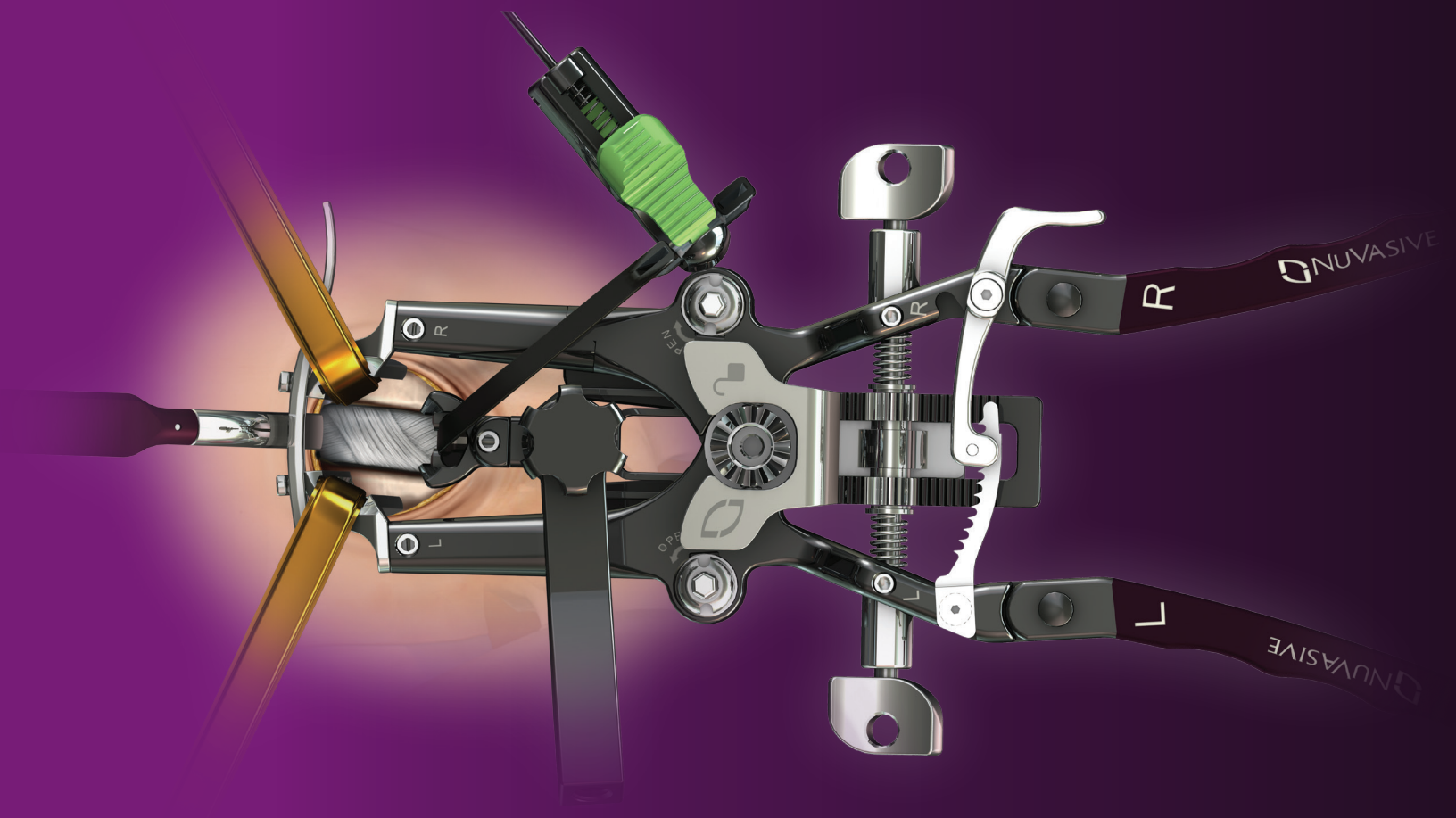
NUVASIVE®
Speed of Innovation®

XLIF®

Surgical Technique



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IPR2019-00362

MAXIMUM ACCESS SURGICAL PLATFORM MAS®

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PREFACE

Fellow Colleagues,

XLIF® was created to be a safer and more reproducible, minimally disruptive procedure that utilizes conventional surgical techniques and a seamlessly intergrated Maximum Access Surgery(MAS®) platform. With years of experience and thousands of successful procedures and system advancements, XLIF applications have expanded from single-level DDD to advanced degenerative spinal pathologies. XLIF is the first clinically validated lateral approach to the spine, allowing surgeons to accomplish fundamental surgical goals–anterior column correction and fusion.

Whereas previous attempts at minimally disruptive spine surgery (e.g., endoscopes, optical trocars, CO_2) typically introduced an inherent difficulty in using the new technology, XLIF is minimally disruptive while utilizing conventional surgical techniques. Over the years, the XLIF procedure and technology has evolved. However, two systems, described below, continue to help enable safer and more reproducible minimally disruptive spine surgery.

The MaXcess® 4 Access system provides maximum surgical access while minimizing the soft tissue disruption that often occurs during open surgery. MaXcess 4 allows the fundamentals of conventional surgical techniques to be achieved, while eliminating the unfamiliar requirements of operating coaxially through tubular portals. Additionally, since there are no adjunctive visualization tools (e.g., endoscope, monitor), the MaXcess 4 Access System enables direct illuminated visualization of the patient's anatomy through conventional methods.

The NVM5® system is another important technology that helps to enable safer and more reproducible minimally disruptive techniques. This system is the only surgeon-driven technology that provides dynamic, discrete information on nerve location and condition. The XLIF technique described in this guide utilizes a direct lateral, retroperitoneal, transpsoas approach to access the intervertebral disc. NVM5 was designed to enable a safer trajectory past the nerves in the psoas muscle by communicating nerve proximity and directionality information. This enables the surgeon to locate and avoid the lumbar plexus while accessing the disc. NVM5 is the only clinically validated nerve avoidance system for safety and reproducibility during a lateral transpsoas technique.

XLIF adoption has grown significantly since its introduction. Initially, the XLIF technique was used to address mainly single-level degenerative conditions in the lumbar spine. Since then, the indications have evolved and expanded. Today it is used routinely as a minimally disruptive solution to address many degenerative spinal pathologies that require anterior column support and/or reconstruction, including deformity.

As we continue to evolve spine surgery and decrease patient morbidity, it is imperative that the techniques do not undermine the surgical fundamentals that have served us well. The XLIF technique satisfies this requirement and should be considered as one of the many viable treatment options available to the spine surgeon.

Cordially,

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PRESURGICAL PREPARATION

EQUIPMENT REQUIREMENTS:

To successfully complete this technique, the following patient positioning supplies, instruments, implants, and fixation options are required.

PATIENT POSITIONING:

- 3 Inch Tape
- Axillary Roll
- Foam Padding
- Radiolucent Bendable Surgical Table

INSTRUMENTS:

- C-Arm
- Light Source
- MaXcess® 4 Access System
- MaXcess 4 Articulating Arm Tray
- MaXcess 4 Kit
- MaXcess Fixation Shim Kit *(optional)*
- XLIF® Instruments
- Anterior/Lateral General Instruments
- NVM5®
- NVM5 XLIF Dilator Kit
- NVM5 EMG Module

IMPLANTS:

- CoRoent® (XL, XL-W, XL-XW, XL-CT, XL-F, XL-FW, XL-K, XL-T)

LATERAL FIXATION OPTIONS:

- XLP®
- XLP Plus

POSTERIOR FIXATION OPTIONS:

- Precept®
- Armada®
- SpheRx® II
- SpheRx DBR III
- SpheRx PPS
- SpheRx PPS + EXT
- Radian® Facet Screws

Reference the CoRoent, MaXcess 4, NVM5, SpheRx II, SpheRx DBR III, Armada, Precept, Radian, and XLP Surgical Technique(s) or Reference Manual(s) and/or Instructions for Use (IFU) for additional important labeling information.

SURGICAL CONSIDERATIONS:

The XLIF procedure enables access to the spine via a lateral, retroperitoneal approach. The anatomic landmarks the surgeon should consider when preparing for this technique are the iliac crest, the 12th rib, and the lateral border of the erector spinae muscles.

Two small incisions will be made during this procedure. The surgeon will use the first incision, located near the lateral border of the erector spinae muscles, to access the retroperitoneal space and safely guide the initial XLIF Dilator to the psoas muscle. The second incision, located in a direct lateral position, will be used to place the Dilators and retractor, and will provide disc space access. This two-incision technique was specifically developed to offer simple and efficient access to the spine, while minimizing the potential for peritoneal injury, however various single-incision techniques may be used alternatively.

RETROPERITONEAL ACCESS:

Alternating blunt scissor and finger dissection is used to safely enter the retroperitoneal space. Once the index finger is inside the space, a gentle sweeping motion is used to release the peritoneum anteriorly and create a space through which the Dilators and retractor will pass. The initial XLIF Dilator will first pass through the oblique muscle layers and meet the index finger just inside the retroperitoneal space. The index finger will then escort the Dilator safely past the peritoneum down to the surface of the psoas muscle.

TRANSPSOAS ACCESS:

Once the initial XLIF Dilator is on the surface of the psoas muscle, the Dynamic Stimulation Clip is connected to the Dilator. As the Dilator is advanced through the psoas, the surgeon uses the NVM5® neuromonitoring system to detect and avoid the nerves of the lumbar plexus. A direct lateral trajectory targeting just posterior to the middle of the disc minimizes the chance of encountering a nerve and ensures that the anterior vessels remain well anterior to the access corridor. Once docked on the spine, the Dilator is affixed to the disc with a K-Wire, and subsequent dilation and muscle-splitting retraction establish the operative corridor.

XLIF® SURGICAL TECHNIQUE

STEP 1:

PATIENT POSITIONING & O.R. SETUP

Under AP fluoro guidance, the patient is placed on a radiolucent and bendable surgical table in a direct lateral decubitus (90°) position so that the greater trochanter is slightly inferior to the table break. The patient is then secured with tape at the following locations *(Fig. 1)*:

Just below the iliac crest **(A)**

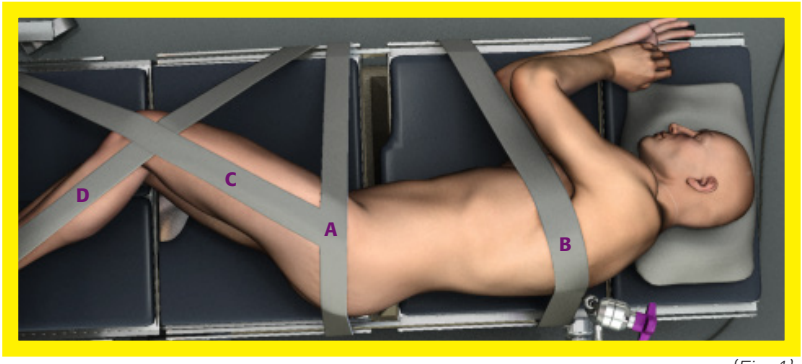
Over the thoracic region **(B)**

From the greater trochanter to the knee, then secured to the table with padding placed between knees **(C)**

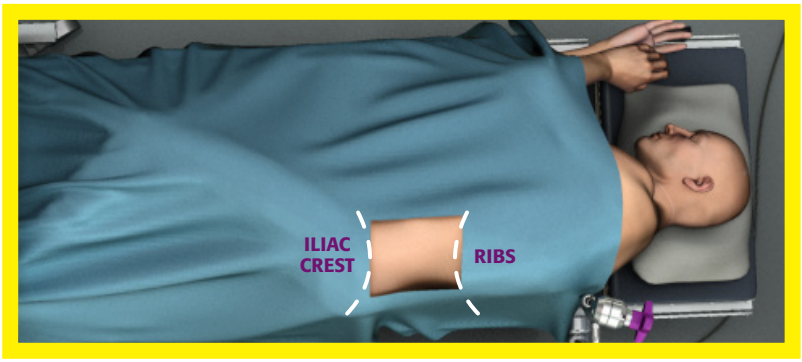
From the table to the knee, past the ankle, then secured to the table **(D)**

This configuration ensures that the pelvis tilts away from the ipsilateral spine, allowing access to all lumbar levels, particularly L4-L5, without interference from the iliac crest.

Using fluoroscopy to verify location, the surgical table may be flexed to increase the distance between the iliac crest and the ribs in order to gain direct access to the disc *(Fig. 2)* and tension the skin.



(Fig. 1)



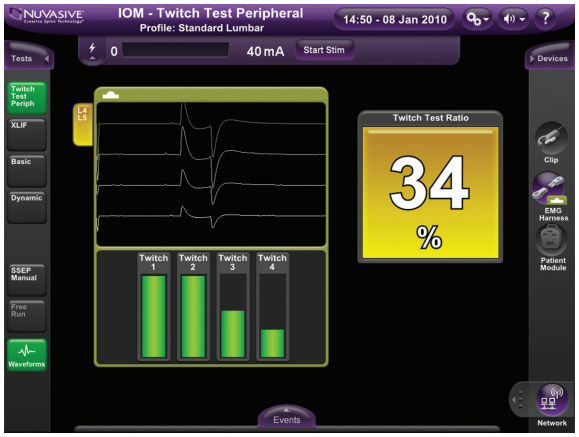
(Fig. 2)

STEP 1:

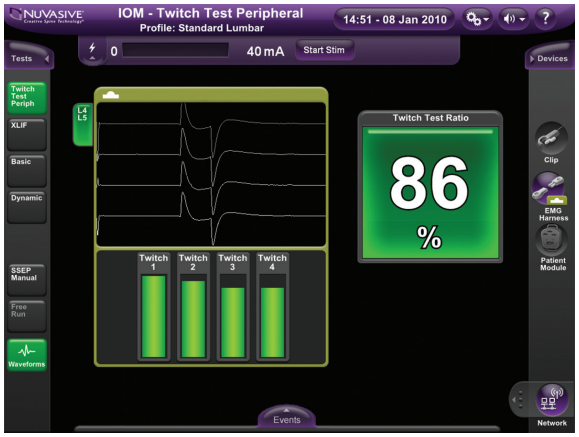
PATIENT POSITIONING & O.R. SETUP (CONT'D)

NVM5® TWITCH TEST

In order to ensure that accurate EMG readings are obtained later in the procedure, it is imperative that a Twitch Test be performed once the patient is positioned and the NVM5 electrodes are in place (see NVM5 Reference Manual for details). If the Twitch Test results are unacceptable *(Fig. 3)*, anesthesia should be instructed to reverse paralytics and muscle relaxants until an acceptable Twitch Test is conducted *(Fig. 4)*.



(Fig. 3)



(Fig. 4)

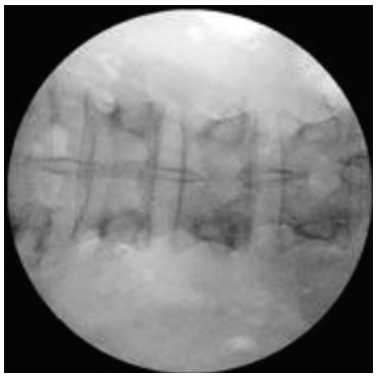
STEP 1:

PATIENT POSITIONING & O.R. SETUP (CONT'D)

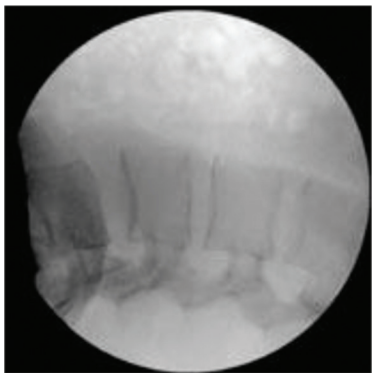
Once the patient is secured, the table should be adjusted so that the C-Arm provides true AP images when at 0° (distinct endplates and pedicles symmetrical about the spinous process), and true lateral images when at 90° (distinct endplates and superimposed pedicles) (*Figs. 5, 6*).

