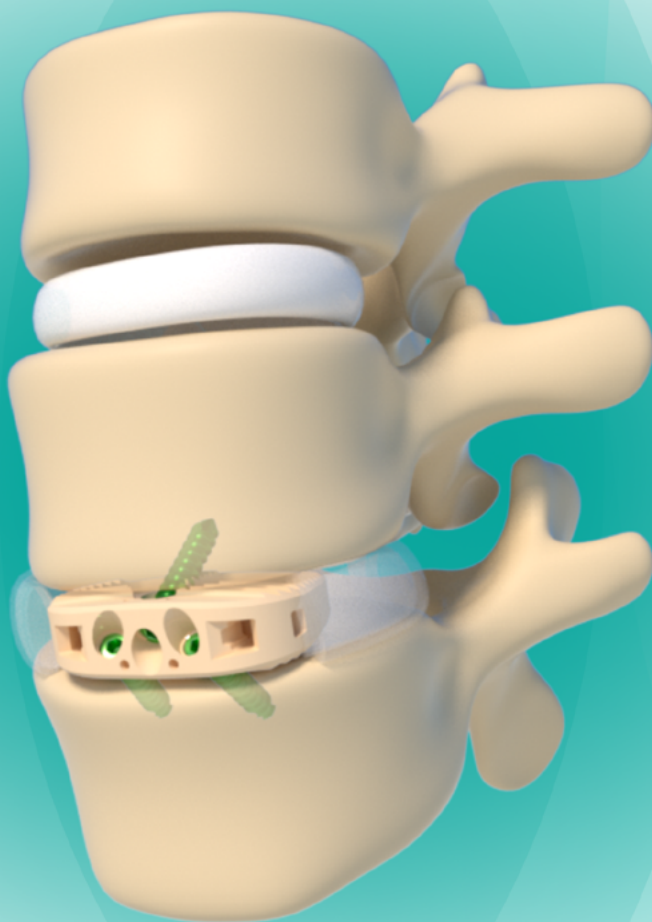


LALIF-V Cage

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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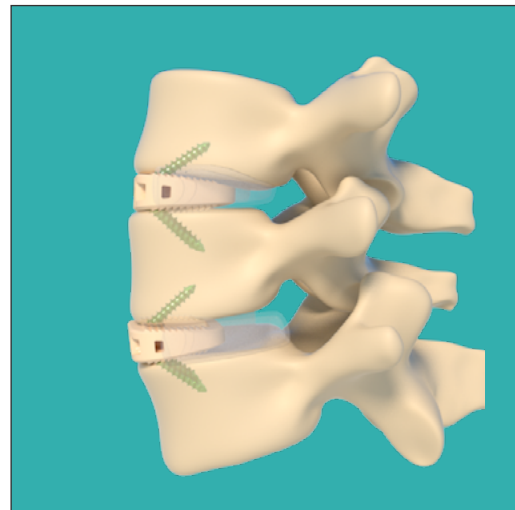
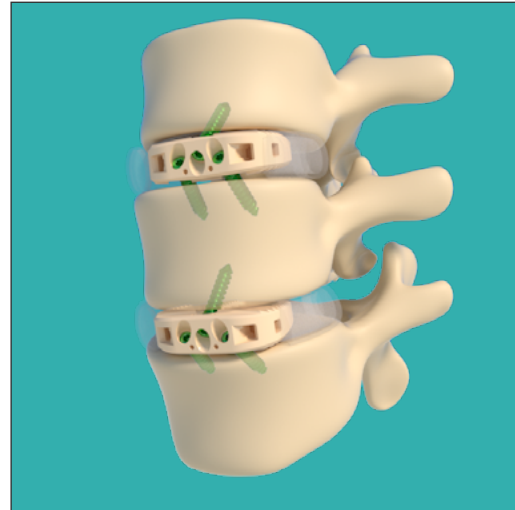
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Products Advantage

- Implant is a LALIF-V Cage, which is a radiolucent interbody fusion cage.

The design creates a zero profile construct and includes three locking screws that provide anterior fixation and stability.

- LALIF-V Cage
 - Biomechanically equivalent to a cage with pedicle screws.
 - PEEK cage provides modulus of elasticity similar to cortical bone.
 - Titanium locking screws provides stable fixation.
 - Zero-profile construct cage fit completely within the disc space.

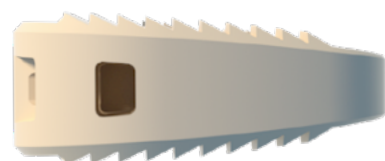
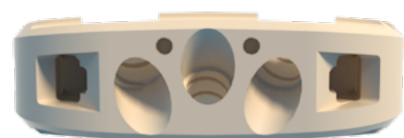


Products Advantage

- Anatomic shape

- The LALIF-V Cage is convex to match the anatomy of the disc space.

