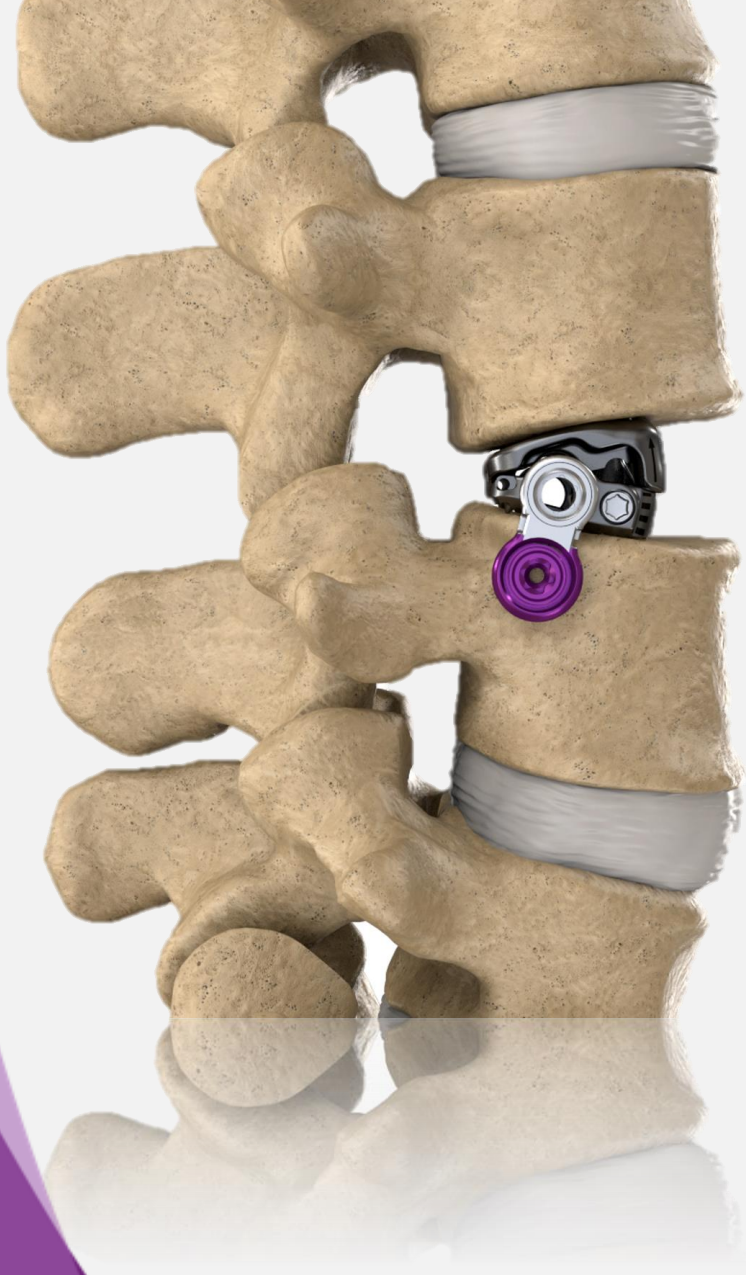


XLX ACR

Surgical Technique Guide

NuVasive

Contents

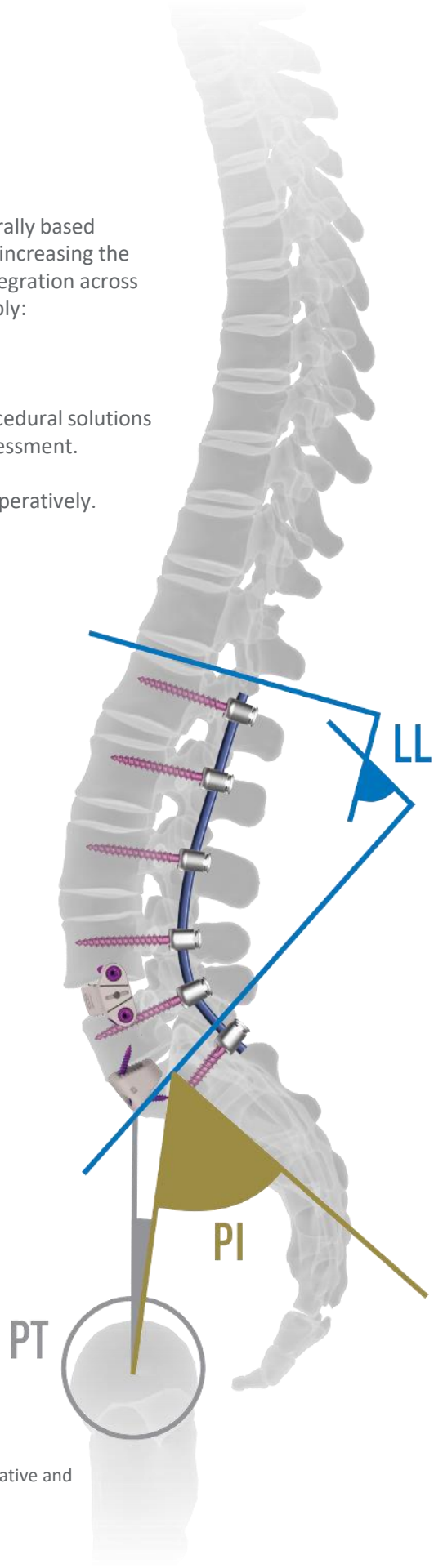
Overview

Integrated Global Alignment (iGA) is a platform comprosed 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 illustrate a direct correlation between spinal alignment and long-term clinical Outcomes.[1] Specific spinopelvic parameters, including the proportionality of 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.**



[1] 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.

XLX ACR Implant Overview

Width (Anterior-posterior)	**23mm**
Lengths (Medial-lateral)	**50, 55, 60mm**
Lordosis	**10° - 30°**
Heights (Posterior)	**4, 6, 8, 10mm**
Plate Offering (Length)	**10.5mm**

Key Instrumentation

Implant Assembly

Set Screw Driver
(1676833)

Set Screw Torque Limiting Handle
(1676634)

Loading Block
(1676670)

Insertion

Standard Inserter
(D1871500)

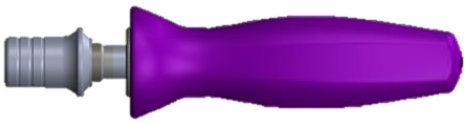
Drive Shaft
(1871530)

Plated Main Shaft
(1871520)

Attachment Tool
(1871540)

Expansion

Standard Expansion Driver
(1871535)



Expansion Torque Limiting Driver
(1676632)

*Based on use with Standard Inserter

Presurgical Preparation

Equipment Requirements

To perform the XLIF procedure, 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
- XLX™ ACR® Instruments
- XLIF® Instruments
- MaXcess 4 Articulating Arm
- MaXcess 4 Access System
- NVM5
- NVM5 EMG Module
- NVM5 XLIF Dilator Kit
- MaXcess Fixation Shim Kit (Optional)
- XL-H Instruments (Optional)

Implants:

- XLX™ ACR® Implants

Posterior Fixation

- Reline (or desired fixation)

Reference the applicable CoRoent, MaXcess 4, NVM5, and XLIF Technique Guide(s) or Reference Manual(s) and/or Instructions for Use (IFU) for additional important labeling information.

IFUs can be referenced at www.nuvasive.com/eIFU.

