ChoiceSpine™
Propelling Spinal Surgery

TiGER SHARK™

3D Printed Titanium Interbody

Surgical Technique

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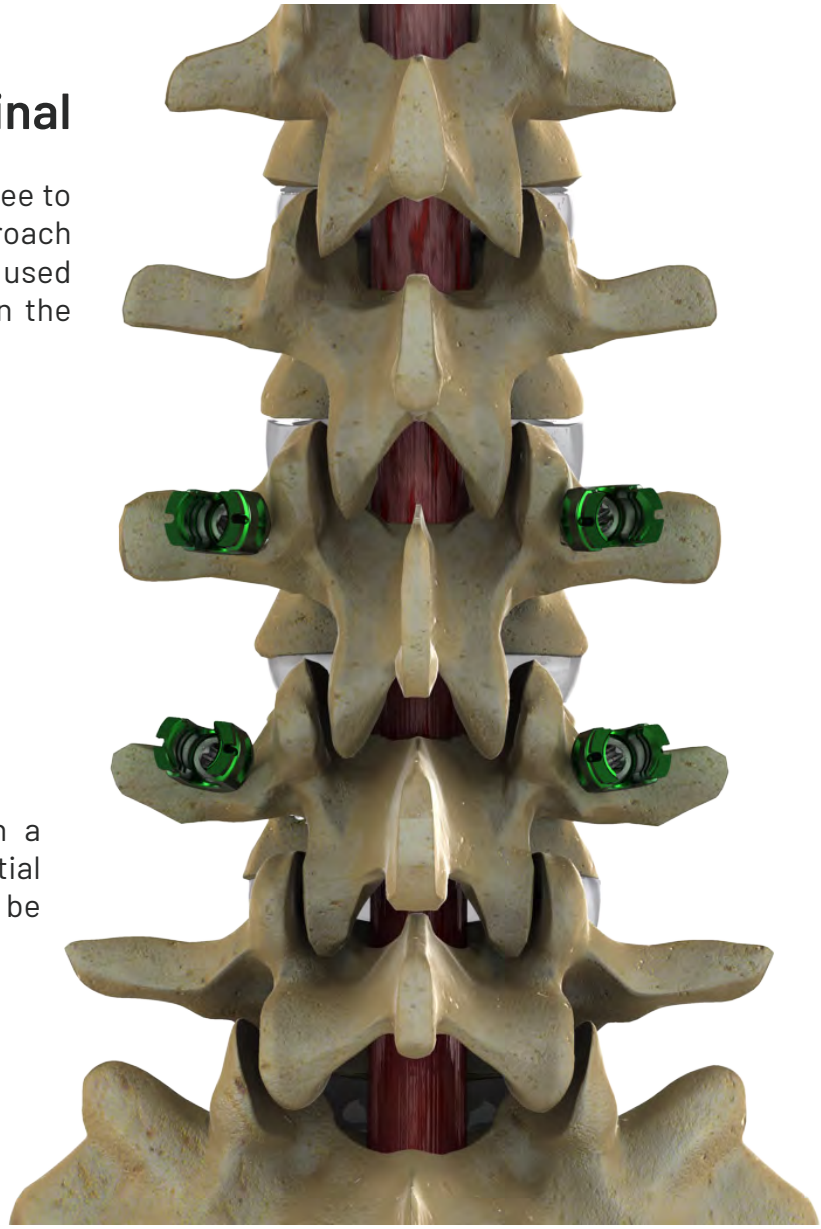
Approach: Posterior/Transforaminal

The patient is placed on the operating table in the knee to chest position or in prone position. Incision and approach are performed. The TiGER SHARK System must be used with supplemental fixation that is cleared for use in the lumbar spine.

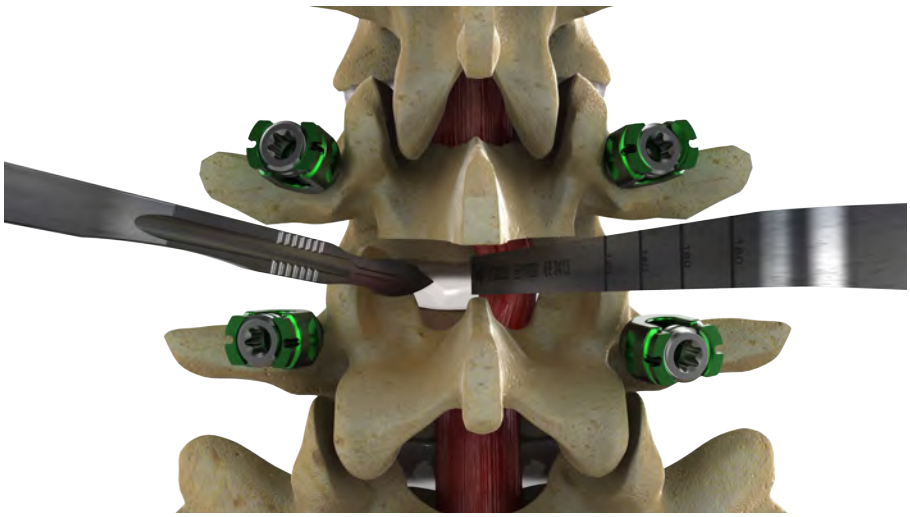


Dura and Disc Exposure

Exposure of the dura and disc is performed with a unilateral or bilateral hemilaminectomy and partial facetectomy. At this stage, the nerve roots can be decompressed before the following steps.

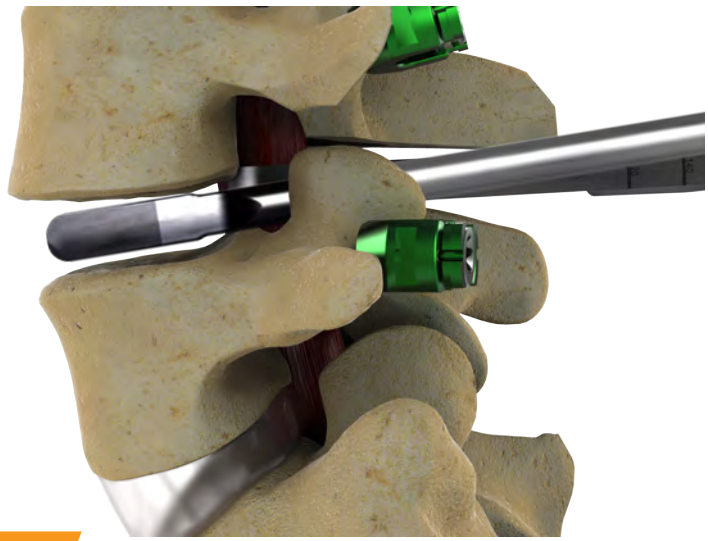
Discectomy

The nerve root retractor is inserted to protect the dura and nerve roots. Incision of the disc is then performed and the window is opened with a pituitary rongeur. A complete discectomy is not possible at this stage since the disc space has not yet been distracted.



