Spineology®

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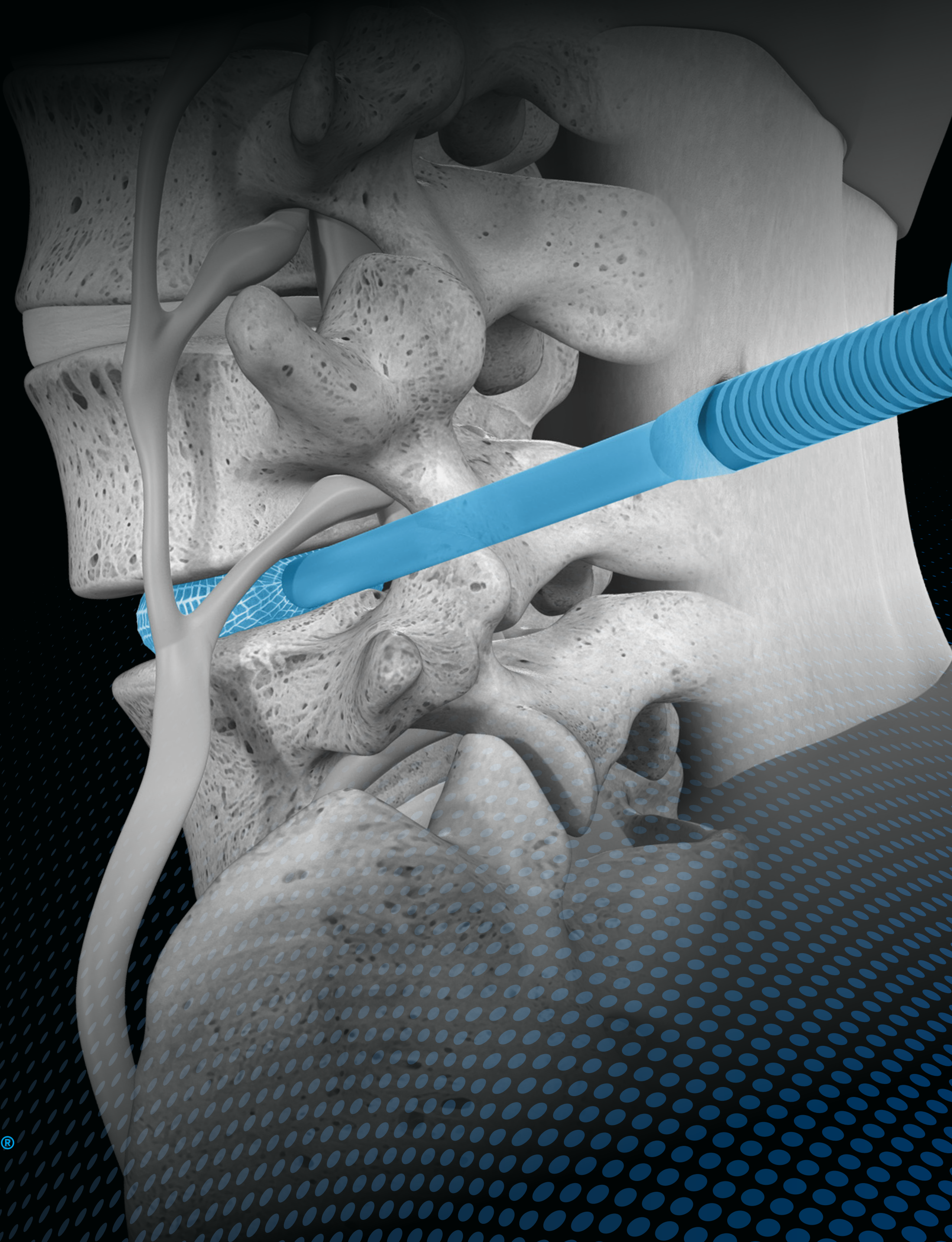

OptiLIF®

Surgical Technique

Spineology®

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About this Guide:

Spineology's OptiMesh® features our unique Conform and Expand™ technology, designed to provide a custom anatomical fit for lumbar fusion surgical patients. OptiMesh's powerful distraction forces and conformance to the endplates provide strength and stability to restore disc height, achieve alignment goals, and promote a robust fusion. With nearly the entire implant comprised of biologics, OptiMesh offers a comprehensive fusion scaffold and provides one of the most efficient ways to deliver biologics to the spine. OptiMesh is delivered through the smallest insertion profile and is the only in situ, conforming, patient specific expandable implant on the market. Backed with IDE level data, this is an implant category of its own.

A Note for Physicians:

As with any spinal fusion procedure, proper imaging and interpretation of the images are critical to safety. This technique manual describes the parameters for instrument trajectory selection on typical anatomy but does not purport to teach radiographic image interpretation. These instructions are intended as an outline for the use of the OptiMesh Multiplanar Expandable Interbody Fusion System for physicians experienced in the interpretation of biplanar fluoroscopic imaging of the lumbar spine and image-guided instrument placement. Physicians should always use their best medical judgment.

Proper aseptic technique, anesthesia and antibiotic use, prone patient positioning, and the ability to obtain proper anterior-posterior (AP) and lateral images are assumed. It is always good practice to verify the ability to obtain useable AP and lateral images before preparing the sterile field.

Access

Determining Incision Location

Orient the C-arm to a lateral image and obtain a true lateral image of the level to be treated.

In this image:

- Pedicles should be superimposed
- Foramen should be visible
- No endplate ellipse on vertebral bodies

Place a short needle into the patient, near midline, confirm with a lateral image that it is in line with a trajectory that encompasses the disc space (Fig. 1).

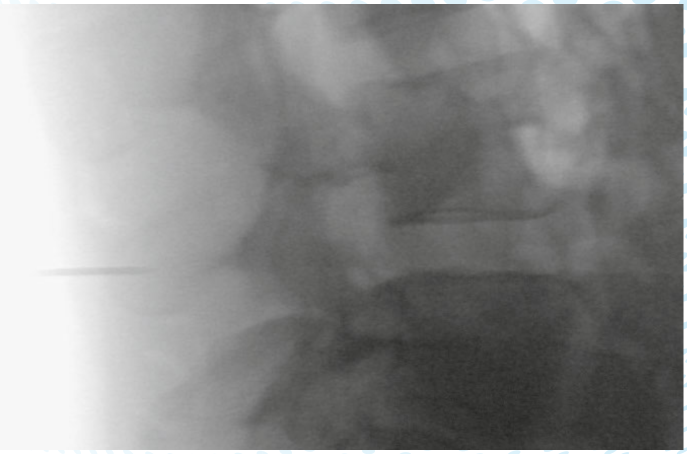


Figure 1

Alter the C-arm position to AP and angle the image intensifier so the needle is colinear with the disc and:

- Pedicles are equidistant from the lateral edges of the vertebral body
- Spinous process is centered in the spine
- No endplate ellipse on vertebral bodies

This will provide a true AP image (Fig. 2).

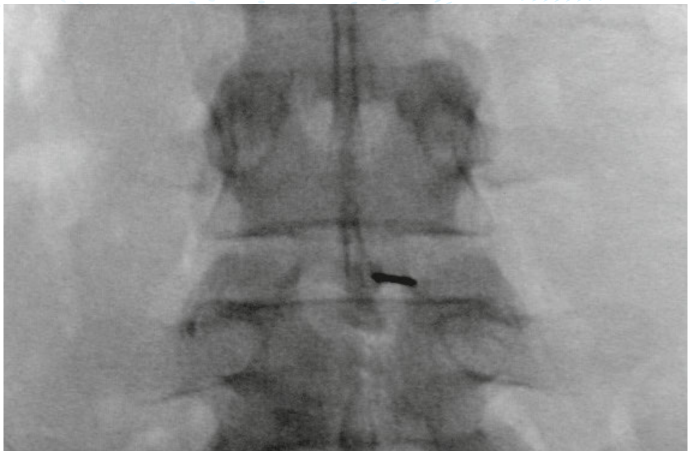


Figure 2

Access

Determining Incision Location continued

Using AP imaging, place a Guide Pin on the skin with the tip located at the junction of the ipsilateral border of the spine and the superior endplate of the inferior vertebral body. Mark the point on the patient's skin with a marker (Fig. 3).

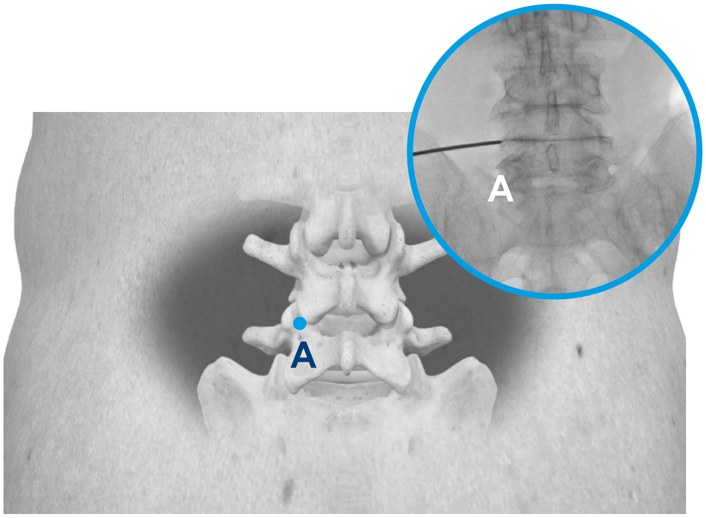


Figure 3

Place the Guide Pin on the skin with the tip located at the junction of the contralateral border of the spine and the superior endplate of the inferior vertebral body. Mark the point on the patient's skin with a marker (Fig. 4).

