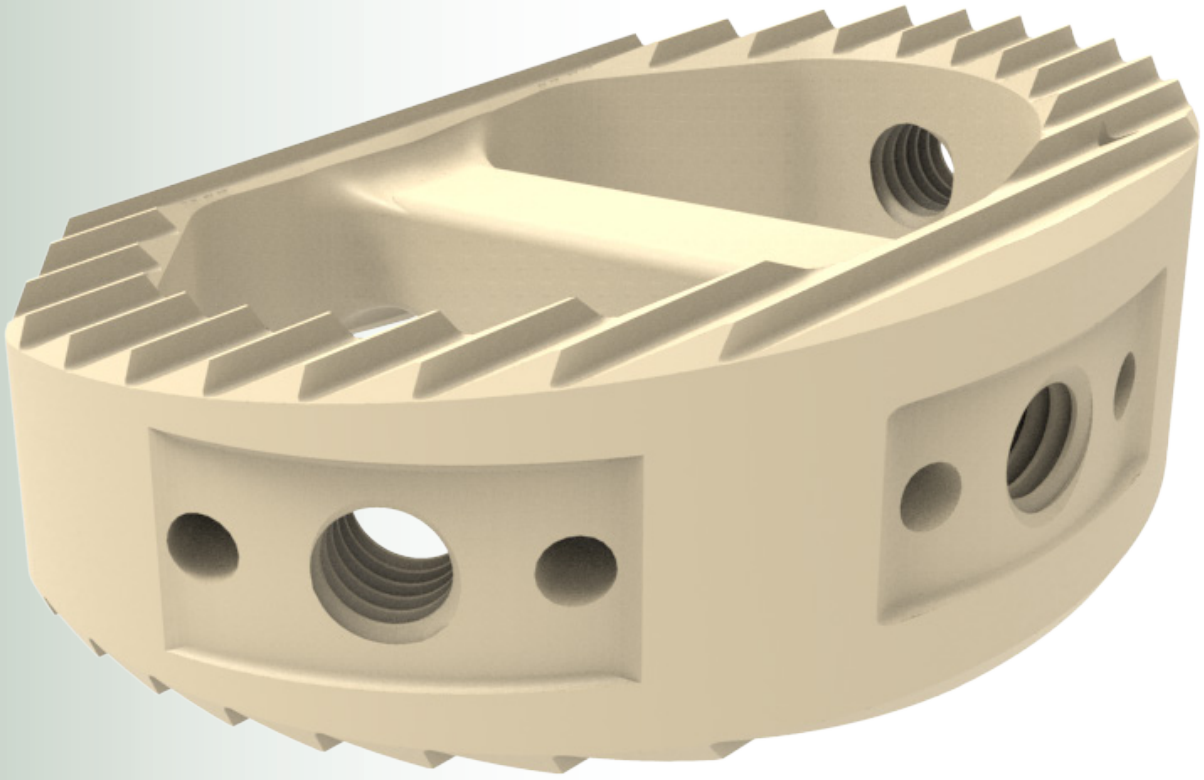
HARRIER™

Anterior Lumbar Interbody Fusion System

Surgical Technique Guide



ChoiceSpine™

Propelling Spinal Surgery

HARRIER™
Anterior Lumbar Interbody Fusion System

Description

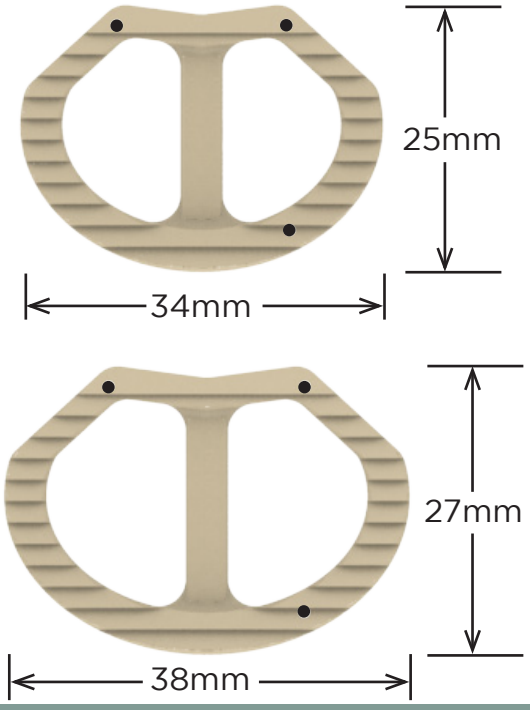
The HARRIER™ Anterior Lumbar Interbody Fusion System consists of PEEK implants meant to be used with supplemental fixation. The devices are offered in a variety of sizes and shapes to accommodate various anatomies. The implants feature windows in the interior geometry in order to accommodate bone graft and maximize bone in-growth.