The table should be adjusted independently when accessing each level in order to maintain this relationship.

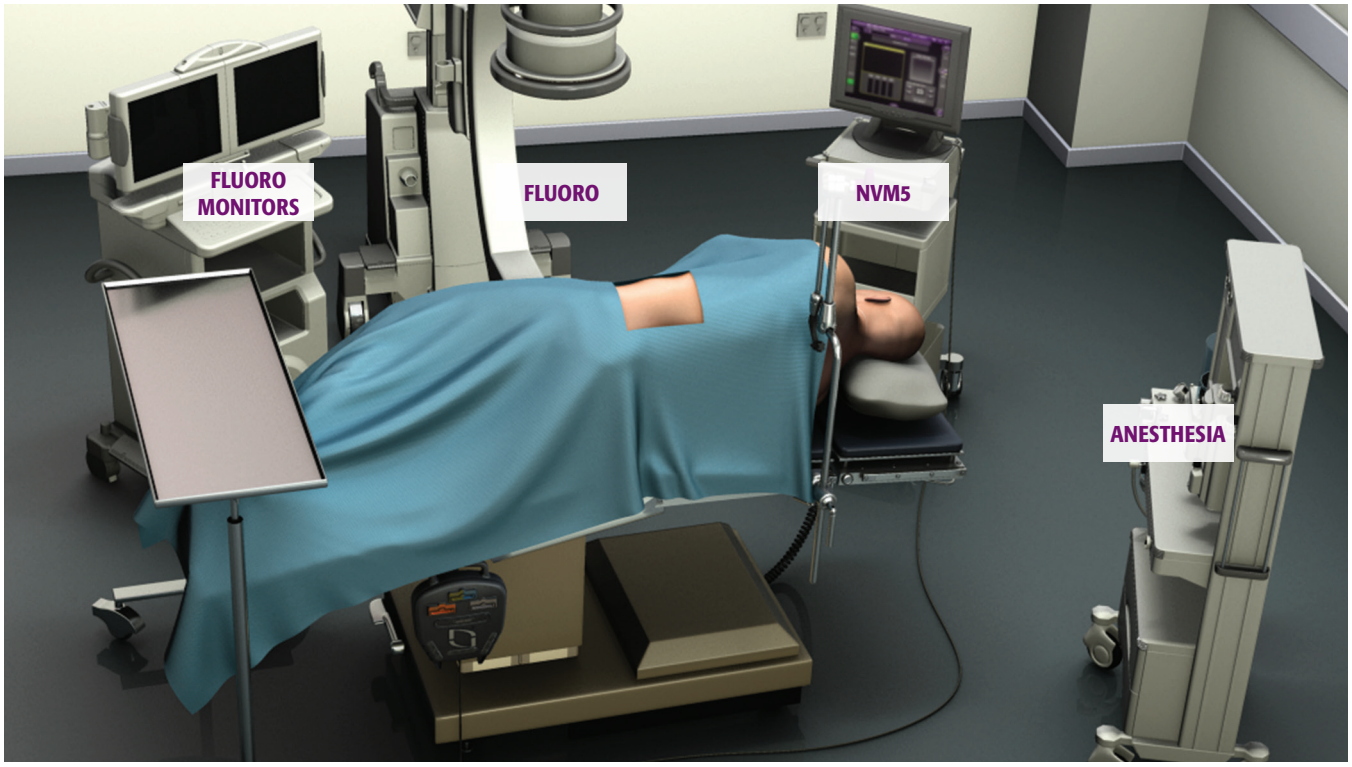
The NVM5® control unit should be placed opposite the surgeon to enable an unobstructed view *(Fig. 7)*.



(Fig. 5)



(Fig. 6)



(Fig. 7)

STEP 2:

ANATOMIC LANDMARK IDENTIFICATION & INITIAL INCISIONS

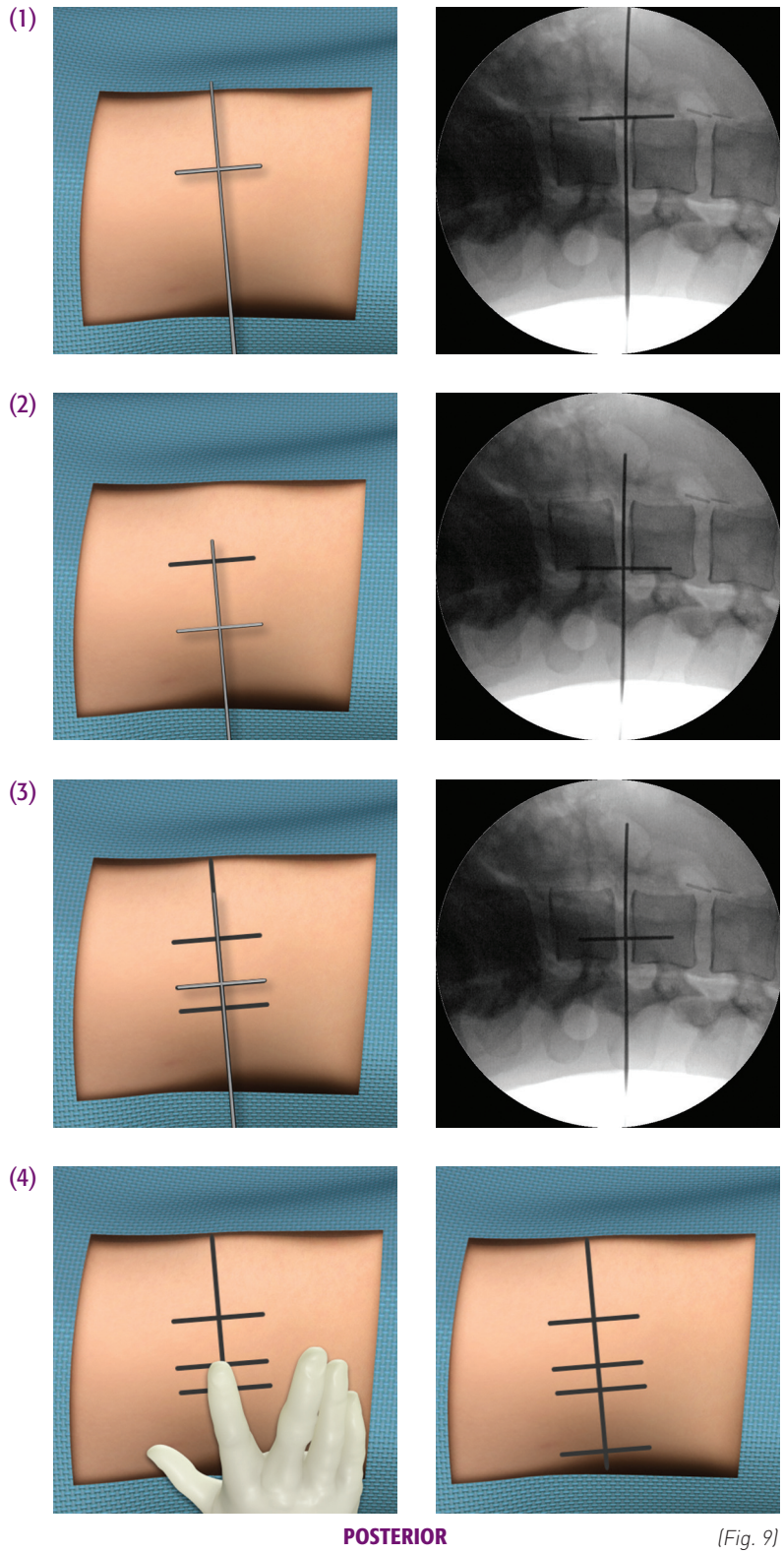
Following standard surgical preparation, the disc space is localized using lateral fluoroscopy *(Fig. 8)*.

Using the Targeting Instrument, longitudinal marks are made on the skin to define the anterior border of the vertebral bodies (1), the posterior border of the vertebral bodies (2), and the posterior third of the disc space (3). Next, a transverse mark, in line with the disc space, is made on the skin (4). Extending this transverse mark serves as a visual reference to both surgeon and C-Arm operator.

Another mark is made on the skin at a posterolateral location that will serve as the location for the skin incision for accessing the retroperitoneal space via blunt scissor and finger dissection. Typically, this is a finger length's distance from the lateral incision and just lateral to the erector spinae muscles *(Fig. 9)*.

ANTERIOR

(Fig. 8)



POSTERIOR

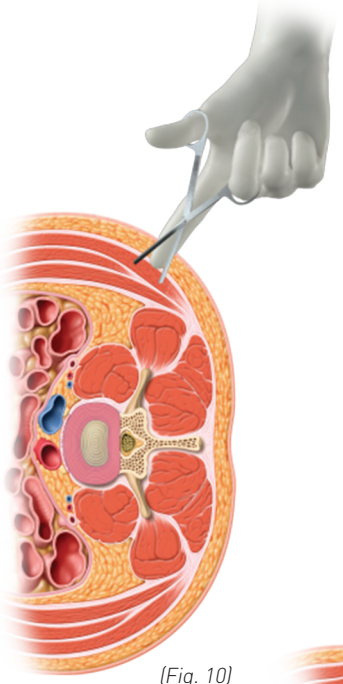
(Fig. 9)

XLIF® SURGICAL TECHNIQUE

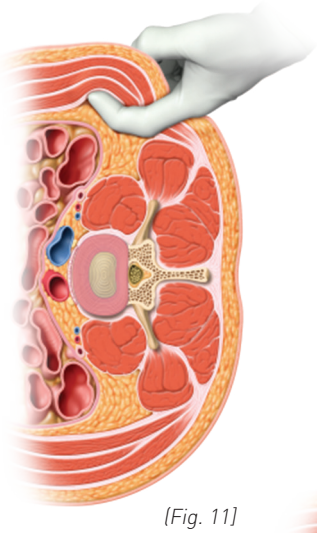
STEP 3:
RETROPERITONEAL ACCESS

The skin and fascia are incised at the posterolateral marking. Through this incision, the muscle layers of the external obliques, internal obliques, and transverse abdominis are dissected using alternating blunt scissor and finger dissection *(Fig. 10)*. Care should be taken to preserve the sensory nerves in these muscle layers (i.e., electrocautery should be avoided). The final fascial layer that will be reached is the transversalis fascia, which can be perforated by gentle pressure with blunt scissors. Typically a loss of resistance by the fascia and constriction around the finger indicates that the retroperitoneal space has been reached. Care should be taken to avoid abrupt advancement, which could cause perforation of the peritoneum.

Once inside the retroperitoneal space, the index finger is used to create space and release the peritoneum anteriorly *(Fig. 11)*. When the peritoneum is released, the finger is then used to palpate the psoas muscle or the anterior surface of the transverse process *(Fig. 12)* for verification of position within the retroperitoneal space.



(Fig. 10)



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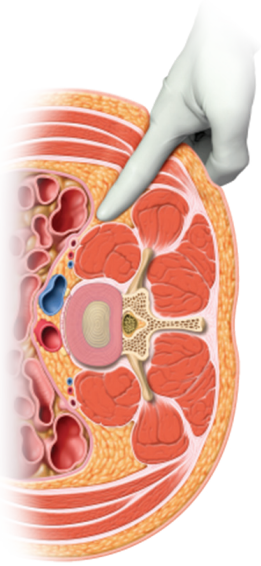


(Fig. 12)

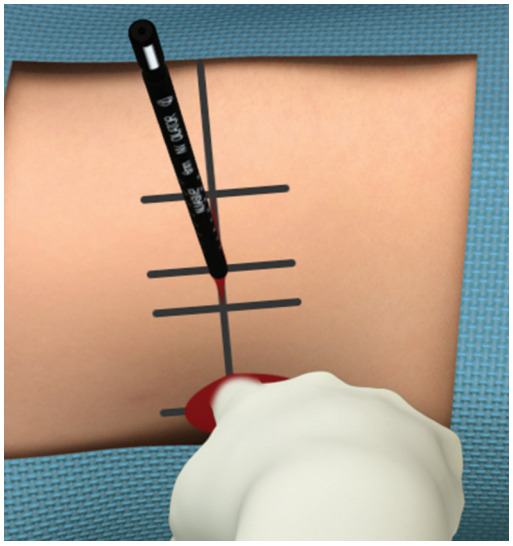
STEP 4:

RETROPERITONEAL APPROACH

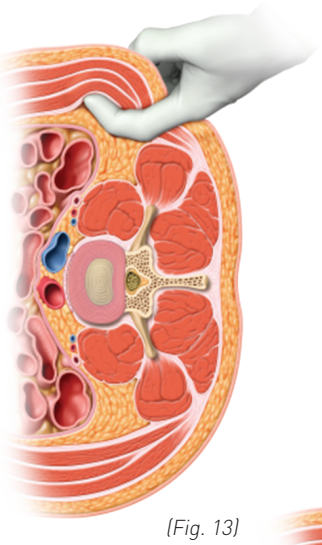
Once the retroperitoneal space is identified, the index finger is brought up to the inside abdominal wall underneath the direct lateral skin mark *(Fig. 13)*. This step ensures that a pathway exists between the abdominal wall and the psoas muscle.

A skin and fascial incision is made at this location *(Fig. 14)* followed by blunt dissection through muscle planes and the transversalis fascia. Then the initial XLIF Dilator (black) is introduced *(Fig 15)*.

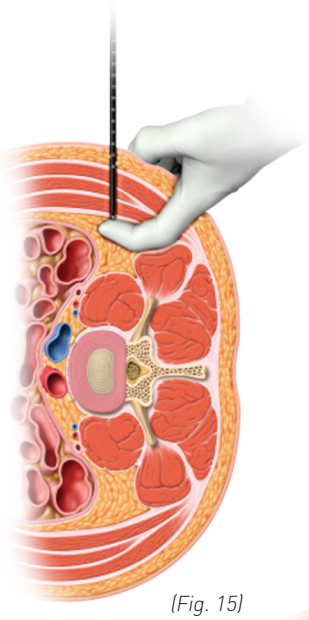
The index finger that is inside the retroperitoneal space is then used to escort the initial Dilator down to the psoas muscle *(Fig. 16)*.



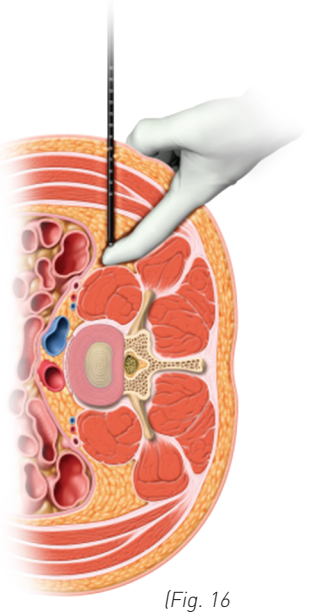
(Fig. 14)



(Fig. 13)



(Fig. 15)



(Fig. 16

STEP 5:
TRANSPSOAS APPROACH

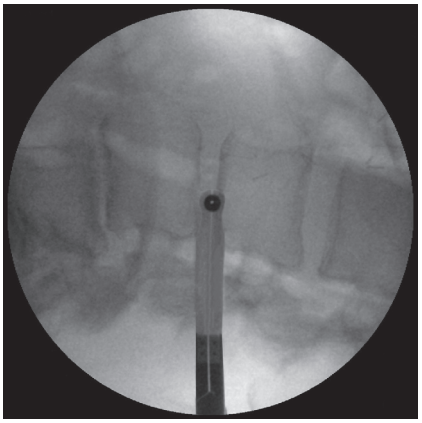
IMPORTANCE OF NEUROMONITORING:
Neuromonitoring is critical to the safety and reproducibility of any lateral transpsoas approach due to the lumbar plexus' positioning within the psoas. The motor nerves of the lumbar plexus generally reside within the posterior third of the psoas, however, their positioning can vary from patient to patient.

