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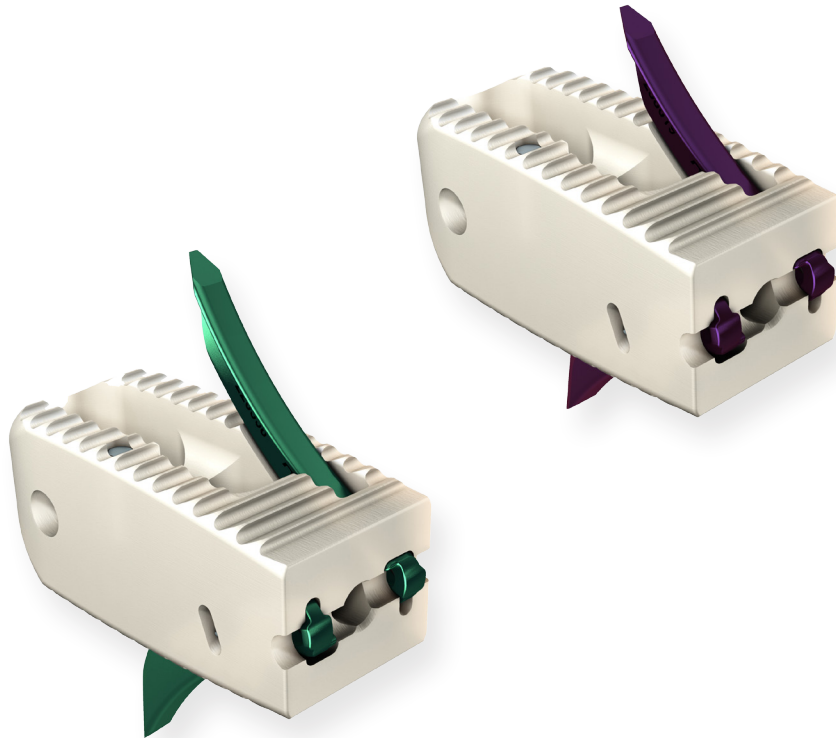
Thoracolumbar Solutions

Avenue® T

TLIF Cage



Surgical Technique Guide



*VerteBRIDGE® Plating is the integrated fixation
designed specifically for the
Avenue T cage.*

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Zimmer Biomet Spine does not practice medicine. This technique was developed in conjunction with health care professionals. This document is intended for surgeons and is not intended for laypersons. Each surgeon should exercise his or her own independent judgment in the diagnosis and treatment of an individual patient, and this information does not purport to replace the comprehensive training surgeons have received. As with all surgical procedures, the technique used in each case will depend on the surgeon's medical judgment as the best treatment for each patient. Results will vary based on health, weight, activity and other variables. Not all patients are candidates for this product and/or procedure.

PATIENT POSITIONING

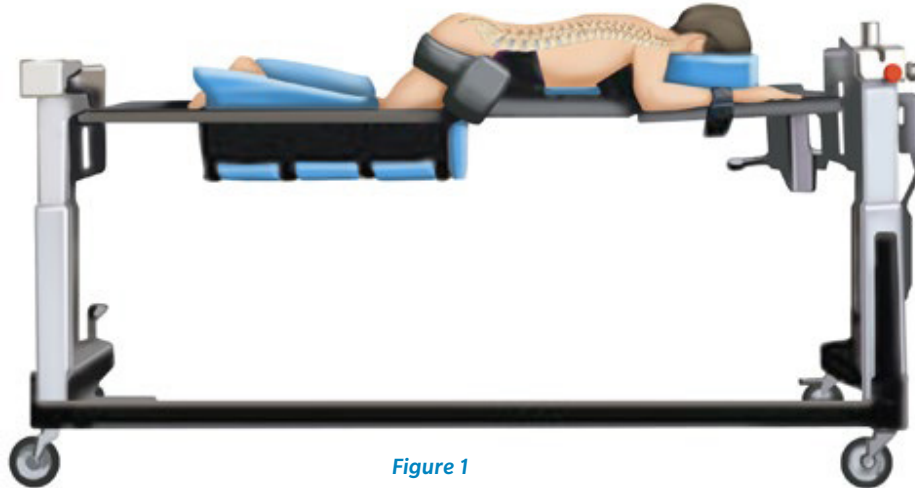


Figure 1
OR layout

STEP 1

Place the patient in the prone or knee-chest position on a radiolucent operating table. Adjust the table (as needed) so that the C-Arm provides true A/P images when at 90° and true lateral images at 0°.

FACETECTOMY AND DISC SPACE PREPARATION

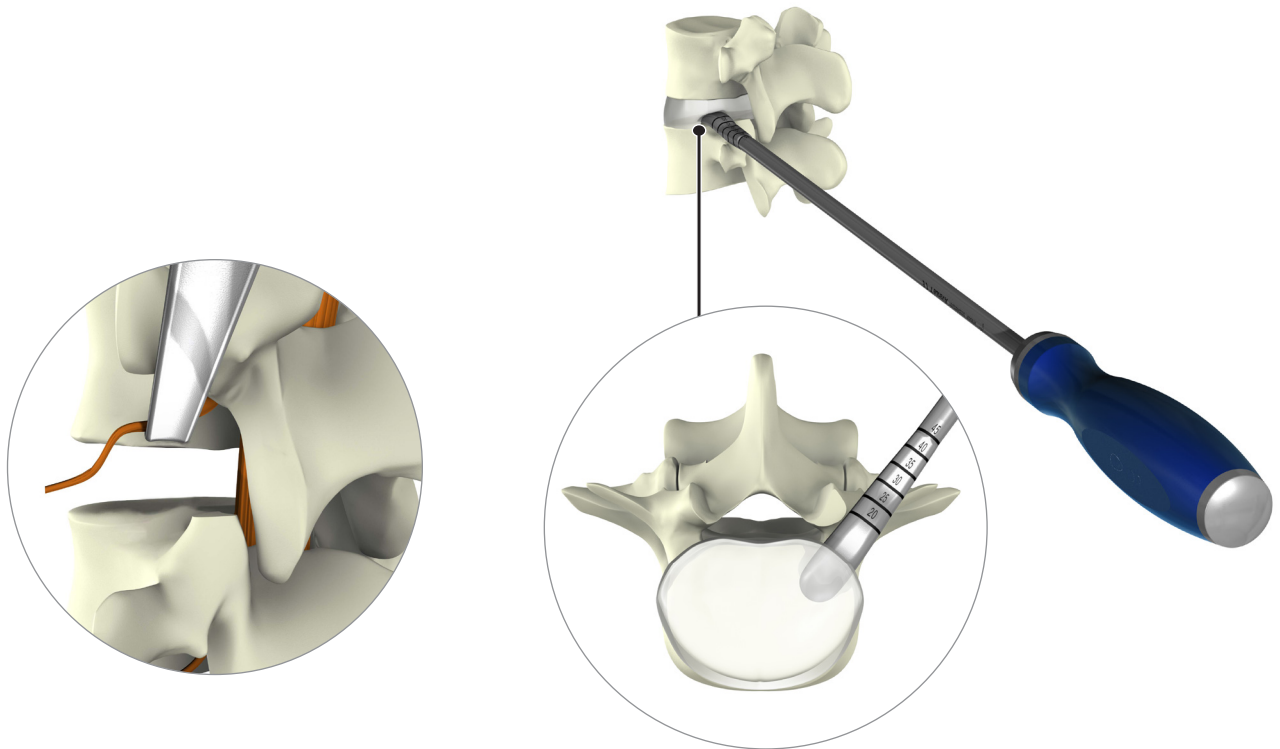


Figure 2

Facet resection for a TLIF approach

STEP 2

Depending on the pathology, it may be necessary to partially or fully resect the facet joint and/or the lamina. A facetectomy and/or laminotomy is performed using the surgeon's preferred technique and instruments.

