NuVasive®
Speed of Innovation™

# Launch Guide

FOR INTERNAL USE ONLY

MAXCESS® 4

MAXCESS 4

# Introduction

We could not be more excited to launch MaXcess® 4, the Fourth Generation XLIF® Access System! The XLIF procedure has revolutionized spine surgery, both in terms of achieving surgical goals and improving patient outcomes. MaXcess 4 will take XLIF to another level. Based on over 8 years of experience in lateral access surgery, the MaXcess 4 Access System was designed to deliver safe and reproducible XLIF outcomes by combining *Strength*, *Precision*, *Fluoro-visibility*, and *Integrated Neuromonitoring*.

The MaXcess 4 access system consists of the following:

- Access Drivers
- Blades
- Access Instruments
- Articulating Arm
- Bedrail Attachment
- Disposables

This launch guide is a resource for system, competition, and selling information related to MaXcess 4.

This is an exciting time in the growth and development of XLIF, and I look forward to working with you to help drive success in the field with MaXcess 4!

Sincerely,

Matt Schwartz
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## Design Rationale

The MaXcess® 4 Access System is the culmination of years of XLIF® experience and the functionality of MaXcess I, II, and III. The encompassing design goal for the new system was to improve upon past systems to create the pinnacle retractor for lateral access. The MaXcess 4 Access System is designed with an emphasis on strength, precision, fluoro-visibility, and integrated neuromonitoring.

### STRENGTH

- MaXcess 4 is over 61% stiffer than the MaXcess III
  - Blades do not toe in at distal exposure
- New stronger Articulating Arm and Attachment
  - MaXcess 4 maintains a consistent access portal throughout procedure
- Competitive retractors are made from weaker materials
  - Blades toe in at distal exposure
  - Potential for intraoperative failure

### PRECISION

- Provides the ability to customize the exposure to meet the patient's anatomical requirements
  - Minimizes unnecessary tissue disruption
  - Dilation up to only 12mm
  - Locks posterior blade and retracts away from the lumbar plexus
  - Provides continuous blade splay (up to 20°)
- Competitive retractors have large one-size-fits-all exposure
  - Unnecessary tissue manipulation
  - Excessive dilation up to 24min
  - Do not provide necessary exposure of the disc space

### FLUORO-VISIBILITY

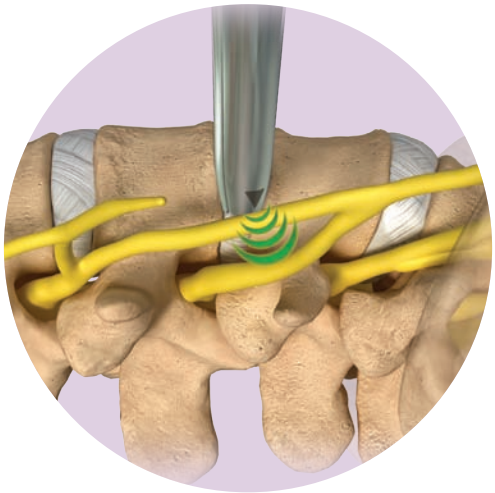
- Fluoro-visibility: The ability to visualize critical anatomical features under fluoroscopy
- Contributing factors to fluoro-visibility
  - Material properties: aluminum is radiolucent; stainless steel is radiopaque
  - Geometry: Strategic geometric designs can promote fluoro-visibility by allowing visualization in crucial areas, while maximizing strength in others

- MaXcess® 4 is constructed from stainless steel for its strength; the geometric design has cored out material allowing optimal visualization, particularly of the posterior border of the vertebral bodies from the lateral fluoro image
- Some competitive retractors are made from weaker and more radiolucent materials
  - Results in blade flex and instability without improving the overall fluoro-visibility, especially the lateral fluoro image
  - Even aluminum blades become radiopaque from the lateral fluoro image due to the overall length and density

## INTEGRATED NEUROMONITORING

- NVJJB™/M5® is the only clinically validated neuromonitoring system for a safe and reproducible lateral approach to the spine
- NVJJB/M5 provides valuable real-time information
  - Surgeon-driven
  - Discrete thresholds
  - Relative proximity
  - Directionality
- NVJJB/M5 is seamlessly integrated into the MaXcess 4 Access System leading to safer manipulation of the retractor
- Competitive retractors do not have integrated neuromonitoring

# Key Instrument Overview



## NVM5® SYSTEM INTEGRATION

NVM5 is seamlessly integrated into the MaXcess® 4 Access System to provide surgeons with detailed information about nerve directionality and relative proximity during the XLIF® Procedure.

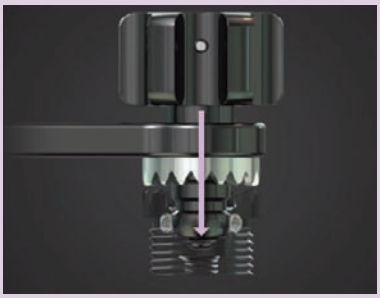
- Clinically Validated
- Real-Time Discrete Thresholds
- Directionality
- Relative Proximity

## ARTICULATING ARM ATTACHMENT

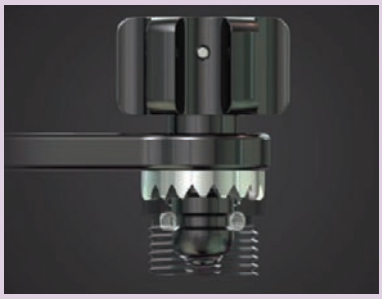
The Articulating Arm Attachment points have been designed to improve function and ease of use.

