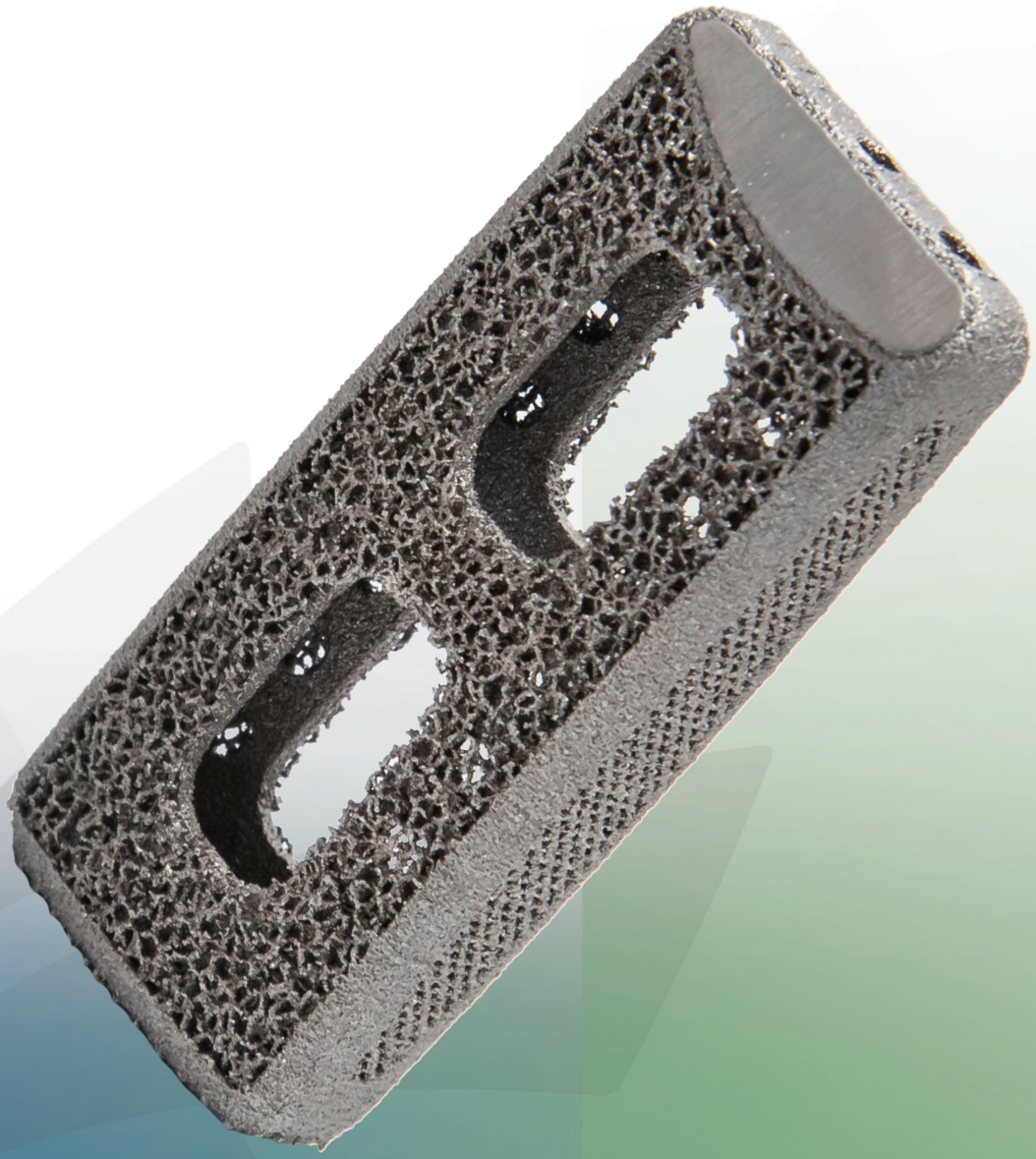
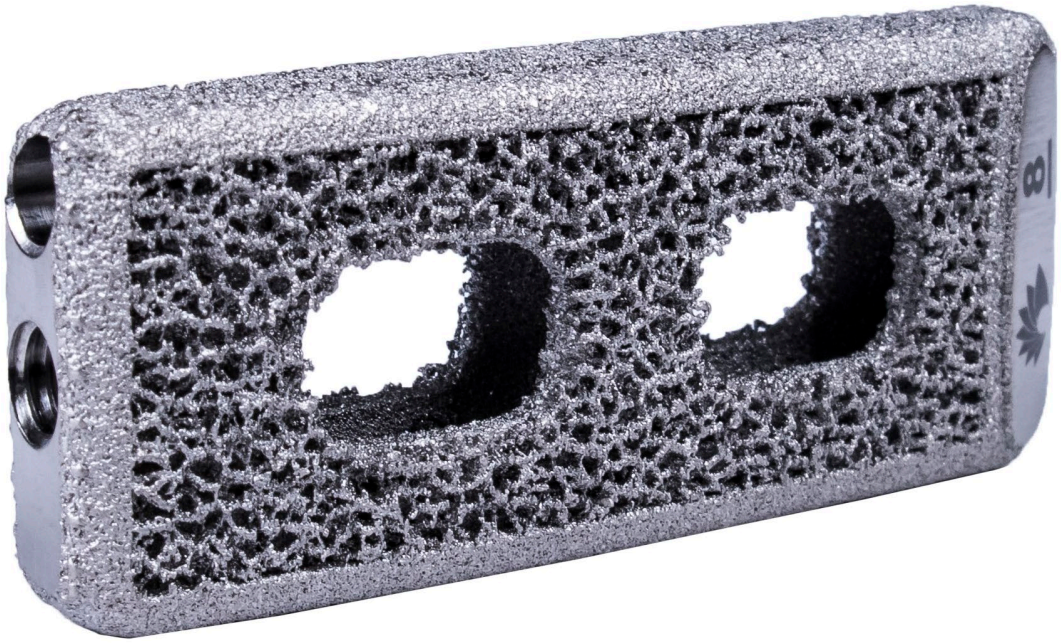
ChoiceSpine
Propelling Spinal Surgery



