ORIO-TL

PEEK-Optima®
TLIF Cage System

ORIO-TL TLIF Cage System
Surgical Technique

SpineCraft

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ORIO-TL PEEK OPTIMA® TLIF CAGE SYSTEM

STRAIGHT AND CURVED TLIF CAGE SYSTEMS SURGICAL TECHNIQUE

Techniques described by:

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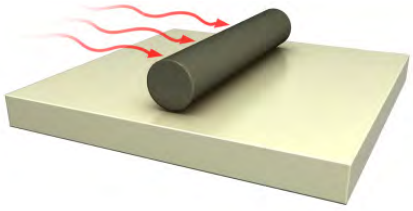
01. Implant Design Rationale

ORIO-TL TLIF Cage System was developed for the following purposes:

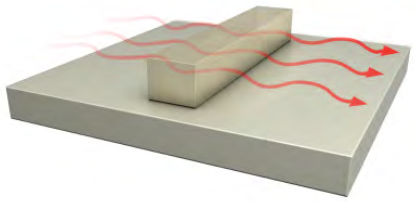
- To distract the disc space and restore normal disc height as well as physiological lordosis, thereby also widening the foramina
- To preserve integrity of the vertebral body endplates
- To provide an optimal implant/endplate interface, thus considerably limiting the risk of subsidence into the adjacent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

Placement of radiopaque markers in radiotranslucent PEEK-Optima®

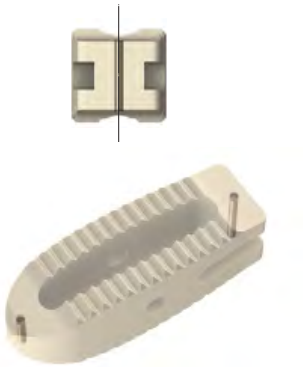
The proper positioning of the ORIO-TL cage is checked with the posterior and anterior markers.

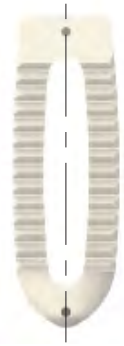


Thanks to the PEEK radiotransparency, the ORIO-TL cage is invisible on X-Rays for a clear assessment of the bone fusion.

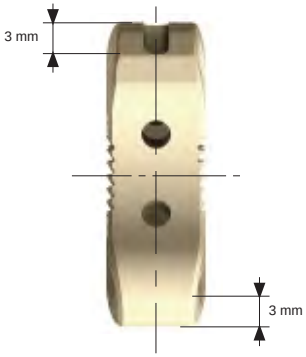


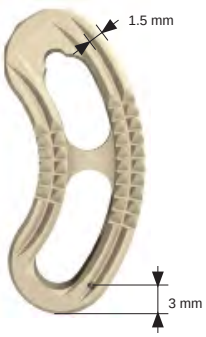
Straight TLIF Markers



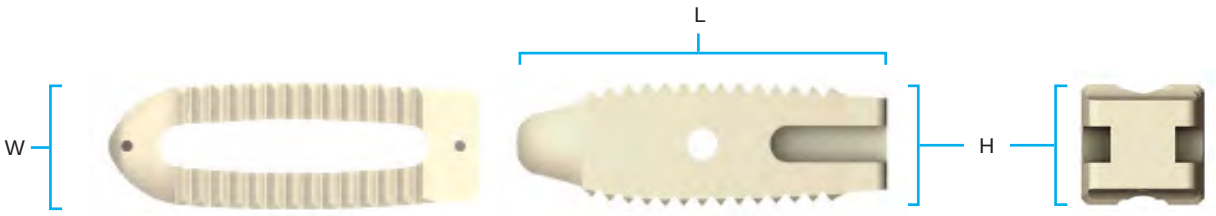


Curved TLIF Markers





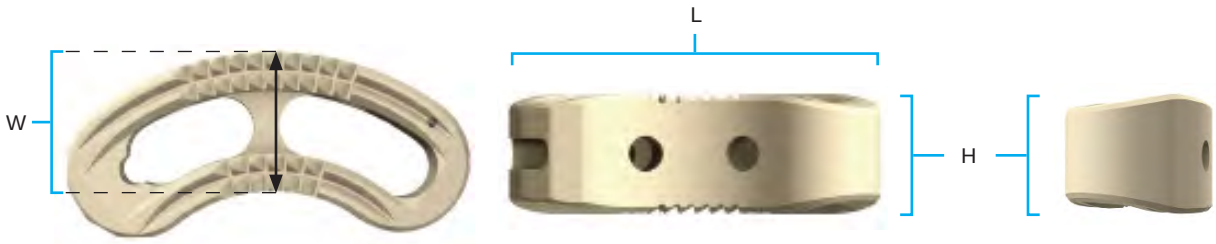
02a. Straight TLIF Implant Ordering Information



