

Luna® XD and Orbit™

Interbody Device and Discectomy System
Surgical Technique

An **MIS Ultra®** Solution



The Posterior ALIF Solution.



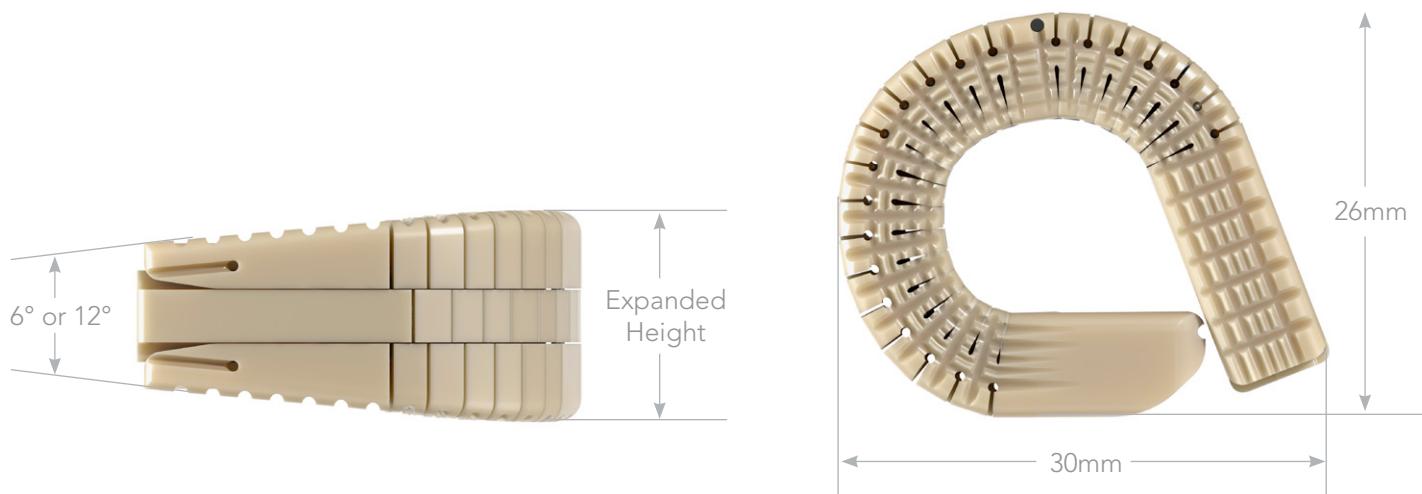
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Product Description

Luna XD Implant

The Luna XD Implant is a circular teardrop shaped device made from polyetheretherketone, with a nitinol spine and tantalum markers. The Luna XD Implant is designed for placement in the disc space to form a columnar support and an enclosure for the placement of bone graft. Luna XD is implanted posteriorly, typically via a PLIF or TLIF approach. Although Luna XD is inserted through a 7mm wide cannula, its unique multi-expandable design deploys the implant into a final footprint configuration of 26mm x 30mm, more closely resembling the footprint of an ALIF cage.



Luna XD Sizing

Catalog #	Lordosis	Cannula Height x Width	Initial Height Posterior/Anterior	Expanded Height Posterior/Anterior
LUN20006-10	6°	8mm x 7mm	5 / 7mm	8 / 10mm
LUN20006-12	6°	10mm x 7mm	7 / 9mm	10 / 12mm
LUN20006-14	6°	12mm x 7mm	9 / 11mm	12 / 14mm
LUN20012-12	12°	10mm x 7mm	5 / 9mm	8 / 12mm
LUN20012-14	12°	10mm x 7mm	5 / 9mm	10 / 14mm
LUN20012-16	12°	12mm x 7mm	7 / 11mm	12 / 16mm

*Mica, Michael Conti, et al. (2017). Biomechanics of an Expandable Lumbar Interbody Fusion Cage Deployed Through Transforaminal Approach. International Journal of Spine Surgery, 11(4), 24. doi:10.14444/4024.

Product Description continued

Luna XD Inserter and Graft Injector

The Luna XD Interbody Fusion System consists of the Luna XD Implant and associated accessories (disposable, single-use and re-usable) for use in lumbar fusion procedures to treat degenerative disc disease. The single-use Luna XD Inserter is used to place the Luna XD Implant, and is provided sterile.

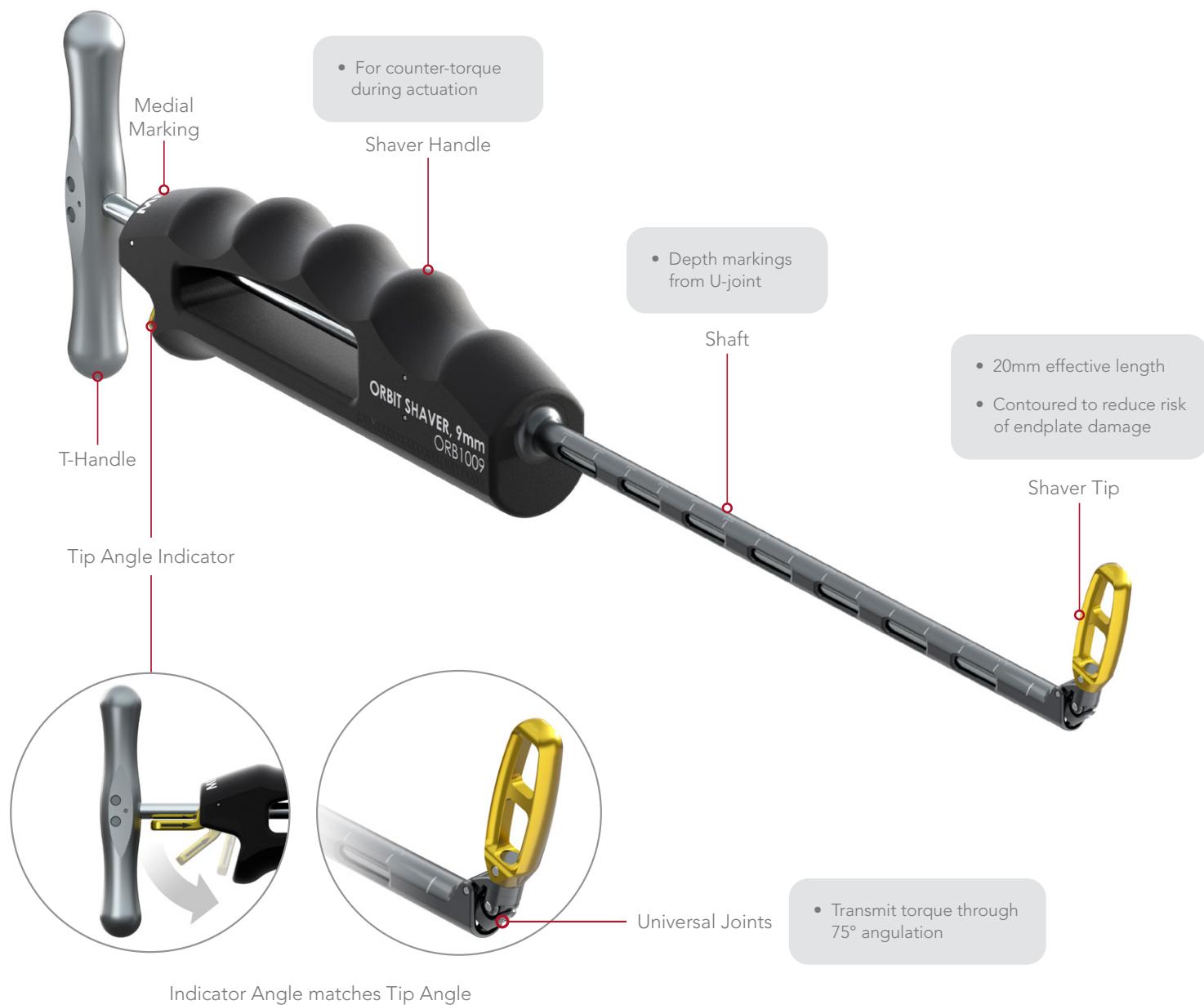
The single-use Luna XD Graft Injector is intended for delivering bone graft to the central enclosure of the Luna XD Implant post-expansion, and is provided sterile. The Luna XD Reusable Accessories, which include the SureGuide Graft Access, Middle Extraction System, and Inserter Ejector Tool are provided non-sterile in a sterilization tray.



Product Description continued

Orbit

The Orbit Discectomy Instrument set are reusable instruments intended to facilitate a complete discectomy in preparation for an intervertebral fusion surgery. The instruments are manufactured from stainless steel and aluminum.



Step 1: Patient Positioning

Position the patient prone on the operating table. Ensure that A/P and Lateral radiographic images of the target level can be easily obtained during the procedure (Fig. 1).

