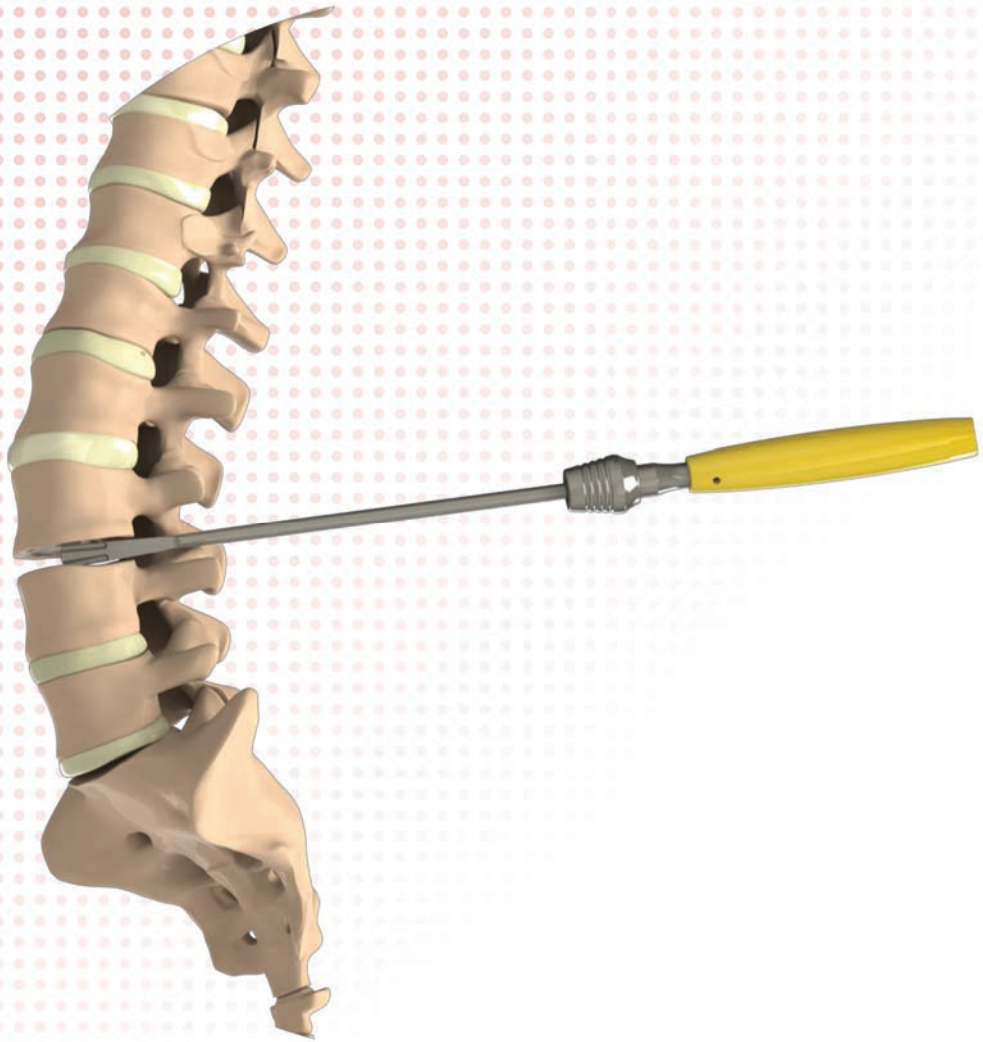
# Alecta™

Transforaminal Lumbar Interbody
Fusion System **(TLIF)**

# SURGICAL TECHNIQUE
# &
# SET INFORMATION

EOS MEDICAL SOLUTIONS



# The ALECTA TLIF System Description

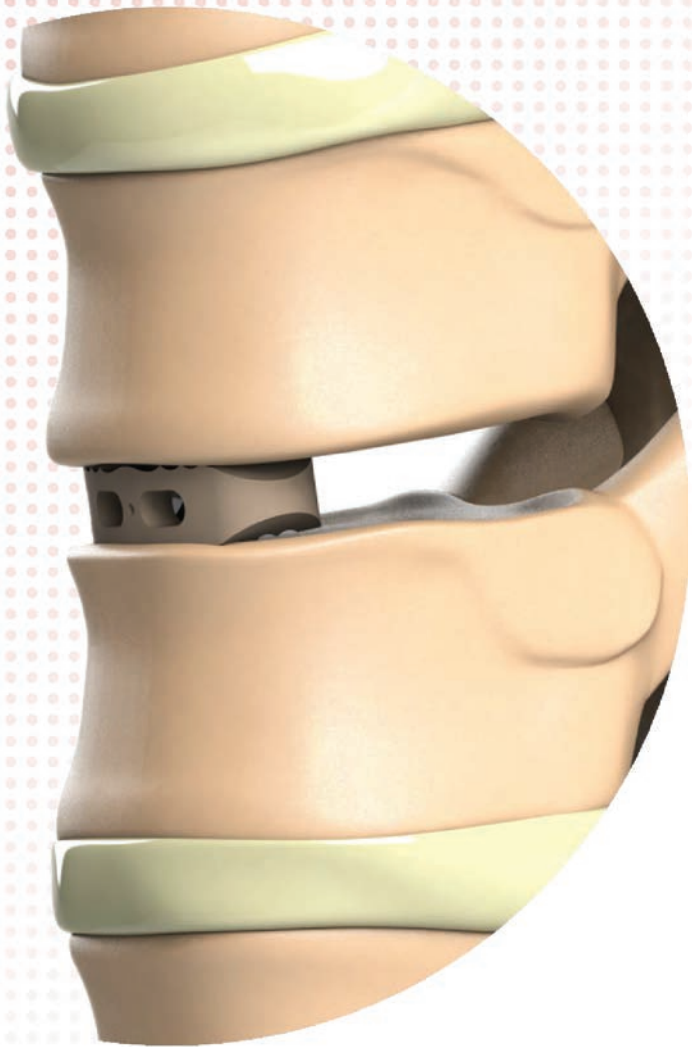
**Purpose**

The Alecta TLIF System is intended to help provide stabilization of spinal segments as an adjunct to fusion of the thoracic, lumbar spine.

**General Description**

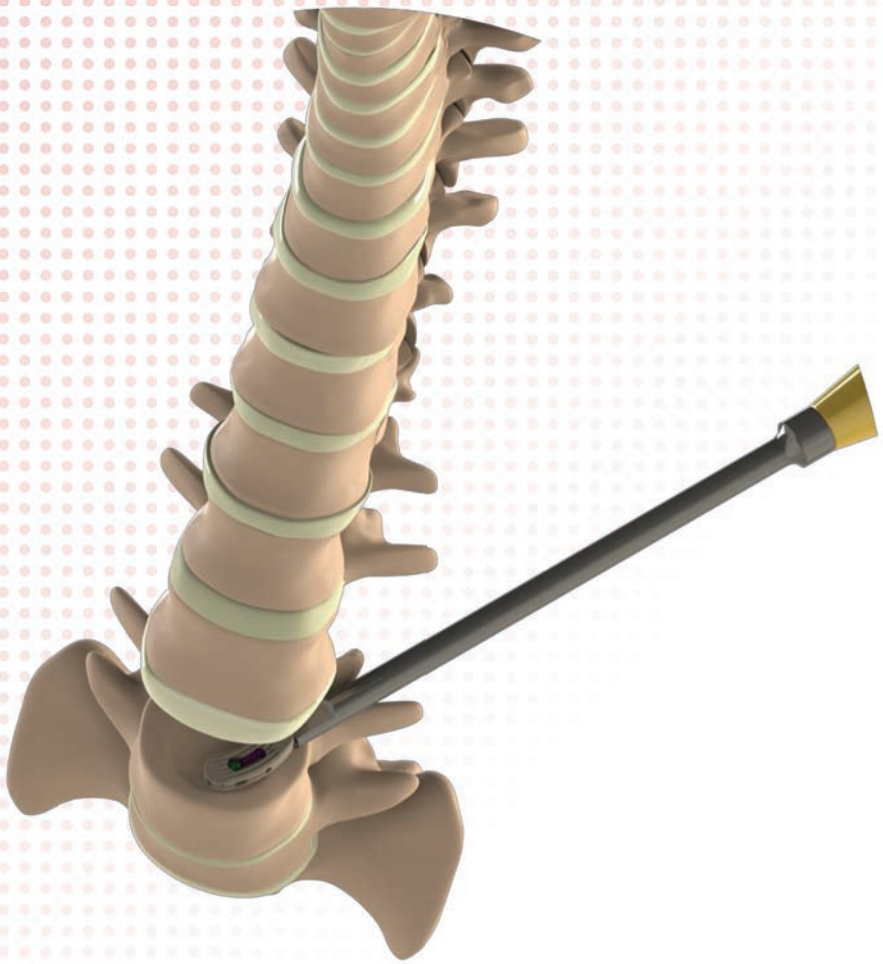
An adaption of the posterior lumbar interbody fusion (PLIF) procedure, the TLIF technique employs a unilateral approach to the disc space through the intervertebral foramen. Requiring only a partial unilateral facet resection, the TLIF procedure when compared to a PLIF;

- Preserves the laminar arch and contralateral facet
- Avoids bilateral scarring
- Avoids significant dural retraction which may reduce the risk of intraoperative dural tears
- Offers a revision strategy that may not exist with a PLIF due to bilateral scarring



# The ALECTA TLIF System Description

The unique unilateral TLIF approach requires specific implants and instrumentation to facilitate thorough disc space preparation and accurate cage placement.
Thoracolumbar interbody fusion is designed as compatible to anatomical constitution at different sizes. It is manufactured from PEEK and Titanium material which is full compatible with body.
It allows to obtain full and quick fusion through the slots which are on it's surface.
These slots doesn't effect the endurance which Cage resists against the pressure caused by body weight. It is fixed to body strongly through the tooths at it's inferior and superior surface.
There are cage sizes different anatomies. The size of the cages; it is between 6 mm and 16 mm.

