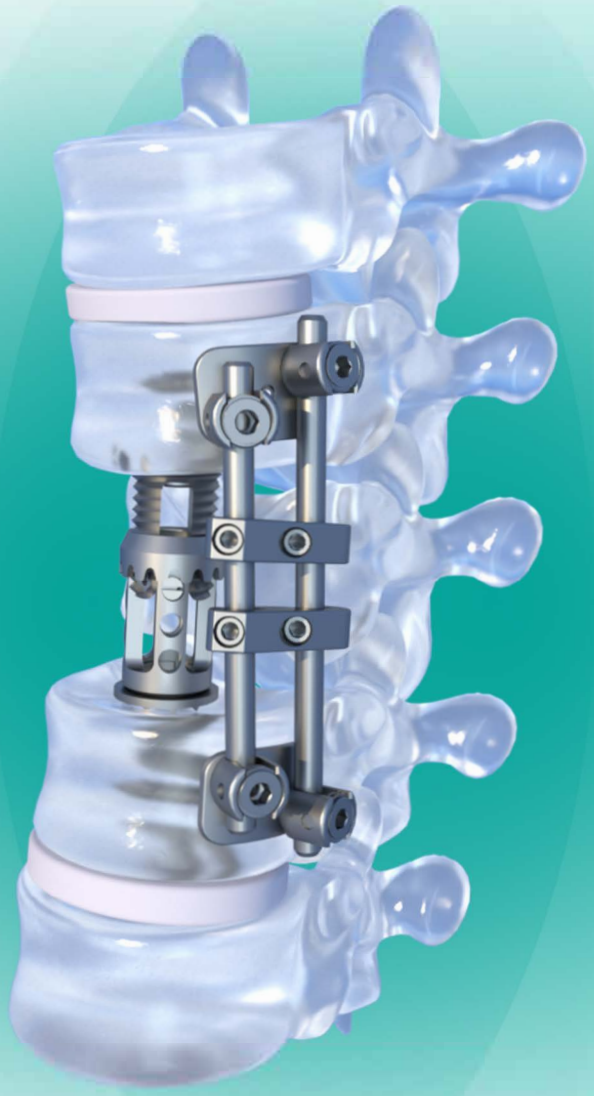
# FAVA Artificial Vertebral Body

## Technical Manual



Fule 富乐

专注骨科事业

## 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.

# Contents

# Products Advantage

- The height of distraction can be adjusted arbitrarily.
(19-24,23-30,29-42,32-48,47-63,63-78)

- Larger contact area between upper and lower end cap, tooth-like protrusions, to ensure stable anchoring

- Diameter: Φ18mm,

  Angle of end cap: 0° ,3° ,8°

  NOTE: The angled end cap options are interchangeable to allow the operator to construct 0°, 3°, 6°, 8°, 11°, and 16° prosthetic configurations.