Nerve root retractors (6 and 10mm) may be used to protect surrounding nerve structures.

Note: *Facet resection is not mandatory, if the approach allows sufficient access for the discectomy.*

Identify the desired disc and start disc resection using a scalpel. Perform the discectomy using the surgeon's preferred technique and instruments (e.g. cobbs, pituitary rongeurs, or curettes) (**Figure 2**).

DISTRACTION

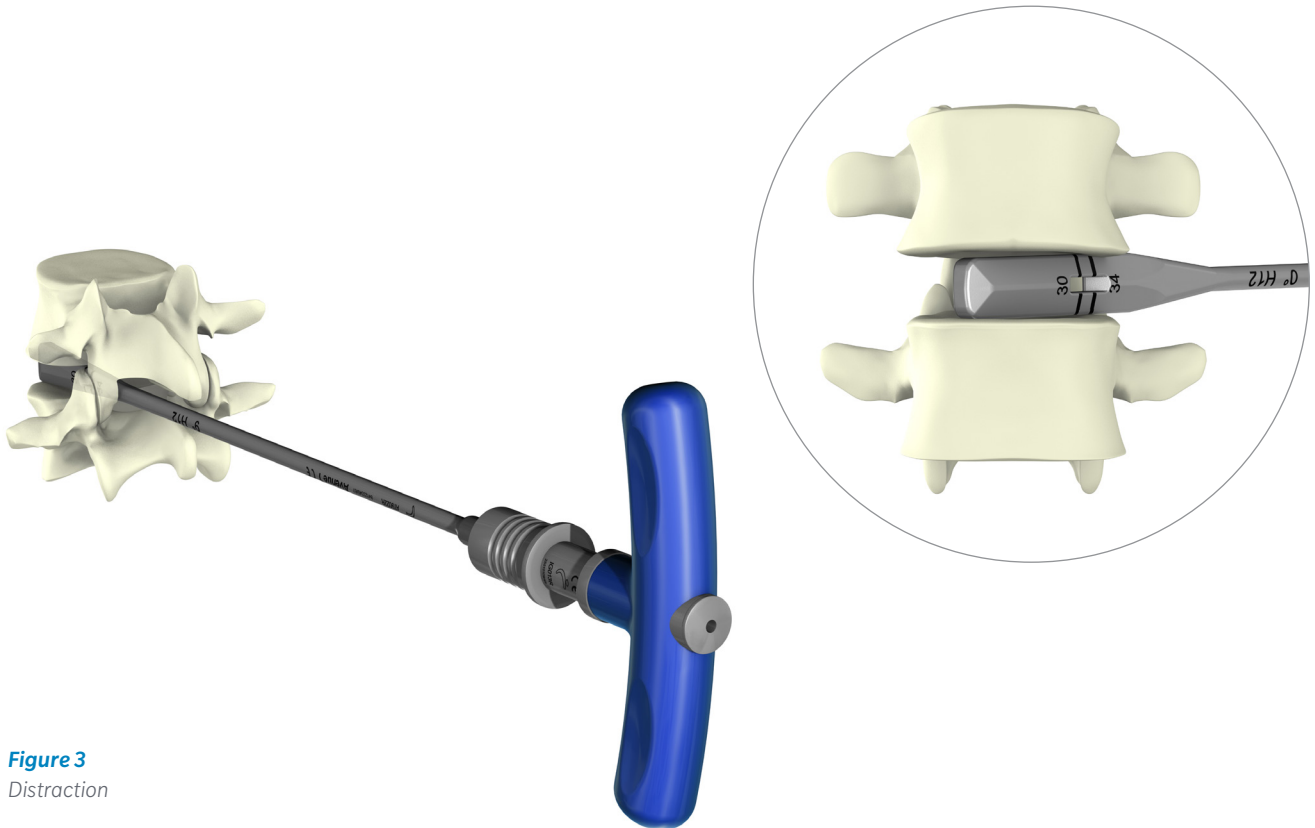


Figure 3
Distraction

STEP 3

Gradually distract the disc space using the paddle distractors, available in 1mm increments. The final disc height achieved should be consistent with the disc heights of the adjacent levels (**Figure 3**).

Note: Proper distraction is required to achieve and maintain desired disc height. Complete a thorough discectomy to ensure that the proper implant size is chosen. 0° paddle distractors in 6 and 7mm heights do not refer to an available cage size in the system and are provided for initial distraction.

DISCECTOMY AND ENDPLATE PREPARATION

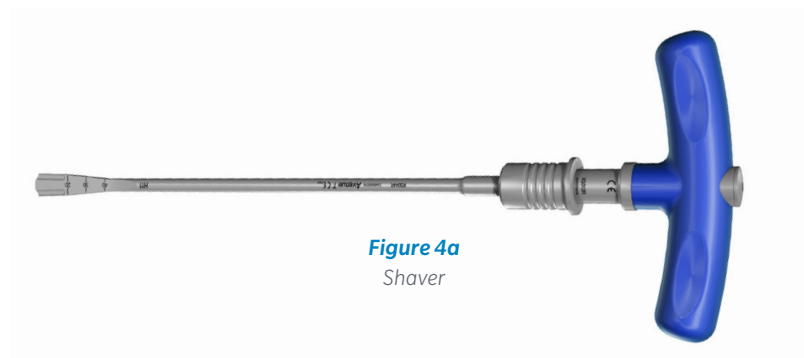


Figure 4a
Shaver

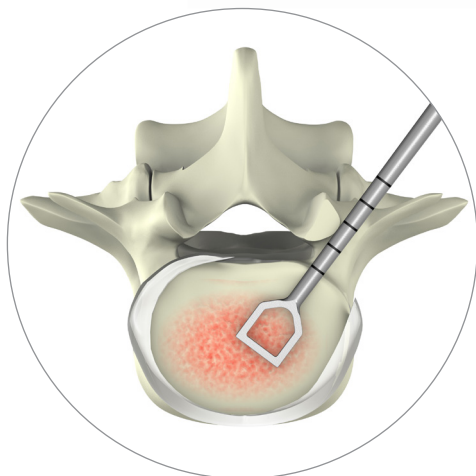


Figure 4b
Straight curette

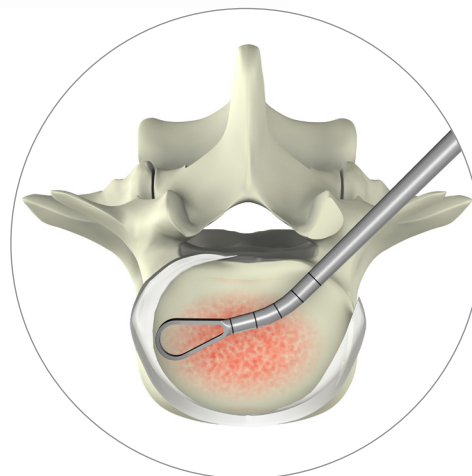


Figure 4c
Angled curette

STEP 4

Use the shavers to continue the discectomy and prepare the vertebral endplates (**Figure 4a**).

Complete the discectomy and prepare the grafting surfaces with straight and/or angled right or left curettes (**Figures 4b/4c**).

Note: Angled curettes can be used to complete the resection in areas of reduced access or to clear an area for additional bone graft insertion.

Caution: Do not use shavers for distraction of the interbody space.

