

INNOV**ASIS**

▶ **L-BOX**[®]

Lateral Lumbar Interbody Fusion System



L-BOX[®] LLIF System

▶ INDICATIONS FOR USE

The Innovasis Box PEEK IBF System is an intervertebral body fusion device for use in patients with degenerative disc disease (DDD) at one or two contiguous levels of the lumbar spine (L2-S1). DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) months of non-operative treatment. In addition, these patients may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These implants are used to facilitate fusion in the lumbar spine and are placed using a lateral approach.

This device is intended to be used with internal supplemental spinal fixation systems such as the Innovasis Excella Spinal System. The interior of the Box implants are intended to be packed with autograft.

WARNING:

Correct selection of the implant is EXTREMELY 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 alignment until normal healing occurs. If healing is delayed, or does not occur, the implant may eventually break due to material fatigue. The degree of 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 full informed of the risks of implant failure.



L-BOX[®] LLIF System

▶ CONTRIBUTING SURGEONS

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Camden M. Whitaker, MD - Wichita, KS

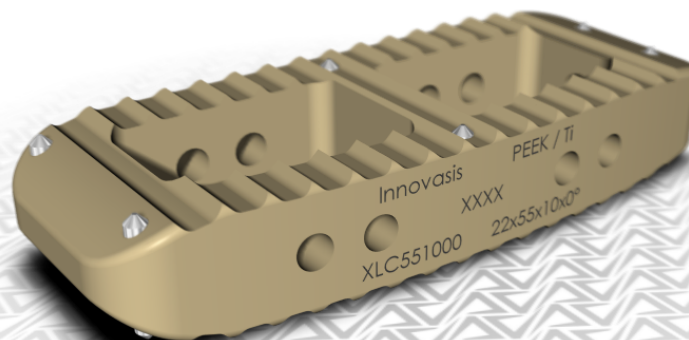
▶ PRODUCT OVERVIEW

The L-Box device is made from PEEK which has a modulus of elasticity similar to human vertebral bone and is radiolucent allowing straightforward assessment of the progress of fusion, while six titanium pins are located around the periphery of the device to allow implant visualization during the procedure.

The L-Box implant has a slightly convex profile to promote a better match to the anatomy. The unique anti-migration teeth ensure implant stability while the fusion process is occurring.

The L-Box implant has two widths (18 and 22mm) with three lengths (45mm, 50mm and 55mm). Each size is uniquely shaped for a better anatomical fit. Implant heights range from 8mm to 14mm, and include lordotic angles of 0°, 7° and 12°.

The implant was designed to maximize the size of its openings to allow for the addition of autograft. In addition, the implants were designed to allow use of the same instruments for all sizes.



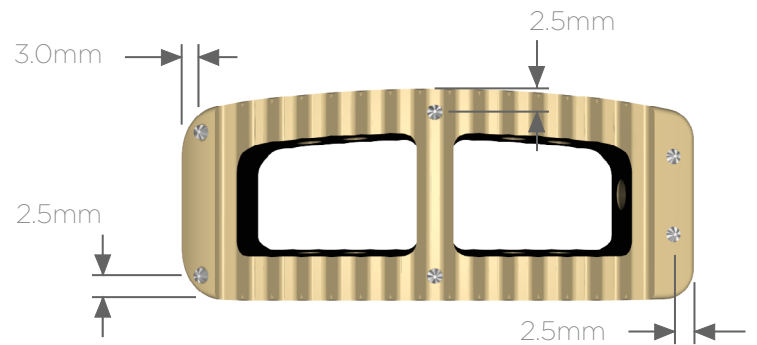
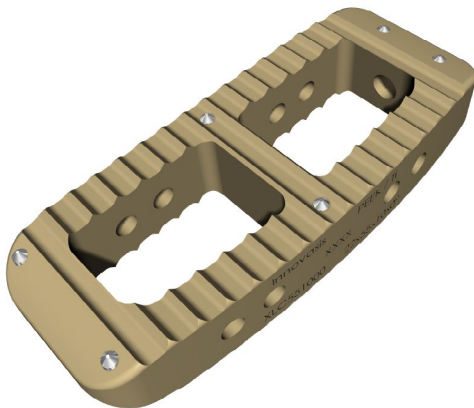
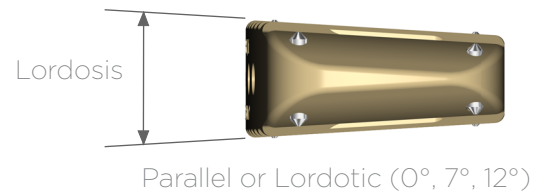
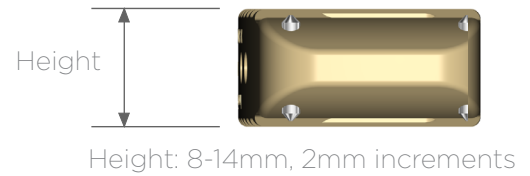
IMPLANT OVERVIEW

▶ Implant Sizes

Width	Length	Lordotic Angles	Height
18mm	45, 50 and 55mm	0°, 7° and 12°	8, 10, 12 & 14mm
22mm	45, 50 and 55mm	0°, 7° and 12°	8, 10, 12 & 14mm

▶ L-BOX IMPLANT

- Convex profile to promote a better anatomical fit.
- 3 Lordotic angle options.
- Anti-migration teeth to improve implant stability.
- Two widths and three lengths.
- Large opening for autograft.
- Titanium markers to enhance radiographic assessment during insertion.



INSTRUMENTS OVERVIEW

INSTRUMENTS



LB-057 Radiographic Target



LB-009 Initial Disc Distractor (4mm)



LB-146-XX Shaver 6mm-14mm



LB-059-XX Box Chisel 8mm-12mm



Sizer 8mm-14mm Height in 18 and 22mm width and 0°, 7° and 12° Lordosis

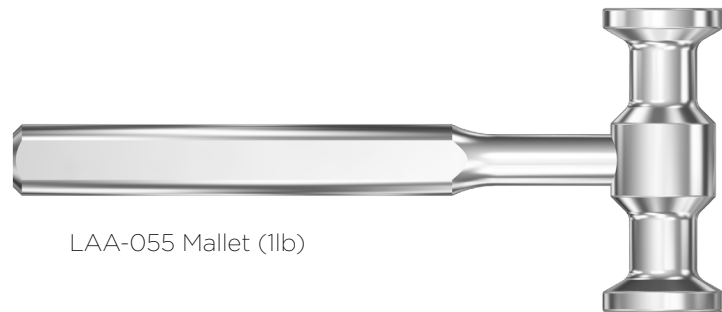
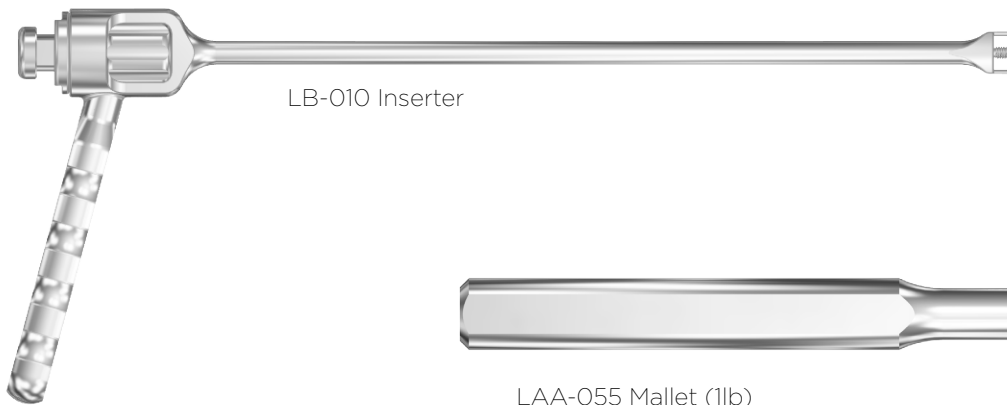


LB-145 Graft Containment Shim



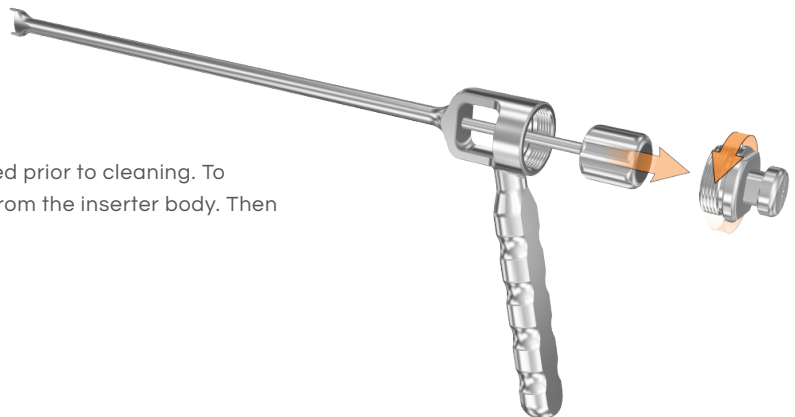
INSTRUMENTS OVERVIEW

INSTRUMENTS



CLEANING:

The L-Box Inserter must be disassembled prior to cleaning. To disassemble, unscrew the impact cap from the inserter body. Then slide out the thumb wheel assembly.



