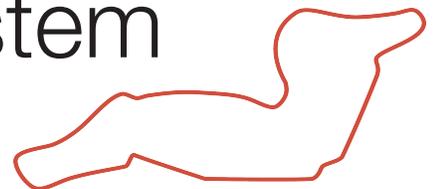


Imola Lateral IBF System

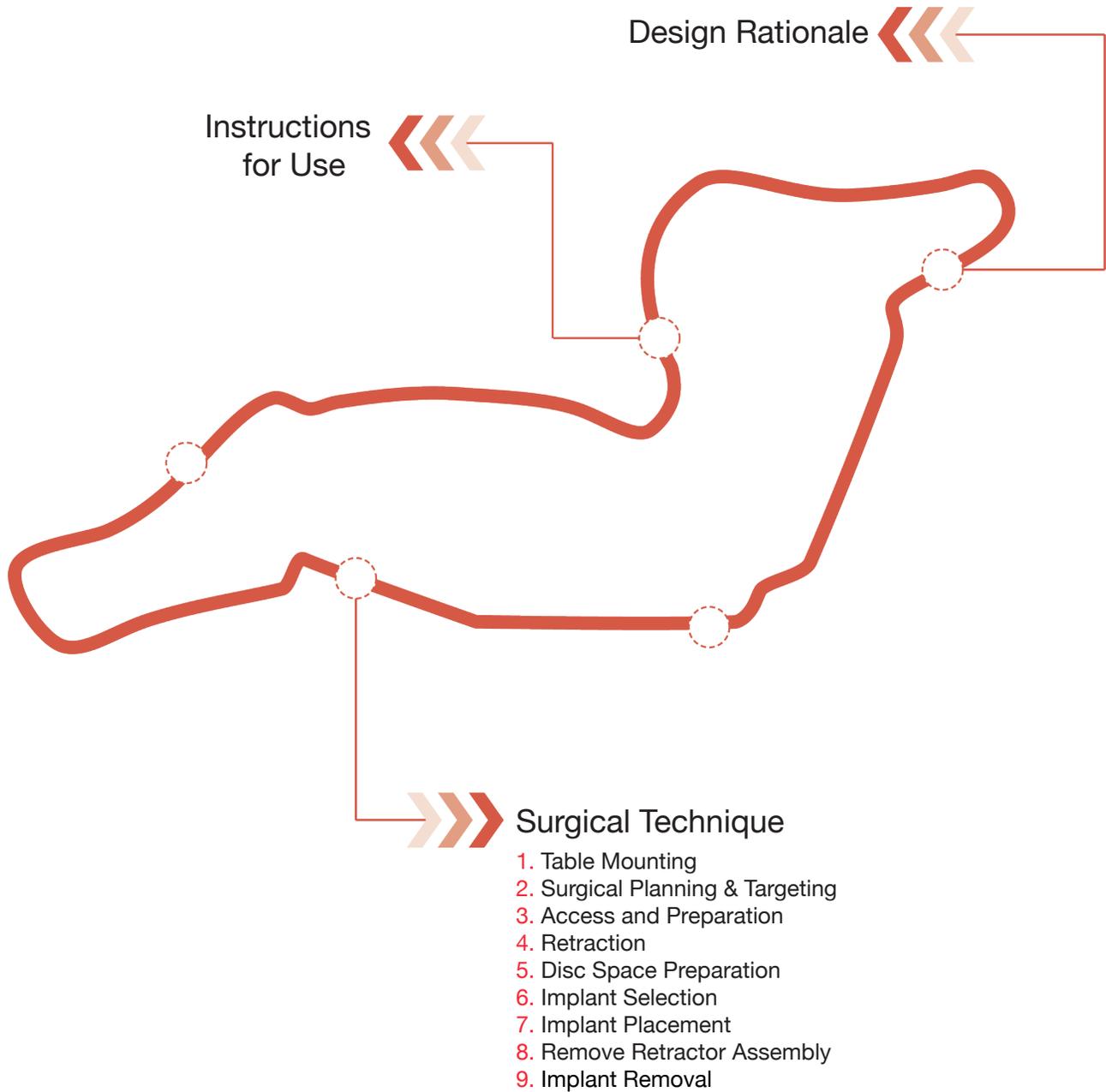
Surgical Technique



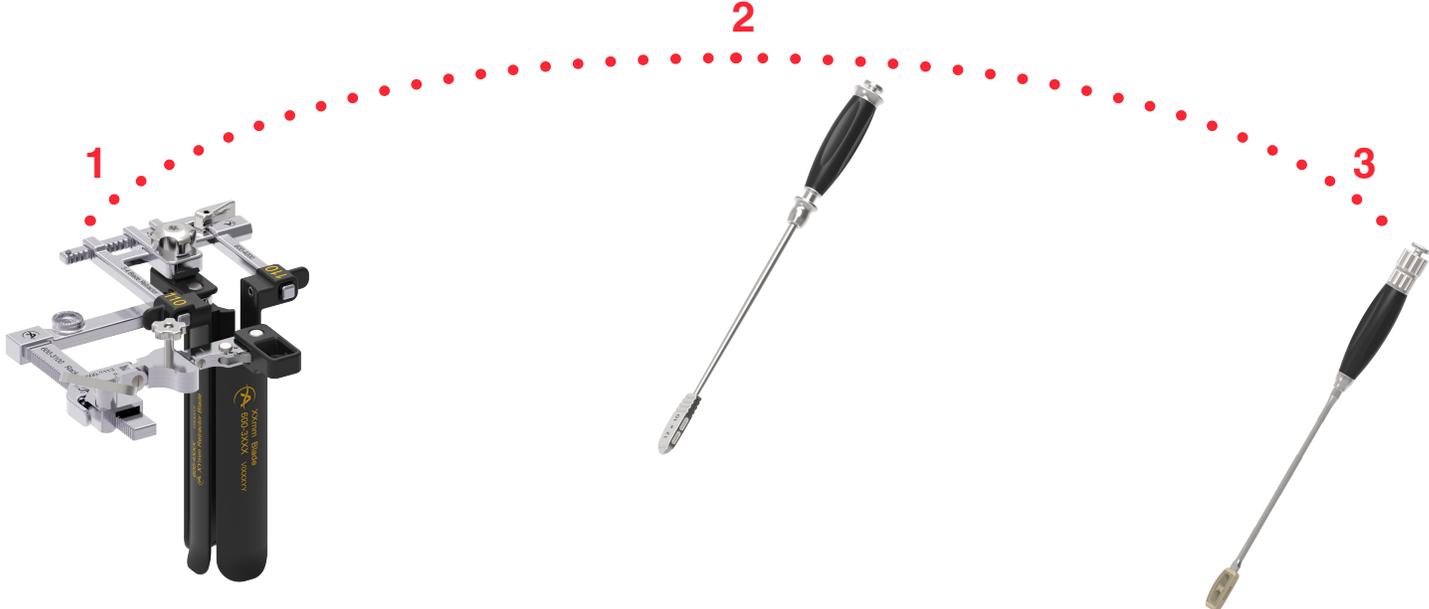


IMOLA CIRCUIT

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DESIGN RATIONALE



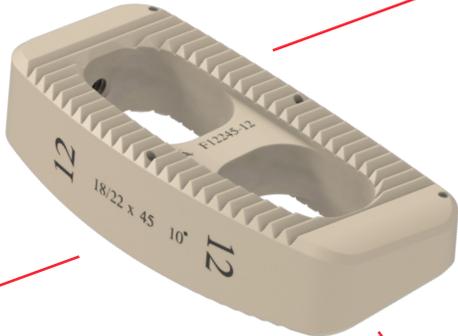
18, 22, 26mm Widths

40, 45, 50, 55, 60mm Lengths

Large axial graft window

Tapered, self-distracting leading edge

Available heights: 8mm to 16mm, in 2mm increments



INDICATIONS FOR USE

The Altus Spine Interbody Fusion System is indicated for use with autogenous bone graft in skeletally mature patients with degenerative disc disease (“DDD”) at one or two contiguous spinal levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six months of non-operative treatment. These DDD patients may have had a previous non-fusion spinal surgery at the involved spinal level(s), and may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s).

The Altus Spine Interbody Fusion System is to be combined with cleared supplemental fixation systems, such as the Altus Spine Pedicle Screw System.

Reference product insert (**PI-009**) for complete system indications for use, description, warnings and precautions

*Covered by U.S. Patent No.: 9,408,598.
Other U.S. and foreign patents additionally pending

1. TABLE MOUNTING

MOUNTING BRACKET

As needed, mount the Table Mount Rail Adapter

Note: The Table Mount Rail Adapter may be mounted to table prior to sterile draping. It remains in non-sterile field throughout procedure

SECURING THE TABLE POST

The Vertical Post mounts to the hospital bed rail or the Rail Adapter as previously determined

Mount the Clamp to the bed rail on the opposite side of the surgeon near the patient's hip

Note: The Vertical Post should remain sterile as the lower clamp is attached in the non-sterile field

Note: Make sure to place the Vertical Post out of the way of the anticipated direction of fluoroscopy

