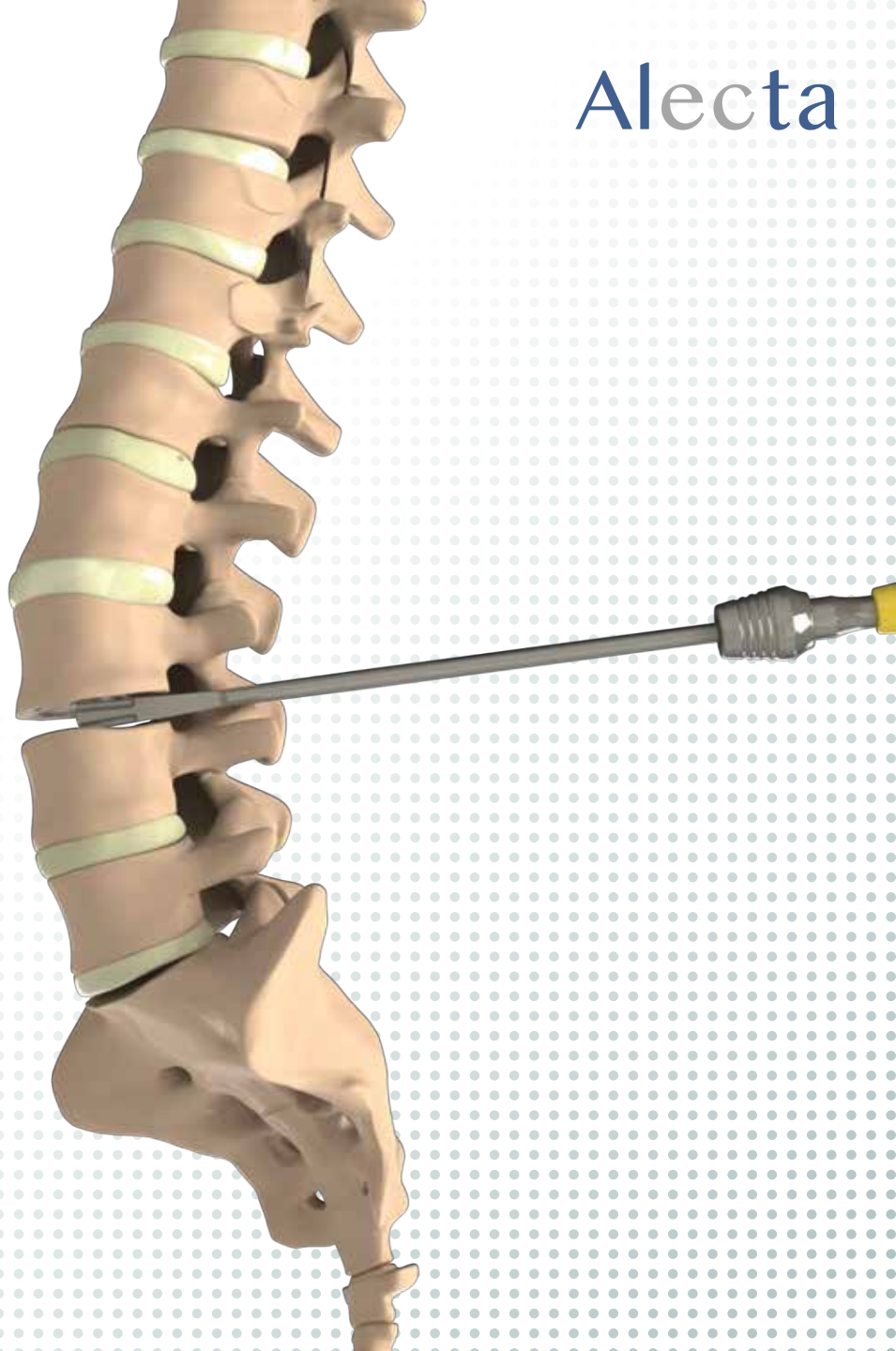
Alecta™

Posterior Lumbar Interbody System **(PLIF)**

SURGICAL TECHNIQUE
&
SET INFORMATION

Eos MEDICAL SOLUTIONS

The ALECTA PLIF System Description



Purpose

Alecta PLIF is an implant system for a unilateral transforaminal approach (TLIF) or optionally for a bilateral posterior approach (PLIF). It is specially designed for small incision, resulting in a relatively atraumatic operation for the patient. Implants provide an adequate stability, restore height and lordosis to provide an optimized fusion.