Distraction and Discectomy

Distraction consists of the opening of the disc space to restore the height of the interbody space and insertion of the cage(s). Distraction starts with the paddle starter which is inserted flat in the disc space and rotated. Impaction can be performed to facilitate its insertion.

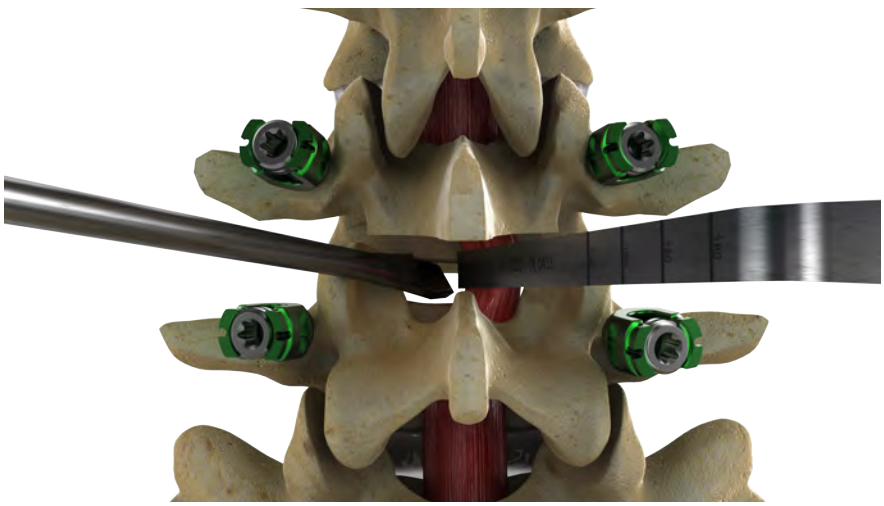


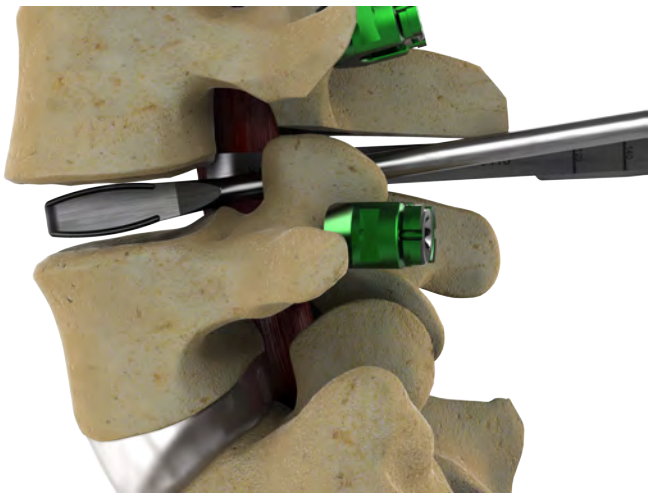
Reaming

A paddle shaver can be inserted flat into the disc space. Rotation of the paddle shaver is carried out to remove a great volume of disc fragments. Remaining disc fragments are then removed from the disc space with a pituitary rongeur.

Progressive Distraction and Discectomy

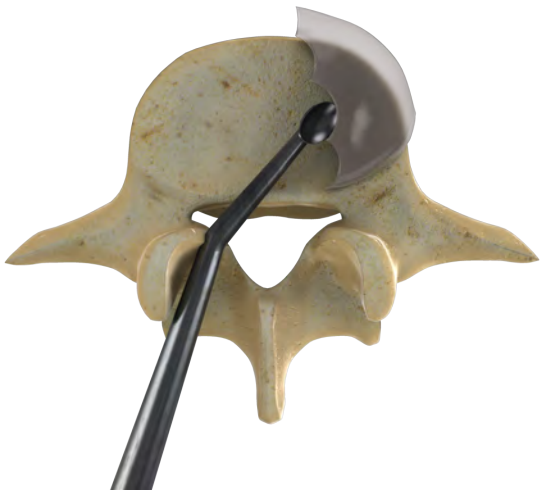
Distraction may continue with the paddle starter until adequate distraction is obtained. Care must be taken to avoid over-distraction. The paddle shavers are inserted, depending on the height obtained, to remove remaining disc material.

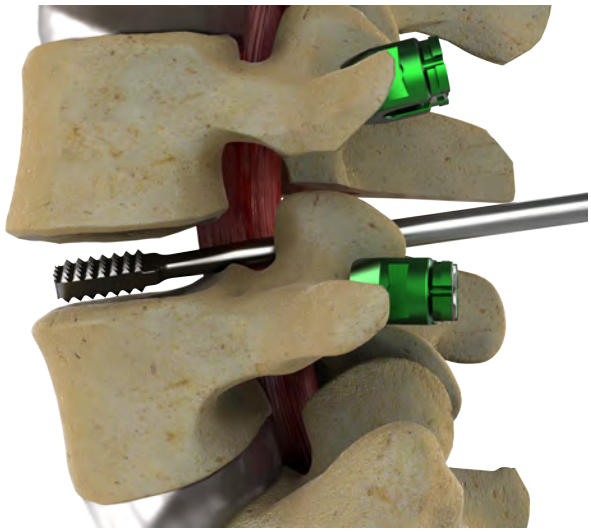




Scraping of the Endplates

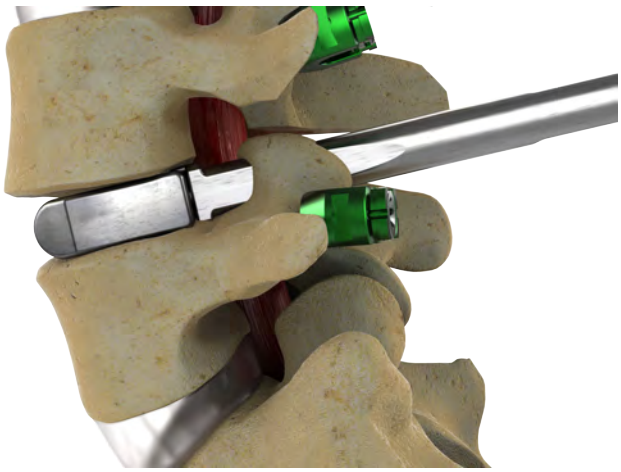
Soft tissues and cartilaginous endplate coverings are removed with the rasp or cup curettes. Scraping of lower and upper endplates can be performed in a single maneuver with the rasp.