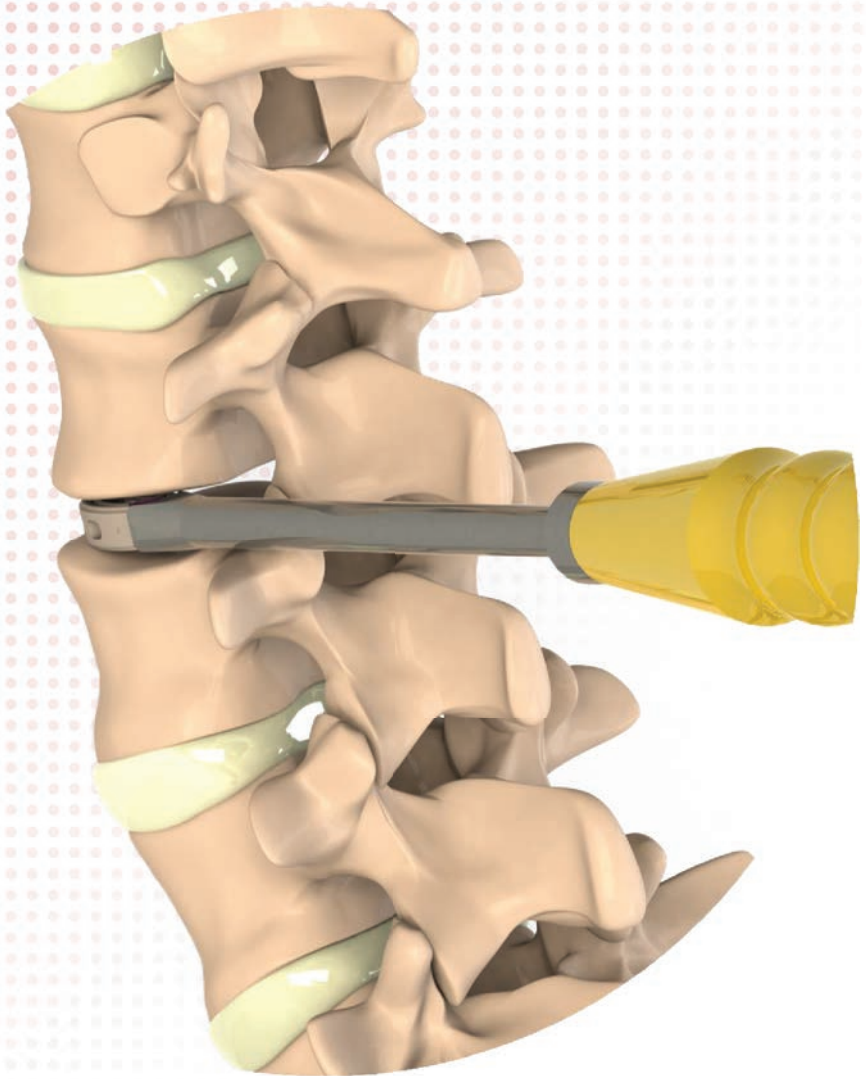


# The ALECTA TLIF System Indications & Contraindications

**Indications for Use**

The Alecta TLIF Cage System is indicated for intervertebral body fusion of the lumbar spine, from L2 to S1, in skeletally mature patients who have had six months of non-operative treatment. The device is intended for use at either one level or two contiguous levels for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis or retrolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The Alecta TLIF Cage is designed for use with or without integrated fixation and must be used in conjunction with supplemental fixation the lumbar spine. The device is implanted via a transforaminal approach and intended for use with autograft and/or allogenic bone graft composed of cancellous and/or corticocancellous bone graft to facilitate fusion.

- Immobilisation of instable spinal segment
- Decompression of the compressed nerve roots and cauda equina
- Provision of spinal arthrodesis



# The ALECTA TLIF System Indications & Contraindications

**Contraindications**

Contraindications include, but are not limited to:

- Local infection or inflammation
- Existence of active infection or pronounced infection risk
- Fever and leucocytosis (increase in leucocytes)
- Active medicine addiction
- Doubted or identified intolerance to PEEK and/or titanium alloys or metal allergy
- Pregnancy
- Spinal instability at three or more levels
- Physical problems such as excessive obesity
- Disorders which causes loss of bones such as joint diseases, bone occlusion, osteopenia, osteomalacia or osteoporosis
- Discitis
- All conditions not specified in the indications
- Spondilolisthesis greater than Grade 2

# The ALECTA TLIF System Surgical Technique

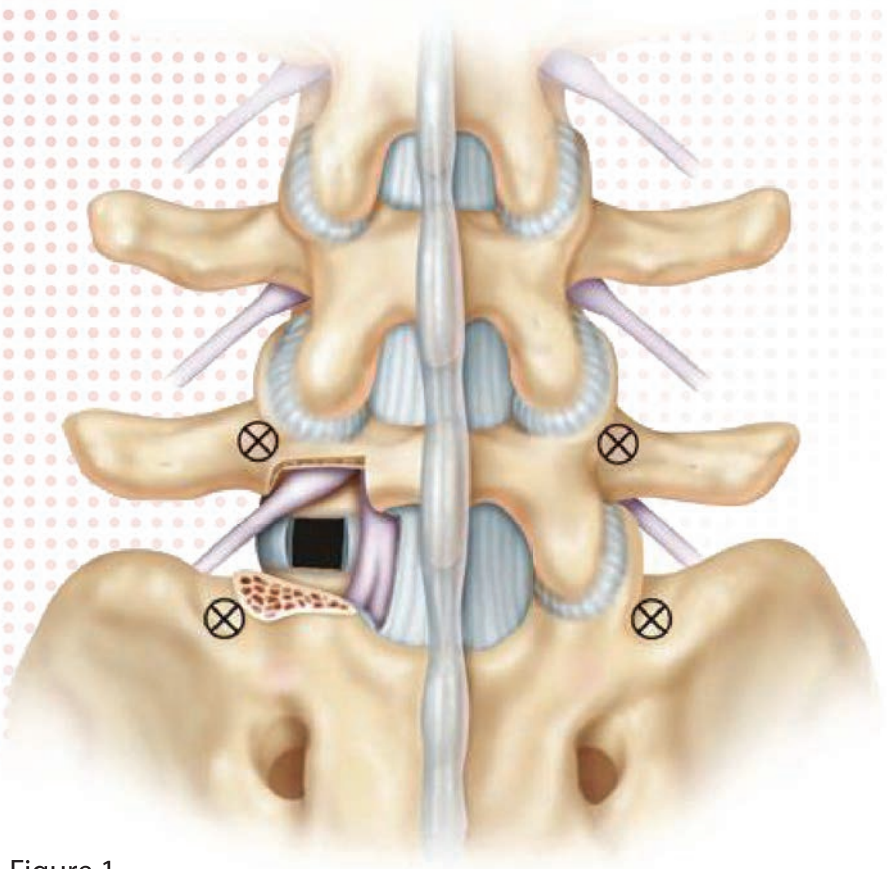


Figure 1

## 1. Pedicle Screw Insertion

Pedicle screws can be placed either before or after the interbody reconstruction.
It is often advantageous to have screws as a distraction point during the procedure.
Many surgeons place screws before the spinal canal is exposed. If placing screws is done after the facetectomy as shown (Figure 1), take extra care to avoid dural injury during the placement of guide wires, taps, or screws.
Identify proper pedicle insertion points for guide wires, taps or screws.
The optimal insertion point is at the intersection of the transverse process and superior articular process.

