# INTRODUCTION

# ADVANTAGES AND FEATURES

# PATIENT PREPARATION

# PRE-OPERATIVE PLANNING

# AXIALIF+® IMPLANTS

# INSTRUMENTATION

## SURGICAL TECHNIQUE

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## APPENDIX A

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Introduction

The AxiaLIF+® (Axial Lumbar Interbody Fusion) System includes surgical instruments for creating a safe and reproducible anterior retroperitoneal pre-sacral access route to the L5-S1 vertebral bodies. The AxiaLIF+® technique features instrumentation to enable standard of care fusion principles, distraction, and stabilization of the anterior lumbar column while mitigating the soft tissue trauma associated with traditional lumbar fusion through open surgical incisions.

Using AxiaLIF+®, the lumbar spine is accessed through an axial channel on the anterior face of the sacrum. This atraumatic tissue plane alleviates the need for the surgeon to cut through supporting muscles and ligaments, thus reducing post-operative pain and the prospect of complications.

*TanS1, and AxiaLIF+ are trademarks or registered trademarks of Quandary Medical, LLC
## Advantages and Features

| Safe, Reproducible, Pre-Sacral Approach (Mini-Open) | • Soft-tissue sparing  
• No native spinal anatomy disruption  
• Patients recover faster with less pain  
• Hospital release averages less than one day post surgery |
|--------------------------------------------------|---------------------------------------------------------------|
| Implant construct locks together and acts as a single, solid rod | • Solid construct spans three cortices of the anterior spinal column (vertebral bodies L5-S1)  
• Ideal for resisting shear  
• Provides unparalleled anterior column stabilization  
• Offloads posterior fixation  
• Upon implantation, provides immediate rigid segmental fixation of L5-S1, while maintaining appropriate distraction |
| Secure Bony Fixation | • Conical thread design and slight increase in diameter provide better bony fixation  
• Distraction at L5/S1 is independent of implant advancement so that implant components can be placed in order to maximize bony fixation  
• Dilation technique and conical L5 thread design resists axial compression at the L5 vertebral body, which helps prevent subsidence |
| Precise measurement and placement of Implant components | • Measurement occurs via insertion of Trial Dilator that matches implant size. This is analogous to an interbody cage trial instrument.  
• Implant components assembled and delivered on rod driver while being held in axial alignment  
• System provides ability to independently advance L5 Anchor after initial insertion |
| Controlled distraction at L5/S1 independent of implant advancement | • Distraction at L5/S1 occurs via internal threads by separating L5 Anchor and S1 Anchor with an independent Distraction Rod  
• Bone-to-implant interface is static during distraction  
• Ensures implant/bony purchase interface is not compromised  
• Enables “dialed in” distraction up to 7mm for individualized disc height restoration, based on each patient’s needs |
Patient Preparation

- Standard bowel preparation the day before
- Standard spine surgery preparation
- Place patient in prone position with pelvic elevation
- Prep the sacrococcygeal region
- Isolate operative area with an occlusive dressing
- Gram-negative / anaerobic antibiotic coverage

OPERATING ROOM SET UP *(Figure i)*

- Biplanar fluoroscopy
- Position C-arm fluoroscope. Orient A/P and Lateral fluoroscopic images to ensure adequate visualization and to determine left vs. right correspondence.
Pre-Operative Planning

AxiaLIF⁺ PLACEMENT
When the L5 Anchor, S1 Anchor, Distraction Rod, and Fixation Rod are joined together, they create one construct that spans the distance between the sacrum and the L5 vertebral body.

TEMPLATES AND PRE-OPERATIVE PLANNING
Trajectory is extremely important with the AxiaLIF⁺ procedure. (Figure ii, iii) Radiographic images, including a full sacral view, can be used to determine if the anatomy is suitable for the AxiaLIF⁺ procedure. MRI is preferred in order to best visualize soft tissue anatomy.

The standard field of view for lumbar MRI and CT must be expanded to include the coccyx to aid in pre-operative planning.
AxialLIF+® Implants

AXIALIF+® COMPONENTS
The AxialLIF+® CONSTRUCT is made up of four components.

- The S1 Anchor is a threaded rod with the same diameter and thread profile as the base of the tapered L5 Anchor.

- The Distraction Rod threads into the S1 Anchor’s internal threads. Once inserted, it engages a shoulder within the L5 Anchor.

- The L5 Anchor is one piece that consists of an L4 and L5 threaded section with an unthreaded waist in between.

- The Fixation Rod inserts through the S1 Anchor/Distraction Rod Assembly and threads into the L5 Anchor. The Fixation Rod locks all components together, allowing them to act as a solid rod.