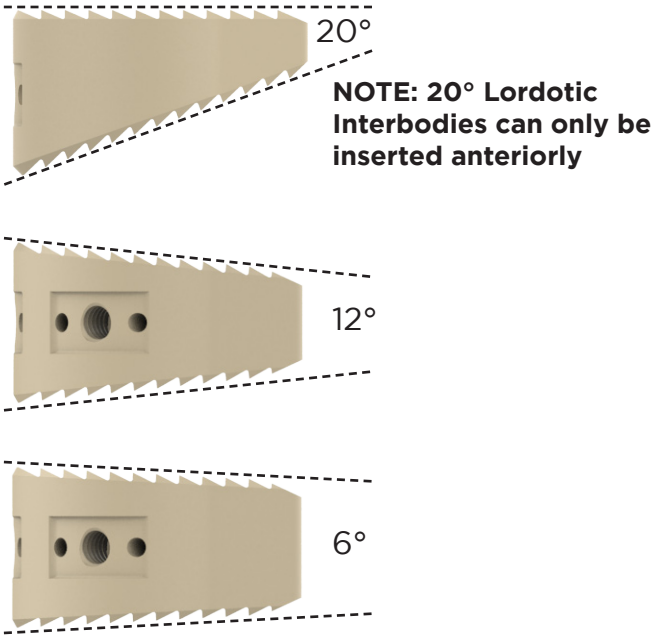
Tantalum markers are incorporated into the material to allow for visualization of the Interbody configuration during and after surgery. The surfaces of the Interbody have machined edges meant to engage the vertebral endplates and prevent expulsion.

Features & Benefits

- Footprints: 34 x 25mm & 38 x 27mm.
- Lordosis: 6°, 12°, and 20°.
- Heights: 10 - 18mm in 2mm increments.
- Provides three points of insertion to facilitate direct anterior, anterolateral, and direct lateral surgical approaches.
- Manufactured of biocompatible PEEK Polymer.
- Reinforced center strut increases strength of implant for impaction.

Implant Sizing





Step 1 Patient Positioning & Access

- Position the patient in the supine position on a radiolucent table.
- Prepare and drape in the conventional manner.
- During the patient positioning, review CT scans or X-rays to estimate implant size.
- An incision is made at the appropriate fusion levels and the disc space is exposed.

Step 2 Disc Site Preparation

- Expose the midline of the intervertebral disc.
- Remove the disc and anterior longitudinal ligament using rongeurs and other disc prep instruments (Fig. 1).
- Use the Distractor to obtain the desired distraction of the disc space.

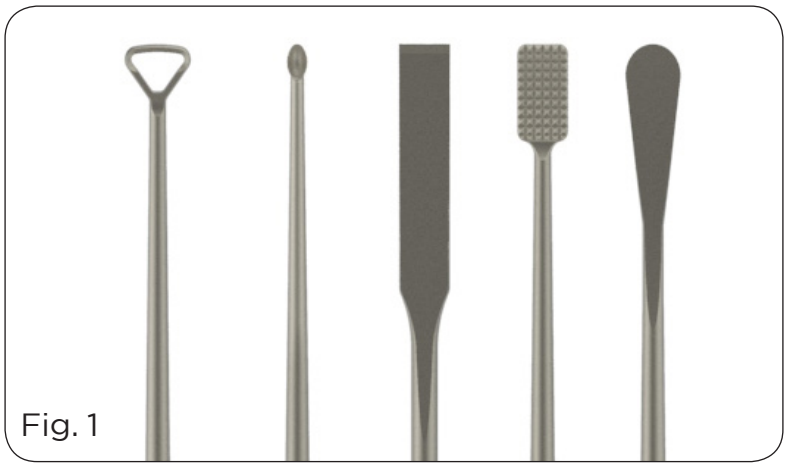


Fig. 1

NOTE: Discectomy instruments include Curettes, Osteotomes, Rasps, & Cobbs (Fig. 1).