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

IMPLANT SIZE SELECTION



Figure 5a
5° H12mm paddle distractor



Figure 5b
5° trial

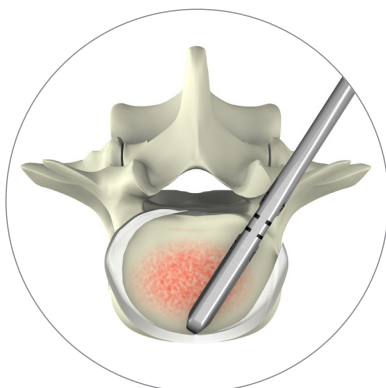


Figure 5c
Axial View

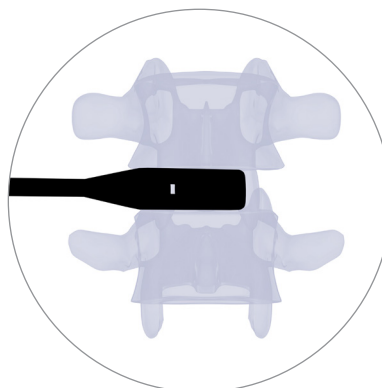


Figure 5d
A/P View



Figure 5e
Lateral View

STEP 5

Paddle distractors or trials are used to select implant size (height, length, and lordosis) best suited to the patient's anatomy. Paddle distractors and trials are available for each implant height and lordosis (**Figures 5a/5b**). Markers present on the paddle distractors and trials allow for the surgeon to determine the appropriate implant length (30mm or 34mm), under fluoroscopy (**Figure 5c**).

Position the paddle distractor or trial in the desired position. The paddle distractor or trial should fit securely within the disc space, but care should be taken to avoid oversizing the implant.

Confirm the position of the paddle distractor or trial using fluoroscopy.

- **A/P View:** Lateral coverage and rotational position (the more visible the paddle hole, the more rotation in the axial plane) (**Figure 5d**).
- **Lateral View:** Length, height, lordosis, and anteroposterior positioning (the posterior edge of the cage should end 2 to 5mm away from the posterior vertebral walls).

Once the proper size is determined, remove the paddle distractor or trial from the intervertebral space.

Example: The best cage length here is 34mm. Paddle distractors and trials can also be used to determine the appropriate lordosis and height (**Figure 5e**).

CAGE PREPARATION



Figure 6
Graft fusion chamber

STEP 6

The graft fusion chamber must be filled with allograft or autograft.

Place the cage in the graft support and lock the cage by turning the graft support knob.

Compact the draft in the bone graft chamber of the cage using the graft compactor (**Figure 6**).

IMPLANT TO CAGE HOLDER ASSEMBLY

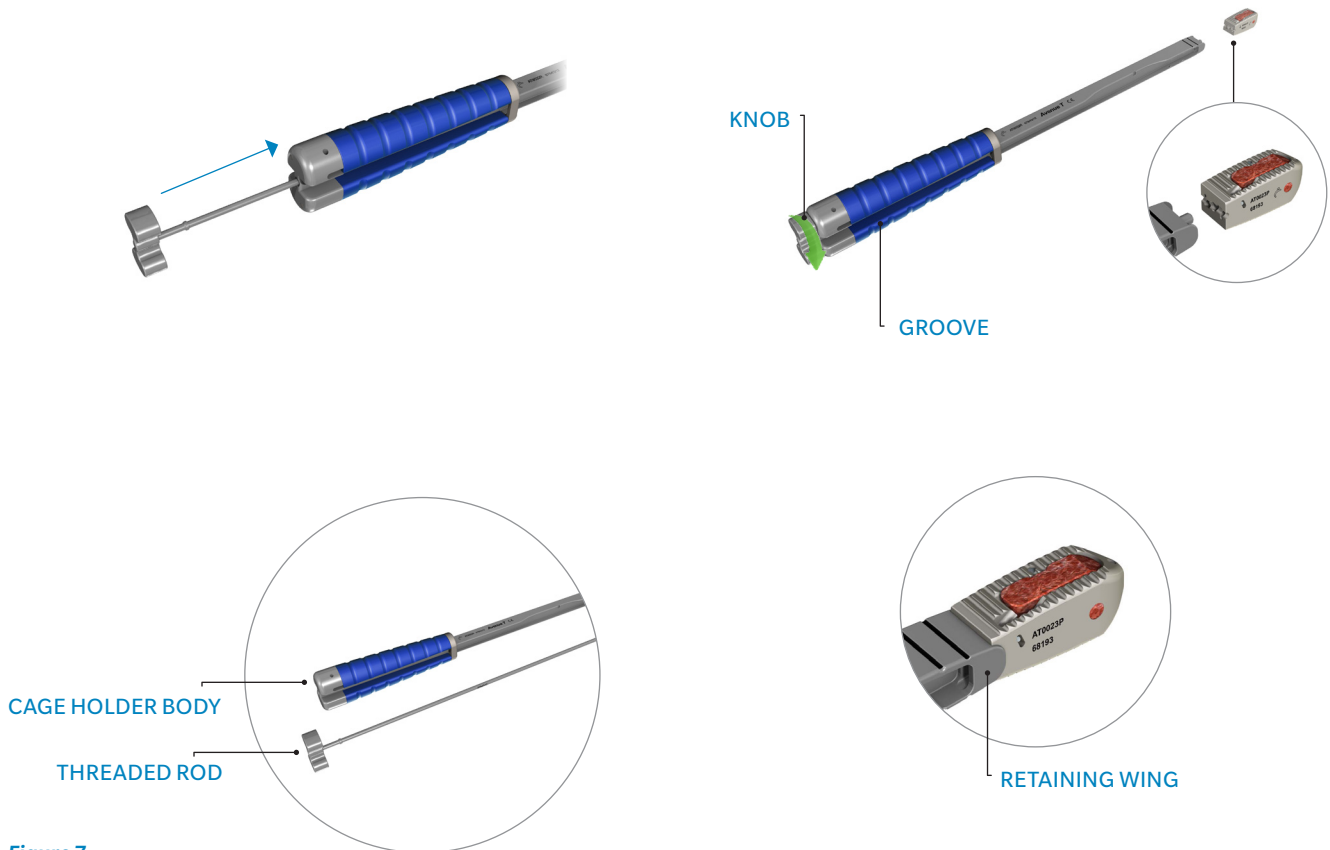


Figure 7
Cage holder assembly

STEP 7

Slide the inner threaded rod inside the cage holder body.

Bring the cage close to the cage holder and position the retaining wing of the cage holder on each side of the cage. Align and insert the inner threaded rod into the threaded hole on the cage.

Tighten the cage on the cage holder by turning the cage holder knob (**Figure 7**).

Caution: The connection between the cage and the cage holder is critical. Tighten until the connection is firm but not excessive in order to avoid damaging the screw thread.

Caution: Confirm the grooves in the knob align with the grooves in the cage holder handle, so that the impactors can be introduced.

