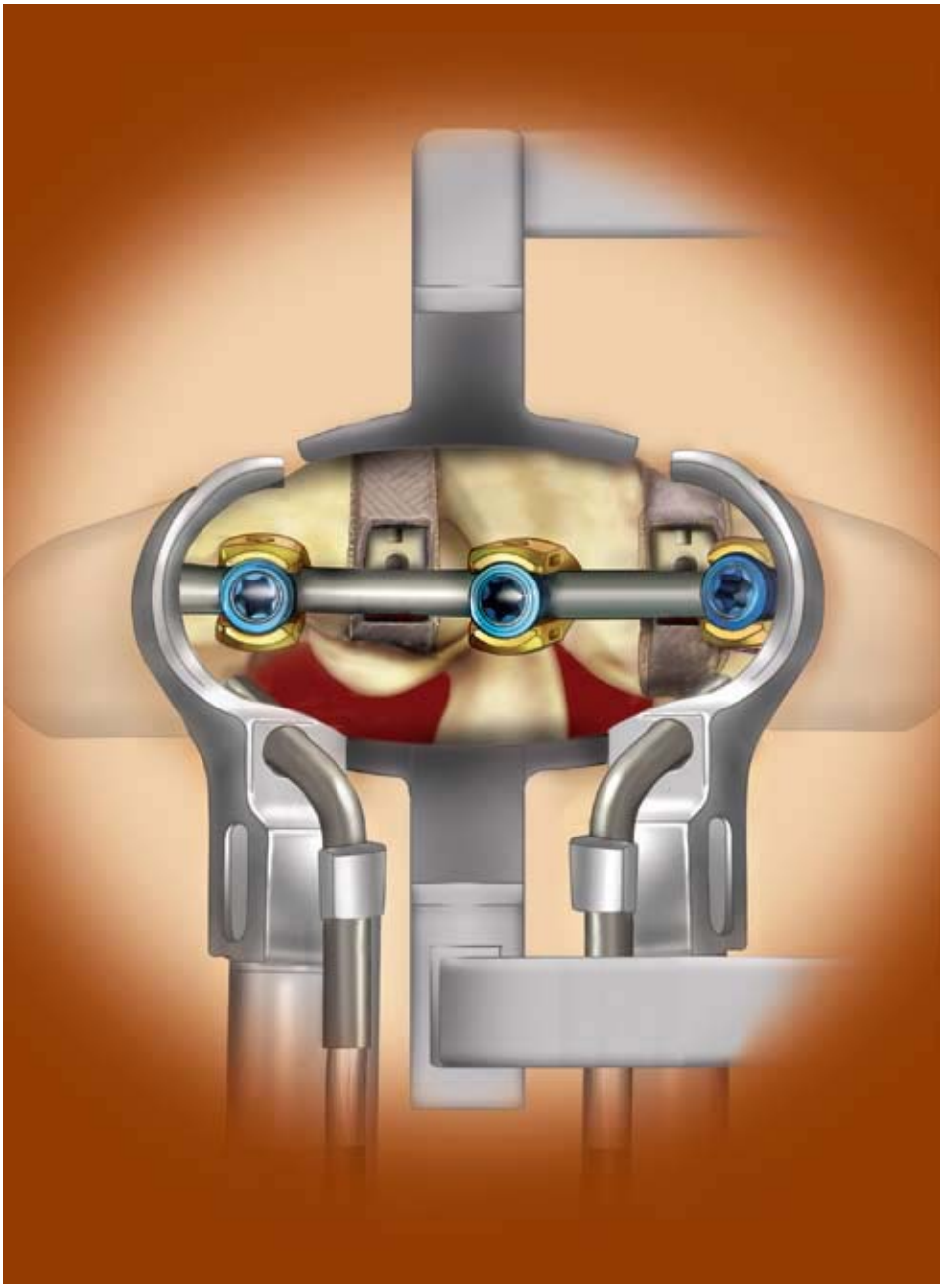
MAST QUADRANT™ Retractor System

Medial Lateral Blades Procedural Solutions Technique



The global leader in today's spine market, we combine Minimal Access Spinal Technologies (MAST™), integrated image-guided products and neural monitoring tools to enable less invasive procedures. Minimally invasive spine surgery may lead to decreased intraoperative blood loss and shorter hospital stays.[1]

As described by:

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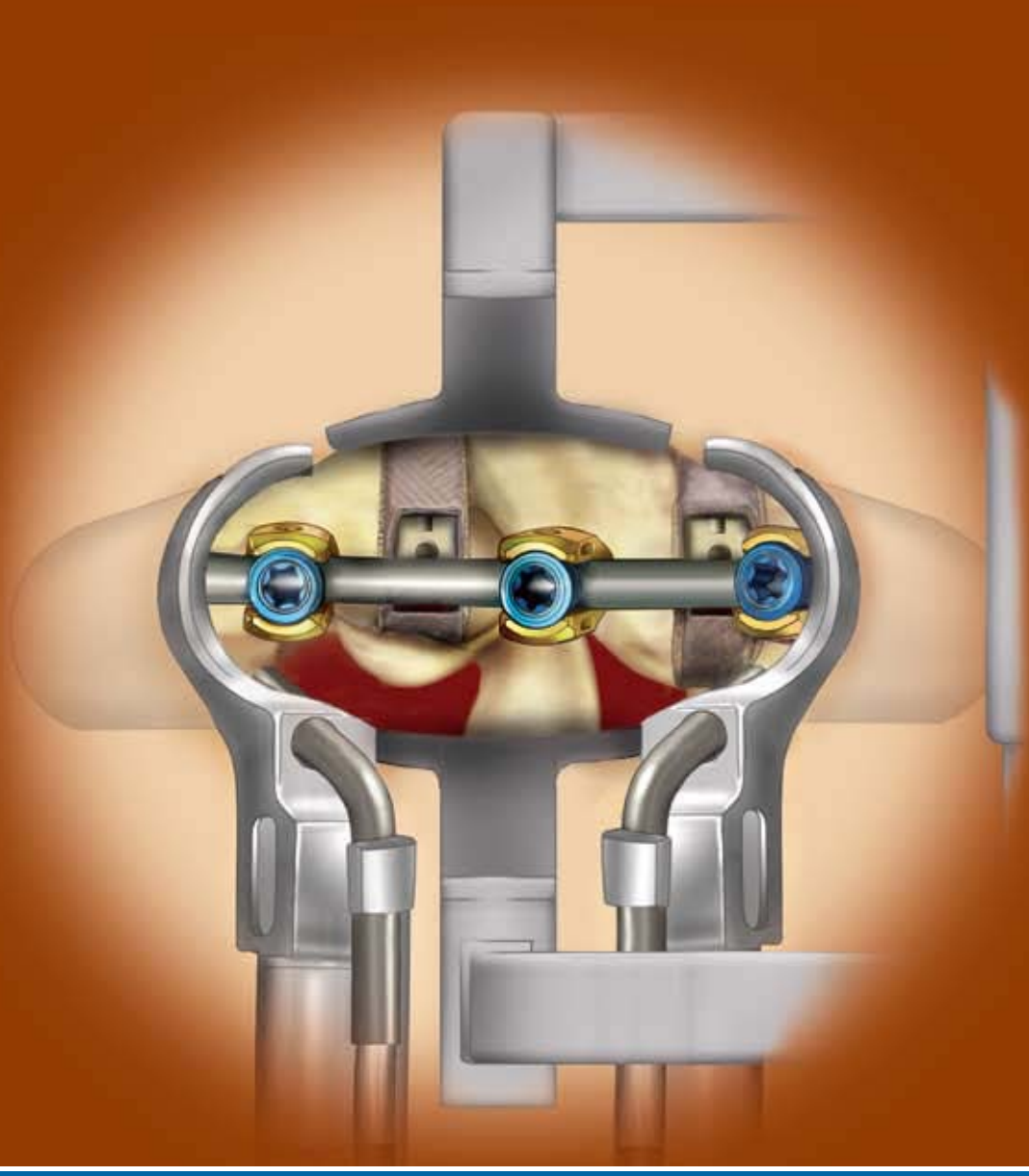
CAPSTONE® Bone and Instrument Set incorporate technology developed by Gary K. Michelson, MD.

MICHELSON TECHNOLOGY AT WORK

The MAST QUADRANT™ Retractor System allows access, fusion, and fixation all through one approach, giving the surgeon more versatility for performing minimally invasive fusion surgery with confidence.

Built upon the foundation of Medtronic's Minimal Access Spinal Technologies (MAST™) platform, the MAST QUADRANT™ Retractor System features a proven dilation technique while allowing enhanced visualization and working space.

When combined with interbody options and our CD HORIZON® LEGACY™ Cannulated Screw System, the MAST QUADRANT™ Retractor System serves as the basis for a complete minimally invasive procedural solution.



