Alecta™

Anterior Lumbar Interbody Fusion System **(ALIF)**

SURGICAL TECHNIQUE
&
SET INFORMATION

EOS MEDICAL SOLUTIONS

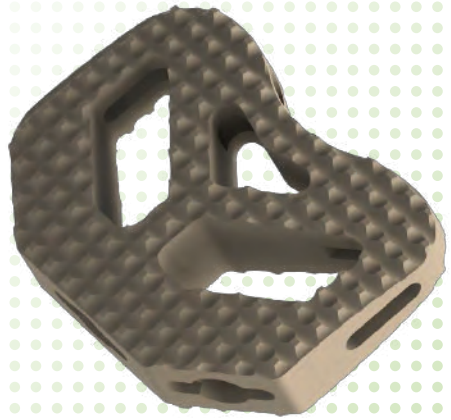
The ALECTA ALIF System Description

Purpose

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

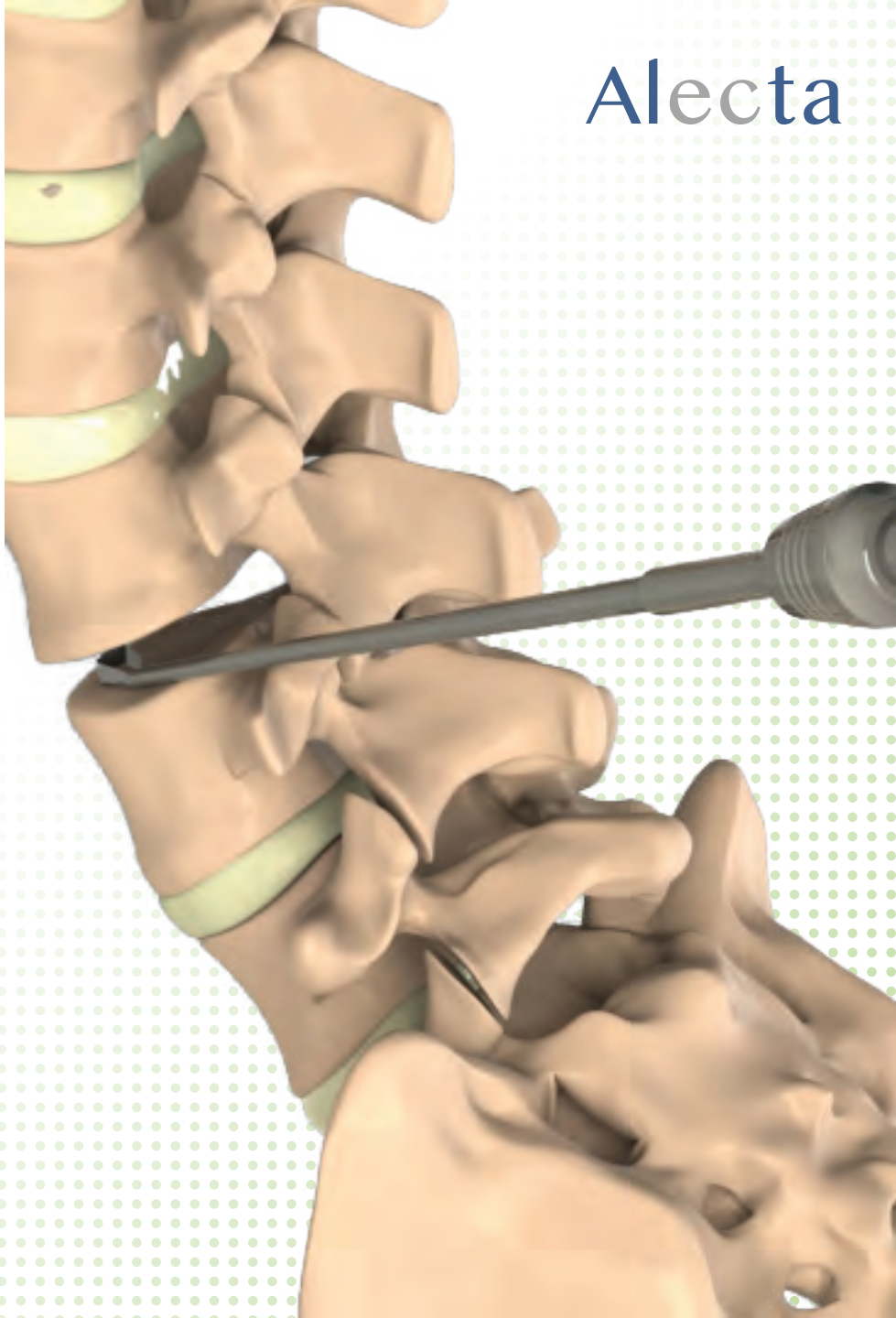
General Description

ALIF Lumbar Cage Sterile system is in the form of an anterior disc made of PEEK (Polyether Ether Ketone) and titanium raw material, which is compatible with the lumbar disc anatomy and interconnected by three one-way bridges from the central section. It is consisted of a single component.
The upper surfaces of the superior (upper) and inferior (lower) parts of the system are threaded, thus both preventing any shifts from the disc space and ensuring a controlled load exchange with the endplates.
Also, space control is provided by means ofthe titanium or gold pins driven into the system.



The ALECTA ALIF System Description

Anterior Lumbar Interbody Fusion (ALIF) alleviates pain through the removal of a damaged or diseased disc through an anterior approach.
This procedure involves the complete removal of the intervertebral disc and the implantation of an interbody fusion device to restore intervertebral height and fuse the vertebral bodies of the affected segment.Anterior Lumbar Interbody Fusion Cage is manufactured from PEEK and Titanium alloy material which is compatible with MRI and CT. There are cage sizes for different anatomies.
The sizes of the cages; it is between 9,5 mm and 15,5 mm.



The ALECTA ALIF System Indications & Contraindications

Indications for Use

- Lumbar and lumbosacral pathologies which may requir anterior segmental arthrodesis, including:
- Localised symptomatic degenerative disc disease
- Revision surgery for failed decompression syndrome
- Pseudoarthrosis