TIGER SHARK™ L Surgical Technique

3D Printed Titanium Lumbar Lateral Spacer



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Approach

Access, Discectomy & Endplate Preparation

- See ChoiceSpine's Veo® Lateral Access System Surgical Technique Guide for a detailed description for access and discectomy

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.
- Place the interbody cage on the inserter and rotate the inserter knob clockwise (Fig. 1) until the implant is secured.
- Pack graft material into the reservoir of the interbody cage and insert into the disc space.
- Take A/P 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 the inserter is removed (Fig. 2a-b).

Fig. 1

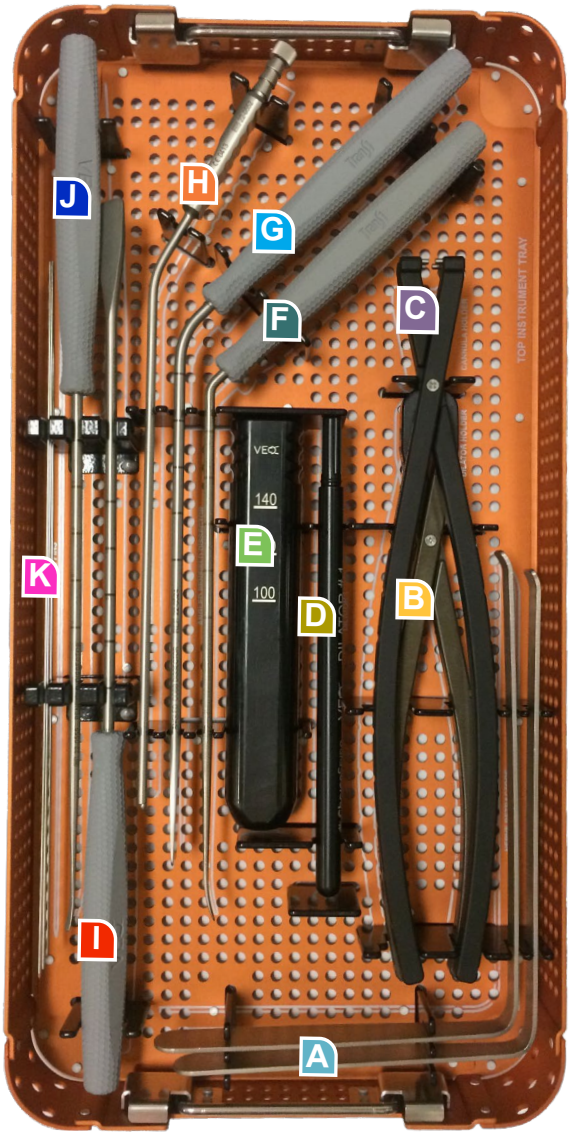
Fig. 2a

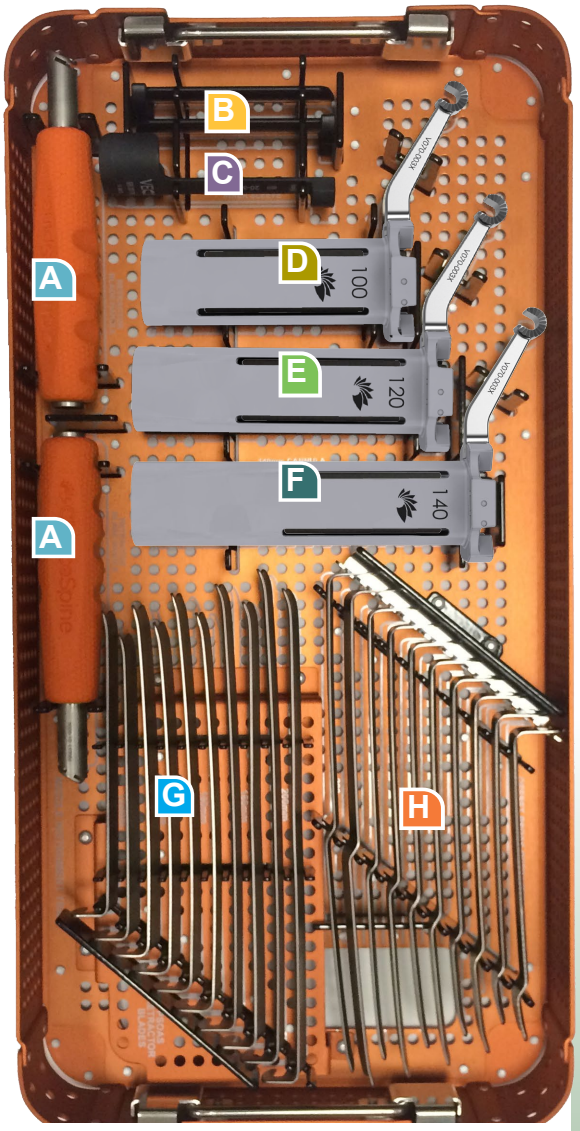
Fig. 2b

Tiger Shark L Instrument list

Part Number	Description	
V070-0110	TAMP	
V070-0002	CAGE INSERTER	
V070-0003L	LEFT ANGLED INSERTER	
V070-0003R	RIGHT ANGLED INSERTER	
V070-0004	SLAP HAMMER	