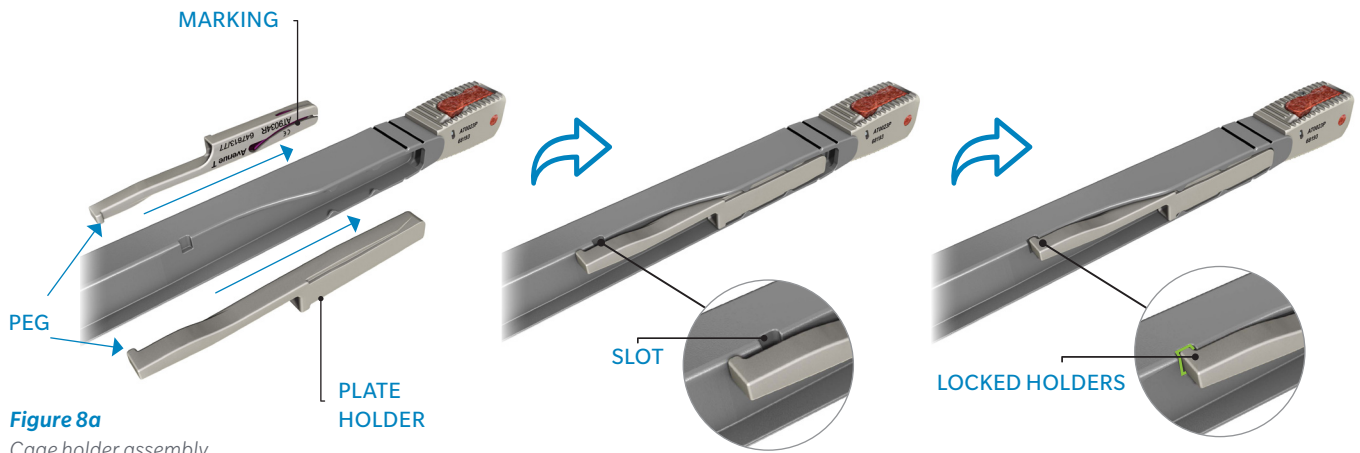


Figure 8a
Cage holder assembly

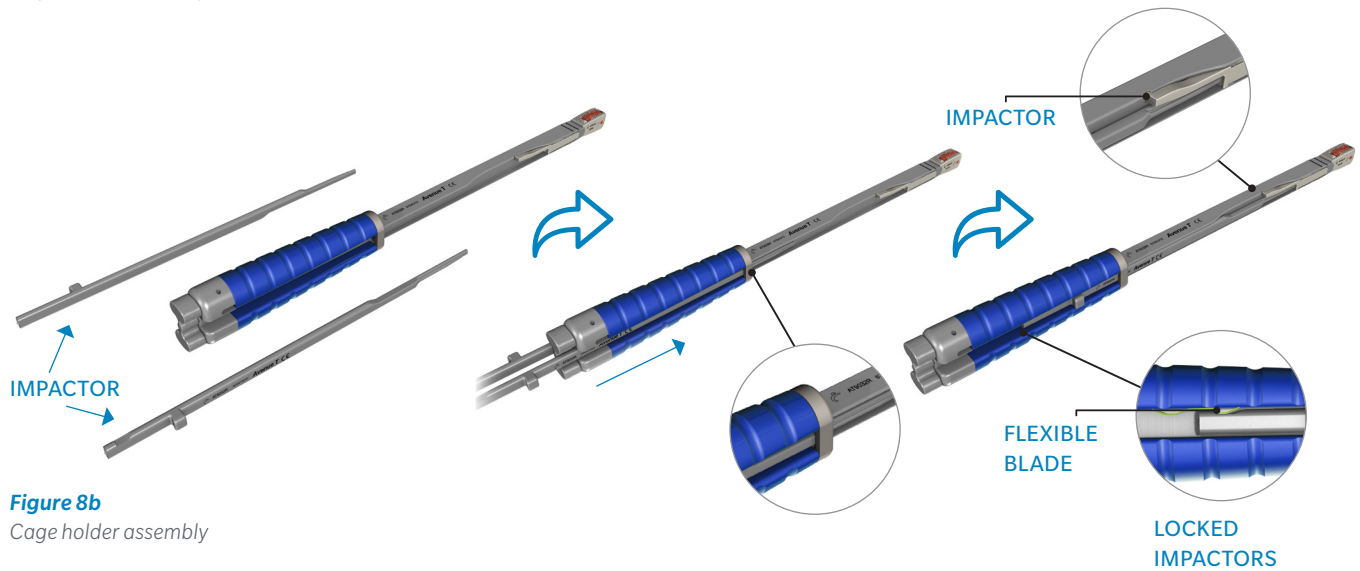


Figure 8b
Cage holder assembly

STEP 8

Select the plate length (S or M) and insert the plate holders on each side of the cage holder (**Figure 8a**).

Plates are pre-assembled in a single-use plate holder made of PEEK CLASSIX™.

Markings on the plate holders should face the cage holder and the peg must be locked into the slots on the cage holder (**Figure 8c**).

Insert impactors on each side of the cage holder handle and slide them until they are locked by the flexible blades. The distal tips of the impactors must be engaged inside the plate holders (**Figure 8b**).



Figure 8c
Plate holders length

CAGE INSERTION

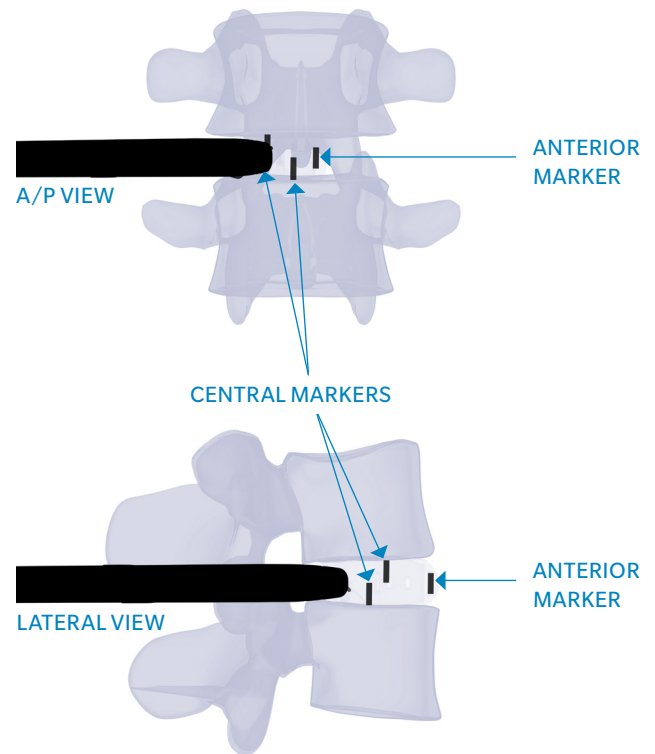


Figure 9

Proper implant placement

STEP 9

Prior to cage insertion, bone graft material may be placed anteriorly or contralaterally.

Insert the cage into the interbody space with successive impactions on the cage holder, parallel to the endplates. A non-parallel insertion may weaken the end plates due to conflict with the cage.

Take care to position the cage as close as possible to its final position.

Confirm proper implant placement using fluoroscopy (**Figure 9**):

A/P View: Lateral and rotational positioning

Lateral View: Anteroposterior and rotational positioning

Note: Anterior marker is 1mm from the anterior cage border. Central markers are 1mm from the lateral cage borders (**Figure 9b**).

