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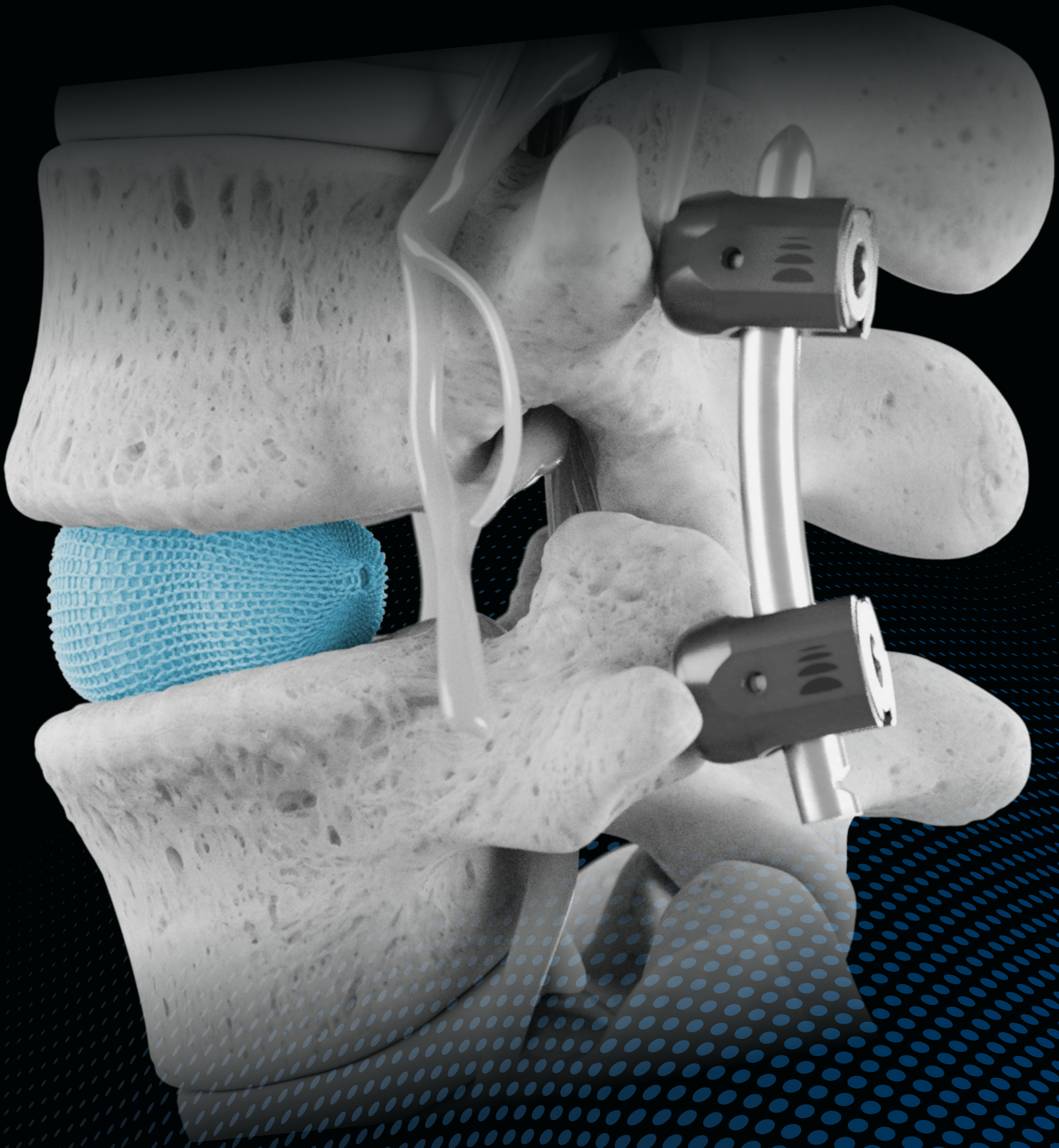


OptiMesh Align™

Surgical Technique

Spineology®

Table of Contents

Access

Discectomy

OptiMesh Align XL Sizing, Delivery, and Filling

OptiMesh Align Dual-Chamber Expandable (DCE) Sizing, Delivery, and Filling

Minimally Invasive Surgery (MIS)

Open Access OptiMesh Implantation

Appendix A: Expandable Interbody Fusion System & Align Interbody

Appendix B: Instrument Assemblies

Appendix C: Intraoperative OptiMesh Align Interbody Removal

About this Guide:

Spineology's OptiMesh Align™ is built on the foundation of OptiMesh® and uniquely differentiated as the only conforming expandable implant that offers one of the broadest expansion ranges in height, footprint, and lordotic shape. OptiMesh Align provides independent control and expansion of the anterior and posterior components, while being delivered through one of the smallest insertion profiles possible. Utilizing biologics-based expansion, OptiMesh Align offers real-time, in situ, independent anterior and posterior expansion, resulting in a customized lordotic shape, up to 20 degrees. This proprietary expansion method is designed to reduce mechanical limitations commonly seen with expandable implant technology, providing complete, real-time intraoperative control while conforming to each patient's unique anatomical requirements. OptiMesh Align is engineered to provide distraction forces and conformance to the endplates, strength and stability to restore disc height, achieve alignment goals, and promote a robust fusion, and is designed for use in multiple posterior lumbar fusion approaches, including MIS, MIS-Open, Open, and Ultra-MIS (OptiLIF) lumbar interbody procedures, based on surgeon preference and patient needs.

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 Align 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).

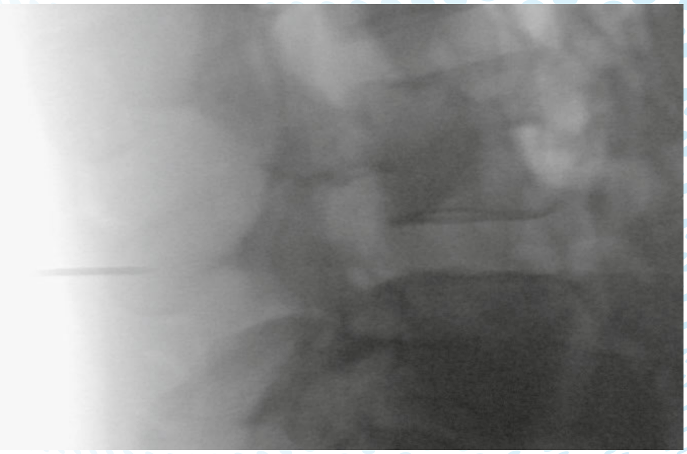


Figure 1

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).

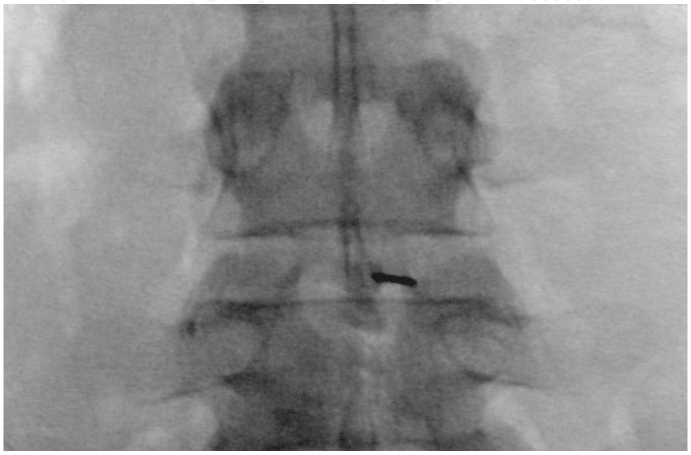


Figure 2

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 point A on the patient's skin with a marker (Fig. 3).