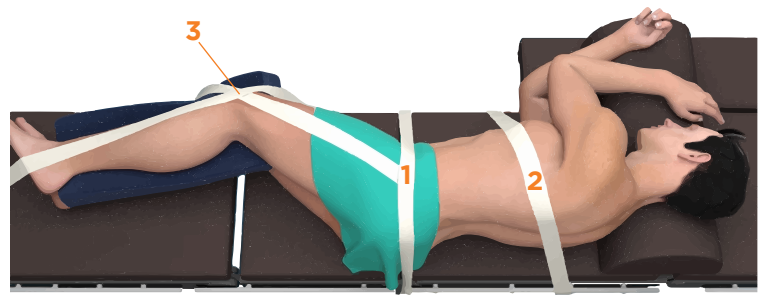
SURGICAL TECHNIQUE

PATIENT PREPARATION

PATIENT POSITIONING

The patient is placed on a flexible surgical table in a direct lateral decubitus position so that the iliac crest is just over the table break as shown. The patient is then secured to the table at the following locations.

1. Just below the iliac crest.
2. Over the thoracic region.
3. From the table to the knee, past the ankle, then secured to the table.



Patient Placement

TABLE SET-UP

The table should be flexed to ensure that the pelvis tilts away from the spine, allowing direct access to the lateral lumbar levels.

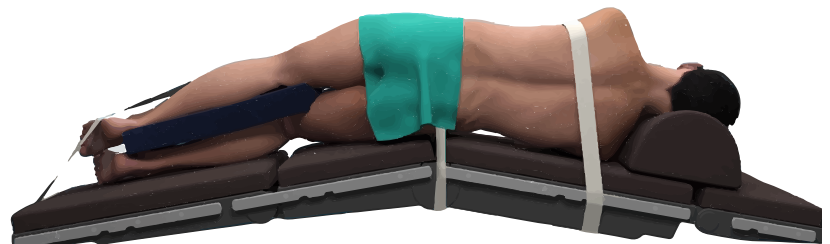


Table Flexed



SURGICAL TECHNIQUE

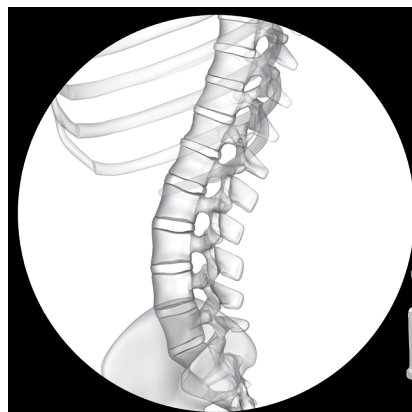
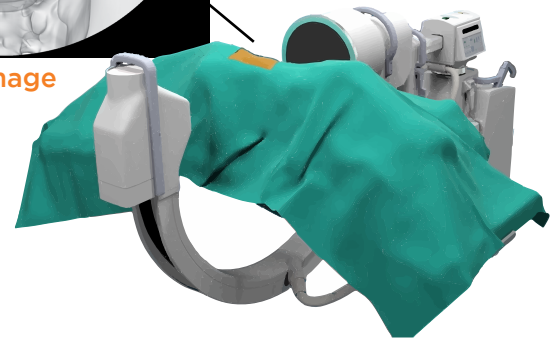
PATIENT PREPARATION

X-RAY CONFIRMATION

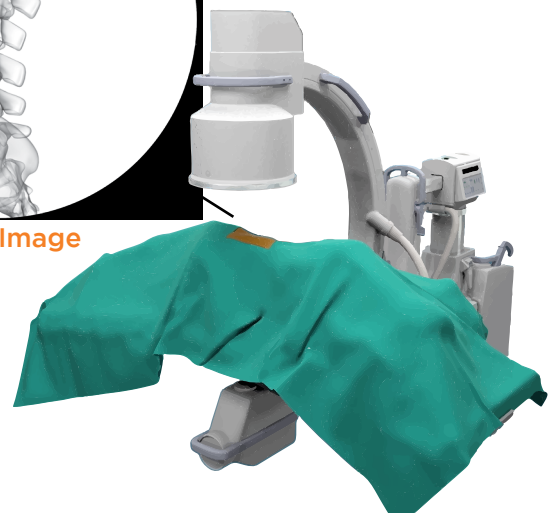
Use fluoroscopy to ensure the spine is oriented in a true lateral position. First, unlock the table and rotate until endplates are aligned for true A/P orientation. Second, use the bed controls to align endplates to obtain a true lateral view.



AP Image



Lateral Image



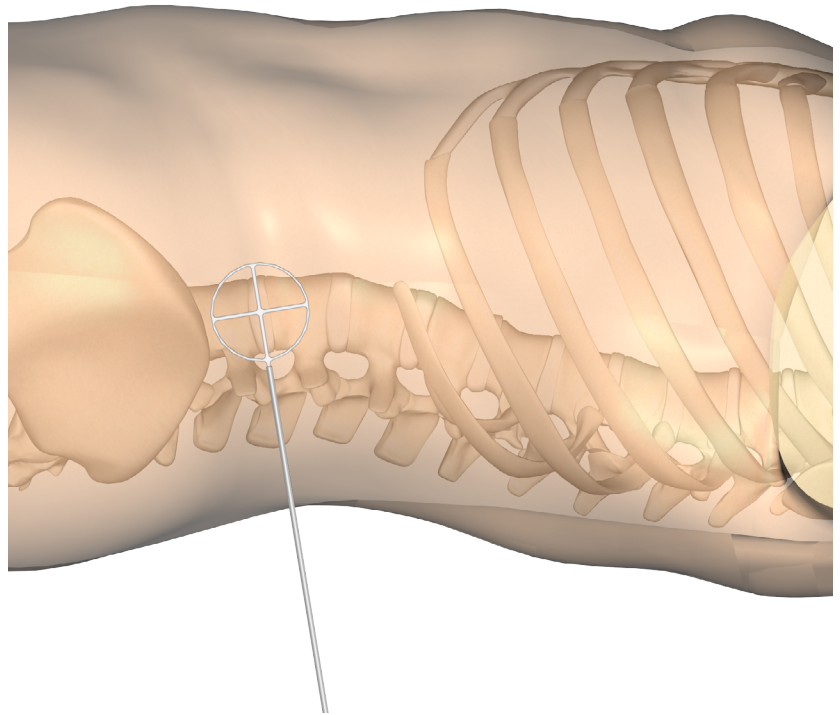
SURGICAL TECHNIQUE

PATIENT PREPARATION

INCISION LOCATION

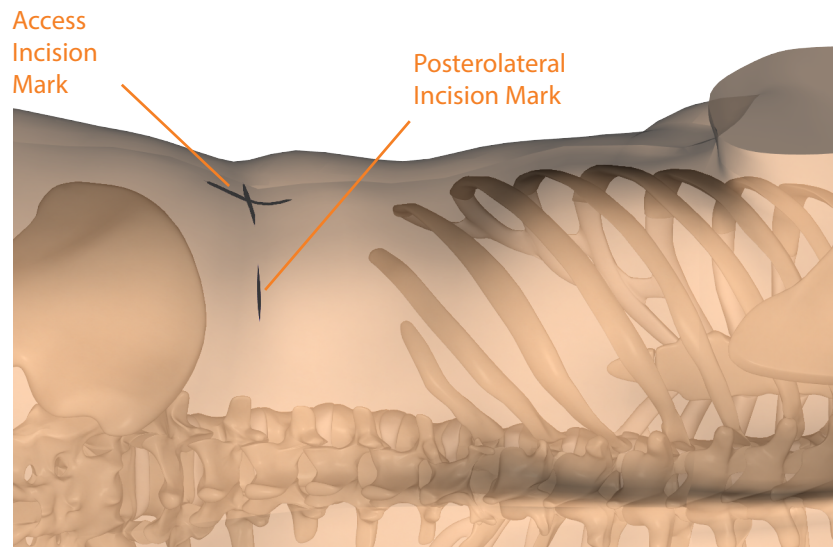
Following cleaning of the operative area, locate the incision site under fluoroscopy. Two intersecting K-wires can be placed over the pathologic level to indicate the incision point.

