ORIO-PL

PEEK-Optima®
PLIF Cage System

ORIO-PL PLIF Cage System
Surgical Technique

SpineCraft

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ORIO-PL PEEKOPTIMA® PLIF CAGE SYSTEM

PLIF CAGE SYSTEM SURGICAL TECHNIQUE

Techniques described by:

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North American Spine Society
Downers Grove, Illinois

Disclaimer

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The information on the products and/or procedures contained in this document is of a general nature and does not represent medical advice or recommendations. Since this information does not constitute any diagnostic or therapeutic statement with regard to any individual medical case, individual examination and advising of the respective patient are absolutely necessary and are not replaced by this document in whole or in part.

In the event that this document could be construed as an offer at any time, such offer shall not be binding in any event and shall require subsequent confirmation in writing.

Table of Contents

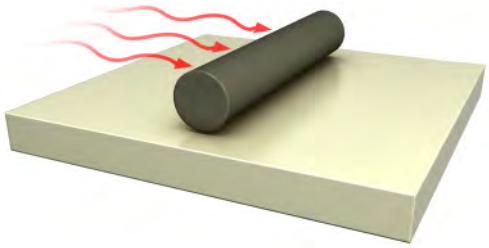
01. Implant Design Rationale

ORIO-PL PLIF Cage System was developed for the following purposes:

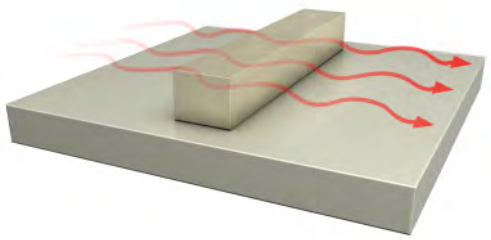
- To distract the disc space and restore normal disc height as well as physiological lordosis, thereby also widening the foramina
- To preserve integrity of the vertebral body endplates
- To provide an optimal implant/endplate interface, thus considerably limiting the risk of subsidence into the adjacent vertebrae
- To stabilize the pathologically unstable segment
- To support bone growth through the implant

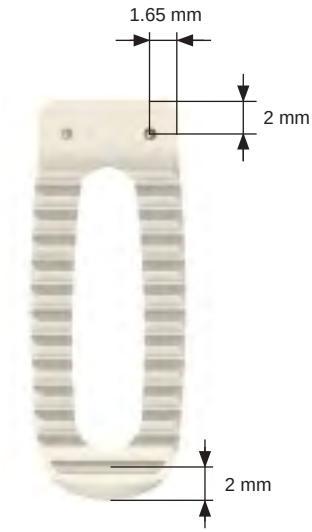
Placement of radiopaque markers in radiotranslucent PEEK-Optima®

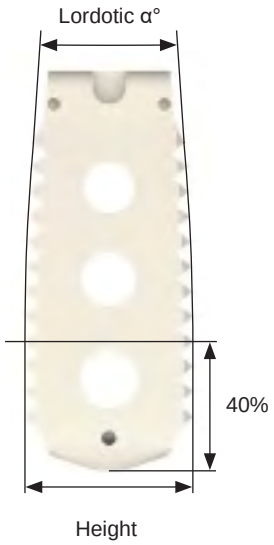
The proper positioning of the ORIO-PL PLIF Cage is checked with the posterior and anterior radiopaque tantalum markers



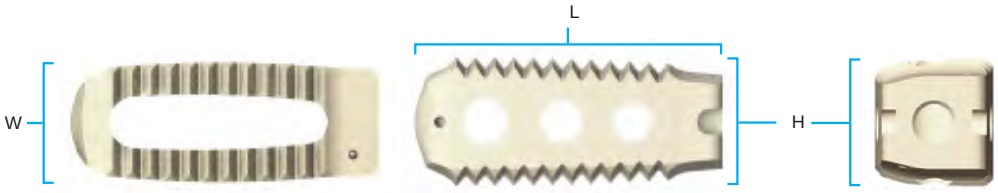
Thanks to the PEEK radiotransparency, the ORIO-PL PLIF Cage is invisible on X-Rays for a clear assessment of bone fusion



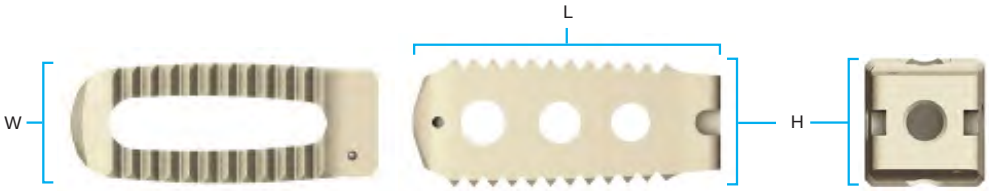




02. Implant Ordering Information

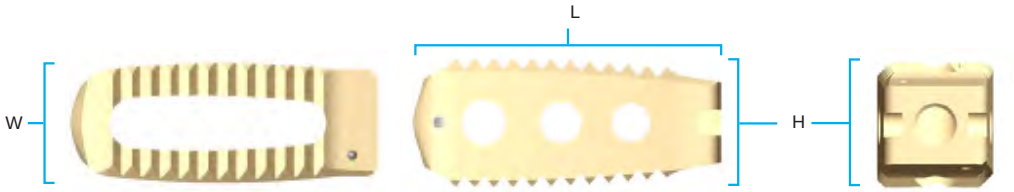


Trapezoidal 5° Lordosis Cages	Width	Height	Length	Catalog n°
ORIO-PL Trapezoidal PLIF Cage, 5° Lordosis	9 mm	9 mm	24 mm	L7309-09-524
ORIO-PL Trapezoidal PLIF Cage, 5° Lordosis	9 mm	9 mm	26 mm	L7309-09-526
ORIO-PL Trapezoidal PLIF Cage, 5° Lordosis	9 mm	10 mm	24 mm	L7309-10-524
ORIO-PL Trapezoidal PLIF Cage, 5° Lordosis	9 mm	10 mm	26 mm	L7309-10-526
ORIO-PL Trapezoidal PLIF Cage, 5° Lordosis	9 mm	11 mm	24 mm	L7309-11-524
ORIO-PL Trapezoidal PLIF Cage, 5° Lordosis	9 mm	11 mm	26 mm	L7309-11-526
ORIO-PL Trapezoidal PLIF Cage, 5° Lordosis	9 mm	12 mm	24 mm	L7309-12-524
ORIO-PL Trapezoidal PLIF Cage, 5° Lordosis	9 mm	12 mm	26 mm	L7309-12-526
ORIO-PL Trapezoidal PLIF Cage, 5° Lordosis	9 mm	13 mm	24 mm	L7309-13-524
ORIO-PL Trapezoidal PLIF Cage, 5° Lordosis	9 mm	13 mm	26 mm	L7309-13-526



5° Lordosis Cages - Standard	Width	Height	Length	Catalog n°
ORIO-PL PLIF Cage, 5° Lordosis	9 mm	8 mm	22 mm	L7109-08-522
ORIO-PL PLIF Cage, 5° Lordosis	9 mm	8 mm	26 mm	L7109-08-526
ORIO-PL PLIF Cage, 5° Lordosis	9 mm	9 mm	22 mm	L7109-09-522
ORIO-PL PLIF Cage, 5° Lordosis	9 mm	9 mm	26 mm	L7109-09-526
ORIO-PL PLIF Cage, 5° Lordosis	9 mm	10 mm	22 mm	L7109-10-522
ORIO-PL PLIF Cage, 5° Lordosis	9 mm	10 mm	26 mm	L7109-10-526
ORIO-PL PLIF Cage, 5° Lordosis	9 mm	11 mm	22 mm	L7109-11-522
ORIO-PL PLIF Cage, 5° Lordosis	9 mm	11 mm	26 mm	L7109-11-526
ORIO-PL PLIF Cage, 5° Lordosis	9 mm	12 mm	22 mm	L7109-12-522
ORIO-PL PLIF Cage, 5° Lordosis	9 mm	12 mm	26 mm	L7109-12-526
ORIO-PL PLIF Cage, 5° Lordosis	9 mm	13 mm	22 mm	L7109-13-522
ORIO-PL PLIF Cage, 5° Lordosis	9 mm	13 mm	26 mm	L7109-13-526

5° Lordosis Cages - Optional	Width	Height	Length	Catalog n°
ORIO-PL PLIF Cage, 5° Lordosis	9 mm	7 mm	22 mm	L7109-07-522
ORIO-PL PLIF Cage, 5° Lordosis	9 mm	7 mm	24 mm	L7109-07-524
ORIO-PL PLIF Cage, 5° Lordosis	9 mm	7 mm	26 mm	L7109-07-526
ORIO-PL PLIF Cage, 5° Lordosis	9 mm	8 mm	24 mm	L7109-08-524
ORIO-PL PLIF Cage, 5° Lordosis	9 mm	9 mm	24 mm	L7109-09-524
ORIO-PL PLIF Cage, 5° Lordosis	9 mm	10 mm	24 mm	L7109-10-524
ORIO-PL PLIF Cage, 5° Lordosis	9 mm	11 mm	24 mm	L7109-11-524
ORIO-PL PLIF Cage, 5° Lordosis	9 mm	12 mm	24 mm	L7109-12-524
ORIO-PL PLIF Cage, 5° Lordosis	9 mm	13 mm	24 mm	L7109-13-524
ORIO-PL PLIF Cage, 5° Lordosis	9 mm	14 mm	22 mm	L7109-14-522
ORIO-PL PLIF Cage, 5° Lordosis	9 mm	14 mm	24 mm	L7109-14-524
ORIO-PL PLIF Cage, 5° Lordosis	9 mm	14 mm	26 mm	L7109-14-526
ORIO-PL PLIF Cage, 5° Lordosis	9 mm	15 mm	22 mm	L7109-15-522
ORIO-PL PLIF Cage, 5° Lordosis	9 mm	15 mm	24 mm	L7109-15-524
ORIO-PL PLIF Cage, 5° Lordosis	9 mm	15 mm	26 mm	L7109-15-526



