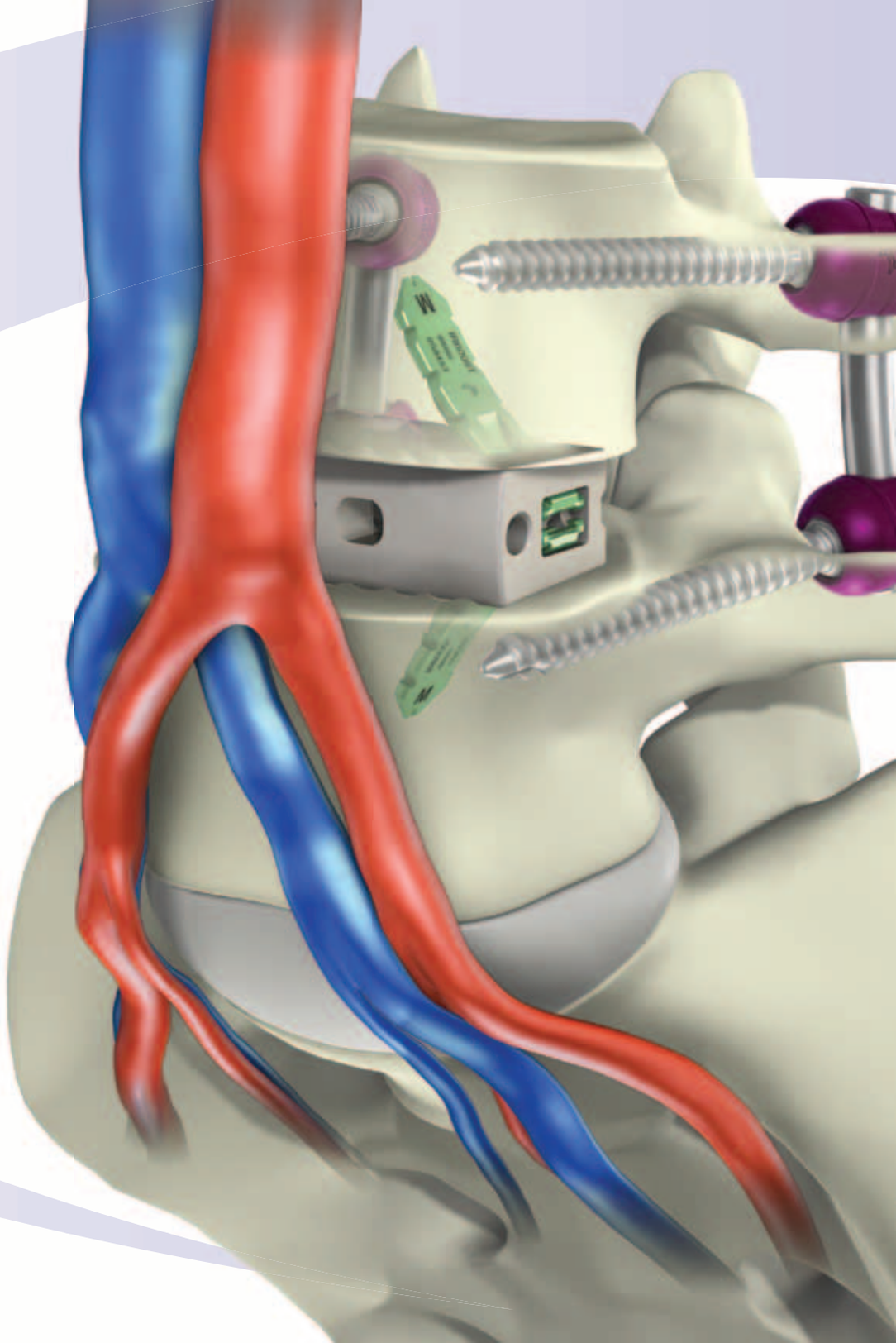
LDR
a passion for innovation

SURGICAL TECHNIQUE

Avenue® L

LATERAL LUMBAR CAGE with

with VerteBRIDGE® PLATING TECHNOLOGY



Avenue® L

LATERAL LUMBAR CAGE

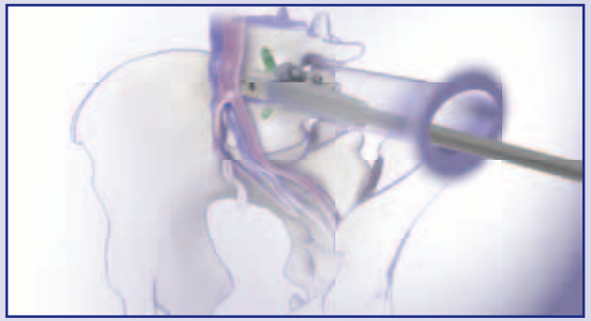


Table of Contents

The surgical technique is for illustrative purposes only. The technique(s) actually employed in each case will always depend upon the medical judgement of the surgeon exercised before and during surgery as to the best mode of treatment for each patient.

Indications (United States)

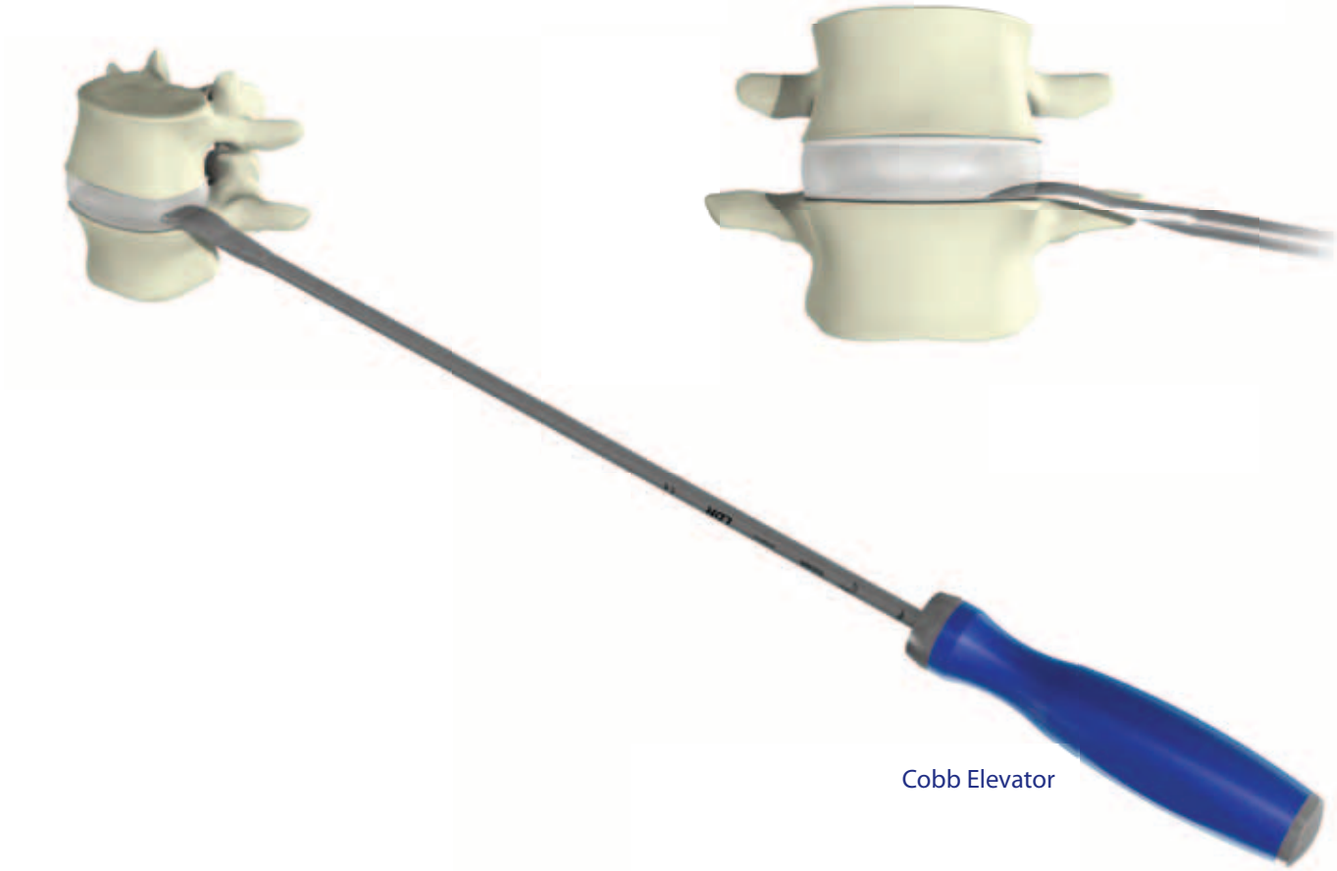
The Avenue® L Interbody Fusion System is indicated for intervertebral body fusion of the lumbar spine, from L2 to S1, in skeletally mature patients who have had six months of non-operative treatment. The device is intended for use at either one level or two contiguous levels for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use with or without integrated fixation and must be used in conjunction with posterior supplemental fixation (e.g., pedicle screws). The device system is intended to be used with autograft to facilitate fusion.

Note: VerteBRIDGE® Plating is the integrated fixation designed specifically for the Avenue L cage. Additional supplemental fixation options must be used with the Avenue L cage (with or without VerteBRIDGE® Plating) which may include posterior pedicle systems or other posterior fusion systems cleared by the FDA.

Step 1 Discectomy and endplate preparation

Once the desired disc space is reached, a Penfield is used to sweep the residual muscle off of the disc space. To begin the discectomy, incise the annulus using a bayoneted knife. The Cobb Elevator is then used to separate the disc from the upper and lower end plates.

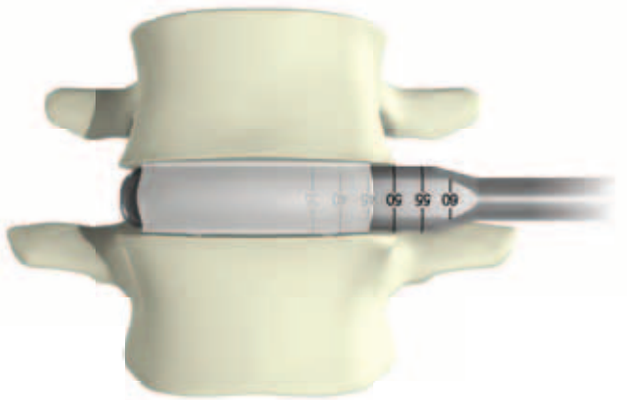
It may be necessary to gently mallet the Cobb Elevator in order to fully release the superior and inferior aspects of the contralateral annulus.