Turn the Clamp locking mechanism clockwise to secure it to the bed

Once the Clamp is secure, attach the Snake Arm or the Rigid Arm to the Vertical Post and lock into place

The Snake/Rigid arm should be positioned to lie across the patient and wrapped in front of the surgeon

Note: When using a Jackson table, an OSI adapter is needed to mount the Clamp to the table

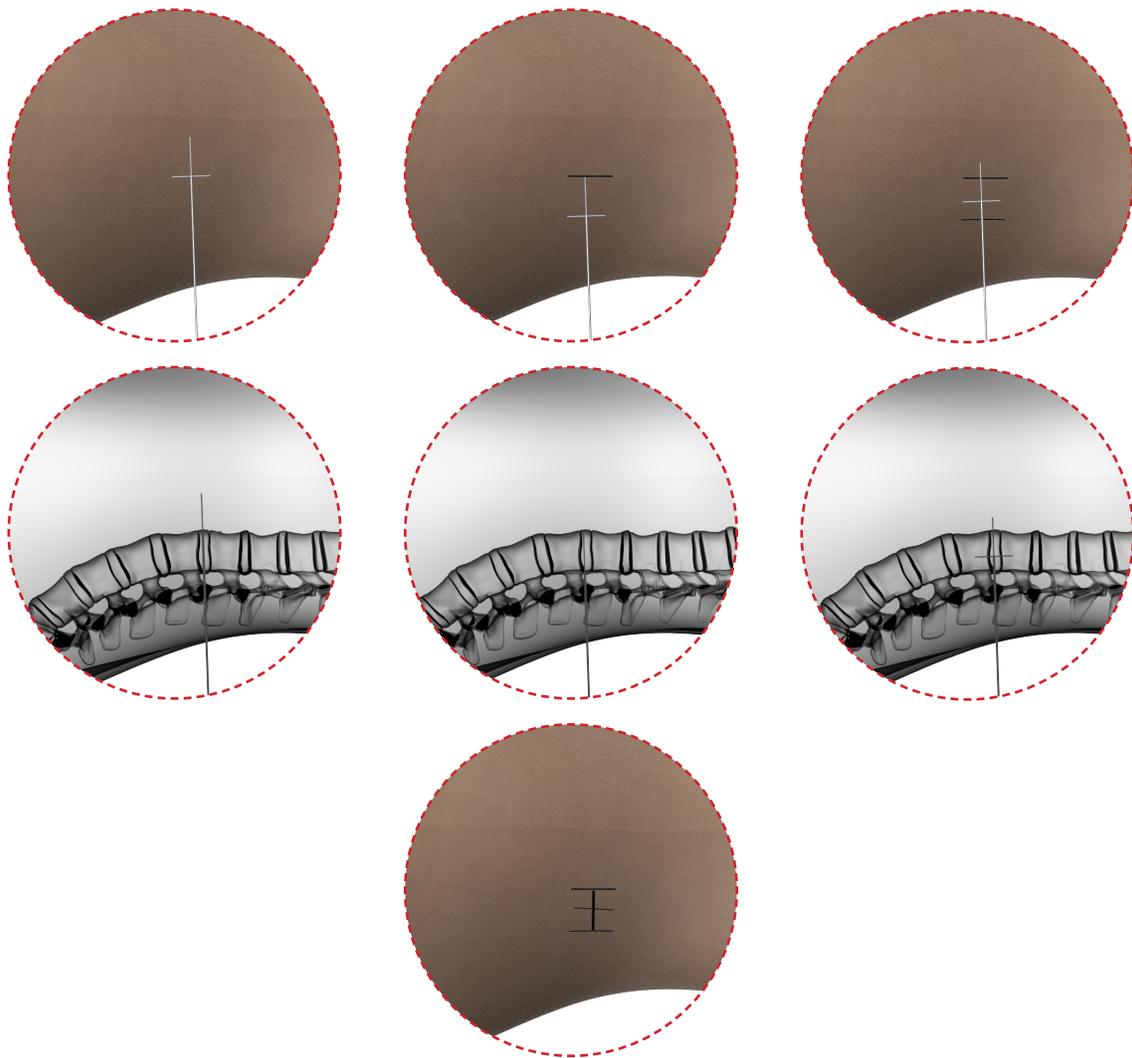


2. SURGICAL PLANNING & TARGETING

TARGETING THE SURGICAL SITE

After the patient is properly positioned, hold the Targeting Instrument over the surgical area, centered over the desired disc space

Using fluoroscopy to target operative level, mark the skin to indicate the anterior and posterior border of the vertebral bodies and a transverse mark for the disc space to serve as location of the skin incision for the operative corridor

