

# OptiMesh® 1500E

Percutaneous Interbody Fusion Surgical Technique

**Spineology®** 

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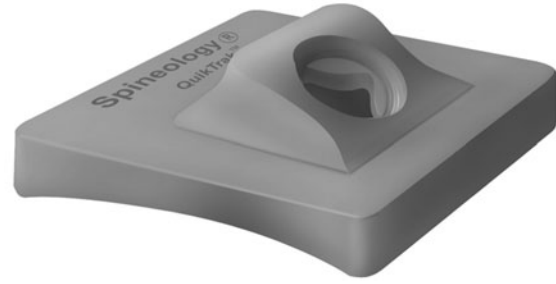
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## A Note to Physicians

As with any percutaneous spinal procedure, proper imaging and interpretation of the images are critical to safety. This technique manual describes the parameters for instrument trajectory selection, but does not purport to teach radiographic image interpretation. These instructions are intended as an outline for the use of the OptiMesh® System for physicians experienced in interpreting biplanar fluoroscopic images of the lumbar spine and experienced in image-guided instrument placement.

# Instruments

311-0087 QuikTrak Base Plate



311-0096 Portal Sleeve & 311-0097 Ball, QuikTrak



QuikTrak Stems **NOT PICTURED**

- 311-0091 Stem #0
- 311-0081 Stem #1
- 311-0082 Stem #2
- 311-0083 Stem #3

311-0038 Guide Pin, Tri cut end, 2.4mm Dia. X 39.4cm long (2)



311-0099 Guide Pin, Tri cut end, 2.4mm Dia. X 50.8cm long (disposable) **NOT PICTURED**

311-0079 Extended Guide Pin, Blunt ends, 2.4mm Dia. X 50.8cm long (disposable)



315-0007 Sequential Dilator Impaction Cap



315-0008 4.5mm Sequential Dilator, disposable (gold)



315-0009 6.5mm Sequential Dilator, disposable (blue)



311-0077 E Drilling Dilator Handle



311-0084 E Drilling Dilator



311-0046 Extractor



301-0140 Impactor



311-0089 Access Portal



311-0019 Drill, 6.5mm



Shaper Assembly

- 311-0041 6.5mm Blade Set
- 311-0042 6.5mm Shaper
- 301-0101 Blade Control Knob
- 301-0055 Drive Knob

311-0100 6.5mm BackHoe™ Articulating Curette



311-0098 Pituitary Rongeur



311-0102 Suction Tube



311-0030 Suction Tube **NOT PICTURED**

311-0088 E Locking Mesh Holder



311-0043 E Mesh Extender



301-0021 Push Rod



301-0013 Mallet



311-0047 Lock Tube Puller



## How the Mesh Works

The OptiMesh 1500E implants are conformable porous three-dimensional mesh pouches knitted with Polyethylene Terephthalate (PET) thread. Each mesh includes a main body, designed to be filled with granular bone graft, and a neck through which the bone is inserted. The mesh enables the formation of a graft pack by providing containment of granular graft and the 1500 micron nominal pore size permits new bone growth and graft incorporation through the mesh pores.

OptiMesh 1500E meshes are available in four sizes:

Part Number	Maximum Body Dimensions (Height x Length)	Neck Length
330-1805	15mm x 18mm	5mm
330-2005	17mm x 20mm	5mm
330-2205	19mm x 22mm	5mm
330-2505	20mm x 25mm	5mm

OptiMesh 1500E series implants are preassembled on a disposable metal tip that eases intraoperative handling and filling of the mesh. Each metal tip consists of two concentric cylinders: a lock tube and a crimp tube. The neck of the mesh is firmly secured between these two cylinders by a crimping process. The metal components are removed after the mesh has been filled.

## Patient Preparation and Positioning

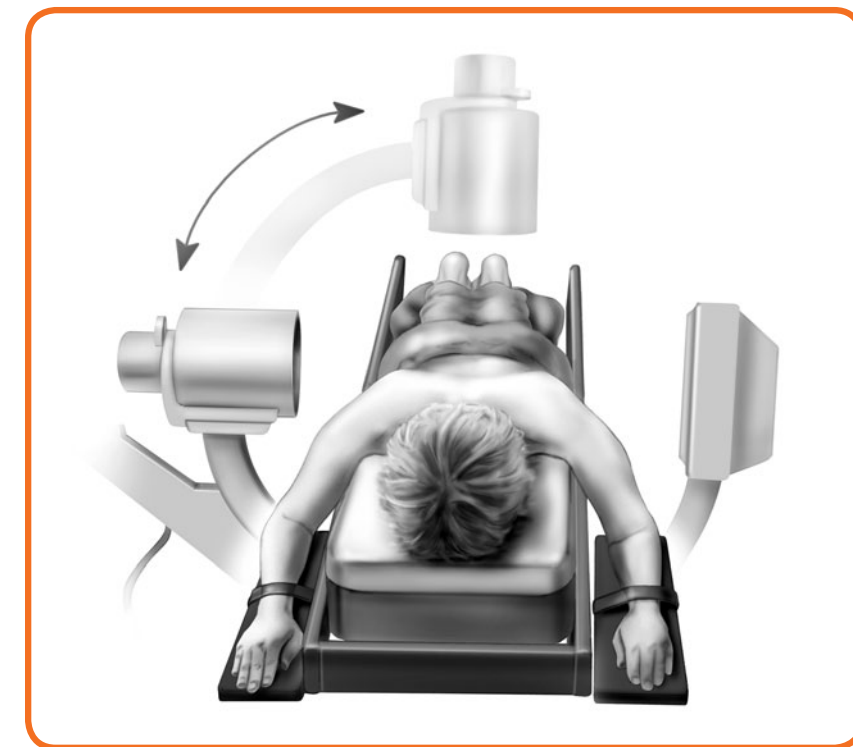
For percutaneous interbody fusion with the OptiMesh system, place the patient in a prone position on a radiolucent table. Anesthetize the patient appropriately but do not use any paralytic agents as these will interfere with Electromyography (EMG) monitoring of the nerve roots.

Prior to surgery, the following recommendations should be followed:

- Administer a broad spectrum prophylactic antibiotic.
- Frequent lateral and anterior/posterior (AP) imaging is required for this procedure to track instrument and implant location. If biplane imaging is not being used,

swing the C-arm under the table to ensure that no obstructions are present at the pathologic level in either AP or lateral views.

- EMG with appropriate monitoring is required to track motor and sensory responses during pin and portal placement. Place appropriate leads to ensure tracking of the nerve roots exiting at, and inferior to, the target implantation level.
- Using the image intensifier, identify the pathologic level.
- Prep and drape the patient and C-arm image intensifier accordingly.