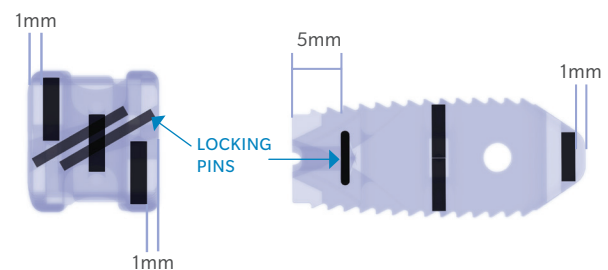


Figure 9b

Markers

PLATE INSERTION

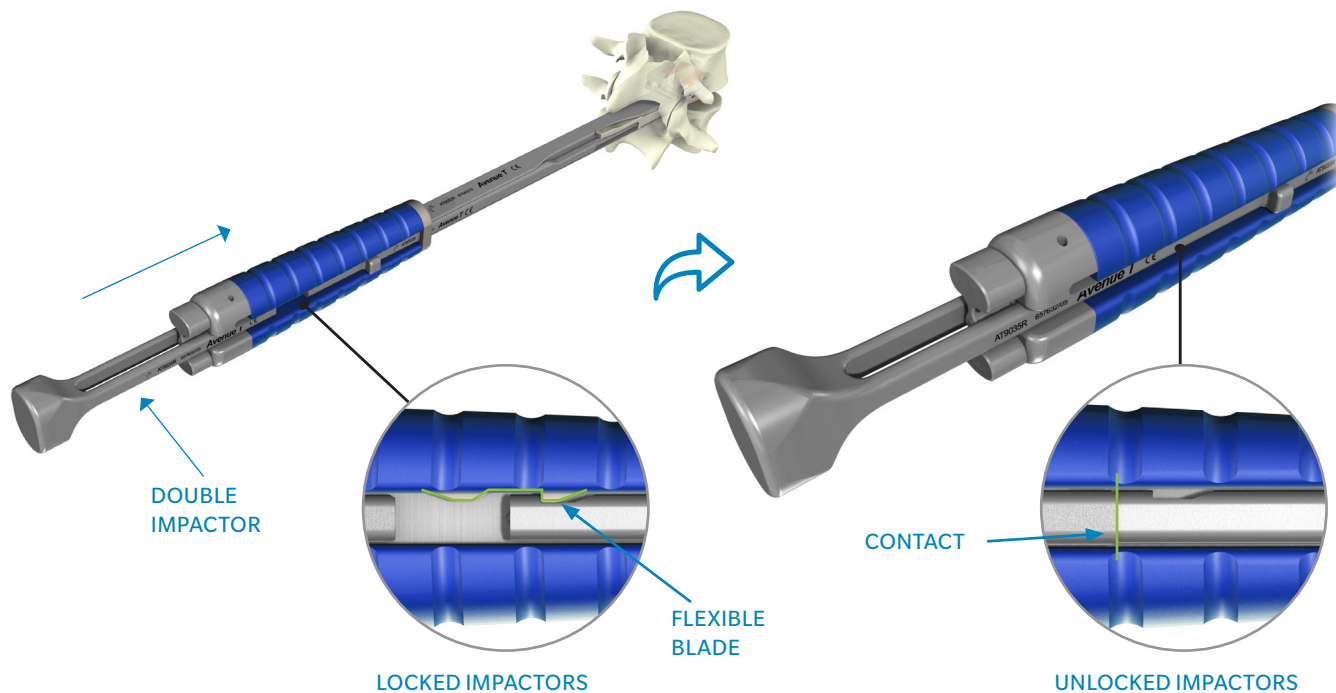


Figure 10
Plate Insertion

STEP 10

Once the final cage position is achieved, the plates can be inserted. The impaction of the plates is performed simultaneously. If a pedicle screw system is already inserted, plate insertion must be done with care to avoid any interference between both constructs (**Figure 10**).

In normal bone structure, the insertion of the plates is a simple step. Avoid applying excessive force to insert plates.

Engage the double impactor on the proximal side of the cage holder until it contacts the impactors.

PLATE INSERTION (continued)

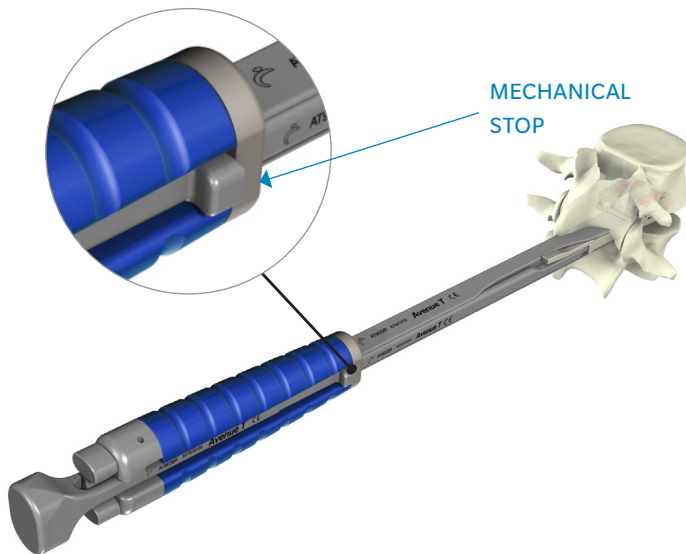


Figure 11a
Plate Insertion

STEP 11

Manually push the double impactor to advance the impactors and bring the tips of the plates in contact with the vertebral endplates.

Caution: Check the alignment of the cage holder with the cage before starting impaction of the plates. If the cage and the cage holder are misaligned, the plates won't be able to follow their predefined trajectory, resulting in contact with the cage.

Impact the double impactor with a mallet until the mechanical stop is reached while holding the cage holder handle firmly to prevent advancement of the cage (**Figure 11a**).

Caution: Once the impactors have reached the mechanical stop, impaction with the mallet must be stopped. Plates are inserted and locked inside the cage.

Use fluoroscopy to check proper plate positioning (**Figure 11b**).

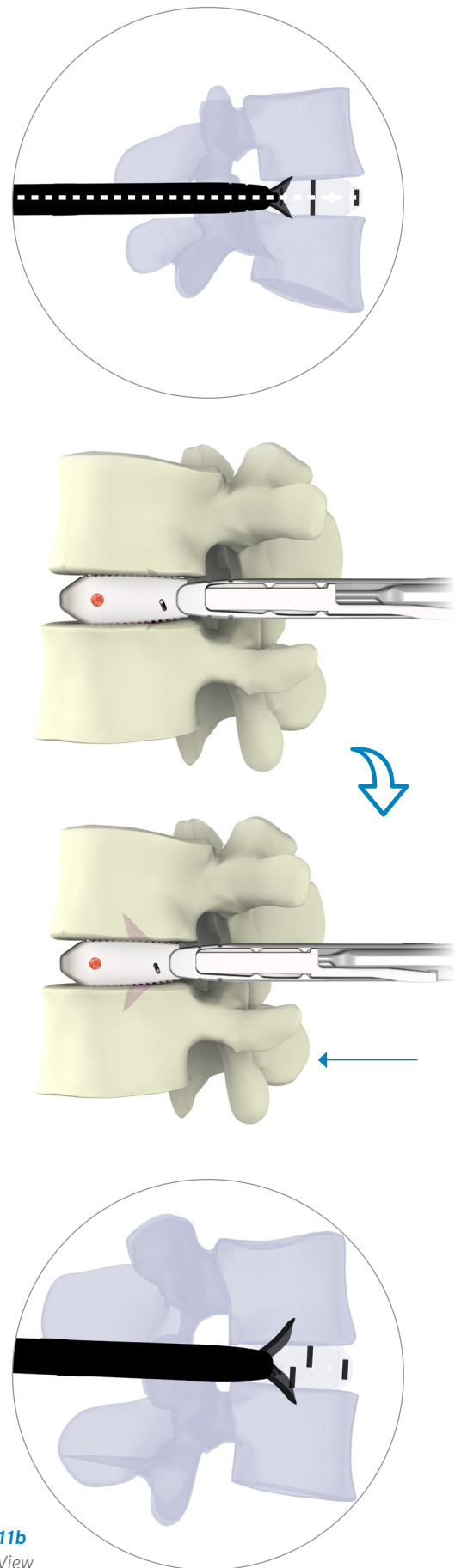


Figure 11b
Lateral View

CAGE HOLDER REMOVAL AND FINAL VERIFICATION

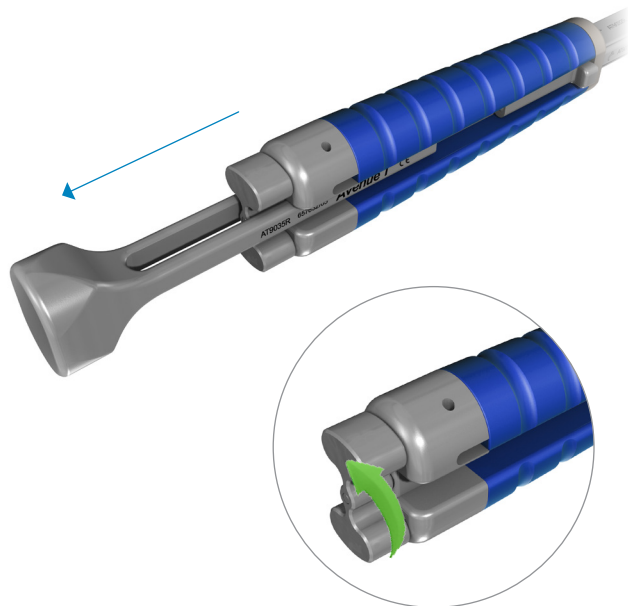


Figure 12a
Cage holder removal

STEP 12

Remove the double impactor.