- Designed for maximum stability with a wider footprint and increased teeth engagement
- Designed for ease of use by incorporating a Quick-Align Canted Coil Latch
    - Allows surgeon to quickly and easily attach the Articulating Arm without assistance
    - Locks Tight with the ergonomic Turn Knob

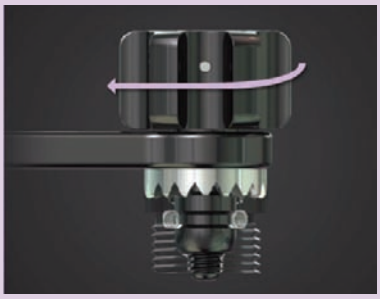
1. The Canted Coil Latch has not been engaged



2. The Canted Coil Latch is engaged

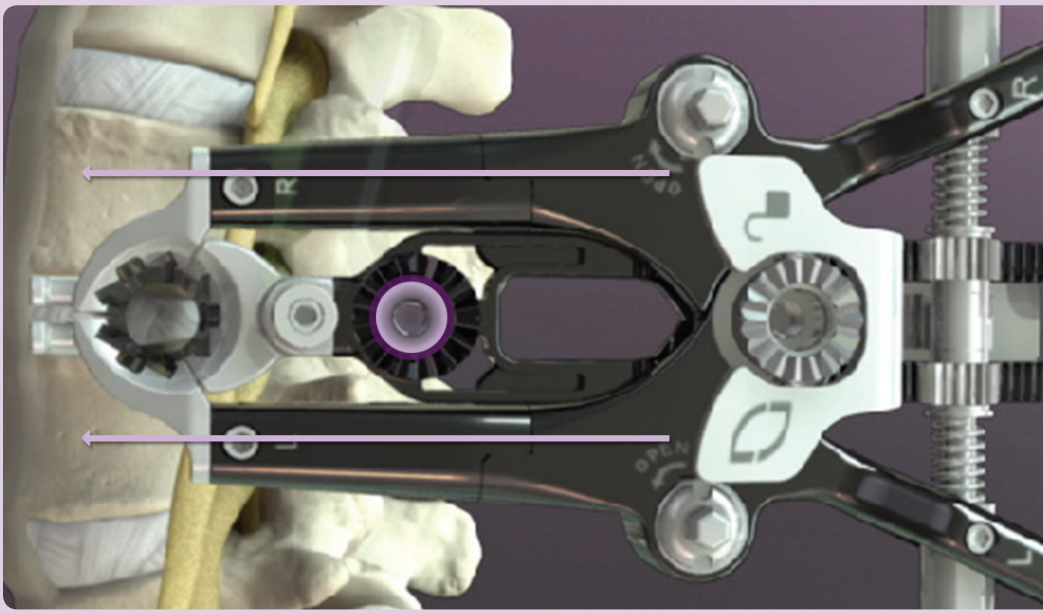


3. The Canted Coil springs into place providing tactile feedback, ensuring alignment

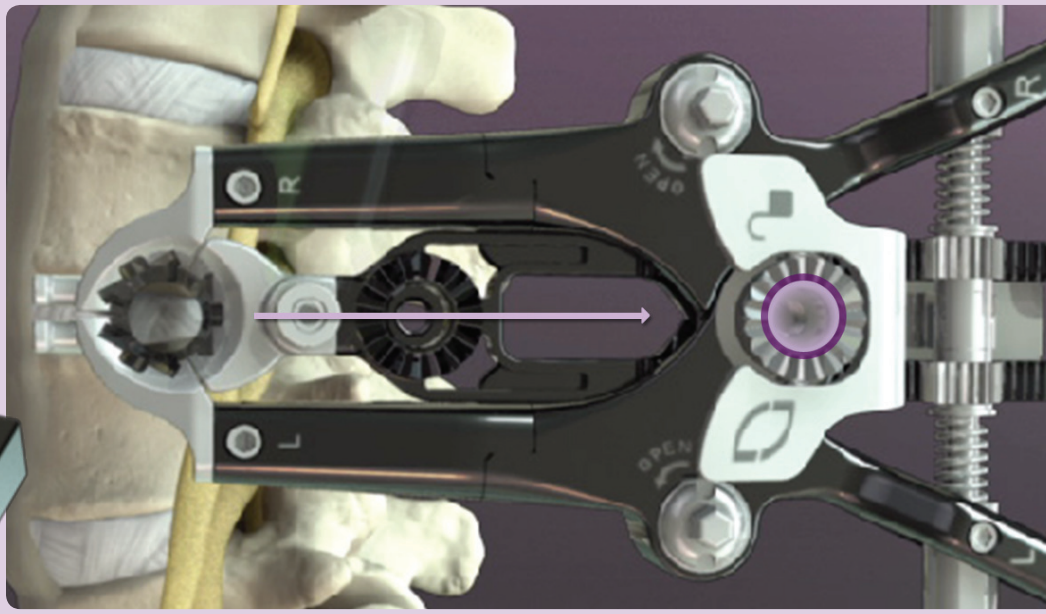


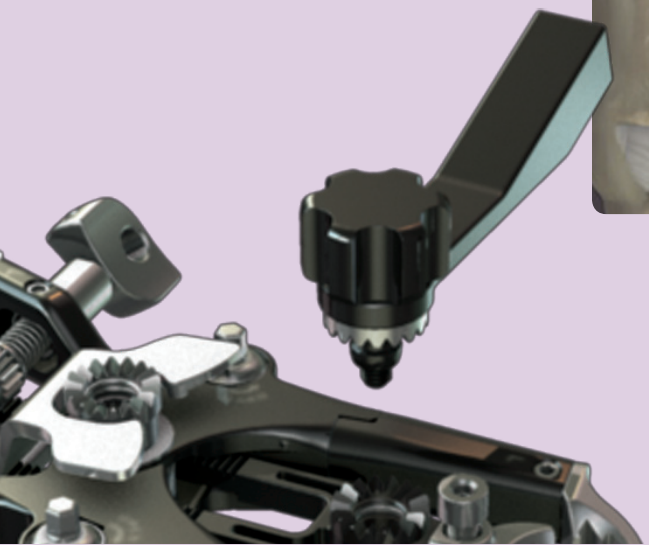
4. The Turn Knob is final tightened

The front Articulating Arm Attachment has been coated black to help designate it as the "Lumbar XLIF® Attachment." By locking the Articulating Arm to this attachment point, the MaXcess® 4 Posterior Blade will be locked and all retraction will be anterior and away from the lumbar plexus.



The back Articulating Arm Attachment is designed to lock the R and L blades and allow the center blade to translate. This attachment point is used frequently in Thoracic XLIF procedures and posterior decompressions.





## CONTINUOUS BLADE SPLAY

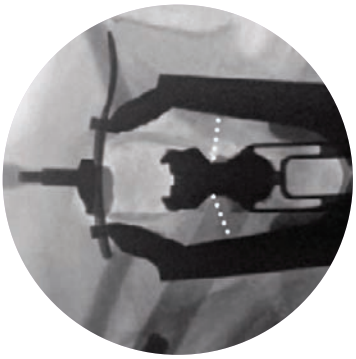
MaXcess® 4 offers continuous splay of the right and left blades up to 20°. The Blade Rotation Driver is set to break-away at 60 in-lbs to inform the surgeon that there is potential interference from anatomy such as osteophytes, ribs, or the iliac crest.