# Guide Pin Insertion

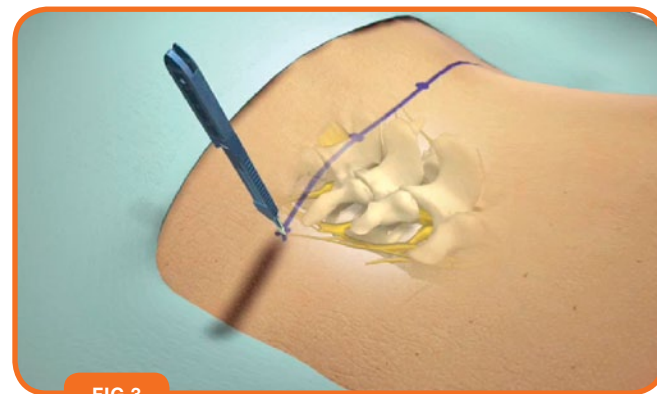
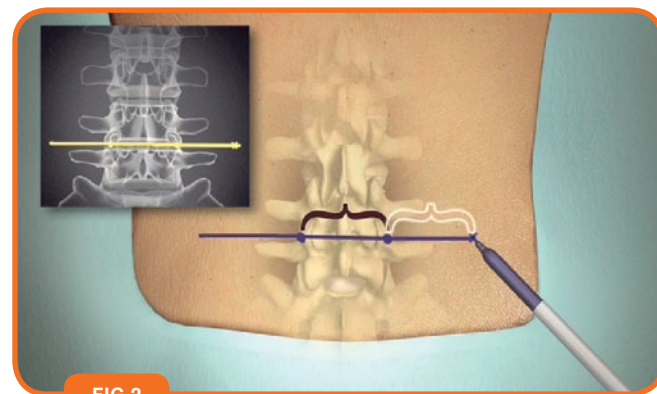
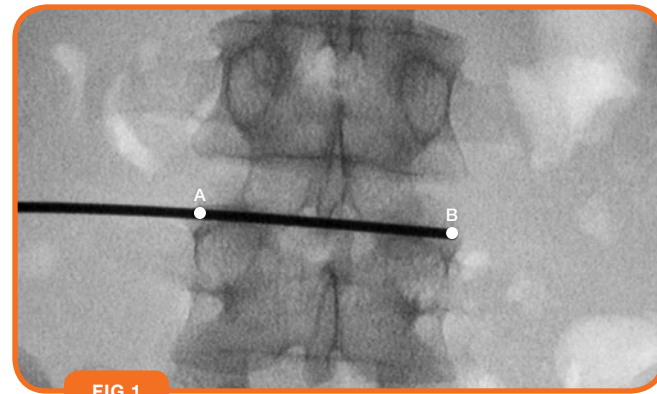
To begin, orient the image intensifier for AP imaging and align it with the spine such that a “true” image coplanar with the inferior endplate of the target disc can be obtained. Using AP imaging, orient the Guide Pin on the skin, such that the tip is located at the junction of the ipsilateral border of the spine and the inferior endplate of the target disc (**FIG. 1, POINT A**).

Mark the point on the skin with marker (**FIG. 1, POINT A**). Re-orient the Guide Pin such that the tip is in an analogous location on the contralateral side and mark the point on the skin with a marker (**FIG. 1, POINT B**). Draw a line that connects the two points and extends well lateral of each marking (**FIG. 2**). This line indicates the implantation trajectory plane.

Measure the distance between the points, and transpose this dimension laterally along the line in both directions from the previously marked locations. Mark these lateral locations. The second set of marks indicates the approximate bilateral incision locations (**FIG. 2**).

**Note:** These marks are for approximation and reference only. The incision’s distance from midline is dependent on patient size and the level of the pathology. The larger the patient and/or the lower the level, the further from midline the incision will likely need to be (example: at L4-5 in a heavy patient, the incision location may need to be an additional 50% further lateral).

Incise the skin at one of these lateral locations (**FIG. 3**).



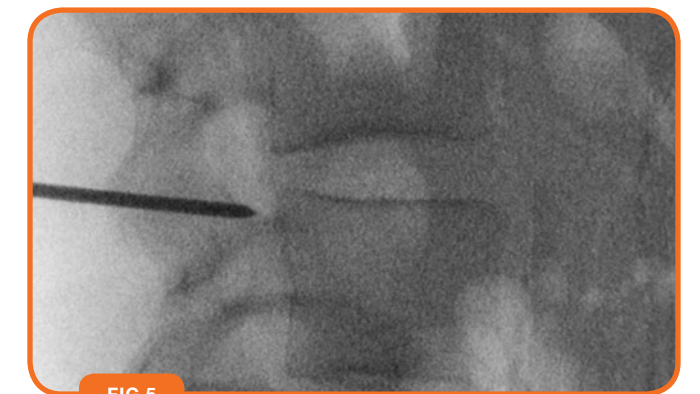
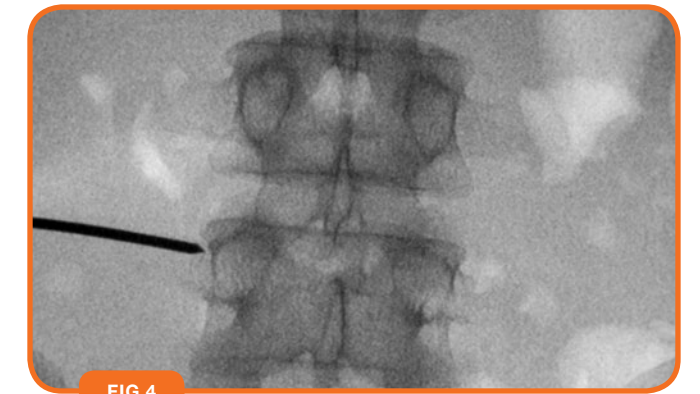
Using frequent AP image guidance, insert and advance the Guide Pin while targeting the lateral wall of the pedicle immediately inferior to the target disc. This trajectory is intended to prevent inadvertent transgression of the foramen and canal. Additionally, utilize a relatively flat posterior to anterior angle to mitigate too ventral a trajectory. Initial bony contact should be with the pedicle or a posterior spinal element. When contact is made, the Guide Pin tip should appear to be on the superior lateral wall of the pedicle immediately inferior to the target disc (**FIG. 4**).

**Note:** If active EMG neuromonitoring is desired, please refer to Spineology Document L148 ProMap EMG Navigation Probe for specific technical guidance.

If this image is not seen, withdraw the Guide Pin slightly, adjust the trajectory, and reinsert. Repeat this process until the tip appears to be on the superior lateral margin of the pedicle.

**Caution:** If during Guide Pin placement, or at any time during the procedure, EMG indicates that prolonged or unexplained neural irritation is present, alter instrument position until the signal clears, or cease the procedure and revert to open placement.

If simultaneous biplane imaging is not being utilized, orient the image intensifier to provide lateral imagery. With lateral imaging, inspect the location of the Guide Pin tip. The objective is to place the tip at the superior edge of pedicle slightly posterior to the junction of the pedicle and vertebral body (**FIG. 5**).



## Guide Pin Insertion, continued

If the tip is not seen at this location, withdraw the Guide Pin slightly, adjust the angle of entry, and carefully reinsert the pin with frequent imaging until the Guide Pin appears in the desired position on lateral imaging.

Re-orient the image intensifier for AP imaging. Slide the Guide Pin tip superiorly and medially along the base of the pedicle until it appears to be on the disc immediately superior to the pedicle, approximately equidistant between the medial and lateral margins, and near the superior endplate of the vertebra (inferior endplate of the target disc) (FIG. 6).

**Caution:** Until subsequent lateral imaging confirms that the Guide Pin tip is safely at or beyond the posterior margin of the disc, the Guide Pin tip should not cross a cephalocaudad reference line defined by the medial borders of the pedicles. This reference line represents the lateral boundary of the spinal canal.

**Note:** The exiting nerve root occupies the superior portion of the foramen. Guide Pin placement into the disc should therefore be as inferior as possible within the foramen. The Guide Pin does not need to be centered on the disc, as subsequent dilation instruments will gradually align the instruments into the center of the disc and gently move the exiting root as the space is distracted.

Re-orient again for lateral imaging and confirm that the Guide Pin tip is on the posterior margin of the disc (FIG. 7).

**Caution:** If the Guide Pin tip is not on the posterior margin of the disc, do not advance it to make it so. This could cause unintended transgression of the lateral margin of the canal.

If the lateral image shows appropriate Guide Pin tip position, revert back to AP imaging and advance the Guide Pin until the tip is observed to be at the lateral margin of the canal (medial borders of the pedicles) (FIG. 8).

