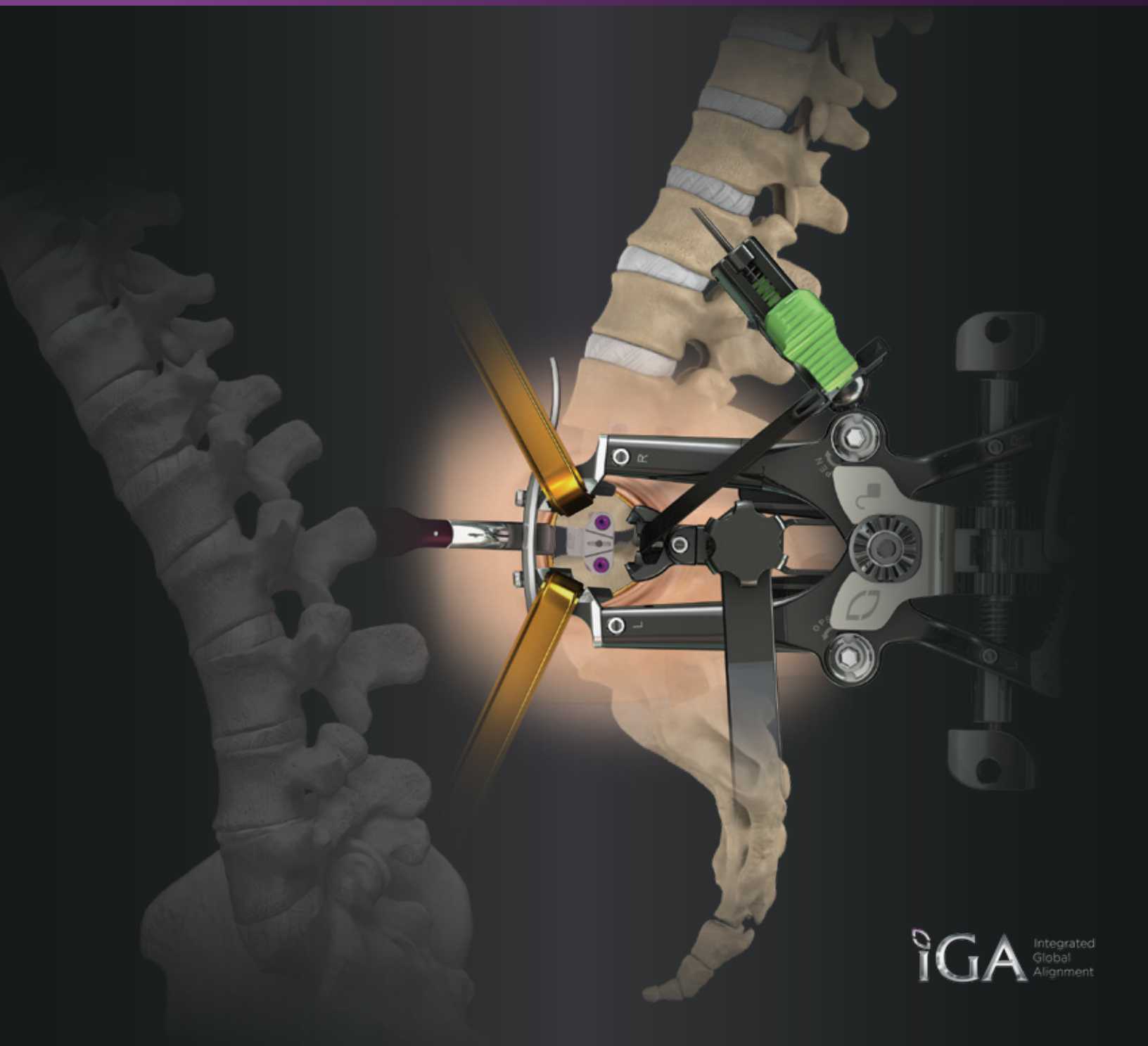
NuVasive

XLIF ACR

Surgical Technique



CONTENTS

PREFACE

Fellow Colleagues:

The XLIF procedure was created to be a minimally disruptive, reproducible technique that utilizes conventional surgical techniques through a seamlessly integrated MAS (maximum access surgery) platform. With thousands of successful patient outcomes and several system advancements, XLIF applications have expanded the treatment of advanced adult deformity.

As the surgeon community continues to appreciate the disability associated with sagittal plane deformity, proper sagittal alignment is recognized as paramount for successful long-term outcomes. Traditional methods to restore sagittal deformity (such as open posterior approaches) are often associated with substantial morbidity and thus, may result in a high volume of blood loss, an elevated risk of infection, lengthy operative time, and neurologic or vascular complications.

Building upon the core principles of traditional surgery, XLIF ACR provides an alternative to conventional approaches with potentially less morbidity through anterior column lengthening. The XLIF approach provides access to the anterior column via the lateral approach to address sagittal alignment and maintain lordotic correction through the release of the anterior longitudinal ligament (ALL), the release of the annulus, and the placement of CoRoent XL-Hyperlordotic interbody implants.

While adhering to standard deformity principles, an XLIF ACR can restore proper sagittal and coronal alignment and can indirectly decompress the posterior neural elements. XLIF ACR takes an historically morbid approach and reproducibly streamlines it by utilizing the MAS platform to obtain access. Restoration via the anterior column is achieved in a reproducible and predictable fashion, thus allowing the surgeon to achieve optimal spinal alignment and the patient to assume erect-standing posture with minimal muscular expenditure.

As we continue to innovate and advance spine surgery, it is imperative that we appreciate the core principles of deformity correction that have allowed us to successfully treat patients with adult spinal deformities. XLIF ACR should be considered a viable treatment alternative to posterior approaches.

Sincerely,

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INTEGRATED GLOBAL ALIGNMENT

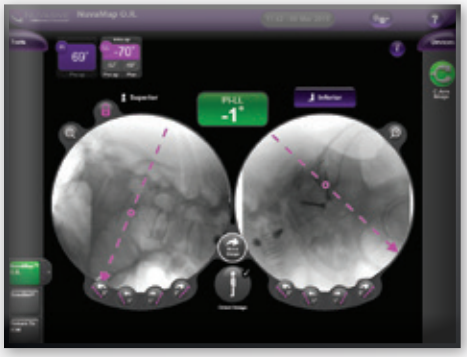
iGA Integrated Global Alignment
PRESERVATION | RESTORATION

CALCULATE
ANTERIOR COLUMN
CORRECT
POSTERIOR COLUMN
CONFIRM

Integrated Global Alignment (iGA™) is a platform comprised of procedurally based technologies, designed to enhance clinical and economic outcomes by increasing the predictability of achieving global alignment in all spinal procedures. Integration across the surgical workflow allows the surgeon to confidently and reproducibly:

- **Calculate** alignment parameters with preoperative planning tools.
- **Correct** the anterior and posterior column with comprehensive procedural solutions from NuVasive with the industry's only real-time intraoperative assessment.
- **Confirm** the restoration and preservation of global alignment postoperatively.

WHY ALIGNMENT MATTERS.



Current and emerging data illustrates a direct correlation between spinal alignment and long-term clinical outcomes* Specific spinopelvic parameters, including the mismatch of the pelvic incidence (PI) and lumbar lordosis (LL), are key predictors in determining successful patient outcomes in all spinal procedures from single- to multi-level pathologies. NuVasive is committed to a global approach for assessing, preserving, and restoring spinal alignment in an effort to promote surgical efficiencies, lasting patient outcomes, and improved quality of life. **Alignment Matters.**

*Terran J, Schwab F, Shaffrey CI, et al. The SRS-Schwab adult spinal deformity classification: assessment and clinical correlations based on a prospective operative and nonoperative cohort. *Neurosurg* 2013;73(4):559-68.

RELINE NUVALINE®
XLIF ACR NUVAMAP®
ALIF ACR NUVAMAP® O.R.
BENDINI NUVASIVE

XLIF ACR INTRODUCTION:

XLIF was created to be a reproducible and minimally disruptive procedure that utilizes conventional techniques with a seamlessly integrated MAS platform. XLIF ACR follows these same established principles by working to restore proper sagittal and coronal alignment and indirectly decompressing neural elements through restoring and maintaining natural disc space and foraminal height. The XLIF ACR procedure allows for restoration of lumbar lordosis and provides an alternative method to traditional open surgery with potentially less blood loss. The release of the Anterior longitudinal ligament (ALL) is facilitated via a lateral, retroperitoneal approach and the placement of CoRoent XL-Hyperlordotic interbody implants.

THE XLIF ACR PROCEDURE IS BROKEN DOWN INTO 10 PRIMARY STEPS:

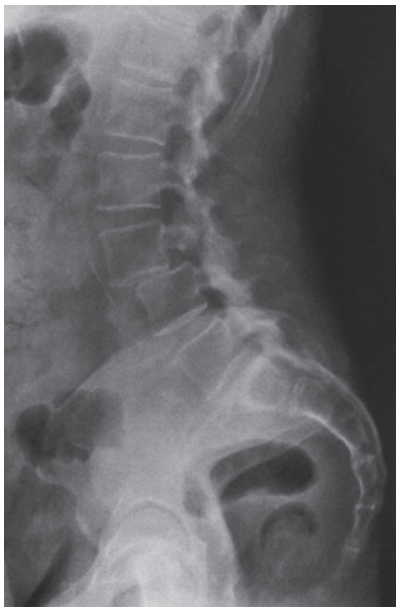
1. Surgical considerations and preoperative planning
2. Patient positioning
3. XLIF access and initial discectomy
4. Exposure and access of the ALL
5. Complete discectomy and annular release
6. ALL division
7. Implant trialing
8. Implant placement
9. Intraoperative alignment assessment
10. Postoperative reconciliation of plan

XLIF ACR SURGICAL TECHNIQUE

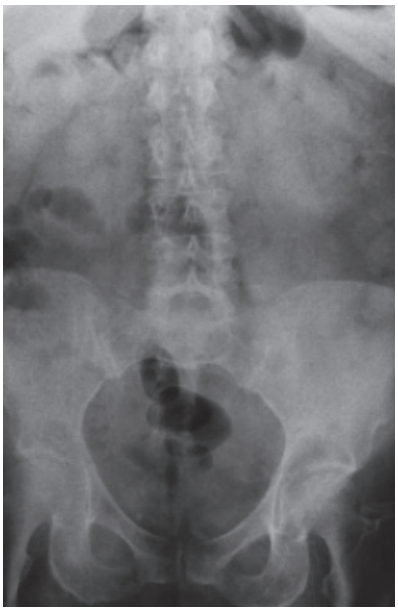
STEP 1:
SURGICAL CONSIDERATIONS AND PREOPERATIVE PLANNING

Prior to surgery, radiographs should be obtained for proper assessment of pathology.