- Two footprints and two angles are offered to accommodate individual patient anatomy.



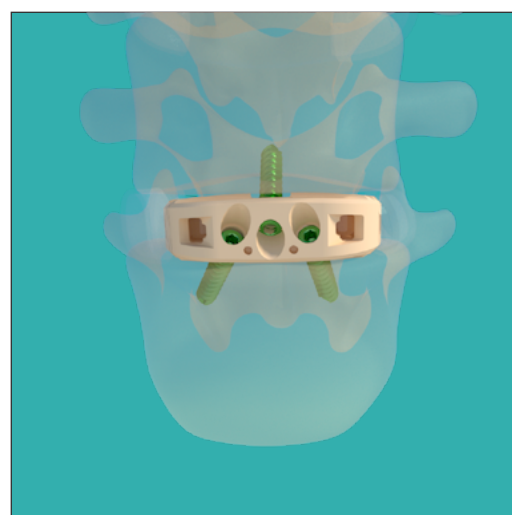
- Screw fixation

- One-step conical locking mechanism ensures screws securely lock to cage.

- Locking screws provide stability and load transfer near the cortex of the vertebral body.

- Three locking screws diverge to form a fixed-angle construct that creates a wedge of bone for fixation.

- Self-tapping cortical threads allow largest possible core diameter for maximum fixation.



IFU

- Indications

Lumbar and lumbosacral pathologies which may require anterior segmental arthrodesis, including:

- Localised symptomatic degenerative disc disease
 - Revision surgery for failed decompression syndrome
 - Pseudoarthrosis

- Contraindications

- Spinal fractures
 - Spinal tumor
 - Osteoporosis
 - Infection

Surgical Technical

Step 1. Preoperative Planning

- Preoperative planning

Determine the approximate implant size by comparing the X-ray template with a lateral radiograph of the patient's adjacent intervertebral discs.

Surgical Technical

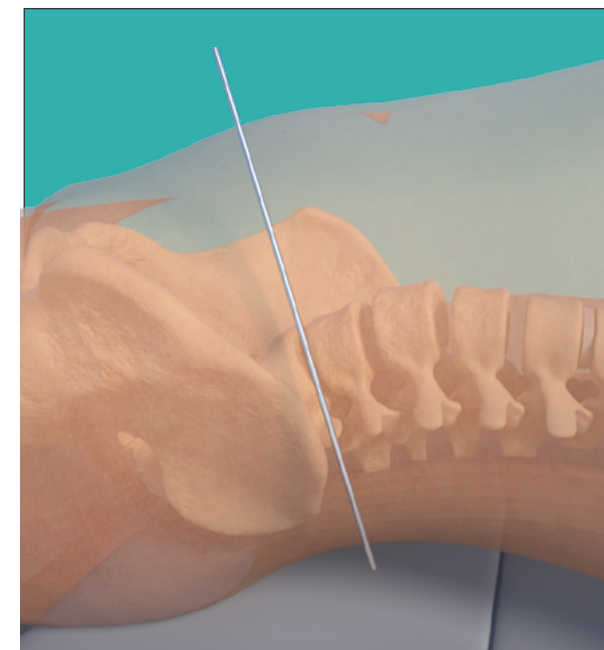
Step 2. Access and Exposure

- Patient positioning

For an anterior approach to the lower lumbar levels, position the patient in a slight Trendelenburg position

- Anterior access and approach

- Locate the correct operative disc level and incision location by taking a lateral fluoroscopic view while holding a straight metal instrument at the side of the patient. This ensures that the incision and exposure will allow direct visualization into the disc space.



Surgical Technical

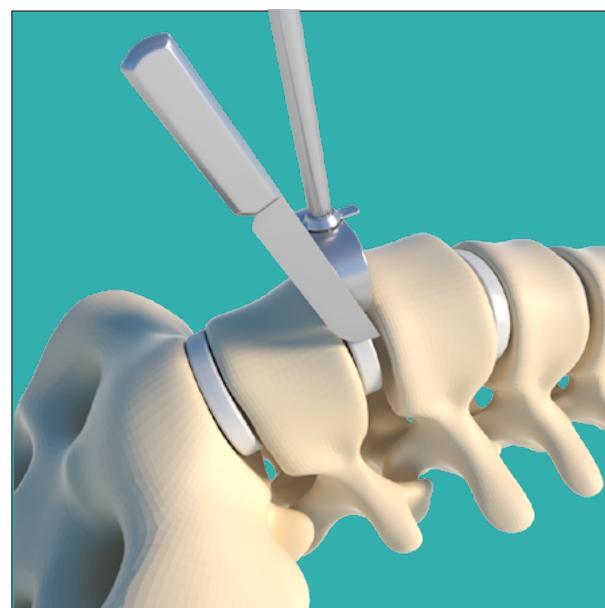
Step 3. Preparation and Trial Implantation

- Cut anterior window

Cut a rectangular window the width of the LALIF-V Cage into the anterior longitudinal ligament and annulus fibrosus.