Step 3 Determining Interbody Size

- Place the Inserter through the appropriate Inserter Sheath (Anterior/ Anterolateral or Lateral) (Fig. 2).
- Align the distal end of the Inserter Sheath with the Trial and engage the pins of the Inserter Sheath with the Trial (Fig. 3).
- Secure the Trial by rotating the proximal end of the Inserter Handle clockwise until finger tight (Fig. 4).
- Place the Trial in the disc space (Fig. 5).
- Repeat, if needed, with alternative Trial sizes until a secure fit is achieved.
- Remove the Trial from the disc space.

Fig. 2

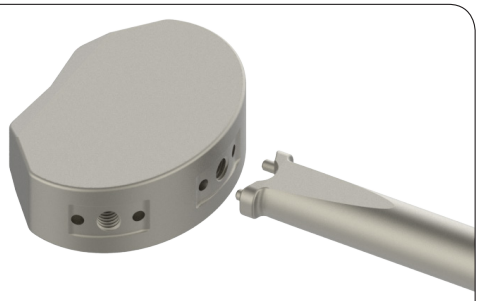


Fig. 3

Fig. 4

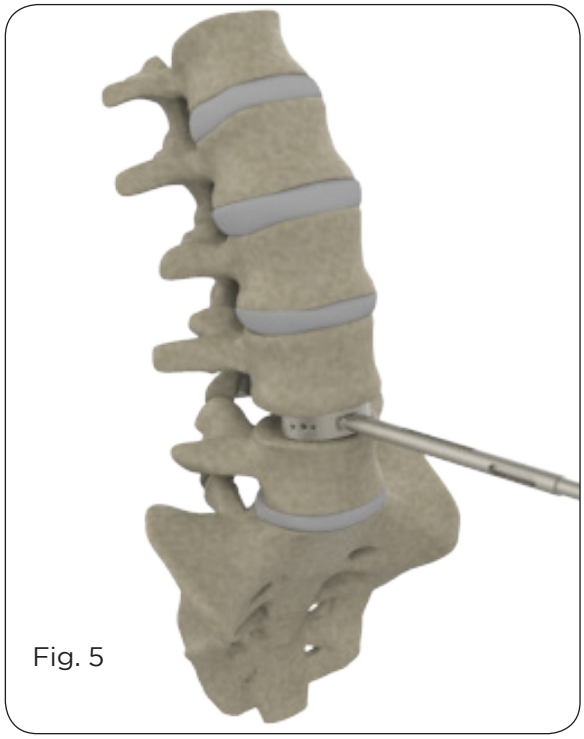
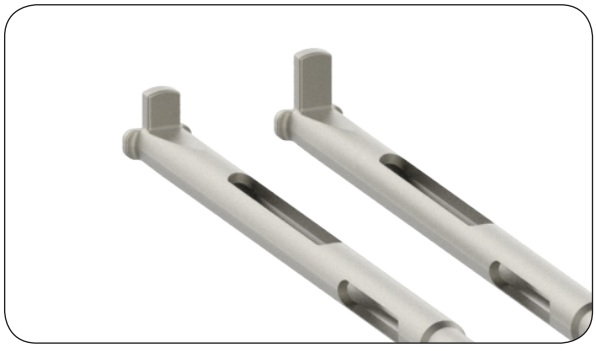


Fig. 5



NOTE: Inserter Sheaths with stops, small & large, are available if the surgeon wishes not to countersink the Interbody.

Step 4 Interbody Selection & Insertion

- Place the Inserter through the appropriate Inserter Sheath (Anterior/Anterolateral or Lateral).
- Select the Interbody based on Trial Selection (Fig. 6).
- Align the distal end of the Inserter Sheath with the Interbody and engage the pins of the Inserter Sheath with the Interbody.
- Secure the Interbody by rotating the proximal end of the Inserter Handle clockwise until finger tight.
- Place the Interbody in the disc space (Fig. 7).
- Disengage the Interbody from the Inserter by rotating the Inserter Handle counterclockwise.