- Independent, Bi-Directional Control
- Up to 20° of Blade Splay

## DESIGNED FOR OPTIMAL STRENGTH AND FLUORO-VISIBILITY

Competitive retractors attempt to achieve fluoro-visibility by using radiolucent materials such as aluminum. However, there are 2 negative consequences of this: 1) Radiolucent materials such as aluminum are weaker than stainless steel, and 2) Even radiolucent materials obscure fluoroscopic images, so the geometry of these retractors prevent true fluoro-visibility. For example, 100mm aluminum blades are radiopaque from the lateral fluoro image due to the material thickness. MaXcess 4 is designed with both strength and fluoro-visibility in mind.

- Strength and Stability for a Precise Exposure
- Designed to Provide Optimal Visualization of the Posterior Border of the Vertebral Body



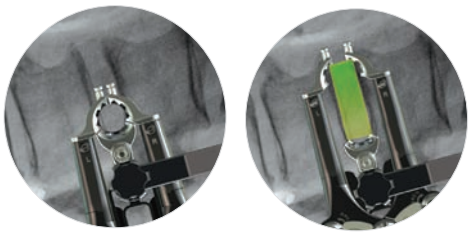
The white lines show how the MaXcess 4 is designed to promote fluoro-visibility, particularly of the posterior border of the vertebral body.

## CUSTOMIZABLE ACCESS

A key differentiator of MaXcess 4 from competitive retractors is the small initial diameter – 12mm. Competitive retractors range from 18-24mm in initial diameter. These unnecessarily large retractors could lead to increased trauma to the psoas or lumbar plexus. Additionally, MaXcess 4 is designed to conform to patient-specific anatomy as needed.

- Smallest Initial Diameter on the Market – 12mm
- Dock Posterior and Retract Away from the Lumbar Plexus
- Designed to Provide the Optimal Exposure With the Least Amount of Tissue Disruption
- Conform to Anatomical Needs

MaXcess 4



Closed Open

Competitive Retractor

Unnecessary Exposure

## BLADES

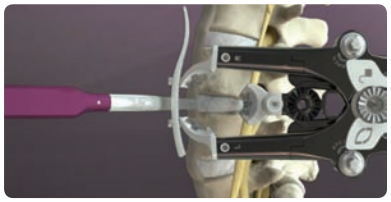
The MaXcess® 4 Access System has blades ranging from 50mm to 160mm in length. With the initial launch, there will only be one center blade in each length, thus if a surgeon would like to use the 4th Blade Attachment, they will need to use a center blade of a different length. The sets will be reworked to include a 2nd Electrode Center Blade of each length in conjunction with the launch of the MaXcess 4 disposables. The Right and Left Blades have alignment dot features that are designed to work with the Electrode Center Blades to help align the Access Driver with the C-Arm.

## BLADE ROTATION DRIVER

The Blade Rotation Driver is used to control the blade splay mechanism of the retractor. The driver is bi-directional and is simply placed over the hex bolt and turned to open and close the blade splay. This driver will break off at 60 in-lbs to prevent loading the blades when pushing against osteophytes. A QUARTER TURN OF THE RETRACTOR IS ROUGHLY EQUAL TO 5° OF SPLAY. BE SURE TO MONITOR BLADE SPLAY WITH FLUORO. Follow the lasermarked instructions to open and close each blade independently.

## ANTERIOR RETRACTORS

The Anterior Retractors are designed to retract tissue out to the anterior longitudinal ligament to help define the anterior border of the procedure. There are four sizes of anterior retractors, consisting of two widths (6mm and 12mm) and two lengths (160mm and 200mm). If desired, they can be held in place using the anterior crossbar.



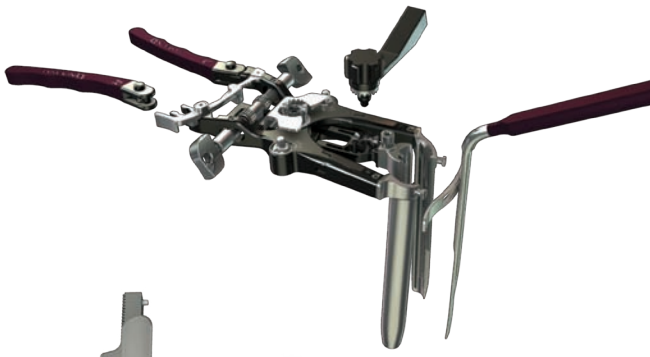
## ANTERIOR CROSSBAR

The Anterior Crossbar is designed to span the proximal, anterior features of the right and left blades to secure the Anterior Retractors in place throughout the procedure. The Anterior Cross Bar aligns to the notches on the Anterior Retractors for maximum stability. It can be placed either from right to left or left to right depending on anatomical constraints. It will also stay in place if the blades are opened cephalad-caudal or if they are splayed. Prior to malleting a Trial or Implant, the Anterior Retractors should be removed.


## IMPROVED ERGONOMICS

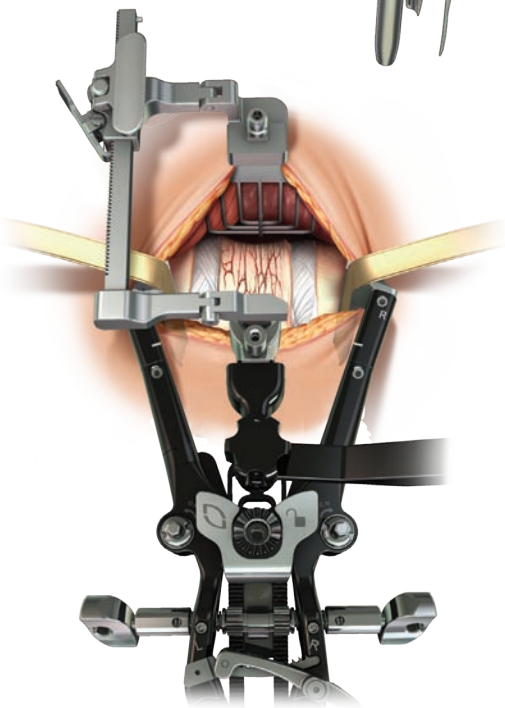
The ergonomics of MaXcess® 4 have been improved to provide the surgeon with optimal leverage and comfort during the procedure.