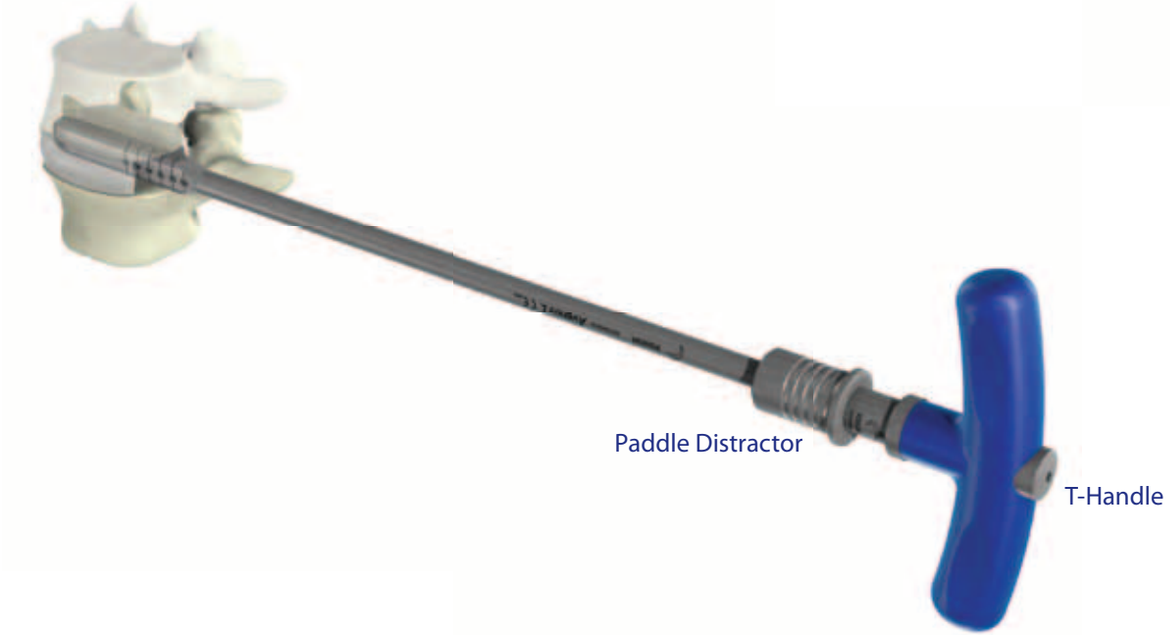


Cobb Elevator

Note: It is not necessary to remove all the annular disc tissue anterio-posteriorly. It is sufficient to remove the space corresponding to the cage. Maintaining the annular layers and the anterior ligament optimizes cage stability and facilitates arthrodesis.

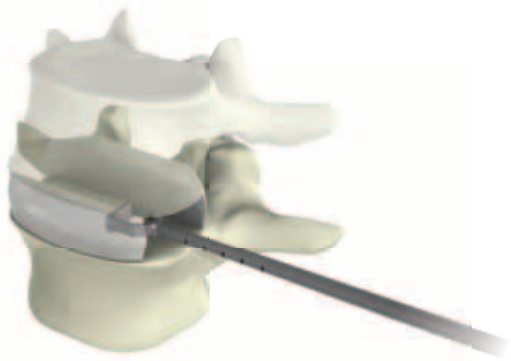
Fully insert the Paddle Distractors, which are provided in incremental heights, and gradually distract the disc space. The final disc height achieved should be consistent with the disc heights of the adjacent levels.

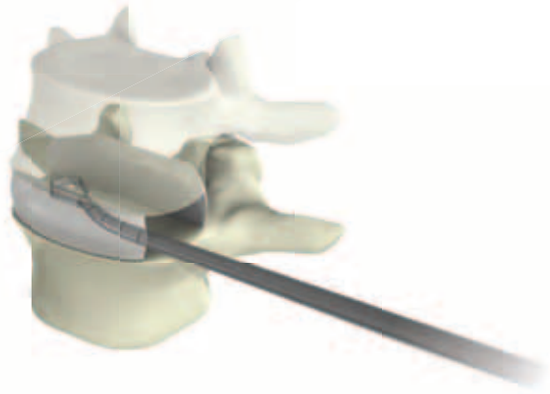




Center the appropriate sized Shaver in the disc space and rotate to continue preparation of the end plates.

Complete the discectomy and end plate preparation using preferred instruments.

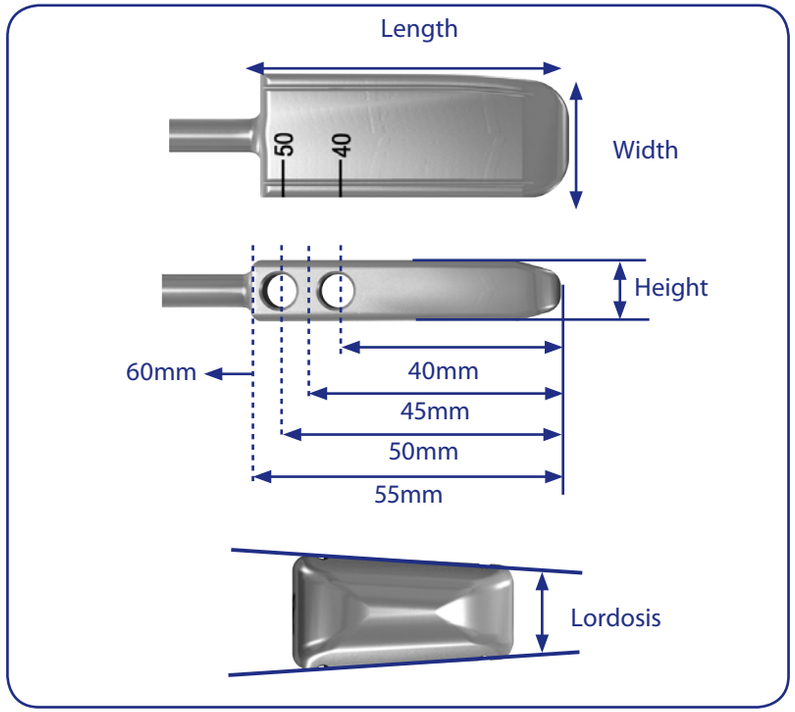


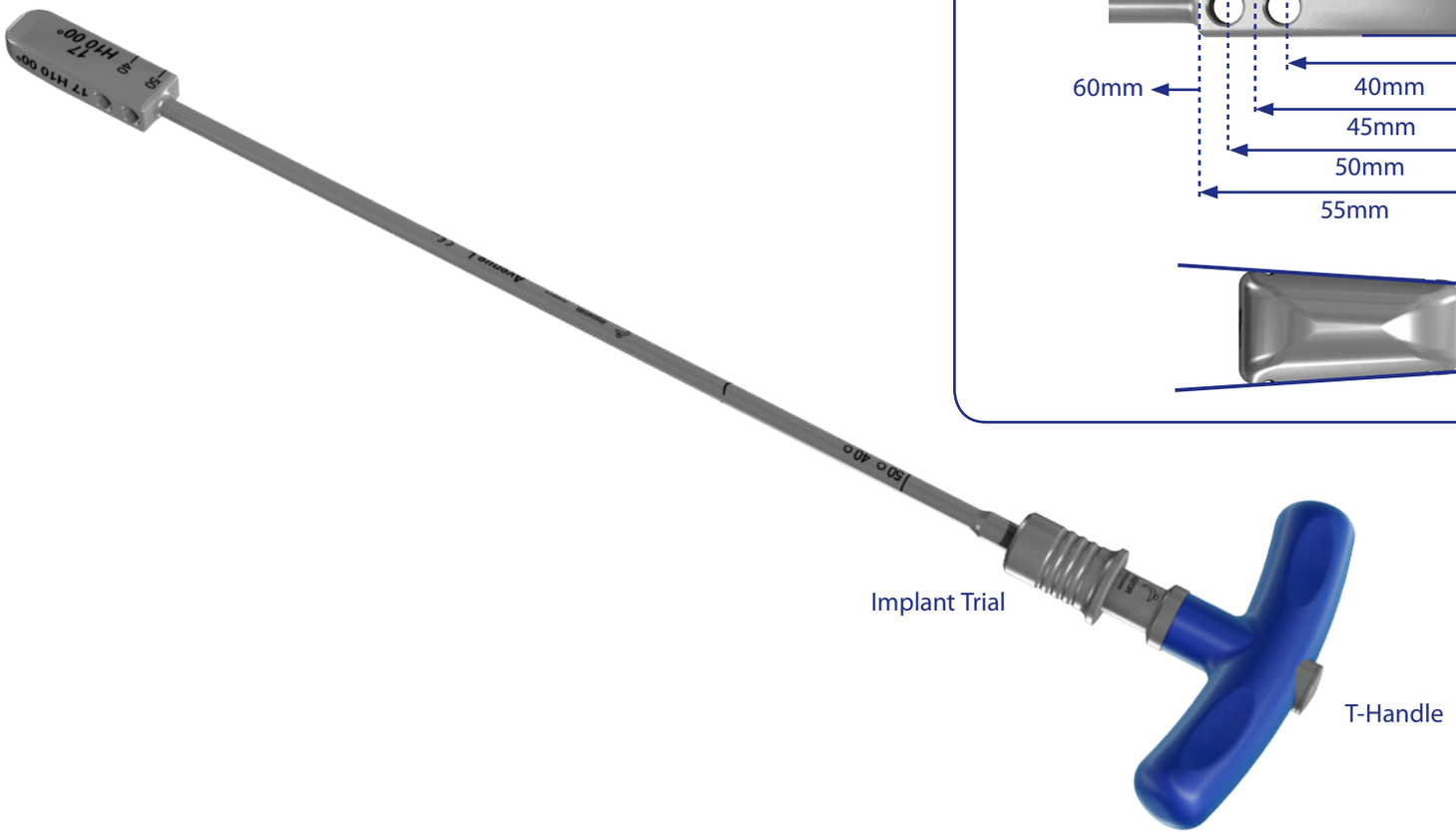


CAUTION: Endplate preparation should result in vascularization between the endplate and bone graft without weakening the cortical layer.

Step 2 Implant Trial selection

Proper implant selection is made using the Implant Trials. They are sized by length, width, height and lordosis in order to accommodate variation in patient anatomy. An implant sizing table is included on Page 9.





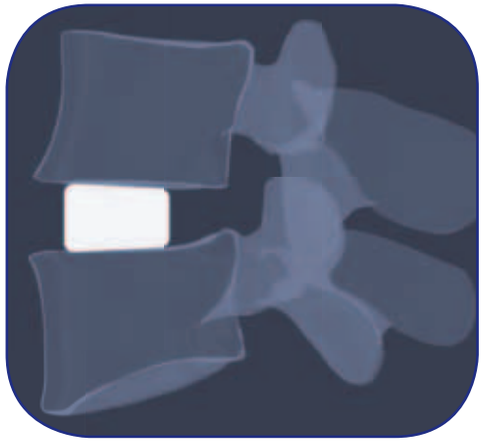
Insert the appropriate Implant Trial in the intervertebral space using the Slotted Mallet.