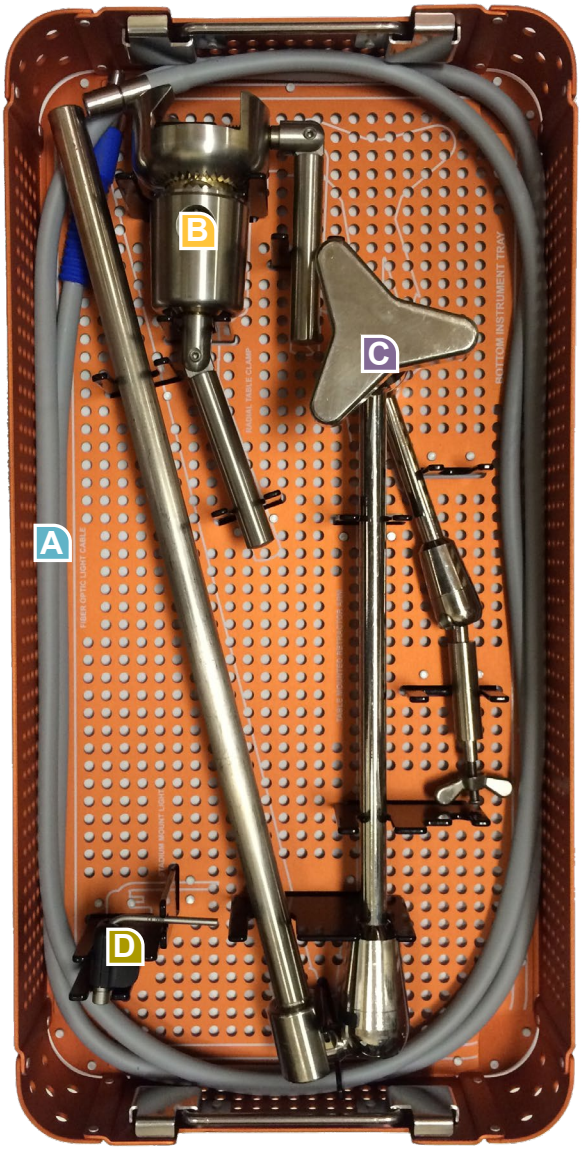
VEO® Lateral Access System

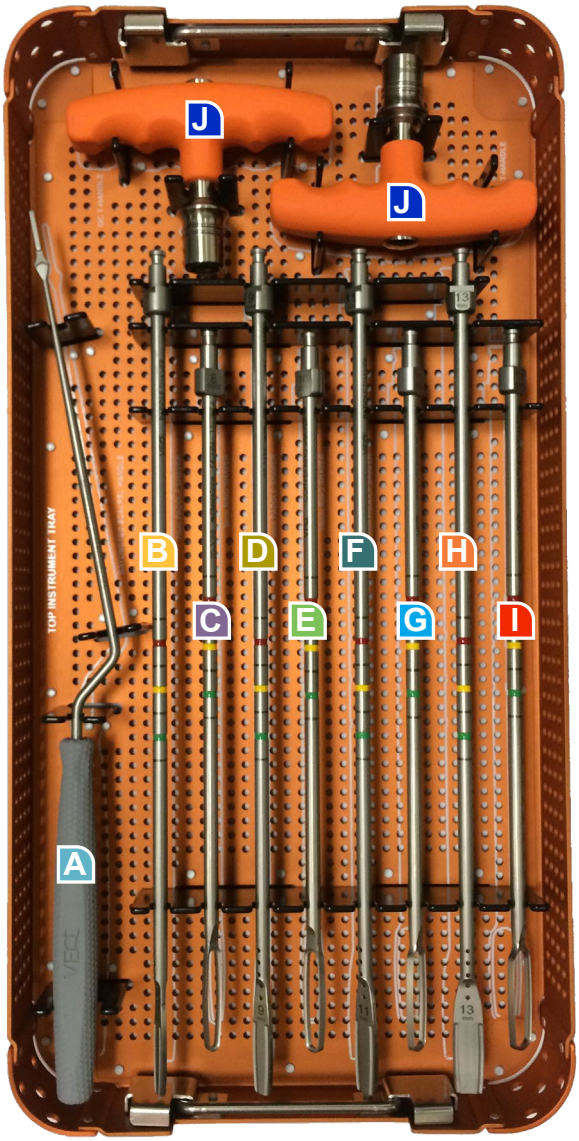




- A 90° Nerve Retractor
- B Dilator Holder
- C Cannula Holder
- D Dilator 1
- E Dilator 2
- F Angled Penfield Dissector
- G Angled Cobb Dissector
- H Frazier Suction Tube
- I Straight Cobb Dissector
- J Straight Penfield Dissector
- K K-wires
- A Retractor Blade Handles
- B Inner Half Sleeves
- C U-Shaped Inner Sleeve
- D 100mm Cannula
- E 120mm Cannula
- F 140mm Cannula
- G Psoas Retractor Blades
- H Offset Psoas Retractor Blades