8° Lordosis Cages - Standard	Width	Height	Length	Catalog n°
ORIO-PL PLIF Cage, 8° Lordosis	9 mm	8 mm	22 mm	L7409-08-822
ORIO-PL PLIF Cage, 8° Lordosis	9 mm	8 mm	26 mm	L7409-08-826
ORIO-PL PLIF Cage, 8° Lordosis	9 mm	9 mm	22 mm	L7409-09-822
ORIO-PL PLIF Cage, 8° Lordosis	9 mm	9 mm	26 mm	L7409-09-826
ORIO-PL PLIF Cage, 8° Lordosis	9 mm	10 mm	22 mm	L7409-10-822
ORIO-PL PLIF Cage, 8° Lordosis	9 mm	10 mm	26 mm	L7409-10-826
ORIO-PL PLIF Cage, 8° Lordosis	9 mm	11 mm	22 mm	L7409-11-822
ORIO-PL PLIF Cage, 8° Lordosis	9 mm	11 mm	26 mm	L7409-11-826
ORIO-PL PLIF Cage, 8° Lordosis	9 mm	12 mm	22 mm	L7409-12-822
ORIO-PL PLIF Cage, 8° Lordosis	9 mm	12 mm	26 mm	L7409-12-826
ORIO-PL PLIF Cage, 8° Lordosis	9 mm	13 mm	22 mm	L7409-13-822
ORIO-PL PLIF Cage, 8° Lordosis	9 mm	13 mm	26 mm	L7409-13-826

8° Lordosis Cages - Optional	Width	Height	Length	Catalog n°
ORIO-PL PLIF Cage, 8° Lordosis	9 mm	8 mm	24 mm	L7409-08-824
ORIO-PL PLIF Cage, 8° Lordosis	9 mm	9 mm	24 mm	L7409-09-824
ORIO-PL PLIF Cage, 8° Lordosis	9 mm	10 mm	24 mm	L7409-10-824
ORIO-PL PLIF Cage, 8° Lordosis	9 mm	11 mm	24 mm	L7409-11-824
ORIO-PL PLIF Cage, 8° Lordosis	9 mm	12 mm	24 mm	L7409-12-824
ORIO-PL PLIF Cage, 8° Lordosis	9 mm	13 mm	24 mm	L7409-13-824
ORIO-PL PLIF Cage, 8° Lordosis	9 mm	14 mm	22 mm	L7409-14-822
ORIO-PL PLIF Cage, 8° Lordosis	9 mm	14 mm	24 mm	L7409-14-824
ORIO-PL PLIF Cage, 8° Lordosis	9 mm	14 mm	26 mm	L7409-14-826
ORIO-PL PLIF Cage, 8° Lordosis	9 mm	15 mm	22 mm	L7409-15-822
ORIO-PL PLIF Cage, 8° Lordosis	9 mm	15 mm	24 mm	L7409-15-824
ORIO-PL PLIF Cage, 8° Lordosis	9 mm	15 mm	26 mm	L7409-15-826

03. Instrument Ordering Information

Bayoneted Curette, 45° Up, Size 2 7010-04-2

Bayoneted Curette, 45° Up, Size 4 7010-04-4

Bayoneted Curette, Reversed 90° Down, Size 2 7010-12-2

Bayoneted Curette, Reversed 90° Down, Size 4 7010-12-4

Bayoneted Curette, Reversed 60° Down Size 2 7010-06-2

Straight Curette, 0° Up, w/ Teeth, Size XL 7010-03-XL

Nerve Retractor, Width 12mm 7010-01-12

Nerve Retractor, Width 8mm 7010-01-08

Offset Straight Rasp 7010-10

Box Curette 7010-07

Curved Chisel 7010-09

Osteotome - Angled Handle 7010-08

Small Bone Graft Compactor 7040-02-01

Large Bone Graft Compactor 7040-02-02

End Impactor - Straight 7040-03

End Impactor - Angled 7040-03-A

PLIF Side Impactor I 7040-05-1

PLIF Side Impactor II 7040-05-2

PLIF Cage Inserter - Straight 7030-01-01

PLIF Cage Inserter - Pistol-Grip (optional) 7030-01-02

Knob Unlocker 7030-01-03

T-Handle 1/4” Square connection 7020-01

Paddle Distractor (height 7-14 mm)

7020-04-07
7020-04-08
7020-04-09
7020-04-10
7020-04-11
7020-04-12
7020-04-13
7020-04-14

PLIF Disc Shaver (height 7, 9, 11, 13mm)

7020-02-07
7020-02-09
7020-02-11
7020-02-13

Slap Hammer 7050-01

ORIO Lumbar Cage System Instruments	Catalog n°
Nerve Retractor, Width 8mm	7010-01-08
Nerve Retractor, Width 12mm	7010-01-12
Straight Curette, 0° Up, w/ Teeth, size XL	7010-03-XL
Bayoneted Curette, 45° Up, Size 2	7010-04-2
Bayoneted Curette, 45° Up, Size 4	7010-04-4
Bayoneted Curette, Reversed 60° Down, Size 2	7010-06-2
Box Curette	7010-07
Osteotome - Angled Handle	7010-08
Curved Chisel	7010-09
Straight Rasp	7010-10
Bayoneted Curette, Reversed 90° Down, Size 2	7010-12-2
Bayoneted Curette, Reversed 90° Down, Size 4	7010-12-4
T-Handle, ¼" Square Connection	7020-01
PLIF Disc Shaver, Size 07	7020-02-07
PLIF Disc Shaver, Size 09	7020-02-09
PLIF Disc Shaver, Size 11	7020-02-11
PLIF Disc Shaver, Size 13	7020-02-13
TLIF Disc Shaver, Size 07	7020-03-07
TLIF Disc Shaver, Size 09	7020-03-09
TLIF Disc Shaver, Size 11	7020-03-11
TLIF Disc Shaver, Size 13	7020-03-13
Paddle Distractor, Size 07	7020-04-07
Paddle Distractor, Size 08	7020-04-08
Paddle Distractor, Size 09	7020-04-09
Paddle Distractor, Size 10	7020-04-10
Paddle Distractor, Size 11	7020-04-11
Paddle Distractor, Size 12	7020-04-12
Paddle Distractor, Size 13	7020-04-13
Paddle Distractor, Size 14	7020-04-14
PLIF Cage Inserter - Straight	7030-01-01
Knob Unlocker	7030-01-03
Straight TLIF Cage Inserter - Straight	7030-02-01
Straight TLIF Cage Inserter - Pistol-grip	7030-02-02
Curved TLIF Cage Inserter - Straight	7030-03-01
Small Bone Graft Compactor	7040-02-01
Large Bone Graft Compactor	7040-02-02
End Impactor - Straight	7040-03
End Impactor - Angled	7040-03-A
PLIF Side Impactor I	7040-05-1
PLIF Side Impactor II	7040-05-2
Curved TLIF Cage Impactor	7040-06
Slap Hammer	7050-01
PLIF 5° & PLIF 8° Cages Caddy	7000-211
PLIF 5° Trapezoidal Cages Caddy	7000-212
Straight TLIF Cages Caddy	7000-214
Curved TLIF Cages Caddy	7000-215
Optional Cages Caddy	7000-213

04. Bilateral Approach PLIF Surgical Technique

The surgical technique is described using the example of a posterior approach to L4/L5.

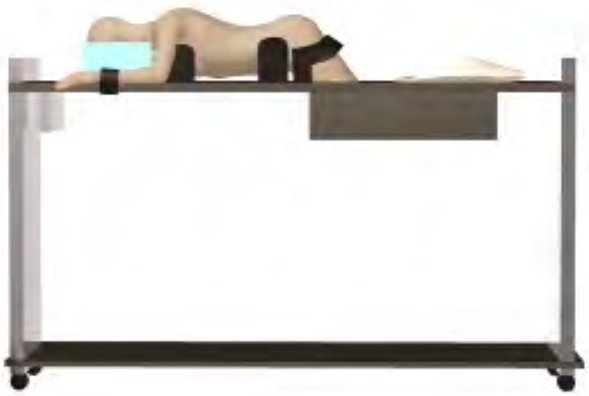
Preoperative planning

1

An estimate of the appropriate ORIO-PL PLIF Cage size must be done prior to surgery.

The initial estimate of correct cage height can be made by comparing the preoperative planning template for ORIO-PL PLIF Cage with the adjacent intervertebral discs on a lateral radiograph. With the segment fully distracted, the implants must fit tightly and accurately between the end-plates. To achieve maximal segment stability, it is essential to implant the largest possible cages. Cage size can be determined with the help of a Paddle Distractor during surgery.

ORIO-PL PLIF Cages are to be used with supplemental fixation. Posterior fixation with pedicle screws (APEX Spine System) is required.



Position of the patient

2

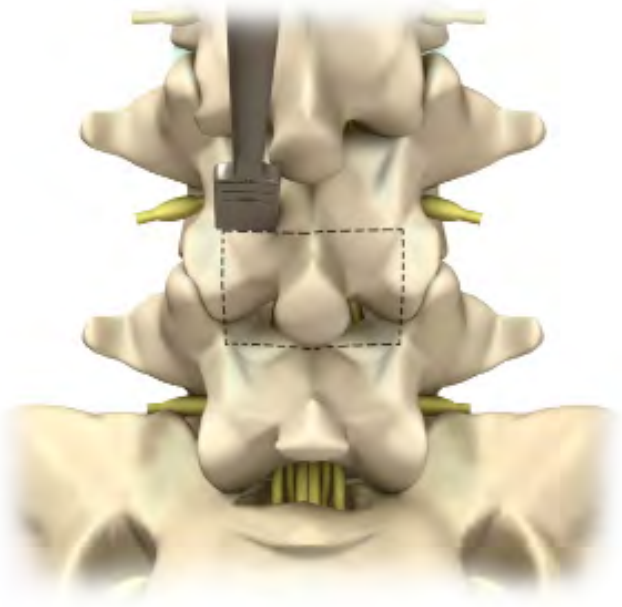
PLIF procedures have to be performed in natural lordosis, either in the prone position or in a “relaxed” knee-chest position.

Laminectomy

3

Make skin incision lateral to the medial line and prepare approach. Locate lamina, spinous processes, dura and nerve roots. The laminectomy should sacrifice as much as 80-90% of the facets, as this will allow room to place the cage with the minimum of dural/root retraction.