The ALECTA ALIF System
Indications & Contraindications

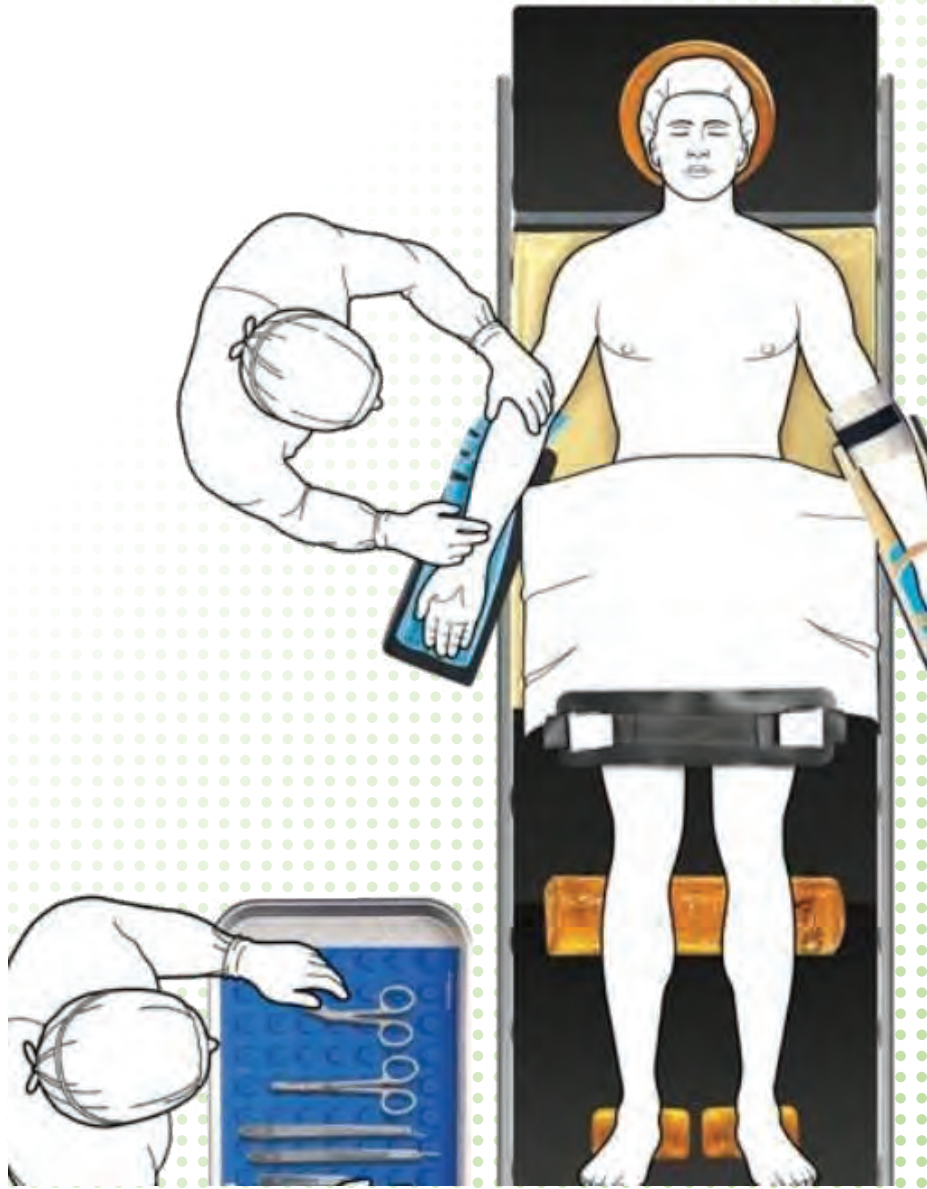
Contraindications

- Spinal fractures
- Spinal tumors
- Osteoporosis
- Infection

The Alecta ALIF System Surgical Technique

1. Position the patient

Positioning of the patient is chosen in accordance with the ALIF technique depending on the patient's pathology.
Once the patient has been monitorised, intubated and anesthetised, the patient is laid in anterior (face up) 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.