Comfirm position under fluoroscopy:

- Lateral image: Antero-posterior positioning and position in rotation.
- A/P image: Centering, lateral coverage and position in rotation.

Note: During fluoroscopy, the T-handle can be removed for better visualization.

Note: The through holes in the Implant Trial are used to determine the appropriate implant length.



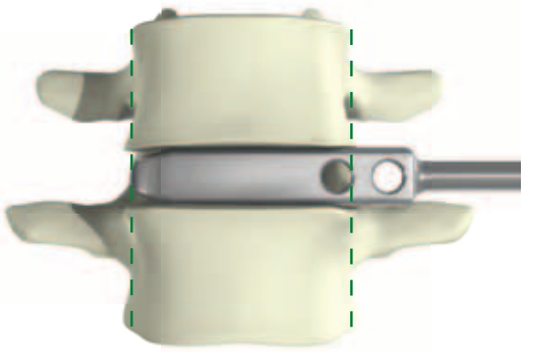
Once the proper size is determined, the Implant Trial is removed from the intervertebral space, and the corresponding cage can be implanted.

Slotted Mallet

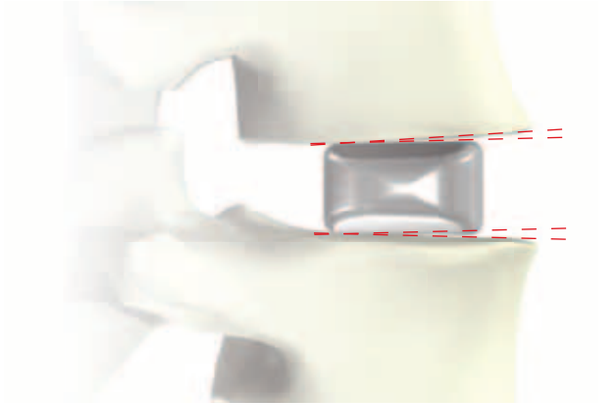
Note: Implant Trial can be removed with the Slotted Mallet by guiding it along the trial shaft.

Choosing the correct Implant Trial is crucial. The antero-posterior and lateral coverage of the Implant Trial on the vertebral endplate must be optimal in order to provide the best possible position and stability of the cage.

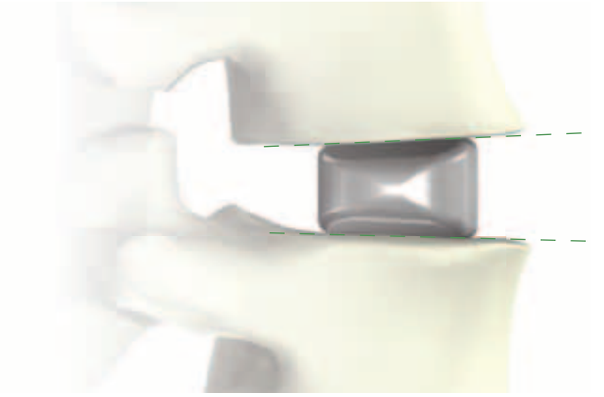
In the A/P view, the Implant Trial must sit on the peripheral ring of the dense cortical bone. The Implant Trial (and resulting cage position) can protrude contralaterally per surgeon preference.



The lordosis as well as the anterior and posterior heights must be chosen to obtain a height similar to adjacent discs, as well as the correct sagittal balance for the patient.



Example: A 0° Implant Trial does not provide proper vertebral plate contact. **INADEQUATE ANTERIOR FIT**



In this example, the 0° Implant Trial has been replaced by a 6° trial: **PROPER ANTERIOR FIT**

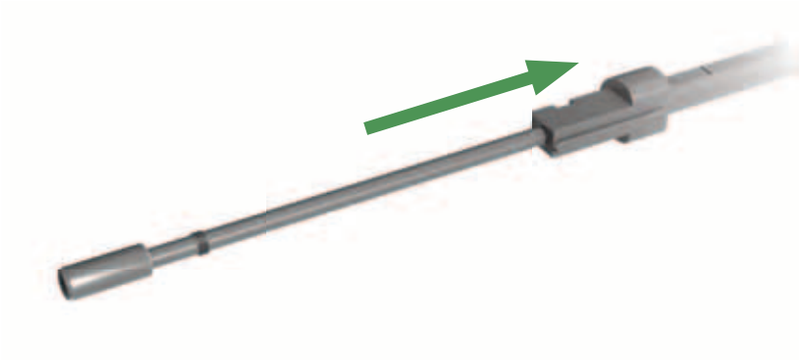
Implant sizing table

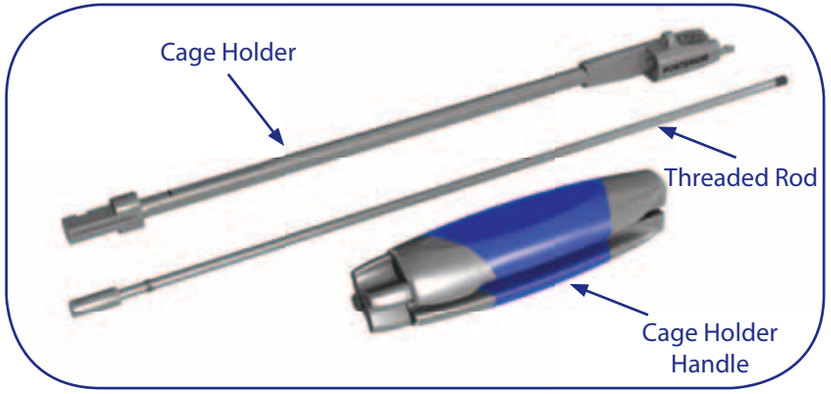
VerteBRIDGE® Plate	Plate Height (mm)				
	H08	H10	H12	H14	H16
Short (IR6001T)	12.0	11.5	10.5	9.5	8.5
Medium (IR6002T)	15.5	14.9	13.9	12.9	11.9
Long (IR6003T)	19.2	18.7	17.7	16.7	15.7

		Reference Number & Graft Volume (cc)									
		0° Lordosis					6° Lordosis				
L	W	H08	H10	H12	H14	H16	H08	H10	H12	H14	H16
40	17	IR6208P (1.7)	IR6210P (2.0)	IR6212P (2.3)	IR6214P (2.7)	IR6216P (3.1)	IR6228P (1.6)	IR6230P (1.9)	IR6232P (2.3)	IR6234P (2.7)	IR6236P (3.1)
	22	IR6808P (2.4)	IR6810P (2.8)	IR6812P (3.4)	IR6814P (3.9)	IR6816P (4.5)	IR6828P (2.3)	IR6830P (2.6)	IR6832P (3.2)	IR6834P (3.8)	IR6836P (4.3)
45	17	IR6308P (2.0)	IR6310P (2.3)	IR6312P (2.8)	IR6314P (3.2)	IR6316P (3.7)	IR6328P (1.9)	IR6330P (2.2)	IR6332P (2.7)	IR6334P (3.2)	IR6336P (3.6)
	22	IR6908P (2.9)	IR6910P (3.4)	IR6912P (4.1)	IR6914P (4.8)	IR6916P (5.4)	IR6928P (2.8)	IR6930P (3.2)	IR6932P (3.9)	IR6934P (4.5)	IR6936P (5.2)
50	17	IR6408P (2.3)	IR6410P (2.6)	IR6412P (3.2)	IR6414P (3.6)	IR6416P (4.1)	IR6428P (2.1)	IR6430P (2.5)	IR6432P (3.0)	IR6434P (3.6)	IR6436P (4.1)
	22	IR7008P (3.4)	IR7010P (3.9)	IR7012P (4.7)	IR7014P (5.5)	IR7016P (6.3)	IR7028P (3.2)	IR7030P (3.7)	IR7032P (4.5)	IR7034P (5.3)	IR7036P (6.0)
55	17	IR6508P (2.5)	IR6510P (2.9)	IR6512P (3.4)	IR6514P (4.0)	IR6516P (4.5)	IR6528P (2.3)	IR6530P (2.8)	IR6532P (3.3)	IR6534P (3.9)	IR6536P (4.4)
	22	IR7108P (3.8)	IR7110P (4.4)	IR7112P (5.3)	IR7114P (6.1)	IR7116P (7.0)	IR7128P (3.6)	IR7130P (4.2)	IR7132P (5.0)	IR7134P (5.9)	IR7136P (6.7)
60	17	IR6608P (2.6)	IR6610P (3.0)	IR6612P (3.6)	IR6614P (4.2)	IR6616P (4.8)	IR6628P (2.5)	IR6630P (2.9)	IR6632P (3.5)	IR6634P (4.1)	IR6636P (4.7)
	22	IR7208P (4.2)	IR7210P (4.8)	IR7212P (5.8)	IR7214P (6.7)	IR7216P (7.7)	IR7228P (4.0)	IR7230P (4.6)	IR7232P (5.5)	IR7234P (6.4)	IR7236P (7.4)

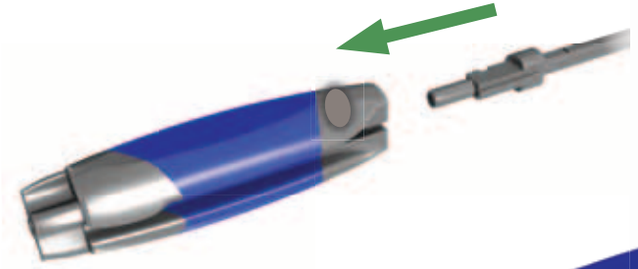
Step 3 Cage Holder assembly and cage loading

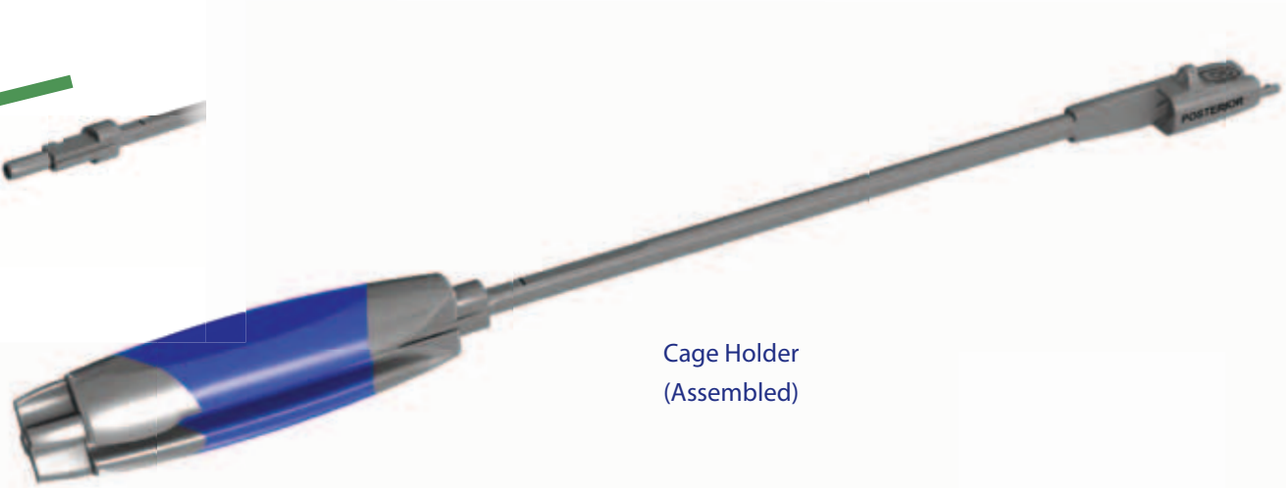
Introduce and screw the threaded rod into the Cage Holder.





