



Surgical Technique Guide:

Minimally Invasive Transforaminal Lumbar Interbody Fusion (“MITLIF”)

Featuring:

MARQUISE[®] MIS CHANNEL SYSTEM

TURBO MIS[®] TLIF SYSTEM

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INTRODUCTION

Transforaminal Lumbar Interbody Fusion (“TLIF”) surgery has proven to be a safe and effective treatment for degenerative disease of the lumbar spine. In recent years, surgeons have focused on minimally invasive TLIF (“MITLIF”) techniques to improve patient outcomes. SpineSelect attempts to further this pursuit by developing minimally invasive systems designed to enable same-day discharge lumbar fusion. The following surgical technique guide features two such systems: the Marquise® MIS Channel System and the Turbo MIS® TLIF System.

Pre-Operative Patient Evaluation

- Verify disc space height is not larger than available interbody devices. The largest Turbo MIS® Interbody Device is currently 16mm in height. There are rare individuals with disc space heights ranging as high as 18-22mm. The Turbo MIS® Interbody Device is not suitable for these individuals. These individuals may require lateral or anterior approaches or potentially an initial effort at discectomy to allow the disc space to collapse before a MITLIF-type approach.
- In cases of severe spondylolisthesis or retrolisthesis, verify that the ventral-dorsal distance is sufficient to house available interbody devices. The current length of all Turbo MIS® Interbody Devices is 24mm. Often, anterior slips can be significantly improved by patient positioning.
- If the disc space is collapsed more on one side, one may wish to place the interbody device asymmetrically to the more collapsed side.
- When disc spaces are properly aligned, it is preferable to place the interbody device with the nose portion near the ventral or anterior part of the central area of the disc. Since the distance between pedicles becomes shorter at higher lumbar levels, this will generally require an incision closer to the midline at higher levels and placement of the interbody device at a less oblique angle during device insertion.

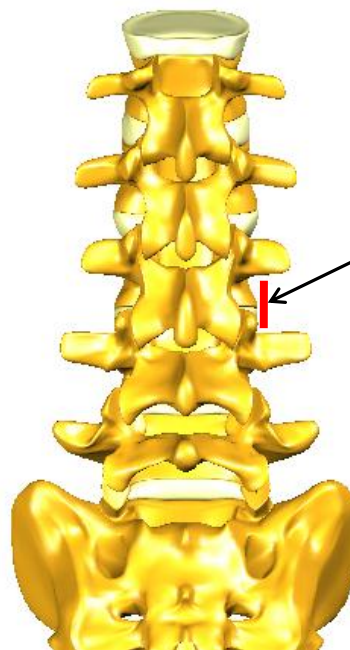
Step 1 – Skin Preparation

- Careful preparation of the skin is essential to limit infection risk.
- Cleanse skin with de-greasing solution.
- Paint targeted skin area with tincture of iodine.
- Remove iodine with fairly concentrated alcohol to avoid skin irritation or burn.
- Conduct final preparation with a standard preoperative skin preparation solution.
- Drape skin with sterile towels around the incision and cover area of incision with sterile adhesive drape (preferably iodine impregnated).

NOTE: an infection rate of zero is one goal of this technique. This result is achievable with proper skin preparation and surgery through a completely closed channel such as the Marquise® MIS Channel System.