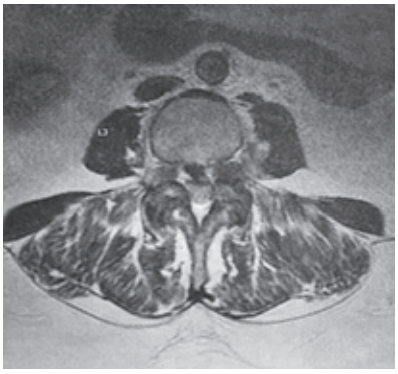
For preoperative templating, it is recommended to obtain full 36 inch standing radiographs in both sagittal and coronal planes. If 36 inch films cannot be obtained, it is critical that the radiograph captures at minimum some of both the femoral heads and the superior endplate of L1 so spinopelvic parameters can be calculated *(Figs. 1-5)*. If evaluation of disc mobility at the apical intervertebral level is required, supine hyperextension lateral radiographs may be obtained. Be cognizant of the vessels anterior to the ALL and note any anomalies or lateralization that would impede mobilization and exposure.



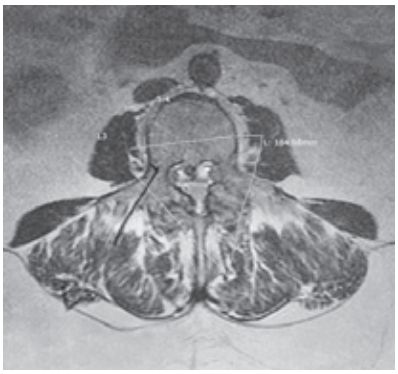
(Fig. 1)



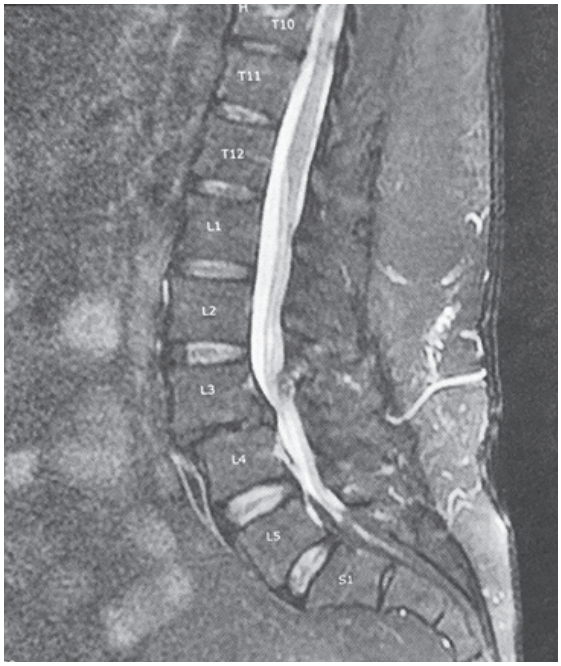
(Fig. 2)



(Fig. 3)



(Fig. 4)



(Fig. 5)

STEP 1:
SURGICAL CONSIDERATIONS AND PREOPERATIVE PLANNING (CONT.)

Calculating Alignment: Preoperative Planning

The restoration or preservation of patient alignment begins with calculating measurements and developing a surgical plan *(Fig. 6)*. The NuvaPlanning portfolio has two software solutions, NuvaMap and NuvaLine, designed specifically for preoperative planning. These solutions intuitively navigate through calculating measurements and developing surgical plans across the surgical workflow in order to restore and preserve patient alignment.

NuvaLine, a simple software application for tablet and mobile devices, is designed to provide an efficient assessment to determine and evaluate key spinopelvic parameters that are based on major landmarks including the femoral heads, sacral endplate, and superior L1 endplate. NuvaLine is designed to capture three important parameters: pelvic tilt (PT), pelvic incidence (PI), and lumbar lordosis (LL). With these, NuvaLine is designed to calculate the proportionality between pelvic incidence and lumbar lordosis, which is a key element in assessing a patient's global sagittal alignment *(Fig. 6)*. Ideally, the patient's lumbar lordosis should be within 10° of their pelvic incidence.[1] The primary alignment objectives that are most closely correlated to Health-Related Quality of Life (HRQOL) outcomes are:

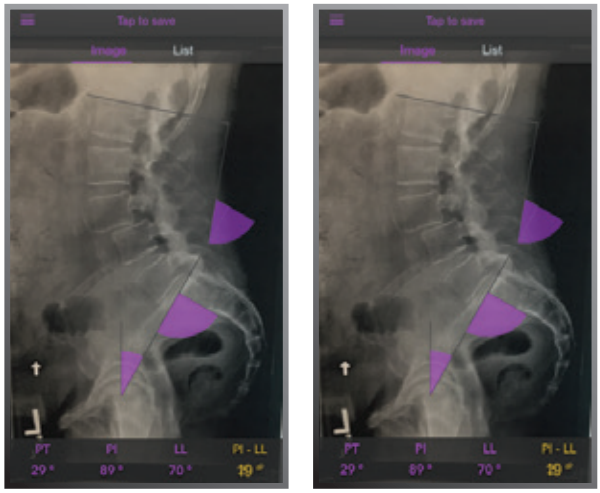
- SVA<4cm
- PT<20°
- PI minus LL≤±10°

NuvaMap, a comprehensive desktop application, is designed to measure key spinal alignment and balance parameters, on radiographs and to optimize planning through case simulation with integrated NuVasive interbody implant options. This allows for calculation of an in-depth pre-operative plan based off the desired alignment attainable via the XLIF ACR procedure and CoRoent XL-H implants *(Fig. 7)*.

With these tools, preoperative planning is simplified and allows the surgeon to assess alignment objectives and create a plan for the case using NuVasive procedural solutions for anterior and posterior column correction and stabilization. Both NuvaMap and NuvaLine are procedurally integrated to transfer key spinal parameters to NuvaMap O.R., to assess real-time alignment values intraoperatively, and help confirm that alignment goals are achieved postoperatively.

[1]Schwab F, Ungar B, Blondel B, et al. Scoliosis Research Society - Schwab adult spinal deformity classification. A validation study. *Spine* 2012;37(12):1077-82
[2]Schwab FJ, Blondel B, Bess S, et al. Radiographical spinopelvic parameters and disability in the setting of adult spinal deformity: a prospective multicenter analysis. *Spine* 2013;38:E803-E812.

CALCULATE: PRE-OP



- PT: 29°
- PI: 89°
- LL: 70°

PI-LL: 19°

(Fig. 6)

PI minus LL 0°

PI minus LL within +/-10 ° Non-pathologic, spinal alignment [1, 2]

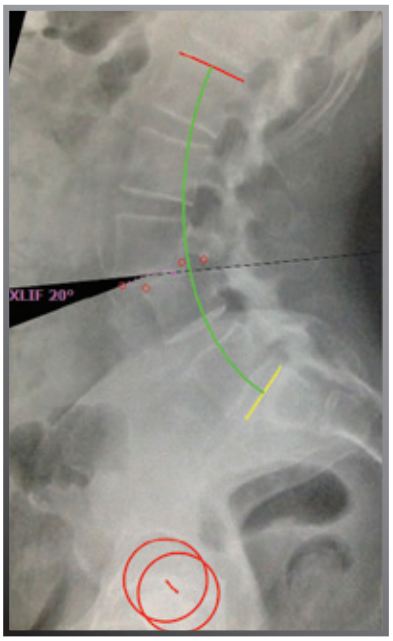
PI minus LL +15°

PI minus LL between 11 and 20° Moderate deformity, more correction required

PI minus LL +45°

PI minus LL >20° Marked deformity, more correction required

CALCULATE: SURGICAL GOAL



- PT: 20°
- PI: 89°
- LL: 82°

PI-LL: 7°

(Fig. 7)

XLIF ACR SURGICAL TECHNIQUE

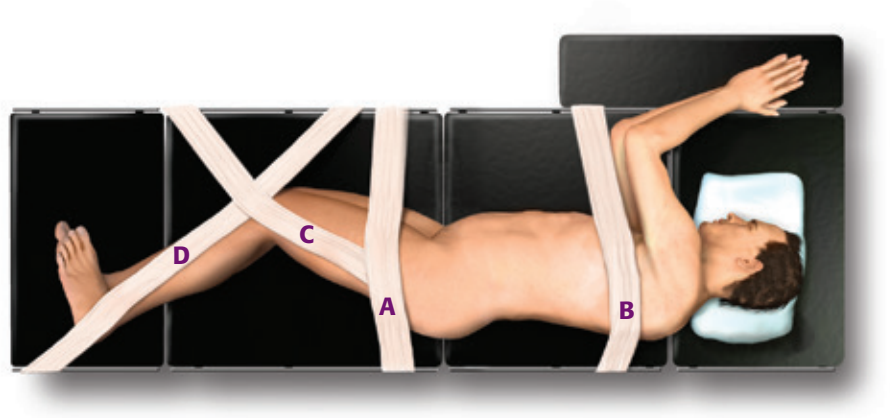
STEP 2:
PATIENT POSITIONING

For degenerative scoliosis cases, surgeon preference and anatomical considerations will determine which side of the curvature (the concavity or convexity) will be favorable for access to the spine via the lateral, retroperitoneal approach *(Fig. 9)*.

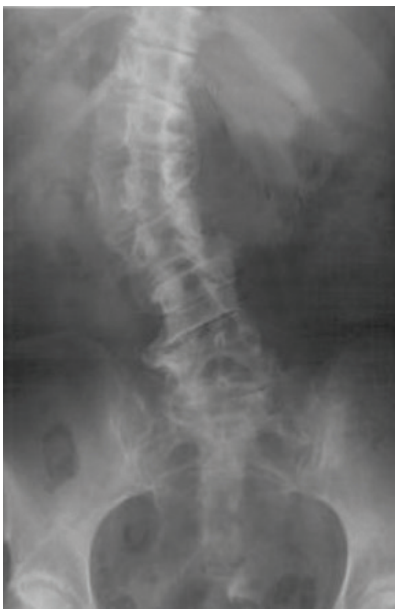
Approaching on the concave side provides a more relaxed psoas and lumbar plexus, may minimize the number of incisions, and may provide enhanced access to the L4-L5 disc space compared to the convex side. However, access to the disc space may be more difficult, due to the collapsed nature of the vertebral bodies on the ipsilateral side, and may require docking the retractor on osteophytes.