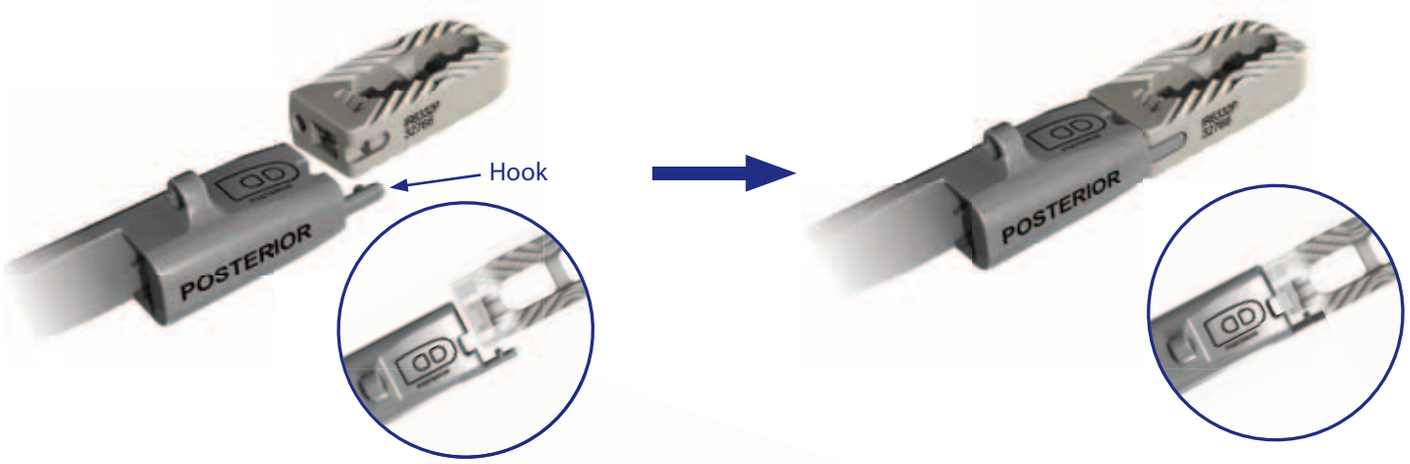
1. Press the button on the Cage Holder Handle
2. Insert the Cage Holder into the Cage Holder Handle
3. Release the Button





Cage Holder
(Assembled)

Hook the Cage Holder in the groove located on the posterior side of the cage.



Screw the slotted knob finger tight to secure the cage onto the Cage Holder.

CAUTION: Do not overtighten, as this may strip the thread in the cage.

Note: Make sure that one of the grooves in the slotted knob aligns with the groove in the Cage Holder handle, so that the Impactor can be introduced.

Step 4 Cage preparation

The graft chamber must be filled with autologous bone.

Place the cage in the Graft Support.

Graft Support

Graft Compactor

Compact the bone graft into the chamber using the Graft Compactor.

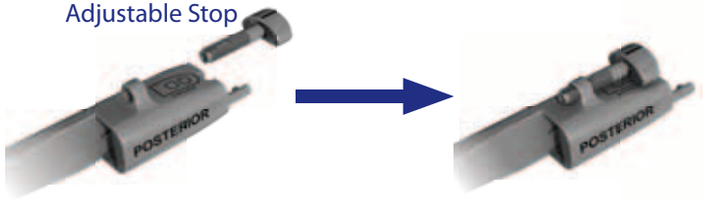
Step 5 Cage insertion

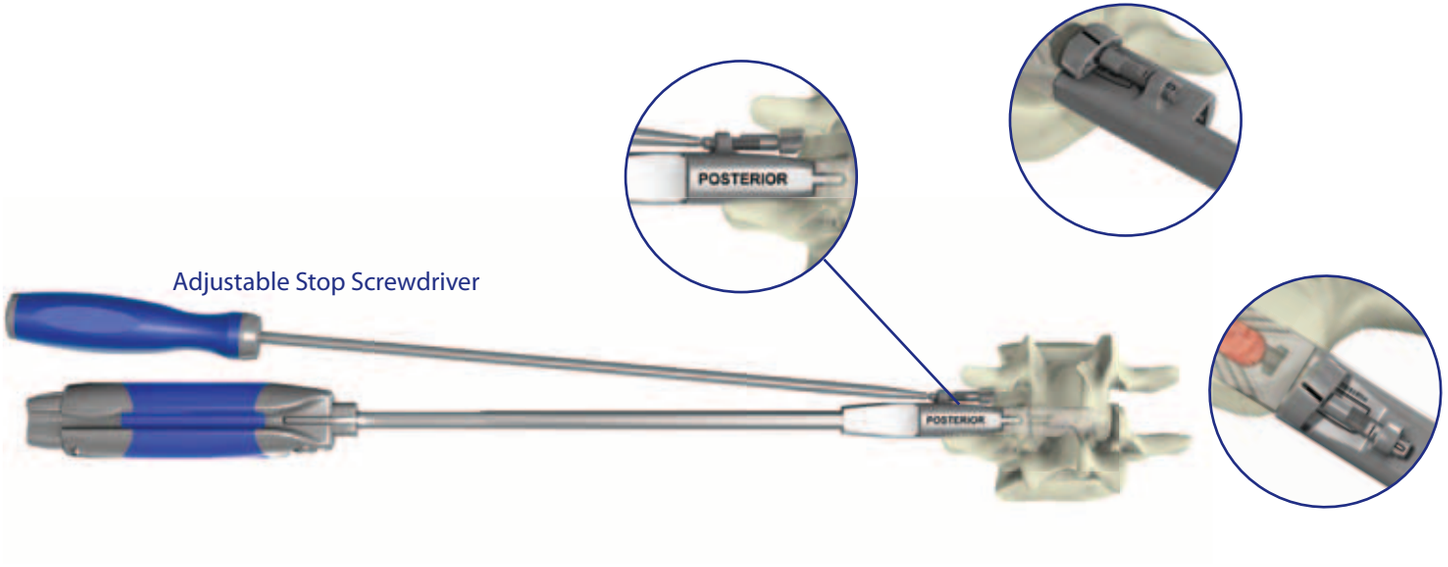
Insert the cage in the intervertebral space by successive impactions on the Cage Holder, along the lateral axis. Note the orientation of the Cage Holder. Its posterior face has been labeled.

The Adjustable Stop can be added to the Cage Holder to control the positioning of the cage during insertion.

The position of the Adjustable Stop can be changed intraopertively with the Adjustable Stop Screwdriver.

Adjustable Stop





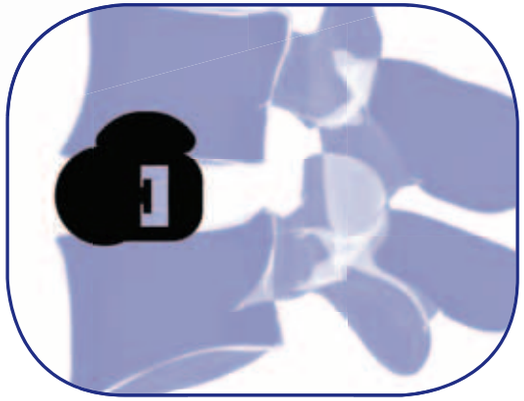
Adjustable Stop Screwdriver

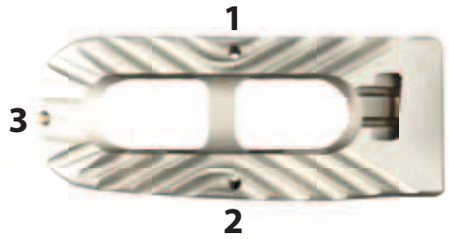
Note: The Adjustable Stop enables a variable positioning of the implant and maintains it during the insertion of the plating.

Note: With the stop set to 0 at the beginning of insertion, the proximal end of the cage will sit approximately 1.25 mm inside the disc space.

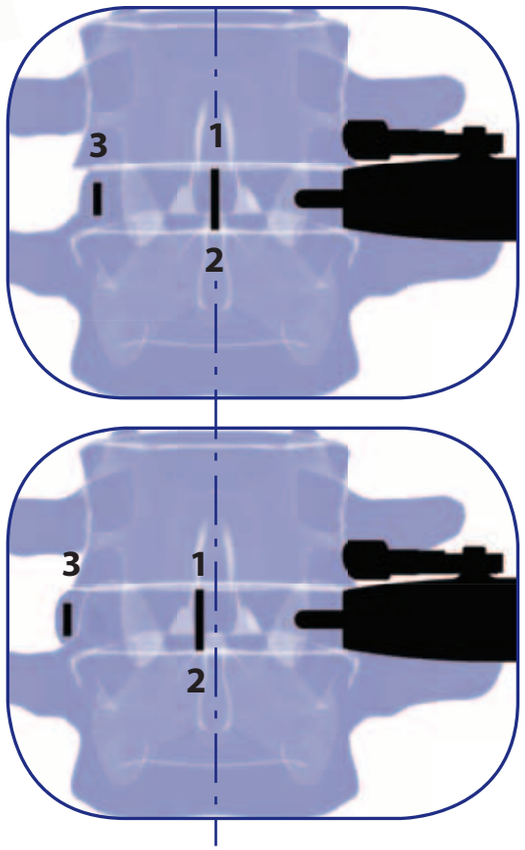
Confirm proper implant placement using fluoroscopy.

- Lateral View: The posterior face of the Cage Holder corresponds to the posterior face of the cage, allowing visualization of the A/P position of the cage.





- A/P View: Central markers 1 and 2 indicate the implant center (their alignment proves the absence of rotation). Lateral marker 3 indicates the lateral edge of the cage. Under fluoroscopy, the edge of the cage inserter will indicate the proximal edge of the cage.



Note: The Modular Handle may be removed to facilitate fluoroscopic imaging.

Note: When placed at the proper depth, the proximal edge of the cage is inset approximately 1.25mm.

Note: If a wider cage is desired to protrude contralaterally to obtain full cortical support, the central markers will be offset from the midline in a true A/P view.