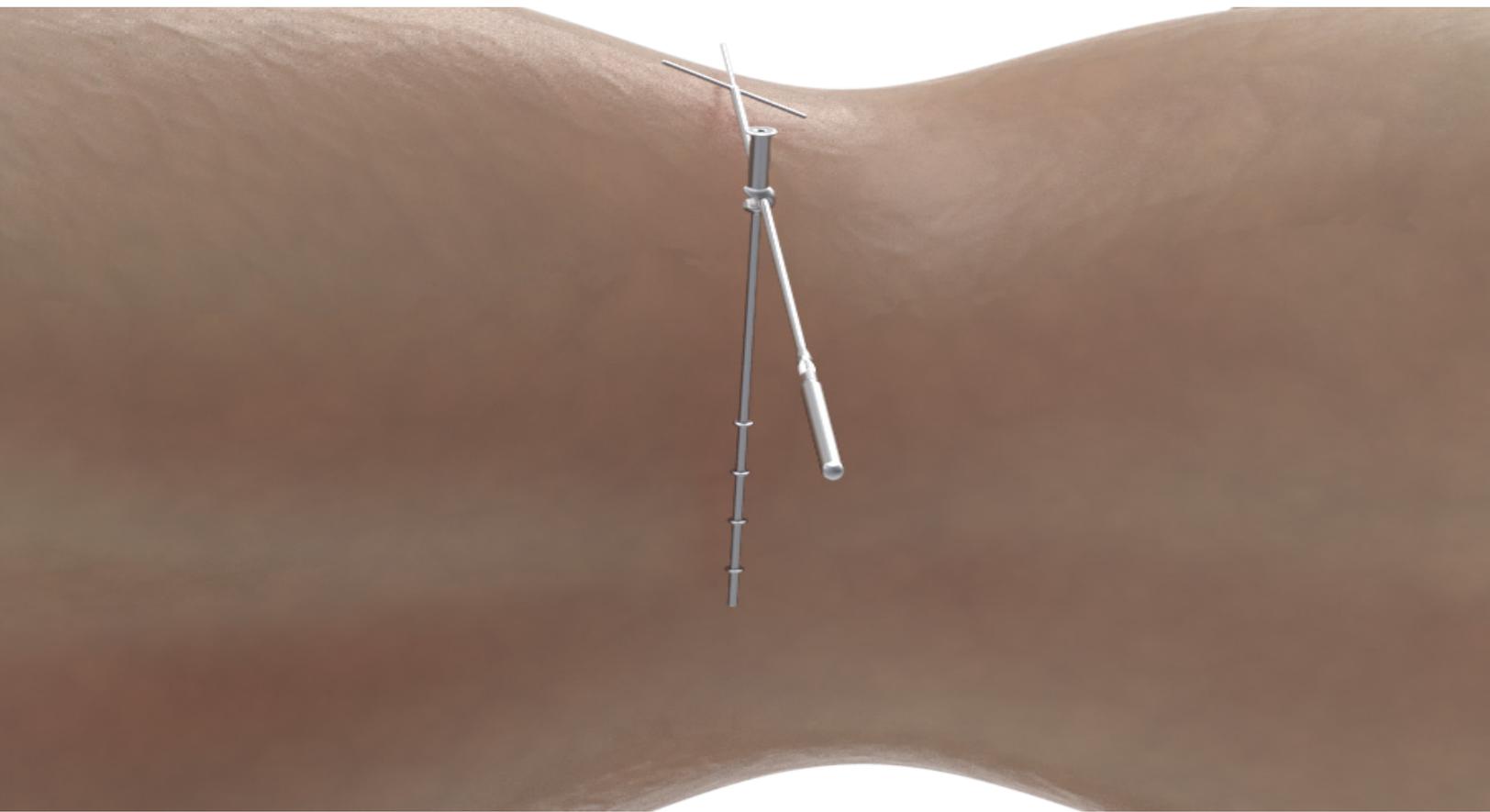
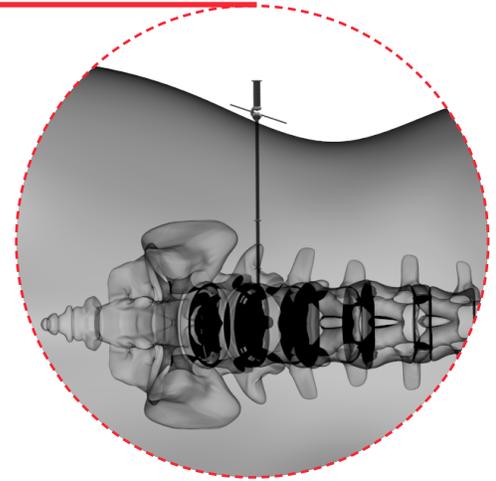


