

颈椎前路 椎间融合器

(楔形、弧形)

操作手册

Anterior Cervical Titanium
Cage (Wedge/Arc)
Technical Manual



Why Choose Fule? Fule advantage

- Beijing Fule is a national high-tech enterprise integrating R&D, production and sales of medical equipment, and has a production line of fully intelligent processing equipment.
- The academician expert studio was established to help Fule improve its research and development capabilities, and further deepen the cooperation of production-academy-research; it was approved as a post-doctoral research station.
- The hardware facilities are complete, the R&D team is excellent, and the clinical experts work closely with more than one hundred domestic and foreign patents.
- Based on the agent cooperation model, it has established a nationwide sales and service network, and its products are supplied to nearly a thousand tertiary hospitals across the country and exported to more than 20 overseas countries.

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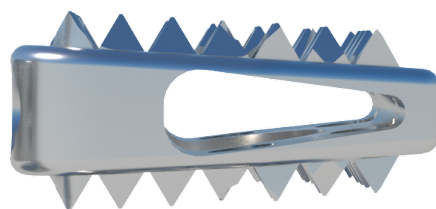
Products Advantage

- Two different shapes are designed to accommodate different cervical endplates

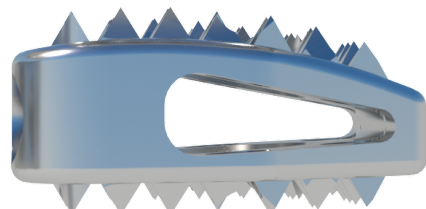
- Arc shape for health end plate
- Wedge shape for degenerative endplate

- The system completely simulates the anatomical structure design of vertebral endplate and ensures the stability of intervertebral height.

- There are 18 specifications in two shapes to choose from, ensuring the smooth operation of all kinds of cases.



Wedge



Arc

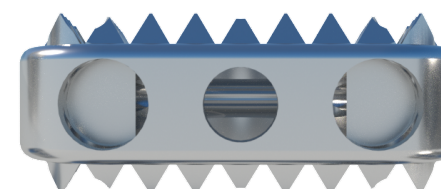
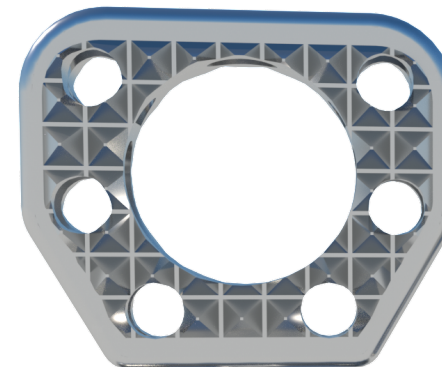
Products Advantage

- The dentate protrusion of the upper and lower surfaces can reduce the displacement after implantation.

- The larger contact area between the top and bottom greatly reduces the incidence of settlement.

- Made of high strength titanium alloy, with MRI/CT compatibility.

- The design of multiple holes and larger holes at the top and bottom promotes the fusion of Cage and bone tissue.



IFU

● 【Indications】

Ruptured or herniated cervical disc;
 Degenerative disease or instability of the cervical disc;
 Pseudojoint formation after joint fusion;

● 【Contraindications】

Cervical vertebra fracture;
 Cervical tumor;
 Severe osteoporosis;
 Severe instability;
 Spinal cord infection;

Surgical Technical

【Step 1】 Expose and remove the nucleus pulposus

- Anterolateral incision of the neck, cervical disc and adjacent vertebral body were exposed(1a)
- A 15 mm wide window was cut on the anterior ligament and fibrous ring in front of the intervertebral disc, through which the nucleus pulposus was cleaned. It should be noted that the anterior ligament and annular fibrous tissue should be preserved as much as possible during the fenestration process, which has a good stabilizing effect on the Cage after implantation.