A trial implant may be used as a template to indicate the width of the window.

Retain as much of the anterolateral, lateral and posterior annulus as possible in order to provide the necessary stability of the instrumented segment.



Surgical Technical

Step 4. Preparation and Trial Implantation

- Prepare disc space

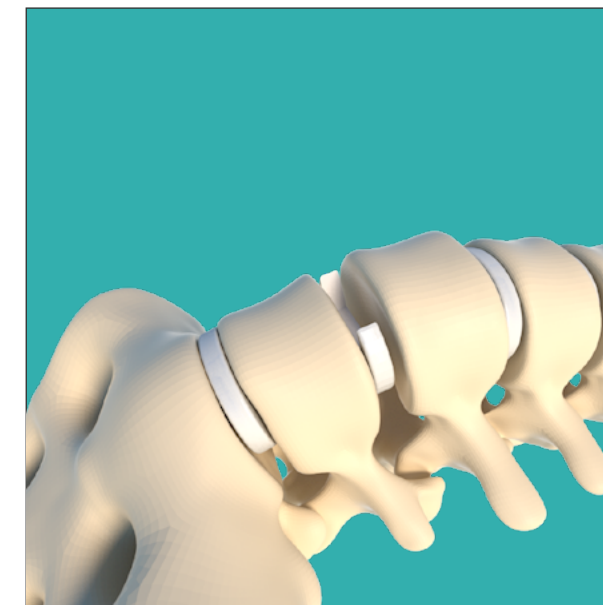
- Excise the disc material and remove the cartilaginous endplates to expose the underlying bony vertebral endplates.

Adequate clearance of the endplates is important to enable the provision of a vascular supply to the bone graft.

Excessive clearance or use of a rasp may, however, weaken the endplate and result in subsidence of the spacer.

Once the endplates have been prepared, complete eventual additional surgical procedures (i.e. removal of a disc fragment from the spinal canal).

- Note: It is essential that the nucleus and the inner annulus are removed to prevent displacement of disc material into the spinal canal during spacer insertion and interference with bone in-growth.