2. SURGICAL PLANNING & TARGETING (CONT.)

BLADE SIZING

Attach the Blade Template to the Targeting Instrument and place against the posterior of the patient

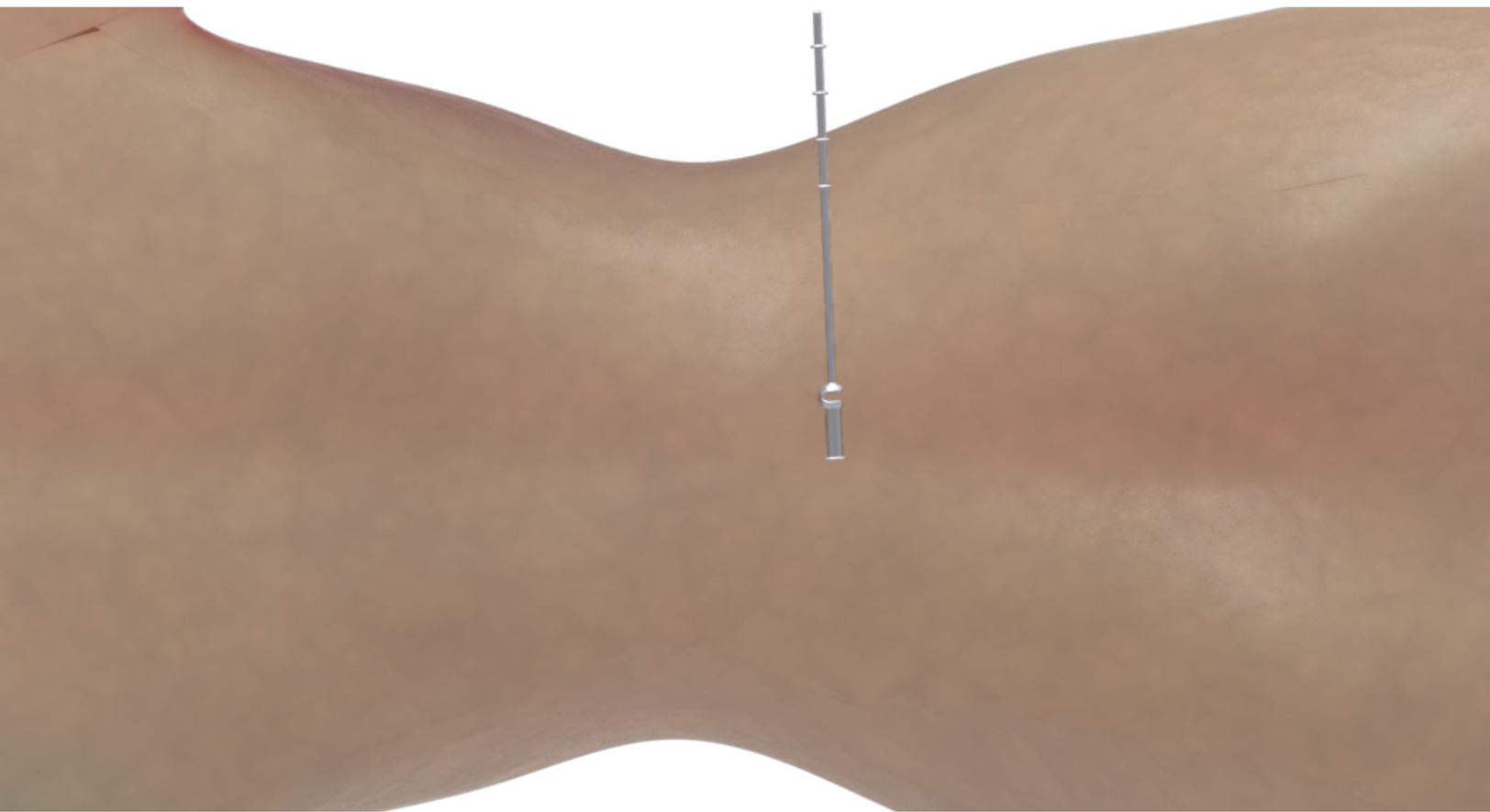
While holding the targeting instrument in a horizontal position, use the depth markers on the Blade Template to determine blade length, by observing the depth measurements etched on the Blade Template at the desired length



2. SURGICAL PLANNING & TARGETING (CONT.)

BLADE SIZING ALTERNATIVE (OPTIONAL)