Step 2 – Targeting and Incision

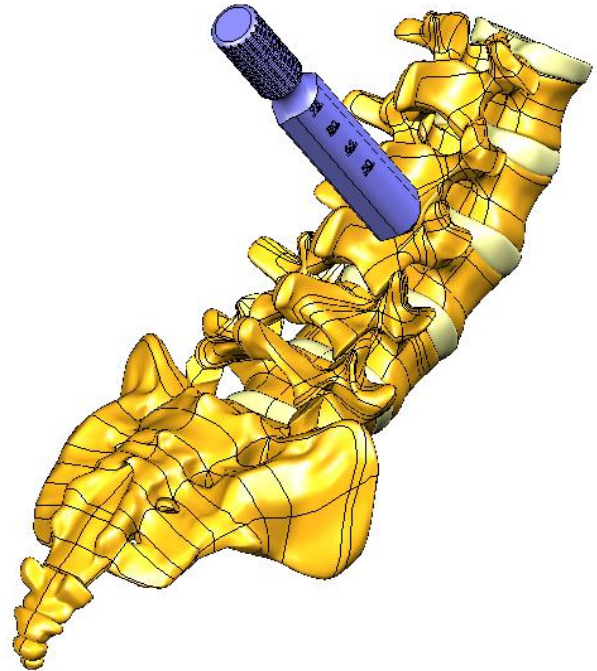
- Feel the spinous processes of adjacent levels to estimate the placement of the incision. Mark a tentative incision area on the skin approximately 3-4cm lateral to the midline.
- Make a small “pin prick” incision with scalpel in line with the marked area and using the blunt end of a steel pin, penetrate the fascia and locate a transverse process. With the steel pin on a transverse process, confirm localization with fluoroscopic image.
- In the same sagittal plane as the pin, make a linear incision which allows access to the transverse processes above and below the targeted disc space.
- Recommended incision length is approximately 30mm for most cases. A longer incision may be required for the largest Marquise® Channel size.

EXAMPLE INCISION PLACEMENT

Step 3 – Placement of Marquise® Insertion Probe

- Divide the deep fascia (often two distinct layers).
- Bluntly dissect the paraspinal muscles, using a finger to palpate down to the transverse processes of the targeted levels.
- Once the transverse processes are located and palpated, place the Marquise® Insertion Probe down to the depth of the transverse processes.

NOTE: if preferred, sequential dilation may be used instead of finger dissection and the Marquise® Probe. Dilate up to a 21mm diameter using a standard tubular sequential dilation system. The Marquise® Channel will then slide down over the dilation tube – see Step 4 detailing Channel placement.

MARQUISE® PROBE PLACEMENT

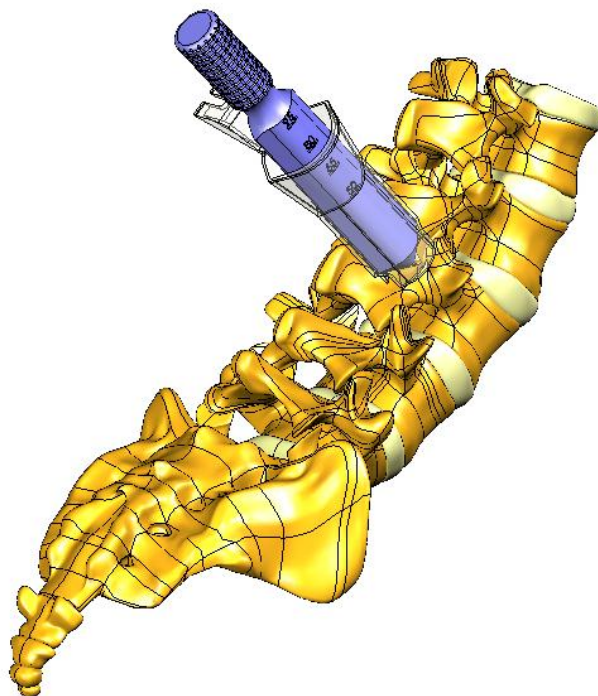
TIP: in obese patients, it is often helpful to resect an elliptical area of subcutaneous fat from the incision area to allow the skin edge to collapse slightly, preventing it from overhanging the top of the obliquely-tilted Channel.

TIP: at lower levels, L5 and S1, it may be necessary to use electrocautery to divide some of the diagonally crossing fibers which make it harder to separate the muscle layers.

Step 4 – Placement of Marquise® MIS Channel

- Choose the appropriate length Marquise® Channel. Markings on the Insertion Probe identify the depth from the level of the transverse processes.
- Slide the Channel over the Insertion Probe and down to the level of the transverse processes – the handle of the Channel should be medial to the incision.
- Attach the Channel handle to an adjustable assembly arm.
- Remove the Insertion Probe.
- With a blunt instrument or probe, palpate the transverse process. Fluoroscopy is useful to confirm the localization of the transverse process with the metal marker so positioned.