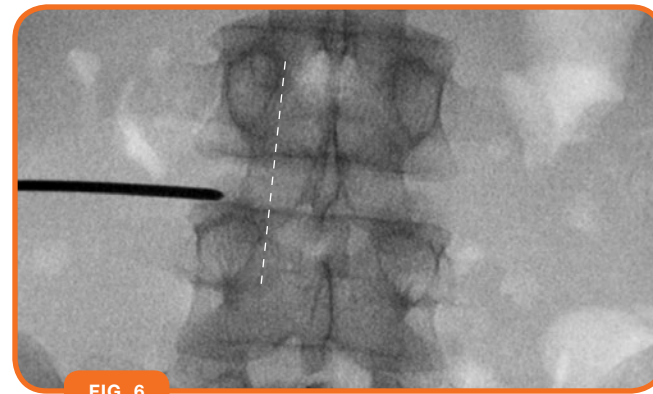


FIG. 6

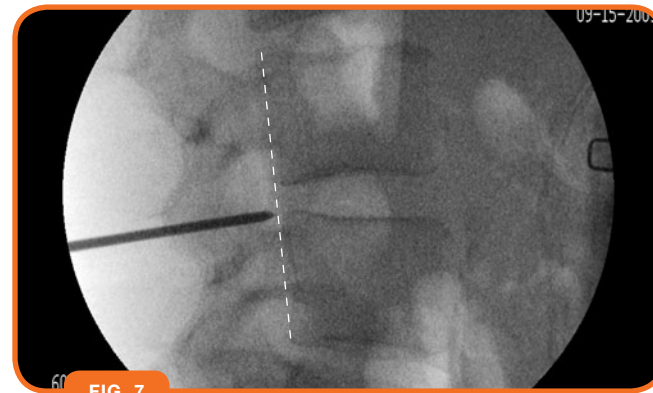


FIG. 7

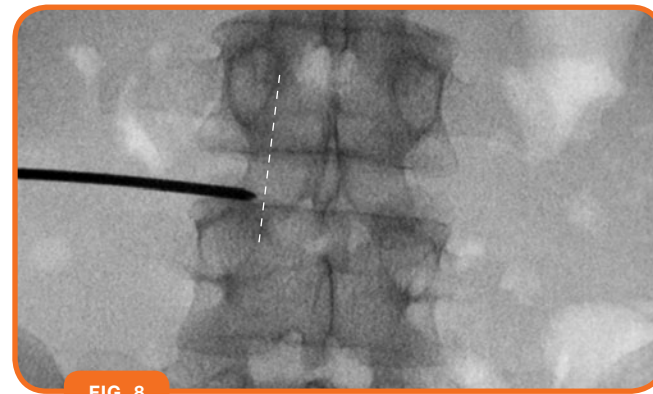


FIG. 8

Revert to lateral imaging. If the Guide Pin tip is now seen to be anterior to the posterior margin of the disc (FIG. 9), the procedure can continue.

While continuing to use lateral imaging, advance the Guide Pin into the disc until the tip appears to be at the midpoint of the disc (FIG. 10).

Re-orient the image intensifier to an AP position and image. If the trajectory is as recommended, the Guide Pin tip will appear to be in the midline on the AP image as well (FIG. 11).

If the trajectory is too flat/lateral (pin tip across midline) or too steep/medial (pin tip is not yet to midline), adjust the Guide Pin trajectory accordingly.

**Note:** Failure to achieve the intended trajectory will result in mesh and graft placement that is either anterior and lateral (angle too steep) or posterior and lateral (angle too flat).

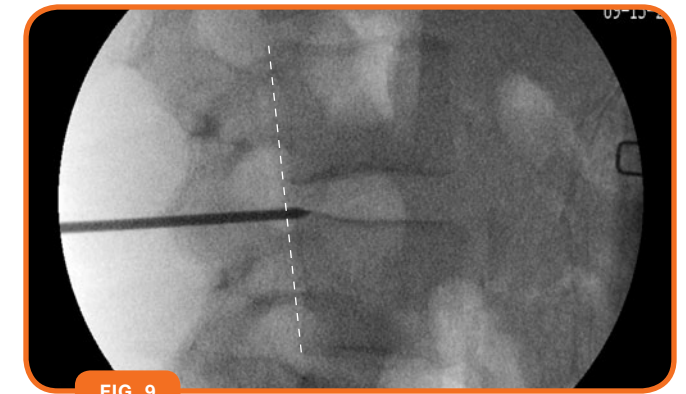


FIG. 9

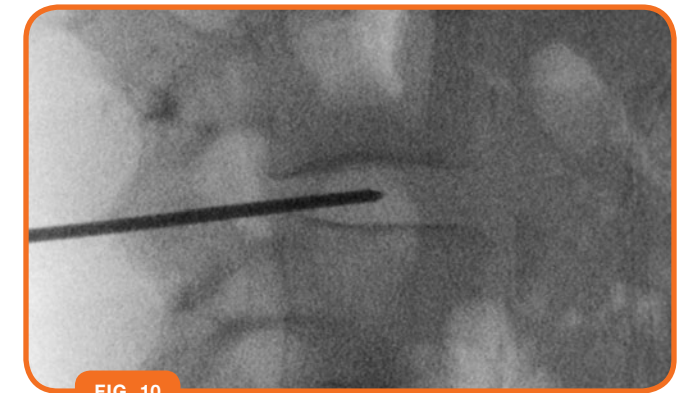


FIG. 10

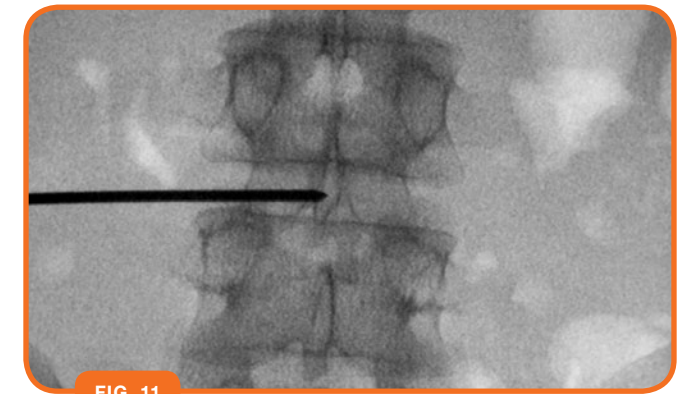


FIG. 11

## Sequential Dilator Insertion

**Note:** For an alternate Dilator method, please refer to Appendix C.

Using lateral imaging, advance the first Dilator (gold) over the Guide Pin (FIG. 12). Place the impaction cap over the pin (gold band of impaction cap against gold Dilator) and tap the Dilator into the disc space with the Mallet while observing advancement with lateral imaging. Stop advancing once the tapered portion of the Dilator is in the disc.

**Caution:** Closely monitor the Guide Pin tip to ensure it does not advance beyond the anterior spinal margin.

Remove the Guide Pin.

Place the second Dilator (blue) over the first and repeat the impaction in a like fashion (with blue band on impaction cap against blue Dilator). Cease advancement when the Dilator nears the anterior annulus (FIG. 13).

Remove the inner Dilator.

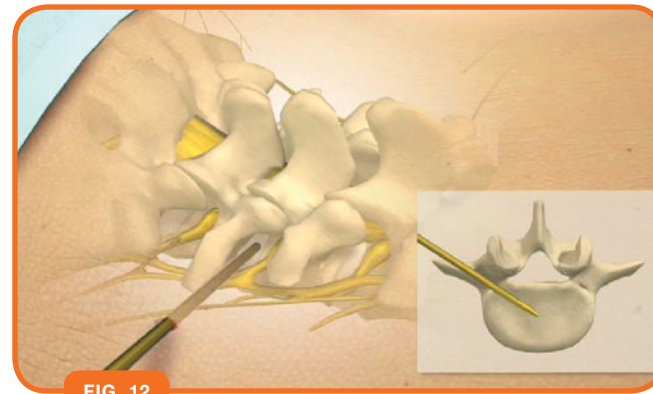


FIG. 12

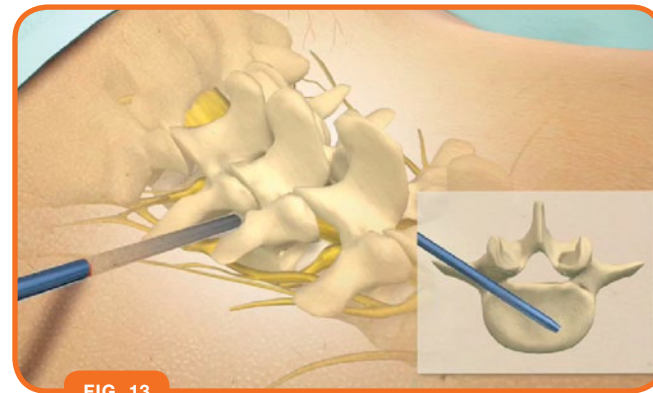


FIG. 13

## QuikTrak Assembly

Assemble the QuikTrak by snapping the adjustment Ball into the Base Plate and then depress the lock button on the adjustment Ball to allow the Stem to be placed into the Ball. Set the Stem at its shallowest setting.