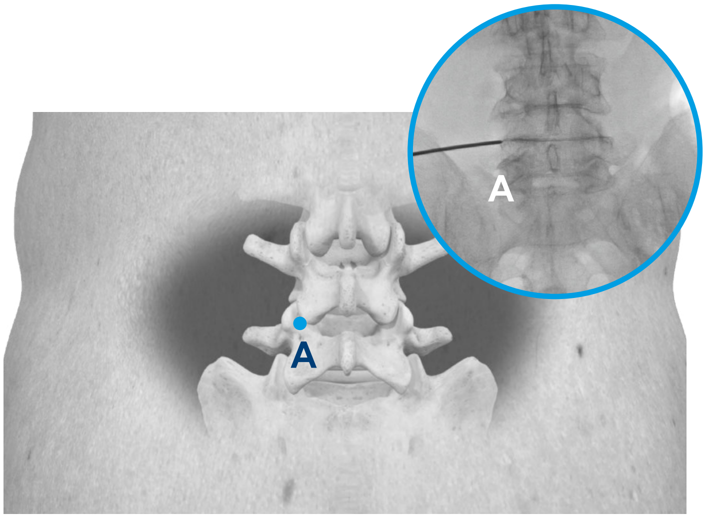


Figure 3

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 point B on the patient's skin with a marker (Fig. 4).

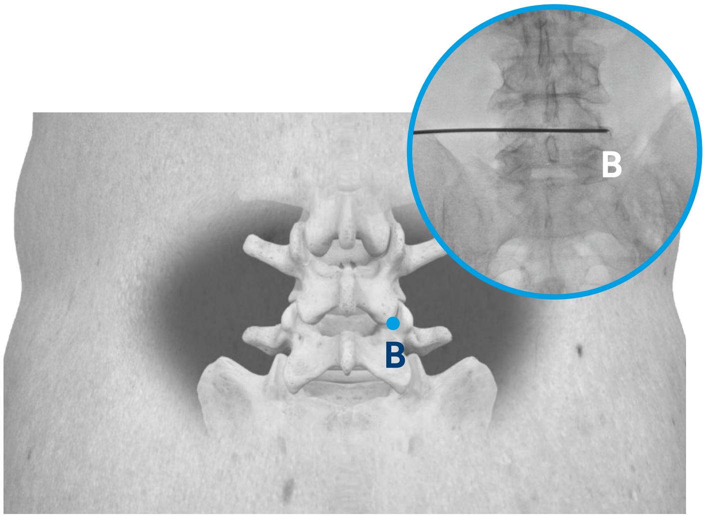


Figure 4

Place the Guide Pin flat on the patient's skin and mark the Guide Pin with the distance from point A to 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.

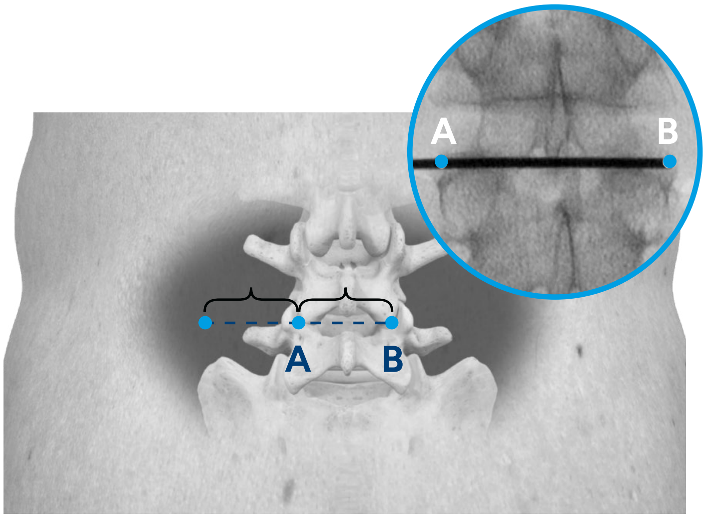


Figure 5

The desired trajectory for the OptiMesh Align XL and DCE Interbody implants will be steeper than a typical OptiLIF procedure. This places the implant more ventral, maximizing anterior height restoration.

In the standard OptiMesh OptiLIF procedure, after entering the disc space with the initial 4 mm Neuro Probe, the target on the ventral annulus is directly below the contralateral pedicle (Fig. 6).

In contrast, the optimal target for the OptiMesh Align OptiLIF procedure is just past midline of the ventral annulus (Fig. 7).

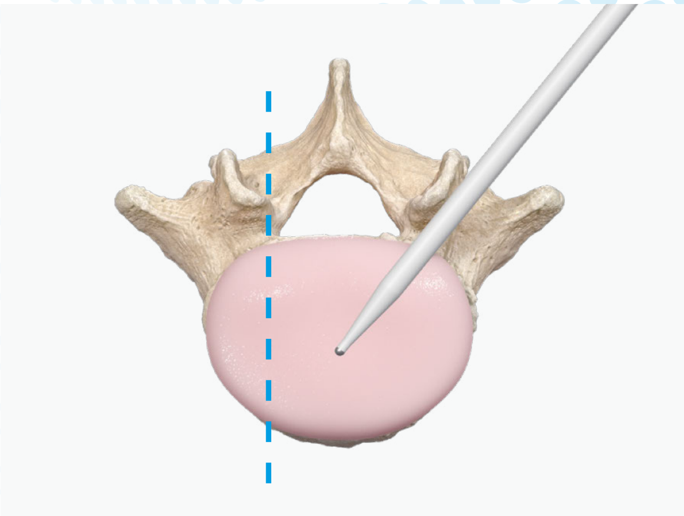


Figure 6: The OptiLIF procedure target is below the contralateral pedicle.

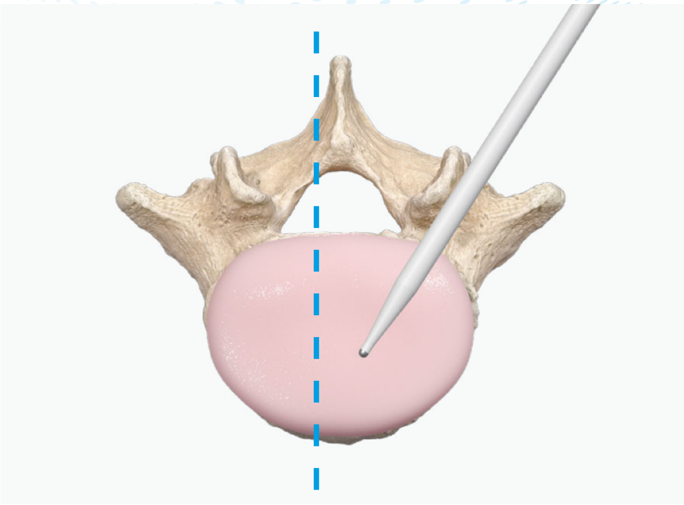


Figure 7: The OptiMesh Align OptiLIF procedure target is just past midline of the ventral annulus.

Access

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 8

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. 8).

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. 9), switch to lateral imaging.

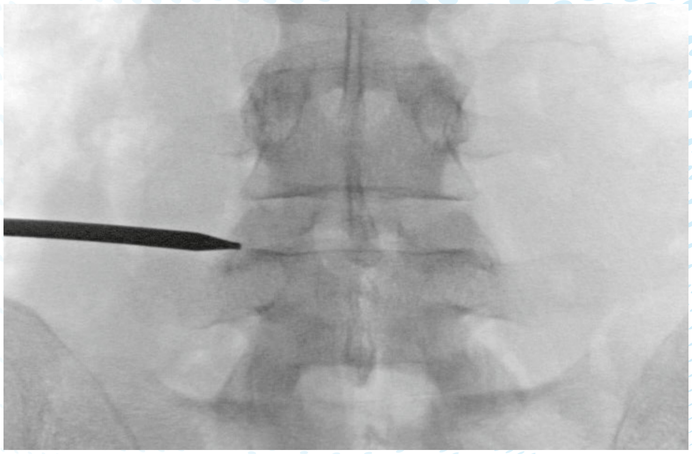


Figure 9

Access

4 mm Neuro Probe Insertion continued

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. 10). 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.