MARQUISE® CHANNEL PLACEMENT



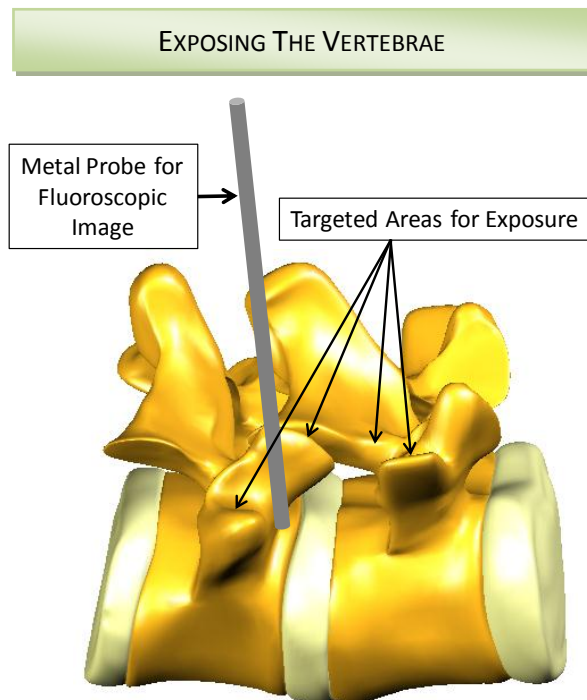
IMPORTANT: the Marquise® MIS Channels are made of polycarbonate and may crack or break if misused. In order to prevent breakage, ***loosen the adjustable assembly arm before attempting to reposition the Channel.***

TIP: often a Channel one size shorter than measured can be used.

NOTE: the small lateral “skin lip” on the Channel will prevent the skin from encroaching into the operating site.

Step 5 – Exposing Transverse Processes, Pars, Facet Joint, and Neuroforamen

- Introduce the operating microscope.
- If additional posterior-lateral fusion is desired, remove muscle overlying the dorsal surface of the transverse processes using electrocautery, fully exposing each of them above and below the targeted disc space.
- Continue to remove muscle to expose the pars, facet joint, and neuroforamen.
- Place a small probe directly ventral to the superior facet adjacent to the junction of the transverse process and the pedicle of the vertebral body caudal to the appropriate disc space and confirm appropriate targeting with fluoroscopic image.



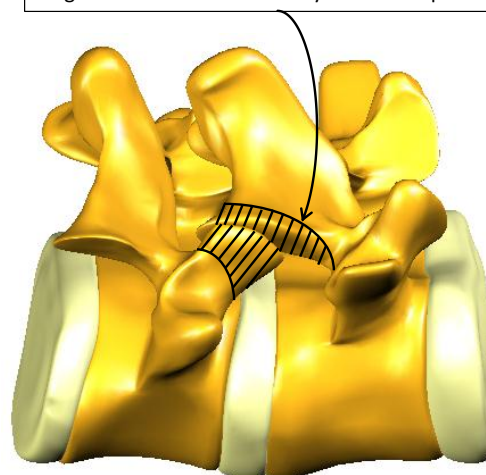
NOTE: the fluoroscopic image detailed at left following placement of the probe is critical to confirm the level which is planned for surgery.

Step 6 – Removal of Facet Joint and Decompression

- Use a high speed drill (or large Kerrison or osteotome) to remove the superior facet of the caudal vertebra. The superior facet should be removed caudally to a point flush with the cephalad margin of the pedicle.
- Remove bone from portions of the pars interarticularis, the inferior articular process (facet), and lamina of the cephalad vertebra. The amount of bone removed will be determined by the extent of decompression or discectomy needed in the canal.
- In a situation where there is significant canal stenosis at the level involved, it is wise to follow around the medial edge of the caudal pedicle to remove the medial continuation of the superior facet and to fully decompress this area of the lateral recess.
- In cases of severe canal stenosis, it is also wise to remove some of the leading edge of the lamina of the caudal level and in occasional cases, it is wise to tilt the Channel and the table in order to allow drilling of both lamina and removal of thick ligament to fully decompress the canal across to the pedicle on the opposite side. In this situation, one can also use Kerrison rongeurs to decompress both neuroforamina on the opposite side as well.