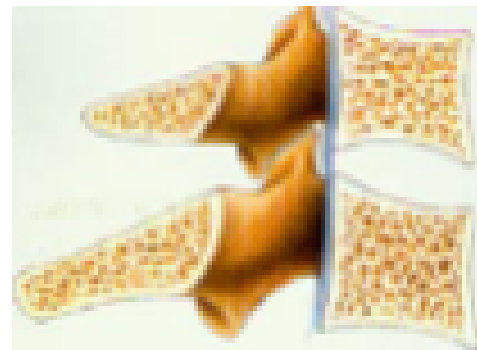


1a

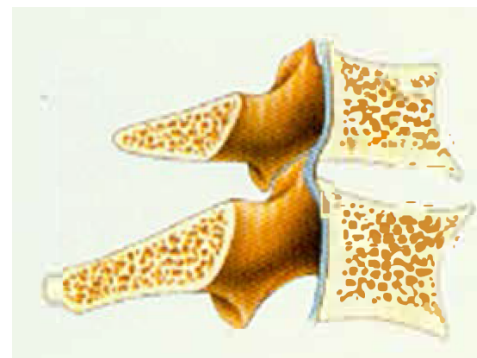
Surgical Technical

【Step 2】 Distract the segments and dispose the endplate

- The diseased vertebra is split to restore normal intervertebral height and the conical foramen is opened. A distraction operation can be performed to estimate whether satisfactory endplate treatment can be performed in the intervertebral space.
- The cartilage on the surface of the intervertebral disc and vertebral end plate was cleaned by means of instruments such as stripper, elbow curette and ring curette. The ultimate goal of the endplate treatment is to protect the hard subchondral layer and natural shape of the vertebral body and reduce the probability of subsidence. Proper handling is also important for blood supply to grafted bone.



2a



2b

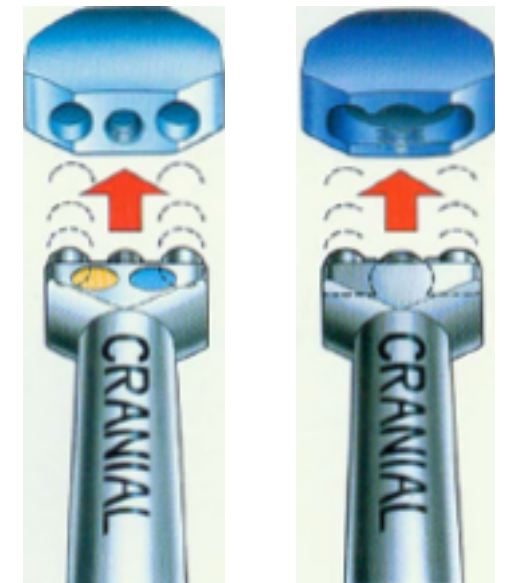
- Curved shape for health endplates (2A)
- Wedge shape for degenerative endplate (2b)

Surgical Technical

【Step 3】 Choose the shape and size of the cage trail

- According to the height of the intervertebral disc measured before the operation and the shape of the endplate observed during the operation, an appropriate height of curved or wedge test body was selected.

(Arc Cage is suitable for the healthy end plate, and the arc protrusions should be upward when installed; wedge Cage is suitable for the degenerative end plate, without positive or negative difference) (3a).

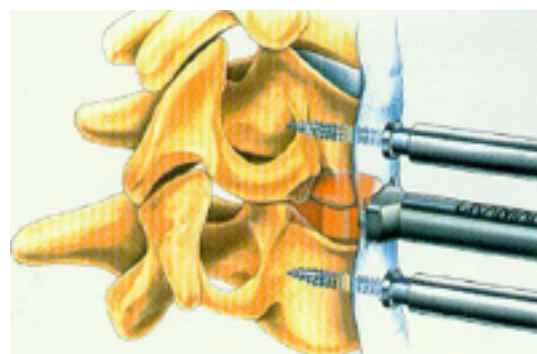


3a

Surgical Technical

【Step 4】 Selection of Insertor

- The trail was implanted into the intervertebral space, and its position and matching degree with the upper and lower endplates were examined by fluoroscopy. If the first trail was not closely matched with the upper and lower endplates, an additional number should be added for a second test (4a).
- Due to the tension of the ligament and annulus fibrosus, the Cage as large as possible must be used to ensure the intervertebral height, and the depth limit block is used to ensure the implantation depth. The leading edge of the Cage is 2mm from the anterior edge of the vertebral body.



