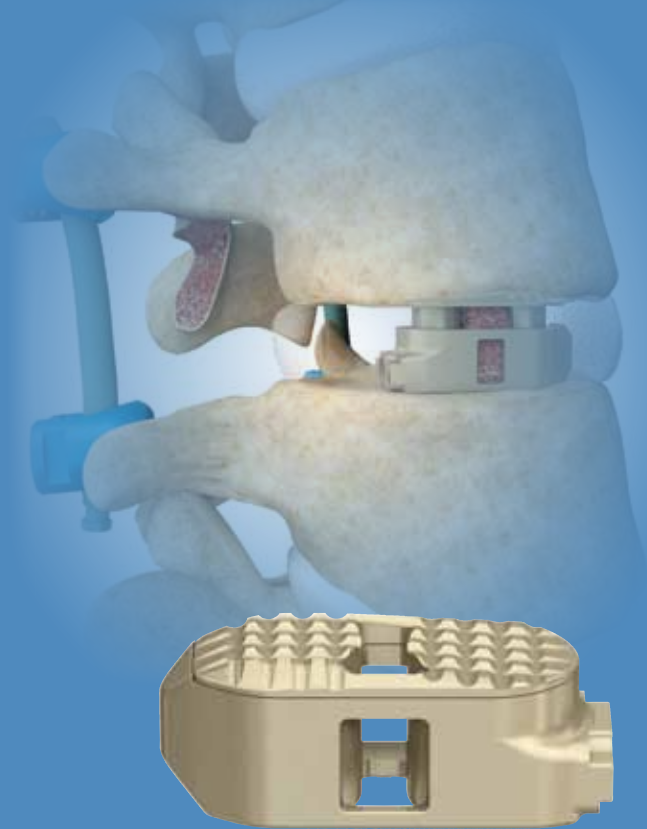
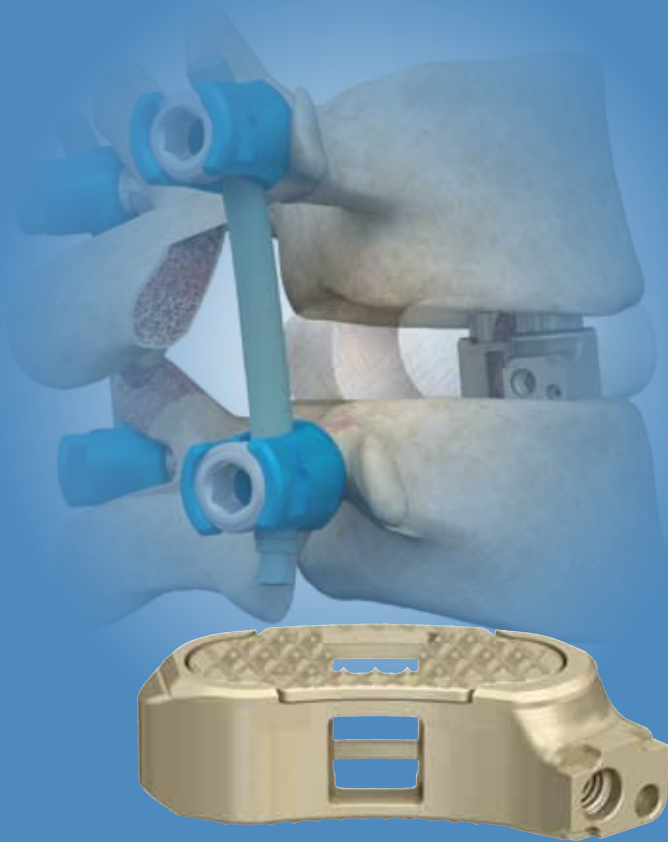


AccuLIF®

Expandable TLIF and PLIF Technology

Surgical Technique



AccuLIF Expandable Lumbar Interbody Fusion Technology Surgical Technique Guide

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Stryker Spine wishes to thank the following surgeons for their dedication and contributions to the development of the AccuLIF expandable lumbar interbody fusion technology.

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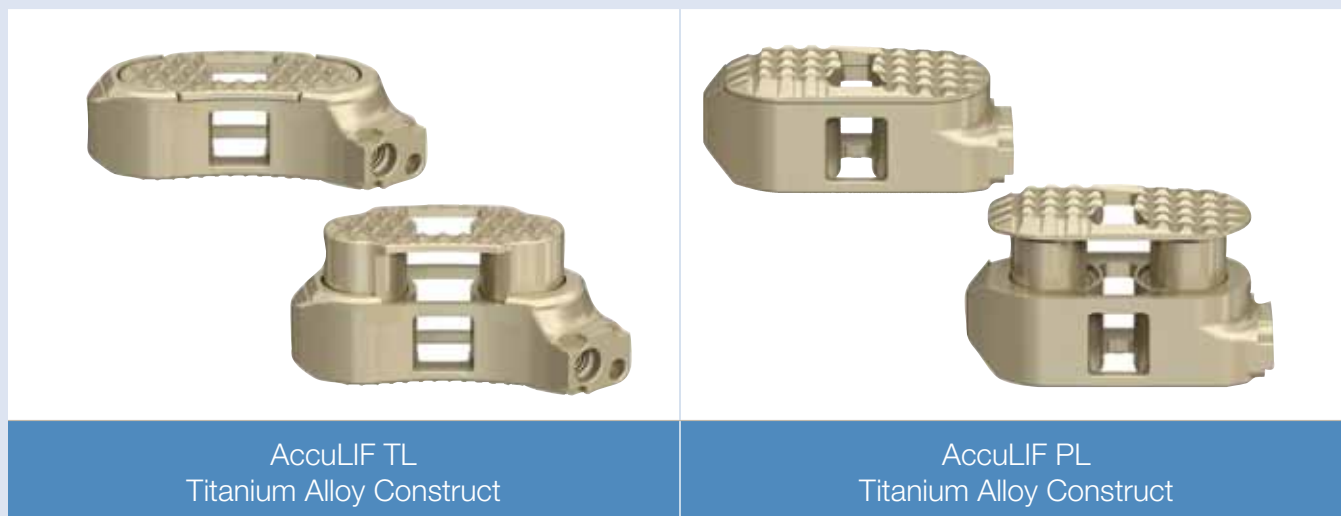
AccuLIF

Expandable Lumbar Interbody Technology

System Overview



As part of Stryker Spine's LITe (Less Invasive Technologies) Platform, the AccuLIF expandable lumbar interbody technology offers surgeon users the ability to insert an interbody device at a smaller starting height, place the device in the desired position within the disc space, and then expand the device to the desired height based on patient anatomy to ensure endplate-to-endplate fit. The small starting height of the implant is designed to help preserve endplate structural integrity, minimize impaction forces during insertion, help reduce nerve root retraction on insertion and during expansion, and help to reduce the potential for neural injury during insertion of the implant.



- Steerable, crescent-shaped expandable TLIF interbody device and straight expandable PLIF interbody device
- Three implant height options covering an expansion range from 6-16mm
- Large central cavity for autogenous bone graft spanning endplate to endplate to aid in fusion
- Surgeon controlled hydraulic expansion mechanism expands or contracts the device *in-situ* in 1mm increments

AccuLIF Expandable Lumbar Interbody Technology

Hydraulic Lift, Mechanical Lock	Large Central Autogenous Bone Graft Window	TLIF and PLIF Procedural Solutions	Low Profile Design
<ul style="list-style-type: none"> • Patented expansion mechanism utilizes hydraulic pressure • Provides tactile and visual feedback during expansion • Expands height of device to fill disc space • Monolithic structure at final height created by internal mechanical lock • Expansion in 1 millimeter increments • Can be unlocked and repositioned, if needed 	<ul style="list-style-type: none"> • Spans endplate to endplate to help aid in fusion • Instrumentation aids in packing autogenous bone graft post-expansion • Maximal volume for bone graft materials with apposition of graft material to endplate for fusion through the cage as well as around the cage 	<ul style="list-style-type: none"> • Steerable, crescent-shaped TLIF expandable IBD designed to facilitate positioning of the cage in the anterior disc space, and to permit cantilever technique for restoration of segmental lordosis • Straight expandable cage offers in line insertion and positioning of the cage obliquely across the disc space with built-in lordosis restoring segmental alignment • One instrument for insertion and expansion • Useful for minimally invasive approaches including tubular procedures 	<ul style="list-style-type: none"> • Small starting height • Three implant options covering an expansion range from 6mm to 16mm • Designed to help preserve endplate structural integrity and minimize impaction forces during insertion • Designed to help reduce nerve root retraction • Designed to help maximize the disc space height and restore lordosis while helping to protect the neural elements



AccuLIF TL Implant Overview									
Height (mm)		Length (mm)		Width (mm)	Lordotic Angle (°)		Graft Volume (cc)		Bullet Nose Height (mm)
Starting	Ending	Overall	Moving Endplate			Moving Endplate	Neutral	Expanded	
6	9	Overall	34	11	Moving Endplate	0	0.44	0.73	2.2
8	12	Moving Endplate	25		Non-Moving Endplate	0	0.53	0.92	3.5
10	16						0.67	1.26	5.5



AccuLIF PL Implant Overview									
Height (mm)		Length (mm)		Width (mm)	Lordotic Angle (°)		Graft Volume (cc)		Bullet Nose Height (mm)
Starting	Ending	Overall	Moving Endplate			Moving Endplate	Neutral	Expanded	
6	9	Overall	27	11	Moving Endplate	6	0.26	0.51	1.8
8	12	Moving Endplate	24		Non-Moving Endplate	2	0.30	0.64	2.4
10	16						0.38	0.88	3.6

Note: This surgical technique is intended as a guide only. It is recommended that the surgeon be thoroughly trained before proceeding. The surgeon user must consider the particular needs of each patient and make the appropriate adjustments when necessary and as required.

Please refer to the AccuLIF device and instrument package inserts for complete information on indications, contraindications, precautions, warnings, potential adverse events and complications, sterilization, packaging and storage.

Note: This is intended as a guide only. There are multiple techniques, and as with any surgical procedure, a surgeon user should be thoroughly trained before proceeding.



Clinical Case with AccuLIF TL



Clinical Case with AccuLIF PL

AccuLIF TL

Expandable Transforaminal Lumbar Interbody Technology



Introduction

The following technique describes a transforaminal lumbar interbody fusion, (TLIF) technique and can be performed as an open, MIS or LIS procedure as is detailed below. This technique may be applied unilaterally to any lumbar interbody space, based on the pathology being addressed and surgeon preference. In an open or minimally invasive TLIF approach, the interbody space is generally accessed from a posterior approach, and an **AccuLIF TL** implant is inserted into the disc space after discectomy and endplate preparation.

Minimally invasive surgical procedures, without compromising surgical goals, may^{1,2,3,4}:

- Reduce incision size
- Reduce blood loss
- Reduce infection
- Lead to faster patient recovery
- Reduce pain
- Reduce hospital stay
- Spare muscle (Multifidus)

Description

The **AccuLIF TL Cage System** offers crescent-shaped implants that are interbody fusion devices intended for use as an aid in spinal fixation. These implants can be expanded in height after insertion in the unexpanded state using the system instrumentation. The implants automatically lock at 1mm increments during expansion. The implants have serrations on the superior and inferior surfaces designed for multidirectional fixation and increased surface area for osteointegration, ergonomically shaped anterior edges to facilitate cage insertion with preservation of endplates and flat posterior edges, and the articulating inserter allows for a 50° intradiscal turn for optimal placement within the disc space. The cages have a large central opening spanning endplate to endplate for graft containment and to permit fusion through the interbody cage.



1. Peng CW, et al. *Clinical and Radiological Outcomes of Minimally Invasive Versus Open Transforaminal Lumbar Interbody Fusion*. SPINE 34: 1385-9, 2009.
2. Kim KT, Lee SH, et al. *The Quantitative Analysis of tissue Injury Markers After Mini-Open Lumbar Fusion*. SPINE 6: 712-6, 2006.
3. Wang MY, et al. *Minimally invasive surgery for thoracolumbar spinal deformity: initial clinical experience with clinical and radiographic outcomes*. NEUROSURG FOCUS 28 (3):E9, 2010.
4. Smith JS, et al. *Rates of Infection After Spine Surgery Based on 108,419 Procedures: A Report from the Scoliosis Research Society Morbidity and Mortality Committee*. SPINE Volume 36, Number 7: 556-563, 2011.