- Locking Silicone Handles
- Teardrop Thumb Wheels



## CORPECTOMY INSTRUMENTS

MaXcess 4 is designed to work seamlessly with the XLIF® Corpectomy Instruments. The XLIF Corpectomy Instruments sets (XLIFCORPINS) are being reworked to include new MaXcess 4 extensions. There are two lengths of these adapters (short for single-level corpectomies, long for multi-level corpectomies). The left, right, and center extensions are all coated black to reduce glare. The center extensions are specially designed to work with MaXcess 4 center blades, as well as the existing lung blades. See the XLIF Corpectomy Launch Binder for additional information on the XLIF Corpectomy Instruments.



## LONG INSTRUMENTS

The XLIF Long Instrument sets (XLIFLONG) will be reworked to include 170mm and 180mm MaXcess 4 blades. The 160mm MaXcess 4 blades will be included in the ACCES4 sets to help reduce the need for XLIFLONG sets.

## MAXCESS III DISPOSABLES

The MaXcess III Disposables are compatible with the MaXcess 4 Access System. The MaXcess III Intradiscal Shim, Plastic Shims, Light Cables, and Fixation Shims are all compatible.

### Intradiscal Shim

- Provides a fixation point for the retractor
- Prevents psoas tissue and nerves from creeping anterior into the exposure

### Plastic Shims

- Intraoperative customizability of the exposure
- Standard shims to lengthen the exposure; wide shims to prevent tissue creep

### Fixation Shims

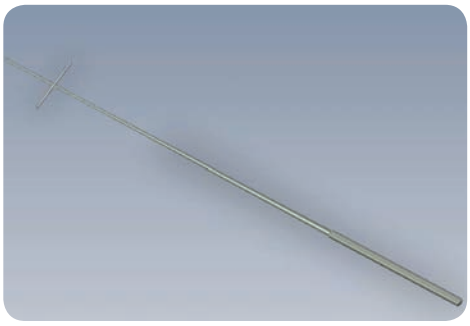
- Allows for visualization of screw engagement point
- Ability to test for nerves using the Ball-Tip Probe
- Adds further stabilization to the retractor

## 4TH BLADE ATTACHMENT

The 4th Blade Attachment in the MaXcess® 4 system has been designed with structural improvements to prevent flex.

## TARGETING INSTRUMENT

The MaXcess 4 Targeting Instrument is designed to reduce the amount of fluoroscopy needed for localization. It is NOT a disposable item.



## SHIM TAMP/RETRIEVAL TOOL

The Shim Tamp/Retrieval Tool is designed to help either tamp a shim down the blade track or retrieve a shim from the blade track. For retrieval, there are three options to help the surgeon gain a mechanical advantage. The first option is a slot which can be used with other instruments such as a screw driver to apply force. The second option is a Slap Hammer attachment, and the third option is to simply grip the flared proximal handle for improved control.

## SHIM INSERTER

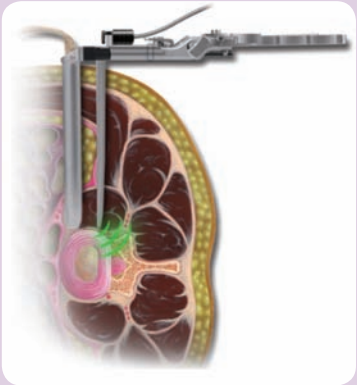
The Shim Inserter is bayoneted for optimal visualization during shim placement.

# Lateral Access Competition

## NUVASIVE® IS THE UNDISPUTED LEADER IN LATERAL ACCESS SURGERY

As first to market, NuVasive pioneered the development and advancement of lateral access spine surgery. With over 8 years of experience and thousands of successful procedures, XLIF® is widely recognized as the Gold Standard.

During this time, NuVasive has placed significant focus on surgeon and representative education, along with system advancements. From this, we have expanded XLIF indications: from single-level DDD to the most advanced deformity, tumor, and trauma pathologies.



## THE CORE VALUE OF XLIF:

XLIF is a safe and reproducible minimally disruptive procedure that utilizes conventional surgical techniques with a seamlessly integrated MAS® Platform.

- **Minimally Disruptive**: Minimal blood loss, shorter O.R. time, and reduced hospital stay when compared with traditional fusion surgeries.
- **Anterior Column Correction and Indirect Decompression**: Implants are designed to span the ring apophysis and provide maximum vertebral support, disc height restoration, and indirect decompression.
- **Expanded Indications**: Treats a number of indications including – DDD, spondylolisthesis, degenerative scoliosis, adjacent segment disease, revision surgery, thoracic disc herniation, and tumor/trauma.

## THE CORE VALUE OF XLIF:

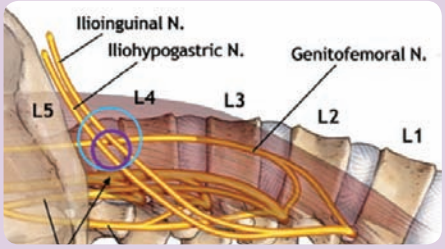
Below are the eight defining XLIF differentiators that combine to provide the most advanced lateral access procedure on the market.

1. NJJB™/M5® – Surgeon-driven, real-time nerve proximity and directionality information
2. Access – Customizable exposure with the 3rd generation lateral access platform
3. Interbody – Indication specific lateral solutions to even the most challenging pathologies
4. Lateral Fixation – Broad range of fixation options for single-approach surgery
5. Biologics – Complete fusion solution
6. Clinical data - Proven short- and long-term benefits
7. Surgeon Education - Unparalleled training program for surgeons
8. Outstanding Service - Most educated and responsive spine company

*The following pages will provide a competitive overview for the primary XLIF competitors.*

## MEDTRONIC - QUADRANT™

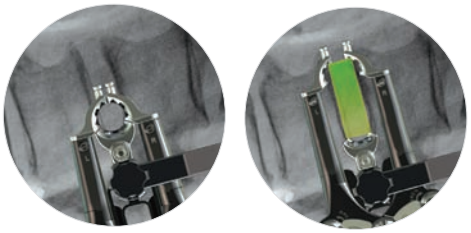
- 5-stage dilation technique without EMG stimulation
- 22mm initial diameter retractor causes wider retraction without optimal exposure
- One-size-fits-all retractor offers limited customizability




Exposure with MDT (blue) compared to NuVasive® (purple)

NuVasive 3rd Dilator (Left) compared to MDT 5th Dilator (right)