MECHANISM OF DISTRACTION AT L5 AND L5/S1
The Distraction Rod rotates internally within the S1 Anchor and pushes on a shoulder within the L5 Anchor to create distraction in the L5/S1 disc space.

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<tr>
<td>30mm</td>
<td>35mm</td>
<td>40mm</td>
<td>ONE SIZE FITS ALL</td>
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<td></td>
<td>20 mm</td>
<td>SIZES CORRESPOND TO L5 ANCHOR SIZES</td>
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The TranS1 AxiaLIF+® System is a multi-component system that includes instrumentation and titanium alloy implants. The instruments, as shown above, are arranged sequentially on a rack from left to right. Instruments specific to AxiaLIF+® are arranged to the right of the rack.

*Standard OR instrument. Not included with Trans1 AxiaLIF IL+ instruments.
STEP ONE
Dissection

MINI-OPEN APPROACH (SEE APPENDIX A)
As Described by:
Josue P. Gabriel, MD, FAAOS
Bonutti Clinic, Effingham, IL

1) Compare landmarks on the MRI/CT image to the intra-operative fluoroscopy images to establish location of the transverse process. (Figure 1a & 1b)
2) Make a paramedian incision (approximately 1cm off of midline) just caudal (distal) to the transverse process of Coccyx 1 or occasionally Coccyx 2 and extend it caudally 2-3cm. (*Figure 2a & 2b*)

3) After making the incision, insert a small Weitlaner retractor. (*Figure 3a & 3b*)
4) Grasp the Weitlaner retractor and mobilize the incision medially until it is positioned over the narrow bony coccyx. The coccyx now acts as a rigid “backstop” for the dissection. *(Figure 4a & 4b)*

5) Continue soft tissue dissection until the dorsal surface of the coccyx is reached. *(Figure 5)*
6) Continue dissection laterally and ventrally along the coccyx using cautery and/or a periosteal elevator. This is the point of entry to the presacral space, and should be in the narrow bony part of the coccyx below the transverse process. *(Figure 6)*

7) Carefully dissect through the parietal fascia, which extends laterally from the ventral surface of the coccyx. When the fascial defect is large enough, insert a finger to conduct blunt dissection of the presacral space. *(Figure 7)*
STEP TWO
Access

INSTRUMENTS NEEDED:
- Blunt Dissecting Tool
- 8” Curved Kelly*
- Surgical Blade

*Standard OR instrument. Not included with Trans1 AxioLIF+® instruments.

After making the initial paracoccygeal skin incision, use an 8” Curved Kelly clamp turned to the anterior face of the sacrum to bluntly dissect down to the parietal fascia. Penetrating the fascia is necessary to access the retroperitoneal space and the anterior face of the sacrum. Penetrating the fascia can be accomplished using: 1) finger dissection 2) blunt guide pin dissection, or 3) a combination of the two.

1) Finger Dissection: Dissect with your index finger to create a pathway to the sacrum while gently pushing the rectum anteriorly from the mesorectal soft tissue plane.

While advancing towards the S1-S2 intersection, you can palpate the peritoneal layer of tissue (Waldeyer’s fascia) that runs between the rectum and sacrum. When you palpate this anatomy with your finger, you will note the retrorectal space. Use your index finger to sweep away tissue from the anterior face of the sacrum. (Figure 8)
Utilizing this method, the Dissecting Tool has a path of least resistance to the anterior face of the sacrum. *(Figure 9)*

This technique also allows for fine trajectory adjustments of the Guide Pin on the sacrum and may reduce any interference from associated soft tissues at the incision site.

2) **Blunt Dissection:** Use the Blunt Dissecting Tool to penetrate the fascia immediately below the ligaments. *(Figure 9)*

Advance the Dissecting Tool cephalad along the midline, *(Figure 10)* keeping the tip engaged on the anterior cortex of the sacrum to approximately the S1/S2 junction. Continue to check the A/P and lateral fluoroscopic views.

This maneuver is accomplished with “fingertip” control on the handle of the Dissecting Tool and should be completed using fluoroscopic guidance in both A/P and lateral planes.
STEP THREE
Trajectory

INSTRUMENTS NEEDED
- Blunt Dissecting Tool
- Beveled Guide Pin with Handle
- Slap Hammer or Mallet*
- Guide Pin Extension

*Standard OR instrument. Not included with Trans AxiaLIF® instruments.

Adjust the Dissecting Tool to match the trajectory suggested by the template. If the Dissecting Tool cannot match the trajectory suggested by the template, adjust the template to the obtainable trajectory of the Dissecting Tool and verify all the criteria are fulfilled. (Figure 11)

Check trajectory with A/P and lateral fluoroscopic views.

