advantages

- The company is a national high-tech enterprise integrating research and development, production and sales of medical devices, with full intelligent processing equipment production line.
- Academician expert studio was established to help Fule improve its R&D capabilities and further deepen production-study-research cooperation; Approved postdoctoral research station.
- With complete hardware facilities, excellent research and development team, and close cooperation with clinical experts, we have obtained more than 100 domestic and foreign patents.
- Based on the agent cooperation model, the company has established a nationwide sales and service network, and its products are supplied to nearly 1,000 third-class A hospitals throughout the country and exported to more than 20 overseas countries.



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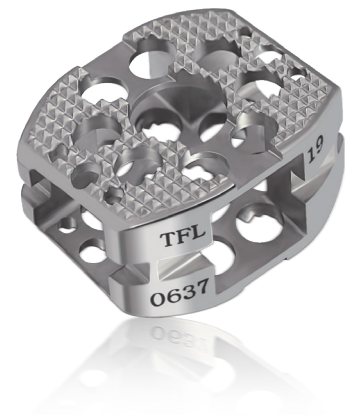


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Product Advantage

- Its wedge-shaped design with a high front and low back helps to restore lordosis and rebuild vertebral height.
- The large contact area between the upper and lower parts greatly reduces the incidence of settlement;
- Dentate protrusions on the upper and lower surfaces reduce the incidence of post-implantation displacement;
- Four sizes and models are available to ensure the smooth operation of a wide range of surgical cases.
- Made of high-strength titanium alloy, with MRI/CT compatibility;
- The design of multiple holes and the design of large holes at the top and bottom promote the fusion of Cage and bone tissue;



Instructions for use

● **【Indications】**

- Lumbar and lumbosacral disc disease and instability;
- Revision surgery for post-discectomy syndrome;
- Pseudarthrosis after fusion surgery;
- Degenerative or isthmus fissure-type slippage

● **【Contraindications】**

- Fracture of the spine;
- Spinal tumors;
- Severe spinal instability;
- Primary spinal deformity;

Surgical Procedure

【Step 1】 Access and fenestration

- Depending on the lesion segment and physician practice, an anterior or anterolateral approach may be chosen, exposing the area of the desired width for implantation after adequate retraction of the surrounding vessels and soft tissues. (Figure 1a).
- A rectangular window of the same width as the Cage is made in the anterior ligament and annulus fibrosus, and the size of the window is measured with the Cage spectroid.

The following illustrations are all from artists who are not in the industry, and are only to illustrate the use process and precautions of the product, and cannot be used as a reference for anatomy.



Fig.1a

Surgical Procedure

【Step 2】 Stretch out the segments and process the endplate

- The diseased vertebral body is stretched open to restore the normal intervertebral height, and the midline of the opener should be aligned with the midline of the vertebral body to ensure proper implantation of the Cage. After manually pressurizing the brace, tighten the nut at the end of the handle to fully open the intervertebral space and hold it that way (Fig. 2a).
- Through the window, the cartilage on the surface of the intervertebral disc and vertebral endplate is removed by using instruments such as periosteal strippings, elbow curettes, and ring curettes. Adequate curettage of the cartilage layer is essential for the blood supply and eventual fusion of the bone graft, but excessive curettage can weaken the strength of endplate.



Fig. 2a

Surgical Procedure

【Step 3】 Select the shape and size of the inner implant subject

- According to the model obtained from the preoperative measurement of the film, clamp the corresponding test body with wrenches (Fig. 3a), then slide into the intervertebral space along the anterior lumbar spreader, if the model is not suitable, select the larger or smaller test body and try again until the test body is completely attached between the two endplates in the intervertebral space, at which point the anterior lumbar spreader can be temporarily released to graft bone into the Cage (Fig. 3b).

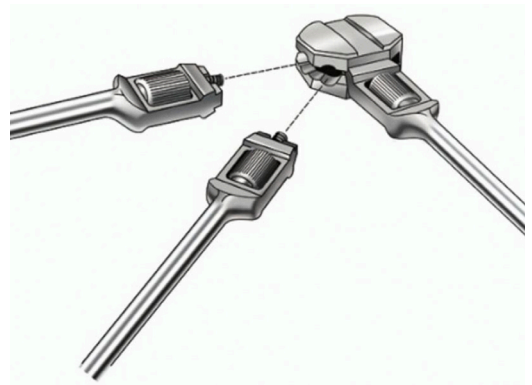


Fig. 3a



Fig. 3b

Surgical Procedure

【Step 4】

Choice of extracting forcep

- The selected Cage is locked onto the extracting forcep, and the Cage is 1 mm larger than the test body of the same size. (Fig. 4a).