Place the QuikTrak assembly over the Dilator and slide it down until the Base Plate contacts the patient (FIG. 14).

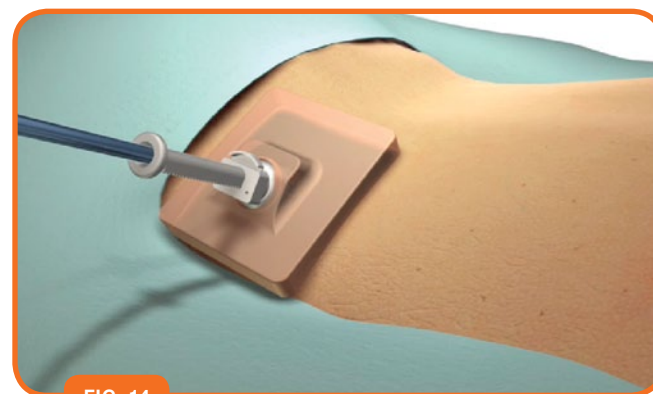


FIG. 14

## Access Portal Placement

Slide the Access Portal over the Dilator and through the Stem until the shoulder on the Access Portal abuts the top of the Stem.

Place the Impactor over the Dilator and against the top of the portal. Depress the lock button on the adjustment ball and tap on the Impactor with the Mallet, while continually imaging, until the Access Portal tip advances approximately 5mm into the disc (FIG. 15).

**Note:** In the event that the QuikTrak Stem proves to be too long (morbidly obese patient), the Bullseye force dissipation set will need to be used to provide adequate instrument working length (see Appendix C).

**Caution:** The Stem adjustable stop provides depth control for the Access Portal. Failure to adjust the Stem adjustable stop may result in anterior movement of the Access Portal.

Hold the Access Portal firmly in place and remove the Impactor and Dilator. If the Drilling Dilator is difficult to remove, connect the Drilling Dilator Handle and remove.

**Caution:** Once the Access Portal is in place, it is important to note that the QuikTrak will resist anterior movement. However, the Access Portal must be firmly held in place when instruments are extracted to prevent dislodgement of the Access Portal tip from the disc.

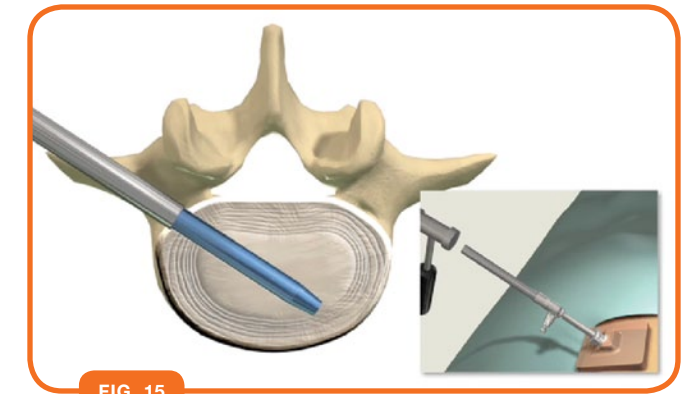


FIG. 15

## Drilling

Set the Access Portal adjustable stop to the minimum depth setting of 24mm (the most proximal position). Pass the Drill through the Access Portal and begin drilling while monitoring progress using lateral imagery. Advance the Drill until contact is made with the positive stop or the tip of the Drill appears to traverse approximately  $\frac{3}{4}$  of the way across the disc, whichever is achieved first (FIG. 16).

In the event deeper drilling is required, press the tab on the positive stop of the Access Portal to disconnect the lock. Adjust the stop down to permit deeper drilling and advance the Drill. Repeat this process incrementally until the target depth is achieved.

Alter the image intensifier to provide an AP image and inspect to see if the Drill has crossed midline (FIG. 17).

If it has, alter the Image intensifier to an oblique position so that the drilling depth can be accurately monitored, and advance the Drill to within 3-5 mm of the anterior margin of the spine (FIGS. 18A & B).

**Caution:** Oblique imagery should only be used after an AP image indicates the Drill has crossed midline.

When the desired depth is achieved, the final drilling depth can be read immediately below the positive stop collar. Make note of this depth as it is required for selecting an implant size.

Hold the Access Portal firmly in place and remove the Drill.

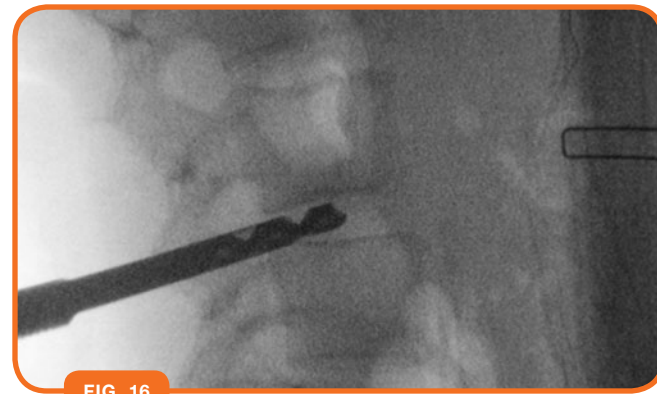


FIG. 16



FIG. 17



FIG. 18A

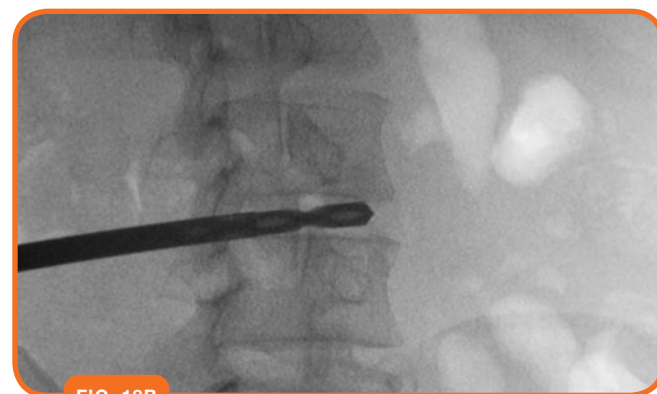


FIG. 18B

## Discectomy

The Shaper is used to facilitate discectomy and decortication of the central portion of the disc space. Assembly instructions for the Shaper are in Appendix A.

Pass the Shaper through the Access Portal until the Shaper body contacts the Access Portal positive stop (FIG. 19).

**Note:** Shaping should always be observed with lateral or oblique imagery to monitor Access Portal tip location, depth of instrument insertion, and amount of decortication.

To begin removal of the disc and preparation of the endplates, expand the Shaper blades by turning the Blade Control Knob, located on the top of the Shaper, clockwise  $\frac{1}{4}$  turn, then rotate the entire instrument clockwise to cut tissue.

**Note:** Do not rotate the Shaper counterclockwise. This can cause damage to the Shaper blades and will loosen the Drive Knob.

