ChoiceSpine™
Propelling Spinal Surgery

TIGER SHARK™ TL Surgical Technique

3D Printed Titanium Passive Steerable Interbody

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Approach: Transforaminal

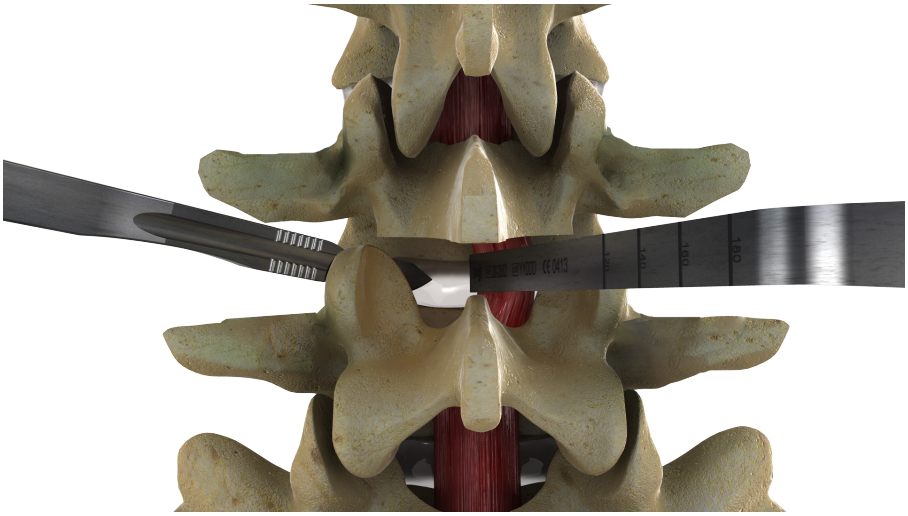
The patient is placed on the operating table in the knee to chest position or in prone position. Incision and approach are performed. The TiGER SHARK TL System must be used with supplemental fixation that is cleared for use in the lumbar spine.

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.

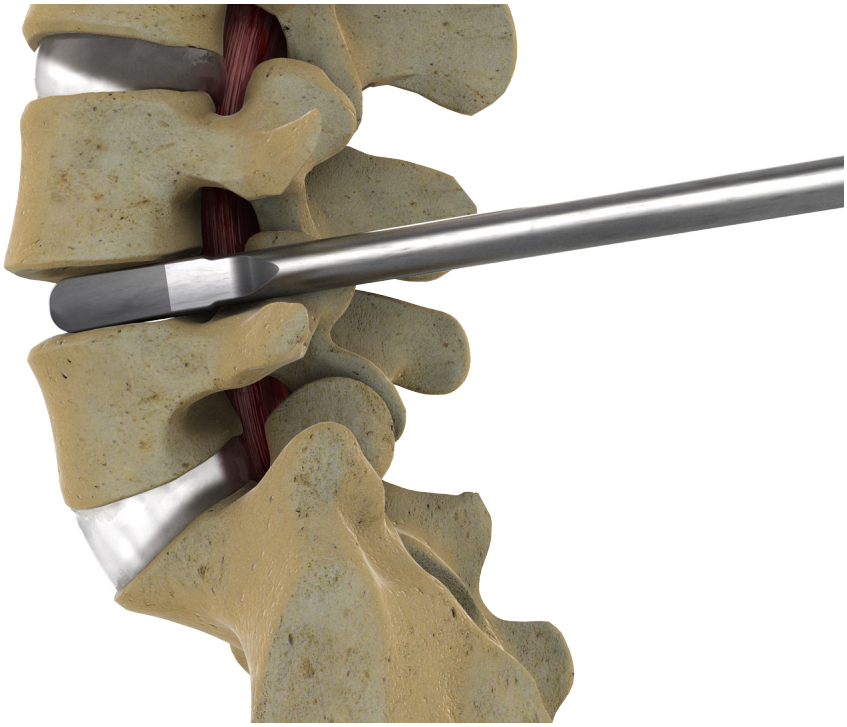
Discectomy

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.