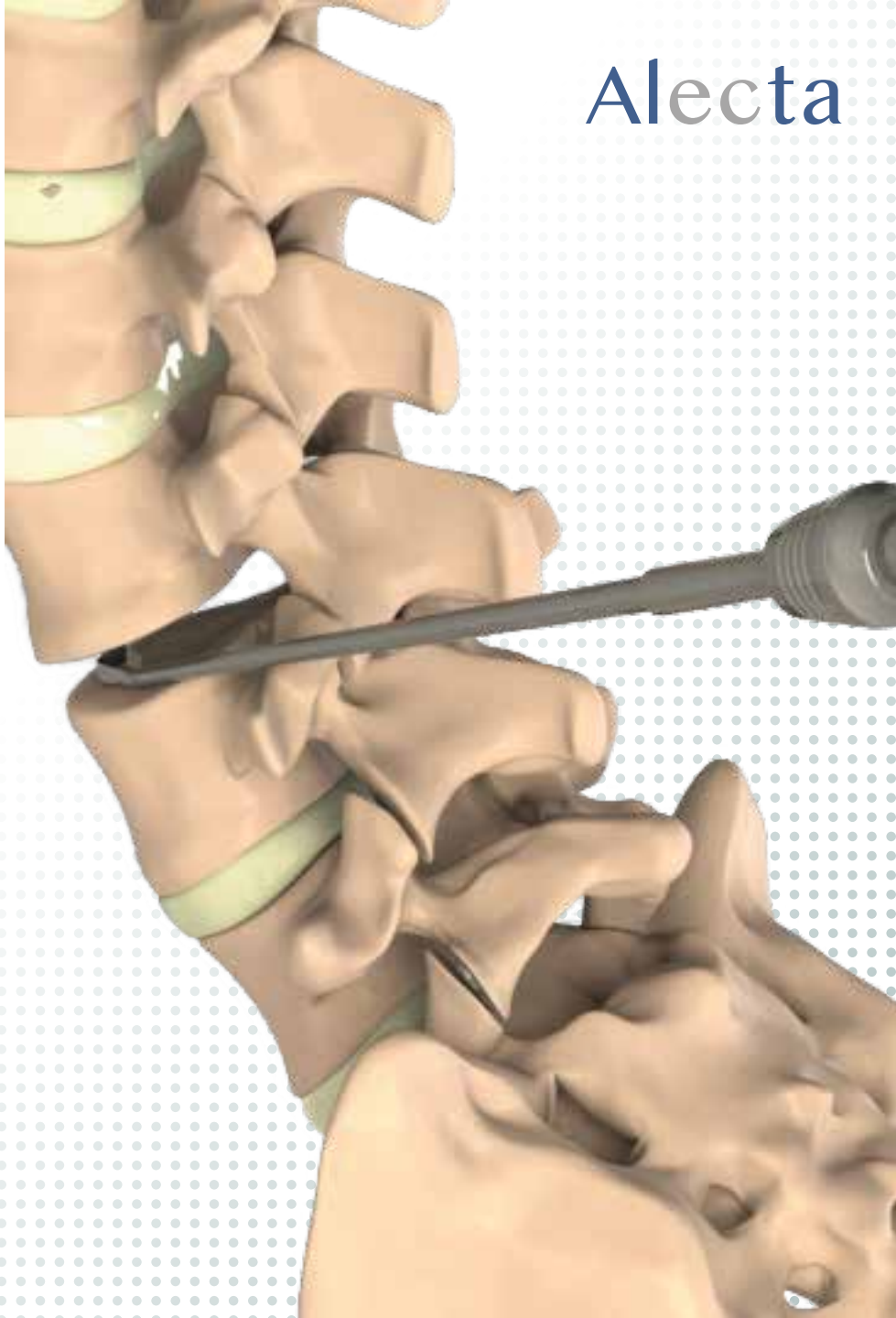
General Description

The Posterior Lumbar Interbody Fusion (PLIF) procedure is intended to stabilize the spine by causing bone to grow between the two vertebral bodies, thus limiting motion at that level. PLIF achieves spinal fusion in the low back by inserting two cages directly into the disc space and is supplemented by a posterolateral spinal fusion surgery, typically a pedicle screw construct.