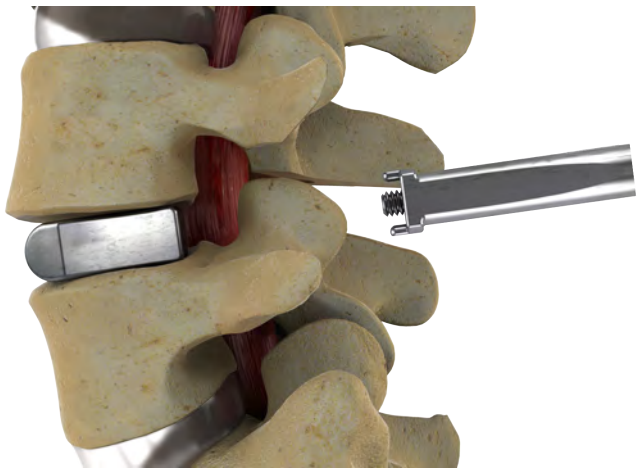




Preservation of the Distraction

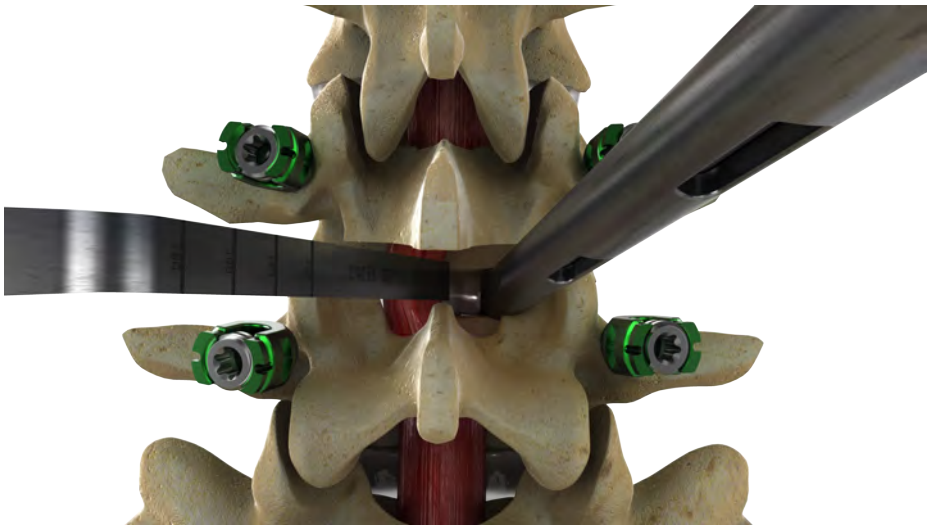
To maintain the disc height during the insertion of a bilateral cage on the opposite side, a trial is inserted in the interbody space with the cage inserter. Distraction is performed and the cage inserter is removed.





Preparation of the Opposite Side

For a bilateral PLIF, the previously described preperation steps are performed on the opposite side.

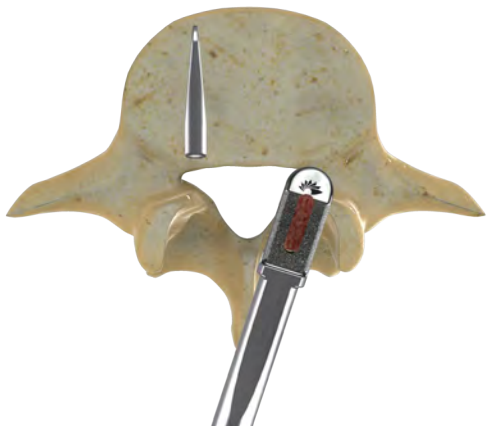


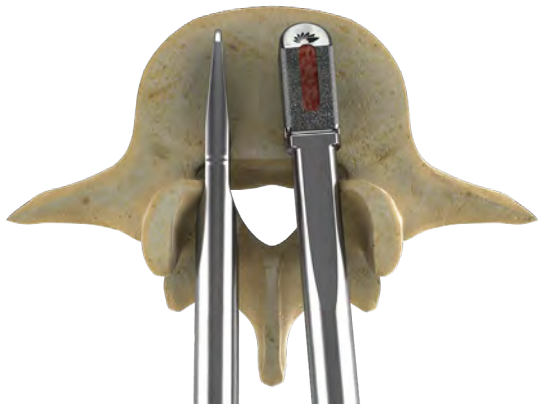
Cage Preparation

The cage is attached to the inserter by mating the posts on the distal end of the inserter with the corresponding implant features. The inserter drawrod is then threaded into the implant until the instrument and implant are flush with one another. This is repeated for the second implant of a bilateral PLIF. The cage is then carefully filled with grafting materials (autogenous and/or allogeneic bone).

Cage Insertion

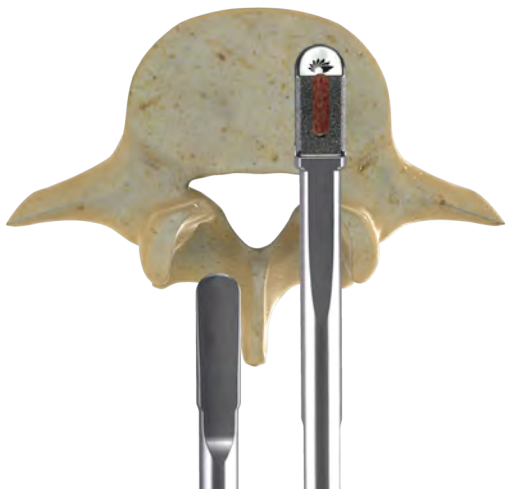
To insert the cage, the cage inserter must be inclined medially. Thus the round tip of the cage will be positioned facing the entry point. During impaction, a straightening movement of the cage inserter is necessary to insert the cage laterally. In the final position, the shaft of the inserter is in contact with the facet.

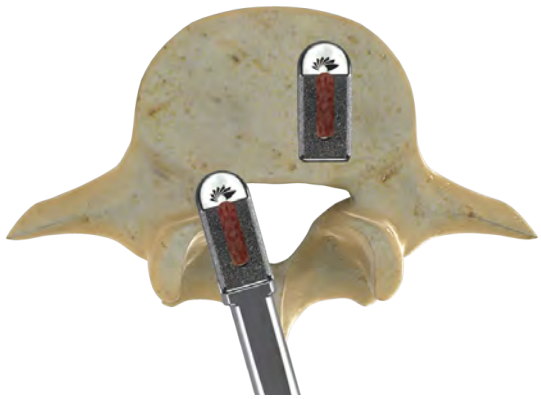




Second Cage Insertion

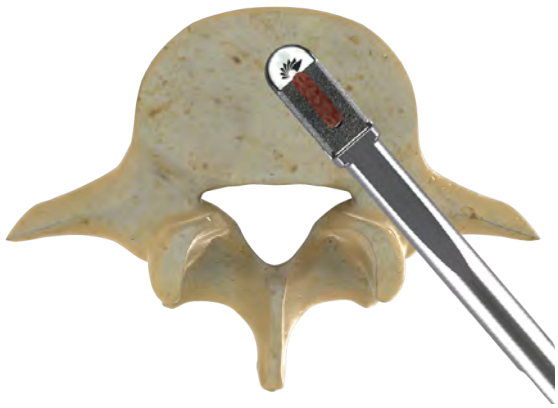
For a bilateral PLIF, the paddle distractor or trial is removed on the opposite side. The second cage is inserted in the same manner as the first.