Step 1: Positioning and Exposure



Figure 1. Prone Patient Positioning

The patient is placed under anesthesia and positioned in the prone position prepped and draped in the usual sterile manner for posterior fusion with supplemental fixation (Figure 1).

Fluoroscopic imaging or other imaging methods may be utilized throughout the procedure to ensure correct implant placement.



Figure 2. Incision for Open or MIS Surgical Approach

A TLIF procedure can be performed using a standard open or minimally invasive approach. Typically, cage insertion is performed from the symptomatic side in patients with radiculopathy or the concave side in patients with coronal deformity.

This technique describes an open TLIF technique. The incision is made over the spinous process of the level above the index disc level and extends to the spinous process of the level below (Figure 2). Sharp paraspinal, subperiosteal dissection is performed exposing the facets of the level above and the facets at the operative level. Care must be taken to avoid damage to the facet capsules at the level above. Unless the surgeon intends to perform concomitant intertransverse fusion, the transverse processes need not be exposed. Exposure to the tips of the transverse processes permits concomitant posterolateral intertransverse fusion.

The expandable implant facilitates insertion with minimal disruption to endplates or soft tissue.

Note: The remaining steps in this surgical technique are similar in both open and minimally invasive surgical approaches. All images in this technique guide depict an open TLIF procedure for image clarity. Please refer to the Stryker Retractor System surgical technique guides, including Luxor, Phantom, and LITe Decompression Tubes, for additional information and detailed images on minimally invasive approaches. In a minimally invasive TLIF procedure, the incision may be made at the midline or approximately 4cm off midline with a more lateral trajectory in line with the disc space (Figure 3).



Figure 3. Incision for MIS Surgical Approach

Step 2: Preparation of Facet Joints

At the operative level, both facet capsules should be removed completely. This is typically accomplished using a cautery device or rongeur. The facet is prepared for fusion by removing the articular cartilage from the facet joint with a burr, rongeur or other appropriate instrument (Figure 5). The inferior and superior articular facets are removed on the side of the TLIF insertion. Complete facetectomy of the contralateral side may permit increased restoration of segmental lordosis.



Figure 4. Intact Spine



Figure 5. Facet Joint Preparation

Step 3: TLIF Site Preparation



Figure 6. TLIF Site Preparation

At the appropriate level(s), an osteotome or Kerrison rongeur may be used to remove the inferior articular process of the cephalad vertebra (Figure 6). If an osteotome is used, this may be done with 2 cuts:

- One vertical cut just medial to the facet extending superiorly to the superior border of the facet.
- One horizontal cut directed laterally towards the foramen.

Once both cuts are made, the inferior articulating process of the cephalad vertebra may be removed with a Kerrison. The lateral edge of the ligamentum flavum can then be visualized. A curette may be used to release (but not resect) the ligamentum flavum from the superior lamina of caudal vertebra allowing for distraction. The ligamentum flavum may be preserved to minimize exposure of the neural elements, but resection of the ligamentum flavum is often required for adequate neural compression.

Step 4: Distraction

Minimal distraction may be required to insert the interbody implant in its unexpanded height. If distraction is needed to insert the implant, there are several techniques that can be utilized including: pedicle screw distraction, distraction between bony elements, and/or distraction with a positioning device. As the AccuLIF TL implant is designed to be inserted at a starting height smaller than the desired final implant height, the disc space may not require significant distraction for safe insertion of the implant with minimal disruption to the endplates. Distraction should be removed when the implant is in the interbody space to minimize external compressive forces on the interbody space.

Step 5: Discectomy and Endplate Preparation

Access to the disc space is achieved through an annulotomy made lateral to the posterior longitudinal ligament. Using a scalpel, vertical cuts are made parallel to the dura and laterally in the foramen from the endplate of the cephalad vertebra to the endplate of the caudal vertebra. Additional cuts extend horizontally along the endplates of the vertebrae, connecting the vertical cuts (Figure 7). Access to the disc space may also be gained using an osteotome at the superior endplate of the lower vertebra.

Note: Disc removal and endplate preparation instrumentation is available in the Reliance Total PLIF Instrument set, the Reliance LITe Instrument set and the LITe Decompression Instrument set.



Figure 7. Annulotomy



Figure 8. Discectomy and Endplate Preparation

The annulus and any accessible disc material are removed with a pituitary rongeur (Figure 8).

Note: It is recommended that the annulotomy be at least 11mm wide in order to facilitate insertion of the implant. The AccuLIF TL implants are 11mm wide.

If osteophytes are present, sharp excision with an osteotome or Kerrison punch will provide a larger entry portal if desired.

Note: Throughout the remainder of the procedure, care must be taken to avoid unintentional disruption of the remaining lateral, anterior, or posterior annulus.

A curette, endplate shaver or narrow Cobb elevator is used to elevate disc material from the endplates of the vertebral bodies. Angled curettes can also be used to elevate the disc from the endplates. An easily missed portion of the disc lies posteriorly and centrally within the disc space, just ventral to the spinal canal. Special effort should be directed to disc removal in this zone to provide optimal surface area for interbody fusion. Straight and angled pituitary rongeurs should be used to remove the disc. Additionally, multiple passes with the straight and angled curettes may be necessary to ensure adequate discectomy of the contralateral as well as ipsilateral disc material. Fluoroscopy may help in ensuring an adequate discectomy while limiting the risk of unintentional disruption to the ventral, lateral, or posteromedial annulus.

Step 6: Sizing the Disc Space

The disc space height can be sized using a series of paddle distractors, reamer distractors or trials. The paddle distractor, reamer distractor, or trial size is serially increased until the appropriate fit within the disc space is achieved. The paddle distractor, reamer distractor, or trial should fit snugly within the disc space with distraction released. Care must be taken to not damage the dense cancellous bony surface of the endplate to optimize the interface between the endplate and the implant.

Trials

Choose an AccuLIF TL Trial and insert into the disc space (Figure 9). The AccuLIF Trials come in three heights; 6mm, 8mm, and 10mm. The Trials are 11mm wide.



Note: Be sure to trial the anterior third of the disc space, as this will be the implant's final position.

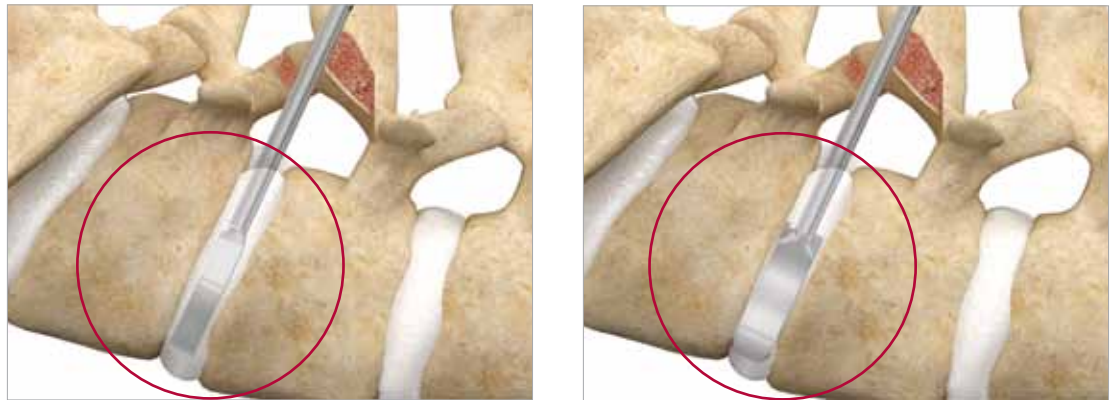


Figure 9. Trialing of the Disc Space

Note: The AccuLIF TL Trials were not designed to be used as paddle distraction devices. For paddle distractors or reamer distractors please utilize the Reliance Total PLIF or Reliance LITe Instrument sets.

Note: The AccuLIF TL Trials are made distinctly to measure the height and length of the interbody spacer to the disc space. The Trials should be evaluated under fluoroscopic imaging to determine the proper fit and placement of the final implant.

Note: The Slap Hammer can be attached to the handle of the Trials to assist in removing the Trials from the disc space if needed (Figure 10).



Figure 10. Slap Hammer Attachment

Note: If the surgeon user utilizes the AVS Navigator Dynamic Distractor, 48394005, to determine the implant height, carefully and slowly expand the Dynamic Distractor as to not over distract the disc space or violate the endplates. Reference the AVS Navigator Surgical Technique Guide for instruction on assembly, use, disassembly, cleaning and sterilization.

Step 7: AccuLIF TL Implant Sizing and Preparation

If the surgeon user is sizing the implant based on the fit and feel of the final distractor, it is recommended to choose a TL implant that is 2mm smaller than the final distractor height. Paddle distraction or reaming to 2mm larger than the insertion size of the implant will permit easy insertion of the device into the optimal position with space to distract *in situ* by expanding the implant to the intended final height and creating congruity with the adjacent endplate. If the surgeon user is sizing the implant based on the final Trial height, it is recommended to choose a TL implant that is equivalent to the final Trial height because the Trial height gives an accurate model of inserting the device, and the device may be expanded beyond the trial height. In contrast, the distractor is placed in the disc space and turned to gain final height *in situ*.

The AccuLIF TL implants are sterile packaged. Select the appropriate implant size and verify before opening the packaging.

To assemble the TL Insertion Handle:

1. Remove the following components from the Instrument Tray:
 - a. TL Insertion Handle
 - b. Inner Shaft
 - c. End Cap
 - d. Rotator Knob

Note: The TL Insertion Handle is held disassembled in the Instrument Tray for cleaning and sterilization purposes.





	800804	TL Insertion Handle
	800094	TL Insertion Handle Inner Shaft
	800074	Insertion Handle End Cap
	800054	Insertion Handle Rotator Knob



Figure 11. TL Insertion Handle Assembly Step 2

2. Place the threaded end of the Inner Shaft through the center opening on the back of the Insertion Handle (Figure 11). Make sure that the distal pivoting head on the Insertion Handle is in the central position so that the screw of the Inner Shaft will extend out of the Insertion Handle.

Note: Handle the Inner Shaft with care. The distal end has a U-joint that enables the articulation of the AccuLIF TL implant and if damaged, could cause the TL Insertion Handle to not work properly during implant insertion/placement.

Note: Make sure the Inner Shaft is completely seated by pressing down on the proximal end until the Inner Shaft bottoms out within the Insertion Handle. This will allow the distal end of the Inner Shaft to fully protrude providing the necessary surface area to securely load the Tubing Set.



Figure 12. TL Insertion Handle Assembly Step 3

3. Then, place the End Cap over the proximal end of the Inner Shaft within the proximal end of the Insertion Handle and turn clockwise until tight (Figure 12).

4. Open the sterile packaged TL Tubing Set.



Note: The TL Tubing Set is sterile packaged, single use only. The TL Tubing Set is designed to be used with the AccuLIF TL implant only.

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Figure 13. TL Insertion Handle Assembly Step 5



Figure 14. TL Insertion Handle Assembly Step 6

5. With the Insertion Handle in the “Lock” position, insert the Rotator Knob through the End Cap and hold the instrument with the exposed threaded end of the Inner Shaft pointing upwards (Figure 13).

6. Locate the center hole of the small stainless steel connector on the Tubing Set. With the plastic tubing pointing down, guide the center hole of the Tubing Set connector over the threaded end of the Inner Shaft and push down firmly to seat (Figure 14).

Note: It should be easier to fully seat the stainless steel connector if the screw threads are held exposed from the Insertion Handle by pressure from the blue Rotator Knob inserted through the End Cap.

7. Attach the proximal connector end of the Tubing Set to the side opening of the syringe connection arm on the Insertion Handle body. Align the barrel of the connector parallel to the Insertion Handle shaft and insert the stem with the colored O-Ring into the side opening of the syringe connection arm. While applying downward pressure, rotate the barrel counterclockwise until rotation stops and the Tubing Set is securely attached (Figure 15).



Figure 15. TL Insertion Handle Assembly Step 7

8. Snap the black plastic clips of the Tubing Set onto the Insertion Handle shaft, spaced evenly along length of the shaft.