Once the trajectory is established, exchange the Blunt Stylet for the Beveled Guide Pin. Ensure the tip of the bevel is aligned with the thumbscrew on the handle. (Figure 12)
Insert the Guide Pin Handle through the Dissecting Tool. While maintaining trajectory, gently tap on the Guide Pin Handle with the Slap Hammer or a small mallet to dock the Beveled Guide Pin into the sacrum. *(Figure 13, 14)*

Confirm trajectory on A/P and lateral fluoroscopy and gently tap the Beveled Guide Pin through the sacrum and 1-2mm into the L5 vertebral body. *(Figure 15)* Confirm trajectory of the Beveled Guide Pin for proper placement of the AxiaLIF+® implant.
Remove the Guide Pin Handle and attach the Guide Pin Extension. Carefully pull the Dissecting Tool back over the Beveled Guide Pin with Extension using the extra length to ensure the Beveled Guide Pin remains in position during Dissecting Tool removal. *(Figure 16)*
A series of instruments are used to sequentially dilate the soft tissue and sacral corticocancellous bone to create the working channel.

Slide the 6mm Dilator over the Beveled Guide Pin. Use the Slap Hammer to advance the Dilator into the sacrum approximately halfway to the disc space. *(Figure 17)*

Remove the 6mm Dilator, leaving the Beveled Guide Pin in place, and repeat with the 8mm Dilator.

Remove the 8mm Dilator and repeat with the 10mm Dilator Assembly. The 10mm Dilator is assembled together with the 10mm Dilator Sheath, which slides over the 10mm Dilator body and engages with a pin and slot configuration.

Advance the 10mm Dilator far enough into the sacrum to ensure the outer diameter of the 10mm Dilator Sheath is placed completely within the sacral cortex. *(Figure 18)*
Once the Dilator with Sheath is anchored in the sacrum, remove the Dilator body from the Sheath by disengaging the pin slot configuration and carefully withdrawing the Dilator body. (Figure 19)
STEP FIVE
Drilling S1: 9MM Drill

INSTRUMENTS NEEDED:
- 10mm Sheath
- Beveled Guide Pin
- 9mm Cannulated Drill

Insert the 9mm Cannulated Drill over the Beveled Guide Pin. Create a channel to the L5-S1 disc space by rotating the drill in a clockwise motion. *(Figure 20)*

*Live fluoroscopy should be used when drilling.*

Remove the 9mm Cannulated Drill. When extracting the drill, continue rotating in a clockwise motion. This technique helps hold pieces of bone in the flutes of the drill. These can be placed aside to be used later in the procedure as supplemental bone graft material. *(Figure 21)*
STEP SIX
Discectomy at L5/S1

INSTRUMENTS NEEDED:
- 10mm Sheath
- All (4) Nitinol Disc Cutters
- Tissue Extractors
- Optional: Tight Disc Cutters
- Optional: Endplate Rasps

A series of Nitinol Disc Cutters, varying in length and shape, are used to prepare the disc space to accommodate various anatomies or surgical situations. Each cutter is designed to debulk the nucleus pulposus and lightly abrade the endplates circumferentially up to a 3cm diameter to create a bleeding bed for fusion. (Figure 22)

NOTE: THE BLADE MUST BE RETRACTED BEFORE REMOVAL FROM THE DISC SPACE.

Retract the flexible Nitinol blade of the Small Radial Cutter into the cutter sleeve. The handle and blade orientation correspond. Insert the cutter through the 10mm Dilator Sheath into the disc space. Once inside the disc space, deploy the blade in the direction that provides the most space for deployment. Using both lateral and A/P views, verify that the blade will not violate the annulus. Begin a series of cutting motions by rotating the handle in 90° turns to cut and remove tissue. (Figures 23, 24)

The double-edged blade allows cutting in both directions. Repeat with the Large Radial Cutter, Small Radial Downcutter, and Large Radial Downcutter.

NOTE: TWO SERIES OF CUTTERS, FOLLOWED BY DISC REMOVAL, SHOULD BE PERFORMED. THE FIRST SERIES OF CUTTERS ARE TO DEBULK THE NUCLEUS AND THE SECOND SERIES OF CUTTERS ARE TO PREPARE THE ENDPLATES.
Tissue extractors are used to remove disc material loosened by the cutters. Tissue extractors may be used after each cutter.

Retract the Tissue Extractor head into the sheath before inserting it through the 10mm Dilator Sheath. Advance the Tissue Extractor to the L5 endplate and deploy the Tissue Extractor head. Rotate the Tissue Extractor Knob no more than six full revolutions counterclockwise and remove by pulling the entire extractor unsheathed. *(Figure 25)* Discard the extractor and repeat as necessary.