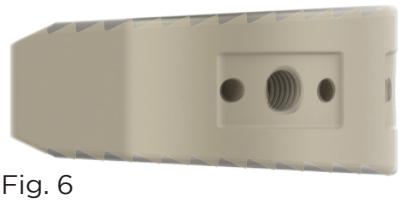


Fig. 6

NOTE: Trials are measured to match Interbody.

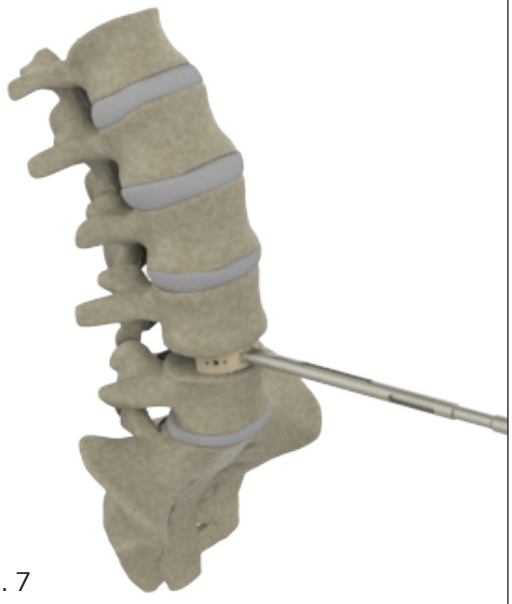
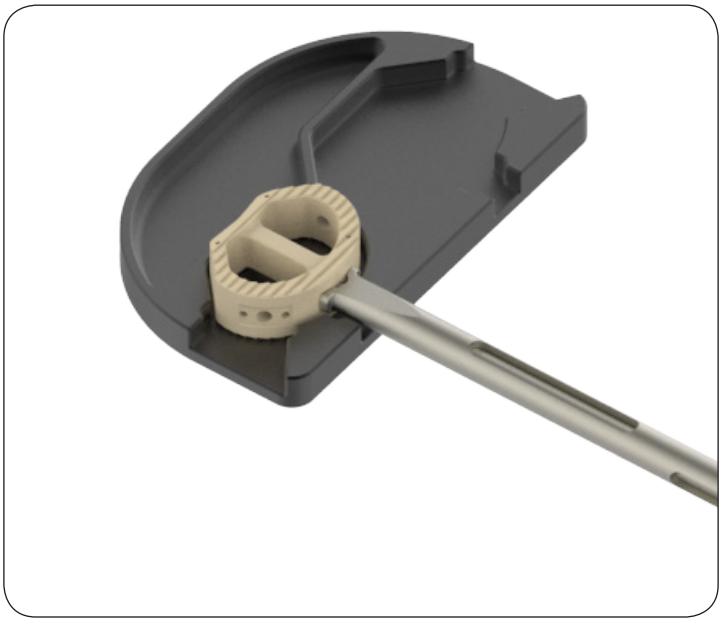