The Radiographic Target can also be used to locate the incision site under fluoroscopy.



ACCESS MARKS

An access mark is traced on the skin at the intersection of the K-wires for the retractor insertion site. A posteriolateral incision mark is then made posterior to the first mark between the ilium and the rib cage.



SURGICAL TECHNIQUE

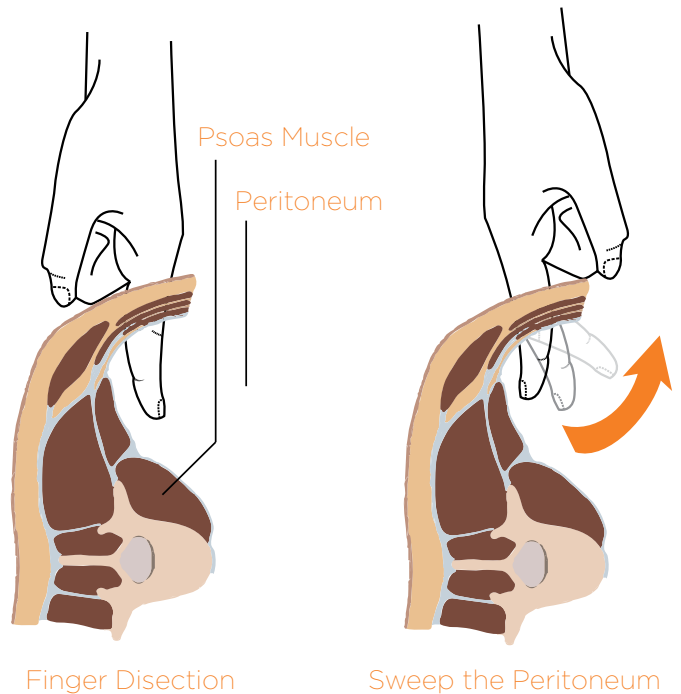
RETROPERITONEAL ACCESS

POSTEROLATERAL INCISION

Make an incision at the posterolateral mark to enter the retroperitoneal space.

⚠ Note: Care should be taken to avoid perforation of the peritoneum.

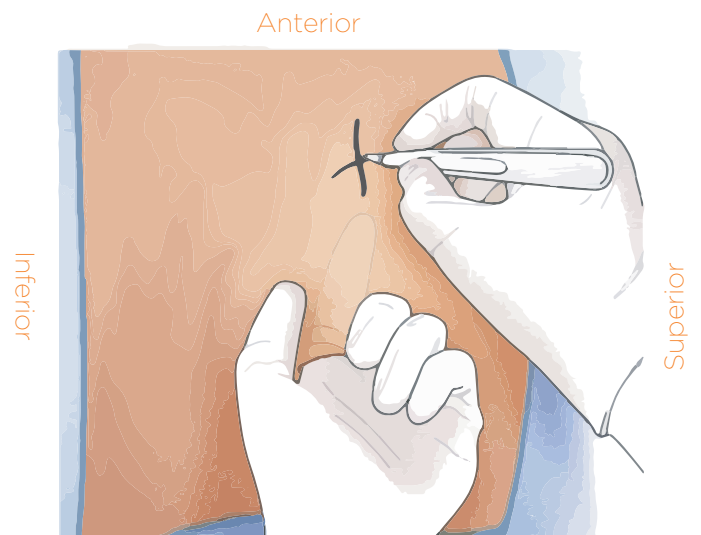
Once inside the retroperitoneal space, the index finger is used to create space and sweep the peritoneum anteriorly. After the peritoneum is released, palpate the psoas muscle, or anterior tip of the transverse process with the index finger.



ACCESS INCISION

Once the psoas muscle is identified, the index finger is swept up to the access incision mark.

A second incision is made at the access mark.



SURGICAL TECHNIQUE

TRANSPSOAS ACCESS

INITIAL DILATOR INSERTION

The initial dilator is introduced to meet the index finger already inside the retroperitoneal space.

The index finger is then used to guide the dilator safely down to the surface of the psoas muscle.

Once the dilator has reached the psoas muscle, the location is verified with a lateral fluoro image. The center of the disc space should be targeted.

The fibers of the psoas muscle are then split using the initial dilator.

- ⚠ *Note: If possible, before initial dilator insertion, sweep the psoas from anterior to posterior trying to place the dilator anterior to the psoas.*
- ⚠ *Note: Be cognizant of the genitor-femoral nerve lying on top of the psoas, a possible source of post operative thigh pain.*



SURGICAL TECHNIQUE

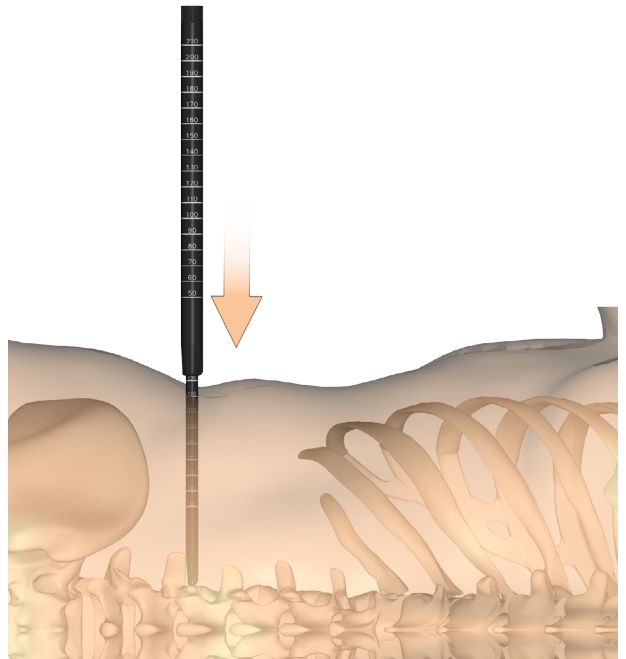
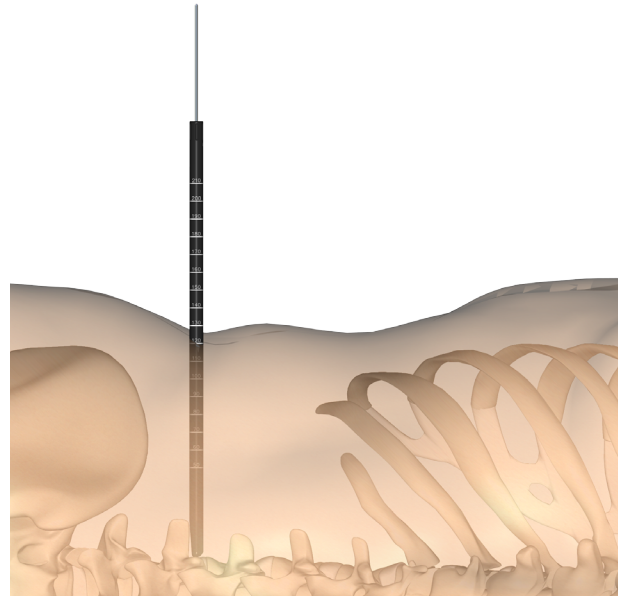
TRANSPSOAS ACCESS

SEQUENTIAL DILATION

Lateral flouroscopy is used to confirm proper initial dilator alignment and a K-wire is inserted through the initial dilator into the disc space, in preparation for sequential dilation.

⚠ Note: *Optionally, once dilator position is confirmed on flouroscopy and probe stimulation is quiet, gently mallet the dilator into the disc space, which could help secure its position. Once in place, the K-wire is inserted through the dilator. (ONLY recomended when using disposable dilator set.)*

With the K-wire in place, a series of cannulas are passed over the initial dilator using a twisting motion, spreading the psoas muscle to prepare for retrator insertion.



SURGICAL TECHNIQUE

DILATOR OPTIONS

OPTION 1: RE-USEABLE DILATOR

Insert the large dilator over the small dilator.

⚠ Note: DO NOT insert probe into small dilator when K-wire is present. If neuro-monitoring is necessary for small dilator, use disposable dilator set. (Option 2)

Use a disposable ball tip probe, pass the probe down the outer cannula of the large dilator.

The probe tip will be exposed at the cannula side of the dilator for neuro-monitoring.