Unscrew the knob to disengage the cage from the cage holder (**Figure 12a**).

Remove the cage holder.

Use A/P and lateral fluoroscopy to confirm final implant positioning (**Figure 12b/12c**).

Caution: Do not impact the plate and the cage once the cage holder has been removed.

Discard the plate holders at the end of the procedure.

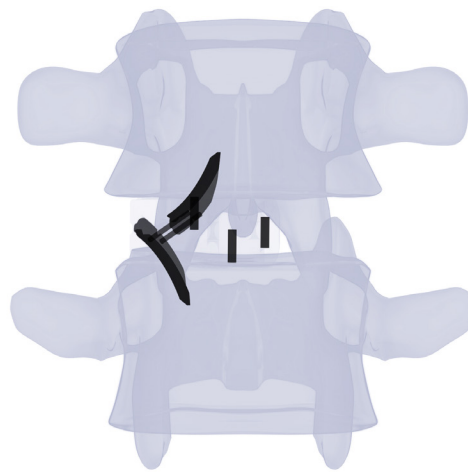


Figure 12b
A/P View

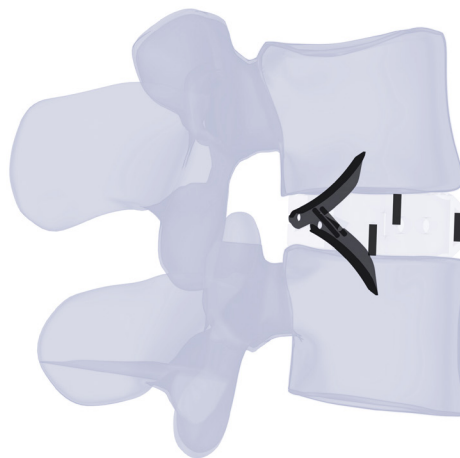


Figure 12c
Lateral View

SUPPLEMENTAL FIXATION

The Avenue T TLIF Cage system is designed for use with or without integrated fixation and must be used in conjunction with supplemental fixation cleared by FDA for use in the lumbar spine.

Implant the supplemental fixation according to the recommended surgical technique for the specific system used.

Caution: *If using a pedicle screw system as supplemental fixation, care should be taken to avoid interference between the screws and VerteBRIDGE plates.*

IMPLANT REMOVAL FOR REVISION

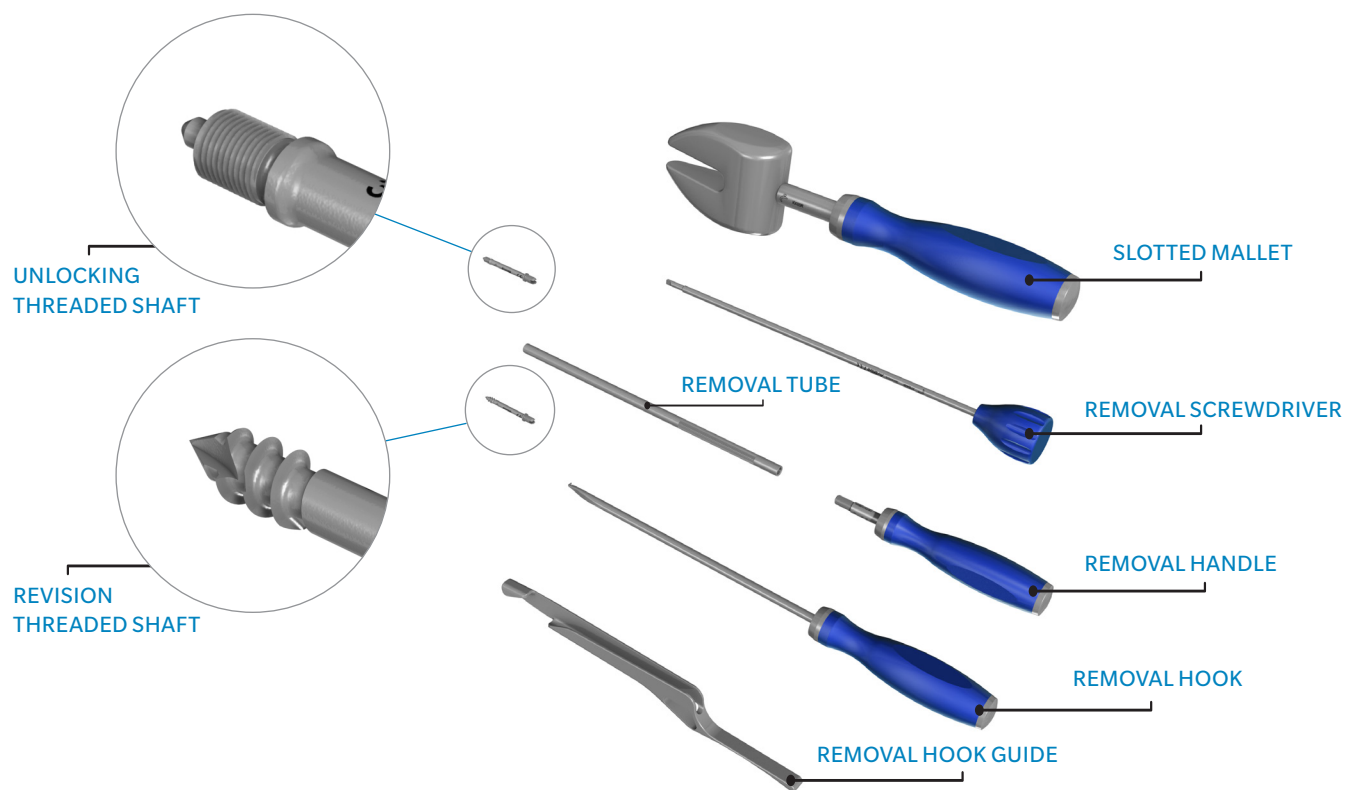


Figure 13
Implant removal tools

STEP 13

If needed, the unlocking threaded shaft facilitates removal of the plates from the cage. If insertion of the unlocking threaded shaft is too difficult, use the revision threaded shaft and restart the removal steps (**Figure 13**).

Important: Never reuse a cage or plates.

IMPLANT REMOVAL FOR REVISION (*continued*)

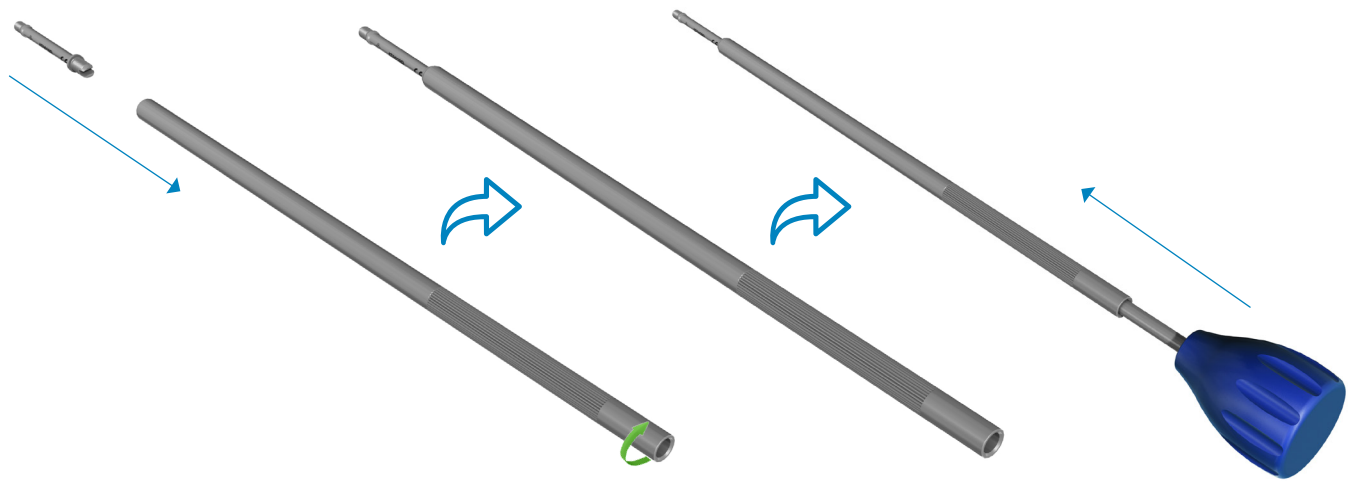


Figure 14a
Implant removal tube

STEP 14

Screw the removal tube onto the unlocking threaded shaft (**Figure 14a**).