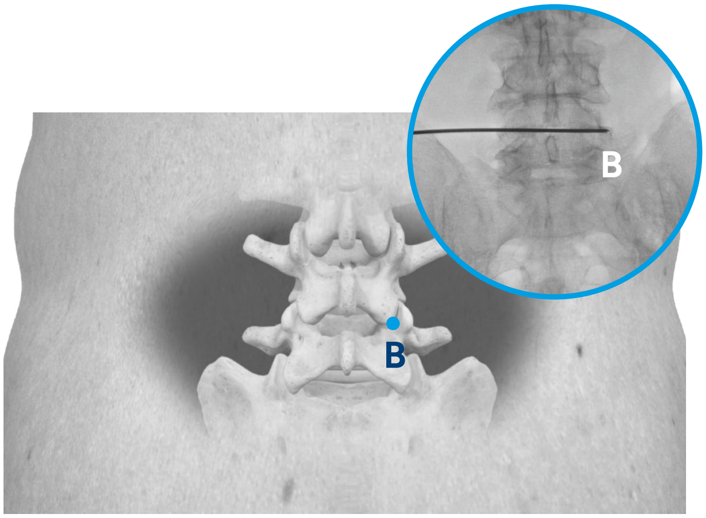


Figure 4

Place the Guide Pin flat on the patient's skin and mark the Guide Pin with the distance from point A to point B. Transfer this distance laterally from the ipsilateral edge of the vertebral body and mark this point on the skin (Fig. 5). This location indicates the approximate incision location.

Note: The incision's distance from midline is dependent on patient size and the level being treated. The heavier the patient and/or the more caudal the level being treated, the further from midline the incision will likely need to be.

Make a one-centimeter, medial-lateral incision.

Note: A medial-lateral incision facilitates trajectory corrections and ability to perform a thorough discectomy.

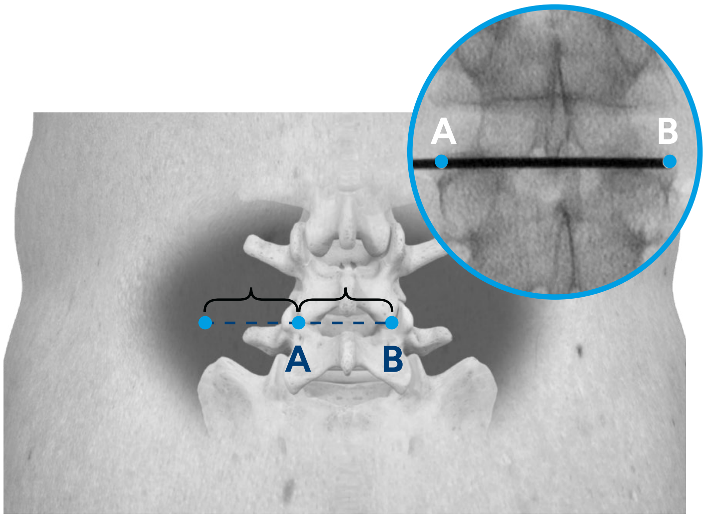


Figure 5

4 mm Neuro Probe Insertion

The disc space can be accessed using a 4 mm or 2 mm Neuro Probe. For 2 mm Neuro Probe instructions, see Appendix E.

Have the monitoring technician:

- Connect the 4 mm Neuro Probe to the cathode (-) output of the stimulator source and a return electrode to the anode (+) input.
- Set the stimulator to deliver a pulsed 5 mA current at approximately 1–2 pulses/second.
- Set the Cmap sensitivity to 100 uV (microvolts).

Note: The objective when using the Probe is to facilitate "mapping" of the nerves at a moderately high level of stimulation and to titrate progressively to a lower stimulation level in the event more precise spatial localization is required.

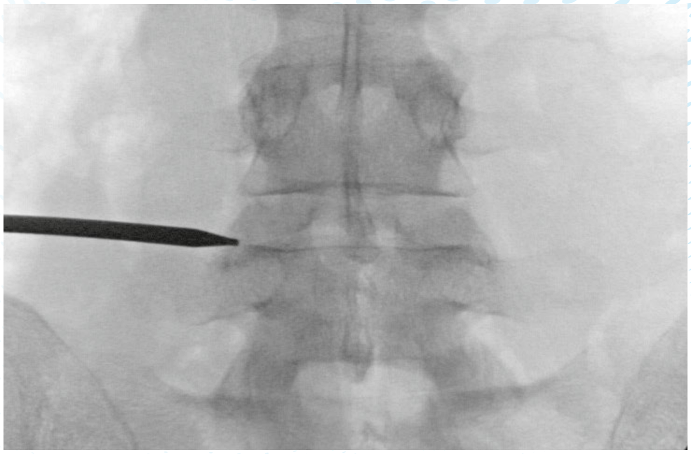


Figure 6

The desired entry location into the disc is immediately superior to the centerline of the ipsilateral inferior pedicle of the motion segment to be fused. Using AP imaging, insert and advance the Probe through the incision until the distal tip is located at the junction of the ipsilateral border of the spine and the superior endplate of the inferior vertebral body (Fig. 6).

Note: When accessing the L5–S1 level, if the ilium is contacted, a transiliac access can be created. See Appendix F.

Access

4 mm Neuro Probe Insertion continued

As the Probe is advanced, the electrified tip may evoke a neural response. If at any time the technician detects a response, this is an indication that the nerve root is in, or near, the trajectory of the Probe. Retract the Probe slightly, redirect the Probe trajectory, and continue advancement. Upon trajectory change and re-advancement, if a response is again evoked, titrate the stimulus down in 1 mA increments to reduce the spatial sensitivity and continue to advance.

During identification of a safe trajectory, the Probe trajectory should be altered slightly in multiple directions from the original trajectory to evoke intermittent responses. This will aid in mapping of neural structures, while also ensuring that the stimulus has not dropped below the threshold necessary to evoke a response.

When the distal tip of the Probe is immediately superior to the center of the ipsilateral inferior pedicle of the motion segment on an AP image (Fig. 7), switch to lateral imaging.

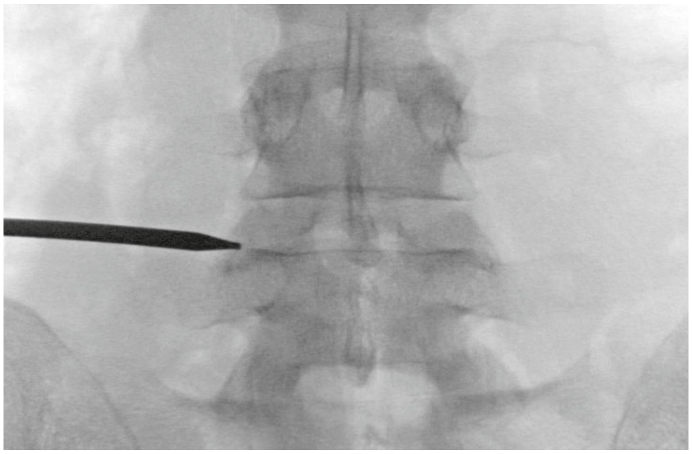


Figure 7

The Probe tip should be at the junction of the posterior wall of the vertebral body and the superior endplate of the inferior vertebral body on the lateral view (Fig. 8). If it is not at this location, retract the Probe, alter the insertion angle, and re-advance the Probe until it is correctly positioned and no response is evoked.

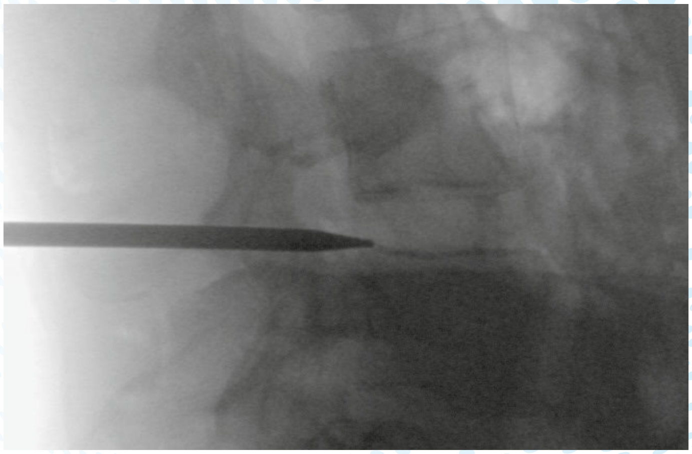


Figure 8

If the Probe tip position was modified, switch back to AP imaging to confirm that the Probe tip is correctly positioned immediately superior to the center of the ipsilateral inferior pedicle of the motion segment.