XLX™ ACR® Surgical Technique

Step 1

Preoperative Planning

Calculating Alignment

The restoration or preservation of patient alignment begins with calculating spinopelvic parameters and developing a surgical plan.

NuvaLine *(Figs. 1, 2),* a simple software application for tablet and mobile devices, is designed specifically for this purpose by intuitively navigating through the calculation measurements. It provides an efficient assessment to determine and evaluate key spinopelvic parameters that are based on anatomical landmarks. Prior to surgery, it is recommended to obtain full 36 inch standing radiographs in both sagittal and coronal planes. If 36 inch standing cannot be obtained, it is critical that the radiograph captures at minimum the following anatomical landmarks:

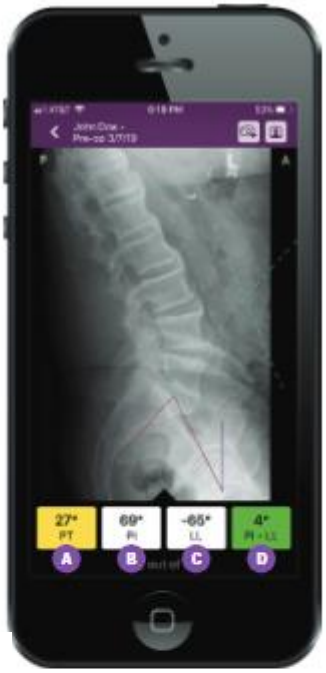
- Femoral heads
- Sacral endplate
- Superior L1 endplate

NuvaLine is designed to capture three important parameters based on these landmarks in the radiographic image:

- Pelvic tilt (PT) **(A)**
- Pelvic incidence (PI) **(B)**
- Lumbar lordosis (LL) **(C)**

With these, NuvaLine is designed to calculate the proportionality between PI and LL (D), which is a key element in assessing a patient's global sagittal alignment, along with the PT of the patient. Ideally the patient's spinopelvic parameters reflect the primary alignment objectives that are most closely correlated to health-related quality of life (HRQOL) outcomes:[2]

- SVA < 4cm
- PT < 20º
- PI – LL within 10º



(Fig.1)

(Fig.2)

[2]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.

Step 2

Patient Positioning and O.R. Setup

Under A/P 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. 3):*

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

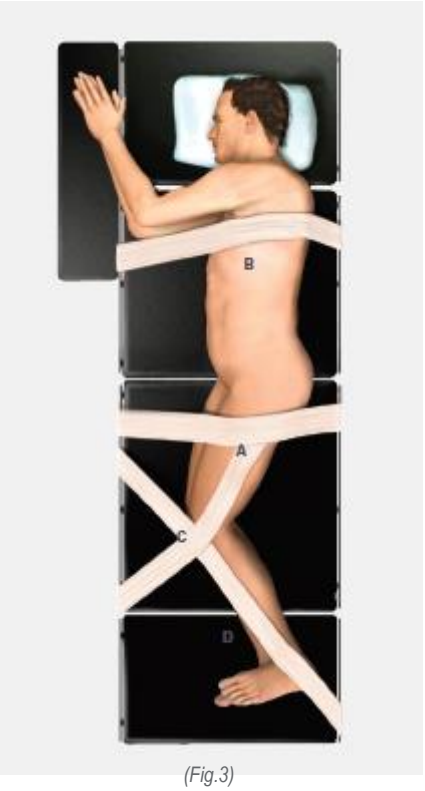
Over the thoracic region **(B)**

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

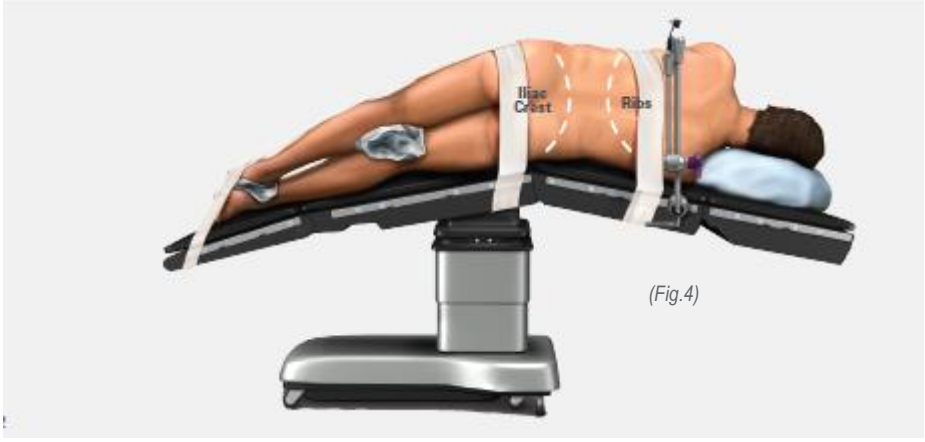
From the table to the knee, past the ankle, and then secured to the table **(D)**

This configuration suggests 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, flex the surgical table (if necessary) to increase the distance between the iliac crest and the ribs in order to gain direct access to the disc *(Fig. 4)* and tension the skin.



(Fig.3)



(Fig.4)

Step 2

Patient Positioning and O.R. Setup (Cont.)

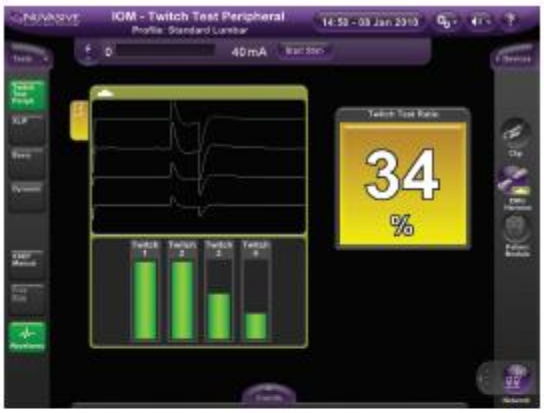
NVM5 Twitch Test

In order to asses how paralytics could be affecting the ability to acquire EMG signals 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 deemed unfavorable by the surgeon *(Fig. 5),* anesthetist should be instructed to reverse paralytics and muscle relaxants until an acceptable Twitch Test is conducted *(Fig. 6).*

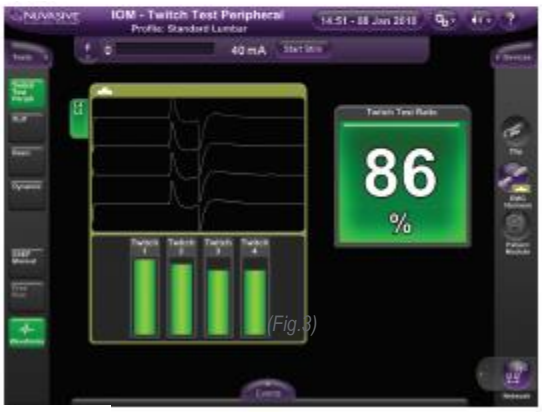
Once the patient is secured, the table should be adjusted so that the C-arm provides true A/P images when at 0° (distinct endplates and pedicles symmetrical about the spinous process), and true lateral images when at 90° (distinct endplates and superimposed pedicles) *(Figs. 7, 8)*.

