MD-Vue™
LATERAL ACCESS SYSTEM
Surgical Technique
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**Device Description:**

- Nested 3 blade radiolucent design w/optional 4th blade (anterior) retraction
- Infinite resolution retraction (additional posterior blade finite adjustment)
- Comprehensive blade anchoring and tissue management options
- Independent blade angulation (up to 20°)
- Increased retraction strength with proprietary gear mechanism
- Integrated adjustable lighting system
- Multiple table arm attachment points for anterior or posterior positioning

**LLIF Indications:**

The Precision Spine ShurFit® LLIF Lateral Lumbar Interbody Fusion Device is indicated for intervertebral body fusion of the spine in skeletally mature patients. The device system is designed for use with autograft to facilitate fusion. One device is used per intervertebral space for the LLIF system.

The Precision Spine ShurFit® LLIF Lateral Lumbar Interbody Fusion Device is intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The lumbar device is to be used with supplemental fixation and autogenous bone graft. Patients should have at least six months of non-operative treatment prior to treatment with a lumbar intervertebral fusion device.
INSTRUMENTS

Dilator Holder
- 54-DH-0001

Initial Dilator
- 54-SD-0007

12mm Dilator
- 54-SD-0012

16mm Dilator
- 54-SD-0016

Penfield Dissector Short Straight
- 54-PD-0100

Penfield Dissector Long Straight
- 54-PD-0150

Penfield Dissector Bayonet
- 54-PD-0250

Hex Driver
- 54-HD-0100

Fixation Pin Driver
- 54-HD-0200
INSUMENTS

2.5mm X 20mm Fixation Pin
- 54-SP-2520

20mm Posterior Shim
- 54-SP-0020

30mm Posterior Shim
- 54-SP-0030

Guidewire
- 54-GW-0051

140mm Wide Anterior Retractor
- 54-RA-2140

140mm Narrow Anterior Retractor
- 54-RA-1140

180mm Wide Anterior Retractor
- 54-RA-2180

180mm Narrow Anterior Retractor
- 54-RA-1180
**INSTRUMENTS**

**Retractor Anterior Bridge**
- 54-RA-1200

**Retractor Handle-Cephalad/Caudal**
- 54-RB-1500

**Retractor Body**
- 54-BK-1000 Rev A

**25mm Widening Shim Left**
- 54-SW-2510

**25mm Widening Shim Right**
- 54-SW-2511

**10mm Lengthening Shim**
- 54-SL-0010

**Shim Remover**
- 54-ST-0200

**Shim Inserter/Impactor**
- 54-ST-0100
INSTRUMENTS

Suction-8 French Long
- 54-SS-0008

Suction-10 French Long
- 54-SS-0010

Jackson Adapter
- 54-TA-0700

Table Clamp
- 54-TA-0600

Table Arm Quick Connect
- 54-TA-0800

Table Arm
- 54-TA-0500

Posterior Blades
- 54-BP-DXXX
INSTRUMENTS

Cranial/Caudal Blades (Left)
- 54-BL-XXXX

Cranial/Caudal Blades (Right)
- 54-BR-XXXX

Posterior Lobe Handle
- 54-RB-2000
1. Patient Preparation

The patient is placed on a flexible surgical table in a true lateral decubitus (90°) position so that the patient’s greater trochanter or iliac crest is directly over the table break. Place an auxiliary roll, bean bag or other device underneath the patient’s greater trochanter. Place pillows under the head, between the knees and under the upper arm.

The patient is taped to the table at the following locations:

A. Directly across the table just beneath the iliac crest.
B. Over the thoracic region just under the shoulder.
C. Superior and anterior to the iliac crest, down to the foot of the table, around the corner of the table and back to the iliac crest.
D. Superior and posterior to the iliac crest, down to the foot of the table, around the corner of the table and back to the iliac crest.
E. From the iliac crest, straight down to the end of the table.
F. From the anterior edge of the table, over the knee and along the lower leg to the posterior, inferior corner of the table.