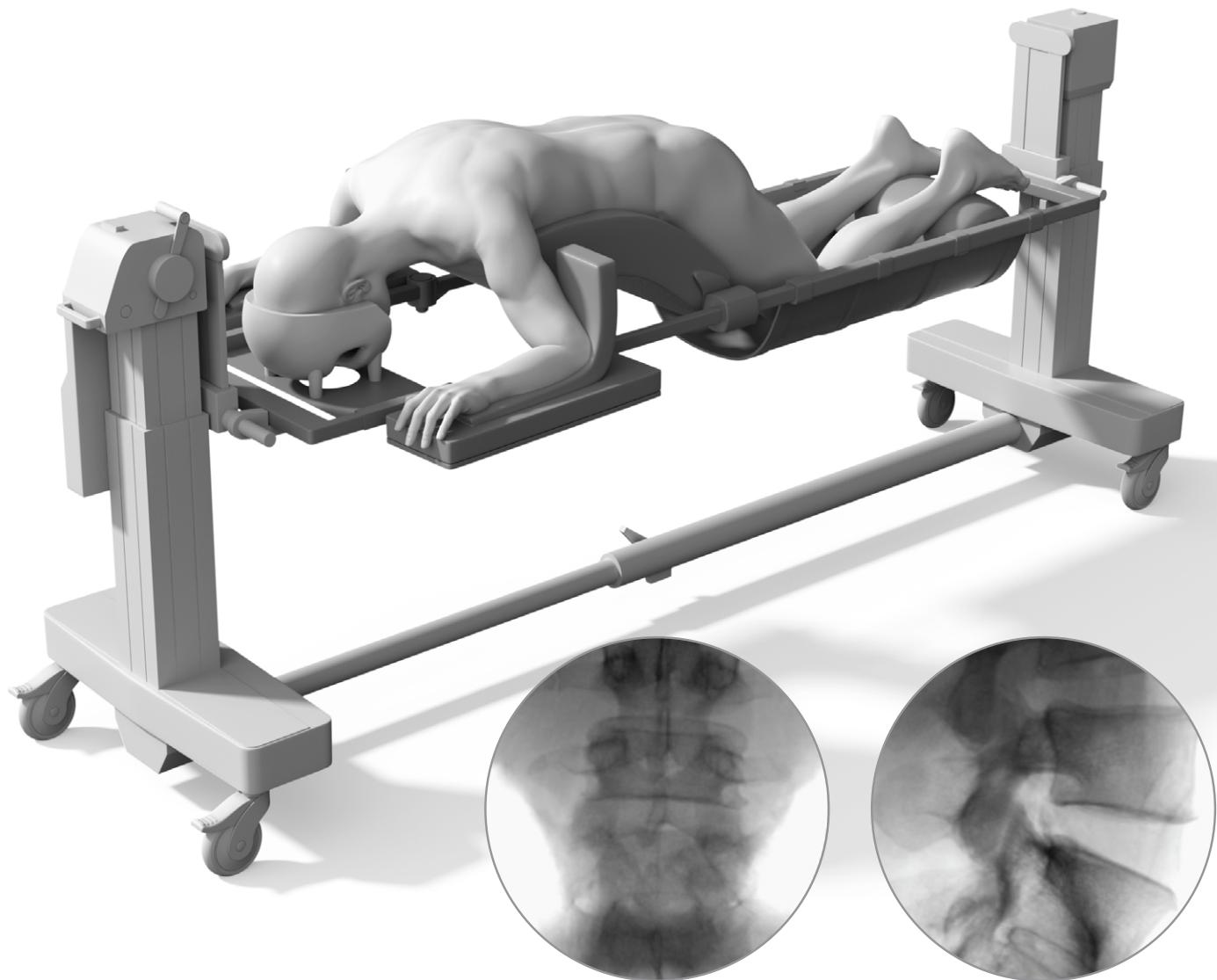


Fig. 1

Step 2: Surgical Access

Perform a skin incision and use a muscle-splitting technique to gain access to the appropriate ipsilateral facet joint. Use standard methods for gaining Transforaminal Lumbar Interbody Fusion (TLIF) access to the disc and perform a decompression until a working space is exposed at the inferomedial aspect of the neural foramen (Fig. 2).

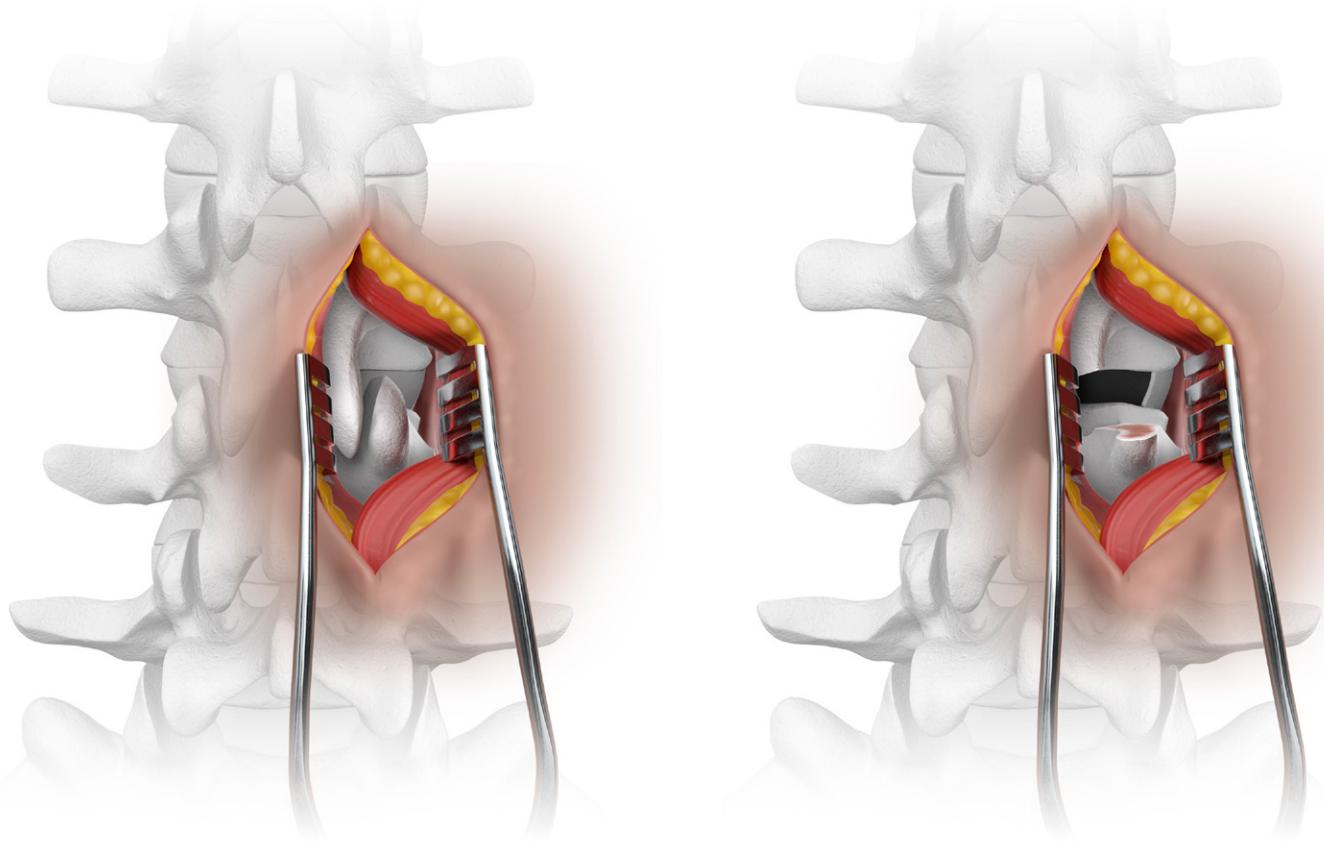


Fig. 2

Step 2: Surgical Access continued

The Luna XD implant is designed for a TLIF approach that is between 15° and 30° off midline (Fig. 3).

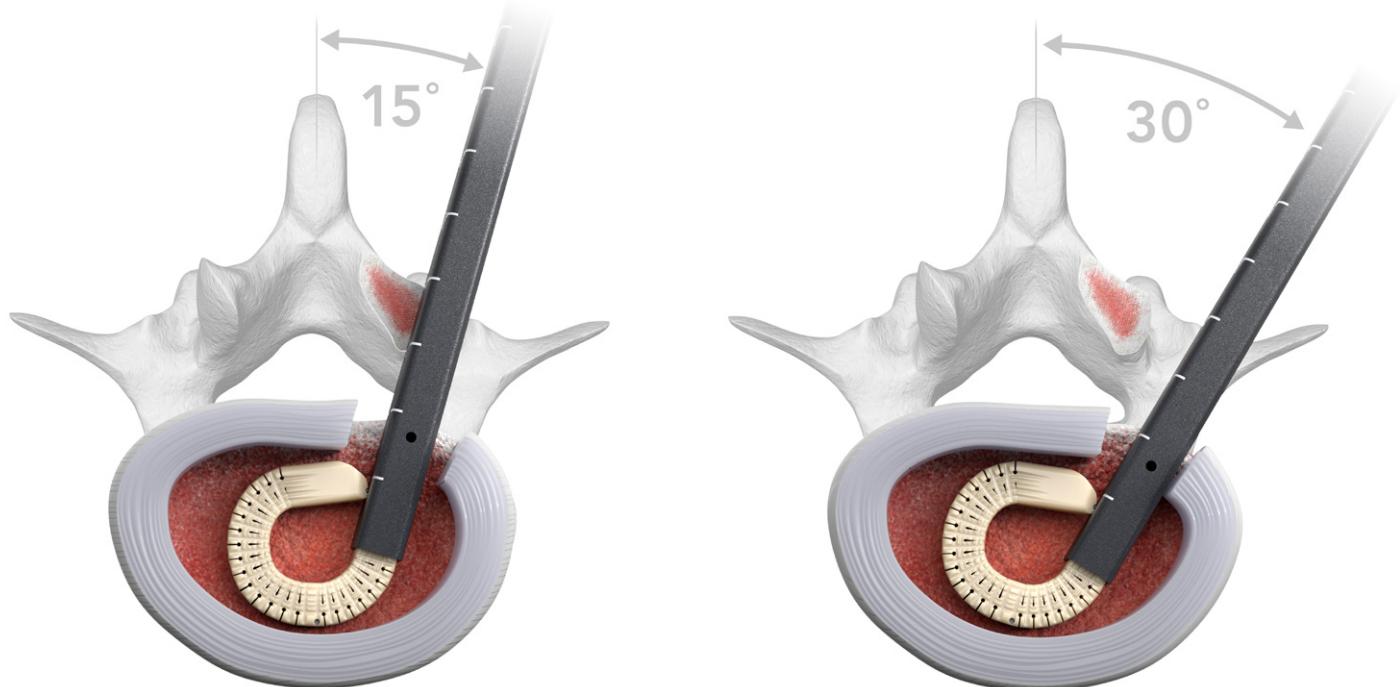


Fig. 3

Note:

Recommended implant placement is achieved with an 8-12mm annulotomy and 15-30° inserter trajectory.

Step 3: Discectomy and Endplate Preparation

Perform a thorough decompressive discectomy and endplate preparation with Orbit Articulating Discectomy System. Thorough removal of the nucleus cartilaginous and endplate on the ipsilateral and contralateral sides is required for optimal placement of the Luna XD implant. For illustrative purposes, the space can be broken into three zones (Fig. 4).