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.

Prior to advancing the Probe, raise the proximal end of the Probe to steepen the trajectory, which will enable the placement of the anterior portion of the implant more ventral. Using AP imaging, use the Mallet to advance the Probe to the medial wall of the pedicle
(Fig. 11).

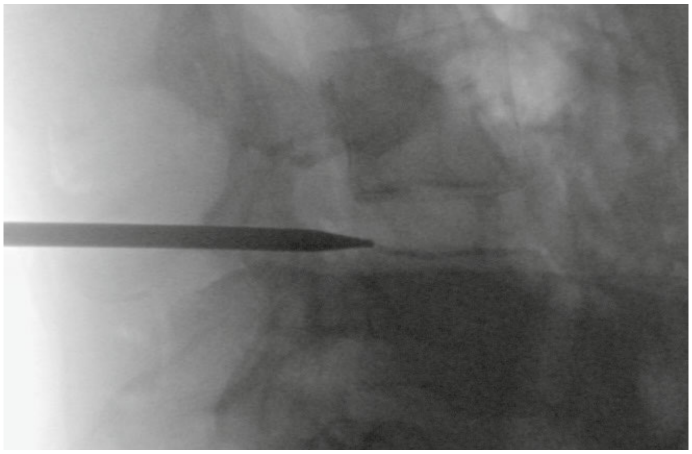


Figure 10

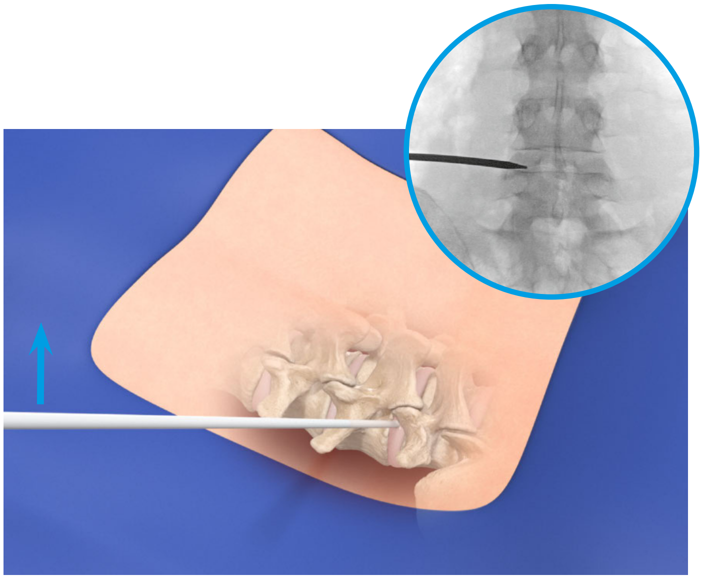


Figure 11: Raise proximal end of the Probe to steepen trajectory to position anterior portion of implant more ventral.

Switch to lateral imaging to confirm that the tip of the Probe has passed the posterior wall of the vertebral body (Fig. 12).

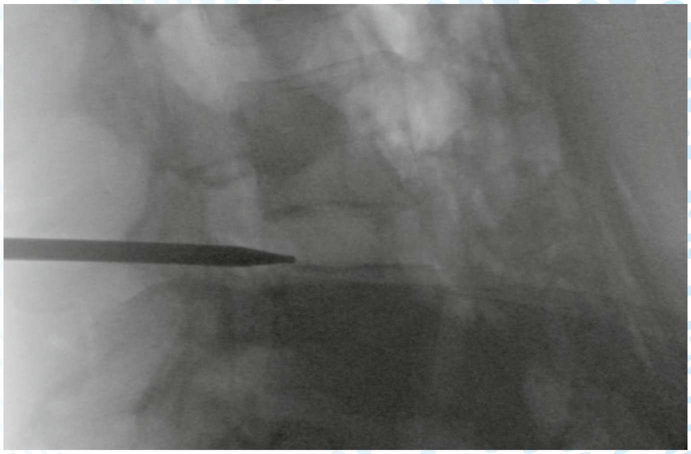


Figure 12

Remain in the lateral view and advance the Probe to the ventral annulus, or within 5 mm of the anterior border of the disc. (Fig. 13).

At this point, the distal tip of the Probe should be past midline, approximately inline with the contralateral border of the spinous process and short of the contralateral pedicle, as viewed on AP imagery (Fig. 14).

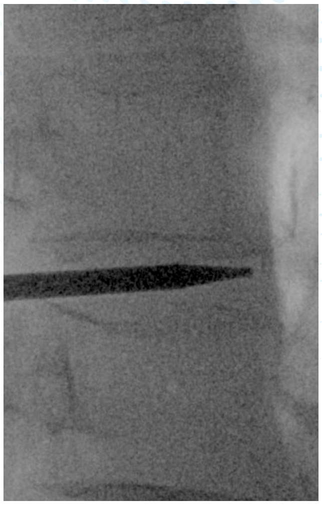


Figure 13

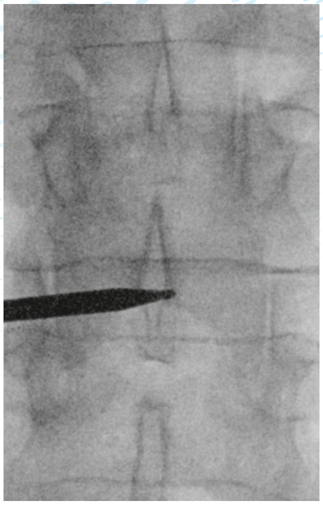


Figure 14

Access

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:

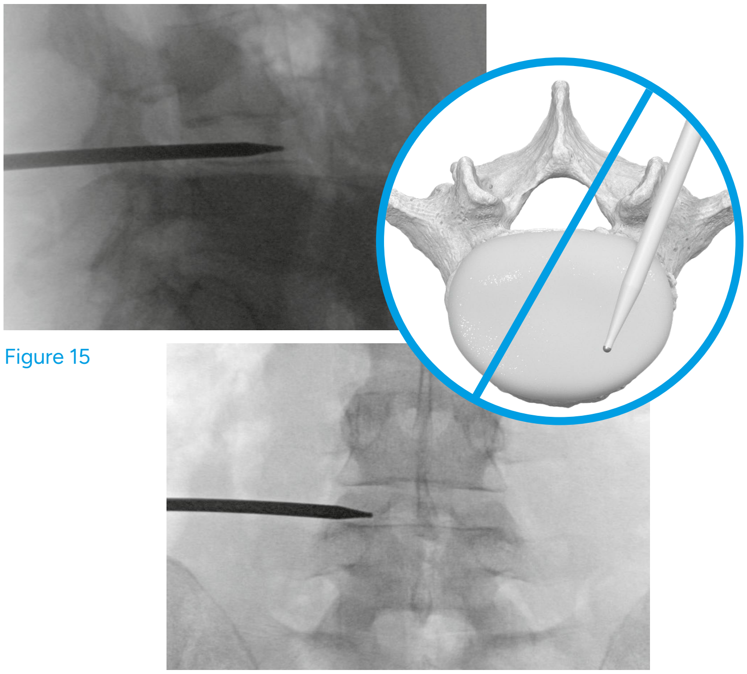


Figure 15

Trajectory is too steep (Fig. 15)

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.