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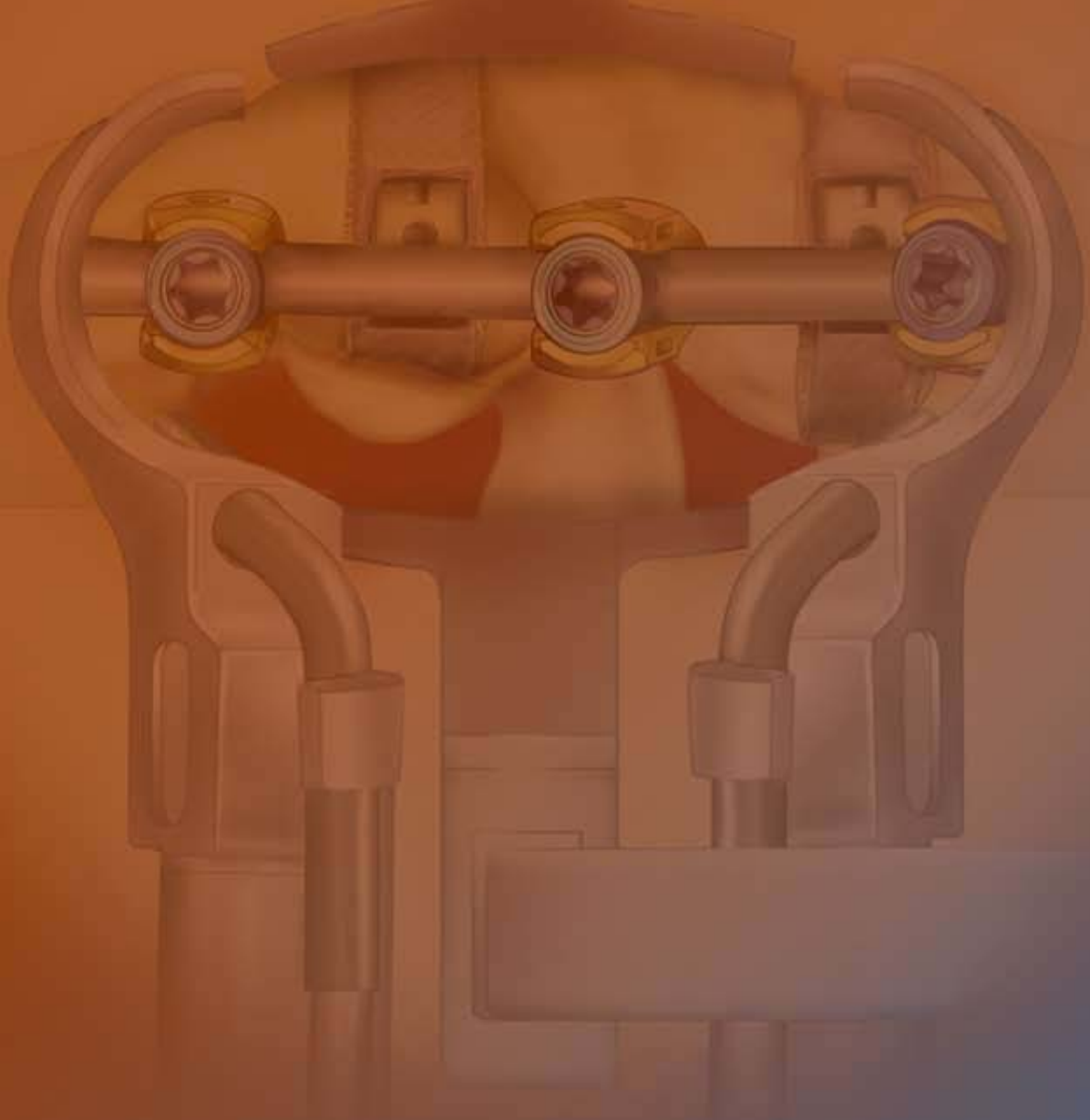
MAST QUADRANT™

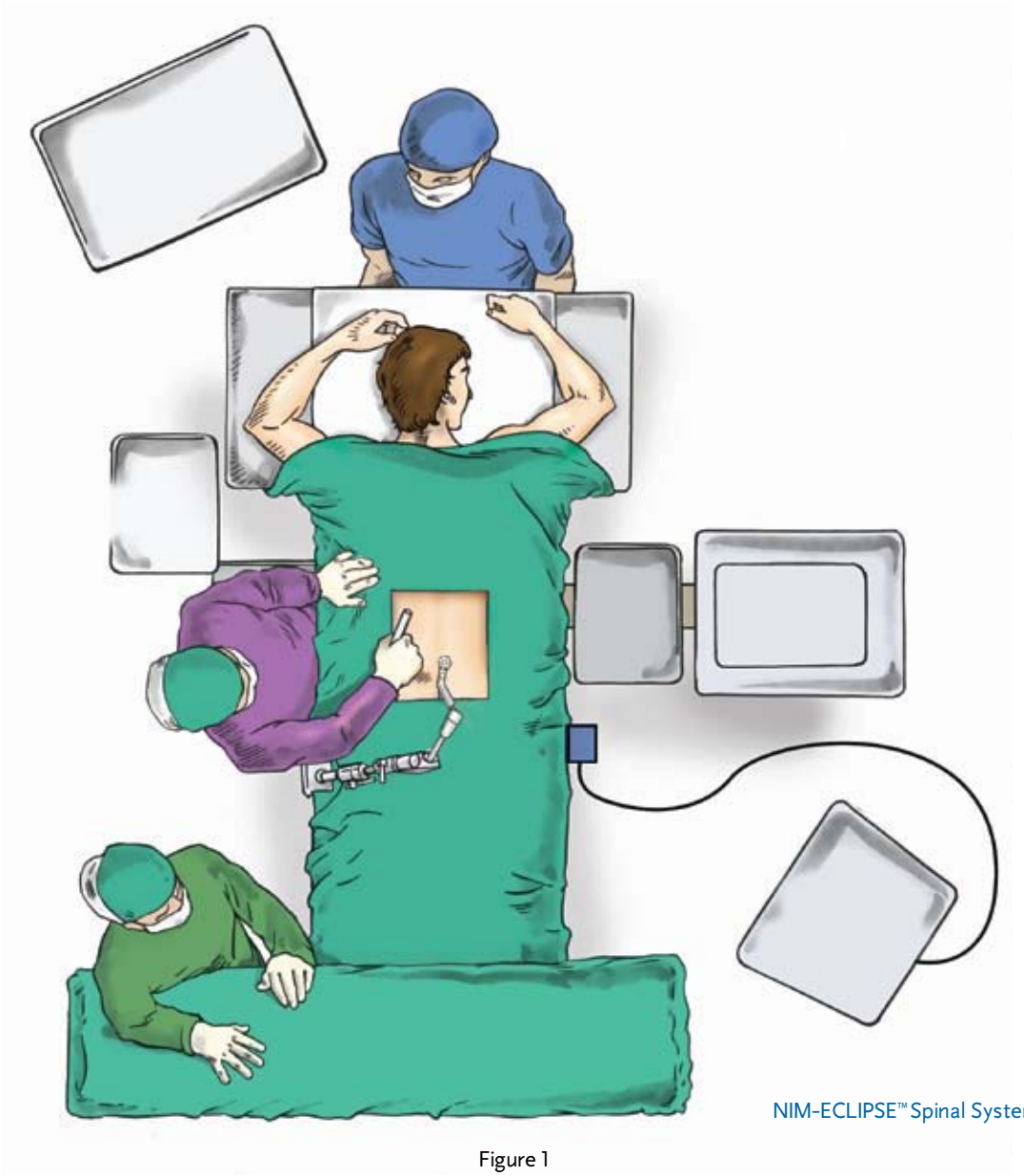
Retractor System

SURGICAL STEPS FOR

Access



The patient is positioned prone on an appropriate table for fluoroscopy. Two Flexible Arms may be required depending upon surgeon technique. The NIM-ECLIPSE™ Spinal System may be utilized for nerve monitoring (Figure 1).



NIM-ECLIPSE™ Spinal System

Figure 1

For a posterior lumbar interbody fusion (PLIF), the incision is made approximately 3.0cm to 4.0cm off midline (Figure 2). After the tube insertion, the trajectory may be shifted medial to accommodate the interbody portion of the procedure and lateral to target the Pedicle Screws.

For a transforaminal lumbar interbody fusion (TLIF), the incision is made approximately 4.0cm to 4.5cm off midline (Figure 3). This trajectory allows direct access to both disc space and pedicles.

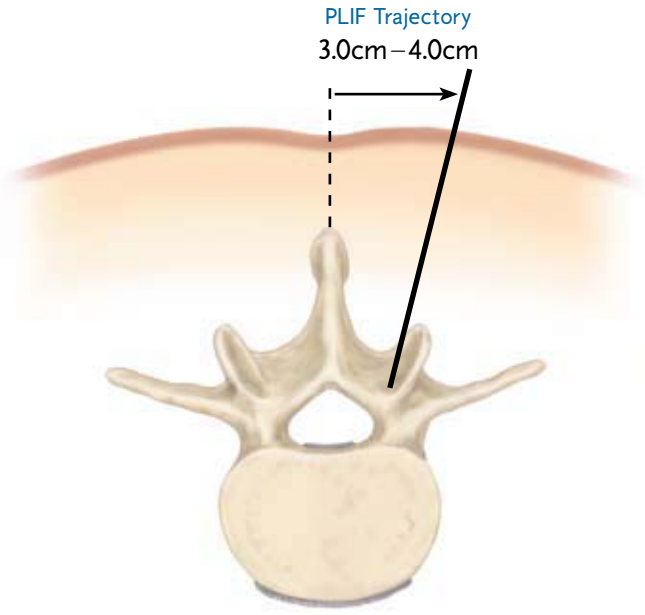


Figure 2

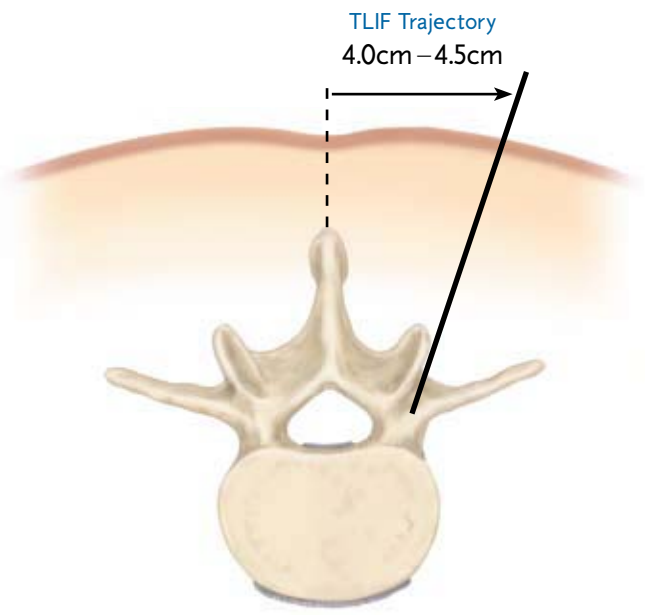


Figure 3

Note: The location of the incision is dependent on the chosen procedure.