The Blade Template can be used independently from the targeting device to determine the blade length. Place the end of the handle on the centerline of the patient. Determine blade length by observing the depth measurement etched on the Blade Template at the desired length



3. ACCESS AND PREPARATION

BLADE PLACEMENT

Engage the threaded portion of the Detachable Blade Handles with the threaded hole of the selected size Blades and then turn the knob until secure

Note: A Torx Screwdriver is supplied for additional tightening

Introduce and position the Blades through the incision and through the retroperitoneal space. Use blades to carefully dissect anterior to, or through, the anterior third of the psoas muscle while visually monitoring for nerves

Retract the Blades to provide appropriate exposure of the operative disc space

The Retractor Blades should be at the disc space with the handles facing anteriorly and posteriorly while maintaining the appropriate surgical exposure



4. RETRACTION

RACK INSERTION

Slide the toothed portion of the Rack into the Slider

Holding the Blades in place, connect the Retractor Frame to the blades

The Blades can be distracted by advancing the Slider along the Rack by turning the knob on the Slider



4. RETRACTION (CONT.)

DISC SHIM (OPTIONAL)

The Retractor Blades can be anchored to the targeted level disc using the Disc Shim

Introduce the Disc Anchor Shim through the blade slot

Use Shim Impactor Tool to fully seat shim in targeted disc

To remove the Disc Anchor Shim, use the Shim Removal Tool to engage the tab of the shim and pull upward to fully disengage from the Blade

Note: Disc Shim protrudes 17mm beyond blade when fully seated

LIGHT MAT (OPTIONAL)

A disposable Light Mat can be positioned at the end of the retractor or at the bottom end of the retractor blades inside the retracted space

After attaching the Light Mat to the Light Mat Attachment, slide the Light Mat Attachment through the blade slot

Use the Shim Removal Tool to fully seat Light Mat Attachment

Follow the instructions for use of the Light Mats

Note: The disposable Light Mat is a sterile, single use product

To remove the Light Mat Attachment, use the Shim Removal Tool to engage the tab of the shim and pull upward to fully disengage from the Blade



4. RETRACTION (CONT.)

MOUNTING THE RETRACTOR

Place the Table Mount Adapter in the desired hole of the Slider and secure with the Retractor Driver which can then be attached to the table using the Positioning Arm and Vertical Arm

Once the retractor is secured, turn the knobs of the Detachable Blade Handles counterclockwise by hand, or using the T25 Driver attached to the Fixed T-Handle, to disengage from the blades and remove



4. RETRACTION (CONT.)

MEDIAL/LATERAL FRAME BLADE (OPTIONAL)

Select the appropriate length Blades

Slide the blades onto the 3-4 Blade Retractor Rack

Insert the Medial/Lateral Blades and frame into the incision

The Frame can sit in the distal end of either of the cranial/caudal Blades

Once positioned in the desired Blade, turn the knob of the 3-4 Blade Retractor Rack until it is securely in place

The gear beside the knob can be used to expand the medial/lateral frame



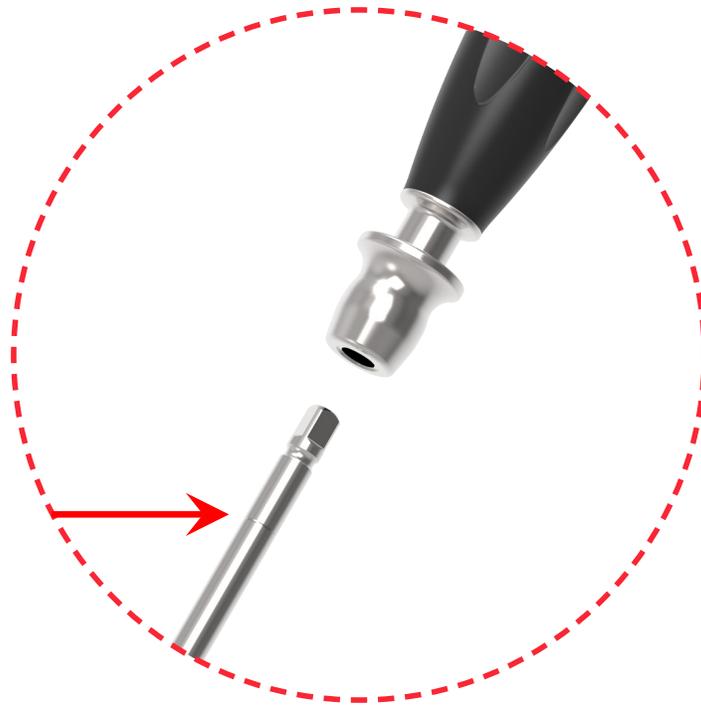
5. DISC SPACE PREPARATION

Select appropriate instruments needed to completely remove central disc material

For loading all instruments, pull back the plunger and insert the shaft until the “load line” is flush with the plunger then release