Note: During neural mapping, if a stimulus level is reached at which: 1) no response can be evoked anywhere along the trajectory, or 2) a continuous response is evoked along the trajectory, the procedure should be attempted from the contralateral side or an alternate procedure considered.

Stop stimulation. Remove the DIN connector from the proximal end of the Probe and place the end of the Dilator Impactor labeled “1” over the end of the Probe.

Using AP imaging, use the Mallet to advance the Probe to the medial wall of the pedicle (Fig. 9).

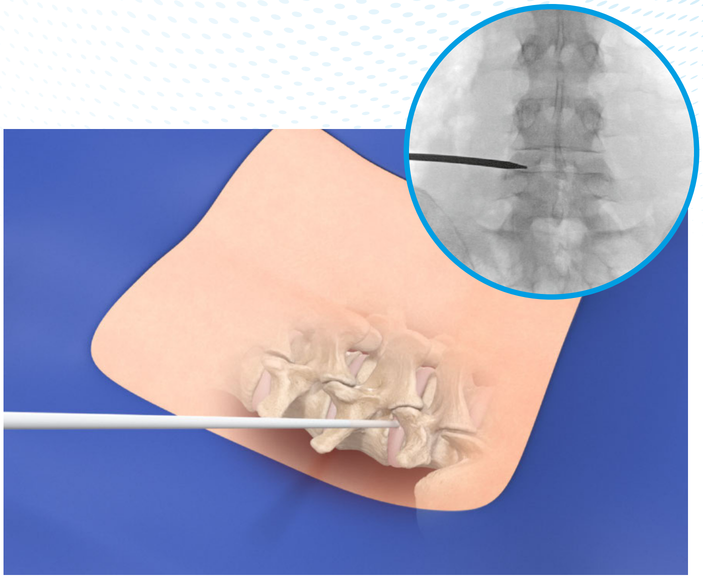


Figure 9

Access

4 mm Neuro Probe Insertion continued

Switch to lateral imaging to confirm that the tip of the Probe has passed the posterior wall of the vertebral body (Fig. 10).

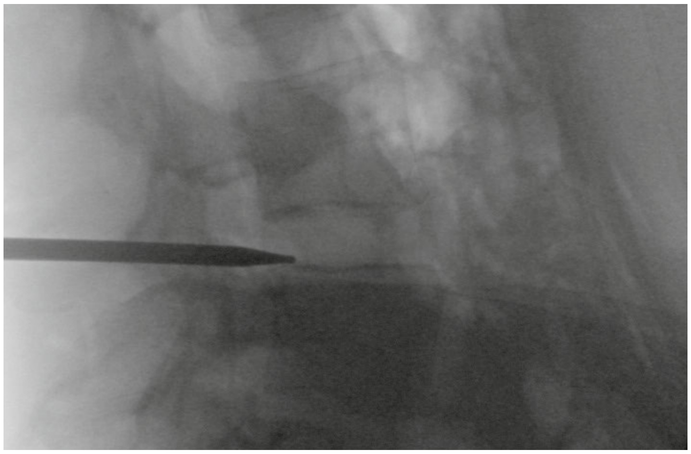


Figure 10

Remain in the lateral view and advance the Probe to the midpoint of the disc space (Fig. 11).

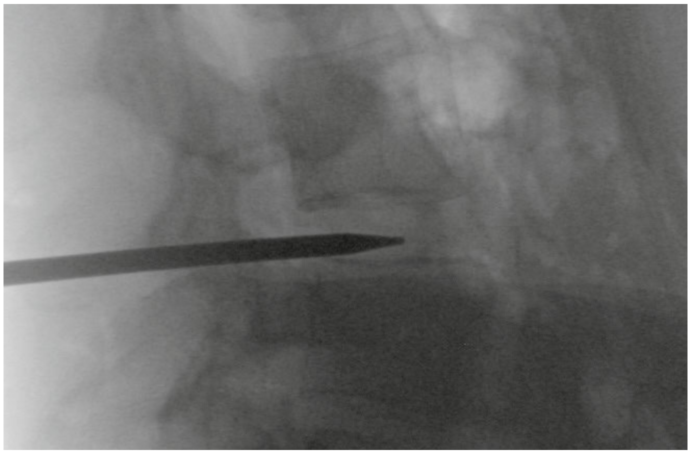


Figure 11

Switch to an AP image and confirm that the Probe is at the midpoint of the disc space (Fig. 12).

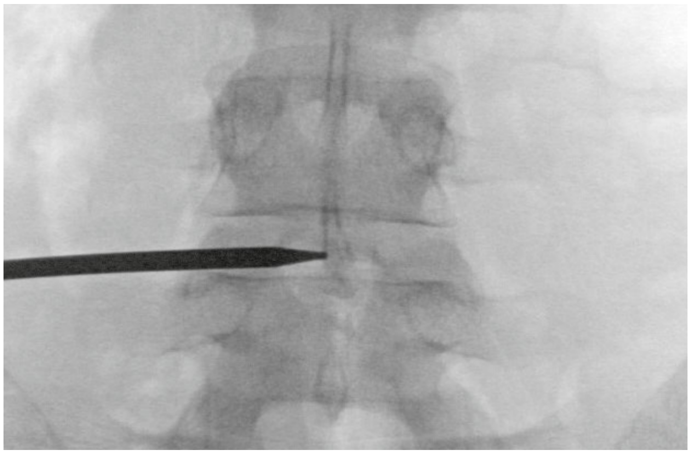


Figure 12

Trajectory Corrections

If trajectory corrections are needed, retract the 4 mm Probe to the annulus. Redirect the 4 mm Probe and re-advance into the disc space. If the trajectory is too steep or too flat, corrections should be made as follows:

Trajectory is too steep (Fig. 13)

Correction: Withdraw the 4 mm Probe to the posterior edge of the disc and "flatten" the trajectory by moving the proximal end ventrally. Re-advance and inspect the trajectory in both AP and lateral views.

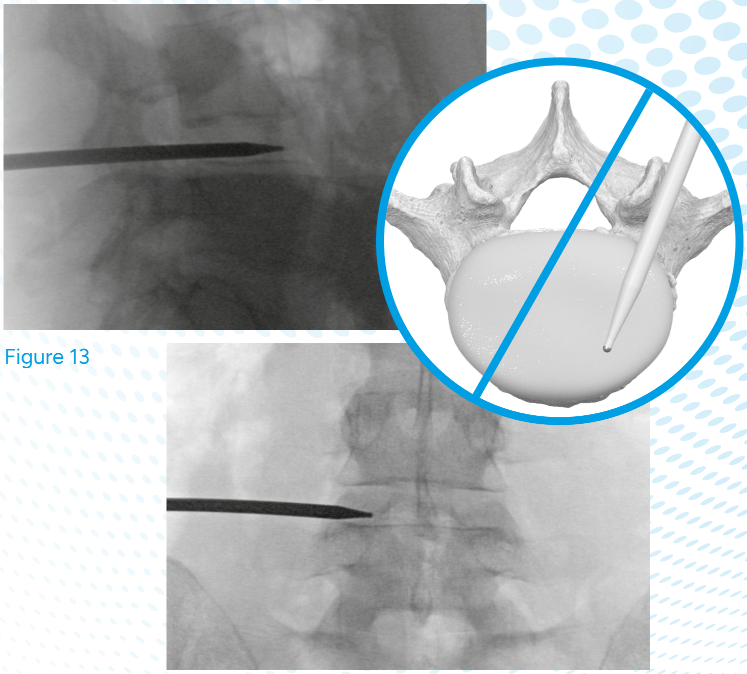


Figure 13

Trajectory is too flat (Fig. 14)

Correction: Withdraw the 4 mm Probe to the posterior edge of the disc and "steepen" the trajectory by moving the proximal end medially. Re-advance and inspect the trajectory in both AP and lateral views.

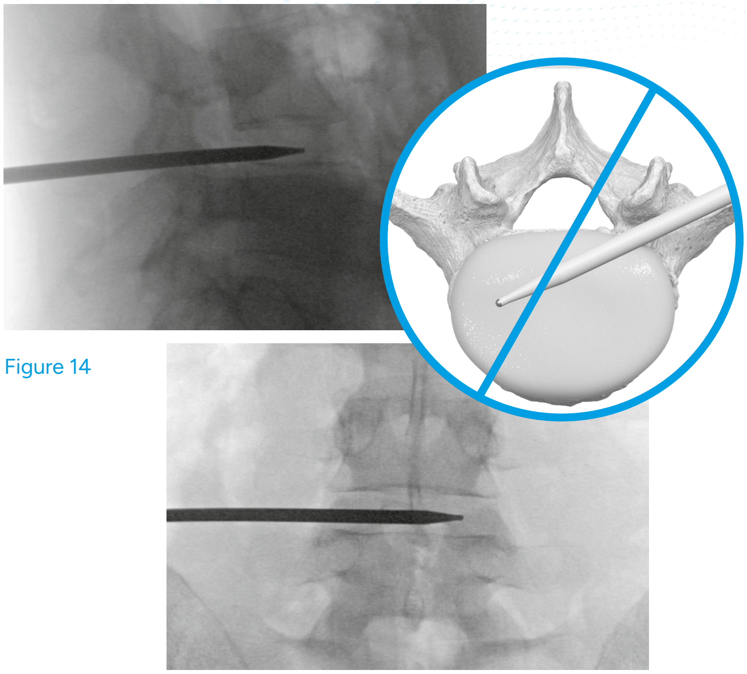


Figure 14

Access Portal Placement

Assemble the Access Portal (see Appendix B). Slide the QuikTrak over the distal end of the Access Portal assembly and seat against the Access Portal stem (Fig. 17).