Step 6 Plate insertion

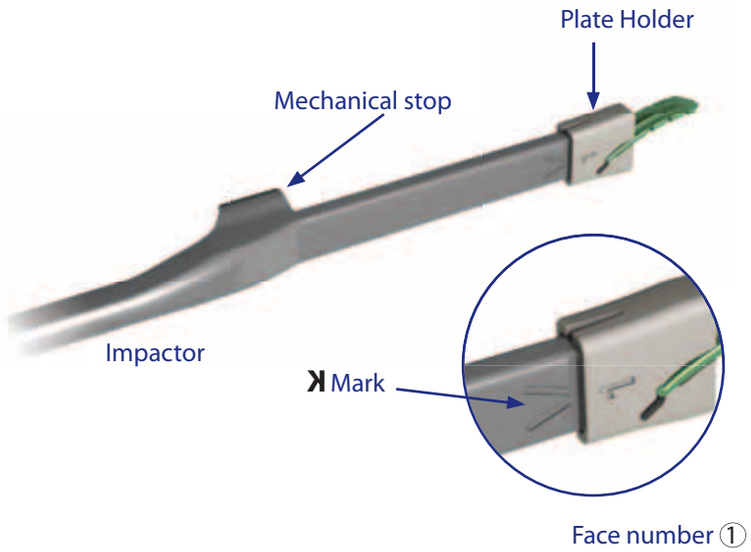
Once the position of the cage is determined, the plating can be inserted. The impaction of the plates is performed sequentially.

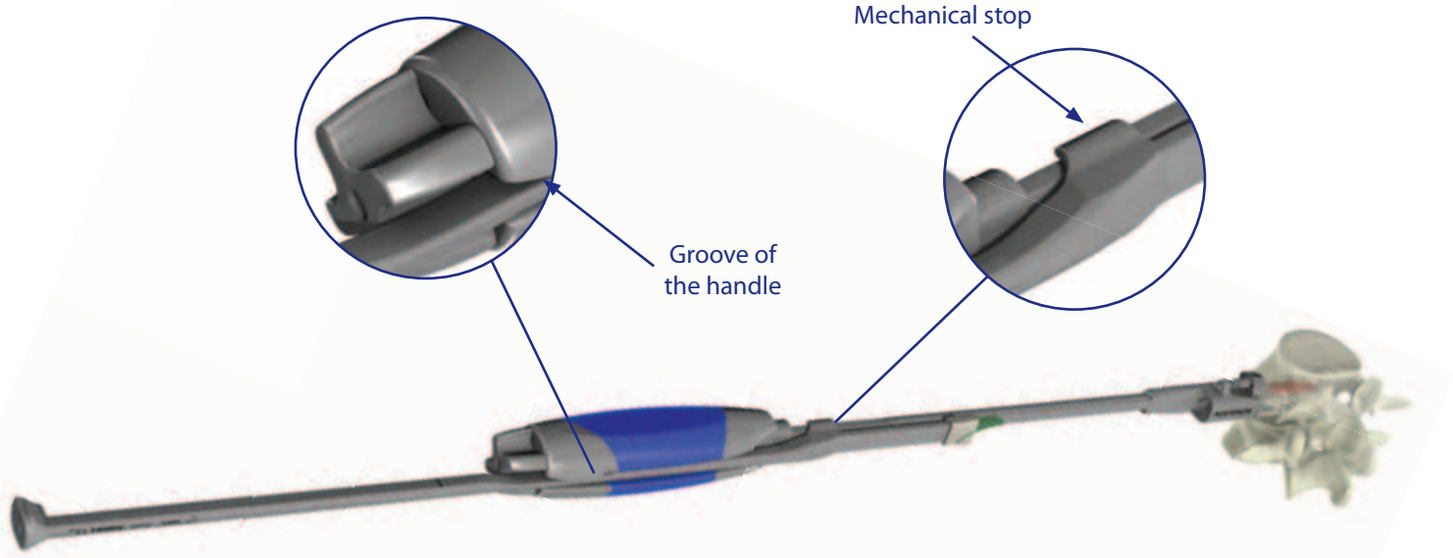
Each plate comes pre-assembled on a radiolucent single-use Plate Holder.

Insert the first Plate Holder on the Impactor up to the ⏭ mark.

Make sure the face marked ① is aligned with the ⏭ mark on the Impactor.

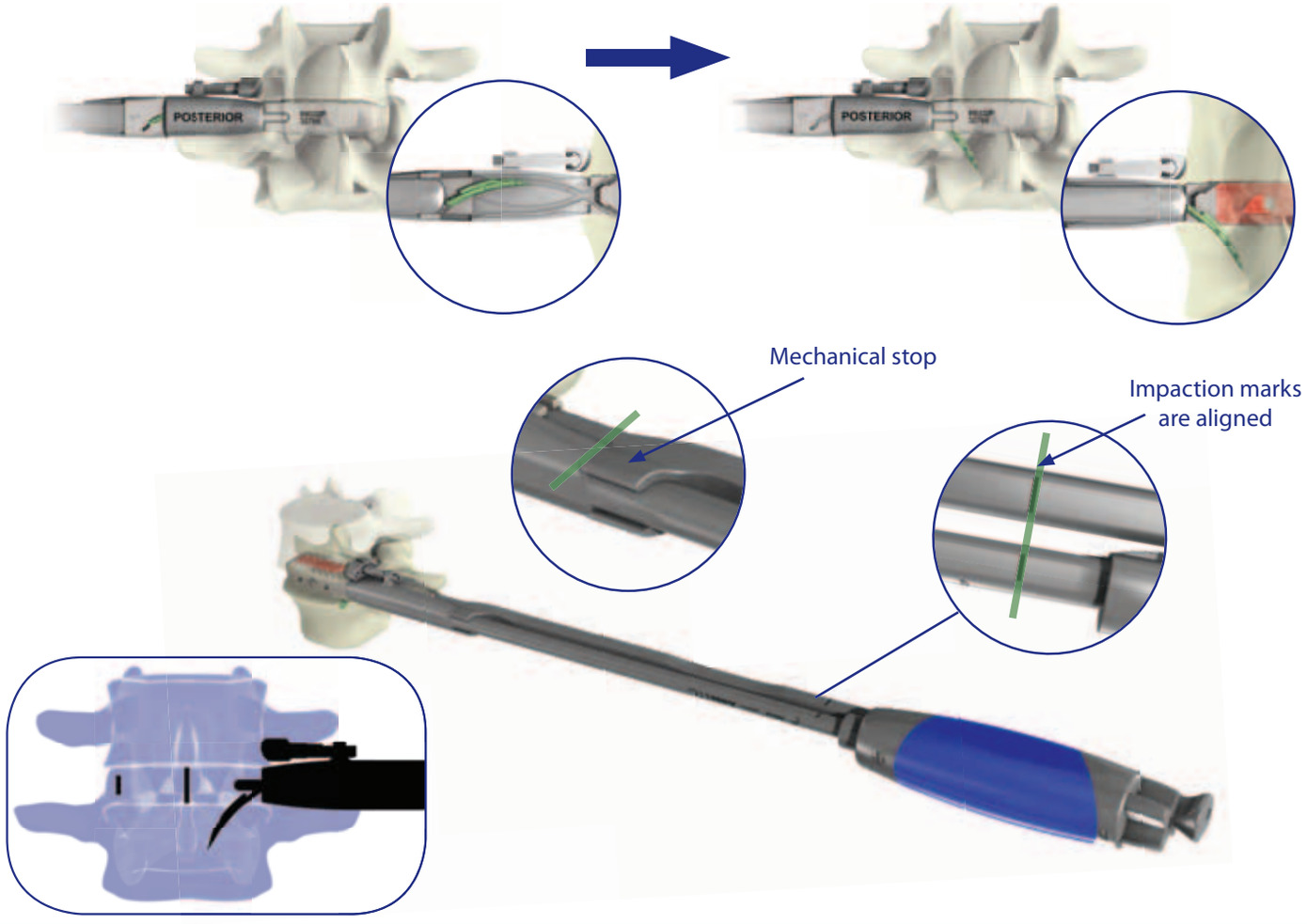
Insert the thinnest part of the Impactor in the groove of the Cage Holder handle. As the two instruments are joined, the mechanical stop guides the Impactor along the Cage Holder.





Using your thumb, press the Impactor until the plate bites into the vertebral body. Confirm plate trajectory with fluoroscopy. When trajectory is confirmed the plate may be fully inserted. Mallet the Impactor until it reaches the mechanical stop and the impaction marks are aligned.

Check for proper placement of the first anchoring plate using fluoroscopy.



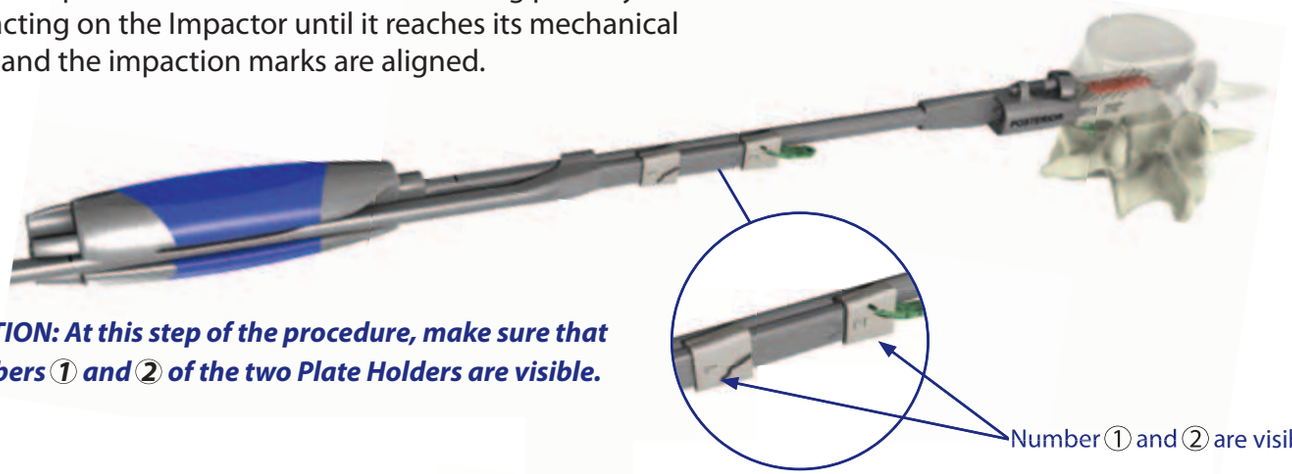
Note: The anchoring plate releases automatically from its holder. The empty plate holder is retained on the Impactor.

Note: When the Impactor is fully seated the impaction marks will be aligned.