Fig. 7



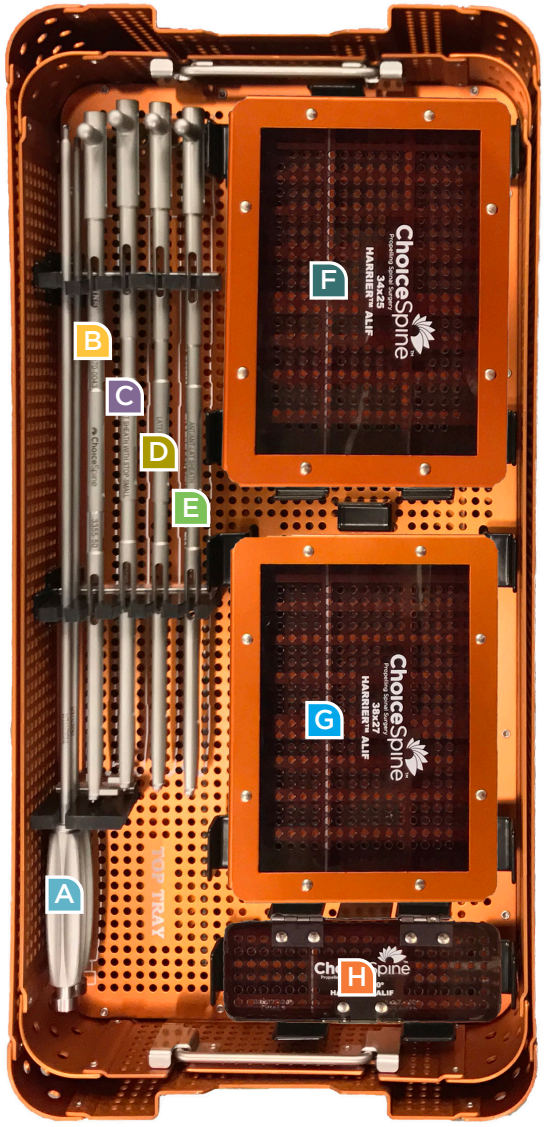
NOTE: The Graft Block may be used to aid in packing autograft material.

Step 5 Removal

- Align the distal end of the Inserter with the hole on the anterior face of the Interbody.
- Engage the Interbody by rotating the Inserter clockwise until finger tight.
- Remove the Interbody by attaching the Slap Hammer to the proximal end of the Inserter (Fig. 8).

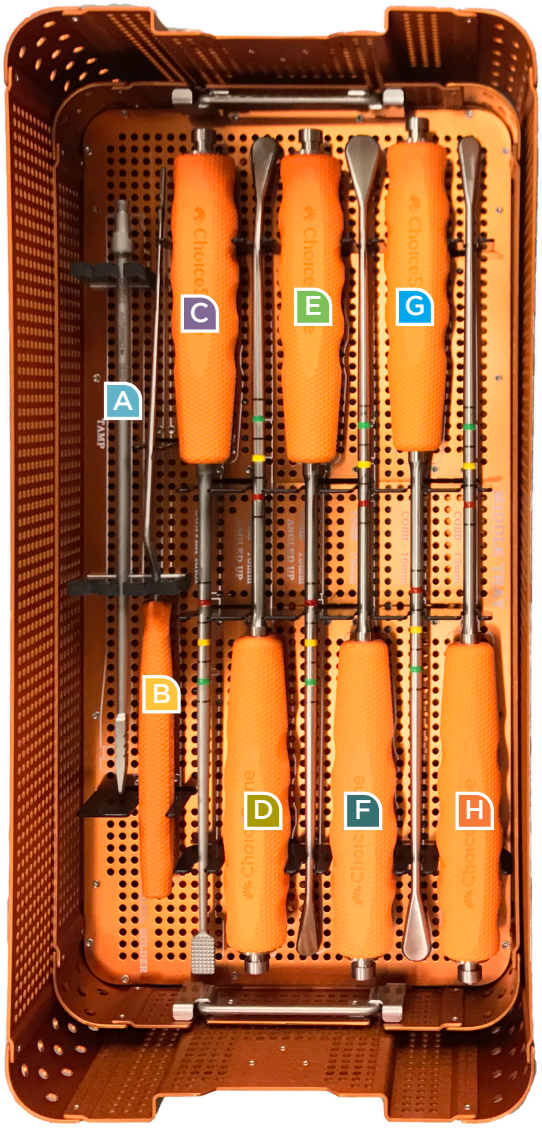
Fig. 8

Implant Kit: Top Tray



- A Inserter
- B Inserter Sheath with Stops: Large
- C Inserter Sheath with Stops: Small
- D Lateral Sheath
- E Anterior/Anterolateral Sheath
- F 34x25mm Implants
- G 38x27mm Implants
- H 38x27 20° Lordotic Implants