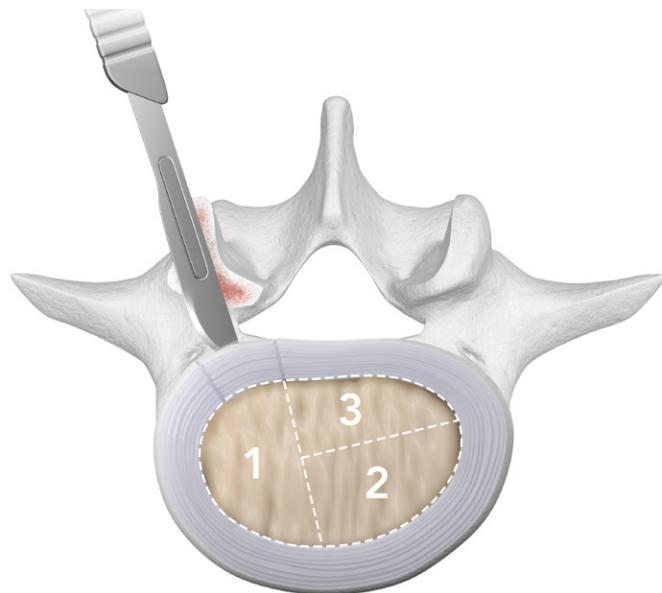


Fig. 4

Disrupt Zone 1 with standard instruments (Pituitaries, Rongeurs, Shavers, etc). (Fig. 5).

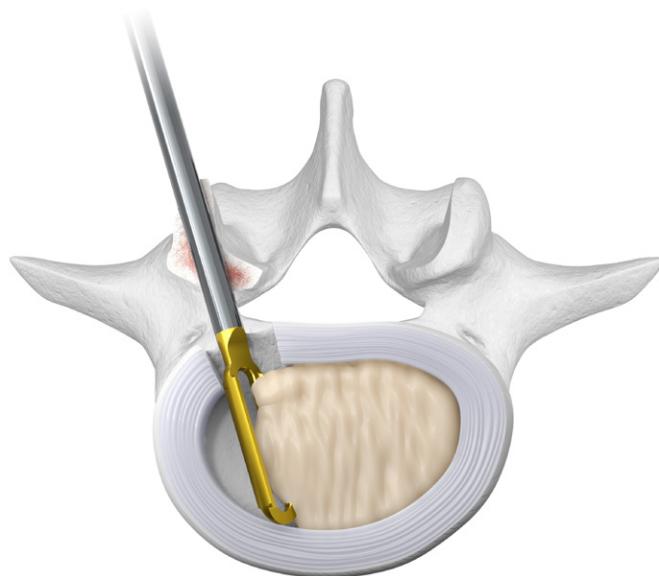


Fig. 5

Step 3: Discectomy and Endplate Preparation continued

Disrupt Zones 2 and 3 with Orbit Shaver (Fig. 6). As T-Handle is turned clockwise, the Orbit Shaver tip rotates clockwise and articulates medially (Fig. 7).

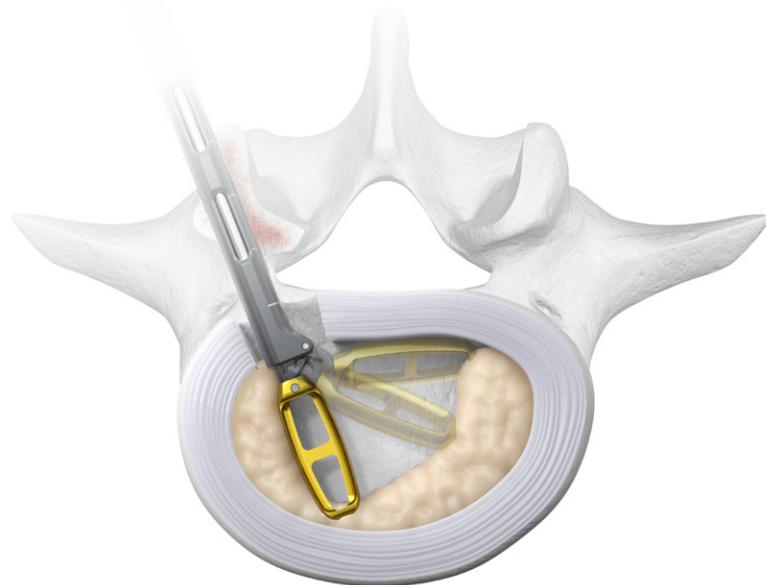


Fig. 6



Fig. 7

Step 3: Discectomy and Endplate Preparation continued

The Orbit Shaver Tips are available in multiple dimensions to adapt to the patient's anatomy. Contoured edges reduce risk of endplate damage.

NOT FOR REMOVAL OF CARTILAGENOUS ENDPLATE.



Choose appropriate size for disc space (7mm, 9mm, or 11mm), so as to minimize endplate contact. Insert Orbit Shaver into space until tip is as anterior as possible (up against annulus) (Fig. 8). Confirm via fluoroscopy or direct visualization that U-Joint is inside the disc space (Fig. 9).

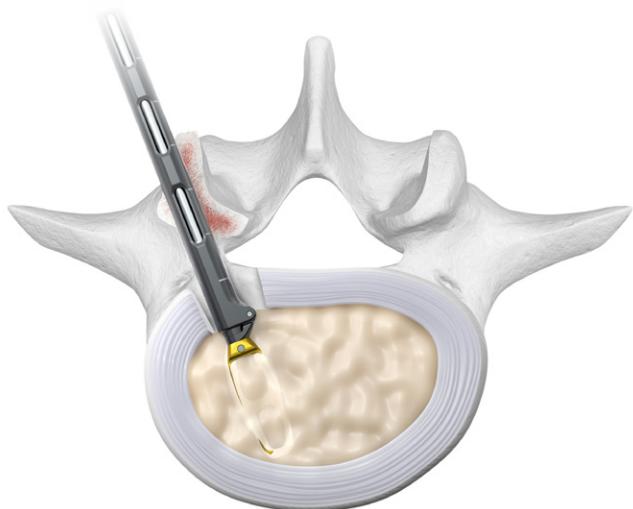


Fig. 8



Fig. 9

Step 3: Discectomy and Endplate Preparation continued

Actuate Orbit Shaver by turning T-Handle clockwise (5.5 turns to achieve 75° sweep), using opposite hand to maintain shaft at consistent A/P position to resist twisting. Continue turning T-Handle clockwise to rotate tip while holding at 75° of articulation to disrupt tissue in posterior-contralateral area (Fig. 10). Return to straight by turning T-Handle counter-clockwise until 5.5 turns (Fig. 11). Remove from disc space and clean tissue from tip of device. Repeat, if desired. Remove disrupted nucleus tissue with Pituitaries.

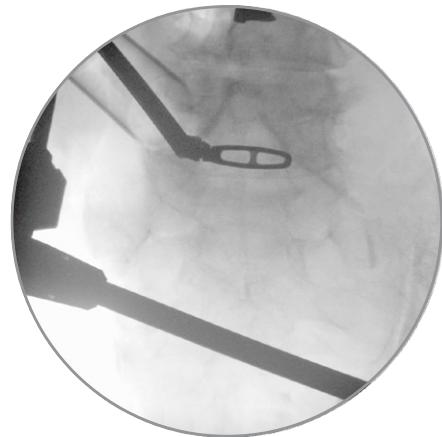
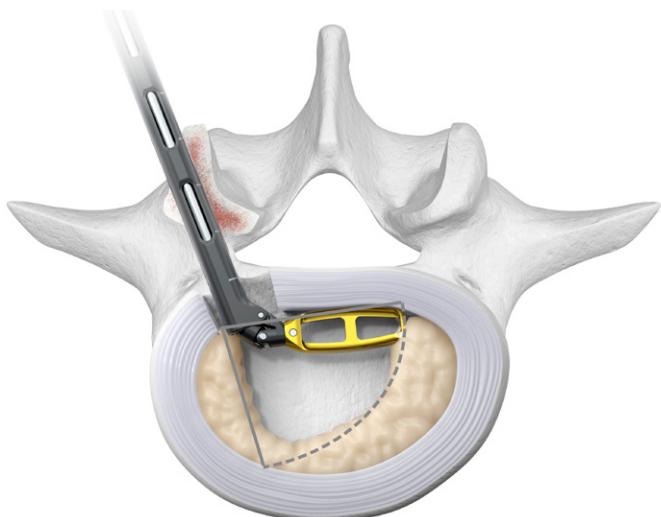


Fig. 10

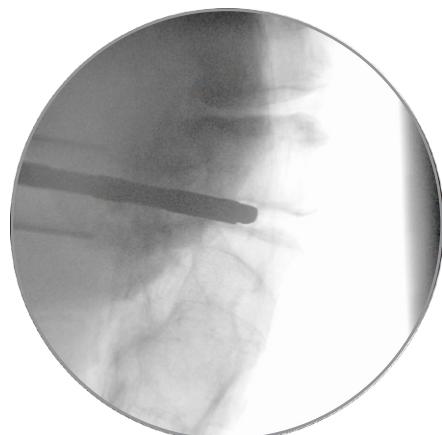
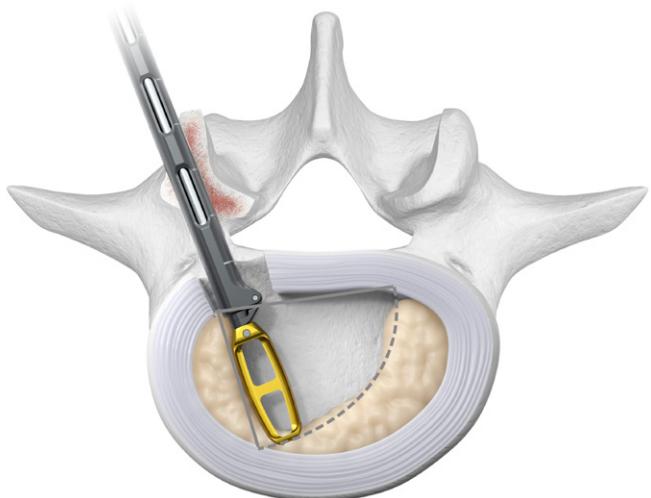


Fig. 11

Note:

The targeted area may not be swept clean with one instrument pass, so multiple passes may be required.

Step 3: Discectomy and Endplate Preparation continued

Disrupt cartilaginous endplates with Orbit Scraper (Fig. 12).