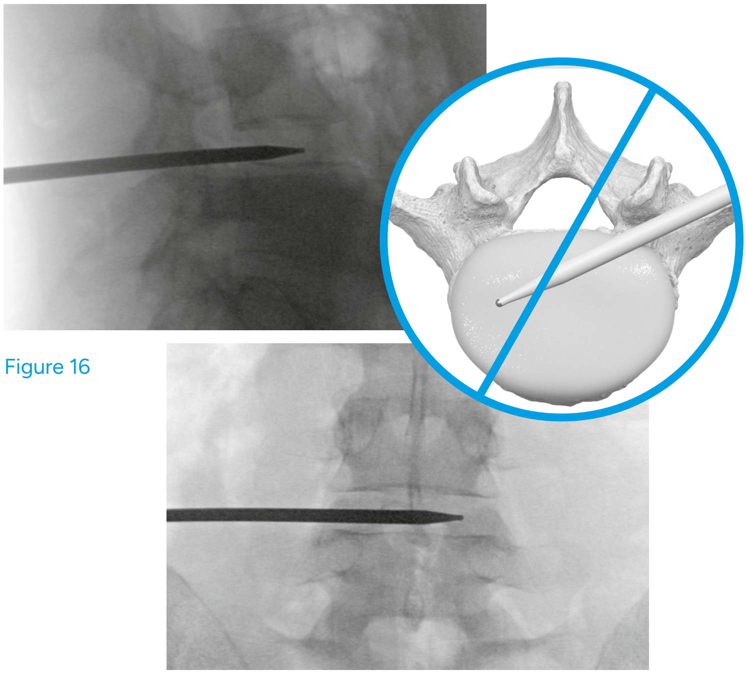


Figure 16

Trajectory is too flat (Fig. 16)

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.

Dilator Placement

Advance Dilator Two over the 4 mm Probe (Fig. 17).

Place the end of the Dilator Impactor labeled “2” over the Probe and using lateral imaging, impact with the Mallet to advance Dilator Two into the disc space. Stop advancement when the distal tip of Dilator Two is at the ventral annulus, or within 5 mm of the anterior border of the disc. (Fig. 18).

Note: During placement of Dilator Two, monitor the 4 mm Probe tip to ensure it does not advance beyond the ventral margin of the disc space.

Remove the Probe, leaving Dilator Two in position.

Note: Use the notches on the Dilator Impactor to assist with 4 mm Probe removal if necessary.

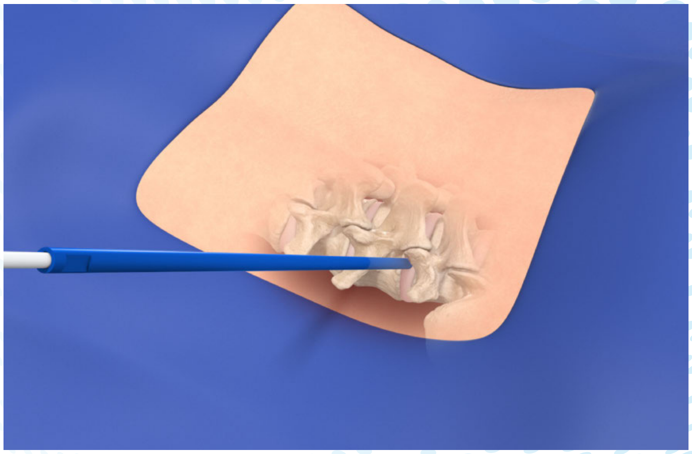


Figure 17

Figure 18

Access

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. 19).

Figure 19

Slide the Access Portal and QuikTrak assembly over Dilator Two (Fig. 20).

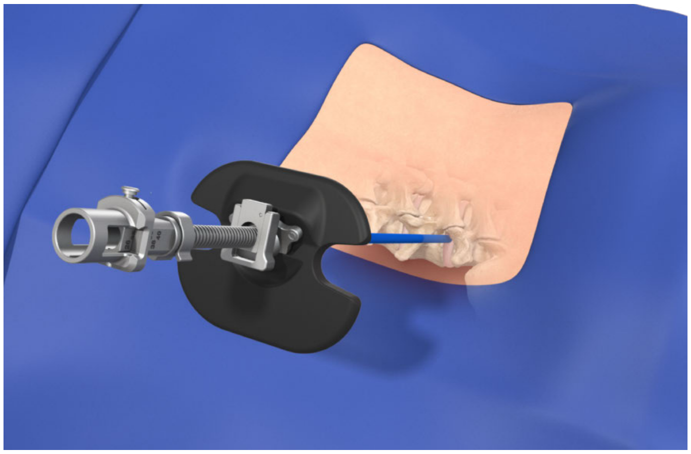


Figure 20

OptiMesh Align™ XL Sizing, Delivery, and Filling

OptiMesh Align XL Description

OptiMesh Align is uniquely differentiated as the only conforming expandable implant that offers one of the broadest expansion ranges in height, footprint, and lordotic shape available. OptiMesh Align provides independent control and expansion of the anterior and posterior components, while being delivered through one of the smallest insertion profiles possible.

Utilizing biologics-based expansion, OptiMesh Align offers real-time, in situ, independent anterior and posterior expansion, resulting in a customized lordotic shape, up to 20-degrees. This proprietary expansion method reduces mechanical limitations commonly seen with expandable implant technology, providing complete, real-time intraoperative control while conforming to each patient's unique anatomical requirements. OptiMesh Align produces distraction forces and conformance to the endplates, strength and stability to restore disc height, achieve alignment goals, and promote a robust fusion, and is designed for multiple posterior lumbar fusion approaches, including MIS, MIS-Open, Open, and Ultra-MIS (OptiLIF) lumbar interbody procedures, based on surgeon preference and patient needs.

The graft delivery occurs sequentially, starting with anterior graft delivery to produce significant distraction and establish ventral disc height. Posterior graft delivery occurs second, which locks anterior graft position, increases overall footprint and foraminal height, and maximizes indirect decompression.

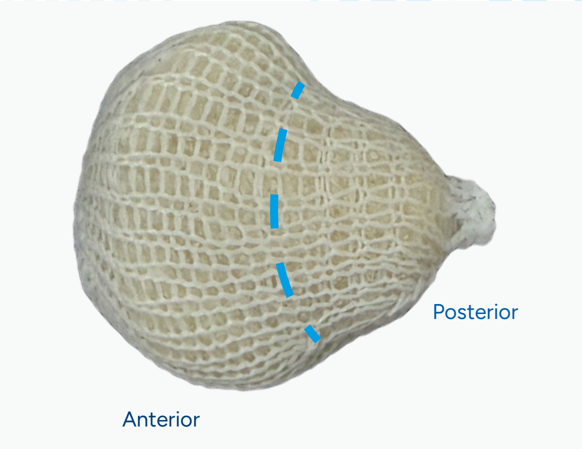


Figure 47

OptiMesh Align XL Implant Sizing

The OptiMesh Align XL interbody is offered in one size, with a length of 26 mm (Table 1). The minimum drill depth for OptiMesh Align XL is 26 mm.

Catalog #	Description
400-2625	OptiMesh Align™ XL Expandable Interbody

Table 1

OptiMesh Align XL Interbody (continued)

OptiMesh Align XL Interbody Delivery

The OptiMesh Align XL Interbody utilizes 3 instruments that are not in the standard OptiMesh instrument tray: the Lordotic Inserter, Posterior Tube Twister, and the Reduced Diameter Mesh Extender (Mesh Extender).