4a

(Cage 4.0~6.5 with insertor (small))

Cage 7.0 ~10 with insertor (large)

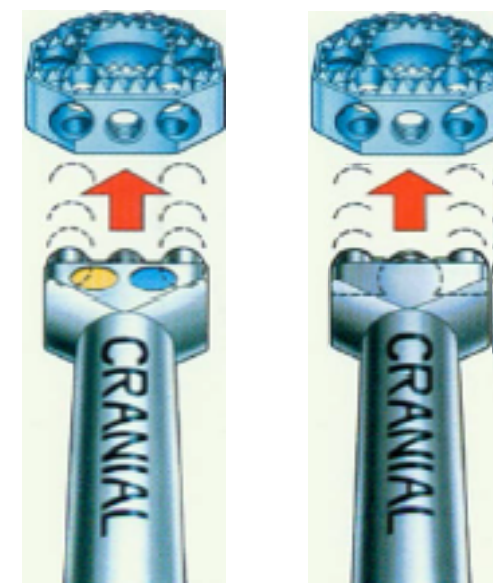
Note: After determining the size of the cage, the trail must be removed from the human body.

Surgical Technical

【Step 5】 Choose the size of the cage

- According to the size of the trail, an appropriate Cage was selected and locked on the insertor (5a).

Note When Cage is locked on the insertor, it should be ensured that the end face of Cage is corresponding to the end face of the insertor. The Cage was 1.5 m larger than the trail.

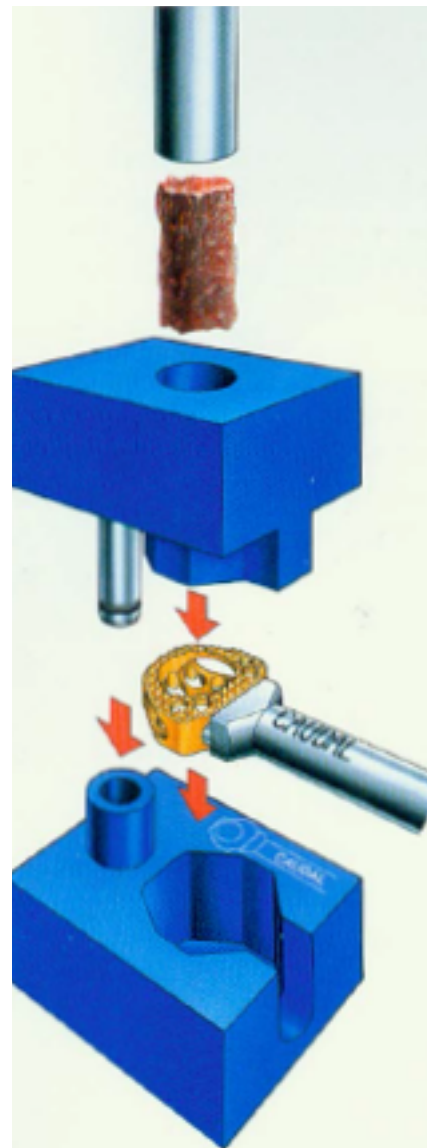


5a

Surgical Technical

【Step 6】 The graft was filled and compacted

- The Cage was placed in the Packing Block, and the autologous bone fragments or artificial bones prepared in advance were placed in the round hole above the Cage. The autologous bone or artificial bone was fully compacted with the Impactor until the autologous bone or human bone spilled out from multiple holes, so as to ensure sufficient blood supply for the transplanted bone (6a)

