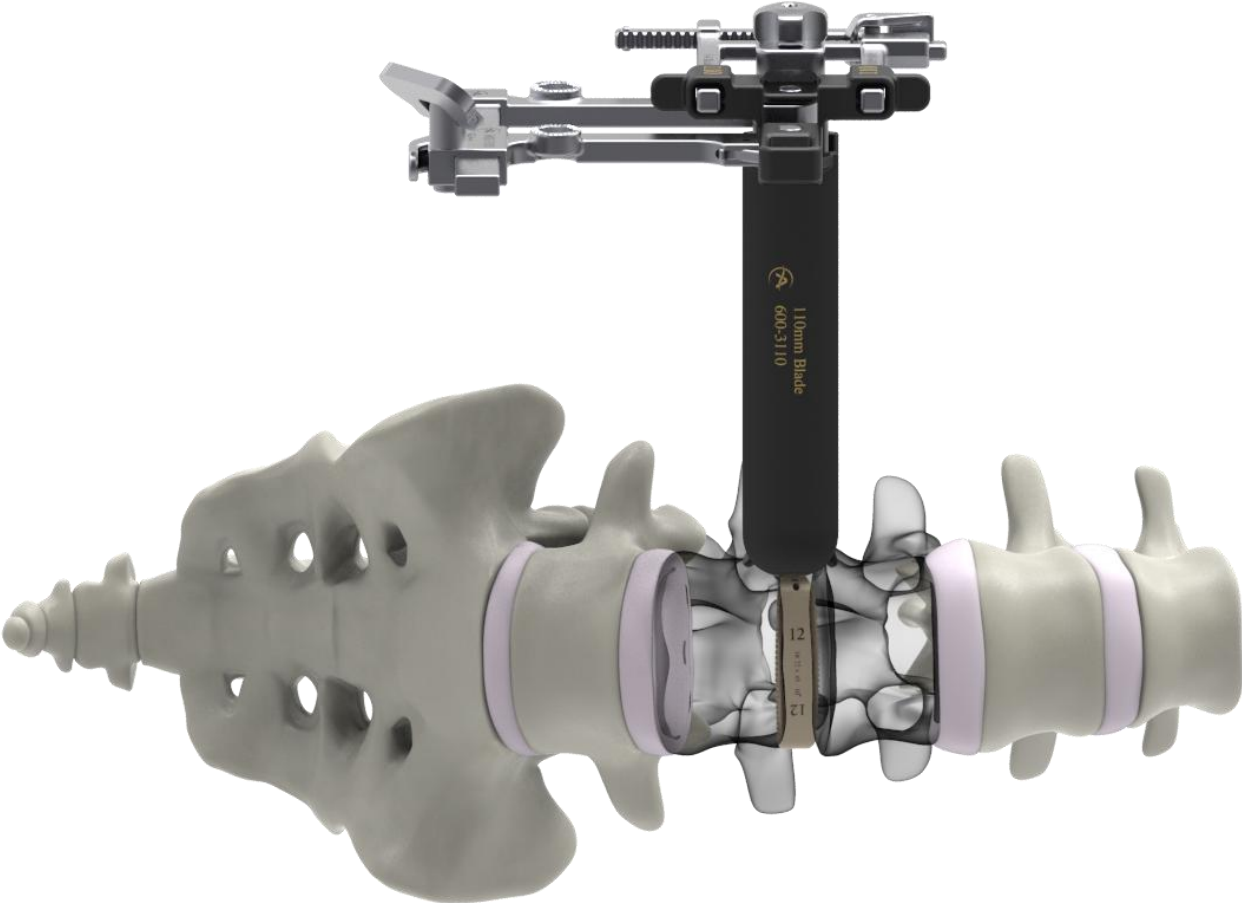
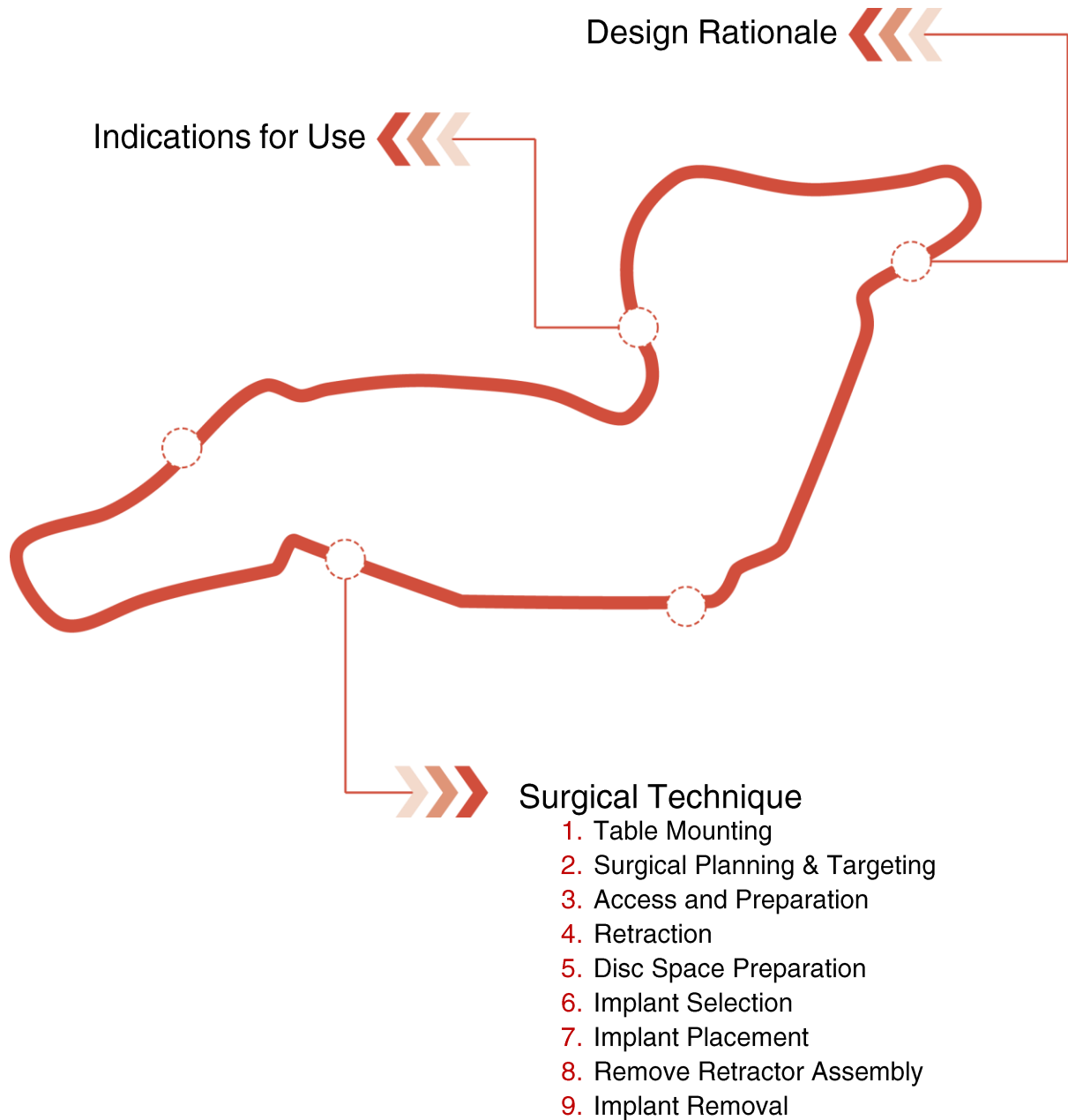