Insert the removal screwdriver inside the tube.

To unlock the plates, screw the removal assembly into the threaded hole on the posterior side until it stops turning (**Figure 14b**).

Caution: Make sure to protect the dura and nerve roots during revision.

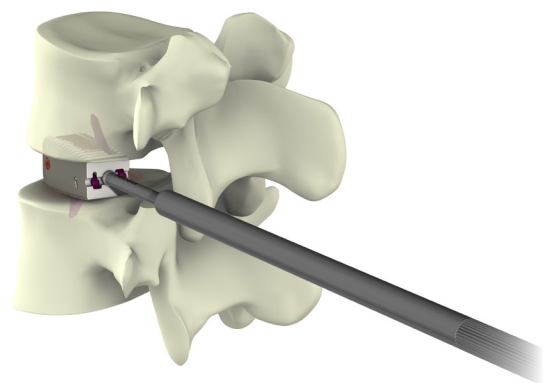


Figure 14b
Implant plate removal

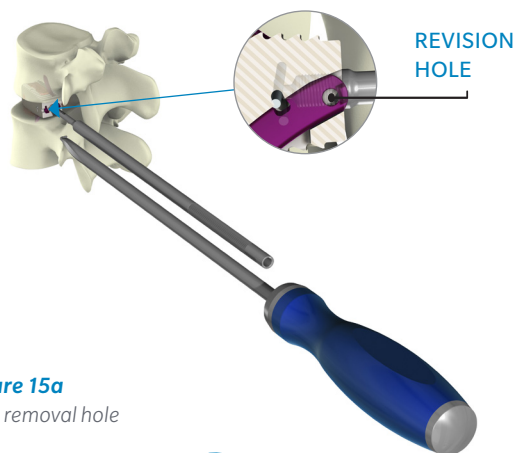


Figure 15a
Find removal hole

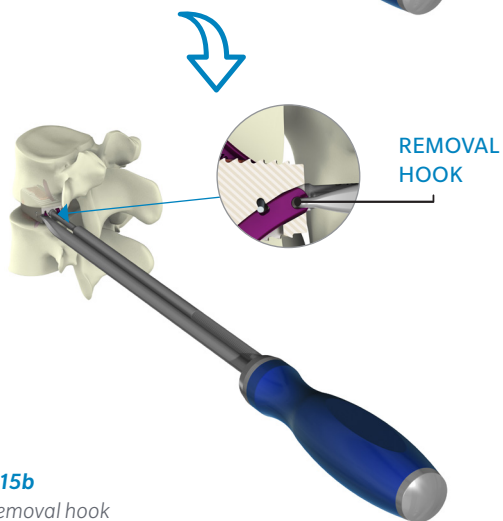


Figure 15b
Insert removal hook

STEP 15

Remove the removal screwdriver and leave the threaded shaft and removal tube.

Insert the removal hook in the revision hole of the first plate to remove (**Figure 15a**).

The removal hook must be parallel to the removal tube (**Figure 15b**).

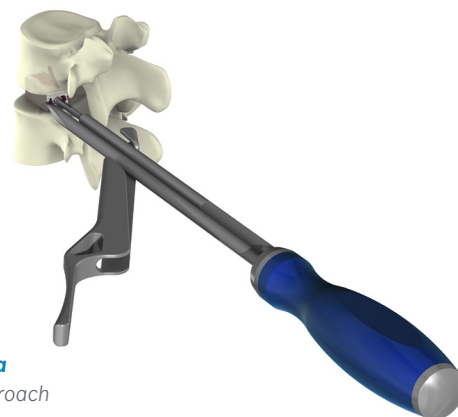


Figure 16a
Guide approach

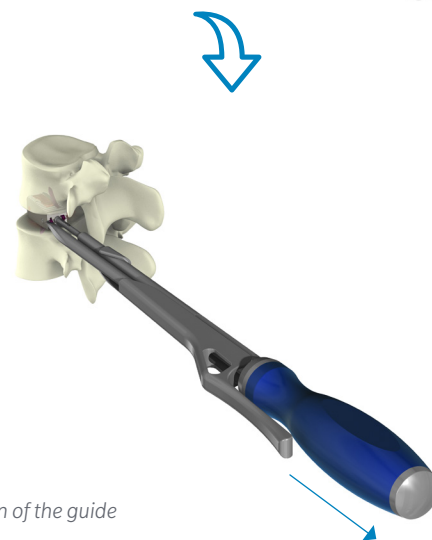


Figure 16b
Final position of the guide

STEP 16

Position the removal hook guide on the tube and removal hook to ensure both are parallel and positioned together. This facilitates removal of the first plate (**Figure 16a/16b**).

IMPLANT REMOVAL FOR REVISION (*continued*)

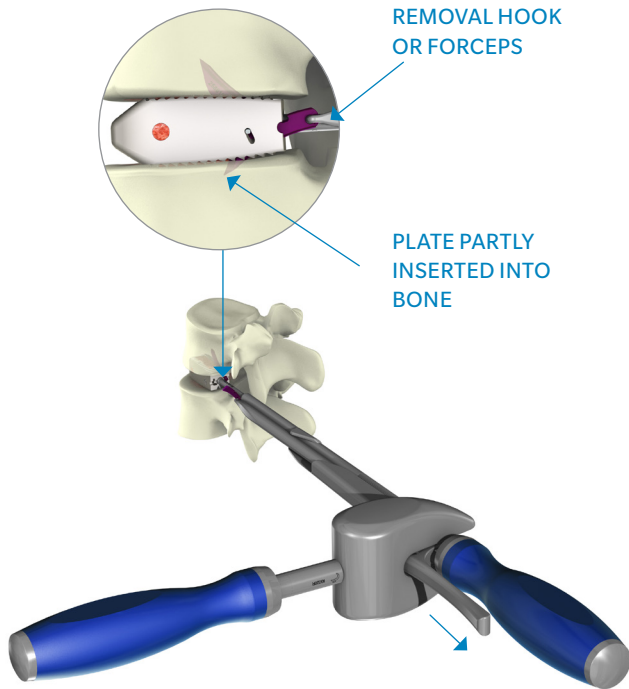


Figure 17a
Position slotted mallet for removal

STEP 17

Place the slot of the slotted mallet across the removal hook guide. Impact under the removal hook handle with the slotted mallet to remove the plate. Keep the removal hook's handle and the guide together to help guide plate removal (**Figure 17a**).

Note: The guide can be removed and the removal hook can be replaced with forceps to grab the plate partly inserted in the bone to complete its removal.

When the first plate is removed, repeat the steps to remove the second plate while making sure the guide is positioned on the side of the hook.