Implant Kit: Middle Tray

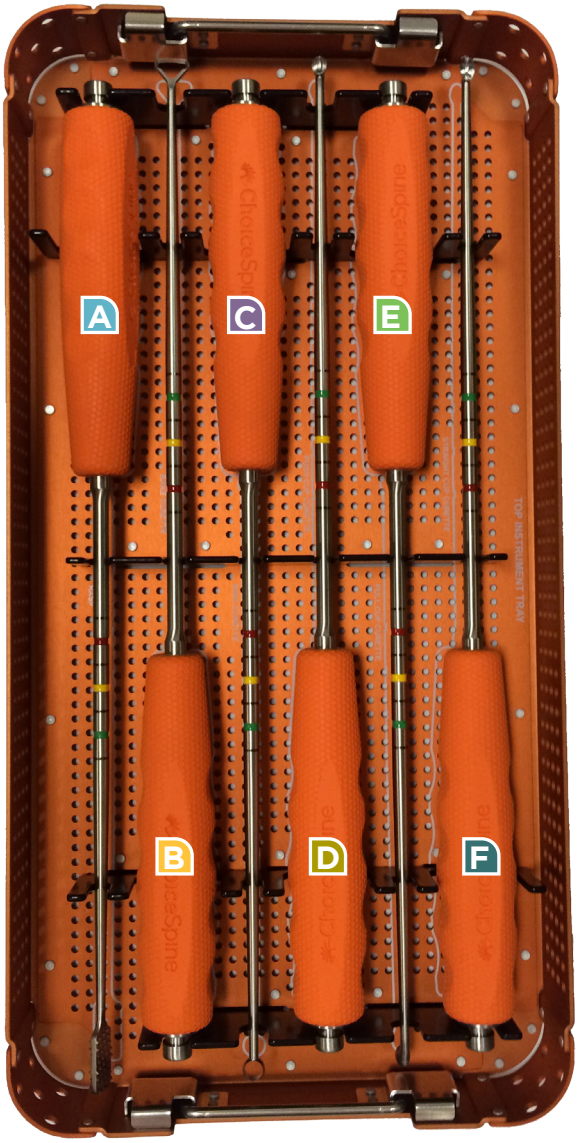


- A Paddle Distractor
- B Bayonetted Scalpel Holder
- C Convex Rasp
- D 16mm Angled Up Cobb
- E 13mm Angled Up Cobb
- F 19mm Cobb
- G 16mm Cobb
- H 13mm Cobb

Implant Kit: Bottom Tray

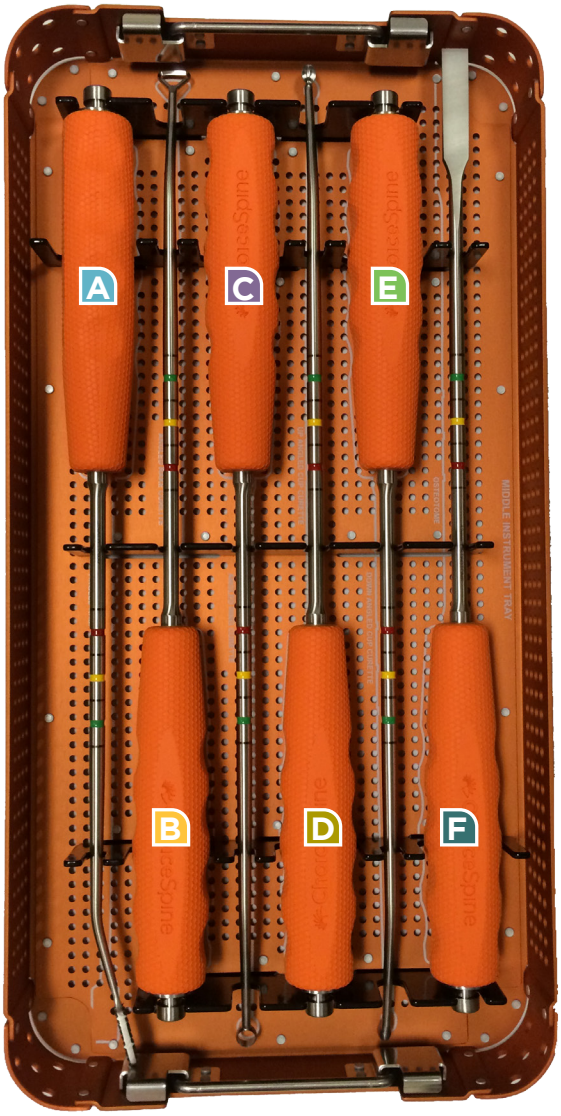
- A Slap Hammer
- B T-Handle
- C Anterior Distractor
- D Graft Block

