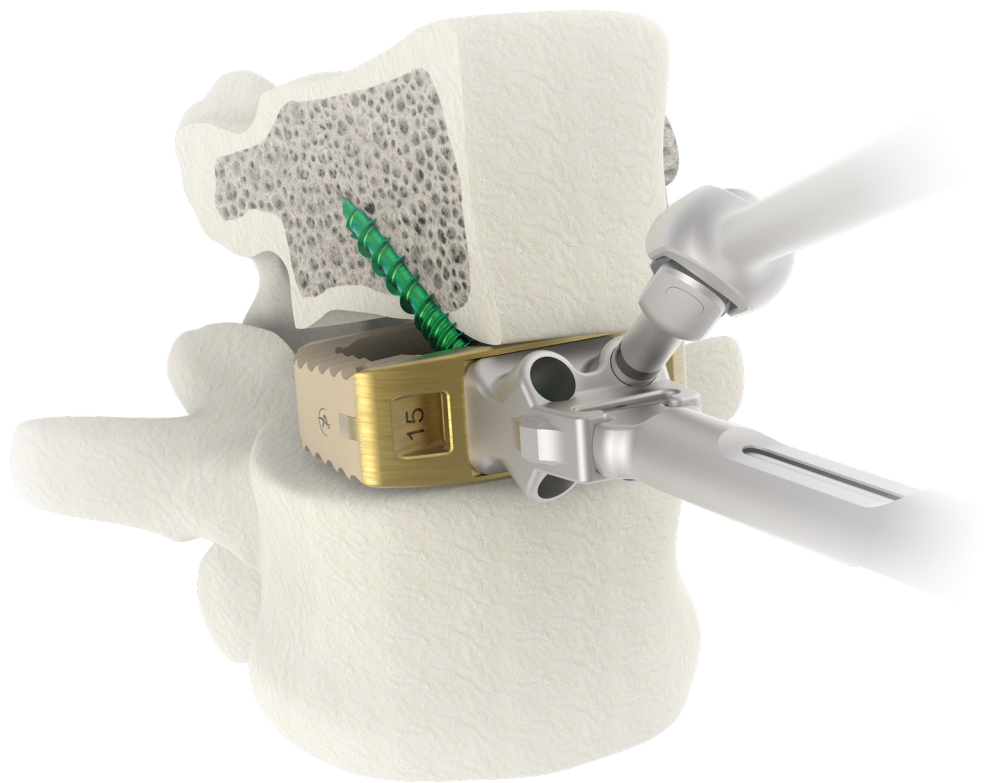




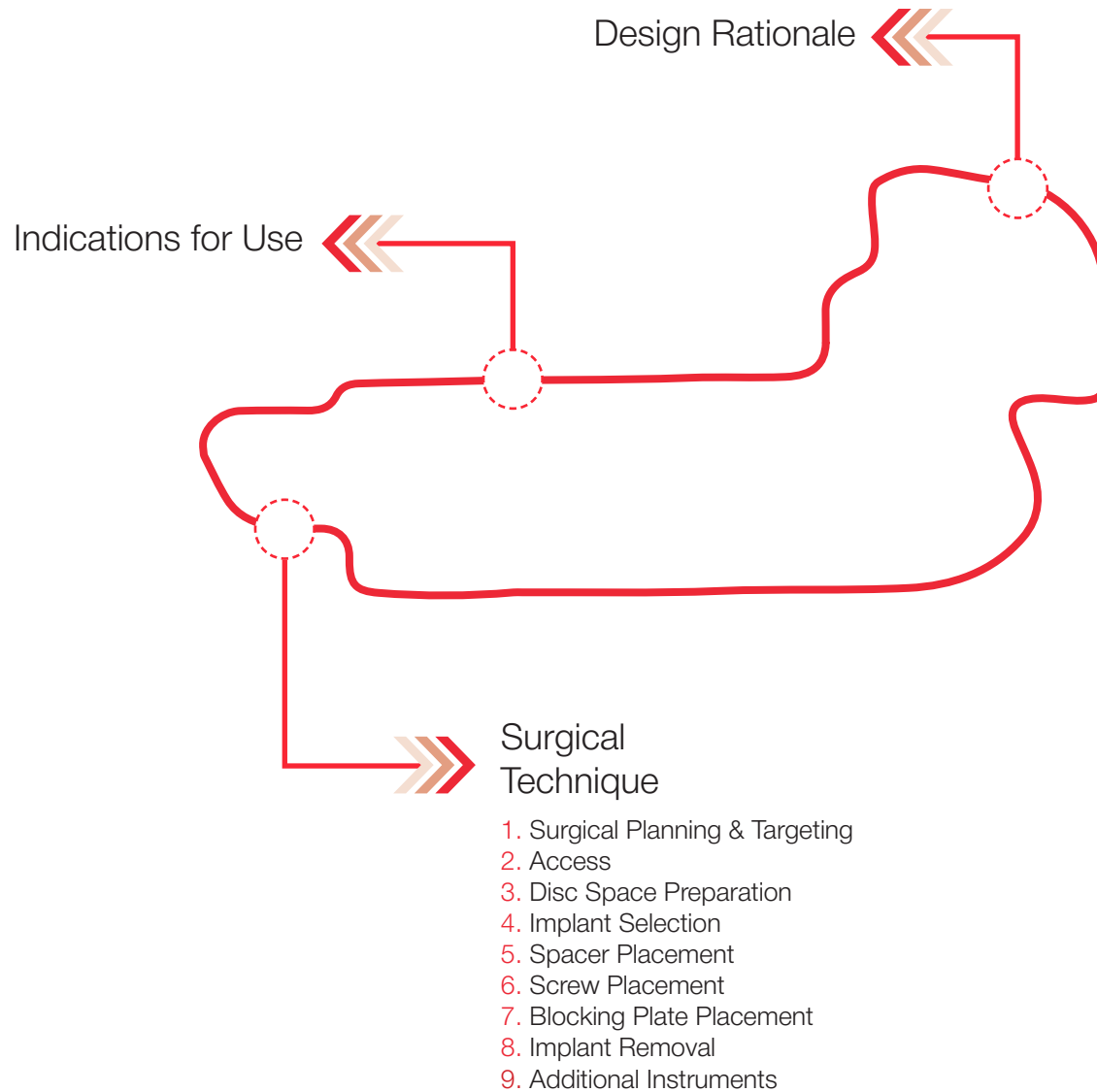
Brickyard Standalone ALIF Surgical Technique