Hold the Access Portal firmly to ensure the tip remains seated in the disc and move the Shaper back and forth along the insertion trajectory, while continuing to rotate the instrument, from the tip of the Access Portal to the anterior aspect of the spine. Repeat this process until the desired decortication, approximately 2mm per endplate, is complete along the trajectory (FIG. 20).

**Note:** Do not rotate the Shaper against the distal tip of the Access Portal. This can distort the tip of the Access Portal and may make later insertion and removal difficult.

**Note:** If there are concerns about cortical endplate integrity (for example, osteopenic bone), use the Shaper to break through the subchondral bone of the endplates only at the center of the disc. This step is critical in order to supply adequate vascular access from the endplates to the graft.

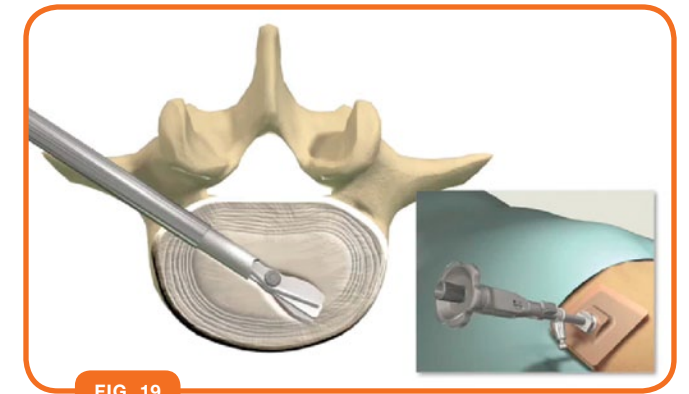


FIG. 19

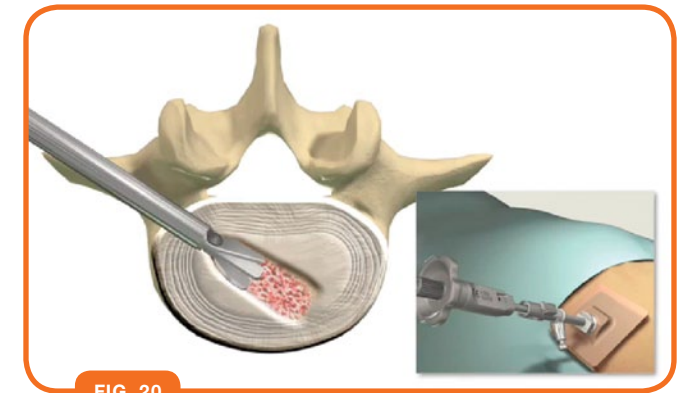


FIG. 20

## Discectomy, continued

To remove the Shaper, rotate the Blade Control Knob counterclockwise to relax the blades, hold the Access Portal firmly and extract the instrument.

The Shaper will cut disc and decorticate endplate, but it does not remove tissue. To remove tissue, irrigate the disc space through the Access Portal, and alternate use of the large bore suction tip and Pituitary Rongeur.

**Note:** During discectomy and decortication, it is important that tissue be “shaved” from the endplate. Opening the Shaper too fast, more than a ¼ turn of the Blade Control Knob at a time, can cause the excision of disc fragments that are too large to easily remove through the Access Portal.

After the Shaper has cleared the disc centrum the BackHoe Curette is used to clear the lateral recesses of the disc.

Set the positive stop on the Access Portal to the shallowest setting (24mm). Slide the BackHoe through the Access Portal until it contacts the positive stop.

**Note:** The hub on the BackHoe should always be in contact with the positive stop on the Access Portal while in use. If it is not, the cuts may be incomplete.

**Caution:** Whenever the BackHoe is activated in a new location, x-ray should be used to ensure the tip remains confined within the borders of the disc throughout the full stroke of the cut.

Align the curette tip parallel to the endplates and squeeze the handle. Repeatedly squeeze it until a clean cut is made (no clutch “popping”) (FIG. 21).

If the clutch “pops”, slow the squeeze rate or alter the angle of the curette blade slightly to a new spot as this is an indication that too large a “bite” is being taken.

**Note:** If the clutch continues to pop, reinsert the E Shaper at a slightly different angle in order to broaden the cavity prior to using the BackHoe. The articulations that drive the curette tip need adequate room to extend out away from the shaft in the opposite direction as the tip is cutting.

**Caution:** Never pull up on the BackHoe handle when it is in an activated position. If the tissue were to yield, the blade could damage the anterior surface of a neural element.

Rotate the BackHoe tip slightly superior and inferior towards the endplate, while simultaneously and frequently squeezing the handle, until the desired debridement has been completed (FIG. 22).



FIG. 21

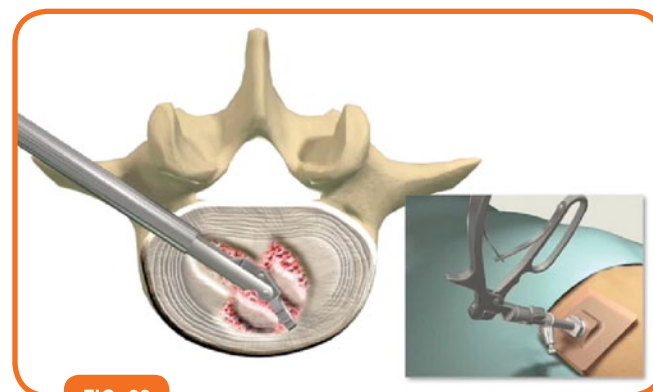


FIG. 22

**Note:** Cutting many small bites or scrapes with the BackHoe rather than one large bite is highly preferable. By taking small amounts of tissue at a time, the clutch will release less frequently and the debris will be much easier to remove.

**Caution:** Never rotate and cut in a full 360° circle with the BackHoe. It has the capacity to make a 26mm tall cavity, 6mm taller than the maximum height of the 330-2505 mesh (largest E). The primary purpose of the BackHoe Articulating Curette is to complete the discectomy and remove endplate cartilage lateral to the path created by the Shaper. Use the Shaper tool to cut into the subchondral bone for vascular access.

Rotate the BackHoe 180° and repeat (FIG. 23).

Adjust the positive stop on the Access Portal down to the maximum drill depth and repeat the curetting, ipsilateral and contralateral, in the same fashion.

Remove the debris with the pituitary and suction (FIG. 24).

**Note:** After the initial usage of the discectomy instruments is complete, repeating the steps will frequently yield the removal of additional disc material.

Following initial discectomy and decortication, a second portal can be placed on the contralateral side and the procedure to this point may be repeated. This enhances the ability to complete a thorough discectomy as needed for optimal fusion (FIG. 25).

**Note:** The second Access Portal should not be placed prior to this point in the procedure. Prior to initial tissue removal, instruments passing into the disc can elevate the intradiscal pressure and may dislodge the first Access Portal tip.