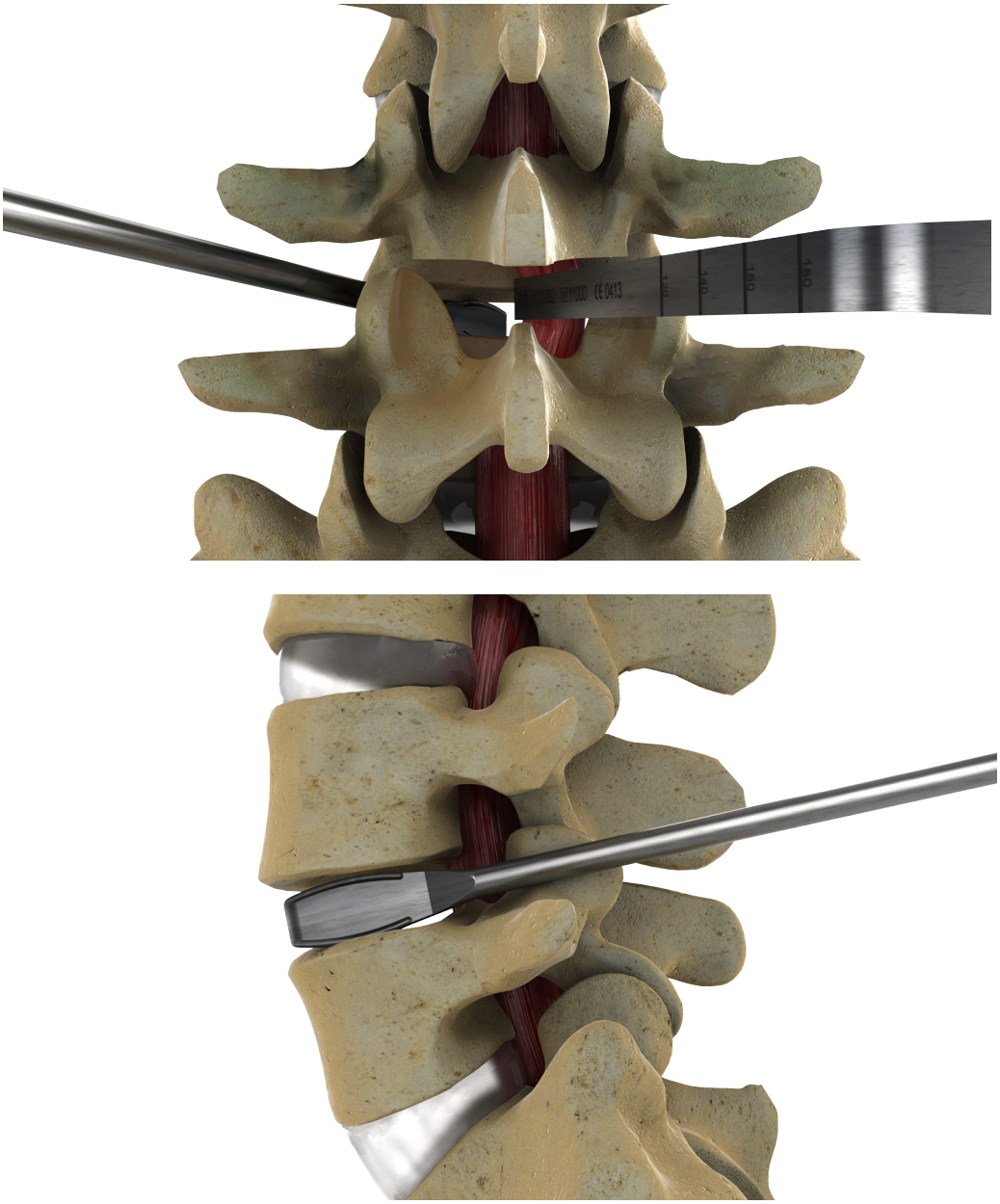


Reaming

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.