GAINING ACCESS TO DISC SPACE

Targeted Areas for Facetectomy and Decompression



TIP: it is helpful to tilt the operating table and Channel to gain better access to targeted areas of the vertebrae.

NOTE: MITLIF decompresses more of the circumference of the canal than posterior decompression.

Step 7 – Cleaning the Disc Space Using the SpineSelect® Endplate Shaver Currettes

- Retract the dura medially and protect the nerve root laterally to gain safe access to the annulus.
- Using a scalpel, make a “window” in the annulus.
- Remove the nerve root retractors.
- Begin as far lateral as possible by driving the smallest Endplate Shaver Curette into the disc space, turning it a few times, and gradually removing and re-entering it as one moves more medial and toward the opposite side of the disc space.
- Gradually increase the size of the Endplate Shaver Currettes to correspond to the size of the disc space, allowing them to work more efficiently in stripping disc material and cartilage from the bone.
- Using pituitary/disc rongeurs, remove loose disc material and debris from the disc space. As one moves more toward the opposite side, it may be wise to briefly retract the dura medially for protection from the rongeurs.

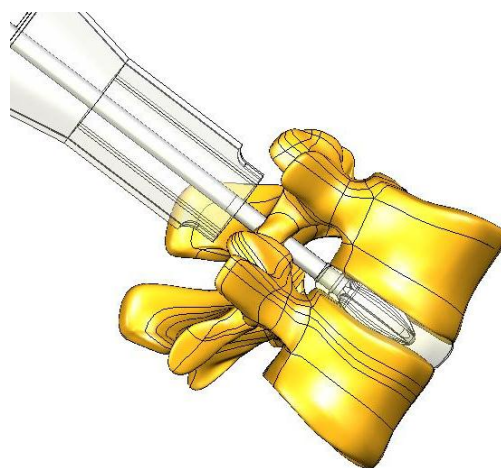
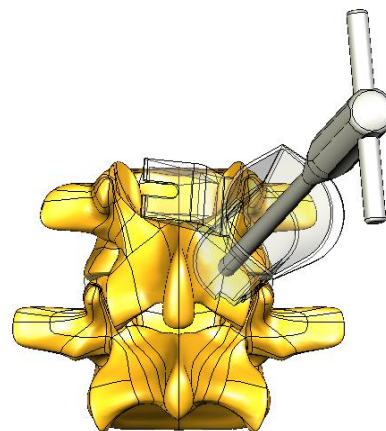
IMPORTANT: it is recommended that in larger disc spaces, the ventral portion of the disc space be left intact during preparation – see Step 10 for explanation.

TIP: the Endplate Shaver Currettes can be impacted into the disc space and rotated, without the use of nerve root retractors.

A NOTE CONCERNING SEVERE DISC DEGENERATION: there will be severely degenerated disc spaces with very small disc height and very sclerotic hard bone on the surfaces of the vertebral bodies. In these situations, it is recommended to use a high speed drill to clean out the disc space instead of the Endplate Shaver Currettes. These disc spaces should be cleaned out generously due to the abnormal bone and cartilage potentially preventing successful fusion. Experiences suggest that it is advisable to enlarge the disc space to approximately 8-9mm height to get good, fresh bone exposed above and below. When high speed drills are used to clean out the disc, it is highly advisable to use nerve root retractors to protect the dura and the lateral nerve root.

TIP: for the annulus incision, the scalpel may be attached to a bayoneted knife handle (such as used in trans-sphenoidal surgery).