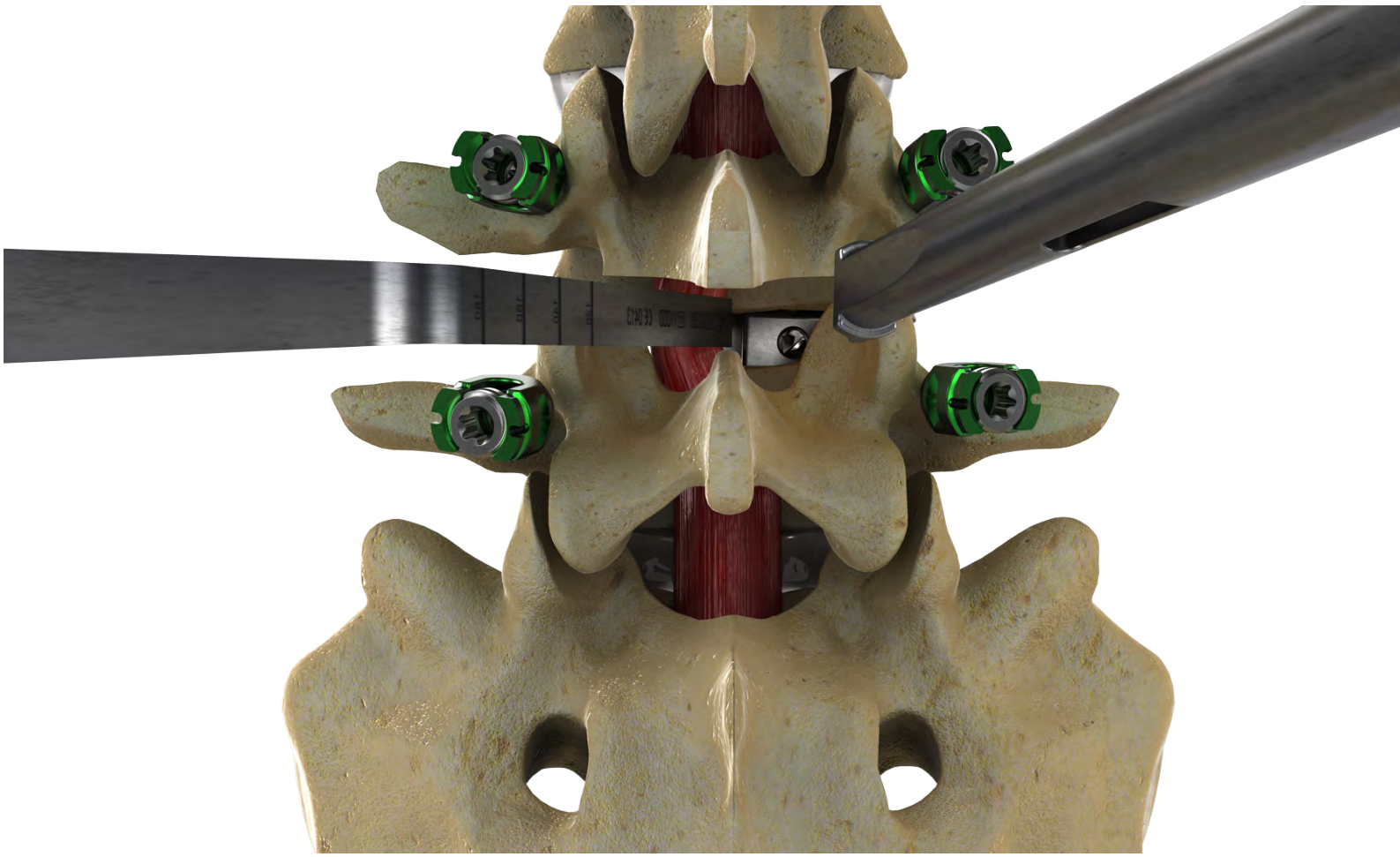


TLIF Cage Insertion

For transforaminal cage insertion, angle the inserter laterally from the midline in an oblique trajectory and impact cage inserter.

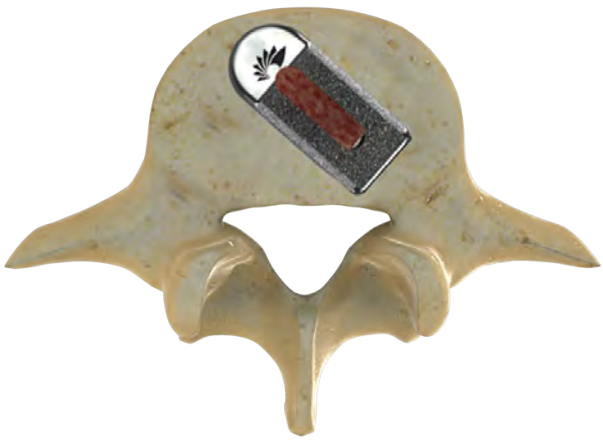


A counterclockwise rotation of the inserter drawrod is performed to remove the inserter from the implant.

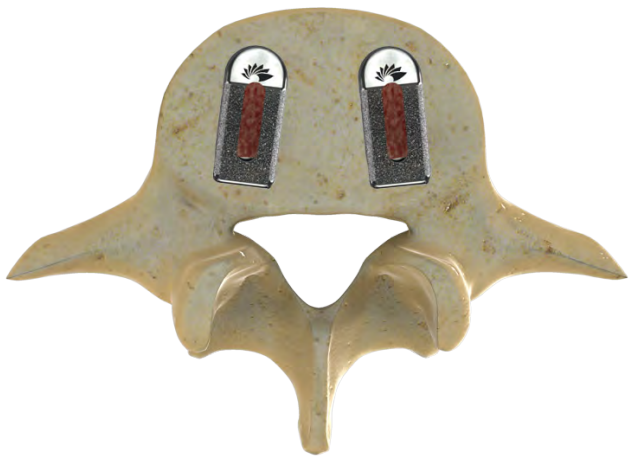


Implant Confirmation

Proper insertion of the implant is verified via AP and lateral fluoroscopy. These images should be reviewed before the surgery is concluded. If the depth of the implant needs to be adjusted in the space, the insertion instrument can be used again, as can the tamp.