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. 9).*

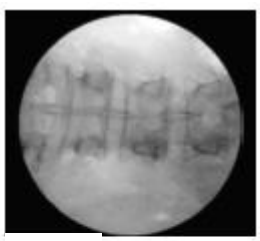


(Fig.5)

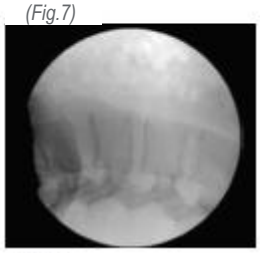


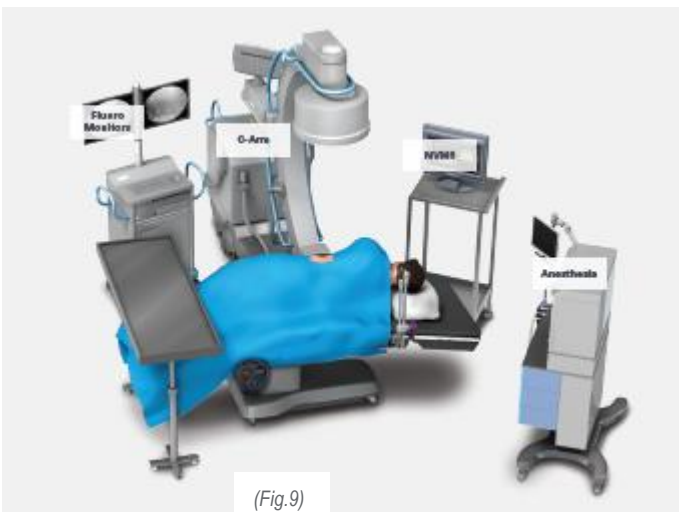
(Fig.6)

(Fig.8)



(Fig.7)



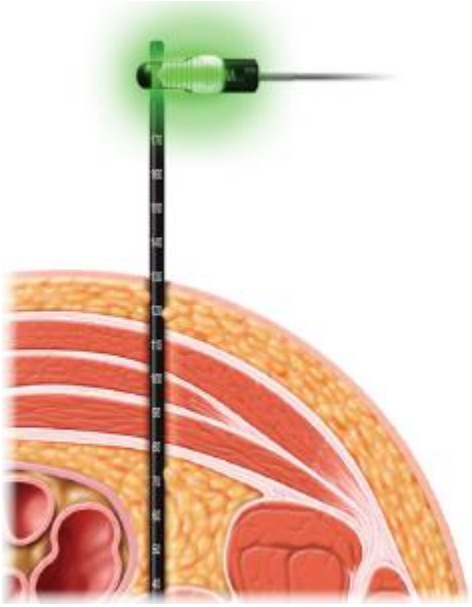


(Fig.9)

Step 3

Retroperitoneal Access

A standard XLIF approach through the retroperitoneal space is performed *(Fig 10).*



(Fig.10)

Specific to the XLX™ 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.

- XLX ACR implant has a width is 23mm which may require more disc exposure and a more posterior placement of the retractor (what NVM5 will favorably allow) than a standard CoRoent XL 18mm cage.

- If the initial black dilator is not in an 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 XLX ACR implant.

- Prior to resecting the ALL, a standard XLIF discectomy utilizing cobb elevators, kerrisons, and pituitaries is performed. 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.

For a more detailed description about retroperitoneal access, please refer to the XLIF Surgical Technique (9500138)

Step 4

Exposure of the ALL

Increased anterior/posterior retraction may be necessary for the steps that follow.

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. 11).* The curved XL-H Anterior Retractor is placed anterior to the penfield (*Fig. 12).*

(Fig.11)

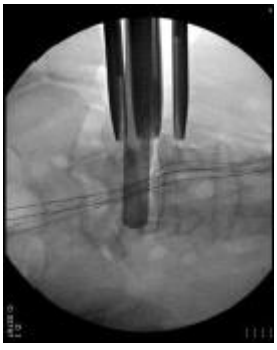
(Fig.12)

Care should be taken while placing the ALL retractors and should not be placed with force. Gentle placement of the retractors should be used to find the proper plane and avoid the vessels.

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. 16)*. The XL-H Anterior Retractor is curved to follow the natural curvature of the vertebral body *(Fig. 17)*.

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. 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. It is recommended to begin with the Narrow ALL Retractor *(Fig. 18).*



(Fig.13)

(Fig.14)

WIDE XL-H RETRACTOR

NARROW XL-H RETRACTOR

(Fig.15)

Step 4

Exposure 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. 16)*. The XL-H Anterior Retractor comes in various lengths and widths. The retractor width should span the disc space to help maintain position once the ALL has been released. Throughout the case verify the position of the ALL retractor.

(Fig.16)

Step 5

Complete Discectomy and annular release

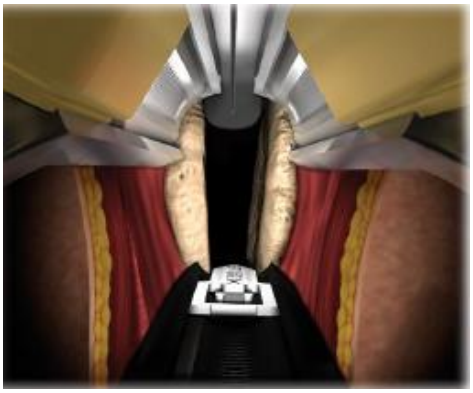
Pituitaries, curettes, disc cutters, endplate scrapers, rasps, and other disc preparation instruments can be used to thoroughly remove the disc and prepare the endplates for fusion.

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 *(Figs. 17&18).*

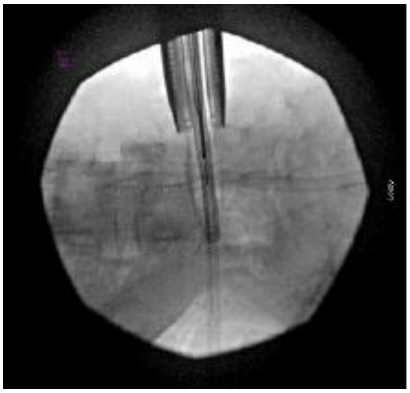
Osteophytes can be either removed with the osteophyte removal tool or left in place; however, removal is necessary if osteophytes are interfering with the placement of the fixation plate.

Note:

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.



(Fig.17)



(Fig.18)

Step 6

Trialing

The total length of the XLX™ ACR® Trial is 60mm, with the notches on the trial marking the implant lengths of 50 and 55mm *(Fig. 19*). Using the XL-W Inserter, thread on the trial and use the thumb-wheel to secure. Use sequential trialing within the disc space to help prevent endplate damage. Under A/P fluoroscopy, the trial is gently impacted into the disc space until centered to determine the desired implant size. Proper anterior/posterior position is verified using lateral fluoroscopy. Trialing is used to determine the starting posterior height and length of the XLX ACR Implant.

(Fig.19)

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

Step 7

ALL Resection

ALL resection can be performed if an implant with greater lordosis (≥20°) is desired. Once proper discectomy and annular release are performed, verify the placement of the ALL retractor and the ALL is resected 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 resection of the ALL that can be seen under direct visualization *(Fig. 20)*.