MaXcess® 4



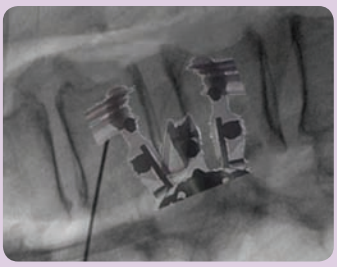
Closed Open

Competitive Retractor

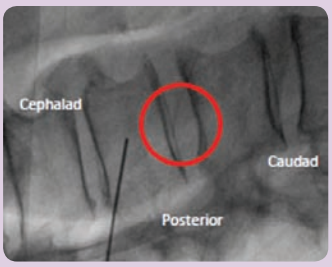
Unnecessary Exposure

## GLOBUS - MARS 3V

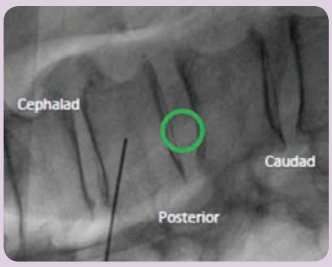
- A 23mm diameter overdilator creates a larger than needed cephalad-caudal exposure
- One-size-fits-all approach with large dilation
- Aluminum components are approximately 1/3 as stiff as steel leading to decreased strength and stability over time
- Limited lateral fluoro-visibility due to retractor geometry
- Splay of posterior blade can crush the lumbar plexus against the transverse process



Mars 3V lateral fluoro image




Mars 3V: Pre-Retraction

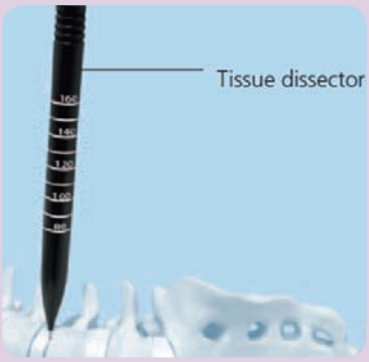


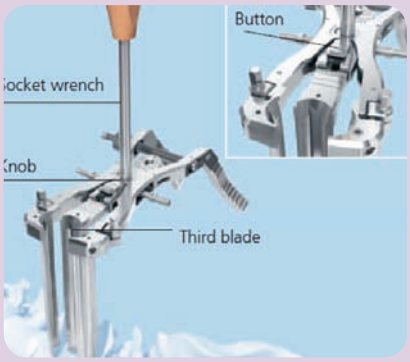

MaXcess 4: Pre-Retraction

The Mars 3V has "radiolucent" components, but they only impact fluoro-visibility when splayed to amounts that are not clinically applicable.

## SYNTHES - ORACLE™

- Only allows the center blade to retract posterior
- Without integrated neuromonitoring, posterior retraction of the center blade could crush the lumbar plexus against the transverse process
- Blades can only splay outward, offering limited customization with challenging anatomy

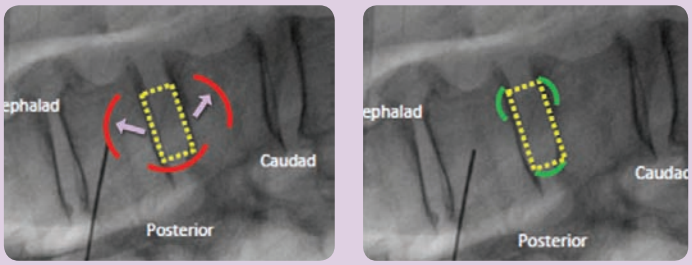


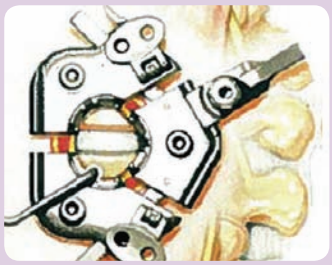

Large initial exposure and anterior targeting could lead to increased psoas trauma and nerve schemia.

## DEPUY - PIPELINE®

- Initial diameter of 24mm which causes a larger than needed cephalad-caudal exposure
- One-size-fits-all approach with large dilation
- Unnecessary retraction of the psoas may result in nerve ischemia
- Retractor must expand in the cephalad-caudal and anterior-posterior directions simultaneously, causing excessive and unnecessary psoas retraction
- Telescoping blades reduce the true exposure size, requiring increased retraction
- No intradiscal, fixation, or wide shims




The MaXcess® retractor offers customizable disc space visualization compared to the Pipeline retractor with a significantly less disruptive exposure.



Simultaneous cephalad-caudal and anterior-posterior retraction leads to an unnecessarily large exposure.

# Disposable Overview

More information will follow as the MaXcess® 4 disposables are launched.

# Marketing Materials

### MaXcess 4 Sales Brochure - 9500835

This four page brochure highlights the new features and benefits of the MaXcess 4. Additionally, it shows the clinical uses for: lumbar XLIF®, thoracic XLIF, XLIF corpectomy, and posterior decompression. This brochure can be ordered through customer service.

### MaXcess 4 Animation

This animation provides a three dimensional view of the retractor while highlighting its features and benefits. It will allow you to easily provide surgeons a glimpse of the new retractor. You can find this animation on the NuVasive® Resource Center.

# Sales Strategy

## TARGETING

MaXcess 4 is a powerful tool for growing your business. There are three general opportunities for you to position MaXcess 4 most effectively: grow the business of existing XLIF surgeons, retain the business of XLIF surgeons that are exploring competitive platforms, and convert surgeons that have yet to try XLIF.

### Current XLIF Surgeons

Current XLIF Surgeons generally understand and appreciate the value and benefits of XLIF. Nonetheless, by talking to your XLIF surgeons about the improvements in the MaXcess 4 system you can help expand their XLIF applications and practice.

### Questions to Ask Current XLIF Surgeons

1. **What do you like and dislike about MaXcess III?**
   Many surgeons may mention general complaints about handling difficulties with MaXcess III. This will allow you to talk about improvements in the MaXcess 4 Access System, such as the locking handles and the Quick-Align Articulating Arm Attachment. It will also allow you to talk to the more advanced features of MaXcess 4, such as the strength of the stainless steel components, the fluoro visibility, and the continuous T-Handle driven blade splay.

2. **What indications are you currently treating with XLIF, and are there any pathologies that you avoid treating with XLIF?**
   This may inform you of potential anatomical challenges that the surgeon does not feel comfortable with (i.e. high crest or strong psoas). It may additionally give you an opportunity to talk to your surgeon about expanding his or her application (i.e., adjacent segment disease, degenerative scoliosis, or corpectomy).

## Objection Handling with Current XLIF® Surgeons

1. **I am currently able to complete my XLIFs just fine with the MaXcess® III Access System.**
   I understand that with your XLIF experience you are satisfied with MaXcess III. However, MaXcess 4 has some new features that may help simplify your XLIF cases and increase your efficiency. The retractor is 61% stiffer than MaXcess III, and at the same time it has significantly better control with the continuous blade splay feature. Additionally, it has been designed to reduce the "fiddle factor" of MaXcess III with features such as locking handles and a quick align Articulating Arm Attachment.