Perform a laminectomy on the medial side of the facet. Use a Nerve Retractor to carefully mobilize and relocate the dura to the other side, then open a 13 mm wide window into the disc space.



Pedicle Screw Insertion

4

The optimum insertion point of the pedicle is at the intersection of a horizontal line joining the midpoint of the transverse process and a vertical line through the midpoint of the superior articular process.

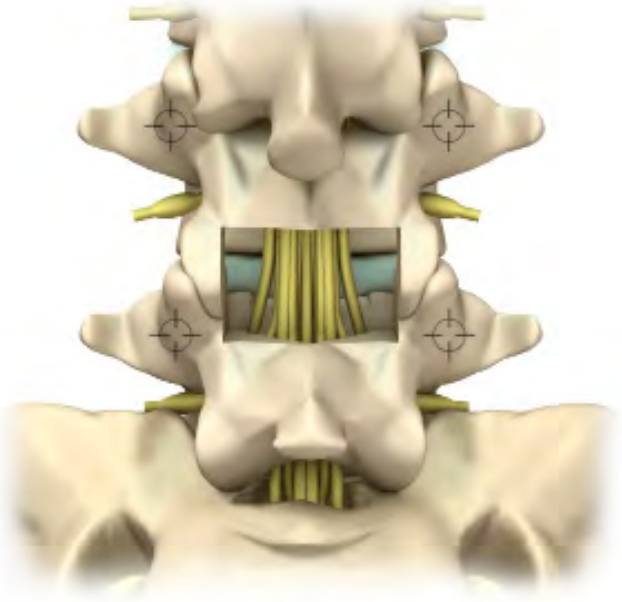
The pedicle walls should be identified as part of the laminectomy exposure. The center of the pedicle canal can easily be identified using a neural dissector.

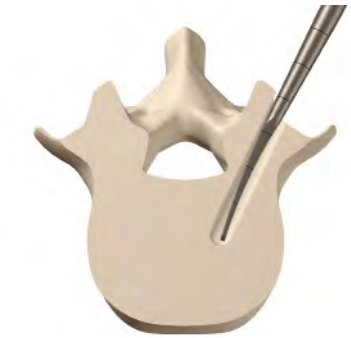
The entrance to the pedicle canal can be exposed using an awl, high-speed burr, or rongeur.

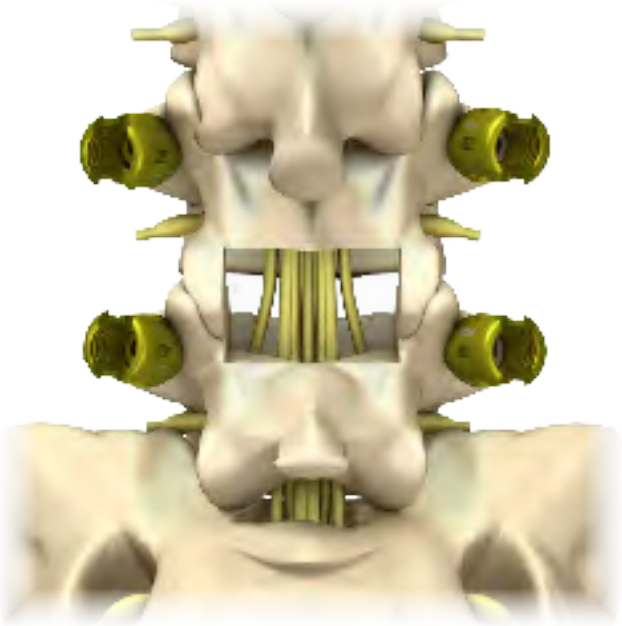
The pedicle canal is entered with a blunt curved-tip probe. Ball-tip feelers and pedicle screw taps are used to prepare the space for screw insertion.

The appropriate sized APEX pedicle screw (diameter and length) is then inserted into the pedicle.

At any point, x-ray or image intensification can be used to verify proper placement.







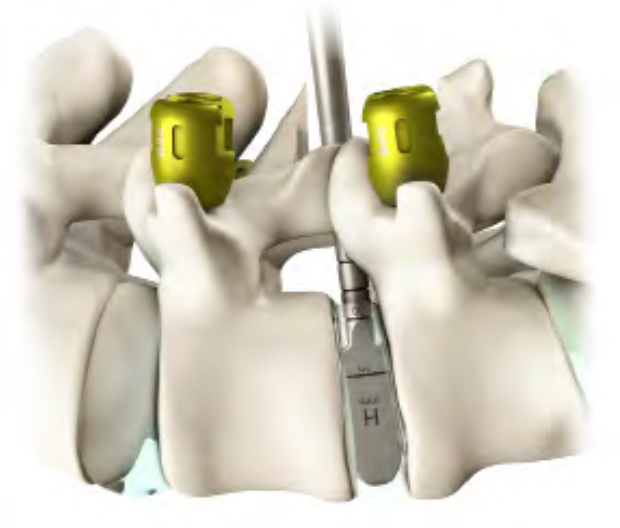
Disc Height Restoration

5

Access the foramen and use Bone Curettes to remove disc material through an incision in the annulus fibrosus. For simplified removal of tissue in the far lateral disc space, use the Bayonetted Bone Curettes.

The annulus must be preserved to provide additional support for the ORIO-PL PLIF Cages.

Remove cartilaginous layers from the surface of the vertebral endplates with the Straight Rasp until bleeding bone is attained.



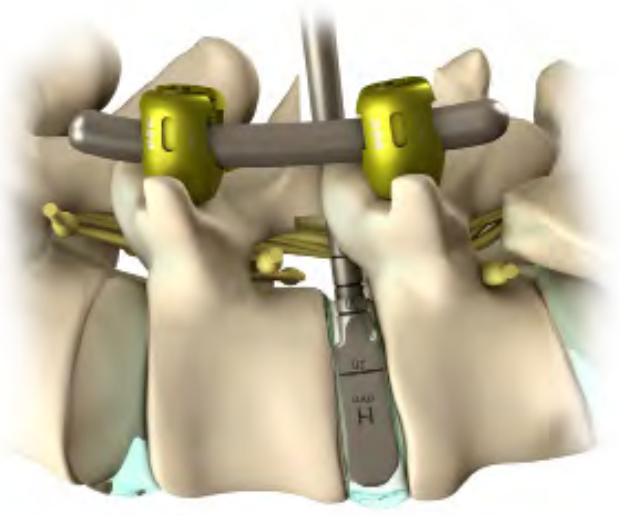
Note : Before the ORIO-PL PLIF Cage is implanted, the anterior and lateral disc space should be filled with autologous bone graft (harvested, for example, from the iliac crest).

Locking Distraction

6

With the disc space fully distracted and the Paddle Distractor in place, rods are implanted into the pedicle screws. The set screws are temporarily tightened, holding the distraction in place.

The Paddle Distractor can then be removed and the site inspected. Some surgeons may prefer to leave the Paddle Distractor on the contralateral side to maintain distraction.



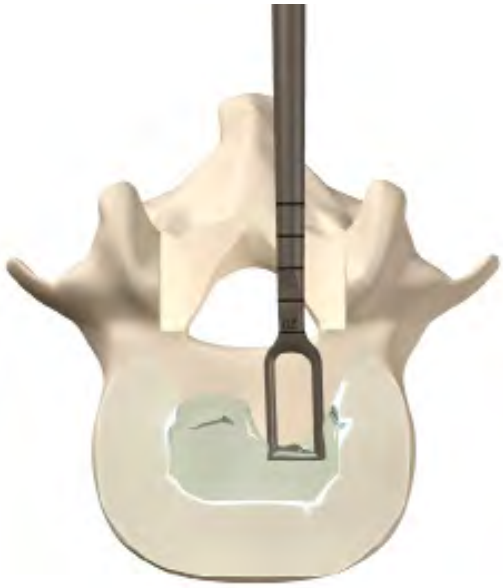
Disc Removal & Endplate Preparation

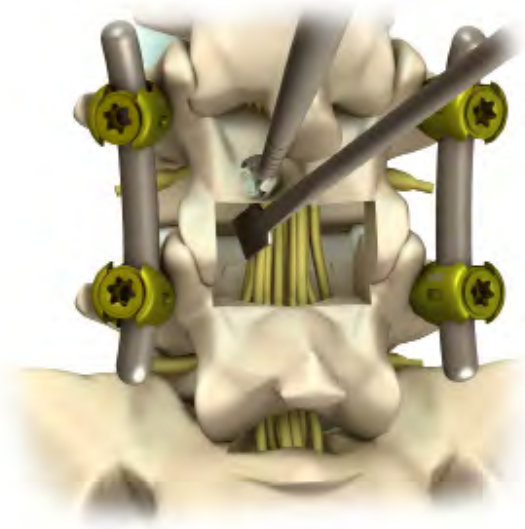
7

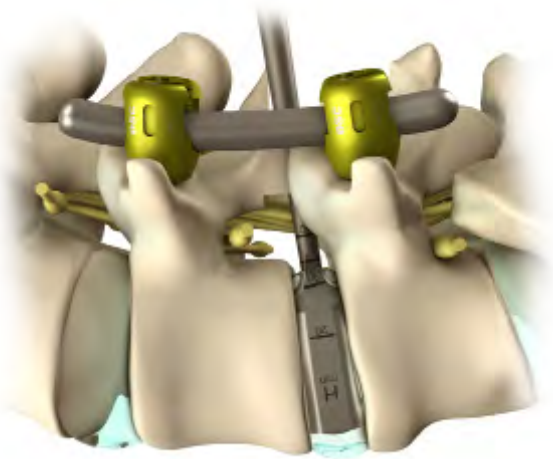
Through the window into the foramen and an incision in the annulus fibrosus, remove disc material with the Box Curette. The anterior and lateral walls of the annulus fibrosus must be preserved (with exception of the incision) to provide additional support for the ORIO-PL PLIF Cages.

