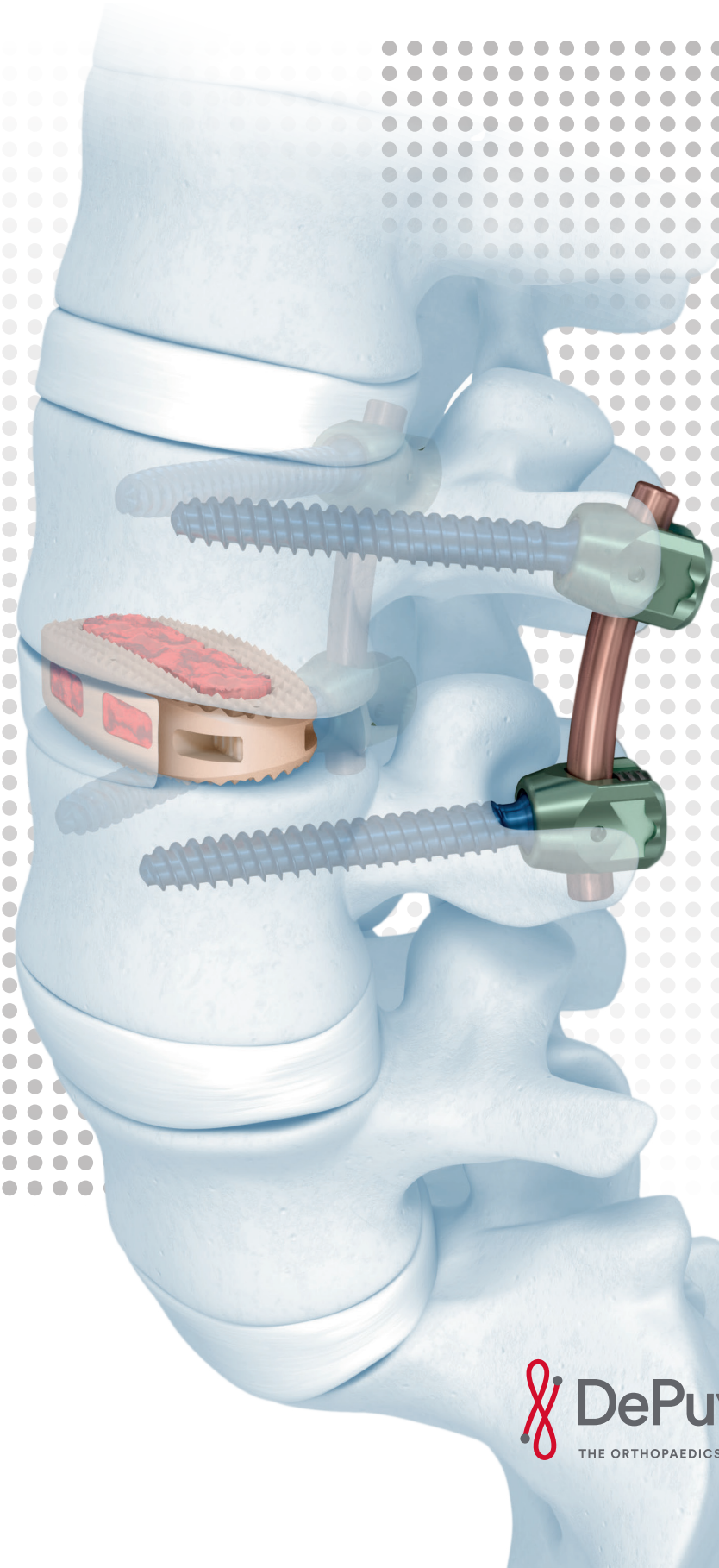
# ORACLE Cage

## Surgical Technique



DePuy Synthes

THE ORTHOPAEDICS COMPANY OF Johnson & Johnson

Image intensifier control

▲ Warnings/Precautions

This description alone does not provide sufficient background for direct use of DePuy Synthes products. Instruction by a surgeon experienced in handling these products is highly recommended.

**Processing, Reprocessing, Care and Maintenance**

For general guidelines, function control and dismantling of multi-part instruments, as well as processing guidelines for implants, please contact your local sales representative or refer to:

http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance

For general information about reprocessing, care and maintenance of Synthes reusable devices, instrument trays and cases, as well as processing of Synthes non-sterile implants, please consult the Important Information leaflet (SE_023827) or refer to:
http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance

# Table of Contents



For Product Catalogue contact your local DePuy Synthes representative.

# ORACLE Cage System

## Approach

The ORACLE Cage system is a modular set of implants and instruments designed to facilitate a direct lateral approach to the lumbar spine.

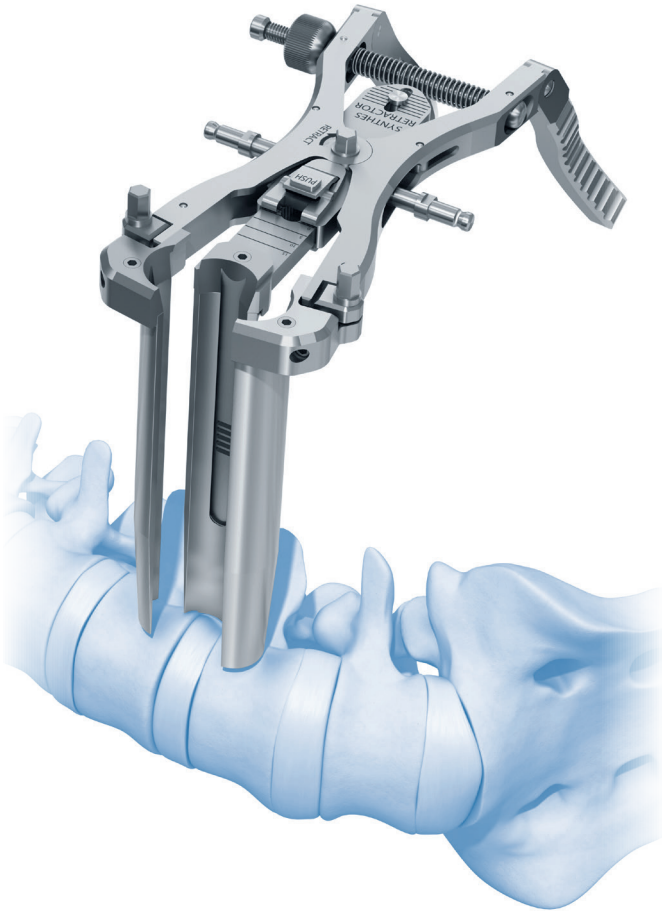
## ORACLE Access Instruments

**Retractor**

- Provides access to operative level
- Blades expand distally

**Retractor Accessories**

- Light Clip contributes to additional illumination of the surgical field
- Intradiscal Anchor and Retractor pins
- Blade Extensions provide an additional 10mm to the blade length in-situ.



## Discectomy

**ORACLE discectomy instruments**

- Two styles of Shavers (four fluted and two fluted) for reaming out disc material
- Bayoneted Curettes
- Matt finish to the instruments helps to reduce glare from OR lighting

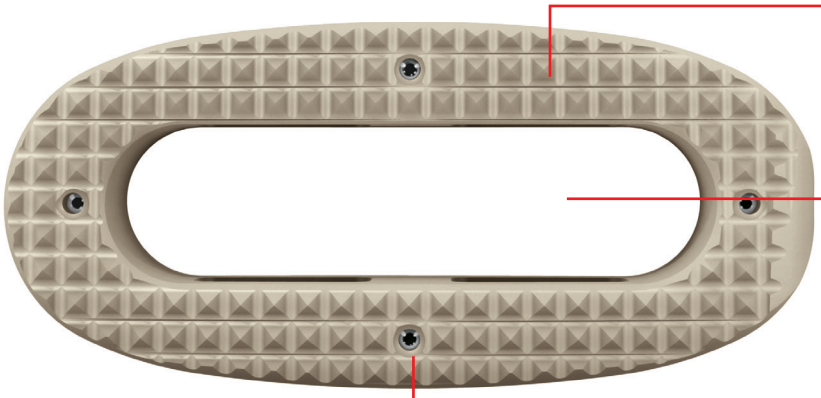
## Insertion

**ORACLE Cage insertion instruments**

- Bulleted nose of the Trial Implant to assist with insertion
- Slide Hammer for Trial Implant removal
- Lateral Quick Inserter Distractor inserts and distracts in one step

## Implant Overview

The ORACLE Cage is intended for lateral lumbar interbody fusion procedures. The implant is available in 4 medial/lateral lengths, 5 heights, and 2 sagittal profiles to accommodate various patient anatomies.



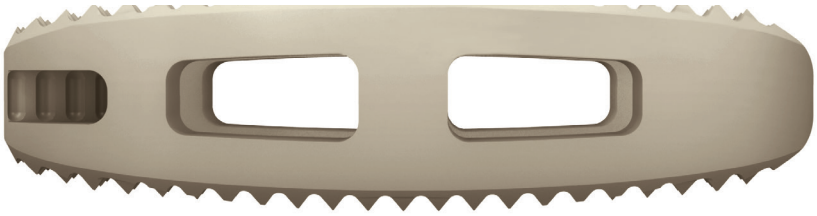
Pyramidal teeth may reduce implant migration

**Large central canal**

Accommodates bone graft material for fusion

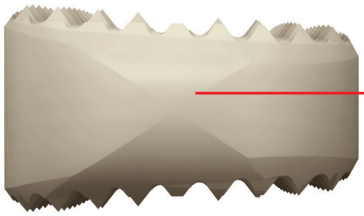
**Four radiographic marker pins**

Enable radiographic visualisation of implant position



**Anatomic shape**

Mimics the anatomy of the disc space



**Bulleted nose**

Aids implant insertion

## Material

ORACLE Cages are manufactured from a biocompatible polymer (Polyetheretherketone (PEEK)) material embedded with four radiopaque marker pins (Titanium alloy (TAN)), which allow the surgeon to radiographically determine the position of the implant, both intraoperatively and postoperatively.

The medial/lateral marker pins are located approximately 4 mm from the edges of the implant. The anterior/posterior marker pins are located approximately 2 mm from the edges of the implant.