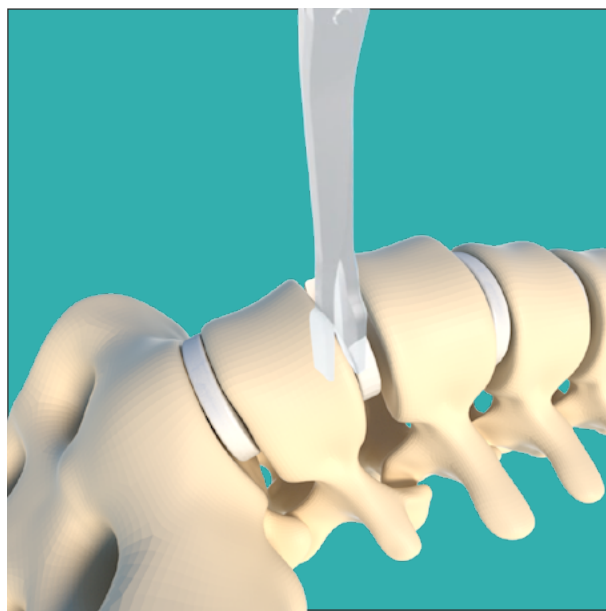


Surgical Technical

Step 5. Preparation and Trial Implantation

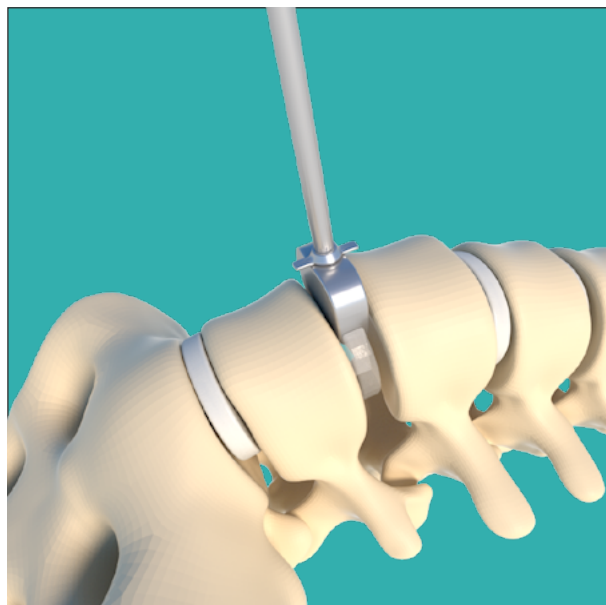
- Cut anterior window

For a safe placement, verify spreader position with the help of an intraoperative lateral X-ray. Distraction of the segment is essential for restoration of disc height, opening of the neural foramina and initial stability of the LALIF-V Cage.



- Trial for implant size

Select the trial implant that corresponds with the LALIF-V Cage size determined during the preoperative planning. Attach it to the handle for trial implants. The handle must be tightened firmly to prevent loosening of the trial implant.



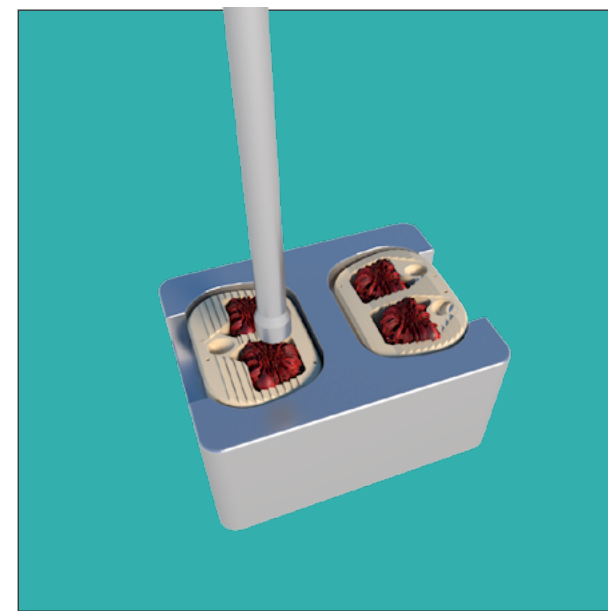
Surgical Technical

Step 6. Pack implant with bone graft or bone substitution

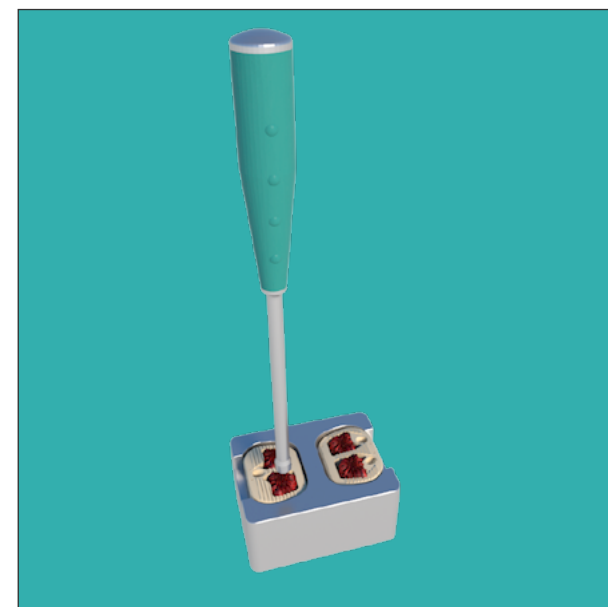
- After attaching the LALIF-V Cage to the implant holder, insert it into the appropriate packing block.

It is important to fill the cage until the filling material protrudes from its perforations in order to ensure optimal contact with the vertebral endplates.

Use a cancellous bone impactor to firmly pack the filling material into the implant cavities.



- The implant holder must be firmly attached to the cage in order to avoid damage to either the implant holder or the cage.