Standard Implants	Width	Height	Length	Catalog n°
ORIO-TL Straight TLIF Cage	10 mm	8 mm	28 mm	L7810-08-028
ORIO-TL Straight TLIF Cage	10 mm	8 mm	30 mm	L7810-08-030
ORIO-TL Straight TLIF Cage	10 mm	8 mm	32 mm	L7810-08-032
ORIO-TL Straight TLIF Cage	10 mm	8 mm	34 mm	L7810-08-034
ORIO-TL Straight TLIF Cage	10 mm	9 mm	28 mm	L7810-09-028
ORIO-TL Straight TLIF Cage	10 mm	9 mm	30 mm	L7810-09-030
ORIO-TL Straight TLIF Cage	10 mm	10 mm	28 mm	L7810-10-028
ORIO-TL Straight TLIF Cage	10 mm	10 mm	30 mm	L7810-10-030
ORIO-TL Straight TLIF Cage	10 mm	10 mm	32 mm	L7810-10-032
ORIO-TL Straight TLIF Cage	10 mm	10 mm	34 mm	L7810-10-034
ORIO-TL Straight TLIF Cage	10 mm	11 mm	28 mm	L7810-11-028
ORIO-TL Straight TLIF Cage	10 mm	11 mm	30 mm	L7810-11-030
ORIO-TL Straight TLIF Cage	10 mm	12 mm	28 mm	L7810-12-028
ORIO-TL Straight TLIF Cage	10 mm	12 mm	30 mm	L7810-12-030
ORIO-TL Straight TLIF Cage	10 mm	12 mm	32 mm	L7810-12-032
ORIO-TL Straight TLIF Cage	10 mm	12 mm	34 mm	L7810-12-034
ORIO-TL Straight TLIF Cage	10 mm	13 mm	28 mm	L7810-13-028
ORIO-TL Straight TLIF Cage	10 mm	13 mm	30 mm	L7810-13-030
ORIO-TL Straight TLIF Cage	10 mm	14 mm	28 mm	L7810-14-028
ORIO-TL Straight TLIF Cage	10 mm	14 mm	30 mm	L7810-14-030
ORIO-TL Straight TLIF Cage	10 mm	14 mm	32 mm	L7810-14-032
ORIO-TL Straight TLIF Cage	10 mm	14 mm	34 mm	L7810-14-034

Optional Implants	Width	Height	Length	Catalog n°
ORIO-TL Straight TLIF Cage	10 mm	7 mm	28 mm	L7810-07-028
ORIO-TL Straight TLIF Cage	10 mm	7 mm	30 mm	L7810-07-030
ORIO-TL Straight TLIF Cage	10 mm	7 mm	32 mm	L7810-07-032
ORIO-TL Straight TLIF Cage	10 mm	7 mm	34 mm	L7810-07-034
ORIO-TL Straight TLIF Cage	10 mm	9 mm	32 mm	L7810-09-032
ORIO-TL Straight TLIF Cage	10 mm	9 mm	34 mm	L7810-09-034
ORIO-TL Straight TLIF Cage	10 mm	11 mm	32 mm	L7810-11-032
ORIO-TL Straight TLIF Cage	10 mm	11 mm	34 mm	L7810-11-034
ORIO-TL Straight TLIF Cage	10 mm	13 mm	32 mm	L7810-13-032
ORIO-TL Straight TLIF Cage	10 mm	13 mm	34 mm	L7810-13-034
ORIO-TL Straight TLIF Cage	10 mm	15 mm	28 mm	L7810-15-028
ORIO-TL Straight TLIF Cage	10 mm	15 mm	30 mm	L7810-15-030
ORIO-TL Straight TLIF Cage	10 mm	15 mm	32 mm	L7810-15-032
ORIO-TL Straight TLIF Cage	10 mm	15 mm	34 mm	L7810-15-034

02b. Curved TLIF Implant Ordering Information



Standard Implants	Width	Height	Length	Catalog n°
ORIO-TL Curved TLIF Symmetrical Cage, 5° Lordosis	11 mm	8 mm	28 mm	L7711-08-528
ORIO-TL Curved TLIF Symmetrical Cage, 5° Lordosis	11 mm	8 mm	30 mm	L7711-08-530
ORIO-TL Curved TLIF Symmetrical Cage, 5° Lordosis	11 mm	8 mm	32 mm	L7711-08-532
ORIO-TL Curved TLIF Symmetrical Cage, 5° Lordosis	11 mm	8 mm	34 mm	L7711-08-534
ORIO-TL Curved TLIF Symmetrical Cage, 5° Lordosis	11 mm	10 mm	28 mm	L7711-10-528
ORIO-TL Curved TLIF Symmetrical Cage, 5° Lordosis	11 mm	10 mm	30 mm	L7711-10-530
ORIO-TL Curved TLIF Symmetrical Cage, 5° Lordosis	11 mm	10 mm	32 mm	L7711-10-532
ORIO-TL Curved TLIF Symmetrical Cage, 5° Lordosis	11 mm	10 mm	34 mm	L7711-10-534
ORIO-TL Curved TLIF Symmetrical Cage, 5° Lordosis	11 mm	12 mm	28 mm	L7711-12-528
ORIO-TL Curved TLIF Symmetrical Cage, 5° Lordosis	11 mm	12 mm	30 mm	L7711-12-530
ORIO-TL Curved TLIF Symmetrical Cage, 5° Lordosis	11 mm	12 mm	32 mm	L7711-12-532
ORIO-TL Curved TLIF Symmetrical Cage, 5° Lordosis	11 mm	12 mm	34 mm	L7711-12-534
ORIO-TL Curved TLIF Symmetrical Cage, 5° Lordosis	11 mm	14 mm	28 mm	L7711-14-528
ORIO-TL Curved TLIF Symmetrical Cage, 5° Lordosis	11 mm	14 mm	30 mm	L7711-14-530
ORIO-TL Curved TLIF Symmetrical Cage, 5° Lordosis	11 mm	14 mm	32 mm	L7711-14-532
ORIO-TL Curved TLIF Symmetrical Cage, 5° Lordosis	11 mm	14 mm	34 mm	L7711-14-534