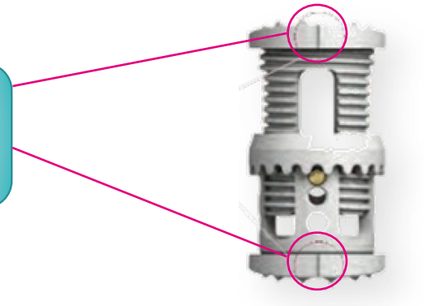




# Products Advantage

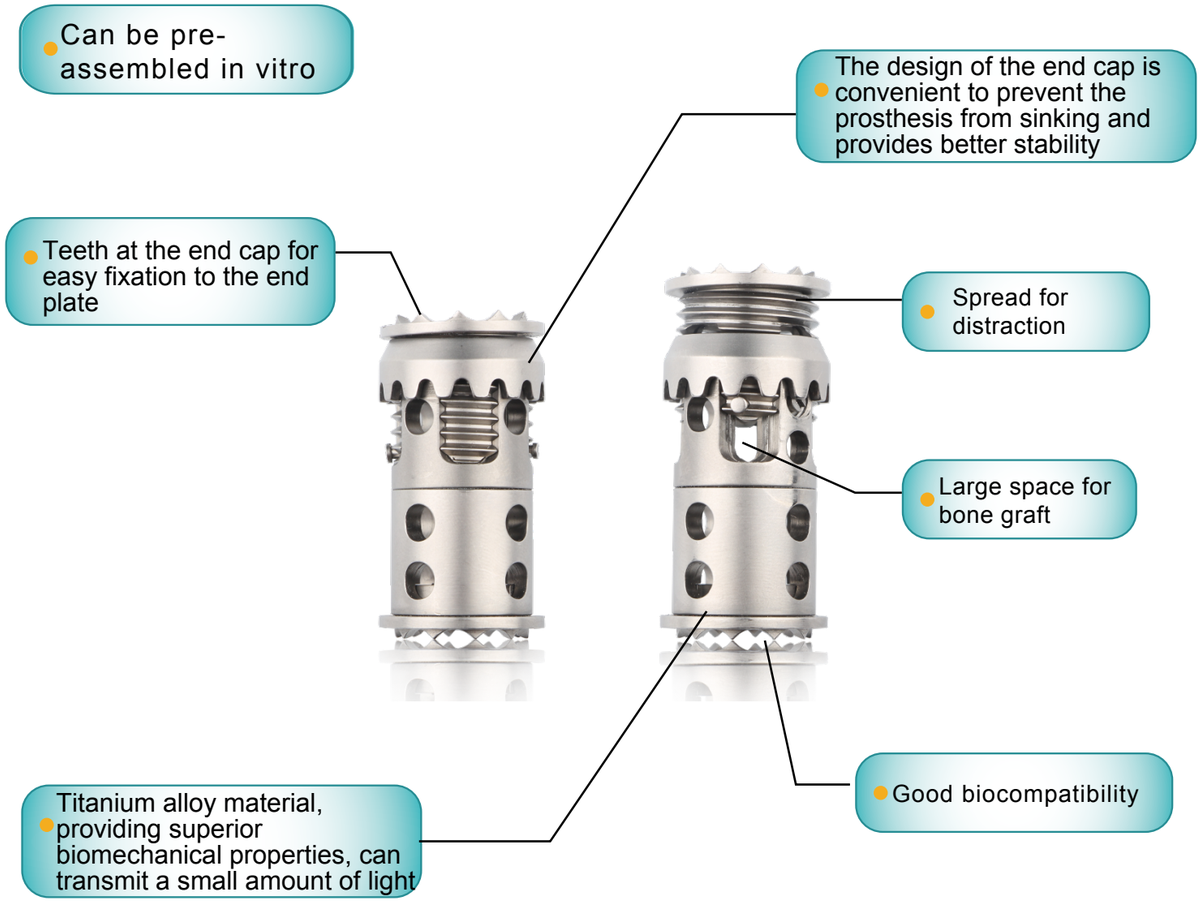
- In the thoracic region, the end cap can be rotated 180° to correct excessive thoracic kyphosis. Example using two 3° end caps

- NOTE:
  1. When using angled end caps, make sure they are oriented parallel.



- 2. Each end cap adds extra height to the vertebral body.
  0° add 3mm
  3° add 3.48mm
  8° add 5.14mm

# Products Advantage






# IFU

## 【Indications】

Multi-level spinal trauma

Multilevel vertebral tuberculosis tumor

## 【Contraindications】

Severe osteoporosis

Active infection

Combined neuromuscular disease

Allergy to Titanium

Immunosuppressive disease

# Surgical Technical

## 【Step 1】 Intraoperative position

- T1-T3 and L5 levels, anterior supine; T4-L 4, lateral position.

- Thoracic spine tumor TES: combined anterior and posterior approach is suitable for T1-T3; pure posterior approach is suitable for T3-T12; it can complete the resection of tumors from a single vertebral body to multiple consecutive vertebral bodies. Preoperative embolization facilitates intraoperative control.

- Lumbar spine tumors TES: L1-L3 can be considered a simple posterior approach; L3-L5 posterior-anterior approach combined with anterior approach surgery via abdominal or extraperitoneal, anatomical structure, nerve root profile; preoperative embolization is helpful for intraoperative Control bleeding.



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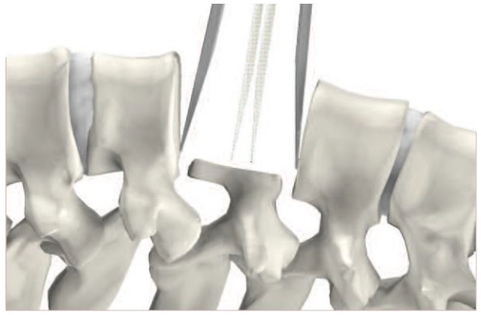
# Surgical Technical

## 【Step 2】 Measuring

- By measuring defects on a patient's film or CT scan, the right-sized implant can be determined preoperatively. It is recommended to measure from the posterior border of the inferior endplate of the vertebral body above the level of the diseased (injured) vertebra to the posterior border of the superior endplate of the vertebral body below the diseased (injured) vertebra (2a).