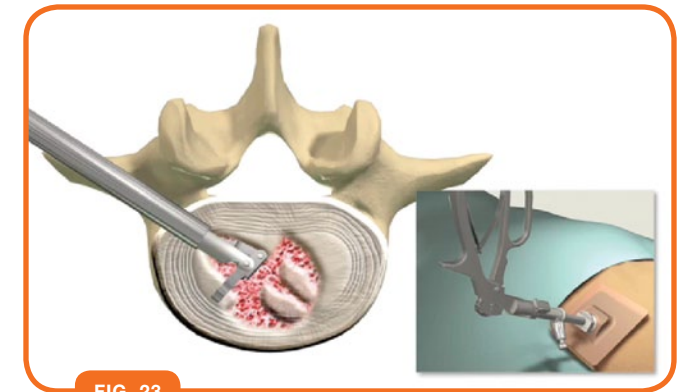


FIG. 23

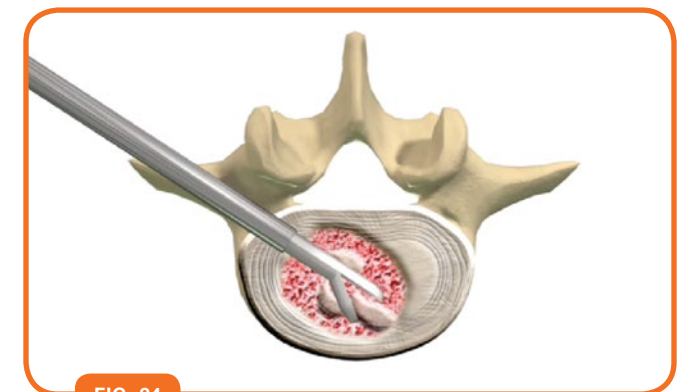


FIG. 24

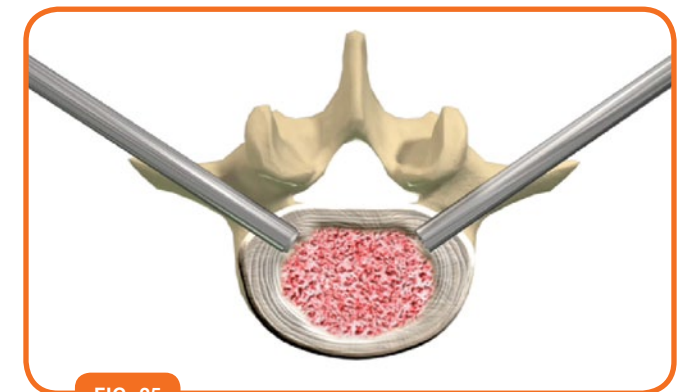


FIG. 25

# Mesh Size Selection

In OptiMesh 1500E procedures, a mesh size is selected by cross-referencing the breadth and height of the disc. The drilling depth indicates the breadth of the disc and the anticipated final cavity height is determined by measuring the pre-disease disc height (height of an adjacent healthy disc on MRI) and adding the amount of decortication (typically 2mm per endplate).

**Note:** Mesh sizing differs between Interbody and Intrabody applications. Ensure the correct sizing guide is being utilized.

**Note:** If sentinel grafting is being utilized, refer to Appendix D for appropriate sizing guide.

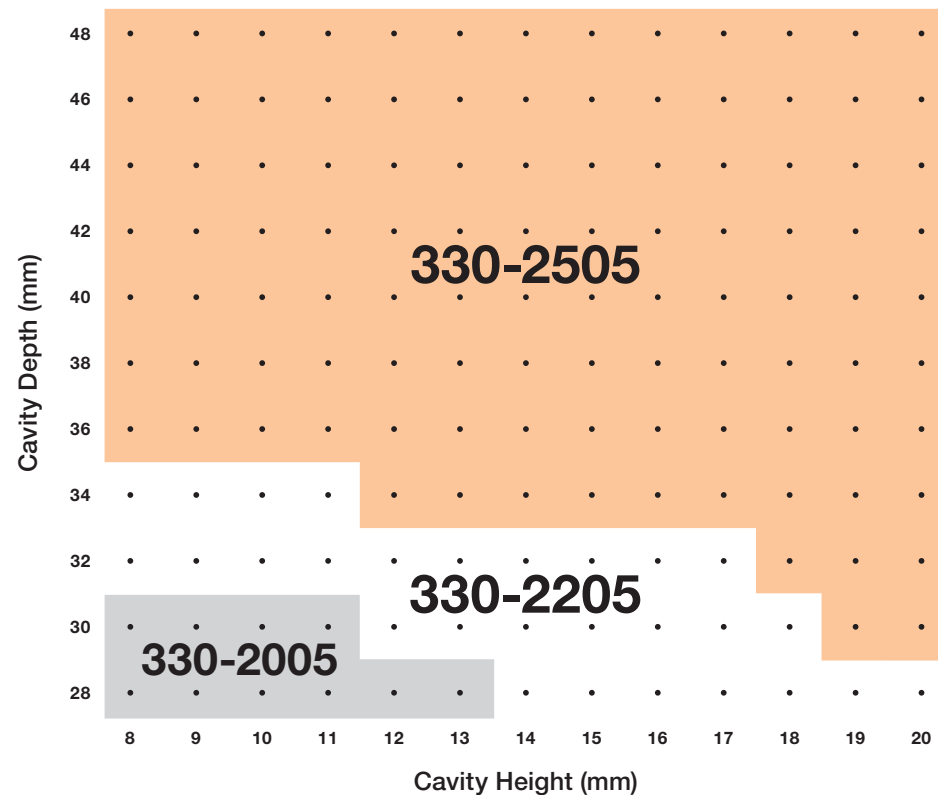
On the chart below, identify the cavity depth (deepest distance drilled) and the estimated disc height.

Using these dimensions, identify the intersection of the cavity height and depth. The mesh size is indicated by the large numbers in the zone that contains the intersection.

**Example:**

Cavity Depth (y-axis in graph below)		Cavity Height (x-axis in graph below)		OptiMesh Part #
34mm	x	16mm	=	330-2505
		<i>Pre-disease height of 12mm + 4mm Decortication</i>		

## E Mesh Sizing without Sentinel Grafting



# Mesh Insertion

To assemble the mesh onto the Mesh Holder, rotate the thumbwheel on the Mesh Holder to move the lock tube stop to a proximal position. Align the arrow on the Mesh Holder shaft with the notch on the metal tip of the implant and the notches in the Mesh Holder with the shoulder of the metal tip and press the mesh into the Mesh Holder. Spin the thumbwheel clockwise until the stop abuts the Lock Tube.

Pass the Mesh Extender through the cannulation in the Mesh Holder and extend the mesh.

**Caution:** Do not apply excessive force to the Mesh Extender. It could damage the mesh. A damaged mesh could tear and lose containment capability.

Reset the positive stop on the Access Portal to the minimum height.

With the mesh extended, advance it through the Access Portal by pressing simultaneously on the Mesh Extender and Mesh Holder. Be sure to orient the Mesh Holder such that when it is released the handle will not rotate (FIG. 26).

**Caution:** Do not rotate the Mesh Holder. Rotation may twist the mesh neck and interfere with filling.

When the circumferential etch line on the proximal end of the Mesh Holder's shaft is even with the top of the Access Portal, release the Mesh Extender and advance only the Mesh Holder until it contacts the positive stop. Once the mesh is seated, extract the Mesh Extender approximately 10cm and gently reinsert. Repeat several times to ensure the mesh is well deployed.

**Caution:** The etch line corresponds to a point at which the Mesh Extender tip is near the anterior spinal margin. Failure to release the Mesh Extender at this point could cause the tip on the Mesh Extender to protrude through the anterior annulus.

Remove the Mesh Extender.

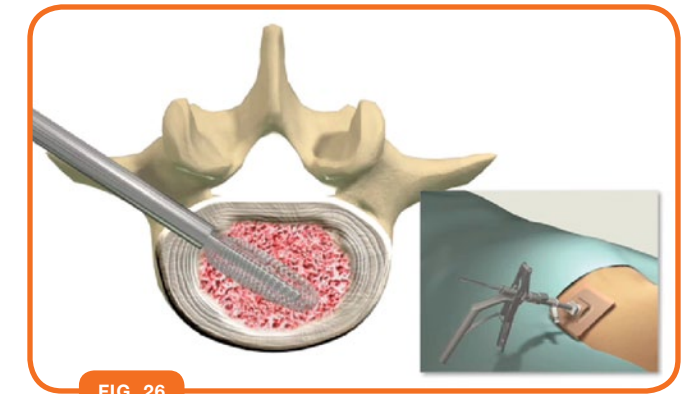


FIG. 26

# Filling the Mesh

Bone graft procurement and fill tube preparation information can be obtained from your Spineology representative. Fill tubes are single-use, disposable items and come in two styles; Straight and Diverted.