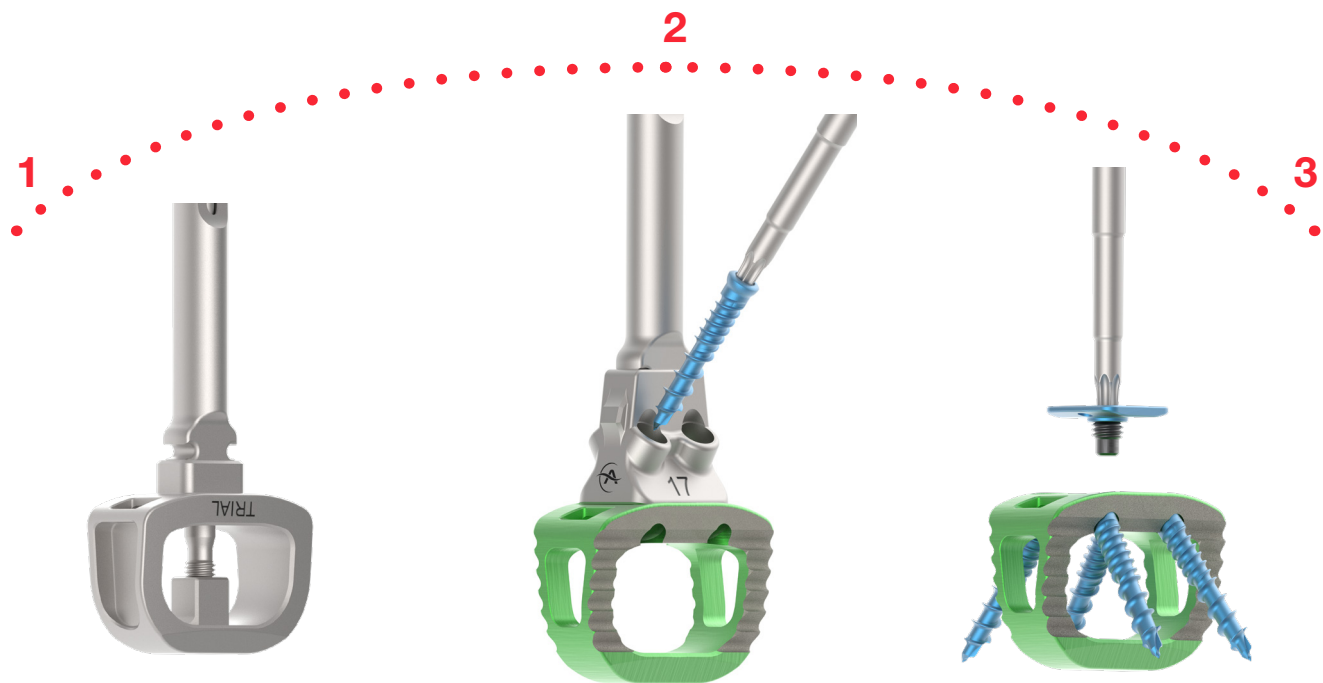


INDIANAPOLIS SPEEDWAY

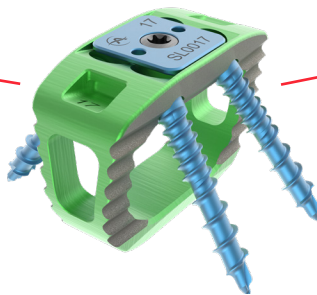
TABLE OF CONTENTS



DESIGN RATIONALE

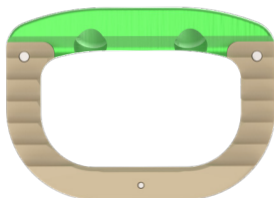


Available Footprints:
32mm x 24mm
38mm x 27mm
42mm x 30mm



Available Heights:
11mm to 19mm in
2mm increments

Available Materials:
Full Titanium or
PEEK/Ti Hybrid



Unique Dual Lead
Thread Profile

Self-Drilling Screws

PRODUCT DESCRIPTION

The Altus Spine Brickyard Standalone Anterior Lumbar Interbody Fusion System is designed for anterior fixation of the lumbar spine. For standalone use, it is required that the lumbar spacer is attached to the vertebral body of the lumbar spine with four bone screws AND a blocking plate that is attached to the anterior face of the lumbar spacer to prevent screw back out.

Supplemental fixation is required if fewer than four screws are used or if a hyperlordotic spacer (greater than 20 degrees) is used.

The Altus Spine Brickyard Standalone Anterior Lumbar Interbody Fusion System offers lumbar spacers in a Titanium alloy per ASTM F136 and Titanium/polyetheretherketone (PEEK) per ASTM F136 and ASTM F2026, respectively. Titanium (per ASTM F136) and tantalum per ASTM F560 wire markers are inserted into the Titanium/PEEK spacer. Fixed bone screws are available in two diameters and a variety of lengths with self-drilling threads. The bone screws are Titanium per ASTM F136. The blocking plate and plate screw are Titanium per ASTM F136.

INDICATIONS FOR USE

The Altus Spine Interbody Standalone Fusion System is indicated for use as an adjunct to fusion in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The DDD patients may also have up to Grade 1 spondylolisthesis at the involved level(s). Patients must have undergone a regimen of at least six (6) months of non-operative treatment prior to being treated with the device.

When used with both the cover plate and the four (4) provided screws, the Altus Spine Interbody Standalone Fusion System requires no additional supplemental fixation. In any other instance, additional supplemental fixation systems cleared by the FDA for use in the lumbar spine must be used.

For implants with hyperlordotic angles > 20 degrees, regardless of screw usage, additional supplemental fixation (e.g. posterior pedicle screw and rod systems) must also be used.

The interior of the interbody spacer is intended to be packed with autogenous bone graft and/or allogeneic bone graft material composed of cancellous and/or corticocancellous bone.

Reference product insert (PI-011) for complete system indications for use, description, warnings, and precautions.

WARNINGS

1. 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 limitation on the size, shape and strength of implants. Internal fixation devices cannot withstand ranges of motion and mechanical loads that are experienced by normal healthy bone. No implant can indefinitely withstand the unsupported stress of full weight bearing.
2. Implants can break when subjected to the increased loading when there is delayed union or nonunion. Internal fixation appliances are load-sharing devices that 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 the patient's level of movement after surgery will, among other conditions, dictate the longevity of the implant. Notches, scratches or bending of the implant during surgery may also contribute to early failure. Patients should be fully informed of the risks of implant failure.
3. Mixing types of metal can cause a heightened occurrence of corrosion. There are many forms of corrosion damage and several of these can occur on metals surgically implanted in humans. General or uniform corrosion can be present on all implanted metals and alloys. The rate of corrosive attack on metal implants is usually very low due to the presence of passive surface films. Dissimilar metals coming in contact with each other, such as titanium and stainless steel, can accelerate the corrosion process, which can lead to material fatigue and fracture. The amount of metal compounds introduced into the body will also increase. Internal fixation devices, such as rods, hooks, wires, etc., which come in contact with other metal objects, must be made from like or compatible metals.
4. Correct handling of the implant is extremely important. PEEK implants are designed to support physiologic loads. Excessive torque, when applied to long-handled insertion tools, can cause splitting or fracture of the implants. When an implant is to be impacted or hammered into place, the broad surface of the insertion tool should be carefully and fully seated 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.
5. Proper implant selection and patient compliance with post-operative precautions will greatly affect the surgical outcome. Patients who smoke have been shown to have an increased level of non-unions. These patients should be advised of this fact and warned of the potential consequences.