(Fig.20)

(Fig.21)

NOTE:

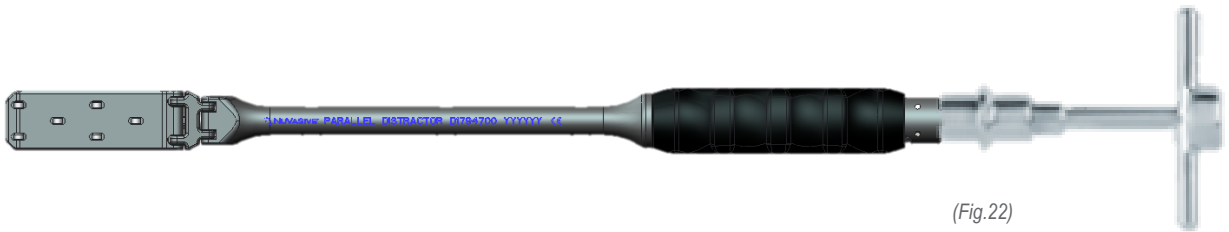
If utilizing the Wide ALL Cutter, the sterile blade (Part Number: 1604105), is loaded on the ALL Cutter by using the MaXcess® Driver to release the set screw (Figs. 21). Insert the blade into the opening of the ALL Cutter at the distal tip with the sharp side of the blade facing out. Once the blade is in place, the set screw is tightened with the MaXcess Driver.

Step 7

ALL Resection(Cont.)

If the ALL is resected and/or using an implant expanded to ≥20° lordosis, XLX™ ACR® fixation plate must be used in addition to supplemental fixation. The remaining fibers of the ALL that were not divided under direct visualization are resected utilizing sequential distraction.

When utilizing the XLX ACR Parallel Distractor, the instrument is placed into the disc space so that the tips span the length of the disc space *(Fig. 22)*. Attach the Hudson T-handle to the parallel distractor and slowly rotate clockwise to initiate parallel distraction. The disc space is carefully distracted and the ALL is fully resected, 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 under direct visualization.



(Fig.22)

A full resection of the ALL is necessary to allow for proper placement of a hyperlordotic implant. Verify the retractor extends to the contralateral annulus using fluoroscopy. To prevent damage to surrounding anatomy when resecting the ALL, do not extend the incision past the contralateral portion of the retractor.

Resection should only be completed under direct visualization.

Step 8
Implant Selection and Assembly

Select the appropriately sized implant and fixation plate *(Fig. 23)*. Fixation plate is required if implant is expanded ≥20° lordosis and/or the ALL has been resected *(Fig. 24).*

If using the fixation plate, see **Step 8.1** entitled **Implant Assembly** below. If not using the fixation plate, see **Step 8.3** entitled **Graft Containment Plug (Optional)**, followed by **Step 9** entitled **XLX™ ACR® Inserter Assembly** below.

Posterior Height	Starting Anterior Height	Max Anterior Height (Approx.)
4mm	8mm	16mm
6mm	10mm	18mm
8mm	12mm	20mm
10mm	14mm	22mm

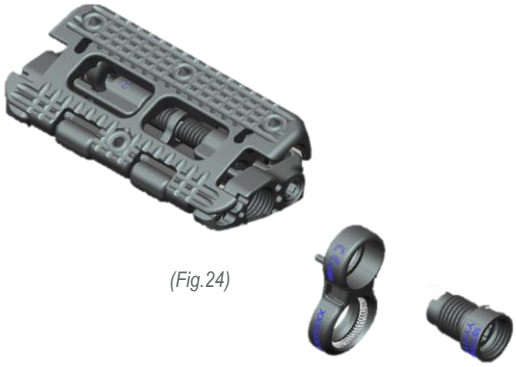
(Fig.23)

NOTE: Implants are referenced by the posterior height.

Step 8.1
Implant Assembly

If the ALL is resected and/or using an implant expanded ≥20° lordosis, XLX ACR fixation plate must be used in addition to supplemental fixation.

The plate may be placed in any of the three orientations, dictated by the keyed locking system. It is recommended to use the XLX ACR Loading Block to help assemble the implant.



(Fig.24)

Step 8.2
Plate Attachment to Interbody

Insert implant into the correct posterior height slot. Align plate on the interbody in the desired orientation(Fig. 25). Using the Set Screw Driver Short (1676833) and Set Screw Torque Limiting Handle (1676634) insert the plate set screw to secure the plate to the interbody.

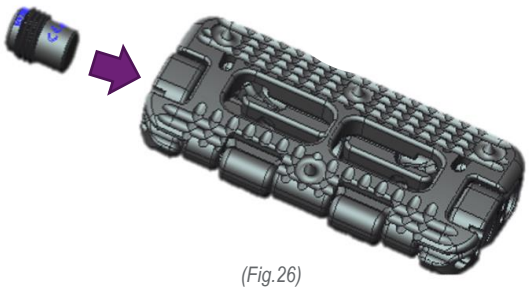
Flip loading block over and insert the XLX ACR Graft Containment Plug. More details about the graft containment plug flow in the next section.

(Fig.25)

Step 8.3
Graft Containment Plug (Optional)

The system is designed for use with autogenous and/or allogenic bone graft composed of cancellous and/or corticocancellous bone graft to facilitate fusion.

If desired, a graft containment plug can be attached to the contralateral side of the interbody to prevent graft migration *(Fig. 26)*. The graft containment plug is secured to the interbody with the Set Screw Driver Short (1676833) which threads and locks the plug into final position using the Set Screw Torque Limiting Handle (1676633).



(Fig.26)

Step 9
XLX ACR Inserter Assembly

Once the implant construct has been assembled, select either the Standard or Low-Profile Inserter for implant insertion *(Fig. 27&28)*. Depending on the selected implant construct and desired inserter, perform the following steps outlined below:

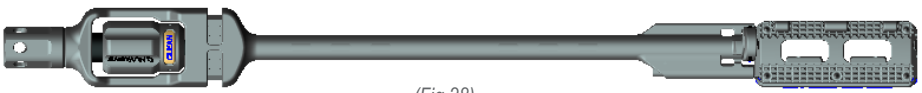
Step 9a
Standard Inserter with XLX ACR Interbody Assembly

Step 9b
Low-Profile Inserter with XLX ACR Interbody Assembly

Standard Inserter

(Fig.27)

Low-Profile Inserter

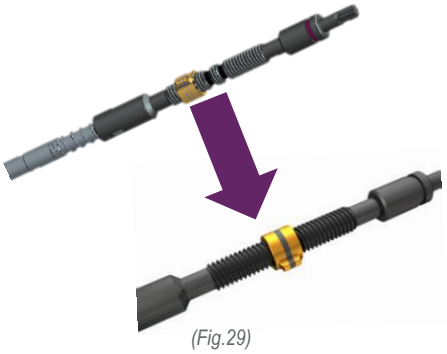


(Fig.28)

Step 9a

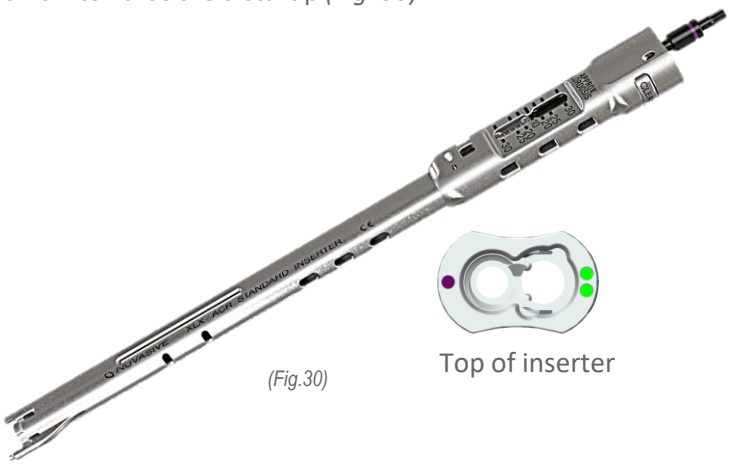
Standard Inserter with XLX ACR Interbody Assembly