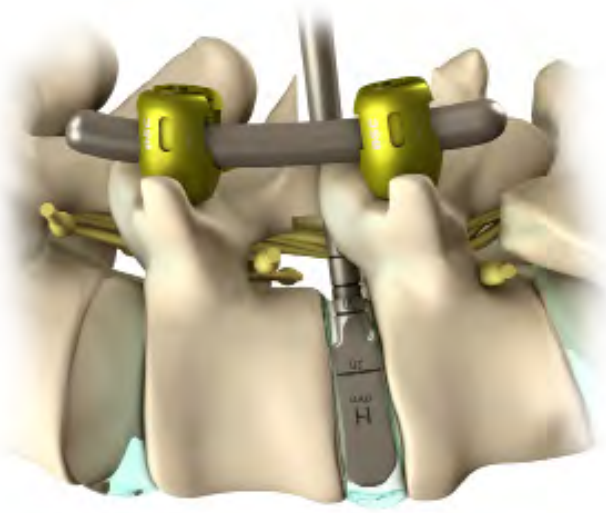
Remove cartilaginous layers from the surface of the vertebral endplates with the Straight Rasp and a PLIF Disc Shaver until bleeding bone is attained. Sufficient cleaning of the endplates is essential for vascular supply of the bone graft, yet excessive cleaning could damage the denser bone layer and weaken the end-plate.

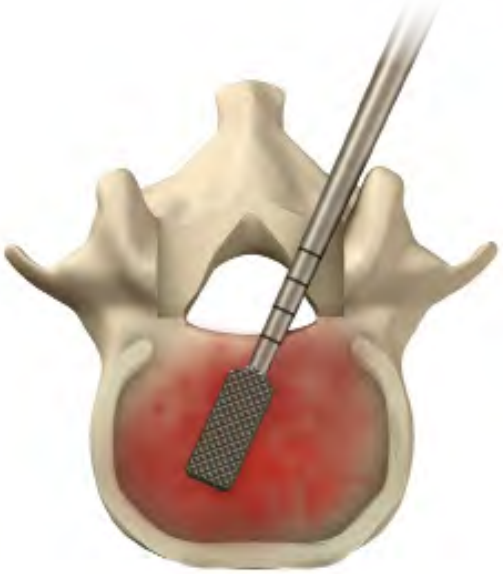
Use the depth etchings on the Paddle Distractors to determine cage length. Note the height of the Paddle Distractor that fits the distracted space to determine cage height.











Select the appropriate ORIO-PL PLIF Cage and attach the PLIF Cage Inserter

8

Select an ORIO-PL PLIF Cage corresponding to the size determined in Step 7 or preoperatively. Attach the PLIF Cage Inserter to the implant as shown graphically.

Position the two prongs of the PLIF Cage Inserter into the two slots at the back of the ORIO-PL PLIF Cage. Then, twist the inner knob to thread and secure the implant to the inserter end.

Bone Graft

9

Pack the ORIO-PL PLIF Cage with autologous bone.

Harvest autologous bone, for example from the iliac crest.

The cages must be filled completely.

Implant the ORIO-PL PLIF Cage

10

When the cage is ready for implantation, distract the segment again.

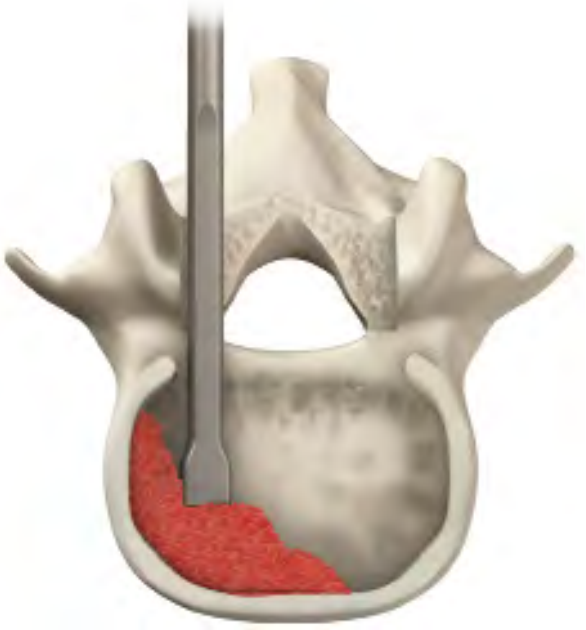
Use a Bone Graft Compactor to fill the anterior disc space with autologous bone or bone.

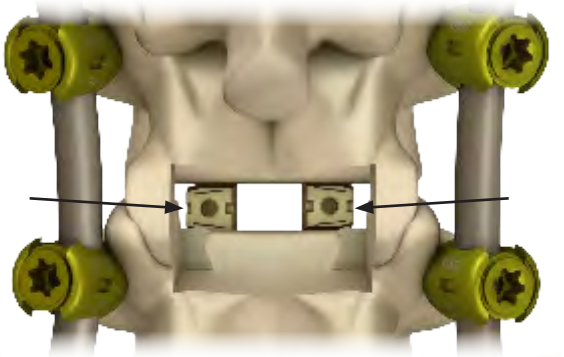
Insert the spacer into the intervertebral disc space.

Slight impaction on the implant inserter may be necessary.

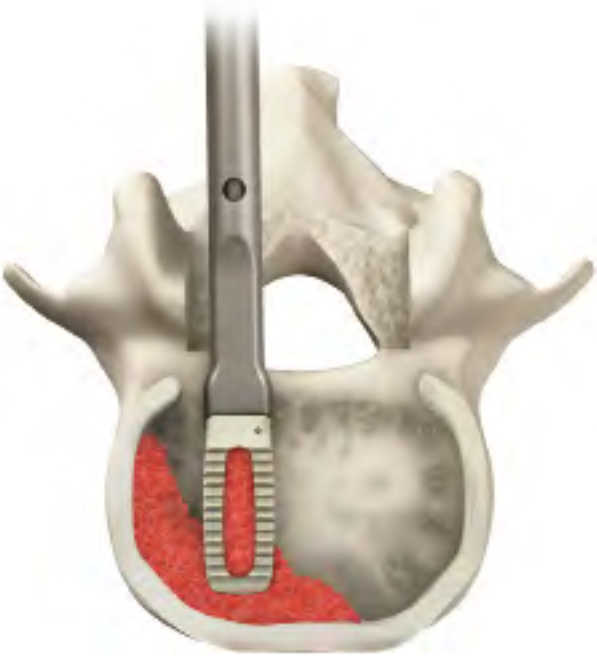
If using ORIO-PL Trapezoidal PLIF Cages, ensure that the implant is being inserted on the appropriate side. The shorter, tapered sides should be located laterally and the taller, untapered sides should be located medially.

The tapered sides can be easily identified with the etchings on the back of the cage.





Arrows point to tapered sides of ORIO-PL Trapezoidal PLIF Cages

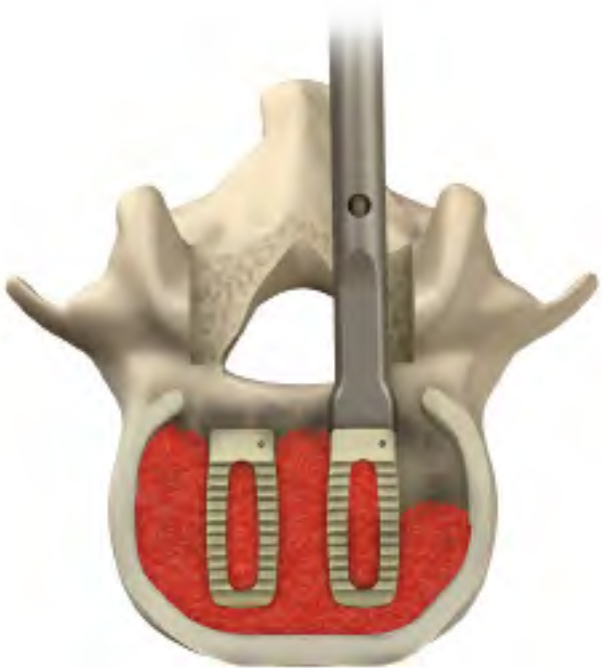


Fill disc space with bone graft

11

Before implanting the second cage, fill the anterior aspect of the disc space and the space between the cages with autologous bone. Implant the second cage.

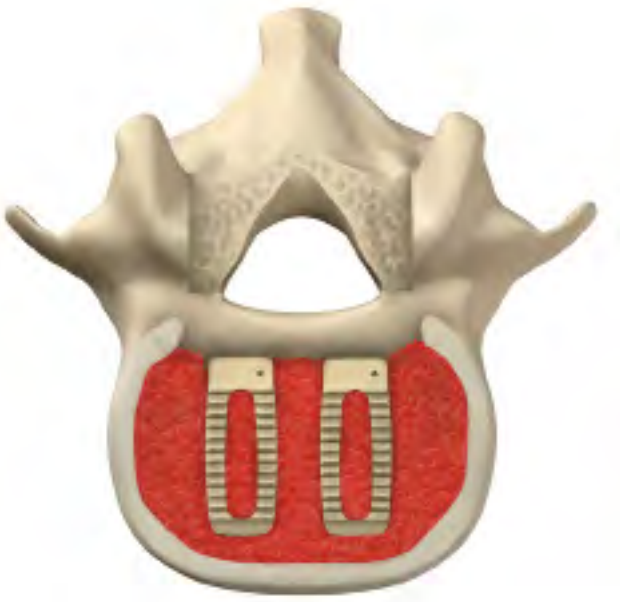
Additional bone graft can be placed in between the two cages after the second cage is placed. This will give additional stability to the construct. The aim should be to create a “honeycomb” of bone graft healing.



Verify the position of the ORIO-PL PLIF Cages

12

Remove all instruments and check the position of the ORIO-PL PLIF Cages under the image intensifier.