PRECAUTIONS

1. The implantation of interbody fusion systems should only be carried out by experienced spinal surgeons with training in the use of this implant system because this is a technically demanding procedure presenting a risk of serious injury to the patient.
2. The surgeon must confirm that all necessary implants and instruments are on hand for the planned surgical construct. The implants should be handled and stored carefully and be protected from any damage including corrosive environments. They should be carefully unpacked and inspected for any damage. The implants and instruments must be cleaned and sterilized before use.
3. The patient must be adequately informed of the risks and limitations related to the implants, the surgery, postoperative care, and rehabilitation.
4. The patient should be instructed in the limitation of physical exertion that would place excessive stresses on the implant or cause a delay of the healing process. The patient should also be instructed in the use of any required weight bearing or assist devices as well as in the proper methods of ambulation, climbing stairs, getting in/out of bed, or other daily tasks while minimizing rotational and bending stresses.
5. If the supplemental fixation is not removed following the completion of its intended use, any of the following complications may occur: 1) Corrosion, with localized tissue reaction or pain; 2) Migration of implant position resulting in injury; 3) Risk of additional injury from postoperative trauma; 4) Bending, loosening, or breakage, which could make removal impractical or difficult; 5) Pain, discomfort, or abnormal sensations due to the presence of the device, 6) Possible increased risk of infection; and 7) Bone loss due to stress shielding. The surgeon should carefully weigh the risks and benefits when deciding whether to remove the implant. Implant removal should be followed by adequate postoperative management to avoid re-fracture. If, for example, the patient is older and has lower movement needs, the surgeon may choose not to remove the implant thus eliminating the risks involved with a second surgery.

1. SURGICAL PLANNING & TARGETING

TARGETING THE SURGICAL SITE

The patient will be positioned supine. Once the operative level(s) are confirmed using fluoroscopy, the initial incision and exposure is completed.

A fluoroscopic lateral image of the lumbar spine with a straight metal instrument will ensure that the incision and exposure allows for direct visualization of the operative level(s).

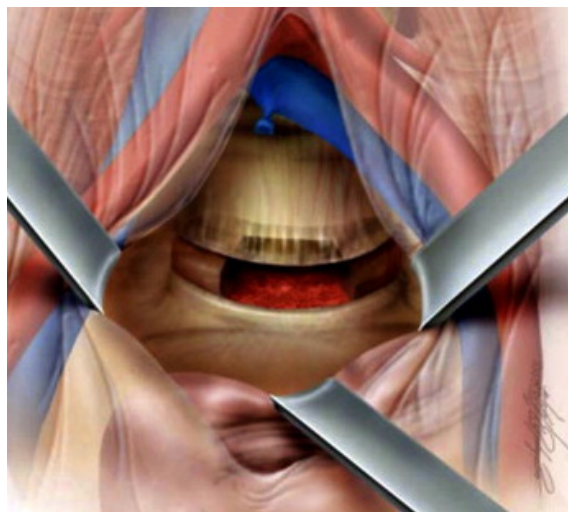
2. ACCESS

ACCESSING THE ANTERIOR COLUMN & DISC SPACE

The exposure can be completed using a standard retroperitoneal approach or via a mini-open retroperitoneal approach which is supported by the Brickyard Standalone Lumbar System's instrumentation. Careful dissection should be undertaken to protect major vessels during the approach with adequate mobility achieved for safe retraction to properly expose the operative intervertebral spaces.

The surgeon(s) will gain general access to the anterior lumbar spinal column using standard techniques.

Retraction should be placed directly over the disc spaces previously identified.

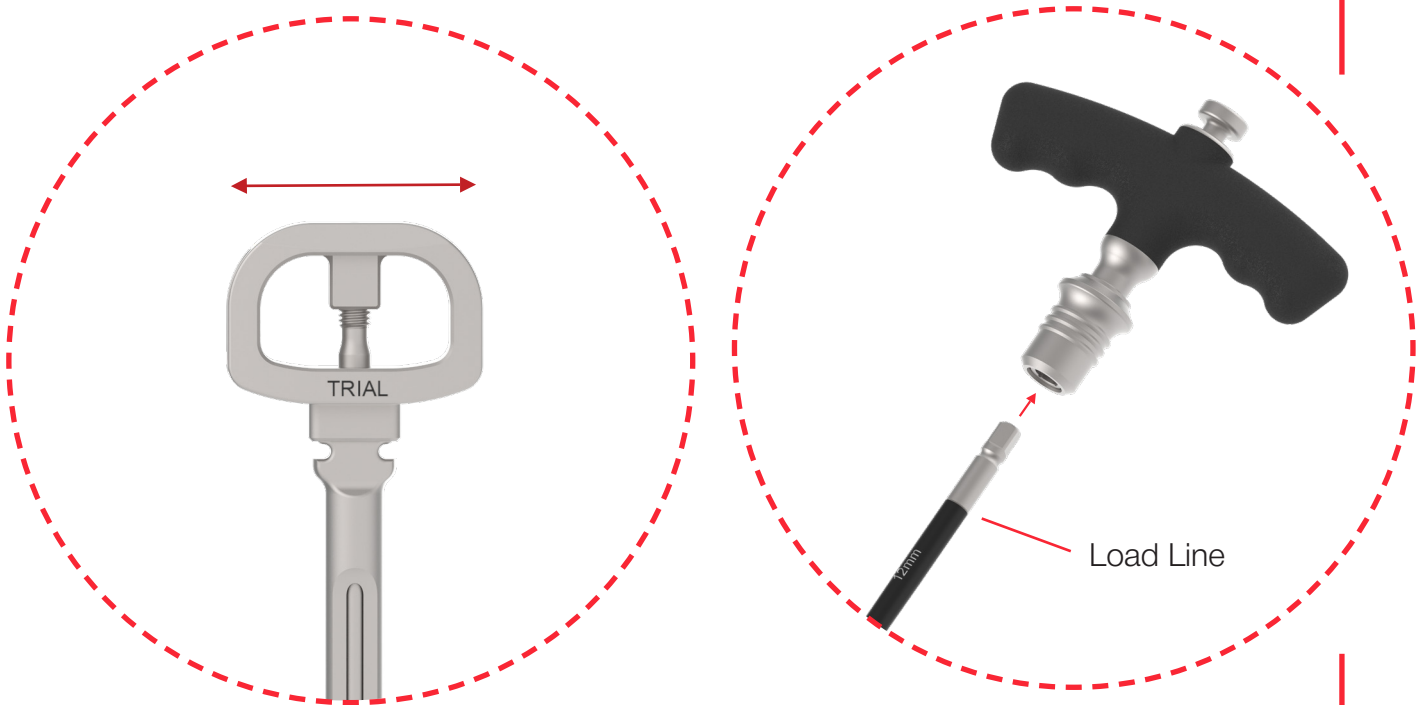


3. DISC SPACE PREPARATION

DEFINING THE WIDTH OF THE ANNULOTOMY

Center the annulotomy on the midline and make it large enough to fit the Spacer width. A Trial may be used to define the minimum width of the annulotomy.