Figure 17

Slide the Access Portal and QuikTrak assembly over Dilator Two (Fig. 18).

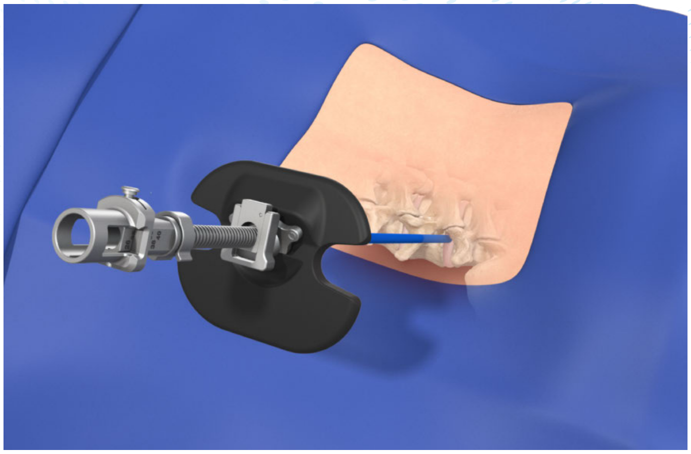


Figure 18

OptiMesh® Sizing, Delivery, and Filling

OptiMesh Sizing

Implant size is determined by the disc space depth and if bone graft will be placed around the implant within the disc space. Disc space depth is identified during the drilling step of the discectomy. Using the disc space depth and taking into consideration if bone graft will be placed around the implant within the disc space, determine the implant size (Fig. 45a–b).

OptiMesh Implant Selection	
Drilling Depth	Implant Selection
26 mm	300-2628
28 mm	
30 mm	300-3032
32 mm	
34 mm	300-3440
36 mm	
38 mm	
40 mm	

Figure 45a

OptiMesh Implant Selection Following Bone Grafting	
Drilling Depth	Implant Selection
26 mm	Do not bone graft
28 mm	
30 mm	300-2628
32 mm	
34 mm	300-3032
36 mm	
38 mm	300-3440
40 mm	

Figure 45b

Bone Grafting

Fill the Graft Tube with flowable autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft.

Place the Graft Tube through the Access Portal and insert the Push Rod. Manually expel the bone graft by applying palm pressure to the Push Rod (Fig. 46).

WARNING: It is not recommended to use mechanical impaction, such as with a mallet, to advance graft material. Impact forces can cause graft tube to advance anterior and increase risk of patient injury.

Remove the Graft Tube.

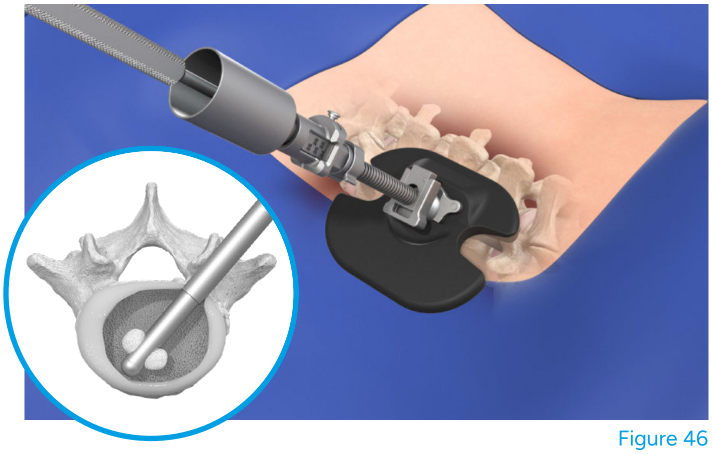


Figure 46

OptiMesh® Delivery

Load the OptiMesh implant into the Inserter by pushing the crimped end of the implant onto the distal end of the Inserter (Fig. 47).

Pass the Mesh Extender through the cannula of the Inserter and extend the implant in preparation for insertion.

Note: The Mesh Extender must be centered on the distal end of the implant to ensure passage through the Access Portal.

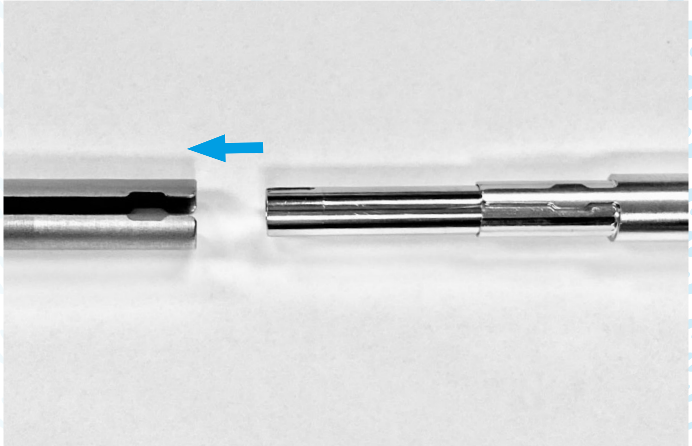


Figure 47

Caution: Do not apply excessive force to the Mesh Extender. Doing so may damage the OptiMesh implant, resulting in a tear and loss of containment capability.

With the OptiMesh implant extended and gentle pressure on the Mesh Extender, place the Inserter through the Access Portal.

Caution: Do not rotate the Inserter; doing so may twist the implant neck and interfere with filling.

Advance the Inserter and Mesh Extender through the Access Portal until the Mesh Extender meets the contralateral annulus. Cease advancement of the Mesh Extender and advance the Inserter until it meets the Access Portal positive stop (Fig. 48).

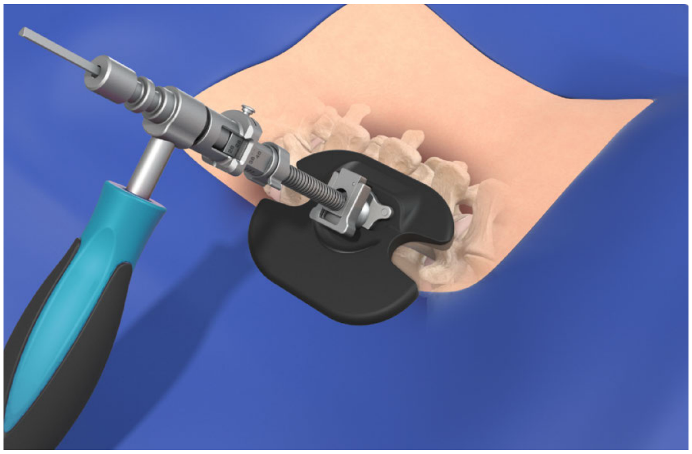


Figure 48

Remove the Mesh Extender.

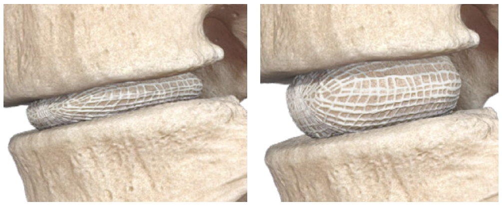
OptiMesh® Sizing, Delivery, and Filling

OptiMesh Filling

The OptiMesh Implant is filled with compatible allograft and autograft. Compatible allograft material includes Diverted Fill Tubes that come prefilled with cortical/cancellous bone chips and DBM (Demineralized Bone Matrix). Each prefilled Diverted Fill Tube contains 6 segments (2 cc) of bone graft material. (Fig. 49)

Refer to the Filling Chart for recommended filling volumes (Fig. 50).

Figure 49



Catalog #	Min. # Diverted Tube Segments	Max. # Diverted Tube Segments
300-2628	11	15
300-3032	13	24
300-3440	18	30

Figure 50

To begin implant filling, pass a Diverted Fill Tube through the Tube Twister. Press the button on the Tube Twister to fully seat the Diverted Fill Tube. Pass the Diverted Fill Tube / Tube Twister assembly through the Inserter and fully seat the Tube Twister onto the proximal end of the Inserter (Fig. 51).

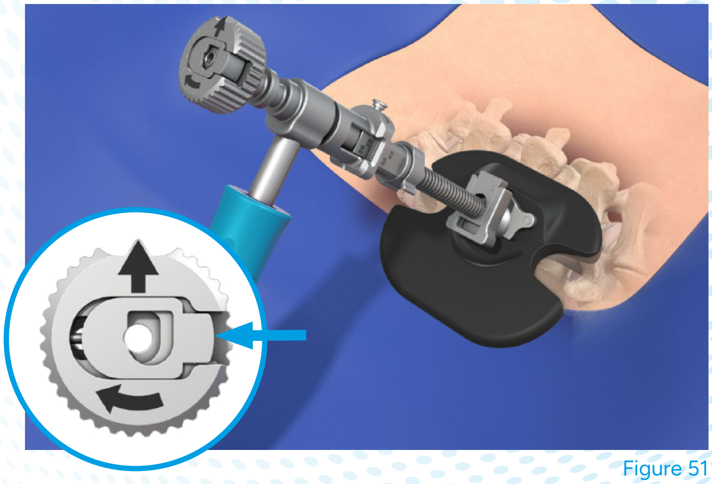


Figure 51

Place the Push Rod into the proximal end of the Diverted Fill Tube. Impact the Push Rod with the Mallet and deliver three segments of bone in either the ipsilateral or contralateral direction within the disc space (Fig. 52).