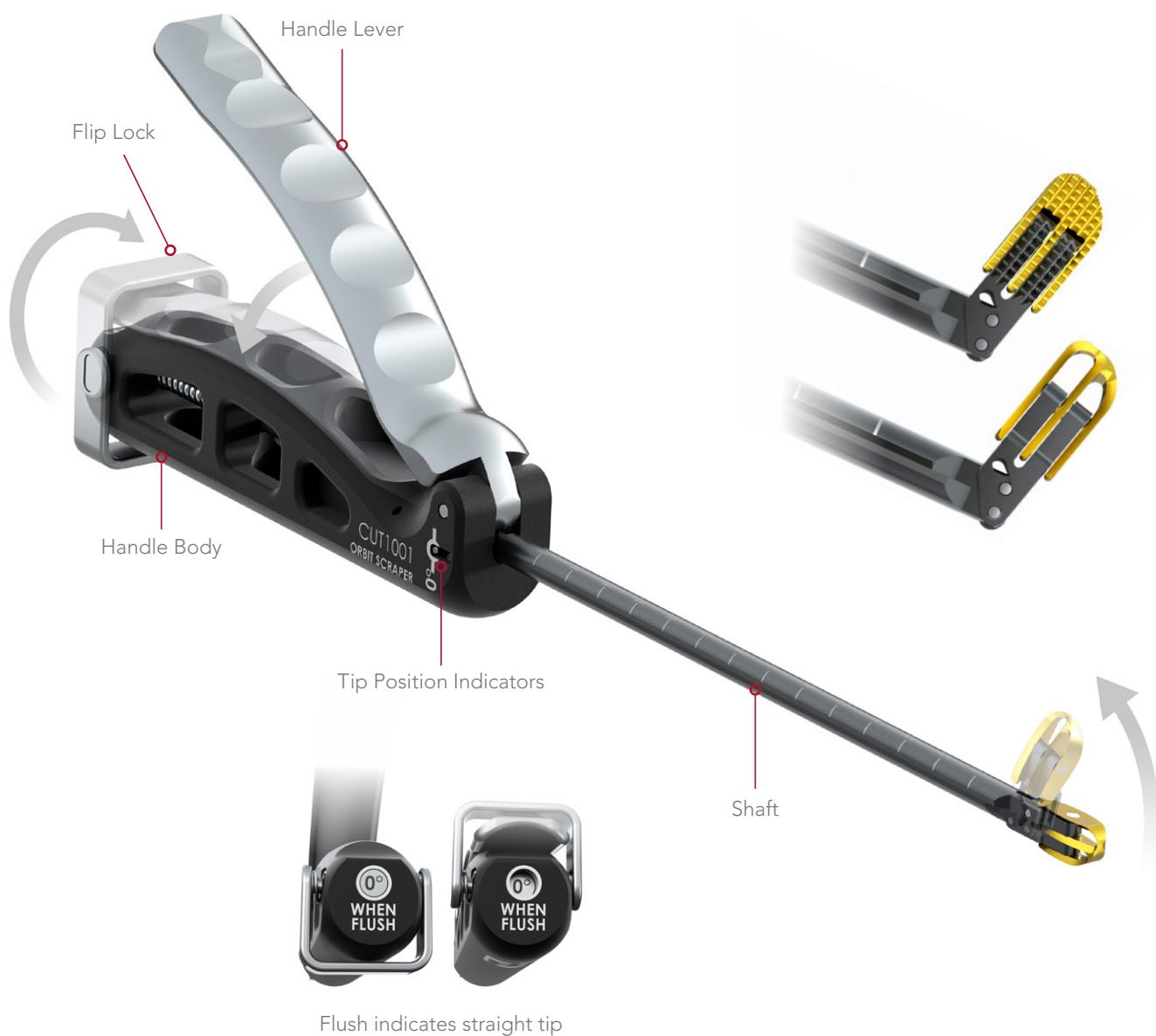


Fig. 12

Step 3: Discectomy and Endplate Preparation continued

Insert Orbit Scraper into space until tip is as anterior as possible (up against annulus). Articulate Scraper tip by squeezing lever; lever can be locked in position by flipping bail lock. Once at the fully articulated (75°) position, rotate device along shaft axis to contact endplate with tip (pivoting tip will maximize endplate contact) and push instrument anteriorly to scrape. Move instrument back-and-forth anterior to posterior (Fig. 13) in a rowing motion with tip not contacting endplate on the back stroke and contacting endplate on the front stroke. Repeat above steps with device rotated to contact opposite endplate. Open bail lock and release lever to straighten tip. Remove from disc space.

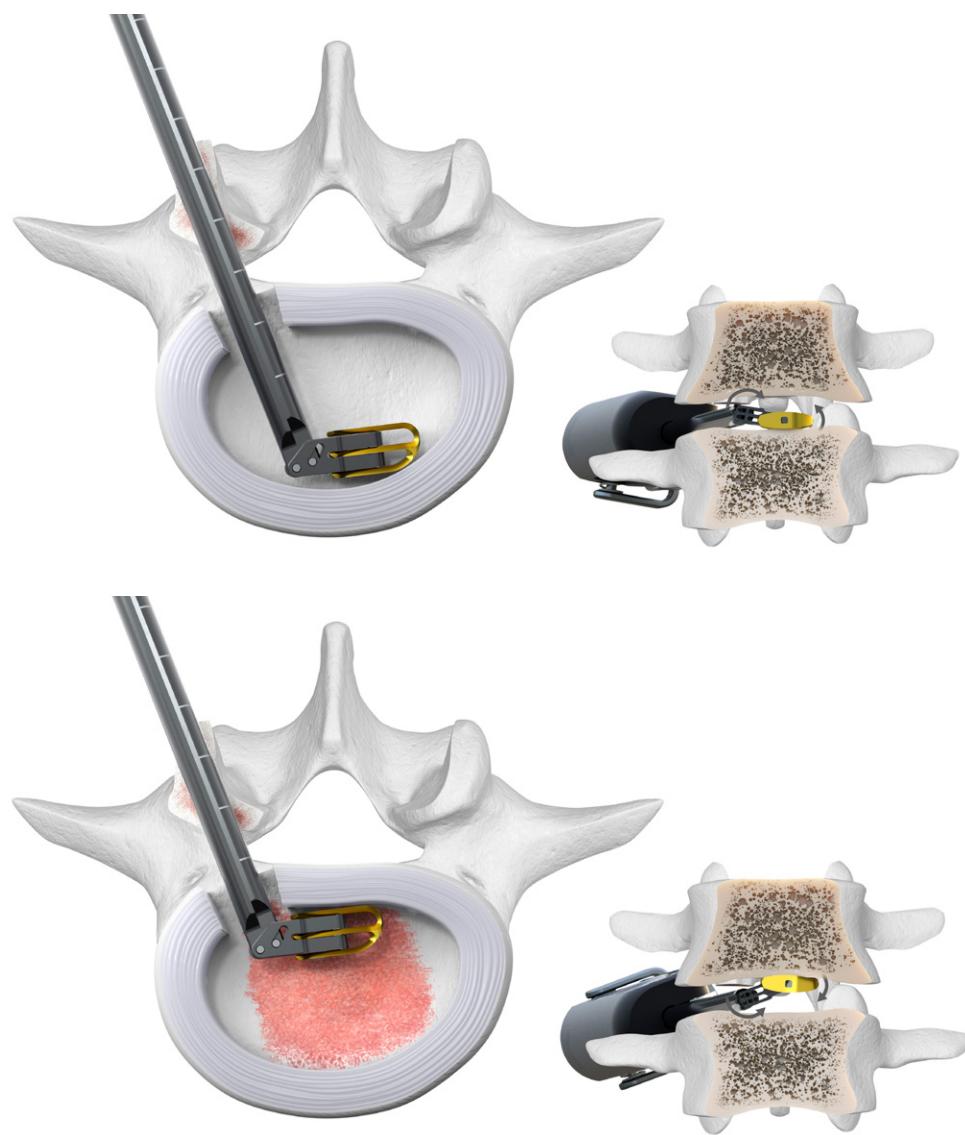


Fig. 13

Step 4: Disc Space Assessment

In addition to its function as an endplate preparation tool, the Orbit Rasp may be used to assess the disc preparation. Insert the Rasp into the disc, then fully articulate to 75°. Push to the most anterior position allowed by the disc space, and note the position by referencing a depth mark on the instrument shaft (Fig. 14).

Then, pull the Rasp to the most posterior position allowed by the disc space. Check the new position by referencing a depth mark on the instrument shaft (Fig. 15).

The difference between the two positions should be approximately 2cm in order for the Luna XD implant to deploy without issue to its full 360° configuration.

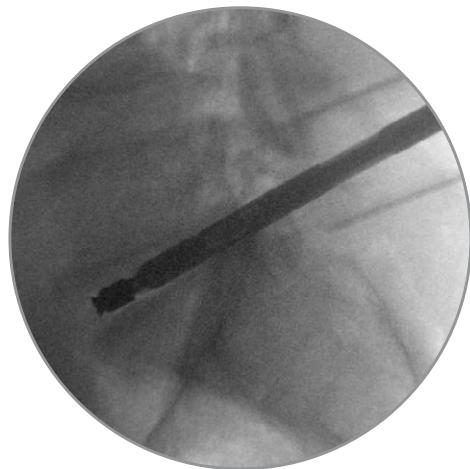
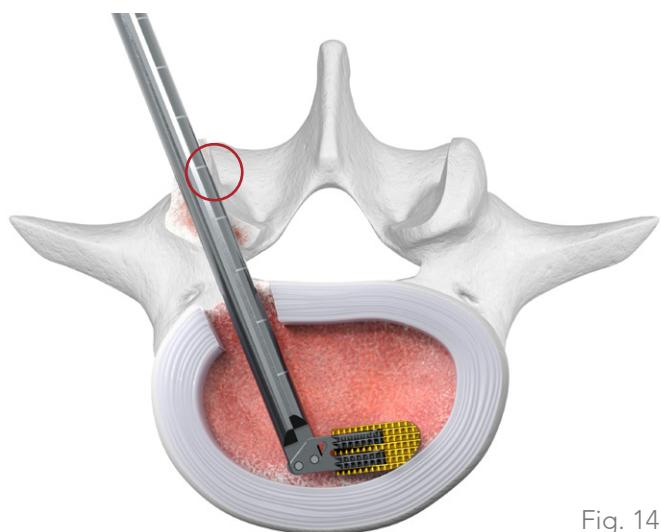


Fig. 14

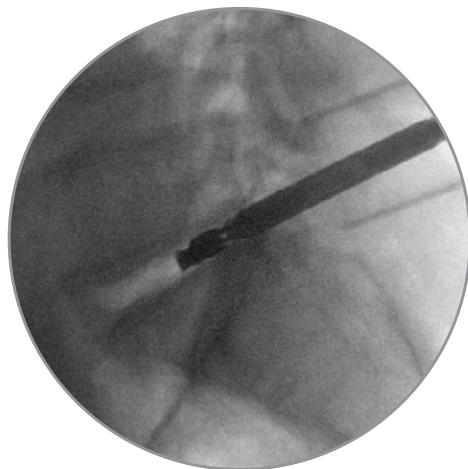
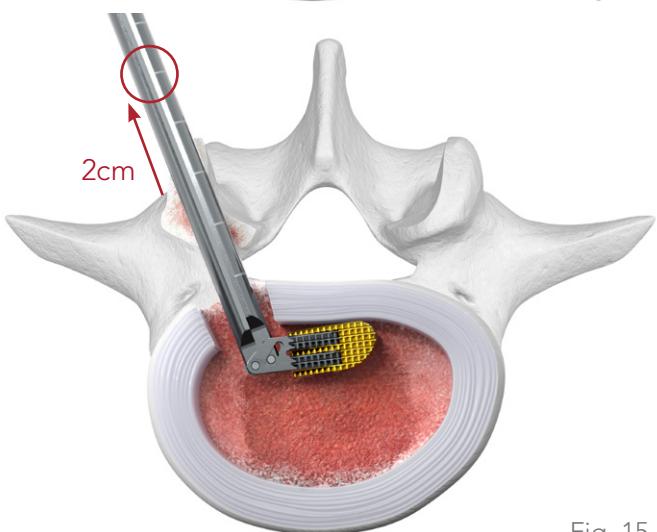


Fig. 15

Note:

The instrument may not reach as anterior as the front of the Luna XD implant due to its tip length. (Note gap in Fig. 15.)