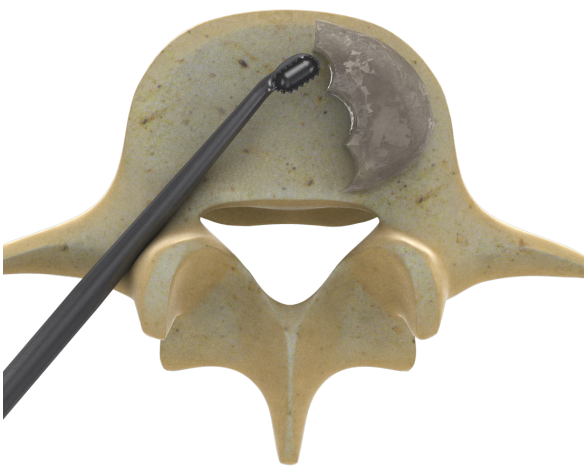
Progressive Distraction and Discectomy

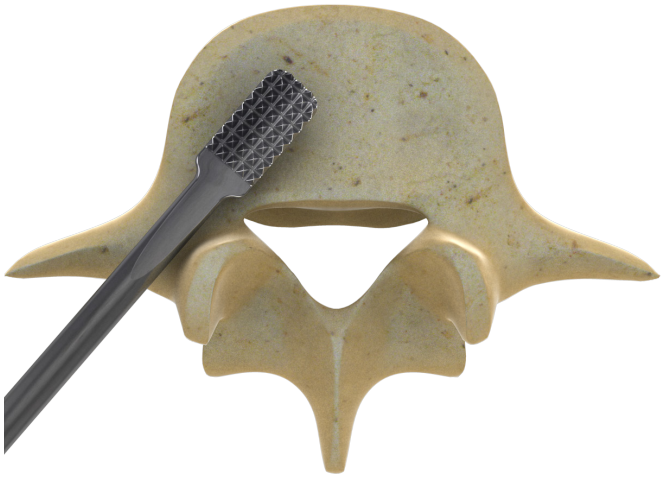
Distraction may continue with the paddle starter until adequate distraction is obtained. Care must be taken to avoid over-distraction. The paddle shavers are inserted, depending on the height obtained, to remove remaining disc material.



Scraping of the Endplates

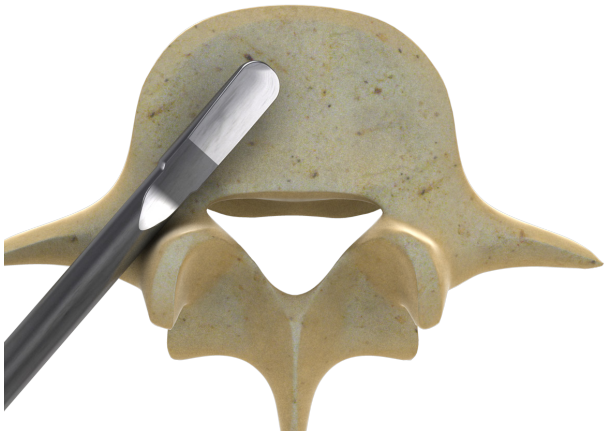
Soft tissues and cartilaginous endplate coverings are removed with the rasp or cup curettes. Scraping of lower and upper endplates can be performed in a single maneuver with the rasp.

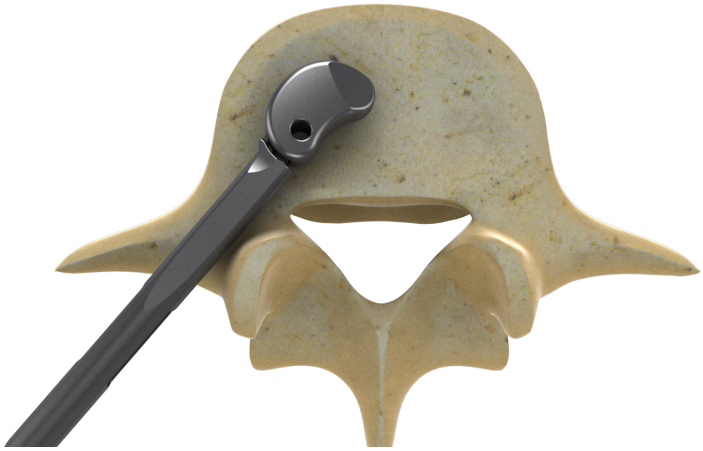




Implant Sizing

Choose the appropriate trial spacer and insert it into the intervertebral space in order to determine the correct size implant. Fluoroscopy can be used to determine the trial fit if necessary.