Note: The diverted opening on the Fill Tube corresponds to the laser mark on the Tube Twister (Figs. 49 and 51).

Use only the Mallet provided in the OptiMesh® Instrument Tray; this will generate the impact loads necessary to properly fill the OptiMesh implant.

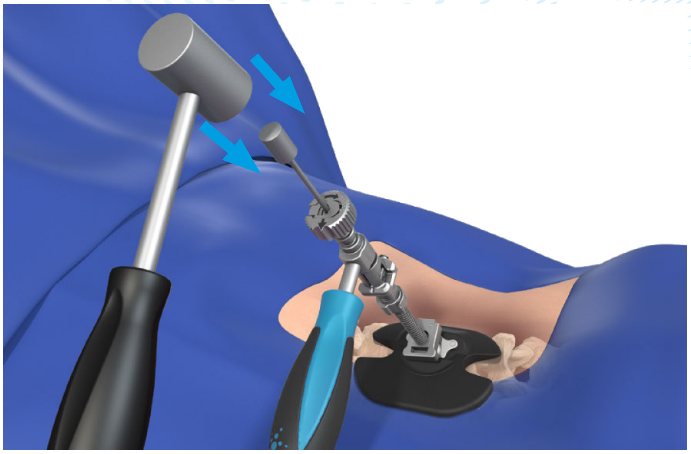


Figure 52

Rotate the Tube Twister 180° and deliver three segments of bone in the opposite direction.

Turn the Tube Twister one-quarter turn and continue to deliver one or two segments of bone at a time into the implant, rotating the Tube Twister one-quarter turn each time. When a Diverted Fill Tube is emptied, replace it with a full Diverted Fill Tube and continue the filling process.

As an OptiMesh implant fills with bone, the resistance to additional bone will be indicated through tactile, auditory, and visual cues.

OptiMesh® Sizing, Delivery, and Filling

OptiMesh Filling continued

Once the minimum fill amount is reached per the Filling Chart (Fig. 50), closely observe the cues indicating OptiMesh is full:

Tactile
Mallet strikes meet resistance, resulting in less bone delivered into OptiMesh and increasing difficulty rotating the Tube Twister.

Auditory
Mallet strikes produce a solid sound compared to the free-flowing sound when bone was delivered early in the fill process.

Visual
Push Rod does not advance with consistent Mallet strikes.

Stop delivering bone into the implant when these cues are observed or when the maximum fill amount for the implant size is reached based upon the disc height present (see Filling Chart, Fig. 50 and OptiMesh Final Footprint Chart, L609).

As OptiMesh is filled and the graft pack forms, it is possible for Diverted Fill Tubes to jam and give a false indication of the implant being full. If a jam is suspected, test the Fill Tube:

1. Remove the Fill Tube from the Inserter
2. Place the Fill Tube through the hole in the Portal Impactor
3. Tap on the Push Rod.

If the bone in the Tube is easily expelled, it is an indication the implant is full. If no graft can be expelled, the Tube is jammed and a new Tube should be inserted into the implant and filling continued.

Caution: As resistance increases during filling, or in the event of a tube jam, do not increase the intensity of Mallet strikes; doing so may damage the implant and lead to loss of graft containment and/or instrument damage. Mallet force should not exceed the force of a six-inch free fall of the Mallet head.

Remove the Diverted Fill Tube and Push Rod.

OptiMesh® Delivery

Pass the Release Driver through the Inserter and rotate counterclockwise until it fully seats into the mesh crimp. Once seated turn the Release Driver counterclockwise until it stops turning. Remove the Inserter from the Access Portal (Fig. 53).

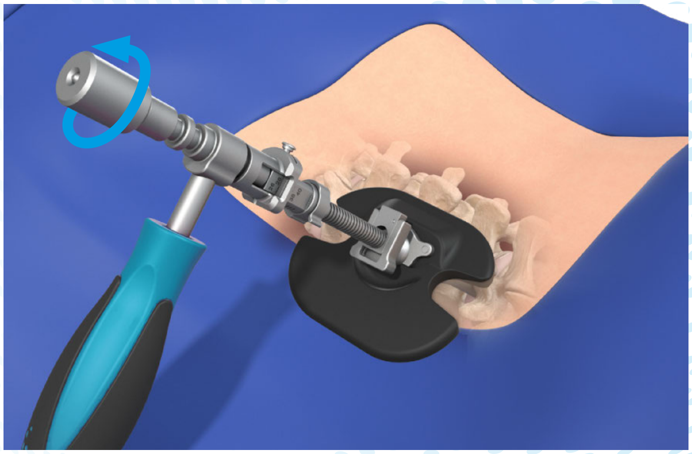


Figure 53

Remove the Access Portal.

Note: Pedicle Screw Installation

Supplemental posterior fixation in the form of bilateral pedicle screw construct components may be installed either before or after OptiMesh, at the surgeon's preference.

Caution: Direct contact between pedicle screws and the filled OptiMesh construct can damage the mesh and may result in loss of graft containment. Screws must not penetrate the vertebral endplates or the central area of the vertebral body adjacent to the endplate where OptiMesh will be positioned.

Do not lock the screws and rods in their final position until OptiMesh placement and filling is complete.

Minimally Invasive Surgery (MIS) Access OptiMesh® Implantation

OptiMesh can be implanted via a traditional MIS TLIF approach using the SOAR™ Tubular Retractor System or Merlon™ Bladed Retractor System. See the SOAR Surgical Technique Guide (L228) or the Merlon Retractor Surgical Technique (L553) for instructions on retractor placement, Access Portal placement, and discectomy via a traditional MIS TLIF approach.

See pages 22–27 for OptiMesh sizing, placement, filling, and release through the Access Portal when using the SOAR or Merlon Retractor Systems.

Open Access OptiMesh Implantation

Following a traditional open discectomy, OptiMesh can be placed in the disc space and filled using one of two methods: the Handheld Brace or the OptiMesh Table Arm.

Handheld Brace

Place Dilator Two into the disc space. Stop advancing when the tip of Dilator Two is halfway across the disc space on a lateral image (Fig. 54).

Note: If the disc space is collapsed, use the Guide Pin and Dilator One to aid in placement of Dilator Two.

Figure 54

Appendix A:
OptiMesh® Expandable Interbody Fusion System

Top Tray

CATALOG #	DESCRIPTION
312-0002	Mallet
312-0013	Non-cannulated Dilator One
312-0014	Dilator One
312-0011	Drilling Dilator
312-0016	Dilator Impactor
900-0024	Palm Handle
312-0054	Drill
312-0039	Suction Tube
312-0053	Shaper Handle
312-0050	Shaper Body
312-0024	Portal Impactor
312-0049	Portal Head
312-0048	Portal Stem
312-0057	Push Rod
312-0056	Graft Tube
312-0019	Stopped Pituitary Rongeur

Middle Tray

CATALOG #	DESCRIPTION
312-0028	Short Articulating Curette
311-0100	Articulating Curette
312-0051	QuikTrak
312-0044	Short Portal Stem
312-0041	I-Beam
312-0045	Transiliac Drill
312-0047	Reverse Articulating Curette

Bottom Tray

CATALOG #	DESCRIPTION
312-0055	Mesh Extender
301-0021	Push Rod
312-0001	Inserter
312-0021	Tube Ejector
312-0003	Tube Twister
312-0004	Release Driver

Table Arm Case

CATALOG #	DESCRIPTION
312-0036	Table Post
312-0037	Table Arm
312-0052	Lock Box

Unique Device Identification (UDI)

All Spineology devices are labeled with UDI in human readable and/or Automatic Identification and Data Capture (AIDC) format. The human readable UDI is formatted starting with M740 and followed by device identifying characters.

The UDI of single use devices is found on the package label in both formats.

The UDI of reusable devices is directly marked on the device in human readable format or can be derived from the catalog number directly marked on the device. For example, a device with catalog number 123-4567 would have a UDI of M74012345670.

Verify Assembly

Fill the Verify syringe with intrathecal rated contrast media.

Thread the stopcock onto the syringe.

Thread the Verify balloon onto the stopcock.

Depress the plunger on the syringe to inject the contrast media into the balloon.

In the event there is air in the balloon, pull back on the plunger to return the contrast media to the syringe

Turn the lever on the stopcock to close off the balloon and open the side port. Slowly press the plunger on the syringe to expel the air out of it. Turn the lever on the stopcock to close off the side port and allow the contrast media to flow between the syringe and balloon.

The Verify device is now ready for use.