Approaching on the convex side may allow for easier access to the disc space, but may require multiple incisions. Access to L4-L5 can potentially be more difficult when approaching from the convexity.

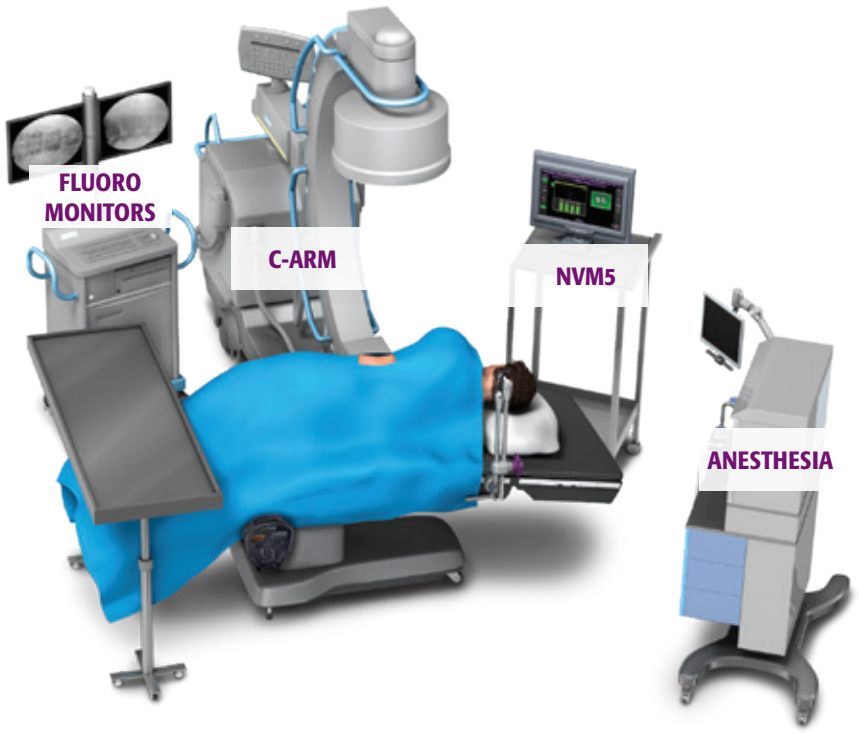
For a more detailed description about standard patient positioning and O.R. setup for XLIF, please refer to the XLIF Surgical Technique (9500138) *(Figs. 8-10)*.



(Fig. 8)



(Fig. 9)



(Fig. 10)

Importance of Neuromonitoring

Neuromonitoring is critical to the reproducibility of any lateral transpsoas approach due to the location of the lumbar plexus within the psoas muscle. 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.[3,4]

The XLIF procedure relies on the clinically validated dynamic electromyographic (EMG) nerve avoidance mode of NVM5 to identify a clear docking position and working area.[5]

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

(Fig. 11)

(Fig. 12)

STEP 3:
XLIF ACCESS AND INITIAL DISCECTOMY

Specific to the XLIF ACR technique, several steps are pertinent for establishing the XLIF access and approach.

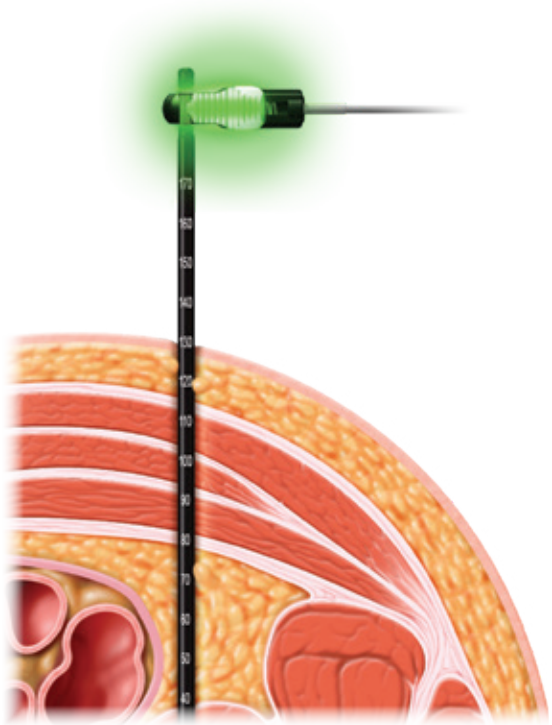
The lateral skin incision may be extended slightly more anterior to allow for leverage and manipulation of the anterior retractor to aid in direct visualization and complete release of the ALL and annulus.

Transpsoas Approach

Following blunt dissection through the muscle planes and transversalis fascia, the XLIF Dilator (black) is introduced in the retroperitoneal space via the lateral incision while the index finger remains in the posterolateral incision. The initial Dilator is then escorted down to the psoas muscle to allow for a desired trajectory through the retroperitoneal space.

Upon reaching the lateral surface of the psoas muscle, the Dynamic Stimulation Clip is attached to the initial dilator and NVM5 is activated in XLIF mode *(Fig. 14)*. The initial dilator is then passed medial through the psoas, while slowly being rotated 360° to determine the three-dimensional position of the nerves. NVM5 will display the continually updated threshold stimulation that triggers a neural response *(Figs. 11-13)*. For more information, refer to the NVM5 Quick Reference manual in the help section on the NVM5 screen.

(Fig. 13)



(Fig. 14)

[3]Park DK, Lee MJ, Lin EL, et al. The relationship of intrapsoas nerves during a transpsoas approach to the lumbar spine: anatomic study. *J Spinal Disord* Tech 2010;23(4):223-8.

[4]Uribe JS, Arredondo N, Dakwar E, et al. Defining the safe working zones using the minimally invasive lateral retroperitoneal transpsoas approach: an anatomical study. *J Neurosurg Spine* 2010;13(2):260-6.

[5]Tohmeh AG, Rodgers WB, Peterson MD. Dynamically evoked, discrete-threshold electromyography in the extreme lateral interbody fusion approach. *J Neurosurg Spine* 2011;14(1):31-7.

XLIF ACR SURGICAL TECHNIQUE

STEP 3:

XLIF ACCESS AND INITIAL DISCECTOMY (CONT.)

Once the initial Dilator is docked on the disc, lateral fluoroscopy should be used to confirm the dilator is approximately centered on, and parallel with, the disc space *(Fig. 15)*. A cross-table A/P image should confirm that the Dilator is in the plane of, and flush with, the disc space *(Fig. 16)*.

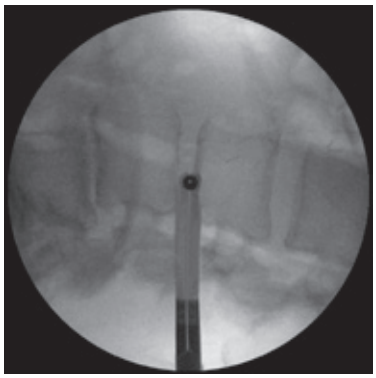
If the Dilator is not in the optimal position, it may be repositioned with the use of NVM5. It is recommended to dock the initial Dilator as posterior as possible (what NVM5 will favorably allow) to aid in a complete discectomy and annular release and proper placement of the CoRoent XL-H (Hyperlordotic) implant.

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. The depth markings on the Dilator indicate the size of the appropriate length Blades to be attached to the MaXcess 4 Access Driver.

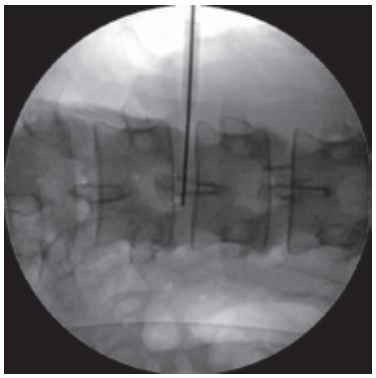
The next two XLIF Dilators (magenta and blue) are subsequently introduced over the initial Dilator using a twisting motion. NVM5 is used as with the previous Dilator to determine relative nerve proximity and direction.

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 Center Blade *(Figs. 17-19)*.



(Fig. 15)



(Fig. 16)

(Fig. 17)

(Fig. 18)

(Fig. 19)

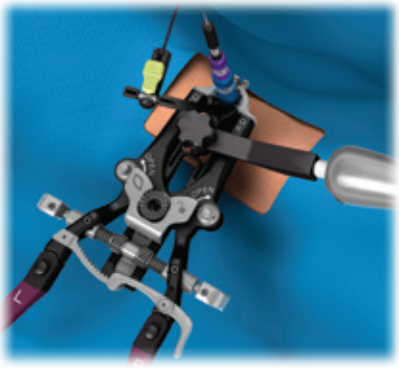
STEP 3:

XLIF ACCESS AND INITIAL DISCECTOMY (CONT.)

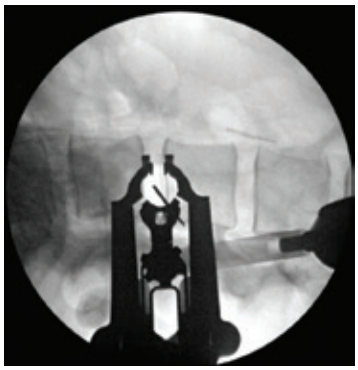
After sequential dilation has been performed, the MaXcess Retractor is docked, the posterior Blade is locked with the MaXcess Articulating Arm, and any residual tissue at the bottom of the exposure is thoroughly explored using the NVM5 Probe *(Figs. 20, 21)*. Following confirmation that no nerves are within the exposure, the Low-Profile Locking Intradiscal Shim is placed under A/P flouroscopy *(Figs. 22, 23)*. A small amount of posterior annulus is preserved to cuff the shim and help prevent retractor migration while the complete discectomy and annular release are performed.

Prior to identifying and exposing the ALL, a standard XLIF discectomy utilizing cobb elevators, kerrisons, and pituitaries is performed *(Figs. 24, 25)*.

Once this discectomy is complete, the retractor is opened in the A/P direction to the anterior border of the vertebral body to set up the exposure of the ALL.