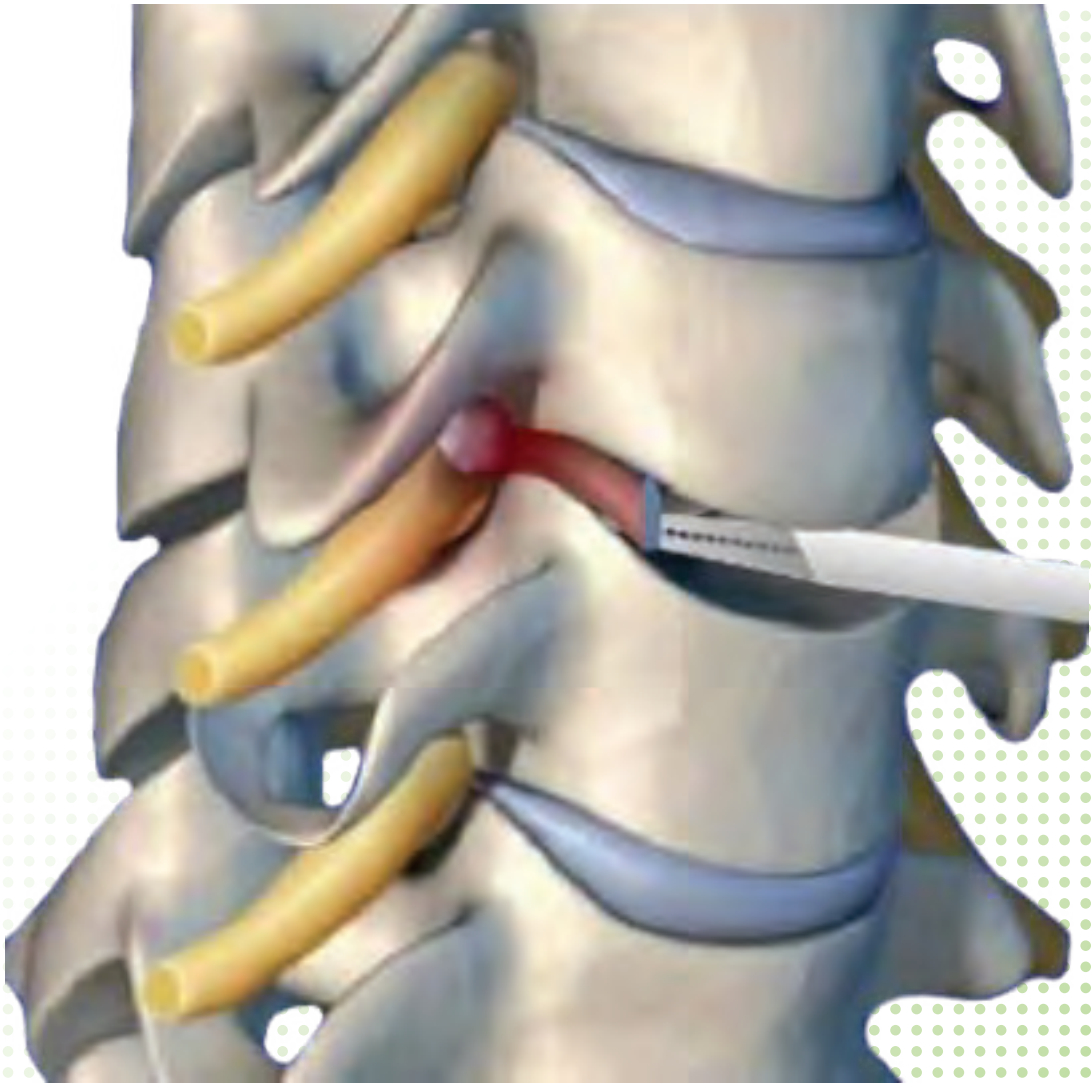


The ALECTA ALIF System Surgical Technique

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 ALIF 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 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 ALIF 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 ALIF 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.

4. Implant Preparation