XLIF® relies on the clinically validated dynamic EMG nerve avoidance mode of NVM5® to identify a safer docking position and working area.[1]

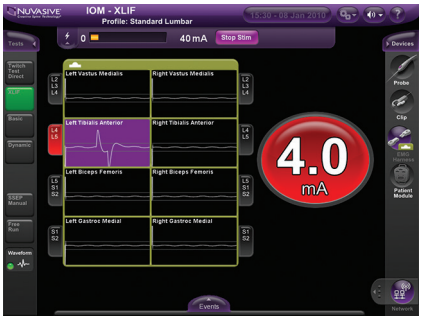
NVM5 offers surgeon-driven, real-time discrete thresholds, as well as directionality and relative proximity nerve information.

Upon reaching the lateral surface of the psoas muscle with the initial XLIF Dilator, the location is verified with a lateral fluoroscopic image. The ideal docking location is the junction of the posterior third and anterior two-thirds of the disc space, or as posterior on the disc space as NVM5 favorably allows *(Fig. 17)*.

The Dynamic Stimulation Clip is attached to the initial Dilator and NVM5 is activated in XLIF mode. The initial Dilator is then passed medially through the psoas, while slowly being rotated 360° to determine the three-dimensional position of the nerves.[2] NVM5 will display the continually updated threshold stimulation that triggers a neural response *(Fig. 18-20)*. A line on the proximal end of the Dilator indicates the stimulation direction, and if this stimulation is directed away from the nerves, the NVM5 monitor will display a higher threshold. If alert-level thresholds indicate an unsafe docking location, the Dilator is removed from the psoas and moved to a new trajectory, away from the nerves. Lower EMG thresholds posterior with higher thresholds anterior, generally indicates a safe position. This process is repeated until a safe path through the psoas to the spine is identified. For more information, refer to the NVM5 Quick Reference Manual in the help section on the NVM5 screen.



(Fig. 17)



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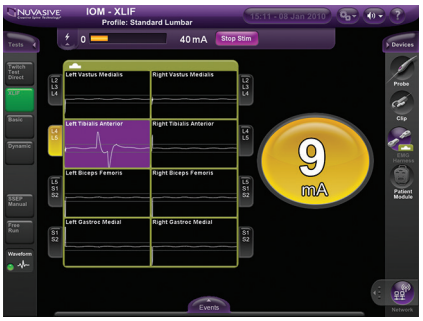


(Fig. 19)

(Fig. 20)

[1] *Uribe JS, et.al. J Neurosurg Spine 13:260-266, 2010*

[2] *Tohmeh AG, et. al. J Neurosurg Spine 14:31-37, 2011*

STEP 5:
TRANSPSOAS APPROACH (CONT'D)

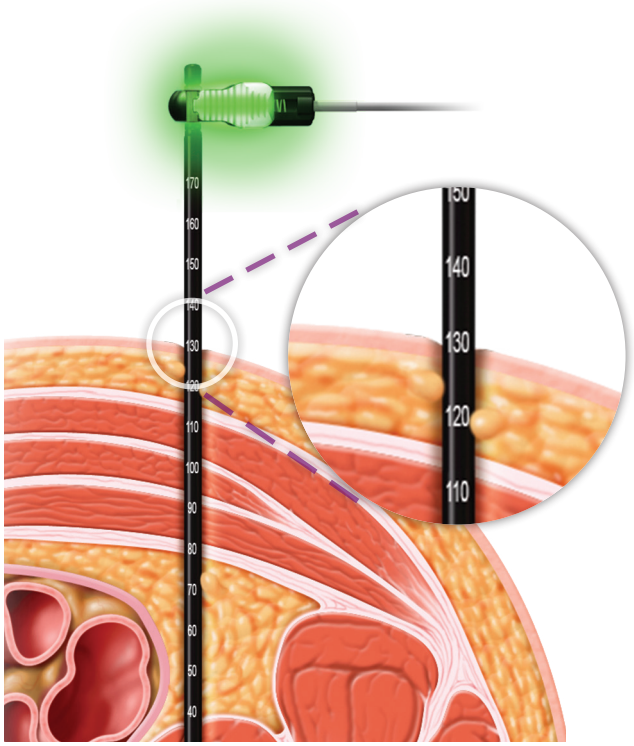
Once the initial Dilator is docked on the disc, fluoroscopy should be used to confirm proper positioning.

A lateral image should confirm that the Dilator is approximately centered on, and parallel with, the disc *(Fig. 21)*. If the Dilator is not in the optimal position, it may be repositioned with the use of NVM5®.

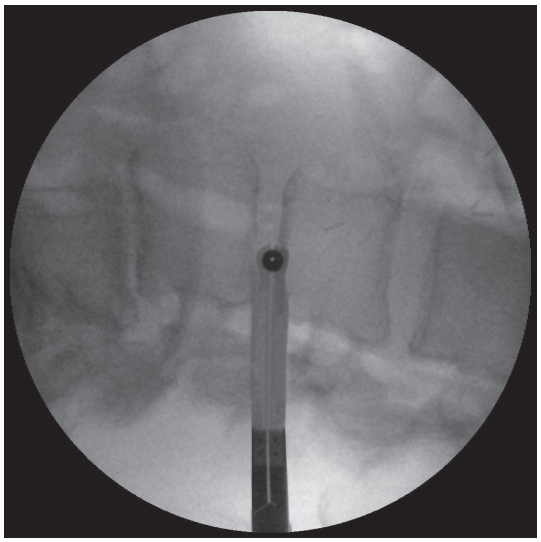
A cross-table AP image should confirm that the Dilator is in the plane of, and flush with, the disc space *(Fig. 22)*.

Following confirmation of the initial Dilator's position, a K-Wire is introduced about halfway into the disc space to secure the position. Laser markings on the K-Wire at 10mm intervals may assist in reaching optimal K-Wire depth. Depth markings on the Dilator indicate the size of the appropriate length Blades to be attached to the MaXcess® 4 Access Driver *(Fig. 23)*.

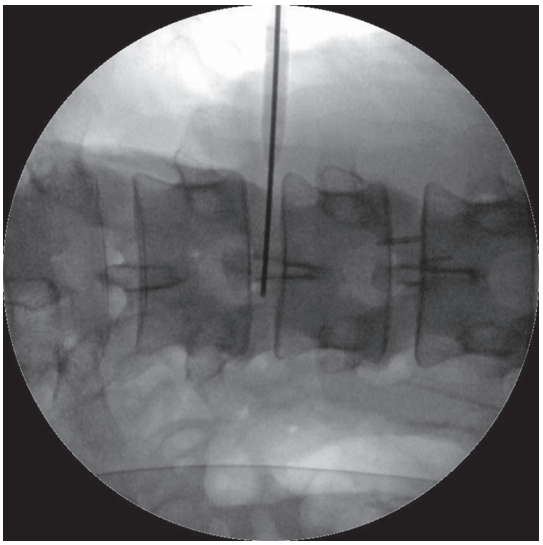
The next two XLIF® Dilators (magenta and blue) are subsequently introduced over the initial Dilator using a twisting motion. NVM5 is used as with the previous Dilator to determine nerve proximity.



(Fig. 23)



(Fig. 21)



(Fig. 22)

STEP 6:

XLIF® ELECTRODE INSTALLATION AND RETRACTOR ASSEMBLY

Once the appropriate Center Blade length has been selected, the XLIF Electrode can be installed by sliding the Electrode into the Center Blade track, cylindrical end first, following the direction of the instructional arrow on the back of the blade *(Figs. 24, 25, 26)*.

(Fig. 24)

(Fig. 25)

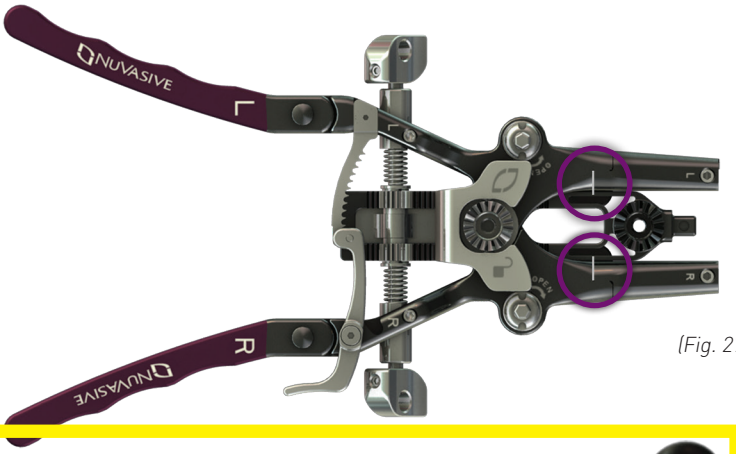
(Fig. 26)

STEP 6:

XLIF® ELECTRODE INSTALLATION AND RETRACTOR ASSEMBLY (CONT'D)

To assemble the Access Driver, the lines of the center arm should be aligned with the lines on the left (L) and right (R) arms with the retractor closed *(Fig. 27)*. The Center (C) Blade should be loaded first and the set-screw tightened.

The L and R Blades can then be loaded and the set-screws tightened *(Fig. 28)*; the L and R handles can be attached to the Access Driver by depressing the button and sliding toward the retractor body.



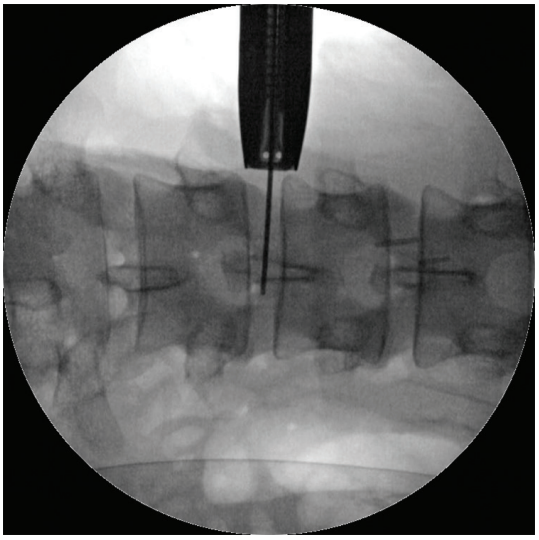
(Fig. 27)

(Fig. 28)

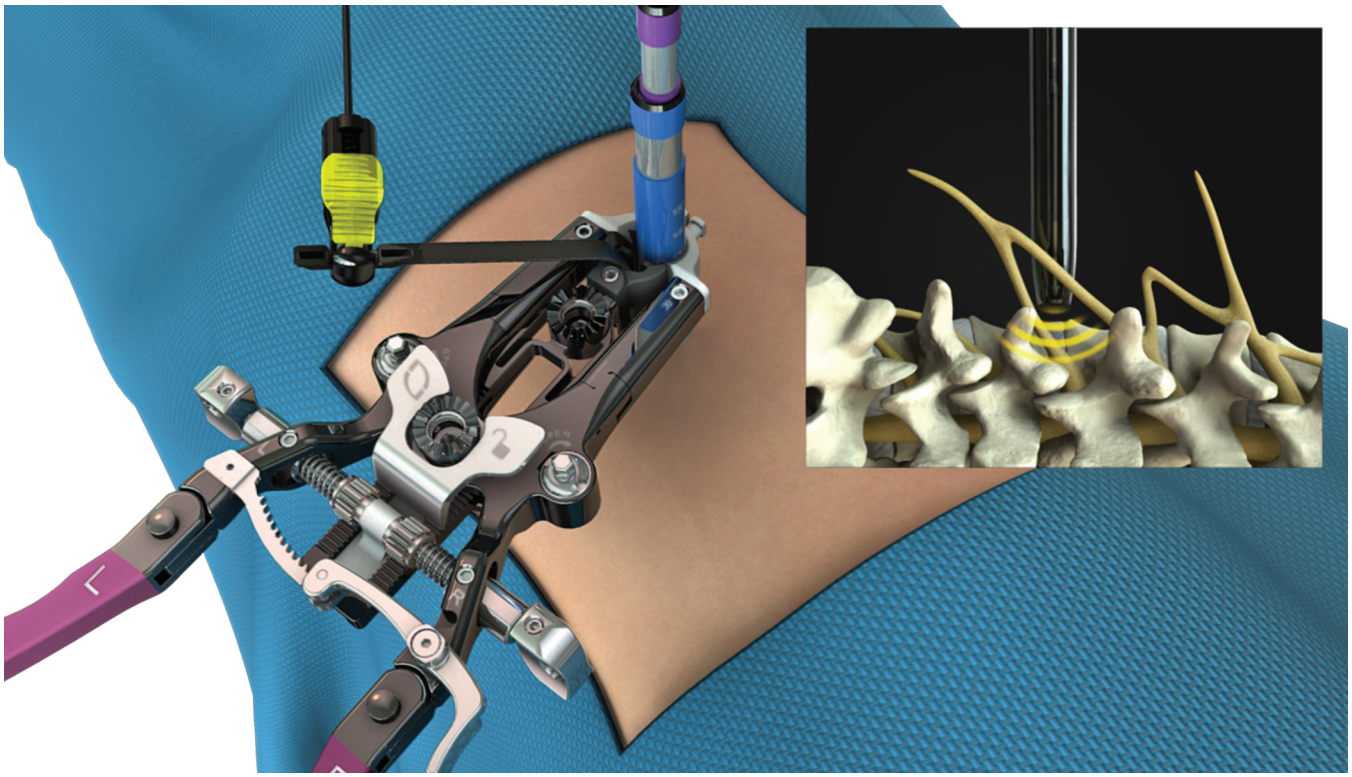
STEP 7:
ACCESS

The Access Driver is introduced over the third Dilator with the handles pointing posteriorly. The NVM5® Dynamic Stimulation Clip may be attached to the cylindrical lead at the proximal tip of the XLIF® Electrode (Fig. 29). The Access Driver is advanced through the psoas muscle with slight rotation in conjunction with stimulated EMG. Threshold EMG readings from the XLIF Electrode provide directionality and relative proximity nerve information throughout the entire procedure. Constant downward pressure on the Access Driver may help mitigate tissue creep.

Cross-table AP fluoroscopy is used to confirm the correct position of the Access Driver Blades on the spine and to ensure that the Blades are parallel with the disc space. The Alignment Dots at the distal tips of the L and R Blades will align with the bottom corners of the C Blade Targeting Window when the retractor is in line with the C-Arm, and thus the disc space, and parallel with the floor (Fig. 30).