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



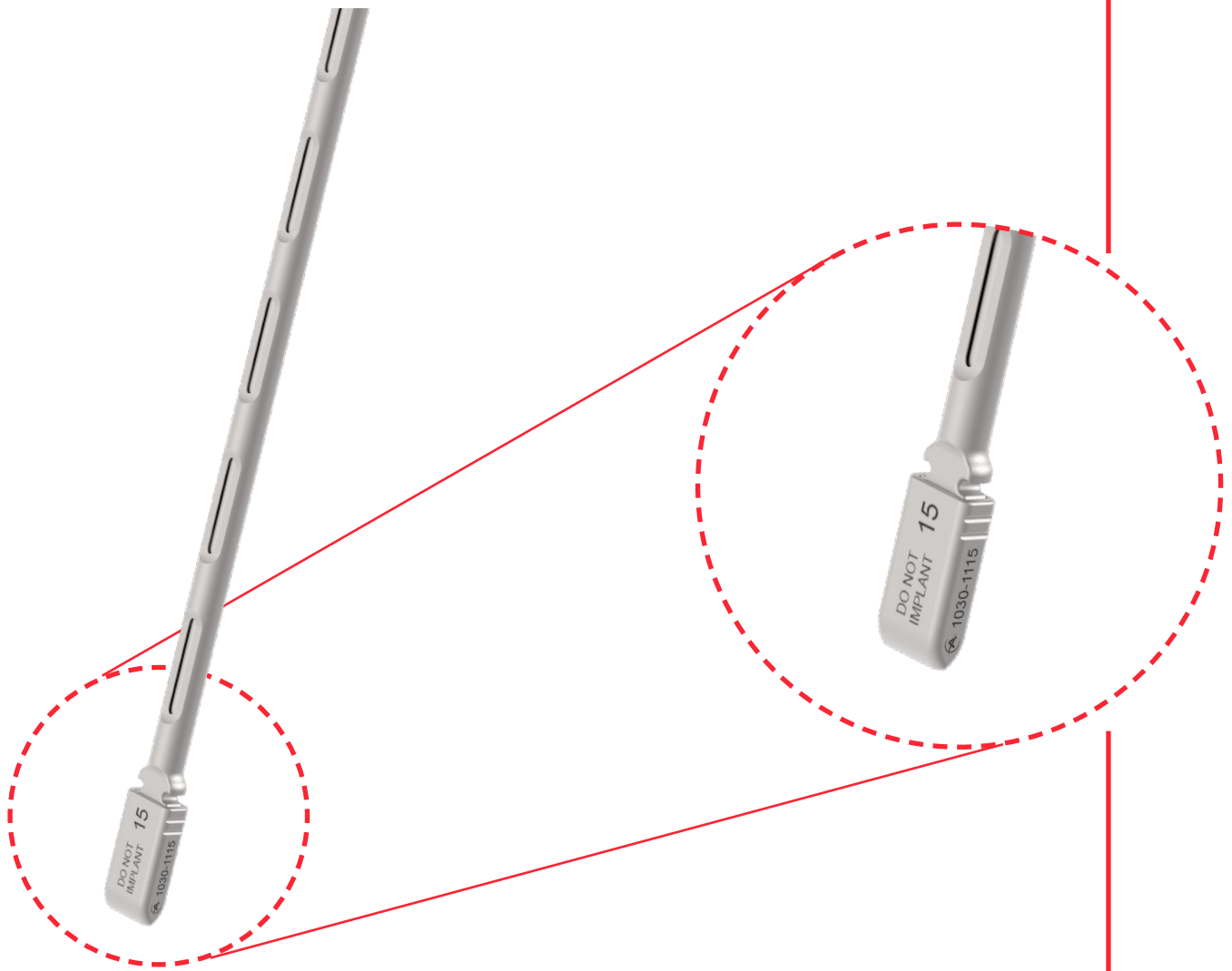
3. DISC SPACE PREPARATION (CONT.)

COMPLETING THE DISCECTOMY

A thorough discectomy must be completed, ensuring the posterolateral corners of the disc space are free of disc tissue. Remove cartilaginous endplates to bleeding bone using the Altus Spine Anterior Lumbar Disc Prep Instruments.

**Note: One must be careful not to remove excessive subchondral bone as it may weaken the vertebral endplates. Excessive removal of the subchondral bone could result in subsidence, a loss of stability, or pseudoarthrosis.*

If additional remobilization or distraction is needed, the Trials, Distractors, or ALIF Disc Space Distractor can be used.



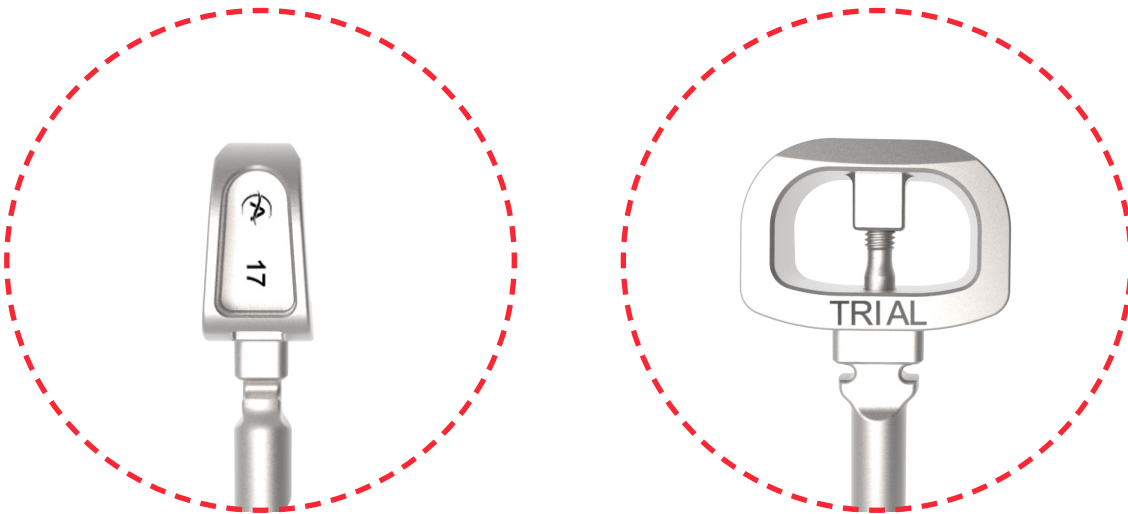
4. IMPLANT SELECTION



TRIAL USAGE

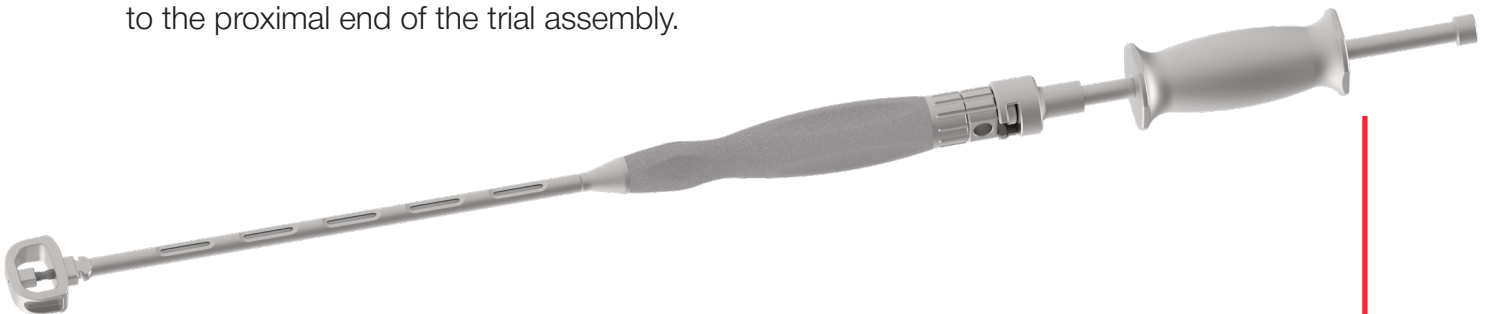
Select an appropriately sized Spacer Trial in the desired footprint based on preoperative measurements and imaging.