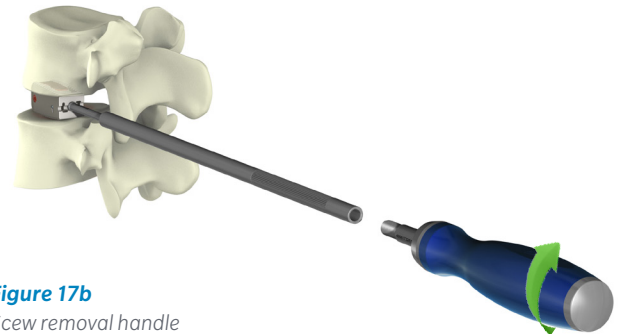


Figure 17b
Screw removal handle

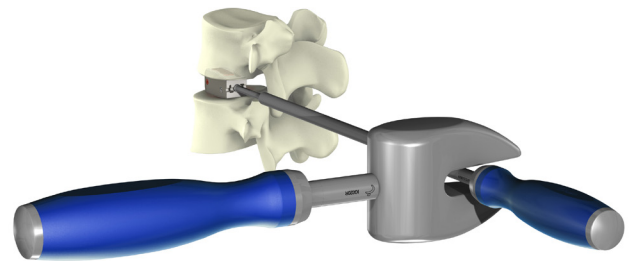


Figure 17c
Remove cage

Screw the removal handle on the removal tube (**Figure 17b**).

Gradually remove the cage using the slotted mallet (**Figure 17c**).

IMPLANTS AND INSTRUMENTS

Avenue T Implants, Kit Number: ATKIT

DESCRIPTION	SIZE	PART NUMBER
Anchoring Plate	S	AT0007T
	M	AT0008T
Avenue T Cage	H8mm L30mm 0°	AT0012P
	H9mm L30mm 0°	AT0013P
	H10mm L30mm 5°	AT0021P
	H11mm L30mm 5°	AT0022P
	H12mm L30mm 5°	AT0023P
	H13mm L30mm 5°	AT0024P
	H14mm L30mm 5°	AT0025P
	H8mm L34mm 0°	AT0042P
	H9mm L34mm 0°	AT0043P
	H10mm L34mm 5°	AT0051P
	H11mm L34mm 5°	AT0052P
	H12mm L34mm 5°	AT0053P
	H13mm L34mm 5°	AT0054P
	H14mm L34mm 5°	AT0055P
Paddle Distractor	H6mm 0°	AT9000R
	H7mm 0°	AT9001R
	H8mm 0°	AT9002R
	H9mm 0°	AT9003R
	H10mm 5°	AT9011R
	H11mm 5°	AT9012R
	H12mm 5°	AT9013R
	H13mm 5°	AT9014R
	H14mm 5°	AT9015R
Shaver	H07	IR9040R or IG040R
	H08	IR9041R or IG041R
	H09	IR9042R or IG042R
	H10	IR9043R or IG043R
	H11	IR9044R or IG044R
	H12	IR9045R or IG045R
	H13	IR9046R or IG046R
	H14	IR9047R or IG047R
Trial	H8mm 0°	AT9046R
	H9mm 0°	AT9047R
	H10mm 5°	AT9053R
	H11mm 5°	AT9054R
	H12mm 5°	AT9055R
	H13mm 5°	AT9056R
	H14mm 5°	AT9057R

Avenue T Instruments, Kit Numbers: ATSET1 and ATSET2

DESCRIPTION	SIZE	PART NUMBER
T-Handle		G10352I
Curette	Right	IG014R
	Left	IG015R
	Straight	IG012R
Nerve Root Retractor	6mm	IR921R or IG038R
	10mm	IR923R or IG039R
Unlocking Threaded Shaft		AT9038R
Revision Threaded Shaft		AT9039R
Removal Handle		AT9037R
Removal Hook		AT9040R
Removal Hook Guide		AT9041R
Narrow Cobb Elevator		AT9042R
Removal Tube		AT9043R
Removal Screwdriver		AT9044R
Slotted Mallet		IG020R
Graft Support (Assembly = Graft Support Base + Graft Support Jaws + Graft Support Knob)		AT9030R
Graft Compactor		AT9031R
Avenue T Cage Holder Assembly (Assembly = Cage Holder + Threaded Rod)		AT9032R
Impactor		AT9033R
Double Impactor		AT9035R
Avenue L In-line Slap Hammer		SI-MULT-0005

IMPORTANT INFORMATION ON THE AVENUE T IMPLANT DEVICE

Device Description

The Avenue T 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 anatomy. In addition, so as to favor bone growth, the Avenue T TLIF Cage must be filled with bone graft.

Indications for Use

The Avenue T TLIF Cage 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 or retrolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The Avenue T TLIF Cage is designed for use with or without integrated fixation and must be used in conjunction with supplemental fixation cleared by FDA for use in the lumbar spine. The device is implanted via a transforaminal approach and intended for use with autograft and/or allogenic bone graft composed of cancellous and/or corticocancellous bone graft to facilitate fusion.

Contraindications

Contraindications include, but are not limited to:

- Patients under treatment inhibiting bone fusion.
- Cardiac problems.
- Abuse of medicine, drugs, tobacco or alcohol (which change the ossification power).
- 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.
- Bony abnormalities or bone stock compromised by disease (such as osteopenia, osteoporosis), infection or prior implantation preventing safe support and/or fixation to the implant.
- Morbid 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.
- Patients having inadequate tissue coverage over the operative site.

- Pregnancy.
- 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 bone tumors, congenital abnormalities, elevation of sedimentation rate unexplained by other diseases.

Warnings

- Potential risks associated with the use of this system, which may require additional surgery, include device component fracture, loss of fixation, non-union, fracture of the vertebra, neurological injury, and vascular or visceral injury.
- Implants damaged in any way that can affect their form or functioning must not be implanted.
- 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.
- Devices cannot withstand activity and loads equal to those placed on normal healthy bone. Until arthrodesis of segment(s) is confirmed, do not subject this device to the stress of heavy loads, or implant failure may result.
- 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 T TLIF Cage system should not be used in conjunction with components from any other manufacturer.
- 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.

- 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 T TLIF 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 T TLIF Cage must be done with the cage holder attached to the cage.
- Do not attempt to reposition the implant after anchoring plates have been deployed into the vertebral endplates.
- As the Avenue T implants must be used with supplemental fixation, close attention should be paid during the insertion of the anchoring plates, in order to limit risk of contact between the anchoring plates and additional spinal hardware (e.g., pedicle screws).
- The Avenue T TLIF Cage system has not been evaluated for safety and compatibility in the MR environment.
- The Avenue T TLIF Cage system has not been evaluated for heating or migration in the MR environment.
- 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, proper reduction, selection and placement of implants, and pre- and post-operative patient management are considerations essential to a successful surgical outcome.
 - Instructions for patient care following treatment should be provided by the surgeon or another medical professional.
- 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. Avenue T implants (cages and anchoring plates) are load-sharing devices which hold a vertebra in alignment until healing occurs. If healing is delayed or does not occur, the implant could eventually break due to material fatigue.
- Risks associated with general surgery by transforaminal approach, orthopedic surgery, and the use of general anesthesia should be explained to the patient prior to surgery.
- 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.

Precautions

- Being a technically demanding procedure presenting a risk of serious injury to the patient, the implantation of intervertebral body fusion 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 T TLIF Cage 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 be so advanced at the time of implantation that they 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.
- 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.
- 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 during plate selection to minimize the possibility of interference with the adjacent plate.
 - 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.
 - If VerteBRIDGE is used in conjunction with pedicle screws, use fluoroscopy to verify the trajectory of the anchoring plates to avoid impingement with pedicle screws.
- Sale of this product is restricted to physicians.

Disclaimer: This document is intended exclusively for physicians and is not intended for laypersons. Information on the products and procedures contained in this document is of a general nature and does not represent and does not constitute medical advice or recommendations. Because this information does not purport to constitute any diagnostic or therapeutic statement with regard to any individual medical case, each patient must be examined and advised individually, and this document does not replace the need for such examination and/or advice in whole or in part.



Caution: Federal (USA) law restricts this device to sale by or on the order of a physician. Rx Only. Please see the product Instructions for Use for a complete listing of the indications, contraindications, precautions, warnings and adverse effects.



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