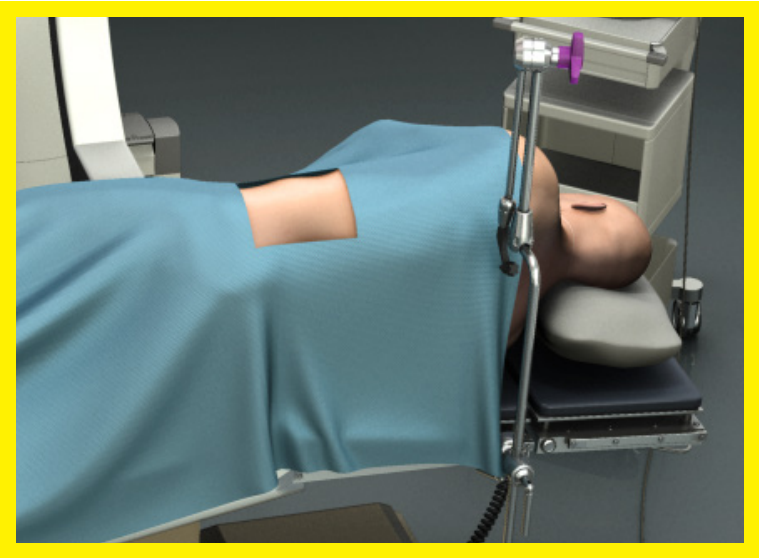
(Fig. 30)



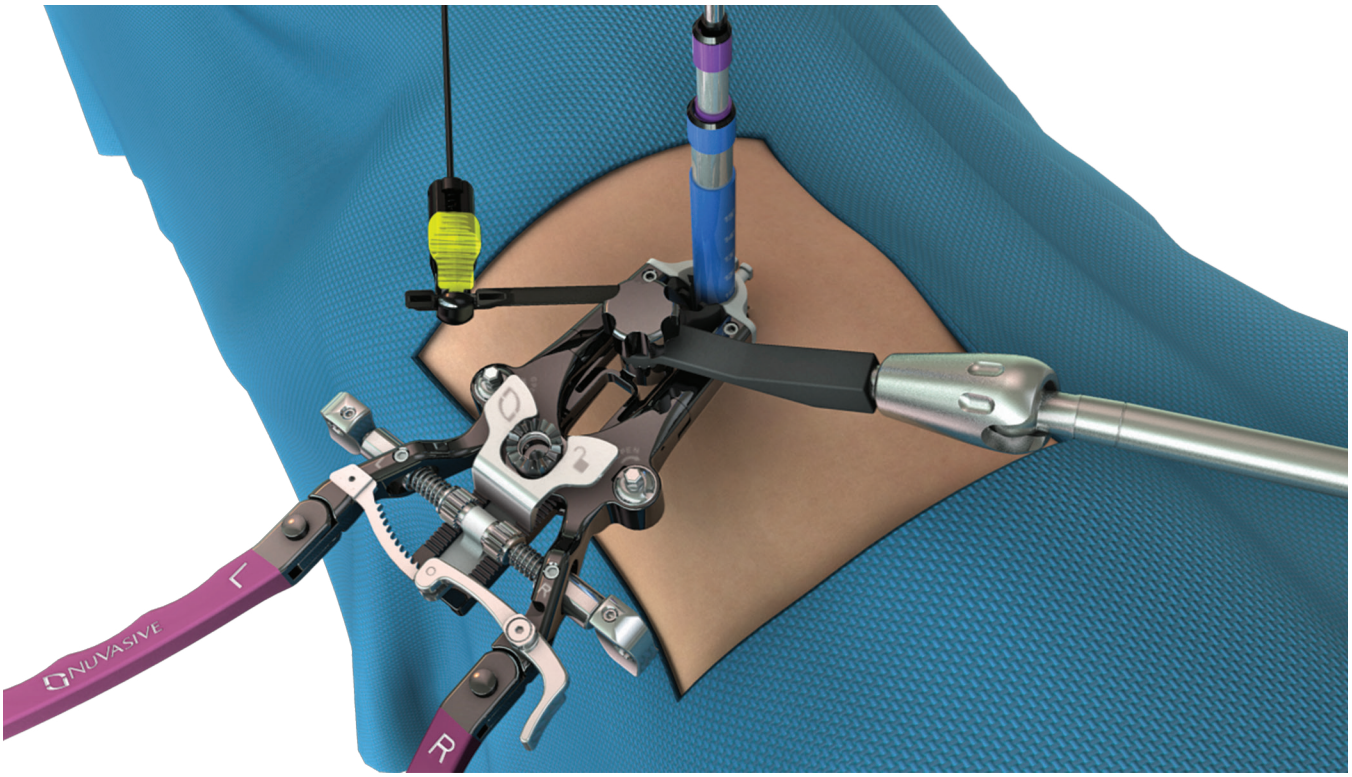
(Fig. 29)

STEP 7:
ACCESS (CONT'D)

The Articulating Arm bedrail attachment should be attached to the bedrail of the table *(Fig. 31)*. The Articulating Arm post is passed through the bedrail attachment, adjusted to the desired height, and locked into position by tightening the handle on the bedrail attachment. The opposite end of the Articulating Arm is attached to the Access Driver *(Fig. 32)*. Maintenance of retractor position may be enhanced by maintaining an upward angle of the Articulating Arm when attaching to retractor body.



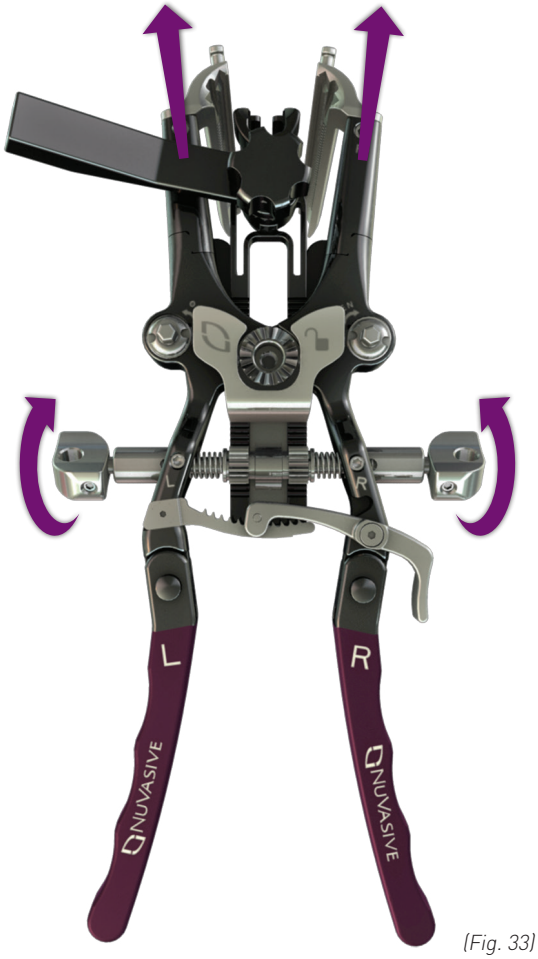
(Fig. 31)



(Fig. 32)

STEP 7:
ACCESS (CONT'D)

The black-coated Articulating Arm attachment point is most commonly used for Lumbar XLIF® procedures. This fixes the C Blade relative to the table and results in the L and R Blades moving anteriorly when opened to minimize pressure at the posterior portion of the psoas muscle, where the majority of the lumber plexus nerves are located *(Fig. 33)*. The silver Articulating Arm attachment point is primarily used for thoracic applications and affixes the L and R Blades to the table which results in the C Blade moving posteriorly when opened *(Fig. 34)*.



(Fig. 33)

(Fig. 34)

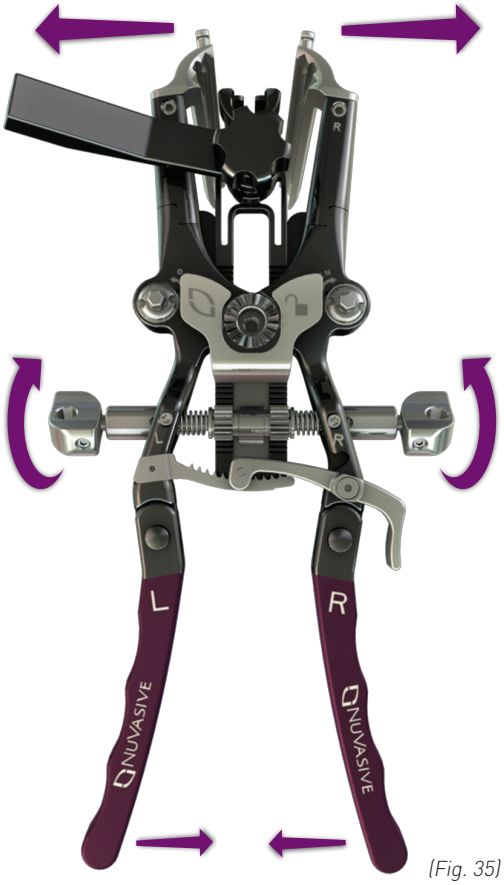
STEP 7:
ACCESS (CONT'D)

The handles of the Access Driver are squeezed one click to open the Blades in the cephalad/caudal direction *(Fig. 35)*.

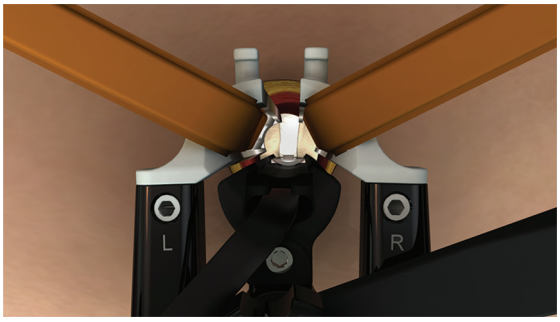
Initial anterior exposure is achieved by turning the knobs on the sides of the Access Driver one click in the direction of arrows *(Figs. 36, 37)*.

The single end of the bifurcated Light Cable and the appropriate light source connector are passed off the sterile field and attached to a light source. The two beveled ends of the Light Cable are placed about halfway down the L and R Blades of the Access Driver and bent flush to the surface of the Access Driver.

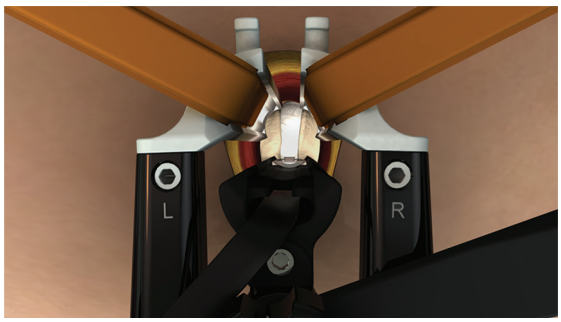
Proper anterior/posterior position is verified using lateral fluoroscopy *(Fig. 38)*.



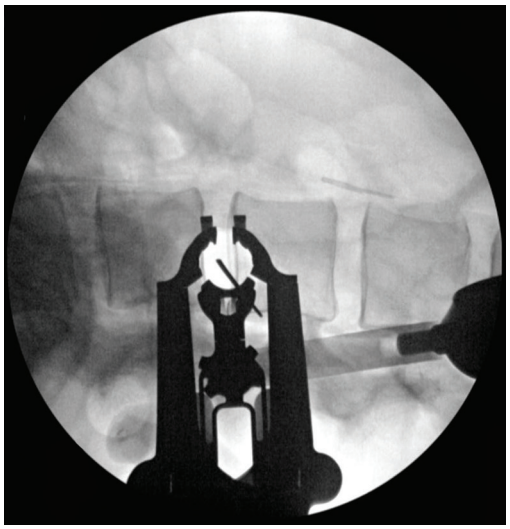
(Fig. 35)



(Fig. 36)



(Fig. 37)



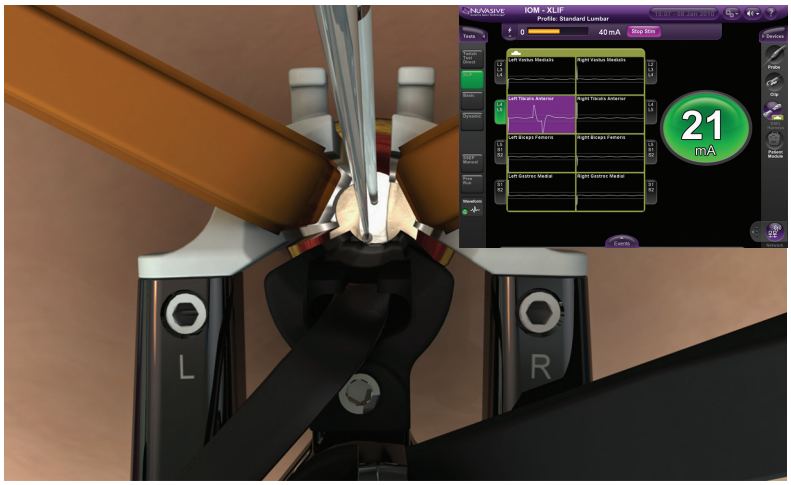
(Fig. 38)

STEP 7:
ACCESS (CONT'D)

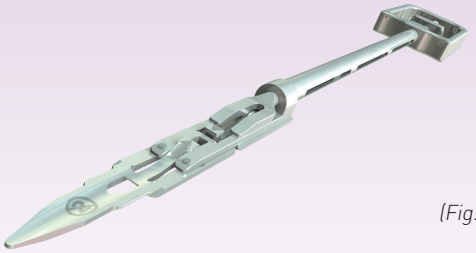
Any residual tissue at the bottom of the exposure is thoroughly explored, using the NVM5® Probe to confirm that no nerves are within the exposure *(Fig. 39)*.

Shims are available in various sizes to both effectively widen and lengthen the Blades to keep tissue out of the exposure. A Locking Intradiscal Shim may be placed into the disc space to further stabilize the retractor and prevent nerves from slipping under the C Blade.

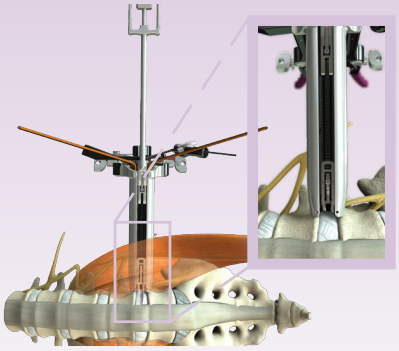
To load the Locking Intradiscal Shim onto the Locking Shim Repositioning Tool, align the laser markings and slide the Shim onto the Repositioning Tool. The Locking Shim Repositioning Tool will click into place when it is fully engaged *(Fig. 40)*. The Locking Shim Repositioning Tool is used to introduce the Locking Intradiscal Shim into the disc space *(Fig. 41)*. To disengage the Locking Shim Repositioning Tool from the Locking Intradiscal Shim, depress the button *(Fig. 42)*. The Locking Intradiscal Shim may also be removed with the Locking Shim Repositioning Tool *(Fig. 43)*.