SURGICAL TECHNIQUE

DILATOR OPTIONS

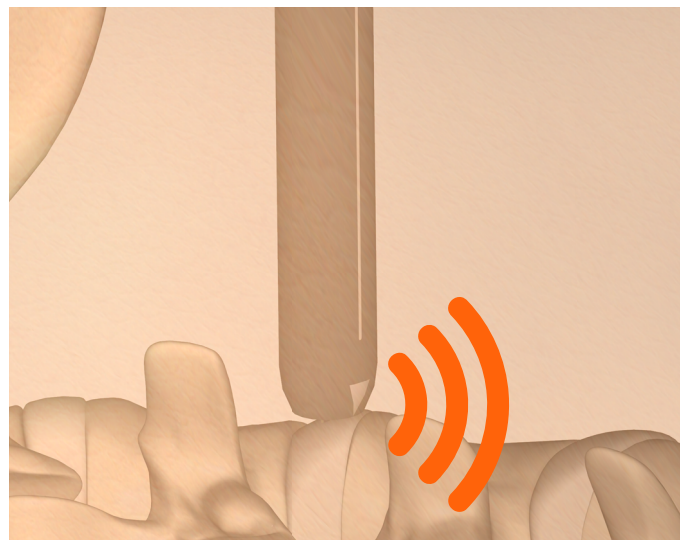
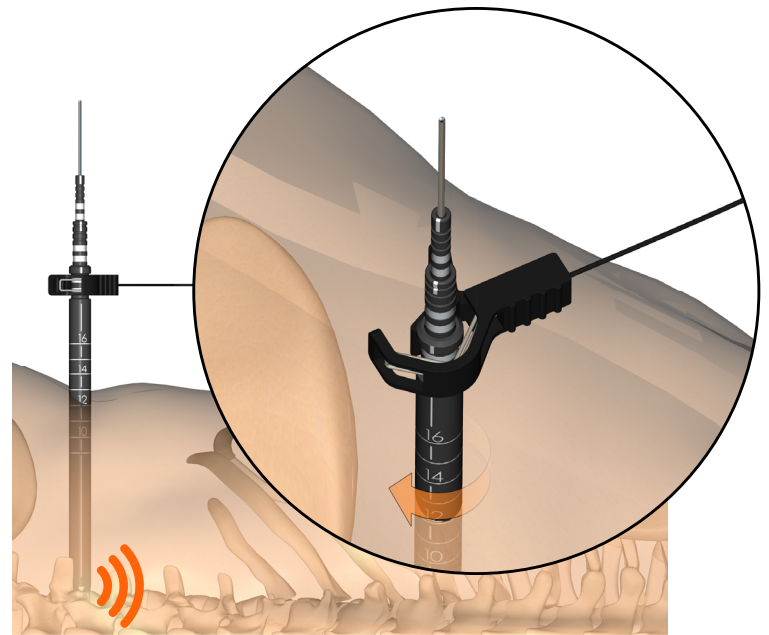
OPTION 2: DISPOSABLE DILATORS

Attach the neuromonitoring clip to the small dilator.

An alignment line on the dilator indicates the direction of the signal.

Remove the clip, insert the second dilator, and repeat neuromonitoring.

Remove the clip, insert the large dilator, and repeat neuromonitoring.

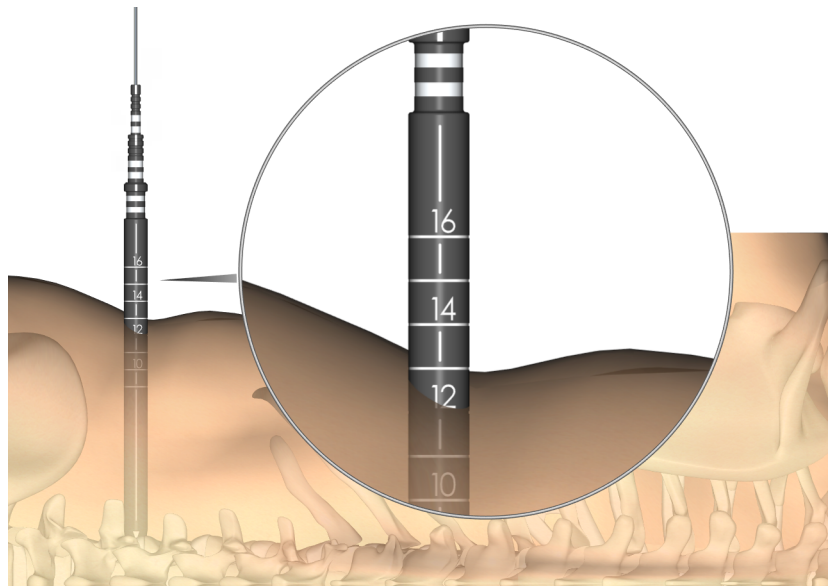


SURGICAL TECHNIQUE

TRANSPSOAS ACCESS

DETERMINE BLADE LENGTH

Depth markings on the largest dilator are used to determine the appropriate retractor blade length.



SURGICAL TECHNIQUE

RETRACTOR INSERTION

⚠ *Note: Innovasis provides 2 retractor system options, depending on surgeon preference. Refer to the retractor specific IFU's for each at www.innovasis.com.*

RETRACTOR ASSEMBLY

Assemble Retractor with selected blade length and ensure that its in the fully closed position.

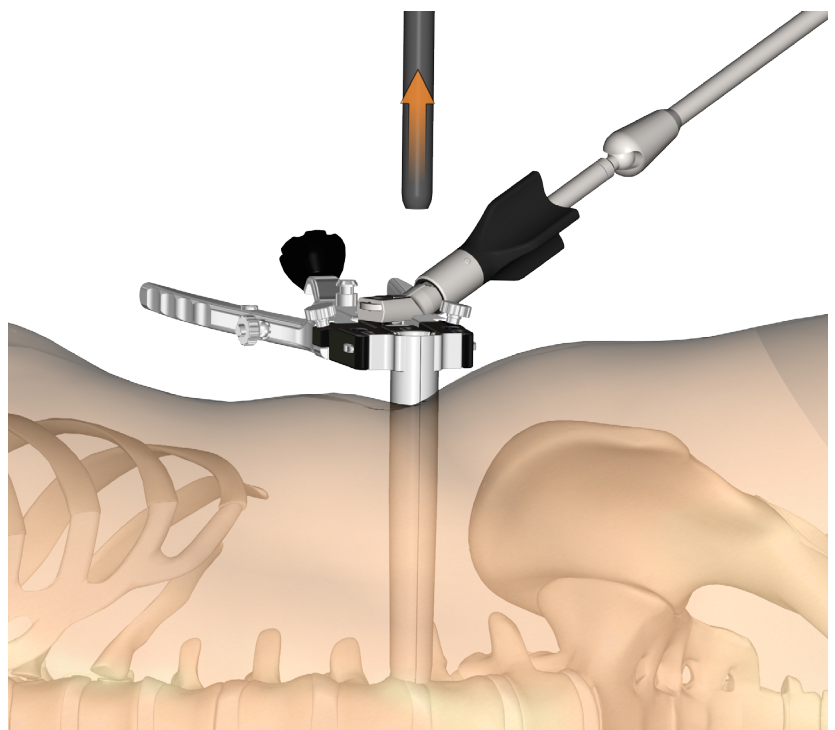
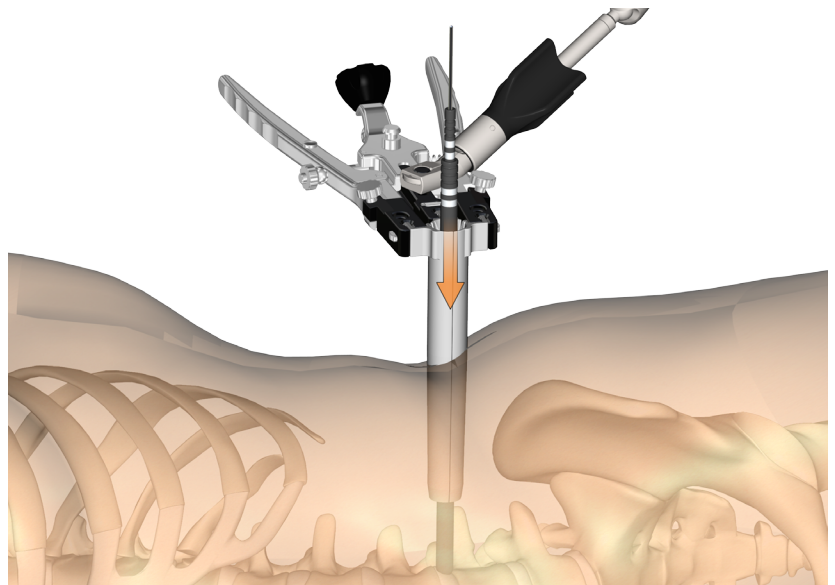
Slide the retractor over the final dilator and apply gentle downward pressure. Fluoroscopy is used to confirm the correct position of the retractor on the spine.