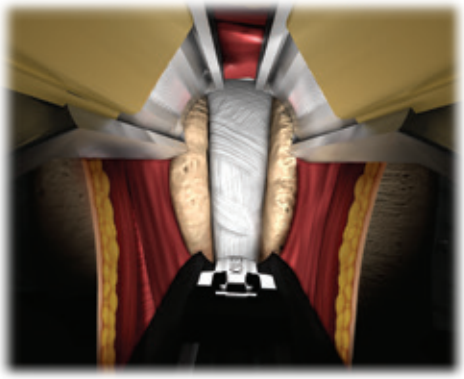
(Fig. 20)



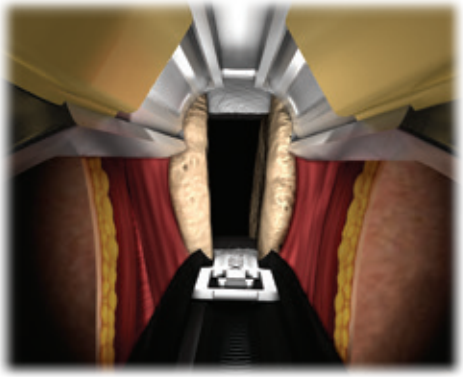
(Fig. 21)

(Fig. 22)

(Fig. 23)



(Fig. 24)



(Fig. 25)

XLIF ACR SURGICAL TECHNIQUE

STEP 4:

EXPOSURE AND ACCESS OF THE ALL

Clear exposure and access to the ALL is paramount to create a reproducible division of the ALL. Gentle anterior dissection is performed to identify the adventitial plane and separate the ALL from the anterior vessels.

A penfield is used to identify and establish the adventitial plane *(Fig. 26)*. The penfield helps provide tactile feedback during initial dissection of the plane, and the curved XL-H Anterior Retractor is placed anterior to the penfield.

Note

Prior to placement of the curved XL-H Anterior Retractor, a surgeon may sequentially place the Straight ALL Retractor from the MaXcess 4 Instrument Tray as an intermediate step. The Straight ALL Retractor should be placed anterior to the penfield. Once the retractor has been placed, the penfield may be removed. The curved XL-H Anterior Retractor can now be placed in the same fashion, and the Straight ALL Retractor may be removed (Fig. 27).

Either the Wide or the Narrow ALL Retractor may be selected – it is recommended to begin with the Narrow ALL Retractor (Fig. 28).

If the Narrow ALL Retractor is initially selected, the Wide ALL Retractor may then be switched out (in same manner as previously described with the penfield). The Wide ALL Retractor provides additional width and coverage of the disc space as it maintains the barrier between the ALL and the anterior vasculature.

Once the XL-H Anterior Retractor has been placed, the penfield may be removed. The retractor is placed completely across the vertebral body to the level of the contralateral pedicle and A/P fluoroscopy is used to confirm placement *(Fig. 29)*. The XL-H Anterior Retractor is curved to follow the natural curvature of the vertebral body *(Fig. 30)*.

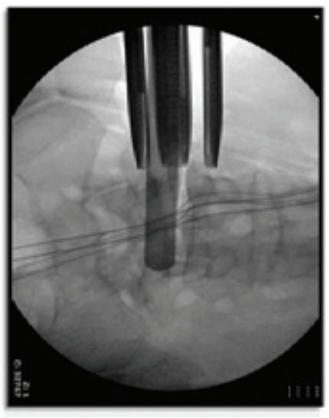
(Fig. 26)

(Fig. 27)

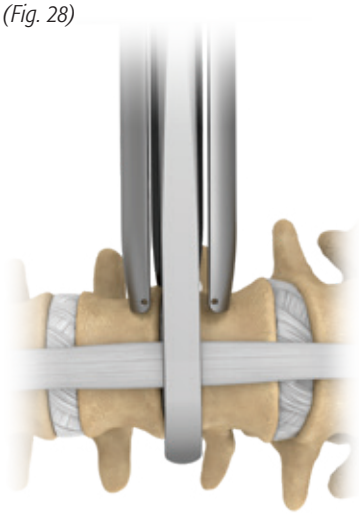
WIDE ALL RETRACTOR

NARROW ALL RETRACTOR

(Fig. 28)



(Fig. 29)



(Fig. 30)

STEP 4:

EXPOSURE AND ACCESS OF THE ALL (CONT.)

Once the adventitial plane is established, the XL-H Anterior Retractor is contained by placing the MaXcess 4 Anterior Crossbar, which will hold the XL-H Anterior Retractor in place between the ALL and the areolar plane *(Fig. 31)*. The XL-H Anterior Retractor comes in various lengths and widths. The retractor width should span the disc space to help maintain its position once the ALL has been released.

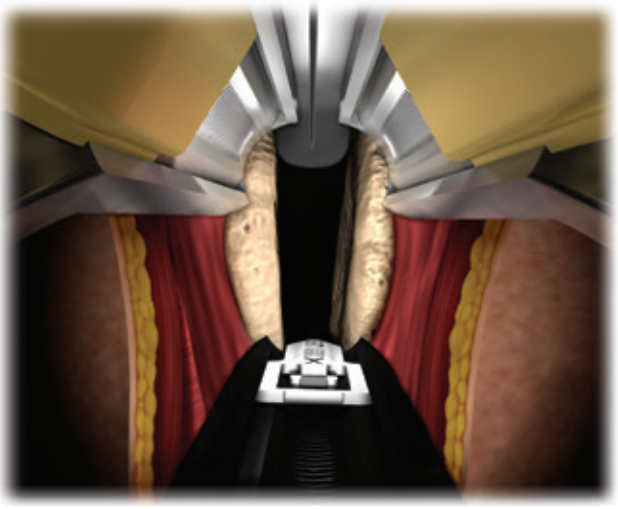
(Fig. 31)

STEP 5:

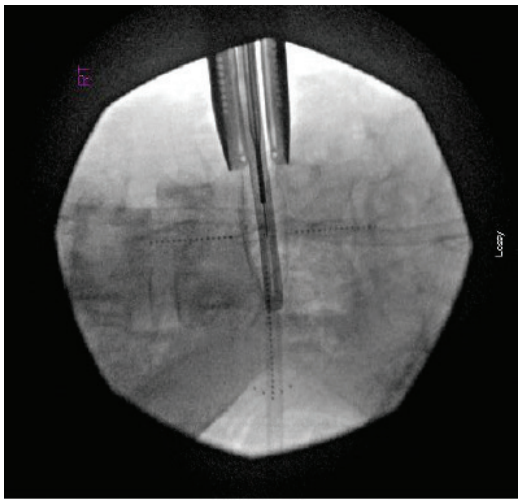
COMPLETE DISCECTOMY AND ANNULAR RELEASE

The XLIF channel discectomy is extended all the way up to the ALL and a thorough release of the ipsilateral and contralateral annulus is completed. Careful attention should be paid to the posterior corner of the contralateral annulus as this will aid in proper distraction for the hyperlordotic implants once the ALL has been released *(Figs. 32, 33)*.

Osteophytes can be either removed with the osteophyte removal tool or left in place; however, removal is necessary if osteophytes are interfering with the placement of the tabbed implant.



(Fig. 32)



(Fig. 33)

XLIF ACR SURGICAL TECHNIQUE

STEP 6:

ALL DIVISION

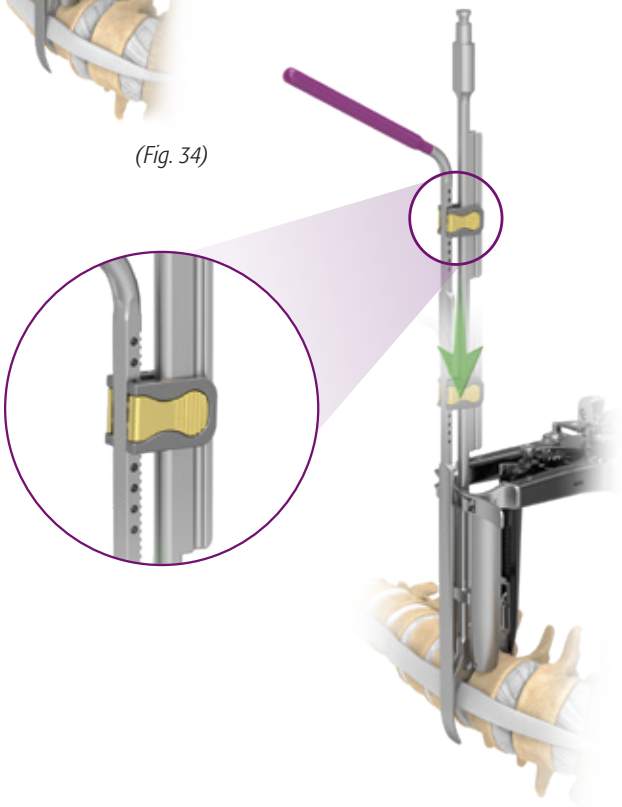
Once proper discectomy and annular release are performed, the ALL is divided under direct visualization with the annulotomy knife or ALL Cutter. When using the annulotomy knife, the groove down the center of the XL-H Anterior Retractor is used to guide the division of the ALL that is under direct visualization *(Fig. 34)*.

> ***Note***
>
> *If utilizing the ALL Cutter, the sterile blade is loaded on the ALL Cutter by using the MaXcess Driver to release the set screw (Figs. 35, 36). Insert the blade into the opening of the ALL Cutter at the distal tip with the sharp side of the Blade facing out. Once the Blade is in place, the set screw is tightened with the MaXcess Driver. The ALL Retractor clip is placed onto the ALL Retractor by pressing the gold tabs to line up the pegs of the clip with the insertion points on the sides of the XL-H Anterior Retractor. The clip will help guide the ALL Cutter down the XL-H Anterior Retractor by mating with the "rail" portion on the shaft of the ALL Cutter (Fig. 37).*

(Fig. 34)

(Fig. 35)

(Fig. 36)



(Fig. 37)

STEP 6:
ALL DIVISION (CONT.)

The remaining fibers of the ALL that were not divided under direct visualization are released utilizing sequential distraction and trialing. Options include the XL-H trials, the XLIF parallel distractor, or the Lordotic Distractor.