Note: Following the procedure, disassemble the TL Insertion Handle by reversing the Assembly Steps outlined above. Place disassembled in the Instrument Tray for cleaning and sterilization purposes and discard the single use only TL Tubing Set.

To assemble the Syringe:

1. Remove the following components from the Instrument Tray:
 - a. Syringe Body
 - b. Syringe Plunger

Note: The Syringe is held disassembled in the Instrument Tray for cleaning and sterilization purposes.

	800247	Syringe Body
	800257	Syringe Plunger
	800347	Syringe Body Green O-Ring
	800357	Syringe Plunger Red O-Ring

Note: Prior to Syringe assembly, ensure that the Body has a green O-Ring and the Plunger has a red O-Ring. If an O-Ring is damaged or missing, replacement O-Rings are available in the Instrument Tray.



Figure 16. Syringe Assembly Step 2

2. Fill the Syringe Body with sterile saline solution up to the side window on the Body (Figure 16).

3. Insert the Syringe Plunger into the Syringe Body until the red O-Ring on the Plunger passes beyond the Syringe Body window (Figure 17).



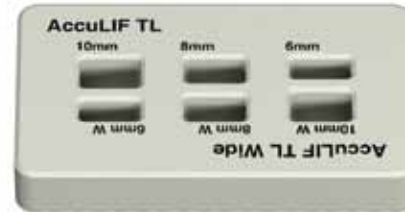
Figure 17. Syringe Assembly Step 3

4. Place the Syringe Body/Plunger assembly aside within the sterile field until the TL implant is within the disc space and ready to be expanded.

Note: Take care to hold the assembled Syringe Body/Plunger at the midpoint of the Syringe Body.

Note: Following the procedure, disassemble the Syringe by reversing the Assembly Steps outlined above. Place disassembled in the Instrument Tray for cleaning and sterilization purposes.

It is recommended to use the **Prep Block** to load the AccuLIF TL implant onto the Insertion Handle. Place the implant into the specific slot with the nose forward into the Block and the connection end parallel.



800006 Prep Block

Note: The Prep Block has specific slots for each sized TL implant; 6mm, 8mm and 10mm.

Note: If packing the AccuLIF TL cage with autogenous bone graft material prior to assembly to the Insertion Handle, take care to keep graft material away from the connection interface. This will help ensure a secure connection between the implant and the Inserter.

Note: The Inserter pivot should be “Locked” with the threaded end of the Inner Shaft in the straight position prior to assembling the implant (Figure 18).

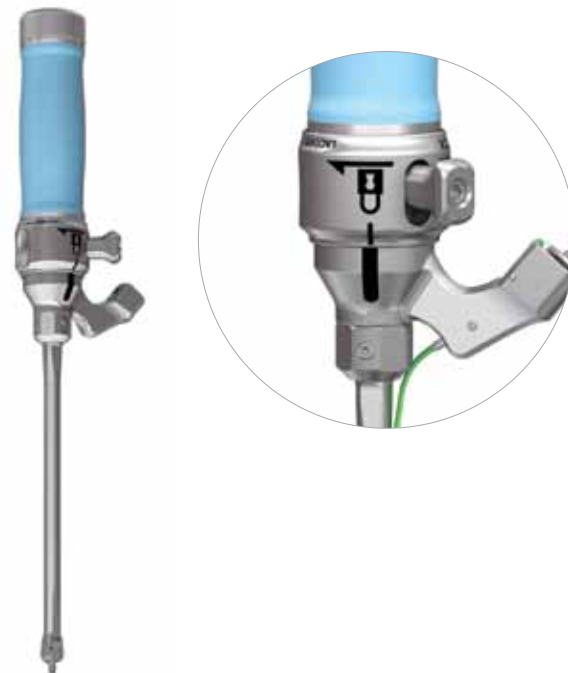


Figure 18. Assembled TL Insertion Handle in “Locked” position.



Figure 19. TL Implant/Inserter Assembly Step 2

To assemble the implant to the Inserter:

1. Insert the implant into the Prep Block to hold the implant upright.
2. Holding the Insertion Handle vertically with the threaded end of the Inner Shaft pointing down, insert the blue Rotator Knob through the End Cap and rotate to seat (Figure 19).
3. Maintaining vertical alignment, align the threaded distal tip of the Inner Shaft and the O-Ring post of the Tubing Set with the appropriate holes on the implant (Figure 20).
4. Secure the Insertion Handle to the implant by gently turning the blue Rotator Knob clockwise while engaging the screw into the threaded bore of the implant. Keep turning the blue Rotator Knob until the implant is connected tightly and two audible clicks are heard (Figure 21).
5. Remove the assembled implant / Insertion Handle from the Prep Block.
6. Inspect the connection between the implant, Tubing Set and Insertion Handle to ensure there are no gaps. If there are gaps, turn the Rotator Knob in a counterclockwise direction to separate the implant and repeat Steps 1-6.
7. Remove the blue Rotator Knob.
8. “Unlock” the Insertion Handle and rotate the Insertion Handle pivot into the lateral position to straighten the implant for insertion. “Relock” the Insertion Handle (Figure 22).
9. Pack the AccuLIF TL implant with autogenous bone graft. The compacted graft should be flush with the upper and lower surfaces of the implant.



Figure 20. TL Implant/Inserter Assembly Step 3



Figure 23. TL Implant/Inserter Assembly Step 6



Figure 21. TL Implant/Inserter Assembly Step 4



Figure 22. TL Implant/Inserter Assembly Step 5

Note: Verify that no gaps exist at the interface between the implant and the stainless steel connector to assure that the attachment is secure.

Step 8: AccuLIF TL Implant Insertion



Figure 24. TL Implant Insertion Step 1

The AccuLIF Insertion Handle is specifically designed to allow a surgeon to insert the implant into the disc space with a fixed engagement between the two components to permit a controlled positioning of the implant in the anterior portion of the intervertebral space, and then activate a rotational component between the Handle and implant for final placement of the crescent-shaped cage across the anterior portion of the disc space. The implant can be locked into three different angles relative to the Handle to facilitate placement of the implant in the position intended by the surgeon (Figure 24).

Note: When using the articulation mechanism, the surgeon user should feel the gear teeth on the steering mechanism engage before “Locking” the Handle. This will help prevent damaging the gear teeth.

1. Prior to insertion, confirm the pivot of the Insertion Handle is “Locked” in the lateral position and the implant is tightly connected.

Note: The lock/unlock lever should be lubricated frequently and checked prior to use. The geared teeth should be inspected prior to use to ensure the teeth are not worn, which will impact the ability to hold the implant in a fixed position during insertion.



Figure 26. TL Implant Insertion Step 3

2. Carefully insert the unexpanded AccuLIF TL implant gently and progressively into the disc space using the mallet when necessary (Figure 25).

Note: To help reduce wearing of the gear teeth, it is important for the surgeon to use the right size implant as well as check the preparedness of the disc space with the 6mm TL trial prior to implant insertion.



Figure 25. TL Implant Insertion Step 2



Figure 27. TL Implant Insertion Step 4

3. Optimal positioning may be facilitated by first directing the implant obliquely until it contacts the ventral annulus (Figure 26).

4. Use the “Unlock/Lock” feature on the Insertion Handle, the position of the Handle and the annulus to gently and progressively rotate the implant into position by realigning the insertion Handle at a progressively more acute angle relative to the implant (Figure 27).



Figure 28. TL Implant Insertion Step 5

5. Continue to use the mallet to impact gently and progressively into the disc space until the implant reaches desired final positioning (Figure 28).

Note: When the AccuLIF TL implant crosses midline and contacts the ventral annulus, “Unlock” the Insertion Handle. Leave the Handle in the “Unlock” position. Using the anatomy and Handle positioning, strike the Insertion Handle with a mallet to passively articulate (turn) the implant perpendicular to the spinous process. “Lock” the Insertion Handle and gently strike the End Cap of the Handle. Take fluoroscopy images to confirm anterior-posterior and lateral implant position. Active control of the insertion position may also be gained by using the locking feature on the Insertion Handle to directly place the implant in the desired position.

Note: There is no specific orientation of the moveable endplate within the disc space. Therefore, the expanding side of the implant may be adjacent to the upper or lower endplate.

Note: Fluoroscopy may be useful in determining the appropriate trajectory for insertion of the implant and appropriate final positioning. Care should be taken to prevent the instrument from pushing too far anteriorly through the anterior annulus.

Note: If difficulty is encountered while positioning the TL implant it most likely represents remaining contralateral disc material blocking passage of the implant. Check for adequacy of the discectomy and be sure distraction, if used, is maintained. Then reposition the implant as needed. The distraction, if used, should be released to facilitate optimal placement of the implant and to permit expansion.

Note: Align the green indicators on the Handle and Syringe (Figure 29). The Syringe is fully connected when an audible click indicates engagement.



Figure 29. Syringe/TL Insertion Handle Alignment



Figure 30. Syringe/TL Insertion Handle Assembly

The correct position of the implant should be confirmed by direct visualization of implant location and/or with lateral and anterior-posterior fluoroscopic images before expanding the implant. After confirmation, align the green indicators on the Handle and Syringe (Figure 29) to connect the Syringe filled with sterile saline to the Handle (Figure 30). The Syringe is fully connected when an audible click indicates engagement.

Note: Distraction should be released before expansion of the implant. Distraction of the posterior elements narrows the interbody space.

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Figure 31. Application of Hydraulic Pressure

Caution: In patients with compromised bone integrity, be mindful that the implant is in apposition to dense bone to maximize distraction of the interbody space and to avoid possible implant subsidence. Check the tightness of fit and pressure frequently.

The implant expansion mechanism is activated by turning the Syringe Plunger T-Handle slowly to the right which applies pressure to the endplate of the device via sterile saline (Figure 31). It should be noted that the amount of pressure necessary to move the endplate of the device depends on the degree of resistance offered by the remaining soft tissue and ligaments around the discectomy.

Expand the device to a point at which the surgeon user is satisfied with the tightness of fit of the implant within the discectomy space (Figure 32). The tightness of the fit can be directly evaluated by:

- Tactile force applied to the Insertion Handle which is still attached to the implant
- The pressure gauge on the Syringe with a color-coded pressure indicator
- Direct visualization of the expanded implant in the disc space
- The use of fluoroscopic imaging

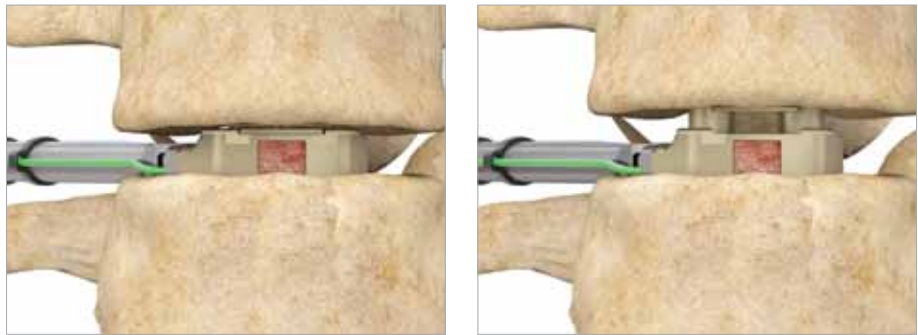


Figure 32. TL Implant Expansion

Evaluate the tightness of fit periodically while expanding the implant. Direct visualization and/or fluoroscopic imaging should be used during expansion to verify the device height. The implant can be expanded in 1mm increments. At each 1mm increment the device mechanically locks under the control of an internal spring mechanism.

The surgeon user must turn the Syringe Plunger T-Handle counterclockwise before taking fluoroscopic images. This action will reduce the pressure within the AccuLIF system and allow the moveable endplate to rest upon the 6 internal stair step risers and show the “Locked” height of the device.

Note: There is a pressure gauge built into the Syringe (Figure 33). The pressure gauge indicates the increasing pressure the device is experiencing. As the pressure indicator advances through the green and yellow colored areas, the tightness of fit of the expanding implant should be evaluated. Pressure should stop being applied when the indicator reaches the magenta colored area. Maximal pressure is indicated by the magenta colored area and evaluation of the bone implant interface is useful to prevent implant subsidence at high pressures. There is a pressure relief valve built into the syringe to prevent the pressure from exceeding 2,000 psi.