The Guidewire is inserted through the incision and directed toward the appropriate reference point. Slide Initial Dilator over Guidewire and place on the bony anatomy (Figure 4). Reference points may be either lamina or facet joint depending on preference and technique.

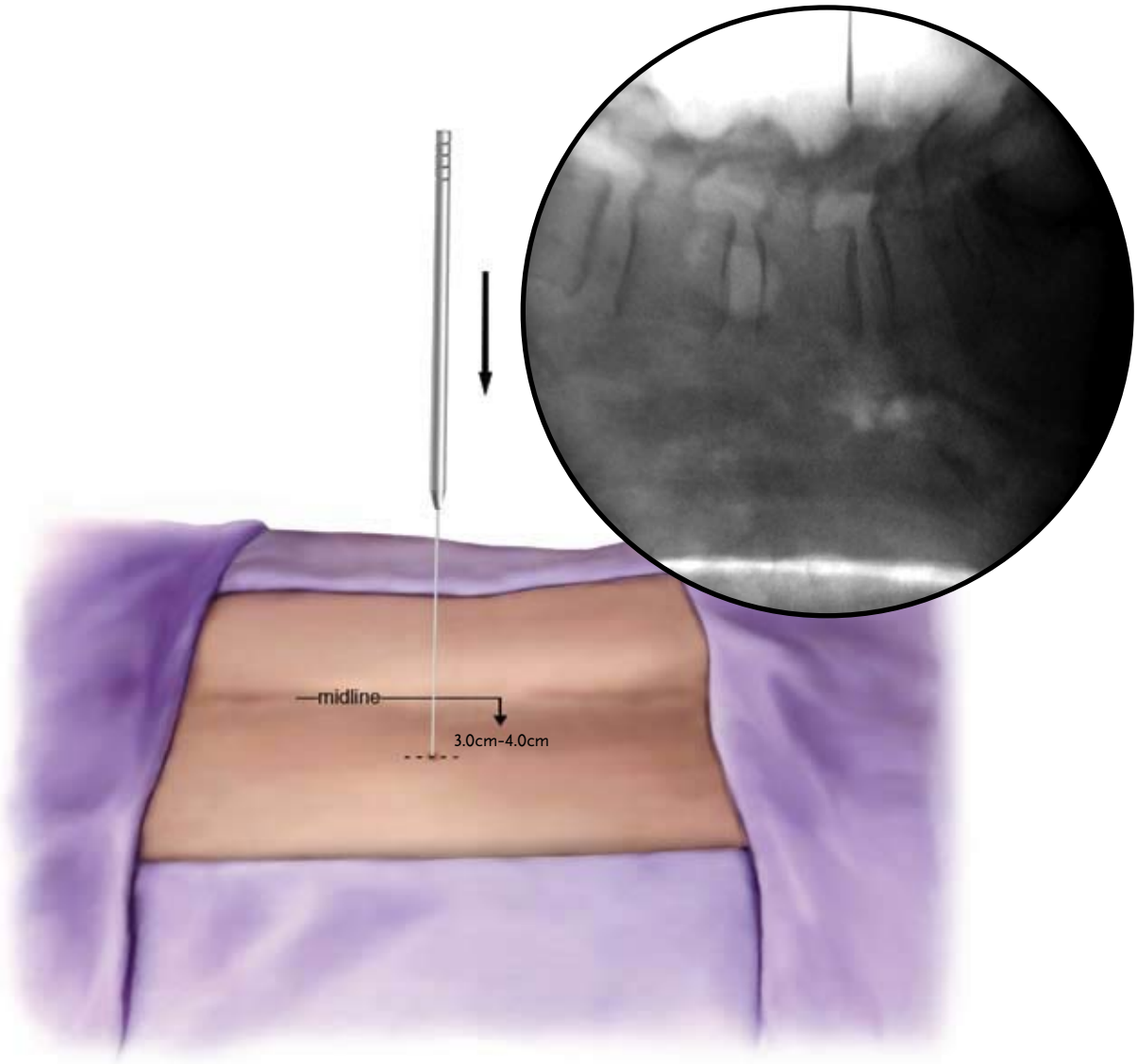


Figure 4

Note: If neuromonitoring is used, free-running EMG should monitor any nerve root irritation throughout the procedure, if performed correctly.*

*Please see the NIM-ECLIPSE™ Spinal System package insert and user's manual for complete instructions and list of warnings, precautions, and other medical information.

Use the Initial Dilator to palpate the bony anatomy in both coronal and sagittal planes to identify proper Dilator positioning (Figure 5).

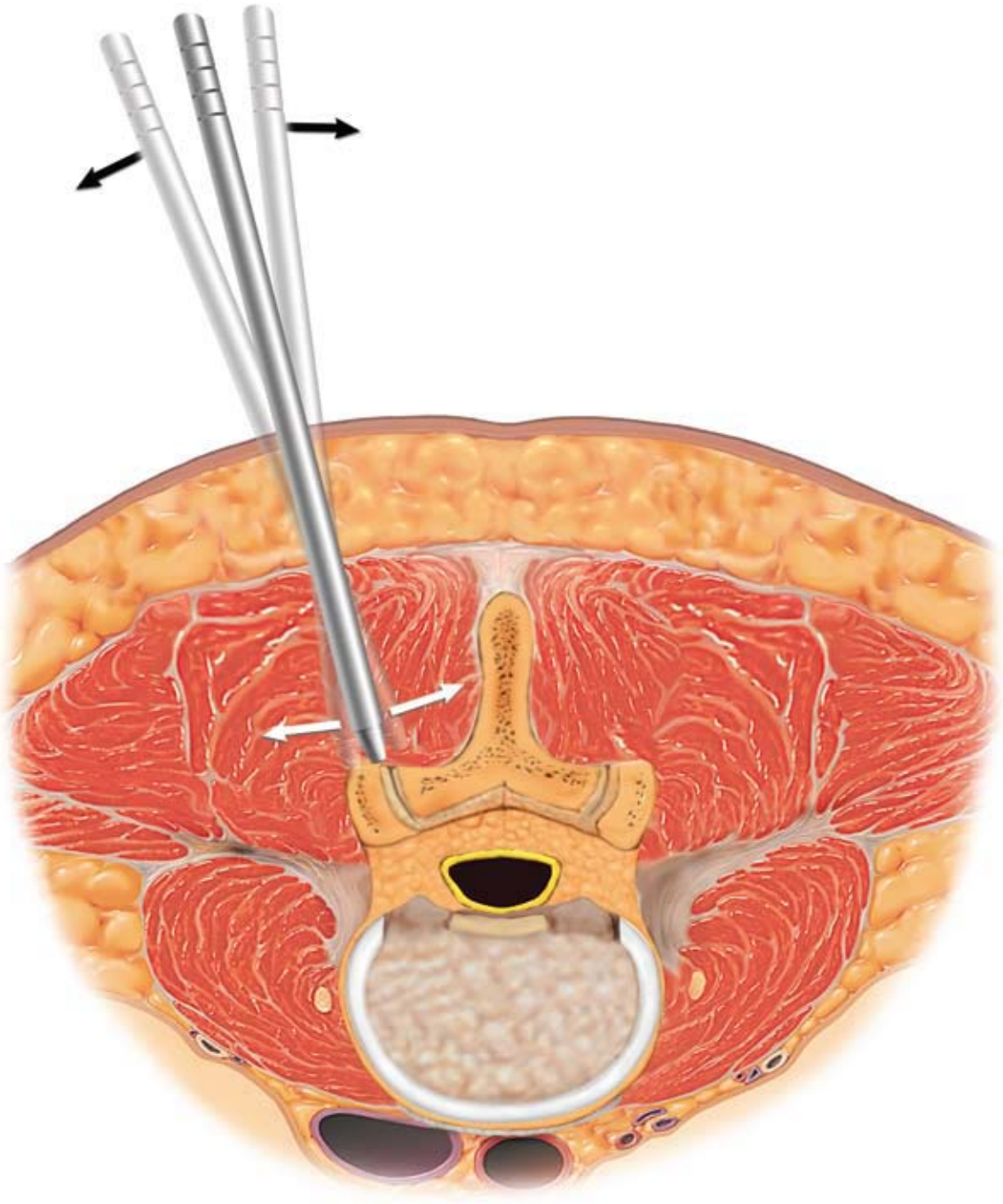


Figure 5

Use a Scalpel to ensure adequate skin incision and to incise fascia along the Dilator track. Dilators are sequentially placed over each other up to 22mm.

It may be beneficial to slide a knife along the side of the Dilators to release the fascia, allowing for easier opening of the Retractor Blades.

The Retractor Blades are selected in accordance with exposed markings on the final Dilator (Figure 6).