CLEANING THE DISC SPACE

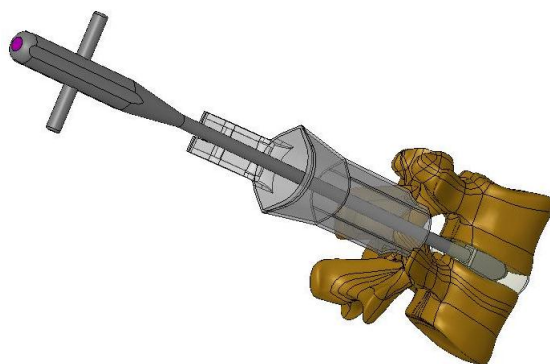


Step 8 – Sizing the Interbody Device Implant with the Turbo MIS® IBD Trials

- After preparation of the disc space, the Turbo MIS® IBD Trials are used to determine the appropriate size of interbody device.
- Insert Trial into the disc space while turned on its side (note that all trials have the same width of 8mm). Initial Trial size can be estimated from the size of the largest Endplate Shaver Curette used.
- Once in the disc space, turn Trial to upright position.
- **Height Evaluation:** Continue to test incremental sizes of the Trials until the height fit is appropriate. The fit is appropriate when the Trial makes good contact with the bone above and below. There is no need for the Trial to be excessively gripped by the bone.
- **Length Evaluation:** With the Trial, also evaluate the depth of disc space to ensure that the IBD will fit fully within the disc space. Note that the Trial contour matches the length and contour of the IBDs.

TIP: after preparation of the disc space and before sizing of the IBD, it is advisable to prepare the edge of the vertebral body adjacent to the inferior (caudal) pedicle to ***form a smooth plane of bone into the disc space***. This will aid in driving the device into the disc space.

SIZING THE IMPLANT



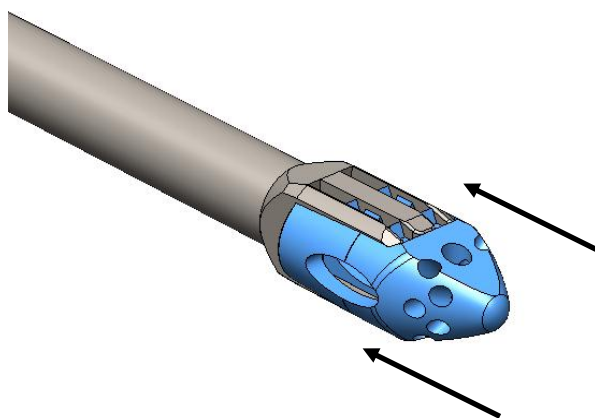
TIP: visually check the depth of the back (or proximal end) of the Trial to see that it is adequately countersunk in the disc space to ensure that the interbody device will not “back out.” This can be confirmed with fluoroscopy. If the Trial will not adequately sit in the disc space, additional disc space preparation will likely be required.

TIP: there are situations when the Trial can be turned upright, but only with considerable force. In these cases, consider reducing the size of the implant to the next lower size.

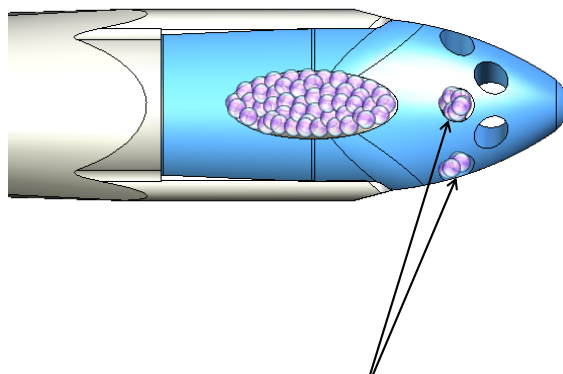
Step 9 – Preparing the Turbo MIS® Interbody Device for Insertion

- Select the appropriately sized Turbo MIS® IBD and Insertion Sheath and connect them to the Insertion Tool using the assembly instructions provided.
- Fill the large side aperture of the IBD with bone graft.