**NOTE:** FLUSH AND ASPIRATE THE DISC SPACE AS NEEDED WITH SALINE, ADDING AN ANTIBIOTIC ACCORDING TO STANDARD PROCEDURE.
STEP SEVEN
Bone Grafting at L5/S1

INSTRUMENTS AND ITEMS NEEDED:
- 10mm Sheath
- Bone Graft Inserter
- Bone Graft Material* (Item not included with AxiaLIF® System)

Prepare the bone graft material (i.e. autogenous bone and allogenic demineralized bone matrix (DBM) mixed with autologous blood) for the L5/S1 disc space by utilizing the autologous material harvested during the drilling. Typically, a total of 7cc to 10cc of grafting material will be required to fill the disc space. Therefore, insert 2-3 cc of bone graft per tube.

Use the Bone Graft Inserter to place the bone graft material into the L5/S1 disc space. Take care not to advance the beveled edge of the Bone Graft Inserter into L5. (Figure 26)
Push the material into the disc space and pack it by pushing the Inserter Rod through the cannula. \((\text{Figure 27, 28})\)

Repeat the loading process until the disc space is full, rotating the beveled tip to deliver material into the disc space in quadrants.  

*Check trajectory with A/P and lateral fluoroscopic views.*

**NOTE:** IN PATIENTS WITH PREVIOUS DISCECTOMY, AIM THE BEVEL ANTERIORLY AND LATERALLY.

**NOTE:** CONFIRM TRAJECTORY ON A/P AND LATERAL FLUOROSCOPY.
STEP EIGHT
Dilating: 12MM Dilator

INSTRUMENTS NEEDED:
- 10mm Sheath
- Beveled Guide Pin
- 8mm Dilator
- 12mm Dilator with Sheath
- Slap Hammer

Reinsert the Beveled Guide Pin/Extension.

Reinsert the 8mm Dilator over the Beveled Guide Pin and engage with the 10mm Dilator Sheath. Remove the 8mm Dilator and the 10mm Dilator Sheath, leaving the Beveled Guide Pin in place.

(Figure 29)

Check trajectory with A/P and lateral fluoroscopic views.
The 12mm Dilator is assembled together with 12mm Dilator Sheath, which slides over the Dilator body and engages the pins on the Dilator. Insert the 12mm Dilator with Sheath Assembly over the Beveled Guide Pin.

Use the Slap Hammer to dock the Dilator with Sheath in the sacrum. Advance the 12mm Dilator far enough into the sacrum to ensure the outer diameter of the sheath is placed completely within the sacral cortex. (Figure 30)

Disengage the 12mm Dilator from the 12mm Dilator Sheath and remove the 12mm Dilator. The Dilator Sheath should remain anchored to the sacrum to serve as a protected working channel for subsequent instrumentation. (Figure 31, 32)
STEP NINE
Drilling S1: 10.5MM Drill

INSTRUMENTS NEEDED:
12mm Dilator Sheath
Beveled Guide Pin
10.5mm Drill

Insert the 10.5 mm Drill through the Dilator Sheath and rotate the handle clockwise, drilling until just through the sacrum or past the S1 endplate. Fluoroscopy is used to verify how far to drill into the sacrum and disc. *(Figure 33)*

When extracting the Drill, twist in a counter-clockwise motion. This technique ensures bone graft will be left in the disc space. *(Figure 34)*
STEP TEN
Advance 12mm Sheath

INSTRUMENTS NEEDED:
- 12mm Dilator Tamp
- 12mm Dilator Sheath
- Slap Hammer
- Beveled Guide Pin

Reinsert the beveled guide pin and tap into the L5 endplate. Using the 12mm Dilator Tamp, advance the 12mm Dilator Tamp and Sheath with the Slap Hammer up to the L5 vertebral body so that the tip of the sheath is flush against the inferior endplate of the L5 vertebral body. (Figure 35)

Once the 12mm Dilator Sheath is flush against the inferior endplate of the L5 vertebral body, remove the Dilator body from the Sheath. (Figure 36)
STEP ELEVEN
Drilling L5 Endplate: 10.5mm Drill

INSTRUMENTS NEEDED:
12mm Dilator Sheath
10.5mm Drill

Insert the 10.5mm drill over the beveled guide wire and drill 10-15mm (or 1/3 to 1/2) into the L5 vertebral body. This enables the L5 Dilator Trial to be inserted into L5. Fluoroscopy is used to verify drill depth into the L5 vertebral body. *(Figure 37)*

Remove the beveled guide pin after drilling.
measurements using the 20mm L5 Dilator Trial. If the 7.5mm tip can go deeper, then remove the 20mm trial and insert the 22.5mm trial until the shoulder is in line with the inferior L5 endplate. (Figure 38)