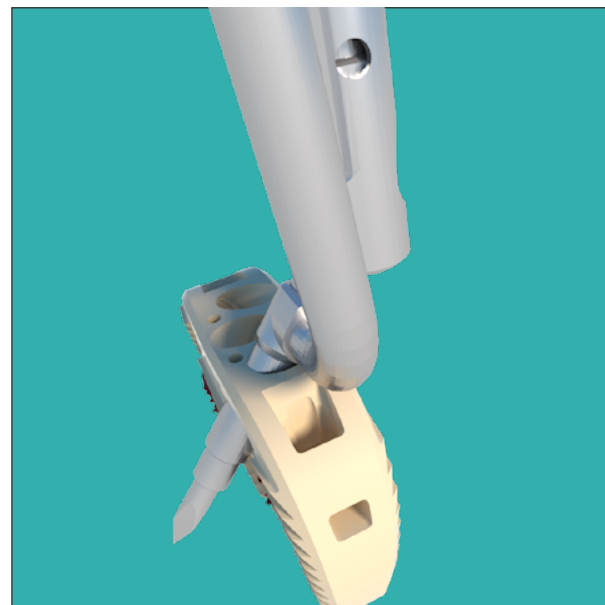
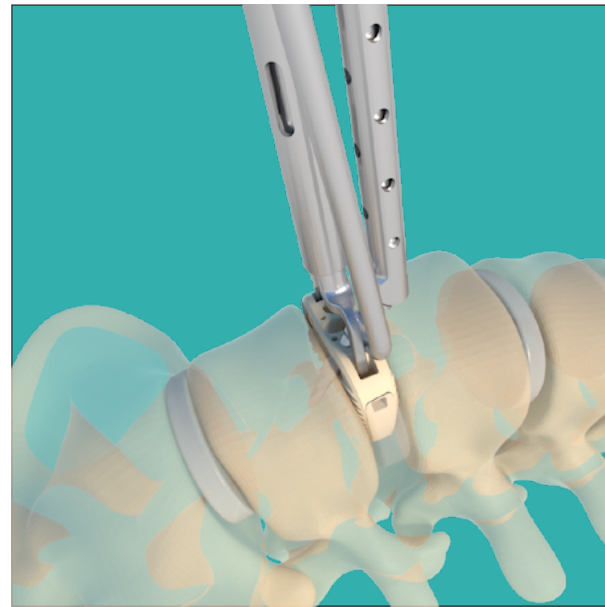
Surgical Technical

Step 7. Create pilot hole (1)

- Insert the awl into the aiming device. Prepare the vertebral body for screw insertion by applying pressure on the handle of the awl with rotational motions

Use the holder to hold the selected cage, and place the awl along the guide hole

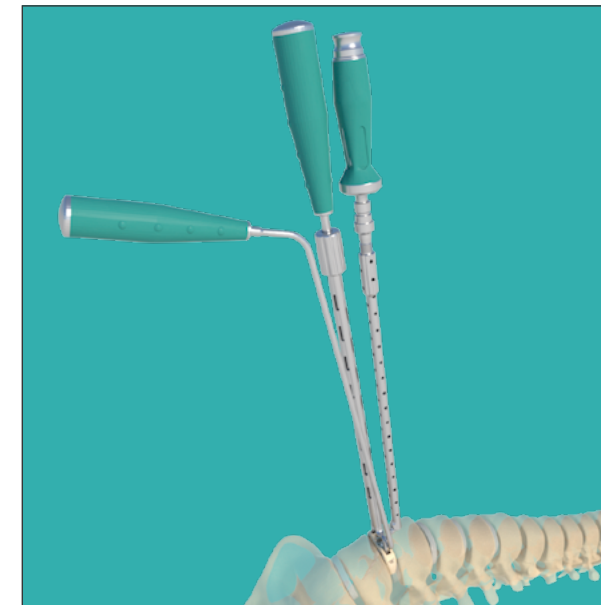
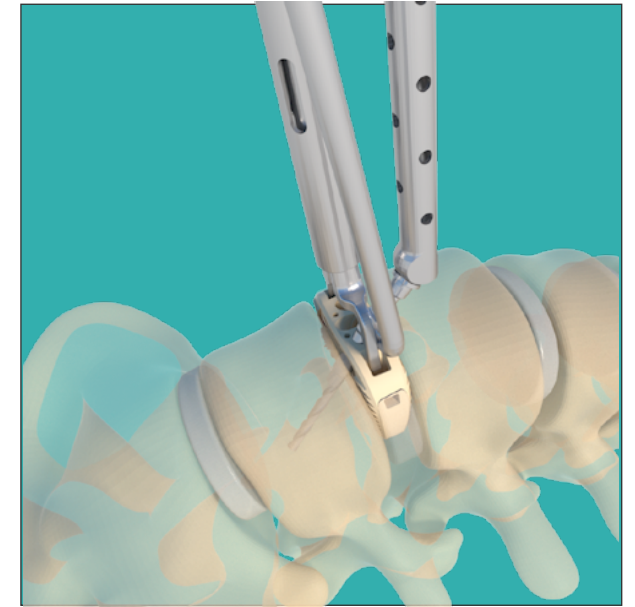
Insert the pilot drill, mate its components with the cage screw mounting holes and drill Road (recommended to install the middle screw first)



Surgical Technical

Step 8. Create pilot hole (2)

- Take out the Awl, select the appropriate length and specification drill bit along the guide, to create screw hole.