Release the contralateral annulus

Prepare the endplates using standard techniques



6. IMPLANT SELECTION

TRIAL USAGE

Select an appropriately sized Implant Trial in the desired footprint

Assemble the appropriate size Trial to the Fixed Cannulated Straight Handle

Insert the trial assembly in to the disc space; impact the trial assembly if necessary

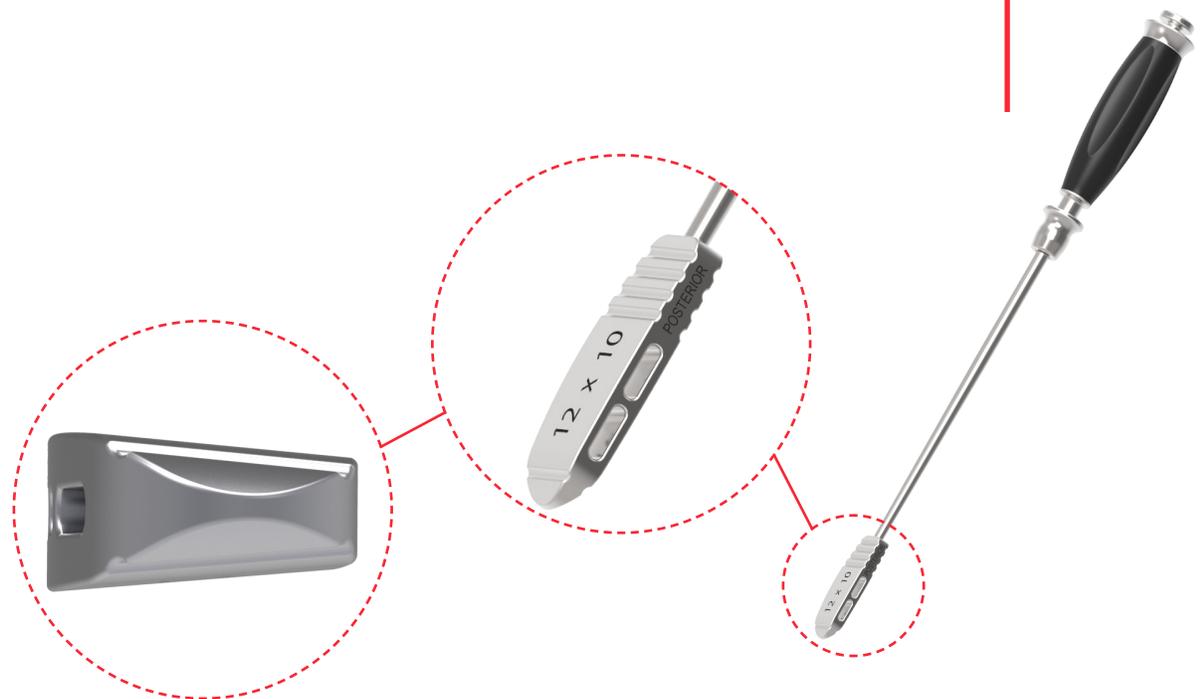
Use fluoroscopy to confirm the position and fit of the trial

REMOVE TRIAL

As needed, a Slap Hammer is available to aid in removing the trial assembly from the disc space

Attach the Slap Hammer to the distal end of the trial assembly

Remove trial assembly from disc space



7. IMPLANT PLACEMENT

ASSEMBLE IMPLANT TO INSERTER

Assemble the Implant Inserters with the inner shafts

Select the appropriately sized Implant with the desired footprint

Engage the forks of the inserter into the slots of the Implant

Thread the inner rod of the Inserter into the female threaded portion of the Implant