Secure the retractor to the table with the table clamp.

REMOVE DILATORS

Once the retractor has been securely positioned remove the dilators and K-wire.

⚠ *Note: Once the retractor is in position, stimulate the corners of the retractor bed to confirm no nerve stimulation is present.*



SURGICAL TECHNIQUE

DISC PREPARATION

BLADE ANCHORING

Anchor the blades using the appropriate screw, shim, and/or trochar.

ANNULOTOMY

Attach scalpel blade to the Bayonneted Annulotomy Knife.

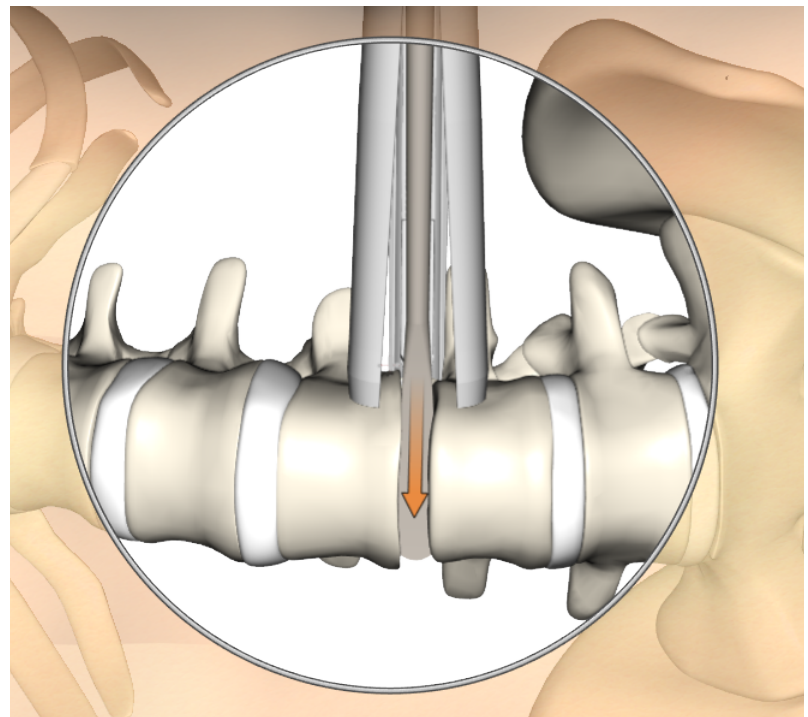
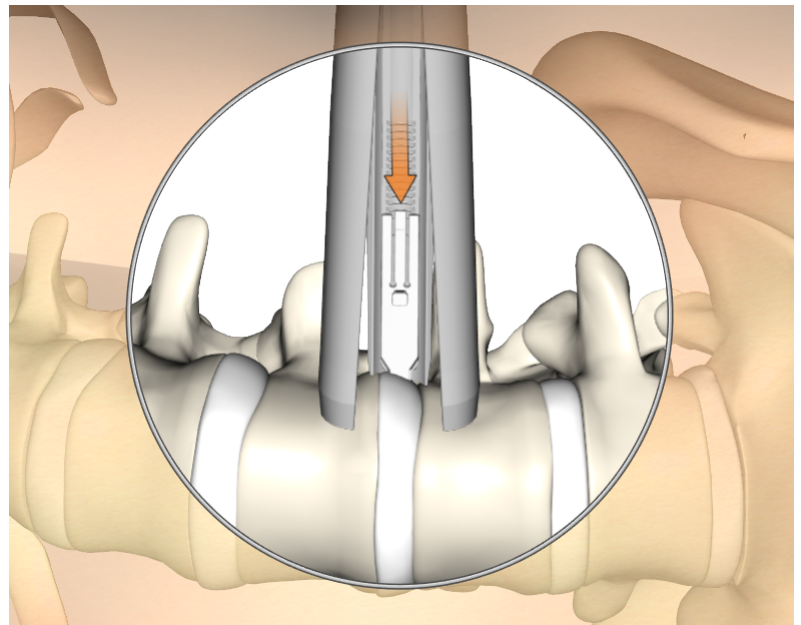
Make annulotomy in the anterior half of the annulus just wide enough for preparing the disc space and implant insertion.

CONTRALATERAL ANNULUS RELEASE

Use a Cobb Elevator to release the contralateral annulus.



Note: This step is critical to ensure that the implant rests on the contralateral apophyseal ring to maximize endplate support.



SURGICAL TECHNIQUE

DISC PREPARATION

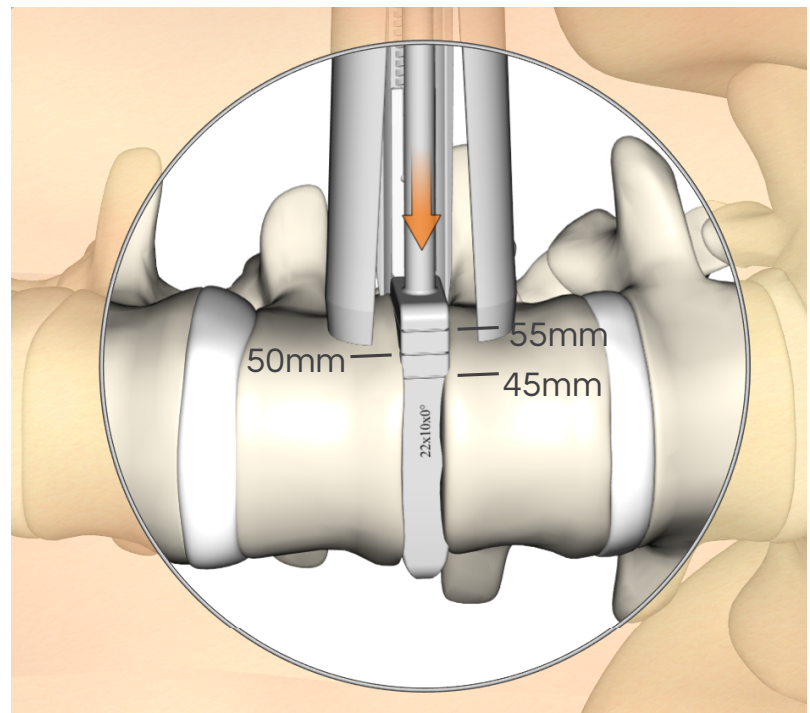
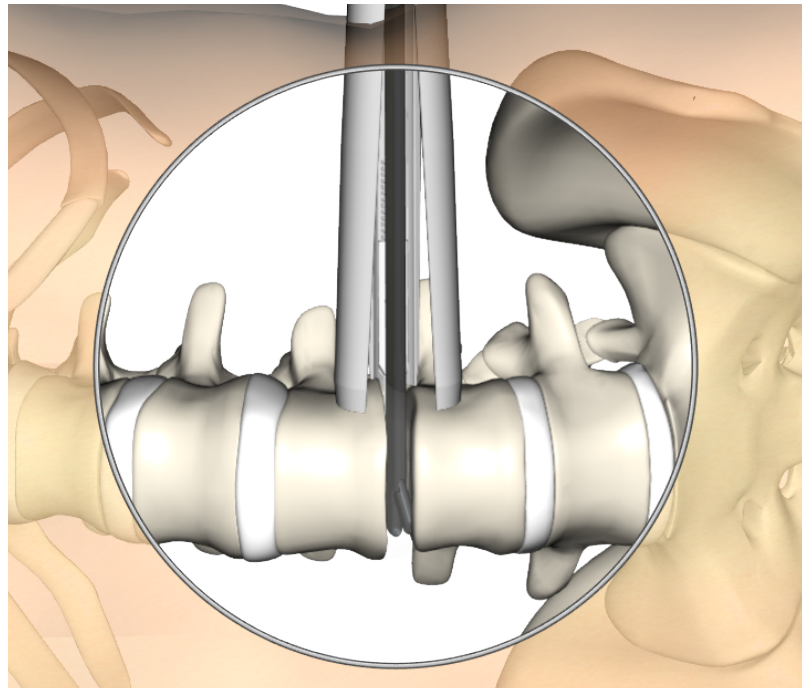
DISC PREPARATION

Leaving the posterior annulus intact, thoroughly evacuate the disc space and prepare the endplates for fusion. The Box Cutters, Shavers and disc preparation instruments are provided for disc removal and endplate preparation.