Insert the 20mm L5 Dilator Trial through the 12mm sheath until the shoulder is in line with the inferior L5 endplate. If the 7.5mm tip is 2/3 to 3/4 of the way into the L5 vertebral body, then take measurements using the 20mm L5 Dilator Trial. If the 7.5mm tip can go deeper, then remove the 20mm trial and insert the 22.5mm trial until the shoulder is in line with the inferior L5 endplate. (Figure 38)
If the L5 tip of the Dilator Trial is 2/3rds to 3/4ths depth in L5 then look at the lateral cross holes in the Dilator Trial shaft to determine the S1 Anchor size. The hole that is closest to the sacral face will represent which S1 Anchor size to select. The hole closest to the L5 tip represents the 25mm S1 Anchor and each of the adjacent holes are 5mm apart. The maximum S1 Anchor size is 40mm. 

*Figure 39*

**NOTE:** THE S1 ANCHOR SIZING HOLES MAY BE DIFFICULT TO SEE THROUGH THE 12MM SHEATH ON FLUORO. TWIST THE T-HANDLE OF THE DILATOR TRIAL IN ORDER TO VISUALIZE THE S1 SIZING HOLES VIA FLUORO. BOOSTING THE FLUORO INTENSITY TEMPORARILY MAY HELP TO VISUALIZE THE S1 ANCHOR HOLES THROUGH THE 12MM SHEATH.
**STEP FOURTEEN**  
Implant Assembly

**IMPLANTS & INSTRUMENTS NEEDED:**  
- Distraction Rod  
- S1 Anchor  
- Optional: L5 Anchor Driver  
- Dual Driver with Ratcheting T-Handle  
- L4/L5 Rod Driver  
- Retention Tube

Step 1: Prior to implant assembly (on dual driver), connect the large Ratcheting T-Handle to the 1/4” square quick-connect portion of the Dual Driver. *(Figure 40)*

Step 2: Thread the Distraction Rod into the base of the S1 Anchor. The L4/L5 Rod Driver can be used as an extension to make it easier to thread the Distraction Rod until the tip emerges and can be grasped with fingers. **The Distraction Rod should be threaded out until the laser marking band is partially visible, but SHOULD NOT be advanced so that the entire band is visible.** *(Figure 41)*

Step 3: Assemble the selected S1 Anchor and Distraction Rod onto the large hexalobe of the Dual Driver so that the longitudinal laser marks on all parts are aligned. *(Figure 42)* This portion of the assembly is fully seated when the small hex of the Dual Driver extends out from the Distraction Rod by approximately a 1/4” and the base of the S1 Anchor is lined up with the laser mark ring on the large hexalobe portion of the Dual Driver. *(Figure 43)*
Step 4: Assemble the L5 Anchor onto the small hex of the Dual Driver by rotating until it pops down fully onto the S1 Anchor. (Figure 44) There should be no gap between the base of the L5 Anchor and the top of the S1 Anchor. (Figure 45)

Step 5: While holding the entire implant assembly together with one hand, use the other hand to insert the Retention Tube through the large Ratcheting T-Handle and the Dual Driver shaft and thread into the L5 anchor. (Figure 46)

NOTE: PRIOR TO INSERTING IMPLANT/DRIVER ASSEMBLY INTO THE TUBULAR RETRACTOR, ENSURE THE RATCHETING T-HANDLE IS IN THE FORWARD DRIVE POSITION. FORWARD, NEUTRAL AND REVERSE POSITIONS CAN BE ADJUSTED BY ROTATING THE SILVER CONNECTION ON THE HANDLE. (SEE FIGURE 39)
STEP FIFTEEN
Exchange System

INSTRUMENTS NEEDED:
12mm Dilator Sheath
Single Piece Guide Wire
10mm Dilator
Exchange Bushing (30, 45 or 60 degrees)
Tubular Retractor (30, 45 or 60 degrees)
(2) Fixation Wires
Wire Driver*

*Standard OR instrument. Not included with Trans AxialIF+® instruments.

Evaluate the sacral face in the lateral view to choose which Exchange System (30°, 45° or 60°) best matches the contact angle.

Insert the Single Piece Guide Wire and remove the Dilator Sheath using the 10mm Dilator while leaving Single Piece Guide Wire in place.