# Imola Lateral IBF System Surgical Technique



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# DESIGN RATIONALE



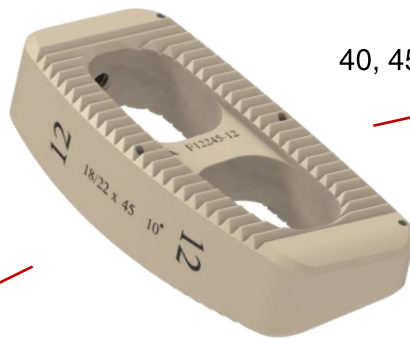
22, 26mm Widths

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).

Reference product insert (PI-002) for complete system indications for use, description, warnings and precautions

# 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 ARM

- The Vertical Arm 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 arm should remain sterile as the lower clamp is attached in the non-sterile field*

*Note: Make sure to place the arm 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 arm post and lock into place

*Note: The Articulating Arm and the Table Clamp may be used as an alternative*

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

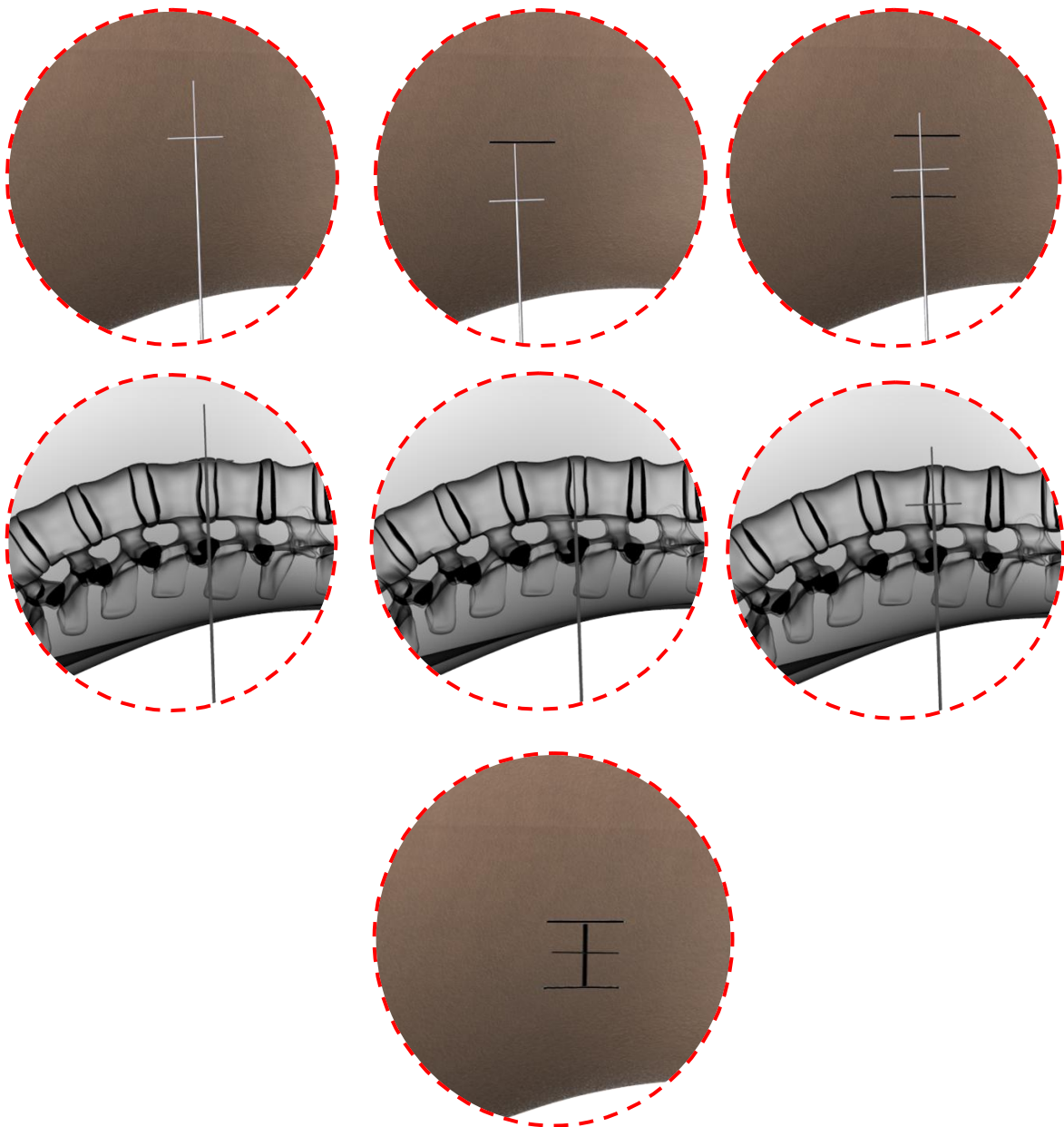
*Note: When using a Jackson table, an OSI adapter is needed to mount the Clamp to the table*