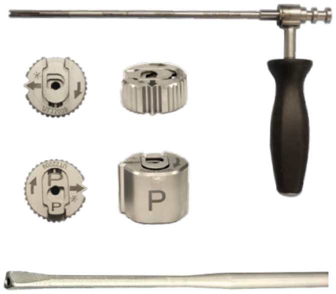
Note: The Tube Twister in the OptiMesh instrument tray will be referred to as the Anterior Tube Twister.

Lordotic Inserter

Anterior Tube Twister

Posterior Tube Twister

Align Mesh Extender



Load the OptiMesh Align XL Interbody into the Lordotic Inserter by pushing the crimped end of the implant onto the distal end of the Inserter aligning the dots (Fig. 45).

Note: If the OptiMesh Align XL Interbody is loaded into the Lordotic Inserter upside down, the distal fork on the Lordotic Inserter will sit proud (Fig. 46) and will not allow the implant to pass through the Access Portal.

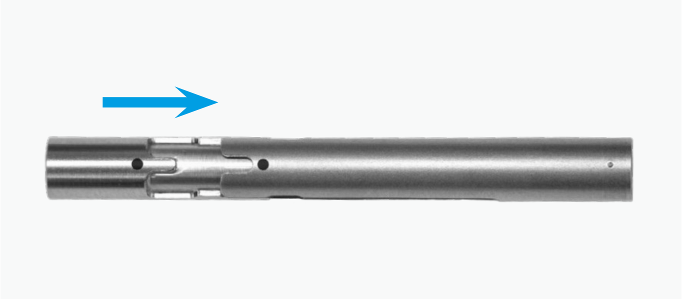


Figure 48

Figure 49: Image showing the Align implant loaded incorrectly, causing the distal fork to sit proud. This will not allow the implant pass through Access Portal.

OptiMesh Align XL Interbody Delivery

Prior to inserting the OptiMesh Align XL Interbody, if not done already, return the depth stop to the drilling depth established during original the initial discectomy.

Note: Unlike how the standard OptiMesh Inserter seats on the Access Portal, the Lordotic Inserter seats in the adjustable stop of the Access Portal. (Fig. 50) Therefore, the adjustable stop needs to be correctly set to the predetermined drill depth to ensure proper placement of the OptiMesh Align XL Interbody.

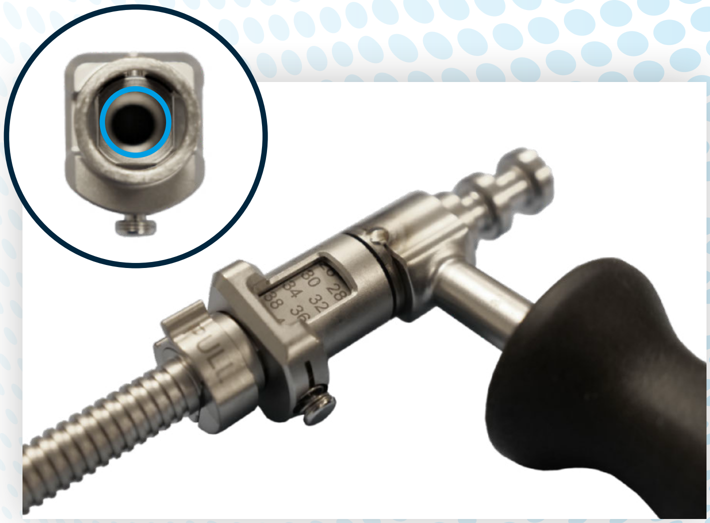


Figure 50: Top view of Depth Gauge: Lordotic Inserter seats into the inner ring and so therefore moves along with the Depth Gauge as it is being adjusted.

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

Caution: Do not apply excessive force to the Mesh Extender. Doing so may damage the OptiMesh Align XL Interbody, resulting in broken threads and possible loss of graft containment capability.

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

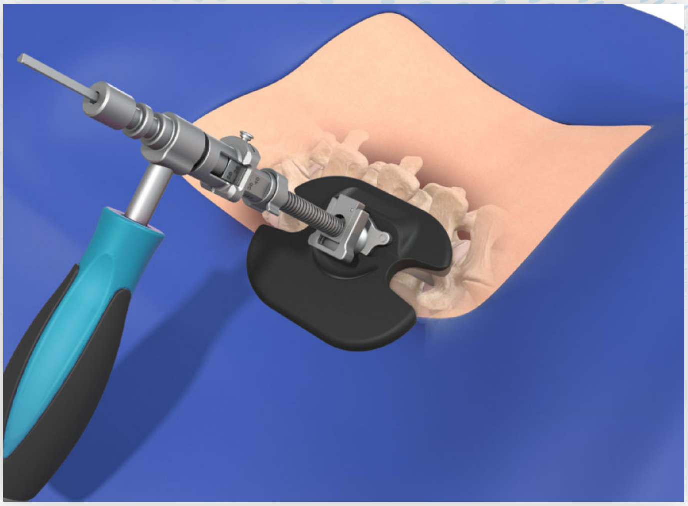


Figure 51

With the OptiMesh Align XL Interbody extended and gentle pressure on the Mesh Extender, place the Lordotic Inserter through the Access Portal.

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

Advance the Lordotic Inserter and Mesh Extender through the Access Portal until distal end of the Mesh Extender meets the ventral annulus. Cease advancement of the Mesh Extender and advance the Lordotic Inserter until it seats into the adjustable stop (Fig. 51).

Remove the Mesh Extender.

OptiMesh Align XL Interbody (continued)

OptiMesh Align XL Interbody Graft Delivery

The OptiMesh Align XL Interbody Implant is filled with compatible allograft and autograft.

Compatible allograft material includes Diverted Fill Tubes that come prefilled with cortical/cancellous bone chips and Demineralized Bone Matrix (DBM).

Each pre-filled Diverted Fill Tube contains 6 segments (2 cc) of bone graft material. (Fig. 52)

Refer to the filling Chart for recommended filling volumes (Table 2).

Figure 52

Catalog #	Description	Min. Total Segments	Max. Total Segments
400-2625	OptiMesh Align™ XL Expandable Interbody	13 (2 1/6 Tubes)	26 (4 2/6 Tubes)

Table 2

Note: It is not recommended that more than 8 segments are added during posterior graft delivery.

Anterior Graft Delivery

To begin the anterior graft delivery, pass a Diverted Bone Tube through the Anterior Tube Twister.

Press the button on the Tube Twister to fully seat the Diverted Bone Tube (Fig. 53).

Pass the Diverted Tube / Anterior Tube Twister assembly through the Lordotic Inserter and fully seat the Anterior Tube Twister onto the proximal end of the Inserter (Fig. 53).

Place the Push Rod into the proximal end of the Diverted Bone Tube. Impact the Push Rod with the Mallet and deliver the bone as you continually rotate your Anterior Tube Twister clockwise to ensure symmetric filling to all portions of the mesh's anterior chamber (Fig. 54).

Note: The diverted opening on the Bone Tube corresponds to the laser mark on the Tube Twister (Figs. 52 and 53).

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

When a Diverted Bone Tube is emptied, replace it with a full Diverted Bone Tube and continue the filling process.