# AO Spine Principles

The four principles to be considered as the foundation for proper spine patient management underpin the design and delivery of the Curriculum: Stability, Alignment, Biology, Function.[1,2]

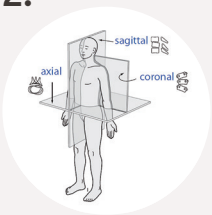
## AO Principles[1,2]

**1.**

**Stability**

Stabilization to achieve a specific therapeutic outcome.

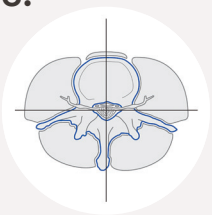
**2.**




**Alignment**

Balancing the spine in three dimensions.

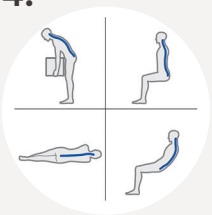
**3.**



**Biology**

Etiology, pathogenesis, neural protection, and tissue healing.

**4.**



**Function**

Preservations and restoration of function to prevent disability.

1. Aebi M, Thalgott JS, Webb JK (1998) AO/ASIF Principles in Spine Surgery. Springer-Verlag, Germany.
2. Aebi M, Arlet V, Webb JK (2007): AOSPINE Manual (2 vols), Stuttgart, New York: Thieme.

## 1. Preoperative Planning and Preparation

| Sets | |
|---|---|
| 187.310 | SYNFRAME™ Basic System in Vario Case* |
| 01.609.102<br>or<br>01.809.002<br>and<br>01.809.018<br>or<br>01.809.040 | Set SYNFRAME RL, lumbar**<br><br>ORACLE Access Instrument Set<br><br>Stability System Set<br><br>INSIGHT™ Lateral Access System Set |
| 01.809.003 | ORACLE Discectomy Instrument Set |
| 01.809.004 | ORACLE Cage Insertion Instrument Set |

| Optional | |
|---|---|
| 03.809.943 | Retractor Pin |
| 03.809.925S | Light Clip for ORACLE Retractor, sterile |
| 01.809.011 | Dilation Instrument Set |
| 01.605.903 | MIPI™ System (Minimally Invasive Posterior Instruments) |

Have all necessary imaging studies readily available to plan implant placement and visualize individual patient anatomy.

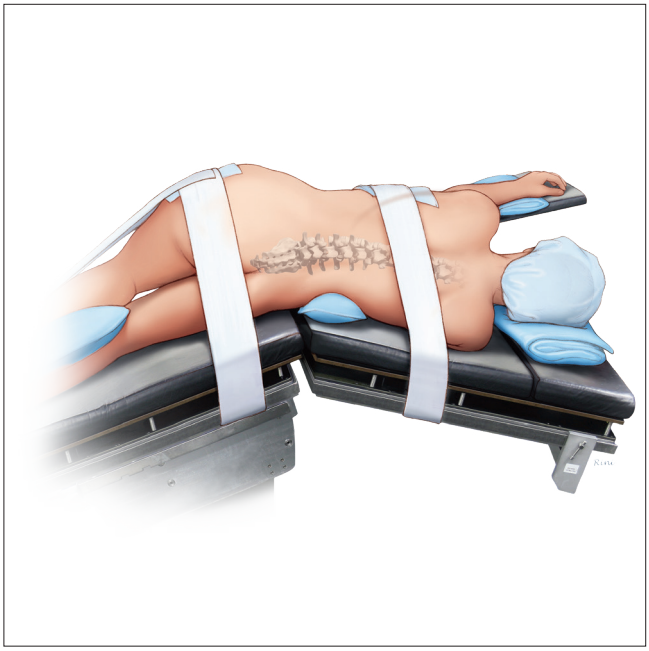
Have all sets readily available prior to surgery.

* SYNFRAME Basic System contains instruments that allow for direct mounting to the operating table.

** SYNFRAME RL, lumbar contains radiolucent soft tissue Retractors and semi-transparent bone levers.

## 2. Patient Positioning

Place the patient in a lateral decubitus position and secure the patient to the table. A bolster placed underneath the hip to aid in opening the space between the twelfth rib and iliac crest is recommended. It is also recommended to flex the table, to aid in opening the space between the twelfth rib and iliac crest. Ensure that the rotational alignment is correct.



**▲ Precaution:**

- **Prevent undue pressure points when positioning and securing the patient.**
- **If neuromonitoring is planned, the neurophysiologist or neuromonitoring technician should make sure all appropriate electrodes are placed prior to patient positioning.**

When preparing and using neuromonitoring equipment, please refer to the specific manufacturer's technique guide and IFUs for guidance.

Use the Universal Arm and Table Clamp to stabilize the Retractor to the OR table. Turn the Table Clamp lever counterclockwise to loosen. Slide the Table Clamp onto the OR table rail.

Insert the post of the Universal Arm through the opening of the Table Clamp with the articulation of the arm facing the patient. Turn the Table Clamp lever clockwise to tighten.

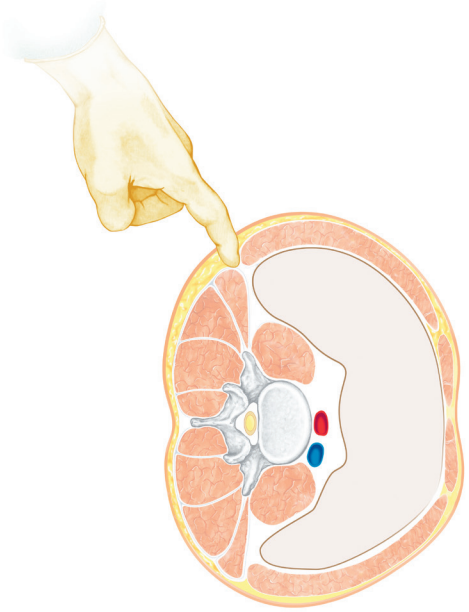
## 3. Access and Exposure

Locate the correct operative level with fluoroscopic views to plan the skin incision.

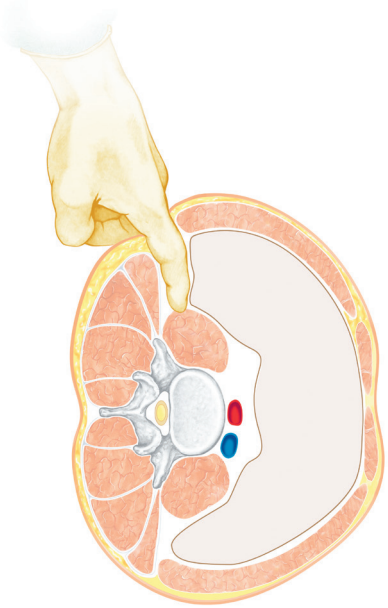
- **Use a longitudinal incision if multiple levels will be fused.**

Once the skin incision is made and the subcutaneous tissue is taken down, the oblique muscles of the abdomen should be visible. Separate the muscle fibers with blunt dissection and enter the retroperitoneal space (1). Move the peritoneum anterior with forefinger and continue blunt dissection to palpate down to the transverse process. Slide forward to psoas muscle (2).

1



2



## A. Approach spine with Tissue Dissector

**Instrument**

03.809.860 Tissue Dissector

**▲ Warnings:**

- Map out a safe corridor through the psoas muscle to the lumbar spine. Fluoroscopy is recommended to target the anterior two-thirds of the disc space of concern. The anterior third of the psoas muscle is the most likely safe zone for avoiding the neural elements of the lumbar plexus.[3]
- Consider using a blunt tipped probe, like a Penfield 4, to confirm disc and bone beneath the psoas with adequate distance from the aorta.

After planning the approach, use fluoroscopy to find the location one-third back from the anterior disc aspect and hold the Penfield 4 at this location. Insert a Kirschner Wire just dorsal to the Penfield 4 into the disc space. This should place the center of the cage in the anterior two thirds of the disc to decrease chances of injury to the lumbar plexus.

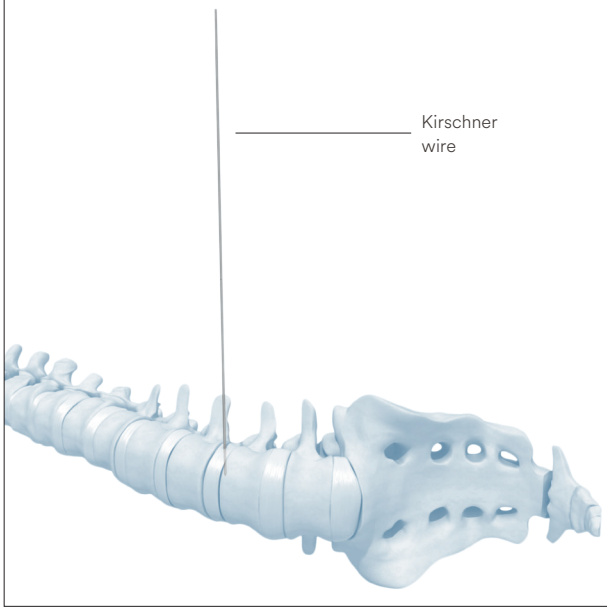
Insert the Kirschner Wire into the annulus of the desired intervertebral disc space[3]. Use fluoroscopy with patient lateral images to determine the location of the Kirschner Wire.

Separate the psoas muscle using the tissue dissector and push the tissue dissector into the disc space (4). Use fluoroscopy to determine the location of the tissue dissector. Remove the Kirschner Wire.

**▲ Warnings:**

- Ensure the Kirschner Wire remains securely in position during these steps.
- Monitor the tip of the Kirschner Wire under A/P fluoroscopy to ensure it does not penetrate the contralateral annulus.