The amount of bone required to fill a mesh is dependent on both the mesh size selected and its final shape. Because of this, it is important to track the amount of bone used to aid in determining when it is filled. In the event that some or all of the tubes are filled interoperatively, the amount of bone in a tube, and the amount of bone being placed in a mesh, can be determined as follows:

- Place a Push Rod in each fill tube and advance the bone to the distal tip of the tube.
- Record the volumes in terms of segments of a tube (how many etch lines are visible on the Push Rod, example, 1, 2, 3). A full tube is considered to be 6 segments.
- Track the segments inserted into the mesh.

The table below, and on the back of the sizing guide, indicates the approximate maximum amount of bone for each mesh size in various filling scenarios. The likelihood is that the amount of bone required will be somewhere between the listed amounts. The amounts listed in the table below do not include the final straight tube volume.

**Caution: Monitoring the amount of bone used and understanding the indicators of a full mesh are critical in avoiding overfilling. Overfilling may damage the mesh and cause a loss of containment.**

To begin filling, pass a diverted fill tube through the cannulation in the Mesh Holder with the tip pointed toward the contralateral side of the disc space until the flare on the top of the fill tube abuts the top of the Mesh Holder. Diverted tip orientation can be observed by noting the position of the vertical etch line on the flared end of the fill tube.

**Note: The first tube should seat fully without the need for impaction. If it does not, remove the tube and mesh and repeat the insertion to ensure the mesh is properly placed.**

Place the bone Push Rod in the end of the fill tube with the tip oriented medially. Tap on the Push Rod with the Mallet and expel approximately one segment (advance the Push Rod one hash mark) of the fill tube into the mesh. Then actuate the lever on the Mesh Holder to pull the fill tube slightly out of the mesh. Rotate the tube 180°, reinsert it into the mesh and resume emptying the tube in the same fashion.

**Caution: Do not lift up on, or rotate, the Mesh Holder when actuating the handle. Moving the Mesh Holder out of position could dislodge the mesh and impair proper filling.**

**Note: Do not hold the shaft of the push rod near the top of the Mesh Holder while filling. The tight tolerances of the push rod and fill tubes can cause pinching of surgical gloves.**

Continue to eject, rotate, reinsert and expel one segment of a tube at a time into the mesh with various random tip orientations until the tube is empty. Hold the Mesh Holder firmly against the Access Portal, remove the tube, replace it with another, and continue. The Mallet included in the set is recommended, as moderate, consistent taps from this Mallet generate the impact loads necessary to appropriately fill the mesh.

As more bone is added, the bone pack will become increasingly rigid and resistant to fill tube insertion. This is an indication the most distal portion of the mesh is full and the entire mesh is nearly full (FIG. 27).

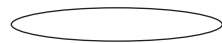
**Note: During this phase of the filling, it will be necessary to gently push or tap in the fill tube. The Diverted Tube must be fully seated in the Mesh Holder during bone delivery.**



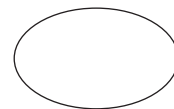
FIG. 27

## Mesh Filling Volume

Mesh shape — Flat



Mesh shape — Round



Catalog#	Number of Tubes & Segments	Number of Tubes & Segments
330-2005	1 tube + 2 segments	3 tubes
330-2205	2 tubes + 4 segments	3 tubes + 3 segments
330-2505	3 tubes + 2 segments	4 tubes + 1 segment

## Filling the Mesh, continued

Once the fill range (see “Mesh Filling Volume” on page 18) is reached, changes in tactile feedback and fill tube flow quality will indicate when the mesh is full. A mesh is full when the Push Rod does not significantly advance during in vivo impaction in any direction. This can be monitored visually by observing the progression of the etched lines on the Push Rod during graft impaction.

As the graft pack forms, it is possible for fill tubes to jam or for the amount of bone remaining in a fill tube (a nearly full tube) to affect perception of mesh fullness. For this reason, it is important to test the fill tubes (see “Testing a Fill Tube”) to ensure that filling resistance is the result of a full mesh.

**Note:** If “jamming” persists, empty half of the bone out of a tube and then attempt to deliver bone into the mesh. The reduced amount of bone in the tube reduces the impact forces necessary to advance bone through the tube and may give a clearer indication of fullness.

**Caution:** As resistance increases during filling, or in the event of a tube jam, do not increase the intensity of the Mallet strikes. This can cause mesh damage and a loss of containment and/or unintended instrument movement and/or damage to the instruments or mesh. Mallet force should not exceed the force of approximately a 6-inch free fall of the Mallet head.

After tight graft compaction is achieved using diverted fill tubes, insert a straight fill tube and repeat the impaction process to fill the channel created by the diverted fill tube tips. When easy advancement of the Push Rod ceases, or the straight fill tube “rises” out of the Mesh Holder, filling is complete. This is commonly achieved with about 1 to 2 segments of a fill tube.

**Note:** Do not continue to fill with the straight tube once it begins to rise out of the Mesh Holder. Continued graft impaction can deposit bone in the lock tube and interfere with lock tube removal.

## Testing a Fill Tube

Remove the Push Rod and the fill tube.

To test the tube currently being used:

- 1) Remove it from the Mesh Holder,
- 2) Place it through the hole in the Impactor, and
- 3) Tap on the Push Rod.

If the bone in the tube is easily expelled, it is an indication that the mesh is full. If the tube is jammed, no graft can be expelled and a new tube should be inserted into the mesh to continue filling.

## Mesh Release

To release the mesh, disengage the Mesh Holder lock tube stop by turning the stop thumbwheel counterclockwise until it stops.

**Note:** The Mesh Holder lock tube stop must be retracted fully or the mesh will not disengage properly.

Ensure that the Lock Tube Puller tip is not expanded or in its extended (cleaning) position. For insertion, the knurled knobs should be touching and the central shaft should be set such that the nose is about to flare the outer tube (FIG. 28).

**Note:** If the Lock Tube Puller does not fully seat into the Mesh Holder, there is bone in the lock tube. To clear the bone, remove the Lock Tube Puller and insert an empty straight fill tube with a Push Rod inside of it into the Mesh Holder. Tap them in until they fully seat, remove them, and proceed.

Pass the Lock Tube Puller through the cannulation in the Mesh Holder until the counter-rotation tabs engage the flats at the top of the Mesh Holder. Rotate the knurled knob clockwise until the top of the central shaft (indicator) is flush with the top of the knurled knob. If necessary, use pliers to tighten the knob (FIG. 29).

Activate the lever on the Mesh Holder in the same manner as was used to remove a fill tube. This removes the Lock Tube from the crimp, which then releases the mesh. Gently pull up on the Mesh Holder to test that the Lock Tube and crimp have been disassembled. If no resistance is felt, the Mesh Holder and Lock Tube Puller can be removed from the Access Portal.

If any resistance is felt, the Lock Tube has not been released. If this occurs, repeat the “release” procedure until no resistance is felt. To repeat the step, it will first be necessary to release the grip of the Lock Tube Puller on the Lock Tube. This is done by unthreading the knurled knob several turns and then tapping on it with the Mallet. This extends the central shaft in the instrument allowing the collet at the Lock Tube Puller tip to collapse and release its grip on the Lock Tube.

Once the Mesh Holder and Lock Tube Puller have been removed, remove the Access Portal and QuikTrak assembly and close (FIG. 30).

If the spinal instrumentation has yet to be installed, do so now according to the manufacturer’s recommended instructions.



FIG. 28



FIG. 29



FIG. 30

## Appendix A — Shaper Assembly

The cavity Shaper is supplied unassembled for cleaning and sterilization purposes. Disassemble after use.

### To assemble:

Orient the small notch in the blade set with the blade catch and slide the blade set into the shaper shaft from the distal end. Slide it in until it is caught by the blade catch. Thread the Blade Control Knob counterclockwise into the shaper body. Thread the drive knob clockwise onto the shaper body.