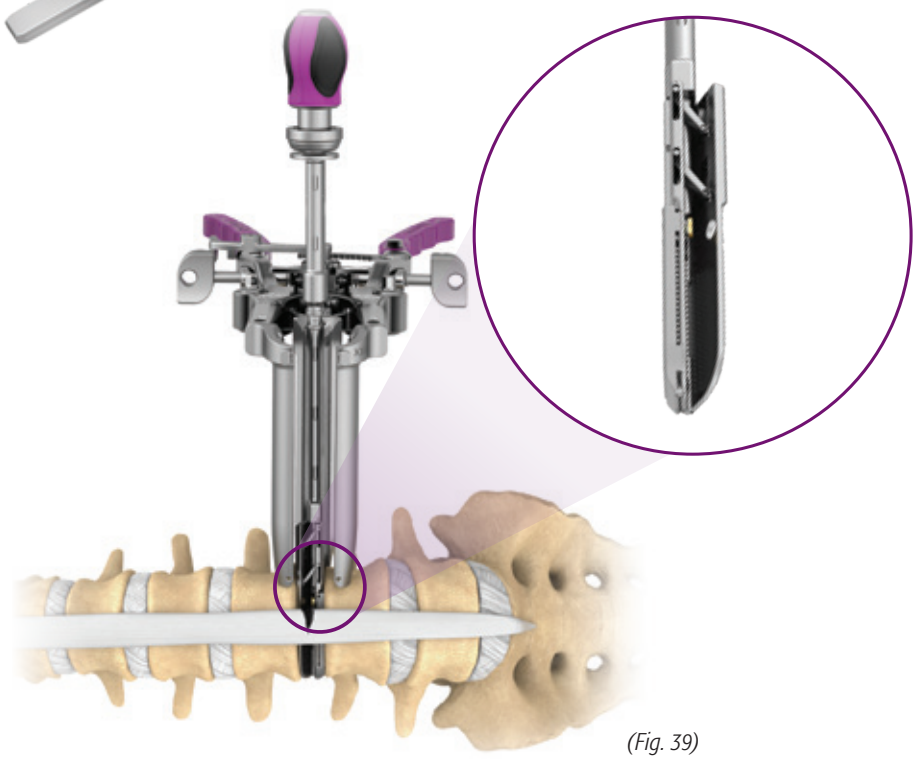
When utilizing the parallel distractor, the instrument is placed into the disc space so that the tips span the length of the disc space *(Fig. 38)*. The purple handle on the shaft is slowly rotated clockwise to initiate parallel distraction. The disc space is carefully distracted and the ALL is fully divided, with careful attention being paid to the endplates. If there is continuous tension while rotating the handle without division of the ALL, further division of the ALL release or contralateral annulus may be required. A full division is necessary to allow for proper placement of the CoRoent XL-H implant.

The Lordotic Distractor is designed to seamlessly distract from 0° to 30° in accordance with the CoRoent XL-H implants *(Fig. 39)*. It contains modular Height Slides that are congruent to the posterior heights of the implant, ranging from 2mm to 10mm *(Fig. 40)*. This instrument can both confirm that the ALL is fully divided, as well as aid in the final division of the ALL if a few remaining fibers are intact.

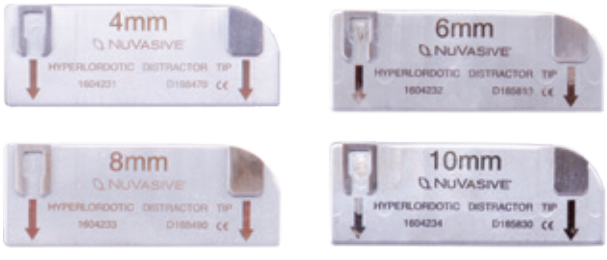
To utilize the Lordotic Distractor, the Teardrop Handle is assembled onto the proximal end of the shaft. The modular Height Slide is loaded onto the distal end of the shaft by aligning the arrows on the Height Slide with the grooves on the Lordotic Distractor and firmly sliding into place. The counter-torque handle is attached to the shaft at the distal end of the lordosis indicator window. The instrument is inserted into the disc space, and the disc is carefully distracted by rotating the Teardrop Handle clockwise. The "lordosis indicator" window will correspond with the amount of lordotic distraction applied to the disc space. To retract the device, the handle is rotated counterclockwise. To switch out the Height Slides, the gold button is depressed on the base of the tip of the Lordotic Distractor, and the Height Slide is slid in the opposite direction of insertion. This process can be repeated to gently increase the Height Slides until the desired posterior height is established and the ALL division has been confirmed.

CAUTION
When utilizing the Lordotic Distractor, it is important that the majority of the ALL has been divided under direct visualization with the annulotomy knife or ALL cutter.

(Fig. 38)



(Fig. 39)



(Fig. 40)

XLIF ACR SURGICAL TECHNIQUE

STEP 7:
IMPLANT TRIALING

Once the ALL is fully divided, the disc space should be fairly mobile in order to allow placement of the CoRoent XL-H trials *(Figs. 41, 42)*.

The XL-H trials are used to sequentially and gently open the disc space to accommodate 20° or 30° lordotic implants. The total length of the trial is 60mm, and the notches on the trials denote implant length (45, 50, 55, and 60mm). The CoRoent XL-H trial is threaded onto the inserter and the thumbwheel is tightened to secure the trial. The Variable Guided Clip is attached to the shaft of the CoRoent XL Inserter.

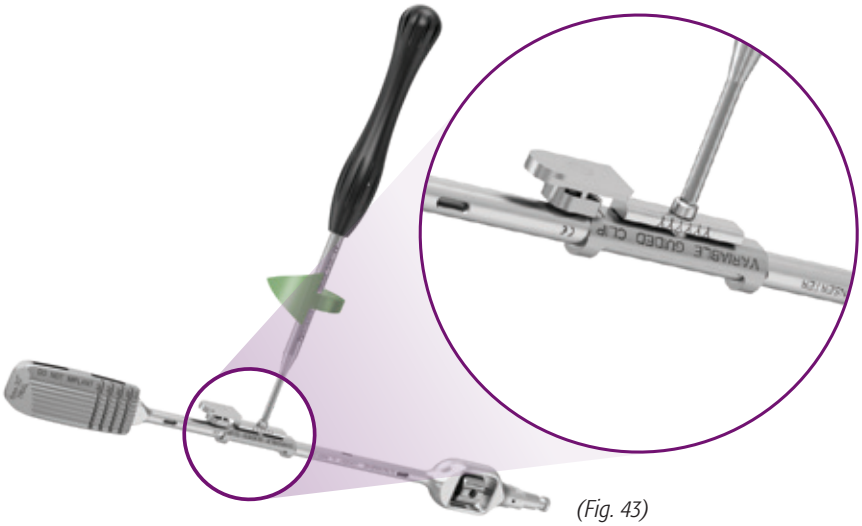
Note

To attach the Variable Guided Clip, the MaXcess Driver is used to back off the set screw – only a few counterclockwise rotations are required. The Variable Guided Clip is snapped onto the CoRoent XL Inserter with the "rounded" portion of the rail facing the distal tip; the set screw is then tightened with the MaXcess Driver (Fig. 43). The Variable Guided Clip is designed to rotate on the CoRoent XL Inserter with some force, as this will allow the surgeon to have some freedom with implant placement and trajectory once the CoRoent XL Inserter and Variable Guided Clip have been secured with the posterior Blade of the MaXcess Retractor.

The Guided rail on the Guided Clip slides down the posterior Blade of the MaXcess Retractor to help prevent anterior migration of the trial *(Fig. 44)*. Consideration of the anterior vasculature and posterior elements should be taken when selecting the CoRoent XL-H trial heights.

(Fig. 41)

(Fig. 42)



(Fig. 43)

(Fig. 44)

STEP 7:
IMPLANT TRIALING (CONT.)

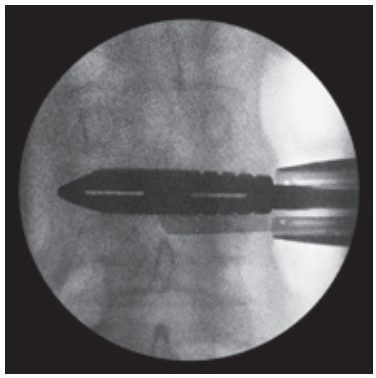
To begin trialing, a 4mm or 6mm, 20° trial is used and sequential distraction of the disc space is performed. From there, the 30° trials may be utilized if more lordosis is required. Under A/P fluoroscopy, the trial is gently impacted into the disc space until centered to determine the desired implant size *(Fig. 45)*. Proper anterior/posterior position is verified using lateral fluoroscopy *(Fig. 46)*.

NUVAMAP™ O.R.

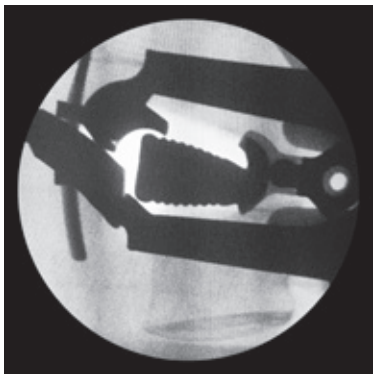
To determine if ideal alignment goals have been met, NuvaMap O.R. is used intraoperatively under lateral fluoroscopy (Fig. 47).

If satisfied with placement and fit of the trial, the surgeon may remove the trial from the disc space *(Fig. 48)*. The Slap Hammer may be used, if necessary, to facilitate trial removal.

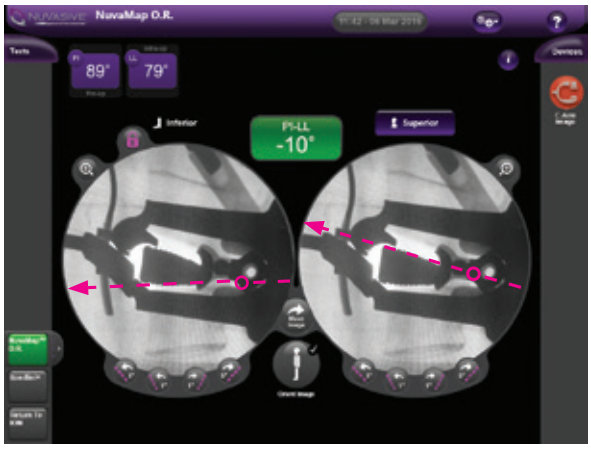
If the disc space is not highly mobile, the ALL may not be fully divided, the contralateral annulus may not be fully released, or the discectomy may not be sufficient.