CONNECTING IBD TO INSERTER



FILLING SIDE APERTURE WITH GRAFT



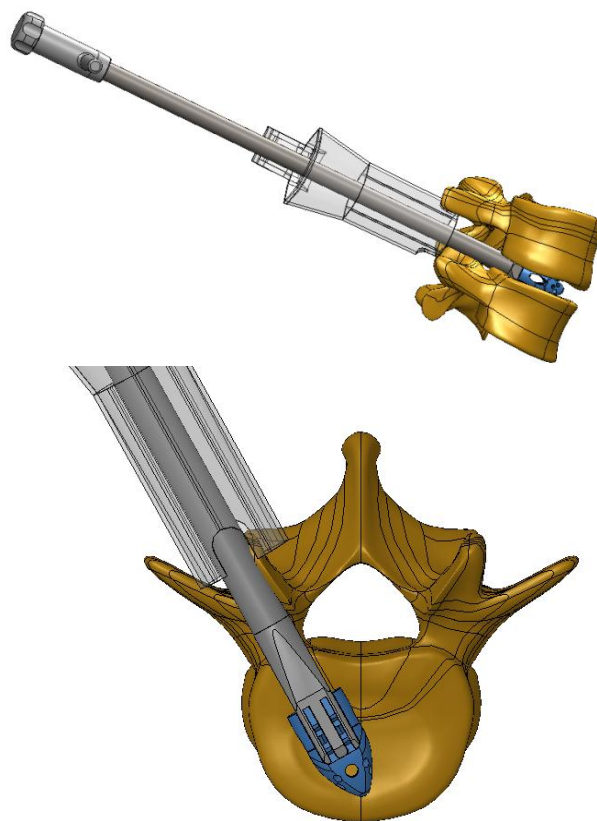
TIP: some surgeons also like to fill the small nose apertures with bone graft material.

Step 10 – Interbody Device Placement

- Insert the Turbo MIS® IBD into the disc space with the nose portion entering the annulus window first and the angle of the tool appropriately arranged. **Be careful to ensure that the forks of the inserter are directed towards the vertebral bodies above and below. In the proper position, the T-handle will be positioned in a direction parallel to the disc space.**
- Drive the IBD into the disc space by tapping on the round handle of the Insertion Tool.
- It is advisable to check the device placement with fluoroscopy during insertion to ensure that the device is being positioned properly.
- Once the desired position of the IBD is achieved, release the Core Rod, which secures the IBD to the insertion tool, by turning the round Palm Handle counter-clockwise until disengaged from the IBD. Confirmation of IBD disengagement occurs when the round Palm Handle may be loosely pulled away from the back of the inserter about 10mm. (Note that internal threads prevent the Palm Handle/Core Rod from completely coming off the inserter).
- Remove the Insertion Tool from the device and disc space by gently tapping backwards on the T-handle.

TIP: prior to placement of the interbody device, some surgeons choose to pack the opposite side of the disc space with graft material.

INSERTION OF IBD

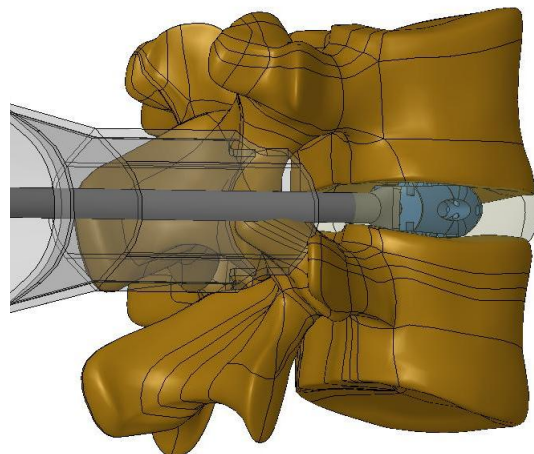


IMPORTANT: it is important to achieve the desired position of the IBD in the disc space prior to removing the inserter. Once the inserter forks are fully off the IBD, it is extremely difficult to reposition them back over the IBD. Options for adjusting the IBD within the disc space after removal of the inserter are discussed on the following page.

Step 10 – Interbody Device Placement (Continued)

