We are surgeons who stand for the Less Exposure Surgery Philosophy.
Quick Steps: S-LIFT at a Glance

1. Dissection
2. Dilation
3. Retractor
4. Discectomy
5. Sizing
6. Secure Implant
7. Insert Implant
8. Release the Implant
9. Verify Implant Position

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About SpineFrontier

SpineFrontier was founded by practicing spine surgeons with the belief that, as surgeons, we are best able to identify our own needs as well as those of our patients. Our team of surgeons, engineers and industry experts collaborate seamlessly on our innovations, helping us develop SpineFrontier into a company that is driven to be a leader in cutting edge technology.

Our mission is to focus on our needs as surgeons, allowing us to improve patient care through innovative technologies.

SpineFrontier would like to thank all the surgeons that contributed to the development of the S-LIFT Lateral Interbody System and the surgical technique.

About the LES Philosophy

LES, or Less Exposure Surgery, is the philosophy of achieving optimum surgical exposure while maximally preserving the anatomy and lessening the exposure to radiation and damaging effects of surgical techniques. It optimizes surgical access, use of radiation, muscle dissection, anatomy removal, and implant selection into one pivotal focus: less exposure with optimal visualization.

LESS, Less Exposure Segmental Spine Surgery, is a component of the LES philosophy. LESS is the practice of applying the LES philosophy to spine surgery securing one segment at a time and repeating procedures segment by segment.

“Each multi-level condition in the spine could be treated and repeated for adjacent segments,” said Kingsley R. Chin, M.D. “The future of spine surgery is dependent upon devices and techniques for less exposure segmental spine surgery.”

About the LES Society

The LES Society seeks to advance research, education and technology for tissue sparing treatments that allow for ease of application for the surgeon with improved outcomes for the patient. The LES Society is a non-profit, tax-exempt, educational organization whose purpose is to protect the health of the patient and to optimize the surgical procedure for the surgeon by promoting the less exposure surgeon philosophy.

The society provides a forum for dialogue amongst spine surgeons and gives them a place to discuss and debate the LES approach, as well as train and contribute to educational endeavors. It will also be a resource to other physicians and patients on the benefits of LES and the latest technologies all in the effort to ease patient healing time post-surgery.

About the System

The S-LIFT Intervertebral Body Fusion Device is a spinal intervertebral body fusion device intended for intervertebral body fusion of the spine of skeletally mature patients, using autogenous bone graft to facilitate fusion. The device is indicated for use in patients with degenerative disc disease (DDD) at one or two contiguous spinal levels from L2-S1. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). The SpineFrontier S-LIFT Intervertebral Body Fusion Device is intended to be used with supplemental spinal fixation system(s) cleared for use in the lumbar spine (example: Facet Screw Fixation).

The implants are provided in two configurations: straight and lordotic (8°). Implants sizes for both configurations are offered with a fixed width of 22mm, lengths from 38mm-68mm (in 5mm increments) and heights from 8mm–16mm, in 2mm increments.

The S-LIFT Intervertebral Body Fusion Device components are supplied non-sterile, are single use, and are fabricated from PEEK-OPTIMA® LT1® with markers for radiographic visualization.

Anatomy of S-LIFT

Features & Benefits

- Large central cavity for bone graft
- The implant has a large footprint for stability
- The lateral approach provides a safe technique for a large interbody
- The open backed design allows for additional bone graft packing
- The system is designed for a minimal incision insertion
- Robust lateral access retractor for positional stability

Surgical Technique Symbols

⚠️ Warning  ⚠️ Additional Information
1 Surgical Procedure

All necessary imaging studies should be available to visualize patient anatomy and plan implant placement.

Care must be taken throughout the procedure to ensure that no damage is caused to the nerve roots.

Within the S-LIFT System certain instruments are designed to allow striking while others are not. Avoid striking instruments without a strike plate. Striking instruments that do not have a strike plate may damage the instruments and it will affect the performance of those instruments. Please note that the Inserter has pinch points. Care must be taken not to get gloves caught in the pinch points when opening and closing the inserter.

2 Patient Positioning

The neurophysiologist or neuromonitoring technician should apply all appropriate electrodes prior to patient positioning.

The patient is positioned in a lateral decubitus. A soft support between the patient and operating table may be used to help maintain positioning. Secure the patient to the table with tape.

It's recommended to use a flexible table and position the iliac crest over the table break. Slight flexion may be applied to open the patient’s flank, but avoid maximum flexion which tensiones lateral roots across the lateral aspect of the vertebral body and disc space.
3 Dissection

Use lateral fluoros to confirm the target segment and to mark the initial incision.