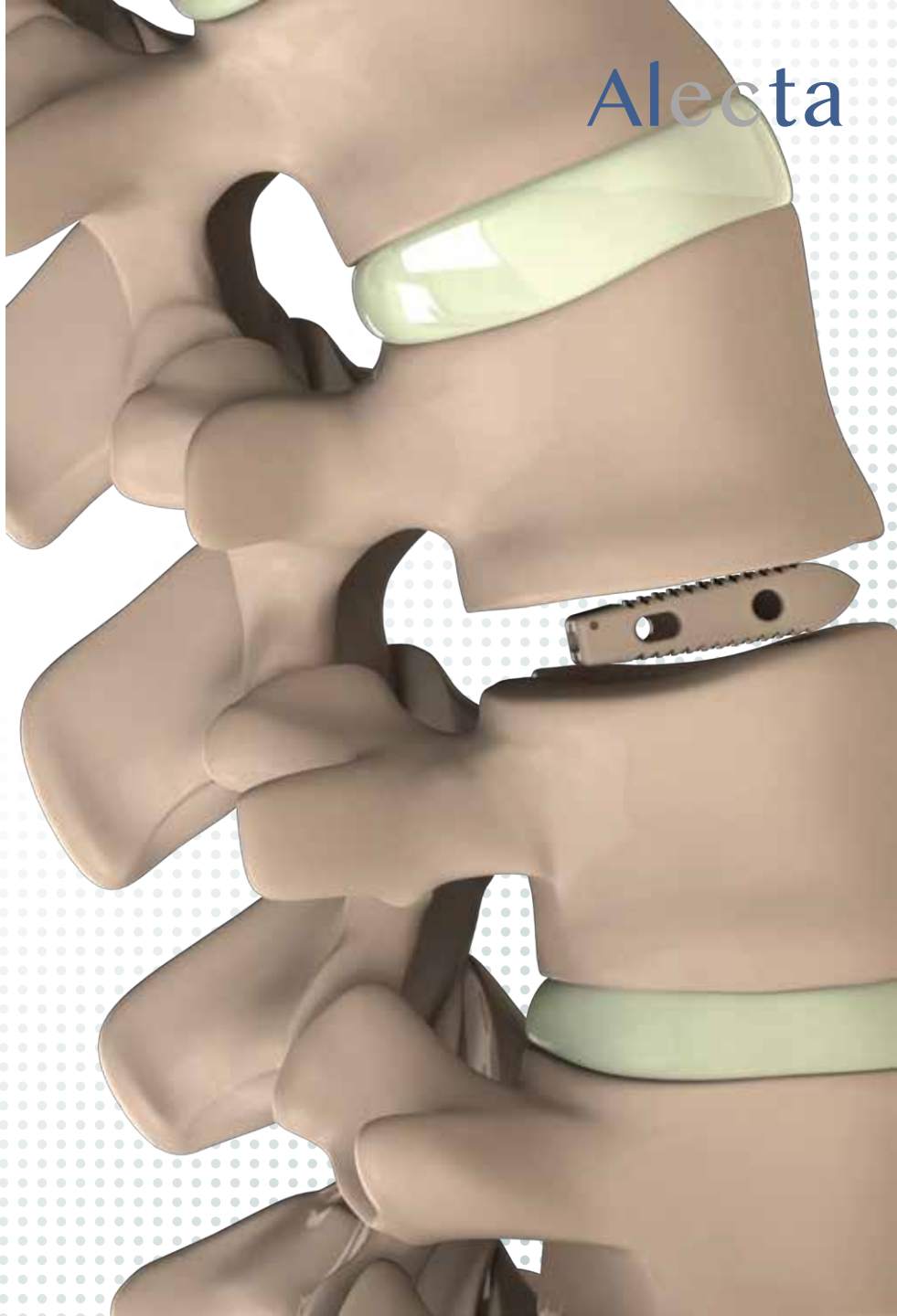
The ALECTA PLIF System Description

Posterior Lumbar Interbody Fusion Cage, is manufactured from PEEK and Titanium alloy material which is compatible with MRI and CT. Does not allow any lesional problems. It's implanted from posterior approach for following indications: Mechanical Instability, Spondylolisthesis, Degenerative Disc Disease. It's toothed surface feature facilitates a strong fixation by superior and inferior area. Through it's grafting spaces, it's possible to reach appropriate fusion by grafting technique.

There are cage sizes for different anatomies.
The sizes of the cages; it is between 6 mm and 13 mm.