Step 5: Disc Height and Implant Selection

Using sizing paddles, measure the height of the disc space (Fig. 16). Ensure the AP distance is adequate by confirming that the hole in the sizing paddle is within the disc space. The sizing paddle should assess the disc height at the midline anterior position.

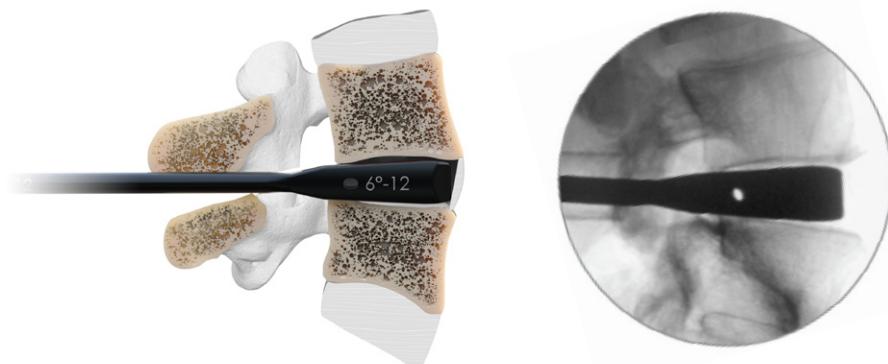


Fig. 16: Measuring Disc Space Height with Sizing Paddle (Left)
and Intraoperative Radiographic Imaging (Right)



The Luna XD implant is available in discrete expanded heights from 10-16mm with either 6° or 12° lordosis.

Luna XD Sizing				
Catalog #	Lordosis	Cannula Height x Width	Initial Height Posterior/Anterior	Expanded Height Posterior/Anterior
LUN20006-10	6°	8mm x 7mm	5 / 7mm	8 / 10mm
LUN20006-12	6°	10mm x 7mm	7 / 9mm	10 / 12mm
LUN20006-14	6°	12mm x 7mm	9 / 11mm	12 / 14mm
LUN20012-12	12°	10mm x 7mm	5 / 9mm	8 / 12mm
LUN20012-14	12°	10mm x 7mm	5 / 9mm	10 / 14mm
LUN20012-16	12°	12mm x 7mm	7 / 11mm	12 / 16mm

Step 6: Insertion

Place the Inserter into the disc space at the same angle as the final position of the Orbit Trial-Rasp, with the minor cannula dimension matching the disc opening. To introduce at the smallest height (7mm), insert with the "MEDIAL" facing superior or inferior.

Ensure that the depth markers are inside the disc space using fluoroscopy or direct visualization, then rotate it into position so that the "MEDIAL" is facing medial (Fig. 17). The Inserter tip should be in the ipsilateral half and anterior third of the disc space.

Note:

If the Inserter is rotated into place with the cannula too shallow, the posterior lip may deform the cannula tip causing problems with Luna XD delivery.

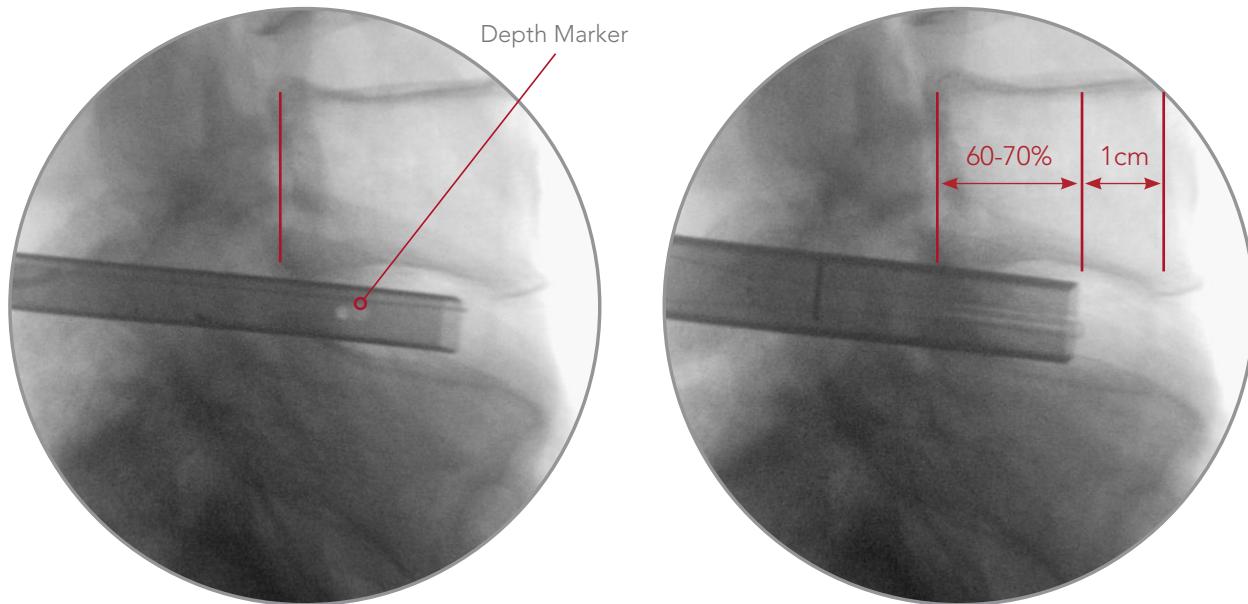


Fig. 17

Note:

An Introducer Sleeve is available to aid insertion into highly collapsed spaces.

Step 7: Implant Delivery and Initial Verification

Deploy the Top and Bottom components of the Luna XD implant by turning the knob of the Inserter clockwise (Fig. 18). The Top and Bottom components may be retracted and re-deployed as needed to ensure appropriate placement in the A/P and lateral images.



Fig. 18

Step 7: Implant Delivery and Initial Verification continued

Deployment cables within the Luna XD components are used to bend the implant into a circular shape during deployment. These cables are visible under fluoroscopy (Fig. 19), and are removed after full deployment of the implant.

Verify the following using fluoroscopy and the radiographic markers:

- Proper position of the implant in the lateral view—biased anteriorly and within the disc space.
- Proper position of the implant in the A/P view—on midline.

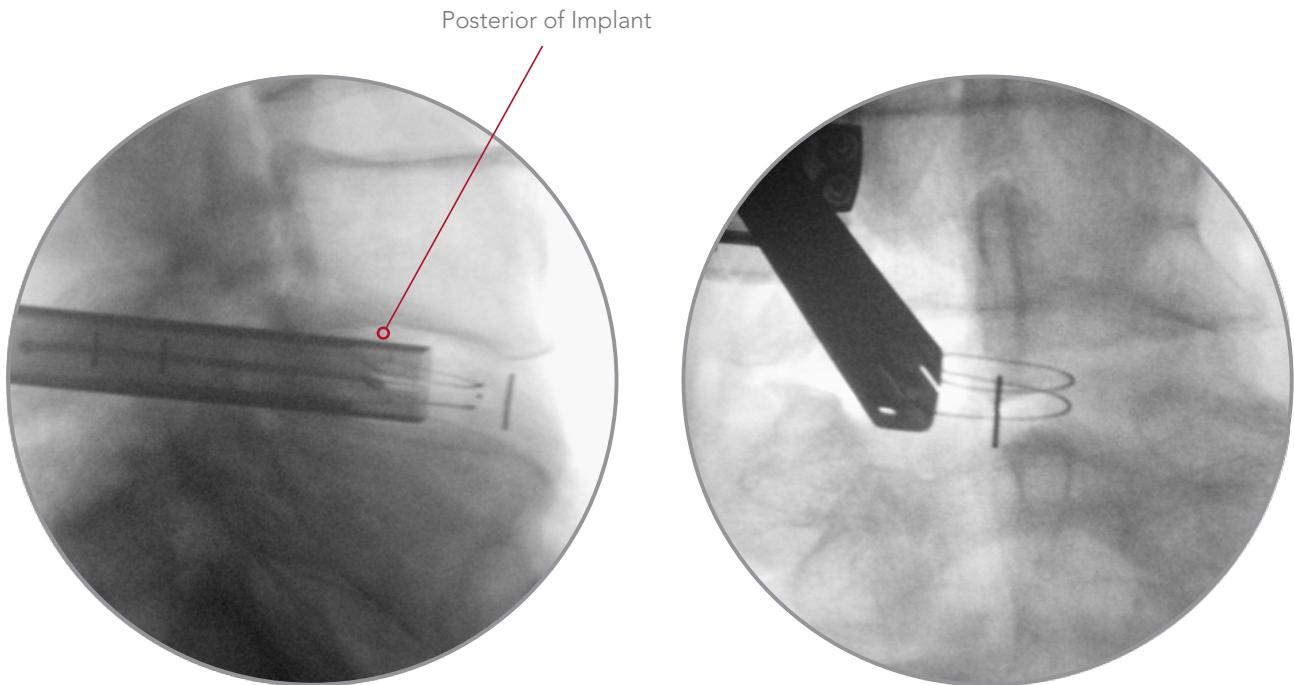


Fig. 19: Radiographic Imaging of the Initial Deployment of Top and Bottom Components of Luna XD

Step 8: Implant Expansion

Implant expansion is achieved by advancing the Middle component in between the Outer components (Fig. 20). Once the Middle component is advanced, the implant position cannot be changed as the Middle component cannot be retracted.