This taping configuration ensures that the pelvis tilts away from the spine, providing greater access to all lumbar levels, particularly L4-L5. Using fluoroscopy, the table should be flexed to open the interval between the 12th rib and iliac crest and provide direct access to the disc space. Once the patient is secured, the table should be adjusted so that the c-arm provides true AP images when at 0 degrees and true lateral images when at 90 degrees. At this time, attached Table Clamp (54-TA-0600) or if applicable Jackson adapter (54-TA-0700) to the table rail on the anterior side of the patient and secure. The Table Clamp should be placed approximately 1 foot away from the incision site and towards the head.
2. Landmark Identification

Under fluoroscopic guidance, flex the table to open the interval between the 12th rib and the iliac crest to provide direct access to the disc space. The table should be adjusted so that the c-arm provides true AP images when at 0° and true lateral images when at 90°.

Use fluoroscopy to identify the level to be fused by laying two crossed Guidewires (54-GW-0051) on the skin above the surgical site. Mark the skin at the anterior and posterior margins of the vertebral body, through the center and posterior third of the disc space.

3. Surgical Approach - Single Incision

After making the skin incision and dividing the subcutaneous tissue, the oblique muscles of the abdomen will be visible. Separate the psoas muscle using blunt dissection. Once the retroperitoneal space has been entered, one should feel the tissue give way into the free space of the retroperitoneum. Move the peritoneum anteriorly with the forefinger and continue blunt dissection. Slide the finger forward to the retro-psoas recess to ensure the retroperitoneal viscera have been safely retracted anteriorly.
4. Dilator Insertion

If neuromonitoring is selected by the surgeon, connect the neuromonitoring probe and insert it into the Initial Dilator’s (54-SD-0007) outer cannula.

Guide the Initial 7mm Dilator (54-SD-0007) down into the retroperitoneal space until the tip of the Dilator is at the lateral margin of the psoas muscle. Confirm positioning using lateral fluoroscopy. If needed, the Dilator can be held in place with the Dilator Holder (54-DH-0001).

Continue advancing the Dilator using a rotating motion through the psoas muscle until it reaches the annulus of the disc. Ensure there is no soft tissue trapped under the Dilator.

Reconfirm positioning using lateral fluoroscopy. If necessary, use the Dilator Holder. If Neuromonitoring is being used, stimulate the Neuromonitoring Probe (302427-000-275).

Insert a Guidewire (54-GW-0051) through the center of the initial dilator and advance it, until it is securely fixed, no more than 30mm into the disc space. Markings on the guidewire indicate depth. Verify the position of the Guidewire and Initial Dilator using A/P and lateral fluoroscopy.

Remove the Neuromonitoring Probe from the Initial Dilator and place it in the outer cannula of the Second 12mm Dilator (54-SD-0012).

Advance the Second Dilator over the Initial Dilator until it is through the psoas and flush against the disc. If Neuromonitoring is being used, stimulate the Neuromonitoring Probe.
Remove the Neuromonitoring Probe from the Second Dilator and place it in the outer cannula of the Third 16mm Dilator (54-SD-0016). Advance the Third Dilator over the Second Dilator until it is through the psoas and flush against the disc. If Neuromonitoring is being used, stimulate the Neuromonitoring Probe.

5. Table Arm Attachment

Insert the Table Arm (54-TA-0500) into the Table Clamp. Connect the Table Arm Quick Connect (54-TA-0800) to the Table Arm.
6. Retractor Body Assembly

Insert the Retractor Body Handle (54-RB-1500) onto the Retractor Body (54-RB-1000). If needed, rotate the Retractor Body Handle clockwise to close the Cranial/Caudal Arms.

If needed, move the Posterior Blade Lock on the Retractor Body to the free position and rotate the Posterior Knob counterclockwise to close the Posterior Arm.

If needed, use the Hex Driver (54-HD-0100) to turn the Cranial/Caudal Blade angle set screws counterclockwise until the toeing pads are completely flush against the Retractor Body. The Retractor is now in the complete neutral position for blade loading.

Load the Posterior Shim (54-SL-00XX) into the appropriately sized Posterior Blade using the Shim Inserter/Impactor until it is flush with the tip of the Blade. Slide the appropriate Posterior Blade (54-BP-0XXX) labeled "P" down the Posterior Arm of the Retractor Body and tighten with the Hex Driver.