IMPLANT SIZING

The L-Box Sizers are used to determine the appropriately sized implant. Under fluoroscopy, the Sizer is gently impacted into the disc space until centered.

⚠ Note: *The posterior side of the L-Box Sizers with lordotic angle are labeled "POSTERIOR".*



SURGICAL TECHNIQUE

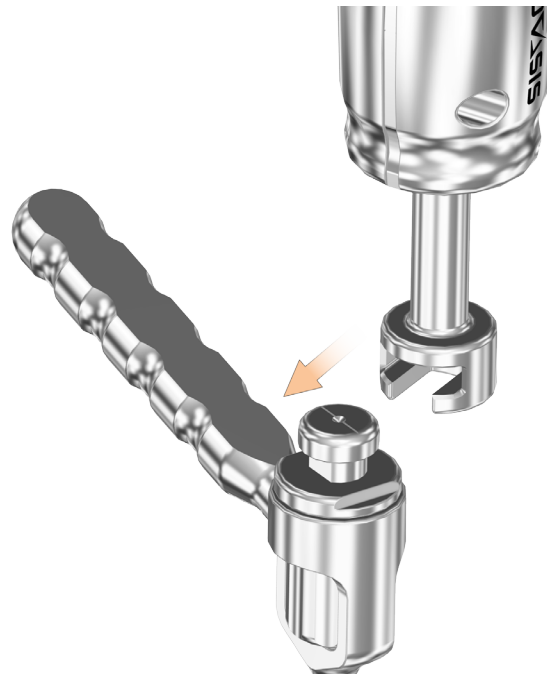
INSTRUMENT REMOVAL

SLIDE HAMMER OPTIONS

The L-Box Slide Hammer offers two options for attaching to instruments in the system.

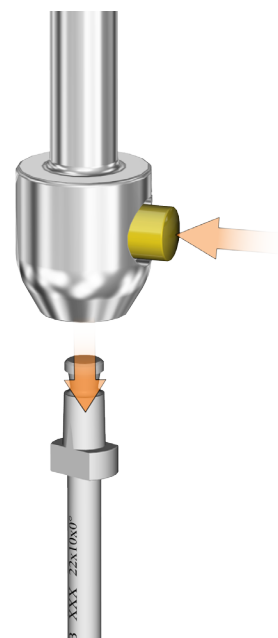
OPTION 1

The distal end of the Slide Hammer is designed to remove the Inserter and Graft Containment Shims. This end attaches to the “mushroom cap” feature as shown.



OPTION 2

The proximal end of the Slide Hammer is designed to remove instruments with a large hudson connection such as the Sizers and Disc Shavers. The Slide Hammer attaches as shown.



⚠ Note: *The proximal end of the Slide Hammer is NOT a push to connect attachment. The button must be pressed prior to placing the Slide Hammer over the large hudson connection.*



SURGICAL TECHNIQUE

IMPLANT INSERTION

IMPLANT INSERTION

The corresponding implant is selected, filled with graft material, and attached to the inserter.

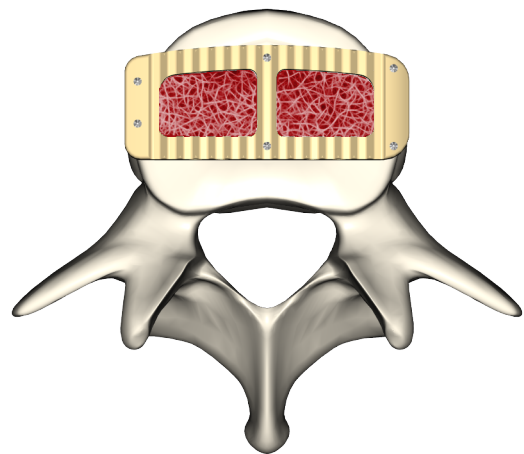
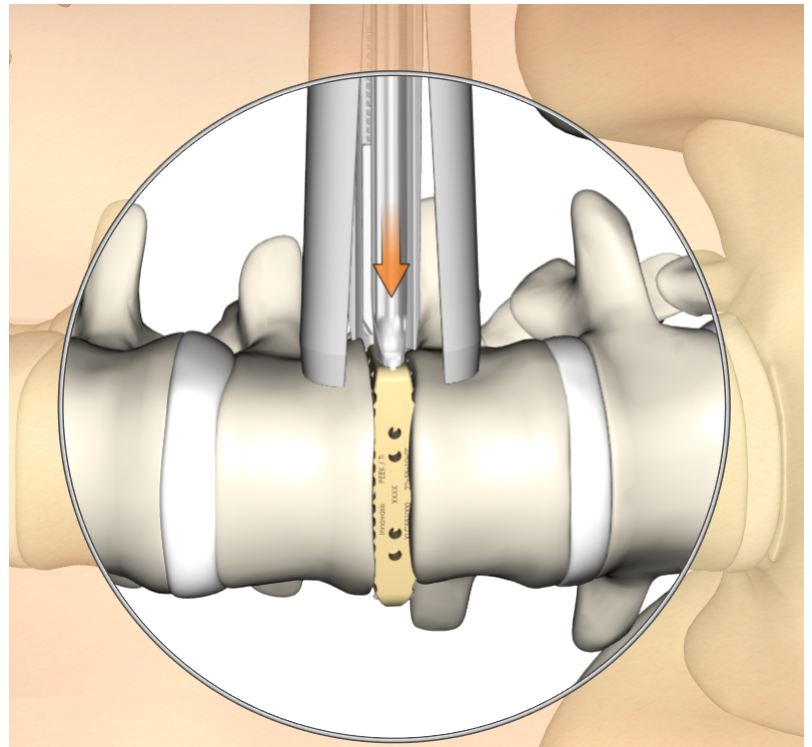
⚠ Note: *The thumbwheel should be tightened securely to ensure the inserter is fully flush with the implant.*

The implant is gently impacted into the disc space under AP fluoroscopy.

Once the position of the implant is confirmed release the inserter.

⚠ Note: *The anterior surface of the implant contains the laser marked size information.*

⚠ Note: *Ideal placement of the implant is centered across the disc space from a medial/lateral perspective, and between the anterior third and middle third of the disc space from an anterior/posterior perspective.*



Axial View



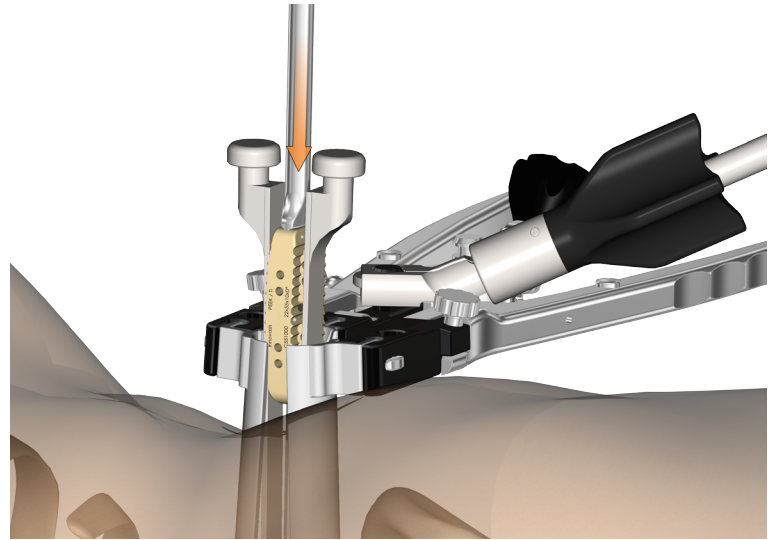
SURGICAL TECHNIQUE

OPTIMAL INSERTION TECHNIQUE

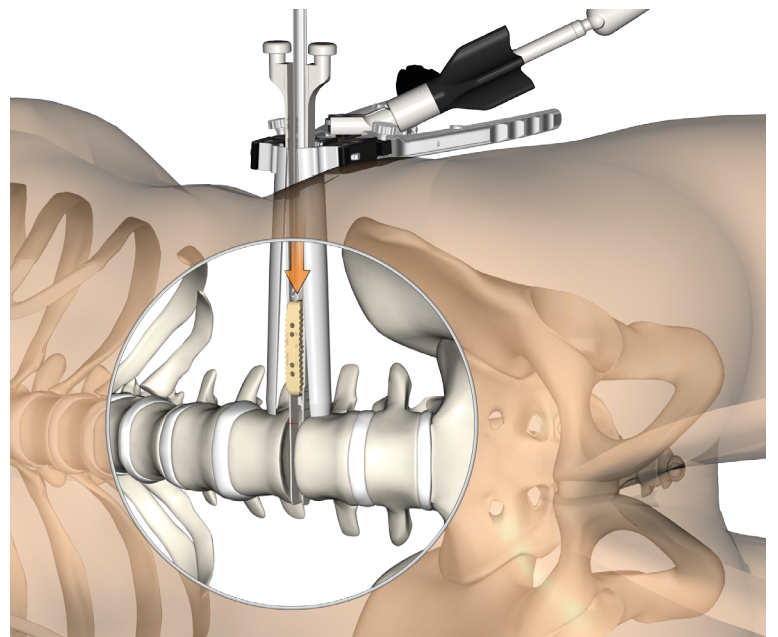
GRAFT CONTAINMENT SHIMS

The graft containment shims can be used to aid implant insertion and assist in containing the graft within the implant during insertion.