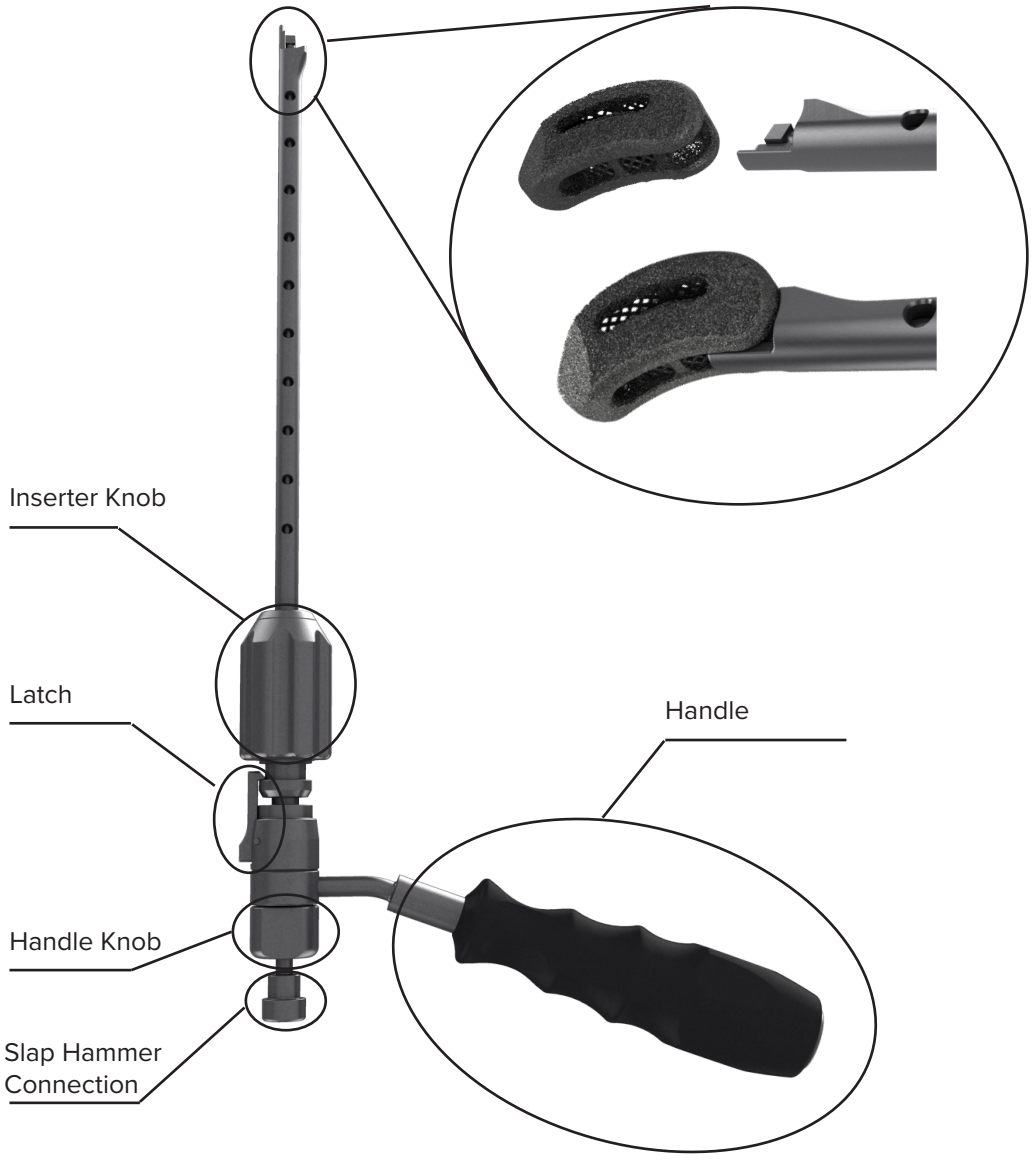
Handle Preparation

The handle is adjustable by turning the handle knob counterclockwise and moving the handle to the desired location. Once the handle is in the desired location using any type of pliers found in surgery tighten handle knob clockwise.

WARNING: If handle is not tightened properly, it can become loose during impaction.

Cage Preparation

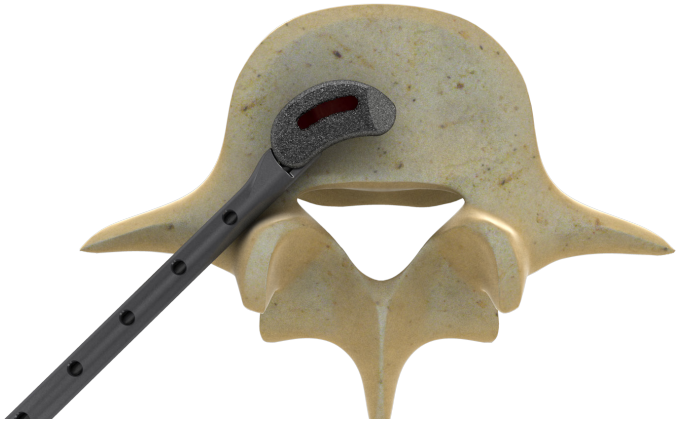
The cage is attached to the inserter by mating the posts on the distal end of the inserter with the corresponding implant features. Rotate inserter knob clockwise until the instrument and implant are flush with one another. The latch will need to fall within the designated area in the inserter knob for a final lock position between the cage and inserter. The cage is then carefully filled with grafting materials (autogenous and/or allogeneic bone).



Implant Positioning

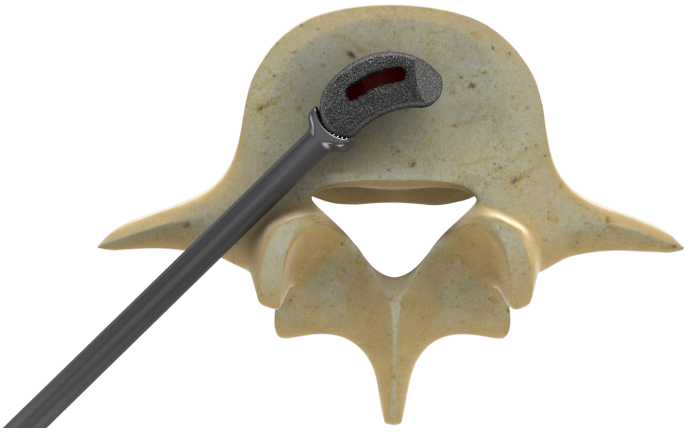
Insert implant into the disc space with the latch lock engaged.