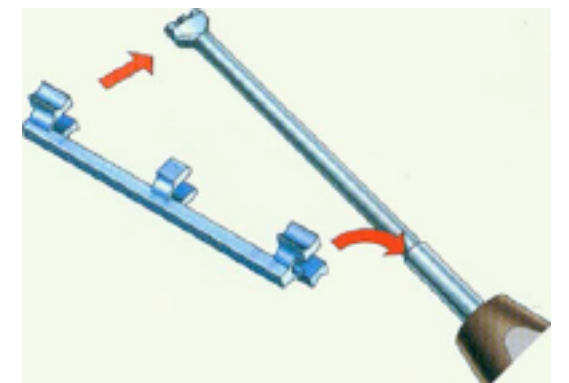


6a

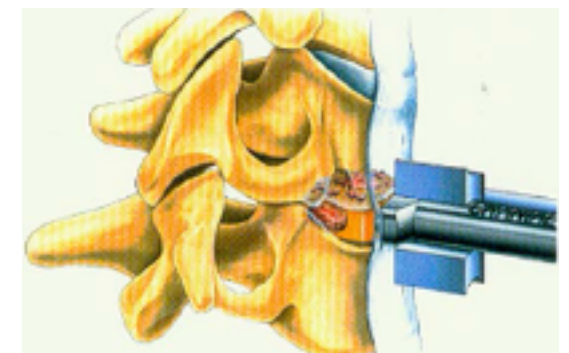
Surgical Technical

【Step 7】 Cage implantation

- The depth limiter can be installed on either side of the insertor and ensure that the insertor is in the correct position (7a)
- The Cage, which had already been boned, was carefully inserted into the managed intervertebral space with the vertebrae stretched (7b)



7a



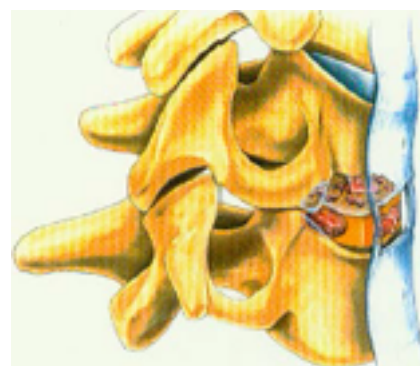
7b

Attention should be paid to ensure the best placement position. The leading edge of C age should be 2mm inside the anterior edge of the vertebral body, and the midline should be aligned with the midline of the vertebral body. At the same time, the depth limiting device can ensure that implantation will not be too deep.

Surgical Technical

【Step 8】 Choose an appropriate internal fixation device

- The distractor is removed after the segment is detached (8a)
- Select appropriate internal fixation devices to increase segmental stability, such as anterior cervical plate.



8a

Product Information

● 【Wedge Cage】



Size	Angle	Thickness	Length	Width	Code
12.5 × 15 × 4	7°	4	15	12.7	100101000
12.5 × 15 × 4.5	7°	4.5	15	12.7	100102000
12.5 × 15 × 5	7°	5	15	12.7	100103000
12.5 × 15 × 5.5	7°	5.5	15	12.7	100104000
12.5 × 15 × 6	7°	6	15	12.7	100105000
12.5 × 15 × 6.5	7°	6.5	15	12.7	100106000
12.5 × 15 × 7	7°	7	15	12.7	100117000
12.5 × 15 × 8.5	7°	8.5	15	12.7	100118000
12.5 × 15 × 10	7°	10	15	12.7	100119000

● 【Arc Cage】



Size	Angle	Thickness	Length	Width	Code
12.5 × 15 × 4	7°	4	15	12.7	100201000
12.5 × 15 × 4.5	7°	4.5	15	12.7	100202000
12.5 × 15 × 5	7°	5	15	12.7	100203000
12.5 × 15 × 5.5	7°	5.5	15	12.7	100204000
12.5 × 15 × 6	7°	6	15	12.7	100205000
12.5 × 15 × 6.5	7°	6.5	15	12.7	100206000
12.5 × 15 × 7	7°	7	15	12.7	100207000
12.5 × 15 × 8.5	7°	8.5	15	12.7	100208000
12.5 × 15 × 10	7°	10	15	12.7	100209000

Instruments



● 302-012
Insertor
(small)



● 302-022
Insertor
(large)



● 302-031
Impactor



● 302-041
Packing Block



● 201-010
Cervical Distractor



● 311-180
Pin Holder



● 311-170
Pin



● 302-076/086
Ring Curette $\phi 2/\phi 3$

Instruments



● 302-081
Elevator



● 302-096
Bent Curette $\phi 3/\phi 9$