The shims are inserted into the disc space to create a ramp or guide for the implant. Once the shims are in place the implant can be inserted between the shims and impacted into place.



⚠ *Note: Care should be taken to ensure the shims do not protrude beyond the distal side of the vertebral body during implant insertion. The tips of each shim are marked with depth markings to provide visual confirmation of depth for each shim.*



SURGICAL TECHNIQUE

CLOSURE

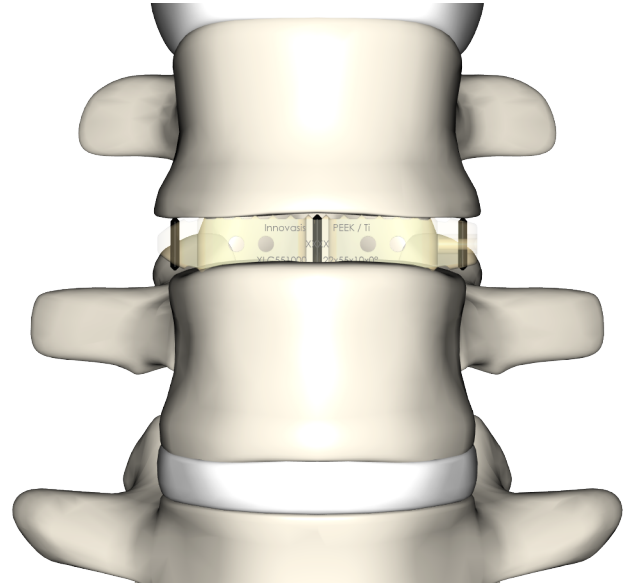
CLOSURE

Disconnect table clamp and remove retractor.

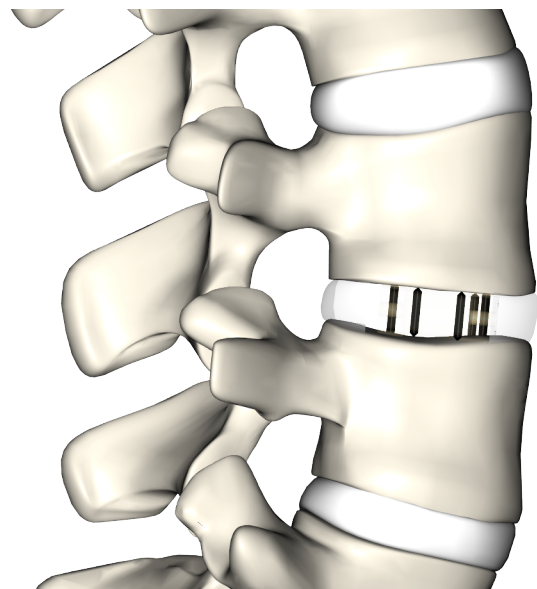
⚠ Note: After removing retractor ensure there is no significant bleeding.

Close the wound in the customary manner.

Reposition the patient as required for posterior spinal fixation.



AP View



Sagittal View



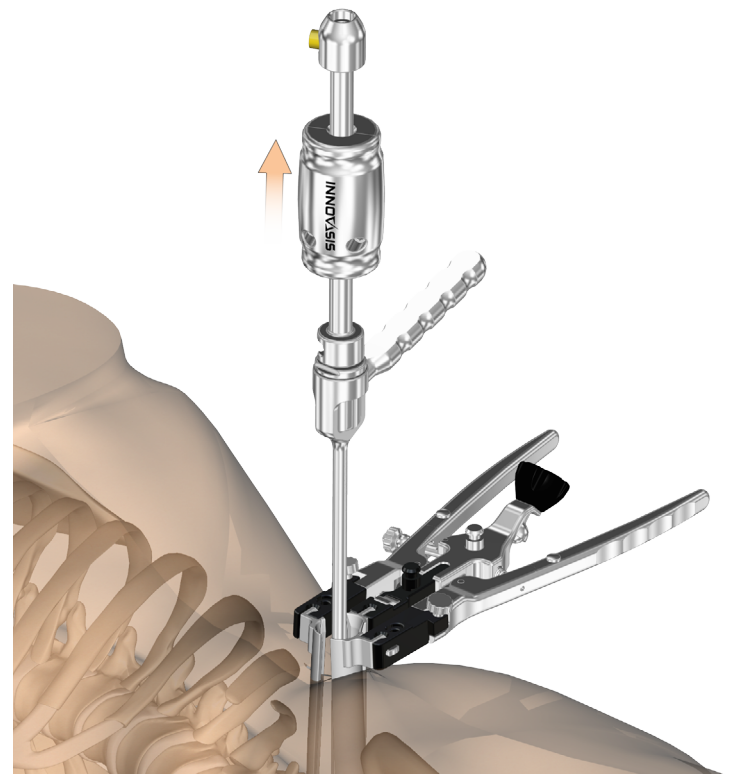
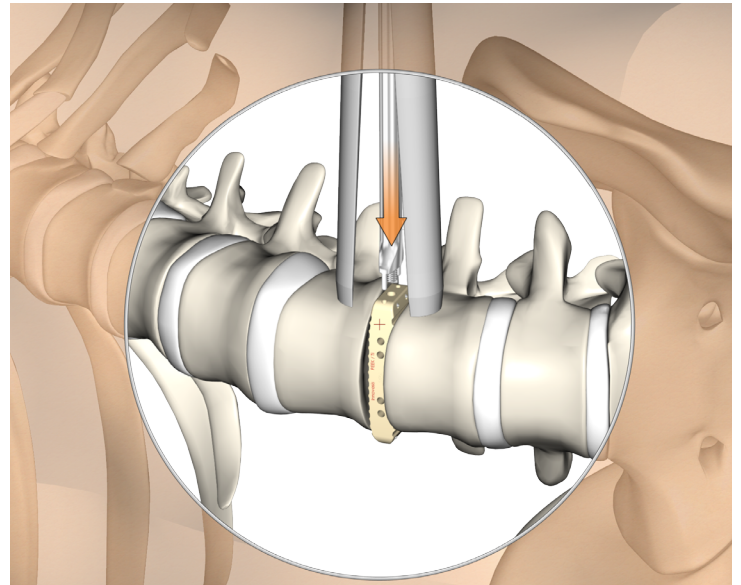
SURGICAL TECHNIQUE

IMPLANT REMOVAL

REMOVAL

After access is gained and the surface of the implant exposed, thread the inserter completely into the implant.

Attach Slide Hammer to the inserter and remove implant.



IMPLANTS

18mm L-BOX IMPLANTS

PART NO.	DESCRIPTION
XLB450800	LATERAL CAGE, 18 X 45 X 8MM X 0 DEG
XLB451000	LATERAL CAGE, 18 X 45 X 10MM X 0 DEG
XLB451200	LATERAL CAGE, 18 X 45 X 12MM X 0 DEG
XLB451400	LATERAL CAGE, 18 X 45 X 14MM X 0 DEG
XLB500800	LATERAL CAGE, 18 X 50 X 8MM X 0 DEG
XLB501000	LATERAL CAGE, 18 X 50 X 10MM X 0 DEG
XLB501200	LATERAL CAGE, 18 X 50 X 12MM X 0 DEG
XLB501400	LATERAL CAGE, 18 X 50 X 14MM X 0 DEG
XLB550800	LATERAL CAGE, 18 X 55 X 8MM X 0 DEG
XLB551000	LATERAL CAGE, 18 X 55 X 10MM X 0 DEG
XLB551200	LATERAL CAGE, 18 X 55 X 12MM X 0 DEG
XLB551400	LATERAL CAGE, 18 X 55 X 14MM X 0 DEG