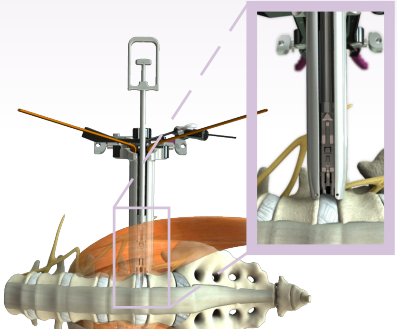
(Fig. 39)



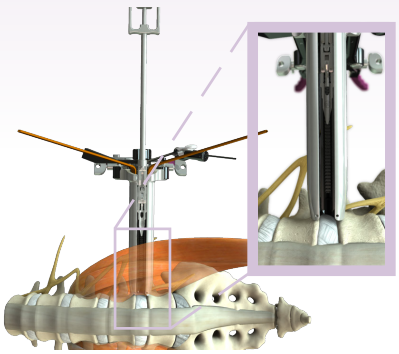
(Fig. 40)



(Fig. 41)



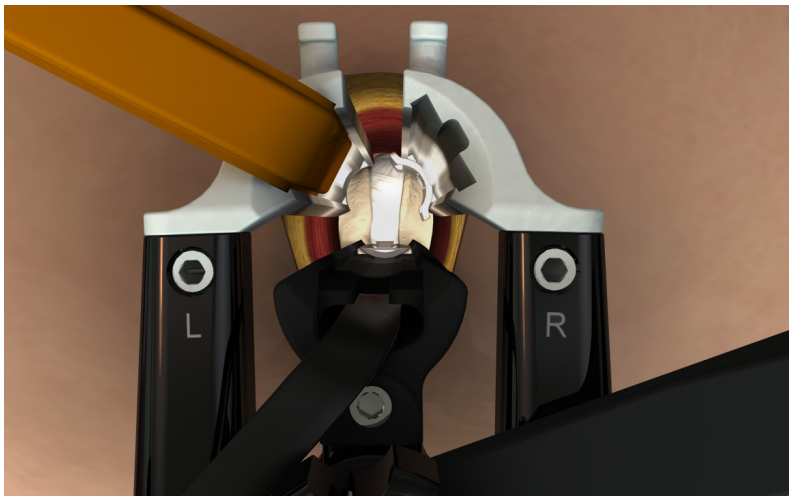
(Fig. 42)



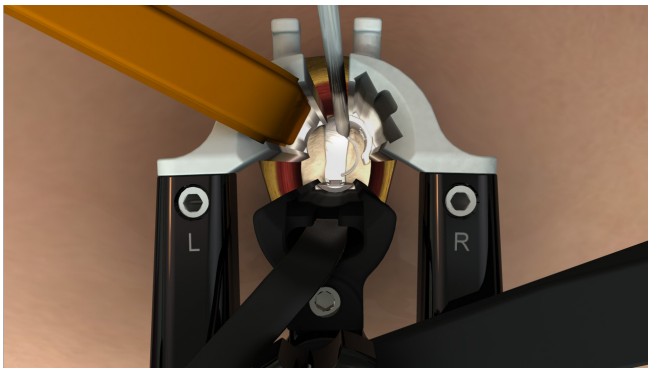
(Fig. 43)

STEP 7:
ACCESS (CONT'D)

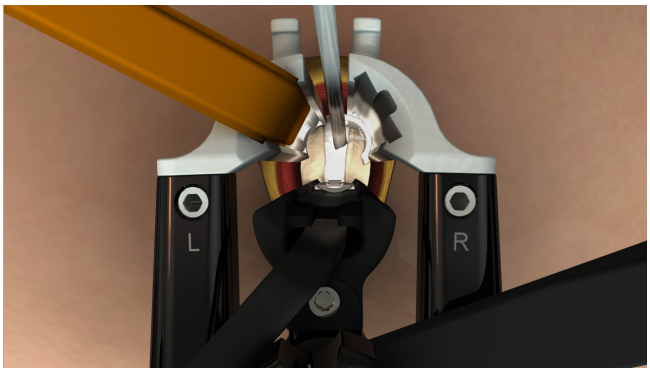
Additional Shims can optionally be placed down the Blades to increase the Blade length or width *(Fig. 44)*. A Penfield, Nerve Retractor, or Psoas Retractor can be used to tuck residual tissue behind the shims *(Figs. 45-48)*. Bipolar electrocautery can be used, if necessary, to further prepare for disc visualization. Monopolar electrocautery is best avoided to prevent inadvertent nerve injury.



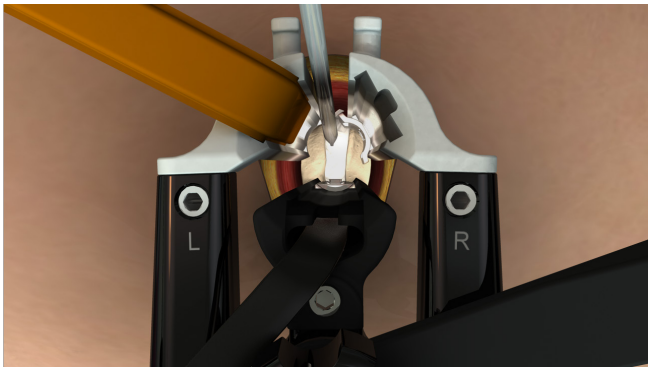
(Fig. 44)



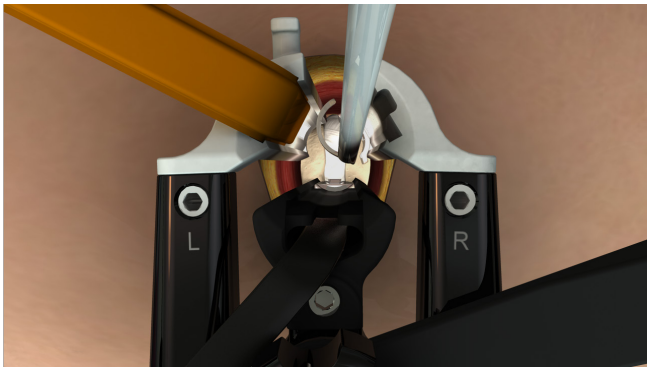
(Fig. 45)



(Fig. 46)



(Fig. 47)

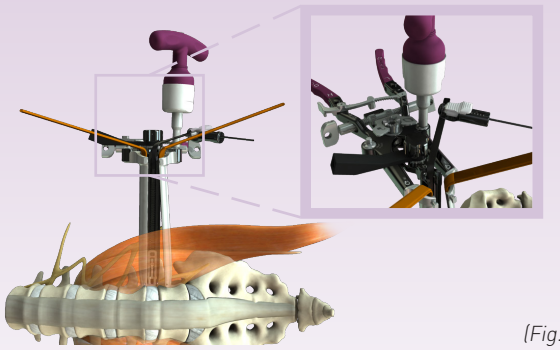


(Fig. 48)

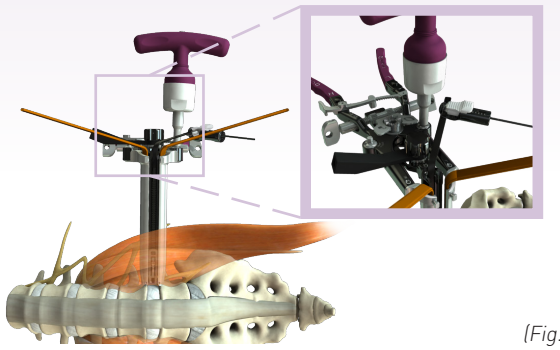
STEP 7:
ACCESS (CONT'D)

If patient anatomy dictates, the Blade Rotation Driver can be used to rotate the left and/or right Blades independently *(Fig. 49)*. This will expand the distal exposure and may assist in preferentially adjusting the exposure cephalad or caudal (e.g., caudal at L4-L5 under iliac crest) to gain optimal access to the disc space *(Fig. 50)*. Care should be taken to avoid expanding the Blades to the mid-vertebral body or beyond to minimize psoas trauma and reduce the risk of segmental vessel injury. A quarter turn of the Blade Rotation Driver corresponds to approximately 5° of blade rotation, which can be visualized using AP fluoroscopy.

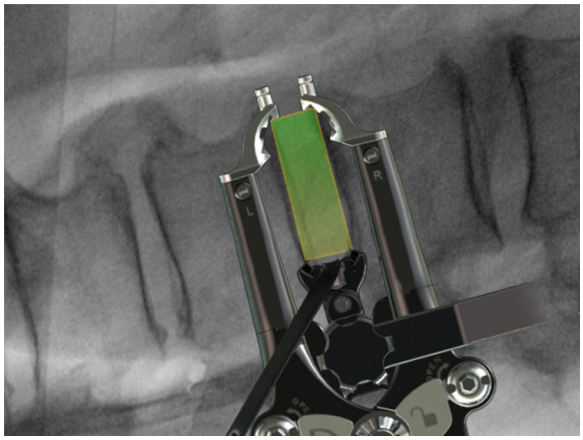
The cephalad/caudal exposure should only be as wide as is necessary to prepare the disc space *(Fig. 51)*. Wider exposure unnecessarily increases psoas muscle trauma. The nerve root retractor or anterior retractors can be used to retract tissue to the anterior border of the spine (i.e., Anterior Longitudinal Ligament) and can be secured using the anterior crossbar *(Fig. 52)*. It is recommended that the Anterior Retractor is removed during any steps that involve impaction.



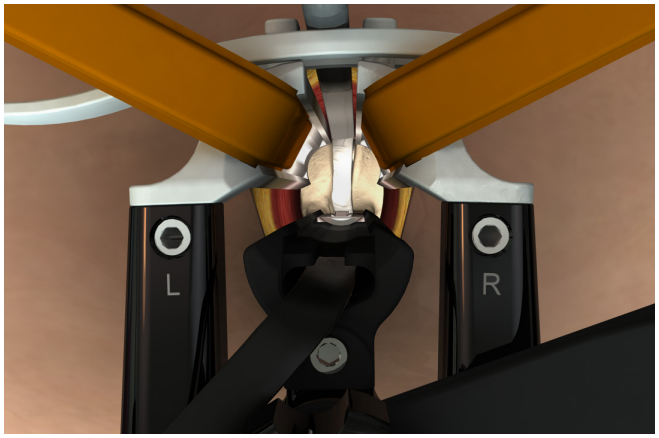
(Fig. 49)



(Fig. 50)



(Fig. 51)

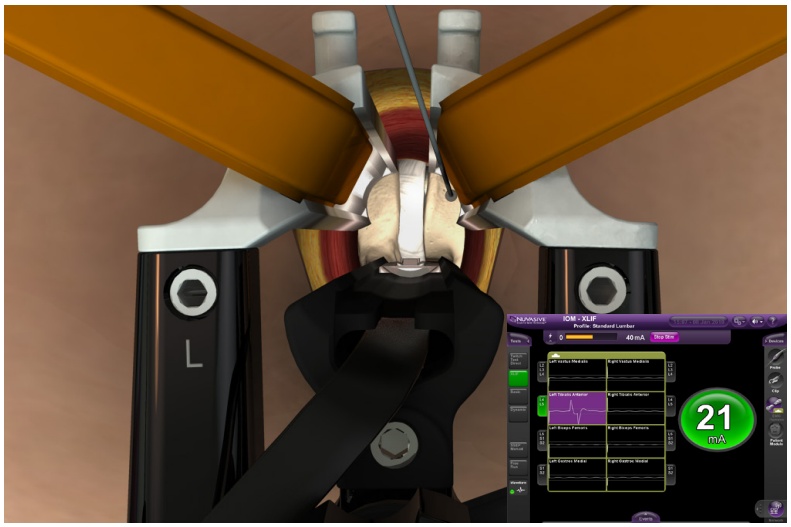


(Fig. 52)

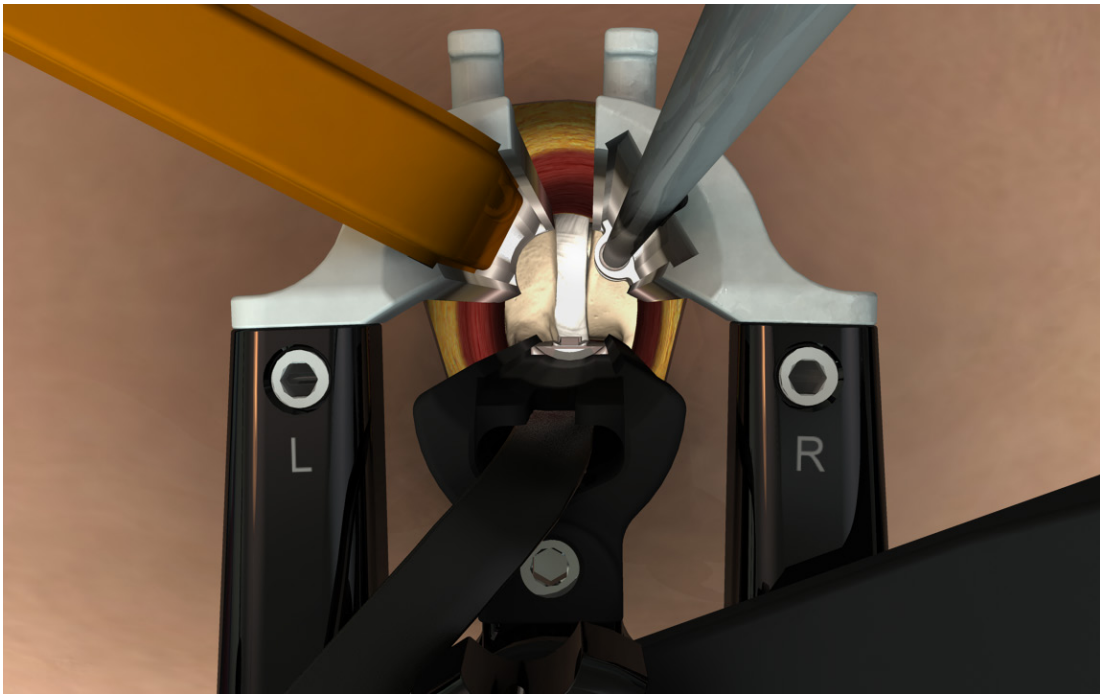
STEP 7:
ACCESS (CONT'D)

FIXATION SHIMS (OPTIONAL)

Following placement of the Locking Intradiscal Shim and any nessessary rotation of the left and right blades, MaXcess® Fixation Shims can optionally be placed down the L and R Blades of the Access Driver and threaded into the vertebral bodies to attach the retractor to the spine and provide further stabilization. First, the location of the vertebra where the screw will engage is identified. Then, the absence of nerves and segmental vessels are verified using direct visualization and the NVM5® Ball Tip Probe *(Fig. 53)*. A Fixation Shim is attached to the Fixation Shim Driver, placed down the Blades, and threaded into the vertebral body under fluoroscopic guidance *(Fig. 54)*. Once the Fixation Shims are placed, the Blades should not be adjusted. The MaXcess Fixation Shims should not be used for vertebral body distraction. A hemostatic agent should be used following removal of the Fixation Shims to minimize bleeding and the risk of hematoma formation.