Disengage the lock by pressing down on the latch button. Rotate the inserter knob counterclockwise until the knob reaches the “TAMP” lasermark. The inserter is now connected to the implant, allowing the implant to passively articulate. Use the inserter to begin advancing the implant into the disc space.



To disconnect the implant from the inserter, rotate the inserter knob to the “OPEN” mark.

Advancing the implant into the final position can also be accomplished by either the inserter or using the straight or angled impaction tools. Gently tap the implant into the desired position using instrument.



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, insert the implant onto the inserter. Rotate the Inserter knob clockwise to the “TAMP” location. Attach the Slaphammer to the connection piece on the inserter. Using the Slaphammer impaction forces to remove the implant.

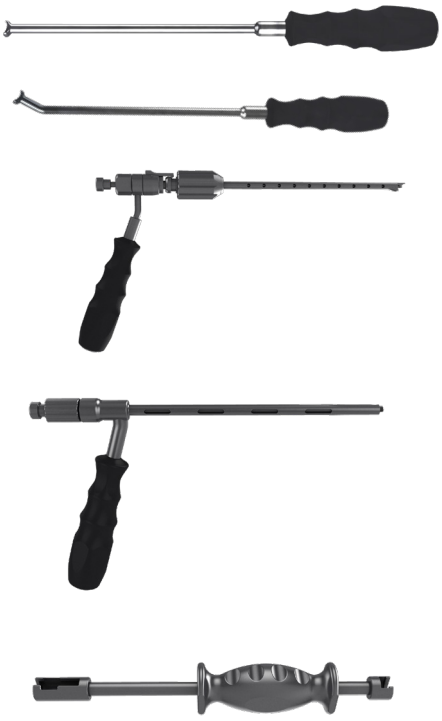
TiGER SHARK Posterior Lumbar Discectomy Set

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

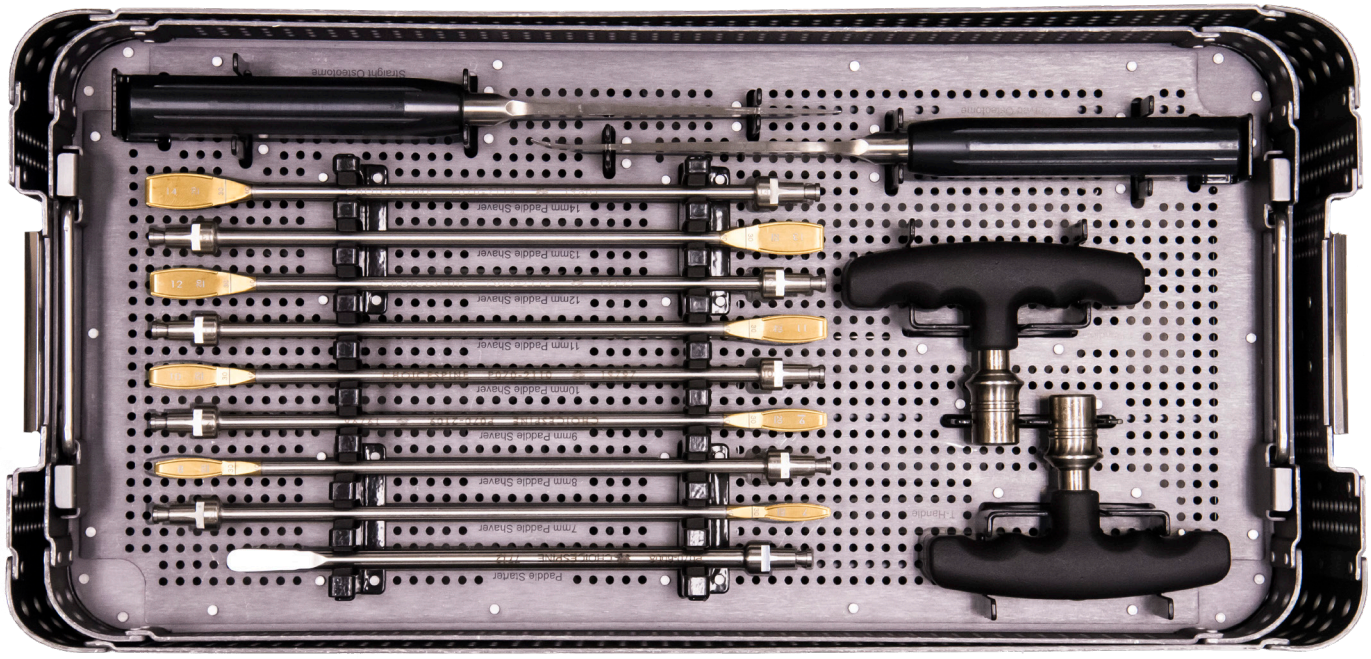
P070-6018	#4 RIGHT ANGLE CUP CURETTE
P070-6019	#4 LEFT ANGLE CUP CURETTE
P070-6020	#4 REVERSE CUP CURETTE
P070-6021	DOWN PUSHING CUP CURETTE