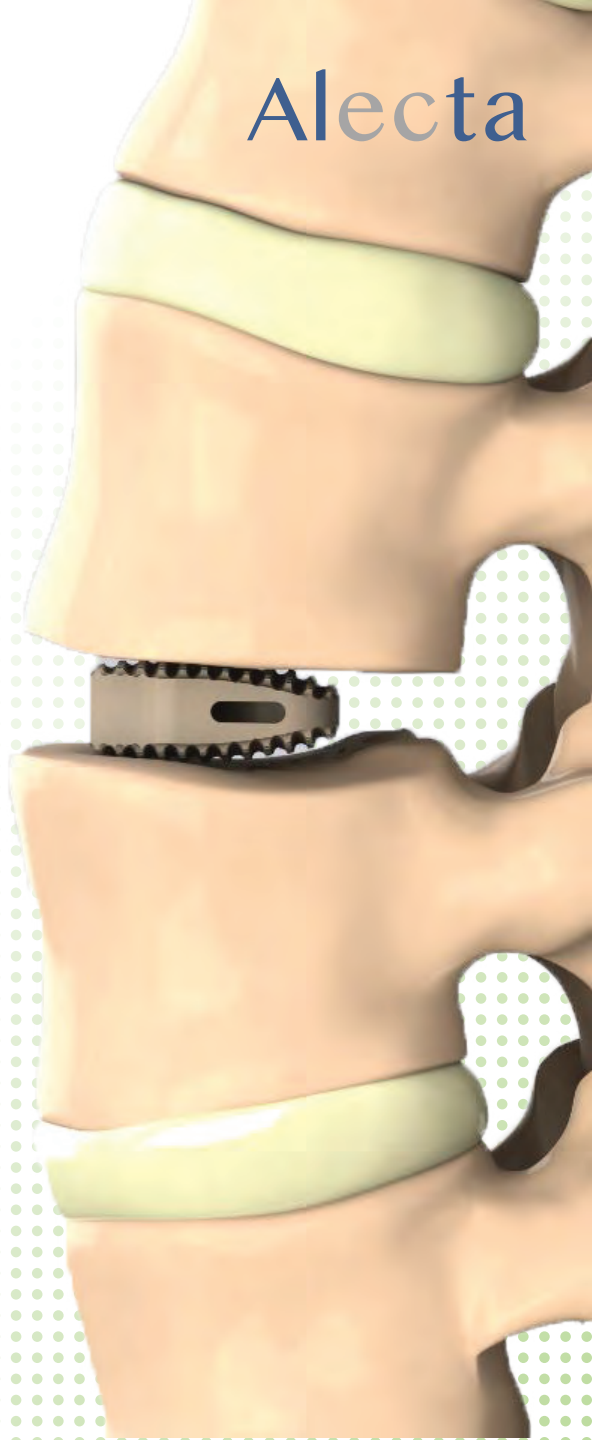
The Alecta® Interbody Spacer is mounted on the inserter by fitting the spacer over the two stabilizing fingers and then turning the knurled thumbwheel clockwise until a snug fit is acheived.
After the Interbody Spacer has been selected and attached to the inserter, it is filled with bone graft by means 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 ALIF System Surgical Technique