(Fig. 53)



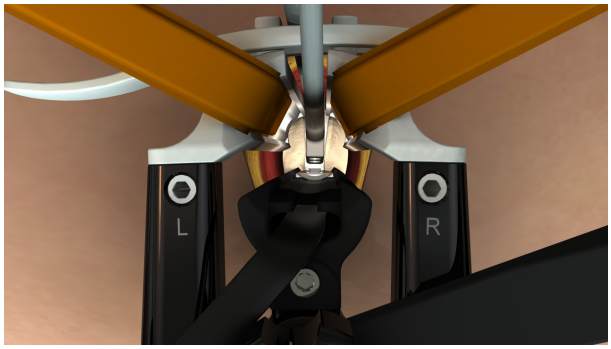
(Fig. 54)

STEP 8:

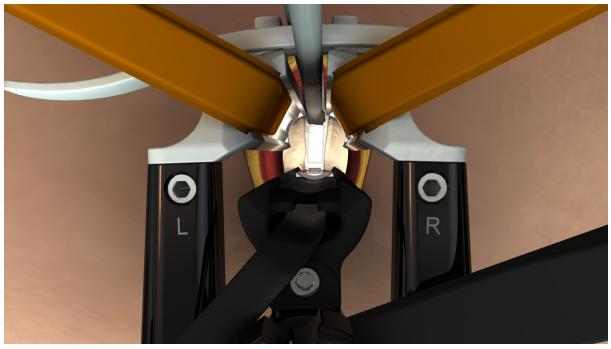
ANNULOTOMY & DISC SPACE PREPARATION

The Annulus Cutter is used to create an annulotomy template, either 18mm or 22mm in AP length depending on the desired implant size, on the lateral face of the disc, leaving at least 1mm-2mm of annulus between the Locking Intradiscal Shim and the template *(Fig. 55)*. Following this, an annulotomy is created with the Annulotomy Knife *(Fig. 56)*. Disc preparation instruments are passed along both endplates and completely through the contralateral annulus *(Fig. 57)*. Contralateral annulus release is critical to facilitate distraction of the disc space, achieve proper coronal alignment, and place a large implant that spans the ring apophysis.

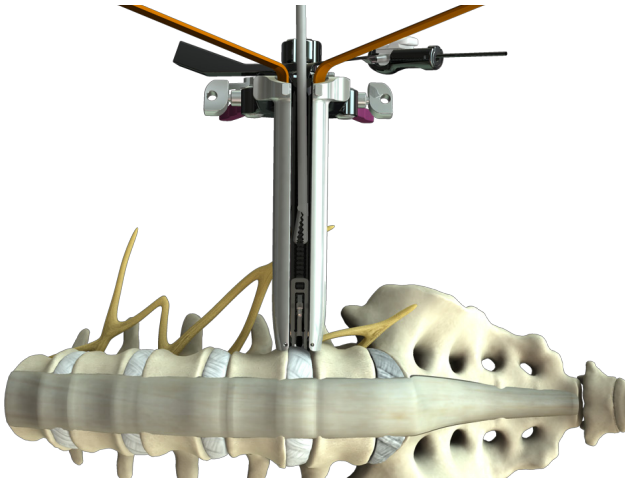
Pituitaries, Curettes, Disc Cutters, Endplate Scrapers, Rasps and other disc preparation instruments can be used to thoroughly evacuate the disc and prepare the endplates for fusion *(Fig. 58)*.



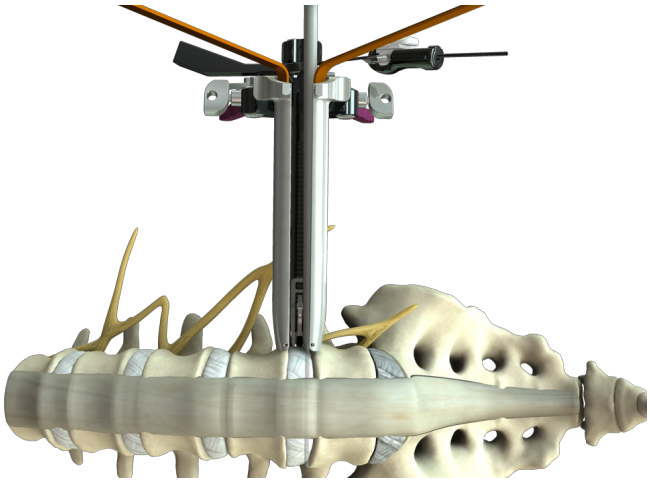
(Fig. 55)



(Fig. 56)



(Fig. 57)

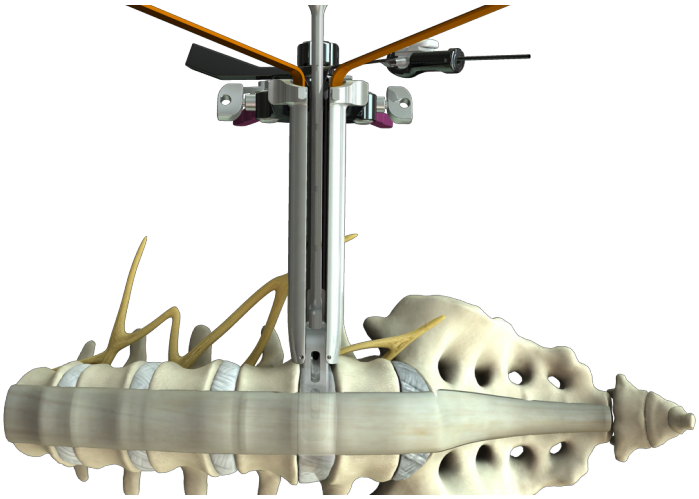


(Fig. 58)

STEP 9:
IMPLANT SIZING

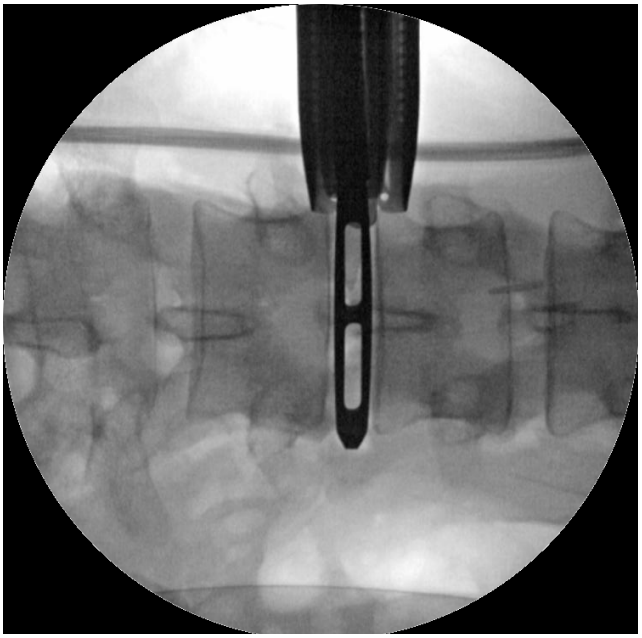
A Coroent® XL Trial is threaded onto the Inserter and the thumb-wheel lock is tightened to secure the Trial *(Fig. 59)*. Under AP fluoroscopy, the Trial is gently impacted into the disc space until centered to determine the desired implant size *(Fig. 60)*. Proper anterior/posterior position is verified using lateral fluoroscopy *(Fig. 61)*.

If satisfied with placement and fit of the Trial, it can be removed from the disc space. The Slap Hammer can be used, if necessary, to facilitate Trial removal.



(Fig. 59)

(Fig. 60)

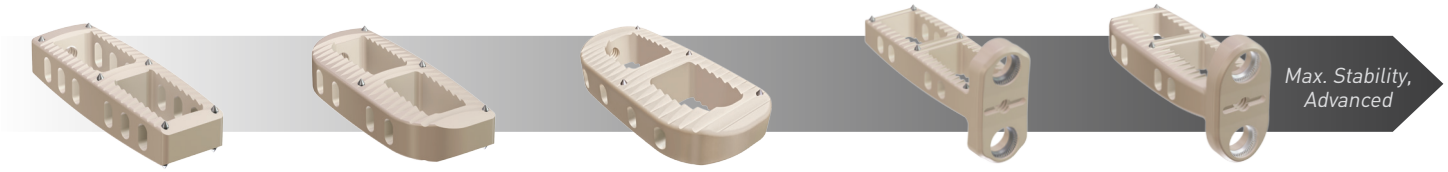


(Fig. 61

XLIF® SURGICAL TECHNIQUE

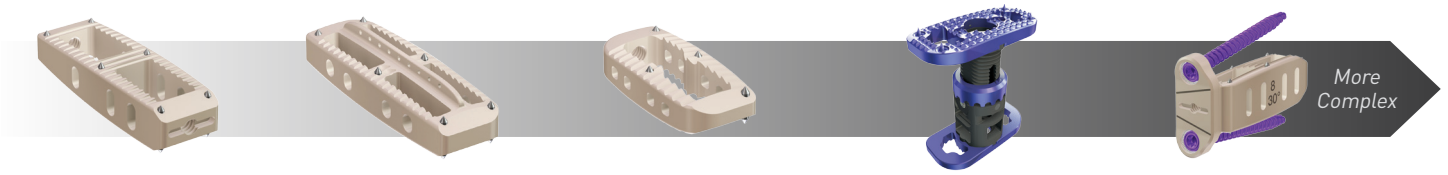
APPLICATION SPECIFIC SOLUTIONS

NuVasive® is the first company to provide a full portfolio of interbody solutions with a variety of applications via the CoRoent® XL platform.



XL (18mm wide) | XL-W (22mm wide) | XL-XW (26mm wide) | XL-F (18mm wide) | XL-F Wide (22mm wide)

Implants offered in 0° and 10° lordosis.



XL-CT (Coronal Tapered) | XL-K (Keeled) | XL-T (Thoracic) | X-CORE 2 Expandable VBR *Tumor/Trauma Corpectomy** | XL-H (Hyderlordotic) *Anterior Column Realignment**

Note: FDA PEEK Implant Clearances:
All PEEK interbody implants are cleared for use as intervertebral body fusion devices at L2-S1 for use with autograft, and supplemental fixation, including the CoRoent family of implants.

STEP 10:
IMPLANT PLACEMENT

The appropriate implant from the CoRoent® XL portfolio is selected and filled with graft material. Refer to the CoRoent XL brochure for detailed implant selection information.

A loading block can be used to ensure that the CoRoent XL graft windows are completely filled. *(Fig. 62)*

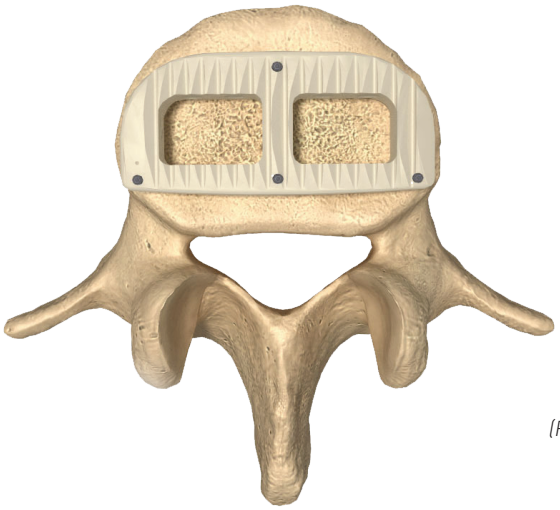
(Fig. 62)

STEP 10:
IMPLANT PLACEMENT (CONT'D)

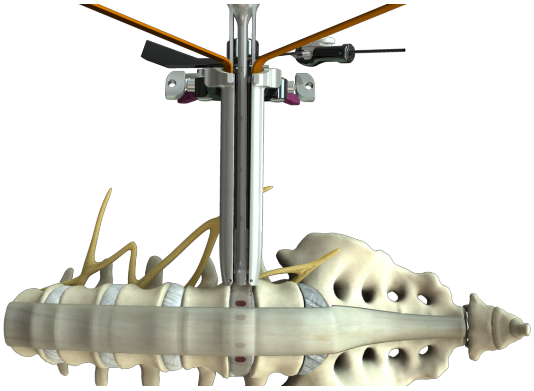
XLIF Slides may be used to protect the endplates and contain graft material during implant insertion. Fluoroscopy should be used to verify XLIF Slides are positioned properly. The Inserter is placed with the attached implant between the XLIF Slides. The implant is advanced across the disc space under AP fluoroscopy.

During insertion of the implant, placement is also monitored with NVM5® Free Run EMG. Placement of the implant is dictated by patient anatomy and the spinal pathology that is being treated. Generally, the implant spans the ring apophysis, is centered across the disc space from a medial/lateral perspective, and is near the center of the disc space from an anterior/posterior perspective *(Figs. 63, 64)*.

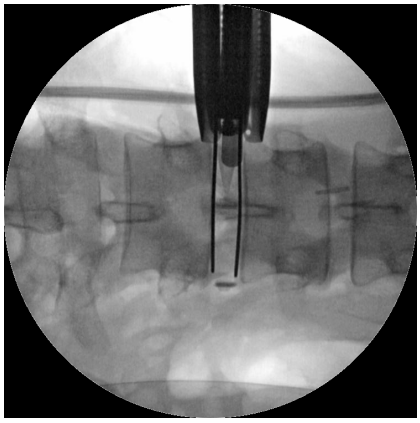
All CoRoent® XL implants have titanium markers that can be used confirm correct implant alignment *(Figs. 65, 66, 67)*.



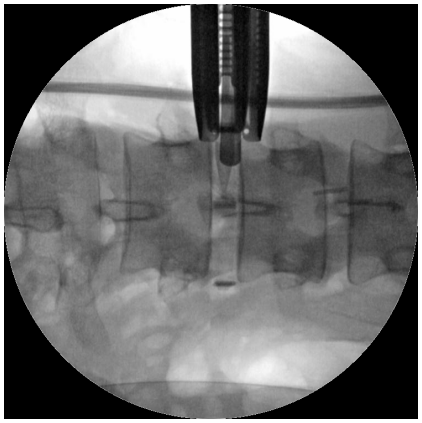
(Fig. 63)



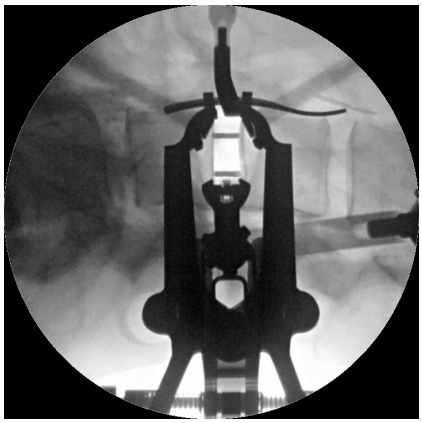
(Fig. 64)



(Fig. 65)



(Fig. 66)



(Fig. 67)

STEP 10:

IMPLANT PLACEMENT (CONT'D)

Coroent® XL Implants may also be inserted with the TL Graft Containment Slide. The implant is attached to the Inserter, and the TL Graft Containment Slide is snapped onto the inserter. The implant is gently impacted into the disc space as the TL Graft Containment Slide keeps graft material inside the implant *(Fig. 68)*.