## 2. SURGICAL PLANNING & TARGETING

### TARGETING THE SURGICAL SITE

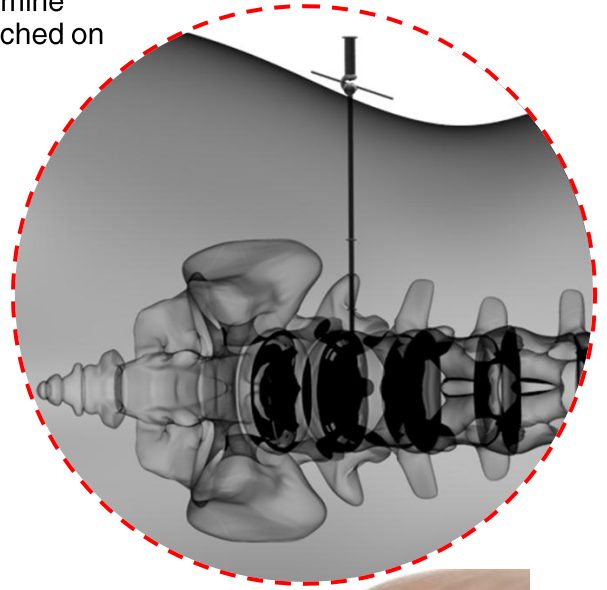
- After the patient is properly positioned, hold the Targeting Instrument over the surgical area, centered over the indicated disc space
- Using fluoroscopy to target operative level, mark the skin to indicate the anterior and posterior border of the vertebral bodies and a transverse mark for the disc 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
- 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