TLIF



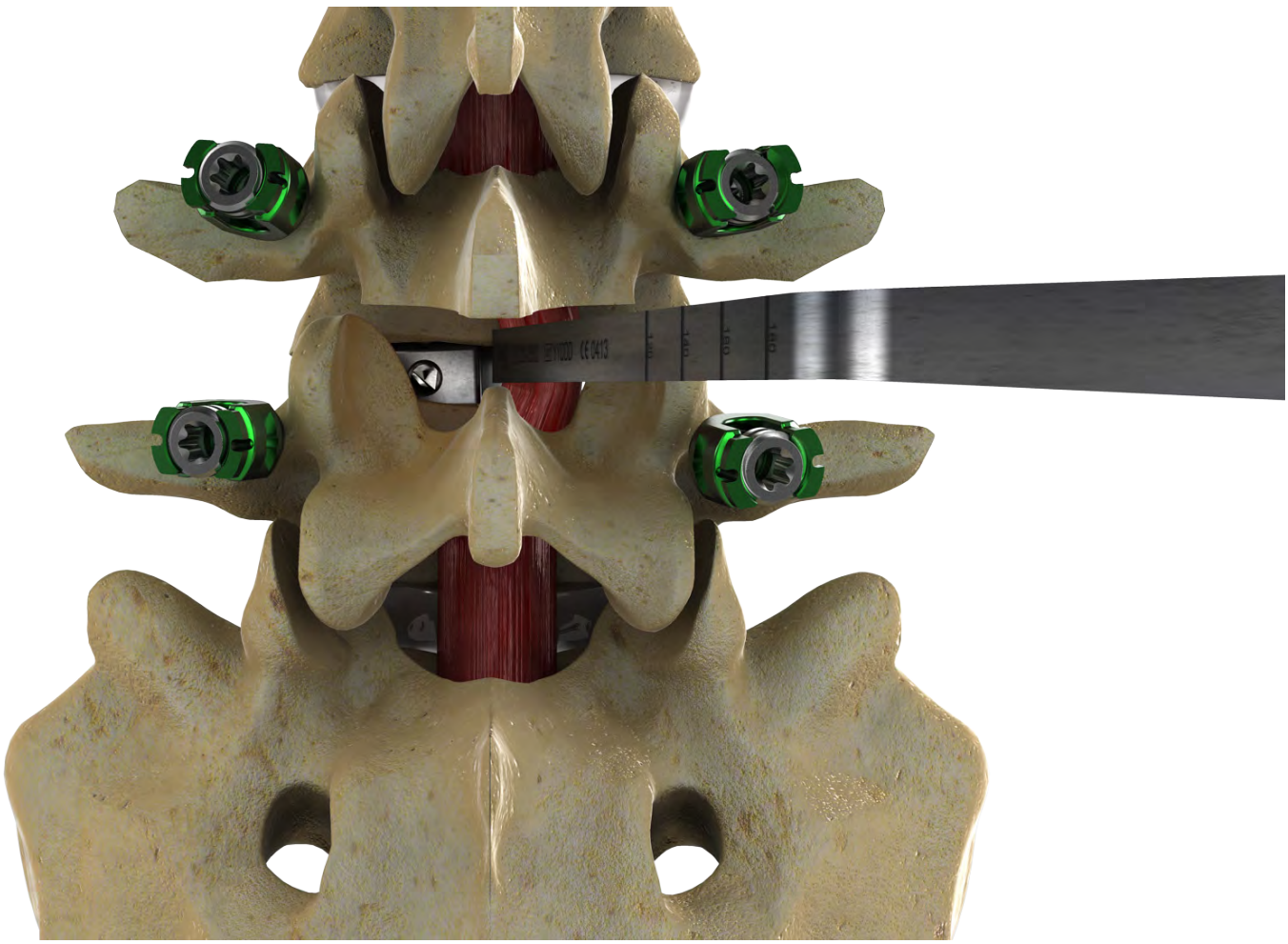
PLIF

Final Checking and Completion of the Posterior Fixation

Implant position can be confirmed using X-ray. Posterior fixation is completed to provide adequate stability to the segment.

Removal

To remove the implant thread the implant onto the inserter until fully seated by rotating the center rod clockwise. The prongs on the end of the inserter should be captured in the pockets on each side of the implant. The slaphammer works in conjunction with the inserter to assist in the removal of implants. Place the slot of the slaphammer over the inserter shaft, slide the slaphammer along the inserter shaft and strike the shoulder of the proximal end of the inserter.



Approach: Lateral

Access, Discectomy & Endplate Preparation

- Use the Veo™ Lateral Access System to expose the disc
- Incise the annulus and perform an annulotomy with a scalpel or bovie.
- Use a Rongeur or other instrumentation to start the discectomy.
- Connect the Paddle Shaver to the Quick-Connect T-Handle by pulling the T-Handle collar up toward the handle. With the collar up, insert the Shaver and release the collar. Ensure the instrument is fully seated before use by gently pulling down on it.
- Under A/P fluoroscopy, insert a Paddle Shaver or Cobb Elevator across the disc space, parallel to the endplates.
- Gently release the contralateral annulus.
- Perform the discectomy and endplate preparation. A variety of instruments, which may include Cup Curettes, Ring Curettes, Rongeurs, Osteotome, Rasps or other appropriate discectomy tools may be used.
- Use the laser etched lines along with the green, yellow, and red markings to maintain consistent depth throughout the procedure.

NOTE:

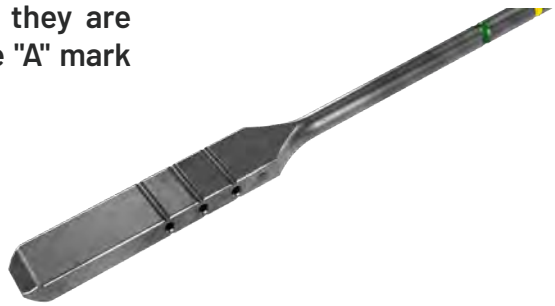
- **Take care when passing sharp instrumentation through the psoas muscle.**
- **Discectomy and endplate preparation surgical technique will vary by Surgeon.**
- **Paddle Shavers may also be used to determine the approximate disc height and length for trial and cage placement.**
- **The holes in the shaver demarkate disc length, starting at the distal end at 40mm and increase by 5mm to 60mm.**

Implant Measurement

- Interbody Trials are available to measure the height, width, and length of the disc space so the appropriate interbody cage can be selected.
- Insert the Interbody Trial into the disc space.
- Using a mallet as needed, gently advance the Interbody Trial into the disc space until the tip of the Interbody Trial is at the contralateral edge of the vertebral body.
- Take a lateral fluoroscopic image to confirm placement of the Interbody Trial.
- The Interbody Trials contain grooves and holes to fluoroscopically determine the length of the disc space. The groove and hole closest to the tip denotes the length of a 40mm long Interbody Cage. The remaining grooves are 10mm apart and denote the available lengths of Interbody Cages up to 60mm in length.
- Attach the Reverse Slap Hammer by sliding the catch of the Reverse Slap Hammer under the quick-connect of the Interbody Trial, and then remove the Interbody Trial.

NOTE:

- **When using the Lordotic Interbody Trials, ensure they are inserted properly by utilizing the markings with the "A" mark facing anterior and the "P" mark facing posterior.**



Interbody Cage Insertion

- Select the desired Interbody Cage.
- Rotate the Inserter Knob counterclockwise and place the Inserter Collar in the unlocked position.
- Place the Interbody Cage on the Inserter and rotate the Inserter Collar into the locked position.
- Rotate the Inserter Knob clockwise until the Interbody Cage is secured .
- Pack graft material into the reservoir of the Interbody Cage and insert into the disc space.
- Take A/P and lateral fluoroscopic images to verify placement prior to releasing the Cage Inserter from the Interbody Cage.
- To release the Interbody Cage from the Inserter, rotate the Inserter Knob counterclockwise until it stops.
- Rotate the Inserter Collar to the unlocked position and rotate the Inserter Knob clockwise while in the unlocked position, then remove the Inserter.