3

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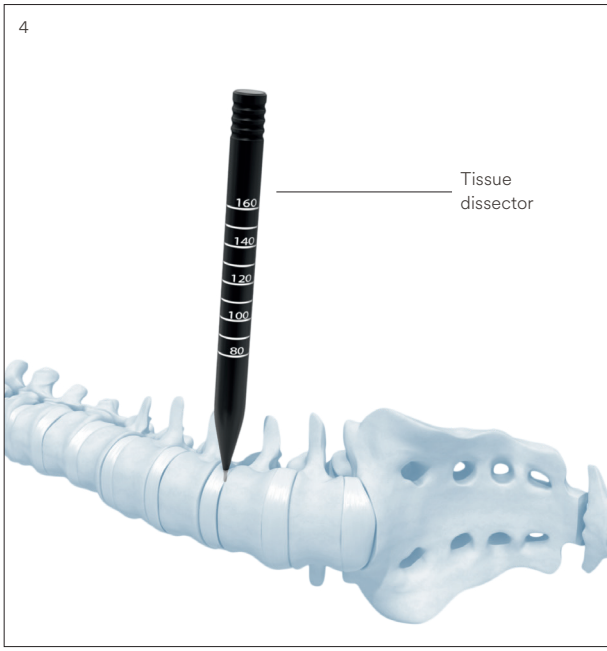
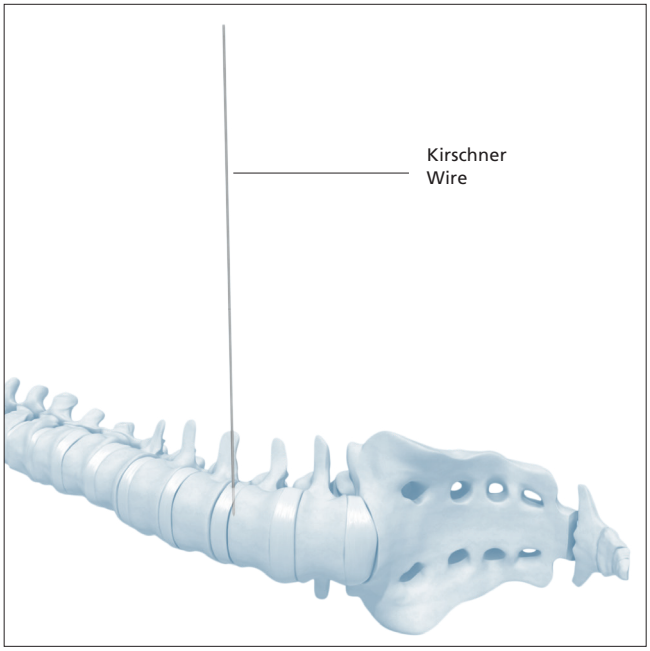



[3] Takatomo Moro, MD, Shin-ichi Kikuchi, MD, PhD, Shin-ichi Konno, MD, PhD and Hiroyuki Yaginuma, MD, PhD: "An Anatomic Study of the Lumbar Plexus with Respect to Retroperitoneal Endoscopic Surgery.", Spine 2003; Volume 28, Number 5, pp 423-428.

## B. Approach spine with Dilators

| Instruments | |
|---|---|
| 03.809.851 | ORACLE Dilator, centred, small |
| 03.809.853 | ORACLE Dilator, centred, medium |
| 03.809.855 | ORACLE Dilator, centred, large |
| 03.809.858 | ORACLE Dilator, not centred, small |
| 03.809.859 | ORACLE Dilator, not centred, large |
| 02.809.001 | Kirschner Wire Ø 1.6 mm with blunt tip, length 285 mm |
| 02.809.002 | Kirschner Wire Ø 3.0 mm with blunt tip, length 285 mm |




**▲ Warnings:**

- **If sequential dilation is planned, map out a safe corridor through the psoas muscle to the lumbar spine. Fluoroscopy is recommended to target the anterior two-thirds of the disc space of concern. The anterior third of the psoas muscle is the most likely safe zone for avoiding the neural elements of the lumbar plexus.[3]**
- **Consider using a blunt tipped probe, like a Penfield 4, to confirm disc and bone beneath the psoas with adequate distance from the aorta.**

After planning the approach, use fluoroscopy to find the location one-third back from the anterior disc aspect and hold the Penfield 4 at this location. Insert a Kirschner wire just dorsal to the Penfield 4 into the disc space. This should place the center the cage in the anterior two thirds of the disc to decrease chances of injury to the lumbar plexus.

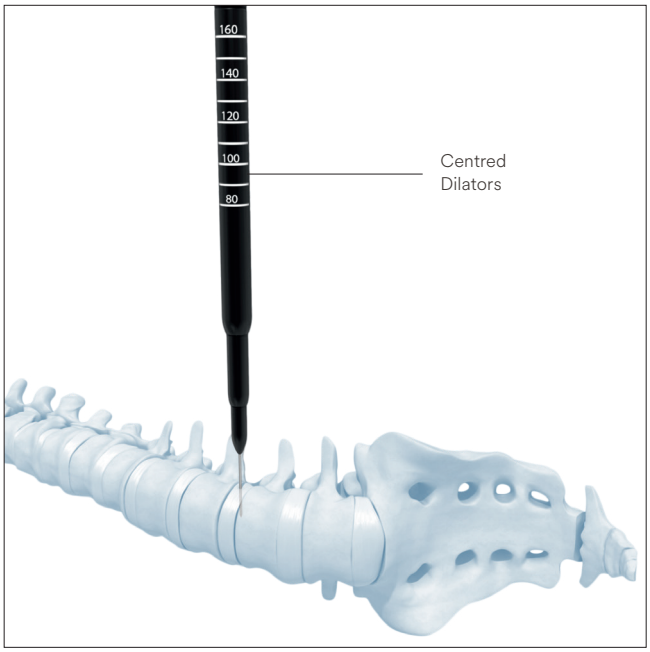
Insert the Kirschner Wire into the annulus of the desired intervertebral disc space. Use fluoroscopy with patient lateral images to determine the location of the Kirschner Wire.

Separate the psoas muscle by inserting the smallest diameter dilator over the Kirschner wire. Repeat with the next larger diameter dilator until the required dilation is achieved. Use fluoroscopy to determine the location of dilator.

ORACLE Dilators, not centred (03.809.858 and 03.809.859), are also available for sequential dilation, and should always be used with a 3.0 mm Kirschner Wire.

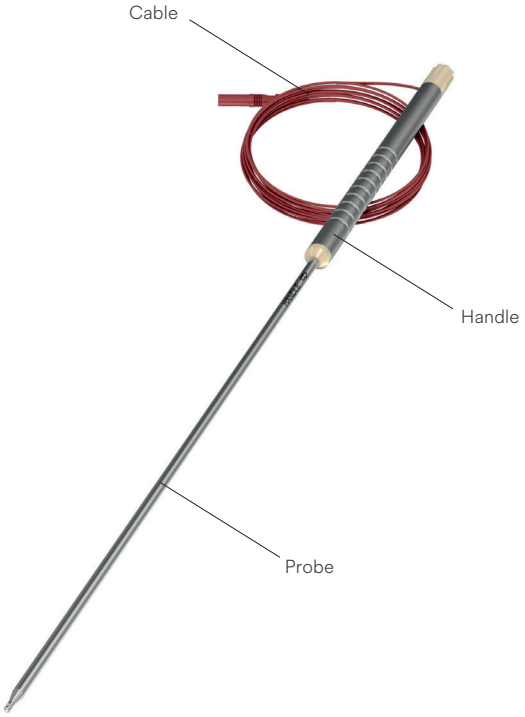
**▲ Warnings:**

- Ensure the Kirschner Wire remains securely in position during these steps.
- Monitor the tip of the Kirschner Wire under A/P fluoroscopy to ensure it does not penetrate the contralateral annulus.



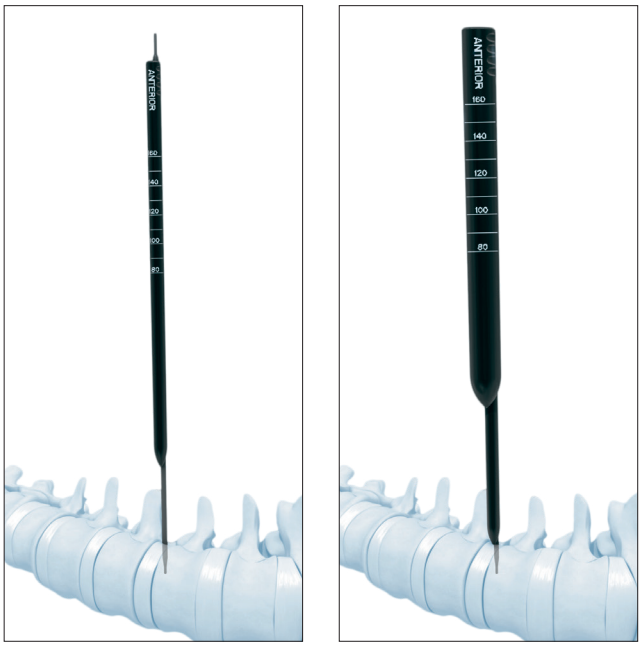
### C. Approach spine with neuromonitoring and Tissue Dissector or Dilators

When preparing and using neuromonitoring equipment, please refer to the specific manufacturer's technique guide and IFUs for guidance.




Perform sequential dilation with the ORACLE Dilators, not centred (03.809.858 and 03.809.859), over the stimulating probe.

Use fluoroscopy to determine location of the dilators and rotate accordingly to adjust access window. Subsequently probe around the Dilators with a second stimulating probe to identify any nerve structures.



## 4. Soft Tissue Retraction

### A. Retraction with SYNFRAME

| Sets | |
|---|---|
| 187.310 | SYNFRAME Basic System in Vario Case |
| 01.609.102 | Set SYNFRAME RL, lumbar |

It is recommended to use at least three radiolucent SYNFRAME Retractors to hold the soft tissue and enable the passage of the instrumentation. Because there may be significant forces acting on the Retractors applied by the psoas during retraction, the Retractors need to be well stabilized with the aid of the Retractor holders and the SYNFRAME Ring.

For further information please refer to SYNFRAME Handling Technique.

**▲ Precaution:**

- **Careful positioning of the Retractors is required to reduce the risk of soft tissue damage.**

### B. INSIGHT Lateral Access System

| Sets | |
|---|---|
| 01.809.040 | INSIGHT Lateral Access System Set, complete |

For information about the operation and use of the INSIGHT Lateral Access System, please refer to the INSIGHT Lateral Access System Surgical Technique.