Optional Implants	Width	Height	Length	Catalog n°
ORIO-TL Curved TLIF Symmetrical Cage, 5° Lordosis	11 mm	9 mm	28 mm	L7711-09-528
ORIO-TL Curved TLIF Symmetrical Cage, 5° Lordosis	11 mm	9 mm	30 mm	L7711-09-530
ORIO-TL Curved TLIF Symmetrical Cage, 5° Lordosis	11 mm	9 mm	32 mm	L7711-09-532
ORIO-TL Curved TLIF Symmetrical Cage, 5° Lordosis	11 mm	9 mm	34 mm	L7711-09-534
ORIO-TL Curved TLIF Symmetrical Cage, 5° Lordosis	11 mm	11 mm	28 mm	L7711-11-528
ORIO-TL Curved TLIF Symmetrical Cage, 5° Lordosis	11 mm	11 mm	30 mm	L7711-11-530
ORIO-TL Curved TLIF Symmetrical Cage, 5° Lordosis	11 mm	11 mm	32 mm	L7711-11-532
ORIO-TL Curved TLIF Symmetrical Cage, 5° Lordosis	11 mm	11 mm	34 mm	L7711-11-534
ORIO-TL Curved TLIF Symmetrical Cage, 5° Lordosis	11 mm	13 mm	28 mm	L7711-13-528
ORIO-TL Curved TLIF Symmetrical Cage, 5° Lordosis	11 mm	13 mm	30 mm	L7711-13-530
ORIO-TL Curved TLIF Symmetrical Cage, 5° Lordosis	11 mm	13 mm	32 mm	L7711-13-532
ORIO-TL Curved TLIF Symmetrical Cage, 5° Lordosis	11 mm	13 mm	34 mm	L7711-13-534

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

Curved TLIF Cage Impactor 7040-06

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

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

Paddle Distractor (height 7-14mm)

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

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

7020-03-07
7020-03-09
7020-03-11
7020-03-13

Slap Hammer 7050-01

Knob Unlocker 7030-01-03

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. Surgical Technique

Preoperative planning

1

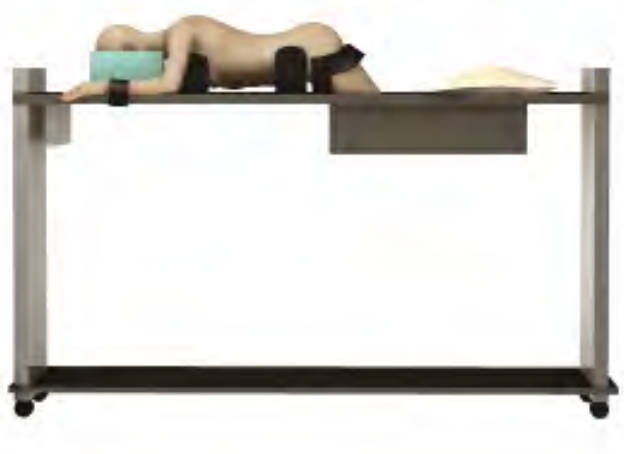
An estimate of the appropriate ORIO-TL TLIF Cage size should be made prior to surgery. With the segment fully distracted, the implant must fit tightly and accurately between the endplates. To achieve maximal segment stability, it is essential to implant the largest possible cage. Cage size can be determined with the help of a Paddle Distractor during surgery.

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

Position of the patient

2

In transforaminal lumbar surgery, the patient is positioned in restored physiological lordosis.



Exposure and pedicle screw insertion

3

Make the incision after viewing a radiograph of the segment. Retract the muscle layer.

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.

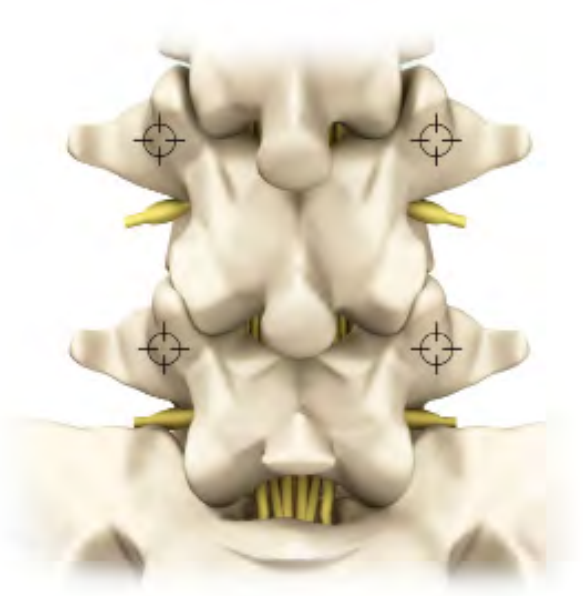
The pedicle walls can be identified as part of the laminectomy exposure.