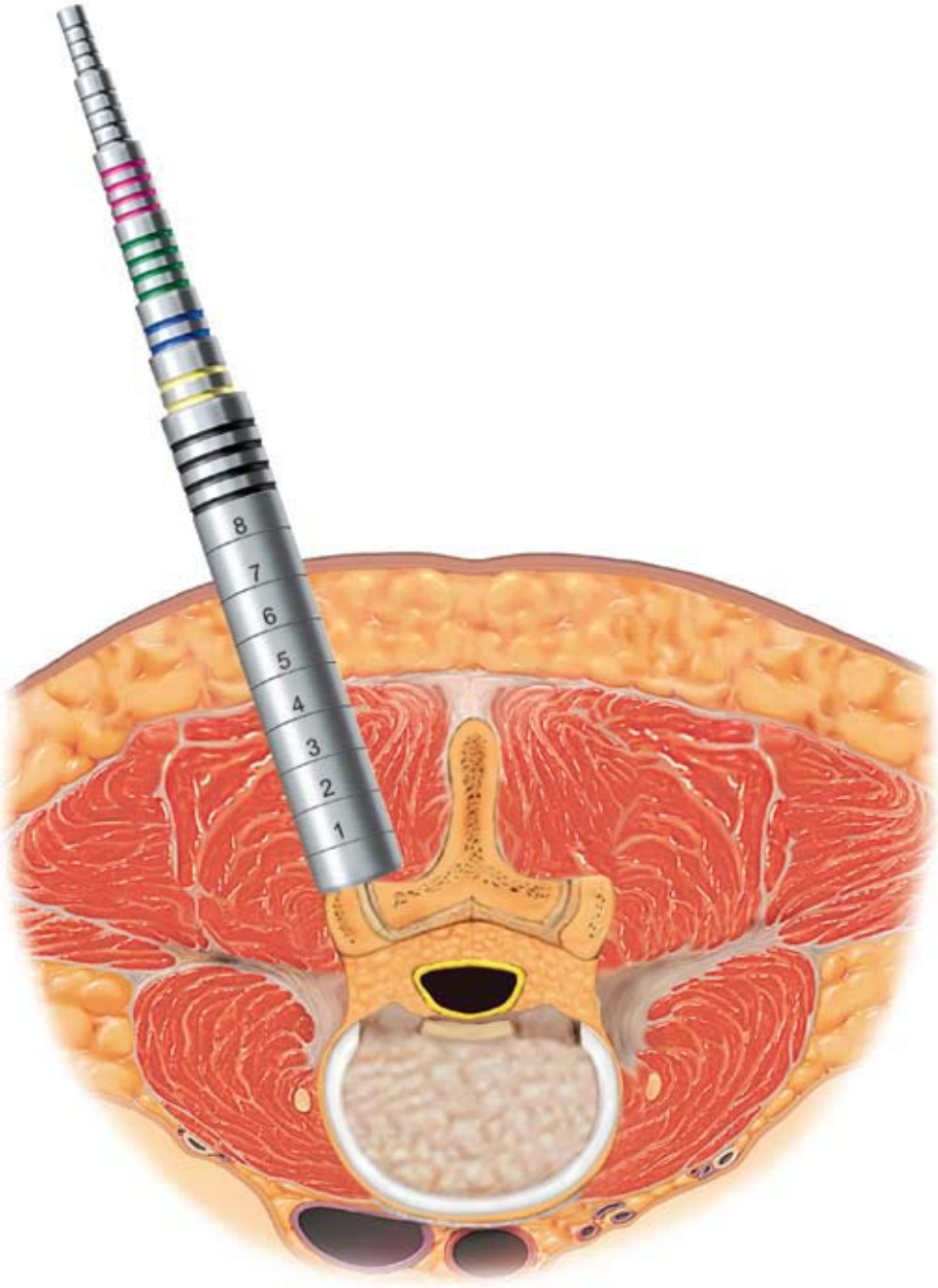


Figure 6

The Flex Arm attachment may be attached to either of the two attachment points on the Retractor before it is handed to the surgeon (Figure 7).

The MAST QUADRANT™ Retractor is inserted over the Dilators and placed over the bony anatomy and locked in place with the Flex Arm (Figure 8). The Dilators are then removed establishing a tubular operative corridor. Again, ensure the skin incision is adequate, including incising of the fascia to allow for opening of MAST QUADRANT™ Retractor Blades.

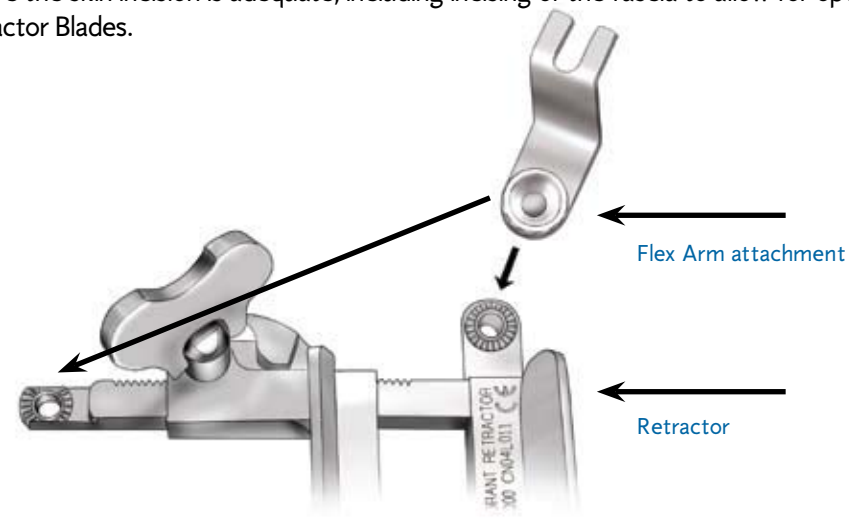


Figure 7

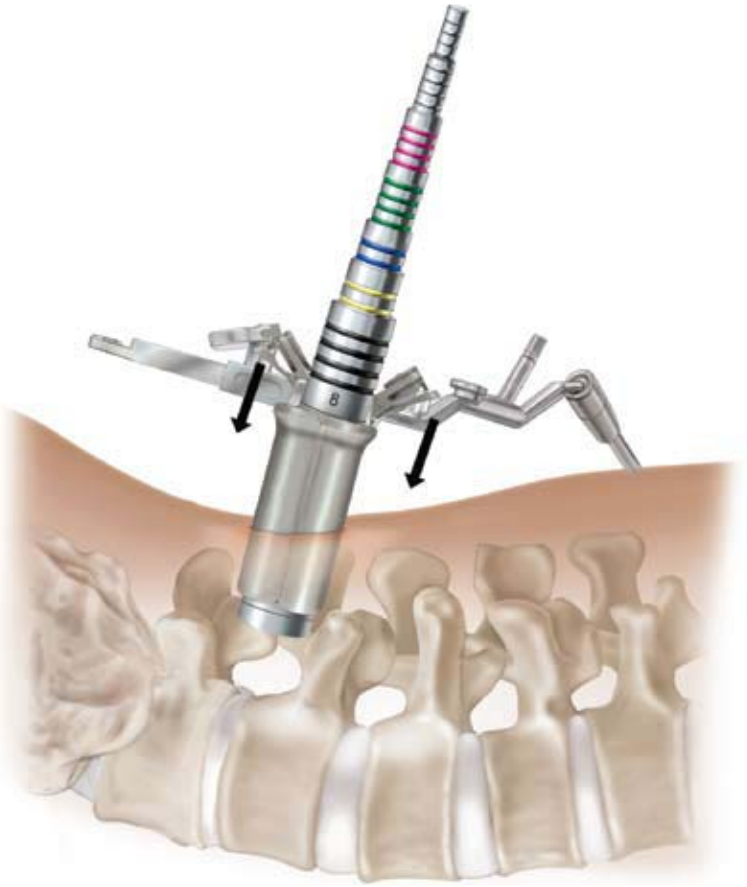
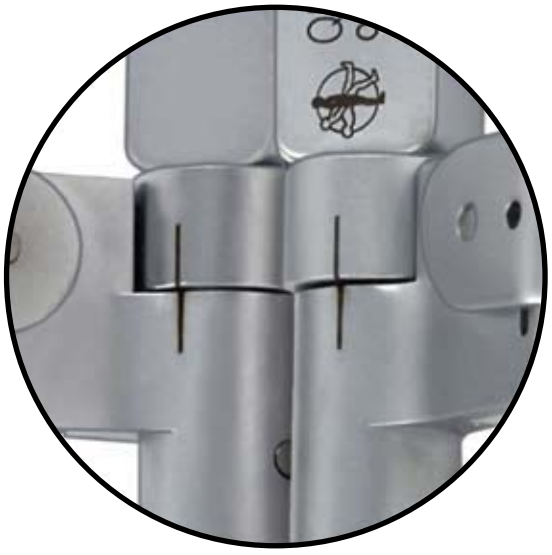


Figure 8



Note: Ensure that blades are closed and perpendicular to the Retractor. Etched marks should be aligned.

The MAST QUADRANT™ RADIANCE™ Light Source may now be attached to the Retractor Blade. Place the metal tip of the light into the hole in the blades and then push the light under the built-in retaining sleeve (Figure 9).

Figure 9

Open the MAST QUADRANT™ Retractor by turning the base knob in a counterclockwise direction (Figure 10). The Retractor will open up to 30mm allowing visualization of up to 52mm (surgeon should lengthen the skin incision to allow for the increase in Retractor opening).