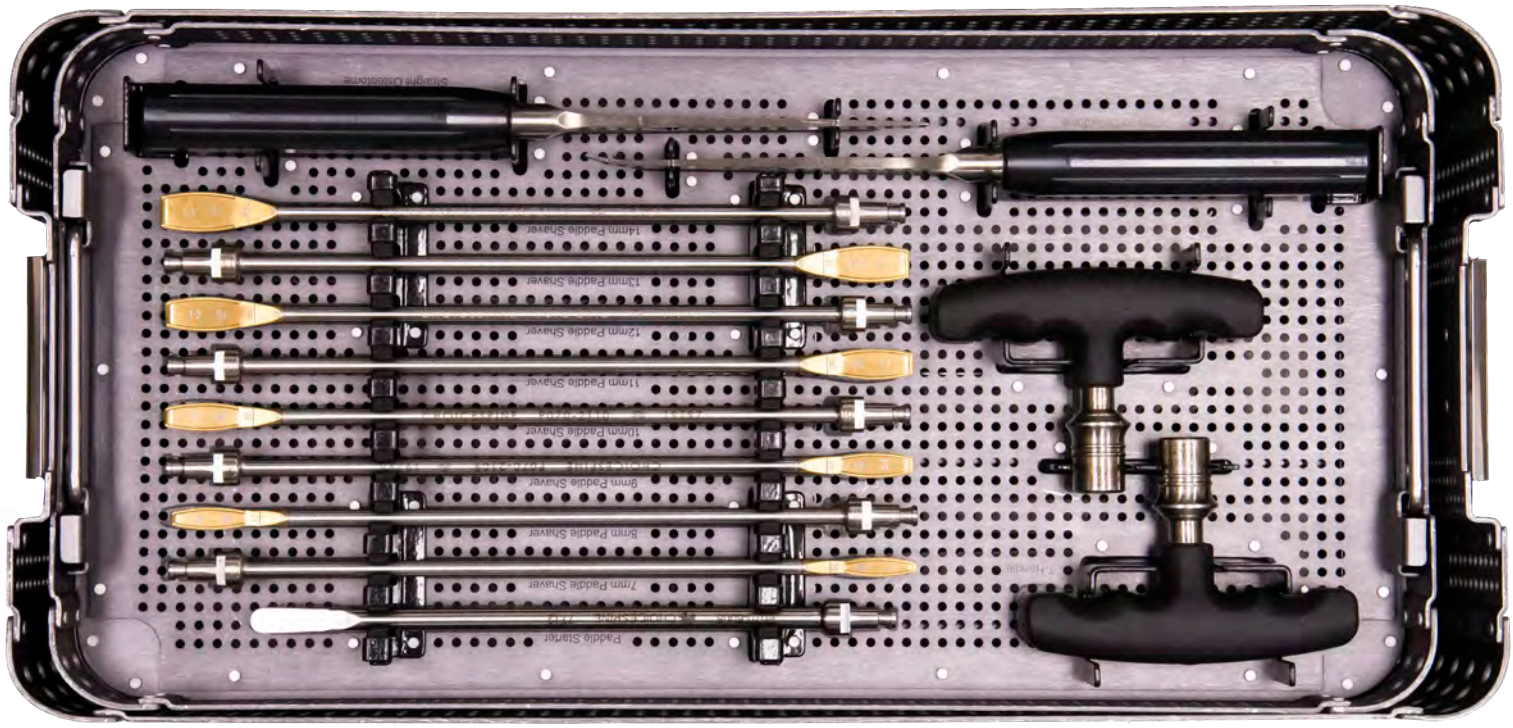
TiGER SHARK Straight

P070-2107	7 PADDLE SHAVER
P070-2108	8 PADDLE SHAVER
P070-2109	9 PADDLE SHAVER
P070-2110	10 PADDLE SHAVER
P070-2111	11 PADDLE SHAVER
P070-2112	12 PADDLE SHAVER
P070-2113	13 PADDLE SHAVER
P070-2114	14 PADDLE SHAVER
P070-6003	QUICK CONNECT T-HANDLE
P070-6006	STRAIGHT RASP
P070-6007	ANGLED RASP
P070-6008	PADDLE STARTER
P070-6009	STRAIGHT OSTEOTOME
P070-6010	CURVED OSTEOTOME
P070-6012	5 STRAIGHT RONGEUR
P070-6013	5 UPBITING RONGEUR
P070-6014	5 DOWNBITING RONGEUR
P070-6015	#4 STRAIGHT CUP CURETTE
P070-6016	#6 STRAIGHT CUP CURETTE
P070-6017	#4 ANGLED CUP CURETTE