Place the selected Exchange Bushing over the Single Piece Guide Wire, advancing it with the long mark facing dorsal until it contacts the sacral face. Verify correct placement. Simultaneously rotate the Bushing 180° and continue advancing the bushing until the angled surface of the bushing meets the sacral face. (Figure 47)

Advance the corresponding Tubular Retractor over the bushing with the arrow pointing dorsal until it contacts sacral face. Verify correct placement. Simultaneously rotate the Tubular Retractor 180° while continuing to advance the Cannula until the angled surface of the Cannula meets the sacral face. (Figure 47, 48)

Anchor the Tubular Retractor to the sacrum using two Fixation Wires. Insert each Fixation Wire through the small lumen at the proximal end of the T-shaped handle on the Tubular Retractor. Advance each Fixation Wire 1-2cm into the sacrum using a wire driver. When correctly placed, bend each wire out of the way.

Remove the bushing, leaving the Single Piece Guide Wire and Tubular Retractor in place. This step should be completed under fluoroscopic guidance to ensure the Tubular Retractor and Guide Wire remain in position. Maintain constant forward pressure on the Tubular Retractor for the duration of the surgery. (Figure 49)
STEP SIXTEEN
Implant Delivery

IMPLANTS & INSTRUMENTS NEEDED:
- Tubular Retractor (30, 45 or 60 degree)
- Single Piece Guide Wire
- Assembled Implant Construct (S1 Anchor, Distraction Rod, L5 Anchor) on Dual Driver with Retention Tube

Insert the assembled implant construct into the Tubular Retractor and over the Single Piece Guide Wire and carefully advance the Dual Driver until the superior end of the implant is engaged with the sacrum. While maintaining position of the Tubular Retractor, advance the construct by rotating the Dual Driver clockwise. Axial pressure may be required to initially engage the rod threads into bone. (Figure 50)

Continue implant insertion until the L5 Anchor is fully engaged in the L5 vertebral body. The waist section between the S1 and L5 Anchors must be in the L5/S1 disc space to allow for distraction. (Figure 51) The inferior portion of the S1 Anchor should be proud on the face of the sacrum by 1 or 2 threads. Remove the Retention Tube by unthreading it in a counterclockwise direction and remove the Retention Tube. To remove the Dual Driver, put the ratcheting handle in the fixed or neutral position and pull back while lightly rocking back and forth. (Figure 52)

NOTE: IT IS IMPORTANT TO STOP THE INITIAL IMPLANT INSERTION WHEN THE L5/S1 IMPLANT JUNCTION IS IN THE L5/S1 DISC SPACE.

NOTE: CHECK TO MAKE SURE DUAL DRIVER T HANDLE IS IN THE FORWARD DRIVE POSITION IF THE IMPLANT DOES NOT APPEAR TO BE ENGAGING IN THE BONE.
STEP SEVENTEEN
S1 Distraction

INSTRUMENTS NEEDED:
Tubular Retractor (30 or 45 degree)
Single Piece Guide Wire
Counter Torque Tube
Distraction Driver

Insert the Counter Torque Tube over the Single Piece Guide Wire and through the Tubular Retractor and rotate slightly until engaged in the back of the S1 Anchor. *(Figure 53)*

Remove Single Piece Guide Wire.

Insert the Distraction Driver through the Counter Torque Tube and press forward while initially rotating to engage it in Distraction Rod. *(Figure 54)*

Use the Distraction Driver to distract the L5-S1 disc space by slowly rotating the handle clockwise while maintaining the rotational position of the Counter Torque Tube. One full rotation of the handle will produce approximately 1.25 mm of distraction (12mm maximum separation, however this is not recommended due to potential risk of implant strippage/migration due to bone quality). *(Figure 54, 55)*

Remove the Distraction Driver and Counter Torque Tube while maintaining constant forward pressure on the Tubular Retractor.

**NOTE:** EVEN IF NO DISTRACTION IS DESIRED AT L5/S1, THIS STEP MUST BE PERFORMED UNTIL RESISTANCE IS FELT. THIS WILL ENSURE THAT THE DISTRACTION ROD HAS BEEN MOVED UP ENOUGH TO ALLOW THE FIXATION ROD TO FULLY SEAT INSIDE AND SPAN THE ENTIRE IMPLANT ASSEMBLY.
STEP EIGHTEEN
Fixation Rod Insertion

IMPLANTS AND INSTRUMENTS NEEDED:
- Tubular Retractor (30, 45 or 60 degree)
- Fixation Rod
- Fixation Rod Driver
- Fixation Rod Retention Tube
- Ratcheting Torque Limiting (RTL) Handle

Connect Ratcheting Torque Limiting (RTL) Handle to the quick connect portion of the Fixation Rod Driver (either end). Assemble the Fixation Rod onto the small hex of the Fixation Rod Driver. Next thread the Retention Tube into the back of the RTL Handle and Fixation Rod Driver and turn it clockwise until it is fully tightened into the Fixation Rod. *(Figure 56)*

Insert the Fixation Rod through the Tubular Retractor and engage it in the internal threads of the L5 Anchor portion of the AxiaLIF® construct by turning clockwise. Make sure the driver is aligned with the trajectory of the implant when inserting.