VEO® Lateral Access System

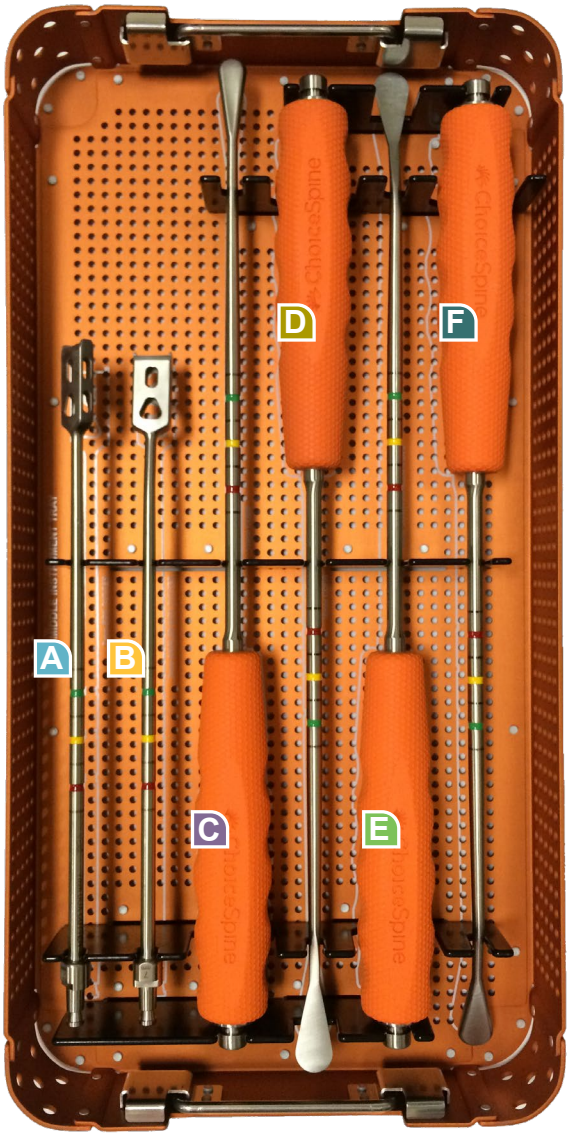


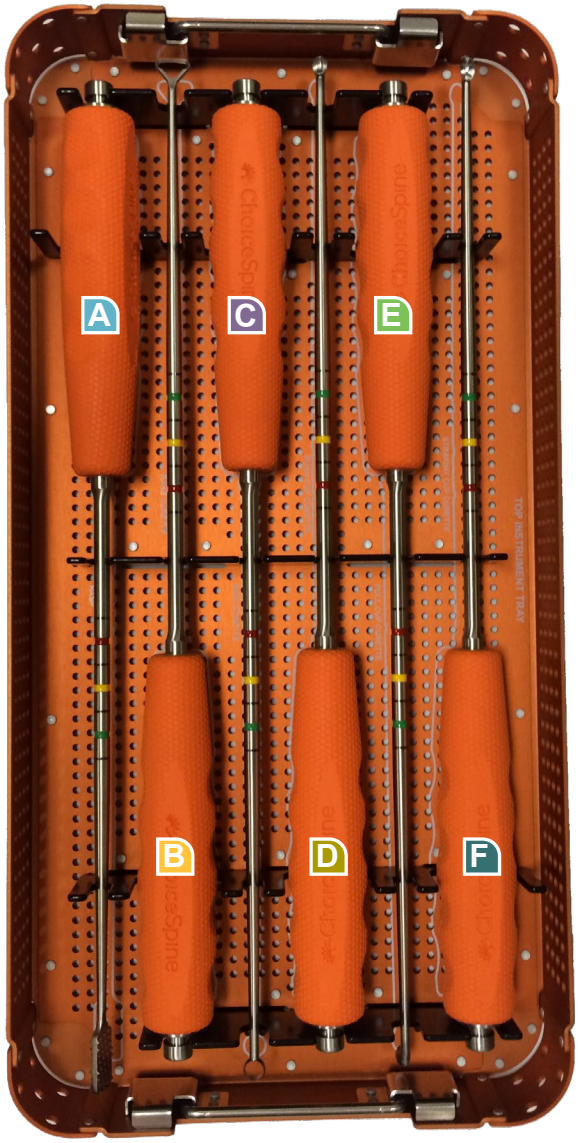


- A Fiber Optic Cable
- B Radial Table Clamp
- C Table Mounted Retractor Arm
- D Stadium Mount Light

- A Bayoneted Scalpel Handle
- B 7mm Paddle Shaver
- C 8mm Ring Shaver
- D 9mm Paddle Shaver
- E 10mm Ring Shaver
- F 11mm Paddle Shaver
- G 12mm Ring Shaver
- H 13mm Paddle Shaver
- I 14mm Ring Shaver
- J QC T-Handles