Compression & Final Tightening

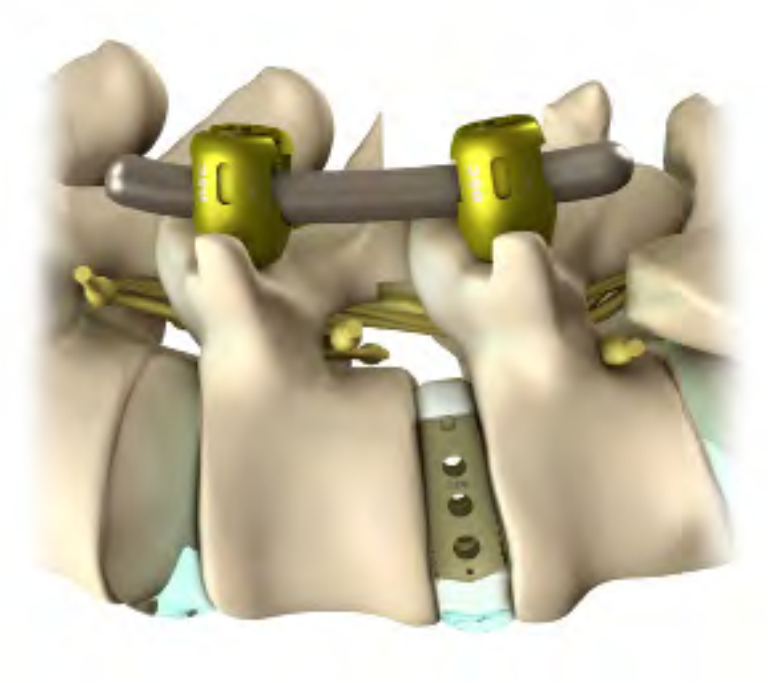
13

Once the cages are in place, final compression is applied.

Final compression can be applied by first tightening the top screws then applying the tightening wrench over the loose bottom screw. A Compressor is then placed over both screws and compression is applied. The set screws are tightened with the Cannulated Anti-Torque, the T-30 Hexalobe Driver, and Torque-Limiting T-Handle, 9.5 Nm.

It is important to match the desired segmental lordosis to the lordosis of the cage and contoured rod assembly.

A thorough inspection of the neural elements is then carried out.



05. Monoportal Approach PLIF Surgical Technique

The surgical technique is described using the example of a posterior approach to L4/L5.

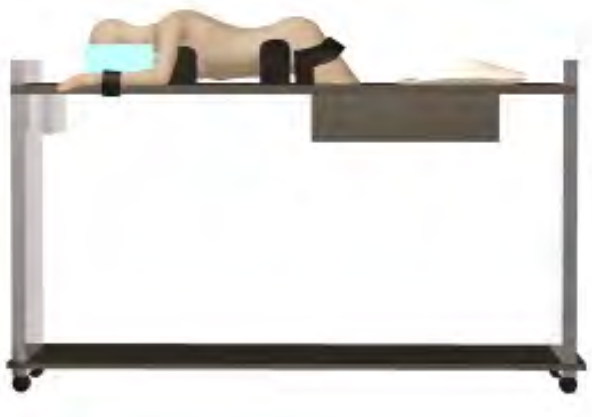
Preoperative planning

1

An estimate of the appropriate ORIO-PL PLIF Cage size must be done prior to surgery.

The initial estimate of correct cage height can be made by comparing the preoperative planning template for ORIO-PL PLIF Cage with the adjacent intervertebral discs on a lateral radiograph. With the segment fully distracted, the implants must fit tightly and accurately between the end-plates. To achieve maximal segment stability, it is essential to implant the largest possible cages. Cage size can be determined with the help of a Paddle Distractor during surgery.

ORIO-PL PLIF Cages are to be used with supplemental fixation. Posterior fixation with pedicle screws (APEX Spine System) is required.



Position of the patient

2

PLIF procedures have to be performed in natural lordosis, either in the prone position or in a “relaxed” knee-chest position.

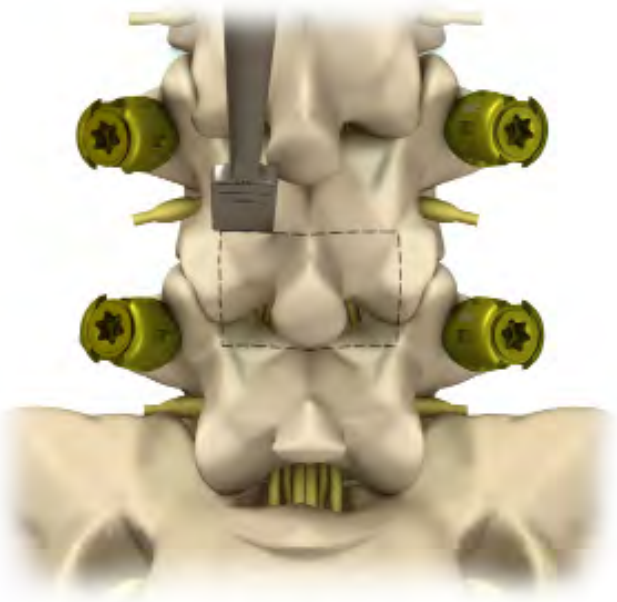
Laminectomy

3

A posterior midline incision is performed, the symptomatic side of the paravertebral muscle is split and retracted laterally, and the lamina and facet joints are exposed.

A partial hemilaminectomy is performed first, followed by the unilateral medial facetectomy. Adequate decompression of the foraminal stenosis is accomplished simultaneously, and the facet joints are preserved as much as possible.

The thecal sac and traversing nerve root are mobilized and retracted to the midline.



APEX Pedicle Screw Insertion

4

The optimum insertion point of the pedicle is at the intersection of a horizontal line joining the midpoint of the transverse process and a vertical line through the midpoint of the superior articular process.

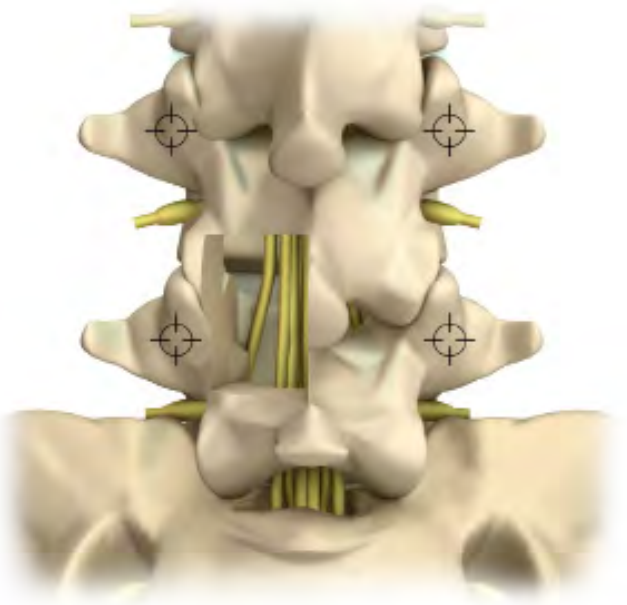
The pedicle walls should be identified as part of the laminectomy exposure. The center of the pedicle canal can easily be identified using a neural dissector.

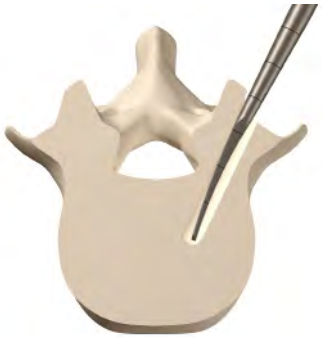
The entrance to the pedicle canal can be exposed using an awl, high-speed burr, or rongeur.

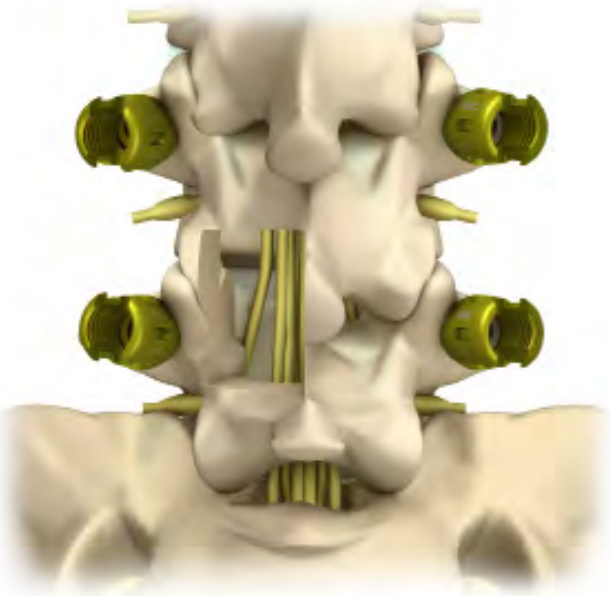
The pedicle canal is entered with a blunt curved-tip probe. Ball-tip feelers and pedicle screw taps are used to prepare the space for screw insertion.

The appropriate sized APEX pedicle screw (diameter and length) is then inserted into the pedicle.

At any point, x-ray or image intensification can be used to verify proper placement.







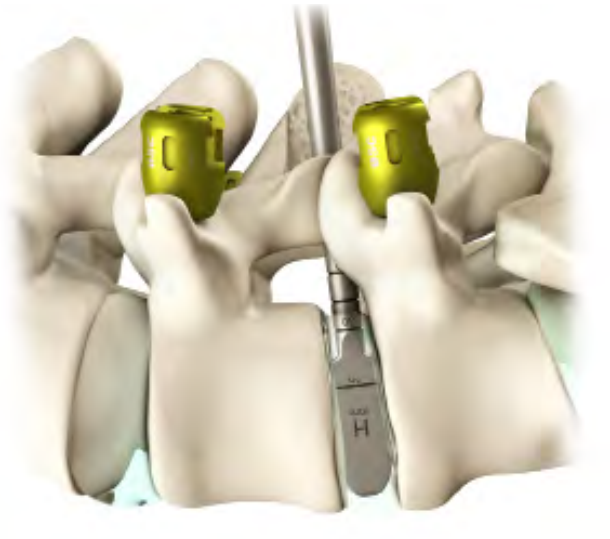
Disc Height Restoration

5

Access the foramen and use Bone Curettes to remove disc material through an incision in the annulus fibrosus. For simplified removal of tissue in the far lateral disc space, use the Bayonetted Bone Curettes.

The annulus must be preserved to provide additional support for the ORIO-PL Trapezoidal PLIF Cages.

Remove cartilaginous layers from the surface of the vertebral endplates with the Straight Rasp until bleeding bone is attained.