## C. Retraction with ORACLE access instruments

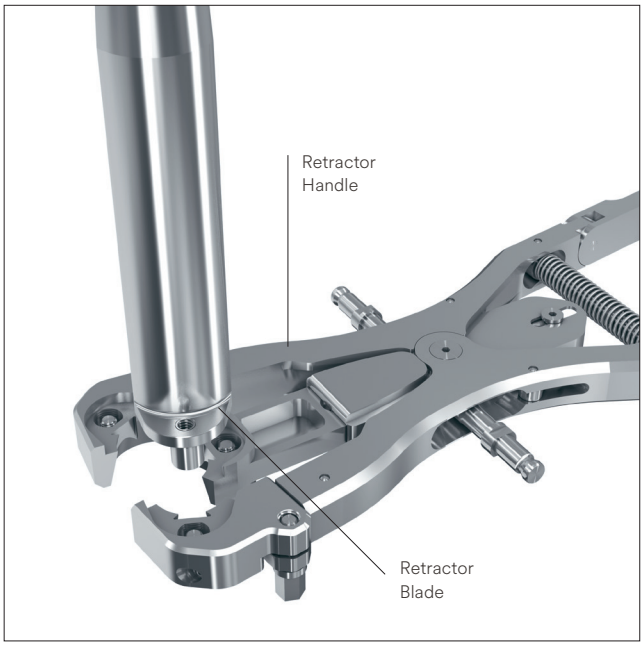
| Instruments | |
|---|---|
| 03.809.857 | Retractor Blade Screwdriver |
| 03.809.900 | ORACLE Retractor Handle |
| 03.809.903–<br>03.809.915 | ORACLE Retractor Blades,<br>40 mm–160 mm |
| 03.809.923 | Retractor Extension Driver |
| 03.809.941 | Universal Arm |
| 03.809.942 | Table Clamp for Universal Arm |
| 388.140 | Socket Wrench 6.0 mm,<br>with straight handle |

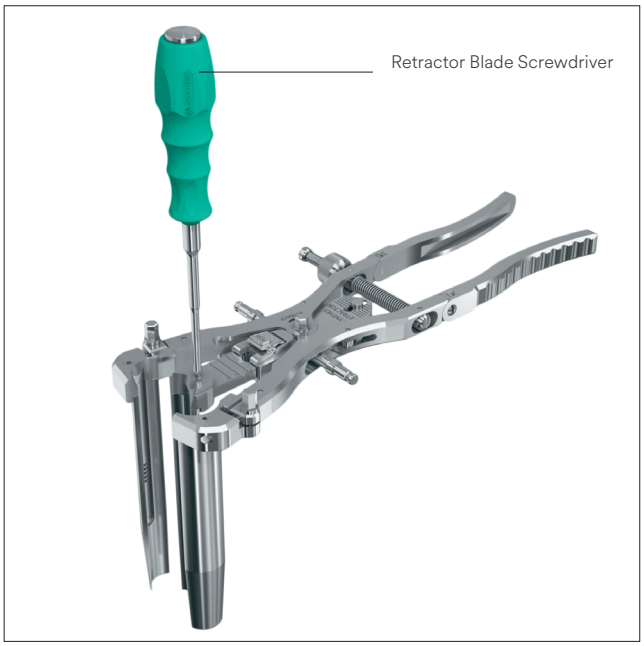
| Optional instruments | |
|---|---|
| 03.612.031 | Fibre Optic Cable for Light Strip |
| 03.809.925S | Light Clip for ORACLE Retractor,<br>sterile |
| 03.809.943 | Retractor Pin |
| 03.820.101 | Screwdriver |
| 03.809.918 | ORACLE Retractor Blade Extension |
| 03.809.919 | ORACLE Retractor Intradiscal Anchor |

Determine the appropriate Retractor Blade lengths from the depth indicators on the Tissue Dissector or Optional Dilators. Assemble the blades to the Retractor Handle with the Retractor Blade Screwdriver.

**▲ Precaution:**

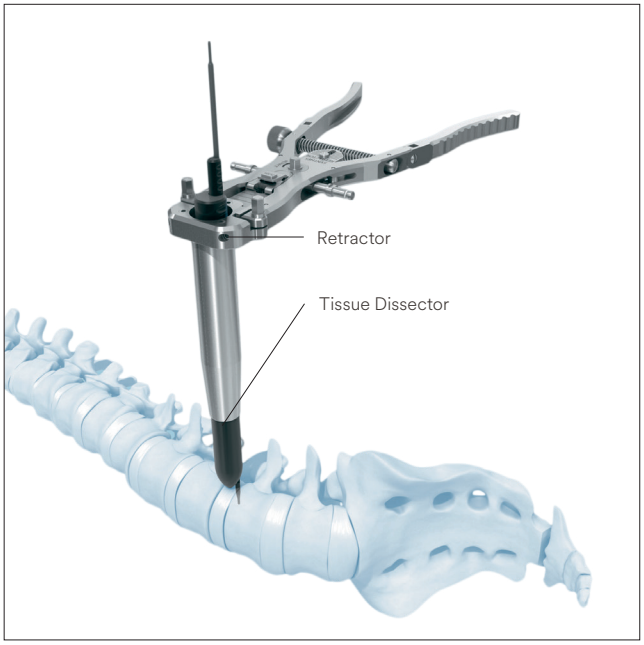
- Do not over-tighten the Screwdriver. Two finger tightening is sufficient to secure the blades to the Retractor Handle.



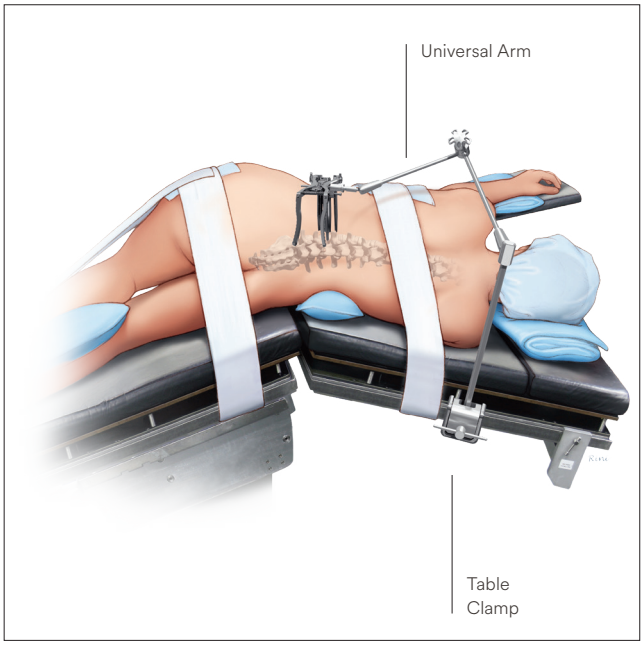
Slide the Retractor over the Tissue Dissector or Optional Dilator. Use patient anterior/posterior fluoroscopic imaging to determine the position of the Retractor Blade tips.

Retractor Blades should contact the disc space and/or vertebral endplates, perpendicular to the disc space. If they do not contact the disc space and/or vertebral endplates, push down on the Retractor with gentle twisting back and forth to push through the psoas muscle before opening the Retractor to minimize tissue creep or risk of catching a nerve.




To connect the Retractor to the Universal Arm secured to the table, insert the Universal Arm into the connector on the Retractor Handle and turn the knob on the arm clockwise to tighten.

Remove the Tissue Dissector or Optional Dilator and the Kirschner Wire, open the Retractor to the desired position and turn the speed nut to lock it.



- **The independent third blade provides up to 20 mm retraction.**

Retract the third blade posteriorly by turning the knob clockwise with the Socket Wrench. To release the amount of retraction, push the button and turn the knob counterclockwise with the Socket Wrench.

**▲ Warning:**

- **The third blade should not be placed beyond the posterior 1/3 margin of the disc space to avoid any neural structures.**

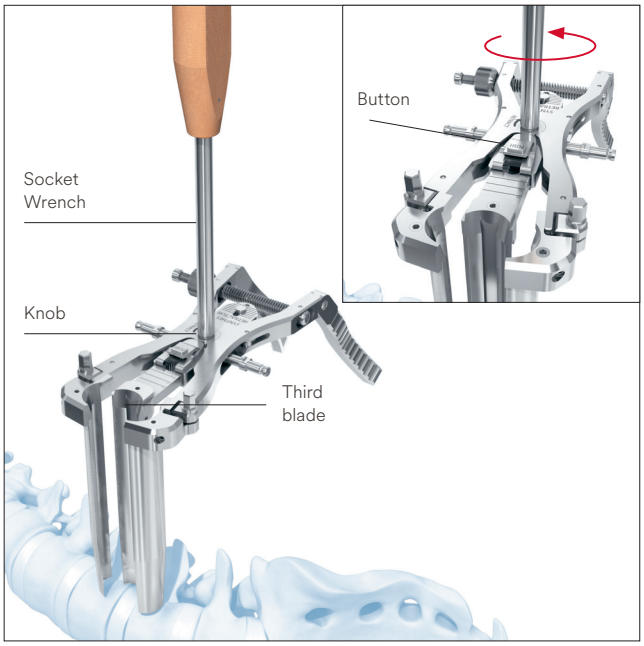
Insert the Light Clip to contribute to additional illumination of the surgical field.

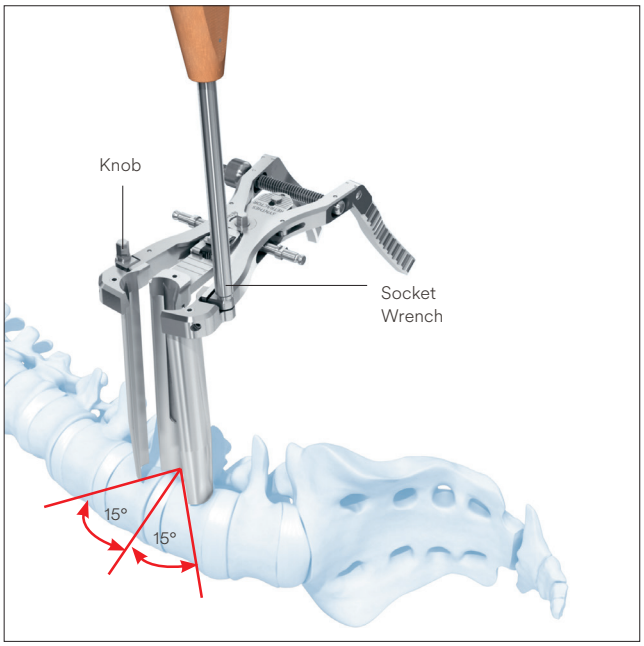
With the blades open and secure, slide the Light Clip down the grooves of the cranial or caudal blades of the Retractor. Insert the Light Clip into the end of the Fiber Optic Light Cable and connect to the light source. Turn on the light source.