Appendix C:
Intraoperative OptiMesh® Removal

Intraoperative OptiMesh Removal/Revision

If removal of OptiMesh is needed, begin by incising the mesh. Use the Drill provided in the instrument set to drill through the mesh and bone graft pack. Remove bone graft and mesh fragments with pituitary rongeurs, curettes, irrigation, and suction.

If revision with a new OptiMesh is desired, size for a new mesh per the sizing instructions on page 22. Following OptiMesh size selection, insert, fill, and release the new mesh per the instructions on pages 22–27.

Explantation

If it becomes necessary to remove a pedicle screw or components of the posterior fixation construct, contact the screw manufacturer for appropriate instructions.

If removal of OptiMesh becomes necessary, it will likely be necessary to cut the mesh apart to remove it and the bone graft in a piecemeal fashion. A guide pin can be placed into the central portion of the intervertebral mesh construct and then used to orient a cannula or portal for protected access to the disc space. Drilling into the central portion of the disc space will cut the mesh and permit access to any bone within it. Bone and mesh fragments may be removed with pituitary rongeurs, curettes, irrigation, and suction.

Appendix D: 2 mm Neuro Probe

A 2 mm Neuro Probe and Guide Pin are an alternative method for accessing the disc space. Slide the Exchange Tube over the distal tip of the Probe, flanged end first, until it contacts the handle (Fig. 71).

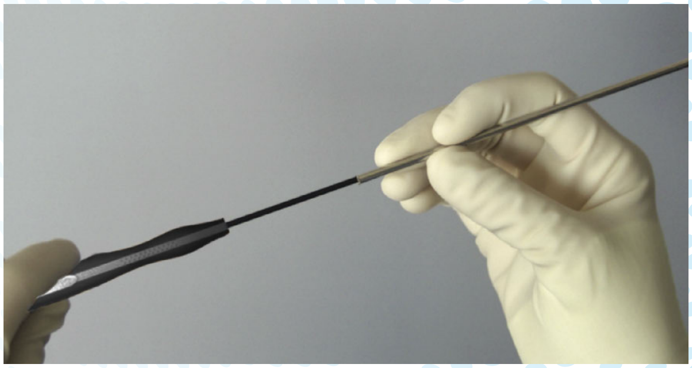


Figure 71

Have the monitoring technician:

- Connect the Probe to the cathode (-) output of the stimulator source and a return electrode to the anode (+) input.
- Set the stimulator to deliver a pulsed 5 mA current at approximately 1–2 pulses/second.
- Set the Cmap sensitivity to 100 uV (microvolts).

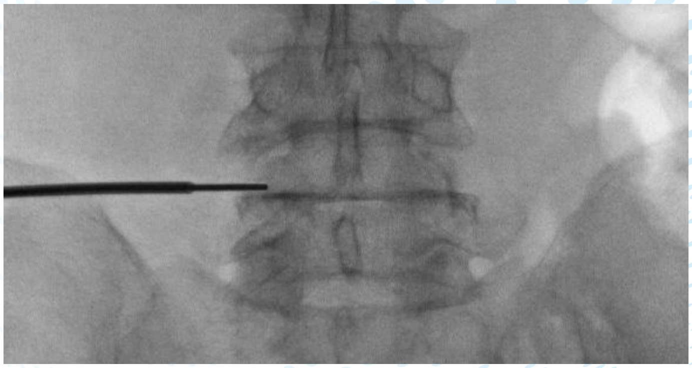


Figure 72

Follow the same safe trajectory targeting steps as done with the 4 mm Neuro Probe (pgs. 5–7) and stop advancement when the distal tip of the Probe is immediately superior to the centerline of the ipsilateral inferior pedicle of the motion segment on an AP image (Fig. 72) and at the junction of the posterior wall of the vertebral body and the superior endplate of the inferior vertebral body on the lateral view (Fig. 73).

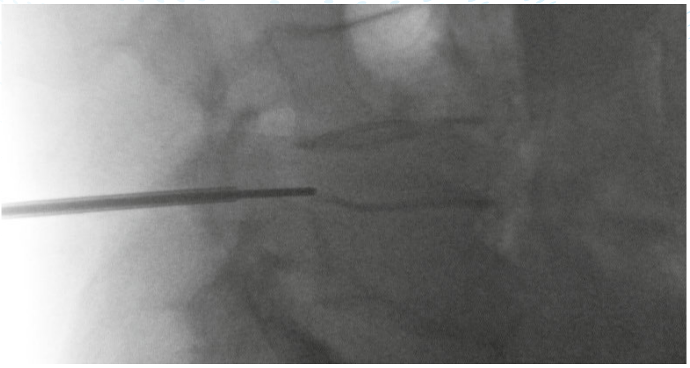


Figure 73

Slide the Exchange Tube down the Probe shaft to the disc (Fig. 74).

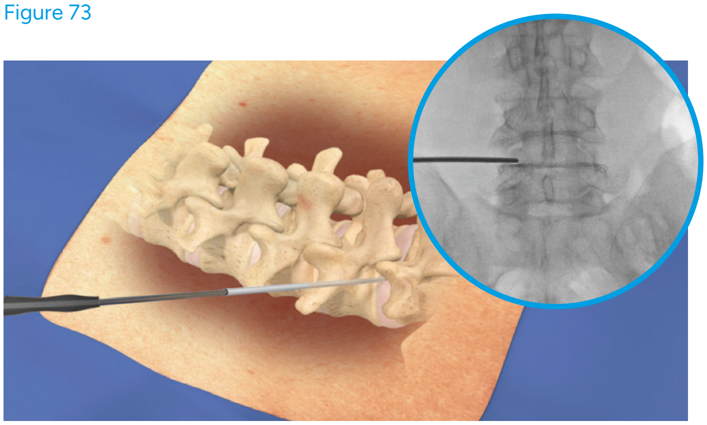


Figure 74

Apply slight downward pressure to hold the Exchange Tube against the disc and remove the Probe.

Replace the Probe with a Guide Pin (The distal line on the Guide Pin indicates when the Guide Pin is at the end of the Exchange Tube, the proximal line indicates when the Guide Pin is 20 mm past the end of the Exchange Tube.).

Using AP imaging, advance the Guide Pin to the medial wall of the pedicle (Fig. 75).

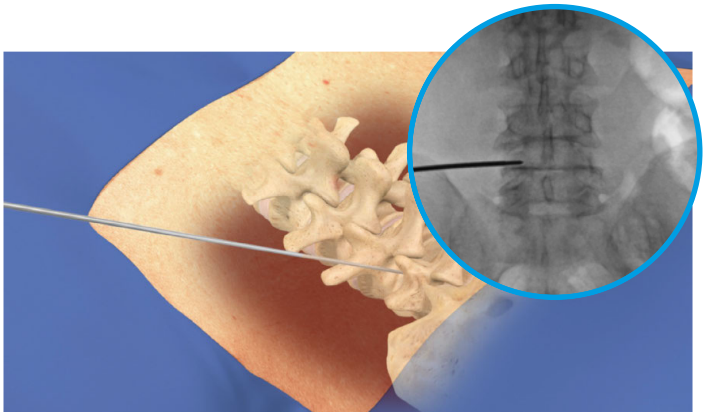


Figure 75

Switch to lateral imaging to confirm that the tip of the Guide Pin has passed the posterior wall of the vertebral body (Fig. 76).

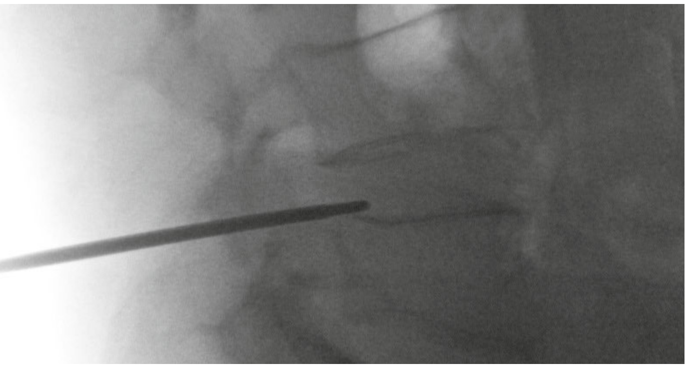


Figure 76

Remain in the lateral view and advance the Guide Pin to the midpoint of the disc space (Fig. 77).

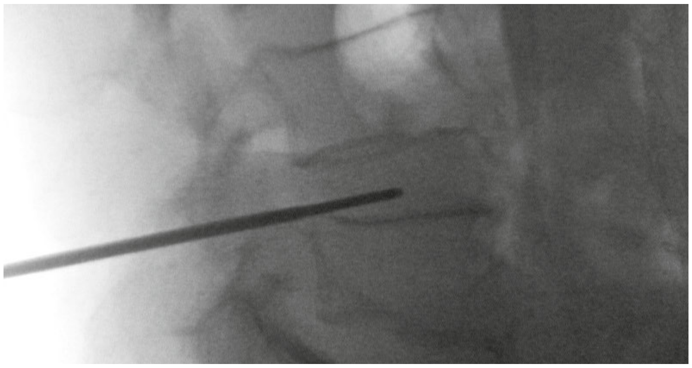


Figure 77

Switch to an AP image and confirm that the Guide Pin is at the midpoint of the disc space (Fig. 78).