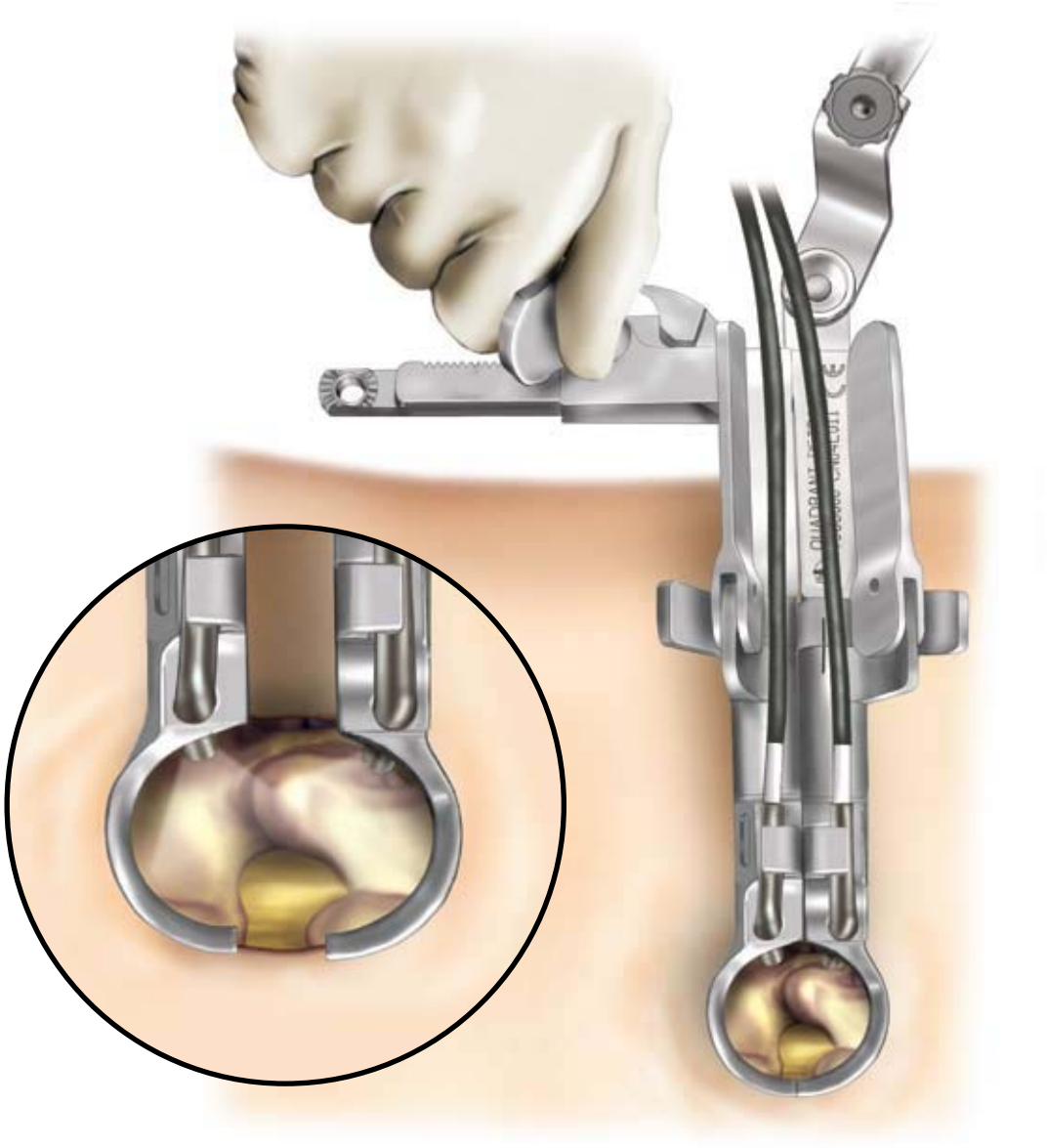


Figure 10

Articulation may now be achieved by moving the MAST QUADRANT™ Tabs to a vertical position. Blades can be angled up to 30 degrees (Figure 11). The Tabs can be used as levers to articulate or angle the blades. If articulation requires excessive force, in spite of adequate skin and fascia incision, the Blade Openers may be used. The Blade Openers are placed on the outside lip of each blade and used as lever arms to help assist in articulation (Figure 12).

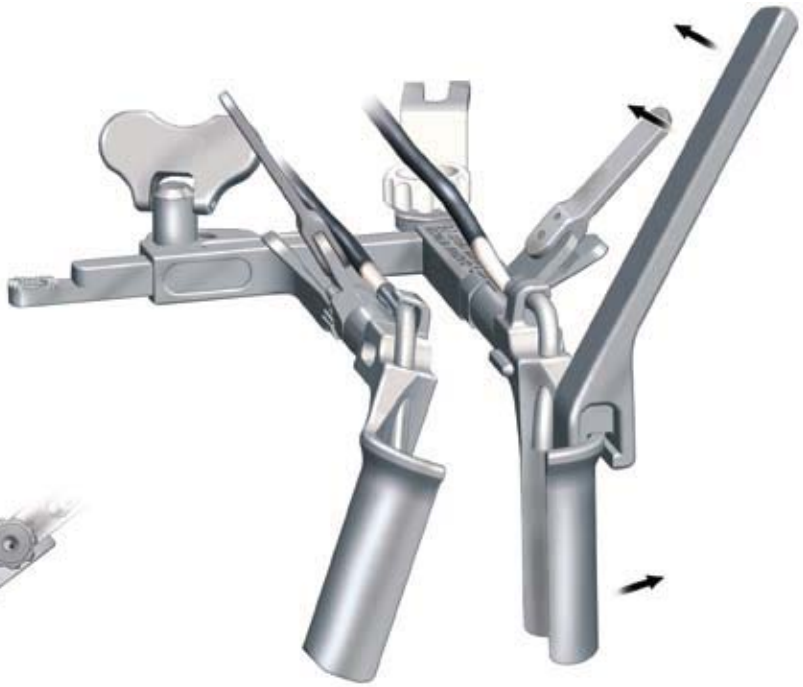


Figure 11

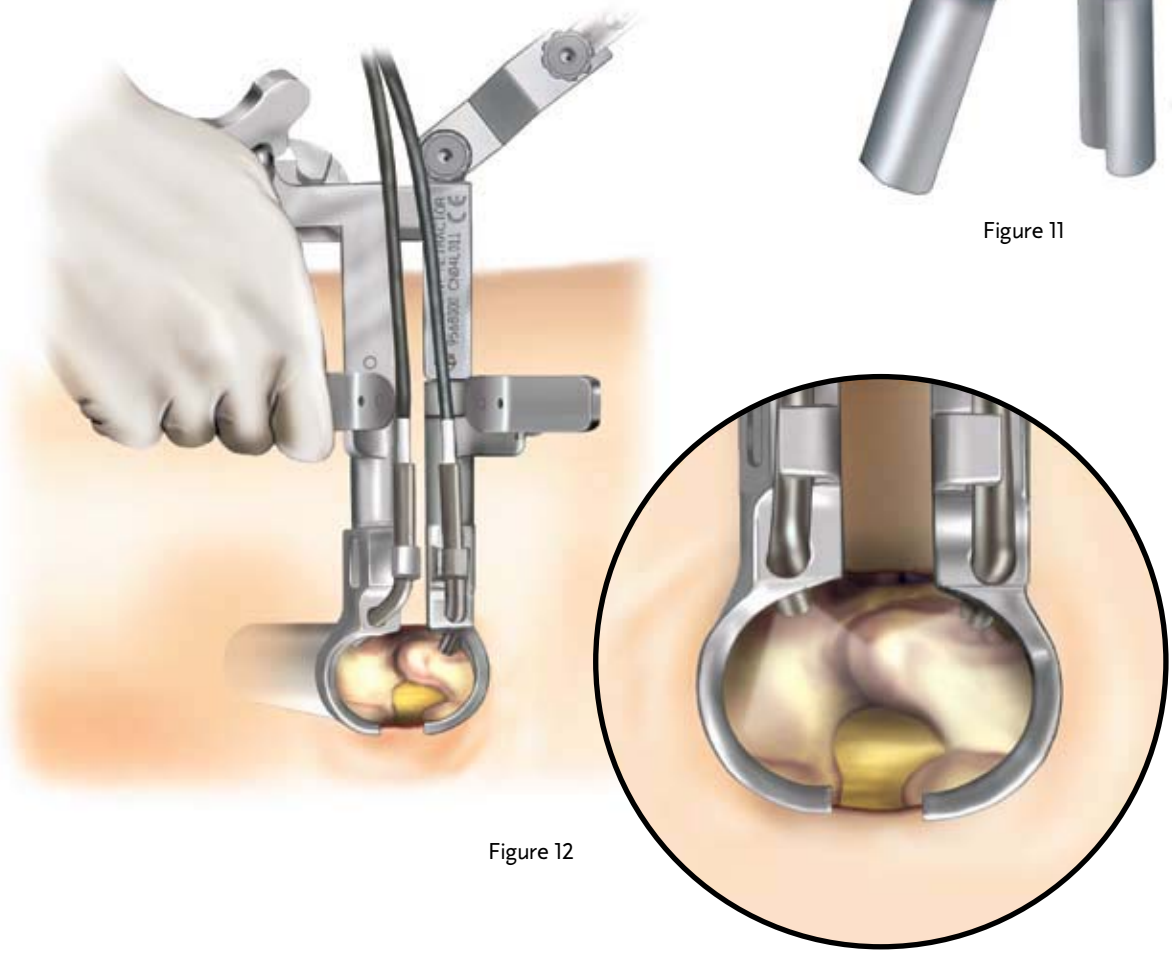


Figure 12

To release the angle of the blades, press the buttons under the Tabs (Figure 13).