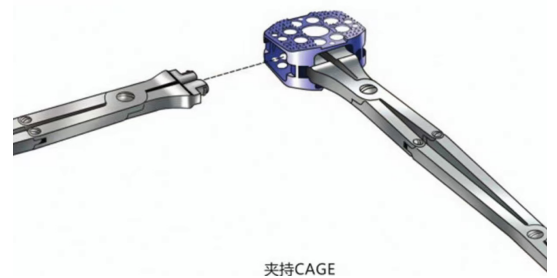


Fig. 4a

Surgical Procedure

【Step 5】

Fill and compact the grafted bone

- Place the Cage in a bone grafting instrument (compaction box), implant the pre-prepared autologous bone or artificial bone through the anterior or lateral hole of the Cage, and finally compact with the bone grafting instrument (compactor) until the autologous or artificial bone escapes from the hole (Fig. 5a).

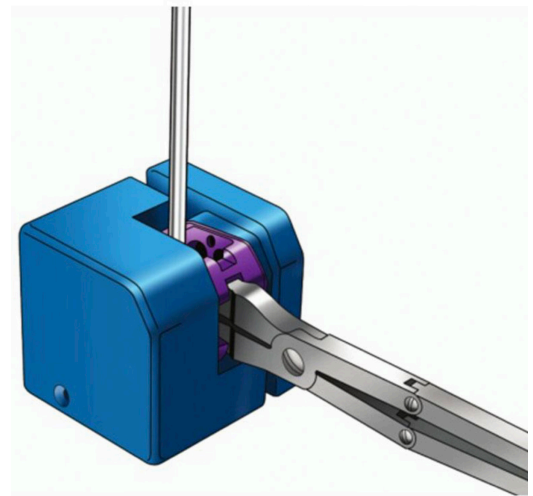


Fig. 5a

Surgical Procedure

【Step 6】

Implanted inside the implants

- Stretch it out again and slide the Cage along the anterior lumbar spreader into the intervertebral space up to 4 mm medial to the anterior edge of the vertebral body. At the same time, its midline should be aligned with the midline of the vertebral body. If the implantation depth is not enough, you can remove the extracting forcecep and gently tap the cage clamping area until the cage is completely in place. (Fig. 6a).

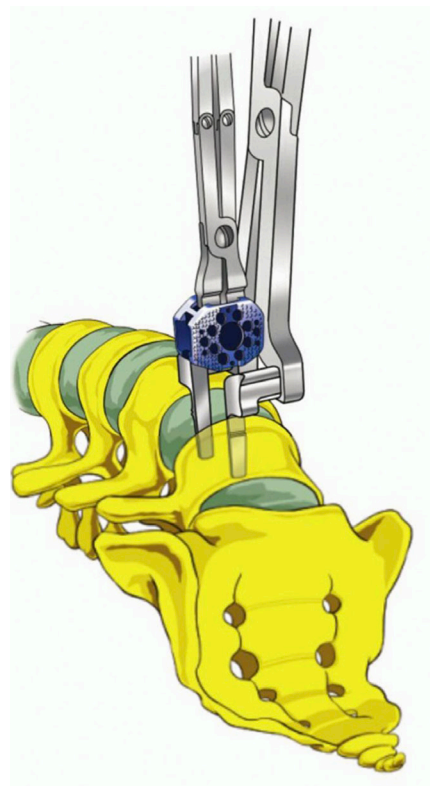


Fig. 6a

Surgical Procedure

【Step 7】

Fluoroscopy inspection, release the stretch

- After implantation, the implant placement is examined by X-ray fluoroscopy, and the anterior lumbar spreader is removed once the position is confirmed to be accurate (Fig. 7a).

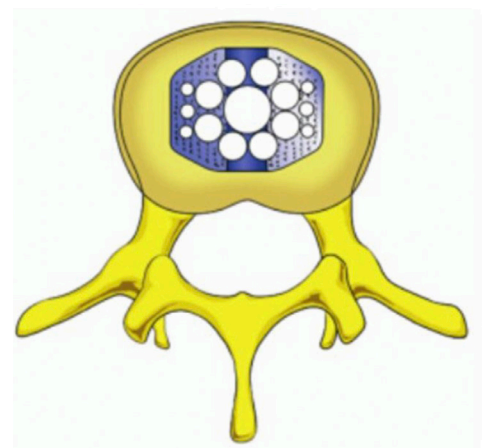


Fig. 7a

Product Information

● 【Anterior Lumbar Interbody Fusion Cage】



| Description | Angle | Thickness | Length | Width | Product Code |
|----------------|-------|-----------|--------|-------|--------------|
| 25 × 30 × 13.5 | 11° | 13.5 | 30 | 25 | 100301000 |
| 25 × 30 × 13.5 | 11° | 15 | 30 | 25 | 100302000 |
| 25 × 30 × 13.5 | 11° | 17 | 30 | 25 | 100303000 |
| 25 × 30 × 13.5 | 11° | 19 | 30 | 25 | 100304000 |

Instrument information



● 301-016
Ring curette



● 301-022/023
Periosteal stripping (silicone stem)



● 303-096
Elbow curette



● 301-050
Anterior lumbar spreader



● 301-060
Wrench (straight type - test mold)



● 301-081
Wrench (bent - test mold)



● 301-091
Bone grafting instrument (compactor)



● 301-101
Bone grafting instrument (compaction box)

Instrument information



● 301-110~301-113

Anterior lumbar fusion cage test body



● 301-120

Extracting forcep (bent type)