Reset the indicator on the XLX ACR Drive Shaft (1871530) by spinning the gold nut until it covers the two black bands on the shaft, “Zero Line” which corresponds with 10° of lordosis *(Fig. 29).*



(Fig.29)

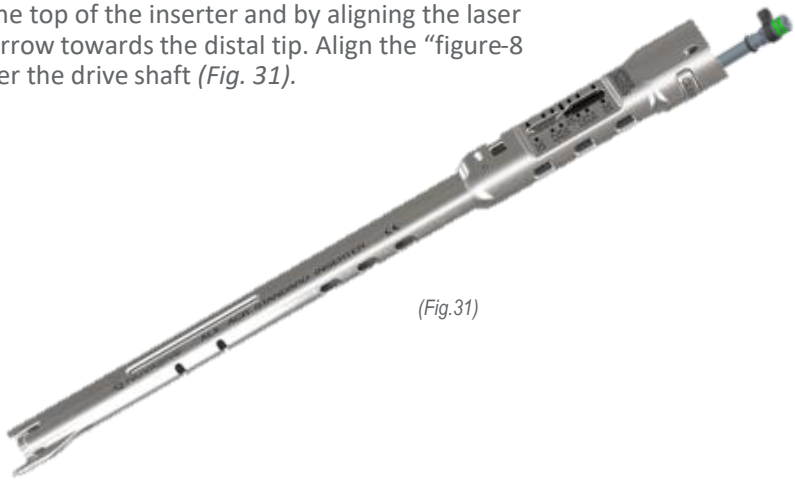
Slide Drive Shaft into Standard Inserter (D1871500) by verifying the single purple line on the shaft to the purple dot on top of the inserter and orienting the laser marked arrow towards the distal tip *(Fig. 30).*



(Fig.30)

Top of inserter

Slide Plated Main Shaft (1871520) into the inserter by verifying the double green lines match the two green dots on the top of the inserter and by aligning the laser marked arrow towards the distal tip. Align the “figure-8 plate” over the drive shaft *(Fig. 31).*



(Fig.31)

Confirm that the shafts are fully seated . Confirm the implant is in the fully collapsed state by verifying that the lordosis indicator laser marks on the implant are not visible.

Step 9a

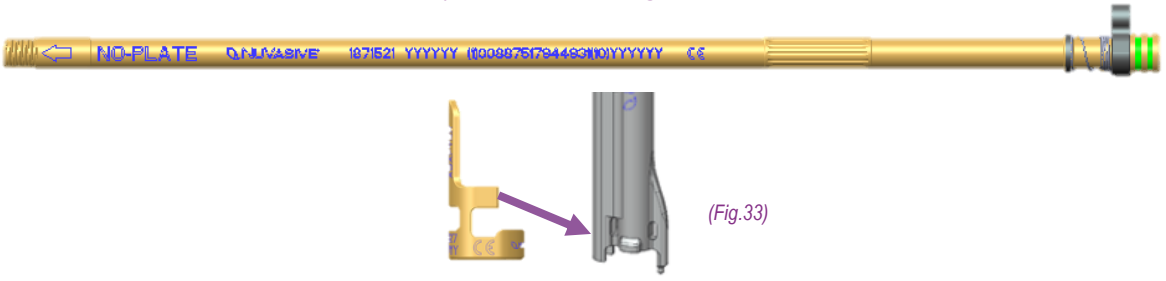
Standard Inserter with XLX ACR Interbody Assembly

Align inserter to engage into the implant, verifying the distal engagement points are fully aligned with the implant. Using the Implant Attachment Tool (1871540) thread the inserter onto the implant construct until snug *(Fig. 32)* Remove the attachment tool from the inserter. Pre-pack interbody with graft material to prepare for delivery of the interbody to the disc space.

(Fig.32)

NOTE:

If used without a plate, swap out Plated Main Shaft (1871520) for the Unplated Main Shaft (1871521). Before fully seating the shaft, align the arms of the XLX ACR Unplated Adapter (**1871527**) with the distal cutouts on XLX ACR Standard Inserter (**D1871500**) and press to attach *(Fig. 33).*



(Fig.33)

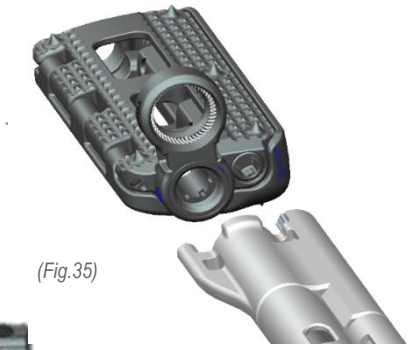
Step 9b

Low Profile Inserter with XLX ACR Interbody Assembly

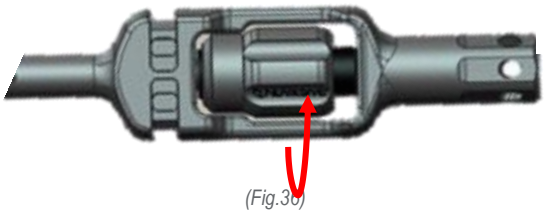
Slide Low-Profile Plated Inner Shaft (1676604) into Low-Profile Inserter (D1676601)*(Fig. 34)* Confirm that the shaft is fully seated by verifying that no shaft is visible through the top holes of the inserter. Determine that the implant is in the fully-collapsed state by verifying that the lordosis indicator laser marks on the implant are not visible.

(Fig.34)

Align the inserter to the interbody, verifying the distal engagement is properly aligned *(Fig. 35).* Thread the inserter onto the implant construct by rotating the integrated thumbwheel clockwise until snug *(Fig. 36).* Pre-pack interbody with graft material to prepare for delivery of the interbody to the disc space.



(Fig.35)

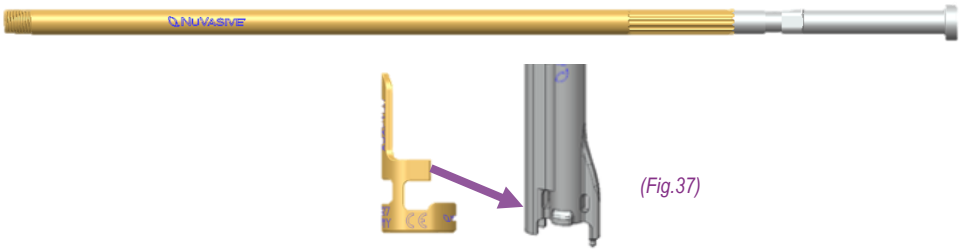


(Fig.36)

Confirm that the shafts are fully seated and that the implant is in the fully-collapsed state by verifying that the lordosis indicator laser marks on the implant are not visible.