**▲ Warnings:**

- **If neuromonitoring is used, stimulate the exposed area to check that the surgical field is free of nerve structures.**
- **Do not stimulate against the Retractor.**

For further retraction, the cranial and caudal blades can independently provide up to 15° of cranial and caudal angulation. Use the Socket Wrench on either the cranial or caudal knob. Turn counterclockwise to release, or clockwise to tighten into the desired position.



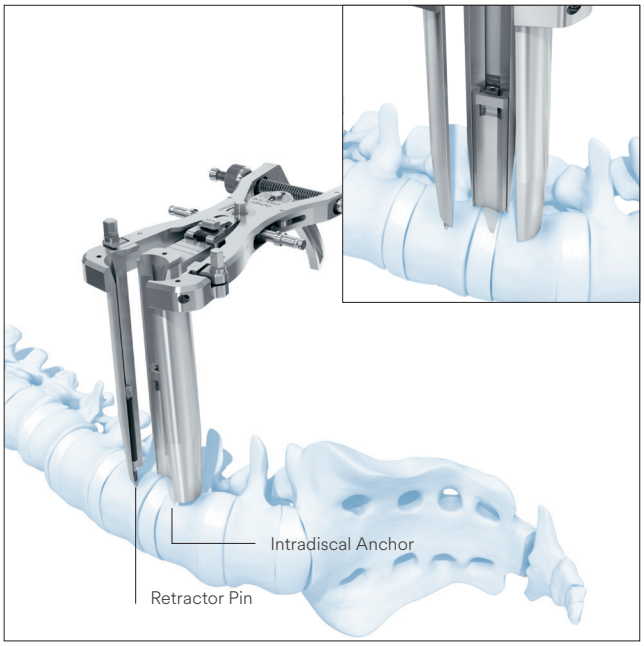
For increased Retractor stability, attach the Intradiscal Anchor to the third blade by screwing the Anchor onto the Retractor extension driver (03.809.923). Slide the Anchor down the grooves of the third blade. Unscrew the driver from the Anchor.

For additional Retractor stability, attach the Retractor Pin to the Screwdriver (03.820.101). Slide the pin down the grooves of either the cranial or caudal blade and screw the pin into the vertebral body.

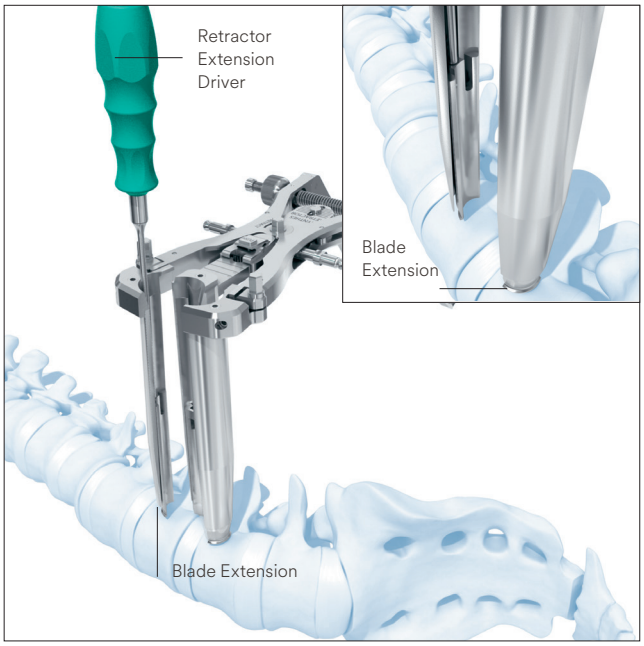
- **Remove the Retractor Pin before any distraction or trialing of disc space.**

**▲ Warning:**

- **Prior to Intradiscal Anchor and/or Retractor Pin placement, both lateral and anterior-posterior fluoroscopy should be performed to confirm that the Retractor is safely placed for such instrument insertion.**



If the psoas or other soft tissue creeps beneath the cranial or caudal blades, the Blade Extensions provide an additional 10 mm extension. Assemble the Blade Extension to the Retractor Extension Driver (03.809.923) and slide the Blade Extension down the grooves of either the cranial or caudal blade, while holding back the psoas muscle.



## 5. Discectomy

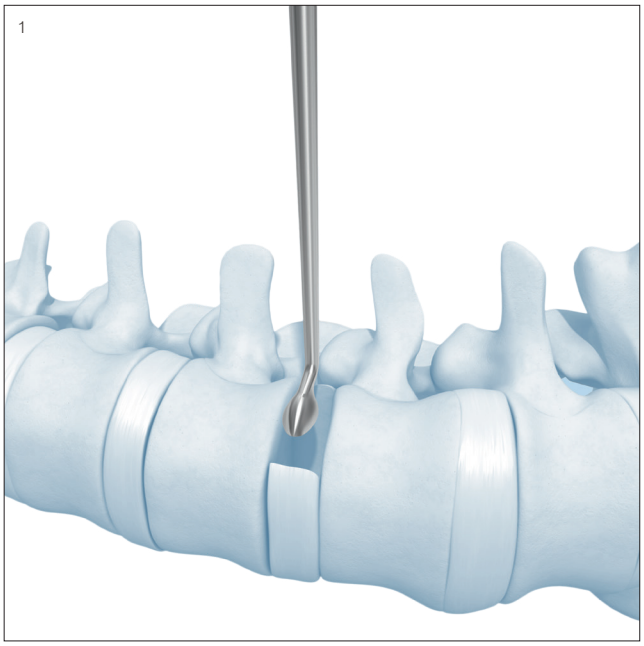
| Instruments | |
|---|---|
| 03.605.001/<br>03.605.002 | Rongeur for Intervertebral Discs, straight, widths 4 and 6 mm, length 330 mm |
| 03.605.004 | Periosteal Elevator, width 20 mm |
| 03.809.819–<br>03.809.827 | ORACLE Shavers, paddle-shaped 9 mm–17 mm heights |
| 03.809.829–<br>03.809.837 | ORACLE Shavers, 9 mm–17 mm heights |
| 03.809.861–<br>03.809.870 | ORACLE Curettes, bayoneted, straight, up biting or forward biting, width 5.5 or 7.5 mm |
| 03.809.872–<br>03.809.873 | ORACLE Ring Curettes, bayoneted, width of tip 8 mm and 6 mm |
| 394.951 | T-Handle with Quick Coupling |

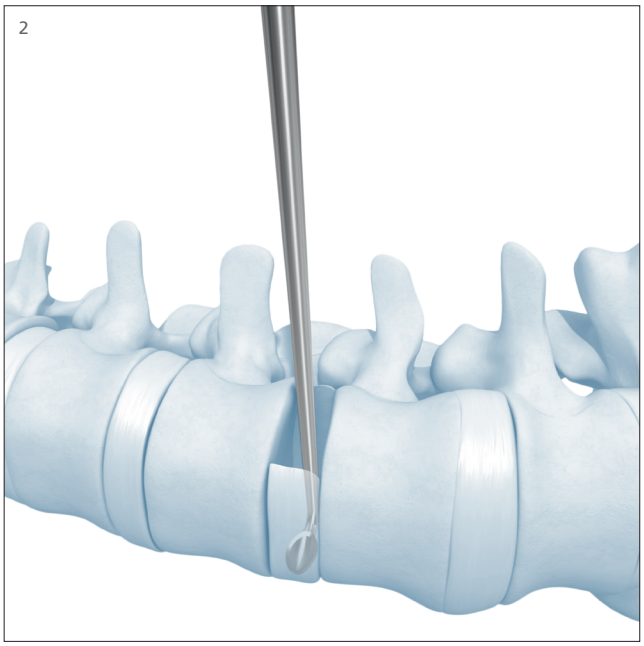
| Optional Instruments | |
|---|---|
| 03.809.875–<br>03.809.877 | ORACLE Spreaders, heights 9 mm–13 mm |

Remove disc material from the intervertebral space using any of the following: Rounded Periosteal Elevator, Cup and Ring Curettes, Rongeurs or Shavers.

The Periosteal Elevator can be used to loosen the disc material from the endplates. Use fluoroscopy for safe placement of the instrument to allow for complete removal of disc material.

Use the forward Biting Cup Curettes to push disc material (1) and the 90° Up-Biting Curettes to collect disc material from the disc space (2). The Cup Curettes are available in two cup sizes, 5.5 mm denoted by the white band, and 7.5 mm denoted by the green band.



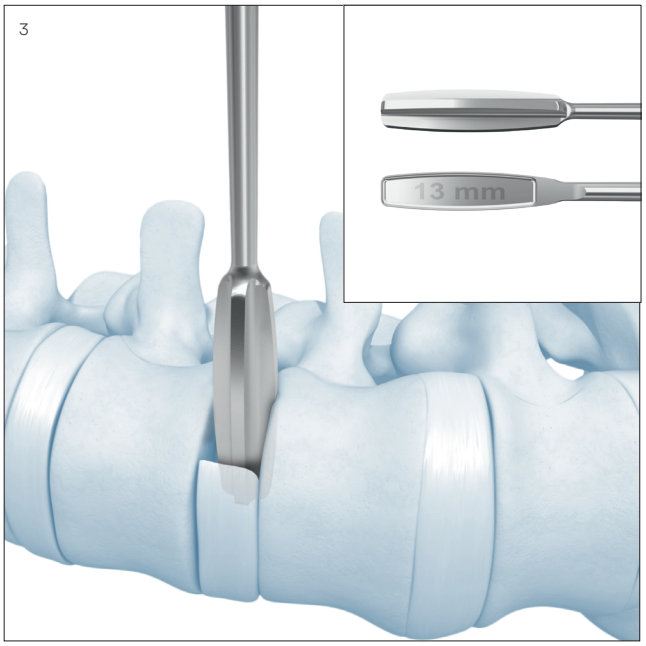
The Shavers can be used initially to ream out disc material or for final removal of the disc material and cartilaginous tissue (3).