Figure 33. Pressure Gauge

Once the tightness of the fit of the implant within the discectomy space is satisfactory, slowly release the pressure by turning the T-Handle of the Syringe Plunger counterclockwise one or two turns. Confirm the desired expansion via fluoroscopy.

Note: If the implant was not fully expanded to the next millimeter increment, the implant will settle back down to the lower millimeter increment once the pressure has been released. Confirm expansion of implant via fluoroscopy after releasing the pressure and before disconnecting the Insertion Handle to ensure desired expansion has been achieved.

Note: If the surgeon user should want to reposition the expanded implant, the device should be pressurized again by turning the Syringe Plunger T-Handle slowly to apply enough pressure to raise the implant endplate above the last locked position. Then, slide the Unlocking Button on the Tubing Set forward to release the internal mechanical locking mechanism (Figure 34). Next, release the pressure on the Syringe to allow the implant endplate to collapse. The Unlocking Button is then retracted and the implant repositioned and re-expanded following the same steps above.

Note: If the endplate is violated, the surgeon user should collapse the implant as outlined above. The surgeon should slowly re-expand the implant until it is just snug within the disc space. Be sure to check the expansion under fluoroscopy. With the implant re-expanded to a lower height and a just snug fit, detach the Insertion Handle using the Rotator Knob as outlined below. Use the supplemental fixation to lock the construct in place and compress onto the AccuLIF implant.

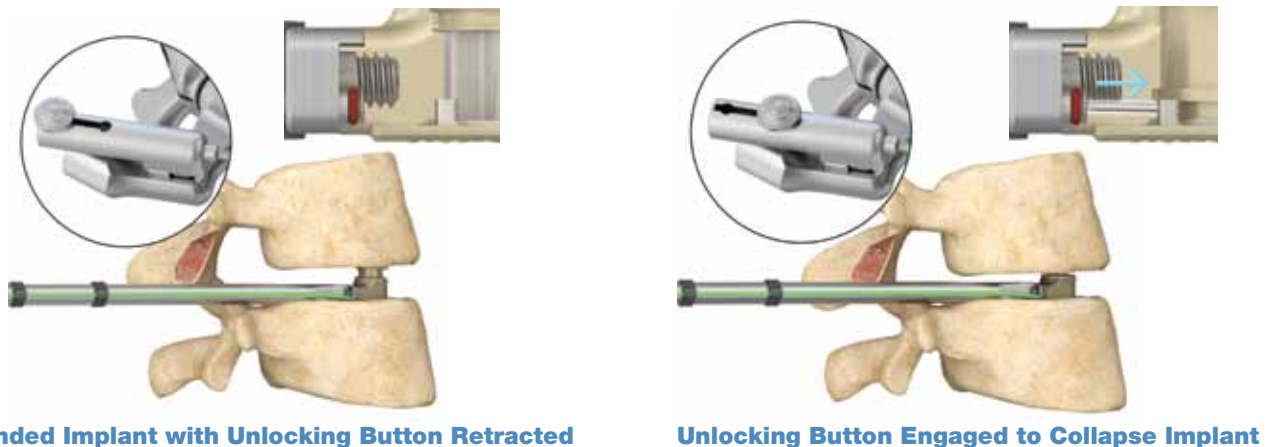


Figure 34. Expansion Mechanism Release



Figure 35. Slap Hammer Used to Aid in Removal

Note: When deemed medically necessary, for intraoperative removal of the interbody device when the Insertion Handle is still attached to the implant, the Handle can be in either the “Locked” or “Unlocked” position. The “Unlocked” position may allow the implant to follow the path of least resistance on removal. If needed, the Slap Hammer can be threaded onto the back of the Insertion Handle (Figure 35).

With the desired expansion achieved, detach the Insertion Handle with the Tubing Set from the implant by inserting the Rotator Knob into the proximal end of the Insertion Handle and turning in a counterclockwise direction.

Note: The Handle will disengage from the implant in approximately seven turns of the Rotator Knob.



800305 Graft Insertion Cannula



800307 Graft Insertion Pusher

Step 9: Placement of Bone Graft

Bone graft material may be placed in the interbody space prior to insertion of the implant. With the central opening of the implant filled with autogenous bone graft prior to insertion, the area between the raised endplate and the body of the device should be filled with additional autogenous bone graft material after the implant has been expanded. The bone graft material can be inserted using the **Bone Graft Cannula and Pusher**; the graft material is loaded into the Cannula, and the Pusher is used to deliver material to the expanded space within the implant (Figure 36). The end of the Cannula is curved to facilitate ease of insertion into the central area of the implant. Additional bone graft material may be placed lateral, and/or dorsal to the implanted AccuLIF TL device.

Note: The inner diameter of the Graft Insertion Cannula is 6mm. It is important to make sure all graft material placed within the Cannula is smaller than 6mm in diameter. Additionally, placing incremental amounts of bone graft through the cannula allows for easier placement into the cage and disc space.



Figure 36. Filling the TL Implant with Autogenous Bone Graft Material Post-Expansion

Step 10: Posterior Fusion

The AccuLIF TL and PL Cages are to be used with supplemental fixation that has been cleared by the FDA for use in the lumbosacral spine (e.g. pedicle screws, or, when performing a single-level fusion, an interspinous process plate). If pedicle screws were not inserted earlier in the procedure, insert pedicle screws at this point or other appropriate supplemental fixation (Figure 37). Compression of the pedicle screws or interspinous device may be used to create segmental lordosis of the segment fused. A tall, anteriorly placed interbody device will provide a fulcrum for creating segmental lordosis while preserving foraminal height.

The remaining bone graft may be placed in the decorticated facet to promote fusion.

Intraoperative radiographs should be performed to confirm satisfactory position of the AccuLIF TL implant, supplemental fixation and bone graft material.

Note: Choices for supplemental spinal fixation systems include, but are not limited to, Stryker Spine pedicle screw or interspinous process fixation plate systems (Xia, Radius, Trio, Techtonix, UniVise and ES2). Please refer to the respective surgical techniques of the above mentioned Stryker Spine supplemental fixation systems for additional information on implantation.



AccuLIF TL and Xia 3 or Xia 4.5



AccuLIF TL and UniVise



AccuLIF TL and ES2

Figure 37. AccuLIF TL with Different Supplemental Fixation Options

Step 11: Closure

Check the foramen and TLIF site for any bone fragments or extraneous soft tissue. Once satisfactory decompression of the exiting and traversing nerve roots is confirmed, the wound should be closed in a routine manner.

Step 12: Revision

A surgical revision may be indicated for many reasons including new or unresolved pain or neurological symptoms, changes in device positioning, non-union or incomplete fusion, etc. If necessary, the AccuLIF TL implant can be removed with the use of the Insertion Handle and Slap Hammer. The surgeon user must use his/her professional judgment to determine the appropriate revision strategy taking into consideration the patient's health, the nature of the problem and/or device failure, the patient's bone quality, and the surgeon's expertise with other spinal treatments and instrumentation.

Revision guidelines:

1. Soft tissue around the surface of the implant should be removed.
2. An osteotome or rongeurs can be used to remove any bony tissue secured to the implant.
3. The Insertion Handle is reattached to the implant to remove it from the surgical site.
4. The Slap Hammer can be attached to the proximal end of the Insertion Handle to aid in withdrawal of the device.

Alternatively, if the Insertion Handle cannot be reattached to the implant, forceps or other manual surgical instruments may be used to grasp and extract the implant.

AccuLIF PL

Expandable Posterior Lumbar Interbody Technology

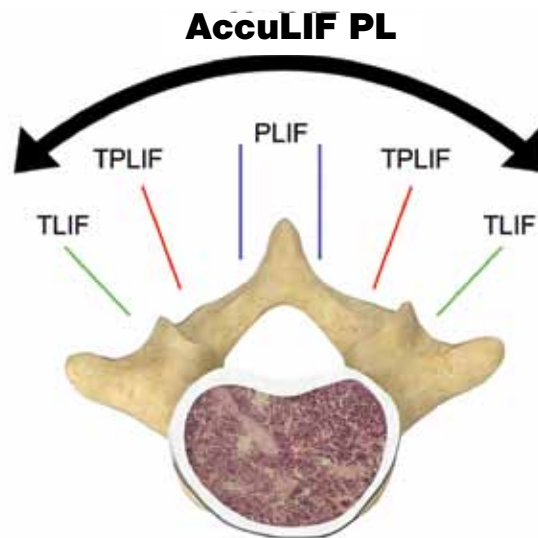


Introduction

The following technique describes the unilateral insertion of a single implant into the disc space through a posterior lumbar interbody fusion (PLIF) approach, transforaminal lumbar interbody fusion (TLIF) approach or anywhere in between based on the pathology being addressed and surgeon preference. This technique may be performed through an open or minimally invasive approach.

Minimally invasive surgical procedures, without compromising surgical goals, may^{5,6,7,8}:

- Reduce incision size
- Reduce blood loss
- Reduce infection
- Lead to faster patient recovery
- Reduce pain
- Reduce hospital stay
- Spare muscle (Multifidus)



Description



The **AccuLIF PL Cage System** offers rectangular-shaped implants that are interbody fusion devices intended for use as an aid in spinal fixation. These implants can be expanded in height after insertion in the unexpanded state using the system instrumentation. The implants automatically lock at 1mm increments during expansion. The implants have serrations on the superior and inferior surfaces designed for multidirectional fixation and to maximize surface area for osteointegration of the implant, ergonomically shaped anterior edges to facilitate cage insertion with preservation of endplates and flat posterior edges. The cages have a large central opening spanning endplate to endplate for graft containment and to permit fusion through the interbody cage.

5. Peng CW, et al. *Clinical and Radiological Outcomes of Minimally Invasive Versus Open Transforaminal Lumbar Interbody Fusion*. SPINE 34: 1385-9, 2009.
6. Kim KT, Lee SH, et al. *The Quantitative Analysis of tissue Injury Markers After Mini-Open Lumbar Fusion*. SPINE 6: 712-6, 2006.
7. Wang MY, et al. *Minimally invasive surgery for thoracolumbar spinal deformity: initial clinical experience with clinical and radiographic outcomes*. NEUROSURG FOCUS 28 (3):E9, 2010.
8. Smith JS, et al. *Rates of Infection After Spine Surgery Based on 108,419 Procedures: A Report from the Scoliosis Research Society Morbidity and Mortality Committee*. SPINE Volume 36, Number 7: 556-563, 2011.



Figure 1. Prone Patient Positioning

Step 1: Exposure Open Approach

The patient is placed under anesthesia and positioned in the prone position prepped and draped in the usual sterile manner for posterior fusion with supplemental fixation (Figure 1).

Fluoroscopic imaging or other imaging methods may be utilized throughout the procedure to ensure correct implant placement.

The procedure to implant an AccuLIF PL device can be performed using a standard open or minimally invasive approach, from the patient's left or right side. Typically, cage insertion is performed from the symptomatic side in patients with radiculopathy or on the concavity in patients with segmental coronal deformity. This technique describes an open surgical approach.

This technique describes an open TLIF technique placing the AccuLIF PL cage obliquely across the disc space. The incision is made over the spinous process of the level above the index disc level and extends to the spinous process of the level below (Figure 2). Sharp paraspinous, subperiosteal dissection is performed exposing the facets of the level above and the facets at the operative level. Care must be taken to avoid damage to the facet capsules at the level above. Unless the surgeon intends to perform concomitant intertransverse fusion, the transverse processes need not be exposed. Exposure to the tips of the transverse processes will permit a posterolateral fusion in addition to the interbody fusion.

The expandable implant facilitates insertion with minimal disruption to endplates or soft tissue.



Figure 2. Incision for Open or MIS Surgical Approach.

Note: The remaining steps in this surgical technique are similar in both open and minimally invasive surgical approaches. All images in this technique guide depict an open approach for image clarity. The AccuLIF PL system lends itself to minimally invasive approaches as well. Minimally invasive techniques rely on proprietary retractor systems and specialized tools, the use of which is best depicted in their individual technique guides. Please refer to the Stryker Retractor System surgical technique guides, including Luxor, Phantom, and LITe Decompression Tubes, for additional information and detailed images on minimally invasive approaches. In a minimally invasive TLIF procedure, the incision may be made at the midline or approximately 4cm off midline with a more lateral trajectory in line with the disc space (Figure 3).