6. Implantation

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.

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.



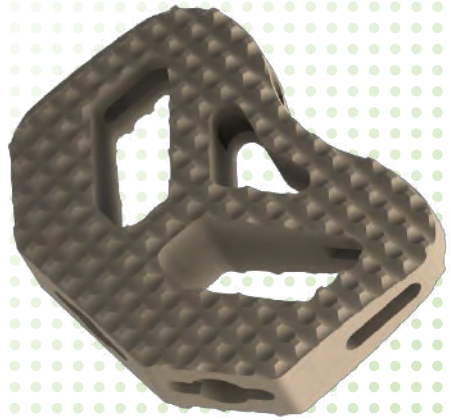
The ALECTA ALIF System Implants

ALECTA LUMBAR PLIF CAGE, RIGID, PEEK (Sterile)

Ref No (Sterile): AT1107.0000000

Height (H): 9,5mm – 15,5mm

Length (L): 30mm-24mm , 38mm-28mm



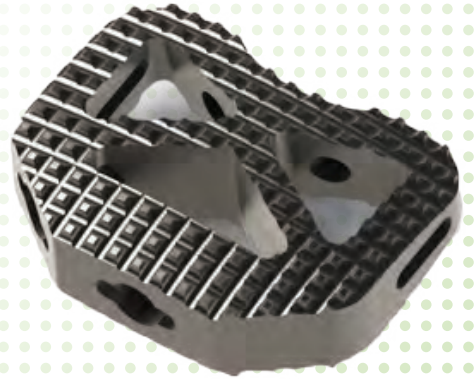
The ALECTA ALIF System Implants

ALECTA LUMBAR PLIF CAGE, RIGID, TITANIUM (Sterile)

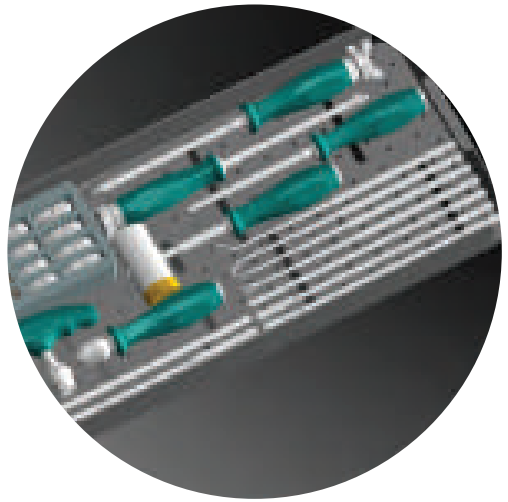
Ref No (Sterile): AT1108.0000000

Height (H): 9,5mm – 15,5mm

Length (L): 30mm-24mm , 38mm-28mm



The ALECTA ALIF
System Instruments (Same set for PLIF-TLIF-ALIF)



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 7 - 13mm	**14000.INS0114**	Cage Box

Produced Exclusively for

EOS
MEDICAL SOLUTIONS

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