Assemble the appropriate height Spacer Trial to the Implant Inserter. Insert the trial assembly into the disc space; gently impact the trial assembly as necessary. Use fluoroscopy to confirm the position and fit of the Trial and the intended correction.



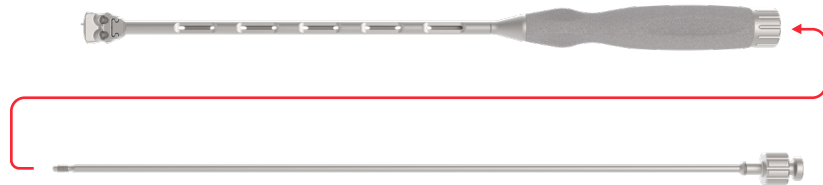
TRIAL REMOVAL

As needed, a Slap Hammer is available to aid in removing the trial assembly from the disc space. Attach the Slap Hammer to the proximal end of the trial assembly.

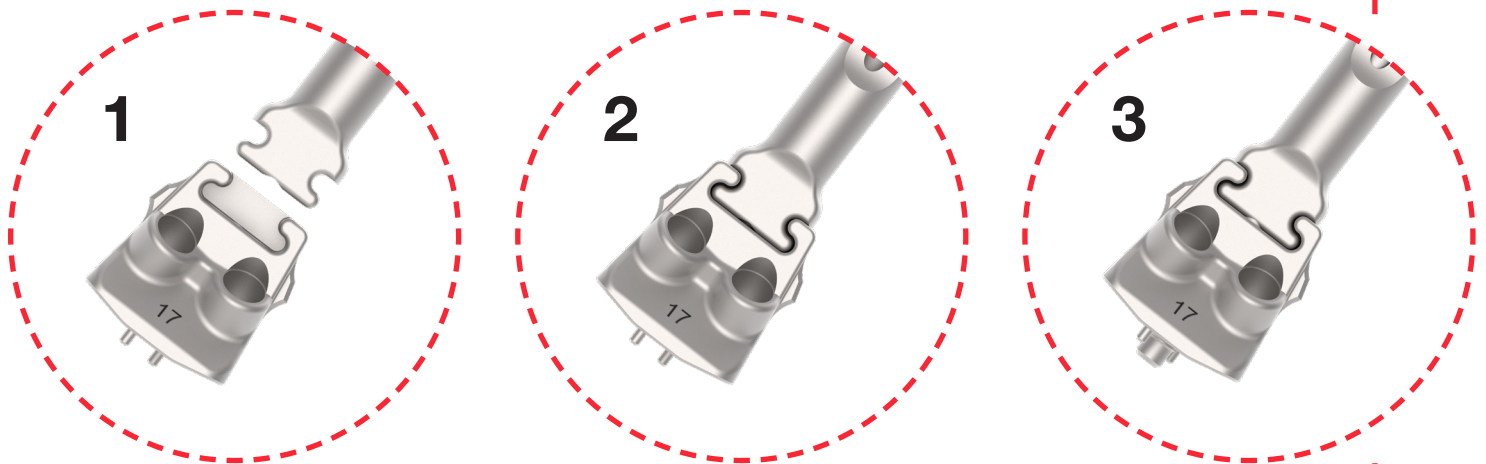


5. SPACER PLACEMENT

IMPLANT INSERTER ASSEMBLY



When satisfied with the fit of the selected Trial, take the corresponding sized Inserter DTS Guide and the Implant Inserter, and assemble by fitting the Implant Inserter head into the slot of the Inserter DTS Guide until the flats are flush.



Once the Inserter DTS Guide is engaged with the Implant Inserter, insert the Draw Bar into the proximal end of the Implant Inserter and thread clockwise into assembled position.

The appropriate Spacer is now ready to be loaded.



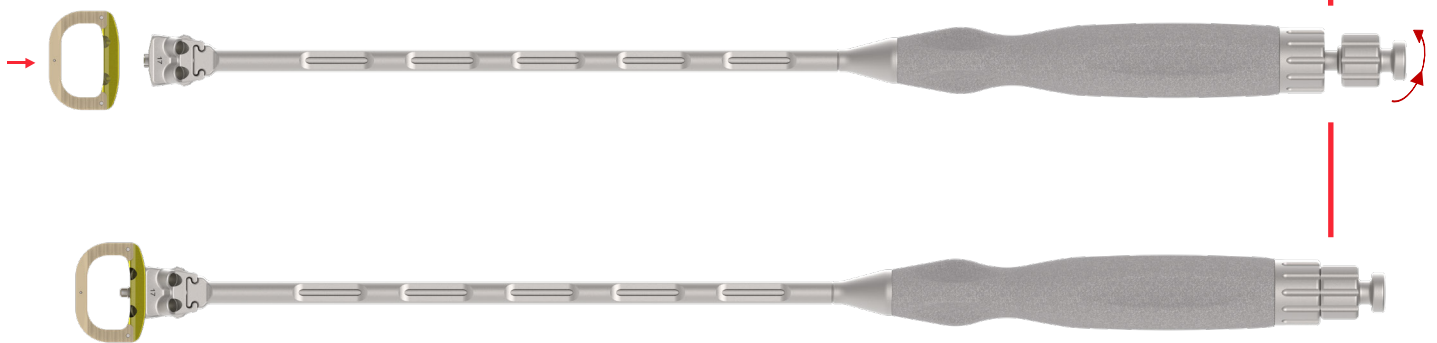
5. SPACER PLACEMENT (CONT.)

LOADING THE SPACER

Select the appropriately sized Brickyard Standalone Spacer and align the distal end of the Implant Inserter assembly to the proximal face of the Spacer.

Align the threaded tip of the Draw Bar with the mating thread hole in the center of the Spacer, align and insert the prongs of the Inserter DTS Guide into the mating holes of the Spacer.

Hold Spacer in place on the Implant Inserter assembly or rest the Spacer on a sterile surface while turning the proximal knob of the Draw Bar clockwise until finger tight. Verify Spacer attachment to the Implant Inserter prior to implantation.



GRAFT PACKING

Pack the central lumen (and lateral windows of Titanium Spacers) with autograft. Use the Graft Packing Block if necessary to adequately pack the Spacer.