Figure 3. Incision for MIS Surgical Approach.

Step 2: Preparation of Facet Joints

At the operative level, both facet capsules should be removed completely. This is typically accomplished using a cautery device. The facet is prepared for fusion by removing the articular cartilage from the facet joint with a burr, rongeur or other appropriate instrument (Figure 5). The inferior and superior articular facets are removed on the side of the TLIF insertion. Complete facetectomy of the contralateral side may permit increased restoration of segmental lordosis.



Figure 4. Intact Spine



Figure 5. Facet Joint Preparation

Step 3: Insertion Site Preparation: Facet Sparing or Transforaminal



Figure 6. TLIF Site Preparation

The AccuLIF PL device may be inserted into the disc space using either a facet sparing or a transforaminal approach. For the TLIF approach, at the appropriate level(s), an osteotome may be used to remove the inferior articular process of the cephalad vertebra. If an osteotome is used, this may be done with 2 cuts (Figure 6):

- One vertical cut just medial to the facet extending superiorly to the superior border of the facet.
- One horizontal cut directed laterally towards the foramen.

Once both cuts are made, the inferior articulating process of the cephalad vertebra may be removed with a Kerrison. The lateral edge of the ligamentum flavum can then be visualized. A curette may be used to release (but not resect) the ligamentum flavum from the superior lamina of caudal vertebra allowing for distraction. The ligamentum flavum may be preserved to minimize exposure of the neural elements, but resection of the ligamentum flavum is often required for adequate neural compression.

Step 4: Distraction

Minimal distraction may be required to insert the interbody implant in its unexpanded height. If distraction is needed to insert the implant, there are several techniques that can be utilized including: pedicle screw distraction, distraction between bony elements, and/or distraction with a positioning device. As the AccuLIF PL implant is designed to be inserted at a starting height smaller than the desired final implant height, the disc space may not require significant distraction for safe insertion of the implant with minimal disruption to the endplates. Distraction should be removed when the implant is in the interbody space to minimize external compressive forces on the interbody space.

Step 5: Discectomy and Endplate Preparation

Access to the disc space is achieved through an annulotomy made lateral to the posterior longitudinal ligament. Using a scalpel, vertical cuts are made parallel to the dura and laterally in the foramen from the endplate of the cephalad vertebra to the endplate of the caudal vertebra. Additional cuts extend horizontally along the endplates of the vertebrae, connecting the vertical cuts (Figure 7). Access to the disc space may also be gained using an osteotome at the superior endplate of the lower vertebra.

Note: Disc removal and endplate preparation instrumentation is available in the Reliance Total PLIF Instrument set, the Reliance LITe Instrument set and the LITe Decompression Instrument set.



Figure 7. Annulotomy



Figure 8. Discectomy and Endplate Preparation

The annulus and any accessible disc material are removed with a pituitary rongeur (Figure 8).

Note: It is recommended that the annulotomy be at least 11mm wide in order to facilitate insertion of the implant. The AccuLIF PL implants are 11mm wide.

If osteophytes are present, sharp excision with an osteotome or Kerrison punch will provide a larger entry portal if desired.

Note: Throughout the remainder of the procedure, care must be taken to avoid unintentional disruption of the remaining lateral, anterior, or posterior annulus.




A curette, endplate shaver or narrow Cobb elevator is used to elevate disc material from the endplates of the vertebral bodies. Angled curettes can also be used to elevate the disc from the endplates. An easily missed portion of the disc lies posteriorly and centrally within the disc space, just ventral to the spinal canal. Special effort should be directed to disc removal in this zone to provide optimal surface area for interbody fusion. Straight and angled pituitary rongeurs should be used to remove the disc. Additionally, multiple passes with the straight and angled curettes may be necessary to ensure adequate discectomy. Fluoroscopy may help in ensuring an adequate discectomy while limiting the risk of unintentional disruption to the ventral, lateral, or posteromedial annulus.

Step 6: Sizing the Disc Space

The disc space height can be sized using a series of paddle distractors, reamer distractors or trials. The paddle distractor, reamer distractor, or trial size is serially increased until the appropriate fit within the disc space is achieved. The paddle distractor, reamer distractor, or trial should fit snugly within the disc space with distraction released. Care must be taken to not damage the dense cancellous bony surface of the endplate to optimize the interface between the endplate and the implant.

Trials

Choose an AccuLIF PL Trial and insert into the disc space (Figure 9). The AccuLIF Trials come in three heights; 6mm, 8mm, and 10mm and are 11mm wide.

	851006	6mm PL Trial
	851008	8mm PL Trial
	851010	10mm PL Trial

Note: Be sure to trial the anterior third of the disc space, as this will be the implant's final position.

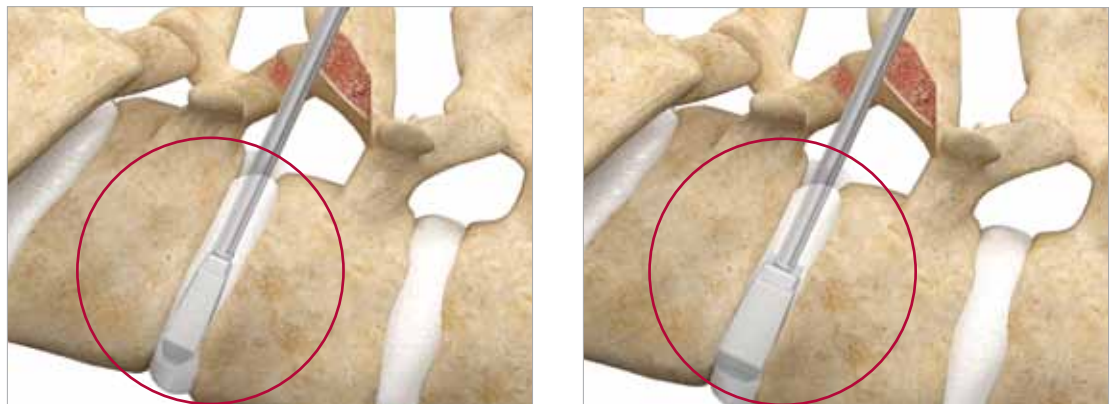


Figure 9. Trialing of the Disc Space

Note: The AccuLIF PL Trials were not designed to be used as paddle distraction devices. For paddle distractors or reamer distractors please utilize the Reliance Total PLIF or Reliance LITe Instrument sets.

Note: The AccuLIF PL Trials are made distinctly to measure the height and length of the interbody spacer to the disc space. The Trials should be evaluated under fluoroscopic imaging to determine the proper fit and placement of the final implant.

Note: The Slap Hammer can be attached to the handle of the Trials to assist in removing the Trials from the disc space if needed (Figure 10).



800005 Slap Hammer



Figure 10. Slap Hammer Attachment

Note: If the surgeon user utilizes the AVS Navigator Dynamic Distractor, 48394005, to determine the implant height, carefully and slowly expand the Dynamic Distractor as to not over distract the disc space or violate the endplates. Reference the AVS Navigator Surgical Technique Guide for instruction on assembly, use, disassembly, cleaning and sterilization.

Step 7: AccuLIF PL Implant Sizing and Preparation

If the surgeon user is sizing the implant based on the fit and feel of the final distractor, it is recommended to choose a PL implant that is 2mm smaller than the final height. Paddle distraction or reaming to 2mm larger than the insertion size of the implant will permit easy insertion of the device into the optimal position with space to distract *in situ* by expanding the implant to the intended final height and creating congruity with the adjacent endplate. If the surgeon user is sizing the implant based on the final Trial height, it is recommended to choose a PL implant that is equivalent to the final Trial height because the Trial height gives an accurate model of inserting the device, and the device may be expanded beyond the trial height. In contrast, the distractor is placed in the disc space and turned to gain final height *in situ*.

The AccuLIF PL implants are sterile packaged. Select the appropriate implant size and verify before opening the packaging.

To assemble the PL Insertion Handle:

1. Remove the following components from the Instrument Tray:
 - a. PL Insertion Handle
 - b. Inner Shaft
 - c. End Cap
 - d. Rotator Knob

Note: The PL Insertion Handle is held disassembled in the Instrument Tray for cleaning and sterilization purposes.

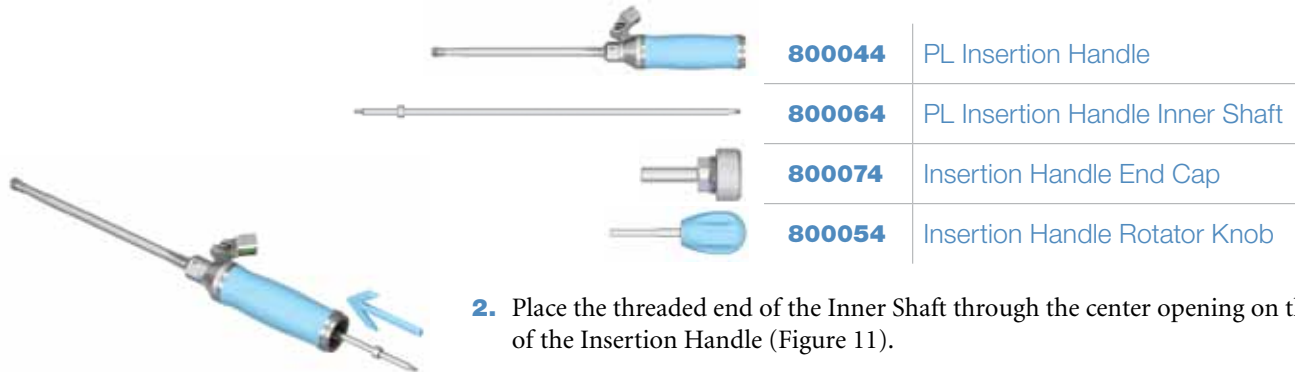


Figure 11. PL Insertion Handle Assembly Step 2

2. Place the threaded end of the Inner Shaft through the center opening on the back of the Insertion Handle (Figure 11).

Note: Make sure the Inner Shaft is completely seated by pressing down on the proximal end until the Inner Shaft bottoms out within the Insertion Handle. This will allow the distal end of the Inner Shaft to fully protrude providing the necessary surface area to securely load the Tubing Set.



Figure 12. PL Insertion Handle Assembly Step 3

3. Then, place the End Cap over the proximal end of the Inner Shaft within the proximal end of the Insertion Handle and turn clockwise until tight (Figure 12).
4. Open the sterile packaged PL Tubing Set.



900301 PL Tubing Set

Note: The PL Tubing Set is sterile packaged, single use only. The PL Tubing Set is designed to be used with the AccuLIF PL implant only.

AccuLIF PL

Surgical Technique

AccuLIF PL



Figure 13. PL Insertion Handle Assembly Step 5



Figure 14. PL Insertion Handle Assembly Step 6

5. Insert the Rotator Knob into the End Cap and hold the Insertion Handle with the exposed threaded end of the Inner Shaft pointing upwards (Figure 13).

6. Locate the center hole of the small stainless steel connector on the Tubing Set. With the plastic tubing pointing down, guide the center hole of the Tubing Set connector over the threaded end of the Inner Shaft and push down firmly to seat (Figure 14).

Note: It should be easier to fully seat the stainless steel connector if the screw threads are held exposed from the Insertion Handle by pressure from the blue Rotator Knob inserted through the End Cap.

7. Attach the proximal connector end of the Tubing Set to the side opening of the syringe connection arm on the Insertion Handle body. Align the barrel of the connector parallel to the Insertion Handle shaft and insert the stem with the colored O-Ring into the side opening of the syringe connection arm. While applying downward pressure, rotate the barrel counterclockwise until rotation stops and the Tubing Set is securely attached (Figure 15).



Figure 15. PL Insertion Handle Assembly Step 7

8. Snap the black plastic clips of the Tubing Set onto the Insertion Handle shaft, spaced evenly along length of the shaft.

Note: Following the procedure, disassemble the PL Insertion Handle by reversing the Assembly Steps outlined above. Place disassembled in the Instrument Tray for cleaning and sterilization purposes and discard the single use only PL Tubing Set.