Slide the appropriate Cranial/Caudal Blades labeled R (Right) (54-BR-XXX) and L (Left) (54-BL-XXXX) down the Cranial/Caudal arms of the Retractor Body and tighten with the Hex Driver. If needed intraoperatively, the Lengthening Shims (54-SL-0010) or Widening Shims (54-SW-25XX) can be loaded into the Cranial/Caudal Blades using the Shim Inserter/Impactor (54-ST-0100).
7. Retractor Insertion

Slide the Retractor Body assembly over the Third Dilator. Align the Retractor Body with the C-arm and verify using fluoroscopy that the Blades of the Retractor Body are in line with the disc space.* Attach the Table Arm to the Retractor Body or Posterior Arm, maintaining downward pressure on the Retractor Body.

Attaching the Table Arm to the Posterior Arm maintains retractor position relative to the Posterior Arm position and translates the Cranial/Caudal Arms anterior when the Posterior Blade Knob is turned clockwise.

Attaching the Table Arm to the Retractor Body maintains retractor position relative to the Cranial/Caudal Arms and retracts the Posterior Blade posteriorly when the Posterior Blade Knob is turned clockwise.

Verify the top surface of the Retractor Body is parallel to the floor. While applying downward pressure to the Retractor Body, lock the Table Arm in the desired position. Posterior Lobe Handle (54-RB-2000) may be used if extra leverage is needed to lock the Table Arm in place.

*If desired, and at the surgeon’s discretion, the Neuromonitoring Probe may be placed into the Blades to check for proximity to the neural elements.

- The Cranial/Caudal Blades are designed with two cannulas in which the neuromonitoring probe can be inserted.
- The Posterior Blade is designed with one center cannula in which the neuromonitoring probe can be inserted.
8. Tissue Retraction

Open the Cranial/Caudal Arms by rotating the Retractor Body Handle Counter Clockwise. If needed, toe the Cranial/Caudal Blades outward using a clockwise rotation with the Hex Driver.

If needed and depending on the table arm attachment, either retract the cranial/caudal blades anteriorly or the posterior blade posteriorly by rotating the Posterior Knob clockwise.

Once the Retractor Arms have been opened to the desired position, remove the Initial Dilator, the Second and Third Dilator, leaving the Guidewire in place. If additional anterior retraction is needed, the Anterior Bridge (54-RA-1200) may be attached to the Retractor Body. The appropriate Anterior Retractor (54-RA-XXXX) is then attached to the Anterior Arm.
9. Light Source

Attach the Bifurcated Illuminator (54-LC-5200) to the Light Cable (54-LC-5100). Slide the Illuminators down the slot in the Cranial/Caudal Blades and bend the Illuminator to the appropriate angle.

Turn on the Light Source and adjust the light intensity as needed.

10. Retractor Final Positioning

Using the Shim Inserter/Impactor, advance the Posterior Intradiscal Shim into the intervertebral disc until it bottoms out in the Posterior Blade. Verify the Posterior Shim position using anterior/posterior fluoroscopy.

Remove the Guidewire. If needed, advance the Widening or Lengthening Shims. If needed, secure the Cranial or Caudal blades using the 2.5mm x 20mm Fixation Pin (54-SP-2520)

Locate the anterior border of the disc space, use the Retractable Annulotomy Knife (1587) to cut the annulus.

Use a Straight Cobb Elevator to disrupt the disc from both vertebral endplates and release the contralateral annulus.

Pituitary rongeurs, curettes, ring curettes and rasps are provided for disc removal and endplate preparation.
11. ShurFit® LLIF Sizing And Insertion

Use the Implant Sizers to determine the correct Implant size. Confirm correct placement of the cage using fluoroscopy.

The Sizer should be centered across the disc space and appropriately centered in the anterior/posterior plane. Select the corresponding size Implant.

Attach the Implant to the Inserter (23-9001).

- There are two locating pins that help center the inserter over the insertion hole of the Implant.
- Rotate the thumb wheel clockwise until the Implant is securely attached to the Inserter.

**Note:** The ShurFit® LLIF cages are marked with the letter “A” & “P” to designate the anterior and posterior position as it relates to the implant.