(Fig. 68)

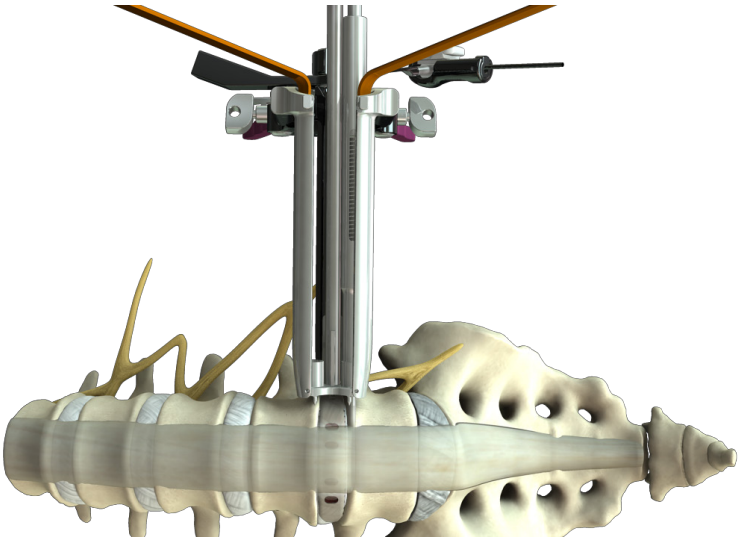
XLIF® SURGICAL TECHNIQUE

STEP 11:
XLP® PLATE

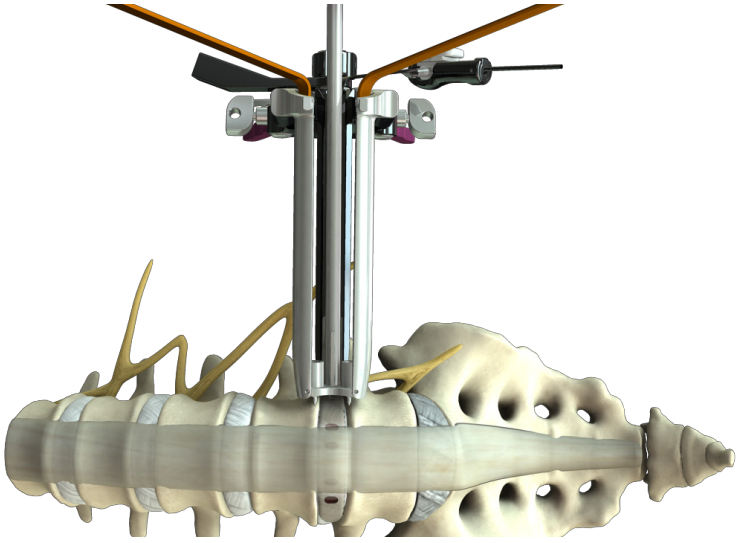
The XLP plate is one of many supplemental fixation options available for XLIF. A brief overview of the XLP plate surgical technique is described below. Proper patient selection and technique is critical to ensure success with lateral plating. For additional details on the XLP plate or other fixation options, please refer to the appropriate product technique guide.

Pilot hole preparation and bolt insertion are performed through XLP Guides. The appropriately sized Guide is introduced through the XLIF exposure and centered over the disc space. With the Guide properly positioned, the spikes are inserted into both vertebral bodies to secure them into place *(Fig. 69)*.

Several instruments are available in the XLP set to create pilot holes including taps, drills, and awls. The selected instrument(s) should be inserted through the XLP Guide and a pilot hole created to the desired depth and trajectory *(Fig. 70)*.



(Fig. 69)



(Fig. 70)

STEP 11:

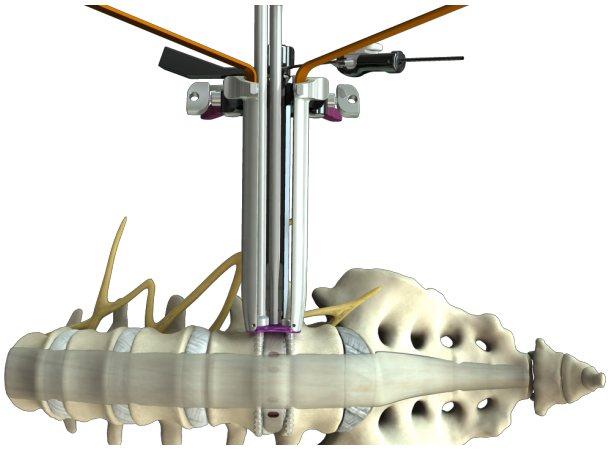
XLP® PLATE (CONT'D)

With a pilot hole prepared, the appropriate length bolt is introduced through the Guide barrel and inserted to appropriate depth *(Fig. 71)*. Bolt insertion is repeated on the adjacent level. Bicortical bolts, placed as parallel as possible, are recommended.

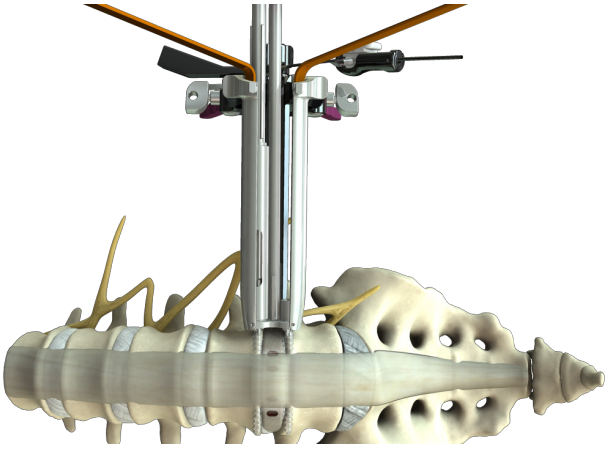
With both bolts in place, the appropriately sized plate is inserted over both bolts, ensuring the heads are properly exposed above the Plate for Lock Nut insertion. After verification that the Plate is fully seated, Lock Nuts are inserted onto both bolts.

Prior to final tightening of Lock Nuts, the table should be flattened (i.e., table break removed).

Final tightening on both Lock Nuts *(Fig. 72)* completes the procedure *(Fig. 73)*.



(Fig. 71)



(Fig. 72)

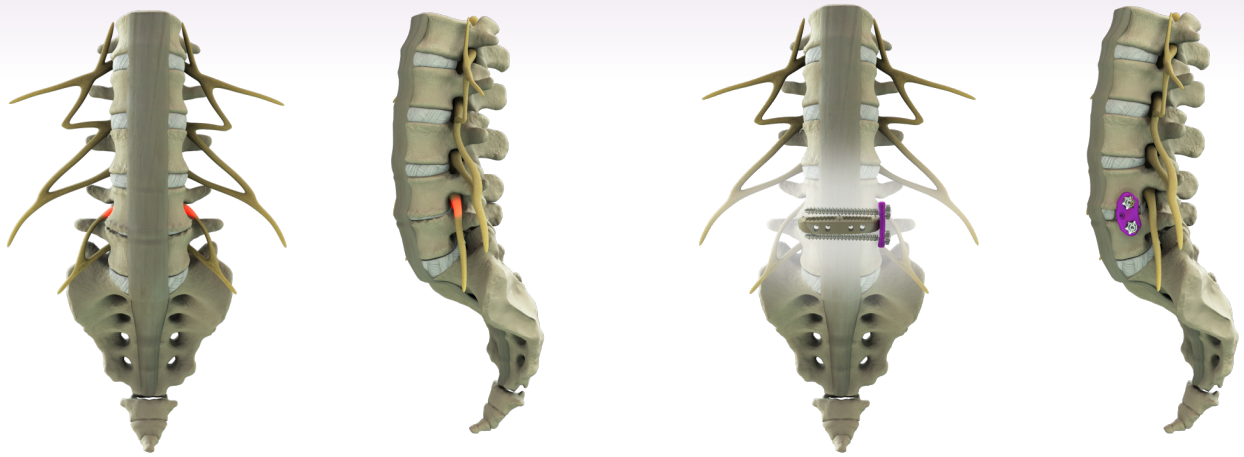
(Fig. 73)

XLIF® APPLICATIONS

DEGENERATIVE DISC DISEASE

PRE-OP

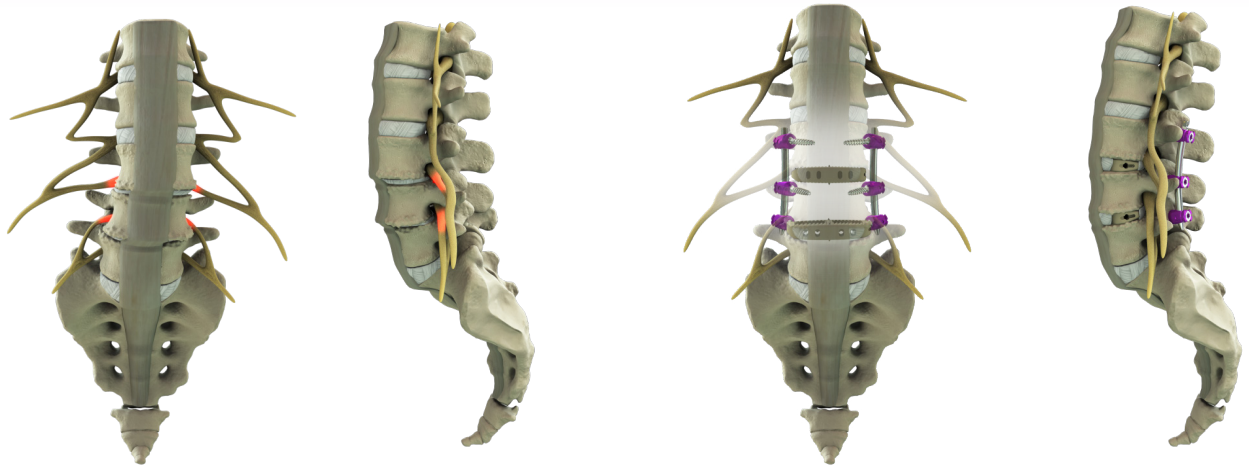
POST-OP



DEGENERATIVE SPONDYLOLISTHESIS SECONDARY TO ADVANCED DDD

PRE-OP

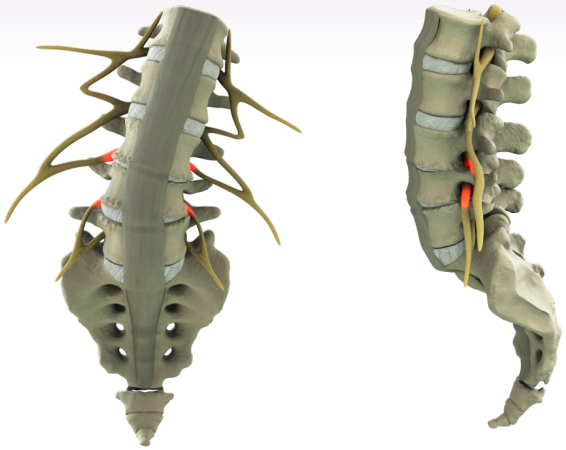
POST-OP



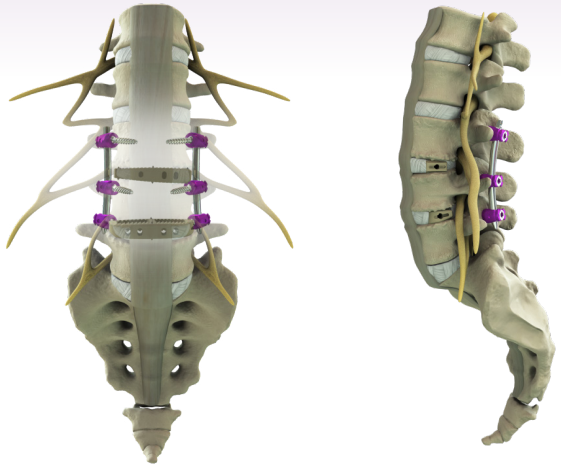
XLIF® APPLICATIONS (CONT'D)

DEGENERATIVE SCOLIOSIS SECONDARY TO ADVANCED DDD

PRE-OP

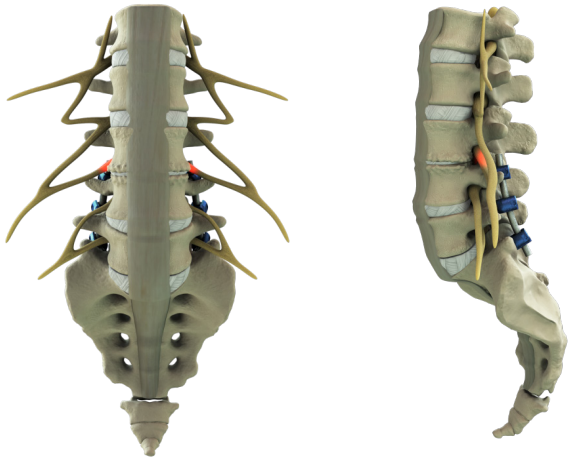


POST-OP

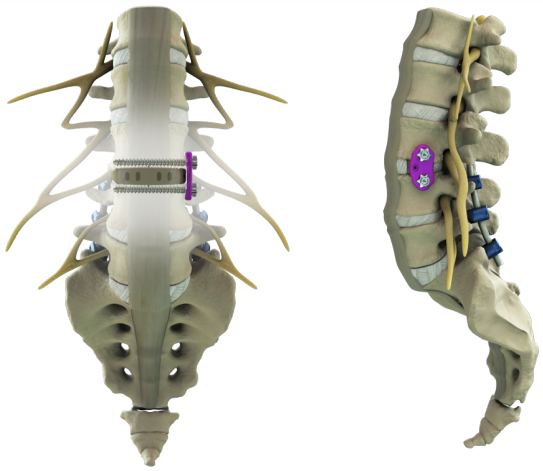


ADJACENT SEGMENT DISEASE SECONDARY TO ADVANCED DDD

PRE-OP



POST-OP



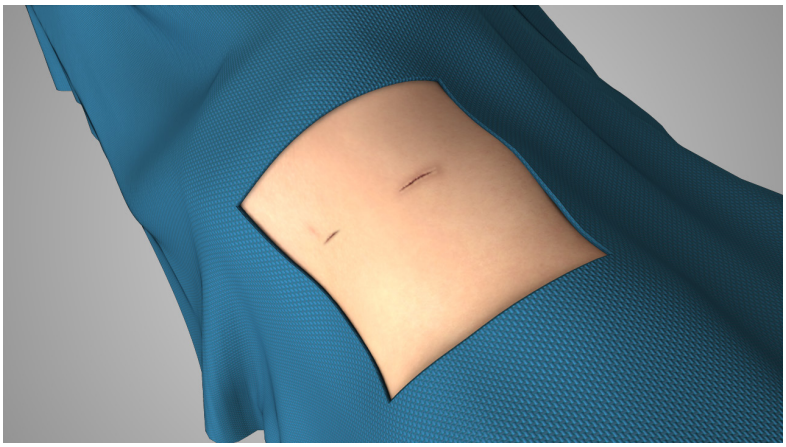
XLIF® SURGICAL TECHNIQUE

STEP 12:
REMOVAL AND CLOSURE

Once the procedure is completed, the Access Driver is removed while using direct visualization to verify the absence of significant bleeding in the disc space or psoas muscle. The Locking Intradiscal Shim should be removed from the C Blade prior to removing the Access Driver.

The skin is closed using standard surgical techniques.

Supplemental instrumentation is required and warranted.



(Fig. 74)

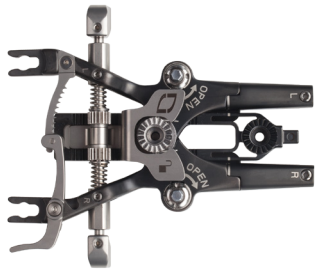
STEP 13:
IMPLANT REMOVAL

If it becomes necessary to revise the implanted CoRoent device, access to the implantation site can be achieved in a similar fashion to the original access. Once the implanted device is exposed, it can be removed by reattaching the Inserter. If the device is difficult to remove, additional engagement or dislodging may be achieved with the XLIF Revision Instruments.

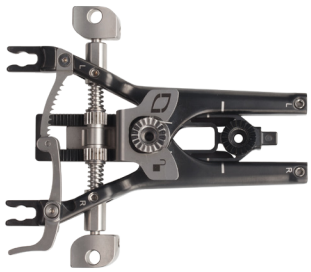
All supplemental instrumentation should be revised in accordance with its respective product technique guide.