2. **The MaXcess 4 retractor feels heavy compared to MaXcess III.**
   MaXcess 4 is constructed entirely from stainless steel to add strength and stability. Additionally this weight helps maintain downward pressure to keep the retractor in place. While the retractor is made from stainless steel, it has been thoughtfully engineered such that the geometry affords great fluoro-visibility.

3. **I prefer to use the Solid Access Driver because of its strength.**
   MaXcess 4 has a solid access driver in the set, however, it is intended primarily as a backup retractor. The full-featured MaXcess 4 access driver is designed to be as strong as the Solid MaXcess III access driver. Additionally, it has continuous blade splay capability.

## XLIF Surgeons Exploring Competitive Lateral Offerings

There is a strong push from competitors to target our XLIF-trained surgeons. Competing sales representatives have been known to tout their retractor offerings to our XLIF surgeons. However, MaXcess 4 is clearly and significantly superior to these other systems. There are three primary concepts that distinguish MaXcess 4 from the competition:

1. **Dilator and retractor diameter** – The MaXcess 4 retractor has a 14mm diameter when closed. Competing retractors are significantly larger (ranging from 18mm-24mm). Aggressive dilation and a large retractor increase psoas trauma. Additionally, with a large diameter retractor, it will be difficult to find a safe transpsoas passage to the spine without damaging the motor and/or sensory nerves of the lumbar plexus.
2. **Customizable exposure** – The MaXcess 4 retractor allows a surgeon to customize the exposure through independent cephalad-caudal and anterior-posterior retraction. Additionally, the continuous blade splay of MaXcess 4 can be finely controlled depending on anatomical needs. Competitive retractors have limits to the modes of retraction.
3. **Integrated neuromonitoring** – NVJJB™/M5® is the only neuromonitoring system that has been validated for a safe and reproducible lateral approach to the spine.[1-7] The MaXcess retractors are the only retractors on the market with integrated neuromonitoring. This provides important nerve information in real time that allows the surgeon to dock posterior without impinging nerves, and then retracting tissue anterior to gain exposure to the disc space.

1 Oliveira L, et al. WScJ 2010;1:19-25.
2 Dakwar E, et al. Neurosurg Focus 2010;28(3):E8.
3 Dhall SS, et al. J Neurosurg Spine 2008;9:560-565.
4 Whitecloud TS, et al. J Spinal Disord 2001;14(2):100-103.
5 Deluzio KJ, et al. SAS Journal 2010;4:37-40.
6 Ozgur BM, et al. SAS Journal 2010;4:41-46.
7 Park Y, et al. Spine 2007;32(5):537-543.

## Questions to ask XLIF® Surgeons that are Exploring Competitive Lateral Offerings

1. **Have you seen transient thigh weakness in your XLIF/other competitive lateral cases? Are you concerned with injuring the genitofemoral or other sensory nerves of the plexus?**
   If the surgeon answers yes, you may engage them in a discussion about what might cause this transient thigh weakness. You may be able to suggest that this transient weakness is at least partially due to trauma to the psoas muscle itself. This is a great time to bring up the size difference between MaXcess® 4 and competitive offerings. Competitive retractors are significantly larger than MaXcess 4, and it stands to reason that they will cause significantly more psoas trauma, leading to more transient thigh weakness. Additionally, with a large retractor it may be difficult to navigate a safe trajectory to the disc space through the psoas that does not impinge upon the genitorfemoral nerve.

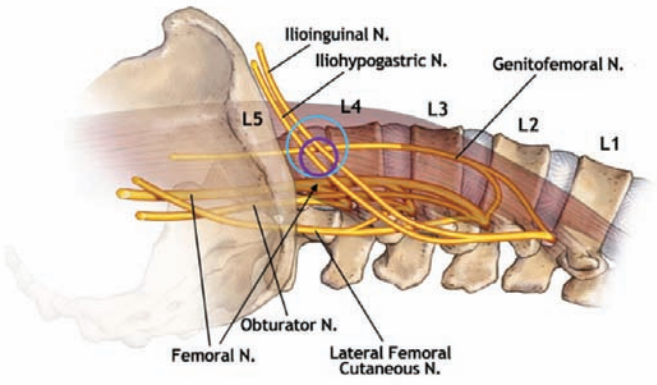
2. **What aspects of the spine are you trying to visualize in your XLIF/other competitive lateral cases?**
   Most surgeons will respond that it is important only to expose beyond the endplates of the disc. If they do not respond this way, you can suggest that this exposure would minimize unnecessary trauma. Once it is established that the only necessary exposure is over the disc space you can explain to the surgeon that the MaXcess 4 retractor is designed with a small diameter to match the disc space. It can then be opened slightly in the cephalad-caudal direction to expose the endplates, and expanded anterior to expose enough disc for disectomy followed by interbody placement. Further cephalad-caudal retraction can be obtained at the end of the procedure when placing the XLP® plate. Competitive retractors have a large diameter which unnecessarily exposes the vertebral bodies above and below the disc, possibly increasing risk to the segmental vessels.

3. **Do you have issues with retractor blades toeing in at the distal exposure, either with MaXcess III or a competitive retractor?**
   MaXcess 4 is designed to be extremely strong to prevent blade flex. At the same time it still has blade splay capability. MaXcess 4 is over 61% stronger than the MaXcess III. Other retractors such as the Globus Mars™ 3V and Medtronic Quadrant™ are made from aluminum components that will likely flex when retraction is attempted.

## Objection Handling with Surgeons that are Exploring Competitive Lateral Offerings

1. **I like Medtronic Quadrant/Globus Mars 3V/DePuy Pipeline™/Synthes Oracle™ because I can perform the case with minimal or even NO retraction.**
   Many surgeons don't realize that they are able to perform the case using these other retractors with minimal or no retraction because the initial diameters of these retractors are so large. Be sure to point this out to them. A visual representation can help clarify. Use the XLIF Expanded Applications with Procedural Sophistication Brochure (9500790 A) to help demonstrate the difference of a 14mm vs. a 22mm retractor diameter in relation to a patients anatomy (i.e., lumbar plexus and genitofemeral nerve). Explain the effects of aggressive dilation potentially causing psoas or nerve trauma.