<table>
<thead>
<tr>
<th>Item No.</th>
<th>Description</th>
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<th>Description</th>
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<tbody>
<tr>
<td>23-EC1845-08</td>
<td>18x45x08mm - 7° PEEK Cage</td>
<td>23-EC2245-08</td>
<td>22x45x08mm - 7° PEEK Cage</td>
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<td>23-EC2255-14</td>
<td>22x55x14mm - 7° PEEK Cage</td>
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</tbody>
</table>
12. Implant Selection And Preparation

Impact the Implant into the disc space. Fluoroscopy should be used to confirm correct Implant placement. The Implant should traverse the apophyseal ring and be centered within the disc space.

Remove the Inserter from the Implant and verify the final position of Implant with fluoroscopy. Adjust with the Implant Tamp (23-9038) as necessary.

13. Retractor Removal

Retract the Posterior Shim from the Posterior Blade using the Shim Remover (54-ST-0200). If used, remove the Anterior Retractor and Anterior Bridge. Remove the Bifurcated Illuminators.

Remove all other shims in the Cranial/Caudal Blades. If the Cranial/Caudal Blades were toed, return them to the neutral position. Rotate the Retractor Body Handle Clockwise to close the Cranial/Caudal Arms.

Move the Posterior Blade Lock on the Retractor Body to the forward position and rotate the Posterior Knob Counter Clockwise to close the Posterior Arm. Disengage the table arm from the retractor. Remove the Retractor Body.

14. Closure

The wound is closed using standard techniques.
54-BK-1000
Instrument Kit
Tray Layout

Instrument Tray – Top Level

Instrument Tray – Mid Level

Instrument Tray – Bottom Level Right, Posterior, and Left Blades

<table>
<thead>
<tr>
<th>Item No.</th>
<th>Description</th>
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<tbody>
<tr>
<td>1</td>
<td>Guidewire</td>
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<tr>
<td>2</td>
<td>Serial Dilators</td>
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<tr>
<td>3</td>
<td>Dilator Holder</td>
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<tr>
<td>4</td>
<td>Fixation Pins</td>
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<tr>
<td>5</td>
<td>Penfield Dissectors</td>
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<tr>
<td>6</td>
<td>Shims</td>
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<td>7</td>
<td>Hexalobe Handle</td>
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<td>8</td>
<td>Retractor Handle</td>
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<td>Shim Inserter</td>
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<td>Shim Remover</td>
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<td>Anterior Bridge</td>
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<td>6</td>
<td>8 Fr Suction</td>
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<td>7</td>
<td>10 Fr Suction</td>
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<td>8</td>
<td>140mm Anterior Retractors</td>
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<td>9</td>
<td>180m Anterior Retractors</td>
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</table>
Table Arm Tray

54-BK-2000
Tray Layout

Item No. | Description
---|---
1 | Posterior Lobe Handle
2 | Table Arm Clamp
3 | Jackson Adapter Clamp
4 | Table Arm
5 | Table Arm Quick Connect

Light Cable Tray

54-BK-3000
Tray Layout

Item No. | Description
---|---
1 | Reusable Light Cable
Disposables

43-5000 – Light Box

54-BK-4000 Disposables Kit*

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<td>54-LC-5200</td>
<td>Illuminator (Light)</td>
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<td>302427-000-275</td>
<td>Neuromonitoring Probe</td>
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<td>302404-000-160</td>
<td>Ball tip NM Probe</td>
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<tr>
<td>54-BP-5000</td>
<td>Bipolar Forceps</td>
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</tbody>
</table>

* Order Disposable items individually
ShurFit® LLIF Lateral Disc Prep Set 1
23-9101-CA

Disc Prep Set 1 – Top Layer

Disc Prep Set 1 – Bottom Layer
ShurFit® LLIF Lateral Disc Prep Set 2
23-9102-CA

LLIF Disc Prep Set 2 – Top Layer

LLIF Disc Prep Set 2 – Middle Layer

LLIF Disc Prep Set 2 – Bottom Layer
23-9103-CA

Implant Set – Top Layer

Implant Set – Bottom Layer