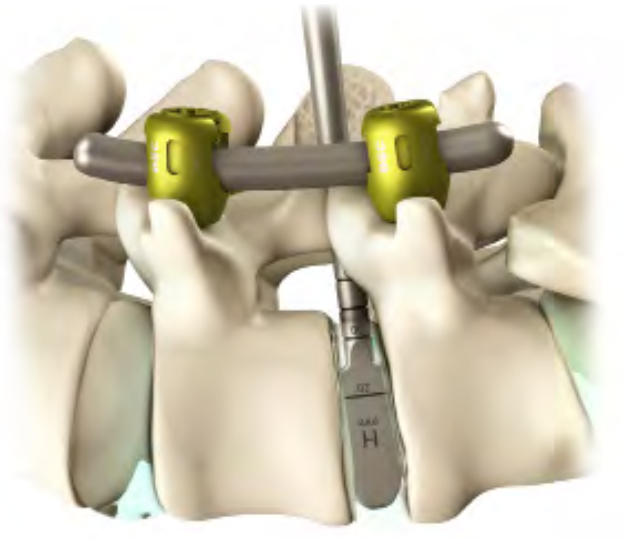


Note : Before the ORIO-PL PLIF Cage is implanted, the anterior and lateral disc space should be filled with autologous bone graft (harvested, for example, from the iliac crest).

Locking Distraction

6

With the disc space fully distracted and the Paddle Distractor in place, rods are implanted into the pedicle screws. The set screws are temporarily tightened, holding the distraction in place.



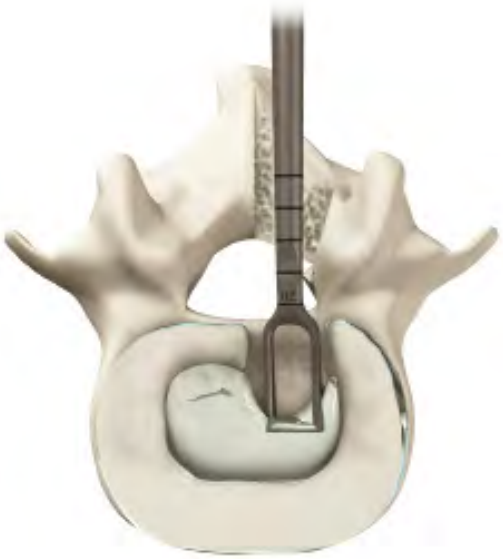
Disc Removal & Endplate Preparation

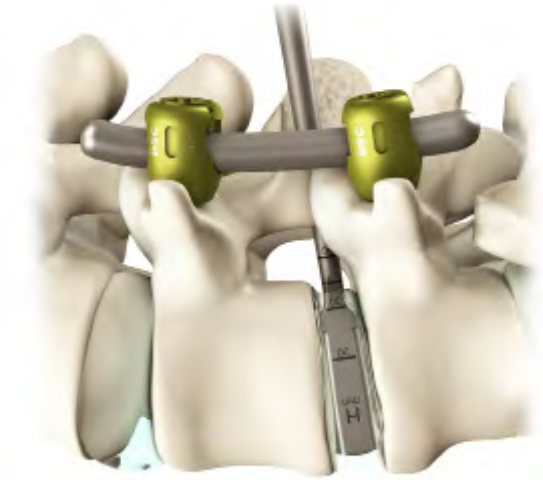
7

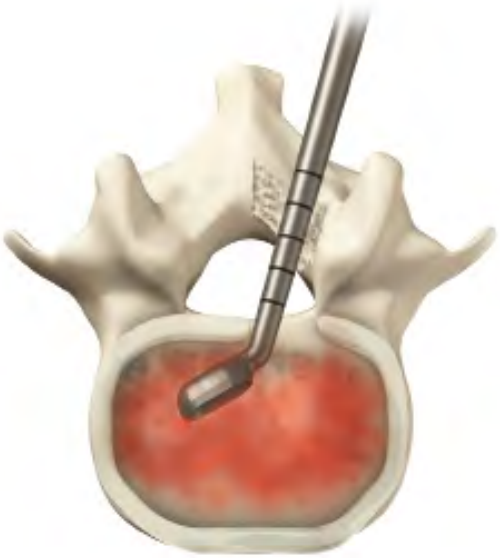
Through the window into the foramen and an incision in the annulus fibrosus, remove disc material with the Box Curette. The anterior and lateral walls of the annulus fibrosus must be preserved (with exception of the incision) to provide additional support for the ORIO-PL Trapezoidal PLIF cages.

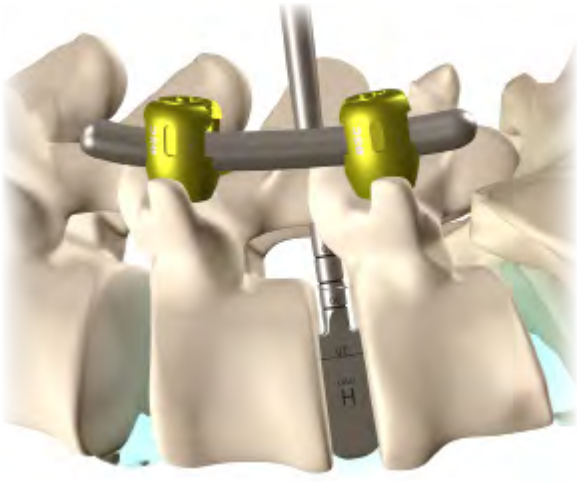
Remove cartilaginous layers from the surface of the vertebral endplates with the Straight Rasp and a PLIF Disc Shaver until bleeding bone is attained. Sufficient cleaning of the endplates is essential for vascular supply of the bone graft, yet excessive cleaning could damage the denser bone layer and weaken the end-plate.

Use the depth etchings on the Paddle Distractors to determine cage length. Note the height of the Paddle Distractor that fits the distracted space to determine cage height.









Select the appropriate ORIO-PL PLIF Cage and attach the implant holder

8

Select an ORIO-PL Trapezoidal PLIF Cage corresponding to the size determined in Step 7 or preoperatively. Attach the cage to the PLIF Cage Inserter as shown graphically.

Position the two prongs of the PLIF Cage Inserter into the two slots at the back of the ORIO-PL Trapezoidal PLIF Cage. Then, twist the inner knob to thread and secure the implant to the inserter end.

Bone Graft

9

Pack the ORIO-PL Trapezoidal PLIF Cages with autologous bone.

Harvest autologous bone, for example from the iliac crest.

The cages must be filled completely.

Implant the ORIO-PL PLIF Cage

10

At this point, loosen the pedicle set screws, distract across the disc space, and lock the rod in place.

Before cage insertion, the lamina and cortical bone from the iliac crest should be grafted into the contralateral and anterior sides of the intervertebral space as much as possible.

ORIO-PL Trapezoidal PLIF Cages are recommended for the monoportal approach PLIF surgical technique. While using trapezoidal cages, ensure that the implant is being inserted on the appropriate side. The shorter, tapered sides should be lateral and the untapered, taller sides should be medial when the cage is pushed over to its final position.

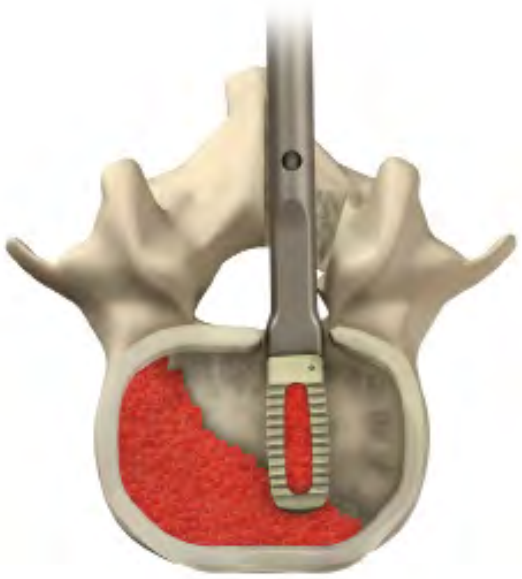
The tapered sides can be easily identified with the etchings on the back of the cage.

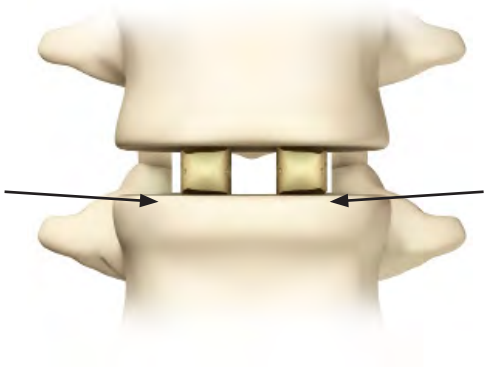
Insert the first cage into the intervertebral disc space.

Slight impaction on the Inserter may be necessary. This should be followed by careful pushing to the contralateral side with the PLIF Side Impactor I, followed by the use of PLIF Side Impactor II.

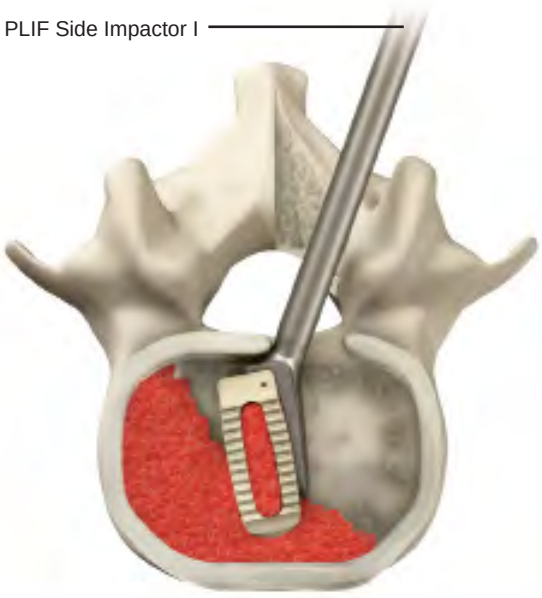
Since the ORIO-PL Trapezoidal PLIF Cage has a shorter lateral sidewall and beveled edges, the first cage can be moved to the contralateral side without any difficulty.