2. **If I've stimulated with my dilators, why do I need to use NVM5® monitoring with my retractor?**
   All retractors have a larger initial diameter than the dilator that they are placed over, thus it is important to know if the retractor has been placed too close to a nerve. Additionally, neuromonitoring throughout a lateral approach surgery gives the surgeon valuable information about nerve health. Only MaXcess 4 has neuromonitoring fully integrated into the access system.




3. **Competitive retractors are made from radiolucent materials.**
   Radiolucent is a buzzword being pushed by competitive retractor offerings. However, you must inform surgeons that a retractor made from radiolucent materials is likely too weak to be functional AND it does not guarantee fluoro-visibility. The MaXcess® 4 retractor is constructed from stainless steel to promote strength, and has a design based on years of lateral experience to promote fluoro-visibility where it is needed most (posterior border of the lateral fluoro image).

### Surgeons that have not converted to XLIF®

Though XLIF has revolutionized spine surgery and improved patient care, the majority of spinal fusions are still performed as either ALIF, TLIF, and PLIF procedures. There are still great opportunities in all territories to convert surgeons to XLIF. Be sure to target surgeons that have expressed mild interest before or even surgeons that have been MVP trained but have not performed their first XLIF. Additionally you can use the excitement and new features of MaXcess 4 to engage surgeons that have previously been tough targets.

### Questions to Ask Surgeons that have not Converted to XLIF

1. **Have you seen MaXcess 4, our new XLIF Access System?**
   MaXcess 4 is an exciting new product launch that can be used to catch the attention of a surgeon who is unfamiliar with XLIF. The MaXcess 4 animation and sales brochure are both great tools to discuss the latest XLIF advancements with your surgeon.

2. **What is your preferred approach for an adjacent level disease case?**
   Adjacent level disease is a great indication to get your foot in the door with XLIF, particularly if the surgeon primarily does TLIF. Use the XLIF for Adjacent Segment Disease brochure (9500797 A) and the new MaXcess 4 brochure (9500835 A) to show the surgeon the benefits of a minimally invasive approach that avoids scar tissue from prior surgery. It will be important to drive deeper XLIF penetration by introducing other indications with the sales tools – Degenerative Scoliosis, Degenerative Spondylolisthesis, DDD, Thoracic Disc Herniations, Revision Surgeries, Tumor, Trauma, etc.

3. **Have you performed lateral interbody fusion using another system?**
   If a surgeon has experience with lateral access surgery using another system they likely have an appreciation for the technique. This is a perfect opportunity to talk about the features and benefits of XLIF and MaXcess 4. Key points to touch on are NVM5® system integration, strength of the retractor, fluoro-visibility using the system, and the ability to precisely customize their exposure.

**Objection Handling with Surgeons that have not Converted to XLIF®**

4. **I use TLIF for nearly all of my fusion procedures and am very proficient in the procedure so there is minimal morbidity and blood loss.**
   Experienced TLIF surgeons can be difficult to convert to XLIF, especially if they do not see the need to switch to XLIF if their TLIF cases are successful. However, talk to these surgeons about the application of XLIF for adjacent segment disease cases, where TLIF is a very difficult and risky approach.

5. **I've heard that lateral approaches damage the lumbar plexus.**
   If a surgeon is concerned about the lumbar plexus, you have a great opportunity to inform them of the power of NVJJB™/M5® for nerve avoidance. Use the dilator study paper[8] to help reinforce the effectiveness of NVJJB/M5 and be sure to discuss the integrated neuromonitoring of MaXcess® 4.

6. **Most of my fusions are at L4-5, isn't this a difficult level for XLIF?**
   There have been thousands of successful L4-5 XLIF cases.[1-7] MaXcess 4 is designed to provide the optimal exposure for an L4-5 case. If the crest is particularly high, an oblique approach with angled instruments can be utilized. Furthermore, the integrated neuromonitoring with MaXcess 4 provides the surgeon with the information they need for safe and reproducible nerve avoidance. Additionally, the XLIF Angled Instrument can help you work in line with the disc space, even with the retractor at an oblique angle.

1 Oliveira L, et al. WScJ 2010;1:19-25.
2 Dakwar E, et al. Neurosurg Focus 2010;28(3):E8.
3 Dhall SS, et al. J Neurosurg Spine 2008;9:560-565.
4 Whitecloud TS, et al. J Spinal Disord 2001;14(2):100-103.
5 Deluzio KJ, et al. SAS Journal 2010;4:37-40.
6 Ozgur BM, et al. SAS Journal 2010;4:41-46.
7 Park Y, et al. Spine 2007;32(5):537-543.
8 Uribe. Spine 2010. Electromyographic Monitoring in MIS.