Anterolateral Disc Prep: Top



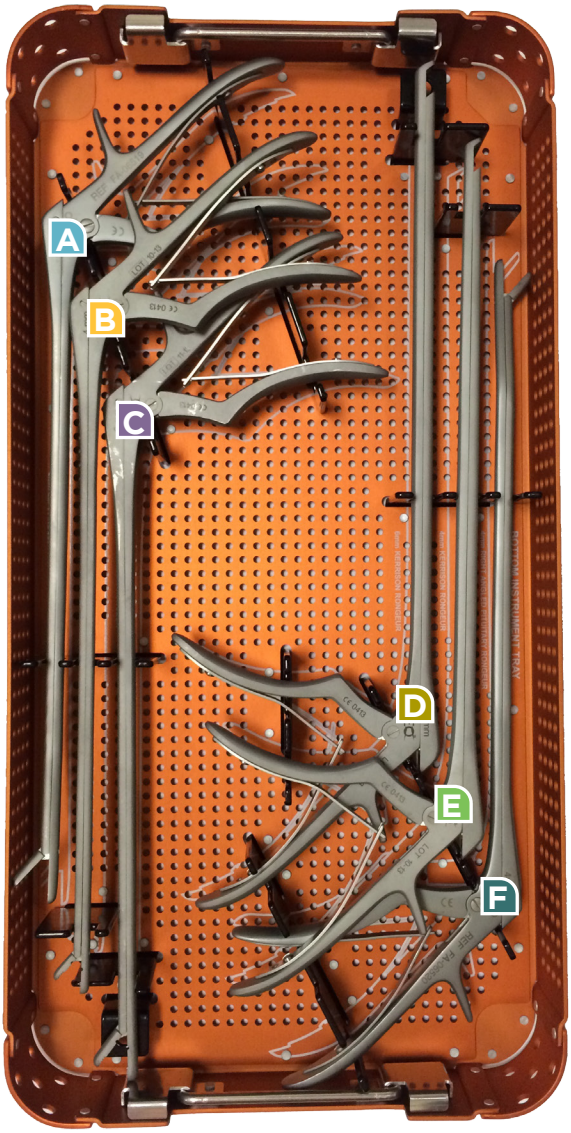
- A Rasp
- B Rake Curette
- C Ring Curette
- D Push Cup Curette
- E Pull Cup Curette
- F Straight Cup Curette

Anterolateral Disc Prep: Middle



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

Anterolateral Disc Prep: Bottom



- 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

HARRIER™
Anterior Lumbar Interbody Fusion System

DESCRIPTION:
The Choice Spine Interbody Fusion System is a family of implants intended to aid in spinal fixation of the lumbar spine. This system includes implants made of PEEK (ASTM F2026) with Tantalum markers (ASTM F560) and Ti 6AL4V ELI (ASTM F136), which may be delivered via an Anterior, Transforaminal,
and/or Posterior approach. Each configuration includes surgical instrumentation designed for implant delivery, which are made of biocompatible materials such as Stainless Steel, Aluminum, and Radel R.

INDICATIONS:
The Choice Spine Interbody Fusion System is indicated for spinal fusion 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 had six months of non-operative treatment. The Choice Spine Interbody Fusion System is designed to be used with autogenous and/or allogeneic bone graft comprised of cancellous, and/or corticocancellous bone graft to facilitate fusion and a supplemental spinal fixation system that is cleared for use in the lumbar spine.