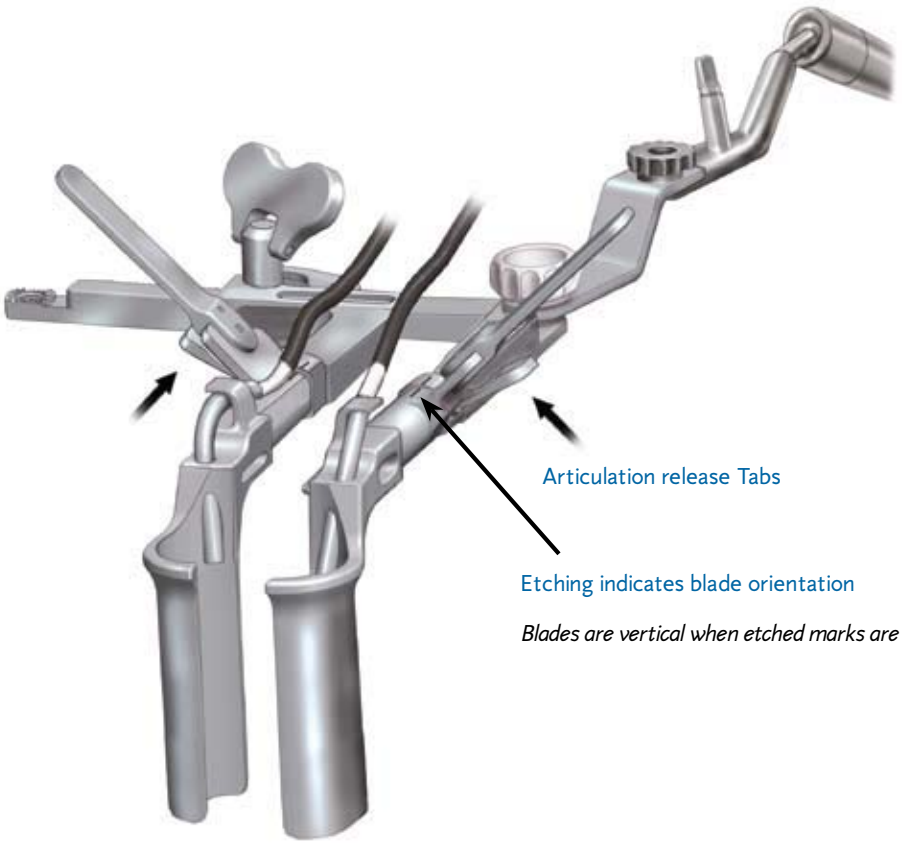


Figure 13

If needed, the MAST QUADRANT™ Medial Lateral Blades may be added at this time (Figure 14). The blades slide onto the medial lateral rack and sit between the existing MAST QUADRANT™ Retractor Blades (Figure 15).

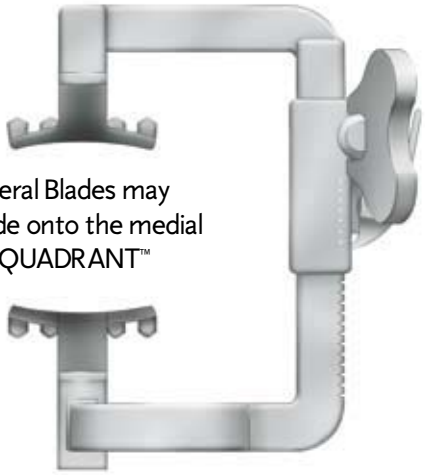


Figure 14

Figure 15

Perform the same dilation steps on the contralateral side to gain bilateral access (Figure 16).

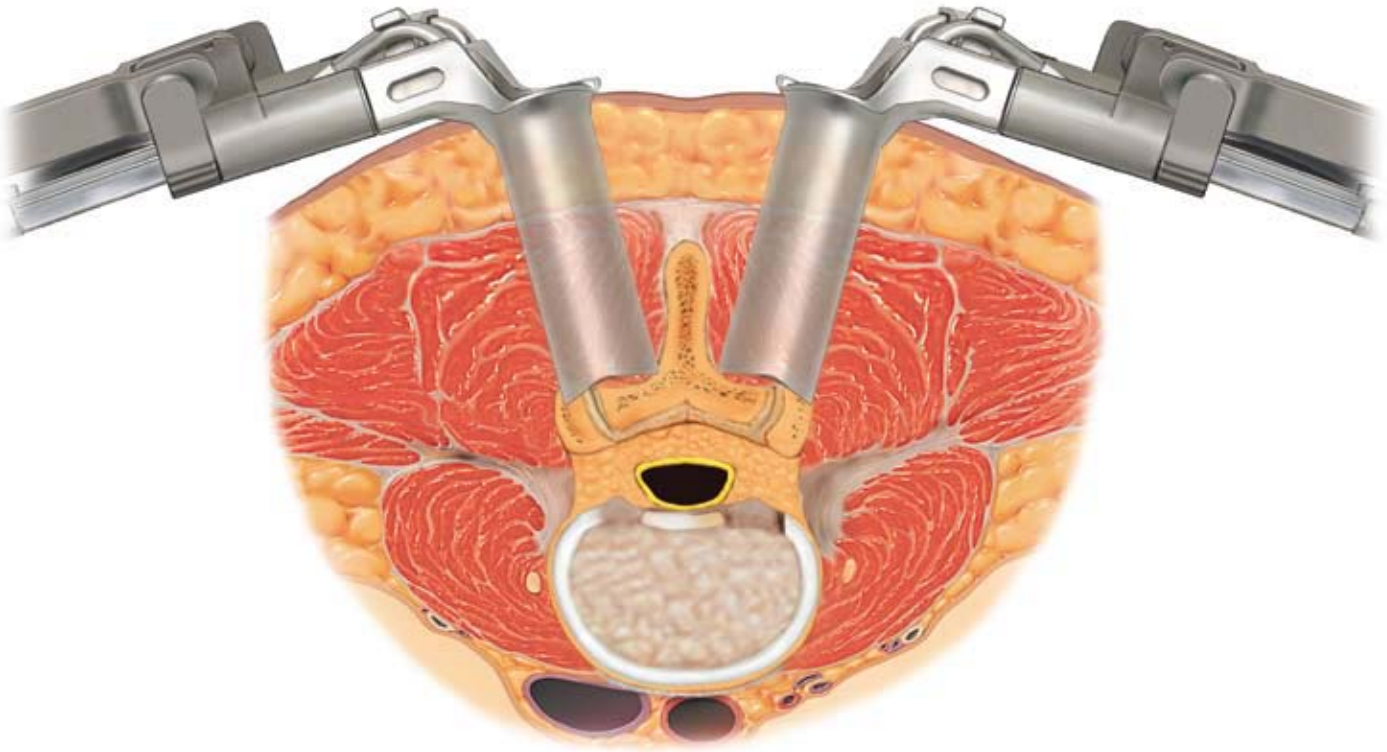
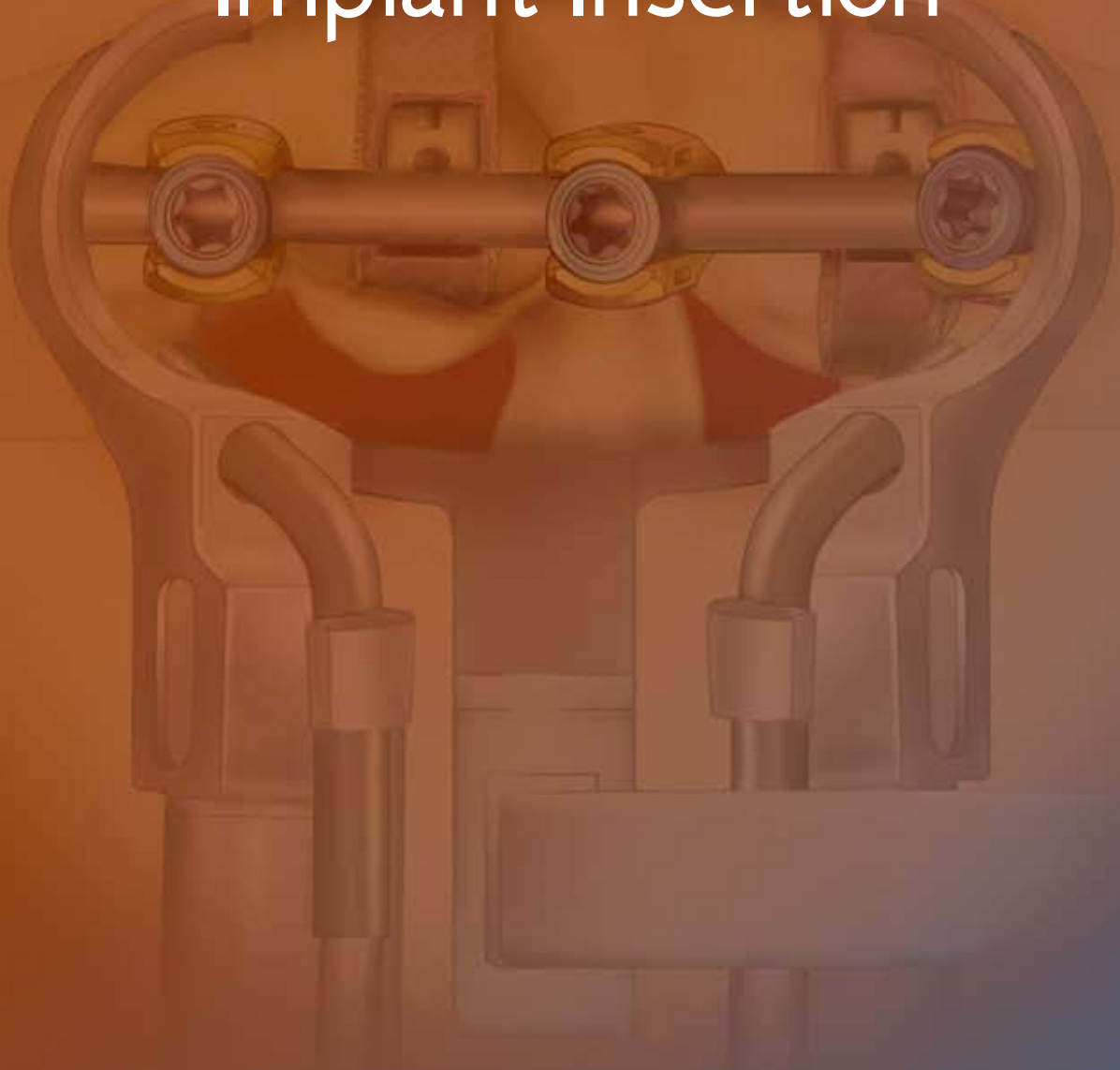


Figure 16

MAST QUADRANT™
Retractor System

SURGICAL STEPS FOR

Interbody Implant Insertion



A facetectomy is performed ipsilaterally or bilaterally. Using a Bone Rongeur, Osteotome, or Drill, remove the superior and inferior facets (Figures 17 and 18).