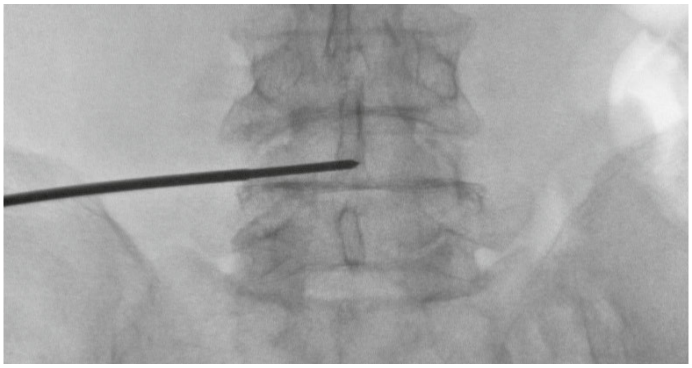


Figure 78

Appendix D: 2 mm Neuro Probe continued

Trajectory Corrections

Instrument Requirements

If trajectory corrections are needed, apply slight downward pressure to hold the Exchange Tube tip against the disc, retract the Guide Pin into the Exchange Tube, adjust the trajectory, and re-advance the Guide Pin along the desired trajectory.

If the trajectory is too steep or too flat, corrections should be made as follows:

Trajectory is too steep (Fig. 79)

Correction: Withdraw the Guide Pin from the disc and "flatten" the trajectory by moving the proximal end lateral and ventral. Re-insert and inspect the trajectory in both AP and lateral views and re-advance.

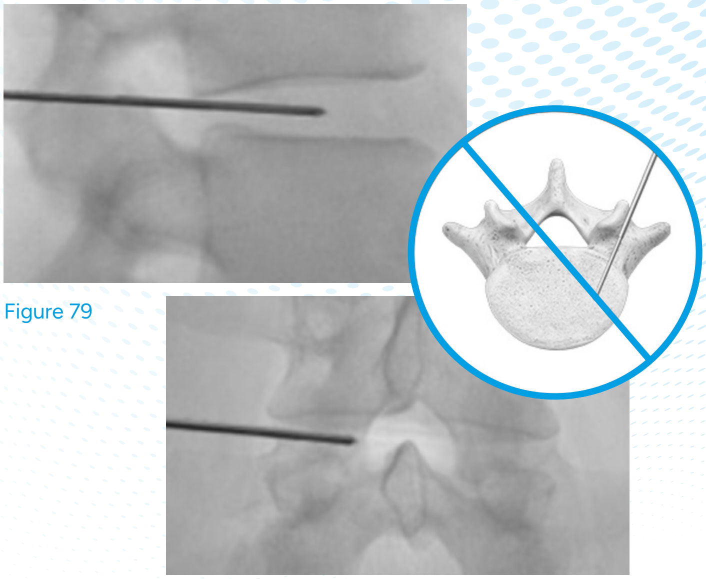


Figure 79

Trajectory is too flat (Fig. 80)

Correction: Withdraw the Guide Pin from the disc and "steepen" the trajectory by moving the proximal end medial and dorsal. Re-insert and inspect the trajectory in both AP and lateral views and re-advance.

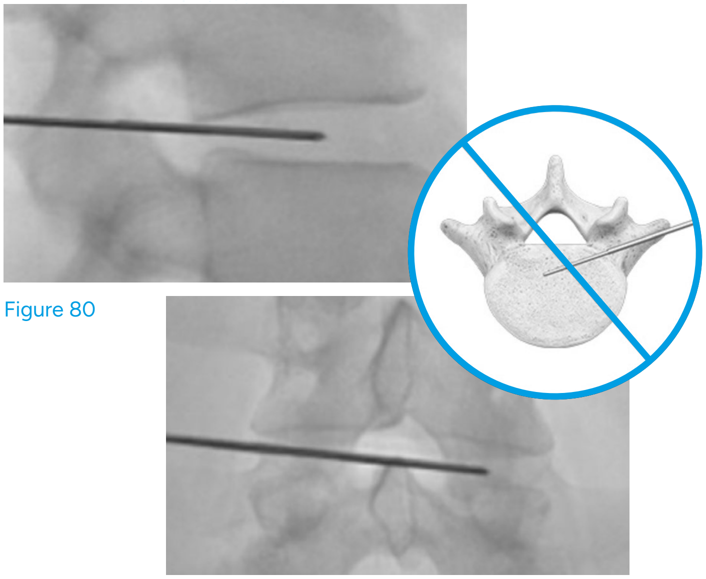


Figure 80

Appendix E:
Transiliac Access to the L5-S1 Disc Space

Instrument Requirements

To complete this procedure an OptiMesh® Instrument Set, disposables, and the following equipment is required:

- Diamond Tip Pin Introducer (catalog #310-0009)
- Blunt Guide Pin (catalog #300-1011)
- 2 mm Neuro Probe (catalog # 315-0000) and Exchange Tube (catalog #315-0001) if active EMG monitoring is desired

Surgical Technique

The technique to access the disc space is identical to the standard technique following the preparation of an 8 mm hole through the iliac crest at a point along the trajectory desired to perform the discectomy. To accurately determine the incision location, the preparation point on the crest, and the trajectory requires the use of an en face approach to the L5–S1 foramen.

To establish the correct en face image angle, position the C-arm to acquire a true lateral image of the L5–S1 space. Place a short needle into the patient in line with a trajectory that is parallax (or parallel) with the L5–S1 disc space (Fig. 85).

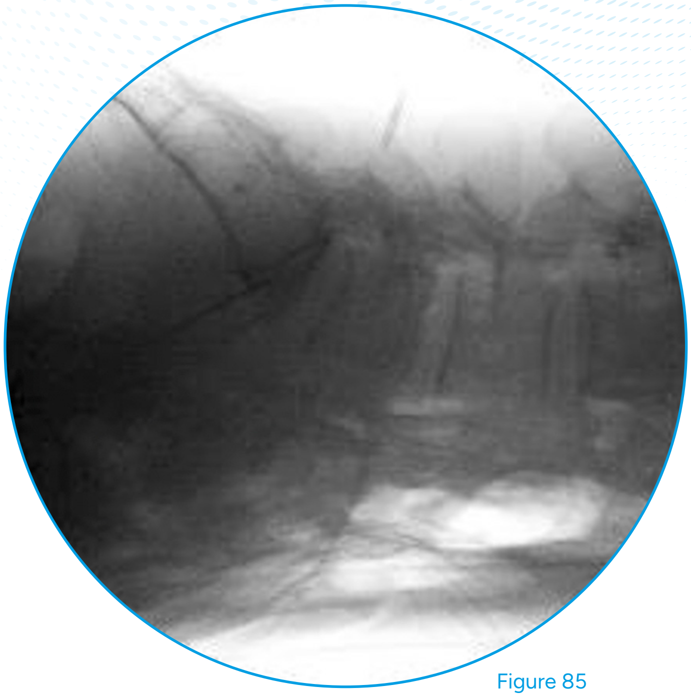


Figure 85

Appendix E:
Transiliac Access to the L5-S1 Disc Space continued

Alter the C-arm position to AP and angle the image intensifier superiorly until the hub of the needle is aligned with the disc. This will provide a true AP image (Fig. 86).

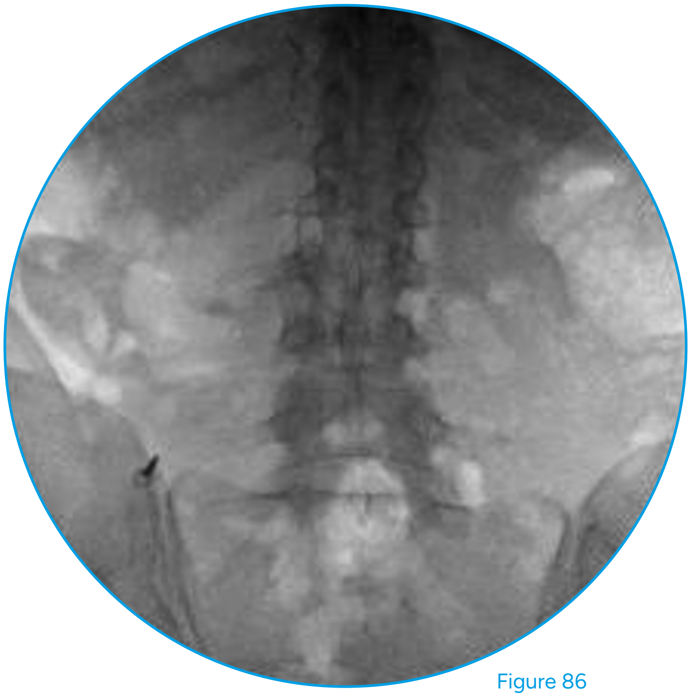


Figure 86

Without adjusting the AP angle rotate the image intensifier contralateral until the articular surfaces of the contralateral facet joint are clearly seen on the image and appear to bisect the disc in roughly a 1/3 posterior : 2/3 anterior split (Fig. 87).