VEO® Lateral Access System

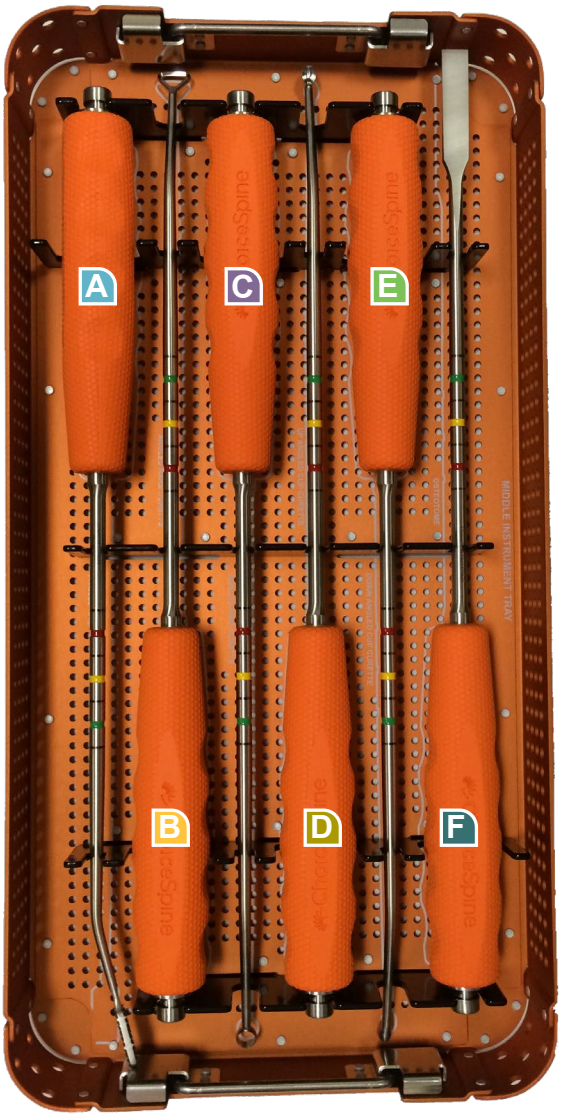




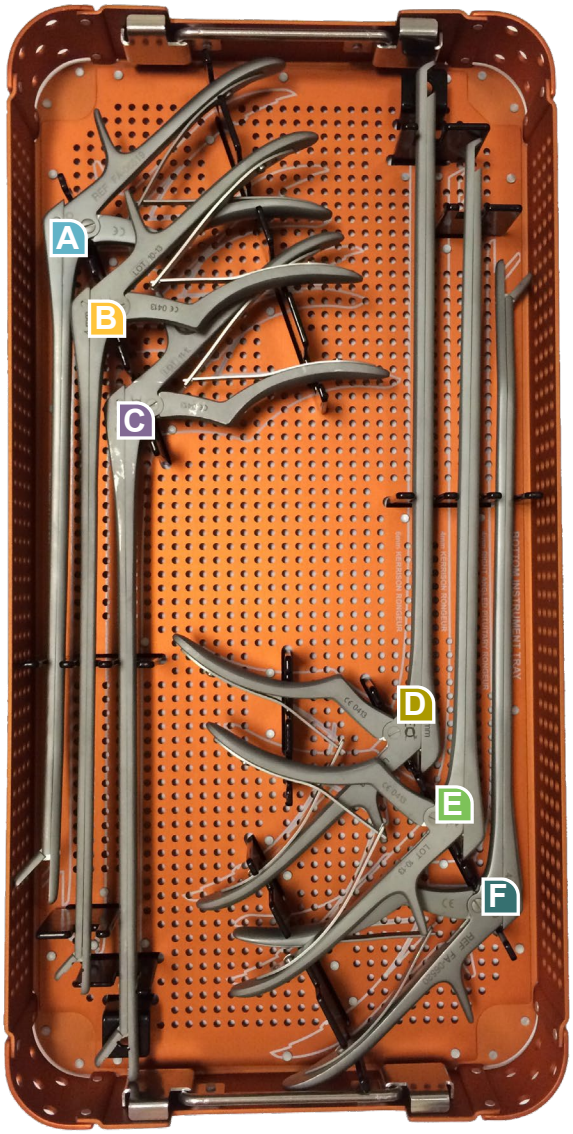
- A 7mm Box Cutter
- B 7mm Angled Box Cutter
- C 13mm Cobb
- D 16mm Cobb
- E 16 mm Down Angled Cobb
- F 16mm Up Angled Cobb

- A Rasp
- B Rake Curette
- C Ring Curette
- D Push Cup Curette
- E Pull Cup Curette
- F Straight Cup Curette