To assemble the Syringe:

1. Remove the following components from the Instrument Tray:
 - a. Syringe Body
 - b. Syringe Plunger

Note: The Syringe is held disassembled in the Instrument Tray for cleaning and sterilization purposes.

	800247	Syringe Body
	800257	Syringe Plunger
	800347	Syringe Body Green O-Ring
	800357	Syringe Plunger Red O-Ring

Note: Prior to Syringe assembly, ensure that the Body has a green O-Ring and the Plunger has a red O-Ring. If an O-Ring is damaged or missing, replacement O-Rings are available in the Instrument Tray.



Figure 16. Syringe Assembly Step 2

2. Fill the Syringe Body with sterile saline solution up to the side window on the Body (Figure 16).

3. Insert the Syringe Plunger into the Syringe Body until the red O-Ring on the Plunger passes beyond the Syringe Body window (Figure 17).

Note: Following the procedure, disassemble the Syringe by reversing the Assembly Steps outlined above. Place disassembled in the Instrument Tray for cleaning and sterilization purposes.



Figure 17. Syringe Assembly Step 3

4. Place the Syringe Body/Plunger assembly aside within the sterile field until the PL implant is within the disc space and ready to be expanded.

Note: Take care to hold the assembled Syringe Body/Plunger at the midpoint of the Syringe Body.

AccuLIF PL

Surgical Technique



Figure 18. PL Implant/Inserter Assembly Step 1

Note: At this time, there is no Prep Block for the PL implants.

Note: If packing the AccuLIF PL cage with autogenous bone graft material prior to assembly to the Insertion Handle, take care to keep graft material away from the connection interface. This will help ensure a secure connection between the implant and the Inserter.

To assemble the implant to the Inserter:

1. Insert the blue Rotator Knob through the Inserter End Cap and rotate to seat (Figure 18).



Figure 19. PL Implant/Inserter Assembly Step 2

2. Hold the implant in line with the prepared Insertion Handle shaft (Figure 19).



Figure 20. PL Implant/Inserter Assembly Step 3

3. Align the threaded distal tip of the Inner Shaft and the O-Ring post of the Tubing Set with the appropriate holes on the implant (Figure 20).



Figure 21. PL Implant/Inserter Assembly Step 4

4. Secure the Insertion Handle to the implant by turning the blue Rotator Knob clockwise while engaging the screw in the threaded bore of the implant (Figure 21). Keep turning the blue Rotator Knob until the implant is connected tightly and two audible clicks are heard.

AccuLIF PL

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Figure 22. PL Implant/Insertion Handle Assembly Step 5

5. Inspect the connection between the implant, Tubing Set and Insertion Handle to ensure there are no gaps (Figure 22). If there are gaps, turn the Rotator Knob in a counterclockwise direction to separate the implant and repeat Steps 1-4.
6. Remove the blue Rotator Knob.
7. Pack the AccuLIF PL implant with autogenous bone graft. The compacted graft should be flush with the upper and lower surfaces of the implant.

Note: Verify that no gaps exist at the interface between the implant and the stainless steel connector to assure that the attachment is secure.

Note: The TL Insertion Handle can be used to insert the AccuLIF PL implant. If using the TL Insertion Handle, the PL Tubing Set must be used with the AccuLIF PL implant. Assemble the TL Insertion Handle as outlined in the AccuLIF TL Surgical Technique Guide. Keep the TL Insertion Handle “Locked” in the central position for the entire time when using it to insert a PL implant.

Step 8: AccuLIF PL Implant Insertion

Carefully insert the unexpanded AccuLIF PL implant gently and progressively into the disc space using the mallet when necessary (Figure 23). Optimal positioning may be facilitated by directing the implant obliquely until it contacts the ventral annulus (Figure 24). If difficulty is encountered while inserting the implant, it most likely represents contralateral disc material which may be blocking passage of the implant. Check for adequacy of the discectomy and be sure distraction, if used, is maintained. Then, reposition the implant as needed. The distraction, if used, should be released to facilitate optimal placement of the implant and to permit expansion.



Figure 23. PL Implant Insertion

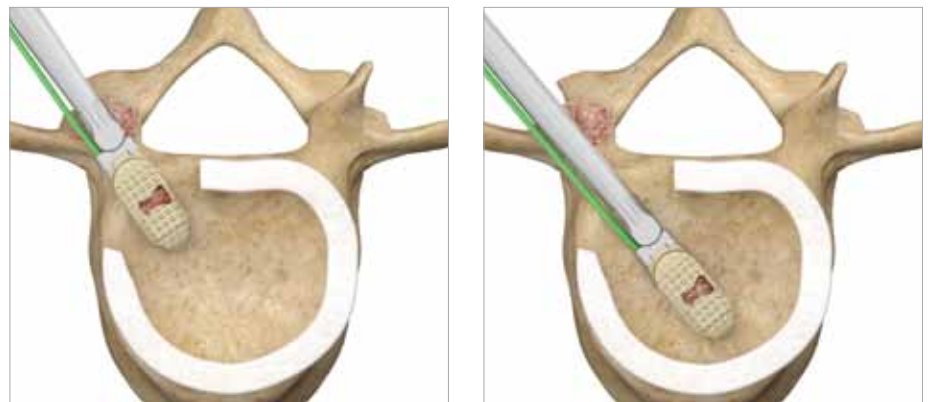


Figure 24. PL Implant Insertion and Positioning Obliquely Across the Disc Space

Note: Fluoroscopy may be useful in determining the appropriate trajectory for insertion of the implant and appropriate final positioning. Care should be taken to prevent the instrument from pushing too far anteriorly.

Note: The AccuLIF PL implant can be used from a traditional PLIF approach with two implants placed in a straight orientation bilaterally within the disc space (Figure 25).

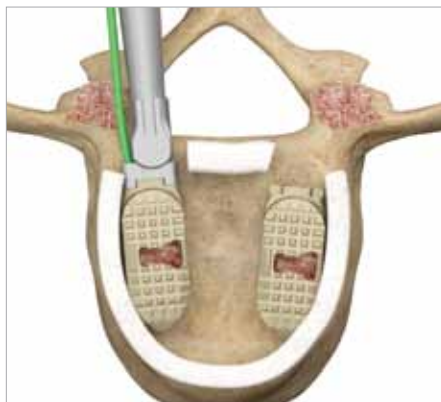


Figure 25. PL Implant Insertion and Positioning Bilaterally within the Disc Space

Note: The AccuLIF PL implant has 8° of lordosis, the moveable endplate has a lordotic angle of 6° and the fixed endplate has a lordotic angle of 2°.

Note: There is no specific orientation of the moveable endplate within the disc space so the implant expansion may occur toward the upper or lower endplate.

AccuLIF PL

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The correct position of the implant should be confirmed by direct visualization of implant location and/or with lateral and anterior-posterior fluoroscopic images before expanding the implant. After confirmation, align the green indicators on the Handle and Syringe (Figure 26) to connect the Syringe filled with sterile saline to the Handle (Figure 27). The Syringe is fully connected when an audible click indicates engagement.

AccuLIF PL

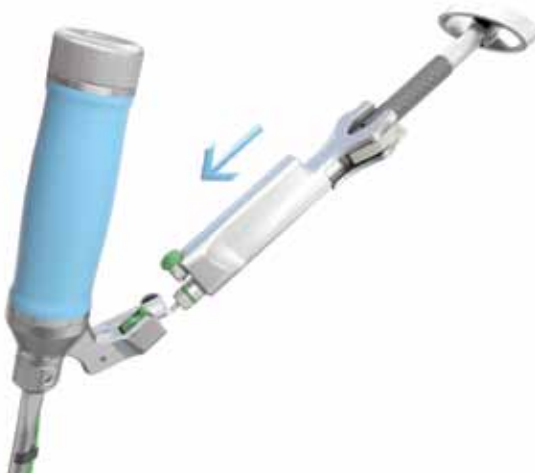


Figure 26. Syringe/PL Insertion Handle Alignment



Figure 27. Syringe/PL Insertion Handle Assembly

The implant expansion mechanism is activated by turning the Syringe Plunger T-Handle slowly to the right which applies pressure to the endplate of the device via sterile saline (Figure 28). It should be noted that the amount of pressure necessary to move the endplate of the device depends on the degree of resistance offered by the remaining soft tissue and ligaments around the discectomy.



Figure 28. Application of Hydraulic Pressure

Expand the device to a point at which the surgeon user is satisfied with the tightness of fit of the implant within the discectomy space (Figure 29). The tightness of the fit can be directly evaluated by:

- Tactile force applied to the Insertion Handle which is still attached to the implant
- The pressure gauge on the Syringe with a color-coded pressure indicator
- Direct visualization of the expanded implant in the disc space
- The use of fluoroscopic imaging

Evaluate the tightness of fit periodically while expanding the implant. Direct visualization and/or fluoroscopic imaging should be used during expansion to verify the device height. The implant can be expanded in 1mm increments. At each 1mm increment the device mechanically locks under the control of an internal spring mechanism.

The surgeon user must turn the Syringe Plunger T-Handle counterclockwise before taking fluoroscopic images. This action will reduce the pressure within the AccuLIF system and allow the moveable endplate to rest upon the 6 internal stair step risers and show the “Locked” height of the device.

Caution: In patients with compromised bone integrity, be mindful that the implant is in apposition to dense bone to maximize distraction of the interbody space and to avoid possible implant subsidence. Check the tightness of fit and pressure frequently.

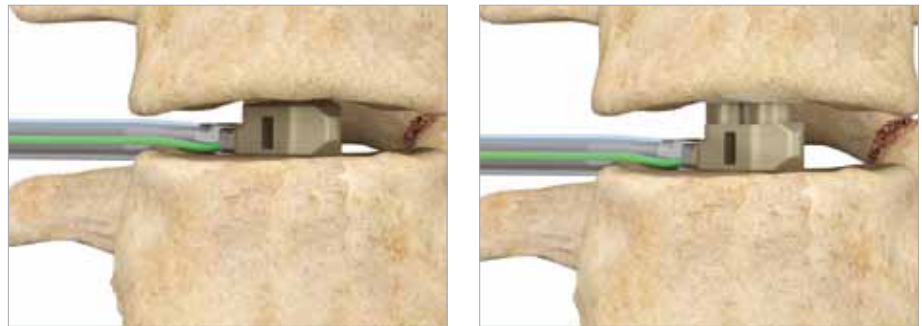


Figure 29. PL Implant Expansion

Note: There is a pressure gauge built into the Syringe (Figure 30). The pressure gauge indicates the increasing pressure the device is experiencing. As the pressure indicator advances through the green and yellow colored areas, the tightness of fit of the expanding implant should be evaluated. Pressure should stop being applied when the indicator reaches the magenta colored area. Maximal pressure is indicated by the magenta colored area and evaluation of the bone implant interface is useful to prevent implant subsidence at high pressures. There is a pressure relief valve built into the syringe to prevent the pressure from exceeding 2,000 psi.



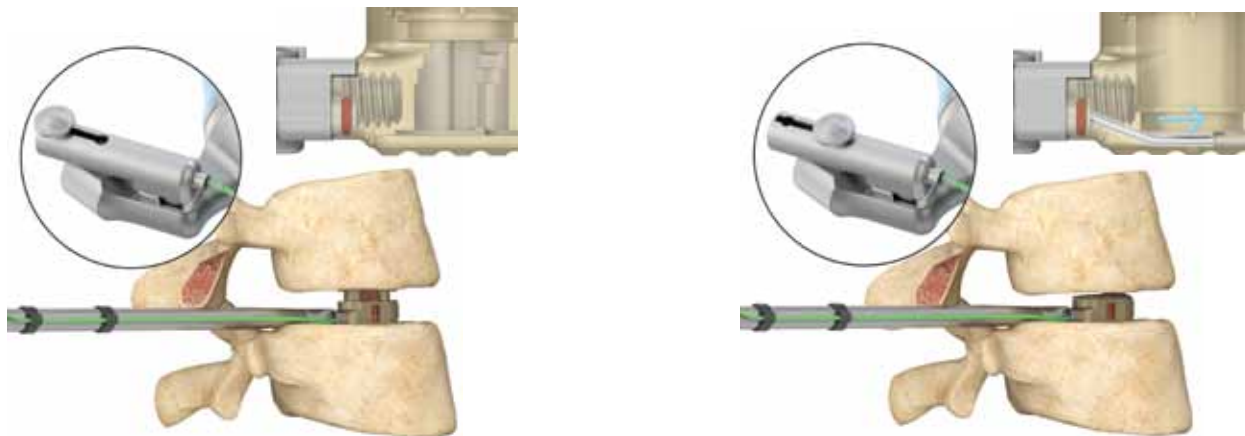
Figure 30. Pressure Gauge

Once the tightness of the fit of the implant within the discectomy space is satisfactory, slowly release the pressure by turning the Plunger T-Handle counterclockwise one or two turns. Confirm the desired expansion via fluoroscopy.