Make a skin incision targeting the anterior third of the disc space.

Separate the abdominal oblique muscles with blunt dissection and enter the retroperitoneal space.

Move the peritoneum anterior with forefinger and continue blunt dissection to palpate down to the psoas muscle.

Insert the Stage One Dilator into the retroperitoneal space down to the psoas muscle. Assemble the accessory handle to the Monopolar Stimulating Probe.

Insert the Monopolar Stimulating Probe assembly in the Stage One Dilator. With the assistance of the neurophysiologist or neuromonitoring technician, use the dilator and probe assembly to map out a safe path through the psoas muscle to the lumbar spine by stimulating with the Probe. Stop your approach and investigate your positioning if the triggered EMG response is generated.

Once on the disc space, carefully hold the dilator in place and remove the probe and handle assembly.

Confirm the proper dilator position with fluoro. Use the dilator holder to keep hands free of direct fluoro exposure. Insert the guidewire through the dilator and continue your dilation procedure to largest dilator.

4 Tissue Dilation

Insert the Stage One Dilator into the retroperitoneal space down to the psoas muscle. Assemble the accessory handle to the Monopolar Stimulating Probe.

Insert the Monopolar Stimulating Probe assembly in the Stage One Dilator. With the assistance of the neurophysiologist or neuromonitoring technician, use the dilator and probe assembly to map out a safe path through the psoas muscle to the lumbar spine by stimulating with the Probe. Stop your approach and investigate your positioning if the triggered EMG response is generated.

Once on the disc space, carefully hold the dilator in place and remove the probe and handle assembly. Confirm the proper dilator position with fluoro. Use the dilator holder to keep hands free of direct fluoro exposure. Insert the guidewire through the dilator and continue your dilation procedure to largest dilator.

Assemble the Inner Stage Two Dilator by sliding the Outer Stage Two Dilator over the Inner Stage Two Dilator. The probe can be used through the access ports of the Inner Stage Two Dilator to ensure safe dilation.

Care must be taken throughout the procedure to ensure that no damage is caused to the nerve roots.

Within the S-LIFT System certain instruments are designed to allow striking while others are not. Avoid striking instruments without a strike plate. Striking instruments that do not have a strike plate may damage the instruments and it will affect the performance of those instruments. Please note that the Inserter has pinch points. Care must be taken not to get gloves caught in the pinch points when opening and closing the Inserter.
5 Assemble the Retractor System

With the dilator on the disc space, determine the blade length needed by reading the dilator markings at the skin. Insert the three appropriate length blades in the retractor blade slots and tighten down the set screws with the driver. The assembled retractor is inserted over the Stage Two Dilator. The probe can be used through the blade access port to ensure safe insertion. Use AP fluoroscopy to verify that the blades are parallel and in contact with the end plates.

Attach the Rail Clamp to the table rail, slide into the desired position and turn the Rail Clamp handle (bottom) clockwise to tighten clamp. Turn the arm clamp handle (side) counter-clockwise to open the screws.

Optional: the Hohmann Retractor can be used to retract anterior tissue anchoring the tip through the annulus.

Remove the dilators and guidewires. Incrementally open the blades. The cephalocaudal blades are opened by squeezing the retractor handles. The AP blade is opened by rotating the side paddles. Anchor screws can be inserted into center slot of the cephalocaudal blades to fix the blade position to the vertebral body. Choose the proper sized anchor screw relative to blade length.

The lighting assembly has a clip attached to the illumination end. This clip is inserted into the retractor blade rail from the top of the blade. Set the depth of the light as required and bend back the remaining blade to the light source. The assembled retractor is inserted over the Stage Two Dilator. The probe does not cut past the contralateral annulus by continually working under fluoroscopy.

6 Discectomy

Create an incision through the annulus with the Annulus Cutting Knife or Scalpel.

Release the contralateral annulus and shave the cartilaginous endplates with the Cobb Elevators. Continue along the endplates of the disc space and cut through the contralateral annulus. Ensure that the Cobb does not cut past the contralateral annulus by continually working under fluoroscopy.

Use Rongeurs, Curettes and other disc preparation instruments to thoroughly evacuate the disc material.

Use the Rasp on the endplate to expose bleeding bone.

When assembling the retractor blades, avoid using the Hex Driver to back out the set screws beyond the retractor thread limit and/or excessively tighten the set screws. Excessive tightening may cause the tip of the hex driver or the set screw to fracture. Avoid excessive retraction to ensure no damage is caused to the soft tissue and nerve roots.