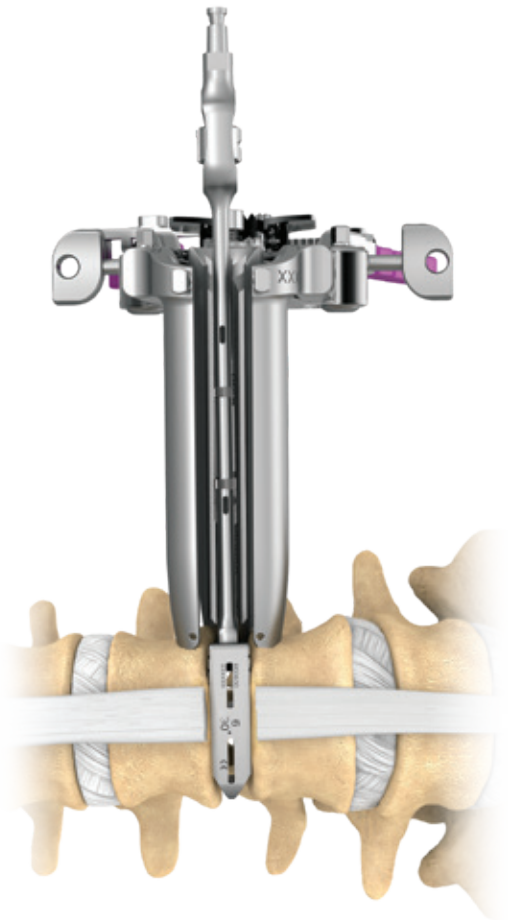
(Fig. 45)



(Fig. 46)



(Fig. 47)



(Fig. 48)

XLIF ACR SURGICAL TECHNIQUE

STEP 8:
IMPLANT PLACEMENT

The appropriate CoRoent XL-H implant is selected and filled with autograft material *(Fig. 49)*. During insertion of the implant, neuromonitoring can be performed using NVM5 Free Run EMG. Placement of the implant is dictated by patient anatomy and the spinal pathology that is being treated *(Figs. 50, 51)*. 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. 52, 53)*.

Titanium markers on all CoRoent XL implants can be used to confirm correct implant alignment.

22mm Hyperlordotic, 20°

POSTERIOR HEIGHT	ANTERIOR HEIGHT	TAB LENGTH
2	10	29.5
4	12	31.4
6	14	33.3
8	16	35.3
10	18	37.3

22mm Hyperlordotic, 30°

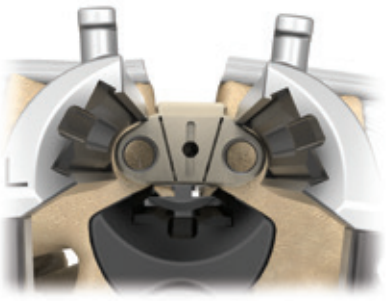
POSTERIOR HEIGHT	ANTERIOR HEIGHT	TAB LENGTH
2	14	31.4
4	16	33.3
6	18	35.3
8	20	37.3
10	22	39.3

COROENT XL-H (HYPERLORDOTIC)

(Fig. 49)

(Fig. 50)

(Fig. 51)



(Fig. 52)

(Fig. 53)

STEP 8:
IMPLANT PLACEMENT (CONT.)

Screw placement is necessary to prevent dislodgment and antimigration of the implant during patient positioning for posterior instrumentation. According to surgeon preference and anatomical requirements, a selection of Drills, Taps, and Awls are available for pilot hole preparation.

The tip of the Self-Centering Awl is placed directly into one of the implant screw holes. When engaged, it will sit firmly inside the implant. The Awl is advanced into the vertebral body until the desired depth is reached *(Fig. 54)*.

Screw length is determined using interbody graft length and pilot hole depth for reference. Additional length may be needed if bicortical purchase is desired. The desired length is selected and the tip of the Starter Screwdriver is inserted into the hexalobe engagement feature on the screw head *(Fig. 55)*. The knurled section on the Starter Screwdriver is rotated clockwise to thread the Screwdriver into the screw.

> ***Note***
>
> *Awl depth should be closely monitored using both A/P fluoroscopy and the markings on the Awl shaft. The Awl's adjustable depth stop is used to avoid excessive advancement of the instrument.*

The Awl is removed and the Screwdriver is used to insert the desired length screw directly through the implant *(Fig. 56)*. When ¾ of the screw has passed through the implant tab, the Starter Screwdriver is detached and the Final Screwdriver is used to advance the screw into the locked position. Proper screw locking is confirmed by the Canted Coil covering the entire circumference of the screw head *(Fig. 57)*. In addition, there may be a noticeable audible click and tactile sensation upon locking.

(Fig. 54)

(Fig. 55)

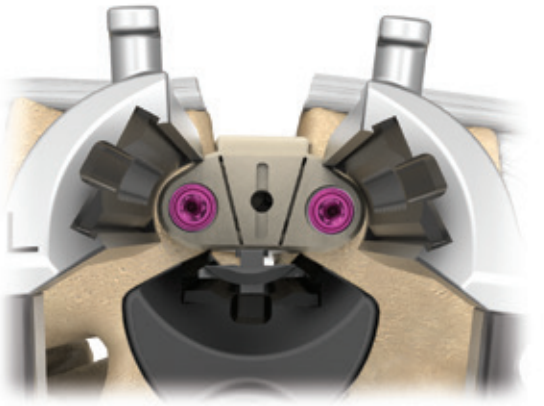
(Fig. 56)

(Fig. 57)

XLIF ACR SURGICAL TECHNIQUE

STEP 8:
IMPLANT PLACEMENT (CONT.)

Final placement of the CoRoent XL-H implant is verified *(Figs. 58, 59)*. The implant should rest fully across the disc space under A/P fluoroscopy with the screws extending nearly parallel to the endplates *(Fig. 60)*. On lateral fluoroscopy, the implant should be centered in the intervertebral space from an anterior/posterior perspective *(Fig. 61)*. Similar to the entire CoRoent XL family of interbody implants, CoRoent XL-H is intended to be used with supplemental internal spinal fixation.

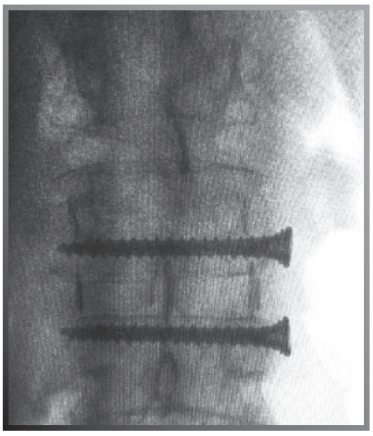


(Fig. 58)

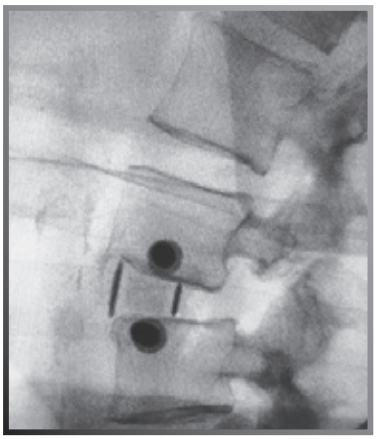
STEP 9:
INTRAOPERATIVE ALIGNMENT ASSESSMENT

For immediate intraoperative assessment NuvaMap O.R. may be used to ensure alignment objectives have been met. *(Fig. 62)*. If additional lordosis is desired, it can be obtained in the second stage of surgery with posterior fixation.

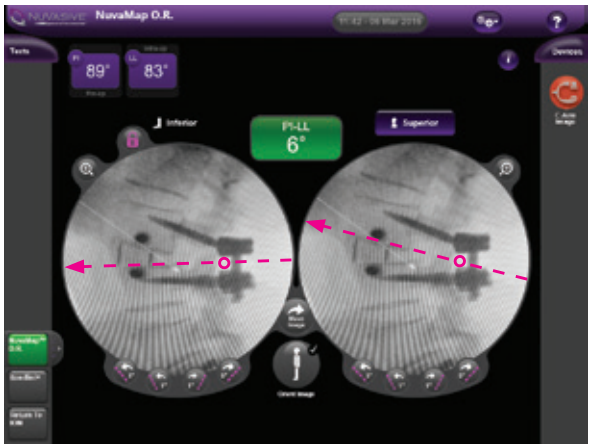
(Fig. 59)



(Fig. 60)



(Fig. 61)



(Fig. 62)

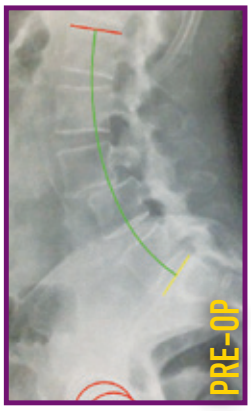
STEP 10:

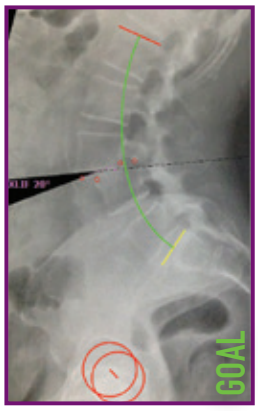
POSTOPERATIVE RECONCILIATION OF PLAN

For postoperative assessment of spinopelvic alignment, NuvaMap™ or NuvaLine™ may be used. Both software solutions allow the surgeon to calculate the postoperative spinopelvic parameters and evaluate the lordosis obtained from the XLIF ACR procedure. If additional lordosis is desired, it can be achieved in the second stage of surgery with NuVasive posterior procedural solutions.

In the case example, a one-level XLIF ACR at L3-L4 using a 20° cage resulted in 9° of lordotic correction. NuVasive pedicle screws afforded 4° of additional compression, leaving the patient with a pelvic incidence and lumbar lordosis mismatch of 6° *(Fig. 63)*.