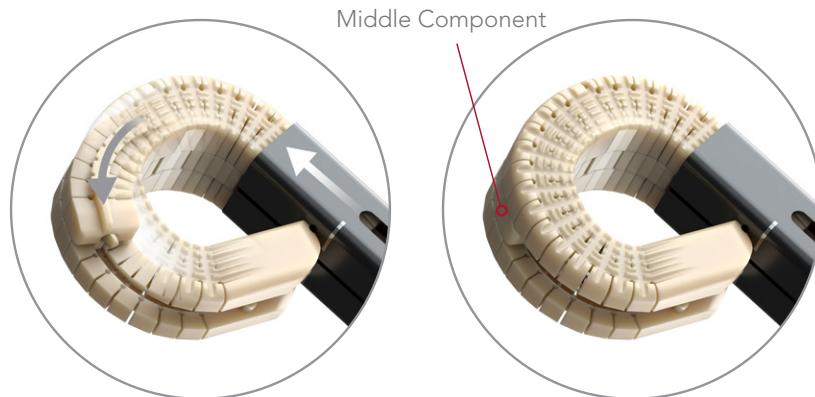


Fig. 20

Insert the Pusher into the Inserter and turn clockwise to advance the Middle component (Fig. 21).



Fig. 21

Step 8: Implant Expansion continued

Under fluoroscopic guidance, continue to advance the Middle component of the implant until the Top, Bottom and Middle radiographic markers are aligned (Fig. 22).

In the lateral view, ensure that the long marker of the middle member is past the ball markers of the outer members and verify that the anterior long markers are stacked with no vertical gaps in between.

In the AP view, ensure that the long markers are stacked in one continuous line or within a marker's width of being in one continuous line. When the radiographic markers are aligned as described, the Top, Bottom and Middle components are locked together. Once alignment is confirmed, remove the Pusher from the Inserter.

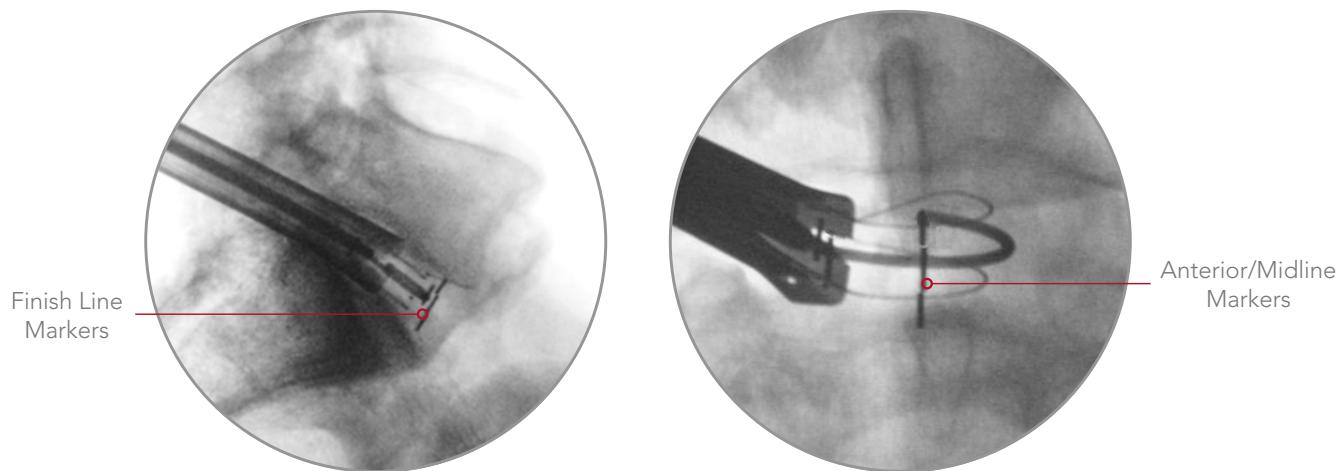


Fig. 22: Radiographic Imaging of the Middle Component Deployment

Verify final implant position using both lateral and A/P fluoroscopic images (Fig. 23).

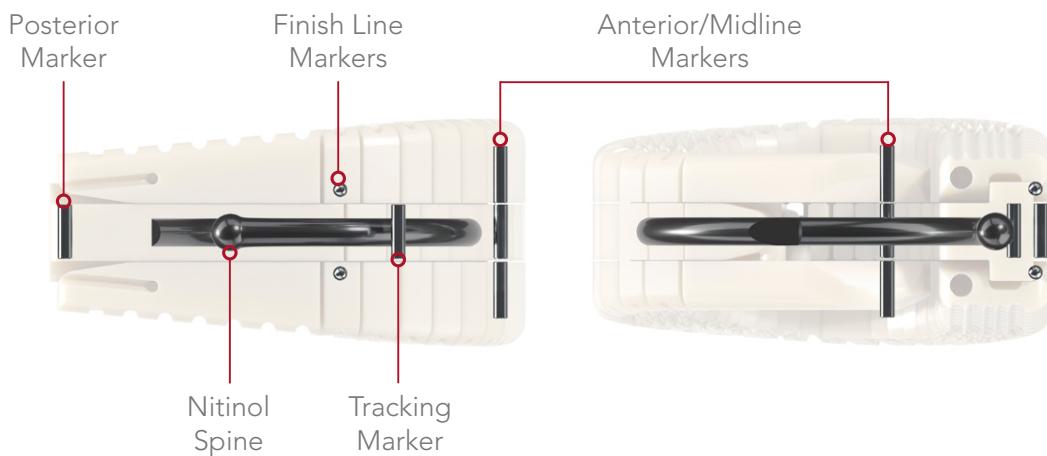


Fig. 23

Step 9: Inserter Removal

Replace the Pusher with the re-usable Ejector tool (Fig. 24). Actuate the Cutter Arms on the Inserter handle to cut deployment cables, and turn the Ejector clockwise to safely remove the Inserter and anchor cables from the disc space without disturbing the position of the implant (Fig. 25).



Fig. 24



Fig. 25

Note:

The Ejector Tool may also be used to finish the Middle component deployment if it is short of the finish line with the Pusher Tool. Simply replace the Pusher Tool with the Ejector Tool and advance until the tracking marker is past the finish line. Do this BEFORE cutting cables.

Step 9: Inserter Removal continued

The SureGuide Rod and Pull Cable will still be attached to the implant. Remove Pull Cable using hemostats; leave SureGuide Rod in place for now (Fig. 26).

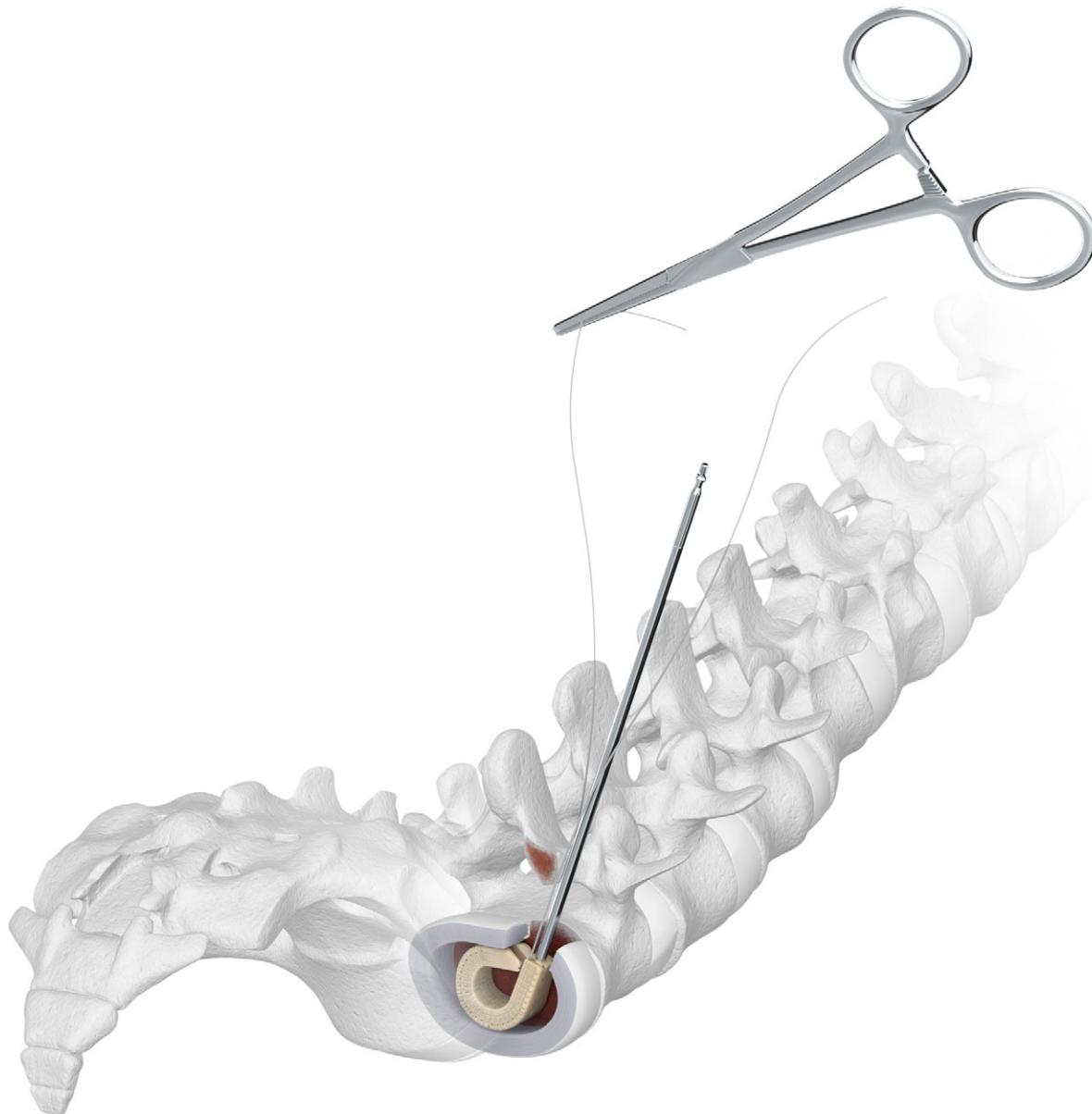


Fig. 26

Step 10: Graft Delivery

Load graft into the distal end of the Graft Injector using the Loading Hopper. To load, pull back the plunger and the Cover Tube to expose the graft loading slot. Insert the Graft Injector into the Loading Hopper and lightly pack graft into the Injector.