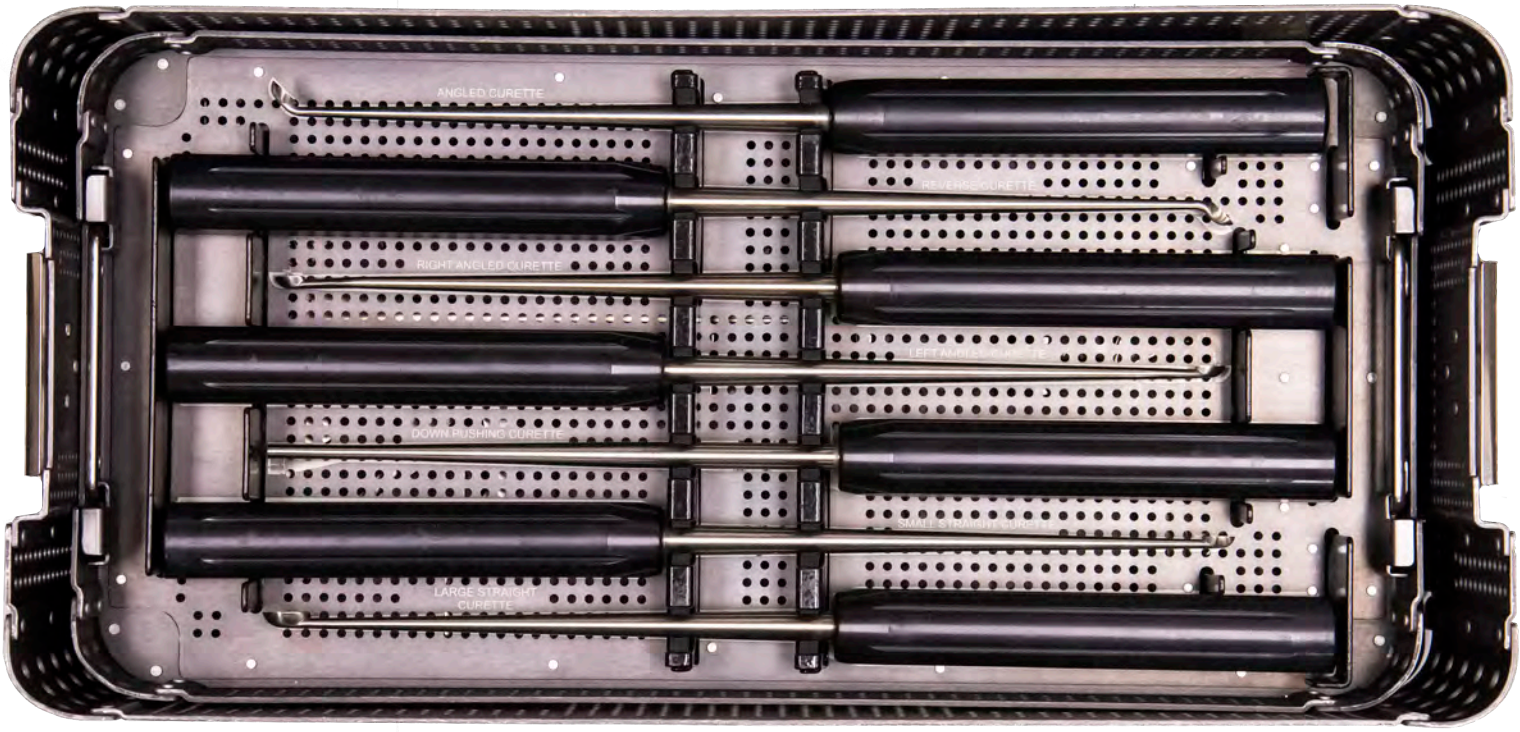
P070-6018	#4 RIGHT ANGLE CUP CURETTE
P070-6019	#4 LEFT ANGLE CUP CURETTE
P070-6020	#4 REVERSE CUP CURETTE
P070-6021	DOWN PUSHING CUP CURETTE
P070-6022	MULTI-TOOL
P070-6023	STRAIGHT TAMP
P070-6024	ANGLED TAMP
P070-6031	SLAPHAMMER
P070-6049	2 PIECE PISTOL INSERTER
P070-6005	HEX WRENCH
P070-6029	PISTOL INSERTER
P070-4220	T-HANDLE INSERTER

Please refer to the Veo™ Lateral System surgical technique guide for complete list of instrumentation needed to complete TiGER SHARK Lateral surgical approach.