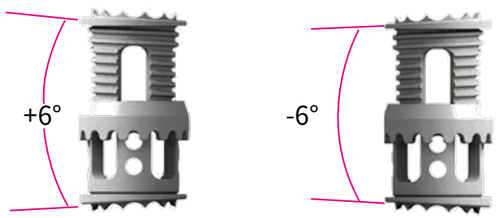


2a

# Surgical Technical

## 【Step 3】 Implant selection

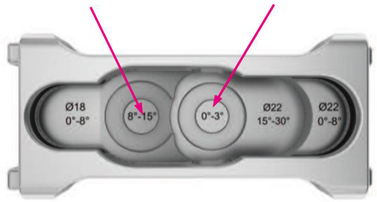
- Select the appropriate artificial vertebral body according to the measured results.




3a

- End cap angles include 0°, 3°, 8°, the end cap can be rotated 180°, and the angled end cap is suitable for lordosis or kyphosis. Preset according to the surgical site (3 a).

- Use packing block to complete the pre-installation of end caps, using different working surfaces for different angles ( 3b ).




3b





# Surgical Technical

## 【Step 4】 End cap assembly (1)

- Place the first end cap into the packing block ( 4a).

- Place the artificial vertebral body（4b）.

- Use the hammer to pound, make sure the end cap is fully installed（4c）.

4a

4b

4c

# Surgical Technical

## 【Step 5】 End cap assembly (2)

- Assemble the second end cap onto the implant construct (5a).

5a

- Choose the right angle before pounding with the pusher. The end cap pusher has two wide notches, which can be used as reference points when aligning angled end caps (5b).



5b

- A second end cap is implanted, which is placed on top of the implant construct (5c).

5c



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# Surgical Technical

## 【Step 6】 End cap assembly (3)

- L5 Vertebrectomy, Anterior Approach

  The artificial vertebral body requires the selection of a large angle lordosis (6a).

6a

- L3 Vertebrectomy, Left Anterolateral Approach

  The artificial vertebral body needs to restore lumbar lordosis (6b)

- T7 Vertebrectomy, Left Anterolateral Approach

  The artificial vertebral body is required to restore thoracic kyphosis (6c)

6b

6c

# Surgical Technical

## 【Step 7】 Bone graft

- The impactor has a knurled tip for more precise filling of the bone graft (7a).

- Before implantation of the prosthesis, it is recommended to fit additional bone particles into the opening of the upper end cap, and after assembling the two end caps, "overfill" the implant with bone graft (7b).

- The amount of pre-grafted bone can be slightly larger and flush with the end cap. Try to ensure that the bony surface is in contact with the endplate after distraction.

7a

7b



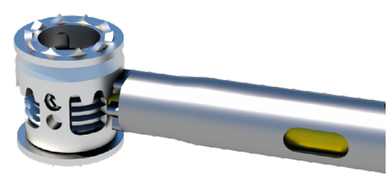


Surgical Technical

## 【Step 8】 Holder & Insertor

- Holder & Insertor is used to insert and spread the artificial vertebral body to its final height. The expansion rod has three parts: the main shaft, the inner threaded shaft and the outer hollow shaft.

The internally threaded shaft holds the implant at the end of the dilator by engaging the threaded holes of the implant (8a).



8a

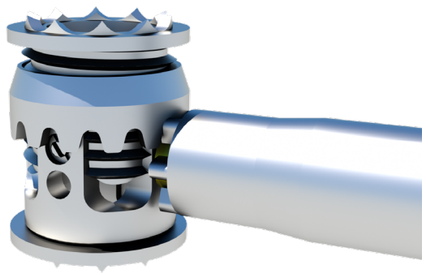
The threaded hole of the artificial vertebral body is located just below the locking screw, and the threaded hole of the implant is compatiable with the internally threaded shaft of the Insertor (8b).

8b

# Surgical Technical

## 【Step 9】 Holding

- Proper installation on the artificial vertebral body with the holder ( 9a) .