Continue turning using a light touch until the Fixation Rod is fully seated as indicated by an initial positive stop on the driver as well as visual fluoroscopy confirmation. After the initial positive stop is felt, continue to tighten down the Fixation Rod by rotating the RTL Handle 1/4 turn or until it breaks free or clicks. **This must be performed while closely monitoring fluoroscopy to ensure the L5 Anchor does not advance.** If the L5 Anchor starts advancing during this step, **STOP** and remove Retention Tube and driver. Remove the Retention Tube by rotating counter clockwise and then remove the Fixation Rod Driver. *(Figure 57)*

**NOTE: FIXATION ROD INSERTION IS A REQUIRED STEP. IT SERVES TO LAG THE ENTIRE CONSTRUCT TOGETHER, AS WELL AS PROVIDE BENDING STABILITY TO THE L5/S1 SECTION OF THE IMPLANT.**

**FLUOROSCOPIC VISUAL CONFIRMATION OF FULL ENGAGEMENT: A SMALL DOME ON THE TIP OF THE FIXATION ROD WILL PROTRUDE FROM THE SUPERIOR END OF THE L5 ANCHOR WHEN FULLY ENGAGED.**
STEP NINETEEN
Finish and Close

ITEMS NEEDED:
Standard Closing Sutures*  
Dermabond®*

Flush and aspirate the presacral corridor as needed with an antibiotic according to standard procedure. Remove the Fixation Wires and then remove the Tubular Retractor. Close the skin in routine fashion and apply a dressing to the access site. *(Figure 58)*

Complete the 360° construct with legally marketed posterior instrumentation.

Please see Package Insert for additional labeling information including indications, contraindications, warnings, and precautions.
Indications

INTENDED USE and INDICATIONS:
TranSL® AxiaLIF+® System is intended to provide anterior stabilization of the L5-S1 or L4-S1 spinal segment(s) as an adjunct to spinal fusion. The AxiaLIF+® System is indicated for patients requiring fusion to treat pseudoarthrosis (unsuccessful previous fusion) spinal stenosis, spondylolisthesis (Grade 1 or 2 if single-level; Grade 1 if two-level), or degenerative disc disease as defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. Its usage is limited to anterior supplemental fixation of the lumbar spine at L5-S1 or L4-S1 in conjunction with use of legally marketed posterior fixation such as facet screw or pedicle screw systems at the same levels that are treated with AxiaLIF.

CONTRAINDICATIONS:
Coagulopathy; bowel disease including any condition that may make the likelihood of the adhesion of the bones to the sacrum more likely (e.g. Crohn’s, ulcerative colitis); pregnancy; scoliosis that extends to the treated level(s); sacral agenesis; severe spondylolisthesis (L5-S1 > grade 2 or L4-L5 > grade 1); tumor; prior radiation treatment to the sacral or pre-sacral anatomy; trauma. Do not use with facet screws when correction of spinal stenosis requires removal of significant portions of the lamina or any portion of the facets.

WARNINGS:
The safety and effectiveness of this device has not been established in patients with osteoporosis. The 3D Axial Rod is used for anterior stabilization but may not remain stable in patients with osteoporosis (defined as a bone density z-score of < -1.5).

The most frequently stated risks are: bowel injury and associated presacral or disc infection, or intraoperative hypotension. Other risks based upon rarely reported incidents include: general infection, vascular injury, superficial wound infection, presacral hematoma, device subsidence requiring treatment, implant migration, graft protrusion, sacral fracture, and ureter injury. Finally there may be risks from surgery including: bleeding (including occult during and after surgery), neurological damage, damage to soft tissue, spinal cord impingement or damage, loss of bowel or bladder function, loss of erectile or ejaculatory function, meningitis, pain, or anesthesia complications. The safety and effectiveness of this device has not been evaluated in patients with spondyloysis. Pedicle screw systems, not facet screws, should be considered when there is degenerative disease of the facets with instability. The risks associated with the implant include: breakage of the implants, loosening or expulsion of the implants possibly causing delayed nerve root impingement or damage, fracture of osseous structures, and bursitis. There may be pain, discomfort or abnormal sensations due to the presence of the device. There may be risks associated with harvesting autologous grafts such as pain at the donor site, infection, herniation, and fracture. There may be nonunion or delayed union of fusion with the autologous graft.