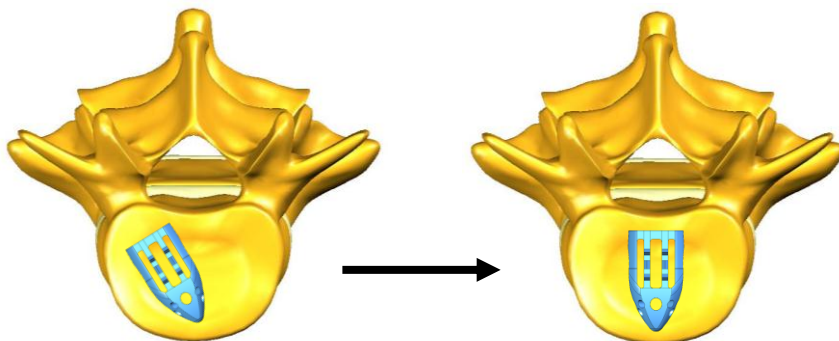
- Check IBD position to confirm the nose of the IBD is not too far forward in the disc space. If it appears too far forward, the IBD Removal Tool can be used to pull the IBD back. Screw the tip of the Removal Tool into the back of the IBD. Tap backward on the T-handle of the Removal Tool to pull the IBD backwards. Unscrew the tip of the Removal Tool once desired position is achieved.
- If vertical realignment is required after the Insertion Tool has been removed, use the Adjuster Tool to rotate the IBD (pictured right).
- If desired, attempt to position the IBD in alignment with the sagittal axis of the vertebrae (see NOTE below).
- If desired, pack disc space with additional bone graft material and cover the dorsal area of the disc space with material such as oxidized cellulose.

REALIGNING IBD WITH ADJUSTER TOOL



TIP: leave a small portion of the dorsal disc space free of graft since subsidence may force material back toward the canal.

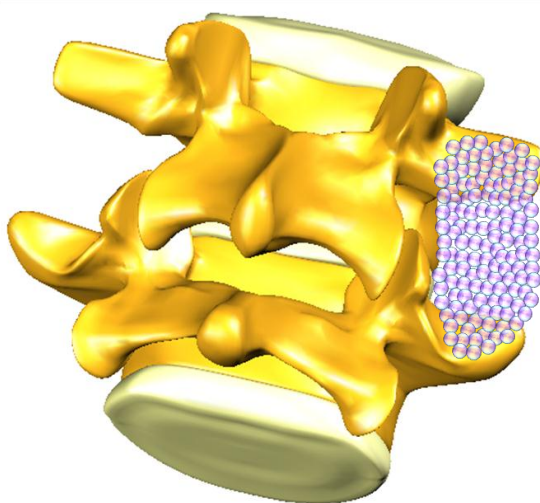
NOTE: After separation from the Insertion Tool, the IBD will be situated in a slightly oblique position. It is possible to reposition the IBD by tapping the opposite posterior corner of the device with a blunt instrument to align the IBD with the sagittal axis of the vertebrae. Check IBD placement with fluoroscopy, **being careful to not drive the IBD too far forward in the disc space.**



Step 11 – Posterior-Lateral Fusion (Optional)

- Prior to placement of pedicle screws, decorticate the transverse processes of each vertebra using a high speed drill.
- Following the placement of pedicle screws (see Step 12 below), place graft material across the decorticated transverse processes and in the space between.

POSTERIOR-LATERAL FUSION



NOTE: the Marquise® MIS Channel provides sufficient access to perform both interbody fusion and posterior-lateral fusion. While optional, many surgeons perform the posterior-lateral fusion procedure to increase the likelihood of a successful fusion and to provide wider fusion stability.

Step 12 – Pedicle Screw Fixation

- If pedicle screw fixation is desired, confirm that screws, rods or plates, and corresponding instrumentation fit through the Marquise® MIS Channel.
- The Marquise® Channel can be tilted and maneuvered to provide direct access to the respective pedicles.
- Follow instructions provided with chosen pedicle screw fixation system to implant pedicle screws and connecting rods or plates.
- Note that the Marquise® Channel has convenient “mouse doors” at the distal end to allow for easy movement across single-post screws and to enable Channel to easily rest on a rod in order to allow better access to variable angle screws.

NOTE: the Turbo MIS® IBD is approved by the FDA as a stand-alone device that does not require fixation; however, many surgeons perform pedicle screw fixation to increase the likelihood of a successful fusion.