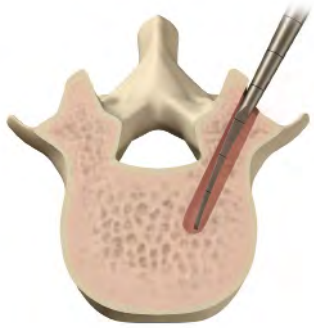
The entrance to the pedicle canal can be exposed using an awl, high-speed burr, or rongeur.

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.

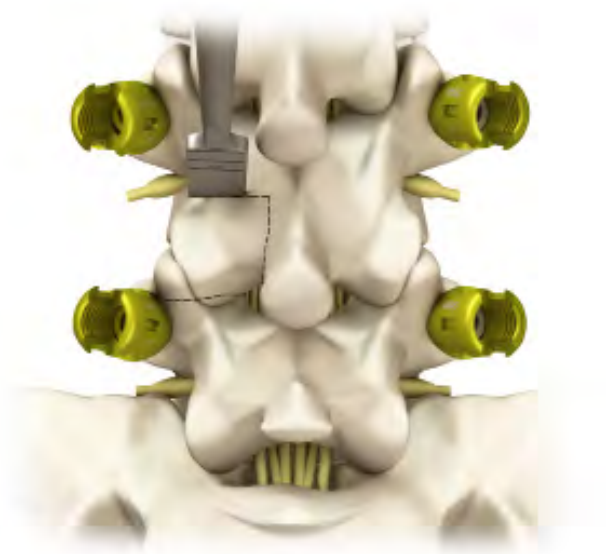




Cut the transforaminal window

4

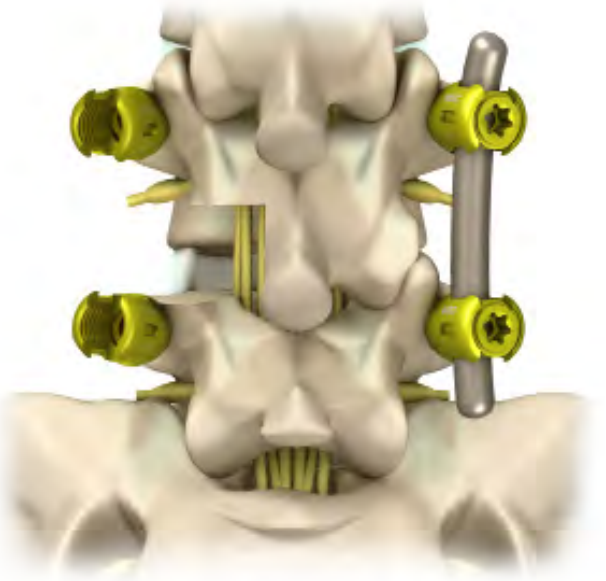
Prepare a window for transforaminal approach using the Osteotome, a burr, or a Kerrison rongeur to remove the inferior facet of the cranial vertebra and the superior facet of the caudal vertebra.



Distraction of disc space

5

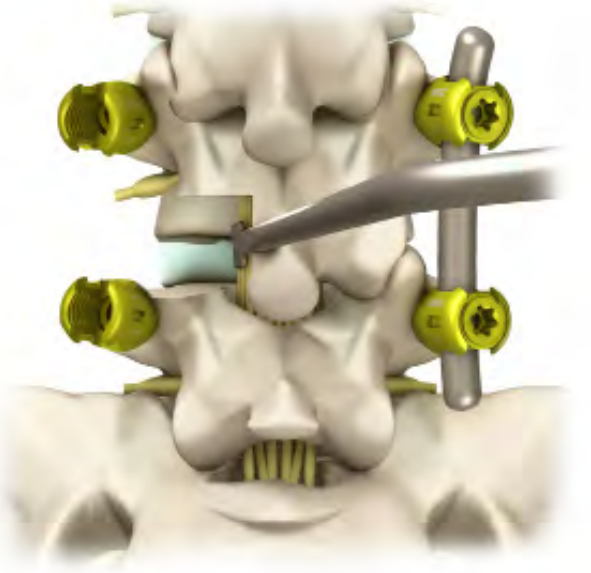
Distraction of the disc is optional in order to help prepare the disc space. After distraction with a Paddle Distractor, place a rod on the contralateral side and tighten set screws to maintain disc distraction.



Nerve retraction

6

Retract the nerve roots with the Nerve Retractor. Minimal retraction is required during TLIF insertion.