TiGER SHARK TL Instrument Set

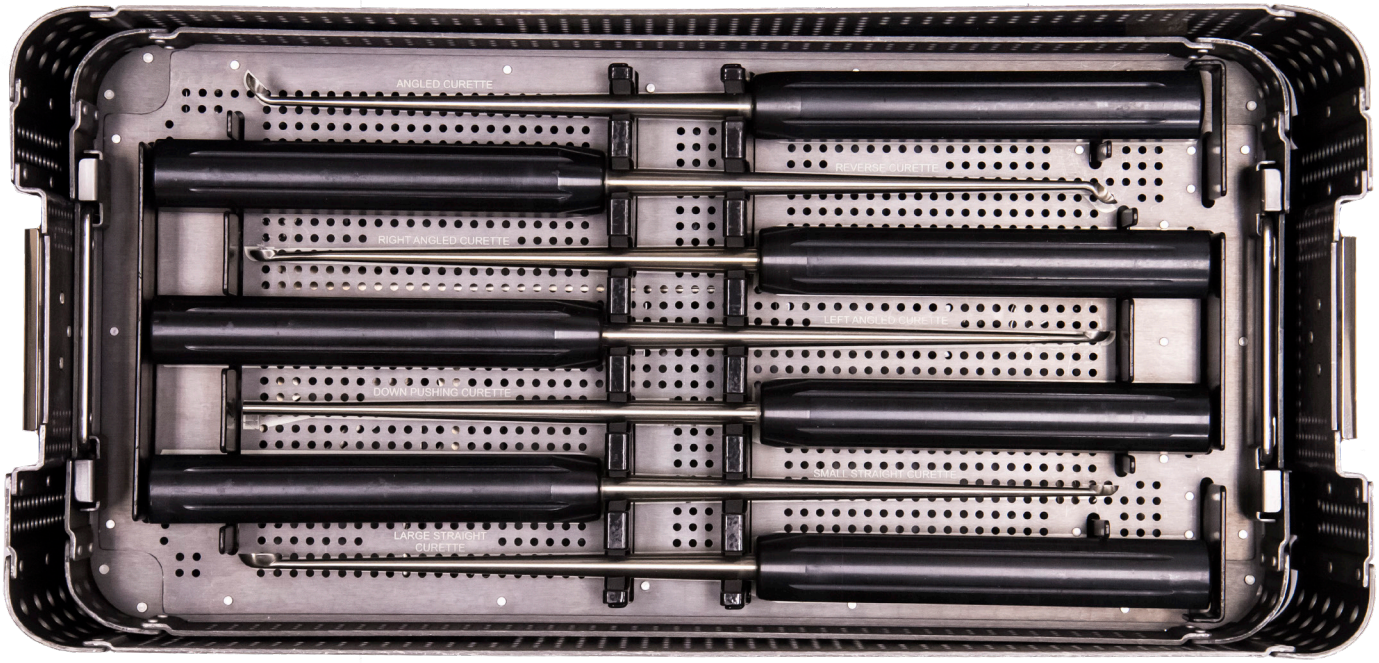
P070-6023	STRAIGHT TAMP
P070-6024	ANGLED TAMP
P070-6063	PISTOL INSERTER
P070-1000	TRIAL INSERTER
V070-0004	SLAP HAMMER
P070-24XXXX	24MM TRIALS
P070-28XXXX	28MM TRIALS
P070-32XXXX	32MM TRIALS