MAXCESS® 4 ACCESS SYSTEM

Access Driver Body



Solid Access Driver Body



4th Blade Attachment

Access Driver Handle Left

Access Driver Handle Right

Blades - 90, 100, 110, 120, 130, 140 150mm

Wide Anterior Retractor, Short

Blade Rotation Driver

XLIF® SYSTEM

MAXCESS® 4 ACCESS SYSTEM (CONT'D)

Targeting Instrument

Lock Shim Inserter / Repositioning Tool

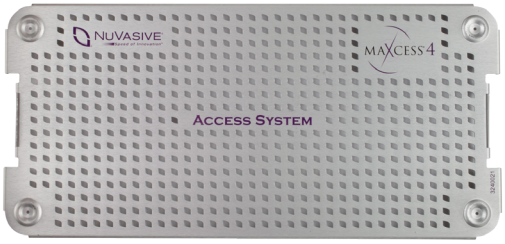
Lock Shim Removal Tool

Anterior Crossbar

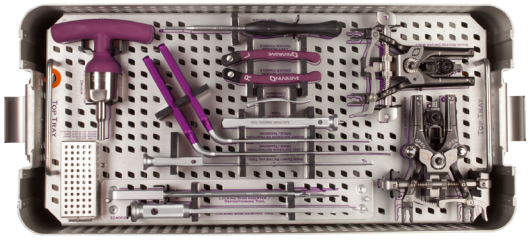
Electrode Removal Tool

Blades - 50, 60, 70, 80mm

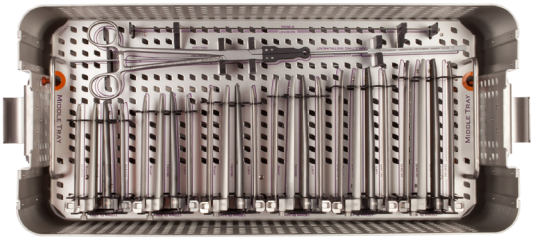
MaXcess 4 Sterilization Case



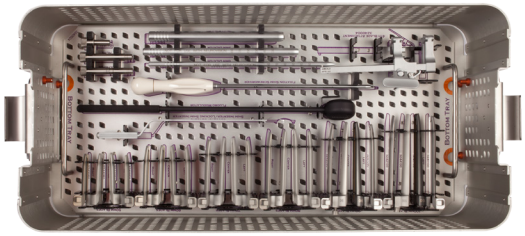
MaXcess 4 Sterilization Case, Top Tray



MaXcess 4 Sterilization Case, Middle Tray



MaXcess 4 Sterilization Case, Bottom Tray



MAXCESS® 4 DISPOSABLES

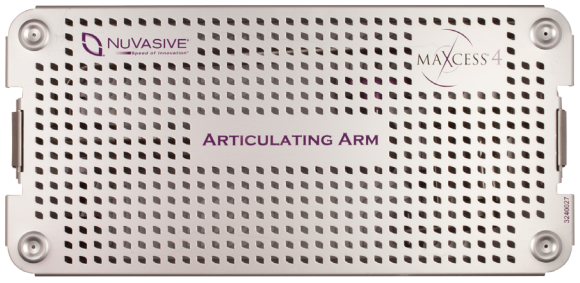
MaXcess 4 Kit

MaXcess 4 Shim Kit

MAXCESS 4 ARTICULATING ARM

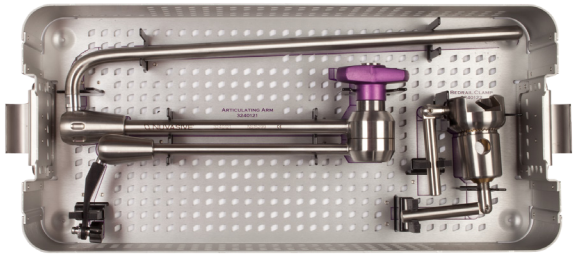
MaXcess 4 Articulating Arm

MaXcess 4 Articulating Arm Sterilization Case



MaXcess 4 Articulating Arm Bedrail Clamp

MaXcess 4 Articulating Arm Sterilization Case Base



XLIF® SYSTEM

XLIF® INSTRUMENTS

Broaches - 6, 8, 10, 12, 14mm x 18mm

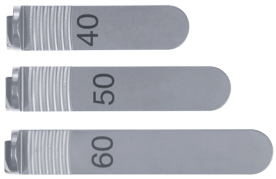
Paddle Shaver - 8, 10, 12, 14, 16mm

Paddle Sizers - 8, 10, 12, 14, 16mm

Psoas Retractors - 4, 10mm

XLIF Distractor

Distraction Tangs - 40, 50, 60mm



Implant Tamp

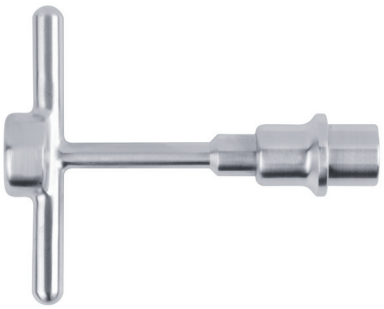
XLIF Slides

Envoy XLIF T-Handle

EnVoy™ XLIF Delivery System Body

EnVoy XLIF Hex Driver

Hudson T-Handle



ANTERIOR/LATERAL GENERAL INSTRUMENTS (TRAY ONE)

Kerrison Rongeurs - 3, 5mm

Pituitary Rongeurs - Medium, Large

Bipolar Forceps - Angled, Straight

Bipolar Forceps Cable

Chisels - 7, 12mm Straight

Nerve Retractor

Suction Nerve Retractor

Penfield - Push, Pull Long

Suction - 10 FR, 12 FR Long

Implant Removal Tool

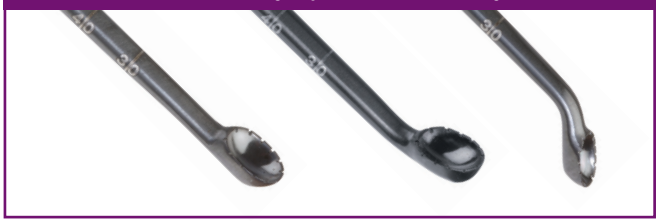
Threaded Hudson Adapter

Slap Hammer

XLIF® SYSTEM

ANTERIOR/LATERAL GENERAL INSTRUMENTS (TRAY TWO)

Curettes - Straight, Up, Down; Small, Medium, Large



Serrated Rasp

Endplate Scraper - Push, Pull

Disc Cutter - 8, 10, 12, 14mm

Cobb Elevator - Straight, Down; Small, Large

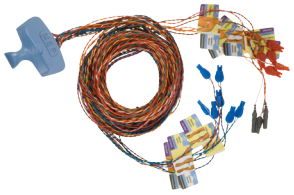
NVM5® SYSTEM

Control Unit

Patient Module

NVM5 Disposable Dilator Kit

EMG Harness



Reference, Anode, And Recording Needle Electrodes (Sterile)

Reference, Anode, And Recording Surface Electrodes

MAXCESS® 4 XLIF®

SYSTEMS
MaXcess 4 Access System
MaXcess 4 Articulating Arm
MaXcess 4 Kit
XLIF Instruments
Anterior/Lateral General Instruments (Tray One)
Anterior/Lateral General Instruments (Tray Two)
NVM5 System
NVM5 Disposables

MAXCESS 4 DISPOSABLES

DESCRIPTION	CATALOG #
MaXcess 4 Kit	3240060
MaXcess 4 Shim Kit	3240061
Light Cable (Sterile)	3200220
Annulotomy Knife	3101055
K-Wire (13.5")	3230101
MaXcess Fixation Shim Kit	3200028

MAXCESS 4 ACCESS SYSTEM

DESCRIPTION	CATALOG #
Dilator - 6mm	1010966
Dilator - 9mm	1010967
Dilator - 12mm	1010968
Hex Driver (3/32")	1011691
Hex Key (3/32")	1011748
Light Cable Adapter, ACMI	1011810
Light Cable Adapter, Storz	1011811
Light Cable Adapter, Olympus	1011812
Fixation Shim Screw Driver	3200052
Bayonetted Shim Inserter	3200215
Fluoro Modulator	3220131
K-Wire (13.5")	3230101
Initial Dilator Holder	3230140
Targeting Instrument	3240000
Lock Shim Inserter/ Repositioning Tool	3240001
Lock Shim Removal Tool	3240002
Anterior Crossbar	3240003
MaXcess 4 4th Blade Attachment	3240004
Blade Rotation Driver	3240005

DESCRIPTION	CATALOG #
Electrode Removal Tool	3240006
Shim Tamp/Retrieval Tool	3240007
MaXcess 4 Set Screw, Short	3240008
MaXcess IV Caddy, Sterilization Case	3240026
Wide Anterior Retractor, Short	3240028
Wide Anterior Retractor, Long	3240029
Narrow Anterior Retractor, Short	3240030
Narrow Anterior Retractor, Long	3240031
MaXcess 4 Set Screw, Long	3240032
MaXcess 4 Set Screw, Knurled	3240033
MaXcess 4 Access Driver Body	3240309
MaXcess 4 Solid Access Driver Body	3240310
Access Driver Handle, Left	3240312
Access Driver Handle, Right	3240311
MaXcess 4 Sterilization Case, Base	3240020
Generic NuVasive® Tray Lid	8801333
MaXcess 4 Sterilization Case, Top Tray	3240022
MaXcess 4 Sterilization Case, Middle Tray	3240023
MaXcess 4 Sterilization Case, Bottom Tray	3240024

MAXCESS® 4 ACCESS SYSTEM (CONT'D)

DESCRIPTION	CATALOG #
50mm Left Blade	3241050
60mm Left Blade	3241060
70mm Left Blade	3241070
80mm Left Blade	3241080
90mm Left Blade	3241090
100mm Left Blade	3241100
110mm Left Blade	3241110
120mm Left Blade	3241120
130mm Left Blade	3241130
140mm Left Blade	3241140
150mm Left Blade	3241150
160mm Left Blade	3241160
50mm Right Blade	3242050
60mm Right Blade	3242060
70mm Right Blade	3242070
80mm Right Blade	3242080
90mm Right Blade	3242090
100mm Right Blade	3242100
110mm Right Blade	3242110
120mm Right Blade	3242120
130mm Right Blade	3242130
140mm Right Blade	3242140

DESCRIPTION	CATALOG #
150mm Right Blade	3242150
160mm Right Blade	3242160
90mm Electrode Center Blade	3243090
100mm Electrode Center Blade	3243100
110mm Electrode Center Blade	3243110
120mm Electrode Center Blade	3243120
130mm Electrode Center Blade	3243130
140mm Electrode Center Blade	3243140
150mm Electrode Center Blade	3243150
160mm Electrode Center Blade	3243160
50mm Aluminum Center Blade	3244050
60mm Aluminum Center Blade	3244060
70mm Aluminum Center Blade	3244070
80mm Aluminum Center Blade	3244080
90mm Aluminum Center Blade	3244090
100mm Aluminum Center Blade	3244100
110mm Aluminum Center Blade	3244110
120mm Aluminum Center Blade	3244120
130mm Aluminum Center Blade	3244130
140mm Aluminum Center Blade	3244140
150mm Aluminum Center Blade	3244150
160mm Aluminum Center Blade	3244160

MAXCESS 4 ARTICULATING ARM

DESCRIPTION	CATALOG #
MaXcess 4 Articulating Arm	3240121
MaXcess 4 Articulating Arm Bedrail Clamp	3240122
MaXcess 4 Articulating Arm Sterilization Case Base	3240025
Generic NuVasive® Tray Lid	8801333

CATALOG

XLIF® INSTRUMENTS

DESCRIPTION	CATALOG #
Hudson T-Handle	1001992
Implant Tamp	3300020
Psoas Retractor - 4mm	3300023
Psoas Retractor - 10mm	3300024
Distractor	3300040
Paddle Sizer - 8mm	3300608
Paddle Sizer - 10mm	3300610
Paddle Sizer - 12mm	3300612
Paddle Sizer - 14mm	3300614
Paddle Sizer - 16mm	3300616
Paddle Shaver - 8mm	3300808
Paddle Shaver - 10mm	3300810
Paddle Shaver - 12mm	3300812
Paddle Shaver - 14mm	3300814
Paddle Shaver - 16mm	3300816
Broach - 6 x 18mm	5001206
Broach - 8 x 18mm	5001208
Broach - 10 x 18mm	5001210
Broach - 12 x 18mm	5001212
Broach - 14 x 18mm	5001214
Instruments Sterilization Case	3300130
XLIF Slides	3300063
XLIF Slides 40mm EnVoy™ XLIF Distraction Tangs	3300051
50mm EnVoy XLIF Distraction Tangs	3300052
60mm EnVoy XLIF Distraction Tangs	3300053
EnVoy XLIF Delivery System	3300055
EnVoy XLIF Hex Driver	3300056
EnVoy XLIF T-Handle	3300058

ANTERIOR/LATERAL GENERAL INSTRUMENTS (TRAY ONE)

DESCRIPTION	CATALOG #
Bipolar Forceps Cable	3100052
Nerve Retractor - Long	3300014
Suction Nerve Retractor - Long	3300015
Suction - 10 FR Long	3300017
Suction - 12 FR Long	3300028
Bipolar Forceps - Angled	3300012
Bipolar Forceps - Straight	3300022
Penfield - Long, Push	3300118
Penfield - Long, Pull	3300218
Slap Hammer	5000120
Threaded Hudson Adapter	5001901
Implant Removal Tool	6600171
7mm Chisel - Straight	6900123
12mm Chisel - Straight	6900124
Kerrison Rongeur - 3mm	6900133
Kerrison Rongeur - 5mm	6900135
Pituitary Rongeur - Medium	6900430
Pituitary Rongeur - Large	6900431
ALGI Sterilization Case One	6900089

ANTERIOR/LATERAL GENERAL INSTRUMENTS (TRAY TWO)

DESCRIPTION	CATALOG #
8mm Disc Cutter	6900151
10mm Disc Cutter	6900152
12mm Disc Cutter	6900153
14mm Disc Cutter	6900154
Cobb Elevator - Straight, Large	6900220
Cobb Elevator - Straight, Small	6900222
Cobb Elevator - Down, Large	6900221
Cobb Elevator - Down, Small	6900223
Straight Curette - Large	6900300
Straight Curette - Medium	6900310
Straight Curette - Small	6900301
Up-Angled Curette - Large	6900306
Up-Angled Curette - Medium	6900305
Up-Angled Curette - Small	6900314
Down-Facing Curette - Large	6900309
Down-Facing Curette - Medium	6900308
Down-Facing Curette - Small	6900307
Endplate Scraper - Push, Large	6900320
Endplate Scraper - Pull, Large	6900321
Serrated Rasp	6900340
ALGI Sterilization Case Two	6900095

NVM5® SYSTEM

DESCRIPTION	CATALOG #
NVM5 System Includes:	NVM5
NVM5	
Control Unit	
Patient Module	
Keyboard	
(2) Connection Cables	
Impedance Meter	
Impedance Meter Leads	
NVM5 Product Reference Manual	

NVM5 DISPOSABLES

DESCRIPTION	CATALOG #
NVM5 XLIF® Module Kit Options:	
Surface Electrodes	8020029
NVM5 Surface Module	
(1) NVM5 Probe (Sterile)	
(1) NVM5 Probe (Sterile)	
(1) NVM5 Clip	
XLIF Disposable Dilators	
(2) K-Wires	
Needle Electrodes	8050029
NVM5 Needle Module	
NVM5 Needle Module	
(1) NVM5 Probe (Sterile)	
(1) NVM5 Clip	
XLIF Disposable Dilators	
(2) K-Wires	

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