CALCULATE





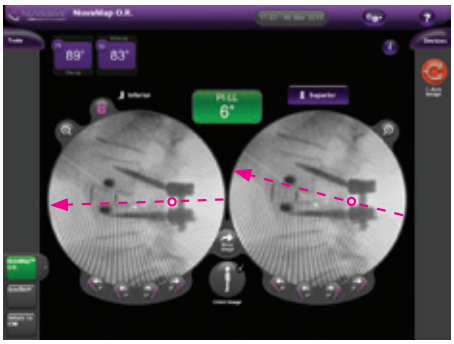
PRE-OP:
- PT: 29°
- PI: 89°
- LL: 70°

PI-LL: 19°

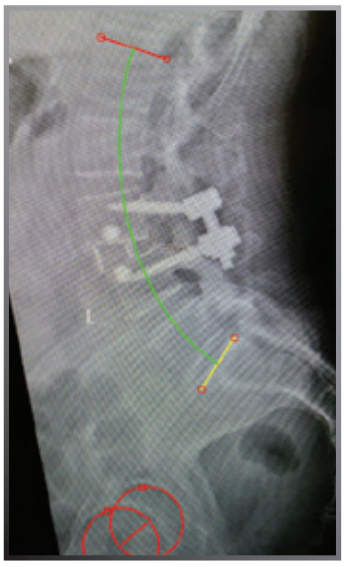
GOAL:
- PT: 20°
- PI: 89°
- LL: 82°

PI-LL: 7°

CORRECT



CONFIRM



POST-OP:
- PT: 20°
- PI: 89°
- LL: 83°

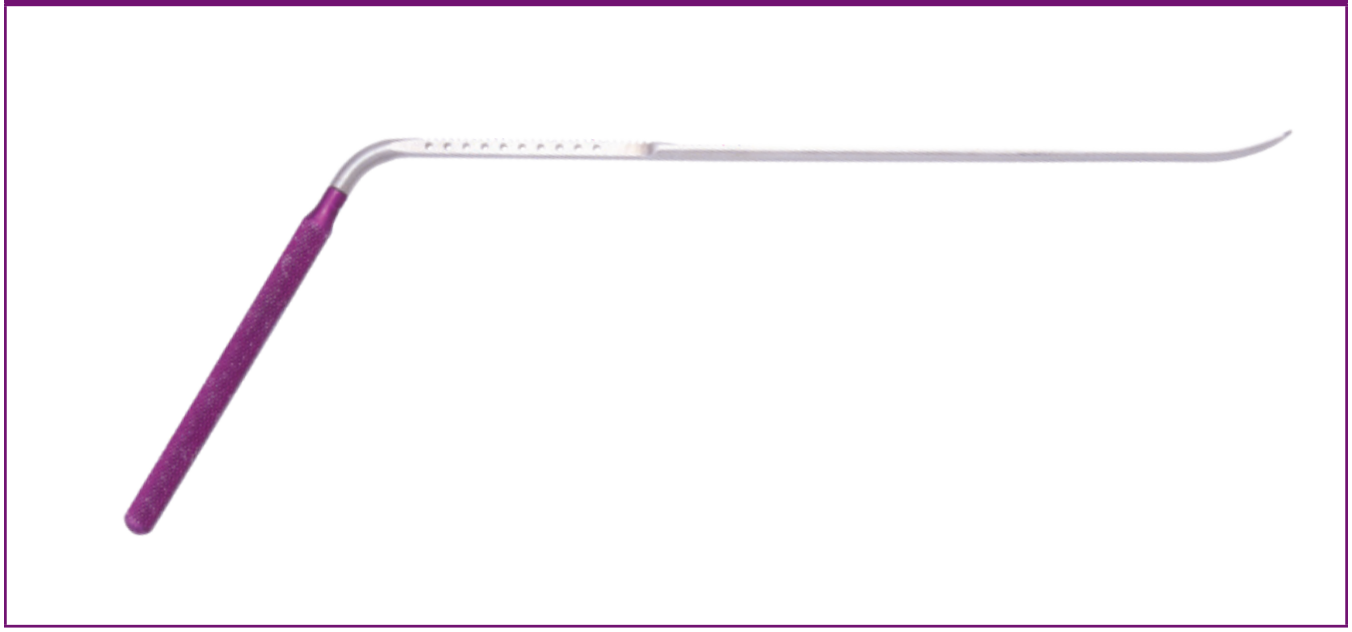
PI-LL: 6°

(Fig. 63)

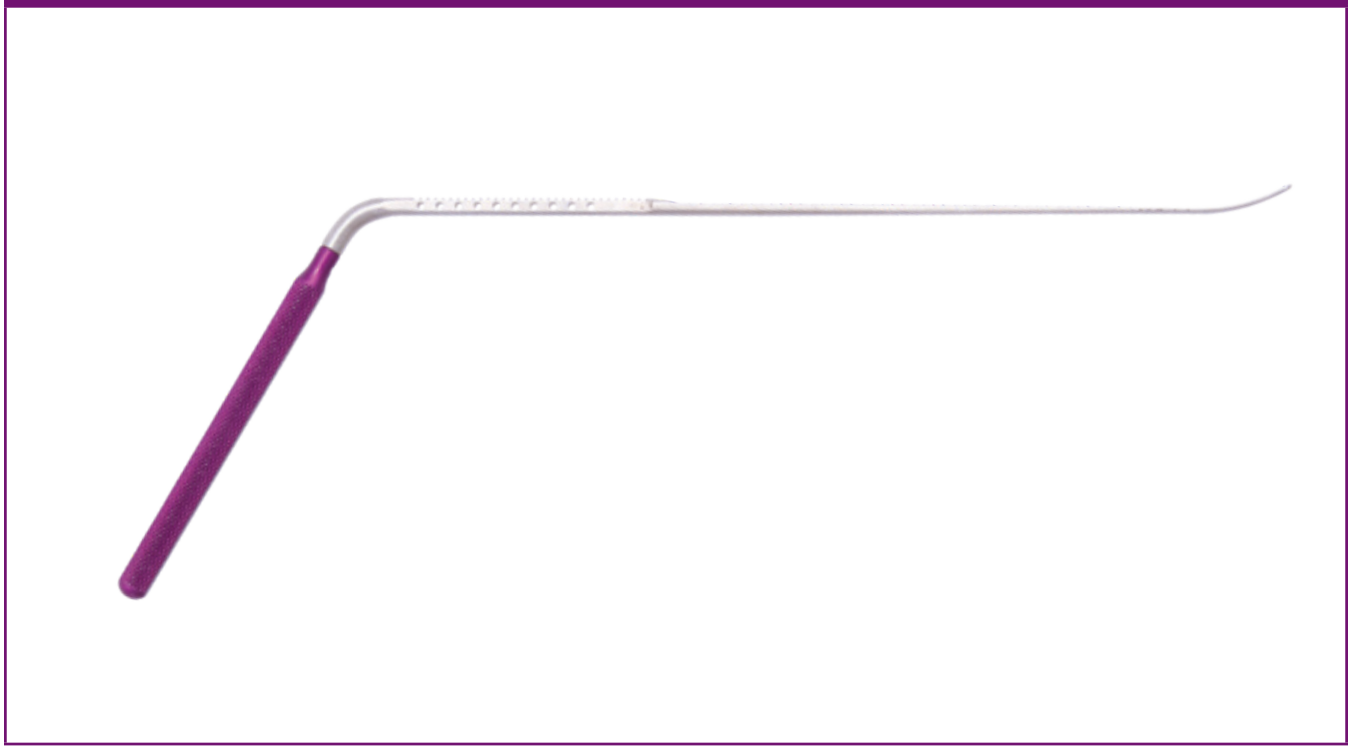
COROENT XL-H SYSTEM

COROENT XL-H INSTRUMENT TRAY

COROENT XL-H RETRACTOR, WIDE XL



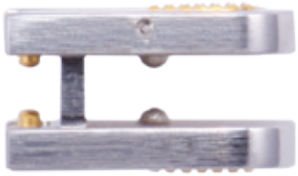
COROENT XL-H RETRACTOR, NARROW XL



COROENT XL-H INSTRUMENT TRAY (CONT.)

COROENT XL-H ALL CUTTER

COROENT XL-H CLIP, ANTERIOR RETRACTOR



COUNTER-TORQUE HANDLE

LORDOTIC DISTRACTOR

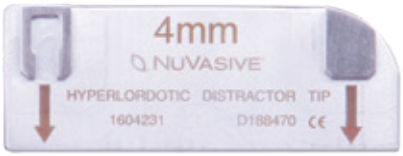
STANDARD HANDLE, RATCHETING

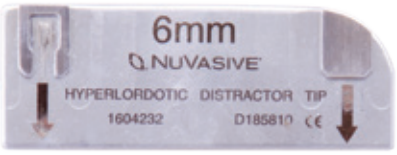
XL-H CLIP, VARIABLE GUIDED

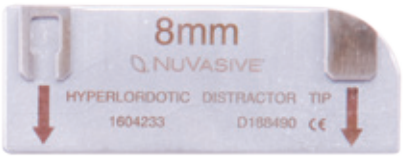
COROENT XL-H SYSTEM

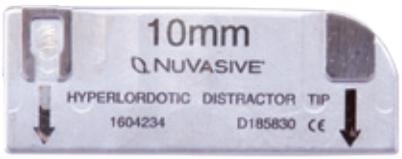
COROENT XL-H INSTRUMENT TRAY (CONT.)

LORDOTIC DISTRACTOR HEIGHT SLIDE – 4mm, 6mm, 8mm, 10mm









STERILE-PACKAGED ALL CUTTER DISPOSABLE BLADES

XL INSERTER

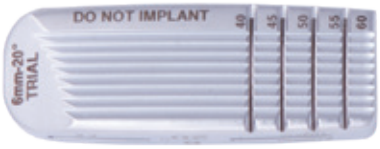
COROENT XL-H SYSTEM

COROENT XL-H IMPLANT TRAY

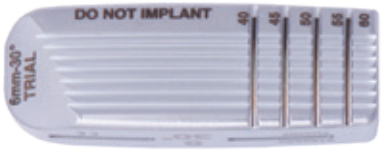
20° COROENT XL-H

30° COROENT XL-H

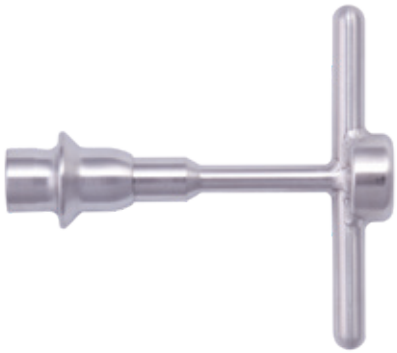
20° COROENT XL-H TRIAL



30° COROENT XL-H TRIAL



T-HANDLE



CATALOG

COROENT XL-H INSTRUMENTS

DESCRIPTION	CATALOG #
Generic NuVasive Tray Lid	8801333
Variable Guided Clip, Standard	6100102
CoRoent XL-H Retractor, Wide XL	1604362
CoRoent XL-H Retractor, Wide Large	1604361
CoRoent XL-H Retractor, Narrow XL	1604372
CoRoent XL-H Retractor, Narrow Large	1604371
CoRoent XL-H Clip, Anterior Retractor	1604270
XL Inserter	6900101
CoRoent XL-H ALL Cutter	1604100
XL-H Clip, Variable Guided	1608000
CoRoent XL-H Top Tray	1604291
CoRoent XL-H Nipple Mat	1604293
Counter-Torque Handle	6790153
Lordotic Distractor	1604240
4mm Height Slide, Lordotic Distractor	1604231
6mm Height Slide, Lordotic Distractor	1604232
8mm Height Slide, Lordotic Distractor	1604233
10mm Height Slide, Lordotic Distractor	1604234
Standard Handle, Ratcheting	7110004
CoRoent XL-H Bottom Tray	1604292
Advantis Medical Generic 2-Level Base	1599103
XL-H Tray Nameplate (large)	1604294
XL-H Tray Nameplate (small)	1604295
Universal Distractor, XLIF Interbody	3300040
IFU PEEK CR English	9003936