PRECAUTIONS:
Preoperative: Portions of this system are supplied non-sterile and need to be cleaned and sterilized according to the CLEANING AND STERILIZATION section of this insert. Care should be taken during the preoperative preparation to evaluate the ability to achieve a desirable implant trajectory that allows the device to be fully contained within the vertebral bodies without protrusion anterior or posterior. The provided templates should be used. Severe angulation of the vertebral bodies may make achievement of an effective trajectory difficult. Preoperative planning should include identification of any pre-existing adhesions of the bowel to the sacrum or abberant anatomy such as vessels crossing the Sacrum (MRI view to tip of coccyx is recommended per established surgical technique). A bowel perforation could occur during creation of the presacral channel if there is an adhesion of the bowel to the sacrum. Unusual bleeding could occur if a vessel crossing the Sacrum is injured.

Radiolucencies have been observed around the 3D Axial Rod in patients where posterior pedicle screw fixation was secured and spanned only from L4 to S1. Segmental posterior screw fixation at L4, L5 and S1 is recommended.

Physicians using the TranSL® AxiaLIF+® System should have significant experience in spinal surgery, including spinal fusion procedures. Physicians should not independently use the AxiaLIF+® System prior to participation in specific training on its use.

Intraoperative: All steps of the procedure should be followed as per the “Surgical Technique.” All steps in this technique require the use of active or real time fluoroscopy. Refer to “Surgical Technique” for proper implant sizing. Risk of fluctuation in blood pressure exists in any surgery where instruments are introduced through tubes. Rapid introduction of instruments should be avoided in order to minimize introduction of excessive pressure or air into the disc space. As with any surgical procedure, careful patient monitoring is required to minimize risk. As with any surgical procedure, there is some risk that instrumentation will fail to perform as expected or may result in an unretrievable device fragments.

Postoperative: Risk of occult bleeding exists during and after the procedure. As with all surgical procedures, careful patient monitoring is required to minimize this risk. Following the procedure the patient should be monitored until released for any effects of the procedure. Specifically, patients should be monitored for any sign of potential bowel perforation that include but may not be limited to: severe abdominal pain, blood in stool, fever, and/or elevated white cell counts. In the event that a bowel injury is present, a colorectal surgeon should be consulted. Treatment may range from antibiotics alone (if the injury is small and detected early) to laparoscopic repair of the injury or in instances where a bowel injury is more significant or detected later, the patient may require general antibiotics, gram negative specific antibiotics and possibly a temporary diverting colostomy. The patient should adhere to post-operative instructions as provided by physician.

Revision of the AxiaLIF+® system should not include the use of anterior plates.

AxiaLIF+® has not been evaluated for safety and compatibility in the MR environment. AxiaLIF+® has not been tested for heating or migration in the MR environment.
The Mini-Open Approach (MOA) is based on the maxim that “bone is safe.” The intent of the technique is to maintain contact with coccygeal bone and avoid soft tissue injury during insertion. The current AxialLIF technique describes a 15-20mm paramedian incision through the skin and superficial fascia 1-2cm caudal to the paracoccygeal notch. The MOA employs a slightly more proximal entry point (immediately caudal to the paracoccygeal notch) using the narrow bony coccyx as a rigid landmark for safe access into the presacral space. This proximal entry allows instruments to avoid traversing tissue above the rectum, hence decreasing the risk of distal bowel injuries.

The Sacrotuberous Ligament (STL) is dorsolateral to the proximal coccyx (Coccyx 1-2) and distal sacrum (S3-S5). It is a broad structure that runs from the lower transverse sacral tubercles, the inferior margins sacrum and the upper coccyx to the tuberosity of the ischium. The STL contains the coccygeal branch of the inferior gluteal artery.

The Sacrospinous Ligament (SSL) is attached by its apex to the ischial spine, and medially, by its broad base, to the lateral margins of the sacrum and coccyx, in front of the sacrotuberous ligament, with which its fibers are intermingled.

The Ligamentous Arch formed by the STL and SSL has a broad insertion into the proximal coccyx and distal sacrum. Hence the MOA is a ligamentous sparing procedure. In rare cases of anomalous low ligamentous arch insertion into the coccyx, the “Mini-Open” approach is still not destabilizing. Ventrolateral coccygeal bony dissection is accomplished at the periosteal/ligamentous junction and not via the intra-substance of the Ligamentous Arch.

Examine the patient’s MRI/CT image to identify the transverse processes of the first coccygeal segment. In the vast majority of patients, this is the most caudal point of insertion of the Ligamentous Arch (rarely does the Ligamentous Arch attach to the second coccygeal segment).
## Instrumentation

### AxiaLIF+®

#### Reusable Instrumentation

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### AxiaLIF+®

#### Reusable Instrumentation

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### AxiaLIF+® Optional Instrumentation

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## Instrumentation

### AxiaLIF®

#### 1L+ Implants

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