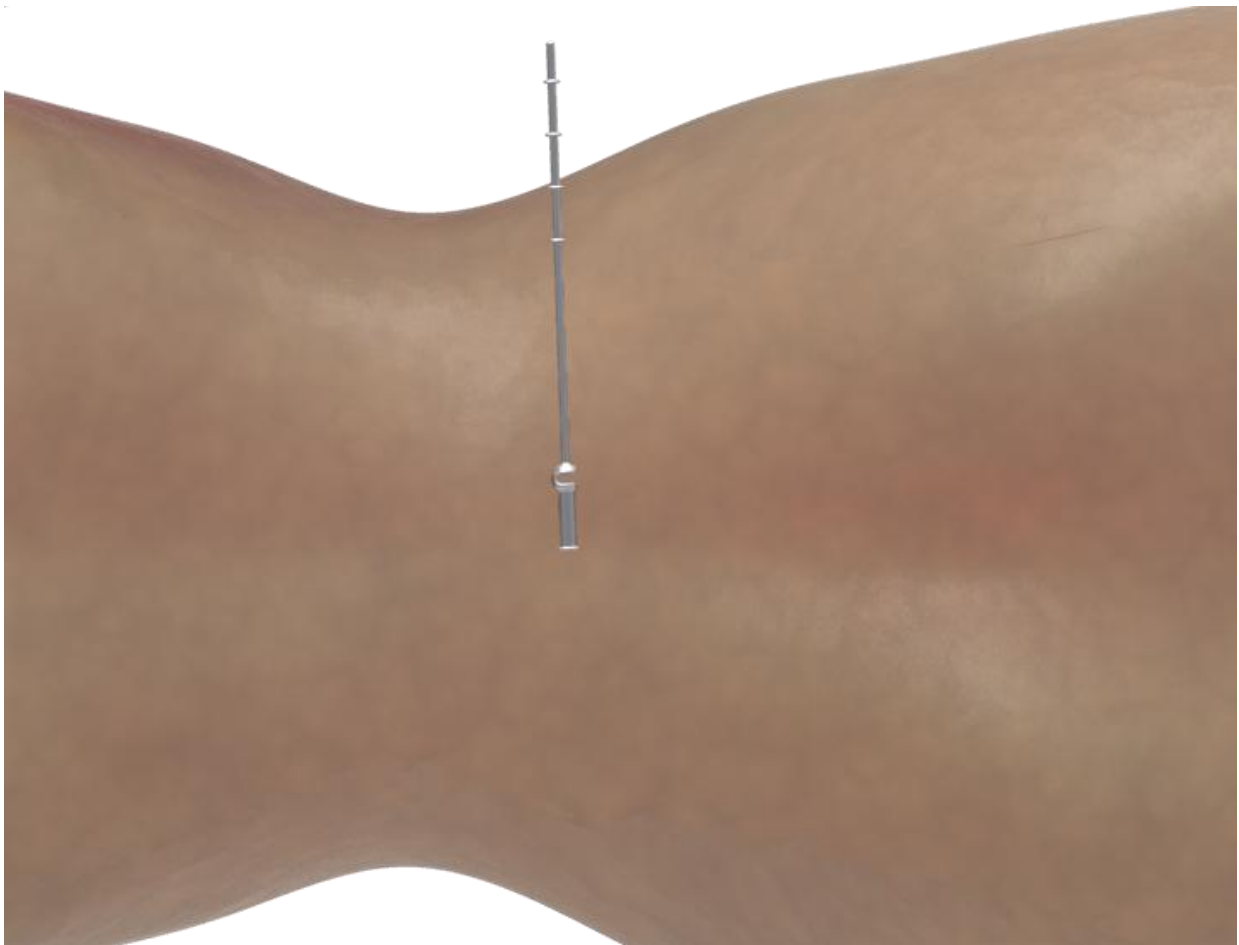




## 2. SURGICAL PLANNING & TARGETING (CONT.)

### BLADE SIZING ALTERNATIVE (OPTIONAL)

- The Blade Template can be used independent of 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

- 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 cable 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

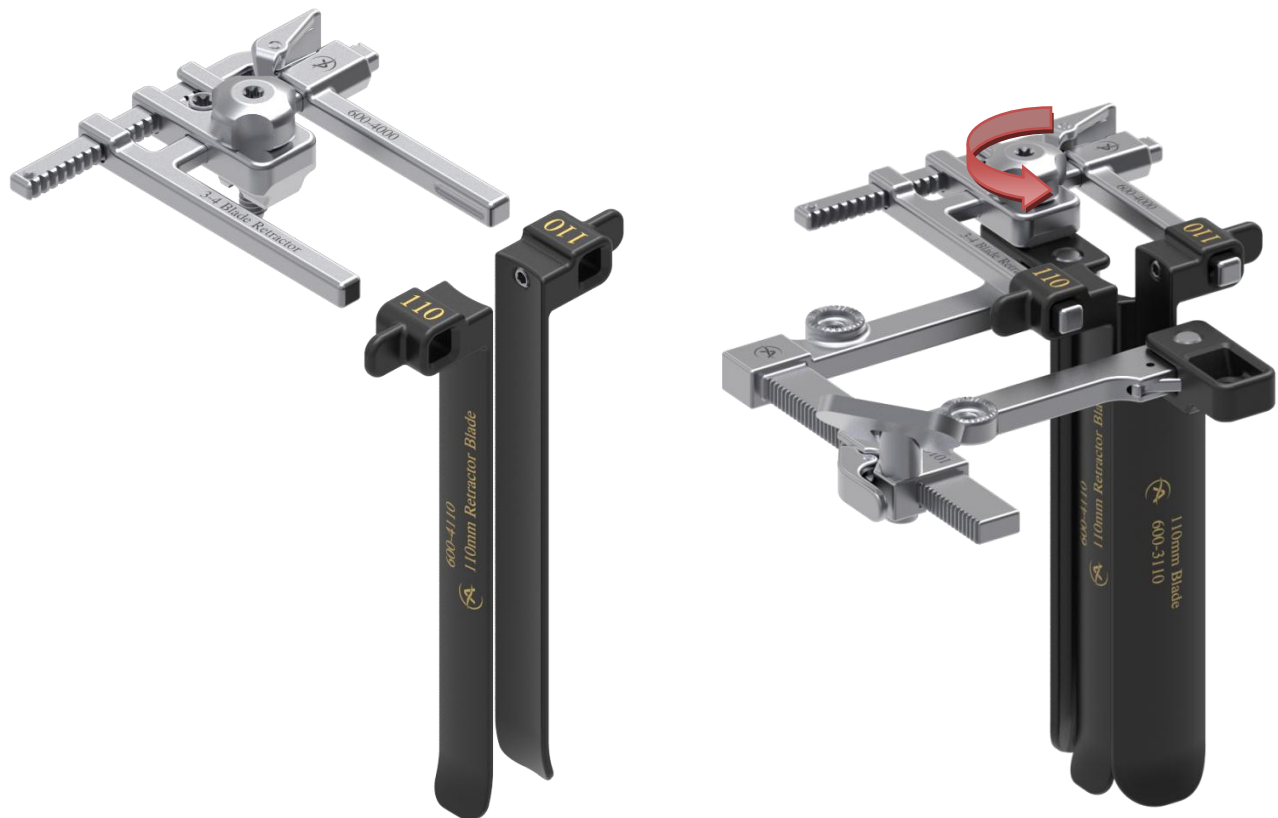
- Place the Table Mount Adapter in the desired hole of the Slider and secure with the Retractor Driver which can then be attached to the table using the Positioning Arm and Vertical Arm
- Once the retractor is secured, turn the knobs of the Detachable Blade Handles counterclockwise by hand or using the T25 Retractor 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
- Release the contralateral annulus
- Prepare the endplates using standard techniques