The ALECTA PLIF System
Indications & Contraindications

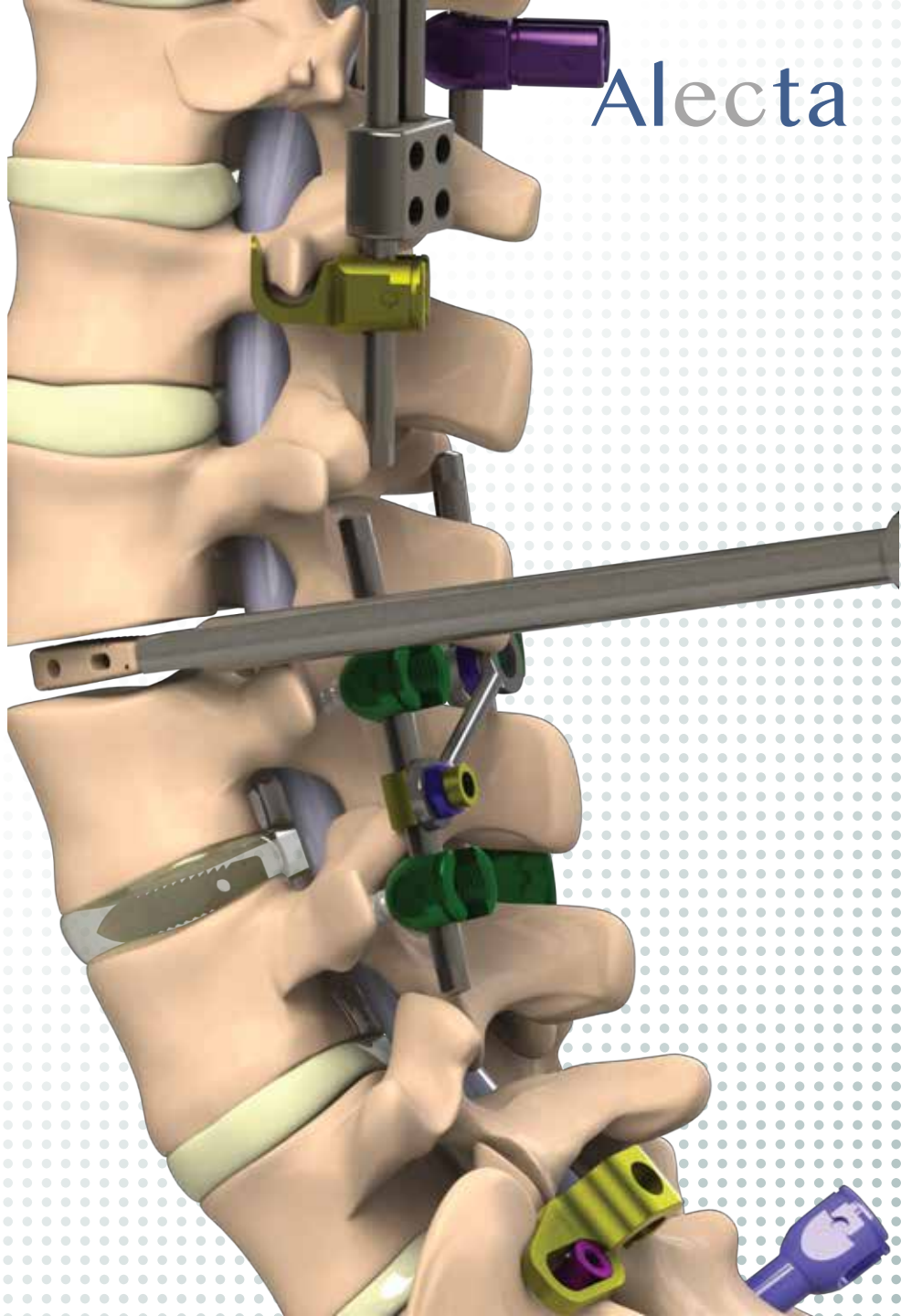


Indications for Use

Indications are lumbar and lumbosacral pathologies in which segmental spondylodesis is indicated, for example:

- Degenerative disc diseases and spinal instabilities
- Revision procedures for post-discectomy syndrome
- Pseudarthrosis or failed spondylodesis
- Degenerative spondylolisthesis
- Isthmic spondylolisthesis

The ALECTA PLIF System
Indications & Contraindications



Contraindications

- Vertebral body fractures
- Spinal tumors
- Major spinal instabilities
- Primary spinal deformities