Prepare disc space

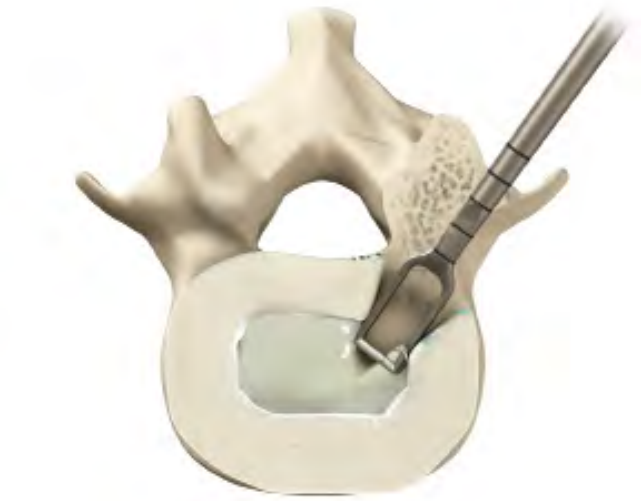
7

Access the foramen and use Bone Curettes and Disc Shavers to remove disc material through an incision in the annulus fibrosus.

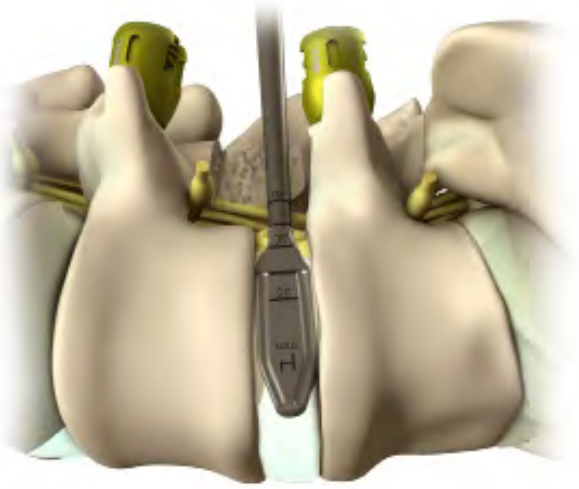
The remaining annulus must be preserved to provide additional support for the ORIO-TL TLIF Cage.

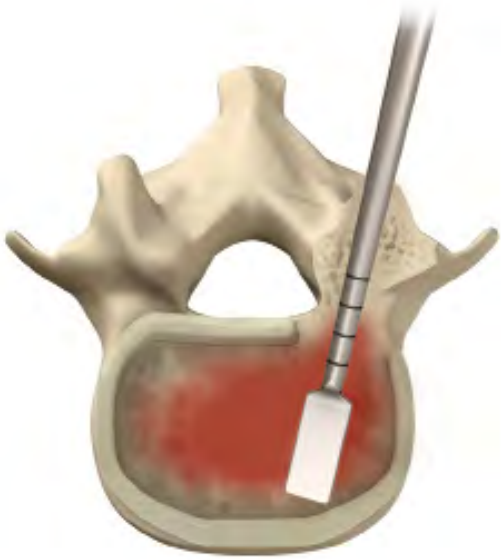
Remove cartilaginous layers from the surface of the vertebral endplates with the Rasp until bleeding bone is attained.

Sufficient cleaning of the endplates is essential for vascular supply to the bone graft; yet excessive cleaning could damage the denser bone layer and weaken the endplate.



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





Determine the cage height and length using the Paddle Distractor

8

Select the Paddle Distractor corresponding to the preoperatively estimated height of the disc space and attach a T-handle.

Carefully insert the selected Paddle Distractor via the transforaminal window into the disc space, applying gentle impaction.

Check the position of the Paddle under the image intensifier.

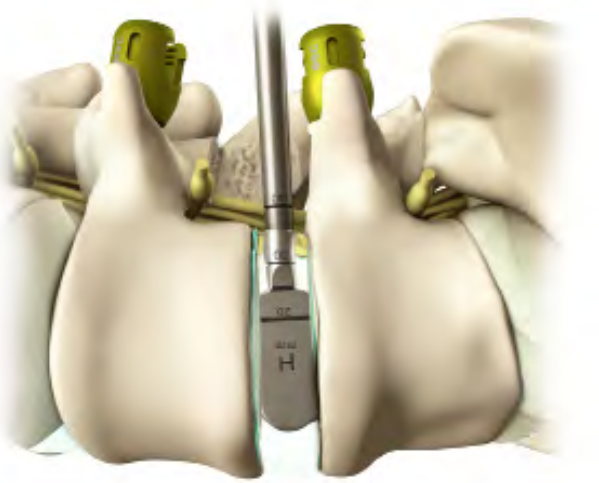
With the segment fully distracted, the Paddle must fit tightly and accurately between the endplates in order to ensure that disc height will be preserved when the distraction is released.

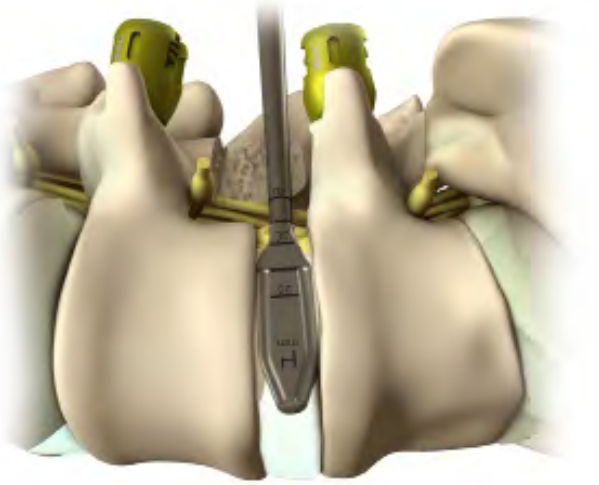
Using the largest possible implant maximizes segment stability by creating tension on the longitudinal ligament and the annulus fibrosus.