Note:

Packing graft too densely will make delivery more difficult or cause the graft injector to jam.

Close the Cover Tube and remove the Injector from the Loading Hopper (Fig. 27).

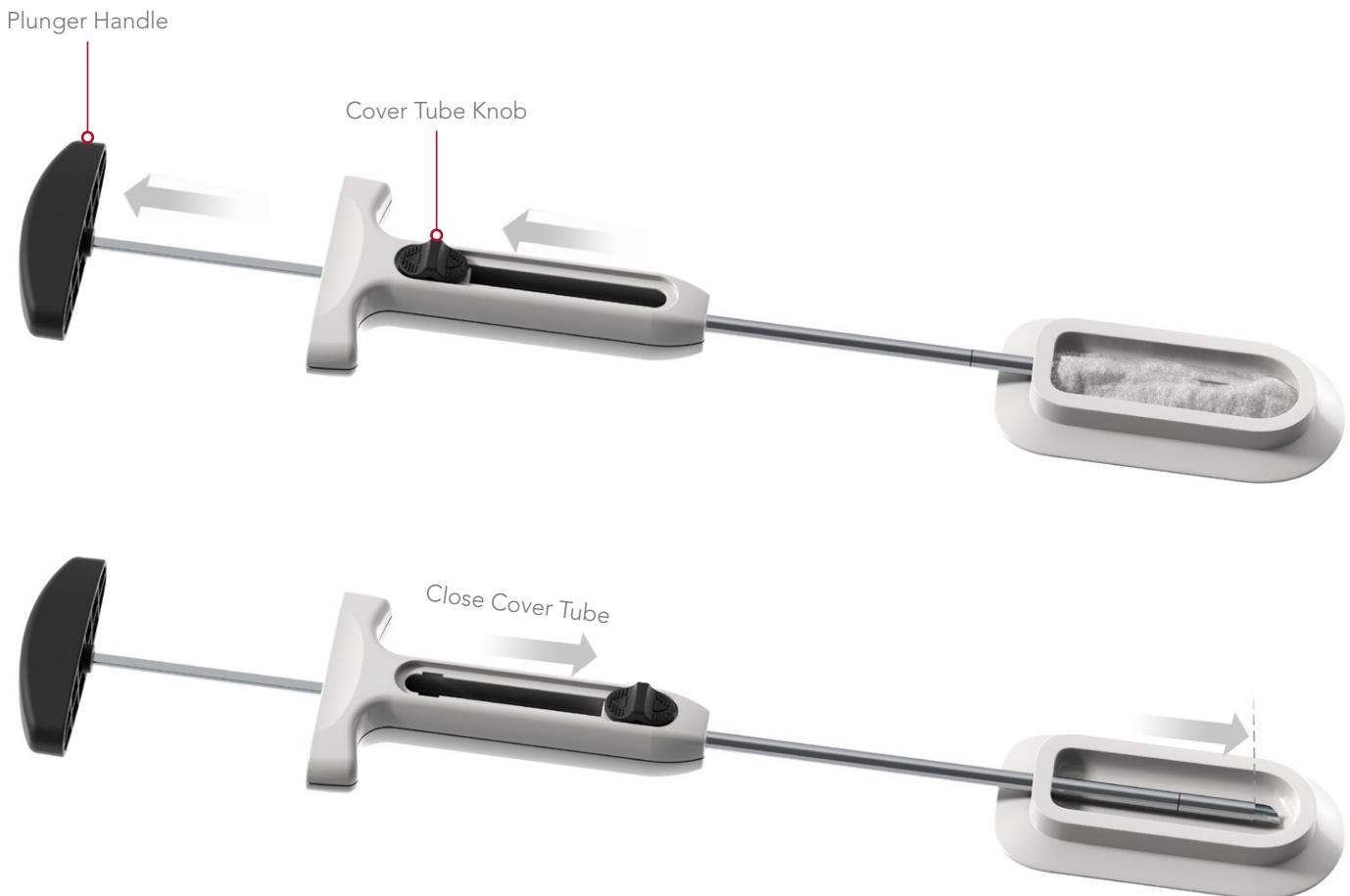


Fig. 27

Step 10: Graft Delivery continued

Insert the Obturator into the SureGuide Graft Access System and pass over the SureGuide Rod into the disc space seating them into the implant graft window (Fig. 28).



Fig. 28

Step 10: Graft Delivery continued

Once seated, remove the Obturator. After the SureGuide Cannula is engaged, the Graft Injector may be passed through multiple times; thus, protecting the neural structures during each pass.

Insert the Graft Injector through the SureGuide Tube and inject graft into the central cavity of the deployed Luna XD implant. Repeat loading and injecting until the cavity is sufficiently filled (~2 cc) (Fig. 29).



Fig. 29

Step 11: SureGuide Rod Removal

If satisfied with Luna XD placement, unthread the SureGuide Rod from the implant by turning counter-clockwise with hemostats (Fig. 30).

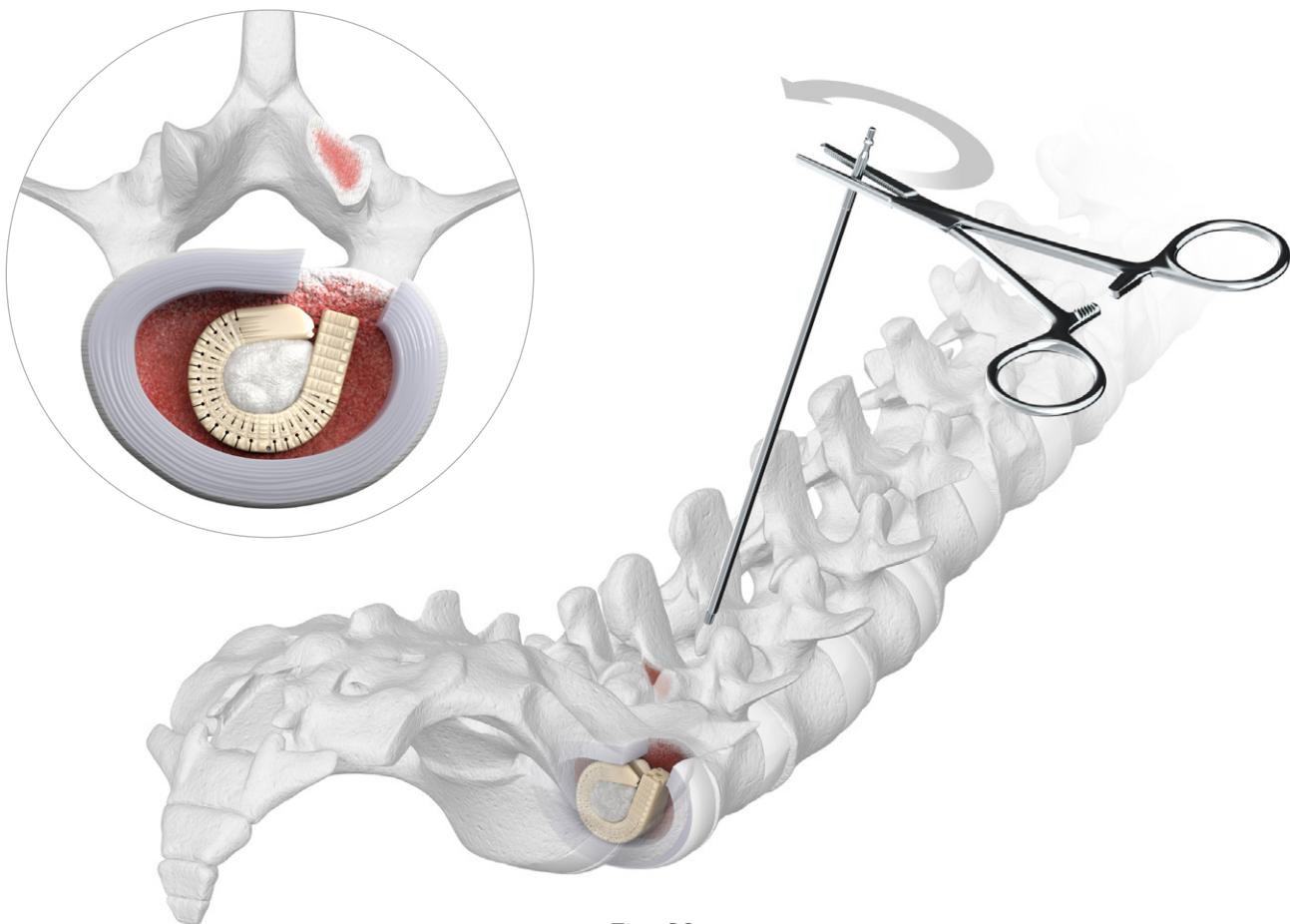
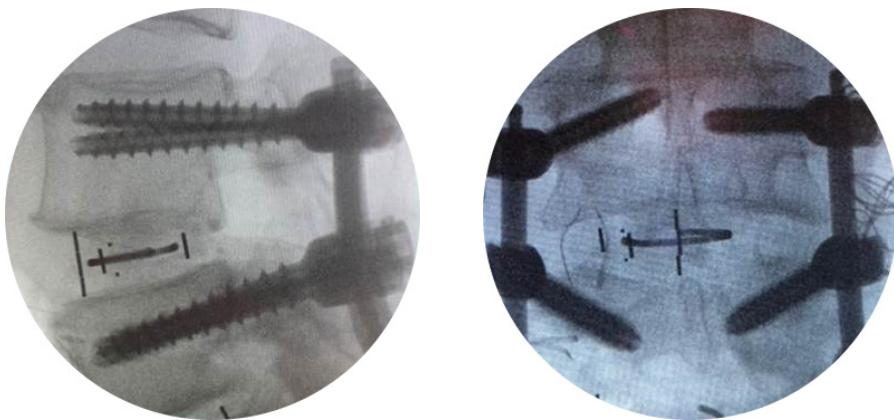


Fig. 30



Radiographic Imaging of Final Luna XD Placement

Step 12: Implant Removal

If not satisfied with Luna XD placement, use the Extractor System to safely remove the middle component.

Insert the appropriately sized Extractor Tube with Drive Screw over the SureGuide Rod down into the disc space (Fig. 31).

Be sure the tangs of the Extractor Tube are on the medial and lateral sides of the implant.

Thread the SureGuide Extender through the Drive Screw and onto the SureGuide Rod.