The Alecta PLIF System Surgical Technique

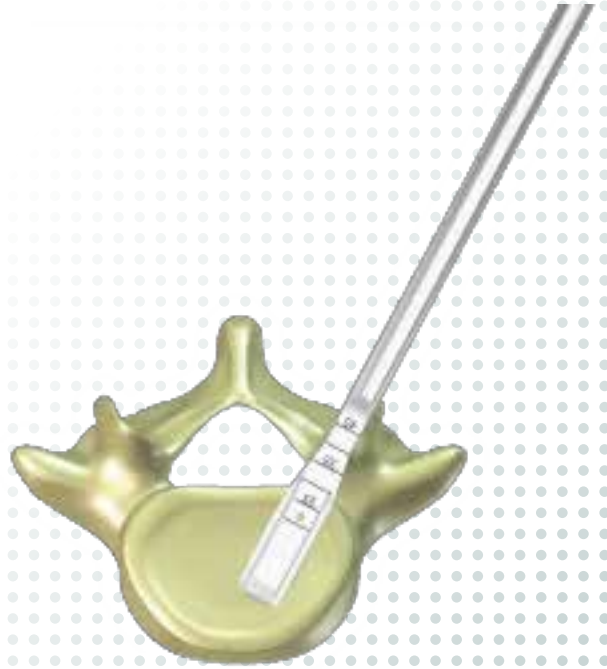
1. Position the patient

Positioning of the patient is chosen in accordance with the PLIF technique depending on the patient's pathology. Once the patient has been monitorised, intubated and anesthetised, the patient is laid in posterior (face down) position. Positioning must be carried out paying attention to those areas on which pressure may be applied and to the chest of the patient. Subsequently, the patient's area of operation is prepared with sterile covers and drapes in compliance with the general procedure.

The ALECTA PLIF System Surgical Technique

2. Preparation and discectomy

Remove disc material using the disc shavers. Attach the appropriate size disc shaver to the large T-Handle and insert the shaver until the cutting edge is completely within the disc space. Rotate the disc shaver to remove disc and endplate cartilage. The disc shavers feature cutting flutes that allow the instrument to cut in two directions by rotating the T- Handle clockwise and counterclockwise as needed to scrape end-plate material and promote bleeding.



The ALECTA PLIF System Surgical Technique

2. Preparation and discectomy

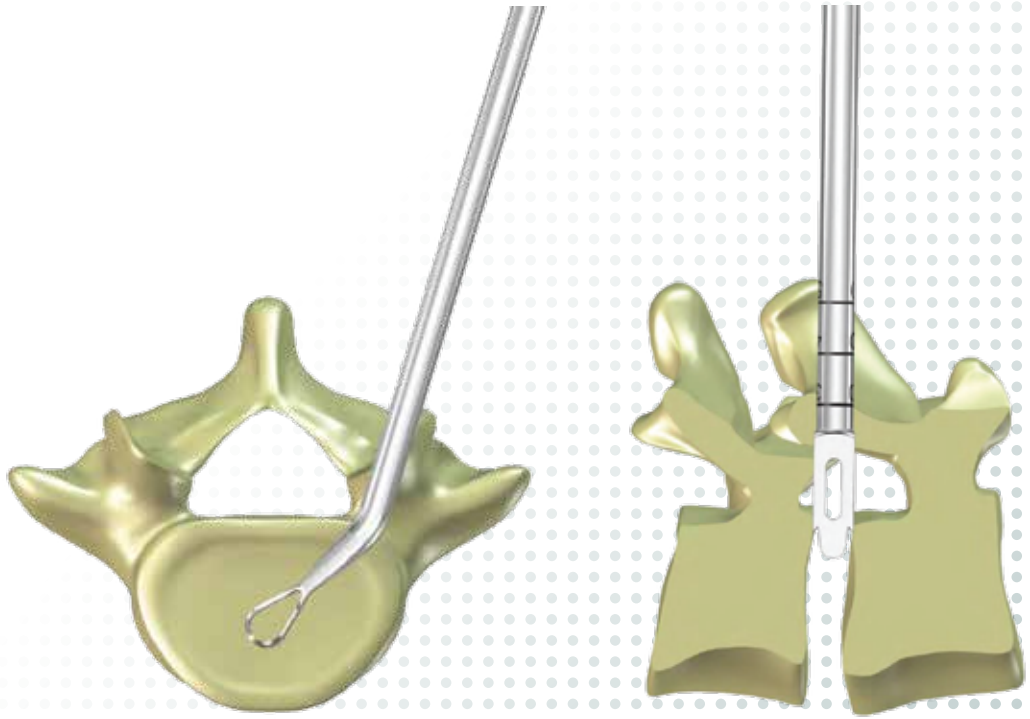
Distraction of the disc space can be achieved using either the paddle distractors or disc shavers. To use the paddle distractors for distraction, attach the smallest paddle distractor to the T-Handle and insert it into the disc space horizontally and rotate 90°, using larger sizes until the desired distraction is achieved. To use the disc shavers for distraction, attach the smallest disc shaver to the T-handle and insert it into the disc space horizontally and rotate 90°, using larger sizes until the desired distraction is achieved.