- **The medial/lateral dimension of the Shavers is 48 mm (3: inset). The height is undersized by 1 mm compared to the implant height to allow for a tight fit for final implant insertion.**

After the discectomy is performed, break through the contralateral part of the annulus with the Periosteal Elevator. Use A/P fluoroscopy to determine that the contralateral annulus has been perforated.

**▲ Warning:**

- **Excessive tissue debridement and the removal of dense bone may weaken the endplate and therefore impair the seating of the implant, potentially resulting in subsidence.**

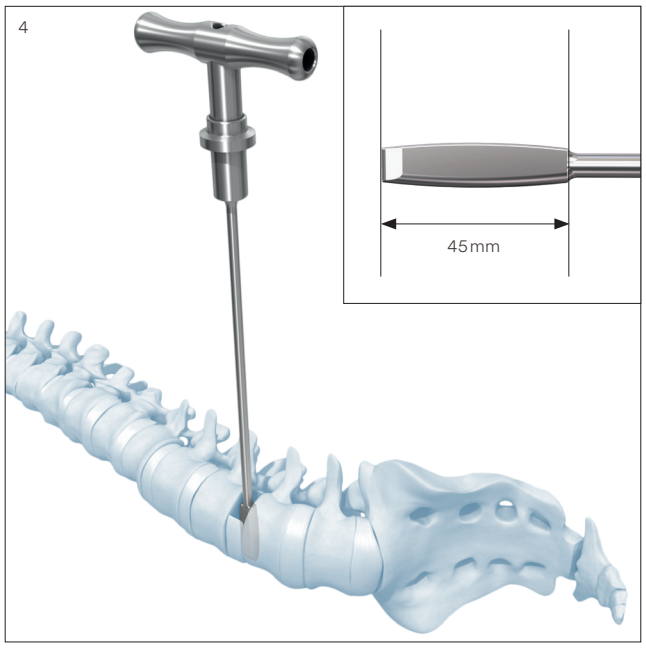


If the disc is severely collapsed, use the Spreaders to help distract and recreate the disc space, which may allow restoration of lordosis and open the neuroforamina(4).

- The medial/lateral dimension of the Spreaders is 45 mm (4: inset).

**▲ Warnings:**

- In order to reduce the risk of damaging vital structures, it is recommended to keep as much of the anterior and posterior annulus intact as possible.
- Excessive tissue debridement and the removal of dense bone may weaken the endplate and therefore impair the seating of the ORACLE implant, potentially resulting in subsidence.
- The anterior and posterior longitudinal ligaments (ALL and PLL) must stay intact in all cases.
- Avoid over distraction of the segment and prevent injury of the ligamentous, neural structures and/or vertebral endplates.
- Turn the Spreader clockwise by a quarter turn to distract the segment. Turn the spreader counterclockwise for removal. Turning the Spreader in the wrong direction may cause damage to the bony structures.



## 6. Prepare Endplates

**Instrument**

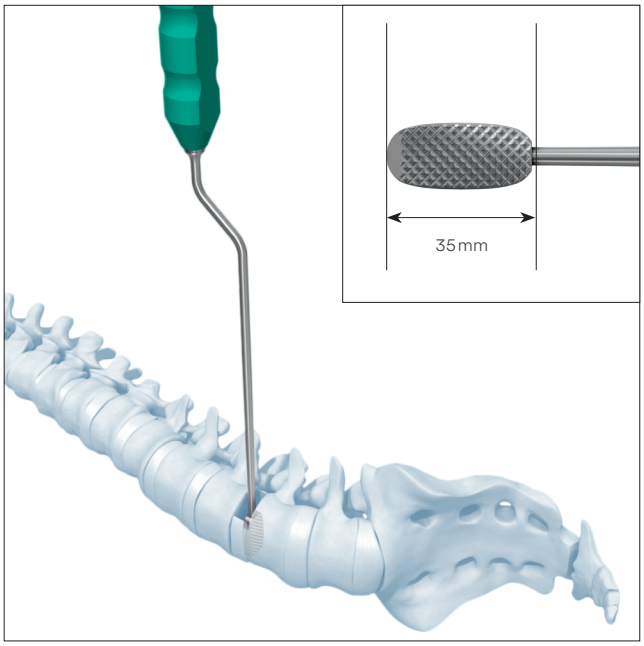
03.809.849 ORACLE Rasp

When the discectomy is complete, use the ORACLE Rasp to remove the superficial cartilaginous layers of the endplates and to expose the bleeding bone.

The medial/lateral dimension of the ORACLE Rasp is 35 mm. The height is 8 mm.

**▲ Warning:**

- **Excessive tissue debridement and the removal of dense bone may weaken the endplate and therefore impair the seating of the ORACLE implant, potentially resulting in subsidence.**

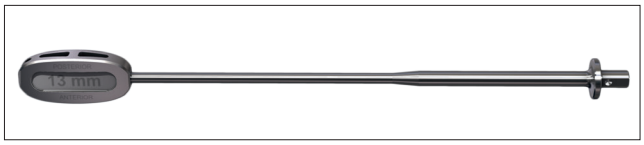


## 7a. Insert Trial Implant

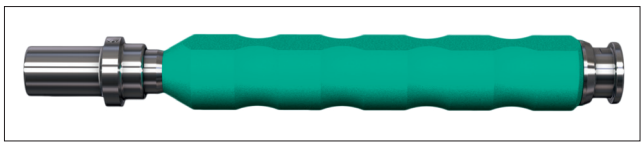
| Instruments | |
|---|---|
| 03.809.229–<br>03.809.237 | ORACLE Trial Implants, 0° angle, heights 9–17 mm |
| 03.809.629–<br>03.809.237 | ORACLE Trial Implants, 8° angle, heights 9–17 mm |
| 03.809.930 | Handle with Quick Coupling |

Connect an appropriately sized Trial Implant to the Handle. Insert the Trial Implant into the disc space, ensuring that the orientation of the Trial Implant is correct. Each lordotic Trial Implant is etched with anterior and posterior markings. Controlled and light hammering on the Trial Implant handle may be required to advance the Trial Implant into the intervertebral disc space.

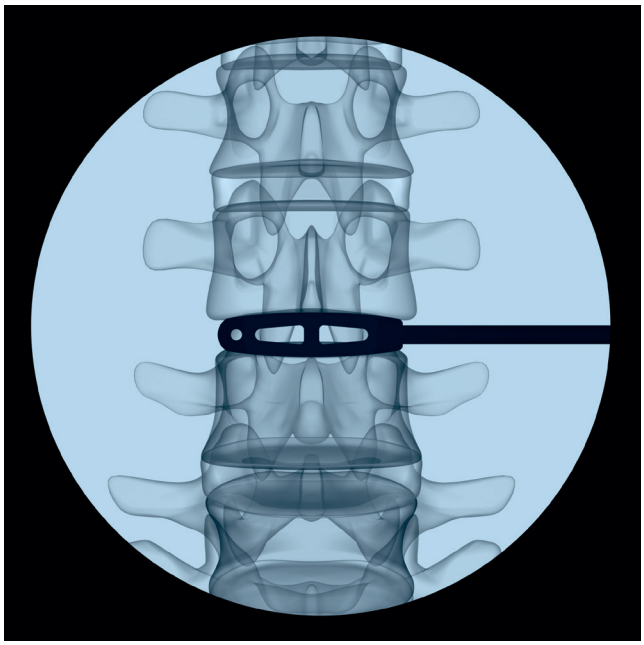
Use fluoroscopy to confirm the fit of the Trial Implant. Each Trial Implant has a center opening that can be visualized in an anterior/posterior fluoroscopic view. The bridge dividing the center opening should align with the spinous processes or be equidistant from the pedicles on an anterior/posterior fluoroscopic view. If the Trial Implant appears too small or too tight, try the next larger or smaller size height until the most secure fit is achieved.



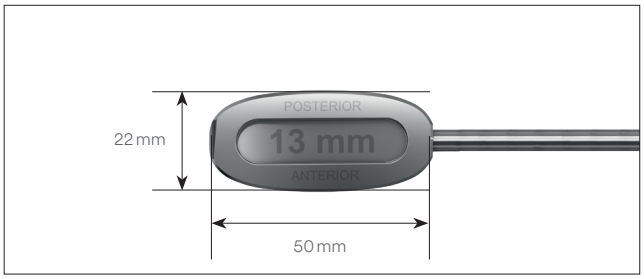

ORACLE Trial Implant



Handle with Quick Coupling



- **The anterior/posterior dimension of the Trial Implants is 22 mm in order to correspond with the implant.**
- **The Trial Implants' medial/lateral dimension is 50 mm.**




Use fluoroscopy to determine the appropriate medial/lateral dimension of the implant for the patient. Take a lateral fluoroscopic image to determine the anterior and posterior position of the Trial Implant. The Trial Implant and ultimately the implant, should sit within the anterior 2/3 of the intervertebral disc space. The height of the Trial Implants are undersized by 1 mm compared to the implant height to allow for a tight fit for final implant insertion.