The extent of facetectomy is determined by the need for visualization of the disc space and decompression of the neural elements.

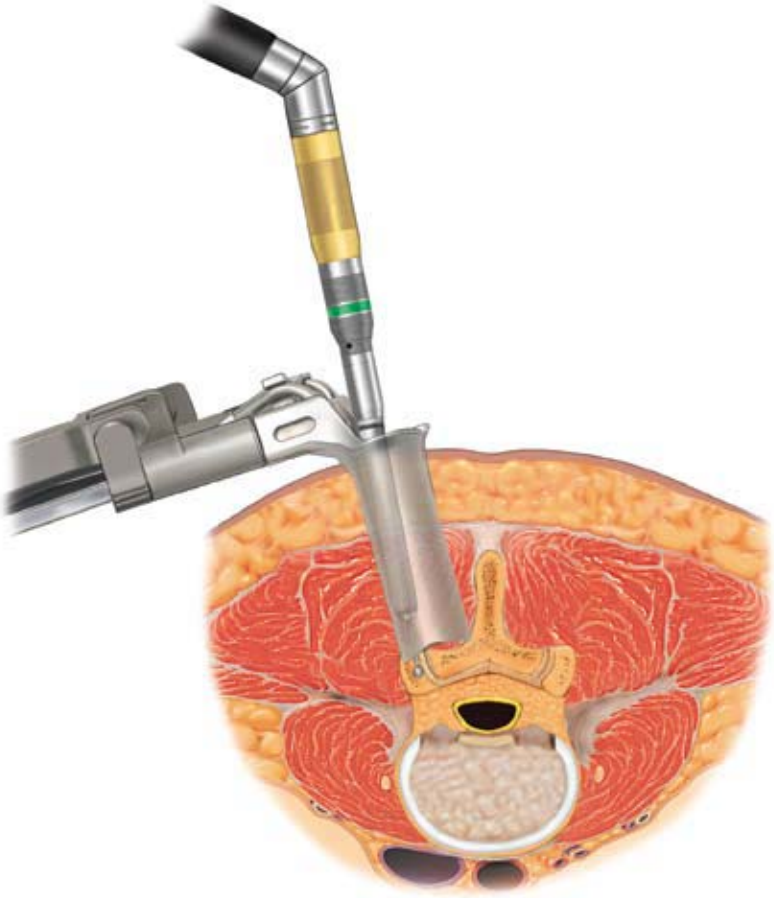


Figure 17

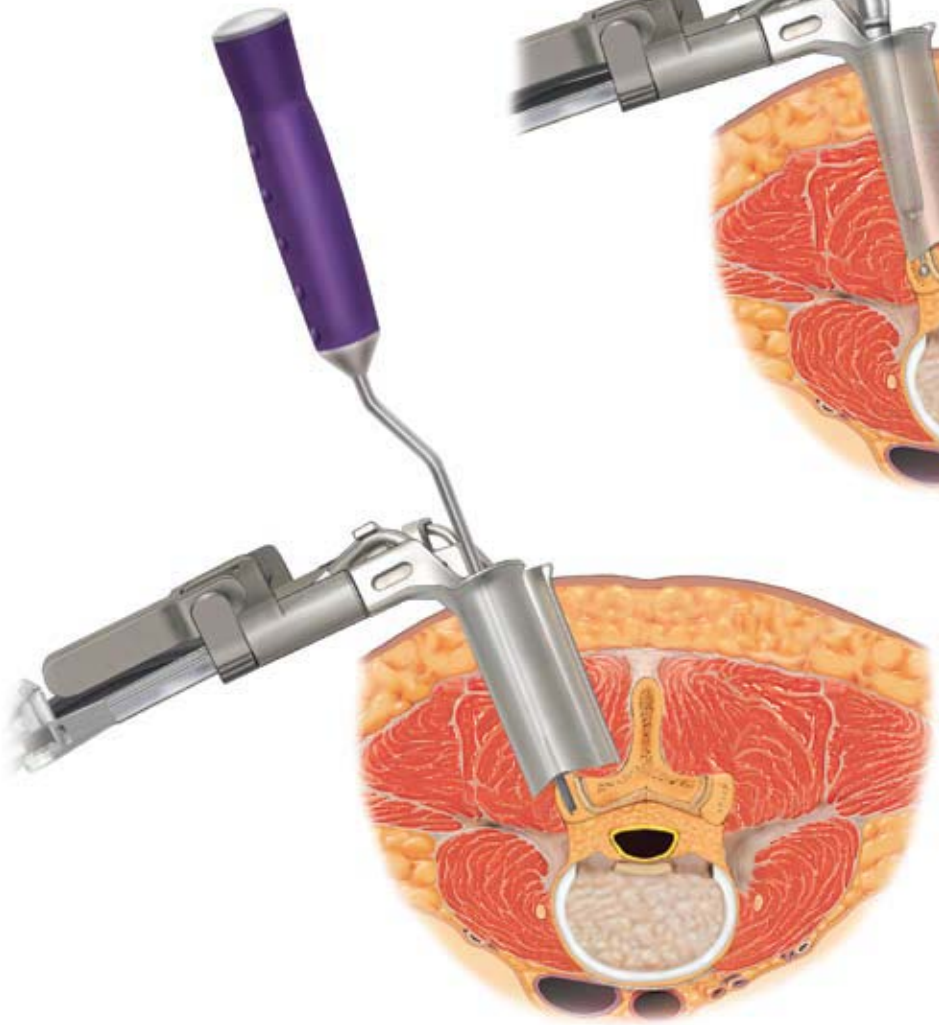


Figure 18

A conventional discectomy is performed by incising the annulus to the dural sac. This may be performed using a disposable Bayoneted Discectomy Knife. This is done unilaterally and/or bilaterally. Soft fragments from the intradiscal space or extruded fragments are removed with Disc Rongeurs in a conventional fashion (Figure 19).

The main goal of this step is to remove extruded fragments, to decompress neural elements, and to provide entry to the disc space for distraction with minimal or no nerve root retraction. If there is significant disc space collapse, a complete discectomy may not be possible until disc space distraction is accomplished.

If neuromonitoring is used, evaluate the status of adjacent nerve roots during this procedure with NIM-ECLIPSE™ Spinal System free-running EMG monitoring (Figure 20).

Note: Free-running EMG should monitor any nerve root irritation throughout the procedure, if performed correctly.*

Figure 20

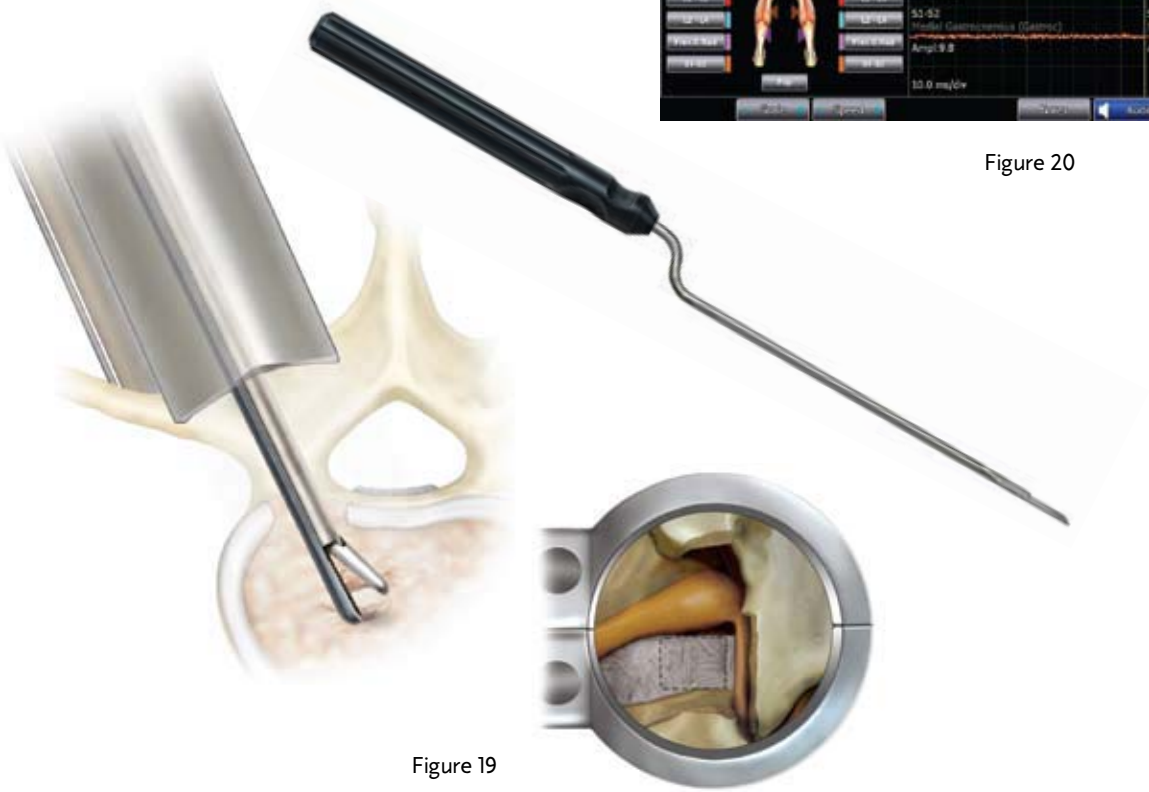
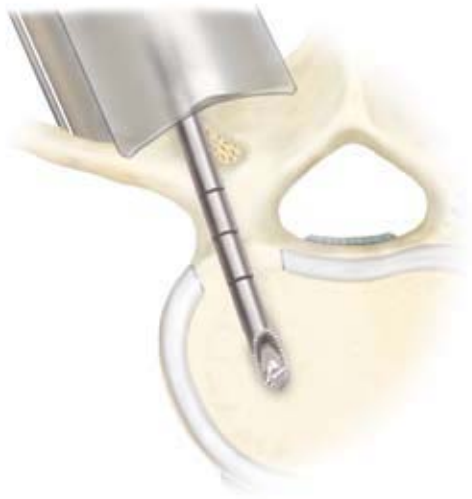


Figure 19

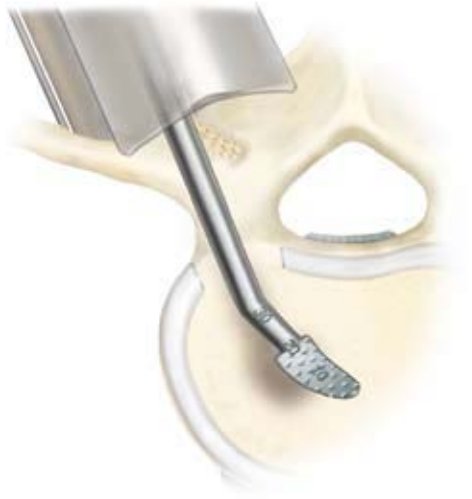
*Please see the NIM-ECLIPSE™ Spinal System package insert and user's manual for complete instructions and list of warnings, precautions, and other medical information.