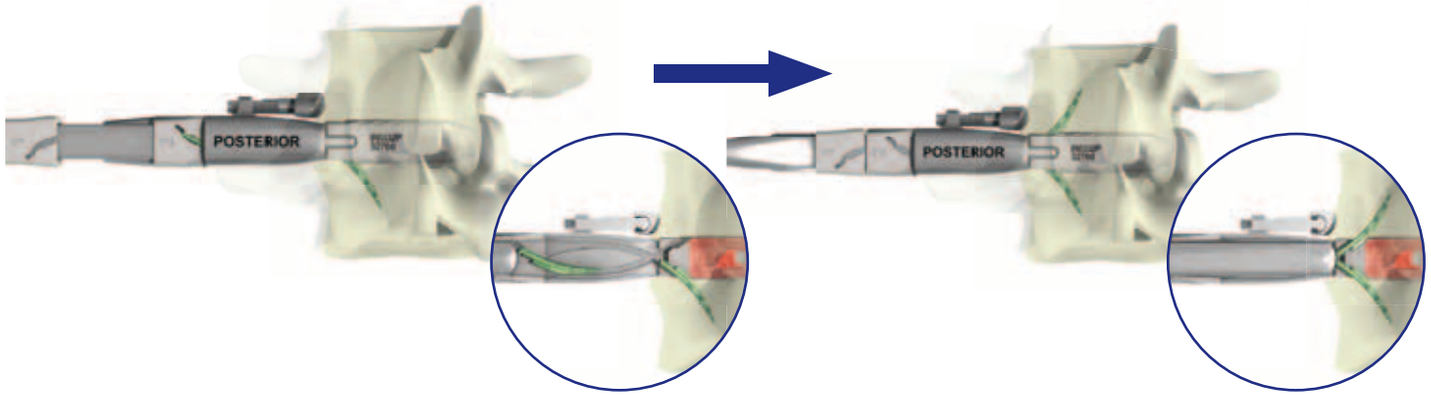
Note: For 2-level implantation, "L" anchoring plates should not be used in the shared vertebra. Before inserting the plates, make sure that the vertebral bodies have sufficient height to avoid contact between the plates of the two implants.

Insert the second anchoring plate holder on the Impactor up to the ⏭ mark.

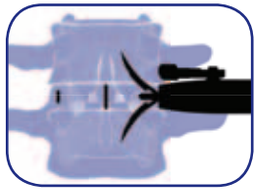
Make sure the face marked ② is aligned with the ⏭ mark on the Impactor. Insert the second anchoring plate by impacting on the Impactor until it reaches its mechanical stop and the impaction marks are aligned.



CAUTION: At this step of the procedure, make sure that numbers ① and ② of the two Plate Holders are visible.



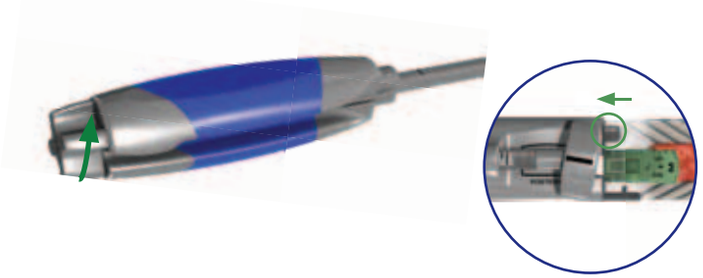
Check for proper placement of the second anchoring plate using fluoroscopy.



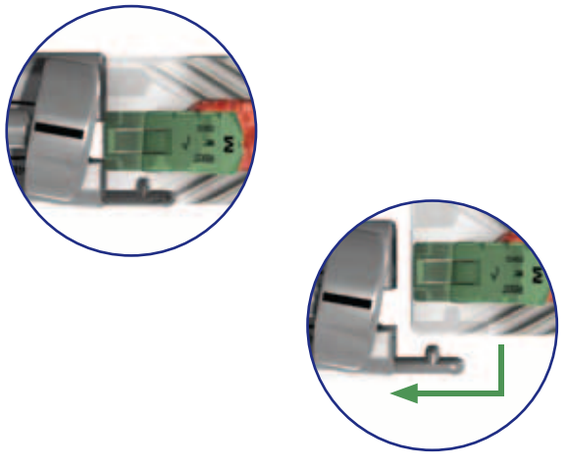
Note: The anchoring plate releases automatically from its Plate Holder. The empty Plate Holder is retained on the Impactor.

Step 7 Final verification and Cage Holder removal

Unscrew the slotted knob to release the threaded shaft from the cage.

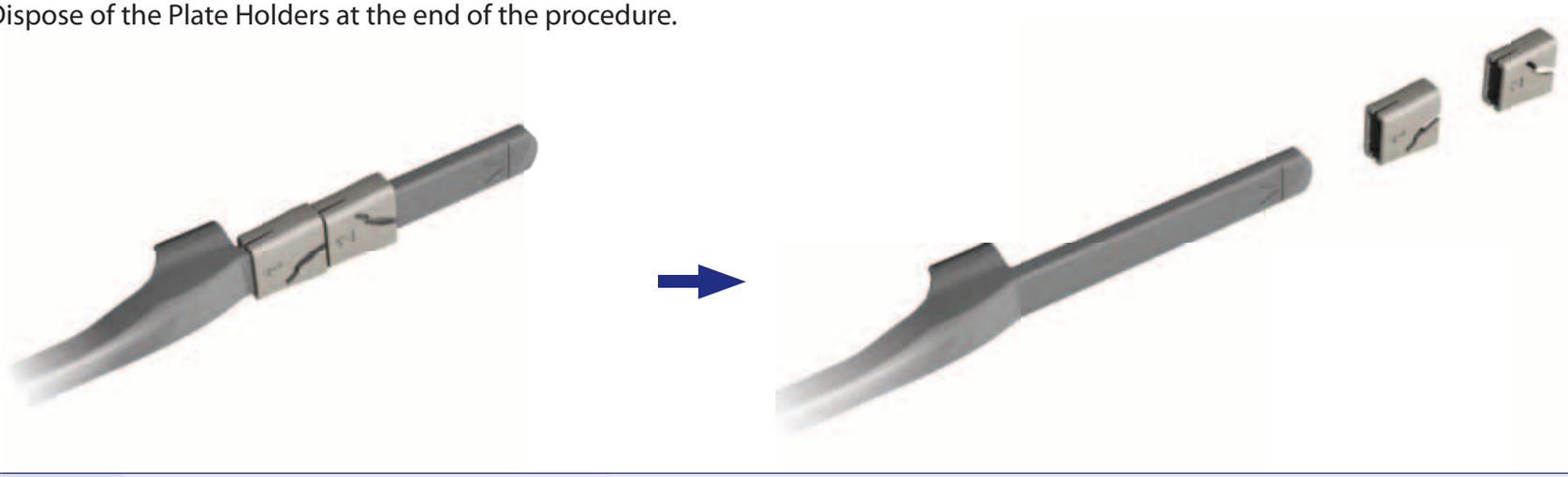


Disengage the Cage Holder's hook from the cage groove with a slight posterior translation and remove it carefully from the intervertebral disc space.



A/P and lateral fluoroscopic verification of the plate placement confirms optimal position.

Dispose of the Plate Holders at the end of the procedure.

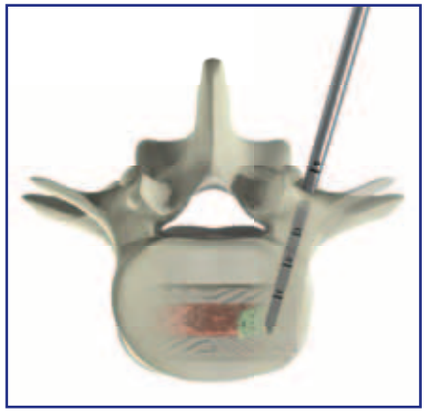
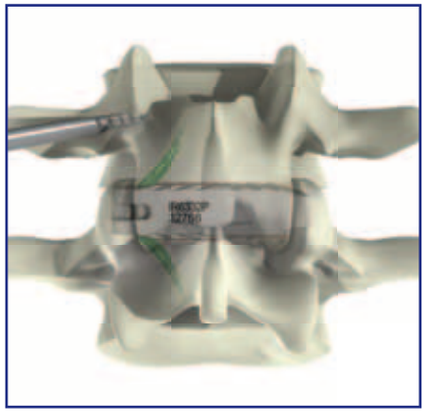


Step 8 Supplemental fixation

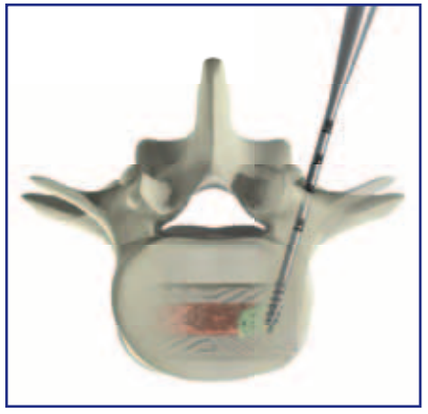
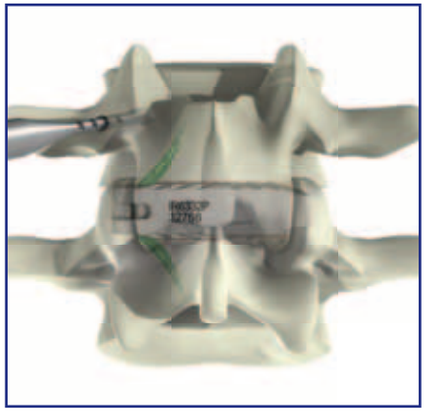
VerteBRIDGE® plate trajectory must be reviewed via fluoroscopy prior to implanting supplemental posterior fixation.

Steps should be taken during pedicle screw placement to confirm the screws will not contact the deployed VerteBRIDGE plating.

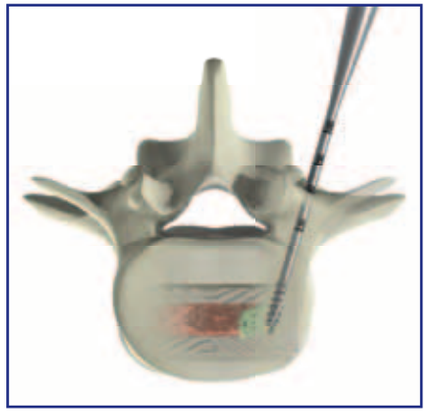
1. Make the initial path through the pedicle with the awl and/or pedicle probe.

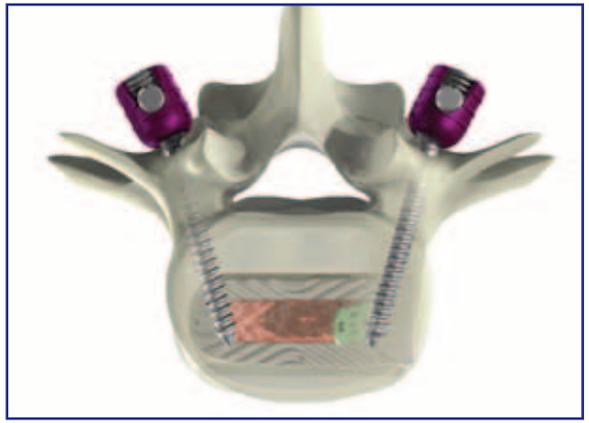
2. Use the tap to create a path for the screw threads.