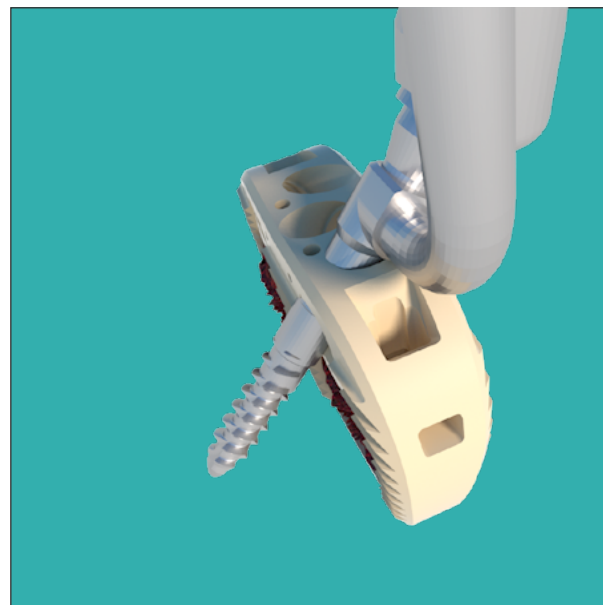
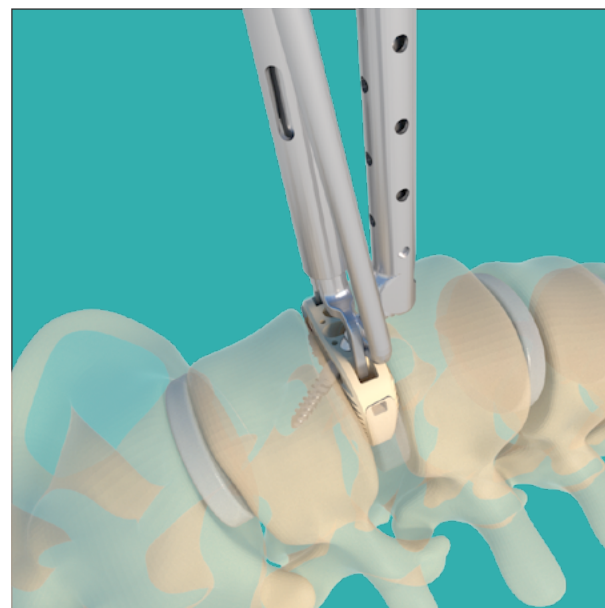


Surgical Technical

Step 9. Create pilot hole (3)

- Use the tap through the thread at the cage screw mounting hole.

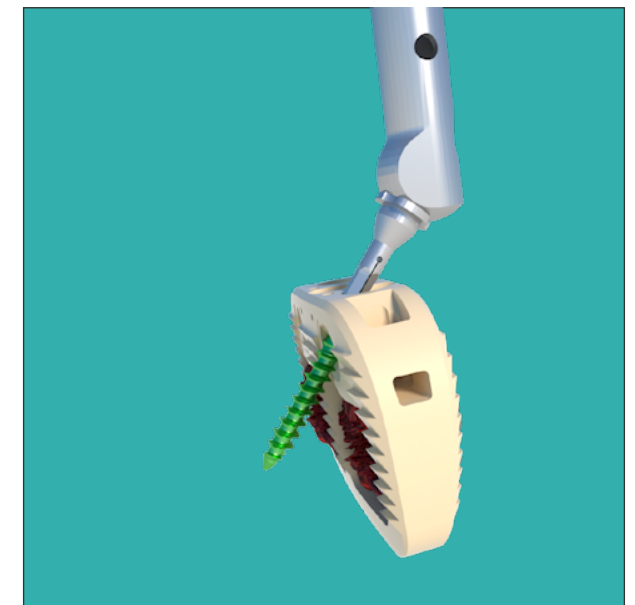
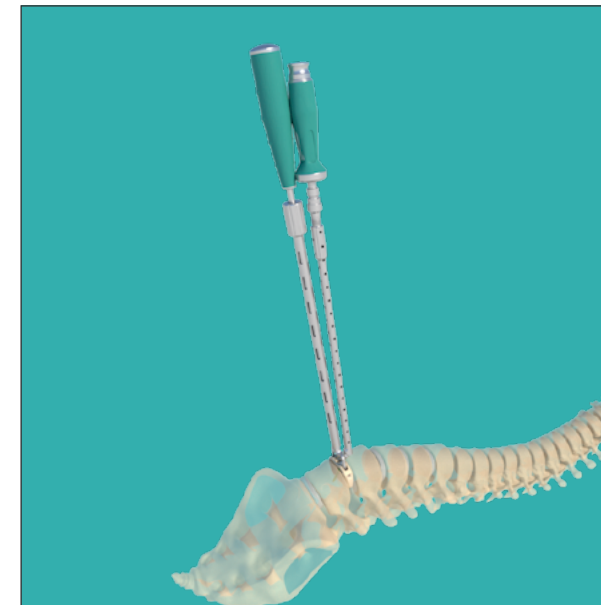
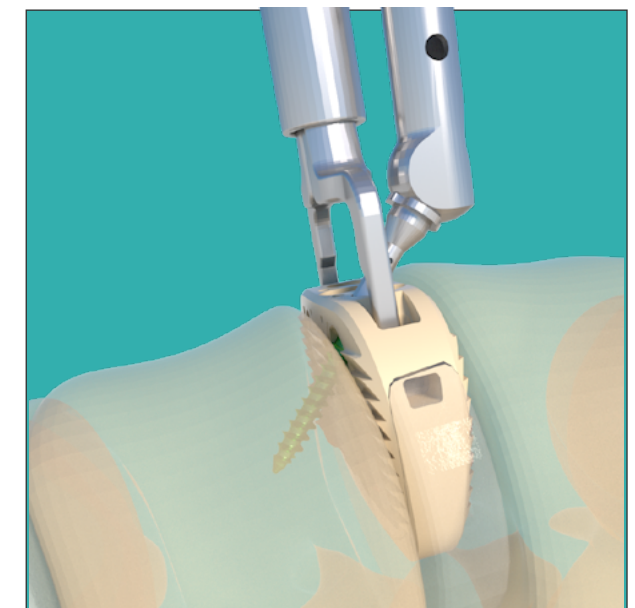
The above-mentioned establishment of the screw hole for tapping is more convenient for screw implantation.