## 7b. Remove Trial Implant

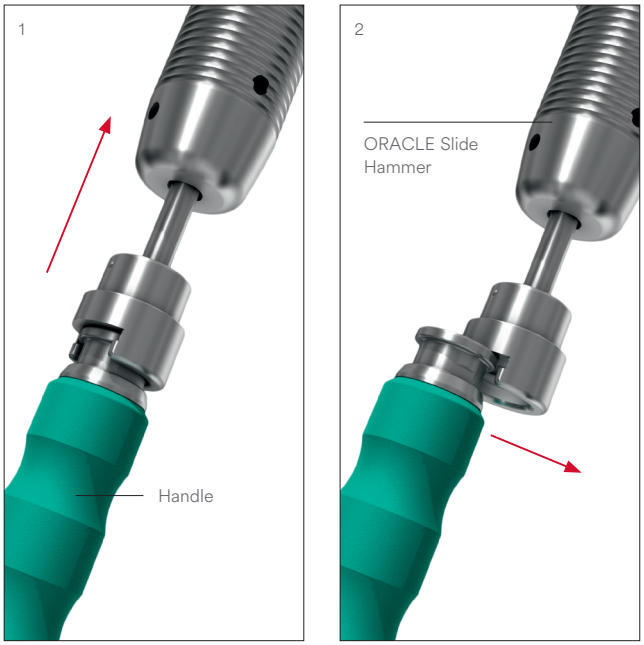
**Instrument**

03.809.972 ORACLE Slide Hammer

Slide the ORACLE Slide Hammer onto the end of the Handle with Quick Coupling. While holding the Handle with one hand, apply an upward force to the Slide Hammer with the other hand (1). Repeat this process until the Trial Implant is removed.

Remove the ORACLE Slide Hammer from the Handle by pushing on the end of the slide hammer (2).

- **Hold down the Retractor while removing the Trial Spacer.**



## 8. Insert Implant

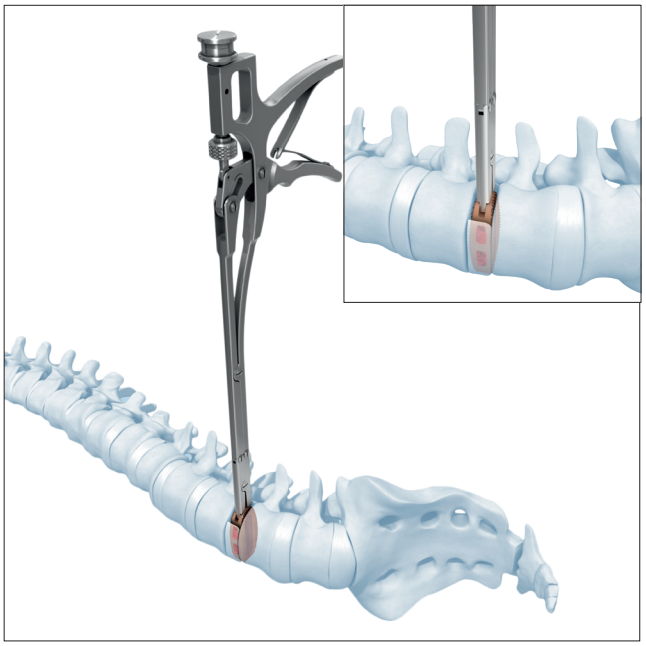
### A. Insertion with implant holder

| Instruments | |
|---|---|
| 03.809.874 | Implant Holder for ORACLE Cage |
| 03.809.881 | ORACLE Impactor |

Select an ORACLE implant that corresponds to the height measured using the Trial Implant in the previous steps.

Attach the jaws of the Holder to the instrument slot of the implant and tighten the speednut. Ensure that the implant is held flush against the neck of the implant holder and securely in the jaws of the Holder.

After being fixed to the Implant Holder, the interior of the implant can be packed with bone graft material. Introduce the implant into the intervertebral disc space, ensuring that the orientation of the implant is correct.



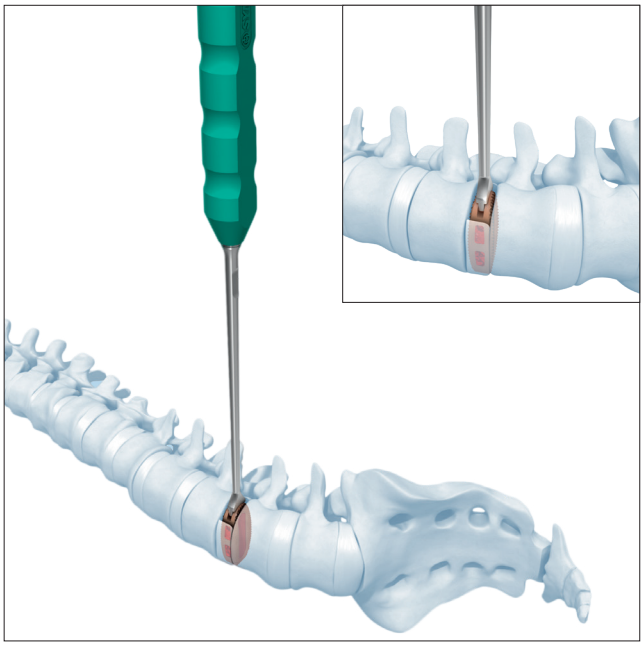
- Remove the Implant Holder and use the Impactor to seat the implant in its final position.

- Use fluoroscopy to determine the position of the implant. On a patient anterior/posterior fluoroscopic image, the two anterior/posterior radiopaque pins of the implant should appear as one marker. The midline pins should line up with the midportion of the spinous process and the lateral pins should be equidistant from the lateral edges of the vertebral bodies.

  - **The medial/lateral marker pins of the implant are located approximately 4 mm from the edges of the implant.**

- With a patient medial/lateral fluoroscopic image, the medial/lateral radiopaque pins of the implant should appear as one marker.

  - **The anterior/posterior marker pins of the implant are located approximately 2 mm from the edges of the implant.**



### B. Insertion with Lateral Quick Inserter Distractor (SQUID)

**Optional instrument**

| | |
|---|---|
| 03.809.921 | ORACLE Lateral Quick Inserter Distractor (SQUID) |

Select an ORACLE implant that corresponds to the height measured using the Trial Implant in the previous steps.

If using the ORACLE Lateral Quick Inserter Distractor, turn the T-handle counterclockwise until the pusher stops. When the thread is completely turned, place the instrument flat on the table to load the implant.

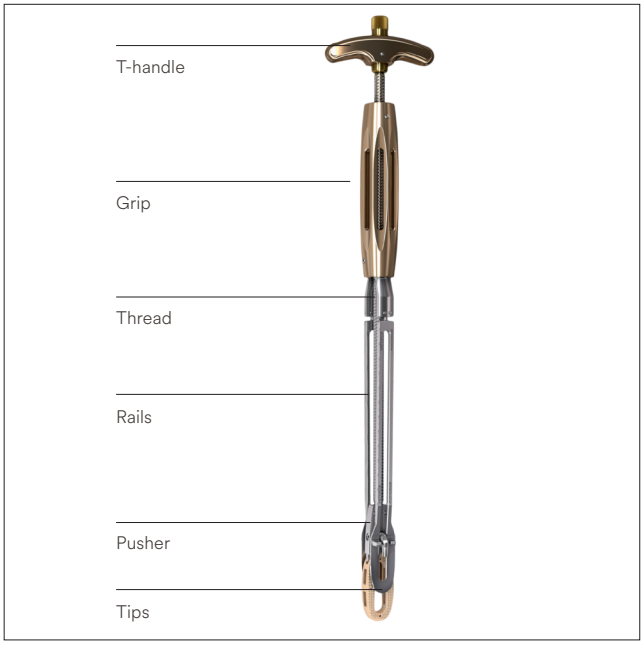
Pack the interior of the implant with bone graft material. Place the implant into the rails, ensuring the implant is seated into the pusher.

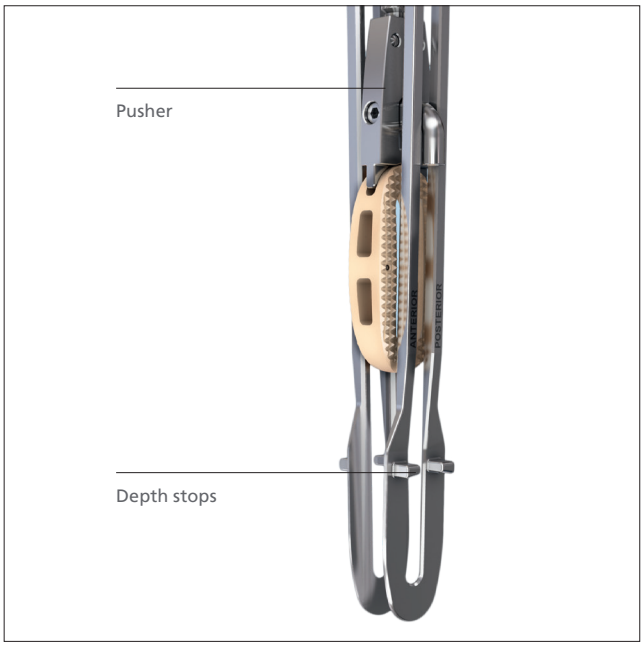
- **Anterior/Posterior etchings on the rails help with orientation when loading lordotic implants.**

While holding the implant against the pusher, turn the T-handle clockwise until the implant is engaged by both rails. Maintain compression on the rails to retain the implant.

- **Ensure that the implant is centered and follows the rails between the implant teeth.**

While maintaining compression on the rails, place the tips of the instrument into the disc space so the depth stops touch the lateral rim of the vertebral bodies. To ensure proper insertion of the implant, take an anterior/posterior fluoroscopic image to determine that the inserter is perpendicularly oriented in the intervertebral space and that the depth stops are touching the lateral rim of the vertebral bodies. The tips of the instrument are 35 mm in depth from the depth stops, 20 mm in width, and 1 mm thick.



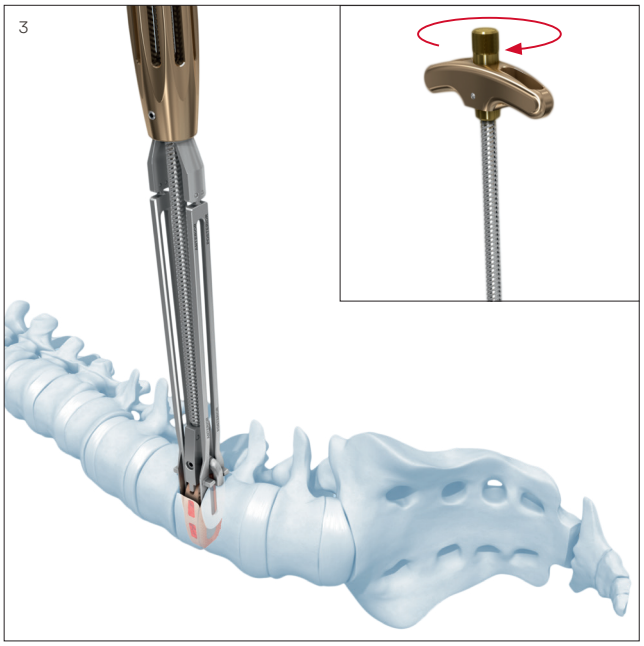



While holding the grip steady with one hand, turn the T-handle clockwise to advance the implant down the rails into the disc space (3). Using fluoroscopic images, verify the implant's progression and the location of the depth stops on the vertebral bodies.