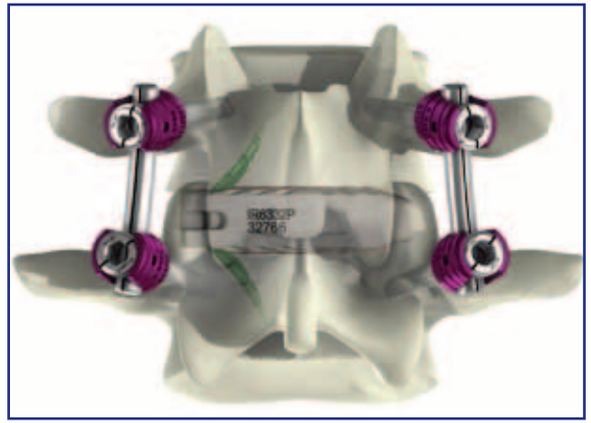



3. Use a pedicle probe to ensure that there is no interference between the screw trajectory and the VerteBRIDGE plating.



4. If there is interference between the screw path and the VerteBRIDGE® plating during Steps 1-3, either create a new screw trajectory or select a shorter screw.

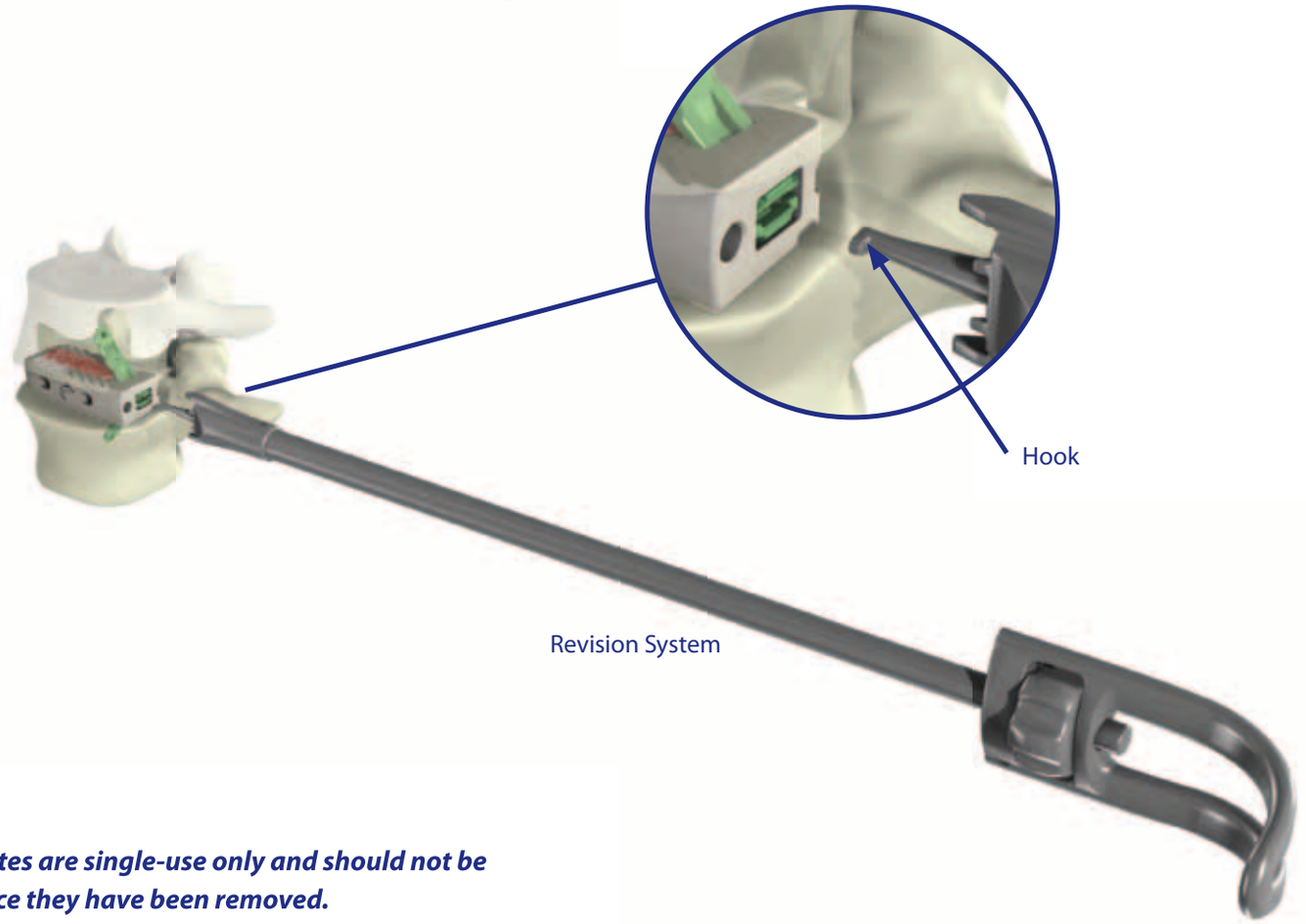




VerteBRIDGE plate removal

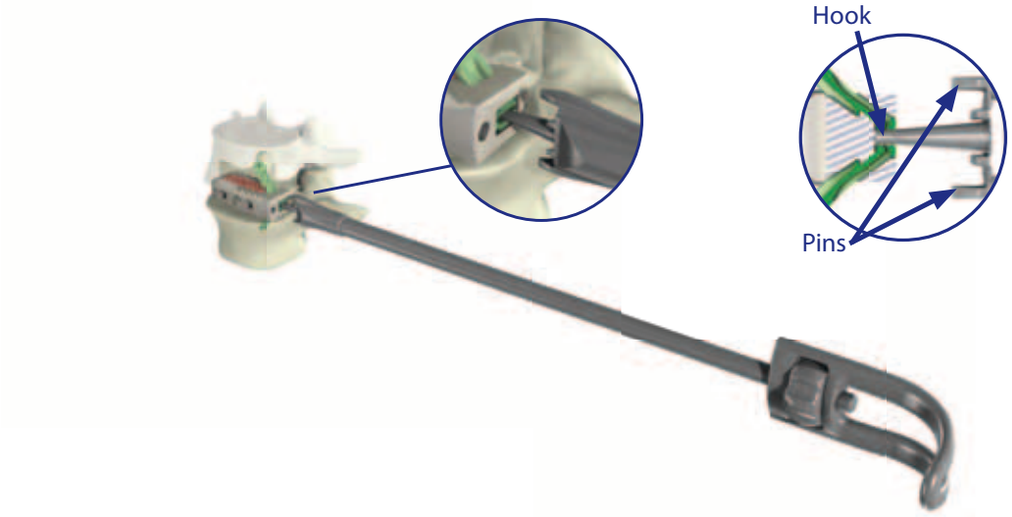
Revision - plate removal

A Revision System is provided in the event the plating must be removed.

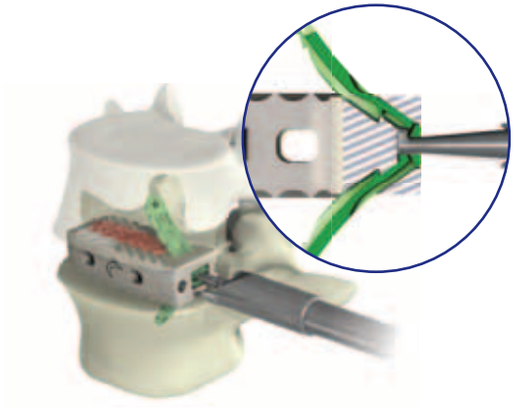


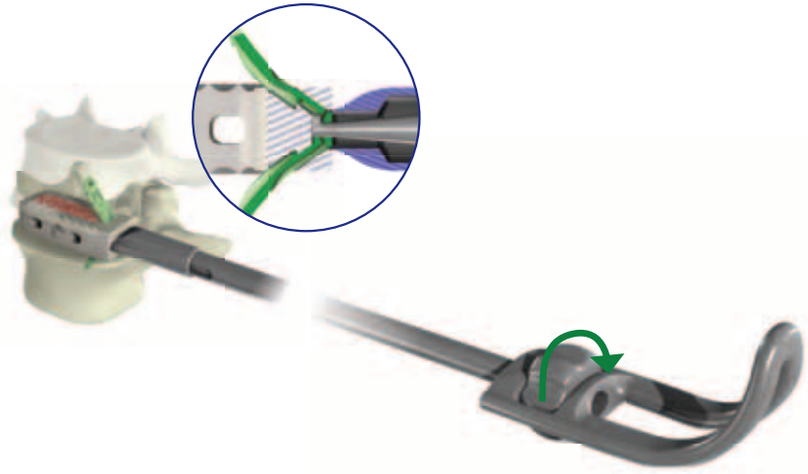
CAUTION: Plates are single-use only and should not be reinserted once they have been removed.