Note: If the implant was not fully expanded to the next millimeter increment, the implant will settle back down to the lower millimeter increment once the pressure has been released. Confirm expansion of implant via fluoroscopy after releasing the pressure and before disconnecting the Insertion Handle to ensure desired expansion has been achieved.

Note: If the surgeon user should want to reposition the expanded implant, the device should be pressurized again by turning the Syringe Plunger T-Handle slowly to apply enough pressure to raise the implant endplate above the last locked position. Then, slide the Unlocking Button on the Tubing Set forward to release the internal mechanical locking mechanism (Figure 31). Next, release the pressure on the Syringe to allow the implant endplate to collapse. The Unlocking Button is then retracted and the implant repositioned and re-expanded following the same steps above.

Note: If the endplate is violated, the surgeon user should collapse the implant as outlined above. The surgeon should slowly re-expand the implant until it is just snug within the disc space. Be sure to check the expansion under fluoroscopy. With the implant re-expanded to a lower height and a just snug fit, detach the Insertion Handle using the Rotator Knob as outlined below. Use the supplemental fixation to lock the construct in place and compress onto the AccuLIF implant.



Expanded Implant with Unlocking Button Retracted

Unlocking Button Engaged to Collapse Implant

Figure 31. Expansion Mechanism Release



Figure 32. Slap Hammer Used to Aid in Removal

Note: For intraoperative removal of the interbody device, when deemed medically necessary, use the Insertion Handle still attached to the implant to remove the implant from the disc space. If needed, the Slap Hammer can be threaded onto the back of the Insertion handle (Figure 32).

With the desired expansion achieved, detach the Insertion Handle with the Tubing Set from the implant by inserting the Rotator Knob into the proximal end of the Insertion Handle and turning in a counterclockwise direction.

Note: The Handle will disengage from the implant in approximately seven turns of the Rotator Knob.

Step 9: Placement of Bone Graft

Bone graft material may be placed in the interbody space prior to insertion of the implant. The device should be filled with autogenous bone graft prior to insertion. Additional bone graft material may be placed lateral or dorsal to the implanted AccuLIF PL device using the Bone Graft Cannula and Pusher.

Note: The inner diameter of the Graft Insertion Cannula is 6mm. It is important to make sure all graft material placed within the Cannula is smaller than 6mm in diameter. Additionally, placing incremental amounts of bone through the cannula allows for easier placement into the cage and disc space.



800305 Graft Insertion Cannula



800307 Graft Insertion Pusher

Step 10: Posterior Fusion

The AccuLIF TL and PL Cages are to be used with supplemental fixation that has been cleared by the FDA for use in the lumbosacral spine (e.g. pedicle screws, or, when performing a single-level fusion, an interspinous process plate). If pedicle screws were not inserted earlier in the procedure, insert pedicle screws at this point or other appropriate supplemental fixation (Figure 33). Compression of the pedicle screws or interspinous device may be used to create segmental lordosis of the segment fused. A tall, anteriorly placed interbody device will provide a fulcrum for creating segmental lordosis while preserving foraminal height.

The remaining bone graft may be placed in the decorticated facet to promote fusion.

Intraoperative radiographs should be performed to confirm satisfactory position of the AccuLIF PL implant, supplemental fixation and bone graft material.

Note: Choices for supplemental spinal fixation systems include, but are not limited to, Stryker Spine pedicle screw or interspinous process fixation plate systems (Xia, Radius, Trio, Techtonix, UniVise and ES2). Please refer to the respective surgical techniques of the above mentioned Stryker Spine supplemental fixation systems for additional information on implantation.



AccuLIF PL and Xia 3 or Xia 4.5



AccuLIF PL and UniVise



AccuLIF PL and ES2

Figure 33. AccuLIF PL with Different Supplemental Fixation Options

Step 11: Closure

Check the foramen and TLIF site for any bone fragments or extraneous soft tissue. Once satisfactory decompression of the exiting and traversing nerve roots is confirmed, the wound should be closed in a routine manner.

Step 12: Revision



A surgical revision may be indicated for many reasons including new or unresolved pain or neurological symptoms, changes in device positioning, non-union or incomplete fusion, etc. If necessary, the AccuLIF PL implant can be removed with the use of the Insertion Handle and Slap Hammer. The surgeon user must use his/her professional judgment to determine the appropriate revision strategy taking into consideration the patient's health, the nature of the problem and/or device failure, the patient's bone quality, and the surgeon's expertise with other spinal treatments and instrumentation.

Revision guidelines:



1. Soft tissue around the surface of the implant should be removed.
2. An osteotome or rongeurs can be used to remove any bony tissue secured to the implant.
3. The Insertion Handle is reattached to the implant to remove it from the surgical site.
4. The Slap Hammer can be attached to the proximal end of the Insertion Handle to aid in withdrawal of the device.

Alternatively, if the Insertion Handle cannot be reattached to the implant, forceps or other manual surgical instruments may be used to grasp and extract the implant.



Sterile Packaged Implants

	Reference Number	Implant Description
	305006	TL 6-9mm x 11mm x 34mm x 0° Cage
	305008	TL 8-12mm x 11mm x 34mm x 0° Cage
	305010	TL 10-16mm x 11mm x 34mm x 0° Cage
	400006	PL 6-9mm x 11mm x 27mm x 8° Cage
	400008	PL 8-12mm x 11mm x 27mm x 8° Cage
	400010	PL 10-16mm x 11mm x 27mm x 8° Cage















Sterile Packaged Disposable Instruments

	Reference Number	Disposable Instrument Description
	905103	TL Tubing Set
	900301	PL Tubing Set

AccuLIF TL Instruments

	Reference Number	Instrument Description
	841006	6mm TL Trial
	841008	8mm TL Trial
	841010	10mm TL Trial
	800804	TL Insertion Handle
	800094	TL Insertion Handle Inner Shaft
	800074	Insertion Handle End Cap
	800054	Insertion Handle Rotator Knob
	800257	Syringe Plunger
	800247	Syringe Body
	800347	Syringe Body Green O-Ring
	800357	Syringe Plunger Red O-Ring
	800005	Slap Hammer
	800305	Graft Insertion Cannula
	800307	Graft Insertion Pusher
	800006	Prep Block
	820002	Instrument Tray Base
	820011	Instrument Tray Lid
	820021	Instrument Tray Insert

AccuLIF PL Instruments

	Reference Number	Instrument Description
	851006	6mm PL Trial
	851008	8mm PL Trial
	851010	10mm PL Trial
	800044	PL Insertion Handle
	800064	PL Insertion Handle Inner Shaft
	800074	Insertion Handle End Cap
	800054	Insertion Handle Rotator Knob
	800257	Syringe Plunger
	800247	Syringe Body
	800347	Syringe Body Green O-Ring
	800357	Syringe Plunger Red O-Ring
	800005	Slap Hammer
	800305	Graft Insertion Cannula
	800307	Graft Insertion Pusher
	820002	Instrument Tray Base
	820011	Instrument Tray Lid
	820021	Instrument Tray Insert

IMPORTANT PRODUCT INFORMATION FOR AccuLIF TL AND PL EXPANDABLE LUMBAR CAGES

STERILE AND NON-STERILE PRODUCTS

DESCRIPTION

The AccuLIF TL and PL Expandable Lumbar Interbody Cages are crescent and rectangular-shaped titanium implants. These implants are intended for use as interbody fusion devices and are offered in a variety of lengths, footprints, and lordotic angles designed to adapt to different patient anatomies. The implants can be expanded in height after insertion in the unexpanded state using the system instrumentation. The implants automatically lock at 1mm increments during expansion. The implants have serrations on the superior and inferior surfaces designed for multidirectional fixation and increased surface area for osteointegration, ergonomically shaped anterior edges to facilitate cage insertion with preservation of endplates and flat posterior edges. The cages have a central opening spanning endplate to endplate for graft containment and to permit fusion through the device.

MATERIAL

The AccuLIF TL and PL devices are both comprised of the following materials:

- Titanium Alloy (Ti6Al4V)
- Stainless Steel (316 LVM)
- Silicone Rubber (MED-4870)

INDICATIONS

The AccuLIF TL and PL Cages are intended for intervertebral body fusion with autogenous bone graft material in patients with degenerative disc disease (DDD) at one level 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. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). These patients should be skeletally mature and have completed six months of non-operative treatment.

The AccuLIF TL and PL Cages are always to be used with supplemental internal spinal fixation. Additionally, the AccuLIF TL and PL Cages are to be used with autogenous bone graft.

GENERAL CONDITIONS OF USE

The implantation of intervertebral body fusion devices must be performed only by experienced spinal surgeons having undergone the necessary specific training in the use of such systems because this is a technically demanding procedure presenting a risk of serious injury to the patient.

The information contained in the Package Insert is necessary but not sufficient for the use of this device. This information is in no sense intended as a substitute for the professional judgment, skill and experience of the surgeon in careful patient selection, preoperative planning and device selection, knowledge of the anatomy and biomechanics of the spine, understanding of the materials and the mechanical characteristics of the implants used, training and skill in spinal surgery and the use of associated instruments for implantation, securing the patient's cooperation in following an appropriately defined post-operative management program and conducting scheduled post-operative follow-up examinations.

CAUTION

- Federal law (U.S.A.) restricts this device to sale by or on the order of a licensed physician.
- The AccuLIF Expandable Lumbar Interbody Cages have not been evaluated for safety and compatibility in the MR environment. AccuLIF Expandable Lumbar Interbody Cages have not been tested for heating or migration in the MR environment.
- The AccuLIF TL and PL Cages are manufactured from a titanium alloy and stainless steel, which are known to produce MRI artifacts. The AccuLIF TL and PL Cages have not been evaluated for safety and compatibility in the MR environment. The AccuLIF TL and PL Cages have not been tested for heating or migration in the MR environment. Patients should be warned to disclose the presence of the AccuLIF TL or PL Cages prior to an MRI exam. Failure to do so may affect the quality of diagnostic information obtained from the scans.
- This device is not intended for use except where indicated.
- Based on the fatigue testing results, the physician/surgeon must consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact the performance of the intervertebral body fusion device.
- The implantation of the intervertebral body fusion device must be performed only by experienced spinal surgeons with specific training in the use of this device because this is a technically demanding procedure presenting a risk of serious injury to the patient.
- Potential risks identified with the use of this intervertebral body fusion device, which may require additional surgery, include: device component fracture, loss of fixation, pseudoarthrosis (i.e. non-union), fracture of the vertebrae, neurological injury, and vascular or visceral injury.

- Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.
- The components of the system should not be used with components of any other system or manufacturer. Any such use will negate the responsibility of Stryker Spine for the performance of the resulting mixed component implant.
- Do not mix metals (e.g. Titanium based devices with stainless steel items). Some corrosion occurs on all implanted metals and alloys. Contact of dissimilar metals, however, may accelerate corrosion. Corrosion may accelerate fatigue fracture of implants, and cause metal compounds to be released into the body.

INFECTION

Transient bacteremia can occur in daily life. Dental manipulation, endoscopic examination and other minor surgical procedures have been associated with transient bacteremia. To help prevent infection at the implant site, it may be advisable to use antibiotic prophylaxis before and after such procedures.

INSTRUMENTS

Instruments are provided by Stryker Spine and must be used to assure accurate implantation of the device. While rare, intraoperative fracture or breakage of instruments can occur. Instruments which have experienced extensive use or extensive force are more susceptible to fracture depending on the operative precaution, number of procedures, and disposal attention. Instruments must be examined for wear or damage prior to surgery. Instruments must be properly cleaned, maintained and lubricated as usually recommended for all surgical instruments.