# The ALECTA TLIF System Surgical Technique

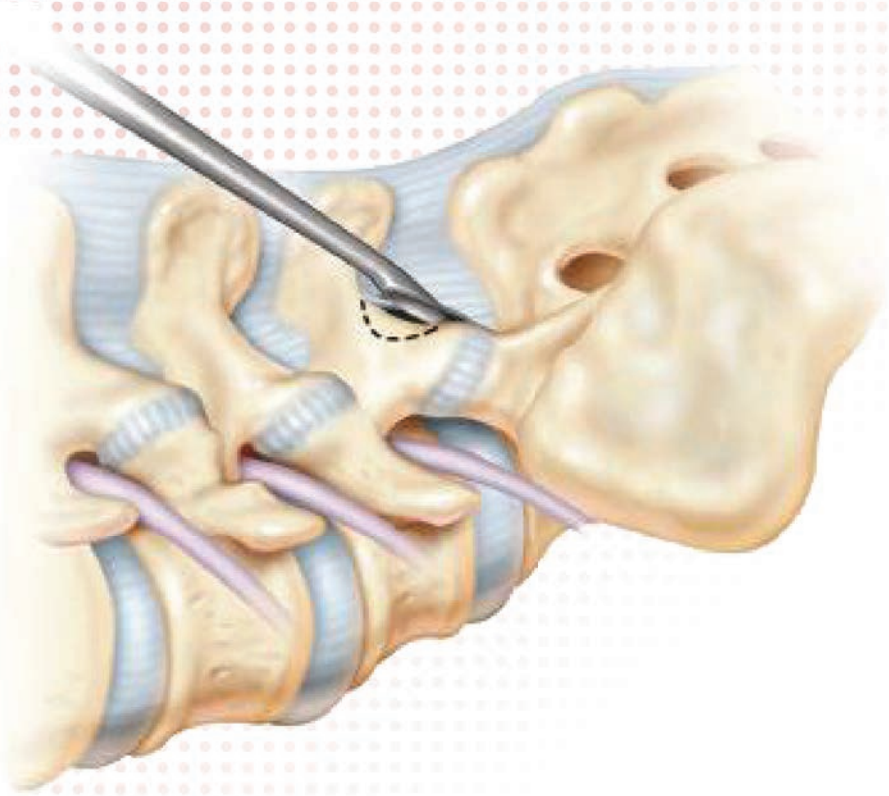


Figure 2

**2. Facetectomy and Working Zone Preparation (L5/S1)**

In order to gain transforaminal access to the disc space, a unilateral facetectomy is performed. The side chosen for the approach is often determined by the location of the pathology or the presence of scar tissue.

Resect the ligamentum flavum from the anterior surface of the lamina with a curette. The inferior lamina of L5 can be removed by a Kerrison rongeur illustrated by the dotted line of Figure 2 to improve access to the ligamentum flavum.

# The ALECTA TLIF System Surgical Technique

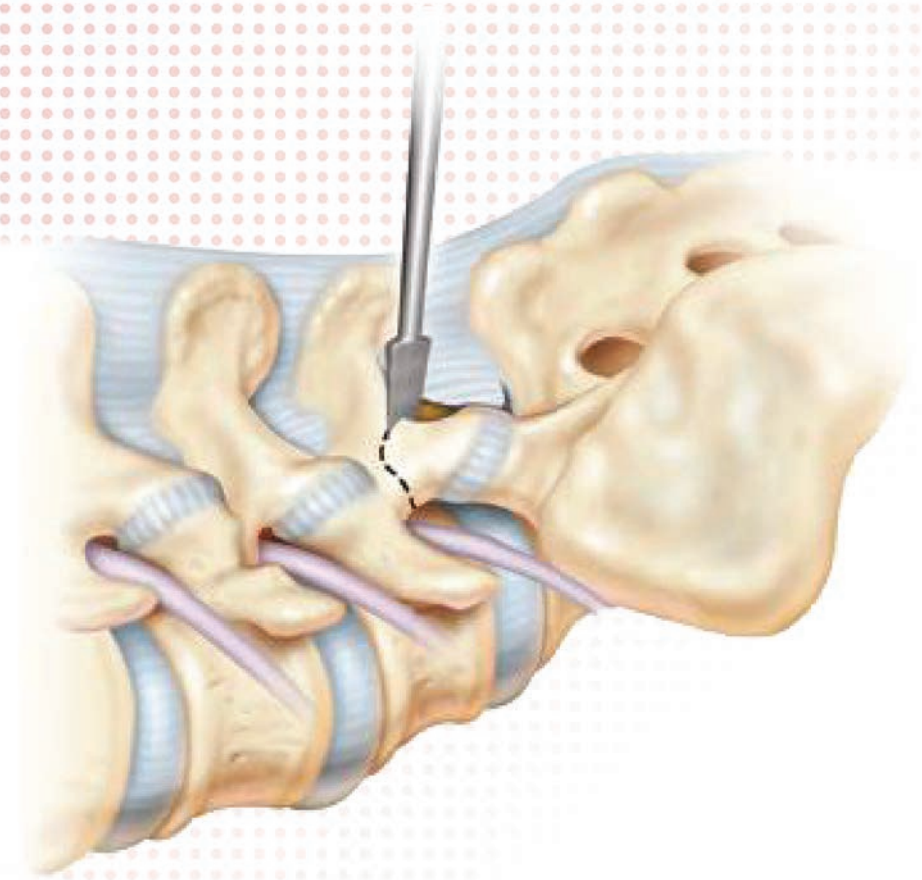


Figure 3

**2. Facetectomy and Working Zone Preparation (L5/S1)**

Resect the inferior articular process of L5 with a straight osteotome or a Kerrison (Figure 3). The osteotomy exits laterally just below the L5 pedicle.

The lateral capsular part of the ligamentum flavum is now visible and can be resected. Unless the pathology mandates excessive spinous process removal, it is recommended to preserve it as a place for the intervertebral distraction should it be required at a later time.

# The ALECTA TLIF System Surgical Technique

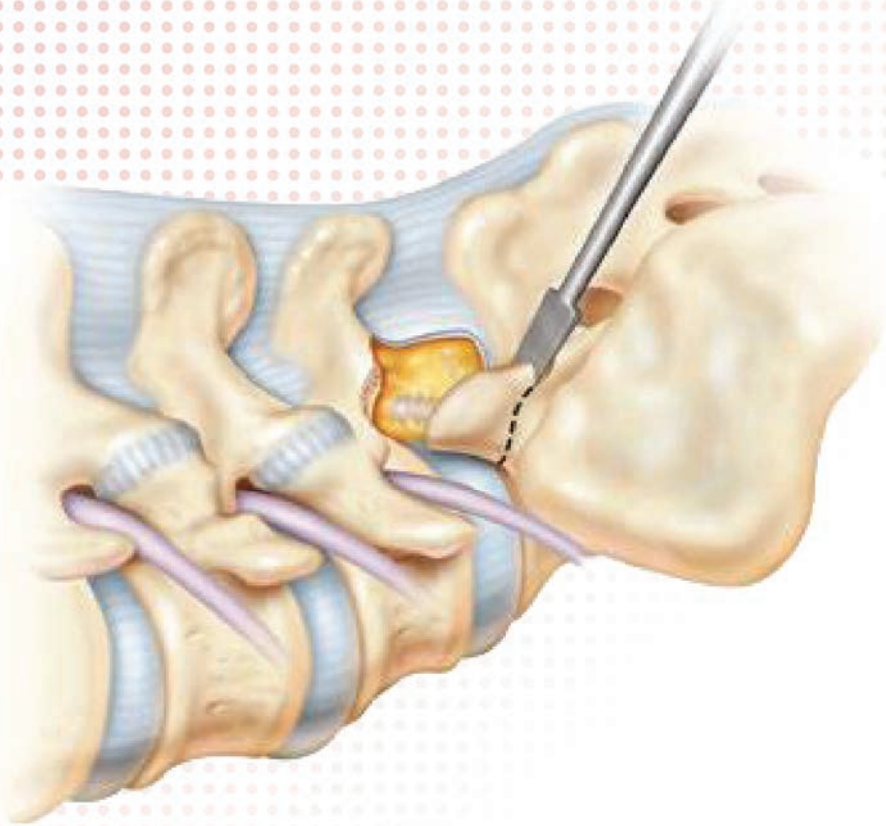


Figure 4

**2. Facetectomy and Working Zone Preparation (L5/S1)**

Resect the superior articular process of S1 with a straight osteotome or a Kerrison while protecting the traversing nerve root to expose the intervertebral foramen (Figure 4).