NOTE:

If used without a plate, swap out Plated Inner Shaft (1676604) for the Unplated Inner Shaft (1676619). Before fully seating the shaft, align the arms of the XLX ACR Unplated Adapter (**1871527**) with the distal cutouts on XLX ACR Low-Profile Inserter (**D1676601**) and press to attach *(Fig. 37).*



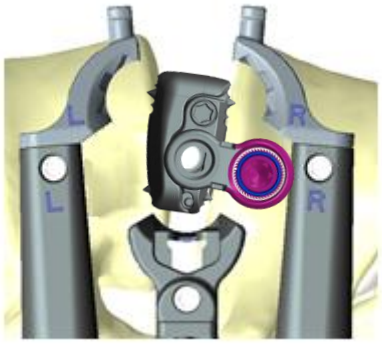
(Fig.37)

Step 10
Implant Insertion

Confirm the implant is fully collapsed and pre-pack the cage. Gently impact the implant into the disc space using the Posterior Guide Clip, if desired. During insertion of the implant, neuromonitoring can be performed using NVM5® Free Run EMG. Monitor insertion of the implant placement under A/P fluoroscopy. Placement of the implant is dictated by patient anatomy and the spinal pathology that is being treated.

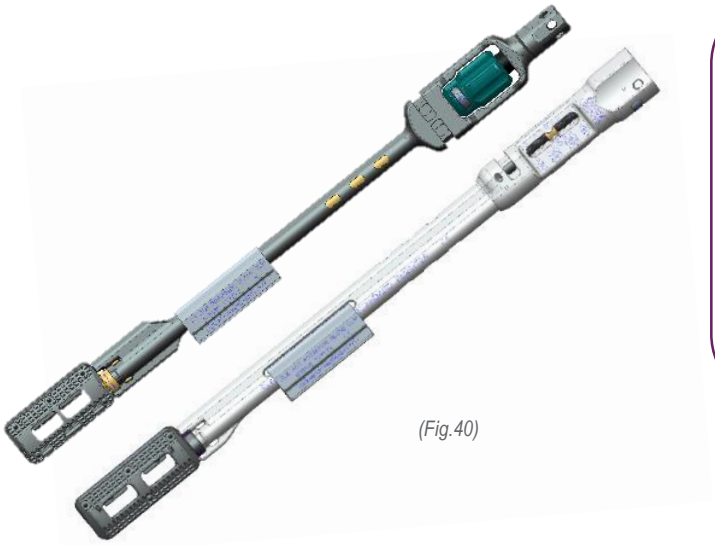
Generally, the implant spans the ring apophysis, is centered across the disc space from a medial/lateral perspective, and is near the center of the disc space from an anterior/posterior perspective *(Figs. 38&39)*.

NOTE:
Increased cranial/caudal retraction may be necessary to allow room for the fixation plate.



(Fig.38)

(Fig.39)



(Fig.40)

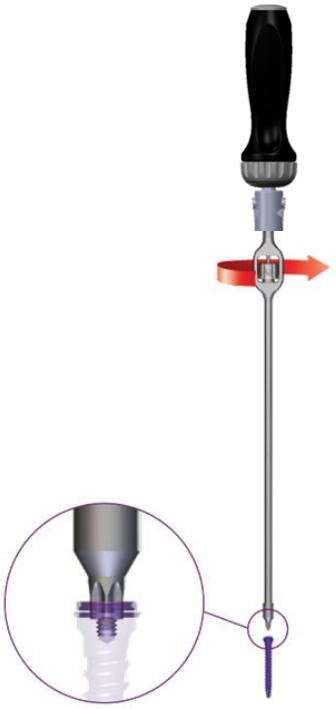
NOTE:
To mitigate the risk of intraoperative implant migration, use the Posterior Blade Clip inserter attachment when inserting the XLX ACR interbody. To assemble the posterior blade clip align centering pins on the clip to mate with the inserter. Verify the clip is fixed in place before engaging into posterior blade of the retractor *(Fig. 40)*.

Step 11

Screw Fixation

(If not using a plate, see Step 12 “Implant Expansion” below.)

Screw placement within the plate is necessary to prevent dislodgment and migration of the implant during patient positioning for posterior instrumentation.



(Fig.41)

Step 11a:

Pilot Hole Preparation

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 tip of the Self-Centering Awl is placed directly into the plate screw hole. When engaged, it will sit firmly inside the implant. Advance the Awl into the vertebral body until the desired depth is reached. Take fluoro shot to confirm.

(Fig.42)

Step 11b:

Screw Placement

Select the desired length bone screw and insert the tip of the Starter Screwdriver into the hexalobe engagement feature on the screw head. Turn the thumbwheel clockwise to thread the screwdriver into the screw *(Fig. 41).*

Using the Starter Screwdriver advance screw ¾ of the way. Detach the Starter Screwdriver and use the Final Screwdriver to advance the screw to the final position. Proper screw locking is confirmed by the canted coil covering the entire circumference of the screw head *(Figs. 42&43).*

(Fig.43)

Note:
Once the screw is 75% seated, the Screw Starter must be removed to allow final placement with the Final Screwdriver.

Step 11c:

Screw Placement Confirmation

Screw placement within the plate is necessary to prevent dislodgment and anti-migration of the implant during patient positioning for posterior instrumentation.

Step 12

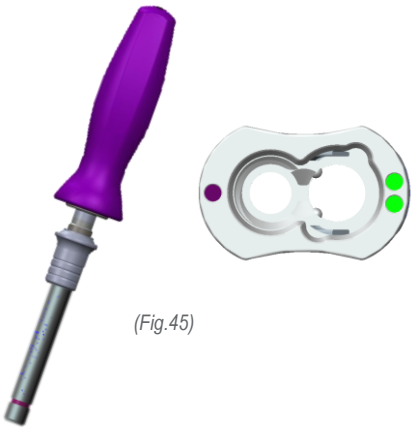
Implant Expansion

To expand the implant, the direction of rotation of the Expansion Driver is dictated by patient set-up and orientation of the implant's dynamic endplate/plate placement relative to the vertebral bodies *(Fig. 44).* If arrow on implant is visible, expansion direction can be dictated by the arrow orientation.

Patient Position	Superior Plate Placement	Inferior Plate Placement
Left Side Up	Counter-clockwise	Clockwise
Right Side Up	Clockwise	Counter-clockwise

(Fig.44)

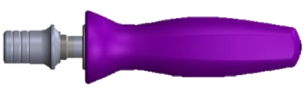
- If using the **Standard Inserter**, assemble the Standard Expansion Driver (1871535) with the Expansion Torque Handle (1676632). Insert the expansion driver into the inserter marked by a purple dot which should match the line on the driver shaft (*Fig. 45*). Under fluoroscopy, expand the implant by slowly turning the Standard Expansion Driver with the Expansion Torque Handle.



(Fig.45)

- If using the **Low Profile Inserter**, Attach the Expansion Torque Handle (1676632) to the Stand Alone Expansion Driver (1676942) *(Fig. 46).* Insert into the distal hexalobe pocket of the inserter. Under fluoroscopy, slowly expand the implant by turning the Expansion Handle.

(Fig.46)



Step 12
Implant Expansion(Cont.)

Tactile resistance will be felt as the implant continues to expand. Expand the implant until proper lordosis has been achieved.