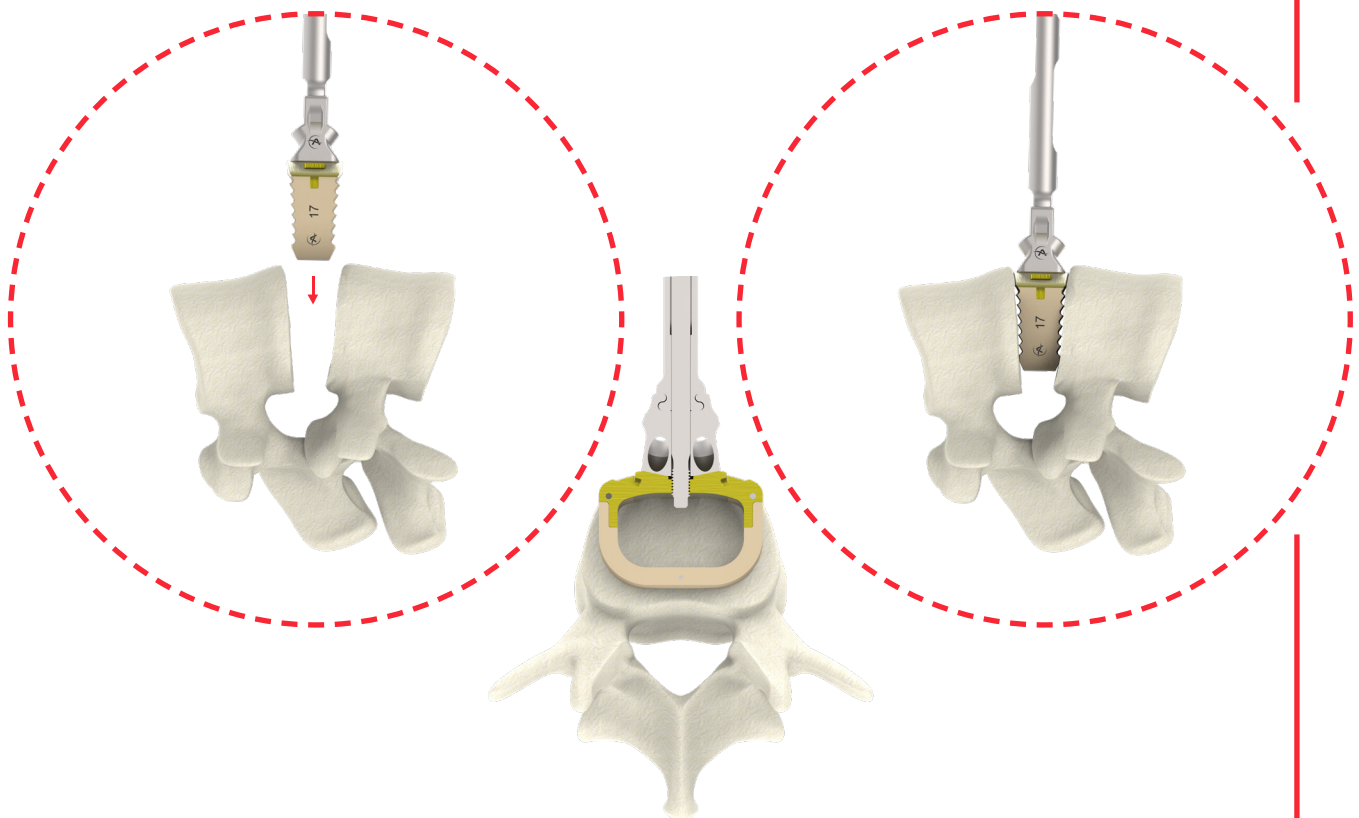
5. SPACER PLACEMENT (CONT.)

SPACER IMPLANTATION

With the Spacer rigidly attached to the Implant Inserter assembly, align the Spacer over the prepared disc space and implant the Spacer. If necessary, gently impact Implant Inserter to position the Spacer within the disc space.

Use fluoroscopy to confirm the position and fit of the Spacer, as well as the intended correction. The anterior wall of the Spacer must be flush to the anterior column of the lumbar spine or 2-3mm deep within the disc space. Use A/P fluoroscopy to verify the implant is centered.

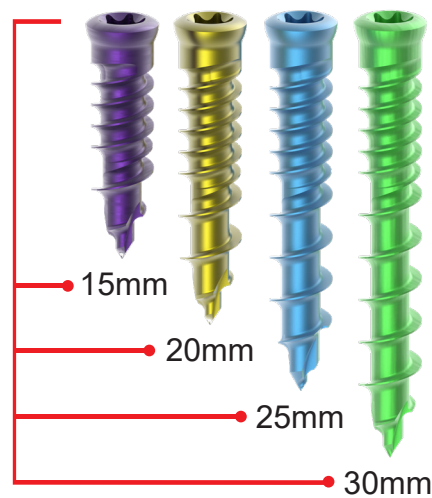
Do not remove the Implant Inserter assembly.



6. SCREW PLACEMENT

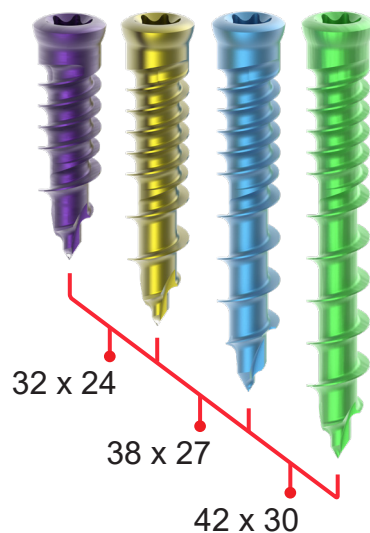
SCREW SELECTION

The Brickyard Standalone ALIF System offers Ø4.2mm and Ø4.5mm Bone Screws for anchoring the Spacer to the superior and inferior vertebral bodies. The Screws are available in 5mm incremental lengths from 15mm to 30mm, with optional 35mm and 40mm lengths.



The thread of the Screw transitions from a single to double lead in order to maximize screw purchase on the cortical and cancellous bone of the vertebral endplates and vertebral bodies.

Proper selection of Screw length can be chosen through pre-operative planning and by referencing the chart below, per BR-3501.