# The ALECTA TLIF System Surgical Technique

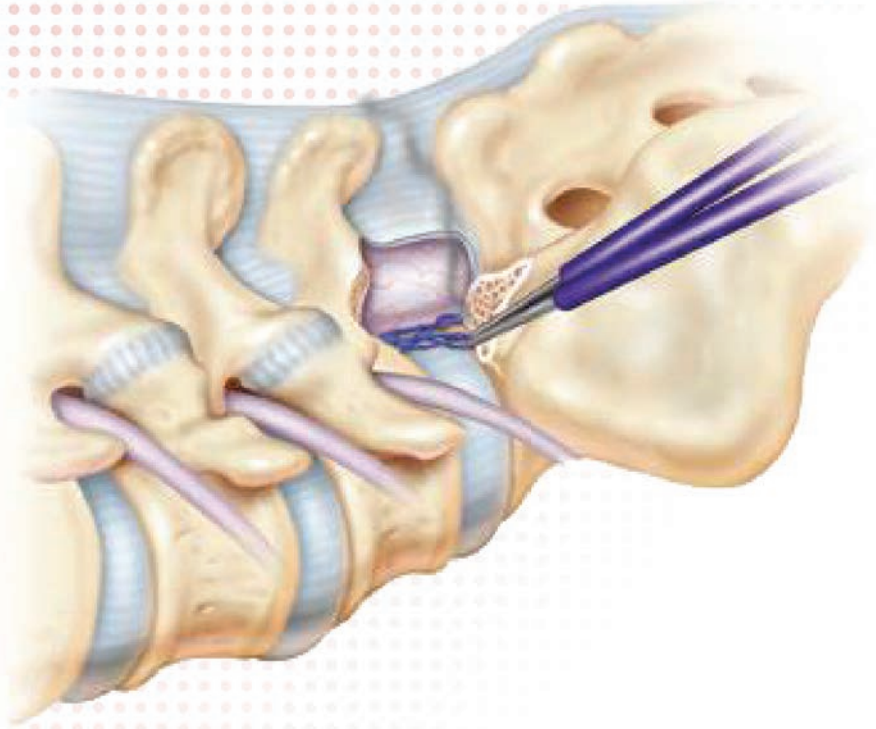


Figure 5

**2. Facetectomy and Working Zone Preparation (L5/S1)**

Expose the medial and cephalad margin of the S1 pedicle by removing the overhanging superior articular process with a Kerrison punch to gain final exposure of the L5/S1 disc.
Complete thorough hemostasis over the exposed disc space with the use of bipolar cautery (Figure 5). It is essential at this point to coagulate the epidural veins overlying the disc space.

# The ALECTA TLIF System Surgical Technique

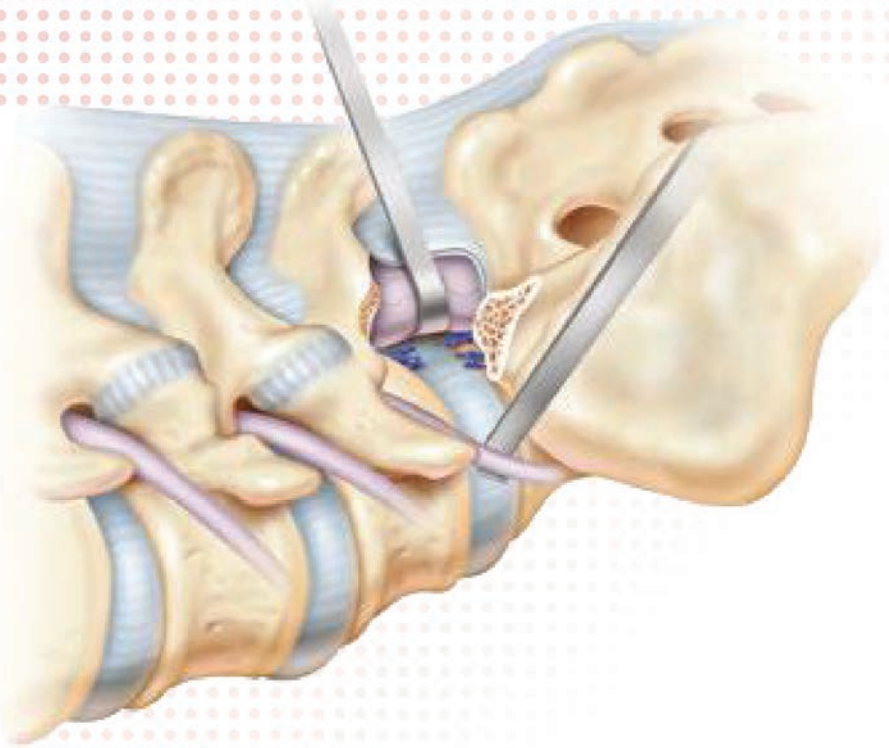


Figure 6

### 3. Annulotomy and Initial Disc Dissection

Care should be taken to gently retract and protect the exiting L5 nerve root and lateral part of the central dural sac. A dissector or nerve root retractor is used to protect these structures at every step of the procedure (Figure 6).
The epidural veins have now been ligated to afford a corridor of approach to the disc space.

# The ALECTA TLIF System Surgical Technique

Figure 7

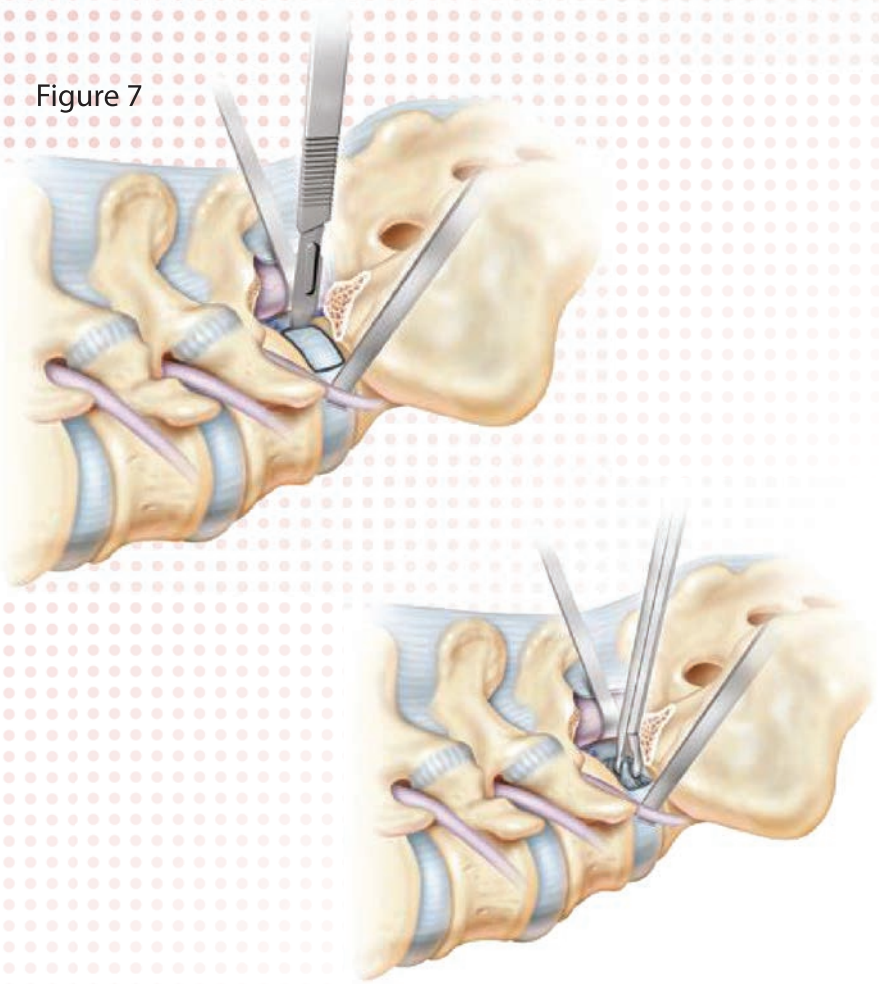


Figure 8

### 3. Annulotomy and Initial Disc Dissection

Perform a box annulotomy to create a window into the disc space (Figure 7). After the box annulotomy, a pituitaryrongeur is used to initially remove loose nuclear tissue in order to clear an initial space for the distractors (Figure 8).