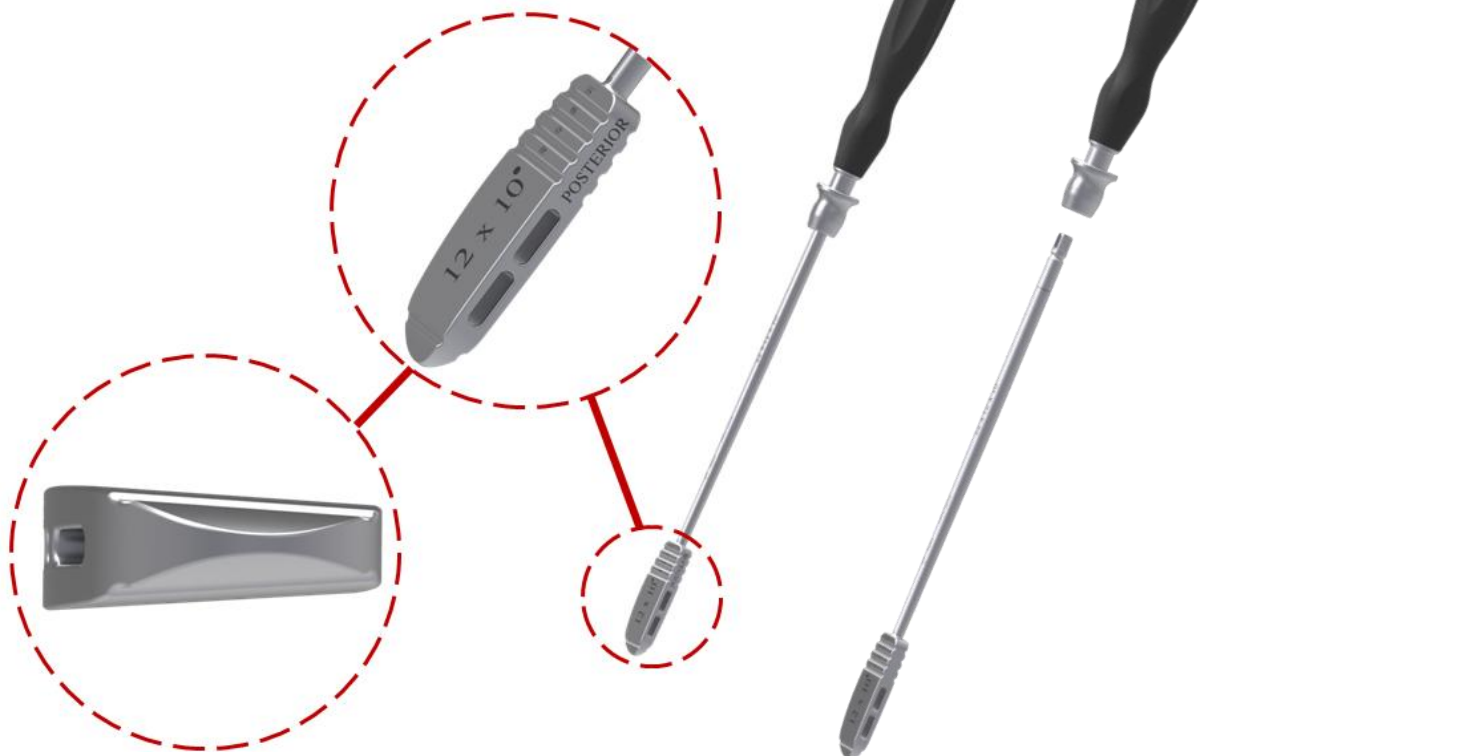
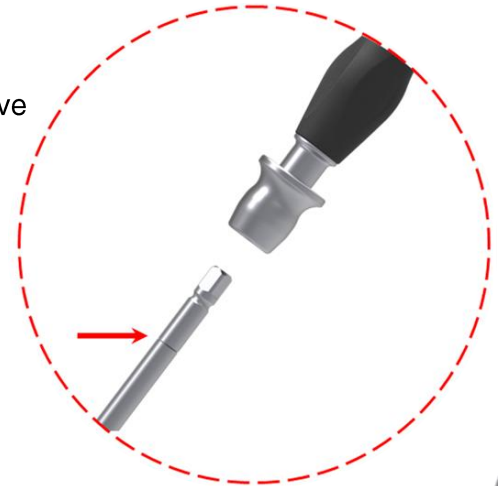
## 6. IMPLANT SELECTION