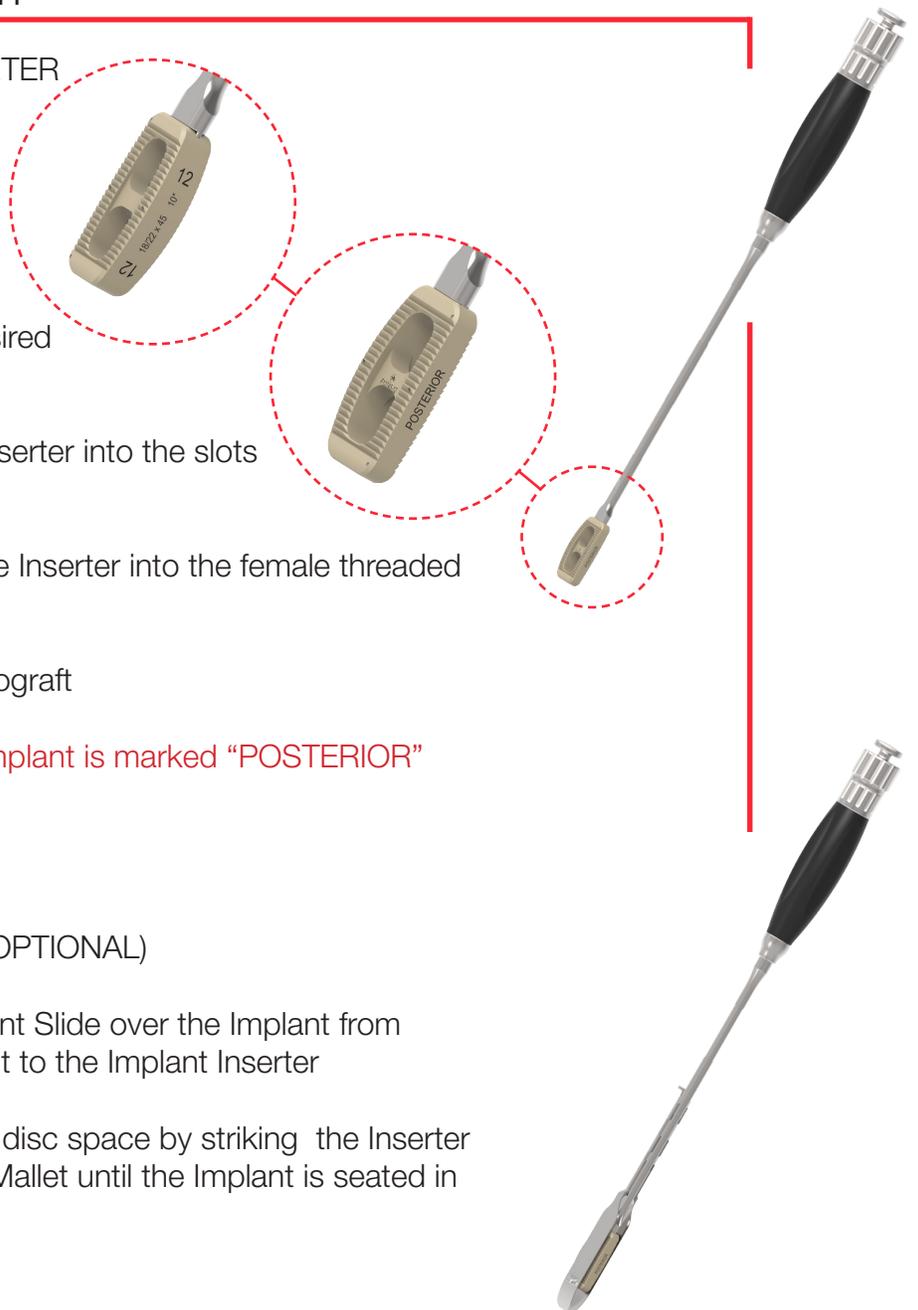
Pack the Implant with autograft

Note: The posterior side of the implant is marked "POSTERIOR"

GRAFT CONTAINMENT SLIDE (OPTIONAL)

Slide the Graft Containment Slide over the Implant from posterior side and attach it to the Implant Inserter

Insert the Implant into the disc space by striking the Inserter impaction surface with a Mallet until the Implant is seated in the disc space as desired



7. IMPLANT PLACEMENT (CONT.)

REMOVE THE INSERTER

Rotate the thumbwheel of the Inserter in a counterclockwise motion to release the Implant from the Inserter

Utilize the Impactor or Tamp for further Implant manipulation



8. REMOVE RETRACTOR ASSEMBLY

Remove the Retractor by pressing the release button on the slider

The Retractor can be lifted and removed from the incision

9. IMPLANT REMOVAL

USING IMPLANT INSERTER

Thread the Implant Inserter to the implant

Attach the Slap Hammer to the end of the Implant Inserter

Remove assembly from disc space

USING IMPLANT REMOVER

Insert the Remover into the disc space with its flat surface parallel to the endplates

Press the Remover under the tapered edge of the implant

Use fluoroscopy and the tantalum markers of the implant to confirm that the location of the Remover tip is beyond the centerline of the implant

Rotate the Remover 90° to allow the tip to hook on to the implant

Attach the Slap Hammer Adapter and Slap Hammer to the end of the Implant Inserter

Remove assembly from disc space