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

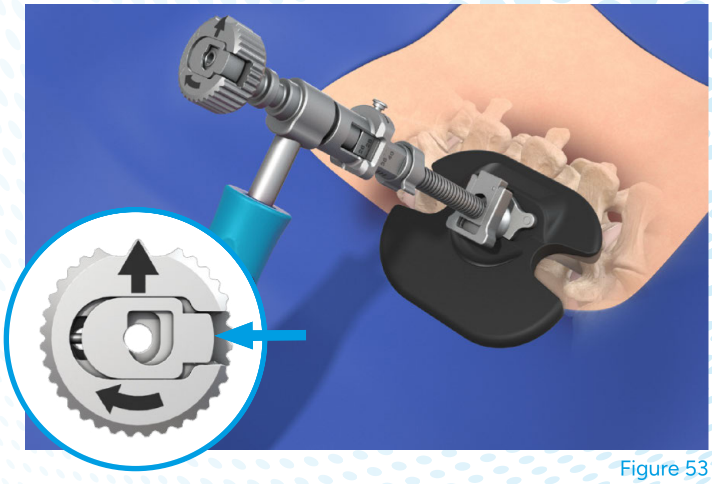


Figure 53

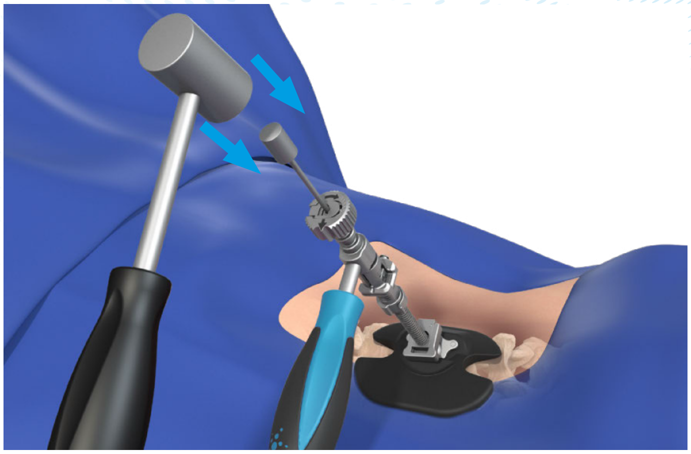


Figure 54

OptiMesh Align XL Interbody (continued)

OptiMesh Align XL Interbody Graft Delivery continued

Once the desired lordotic shape or maximum fill amount is reached per the Filling Chart (Table 2), closely observe the cues indicating OptiMesh Align XL Interbody is full:

Tactile

Mallet strikes meet resistance, resulting in less bone delivered into OptiMesh Align XL 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 desired lordotic shape (see Filling Chart, Table 2).

Note:

1. **The tactile, auditory, and visual cues indicate a full graft pack. This point may occur prior to inserting the maximum Bone Tube segments.**
2. **Using more than the maximum Bone Tube segments may result in thread damage and loss of graft containment capacity.**

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

3. Remove the Bone Tube from the Inserter
4. Place the Bone Tube through the hole in the Portal Impactor
5. 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.

OptiMesh Align XL Posterior Graft Delivery

To begin filling the posterior chamber, pass a Diverted Bone Tube through the Posterior Tube Twister. Pass the Diverted Tube / Posterior Tube Twister assembly through the Lordotic Inserter and fill the OptiMesh Align XL implant using the same process as described above, until the tactile, auditory, and visual cues indicate that the implant is fully filled.

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. When a Fill Tube is nearly empty, avoid impacting the Push Rod beyond the force necessary to expel the remaining graft; failure to do so may lead to damage to the adjustable depth stop of the Access Portal depth stop.

OptiMesh Align XL Interbody Release

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. 55).

Remove the Access Portal.

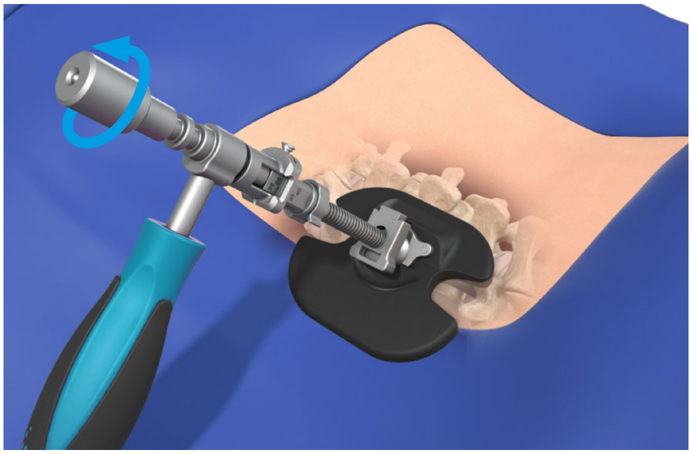


Figure 55

Note: Pedicle Screw Installation

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

Caution: Direct contact between pedicle screws and the filled OptiMesh Align XL Interbody 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 Align XL Interbody will be positioned.

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

OptiMesh Align DCE Interbody

OptiMesh Align DCE Interbody Description

The OptiMesh Align DCE Interbody is designed with asymmetrical dual chambers with the anterior chamber used for load bearing while the posterior chamber is used for load sharing with posterior supplemental fixation. The anterior chamber will be filled first to generate the lift and the posterior chamber will be filled afterwards. Due to the asymmetry of the two mesh chambers when filled, the implant is designed to result in a lordotic shape.

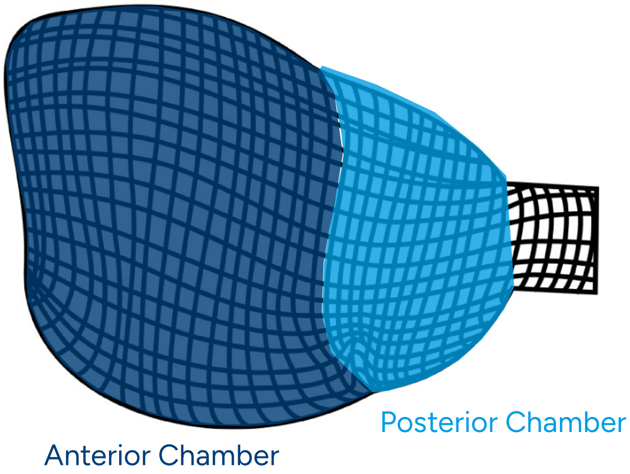


Figure 56

OptiMesh Align DCE Interbody Sizing

There are two OptiMesh Align DCE Interbody sizes available: Small and Large (Table 3). Both have a length of up to 26 mm. The implant chosen will be based off the surgeon's desired radiographic outcome.

OptiMesh Align DCE Interbody Selection	
Size	Implant Selection
Small	400-2610
Large	400-2620

Table 3

OptiMesh Align DCE Interbody (continued)

OptiMesh Align DCE Interbody Delivery

The OptiMesh Align DCE Interbody utilizes two new instruments that are not in the standard OptiMesh instrument tray: Lordotic Inserter and Posterior Tube Twister.

Note: The Tube Twister in the OptiMesh instrument tray will be referred to as the Anterior Tube Twister.

Load the OptiMesh Align DCE Interbody into the Lordotic Inserter by pushing the crimped end of the implant onto the distal end of the Inserter Aligning the dots (Fig. 57).

The OptiMesh Align DCE Interbody can only be inserted in one direction with the asymmetric curved portion of the mesh on the side of the Lordotic Inserter handle (Fig. 58). This will ensure the expanding portion of the implant faces the ventral annulus.

Note: Insertion of the OptiMesh Align DCE Interbody into the disc space is directional, meaning that with correct attachment of the implant to the Lordotic Inserter (Fig. 58), the handle of the Inserter should be pointed down to the floor when placing the implant into the Access Portal. This will ensure the expanding portion of the implant faces the ventral annulus.

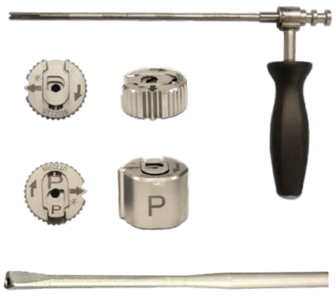
Note: If the OptiMesh Align DCE Interbody is loaded into the Lordotic Inserter upside down, the distal fork on the Lordotic Inserter will sit proud (Fig. 59) and will not allow the implant to pass through the Access Portal.