Surgical Technical

Step 10. Screw implantation (Pre-loading)

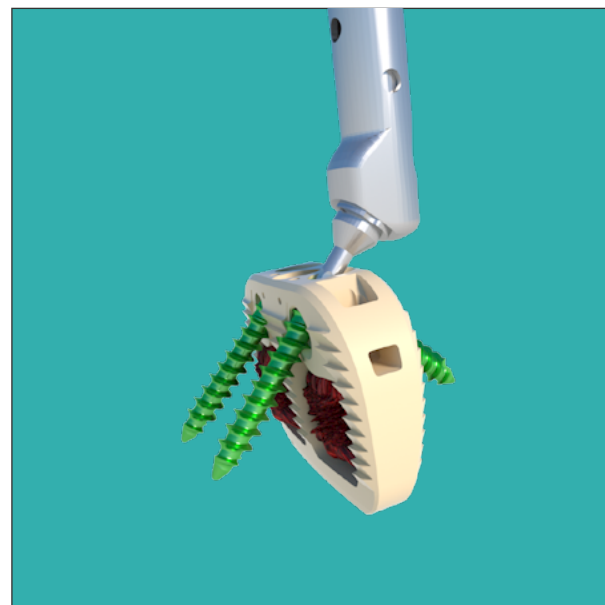
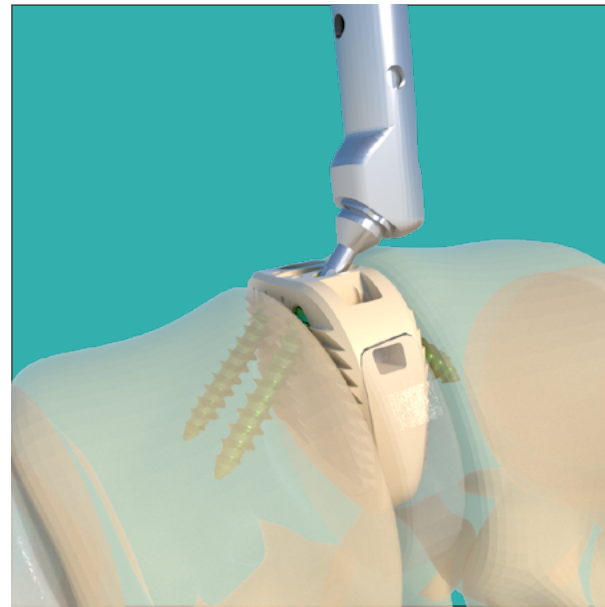
- Connect the pre-loading wrench to the quick-release handle, hold the vertebral body screws and screw them into the vertebral body along the established screw hole.