Visual confirmation of the interbody should be performed to ensure proper expansion of the interbody. Graduated markings on the interbody at 5 degree intervals display an approximate indication of lordotic expansion from 15° (lowest marking) to 30° (highest marking)*(Fig. 47).*

In addition to fluoroscopy, the indicator on the proximal end of the Standard Inserter may be used to assess the lordosis achieved by the interbody. As the Expansion Driver is rotated, the indicator will translate up or down (based on patient set-up and implant orientation), and display the lordosis from 10° to 30° *(Fig. 48).*

(Fig.47)

(Fig.48)

NUVAMAP™ O.R.
To determine if ideal alignment goals have been met, NuvaMap O.R. is used intraoperatively under lateral fluoroscopy

Step 13
Graft Delivery

After the interbody has reached preferred expansion and the desired implant positioning had been achieved, insert the funnel into the side of the loading block. Measure 1cc of graft material with the spoon end of the Graft Tamp (1 heaping scoop is equivalent to 1cc) and place into a funnel *(Fig. 49)*. Using the opposite end of the tamp, pack the graft material into the neck of the funnel. Repeat these steps until the neck of the Funnel is full of graft material. Post-pack into expanded implant

While stabilizing the Inserter, attach the funnel and insert the graft plunger into the funnel. Continue until the plunger bottoms out on the funnel. Press funnel tabs to remove from inserter.

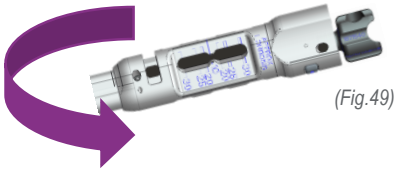

(Fig.49)

CAUTION
The XLX™ ACR® implant must not be re-expanded and reused after it has been filled with graft, as mechanical failure may occur.

Step 12

Inserter Removal and Closure

Standard Inserter:
Reattach the Implant Attachment Tool to the proximal end of the inserter. Rotate the attachment tool counter-clockwise to release the implant *(Fig. 49).*



(Fig.49)

Low-Profile Inserter:
Rotate integrated thumbwheel counter-clockwise to release the implant *(Fig. 50).*

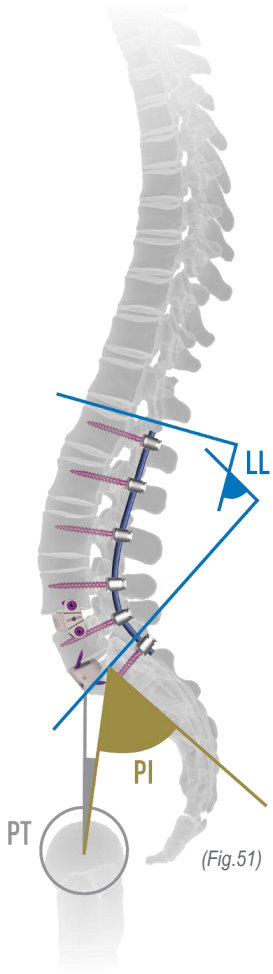
(Fig.50)

Complete the surgery with supplemental internal spinal fixation systems that are cleared for use in the thoracolumbar spine. See the system IFU and surgical technique for instructions.

Step 15:

Postoperative Confirmation

NuvaLine, a simple software application for tablet and mobile devices, may also be used for postoperative assessment of spinopelvic alignment. It allows the surgeon to calculate the lordosis obtained from the XLIF ACR procedure *(Fig. 51)*. If additional lordosis is desired, it can be achieved in the second stage of surgery with NuVasive® posterior procedural solutions.



(Fig.51)

Screw Removal

If screw removal is necessary, use the Screw Extractor to extract the screw from the vertebral body.

Interbody and Plate Removal

Exposure is performed in the same fashion as the primary surgery. The interbody implant may be removed using an inserter in reverse fashion by attaching the inserter onto the interbody or plate set screw thread, tightening to hold it securely.

If a plate has been attached for additional fixation, the bone screw should be removed before the implant (steps shown above). The implant should be collapsed as much as possible and removed. Care should be exercised to avoid neural elements during removal.

CAUTION
The XLX™ ACR® implant must not be re-expanded and reused after it has been filled with graft, as mechanical failure may occur.

XLX ACR Implant Tray

ALPXLXACRINS1

CATALOG #	DESCRIPTION		CATALOG #	DESCRIPTION
D1871500	XLX ACR Inserter, Standard		D1676640	XLX ACR Awl
1871540	XLX ACR Implant Attachment Tool		D1676925	XLX ACR Screw Starter
1871530	XLX ACR Drive Shaft, Standard Inserter		1845198	XLX ACR Driver, Screw Final
1871520	XLX ACR Pltd Main Shaft, Stand Inserter		1676630	XLX ACR Handle, Hex Straight Ratcheting
1871545	XLX ACR Counter Torque		1676693	XLX ACR Funnel, Graft
1871535	XLX ACR Driver, Expansion Stand Inserter		1676635	XLX ACR Tube, Graft Packing
1676632	XLX ACR Handle, Torque Expansion		1845202	XLX ACR Tamp, Graft
1676942	XLX ACR Driver, Expansion Stand Alone		1845203	XLX ACR Impactor, Graft
1676631	XLX ACR Handle, Hex T Ratcheting		7510013	Universal Removal Tool, Osteophyte
1676604	XLX ACR Plated Inner Shaft, LP Inserter		D1845204	XLX ACR Screw Extractor
D1676601	XLX ACR Inserter, Low Profile		1871560	XLX ACR Blade Clip, Posterior
1676701	XLX ACR Trial, 4mm		1871527	XLX ACR Unplated Adapter
1676702	XLX ACR Trial, 6mm		1871521	XLX ACR Unpltd Main Shaft, Std Inserter
1676703	XLX ACR Trial, 8mm		1676619	XLX ACR Unpltd Inner Shaft, LP Inserter
1676704	XLX ACR Trial, 10mm			
1604361	XL-H ALL Retractor Wide Long			
1604362	XL-H ALL Retractor Wide X-Long			
1604371	XL-H ALL Retractor Narrow Long			
1604372	XL-H ALL Retractor Narrow X-Long			
6900401	CoRoent XL-W Trial Inserter			
1704140	XLX ACR Cutter, Ant Long Ligament Wide			
1676699	XLX ACR Cutter, Ant Long Ligament Nrw			
D1794700	XLX ACR Distractor, Parallel			

XLX ACR Implant Tray

ALPXLXACRINS2

CATALOG #	DESCRIPTION		CATALOG #	DESCRIPTION
1675076	XLX ACR Interbody 4x23x50mm		1676910	XLX ACR Short Plate (10.5mm)
1675081	XLX ACR Interbody 4x23x55mm		1677001	XLX ACR Plate Set Screw
1675086	XLX ACR Interbody 4x23x60mm		1676817	XLX ACR Graft Containment Plug
1675077	XLX ACR Interbody 6x23x50mm		5485525	CoRoent® XLF Screw, 5.5x25mm Variable
1675082	XLX ACR Interbody 6x23x55mm		5485545	CoRoent® XLF Screw, 5.5x45mm Variable
1675087	XLX ACR Interbody 6x23x60mm		5485550	CoRoent® XLF Screw, 5.5x50mm Variable
1675078	XLX ACR Interbody 8x23x50mm		5485555	CoRoent® XLF Screw, 5.5x55mm Variable
1675083	XLX ACR Interbody 8x23x55mm		5485560	CoRoent® XLF Screw, 5.5x60mm Variable
1675088	XLX ACR Interbody 8x23x60mm		5486525	CoRoent® XLF Screw, 6.5x25mm Variable
1675079	XLX ACR Interbody 10x23x50mm		5486545	CoRoent® XLF Screw, 6.5x45mm Variable
1675084	XLX ACR Interbody 10x23x55mm		5486550	CoRoent® XLF Screw, 6.5x50mm Variable
1675089	XLX ACR Interbody 10x23x60mm		5486555	CoRoent® XLF Screw, 6.5x55mm Variable
1676670	XLX ACR Loading Block		5486560	CoRoent® XLF Screw, 6.5x60mm Variable
1676634	XLX ACR T-Handle, Torque Limiting			
1676833	XLX ACR Set Screw/Graft Plug Driver Sh			
5486560	CoRoent® XLF Screw, 6.5x60mm Variable			