# The ALECTA TLIF System Surgical Technique

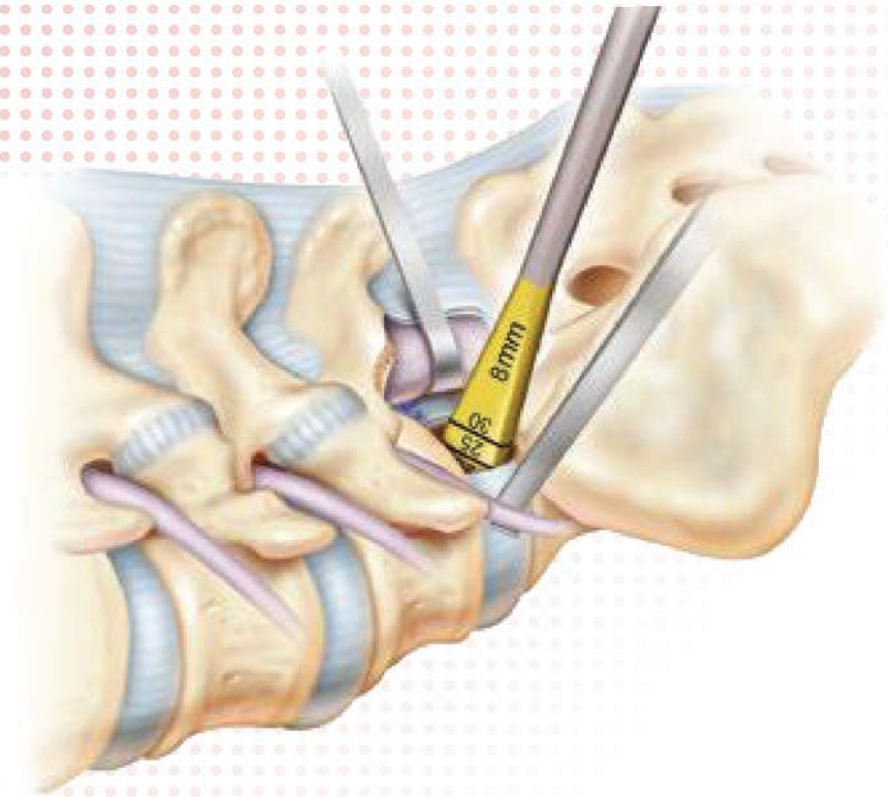



Figure 9

**4. Initial Distraction and Preparation of Disc Space**

Initial distraction of the disc space is necessary in order to access the disc for a thorough discectomy which is required for good fusion preparation and orientation for optimal cage insertion. Distraction can be achieved using one of the following methods:

- Distraction between pedicle screws
- Distraction between the spinous process

Use of a starter dilator (8 mm) or a disc spreader from the disc preparation set as pictured in Figure 9.

# The ALECTA TLIF System Surgical Technique

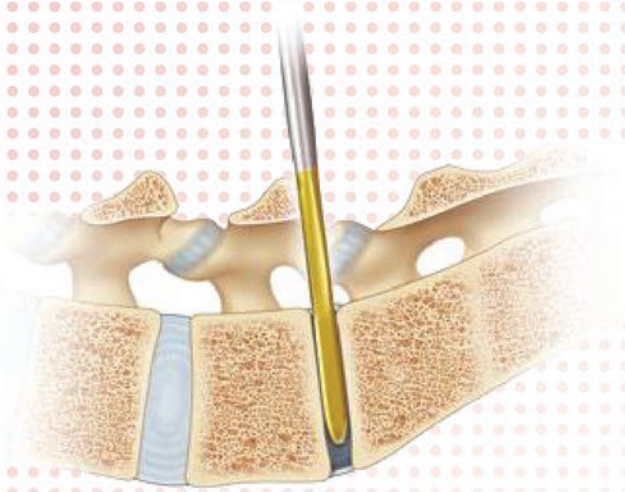


Figure 10

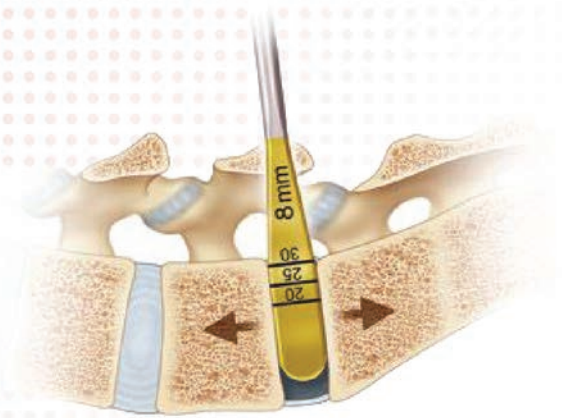



Figure 11

**4. Initial Distraction and Preparation of Disc Space**

After the initial removal of disc tissue, a starter dilator (8 mm) or a spreader from the disc preparation set is inserted horizontally into a collapsed disc space and then rotated 90° to achieve distraction (Figure 10 and 11).
Ideally once distraction is complete, the endplates are parallel (Figure 11) in order to maximise the posterior opening of the disc space to allow optimal access for disc preparation and reconstruction.

# The ALECTA TLIF System Surgical Technique

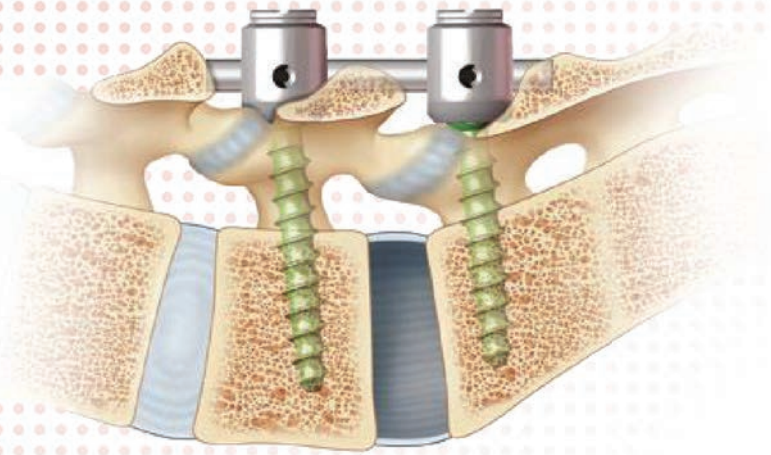


Figure 12

### 4. Initial Distraction and Preparation of Disc Space

Once distraction is obtained, the opening of the disc space can be maintained with either a temporary rod (Figure 12) or the use of a laminar spreader between the spinous processes.

# The ALECTA TLIF System Surgical Technique

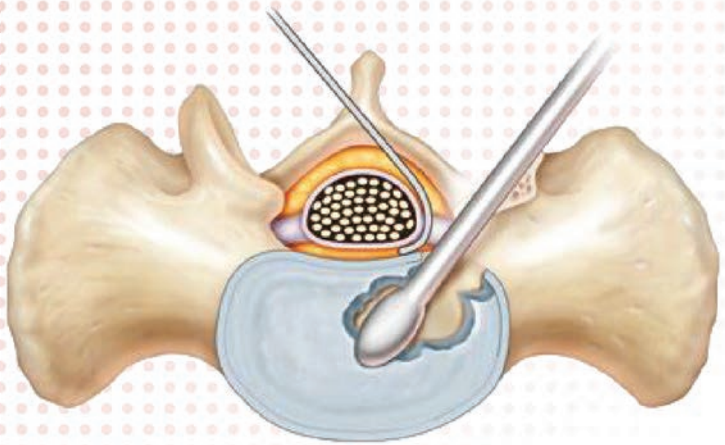


Figure 13

**5. Final Disc Preparation and Endplate Cleaning**

The final discetomy is performed using a combination of curettes, osteotomes, rongeurs, and shavers (Figure 13). Care should be taken to maintain the integrity of the endplates and to protect the dura with appropriate retractors wherever instruments are passed in and out of the disc space. Once the initial central portion of the disc has been removed, there is improved visualization of the orientation of the endplates.

**Warning**: Excessive removal of the subchondral bone may weaken the vertebral endplate. The entire removal of the endplate may result in subsidence and a loss of segmental stability

# The ALECTA TLIF System Surgical Technique

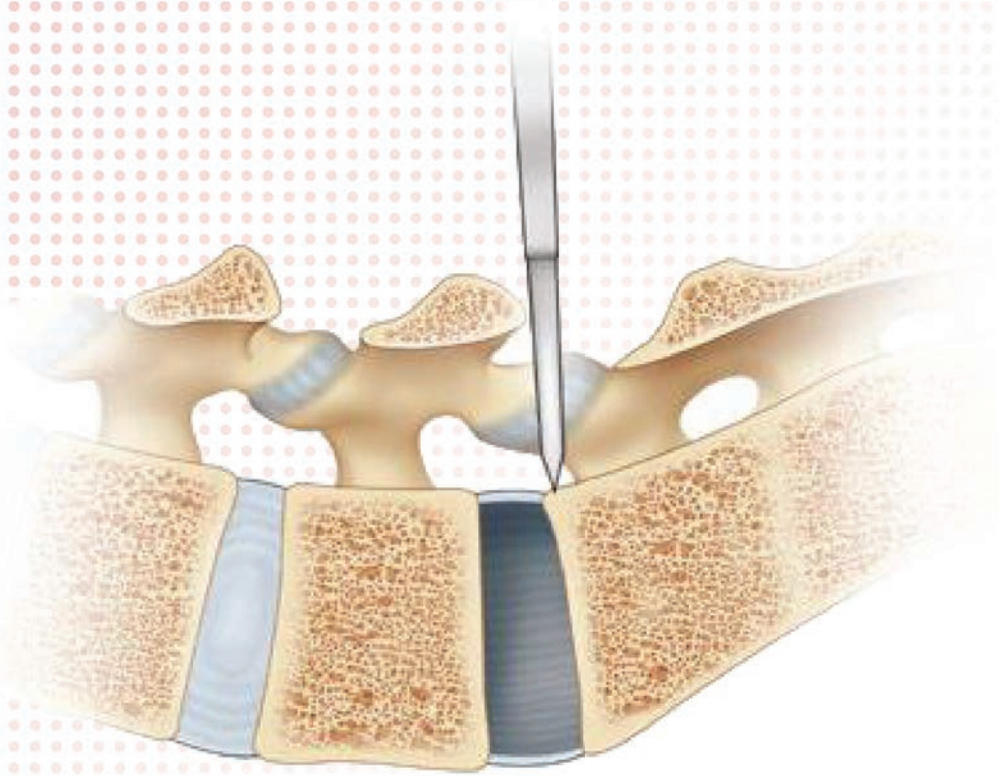


Figure 14

**5. Final Disc Preparation and Endplate Cleaning**

An osteotome can be used to remove the posterior lip of either vertebral body flush to the endplates to optimize visualization and access for the anteriorcontra lateral aspect of the disc (Figure 14). The resection of the posterior lip will also provide a smooth path for insertion of the cage. It is important that a flat, parallel surface is achieved in preparation for the insertion of the interbody device.