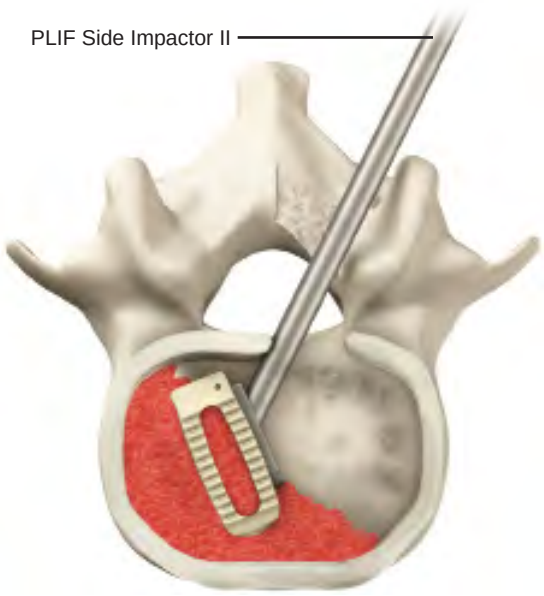
Make sure the lateral (near side) annulus is curetted out to make room for the ensuing second cage.





Arrows point to tapered sides of ORIO-PL Trapezoidal PLIF Cages





Fill disc space with bone graft

11

Before the second cage insertion, the lamina and cortical bone from the iliac crest should be grafted into the space medial to the first cage.

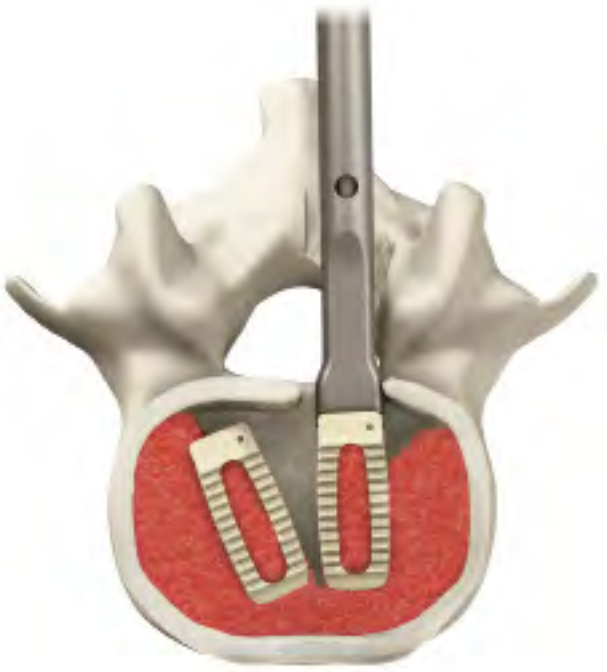
The second cage then should be introduced to the ipsilateral side in the same manner. While using the ORIO-PL Trapezoidal PLIF Cage, ensure that the tapered, shorter side is located laterally and that the taller side is located medially.

The tapered sides can be easily identified with the etchings on the back of the cage.

Pushing bone graft with the Bone Graft Compactor between the cages will help straighten the cages into their final position.

Additional bone graft can be placed in between the cages; it is easier to pack graft between the two cages after the second cage is placed. This will give additional stability to the construct. The aim should be to create a “honeycomb” of bone graft healing.

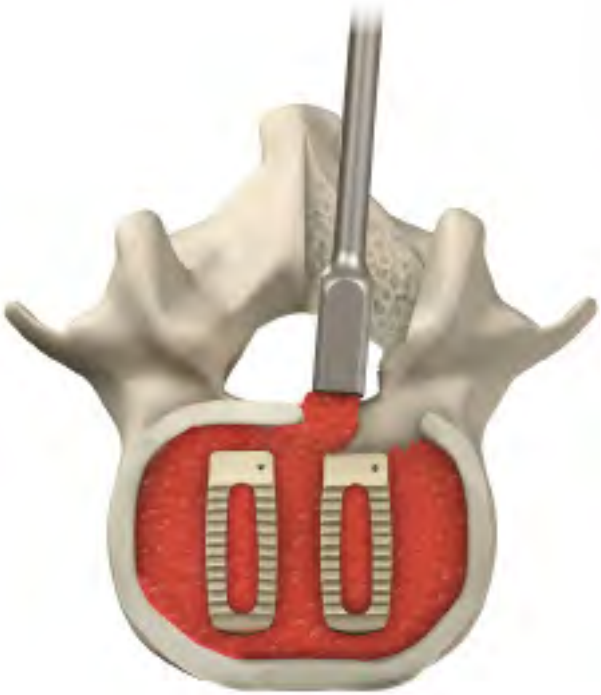
Now loosen the pedicle set screws again and compress, then lock in place. This gives extreme stability to the construct.

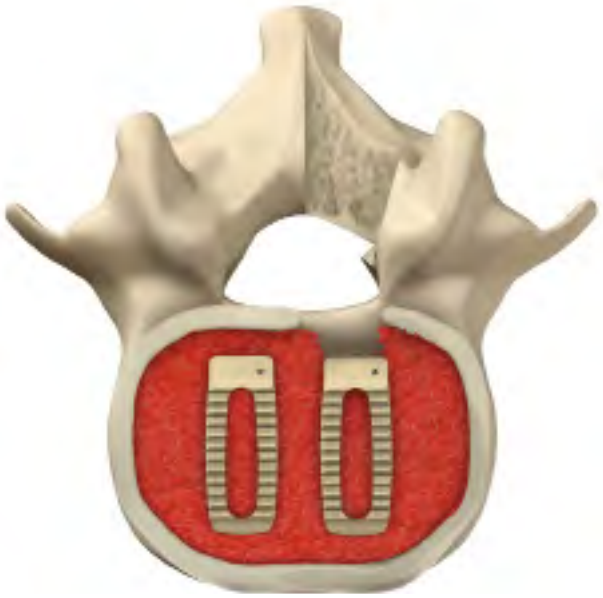


Verify the position of the ORIO-PL cage

12

Remove all instruments and check the position of the ORIO-PL Trapezoidal PLIF Cages under the image intensifier.





Compression & Final Tightening

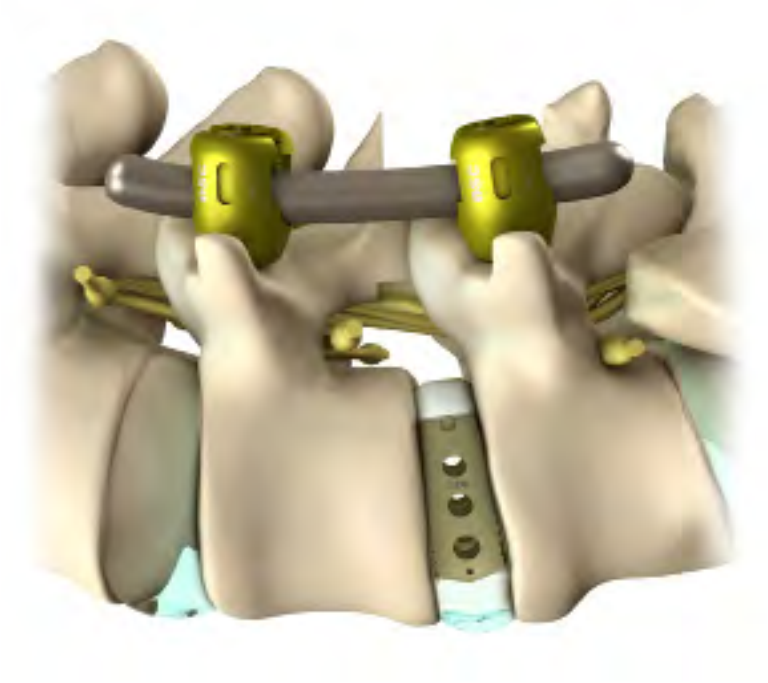
13

Once the cages are in place, final compression is applied.

Final compression can be applied by first tightening the top screws then applying the tightening wrench over the loose bottom screw. A Compressor is then placed over both screws and compression is applied. The set screws are tightened with the Cannulated Anti-Torque, the T30 Hexalobe Driver, and Torque-Limiting T-Handle, 9.5 Nm.

It is important to match the desired segmental lordosis to the lordosis of the cage and contoured rod assembly.

A thorough inspection of the neural elements is then carried out.



Postoperative management

The patient must be warned against activities that place excessive strain on the operated spinal area. Physical activities and trauma with adverse effects on the affected vertebrae could lead to loosening of the implants, endplate fracture and failure of the surgical measure.

Cage Removal

To remove an intact cage that is still attached to an inserter, slide the Slap Hammer over the end of the inserter as pictured. Secure this connection with one hand and then slap the hammer's middle part back to pull the cage out.

PEEK-Optima® composite material has mechanical properties similar to cortical bone. Excessive leverage against the handle of the insertion tool can split or break the cage if non-physiologic loads are applied. If a cage breaks during insertion, it should be replaced. If difficulty is experienced in removing the broken cage, the set screws should be loosened on the upper pedicle screws on both sides. A screw distractor is then used. The set screws can then be tightened in a position of distraction. The broken cage can then be grasped and removed using a Kocher clamp or hemostat. The nerve roots should be carefully protected during cage removal. A cage can also be cut with the Osteotome or other standard bone-cutting instruments and removed in fragments, if necessary.

Please note that the cages should be retrieved as carefully as possible in order to keep the implant and surrounding tissue intact. Also, please document descriptive information about the gross appearance of the device in situ, as well as descriptions of the removal methods, e.g., intact or in pieces.

Important note on sterilization methods

ORIO-PL PLIF Cages must be sterilized with steam. They may not be sterilized using gas (e.g. ethylene oxide or formaldehyde) or gas plasma (e.g. hydrogen peroxide).

Slap hammer

Cage inserter

06. Instructions for Use

ORIO Intervertebral Body Fusion Cage System

INSTRUCTIONS FOR USE

CAUTION: USA law restricts this device to sale by or on the order of physician.

1. PRODUCT HANDLING

The implants and instruments used as a part of these systems are provided nonsterile and should be stored in their original packaging or placed within the aluminium sterilization container provided. Implants and instruments should be stored in such a manner when not in use, and until they are cleaned and sterilized according to the recommended guidelines listed below. Protect implants from contact with objects that may damage the surface finish. Inspect each implant prior to use for visual damage.