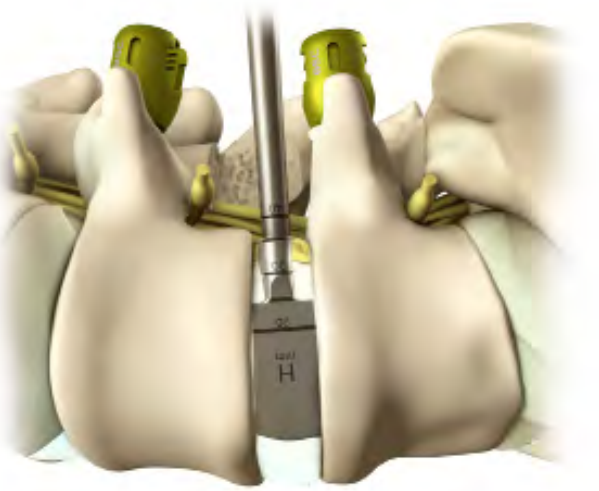
If the Paddle Distractor does not completely fill the intervertebral space, try the next larger size. If the Paddle Distractor cannot be inserted, try the next smaller size.

Cage length can be determined by noting the depth markings on the paddle or disc shaver when the instrument is sufficiently inserted in the disc space.

When the correct ORIO-TL TLIF Cage size has been determined, distraction can be temporarily released.







Select the appropriate ORIO-TL Straight TLIF cage and attach the Implant Inserter

9a

Select the ORIO-TL Straight TLIF Cage size determined in step 8. Attach the cage to the Straight TLIF Cage Inserter (straight style inserter and pistol grip style inserter available).

Make sure the 2 tabs are fully open by turning the knob at the end of the inserter counterclockwise.

Slide the 2 tabs of the inserter into the cage slots until the cage is fully seated.

Tighten the 2 tabs on the cage by turning the knob clockwise (as shown).

Bone Graft

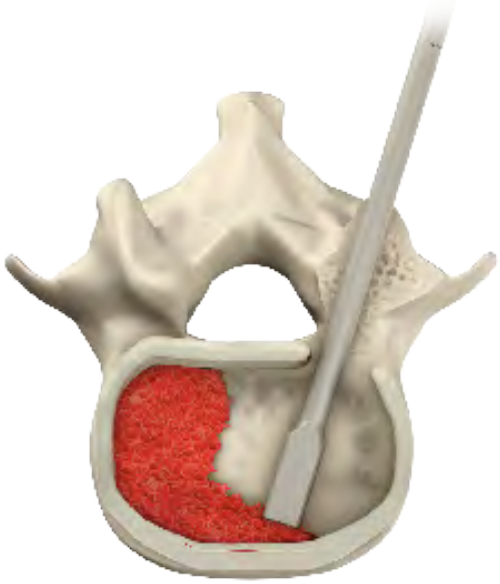
10a

Pack the ORIO-TL TLIF Cage with autologous bone.

Harvest autologous bone, for example from the iliac crest.

The cages must be filled completely.

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

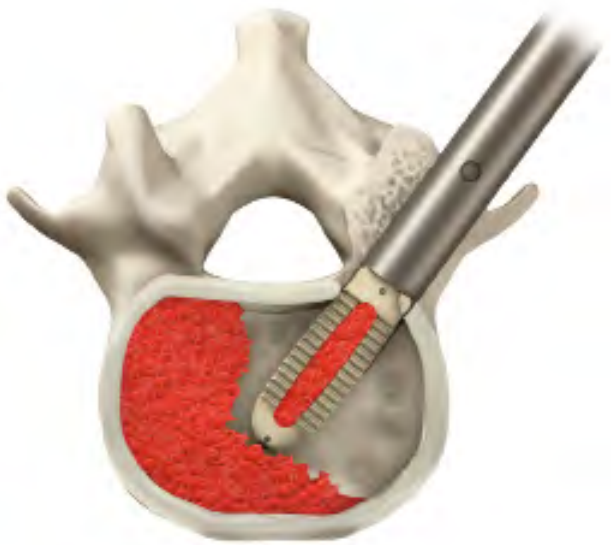


Implant the ORIO-TL Straight TLIF cage

11a

Ensure that the orientation of the cage is correct and then insert it into the intervertebral disc space.

Slight impaction on the inserter may be necessary.



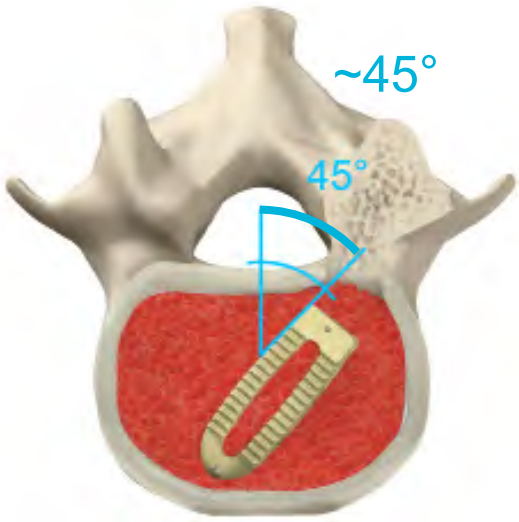
Verify the position of the ORIO-TL cage

12a

Release the cage from the inserter by turning the knob at the back of the instrument counterclockwise, then pull the instrument to detach the cage from the inserter along the cage direction.