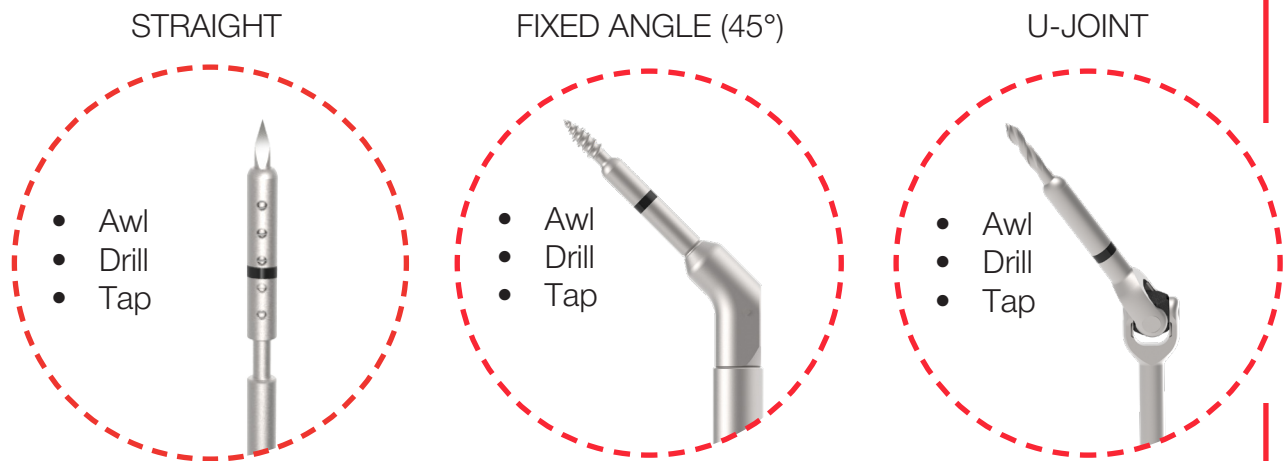


6. SCREW PLACEMENT (CONT.)

PILOT HOLE PREPARATION

To ensure Screw trajectory is properly aligned to the Spacer screw holes, the pilot hole preparation instruments will self-center when used through the Inserter DTS Guide.

The Brickyard Standalone ALIF system offers a selection of screw hole preparation instruments, including angled options for varying anatomies.



Attach to Straight Ratcheting Handle prior to use.

6. SCREW PLACEMENT (CONT.)

AWLING

To break the cortex, insert the Awl into the DTS Guide until it is fully seated and the laser etched band disappears. Repeat this for all (4) screw positions. Depending on the angle and position, a Straight, Fixed Angle, or U-Joint Awl may be used.

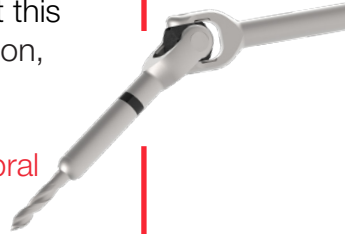
**Note: The Awl features a retractable sleeve that helps protect anatomy until it is inserted into the DTS Guide. Multiple awl lengths to accommodate patient anatomy and surgeon preference*



DRILLING

Insert the Drill into the DTS guide and turn clockwise until the Drill is fully seated and the laser etched band disappears. Repeat this for all (4) screw positions. Depending on the angle and position, a Straight, Fixed Angle, or U-Joint Drill may be used.

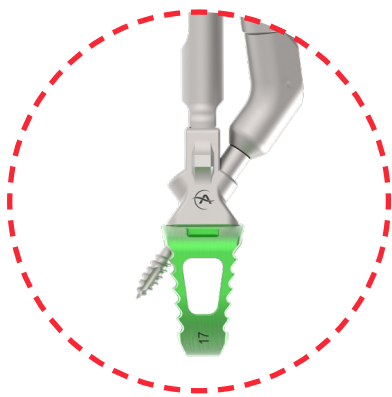
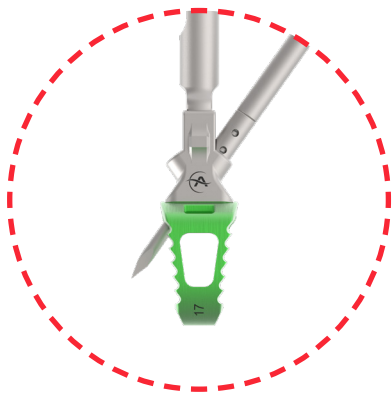
**Note: The Awl, Drill, and Tap will penetrate the vertebral body by 0.5mm less than indicated length.*



TAPPING

Insert the Tap into the DTS Guide and turn clockwise until the Tap is fully seated and the laser etched band disappears. Repeat this for all (4) screw positions. Depending on the angle and position, a Straight, Fixed Angle, or U-Joint Tap may be used.

**Note: Do not advance the Tap once it is fully seated and the laser etched band has disappeared. Continuing to tap will strip the bone and negatively impact thread purchase.*



6. SCREW PLACEMENT (CONT.)

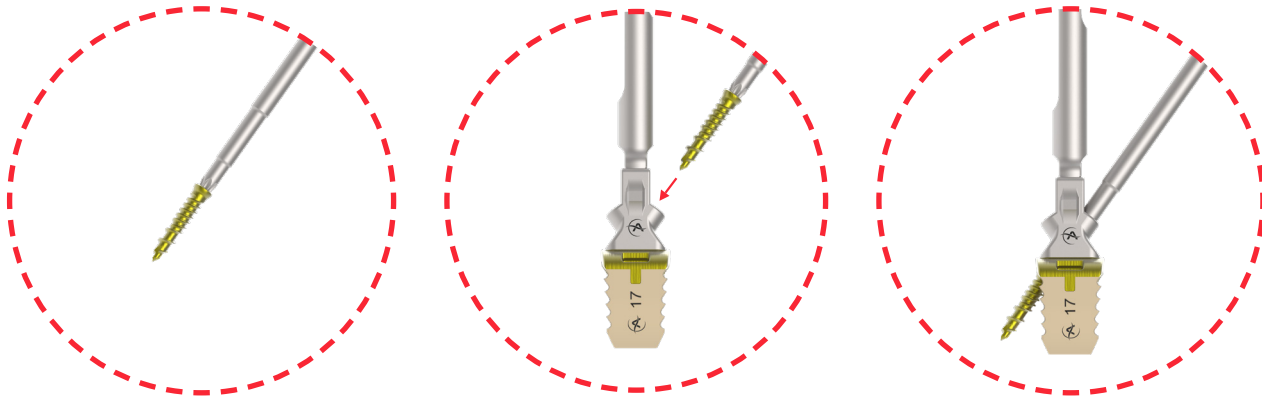
SCREW IMPLANTATION

Attach the T15 Self-Retaining Screwdriver to the straight ratcheting handle. Depending on the angle and position, a Straight, Fixed Angle, or U-Joint Inserter may be used.

Press the tip of the Screwdriver into the selected screw and lift to remove it from the screw module. Prior to implantation, test the Screw to ensure it is properly attached to the Screwdriver.

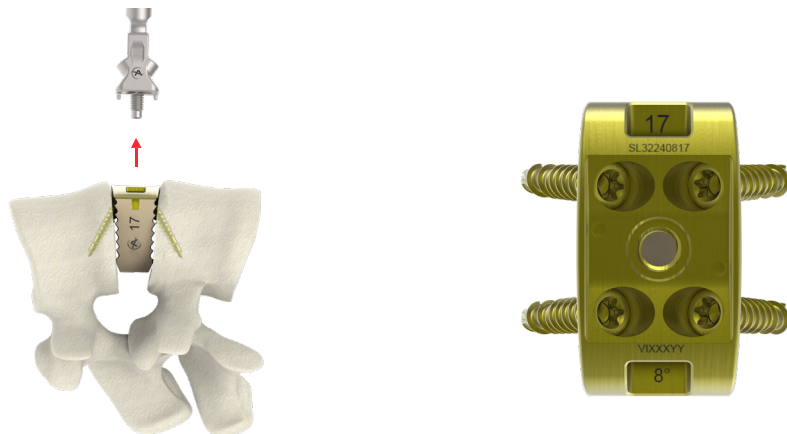
Insert the selected screw into the DTS Guide and turn clockwise until the screw is fully seated and the laser etched band disappears. Repeat this for all (4) screws.