CONTRAINDICATIONS :
Contraindications include, but are not limited to, active systemic infection, localized or spinal infection; morbid obesity; signs of local inflammation; fever or leukocytosis; demonstrated allergy or foreign body sensitivity to any implant materials; any medical or surgical condition which would preclude or impede the potential benefit of spinal implant and/or spinal fusion surgery, which could include, but not be exclusive to, erythrocyte elevated sedimentation unexplained rate, inflammatory/disease processes, elevation of white blood cell count (WBC), marked left shift in the white blood cell count differential; distorted anatomy, due to congenital or remote posttraumatic/postinfectious abnormalities; conditions that may place excessive stresses on bone and implants, such as severe obesity or degenerative diseases, osteopenia, and/or osteoporosis (osteoporosis is a relative contraindication as this condition may limit the degree of obtainable correction and/or height restoration, the amount of mechanical fixation, and/or the quality of the bone graft); any case in which a bone graft and fusion technique or where fracture fixation is not performed or required; any operative case utilizing the mixing of dissimilar metals from different components; patients having inadequate soft tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition; any case not described in the indications; patients whose activity, mental capacity, mental illness, alcoholism, drug abuse, smoking, occupation, or lifestyle may interfere with their ability to follow postoperative instructions and/or activity restriction guidelines and who may place undue stresses on the

WARNINGS
- Correct selection of the implant is important. The potential for satisfactory anterior column support is increased by the selection of the proper size device. While proper selection can help minimize risks, the size and shape of human bones present limitations on the size, shape and strength of implants. Internal fixation devices cannot withstand activity levels equal to those placed on normal healthy bone. No implant can be expected to withstand indefinitely the unsupported stress of full weight bearing.
- Implants can break when subjected to the increased loading associated with delayed union or nonunion. Internal fixation appliances are load sharing devices which are used to obtain an alignment until normal healing occurs. If healing is delayed, or does not occur, the implant may eventually break due to material fatigue. The degree or success of union, loads produced by weight bearing, and activity levels will, among other conditions, dictate the longevity of the implant. Notches, scratches or bending of the implant during the course of surgery may also contribute to early failure. Patients should be fully informed of the risks of implant failure.

PRECAUTIONS:
Physicians using this device should have significant experience in spinal surgery, including spinal fusion procedures. Physicians should not independently use this device prior to participation in specific training on its use.
- Single use risk is limited to the utilization of all instrumentation labeled and marked single use, but used multiple times. Single use instrumentation is clearly labeled as single-use and should be used in the manner consistent to its labeling. Re-cleaning and re-use of single use instrumentation is not recommended. The re-use of single use devices has not been evaluated and therefore the manufacturer does not recommend reuse of items labeled for single use. Some single use devices contain areas that will be difficult to clean after use, which may inhibit re-sterilization. In addition, the function and integrity of single use devices may degrade after multiple uses and cannot be guaranteed to perform as intended.
- Surgical implants must never be reused. An explanted implant should never be reimplanted. Even though a device appears undamaged, it may have small defects and internal stress patterns which may lead to early breakage.
- Correct handling of the implant is extremely important. Contouring of this implant should not be done. The operating surgeon should avoid notching, scratching or reverse bending of the implants. Alterations will produce defects in surface finish and internal stresses which may become the focal point for eventual breakage of the implant.
- The Choice Spine Interbody Fusion System has not been evaluated for safety and compatibility in the MR environment. The device has not been tested for heating or migration in this environment.
- Postoperative care and the patient's ability and willingness to follow instructions are among the most important aspects of successful bone healing. The patient must be made aware of the limitations of the implants. The patient should be encouraged to ambulate to tolerance as soon as possible after surgery, and instructed to limit and restrict lifting and twisting motions and any type of sports participation until the bone is healed. The patient should understand that implants are not as strong as normal healthy bone and could loosen, bend and/or break if excessive demands are placed on it, especially in the absence of complete bone healing. Implants displaced or damaged by improper activities may experience migration to the devices and damage to nerves or blood vessels.
- Postoperative external immobilization, i.e. bracing and/or casting is recommended, at the surgeon's discretion, as is a comprehensive postoperative core stabilization physical therapy program. Instructions to the patient to reduce stress on the implant(s) are an equally important component of the attempt to avoid the occurrence of clinical problems that may accompany fixation failure and delayed/non-union.
- Based upon surgeon preference, neuromonitoring may be used.

NOTES

ChoiceSpine™
Propelling Spinal Surgery

400 Erin Drive
Knoxville, Tennessee 37919
865.246.3332 office 865.246.3334 fax

www.ChoiceSpine.com

Lit # HARRIER STG
Rev 00
2/17