Adjust the cage position with the different cage impactors if needed.

Remove all instruments and check the position of the ORIO-TL cages under the image intensifier.



Compression & Final Tightening

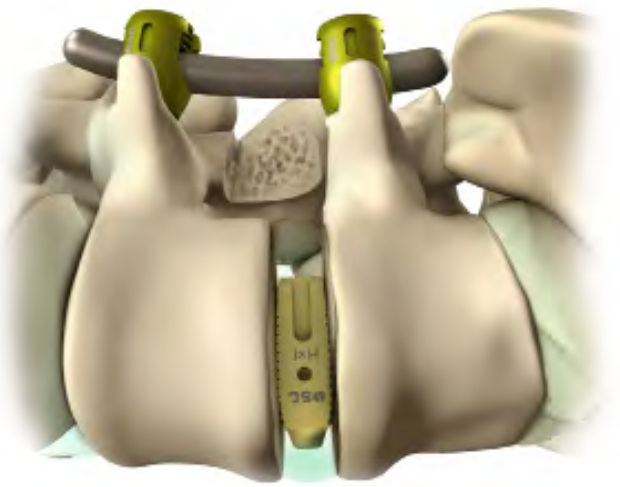
13a

Once the cage is 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.



Select the appropriate ORIO-TL Curved TLIF cage and attach to the Implant Inserter 9b

Select the ORIO-TL Curved TLIF cage corresponding to the cage size determined in step 8.

To attach the Curved TLIF Cage Inserter to the selected cage:

Turn the knob at the end of the instrument counterclockwise (A) until some resistance is encountered.

Twist the button to the “RELEASE” position (push the button forward (B) then to the left (C)).

Slide the “T” shaped tip of the instrument into the slot at the back of the cage. Make sure the cage is properly seated (flat facets in the back of the cage are in contact with the corresponding flat facets of the instrument sleeve).

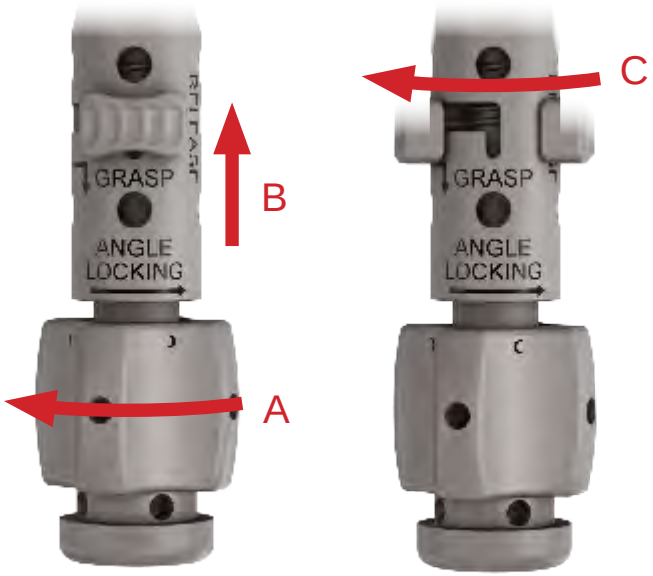
While holding the instrument firmly with the seated cage in one hand, twist the button to the “GRASP” position with the other hand (push the button slightly forward and then to the right (D)).

Turn the knob at the back of the instrument clockwise (E) until you can easily feel the 3 different angular steps of the cage position by pushing it right/left around the pivot tip.

Select the insertion position of the cage by pushing it to the desired angle (the straightest position as shown is recommended), then keep turning the knob clockwise (E) until the cage is firmly held in position.

Note: The cage can be easily loaded onto the inserter from the implant caddy.

ORIO-TL Curved TLIF in the straight position, which is recommended for insertion



Possible angular positions of the ORIO-TL Curved TLIF Cage on the Inserter

Bone Graft

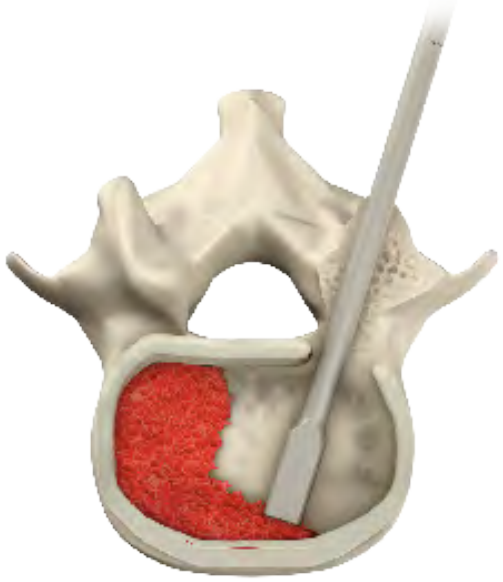
10b

Pack the ORIO-TL TLIF Cage with autologous bone.