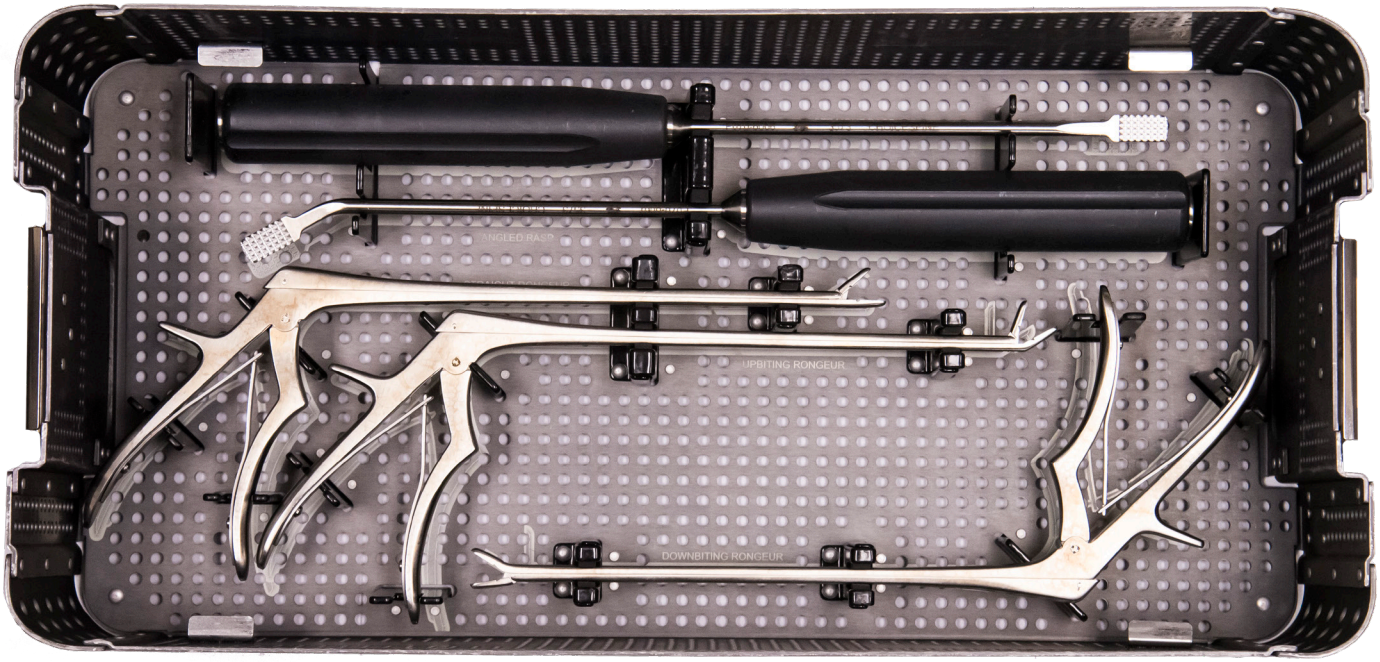
Posterior Lumbar Discectomy Top Tray



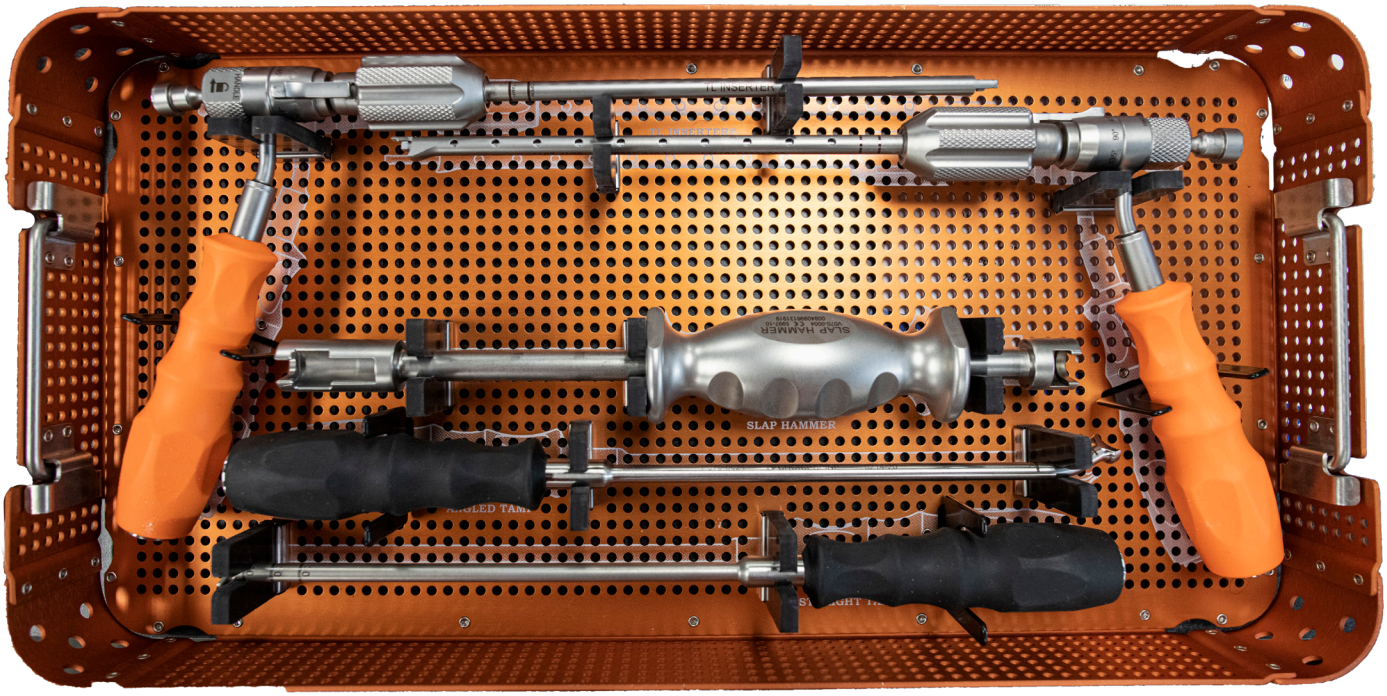
Posterior Lumbar Discectomy Middle Tray



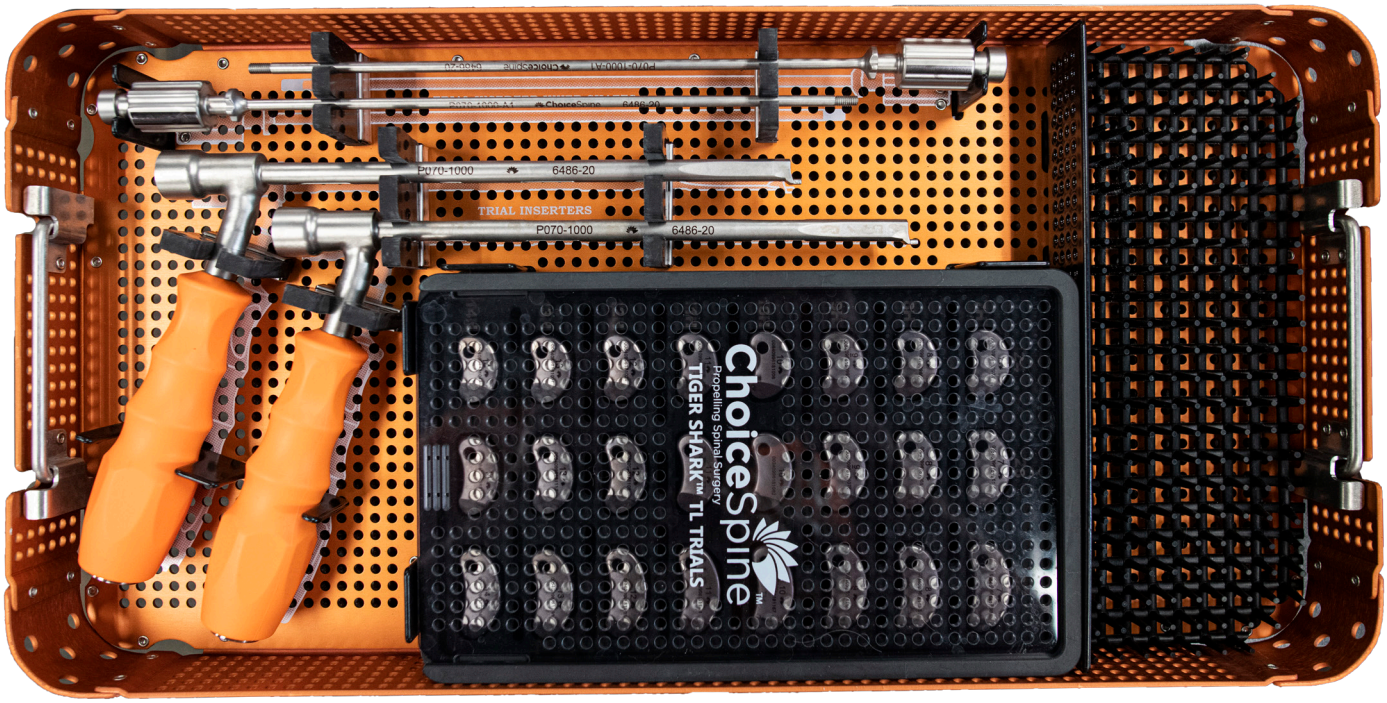
Posterior Lumbar Discectomy Bottom Tray



Tiger Shark TL Top Tray



Tiger Shark TL Bottom 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

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LIT# Tiger Shark TL STG | REV00 | 5/20