1. Insert the Revision System hook parallel to and between the two plates.

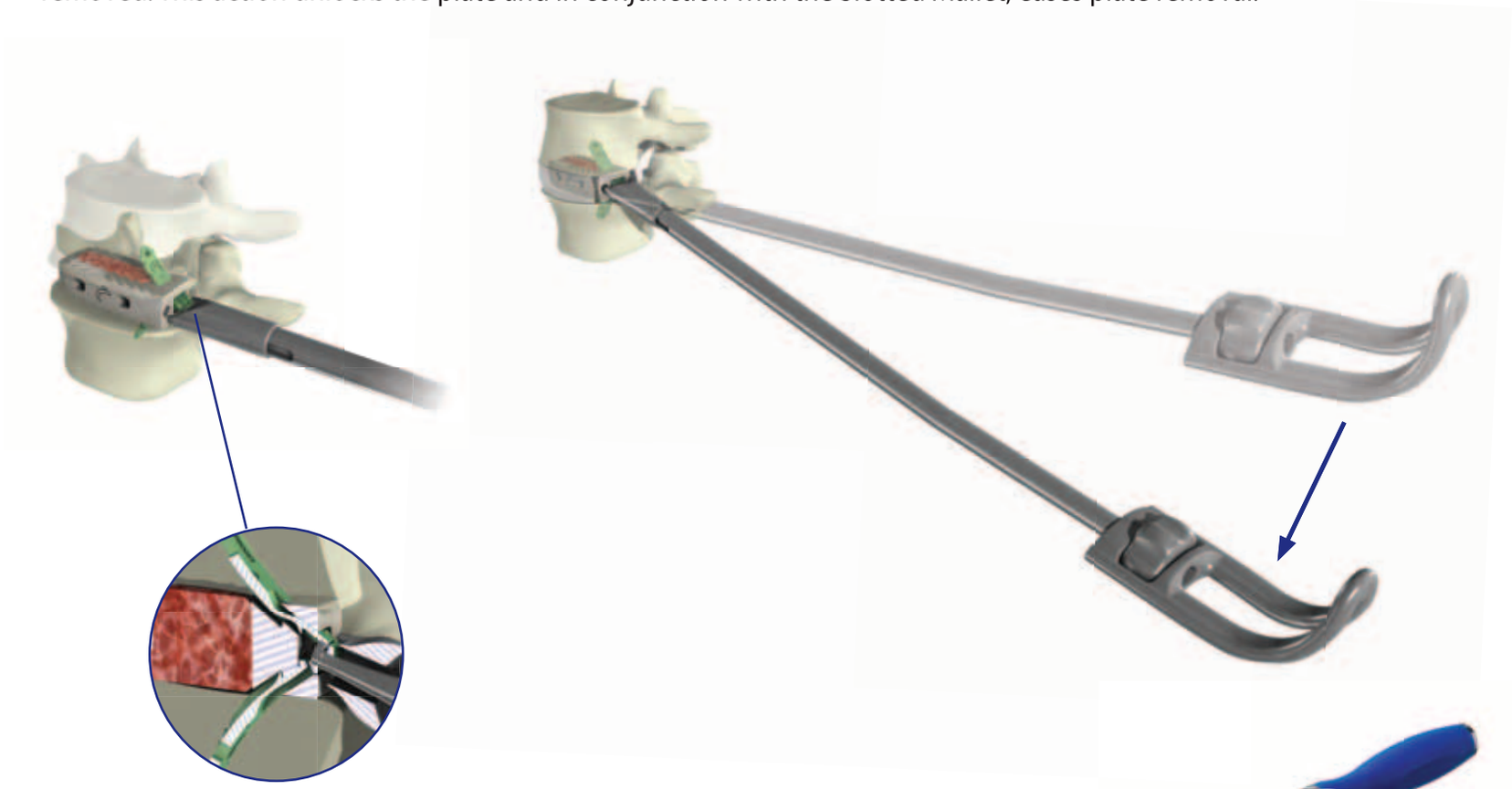


2. Rotate the instrument 90°, so that the curve of the handle points toward the anchoring plate to be removed. This aligns the pins of the Revision System with the corresponding implant slots (threaded hole and groove).
3. Screw the knob until the head of the revision system contacts the cage.





Once the plate is locked to the Revision System, slightly lever the instrument away from the plate that is being removed. This action unlocks the plate and in conjunction with the Slotted Mallet, eases plate removal.



Repeat the previous steps in order to engage and extract the remaining anchoring plate.

Slotted Mallet

Revision - cage removal

Reattach the Cage Holder to the implant and use the Slotted Mallet to progressively extract the implant.

Device description and use guidelines

Device description

The Avenue® L implants are devices whose primary functions are to add a solid structure to a graft so as to enable the stabilization of intervertebral height, after discectomy, during the time of graft setting and achieve a maximum surface of fusion. Various sizes of these implants are available, so that adaptations can be made to take into account the pathology and individual patient. In addition, so as to favor bone growth, the Avenue® L lateral cage must be filled with bone graft.

The Avenue L implants are manufactured from (radiolucent) PEEK-OPTIMA® LT1 with surgical titanium alloy (Ti6Al4V) radiological position markers. The VerteBRIDGE® Anchoring Plates are manufactured from surgical titanium alloy (Ti6Al4V).

Instrumentation designed for implantation of the Avenue L Lateral Lumbar Cage is manufactured from biocompatible materials such as medical grade stainless steel.

Indications for use

The Avenue® L Interbody Fusion System is indicated for intervertebral body fusion of the lumbar spine, from L2 to S1, in skeletally mature patients who have had six months of non-operative treatment. The device is intended for use at either one level or two contiguous levels for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use with or without integrated fixation and must be used in conjunction with posterior supplemental fixation (e.g., pedicle screws). The device system is intended for use with autograft to facilitate fusion.

Contraindications

- Cardiac problems.
- Abuse of medicine, drugs, tobacco or alcohol (which change the ossification power).
- Bony abnormalities preventing safe anchoring plate fixation.
- Material sensitivity, documented or suspected.
- Any mental or neuromuscular disorder which would create an unacceptable risk of fixation failure or complications in post-operative care.
- Bone stock compromised by disease, infection or prior implantation which cannot provide adequate support and or fixation to the implant.
- Obesity can produce loads on the spinal system which can lead to failure of the fixation of the device or to failure of the device itself.
- Recent infection, fever or hyper-leukocytosis.
- Open wounds.
- Bone absorption, osteopenia and/or osteoporosis.
- Patients having inadequate tissue coverage over the operative site.

- Pregnancy.
- Excessive local inflammation.
- Other medical (for example: anesthetics risks) or surgical conditions which would preclude the potential benefit of spinal implant surgery such as the presence of tumors, congenital abnormalities, elevation of sedimentation rate unexplained by other diseases.
- Major spinal instabilities.
- Degenerative spondylolisthesis grade II or more.

Warnings

- Risks associated with general surgery, orthopedic surgery, and the use of general anesthesia should be explained to the patient prior to surgery. It is also recommended that the advantages and disadvantages of surgery, the implants, as well as alternative treatment methods be explained to the patient.
- Potential risks associated with the use of this system, which may require additional surgery, include device component failure (bending, loosening or fracture), loss of fixation, non-union, fracture of the vertebra, neurological injury, vascular or visceral injury, neurological complications, over-distraction, trauma to nerve root or dura, incorrect implant positioning, implant migration, pseudoarthrosis, disc height loss (impaction of implant into vertebral end plates), allergy or inflammation, general adverse effects related to surgical procedures (e.g. anesthesia, infection), subsidence, and expulsion.
- The device can break if it is subjected to increased loading associated with delayed union or non-union. If healing is delayed or does not occur, the implant could eventually break due to material fatigue. Factors such as the patient weight, activity level, and compliance to weight bearing or load bearing instructions, have an effect in the stresses to which the implant may be subjected, and may affect the longevity of the implant.
- Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.
- Discard all damaged or mishandled implants.
- Under no circumstances may the implants be re-used. Although the device may appear intact on removal, internal modification due to the stress and strains placed on it or small defects may exist which may lead to fracture of the implant.
- Implants removed from a patient that contact bodily tissues or fluids should never be reused at risk of contamination of the patient.
- Mixing Metal: Some degree of corrosion occurs on all implanted metal and alloys. Contact of dissimilar metals (e.g. stainless steels and titanium), however, may accelerate this corrosion process. The presence of corrosion may accelerate fatigue fracture of implants and the amount of metal compounds released into the body system may also increase.
- Manufacturers employ different materials, manufacturing specifications and differing design parameters. Components of the Avenue® L Interbody Fusion System should not be used in conjunction with components from any other manufacturer.
- Any decision by a surgeon to remove the device should take into consideration such factors as the risk to the patient of the additional surgical procedure as well as the difficulty of removal.
- Implant removal should be followed by adequate postoperative management to avoid fracture.
- Before implanting the Avenue® L lateral cage, the vertebral plates must be carefully prepared, being careful not to weaken the cortical bone to avoid implant subsidence.
- The setting and possible repositioning of the Avenue® L lateral cage must be done with the cage holder attached to the cage.
- In order to ensure its stability in the intervertebral space, the Avenue® L implant must be used with a supplemental internal fixation system (plate and/or screws type).
- Do not attempt to reposition the implant after anchoring plates have been deployed into the vertebral endplates.
- The Avenue® L Interbody Fusion System has not been evaluated for safety and compatibility in the MR environment.
- The Avenue® L Interbody Fusion System has not been tested for heating or migration in the MR environment.

Precautions

- Being a technically demanding procedure presenting a risk of serious injury to the patient, the implantation of intersomatic systems should be performed only by experienced spine surgeons with specific training in the use of this system and who have knowledge of the present instructions for use.
- Based on fatigue testing results, when using the Avenue® L Implant System, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact on the performance of this system.
- Patients who smoke have been shown to have an increased incidence of non-unions. Such patients should be advised of this fact and warned of the potential consequences.
- If the patient is involved in an occupation or activity which applies inordinate stress upon the implant (e.g., running, lifting of significant loads, or muscle strain), resultant forces can cause failure of the device.
- In some cases, progression of degenerative disease may also be so advanced at the time of implantation that they may substantially decrease the expected useful life to the implant. In such cases, orthopedic devices may be considered only as a delaying technique or to provide temporary relief.
- Before clinical use, the surgeon should thoroughly understand all aspects of the surgical procedure and limitations of the system. This device is recommended for use only by surgeons familiar with preoperative and surgical techniques, cautions and potential risks associated with spinal surgery. Knowledge of surgical techniques, selection and placement of implants, and pre and post-operative patient management are considerations essential to a successful surgical outcome.
- Patients should be instructed in detail about the limitations of the implants, including but not limited to the impact of excessive loading through patient weight or activity, and should be taught to govern their activities accordingly.
- Appropriate selection, placement and fixation of the spinal system components are critical factors which affect implant service life. Accordingly, strict adherence to the indications, contraindications, precautions, and warnings for this product is essential to potentially maximize service life.
- Care must be taken to protect the components from being marred, nicked or notched as a result of contact with metal or abrasive objects. Alterations will produce defects in surface finish and internal stresses which may become the focal point for eventual breakage of the implant.
- Inspection and trial assembly are recommended prior to surgery to determine if the instruments have been damaged during storage or prior procedures.
- After any surgery, it is necessary to check the proper position of the implants and to follow the evolution of the fusion using appropriate techniques. For the anchoring plates, it is imperative to respect the following points:
    - During multi-level implantations, care should be taken in plate size selection to minimize the possibility of adjacent plate interference.
    - Ensure the cage does not protrude proximally outside the intervertebral disc space to be sure that the anchoring plates are properly positioned in the vertebral body.
    - Prior to implanting the posterior construct, use fluoroscopy to verify the trajectory of the anchoring plates to avoid impingement with pedicle screws.
    - If there is potential for the plates to contact pedicle screws, it may be necessary to change the trajectory of the screws.
- Sale of this product is restricted to physicians.

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www.ldrmedical.com

United States
13785 Research Boulevard
Suite 200
Austin, Texas 78750
512.344.3333

France
Hôtel de bureau 1
4, rue Gustave Eiffel
10 430 Rosières Près Troyes, FRANCE
+33 (0)3 25 82 32 63

China
Unit 06, Level 16, Building A,
Beijing Global Trade Center #36
North Third Ring Road
East, Dongcheng District,
Beijing, China, 100013
+86 10 58256655

Brazil
Av. Pereira Barreto, 1395-19º Floor
Room 192 to 196
Torre Sul-Bairro Paraíso
Santo André / São Paulo-Brazil
CEP 09190-610
+55 11 4332 7755

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