To minimize the risk of residual disc material around the dura, the initial incision can be biased to the anterior side.
Paddle Shavers are used to prepare the disc space and provide initial distraction. Connect an appropriately sized Paddle Distractor to the T-Handle (see additional notes for details). Heights are provided in 8mm, 10mm, 12mm, 14mm and 16mm and length of 48mm. Heights are undersized by 0.5mm relative to the implant to ensure a tight fit.

Connect an appropriately sized trial to the T-Handle. Insert the Trial into the disc space. Light malleting may be required to advance the Trial. Use fluoros to confirm the fit and orientation of the spacer for proper implant sizing. The center material between the openings of the Trial should line up with the spinous processes in an AP view. If necessary, insert alternate trials to find the most secure fit. The trials are 48mm long with markers at 38mm, 43mm, 53mm and 58mm, which are used as a reference to define the proper length implant.

Remove the Trial. If assistance is needed, slide the Slap Hammer on the Trial shaft and tap the Trial out.

If using the Paddle Shavers to prepare the disc space the aggressive bone removal feature may create a larger disc space than intended. Size should be verified with Trials.

It is important to select the correct size implant. If the implant is too small subsidence may occur. If the implant is too large expulsion may occur.
9 Securing the Implant to the Inserter

Assemble the proper size implant onto the jaws of the Inserter in such a way that it bottoms out on the back of the jaws. Turn the retention shaft to the lock position. Pull on the implant to verify it is secure.

Optional: Assemble the outer sleeve to the Implant Holder prior to the Lock Shaft.

Screw down the outer sleeve in the clockwise position to a firm stop at the secure position for additional support.

Ensure that the outer sleeve is in the release position when assembling the implant.

Once the outer sleeve stops at the secure position, do not apply additional clamping force.

10 Inserting the Implant

The interior of the implant can now be packed with bone graft material. Insert the implant into the prepared disc space. Continually use fluoro to monitor proper orientation and position.

When using lordotic implants, use fluoroscopy to verify proper orientation of lordosis.
11 Releasing the Implant

Release the implant by turning the retention shaft clockwise to the unlock position and sliding the jaws off the implant.

- Ensure the lock shaft is set to the unlock position and the outer sleeve, if used, is set to the release position when releasing the implant.
- Pull back on the outer sleeve handle or implant holder shaft when removing the inserter after implant release. Pulling on the lock shaft alone may cause disassembly of the lock shaft.

12 Verifying Implant Position

After insertion, verify position and orientation of the implant using AP and lateral fluoros. The implant has five (Figure A) or seven (Figure B) markers: one at the leading edge, two or four in the center and two at the trailing edge. In the AP fluoros, correct orientation is defined when the center markers line up with the trailing edge markers vertically. Proper placement is defined when the center markers line up with the spinous processes.

In the lateral fluoros, correct orientation is defined when the trailing edge markers are in the same position as the center markers relative to the leading edge. If the implant is over-inserted or not in the desired placement, re-engage the Inserter than lock and secure the implant. Adjust to the optimal position as needed and follow the implant release procedure.

Use the Impactor to advance the implant if needed.

Additional bone graft material can be packed into the back opening of the implant and around the implant using the Graft Funnel and Pusher.

- When using the Bone Funnel check your position to be sure the tip is in the position of intent before striking. The tip of the bone funnel may core or damage soft tissue if placed incorrectly.

Excessive bone graft packing could affect the tight fit of the implant thus increasing the risk of subsidence or could affect the placement of the implant. Verify implant fit and position with fluoros.

Avoid excessive Graft Pusher striking as it could push the implant out of position. Verify implant position with fluoros.
13 Closure
Verify the absence of significant bleeding in the disc space or psoas muscle. Remove the retractor system per the manufacturer’s instructions. Close the skin using standard subcuticular suture.

14 Additional Notes: Proper Use of the T-Handle
The quick connect T-Handle is used in conjunction with all Trials and Paddle Shavers. The following instructions demonstrate how to assemble the T-Handle to the shafts and how to disassemble the T-Handle from the shaft.

Shaft insertion into the handle: When inserting the instrument shaft into the handle, grasp the handle and push forward on the connector as far as it will go; this pushes the ball spring mechanism out of the way.
Next, grasp the instrument shaft in the other hand and insert the 1/4" square end into the handle connector as far as it will go (with the connector still pushed forward).

Now release the connector; it should spring back slightly.

**Additional Notes: Insertion of Shaft**

Gently pull on the shaft. You might not hear or feel anything if the shaft is already engaged.

Once the engagement is verified, pull again on the shaft. It should retain securely in the handle even under very strong pulling or pushing forces.