**Precaution**: Care should be taken to preserve the integrity of the endplates when resecting the posterior lips.

# The ALECTA TLIF System Surgical Technique

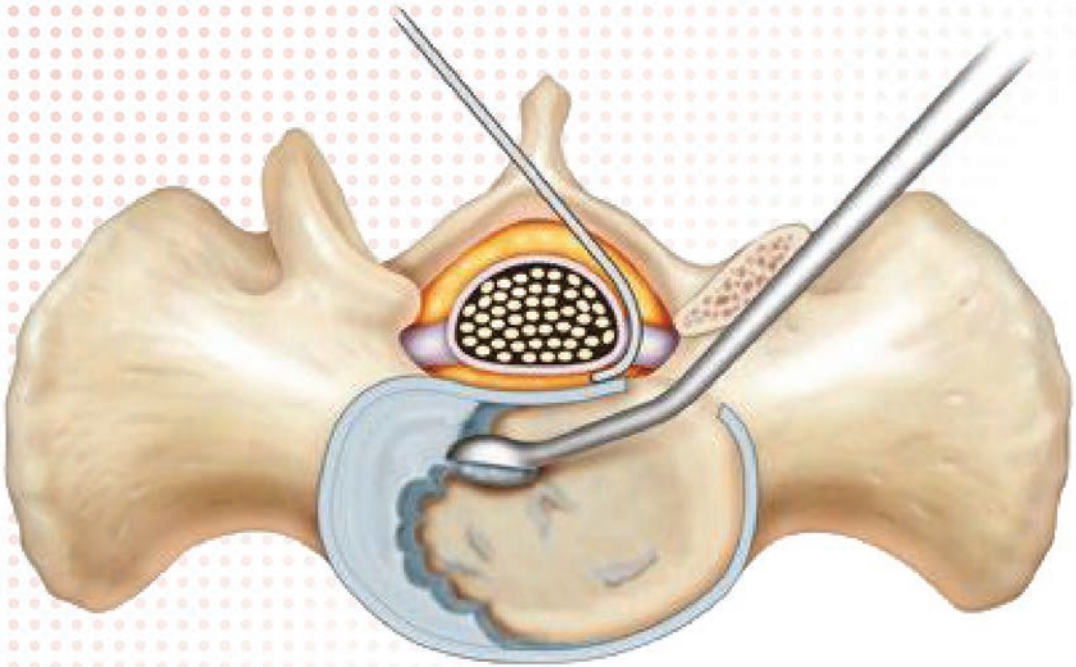


Figure 15

**5. Final Disc Preparation and Endplate Cleaning**

In order to ensure the disc material is removed from the contralateral posterior corner of the disc space, an offset downbiting curette can be used (Figure 15).

# The ALECTA TLIF System Surgical Technique

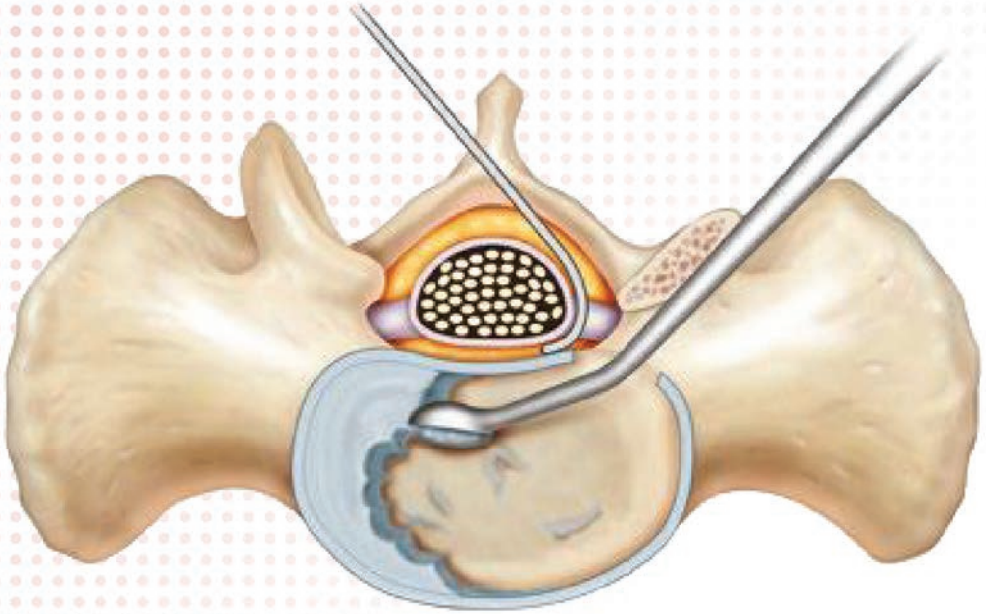


Figure 16

**5. Final Disc Preparation and Endplate Cleaning**

A curette or a rasp can be used in a scraping fashion to separate and remove any remaining disc and cartilage from the bony endplates.
Straight or angled rongeurs are utilized to remove any remaining loose disc material.
A variety of straight, angled, and offset cup, ring, and down biting curettes are available from the disc preparation set to facilitate further disc removal.
Double angled cup curettes (left and right) can also be utilized to remove disc material from the contralateral side of the disc space; these will specifically address the inferior and superior endplates (Figure 16).

# The ALECTA TLIF System Surgical Technique

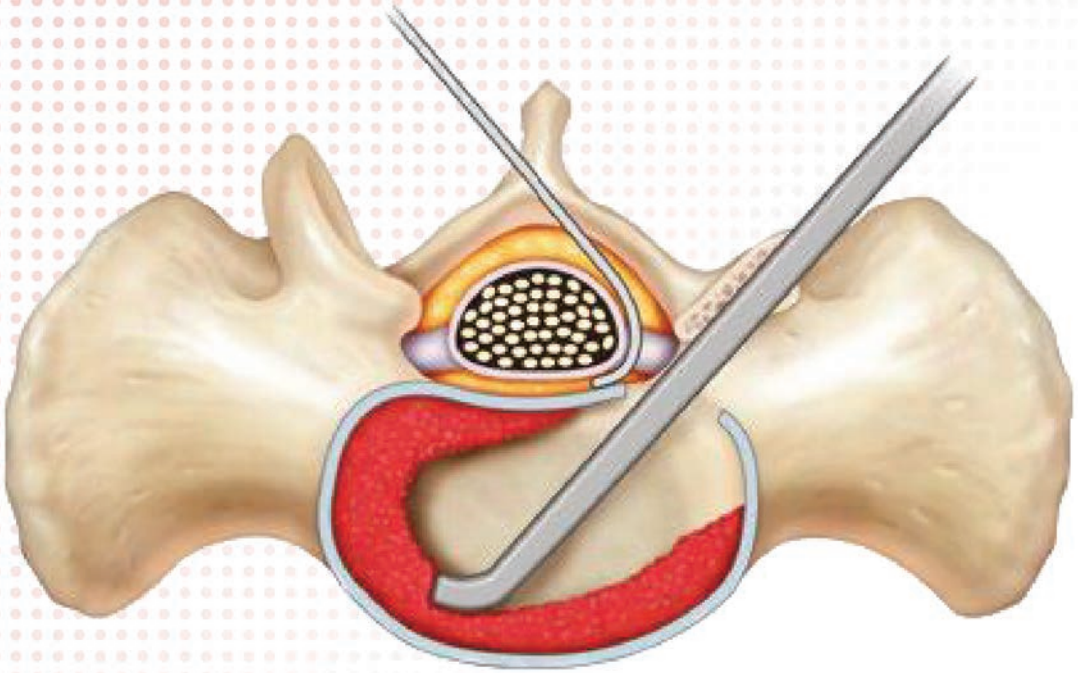


Figure 17

**6. Decortication and Placement of Bone Graft**

Final decortication is done with sharp curettes and osteotomes and should be deep enough to stimulate punctate endplate bleeding.
In order to achieve a solid interbody fusion, the disc space should be filled with as much bone graft as possible. Fill the anterior third and contralateral side of the disc space with bone graft using a variety of straight and curved bone tamps from the disc preparation set (Figure 17).