## Appendix B - Lock Tube and Crimp Removal

Following release of the mesh, the lock tube and crimp must be disassembled for disposal. To remove the lock tube and crimp from the Mesh Holder, pull the Lock Tube Puller to its most proximal position in the Mesh Holder. Insert an empty fill tube into the crimp and “pry” it out of the Mesh Holder by applying force towards the open side of the Mesh Holder tip.

Move the Lock Tube Puller to its most distal position in the Mesh Holder and unthread the Lock Tube Puller knob 6-7 turns, exposing the central shaft. Tap on the knob with a Mallet until the shaft advances. This releases the pressure on the collet tip of the Lock Tube Puller.

Extract the Lock Tube Puller from the proximal end of the Mesh Holder and the lock tube from the distal end.

## Appendix C — Alternate Instrument Instructions

### Drilling Dilator

An alternate single step Drilling Dilator is also available with the 1500E system as an alternative to the Sequential Dilators. If it is being used follow the below instructions

Pull back the collar of the Drilling Dilator Handle and insert the Drilling Dilator into the handle. Release the collar. Advance the Drilling Dilator over the Guide Pin, rather than the Sequential Dilators, and tap it into the disc while simultaneously imaging to ensure the Guide Pin remains stationary. Stop advancing when just the beveled tip of the Drilling Dilator is in the disc. Seating the Drilling Dilator tip too deeply into the disc at this point may result in the selection of a QuikTrak Stem that is too short.

After the Access Portal is in place, remove the Dilator. The handle can be reassembled to aid if necessary.

Proceed as previously described.

### QuikTrak

Two iterations of the QuikTrak are currently in service. If using the original version of the QuikTrak follow the below instructions for use:

#### QuikTrak I

The Dilator shafts are etched with reference marks for QuikTrak Stem selection.

As the tip of the Dilator penetrates the disc, note the number between the reference marks at which the skin is crossing. Select the corresponding Stem. If the reference mark is at skin level, select the shorter Stem.

Once the Stem size is selected, advance the Dilator into the disc until the tip contacts the anterior annulus. If the Drilling Dilator Handle was used, remove it.

To prepare the QuikTrak for use, insert the selected Stem into the QuikTrak Base by pressing the Stem's ball end into the Base.

Place the QuikTrak assembly over the Drilling Dilator and rest the Base on the skin. The Base should lay as flat as possible on the skin.

Adjust the stem adjustable stop to its lowest position (closest to the Base).

Place the Access Portal over the Dilator and through the stem. Place the Impaction Cap on the Access Portal and seat it into the disc 5mm.

Depress the positive stop lock on the Stem and slide it up the shaft of the Access Portal until the stop contacts the shoulder on the Access Portal.

Proceed as previously described.

## Appendix C — Alternate Instrument Instructions, continued

### Bullseye

In the event that the QuikTrak Force Dissipation System length prevents the Access Portal from reaching the disc, the Bullseye system can be used to maintain instrument trajectory and dissipate impact forces during mesh filling. The Bullseye system provides much more Access Portal working length and will facilitate mesh placement in a heavier patient.

When using the Bullseye system, the surgeon installs the Access Portal in the same fashion as previously described with the exception that the QuikTrak is not installed to hold the Access Portal. The Bullseye is assembled to hold the Access Portal instead.

Bullseye assembly and attachment is most easily performed after the Access Portal is positioned, and before the Dilator is removed.

To assemble the Bullseye, begin with the top-most arm lock provisionally tightened and the bottom arm lock loose. Position a post clamp, jaw on the bottom of the post, over

the table rail approximately 15cm caudal of the operative level. Spin the knob on the top of the post clockwise to tighten the clamp.

**Note: if using a Jackson table, the Spineology Jackson Table rail is preferred for the rail section.**

When ready to attach to the Access Portal, loosen the top arm lock and swing the arm out to the Access Portal. With the lever on the Arm receiver in the open/unlocked position, align it with the tapered cone on the Access Portal and place the receiver over the cone. Loosely tighten the receiver lock. Verify that the angle and depth of the Access Portal is in the desired position: parallel to the endplates, approximately 45° to the spine, and 5mm countersunk into the disc. Lock the top arm lock, the receiver and the bottom lock fully.

Remove the Dilator and complete the mesh installation and filling as described in the technique.

## Appendix D — Sentinel Grafting

If desired, additional “sentinel” graft or BMP sponges can be placed around the mesh. Several methods can be used to deliver the graft material:

- Graft can be placed into the Access Portal directly and tamped into place with the flat end of the Dilator; or
- A Mesh Holder, without a mesh attached, can be placed into the Access Portal and graft expelled from a fill tube with a Push Rod.

Regardless of the method employed, care should be exercised to not place too much bone as it can limit mesh size or cause the mesh to deploy posteriorly. Four fill tube segments, or approximately 1.3cc of graft, is the recommended amount.

**Caution: If it is felt that more sentinel graft than the prescribed amount has been placed, re-measure the depth and alter the mesh size accordingly.**

**Note: If placing bone through the Access Portal directly, ensure it is finely morselized. It will pack more effectively around the mesh as the mesh is deployed.**

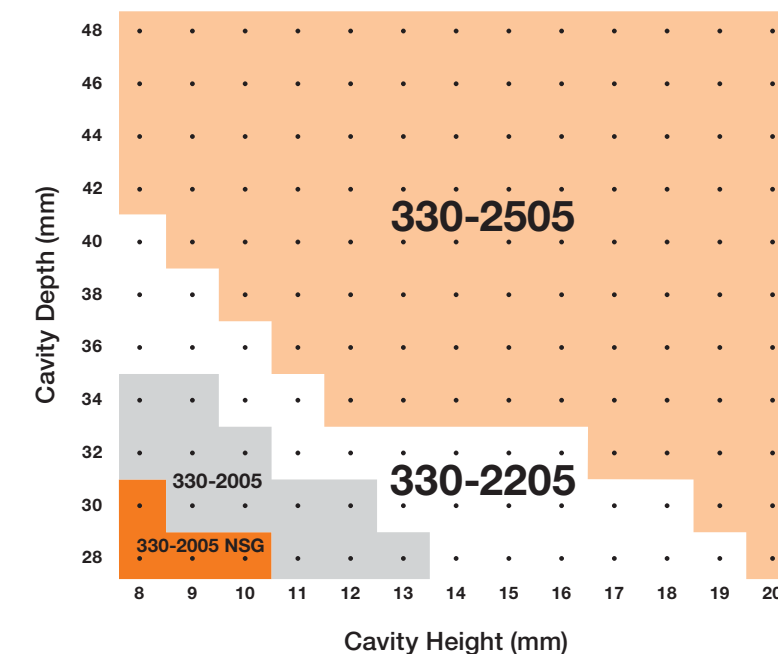
Once the graft is placed, advancing the Drilling Dilator through the Access Portal, beveled tip first, until it contacts the annulus, is recommended as this will displace the graft to the lateral recesses of the disc space and limit any interference the graft may have with mesh deployment.

**Note: If more than the recommended 1.3cc of sentinel graft material is used, the mesh size must be re-evaluated. The Drilling Dilator or Shaper can be re-inserted into the prepared cavity to assist in dispersal of sentinel graft material in the ventral portion of the cavity.**

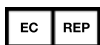
**Note: For every .7cc of additional sentinel graft material implanted beyond the recommended amount of 1.3cc, mesh sizing should be re-calculated by subtracting 2mm from the drilling depth on the mesh sizing guide.**

If sentinel graft is placed it will reduce the available cavity volume and affect the mesh size selected. The chart below should be used in place of the chart on page 16 when sentinel grafting is used.

E Mesh Sizing with Sentinel Grafting



OptiMesh® implants and instruments for interbody fusion are currently protected by US patents 5,015,255; 5,549,679; 5,571,189; 6,383,188; 6,620,169; 6,712,853; 7,025,771, 7,056,345, 7,220,282, and European patent EP0764008. Additional patents pending.



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