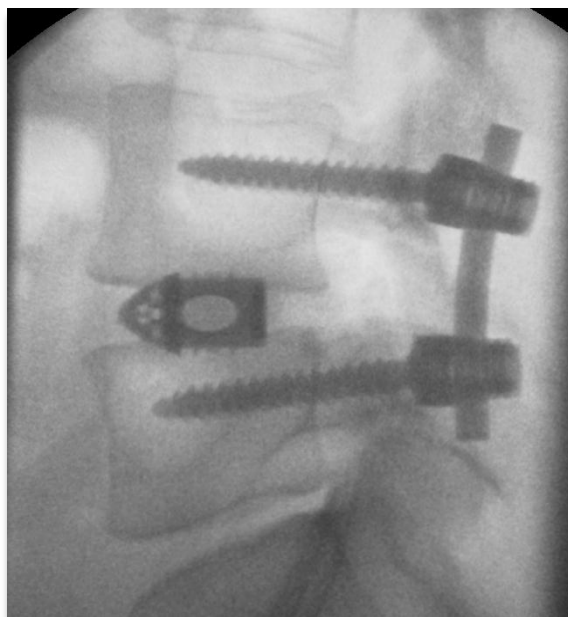
TIP: during pedicle screw insertion, fluoroscopic images can be used to evaluate cranial-caudal angulation of the probes and screws in the pedicle. In addition, the medial and lateral edges of the pedicle can be palpated with a blunt hook. Palpation of the medial pedicle during screw insertion will help prevent medial penetration of the pedicle by the screw.

Step 13 – Completion of Procedure

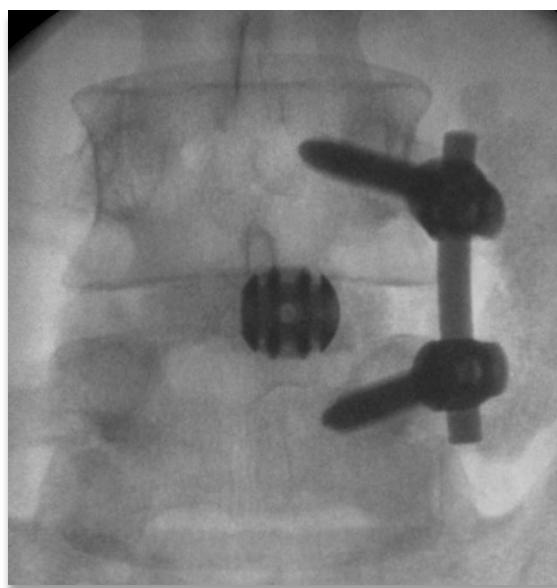
- Check the area of exposure of dura and nerve roots to be sure blood clots have been removed. This space may then be covered with oxidized cellulose or similar material.
- Withdraw the Channel, allowing muscle to close.
- Infiltrate surrounding muscle tissue with 0.25% Marcaine to assist with early ambulation.
- Final AP and lateral fluoroscopic images can be taken and saved for permanent films.
- Close deep fascia with 0 absorbable monofilament suture.
- Irrigate and close subcutaneous tissue with 3–0 absorbable monofilament suture.
- Close skin with 4-0 nylon suture.
- Apply small sterile dressing.
- Apply brace prior to patient transfer to the recovery room.

IMAGES OF SUCCESSFUL DEVICE PLACEMENT

Lateral View



AP View



NOTES



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INDICATIONS:

Marquise® MIS Channel System

The Marquise® MIS Channels are indicated for minimally invasive access to an area of the spine. The Marquise® MIS Channels and accessories are designed to assist the surgeon in maintaining minimally invasive exposure to allow performance of spine surgical procedures.

Turbo MIS® TLIF System

The Turbo MIS® TLIF System is indicated for use in skeletally mature patients with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies who have had at least six months of non-operative care for their DDD. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). It is indicated to be used with autograft bone.

See Instructions For Use for other important information relating to the products featured in this surgical technique guide.

WARNING: See Instructions For Use for important precautions, contraindications, and warnings related to the products featured in this surgical technique guide.

CAUTION: USA Law restricts these devices to sale by or on the order of a physician.

PRODUCT COMPLAINTS: Any healthcare professional who has a complaint or who has experienced any dissatisfaction in the quality, identity, reliability, safety, efficacy, and/or performance of these products should notify SpineSelect.

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