Note: use caution while using the paddle distractors or disc shavers for distraction to avoid damage to the endplates.

The ALECTA PLIF System Surgical Technique

3. Endplate Preparation

Once the disc space is distracted, final discectomy and endplate preparation can be performed by thoroughly decorticating the endplate above and below the disc space using rasps or curettes. With osteotomes, remove osteophytes and the posterior lip of adjacent vertebral bodies. With the dura safely retracted, a box chisel is attached to the T-handle and used to prepare a rectangular channel for the Interbody Spacer. The box chisel should be oriented so that the cutting edges are parallel with the endplates and then gently tapped into the disc space with a mallet to the desired depth. The box chisel can be removed from the disc space with the use of the slide hammer.



The ALECTA PLIF System SURGICAL TECHNIQUE

4. Sizing The Disc Space

The disc space height is sized using a series of trials or paddle distractors. The trials and paddle distractors are serially increased until the appropriate fit within the disc space is acheived. The trials and paddle distractors should fit snugly within the disc space; however, care should be taken not to oversize the implant, as this may result in difficult insertion of the implant and possible subsidence.

Note: The Alecta® trials and paddle distractors match the overall height of the corresponding implant.

The ALECTA PLIF System Surgical Technique

5. Implant Preparation

The Alecta® Interbody Spacer is mounted on the inserter by fitting the spacer over the two stabilizing fingers and then turning the knurled thumbwheel clockwise until a snug fit is acheived.

After the Interbody Spacer has been selected and attached to the inserter, it is filled with bone graft by means of the graft block and graft tamp. Bone graft material is loaded into the cavity of the Alecta® Interbody Spacer by placing it into the corresponding graft block cavity and impacting graft material into the Interbody Spacer with the bone graft tamp.

The ALECTA PLIF System Surgical Technique

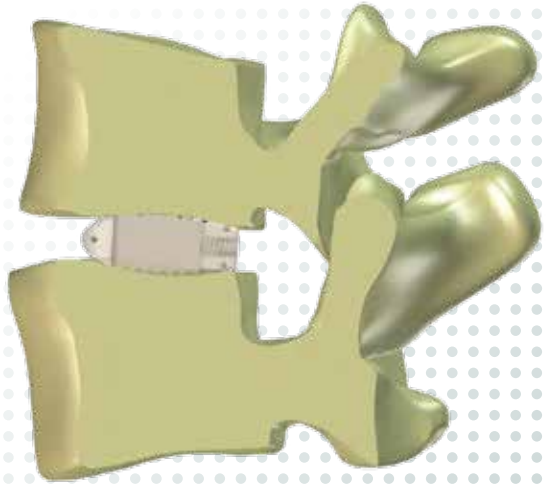
6. Implant Preparation

When the Interbody Spacer has been inserted, it can be detached from the inserter by rotating the knurled thumbwheel counterclockwise. If necessary, the position of the Interbody Spacer can be improved with the implant pusher. Fluoroscopy may be useful in determining the appropriate trajectory for insertion and appropriate final positioning. The presence of tantalum markers enables the spacer position to be precisely determined in the sagittal, coronal and axial planes. Before the second spacer is placed, the anterior and medial sides of the intervertebral space are filled with autogenous cancellous bone or with a bone substitute material.

The ALECTA PLIF System Surgical Technique

6. Implant Preparation

Note: should it become necessary to remove the Interbody Spacer, it may be retrieved from the disc space by re-attaching it to the inserter. This can be accomplished by threading the inserter fully into the Interbody Spacer. Once the Interbody Spacer is attached to the inserter, the Alecta® slide hammer can be attached to the proximal end of the inserter, then with controlled impact, the implant can be carefully removed from the disc space.
Caution: an explanted Interbody Spacer must never be re-used or re-implanted. Even though the device may appear to be undamaged, it may have defects which can lead to failure of the device.