Lordotic Inserter

Anterior Tube Twister

Posterior Tube Twister

OptiMesh Align Mesh Extender



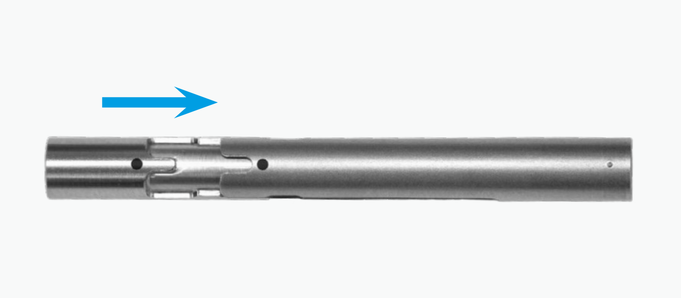


Figure 57

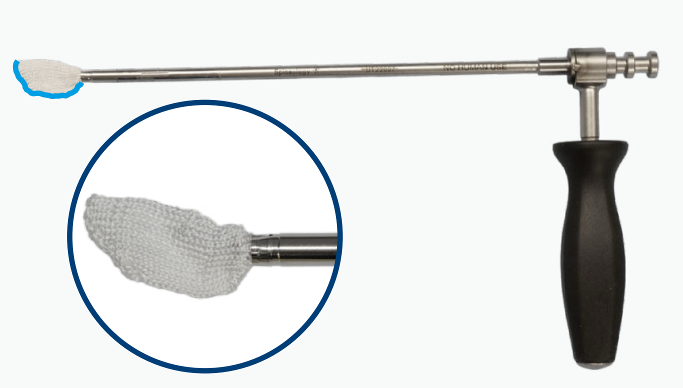


Figure 58: Asymmetric curved portion of mesh is on the same side as the Lordotic Inserter handle to ensure correct orientation during deployment.

Figure 59: Image showing the OptiMesh Align implant loaded incorrectly, causing the distal fork to sit proud. This will not allow the implant pass through Access Portal.

OptiMesh Align DCE Interbody Delivery (cont.)

Prior to inserting the OptiMesh Align DCE Interbody, if not done already, return the depth stop to the drilling depth established during original the initial discectomy.

Note: Unlike how the standard OptiMesh Inserter seats on the Access Portal, the Lordotic Inserter seats in the adjustable stop of the Access Portal. (Fig. 60) Therefore, the adjustable stop needs to be correctly set to the predetermined drill depth to ensure proper placement of the OptiMesh Align DCE Interbody.

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

Caution: Do not apply excessive force to the Mesh Extender. Doing so may damage the OptiMesh Align DCE Interbody, resulting in broken threads and possible loss of graft containment capability. Ensure the Mesh Extender is in the center of the OptiMesh Align DCE Interbody as seen in Figure 62.

With the OptiMesh Align DCE Interbody extended and gentle pressure on the Mesh Extender, place the Lordotic Inserter through the Access Portal.

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

Advance the Lordotic Inserter and Mesh Extender through the Access Portal until distal end of the Mesh Extender meets the ventral annulus. Cease advancement of the Mesh Extender and advance the Lordotic Inserter until it seats into the adjustable stop (Fig. 61).

Remove the Mesh Extender.

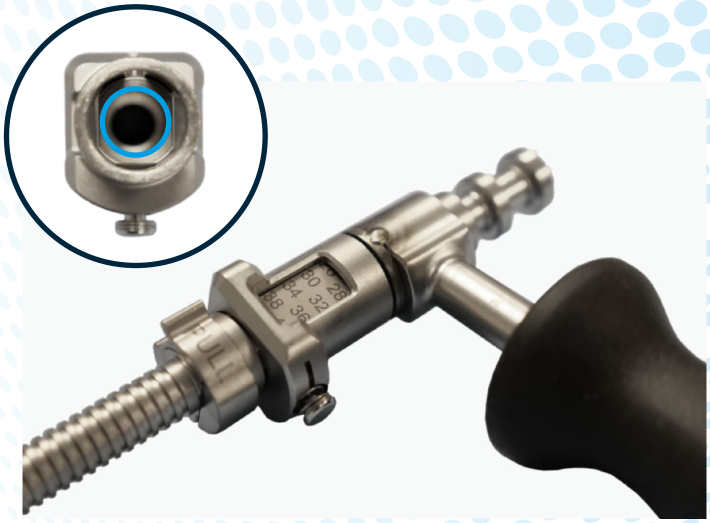


Figure 60: Top view of Depth Gauge: Lordotic Inserter seats into the inner ring and so therefore moves along with the Depth Gauge as it is being adjusted.

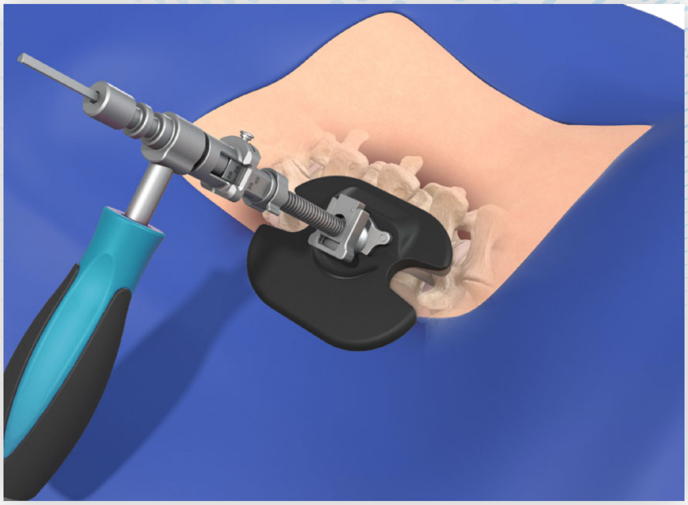
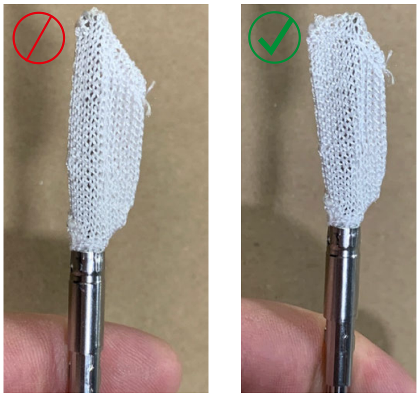


Figure 61



Incorrect   Correct

Figure 62

OptiMesh Align DCE Interbody (continued)

OptiMesh Align DCE Interbody Graft Delivery

The OptiMesh Align DCE Interbody Implant is filled with compatible allograft and autograft. Compatible allograft material includes Diverted Fill Tubes that come prefilled with cortical/ cancellous bone chips and Demineralized Bone Matrix (DBM).

Each pre-filled Diverted Fill Tube contains 6 segments (2 cc) of bone graft material. (Fig. 63)

Refer to the filling Chart for recommended filling volumes (Table 4).

Figure 63

Catalog #	Description	Minimum Anterior Chamber Tube Segments	Maximum Anterior Chamber Tube Segments	Maximum Posterior Chamber Tube Segments
400-2610	OptiMesh Align™ DCE, Small	8 (1 1/3 Fill Tubes)	12 (2 Fill Tubes)	2
400-2620	OptiMesh Align™ DCE, Large	10 (1 2/3 Fill Tubes)	18 (3 Fill Tubes)	2

Table 4

Anterior Graft Delivery

To deliver graft to the anterior chamber of the OptiMesh Align DCE implant, pass a Diverted Bone Tube through the Anterior Tube Twister. Press the button on the Tube Twister to fully seat the Diverted Bone Tube (Fig. 64).