***Note: Each screw must be fully seated into the screw hole prior to implanting the next screw.**



Once all four screws are implanted, remove the Implant Inserter assembly by turning the proximal knob counterclockwise until the Implant Inserter assembly is detached from the Spacer. Lift the Implant Inserter assembly axially to remove it from the disc space.

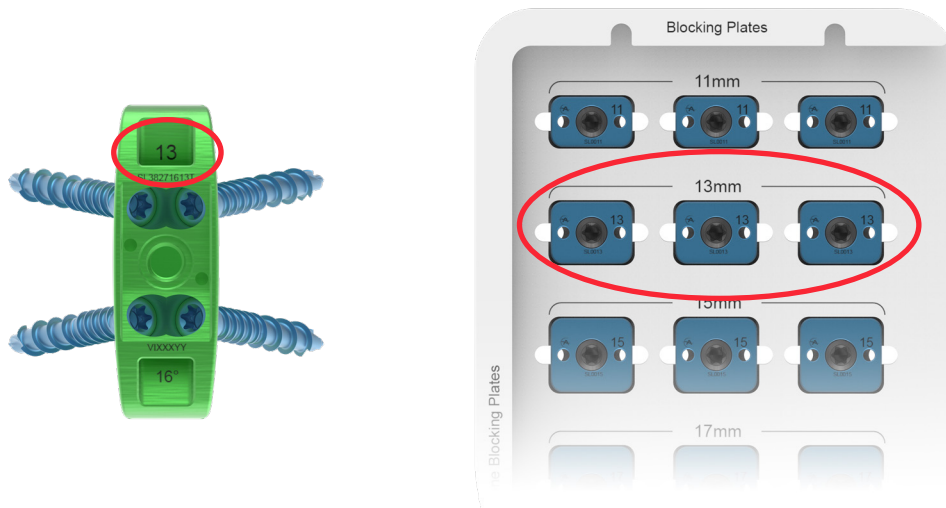
After the Implant Inserter assembly is removed, ensure all (4) screws are fully seated.



7. BLOCKING PLATE PLACEMENT

BLOCKING PLATE SELECTION

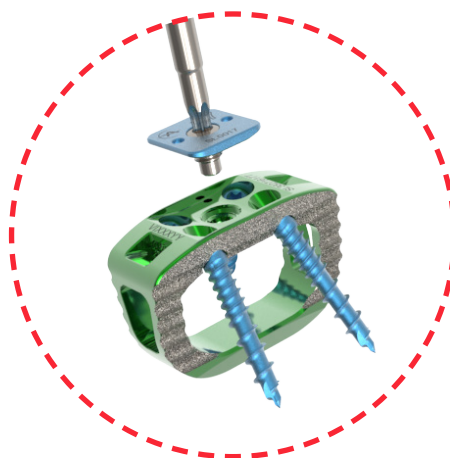
Select the Blocking Plate corresponding to the height of the implanted Spacer.



BLOCKING PLATE IMPLANTATION

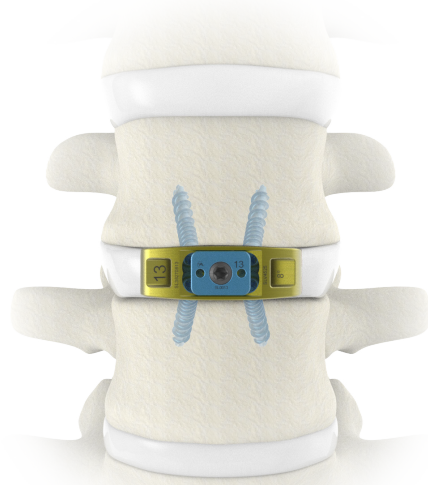
Attach the T15 Screwdriver to the Torque-Limiting Palm Handle. Press the tip of the Screwdriver into the selected Blocking Plate and lift to remove it from the blocking plate module. Prior to implantation, test the Blocking Plate to ensure it is properly attached to the Screwdriver.

Align the Blocking Plate screw to the mating thread hole in the center of the Spacer, align and insert the Blocking Plate into the recessed face of the Spacer. Turn the Torque-Limiting Palm Handle clockwise until it clicks once. The construct is now complete with the Screws secure inside the Spacer and the Spacer secured to the endplates.

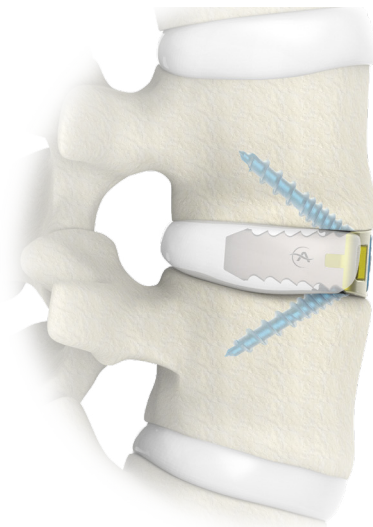


FINAL POSITION

FINAL CONSTRUCT
A/P VIEW



FINAL CONSTRUCT
LATERAL VIEW



*Note: Supplemental fixation is required if fewer than four screws are used or if a hyperlordotic spacer (greater than 20 degrees) is used.

8. IMPLANT REMOVAL

REMOVING THE BLOCKING PLATE

Attach the T15 Screwdriver to the Torque-Limiting Palm Handle.

Re-engage the Screwdriver with the Blocking Plate as described in Section 7 and unthread the Locking Screw from the Spacer by turning the Torque-Limiting Palm Handle counterclockwise until the Blocking Plate is free to be pulled straight back out of the Spacer.

Ensure the Blocking Plate is retained by the Screwdriver prior to removing from the incision.

REMOVING THE SCREWS

Attach the T15 Screwdriver to the Straight Ratcheting Handle.

Re-engage the Screwdriver with the screw as described in Section 6. Remove the screw from the Spacer by turning the Screwdriver counterclockwise until the screw is free to be pulled straight back out of the spacer.

Ensure the screw is retained by the Screwdriver prior to removing from the incision.

Repeat for all (4) Screws.

REMOVING THE SPACER

Assemble the Implant Inserter, DTS Guide, and Draw Bar as described in Section 5.

Re-engage the Implant Inserter assembly with the Implant as described in Section 5. Turn the proximal knob of the Draw Bar counter-clockwise until finger tight.

Attach the Slap Hammer to the proximal end of the assembly. Utilize the Slap Hammer to reverse the Implant from the disc space.

9. ADDITIONAL INSTRUMENTS

ANGLED INSERTER

Upon request, an Angled Inserter is available for varying anatomies.



ANGLED INSTRUMENTATION

As described in Section 6, Fixed Angle and U-Joint instrumentation for pilot hole preparation and screw insertion are optional for use.

Fixed Angle instrument tips are interchangeable and available in a selection of sizes and functions.

The Fixed Angle Side Handle is available for additional control of the distal tip of the Fixed Angle instrumentation.