XLIF ACR ORDERING SUMMARY

DESCRIPTION	CATALOG #
CoRoent XL-F Wide Backup Tray	CORXLFBKP
CoRoent XL-H Implants	CORXLHIMP
CoRoent XL-H Instruments	CORXLHINSR
Sterile-Packaged ALL Cutter Blades (Qty. 12 per box)	1604105

COROENT XL-H IMPLANTS

DESCRIPTION	CATALOG #
Generic Lid Implant Case	8801333
Top Tray Implant Case	1565882
Middle Tray Implant Case	1565883
Bottom Tray Implant Case	1565884
Pin Mat Implant Case	1565885
Base Implant Case	1565880
2 x 22 x 45mm – 20° CoRoent XL-H	6200245
4 x 22 x 45mm – 20° CoRoent XL-H	6200445
6 x 22 x 45mm – 20° CoRoent XL-H	6200645
8 x 22 x 45mm – 20° CoRoent XL-H	6200845
10 x 22 x 45mm – 20° CoRoent XL-H	6201045
2 x 22 x 50mm – 20° CoRoent XL-H	6200250
4 x 22 x 50mm – 20° CoRoent XL-H	6200450
6 x 22 x 50mm – 20° CoRoent XL-H	6200650
8 x 22 x 50mm – 20° CoRoent XL-H	6200850
10 x 22 x 50mm – 20° CoRoent XL-H	6201050
2 x 22 x 55mm – 20° CoRoent XL-H	6200255
4 x 22 x 55mm – 20° CoRoent XL-H	6200455
6 x 22 x 55mm – 20° CoRoent XL-H	6200655
8 x 22 x 55mm – 20° CoRoent XL-H	6200855
10 x 22 x 55mm – 20° CoRoent XL-H	6201055
2 x 22 x 60mm – 20° CoRoent XL-H	6200260
4 x 22 x 60mm – 20° CoRoent XL-H	6200460
6 x 22 x 60mm – 20° CoRoent XL-H	6200660
8 x 22 x 60mm – 20° CoRoent XL-H	6200860
10 x 22 x 60mm – 20° CoRoent XL-H	6201060
2 x 22 x 45mm – 30° CoRoent XL-H	6300245
4 x 22 x 45mm – 30° CoRoent XL-H	6300445
6 x 22 x 45mm – 30° CoRoent XL-H	6300645

COROENT XL-H IMPLANTS (CONT.)

DESCRIPTION	CATALOG #
8 x 22 x 45mm – 30° CoRoent XL-H	6300845
10 x 22 x 45mm – 30° CoRoent XL-H	6301045
2 x 22 x 50mm – 30° CoRoent XL-H	6300250
4 x 22 x 50mm – 30° CoRoent XL-H	6300450
6 x 22 x 50mm – 30° CoRoent XL-H	6300650
8 x 22 x 50mm – 30° CoRoent XL-H	6300850
10 x 22 x 50mm – 30° CoRoent XL-H	6301050
2 x 22 x 55mm – 30° CoRoent XL-H	6300255
4 x 22 x 55mm – 30° CoRoent XL-H	6300455
6 x 22 x 55mm – 30° CoRoent XL-H	6300655
8 x 22 x 55mm – 30° CoRoent XL-H	6300855
10 x 22 x 55mm – 30° CoRoent XL-H	6301055
2 x 22 x 60mm – 30° CoRoent XL-H	6300260
4 x 22 x 60mm – 30° CoRoent XL-H	6300460
6 x 22 x 60mm – 30° CoRoent XL-H	6300660
8 x 22 x 60mm – 30° CoRoent XL-H	6300860
10 x 22 x 60mm – 30° CoRoent XL-H	6301060
2mm – 20° Trial	6100220
4mm – 20° Trial	6100420
6mm – 20° Trial	6100620
8mm – 20° Trial	6100820
10mm – 20° Trial	6101020
2mm – 30° Trial	6100230
4mm – 30° Trial	6100430
6mm – 30° Trial	6100630
8mm – 30° Trial	6100830
10mm – 30° Trial	6101030
T-Handle	1001992
IFU PEEK CR English	9003936

INSTRUCTIONS FOR USE

DESCRIPTION

The *NuVasive CoRoent XL Interfixated System* is manufactured from PEEK-Optima LT-1 conforming to ASTM F2026, Nickel-Cobalt-Chromium-Molybdenum alloy (MP35N) conforming to ASTM F562, and titanium alloy conforming to ASTM F136 and ISO 5832-3. The implants are available in a variety of different shapes and sizes to suit the individual pathology and anatomical conditions of the patient.

The CoRoent XL Interfixated System includes XL-F, XL-H, and XL Single Tab.

INDICATIONS FOR USE

The *NuVasive CoRoent XL Interfixated System* is indicated for intervertebral body fusion of the spine in skeletally mature patients. The System is designed for use with autogenous bone graft to facilitate fusion.

The *CoRoent XL Interfixated System* is intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to L5, for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The lumbar devices are to be used in patients who have had at least six months of non-operative treatment. The system is intended to be used with supplemental internal spinal fixation systems (e.g., pedicle or facet screws) that are cleared by the FDA for use in the lumbar spine in addition to the integrated screw.

CONTRAINDICATIONS

Contraindications include, but are not limited to:

1. Infection, local to the operative site.
2. Signs of local inflammation.
3. Patients with known sensitivity to the materials implanted.
4. Patients who are unwilling to restrict activities or follow medical advice.
5. Patients with inadequate bone stock or quality.
6. Patients with physical or medical conditions that would prohibit beneficial surgical outcome.
7. Prior fusion at the level(s) to be treated.

POTENTIAL ADVERSE EVENTS AND COMPLICATIONS

As with any major surgical procedures, there are risks involved in orthopedic surgery. Infrequent operative and postoperative complications that may result in the need for additional surgeries include: early or late infection; damage to blood vessels, spinal cord or peripheral nerves; pulmonary emboli; loss of sensory and/or motor function; impotence; and permanent pain and/or deformity. Rarely, some complications may be fatal.

Potential risks identified with the use of this system, which may require additional surgery, include:

- Bending, fracture or loosening of implant component(s)
- Loss of fixation
- Nonunion or delayed union
- Fracture of the vertebra
- Neurological, vascular or visceral injury
- Metal sensitivity or allergic reaction to a foreign body
- Infection
- Decrease in bone density due to stress shielding
- Pain, discomfort or abnormal sensations due to the presence of the device
- Nerve damage due to surgical trauma
- Bursitis
- Dural leak
- Paralysis
- Death

WARNINGS, CAUTIONS AND PRECAUTIONS

The subject device is intended for use only as indicated.

The implantation of spinal systems should be performed only by experienced spinal surgeons with specific training in the use of this spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient.

Correct selection of the implant is extremely important. The potential for success is increased by the selection of the proper size of the implant. While proper selection can minimize risks, the size and shape of human bones present limitations on the size and strength of implants. Metallic and internal fixation devices cannot withstand the activity levels and/or loads equal to those placed on normal, healthy bone. These devices are not designed to withstand the unsupported stress of full weight or load bearing alone.

It is important to select the appropriate length screw and confirm trajectory under intraoperative fluoroscopy in order to avoid potential screw impingement.

Caution must be taken due to potential patient sensitivity to materials. Do not implant in patients with known or suspected sensitivity to the aforementioned materials.

These devices can break when subjected to the increased load associated with delayed union or nonunion. Internal fixation appliances are load-sharing devices that hold bony structures in alignment until healing occurs. If healing is delayed, or does not occur, the implant may eventually loosen, bend, or break. Loads on the device produced by load bearing and by the patient's activity level will dictate the longevity of the implant.

Corrosion of the implant can occur. Implanting metals and alloys in the human body subjects them to a constantly changing environment of salts, acids, and alkalis, which can cause corrosion. Placing dissimilar metals in contact with each other can accelerate the corrosion process, which in turn, can enhance fatigue fractures of implants. Consequently, every effort should be made to use compatible metals and alloys in conjunction with each other.

Care should be taken to insure that all components are ideally fixated prior to closure.

Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.

Additional care should be taken at the lower levels of the lumbar spine due to the obstruction of anatomical structures, such as the iliac crest and iliac vessels, surgical access for the subject device at the these levels may not be feasible.

Based on bench testing, resection of the anterior longitudinal ligament (ALL) may facilitate insertion of the implant for greater sagittal correction, when used with supplemental fixation per the indications, and aid in preventing potential end plate damage.

Warning: This device contains nickel. Do not implant in patients with known or suspected nickel sensitivity.

Patient Education: Preoperative instructions to the patient are essential. The patient should be made aware of the limitations of the implant and potential risks of the surgery. The patient should be instructed to limit postoperative activity, as this will reduce the risk of bent, broken or loose implant components. The patient must be made aware that implant components may bend, break or loosen even though restrictions in activity are followed.

Single Use: Reuse of a single use device that has come in contact with blood, bone, tissue or other body fluids may lead to patient or user injury. Possible risks associated with reuse of a single use device include, but are not limited to, mechanical failure, material degradation, potential leachables, and transmission of infectious agents. Resterilization may result in damage or decreased performance.

Magnetic Resonance (MR) Safety: The CoRoent XL Interfixated System has not been evaluated for safety and compatibility in the MR environment. The CoRoent XL Interfixated System has not been tested for heating or migration in the MR environment.

Compatibility: Do not use CoRoent XL Interfixated System with components of other systems. Unless stated otherwise, NuVasive devices are not to be combined with the components of another system.

PREOPERATIVE WARNINGS

1. Only patients that meet the criteria described in the indications should be selected.
2. Patient condition and/or predispositions such as those addressed in the aforementioned contraindications should be avoided.

3. Care should be used in the handling and storage of the implants. The implants should not be scratched or damaged. Implants and instruments should be protected during storage and from corrosive environments.
4. All non-sterile parts should be cleaned and sterilized before use.
5. Devices should be inspected for damage prior to implantation.
6. Care should be used during surgical procedures to prevent damage to the device(s) and injury to the patient.

POST-OPERATIVE WARNINGS

During the postoperative phase it is of particular importance that the physician keeps the patient well informed of all procedures and treatments.

Damage to the weight-bearing structures can give rise to loosening of the components, dislocation and migration as well as to other complications. To ensure the earliest possible detection of such catalysts of device dysfunction, the devices

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