Pass the Diverted Tube / Anterior Tube Twister assembly through the Lordotic Inserter and fully seat the Anterior Tube Twister onto the proximal end of the Inserter (Fig. 65).

Place the Push Rod into the proximal end of the Diverted Bone Tube. Impact the Push Rod with the Mallet and deliver the bone as you continually rotate your Anterior Tube Twister clockwise to ensure symmetric filling to all portions of the mesh's anterior chamber (Fig. 65).

Note: The diverted opening on the Bone Tube corresponds to the laser mark on the Tube Twister (Figs. 63 and 64).

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

When a Diverted Bone Tube is emptied, replace it with a full Diverted Bone Tube and continue the filling process.

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

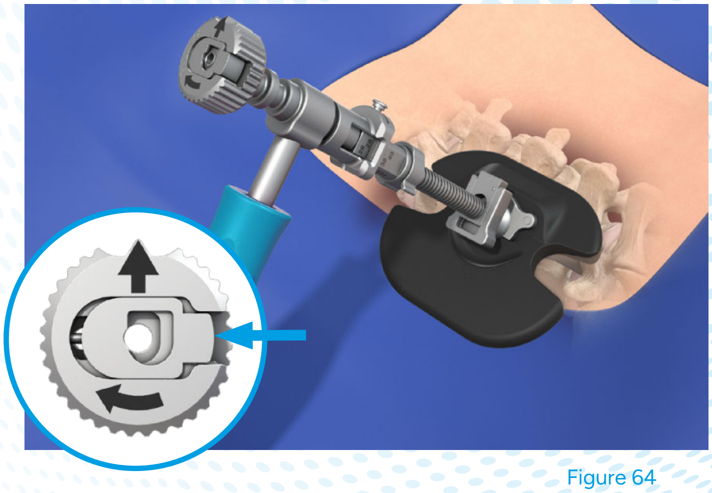


Figure 64

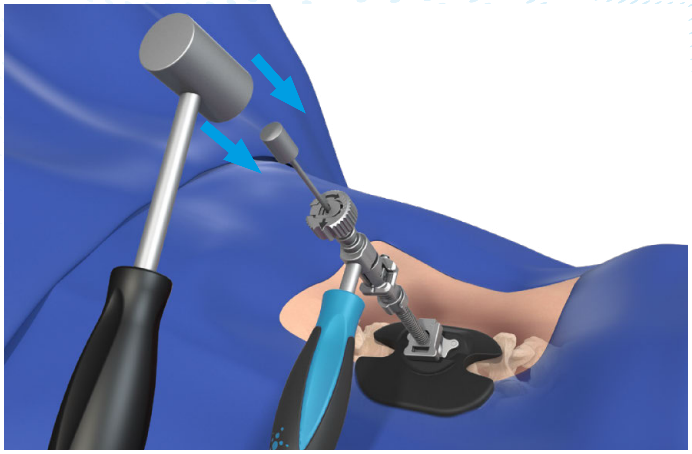


Figure 65

OptiMesh Align DCE Interbody Graft Delivery continued

Once the desired lordotic shape or maximum fill amount is reached per the Filling Chart (Table 4), closely observe the cues indicating OptiMesh Align DCE Interbody is full:

Tactile

Mallet strikes meet resistance, resulting in less bone delivered into OptiMesh Align DCE interbody 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 desired lordotic shape (see Filling Chart, Table 4).

Note:

1. **The tactile, auditory, and visual cues indicate a full graft pack. This point may occur prior to inserting the maximum Bone Tube segments.**
2. **Using more than the maximum Bone Tube segments may result in thread damage and loss of graft containment capacity.**

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

3. Remove the Bone Tube from the Inserter
4. Place the Bone Tube through the hole in the Portal Impactor
5. 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.

Posterior Chamber Filling

To begin the posterior chamber filling, pass a Diverted Bone Tube through the Posterior Tube Twister. Pass the Diverted Tube / Posterior Tube Twister assembly through the Lordotic Inserter and do the same steps as above until the OptiMesh Align DCE Interbody is properly filled.

OptiMesh Align DCE Interbody (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. When a Fill Tube is nearly empty, avoid impacting the Push Rod beyond the force necessary to expel the remaining graft; failure to do so may lead to damage of the Portal Head depth stop.

OptiMesh Align DCE Interbody Release

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. 66).

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 Align DCE Interbody, at the surgeon's preference.

Caution: Direct contact between pedicle screws and the filled OptiMesh Align DCE Interbody 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 Align DCE Interbody will be positioned.

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

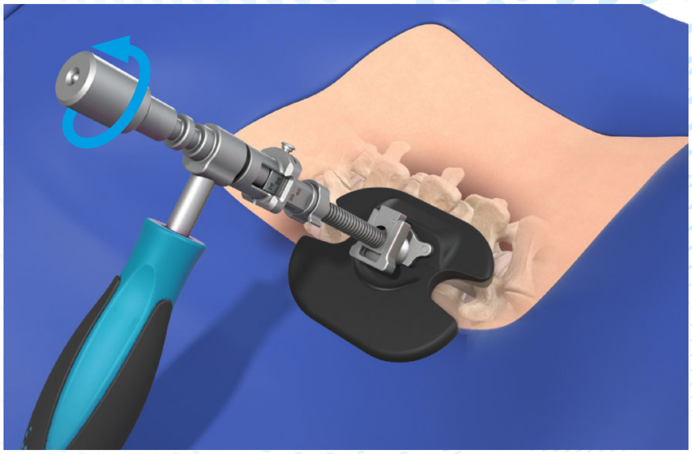


Figure 66

Minimally Invasive Surgery (MIS) Access OptiMesh Align Implantation

The OptiMesh Align Interbody 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 23 and 31 for the OptiMesh Align XL and DCE Interbody sizing, placement, filling, and release through the Access Portal when using the SOAR or Merlon Retractor Systems.

Open Access OptiMesh Align Interbody Implantation

Following a traditional open discectomy, OptiMesh Align Interbody 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. 67).

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

Figure 67

Appendix A:
OptiMesh® Expandable Interbody Fusion System & OptiMesh Align Interbody Instrument Set

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

Table Arm Case

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

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

OptiMesh Align Interbody Instrument Set

CATALOG #	DESCRIPTION
312-0061	Lordotic Inserter
312-0062	Posterior Tube Twister
312-0055	Reduced Diameter Mesh Extender

Unique Device Identification (UDI)

All Spineology devices are labeled with UDI. 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 human readable and Automatic Identification and Data Capture (AIDC) format.

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, the UDI of a device with catalog number 123-4567 will be 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 Align Interbody Removal

Intraoperative OptiMesh Align Interbody Removal/Revision

If removal of OptiMesh Align Interbody 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.

Note: The OptiMesh Align XL Interbody is double-stitched in the posterior one-third of the implant. Therefore, it may take additional time to remove the implant from the disc space due to the added material.

If revision with a new OptiMesh Align Interbody is desired, size for a new implant per the sizing instructions on pages 23 and 31 for the OptiMesh Align XL and DCE Interbody sizing, placement, filling, and release, respectively.

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 Align Interbody 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:
OptiMesh Align™ Ordering Information

Catalog #	Description
400-2625	OptiMesh Align™ XL Expandable Interbody
400-2610	OptiMesh Align™ DCE Interbody, Small
400-2620	OptiMesh Align™ DCE Interbody, Large

Spineology Inc.
7800 Third Street North, Suite 600
Saint Paul, MN 55128-5455
p: 888.377.4633 or 651.256.8500
f: 651.256.8505

spineology.com

OptiMesh Align™

Expand. Conform. Align.

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

The OptiMesh Align™ 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 Align Interbody 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 (10-15-54).