VEO® Lateral Access System

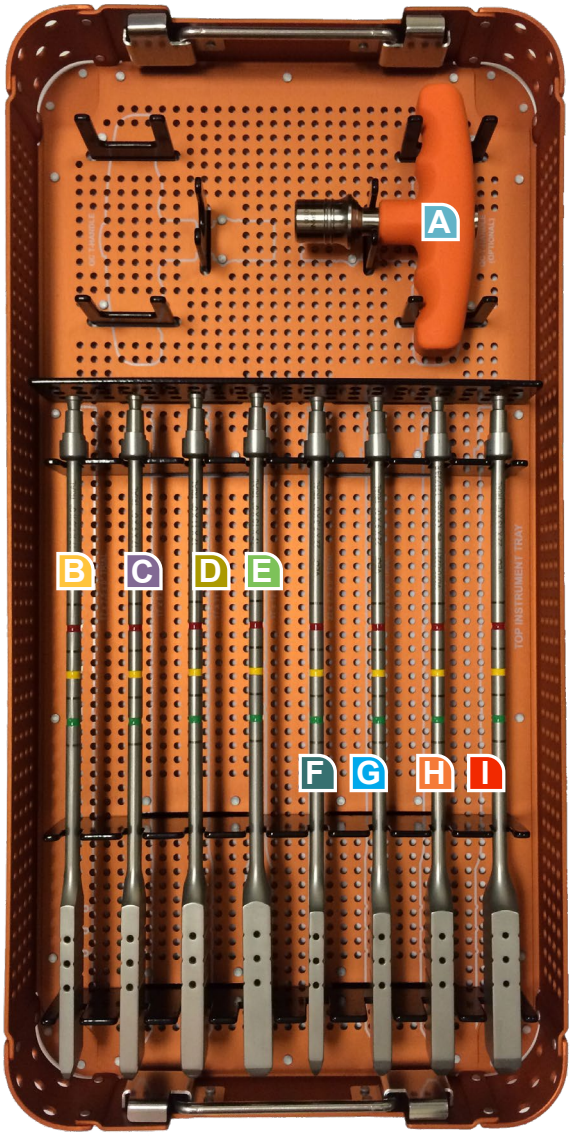


- A Angled Rasp
- B Angled Rake Curette
- C Angled Ring Curette
- D Up Angled Cup Curette
- E Down Angled Cup Curette
- F Osteotome

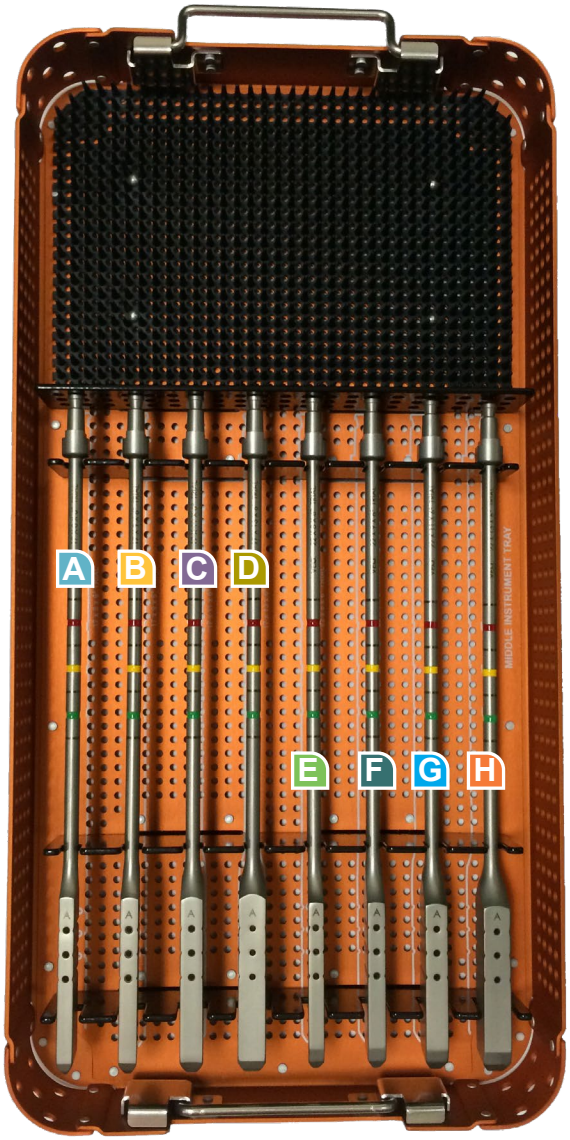


- A 4mm Left Angled Pituitary Rongeur
- B 4mm Pituitary Rongeur
- C 6mm Pituitary Rongeur
- D 6mm Kerrison Rongeur
- E 4mm Kerrison Rongeur
- F 4mm Right Angled Pituitary Rongeur