2. PRODUCT DESCRIPTION AND IMPLANT MATERIALS

The ORIO intervertebral body fusion cage is a single component spinal device made from PEEK-Optima® polymer (polyetheretherketone). The implant is available in a range of sizes and lordotic angles to fit the patient's anatomical and physiological requirements. The implants have cavities to accept packing of bone graft. The entire structure is radiolucent so that healing can be assessed by normal radiographic methods. Additionally, radiotherapy can be performed immediately after surgery.

3. INDICATIONS

ORIO intervertebral body fusion cervical cages are indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine with accompanying radicular symptoms at one disc level. DDD is defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies. ORIO intervertebral body fusion cervical cages are used to facilitate intervertebral body fusion in the cervical spine and are placed via an anterior approach at the C3 to C7 disc levels using autograft bone. ORIO intervertebral body fusion cages are to be used with supplemental fixation. Patients should have at least six (6) weeks of non-operative treatment prior to treatment with an intervertebral cage.

The ORIO intervertebral body fusion lumbar cage is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L2-S1. Degenerative disc disease is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). ORIO intervertebral body fusion lumbar cage implants are to be used with autogenous bone graft and implanted via a transforaminal, open posterior or lateral approach. The ORIO intervertebral body fusion lumbar cages are to be used with supplemental fixation. Patients should have at least (6) months of non-operative treatment prior to treatment with an intervertebral cage.

4. PATIENT SELECTION

In selecting patients for internal fixation devices, the following factors can be of extreme importance to the eventual success of the procedure:

A. The patient's occupation or activity. If the patient is involved in an occupation or activity that includes heavy lifting, muscle strain, twisting, repetitive bending, stooping, running, substantial walking, or manual labor, he/she should not return to these activities until the bone is fully healed. Even with full healing, the patient may not be able to return to these activities successfully.

B. A condition of senility, mental illness, alcoholism, or drug abuse. These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the appliance, leading to implant failure or other complications.

C. Certain degenerative diseases. In some cases, the progression of degenerative disease may be so advanced at the time of implantation that it may substantially decrease the expected useful life of the appliance. For such cases, orthopaedic devices can only be considered a delaying technique or temporary remedy.

D. Foreign body sensitivity. The surgeon is advised that no preoperative test can completely exclude the possibility of sensitivity or allergic reaction. Patients can develop sensitivity or allergy after implants have been in the body for a period of time.

E. Smoking. Patients who smoke have been observed to experience higher rates of pseudo-arthrosis following surgical procedures where bone graft is used. Additionally, smoking has been shown to cause diffuse degeneration of intervertebral discs. Progressive degeneration of adjacent segments caused by smoking can lead to late clinical failure (recurring pain) even after successful fusion and initial clinical improvement.

5. CONTRAINDICATIONS

- Active sepsis;
- Pregnancy;
- Muscular, neurological or vascular deficiencies, which compromise the affected extremity;
- Conditions that place excessive demand on the implant (i.e. Charcot's joints, muscle deficiencies, refusal to modify post-operative physical activities, skeletal immaturity);
- Active infection in the area of proposed surgery;
- Severe osteoporosis;
- Paget's disease;
- Renal osteodystrophy;
- Advanced diabetes;
- Rheumatoid arthritis;
- Immunological suppression;
- Sustained trauma with instability;
- Fracture of the vertebra;
- Conditions requiring steroids in excess of usual doses;
- Obesity
- Signs of local inflammation,
- Fever or leukocytosis,
- Mental illness,
- Any other condition which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors or congenital abnormalities, fracture local to the operating site, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count,
- Suspected or documented allergy or intolerance to composite materials,
- Any case not needing a fusion,
- Any case not described in the indications,
- Any patient unwilling to cooperate with postoperative instructions,
- Patients with a known hereditary or acquired bone friability or calcification problem should not be considered for this type of surgery,
- These devices must not be used for pediatric cases, nor where the patient still has general skeletal growth.
- Spondylolisthesis unable to be reduced to Grade 1,
- Any case where the implant components selected for use would be too large or too small to achieve a successful result,
- Any case that requires the mixing of metals from two different components or systems,
- Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality,
- Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance,
- Prior fusion at the level to be treated

6. PRECAUTIONS

- **SURGICAL IMPLANTS MUST NEVER BE REUSED.** Although the device may appear undamaged, previous stresses could create imperfections that may lead to mechanical failure. Reusing an implant can potentially cause cross contamination. It is advised to utilize new implant of current design.

- **CORRECT HANDLING OF THE IMPLANT IS EXTREMELY IMPORTANT**. Familiarity with, and attention to the surgical technique recommended for this device is imperative for best results. The correct selection as well as the correct seating/placement of the implant is extremely important. SpineCraft instruments and implants should only be used in conjunction with other SpineCraft instruments and implants. The surgical technique may be obtained from the company or its representative.

  Care must be taken to protect surfaces from nicks and scratches that could become focal points for failure. An implant must not be tampered with, as tampering could adversely affect the performance of the implant. Surgical technique brochures are available upon request. Before the initial use of the ORIO System, the surgeon should review all available information and consult with other surgeons having experience with these type of devices. The surgeon should be thoroughly familiar with the assembly of the components.

  The implantation of two devices of the same size at each targeted level is recommended in case of posterior lumbar interbody fusion.

- **IMPLANTS FATIGUE**. Based on the fatigue testing results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact the performance of the system.

- **PREVIOUS SPINAL SURGERY.** Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.

7. PREOPERATIVE PLANNING AND POSTOPERATIVE CARE

Preoperative planning provides essential information regarding the appropriate implant and likely combinations of components. Use instrument trial components for fit verification (where applicable) and extra implants for backup.
Accepted surgical practices should be followed for postoperative care. Excessive physical activity and trauma affecting the implanted devices have been implicated in premature failure by fracture, migration and/or wear of the implants. The patient should be cautioned to govern his/her activities accordingly as the risk of implant failure increases with weight and activity levels of the patient.

8. ADVERSE EFFECTS

- Cracking or fracture of the implants or loss of fixation in bone; attributable to nonunion, osteoporosis, markedly unstable comminuted fractures.
- Loss of anatomic position with malunion.
- Implant dislodgement or subsidence.
- Infections, both deep and superficial.
- Vascular or visceral injuries.
- Allergies and other reactions to device materials.
- Cracking or fracture of the vertebrae.
- Post-operative change in spinal curvature, loss of correction, and/or height reduction.
- Death.
- Patients with previous spinal surgery at the levels to be treated may have different clinical outcomes compared to those without a previous surgery.
- The risk of device expulsion and migration is higher without the use of supplemental fixation.

9. PACKAGING

Packages for each of the components should be intact upon receipt. If a loaner or consignment system is used, all sets should be carefully checked for completeness and all components including instruments should be carefully checked to ensure that there is no damage prior to use. Damaged packages or products should not be used, and should be returned to SpineCraft.

10. CLEANING AND DECONTAMINATION

Unless just removed from an unopened SpineCraft package, all instruments and implants must be disassembled (if applicable) and cleaned using neutral cleaners before sterilization and introduction into a sterile surgical field or (if applicable) return of the product to SpineCraft. Cleaning and disinfecting of instruments can be performed with aldehyde-free solvents at higher temperatures. Cleaning and decontamination must include the use of neutral cleaners followed by a deionized water rinse.

NOTE: Certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used. Also, many instruments require disassembly before cleaning. All products should be treated with care. Improper use or handling may lead to damage and/or possible improper functioning of the device. Unless marked sterile and clearly labeled as such in an unopened sterile package provided by the company.

11. STERILIZATION

The PEEK-Optima® implants and instruments are provided nonsterile and should be stored in their original packaging until cleaned and sterilized according to the recommended guidelines listed below. Implants are single-use devices, thus do not clean or resterilize an implant that has been in contact with or contaminated by blood or other infectious substances. The manufacturer and distributor assume no responsibility for the cleaning and resterilization of implants, components, or reusable instruments performed by the individual or hospital. SpineCraft instruments and instrument cases are generally composed of titanium, stainless steel, aluminum, and/or polymeric materials. The cases may be multi-layered with various inserts to hold surgical instrumentation in place during handling and storage. The inserts may consist of trays, holders, and silicone mats. The instrument cases will allow sterilization of the contents to occur in a steam autoclave utilizing the cleaning, sterilization, and drying cycle that has been validated and listed below. Instrument cases do not provide a sterile barrier and must be used in conjunction with sterilization wrap to maintain sterility.

All implants and instruments used in surgery must be sterilized by the hospital prior to use. Remove all packaging materials prior to sterilization. Only sterile products should be placed in the operative field. Instructions for cleaning and sterilization of ORIO instruments can be found in SpineCraft publication # RG-0010-5 and can be obtained by contacting the company. Unless specified elsewhere, these products are recommended to be steam sterilized by the hospital using the set of process parameters below:

METHOD	CYCLE	TEMPERATURE	EXPOSURE TIME	DRY TIME
Steam	Pre-Vacuum	273° F (134° C)	18 min with Four Pulses	30 Minutes

Wrap: The wrap should be FDA cleared for the proposed cycle specifications.

Monitor every load with a PCD containing a BI and a Class 5 integrating indicator.

This Pre-Vacuum Steam sterilization is not considered by the Food and Drug Administration to be a standard sterilization cycle. It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps, and sterilization cassettes) that have been cleared by the Food and Drug Administration for the selected sterilization cycle specifications (time and temperature).

NOTE: Because of the many variables involved in sterilization, each medical facility should calibrate and verify the sterilization process (e.g. temperatures, times) used for their equipment.
NOTE: SpineCraft does not recommend Flash Sterilization within instrument cases or Chemical Sterilization.

LIMITED WARRANTY AND DISCLAIMER: ORIO CAGE PRODUCTS ARE SOLD WITH A LIMITED WARRANTY TO THE ORIGINAL PURCHASER AGAINST DEFECTS IN WORKMANSHIP AND MATERIALS. ANY OTHER EXPRESS OR IMPLIED WARRANTIES, INCLUDING WARRANTIES OF MERCHANTABILITY OR FITNESS, ARE HEREBY DISCLAIMED.

IF MORE THAN TWO YEARS HAVE ELAPSED BETWEEN THE DATE OF ISSUE/REVISION AND THE DATE OF CONSULTATION, CONTACT SPINECRAFT FOR CURRENT INFORMATION at:
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