REUSE

The AccuLIF TL and PL Expandable Lumbar Interbody cages are packaged sterile for single use only. Re-sterilization of the implants is strictly forbidden, regardless of the method that might be employed. Never reuse or re-implant spinal surgical implants. These could become contaminated resulting in infection. In addition, even though the device appears undamaged, it may have small defects which could compromise structural integrity reducing its service life and/or leading to patient injury.

Surgeons must verify that the instruments are in good condition and operating order prior to use during surgery.

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HANDLING

Correct handling of the implant is extremely important. The operating surgeon must avoid notching or scratching the device.

ALLERGY AND HYPERSENSITIVITY TO FOREIGN BODIES

When hypersensitivity is suspected or proven, it is highly recommended that the tolerance of the skin to the materials that make up the implants be checked before they are implanted.

CONTRAINDICATIONS

Contraindications may be relative or absolute. The choice of a particular device must be carefully weighed against the patient's overall evaluation. Circumstances listed below may reduce the chances of a successful outcome:

- An allergy to titanium or titanium alloy.
- Gross spinal anatomy or disease that would prevent implantation of the device or cause the device to be unstable in situ.
- Significant instability of the lumbar spine, e.g., isthmic spondylolisthesis or degenerative spondylolisthesis greater than grade 1.0 (on a scale of 1 to 4).
- The AccuLIF Expandable Lumbar Interbody Cages are not intended for use except as indicated.
- The AccuLIF Expandable Lumbar Interbody Cages should not be implanted when an active systemic infection or infection localized to the site of implantation has been identified.
- Any abnormality present which affects the normal process of bone remodeling including, but not limited to, severe osteoporosis involving the spine, bone absorption, osteopenia, primary or metastatic tumors involving the spine, active infection at the site or certain metabolic disorders affecting osteogenesis. Diagnosis of severe osteoporosis, defined as bone mineral density (from DEXA scan or equivalent method) in the spine or hip that is more than 2.5 S.D. below the mean of adult normal population.
- Any mental or neuromuscular disorder which would create an unacceptable risk of fixation failure or complications in postoperative care.
- Open wounds.
- Pregnancy.
- Inadequate tissue coverage over the operative site.
- Any neuromuscular deficit which places an unsafe load level on the device during the healing period.
- Obesity. An overweight or obese patient can produce loads on the spinal system which can lead to failure of the fixation of the device or to failure of the device itself.
- A condition of senility, mental illness, or substance abuse. These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the implant, leading to failure or other complications.

- Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests must be made prior to material selection or implantation. Other medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors, congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of white blood cell count (WBC), or marked left shift in the WBC differential count.
- Prior fusion at the levels to be treated.

These contraindications may be relative or absolute and must be taken into account by the physician when making his decision. The above list is not exhaustive. Surgeons must discuss the relative contraindications with the patients.

INFORMATION FOR PATIENTS

The surgeon must discuss all physical and psychological limitations inherent to the use of the device with the patient. This includes the rehabilitation regimen, physical therapy, and wearing an appropriate orthosis as prescribed by the physician. Particular discussion should be directed to the issues of premature weight bearing, activity levels, and the necessity for periodic medical follow-up.

The surgeon must warn the patient of the surgical risks and make them aware of possible adverse effects. The surgeon must warn the patient that the device cannot and does not replicate the flexibility, strength, reliability or durability of normal healthy bone, that the implant can break or become damaged as a result of strenuous activity or trauma, and that the device may need to be replaced in the future. If the patient is involved in an occupation or activity which applies inordinate stress upon the implant (e.g., substantial walking, running, lifting, or muscle strain) the surgeon must advise the patient that resultant forces can cause failure of the device. Patients who smoke have been shown to have an increased incidence of non-unions. Such patients should be advised of this fact and warned of the potential consequences. For patients with degenerative disease, the progression of degenerative disease may be so advanced at the time of implantation that it may substantially decrease the expected useful life of the appliance. In such cases, orthopaedic devices may be considered only as a delaying technique or to provide temporary relief. Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.

PRE-OPERATIVE PRECAUTIONS

The surgical indication and the choice of implants must take into account certain important criteria such as:

- Based on the fatigue testing results, as with other spinal devices, when using the

AccuLIF TL or PL Cages, the surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact the performance of the system.

- Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.
- Patients involved in an occupation or activity that applies excessive loading upon the implant (e.g., substantial walking, running, lifting, or muscle strain) may be at increased risk for failure of the fusion and/or the device.
- Surgeons must instruct patients in detail about the limitations of the implants, including, but not limited to, the impact of excessive loading through patient weight or activity, and be taught to govern their activities accordingly. The procedure will not restore function to the level expected with a normal, healthy spine, and the patient should not have unrealistic functional expectations.
- A condition of senility, mental illness, chemical dependence or alcoholism. These conditions among others may cause the patients to ignore certain necessary limitations and precautions in the use of the implant, leading to failure and other complications.
- Foreign body sensitivity. Where material sensitivity is suspected appropriate tests should be made prior to material implantation.
- Surgeons must advise patients who smoke have been shown to have an increased incidence of non-unions. Such patients must be advised of this fact and warned of the potential consequences.
- Care must be taken to protect the components from being marred, nicked, or notched as a result of contact with metal or abrasive objects.

THE CHOICE OF IMPLANTS

The choice of proper shape, size and design of the implant for each patient is crucial to the success of the surgery. The surgeon is responsible for this choice, which depends on each patient.

The AccuLIF TL and PL Cages are to be used with supplemental fixation that has been cleared by the FDA for use in the lumbosacral spine (e.g. pedicle screws, or, when performing a single-level fusion, an interspinous process plate).

Patients who are overweight may be responsible for additional stresses and strains on the device which can speed up implant fatigue and/or lead to deformation or failure of the implants.

The size and shape of the bone structures determine the size, shape and type of the implants. Once implanted, the implants are subjected to stresses and strains. These repeated stresses on the implants must be taken into consideration by the surgeon at the time of the choice of the implant, during

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implantation as well as in the post-operative follow-up period. Indeed, the stresses and strains on the implants may cause fatigue, fracture or deformation of the implants, before the bone graft has become completely consolidated. This may result in further side effects or necessitate the early removal of the osteosynthesis device.

INTRA-OPERATIVE PRECAUTIONS

- Use only the pressure necessary to expand the AccuLIF TL or PL Cage to the height required to achieve a tight fit in the intervertebral space. Use of additional pressure beyond what is required to achieve a tight fit may cause damage to remaining anatomy such as the vertebral endplates.
- The insertion of the implants must be carried out using instruments designed and provided for this purpose and in accordance with the specific implantation instructions for each implant. Those detailed instructions are provided in the surgical technique brochure supplied by Stryker Spine.
- Discard all damaged or mishandled implants.
- Never reuse an implant, even though it may appear undamaged.

PATIENT CARE FOLLOWING TREATMENT

Prior to adequate maturation of the fusion mass, implanted spinal instrumentation may need additional help to accommodate full load bearing. External support may be recommended by the physician from two to four months postoperatively or until x-rays or other procedures confirm adequate maturation of the fusion mass; external immobilization by bracing or casting may be employed. Surgeons must instruct patients regarding appropriate and restricted activities during consolidation and maturation for the fusion mass in order to prevent placing excessive stress on the implants which may lead to fixation or implant failure and accompanying clinical problems. Surgeons must instruct patients to report any unusual changes of the operative site to his/her physician. The physician must closely monitor the patient if a change at the site has been detected.

ADVERSE EFFECTS

Include but are not limited to:

- Device breakage, dislodgement or migration;
- Late bone fusion or no visible fusion mass and pseudarthrosis;
- While the expected life of spinal implant components is difficult to estimate, it is finite. These components are made of foreign materials which are placed within the body for the potential fusion of the spine and reduction of pain. However, due to the many biological, mechanical and physicochemical factors which affect these devices but cannot be evaluated in vivo, the components cannot be expected to indefinitely withstand the activity level and loads of normal healthy bone;

- Superficial or deep-set infection and inflammatory phenomena;
- Allergic reactions to the implanted materials, although uncommon, can occur;
- Decrease in bone density due to stress shielding;
- Dural leak requiring surgical repair;
- Peripheral neuropathies, nerve damage, heterotopic bone formation and neurovascular compromise, including paralysis, loss of bowel or bladder function, or foot-drop may occur.
- Cessation of growth of the fused portion of the spine;
- Loss of proper spinal curvature, correction, height and/or reduction;
- Delayed Union or Nonunion: Internal fixation appliances are load sharing devices which are used to obtain alignment until normal healing occurs. In the event that healing is delayed, does not occur, or failure to immobilize the delayed/nonunion results, the implant will be subject to excessive and repeated stresses which can eventually cause loosening, bending or fatigue fracture. The degree or success of union, loads produced by weight bearing, and activity levels will, among other conditions, dictate the longevity of the implant. If a nonunion develops or if the implants loosen, bend or break, the device(s) must be revised or removed immediately before serious injury occurs;
- Neurological and spinal dura mater lesions from surgical trauma;
- Early loosening may result from inadequate initial fixation, latent infection, premature loading of the device or trauma. Late loosening may result from trauma, infection, biological complications or mechanical problems, with the subsequent possibility of bone erosion, or pain.
- Serious complications may occur with any spinal surgery. These complications include, but are not limited to, reaction to anesthesia, genitourinary disorders; gastrointestinal disorders; vascular disorders, including thrombus; blood vessel damage/bleeding; deep vein thrombosis; hematoma; pneumonia; neurological system compromise; stroke; bronchopulmonary disorders, including emboli; bursitis, hemorrhage, myocardial infarction, infection, paralysis or death.
- Inappropriate or improper surgical placement of this device may cause distraction or stress shielding of the graft or fusion mass. This may contribute to failure of an adequate fusion mass to form.
- Intraoperative fissure, fracture, or perforation of the spine can occur due to implantation of the components. Postoperative fracture of bone graft or the intervertebral body above or below the level of surgery can occur due to trauma, the presence of defects, or poor bone stock.

Adverse effects may necessitate reoperation or revision.

The surgeon must warn the patient of these adverse effects as deemed necessary.

REMOVAL

If fusion / bone graft growth occurs, the device will be deeply integrated into the bony tissues. As a result, the AccuLIF Expandable Lumbar Interbody Cage is not intended to be removed unless the management of a complication or adverse event requires the removal. Any decision by a physician to remove the device should take into consideration such factors as:

- The risk to the patient of the additional surgical procedure as well as the difficulty of removal.
- Migration of the implant, with subsequent pain and/or neurological, articular or soft tissue lesions
- Pain or abnormal sensations due to the presence of the implants
- Infection or inflammatory reactions
- Reduction in bone density due to the different distribution of mechanical and physiological stresses and strains.

STORAGE

The AccuLIF instrumentation must be stored in the instrument tray in a clean area until ready for use.

FURTHER INFORMATION

A surgical technique brochure is available on request through your Stryker representative or directly from Stryker Spine. Users with brochures that are over two years old at the time of surgery are advised to ask for an updated version.

COMPLAINTS

Any health professional having a complaint or grounds for dissatisfaction relating to the identity, quality, durability, reliability, safety, effectiveness or performance of a device should notify Stryker Spine or its representative. Moreover, if a device has malfunctioned, or is suspected of having malfunctioned, Stryker Spine or its representative must be advised immediately.

If a Stryker Spine product has ever worked improperly and could have caused or contributed to the death of or serious injury to a patient, the distributor or Stryker Spine must be informed as soon as possible by telephone, fax or in writing.

For all complaints, please give the name and reference along with the batch number of the component(s), your name and address and a complete description of the event to help Stryker Spine understand the causes of the complaint.

For further information or complaints, please contact:

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A surgeon must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. Stryker does not dispense medical advice and recommends that surgeons be trained in the use of any particular product before using it in surgery.

The information presented is intended to demonstrate the breadth of Stryker product offerings. A surgeon must always refer to the package insert, product label and/or instructions for use before using any Stryker product. Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your Stryker representative if you have questions about the availability of Stryker products in your area.

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