Harvest autologous bone, for example from the iliac crest.

The cages must be filled completely.

Use the bone graft compactors to fill the anterior disc space with autologous bone.



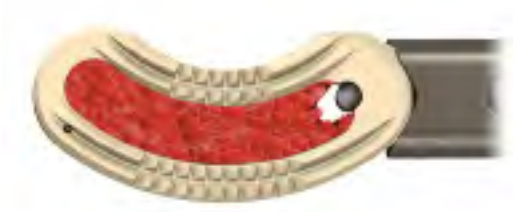
Implant the ORIO-TL Curved TLIF Cage

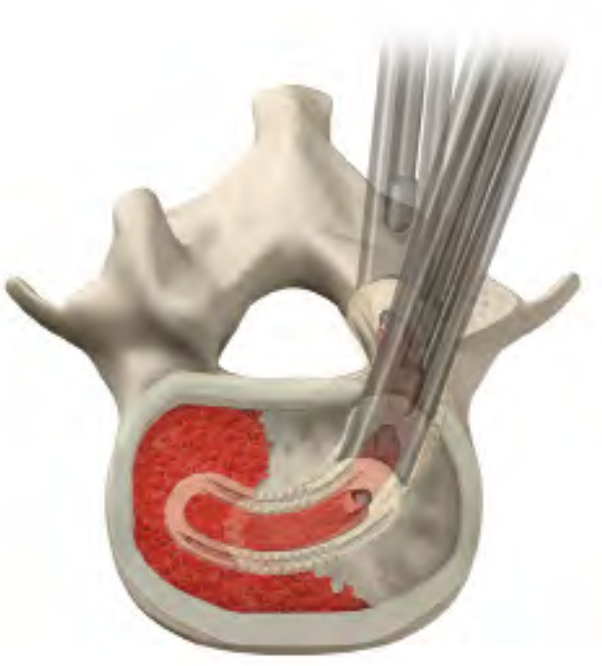
11b

Ensure that the orientation of the cage is correct and then insert into the intervertebral disc space.

The cage's position on the Inserter can be changed by loosening the "ANGLE LOCKING" knob, pivoting the inserter relative to the cage to the next set of facets, and then retightening the knob.

Slight impaction on the Inserter may be necessary.





Verify the position of the ORIO-TL cage

12b

Release the Inserter from the cage:

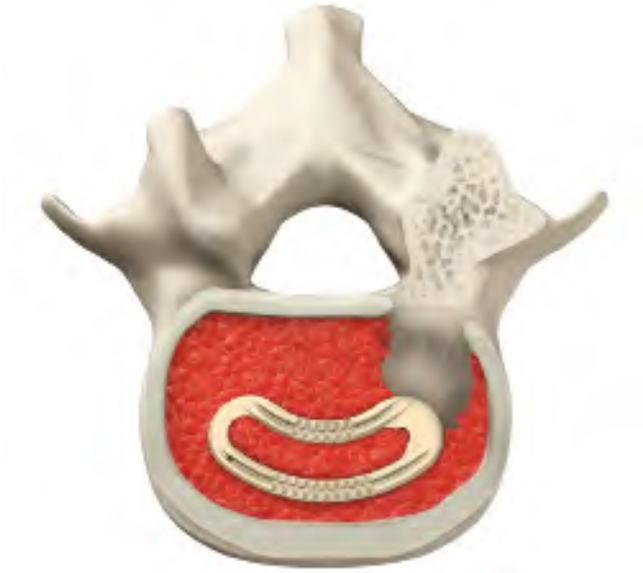
Turn the knob at the back of the instrument counterclockwise until some resistance is encountered.

Twist the button to the “RELEASE” position (push the button forward then to the left).

Pull the instrument to detach it from the cage (some medial-lateral wiggling may help).

Adjust the cage position with the Curved TLIF Cage Impactor if needed.

Remove all instruments and check the position of the ORIO-TL cage under the image intensifier.



Compression & Final Tightening

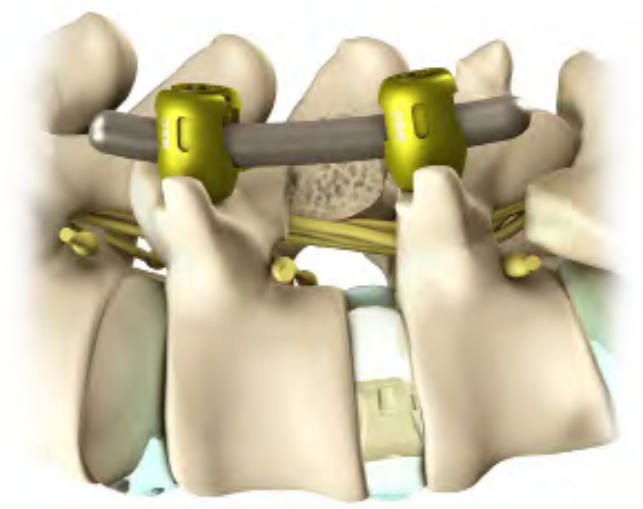
13b

Once the cage is 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.



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-TL TLIF 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

05. 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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