Surgical Technical

Step 11. Screw implantation (Final-tightening)

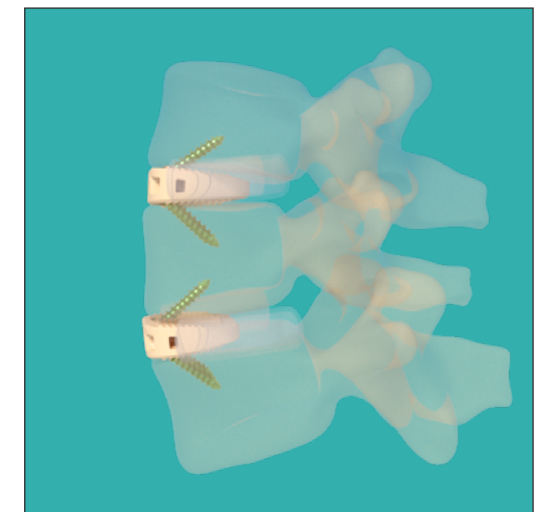
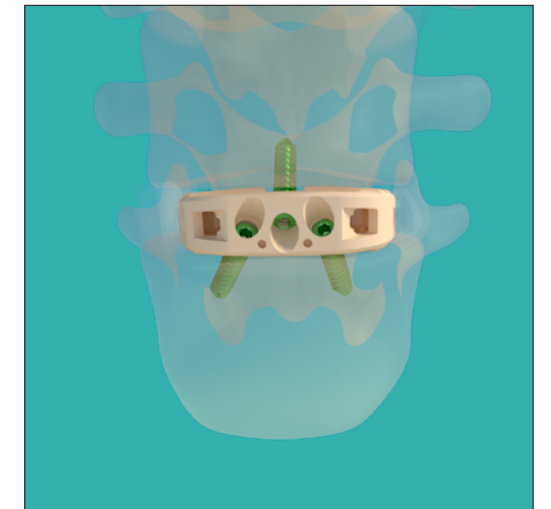
- After all the screws are implanted, connect the final screwdriver to the quick-release handle and then tighten the vertebral body screws one by one.



Surgical Technical

Step 12. Verify placement

- Through the intraoperative X-ray, the final implantation position is determined, and the operation is completed.



Product Information



LALIF-V Cage

Size (mm)	Angle	Code	Size (mm)	Angle	Code
42×31×13 6°	6°	12300034	30×26×13 9°	9°	12400220
42×31×13 10°	10°	12300035	30×26×13 12°	12°	12400221
42×31×15 6°	6°	12300036	30×26×15 9°	9°	12400222
42×31×15 10°	10°	12300037	30×26×15 12°	12°	12400223
42×31×17 6°	6°	12300038	30×26×17 9°	9°	12400224
42×31×17 10°	10°	12300039	30×26×17 12°	12°	12400225
42×31×13 9°	9°	12400213	42×31×13 6°	6°	92100180
42×31×13 12°	12°	12400214	42×31×13 10°	10°	92100181
42×31×15 9°	9°	12400215	42×31×15 6°	6°	92100182
42×31×15 12°	12°	12400216	42×31×15 10°	10°	92100183
42×31×17 9°	9°	12400217	42×31×17 6°	6°	92100184
42×31×17 12°	12°	12400218	42×31×17 10°	10°	92100185

【Screws】

Size (mm)	Diameter	Length	Code
φ5.0×24	φ5.0	24	12100022
φ5.0×29	φ5.0	29	12100023
φ5.0×34	φ5.0	34	12100024



Instruments

Cage Holder
1230044



Drill Guide
1230045



Tap

Size (mm)	Diameter	Length	Code
Φ5.0×25	Φ5.0	25	1230046
Φ5.0×30	Φ5.0	30	1230048
Φ5.0×35	Φ5.0	35	1230049



Drill Bit

Size (mm)	Diameter	Length	Code
Φ3.0×25	Φ3	25	1230050
Φ3.0×30	Φ3	30	1230051
Φ3.0×35	Φ3	35	1230052



Awl
1230053



Instruments

● Screwdriver
1230054



● Screwdriver (Straight)
1230055



● Cage Trial



Size (mm)	Height	Angle	Code
11 6°	11	6°	1230056
11 10°	11	10°	1230057
13 6°	13	6°	1230058
13 10°	13	10°	1230059
15 6°	15	6°	1230060
15 10°	15	10°	1230061

● Wrench for Cardan Tools
1230047



Instruments

● Quick-Release Handle
102205



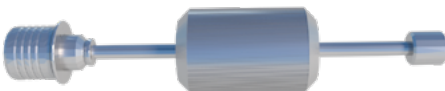
● Packing Block
1230063



● Pre-loading Wrench
1230064



● Slide Hammer
315082



● Handle
102205