9a



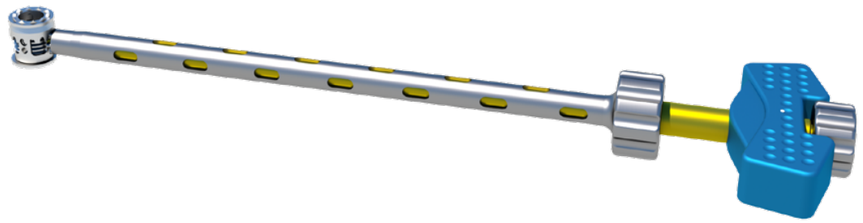


# Surgical Technical

## 【Step 10】 Distraction (1)

- By rotating the handle, the artificial vertebral body can be stretched to reach the ideal height.

10a



# Surgical Technical

## 【Step 11】 Distraction (2)

- In the process of the artificial vertebral body being distracted, once the bottom of the artificial vertebral body thread part is no longer visible, it means that the artificial vertebral body has reached its maximum distraction height and cannot be distracted excessively.

If the artificial vertebral body can not meet the surgical requirements, it is recommended to use a larger artificial vertebral body (11a).

11a



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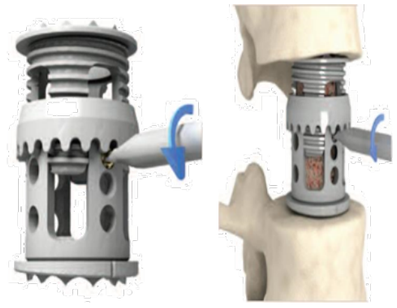
# Surgical Technical

## 【Step 12】 Final locking

- When the artificial vertebral body is distracted to a satisfactory height, it should be locked (12a).
- Use the Flat driver for locking to tighten the locking nut.

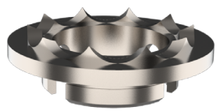


12a

# Product Information

## 【End Cap】

| Size (mm) | Angle | Product Code |
|---|---|---|
| 21×20×6.5 | 0° | 12900007 |
| 21×20×7 | 3° | 12900008 |
| 21×20×8.5 | 8° | 12900009 |



## 【Artificial Vertebral Body】

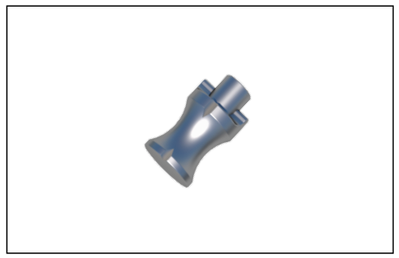
| Size (mm) | Range | Product Code |
|---|---|---|
| Φ18x19x3.0 | 19-24 | 12900001 |
| Φ18x23x3.0 | 23-30 | 12900002 |
| Φ18x29x3.0 | 29-42 | 12900003 |
| Φ18x32x3.0 | 32-48 | 12900004 |
| Φ18x47x3.0 | 47-63 | 12900005 |
| Φ18x62x3.0 | 62-78 | 12900006 |



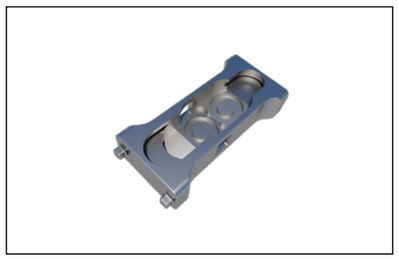


# Instruments

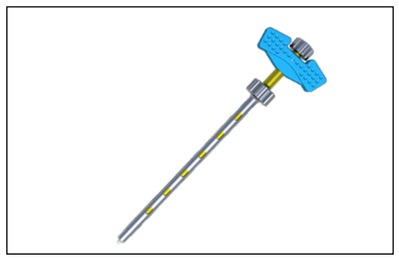
1290001
Flat Driver for Locking



1290002
Pusher for End Cap



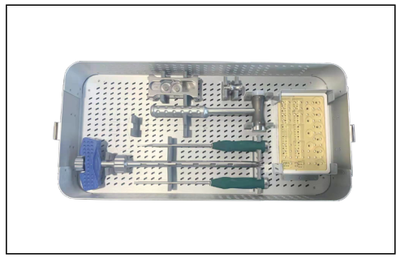
1290003
Packing Block



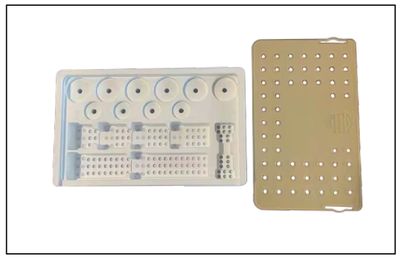
1290004
Holder & Insertor

110-420
Hammer

1290005
Impactor



Container



Cage Box