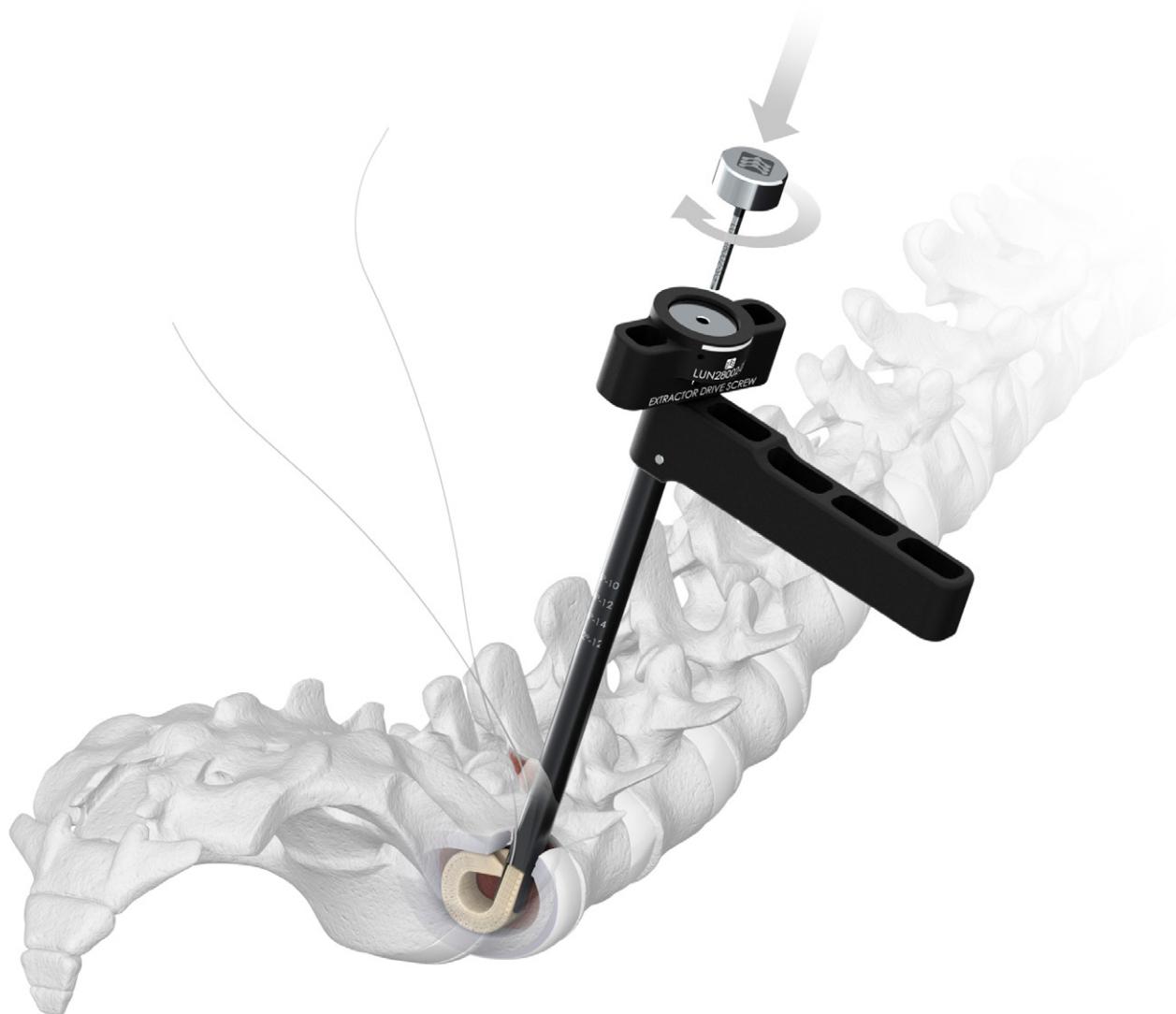


Fig. 31

Step 12: Implant Removal continued

Remove the middle component by turning Drive Screw handle counterclockwise (Fig. 32). Middle component will be pulled safely into the Extractor Tube.

Note:

Special care must be taken in removing the middle component, as the reinforcing Nitinol spine maintains the circular shape quite forcefully. Only remove the middle component using the Extractor System provided.



Fig. 32

Step 12: Implant Removal continued

Remove the Top and Bottom components using standard grasping instruments while protecting any nearby neural structures, as necessary (Fig. 33).

Note:

Be sure to protect the dura and any exposed neural elements during removal.



Fig. 33

System Components

Luna XD Accessory Instruments

Part Number	Part Description
LUN26006-10	10mm Sizing Paddle, 6°
LUN26006-12	12mm Sizing Paddle, 6°
LUN26006-14	14mm Sizing Paddle, 6°
LUN26012-12	12mm Sizing Paddle, 12°
LUN26006-14	14mm Sizing Paddle, 12°
LUN26006-16	16mm Sizing Paddle, 12°
IBS2001	T-Handle for Sizing Paddles
LUN28004	Luna XD Ejector Tool, Reusable
LUN28006	Inserter Introducer Sleeve
LUN4002	SureGuide Graft Access
LUN24003	Funnel Attachment, SureGuide
LUN24004	Graft Tamp, SureGuide
LUN4002-OBT	Obturator, SureGuide
LUN28002-SM	Extractor Tube, Small
LUN28002-LG	Extractor Tube, Large
LUN28002-DS	Extractor Drive Screw
LUN28002-SG	Extractor SureGuide Extension
LUN28002-EO	Extractor Easy Out
LUN28002-GR	Extractor Guide Rod
LUN28005	Easy Out Extender
LUN6310	Luna XD Accessory Instrument Set

Luna XD MIS Interbody Fusion Device

Part Number	Part Description
LUN20006-10	10mm Luna XD Implant Kit, 6°
LUN20006-12	12mm Luna XD Implant Kit, 6°
LUN20006-14	14mm Luna XD Implant Kit, 6°
LUN20012-12	12mm Luna XD Implant Kit, 12°
LUN20012-14	14mm Luna XD Implant Kit, 12°
LUN20012-16	16mm Luna XD Implant Kit, 12°

Luna XD Bone Graft Accessory Kit

Part Number	Part Description
LUN4001	Bone Graft Injector System

Orbit Articulating Discectomy System

Part Number	Part Description
ORB1007	Orbit Rotary Shaver, 7mm
ORB1009	Orbit Rotary Shaver, 9mm
ORB1011	Orbit Rotary Shaver, 11mm
CUT1001	Cutlass Pivoting Tri-Blade Scraper, Large
CUT1003	Cutlass Pivoting Rasp, 5mm

Indications / Contraindications

INDICATIONS

The Luna XD MIS Expandable Interbody Device consists of a Luna XD implant and associated accessories. This system is indicated for spinal fusion procedures in skeletally mature patients with symptomatic degenerative disc disease (DDD) at one or two contiguous levels from L2-S1.

DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to grade I spondylolisthesis or retrolisthesis at the involved level(s). The Luna XD Device is to be used with autogenous bone graft and/or allogenic bone graft composed of cancellous and/or corticocancellous bone graft to facilitate fusion. Patients receiving the device should have had at least six months of non-operative treatment prior to receiving the Luna XD implant. The Luna XD Device is to be used with supplemental fixation.

CONTRAINDICATIONS

- Active systemic or local infection in the proposed area of surgery.
- Involved level is a revision of a previous intervertebral fusion procedure(s).
- Known allergy to the device materials, especially nickel.
- Severe osteoporosis, osteopenia, and/or osteomalacia.
- A medical condition that interferes with postoperative management program.
- Active malignancy.
- Morbid obesity.
- Grade II or greater spondylolisthesis or retrolisthesis at involved spine level.
- DDD affecting three or more spine motion segments.
- Abnormal anticoagulation status.
- Any condition not described in the Indications for Use.

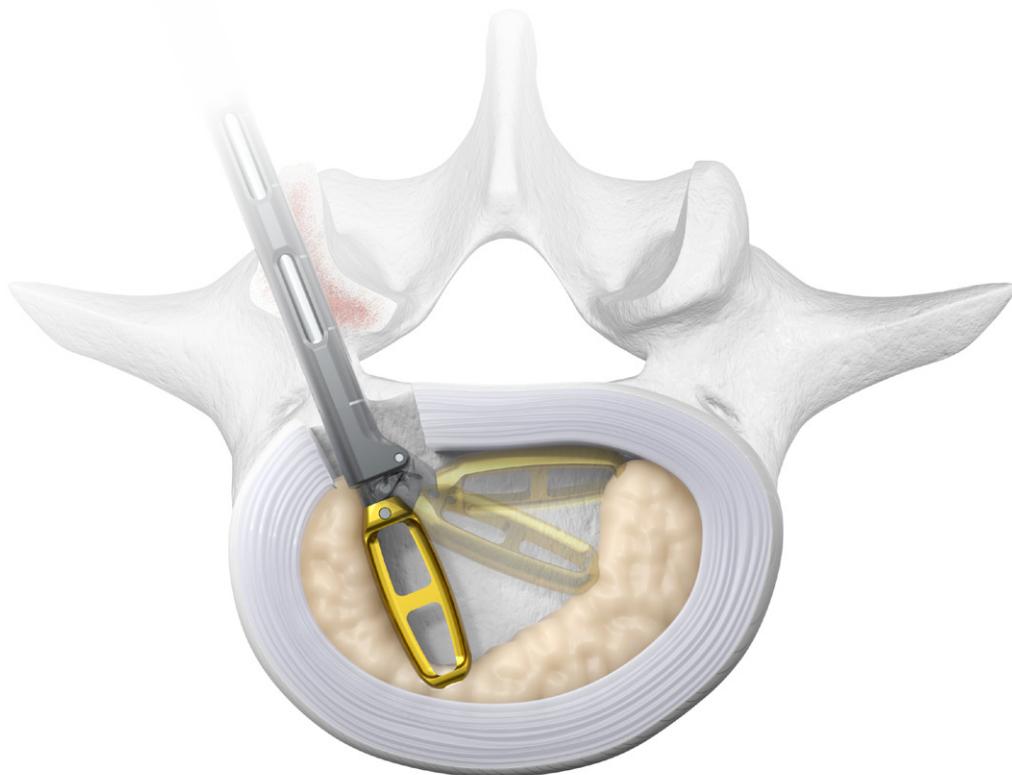
SEE PACKAGE INSERT/INSTRUCTIONS FOR USE FOR FULL CLEANING AND STERILIZATION INSTRUCTIONS.

FOR FULL INSTRUCTIONS, PLEASE VISIT IFU.SPINAELEMENTS.COM

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