The quality of the disc preparation and endplate decortication is as important as the volume of the graft inserted.

# The ALECTA TLIF System Surgical Technique

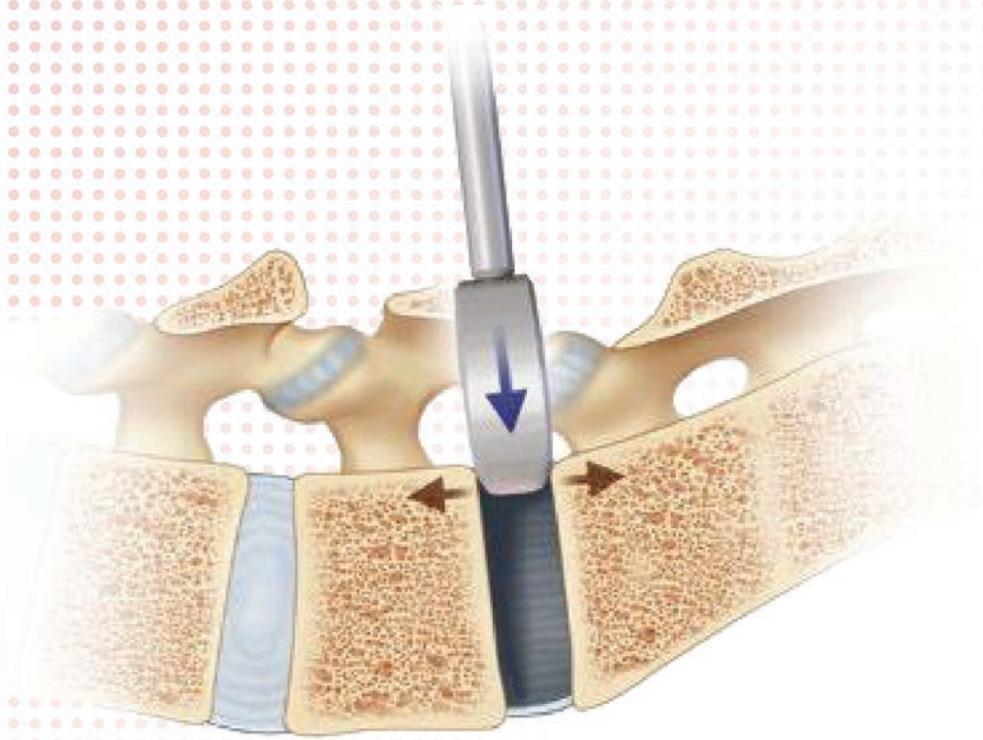


Figure 18

## 7. Cage Trialing

Trialing to aid in correct selection of the implant is extremely important.
A cage trial should be used prior to insertion of the implant to evaluate potential cage placement and determine the optimal implant fit (Figure 18).
Lateral fluoroscopy may be useful in analyzing implant orientation and ultimate desired lordosis.
The cage trials match the parallel configuration available with Alecta Interbody System Implants. Trials are sized to match the overall height of the corresponding implant, including the teeth of the implant.

# The ALECTA TLIF System Surgical Technique

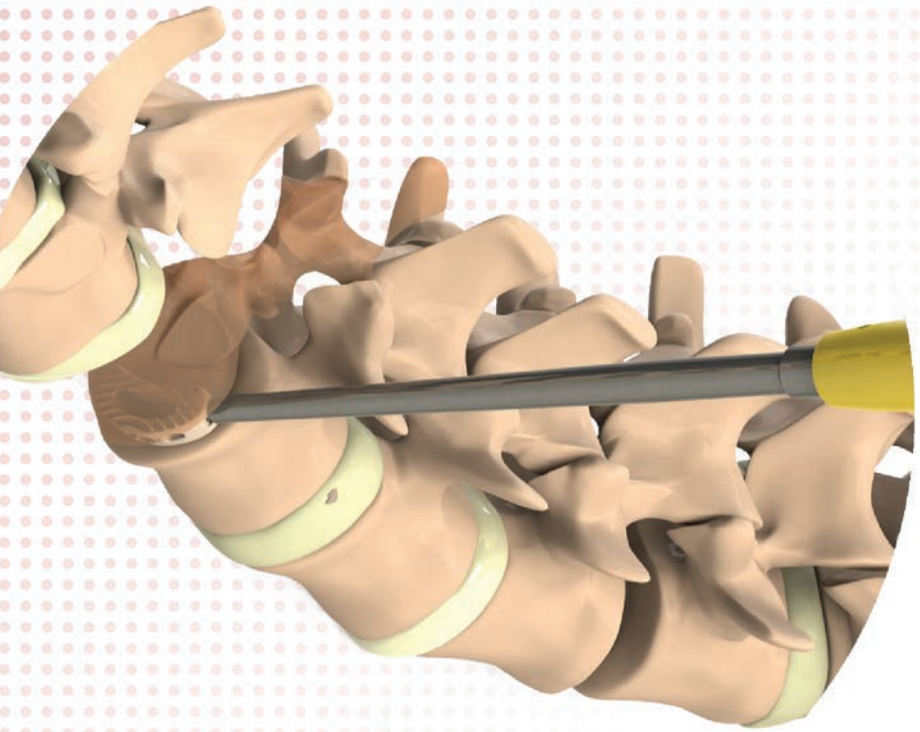


Figure 19

**8. Cage Insertion**
**Alecta Interbody System**

Align threaded hole of cage with threaded tip. Tighten the knob clockwise until cage is secure. Take care not to cross thread or overtighten the inserter (Figure 19).

Alecta Interbody System Implants should only be used with the Alecta Interbody System Inserters.

# The ALECTA TLIF System Surgical Technique

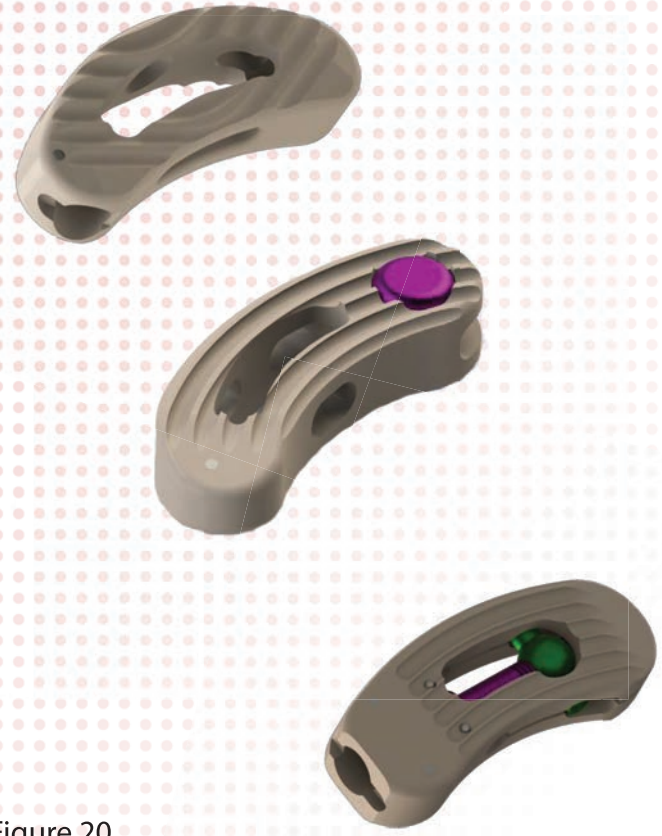


Figure 20

## 9. Implant Orientation for Lordotic ALECTA Interbody System

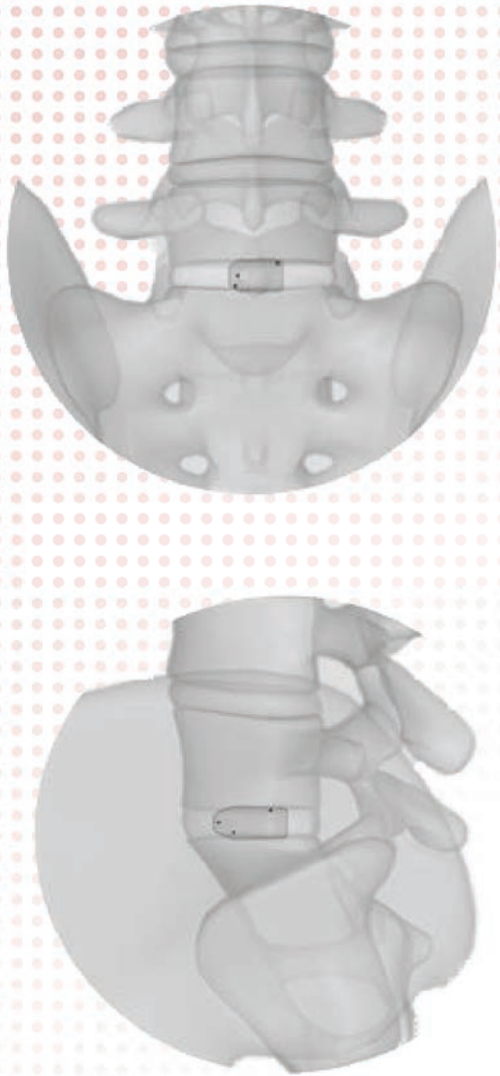
In order to provide the desired 5 degrees of lordotic angulation, confirm that the orientation marker is located on the posterior and medial side of the implant before insertion (Figure 20). Once the implant is loaded on to the inserter, pack the cage with bone graft.
It is important to protect the central dura and traversing and exiting nerve roots during insertion and manipulation of the implant.
Excessive torque or impaction force, when applied to long-handled insertion tools, can cause splitting or fracture of implants.