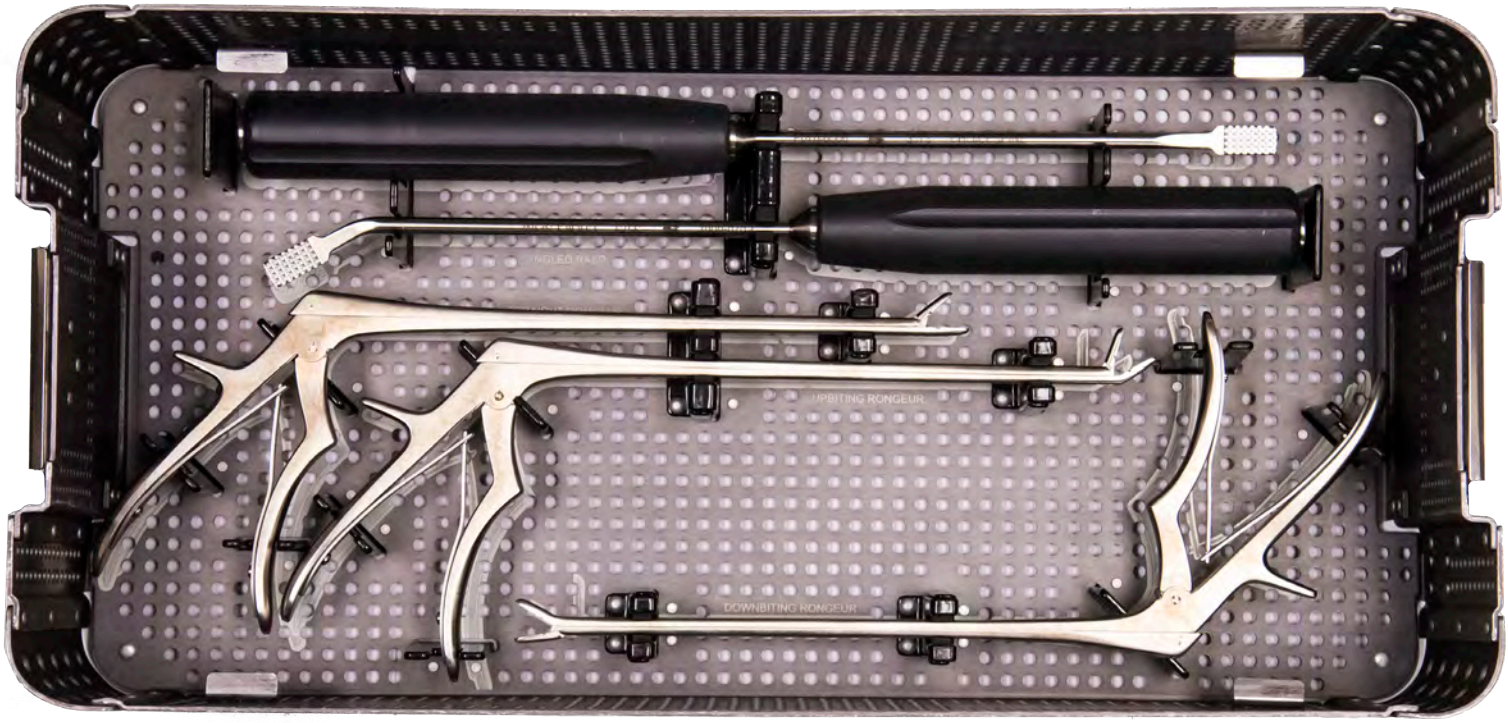
Posterior Lumbar Discetomy Top Tray



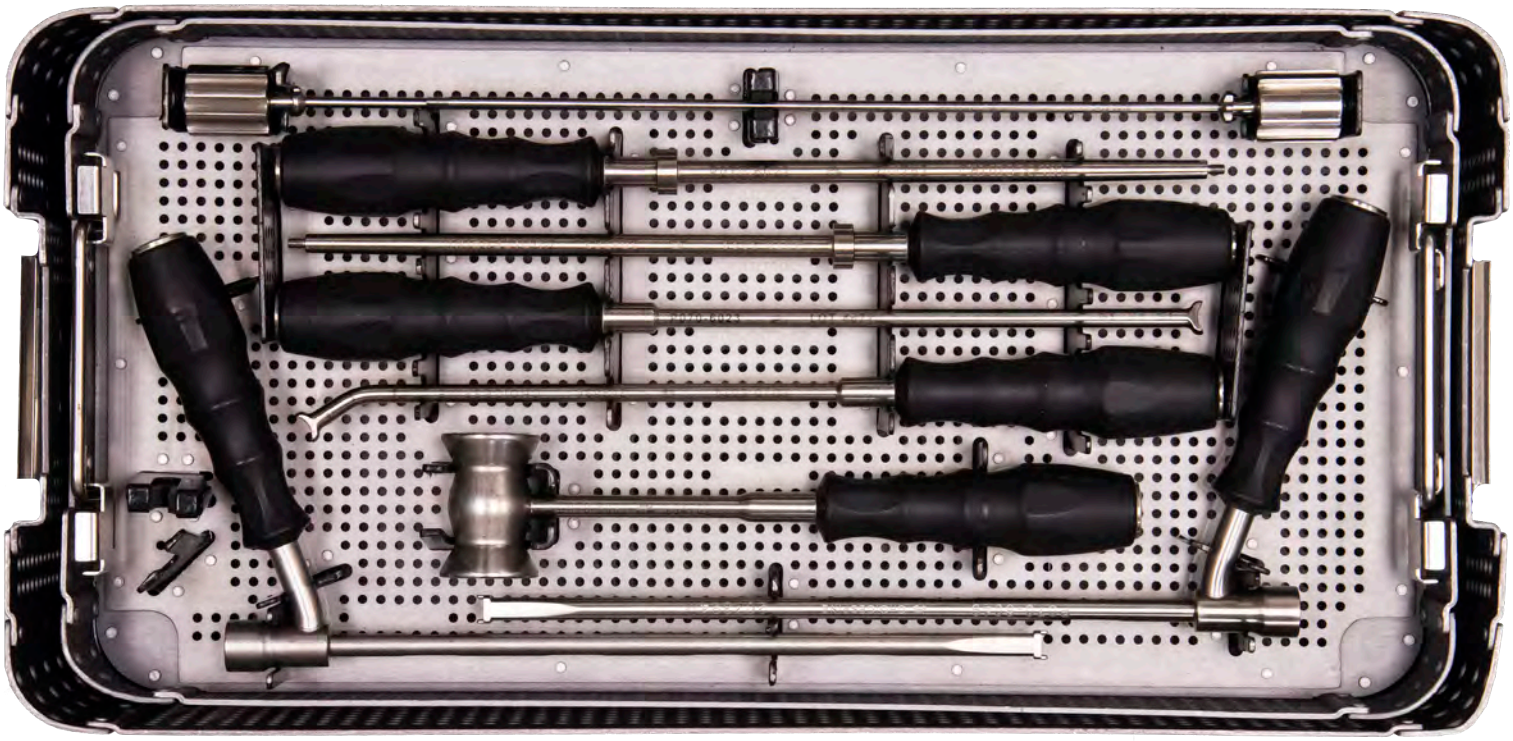
Posterior Lumbar Discetomy Middle Tray



Posterior Lumbar Discetomy Bottom Tray



Posterior Lumbar Interbody Insertion Tray



General Description

The Choice Spine TiGER SHARK Interbody Fusion System consists of implants made of titanium alloy (Ti-6Al-4V ELI per ASTM F3001, Class C). The spacers have a basic rectangle shape, a hollow center for placement of bone graft and a smooth bullet shaped distal surface. They are available in an assortment of height, length and anteroposterior angulation combinations to accommodate many different anatomic requirements. The implants are delivered via a posterior, transforaminal, or lateral approach. The devices are manufactured using the Electron Beam Melting (EBM) additive manufacturing method.

Indications for Use

The Choice Spine TiGER SHARK Interbody Fusion System is indicated for spinal procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These patients should have six (6) months of non-operative treatment. This device is designed to be used with autogenous bone graft and/or allogenic bone graft comprised of cancellous and/or cortico-cancellous bone graft. This device is designed for use with supplemental fixation that is cleared for use in the lumbar spine.

Contraindications

Contraindications for the TiGER SHARK Interbody Fusion System are similar to those of other systems of similar design, and include, but are not limited to:

- Active infectious process in the patient, particularly in or adjacent to the spine or spinal structures
- Conditions, such as morbid obesity, which may put excessive stress on the bone and implants
- Severe osteopenia or osteoporosis may prevent adequate fixation
- Suspected or documented metal allergy
- Use of these implants is relatively contraindicated in patients whose activity, mental capacity, mental illness, alcohol or drug abuse, occupation or life-style may interfere with their ability to follow post-operative instructions
- Pregnancy

Warnings

- Mixing of dissimilar metals can accelerate the corrosion process. Stainless steel and titanium implants must NOT be used together in building a construct.
- A satisfactory outcome is enhanced by the selection of the appropriate device size and angle.
- The TiGER SHARK Interbody Fusion System has not been evaluated for safety and compatibility in MR environment. It has not been tested for heating and migration in the MR environment.

Precautions

- The TiGER SHARK Interbody Fusion System should only be implanted by surgeons who are fully experienced in the use of such implants and the required specialized spinal surgery techniques.
- The implants should not be reused, even if they appear in a perfect state. Any implant that has been used, twisted, bent, implanted and then removed, even if it appears intact, must be discarded.
- The TiGER SHARK Interbody Fusion System is used to augment the development of a spinal fusion by providing temporary stabilization. This device is not intended to be the sole means of spinal support – supplemental internal fixation must be used. Bone grafting must be part of the spinal fusion procedure. If fusion is delayed or does not occur, material fatigue may cause breakage of the implant. Damage to the implant during surgery (i.e., scratches, notches) and loads from weight bearing and activity will affect the implant's longevity.
- Refrain from handling the TiGER SHARK Interbody Fusion System as much as possible before implantation and always with the utmost care. The spacers (in their original packaging) must be stored with care in a clean and dry place away from radiation or extreme temperatures. Should these requirements not be followed, reduced mechanical properties may occur which could lead to implant failure in some cases.

Potential Complications and Adverse Effects

Potential complications and adverse effects for this system are similar to those of other spinal instrumentation systems, and include, but are not limited to:

- Early or late loosening of the components
- Disassembly, bending or breakage of any or all of the components
- Foreign body (allergic) reaction to the implants
- Infection
- Loss of neurological function, including paralysis, spinal cord impingement or damage
- Dural tears, CSF leak or fistula or meningitis
- Bone graft donor complications including pain, fracture or wound healing problems
- Vascular damage resulting in excessive bleeding and displaced devices adjacent to large vessels could cause vessel erosion and catastrophic bleeding
- Loss or impairment of bowel, sexual, and/or bladder function and other types of urological compromise
- Possible local or systemic adverse reactions from potential long-term degradation of the polymer or mechanical grinding causing wear debris
- Bone loss due to resorption or stress shielding
- Death

Additional surgery may be necessary to correct some of these potential adverse effects.

Notes

Notes

Notes

ChoiceSpine™

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Lit# Tiger Shark STG
Rev 00
4/18

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