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| 3101055 | Bayonetted Annulotomy Knife (Non-Sterile, Disposable) | $242 | | |
| 3200220 | Light Cable (Sterile, Disposable) | $621 | | |
| 3200028 | MaXcess III Fixation Shim Kit (Sterile, Disposable) | $525 | | |
| 3200061 | MaXcess III Sterile Disposable Shim Kit | $1,269 | | |
| 3200060 | MaXcess III Sterile Disposable Kit | $2,151 | | |
| 8200001 | Maxcess III Module | $1,304 | | |
| 8200002 | Maxcess III Annulotomy Knife Module | $1,234 | | |
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| 3101055 | Bayonetted Annulotomy Knife (Non-Sterile, Disposable) | $242 | | |
| 3200220 | Light Cable (Sterile, Disposable) | $621 | | |
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| 8200201 | MAS TLIF Light Cable and Hoop Shim Module | $2,664 | | |
| 8200202 | MAS TLIF Hoop Shim Module | $2,043 | | |
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| | MaXcess 4 Kit | $2,350 | | |
| | MaXcess 4 Shim Kit | $1,690 | | |
| | MaXcess NVM5 Electrode Kit | $395 | | |
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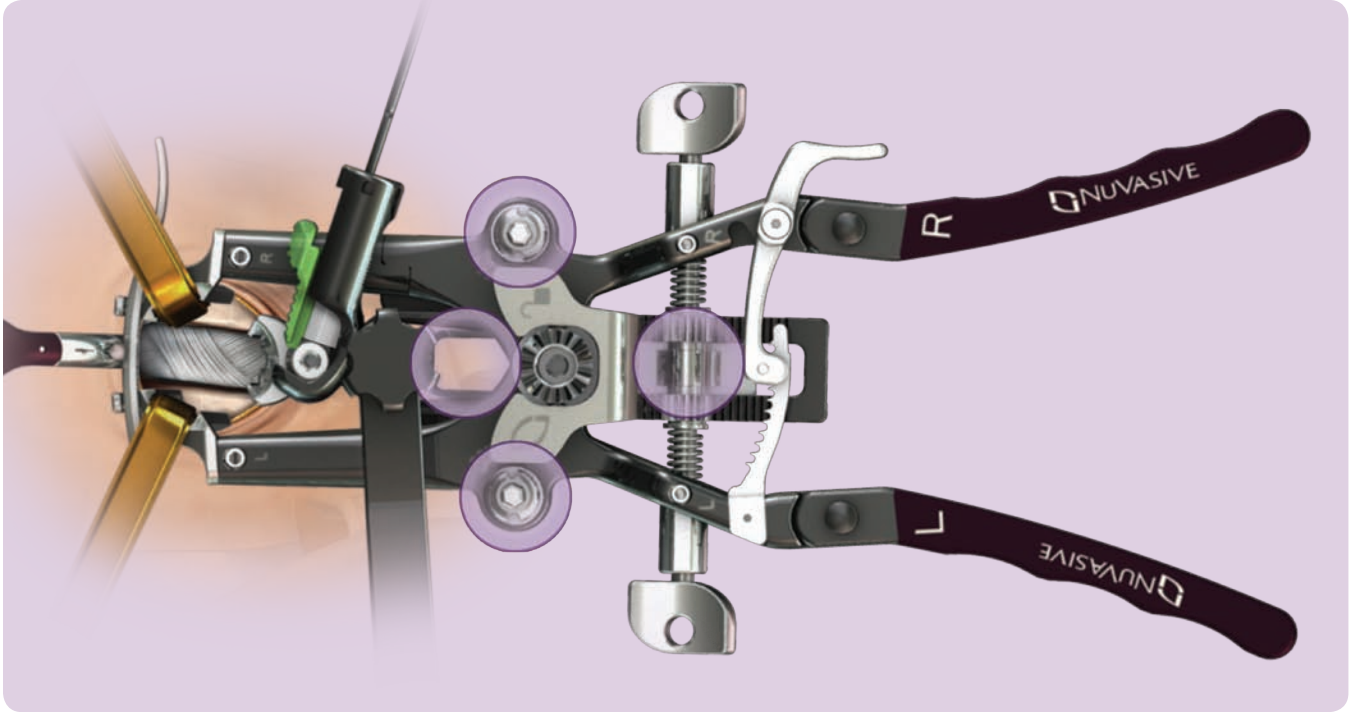
## Maintenance

As with any instrument that has moving parts, it is important to ensure proper instrument maintenance. The MaXcess® 4 Access Driver requires lubrication or "instrument milk" for proper performance. It is recommended that after every use, the Access Driver receives lubrication. Work with the Sterile Processing Department manager at your account to inform them of this maintenance requirement. It is crucial to lubricate the areas highlighted in the image below.



# Frequently Asked Questions

Though XLIF® has revolutionized spine surgery and improved patient care, the majority of spinal fusions are still performed as either ALIF, TLIF, and PLIF procedures. There are still great opportunities in all territories to convert surgeons to XLIF. Be sure to target surgeons that have expressed mild interest before or even surgeons that have been MVP trained but have not performed their first XLIF. Additionally you can use the excitement and new features of MaXcess® 4 to engage surgeons that have previously been tough targets.

1. **What sets should I order for MaXcess 4?**
   The MaXcess 4 Access System has two sets: ACCES4 and M4AARM.

2. **Are the current MaXcess disposables compatible with MaXcess 4?**
   Yes. You can use all of the current MaXcess disposables with MaXcess 4.

3. **How is the retractor assembled?**
   The retractor is assembled in much the same way as the MaXcess III retractor. The blades are attached and then tightened using the set screws (it is important to fully tighten these set screws). It is much easier to close the new retractor, and there are laser markings to help align the center blade prior to closing.

4. **How do I attach the handles to the retractor?**
   The handles can be attached or detached from the retractor by depressing the button on the handle and then sliding the handle in or out of the retractor.

5. **What is the targeting instrument?**
   The targeting instrument is designed to help localization under fluoroscopy as opposed to using K-Wires. This is reusable, and should not be discarded after each case.

6. **Is there anything new about the fourth blade attachment?**
   Yes. The new fourth blade attachment has been redesigned for improved stiffness.

7. **What size blades are in MaXcess 4?**
   MaXcess 4 has blades from 50mm- 160mm. With the initial launch, there will only be one of each size center blade, but a new style center blade of each size will be added in conjunction with the MaXcess 4 disposable launch. The XLIF Long Instruments are being reworked to include 170mm and 180mm MaXcess 4 blades, but this will not be completed until a few months after the MaXcess 4 launch. Thus, it is critical that you pre-case plan with your surgeons to determine the rare cases in which 170mm or 180mm blades will be needed. If so, you will need to use MaXcess III. If 160mm blades will suffice, you can use MaXcess 4.

8. **Can I use MaXcess 4 for XLIF Corpectomy?**
   The XLIF Corpectomy instrument set is being reworked to include new extensions for MaXcess 4. Upon completion of this rework, MaXcess 4 will be fully compatible with XLIF Corpectomy.

9. **How do I splay the right and left blades?**
   The right and left blades can be splayed using the Blade Rotation Driver. This driver will break away at 60 in-lbs to inform the surgeon if they are stuck on anatomy (i.e., osteophyte, ribs, or iliac crest). The driver is bi-directional to open and close the blade splay continuously out to 20°.

10. **Is there a backup Blade Rotation Driver?**
    Yes, the reverse end of the Electrode Removal Tool can be used as a backup Blade Rotation Driver. However, be cautious not to exert too much force with this instrument as it can potentially damage the retractor.

11. **How does the Anterior Crossbar work?**
    The Anterior Crossbar is designed to span the anterior nubs of the right and left blades. The grooves of the Anterior Retractor will then sit in the Anterior Crossbar to help prevent it from moving or plunging. Still be cautious that hammering with this setup in place may dislodge the Anterior Retractor. Again, the Anterior Retractor should be removed prior to inserting a Trial or Implant.

12. **How do I attach the Articulating Arm?**
    The new Articulating Arm attachment is designed with a Canted Coil quick-align system. To align the Articulating Arm, grasp the flat piece of the Articulating Arm tip and guide the tip into the attachment point. There will be a slight "click" into place. From this point, the thumb wheel can be tightened to fully secure the Articulating Arm.

13. **Why are there holes in the right and left blades?**
    The holes in the right and left blades are alignment features that will be used in conjunction with the new version of center blades once those are worked into the sets.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