Continue turning the T-handle until it bottoms out on the grip. The Inserter fully ejects and releases the implant.

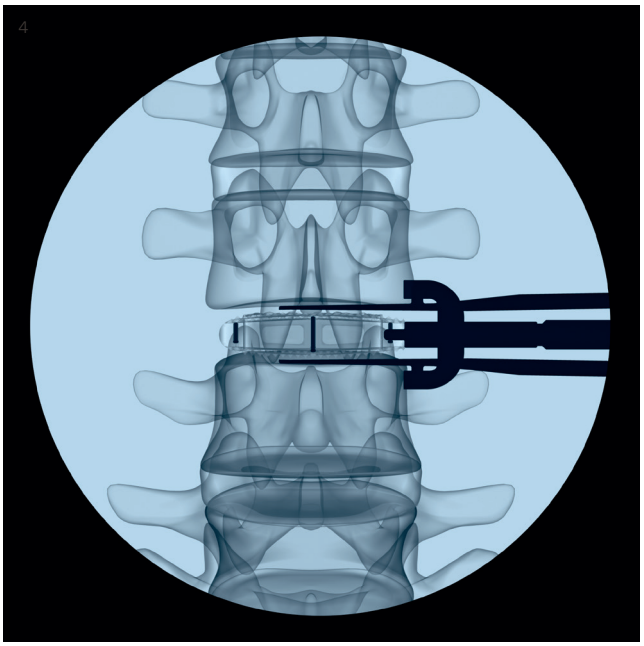
**▲ Precaution:**

- **Do not impact on the ORACLE Lateral Quick Inserter Distractor. The instrument is designed to leave the implant 1 mm proud to the proximal aspect of the vertebral bodies. Depending on surgeon preference of final implant position, the surgeon may choose to use the ORACLE Impactor to seat the implant in its desired position (i.e., flush or recessed).**



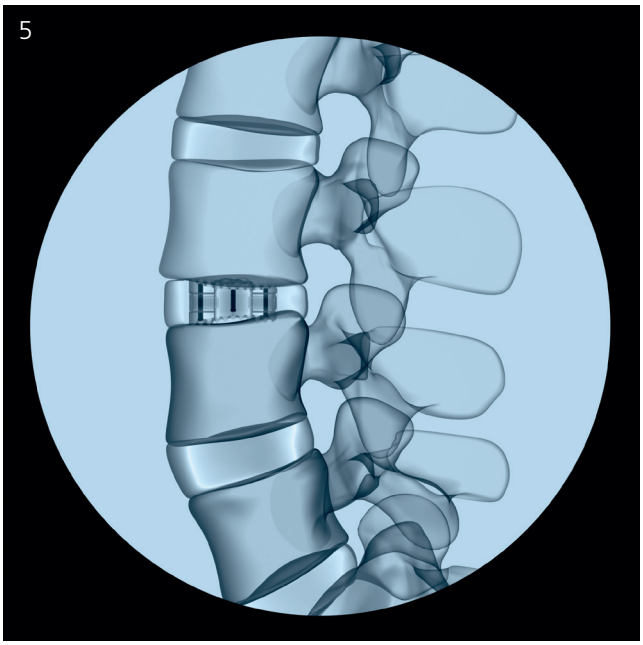

Use fluoroscopy to determine the position of the implant. On an anterior/posterior fluoroscopic image, the two anterior/posterior radiopaque pins of the implant should appear as one marker. These pins should line up with the midportion of the spinous process or the lateral should be equidistant from the lateral edges of the vertebral bodies (4).

- **The medial/lateral marker pins of the implant are located approximately 4 mm from the edges of the implant.**



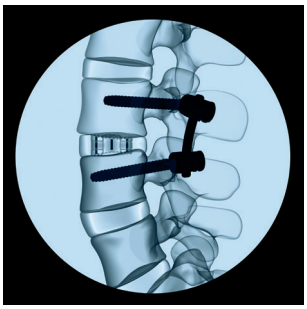
On a patient lateral fluoroscopic image, the medial/lateral radiopaque pins of the implant should appear as one marker. The most anterior, middle radiopaque marker should be countersunk from the anterior edge of the vertebral bodies (5).

- **The anterior/posterior marker pins of the implant are located approximately 2 mm from the edges of the implant.**

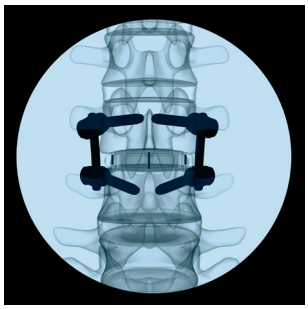

5

## 9. Supplemental Fixation

The ORACLE Cage is intended to be used with supplemental fixation.



Lateral view of one-level ORACLE cage with supplemental fixation.



A/P view of one-level ORACLE cage with supplemental fixation.

# Implant Removal

**ORACLE Implant Removal**

The ORACLE cage Implant is intended for permanent implantation and is not intended for removal.
Any decision to remove the device must be made by the surgeon and the patient taking into consideration the patient's general medical condition and the potential risk to the patient of a second surgical procedure.

**Instrument**

03.809.940 ORACLE Implant Remover

**Optional Instrument**

03.809.972 ORACLE Slide Hammer

If an ORACLE cage implant must be removed, the following technique is recommended:

- Attach the ORACLE Implant Remover to the implant
- Remove the implant

**Optional:**

Controlled and light hammering on the ORACLE Implant Remover may be required to remove the implant out of the intervertebral disc space with the ORACLE Slide Hammer:

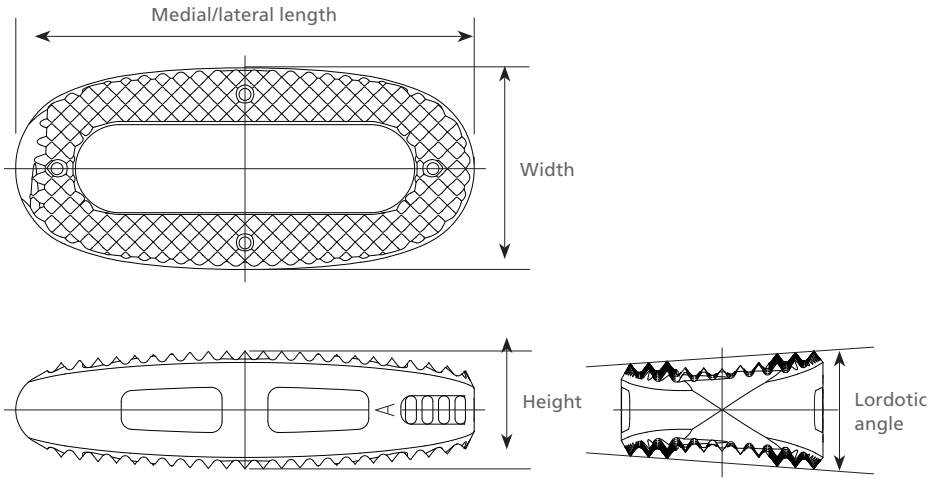
- Slide the ORACLE Slide Hammer onto the end of the ORACLE Implant Remover with quick coupling.
- While holding the ORACLE Implant Remover with one hand, apply an upward force to the ORACLE Slide Hammer with the other hand. Repeat this process until the implant is removed.

**▲ Warning:**

- **The implant may be difficult to remove due to the surface roughness and the position of the cage. If the implant has been inserted past the epiphyseal ring, it may be more difficult to remove and additional distraction may be required.**

### Graft volume

The table below shows the approximate graft volume that ORACLE implants will hold, depending on the dimensions, heights and lordotic angulations. Please note that the width of all cages is 22 mm.




## Filling volumes in cc

| Lordotic angulation | 0° | | | | | 8° | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Medial/lateral length (mm) \ Height (mm) | 9 | 11 | 13 | 15 | 17 | 9 | 11 | 13 | 15 | 17 |
| 40 | 2.0 | 2.7 | 3.4 | 4.0 | 4.6 | 1.8 | 2.5 | 3.2 | 3.8 | 4.5 |
| 45 | 2.4 | 3.4 | 4.1 | 4.9 | 5.7 | 2.2 | 3.0 | 3.8 | 4.6 | 5.5 |
| 50 | 2.8 | 4.0 | 4.9 | 5.8 | 6.7 | 2.5 | 3.5 | 4.5 | 5.5 | 6.5 |
| 55 | 3.3 | 4.5 | 5.6 | 6.7 | 7.7 | 2.9 | 4.1 | 5.1 | 6.1 | 7.2 |

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1. Aebi M, Arlet V, Webb JK (2007). AOSPINE Manual (2 vols.), Stuttgart, New York: Thieme.
2. Aebi M, Thalgott JS, Webb JK (1998): AO ASIF Principles in Spine Surgery. Berlin: Springer.
3. Takatomo Moro, MD, Shin-ichi Kikuchi, MD, PhD, Shin-ichi Konno, MD, PhD and Hiroyuki Yaginuma, MD, PhD: “An Anatomic Study of the Lumbar Plexus with Respect to Retroperitoneal Endoscopic Surgery.”, Spine 2003; Volume 28, Number 5, pp 423-428.

# Indications and Contraindications

Please refer to the corresponding Instructions for Use for specific information on Intended use, Indications, Contraindications, Warnings and Precautions, Potential Adverse Events, Undesirable Side Effects and Residual Risks. Instructions for Use are available at www.e-ifu.com and/or www.depuysynthes.com/ifu."

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