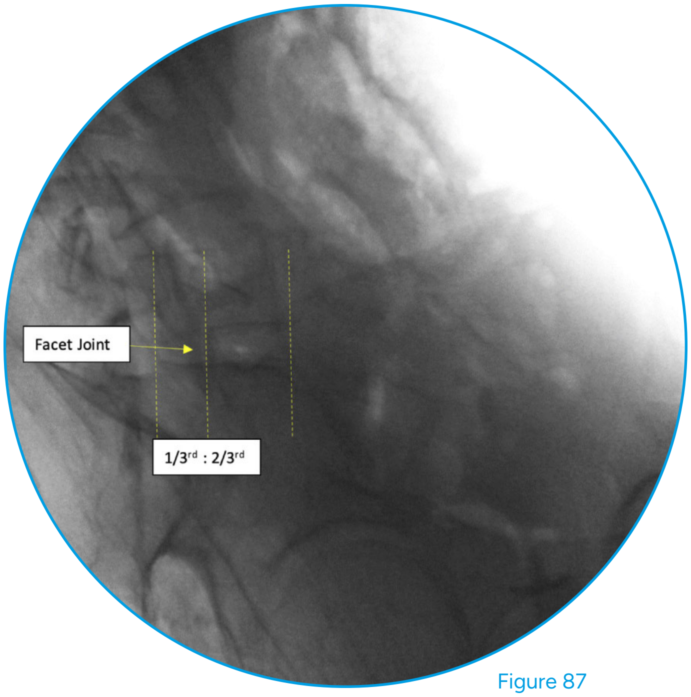


Figure 87

Using a forceps or clamp, align the Pin Introducer such that the shaft is parallel with the beam and a spot on the disc immediately anterior to the contralateral facet joint. This indicates the incision location, iliac crest preparation location and trajectory for the procedure (Fig. 88).

Incise and advance the Pin Introducer to the ilium surface along this trajectory. Dock the Pin Introducer tip against the ilium. Advance the Introducer through the ilium, but not to the spine.

Pass the Blunt Guide Pin through the Pin Introducer and advance it to the surface of the disc.

Note: Free Run EMG should be used during Guide Pin advancement to confirm that the area distal to the Guide Pin tip is clear of neural structures.

Use AP and lateral imaging to confirm that the Guide Pin is appropriately docked on the disc according to the standard technique (Fig. 89).

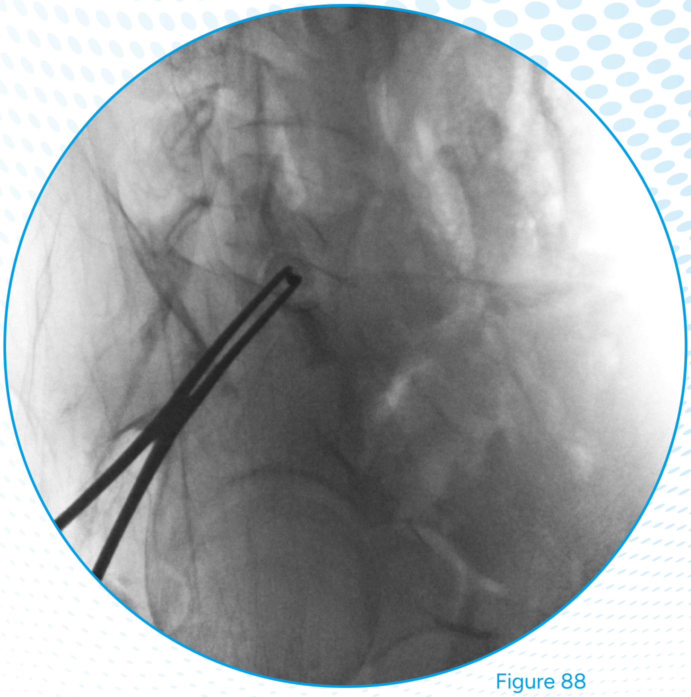


Figure 88

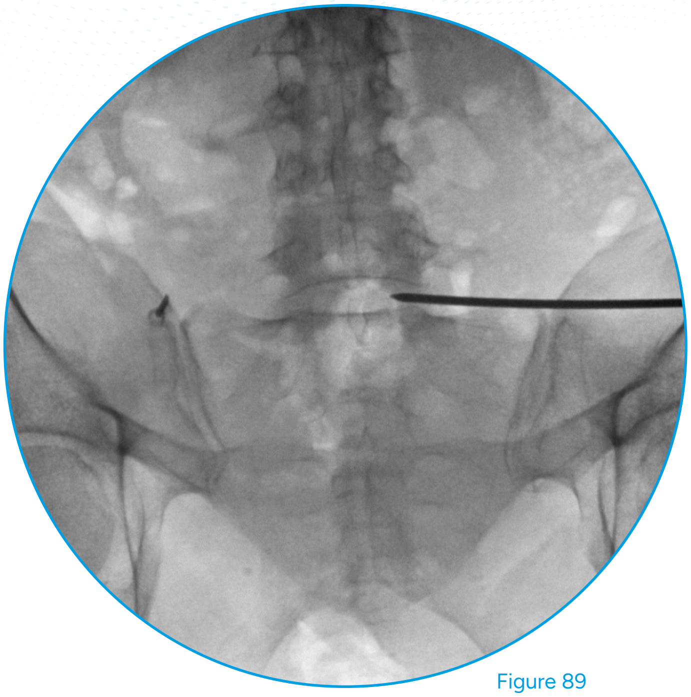


Figure 89

Appendix E:
Transiliac Access to the L5-S1 Disc Space continued

If free-run EMG indicates the docking point is clear of neural structures, advance the Guide Pin to the 50/50 point of the disc space to confirm trajectory. Remove the Pin Introducer leaving the Guide Pin in place (Fig. 90).

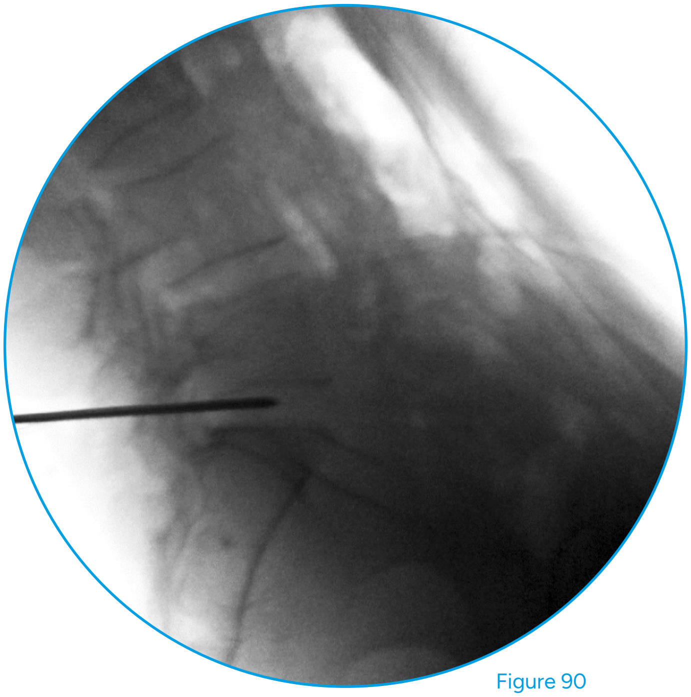


Figure 90

Affix the Transiliac Drill to a powered drill.

Pass the Transiliac Drill over the Guide Pin and drill a hole through the ilium using the Guide Pin to control trajectory. Remove the Transiliac Drill. Remove the Guide Pin if active EMG probing of the foramen is desired.

Note: If the use of active EMG monitoring is desired, place the Exchange Tube over the Guide Pin and advance it to the disc space. Replace the Guide Pin with the 2 mm Neuro Probe and retract the Exchange Tube to allow for neural mapping. Following neural mapping, advance the Exchange Tube to the disc space and replace the 2 mm Neuro Probe with a Guide Pin (blunt or sharp depending on surgeon preference) and advance to the 50/50 position as described above.

At this point the procedure is identical to the standard technique with the exception that the Short Portal Stem is required for the Access Portal Assembly to enable the Access Portal to be passed through the hole in the ilium. If the patient is sufficiently thin that the QuikTrak, once assembled on the Short Stem, does not rest against the patient, the OptiMesh® Table Arm is also required for force dissipation.

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OptiMesh®

Conforms to you.

Federal law (USA) restricts this device to sale by or on the order of a physician.

The OptiMesh Multiplanar Expandable Interbody Fusion System is indicated for use as an adjunct to fusion in an intervertebral body fusion at one level in the lumbar spine from L2 to S1 in skeletally mature patients with degenerative disc disease (DDD) with up to Grade I spondylolisthesis at the involved level. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history, physical examination, and radiographic studies. Eligible patients shall have undergone six (6) months of conservative (non-operative) care. The OptiMesh device with compatible allograft and autograft, or a bone void filler as cleared by FDA for use in intervertebral body fusion to facilitate fusion, is intended for use with supplemental posterior fixation systems intended for use in the lumbar spine.

For a complete list of contraindications, precautions, and warnings please refer to the package insert.