XLB450807	LATERAL CAGE, 18 X 45 X 8MM X 7 DEG
XLB451007	LATERAL CAGE, 18 X 45 X 10MM X 7 DEG
XLB451207	LATERAL CAGE, 18 X 45 X 12MM X 7 DEG
XLB451407	LATERAL CAGE, 18 X 45 X 14MM X 7 DEG
XLB500807	LATERAL CAGE, 18 X 50 X 8MM X 7 DEG
XLB501007	LATERAL CAGE, 18 X 50 X 10MM X 7 DEG
XLB501207	LATERAL CAGE, 18 X 50 X 12MM X 7 DEG
XLB501407	LATERAL CAGE, 18 X 50 X 14MM X 7 DEG
XLB550807	LATERAL CAGE, 18 X 55 X 8MM X 7 DEG
XLB551007	LATERAL CAGE, 18 X 55 X 10MM X 7 DEG
XLB551207	LATERAL CAGE, 18 X 55 X 12MM X 7 DEG
XLB551407	LATERAL CAGE, 18 X 55 X 14MM X 7 DEG

XLB451012	LATERAL CAGE, 18 X 45 X 10MM X 12 DEG
XLB451212	LATERAL CAGE, 18 X 45 X 12MM X 12 DEG
XLB451412	LATERAL CAGE, 18 X 45 X 14MM X 12 DEG
XLB501012	LATERAL CAGE, 18 X 50 X 10MM X 12 DEG
XLB501212	LATERAL CAGE, 18 X 50 X 12MM X 12 DEG
XLB501412	LATERAL CAGE, 18 X 50 X 14MM X 12 DEG
XLB551012	LATERAL CAGE, 18 X 55 X 10MM X 12 DEG
XLB551212	LATERAL CAGE, 18 X 55 X 12MM X 12 DEG
XLB551412	LATERAL CAGE, 18 X 55 X 14MM X 12 DEG

22mm L-Box IMPLANTS

PART NO.	DESCRIPTION
XLC450800	LATERAL CAGE, 22 X 45 X 8MM X 0 DEG
XLC451000	LATERAL CAGE, 22 X 45 X 10MM X 0 DEG
XLC451200	LATERAL CAGE, 22 X 45 X 12MM X 0 DEG
XLC451400	LATERAL CAGE, 22 X 45 X 14MM X 0 DEG
XLC500800	LATERAL CAGE, 22 X 50 X 8MM X 0 DEG
XLC501000	LATERAL CAGE, 22 X 50 X 10MM X 0 DEG
XLC501200	LATERAL CAGE, 22 X 50 X 12MM X 0 DEG
XLC501400	LATERAL CAGE, 22 X 50 X 14MM X 0 DEG
XLC550800	LATERAL CAGE, 22 X 55 X 8MM X 0 DEG
XLC551000	LATERAL CAGE, 22 X 55 X 10MM X 0 DEG
XLC551200	LATERAL CAGE, 22 X 55 X 12MM X 0 DEG
XLC551400	LATERAL CAGE, 22 X 55 X 14MM X 0 DEG

XLC450807	LATERAL CAGE, 22 X 45 X 8MM X 7 DEG
XLC451007	LATERAL CAGE, 22 X 45 X 10MM X 7 DEG
XLC451207	LATERAL CAGE, 22 X 45 X 12MM X 7 DEG
XLC451407	LATERAL CAGE, 22 X 45 X 14MM X 7 DEG
XLC500807	LATERAL CAGE, 22 X 50 X 8MM X 7 DEG
XLC501007	LATERAL CAGE, 22 X 50 X 10MM X 7 DEG
XLC501207	LATERAL CAGE, 22 X 50 X 12MM X 7 DEG
XLC501407	LATERAL CAGE, 22 X 50 X 14MM X 7 DEG
XLC550807	LATERAL CAGE, 22 X 55 X 8MM X 7 DEG
XLC551007	LATERAL CAGE, 22 X 55 X 10MM X 7 DEG
XLC551207	LATERAL CAGE, 22 X 55 X 12MM X 7 DEG
XLC551407	LATERAL CAGE, 22 X 55 X 14MM X 7 DEG

XLC451012	LATERAL CAGE, 22 X 45 X 10MM X 12 DEG
XLC451212	LATERAL CAGE, 22 X 45 X 12MM X 12 DEG
XLC451412	LATERAL CAGE, 22 X 45 X 14MM X 12 DEG
XLC501012	LATERAL CAGE, 22 X 50 X 10MM X 12 DEG
XLC501212	LATERAL CAGE, 22 X 50 X 12MM X 12 DEG
XLC501412	LATERAL CAGE, 22 X 50 X 14MM X 12 DEG
XLC551012	LATERAL CAGE, 22 X 55 X 10MM X 12 DEG
XLC551212	LATERAL CAGE, 22 X 55 X 12MM X 12 DEG
XLC551412	LATERAL CAGE, 22 X 55 X 14MM X 12 DEG



CATALOG

INSTRUMENTS

PART NO.	DESCRIPTION
LAA-055	MALLET (1 LB)
LB-009	INITIAL DISC DISTRACTOR
LB-010	INSERTER, LATERAL CAGE
LB-158	SLIDE HAMMER
LB-020-06	SHAVER, 6MM
LB-020-08	SHAVER, 8MM
LB-020-10	SHAVER, 10MM
LB-020-12	SHAVER, 12MM
LB-020-14	SHAVER, 14MM
LB-056	HANDLE, QUICK CONNECT, LARGE HUDSON
LB-057	TARGET, RADIOGRAPHIC
LB-059-08	SHAFT, BOX CHISEL, 8MM
LB-059-10	SHAFT, BOX CHISEL, 10MM
LB-059-12	SHAFT, BOX CHISEL, 12MM
XTB0800	SIZER, LATERAL CAGE, 18 X 8MM, 0D
XTB0807	SIZER, LATERAL CAGE, 18 X 8MM, 7D
XTB0812	SIZER, LATERAL CAGE, 18 X 8MM, 12D
XTB1000	SIZER, LATERAL CAGE, 18 X 10MM, 0D
XTB1007	SIZER, LATERAL CAGE, 18 X 10MM, 7D
XTB1012	SIZER, LATERAL CAGE, 18 X 10MM, 12D
XTB1200	SIZER, LATERAL CAGE, 18 X 12MM, 0D
XTB1207	SIZER, LATERAL CAGE, 18 X 12MM, 7D
XTB1212	SIZER, LATERAL CAGE, 18 X 12MM, 12D
XTB1400	SIZER, LATERAL CAGE, 18 X 14MM, 0D
XTB1407	SIZER, LATERAL CAGE, 18 X 14MM, 7D
XTB1412	SIZER, LATERAL CAGE, 18 X 14MM, 12D
XTC0800	SIZER, LATERAL CAGE, 22 X 8MM, 0D
XTC0807	SIZER, LATERAL CAGE, 22 X 8MM, 7D
XTC0812	SIZER, LATERAL CAGE, 22 X 8MM, 12D
XTC1000	SIZER, LATERAL CAGE, 22 X 10MM, 0D
XTC1007	SIZER, LATERAL CAGE, 22 X 10MM, 7D
XTC1012	SIZER, LATERAL CAGE, 22 X 10MM, 12D
XTC1200	SIZER, LATERAL CAGE, 22 X 12MM, 0D
XTC1207	SIZER, LATERAL CAGE, 22 X 12MM, 7D
XTC1212	SIZER, LATERAL CAGE, 22 X 12MM, 12D
XTC1400	SIZER, LATERAL CAGE, 22 X 14MM, 0D
XTC1407	SIZER, LATERAL CAGE, 22 X 14MM, 7D
XCT1412	SIZER, LATERAL CAGE, 22 X 14MM, 12D
LB-145	GRAFT CONTAINMENT SHIM




► PRECAUTIONS

1. Box Surgical Implants are for SINGLE USE ONLY. An explanted implant should never be reimplanted. Even though a device appears undamaged, it may have defects and internal stress patterns which may lead to early breakage.
2. Correct handling of the implant is extremely important. Polymer implants are designed to support physiological loads. Excessive torque, when applied to insertion tools, can cause splitting or fracture of the implants. When a polymer implant is impacted or hammered into place, the broad surface of the insertion tool should be carefully seated fully against the implant. Impaction forces applied directly to a small surface of the implant could cause fracture of the implant. Split or fractured implants should be removed and replaced.
3. The patient must be adequately instructed. Postoperative care and the patient's ability and willingness to follow instructions are among the most important aspects of successful bone healing. The patient needs to be aware of the limitations of the implants. The patient should be 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 competent bone healing. Implants displaced or damaged by improper activities may experience migration of the devices and damage to nerves or blood vessels.
4. The Box PEEK IBF System has not been evaluated for safety and compatibility in the MR environment. The Box PEEK IBF System has not been tested for heating or migration in the MR environment.



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