### TRIAL USAGE

- Select an appropriately sized Implant Trial in the desired footprint
- Assemble the appropriate size Trial to the Fixed Cannulated Straight Handle
- Pull back the plunger and insert the shaft until the "load line" is flush with the plunger then release
- 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
- A Slap Hammer Adapter can be threaded into the distal end of the Fixed Cannulated Straight Handle
- 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 desired graft material

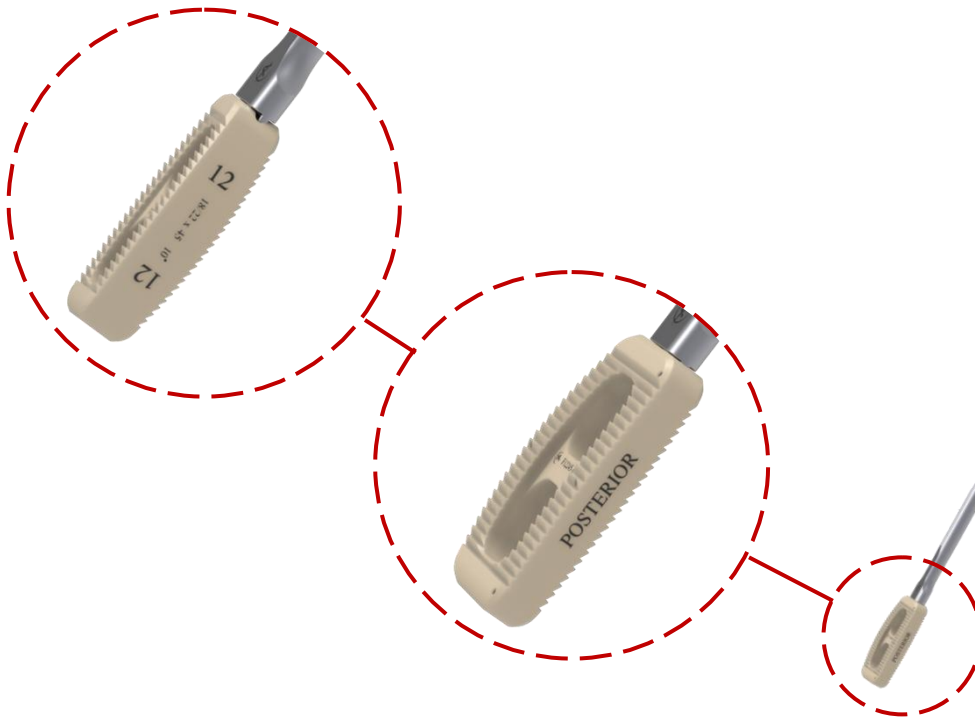
*Note: The posterior side of the implant is marked "POSTERIOR"*

### GRAFT CONTAINMENT SLIDE (OPTIONAL)

- Slide the Graft Containment Slide over the PEEK Spacer 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

### 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 Adapter and 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 point upward
- Attach the Slap Hammer to the end of the Remover
- Remove assembly from disc space