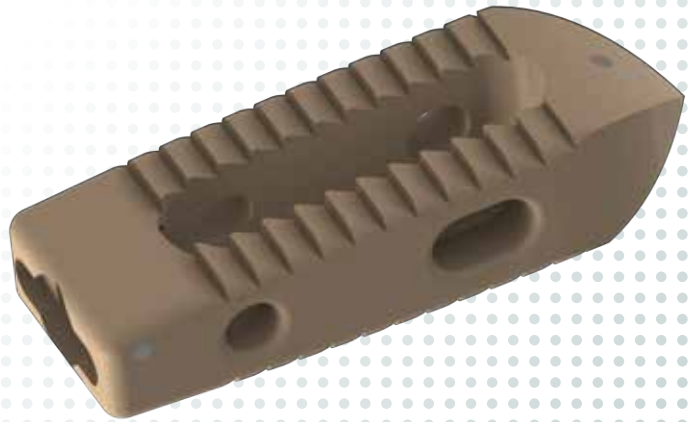
The ALECTA PLIF System Implants

ALECTA LUMBAR PLIF CAGE, RIGID, PEEK
(Sterile and Non-Sterile)

Height (H): 6mm - 13mm

Length (L): 25mm, 29mm

Degree (D): 0°, 5°, 9°



The ALECTA PLIF System Implants

ALECTA LUMBAR PLIF CAGE, RIGID, TITANIUM
(Sterile and Non-Sterile)

Height (H): 6mm - 13mm

Length (L): 25mm, 29mm

Degree (D): 0°, 5°, 9°

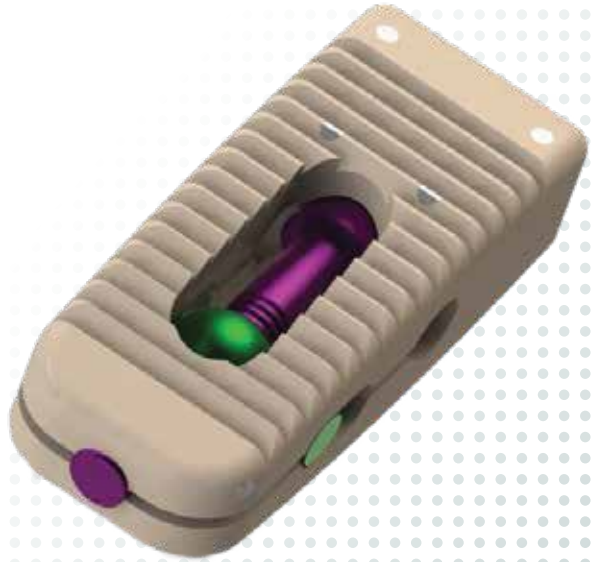
The ALECTA PLIF System Implants

ALECTA LUMBAR PLIF CAGE, EXPANDABLE, PEEK
(Sterile and Non-Sterile)

Height (H): 6mm - 16mm

Length (L): 25mm

Degree (D): 5°



The ALECTA PLIF System Implants

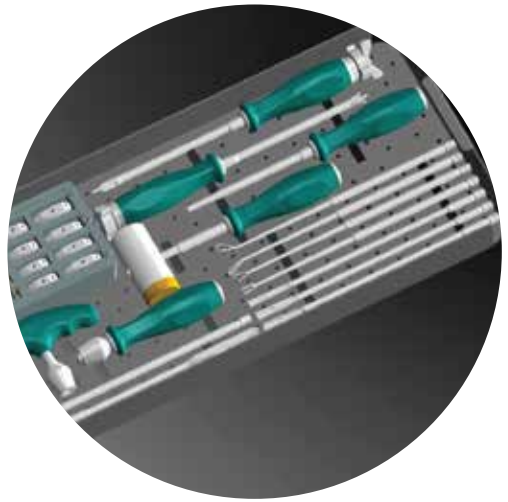
ALECTA LUMBAR PLIF CAGE, EXPANDABLE, TITANIUM
(Sterile and Non-Sterile)

Height (H): 6mm - 16mm

Length (L): 25mm

Degree (D): 5°

The ALECTA PLIF System INSTRUMENTS



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

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MEDICAL SOLUTIONS

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