# The ALECTA TLIF System Surgical Technique

Figure 21

**10. Final Compression**

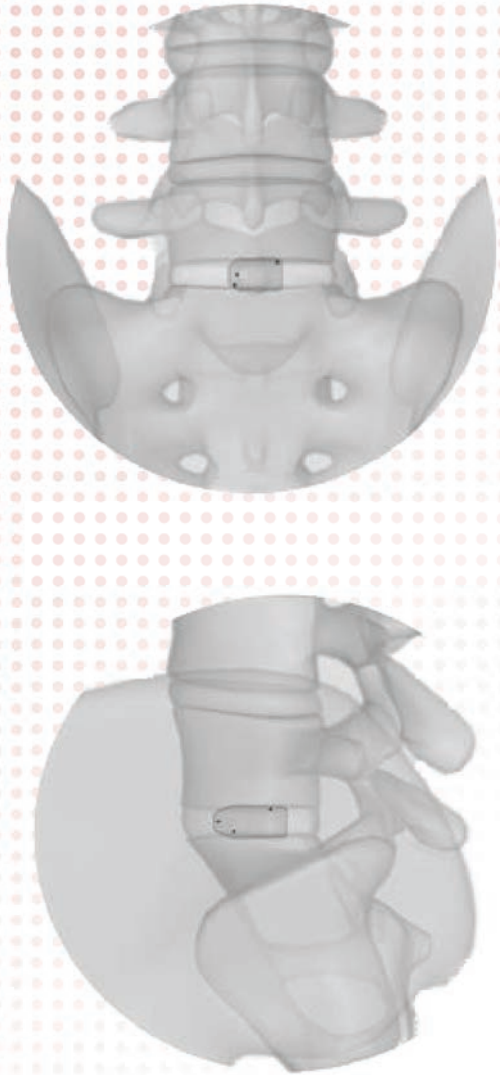
The appropriate length pre-cut, prelordosed rod is selected to match the lordosis of the patient's spine. Rods are seated into the screw heads and active compression is applied to the selected pedicle screw system.
To achieve this, tighten either the caudal or cranial set screws to securely lock one end of the rod in place and provide an anchor point for the compression.
With the remaining set screw loosened, use the compressor to perform final compression.
Lock the compression in place by tightening the remaining set screw.
The same maneuver can then be repeated on the contralateral side.
Following compression, normal segmental lordosis and foraminal height should be maintained.
Confirm that the rod does not impinge on the adjacent facets.
Once desired lordosis of the segment and positioning of the implant is confirmed, revisit all screws for final tightening.



# The ALECTA TLIF System Surgical Technique

**11. Verification of Final Cage Placement**
**Alecta Interbody System**

An X-ray should be taken to verify final cage placement. MRI and CT the appearance will identify the position of the ALECTA Interbody System Cage in the sagittal, coronal, and axial planes.
In the event of a revision, the cage may be removed from an anterior or posterior approach. Preoperative planning should include scan analysis of cage orientation, the location of any embedded bone graft, and any endplate intrusion. If approaching posteriorly it is essential to dissect and protect the exiting and traversing nerve roots, especially where they may be adhesed from scar. It may be easier to enter the canal from the contralateral side due to lack of scar tissue. However, be aware that the position of the cage may dictate which end is easier to reach once revision annulotomy is done.
Also, if approaching on the contralateral side from initial insertion, the leading nose of the cage will not have a threaded hole for engaging the insertion device if necessary.



# The ALECTA TLIF System Surgical Technique

**11. Verification of Final Cage Placement**
**Alecta Interbody System**

Once the nerves are protected, an annulotomy is made to re-enter the disc space. Intervertebral distraction is essential to optimize safe removal. Fine curettes are used to remove any fibrous tissue surrounding the cage. If larger amounts of bone are present, osteotomes maybe required. Once the perimeter of the cage is clear, osteotomes or chisels are used to reestablish a cleft between the cage and endplate. Any fibrous tissue or bone passing through the cage into the endplate must be released before removal.
Overhanging osteophytes that might impede removal are also resected.
Once distraction is optimized and encasing fibrous tissue and bone excised, the cage can be grasped in the sidewalls with the removal tool and backed out. A curved curette or the threaded insertion tool can also be used to engage the cage and provide additional removal force if necessary.
**Precaution:** An explanted implant should never be reimplanted. Even though a device appears undamaged, it may have small defects and internal stress patterns that may lead to early breakage. Reuse can compromise device performance and patient safety. Reuse of single-use devices can also cause cross-contamination leading to patient infection.

# The ALECTA TLIF System Implants

**ALECTA LUMBAR TLIF CAGE, RIGID, PEEK**

Ref No (Sterile): AT1104.0000000
Height (H): 6mm - 16mm
Length (L): 28mm, 34mm
Degree (D): 0°, 5°, 9°

# The ALECTA TLIF System Implants

**ALECTA LUMBAR TLIF CAGE, RIGID, TITANIUM**

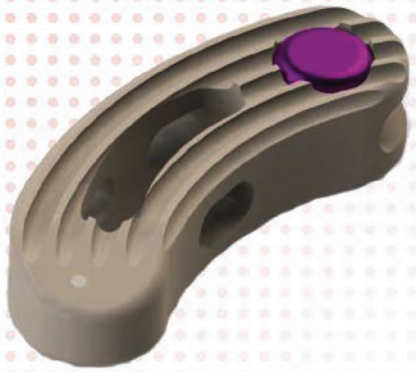
Ref No (Sterile): AT1105.0000000
Height (H): 6mm - 16mm
Length (L): 28mm, 34mm
Degree (D): 0°, 5°, 9°

# The ALECTA TLIF System Implants

**ALECTA LUMBAR TLIF CAGE, EXPANDABLE, PEEK**

Ref No (Sterile): AT1106.0000000
Height (H): 6mm - 16mm
Length (L): 28mm, 34mm
Degree (D): 0°, 5°, 9°

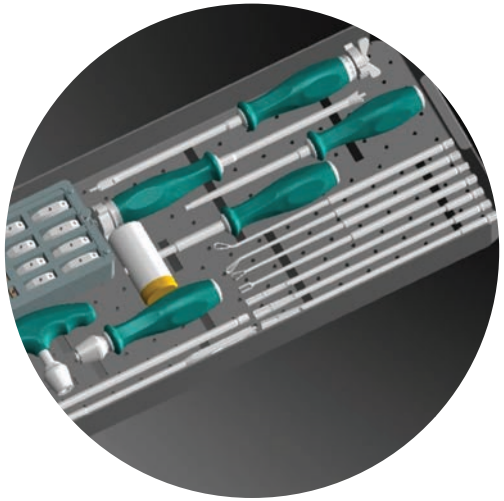
# The ALECTA TLIF System Implants



**ALECTA LUMBAR TLIF CAGE, RIGID, PEEK (TURN)**

Ref No (Sterile): AT1106.0000000
Height (H): 6mm - 16mm
Length (L): 28mm, 33mm
Degree (D): 0°, 5°, 9°

# The ALECTA TLIF System Surgical Technique



| Ref. Number | Description | Ref. Number | Description |
|---|---|---|---|
| **14000.INS0101** | I - Handle | **14000.INS0108** | Shaver 9mm |
| **14000.INS0102** | Mallet | **14000.INS0109** | Shaver 11mm |
| **14000.INS0103** | Right Angled Curette | **14000.INS0110** | Trial Inserter |
| **14000.INS0104** | Rectangular Angled Curette | **14000.INS0111** | TLIF Impactor |
| **14000.INS0105** | Left Angled Curette | **14000.INS0112** | Impactor |
| **14000.INS0106** | Rasp | **14000.INS0113** | Trial Implants |
| **14000.INS0107** | Shaver 7mm | **14000.INS0114** | Cage Box |

Produced Exclusively for

EOS
MEDICAL SOLUTIONS

10, Kassiopis Str., 17237,
Ymittos, Greece
Email: info@eosmed.eu
Website: www.eosmed.eu
Tel:+302160033602

CE
2292