XLX ACR Implant Tray

ALPXLXACRIMP

CATALOG #	DESCRIPTION		CATALOG #	DESCRIPTION
1675076	XLX ACR Interbody 4x23x50mm		1676910	XLX ACR Short Plate (10.5mm)
1675081	XLX ACR Interbody 4x23x55mm		1677001	XLX ACR Plate Set Screw
1675086	XLX ACR Interbody 4x23x60mm		1676817	XLX ACR Graft Containment Plug
1675077	XLX ACR Interbody 6x23x50mm		5485525	CoRoent® XLF Screw, 5.5x25mm Variable
1675082	XLX ACR Interbody 6x23x55mm		5485545	CoRoent® XLF Screw, 5.5x45mm Variable
1675087	XLX ACR Interbody 6x23x60mm		5485550	CoRoent® XLF Screw, 5.5x50mm Variable
1675078	XLX ACR Interbody 8x23x50mm		5485555	CoRoent® XLF Screw, 5.5x55mm Variable
1675083	XLX ACR Interbody 8x23x55mm		5485560	CoRoent® XLF Screw, 5.5x60mm Variable
1675088	XLX ACR Interbody 8x23x60mm		5486525	CoRoent® XLF Screw, 6.5x25mm Variable
1675079	XLX ACR Interbody 10x23x50mm		5486545	CoRoent® XLF Screw, 6.5x45mm Variable
1675084	XLX ACR Interbody 10x23x55mm		5486550	CoRoent® XLF Screw, 6.5x50mm Variable
1675089	XLX ACR Interbody 10x23x60mm		5486555	CoRoent® XLF Screw, 6.5x55mm Variable
1676670	XLX ACR Loading Block		5486560	CoRoent® XLF Screw, 6.5x60mm Variable
1676634	XLX ACR T-Handle, Torque Limiting			
1676833	XLX ACR Set Screw/Graft Plug Driver Sh			
5486560	CoRoent® XLF Screw, 6.5x60mm Variable			

XLX ACR Instructions For Use

Indications for Use

The NuVasive XLX ACR Interbody System is indicated for intervertebral body fusion of the spine in skeletally mature patients. The System is designed for use with autogenous and/or allogeneic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion and supplemental internal spinal fixation systems cleared by the FDA for use in the thoracolumbar spine. When used with or without the XLX ACR internal fixation, the system is intended for use with supplemental spinal fixation systems cleared by the FDA for use in the thoracolumbar spine. XLX ACR interbody devices expanded to ≥20° lordosis must be used with the XLX ACR internal fixation and additional supplemental fixation. The devices are to be used in patients who have had at least six months of non-operative treatment.

The XLX ACR Interbody System is intended for use in interbody fusions in the thoracic spine from T1 to T12 and at the thoracolumbar junction (T12-L1), and is intended for use in the lumbar spine, from L1 to S1, for the treatment of symptomatic disc degeneration (DDD) or degenerative spondylolisthesis at one or two adjacent levels, including thoracic disc herniation (with myelopathy and/or radiculopathy with or without axial pain). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The NuVasive XLX ACR Interbody System can be used as an adjunct to fusion in patients diagnosed with multilevel degenerative scoliosis.

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 known to occur include: early or late infection which may result in the need for additional surgeries; damage to blood vessels; spinal cord or peripheral nerves, pulmonary emboli; loss of sensory and/or motor function; impotence; 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 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.

XLX ACR Instructions For Use

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.

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

These devices can break when subjected to the increased load associated with delayed union or non-union. 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.

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 to ensure a thorough discectomy is completed in order to correctly size, place, and expand the device. An incomplete discectomy may result in difficulty to fully deploy and place the device in its intended position.

Resection of the anterior longitudinal ligament (ALL) may facilitate insertion of the implant for greater sagittal correction, when used with XLX ACR internal fixation and supplemental fixation per the indications, and aid in preventing potential end plate damage. To prevent damage to surround anatomy when resecting the ALL, do not extend the incision past the contralateral portion of the retractor.

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

A XLX ACR implant must not be re-expanded and reused if it has been filled with graft, as mechanical failure may occur.

To mitigate the risk of intraoperative implant migration, use the posterior blade clip inserter attachment when inserting the XLX ACR interbody.

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.

MRI Safety Information

Refer to XLX ACR Interbody System IFU for details.

Compatibility

Do not use the XLX ACR Interbody System with components of other systems. Unless stated otherwise, NuVasive devices are not to be combined with the components of another system.

XLX ACR Instructions For Use

Preoperative Warnings

Only patients that meet the criteria described in the indications should be selected.

Patient condition and/or predispositions such as those addressed in the aforementioned contraindications should be avoided.

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.
All non-sterile parts should be cleaned and sterilized before use.

Devices should be inspected for damage prior to implantation.

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 must be checked periodically postoperatively, using appropriate radiographic techniques.

Method of Use

Please refer to the Surgical Technique for this device.

Packaging

Packages for each of the components should be intact upon receipt. All implant and instrument sets should be carefully examined for completeness, and for lack of damage, prior to use. Damaged packages or products should not be used, and should be returned to NuVasive, Inc.

All implants provided non-sterile are single use and should not be sterilized per instructions provided below. All instruments provided non-sterile are reusable and should be reprocessed using instructions provided below.

Cleaning and Decontamination

All non-sterile instruments must first be thoroughly cleaned using the validated methods prescribed in the NuVasive Cleaning and Sterilization Instructions (doc #9400896) before sterilization and introduction into a sterile surgical field. Contaminated instruments should be wiped clean of visible soil at the point of use, prior to transfer to a central processing unit for cleaning and sterilization. The validated cleaning methods include both manual and automated cleaning. Visually inspect the instruments following performance of the cleaning instructions to ensure there is no visual contamination of the instruments prior to proceeding with sterilization. If possible contamination is present at visual inspection, repeat the cleaning steps. Contaminated instruments should not be used, and should be returned to NuVasive. Contact your NuVasive representative for any additional information related to cleaning of NuVasive surgical instruments.
Instruments with a “D” prefix part number (e.g. DXXXXXXX) may be disassembled. Please refer to the additional disassembly instructions for these instruments.

Sterilization

All instruments and implants are provided non-sterile and must be sterilized prior to use. All components of the XLX Interbody System are sterilizable by steam autoclave using standard hospital practices. Devices are to be packaged in an FDA-cleared sterilization wrap prior to placement in an autoclave. In a properly functioning and calibrated steam sterilizer, effective sterilization may be achieved using the parameters prescribed in the NuVasive Cleaning and Sterilization Instructions (doc #9400896).

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