VEO® Lateral Access System

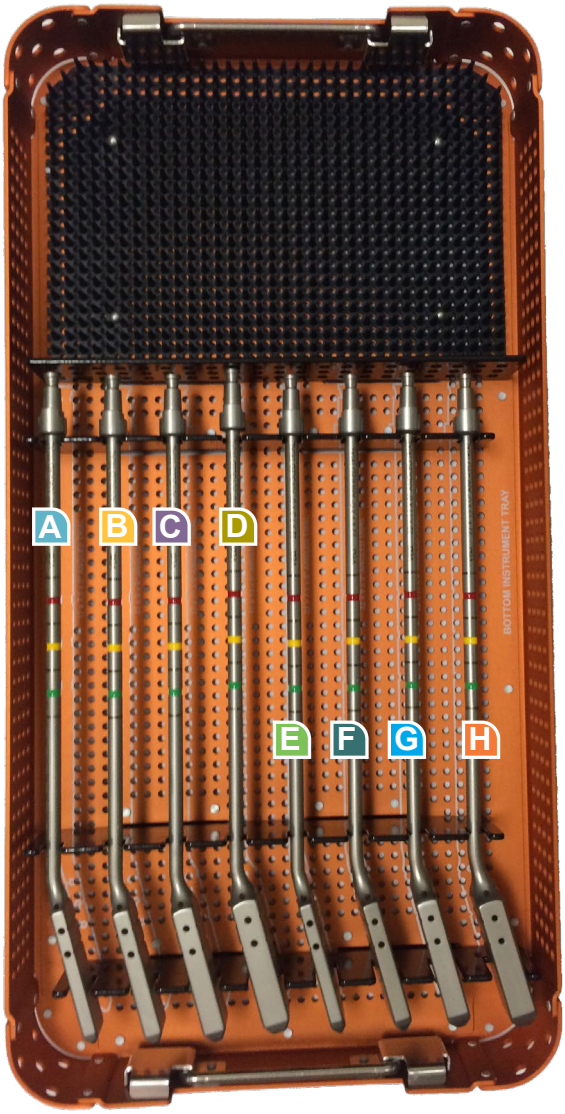


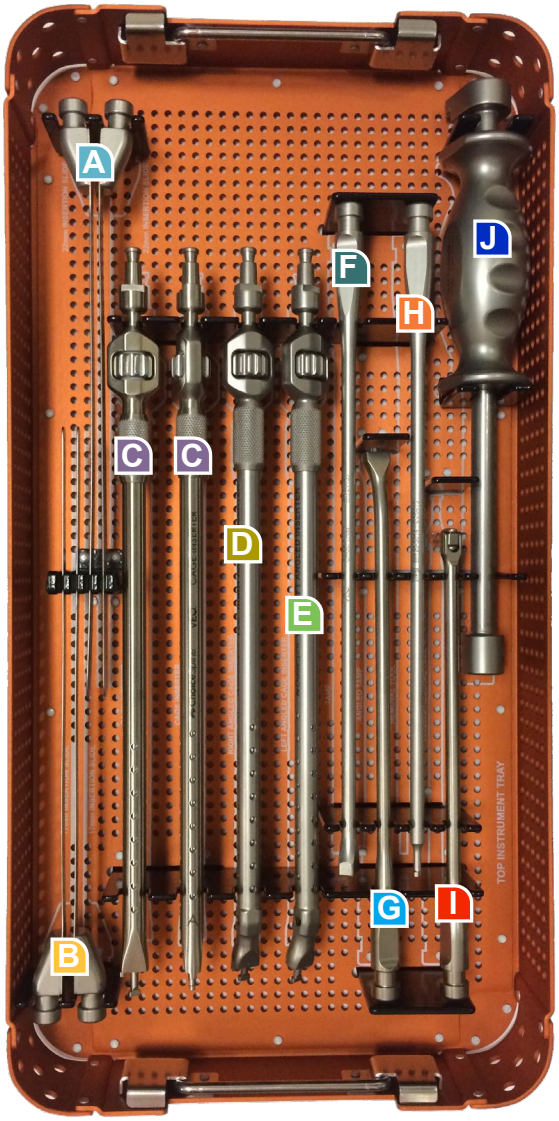
- A QC T-Handle
- B 17mm x 7.5mm x 0° Trial
- C 17mm x 9mm x 0° Trial
- D 17mm x 11mm x 0° Trial
- E 17mm x 13mm x 0° Trial
- F 22mm x 7.5mm x 0° Trial
- G 22mm x 9mm x 0° Trial
- H 22mm x 11mm x 0° Trial
- I 22mm x 13mm x 0° Trial



- A 17mm x 8mm x 6° Trial
- B 17mm x 9mm x 6° Trial
- C 17mm x 11mm x 6° Trial
- D 17mm x 13mm x 6° Trial
- E 22mm x 8mm x 6° Trial
- F 22mm x 9mm x 6° Trial
- G 22mm x 11mm x 6° Trial
- H 22mm x 13mm x 6° Trial

VEO® Lateral Access System





- A 17mm x 7.5mm x 0° Angled Trial
- B 17mm x 9mm x 0° Angled Trial
- C 17mm x 11mm x 0° Angled Trial
- D 17mm x 13mm x 0° Angled Trial
- E 22mm x 7.5mm x 0° Angled Trial
- F 22mm x 9mm x 0° Angled Trial
- G 22mm x 11mm x 0° Angled Trial
- H 22mm x 13mm x 0° Angled Trial

- A 22mm Insertion Slide
- B 17mm Insertion Slide
- C Cage Inserters
- D Right Angled Cage Inserter
- E Left Angled Cage Inserter
- F Tamp
- G Angled Tamp
- H Removal Tool
- I Angled Removal Tool
- J Slap Hammer

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.

ChoiceSpine™
Propelling Spinal Surgery

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LIT# Tiger Shark L STG | REV01 | 12/19