This check should be done upon each assembly of the handle to an instrument shaft.
Revision could be necessary under the following situations:

A. Intra-operative Revision
1. Larger implant preferred after initial implant inserted
2. Misplaced implant; too anterior or not straight
3. Implant placed too far into disc space
4. Implant fracture during impaction/insertion
5. Wrong level surgery
6. Loss of neurologic function of unknown cause

B. Post-Operative Revision
1. Non-Union
2. Infection
3. Subsidence into endplates
4. Psychological patient fear of having a device in forever
5. Painful hardware irritating soft tissues or nerves
6. Cage migration causing neural compression
7. Vertebral body fracture around cage leading to cage malposition

The following steps are taken to revise the implant.

1. Set the Inserter to the “unlock” position.
2. Capture the implant with the Inserter jaws and seat the Inserter against the implant. A/P and lateral fluoroscan can be used to verify position.
3. Set the inserter to the locked position.
4. Pull on the Inserter to expplant the interbody. Tap a Mallet on the underside of the strike plate if additional assistance is needed for removal.
5. Unlock the Inserter and remove the explanted interbody.
6. Optional: If there are any obstructions preventing placement of the inserter lock shaft, then the outer sleeve can be used with the implant holder to clamp on the interbody and facilitate removal.

17 Additional Notes: Removal of Shaft from the Handle

To remove the instrument shaft from the handle, grasp the shaft in one hand and the T-Handle in the other, without pulling.

Use your fingers to push forward on the connector in a squeezing motion. This will retract the ball spring mechanism.

With the connector still pulled back, you can pull the instrument shaft out of the handle.

Glove may pinch into the instrument.
The S-LIFT® Intervertebral Body Fusion Device Package Insert

S-LIFT® Intervertebral Body Fusion Device

Indications

The S-LIFT® Intervertebral Body Fusion Device is a spinal intervertebral body fusion device intended for intervertebral body fusion of the spine of skeletally mature patients, using autogenous bone graft to facilitate fusion. The device is indicated for use in patients with degenerative disc disease (DDD) at one or two contiguous spinal levels from L2-5. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). The SpineFrontier S-LIFT Intervertebral Body Fusion Device is intended for use in patients with degenerative disc disease (DDD) at one or two contiguous spinal levels from L2-5. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s).

PATIENT POSTOPERATIVE ACTIVITIES

1.  Comply with advice from your healthcare provider on the weight-bearing activity restrictions at the level(s) of fusion or the device. Surgical fusion is intended to be performed after all inflammation due to surgery has been resolved. The patient may be allowed to bear weight partially at the discretion of the healthcare provider, based on the healing of the surgical incision.

2.  Discontinue all weight-bearing activity for at least 6 weeks, either by immobilizing the surgical level with a brace or by restriction of body movement.

3.  Instruct the patient to avoid activities that may place stress on the surgical fusion site, such as bending, lifting, or turning.

4.  Advise the patient to avoid any activities that may cause pain or discomfort, as determined by the healthcare provider.

5.  Provide the patient with advice on pain management, as determined by the healthcare provider.

6.  Advise the patient to avoid any activities that may cause pain or discomfort, as determined by the healthcare provider.

7.  Instruct the patient to avoid any activities that may cause pain or discomfort, as determined by the healthcare provider.

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Implant Case Sterilization

Sterilization

The S-LIFT® Intervertebral Fusion Device implants are provided nonsterile and should be sterilized in their original packaging unit cleaned and sterilized according to the recommen-
dations listed below. Implants are single-use devices, are not clean or resterilize an implant that has been in contact with or contaminated by blood or other infectious substances. The manufacturer assumes no responsibility for cleaning and resterilization of implants, components, or reusable instruments performed by the individual or hospital. SpineFrontier S-LIFT Intervertebral Fusion Devices are supplied clean and not AORN recommended practices for in-hospital sterilization to achieve an SAL of 1.0-4.5 should be followed for all components.

This stecklinga cylinder is not designed by the Food and Drug Administration to be a standard sterilization cycle. It is the end user’s responsibility to use only sterilizers and accessories such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization containers that have been cleared by the Food and Drug Administration for the selected sterilization method specified below.

Instrument Case Sterilization

Sterilizer Type: Pre-Vacuum

Pre-Vacuum

Temperature: 270°F (132°C)

Exposure Time: 5 Minutes

Drying Time: 60 Minutes

S-LIFT® Intervertebral Body Fusion Device Package Insert

Implant Case Sterilization

Sterilizer Type: Pre-Vacuum

Pre-Vacuum

Temperature: 270°F (132°C)

Exposure Time: 5 Minutes

Drying Time: 20 Minutes