Using various Curettes and Scrapers, continue disc removal and remove the cartilaginous material from the disc space and the end plates (Figure 21). Thorough end-plate preparation should be accomplished prior to insertion of the interbody construct.

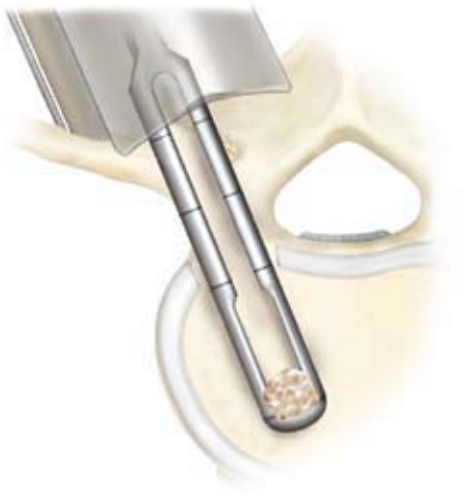


Straight Curette

Ring Curette



Angled Rasp



Round Scraper

Figure 21

The disc space is sequentially distracted until the original disc space height is obtained and normal foraminal opening is restored. Insert the CAPSTONE® System Trial with the curved sides touching the end plates (Figure 22). Sequentially insert the CAPSTONE® System Trial until the desired height is obtained. Figures 23a and 23b show implant insertion from an axial view.

If neuromonitoring is used, free-running EMG should be used to monitor the status of potentially affected nerve roots during this procedure* (Figure 24).

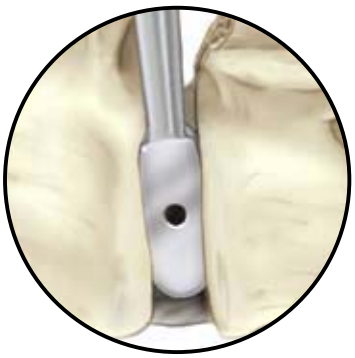


Figure 22

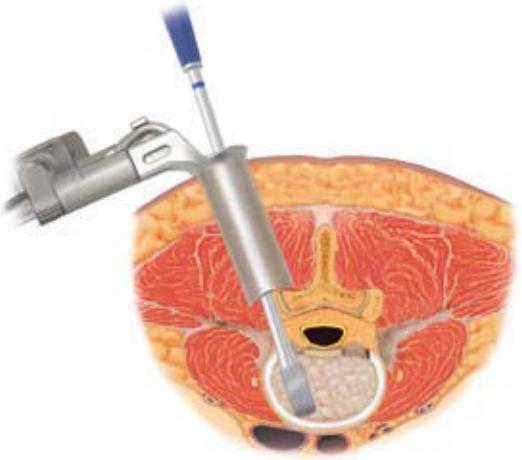


Figure 23a

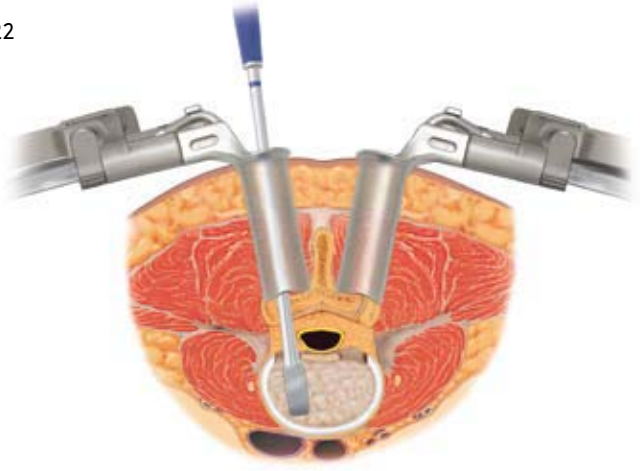


Figure 23b

Figure 24

*Please see the NIM-ECLIPSE™ Spinal System package insert and user's manual for complete instructions and list of warnings, precautions, and other medical information.

Choose the appropriate size construct from the trialing step and attach the selected construct firmly to the Inserter. Before inserting the construct, place autograft anteriorly and contralaterally or in the bone construct central cavity. Taking care to ensure that the construct is aligned properly, gently impact the construct until it is 3mm to 4mm below the posterior margin of the annulus (Figure 25). Figures 26a and 26b illustrate CAPSTONE® Allograft Construct Insertion from an axial view.

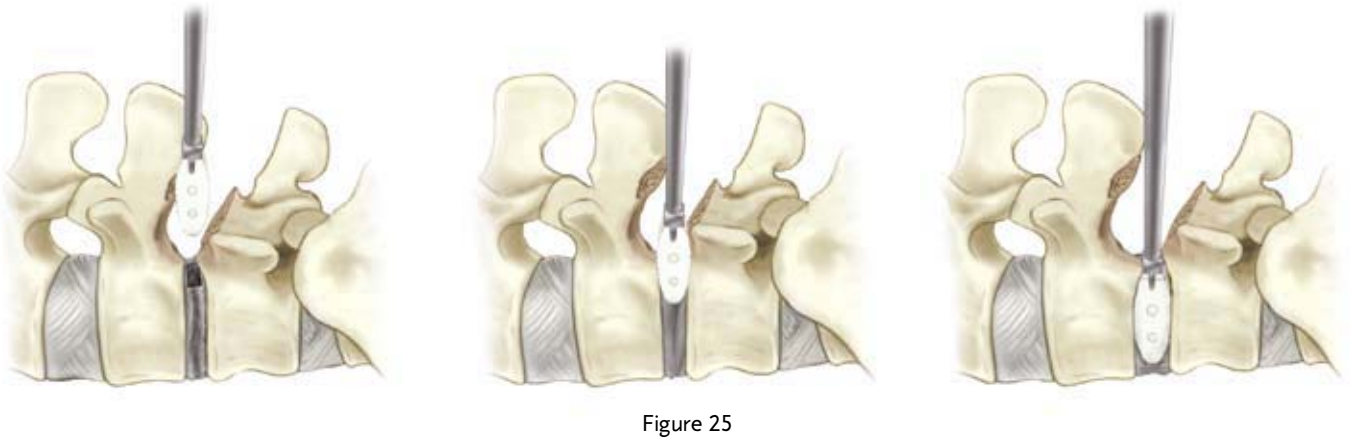


Figure 25

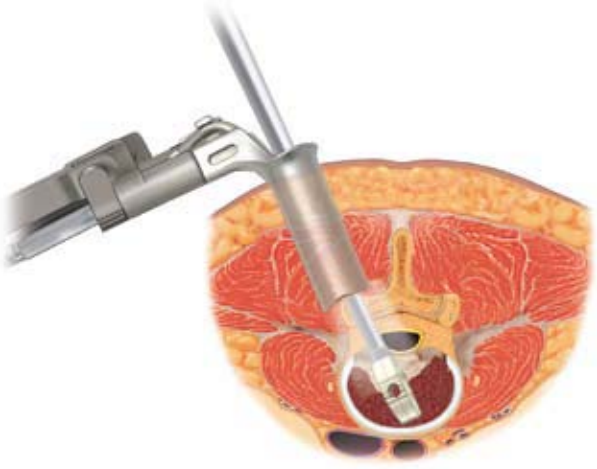


Figure 26a

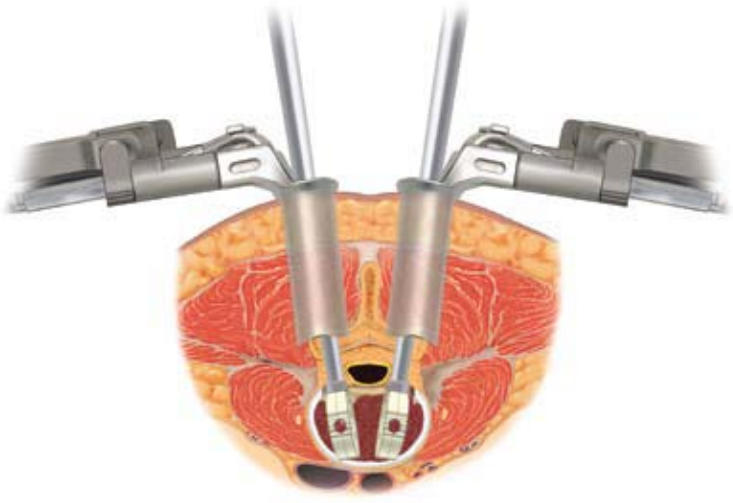


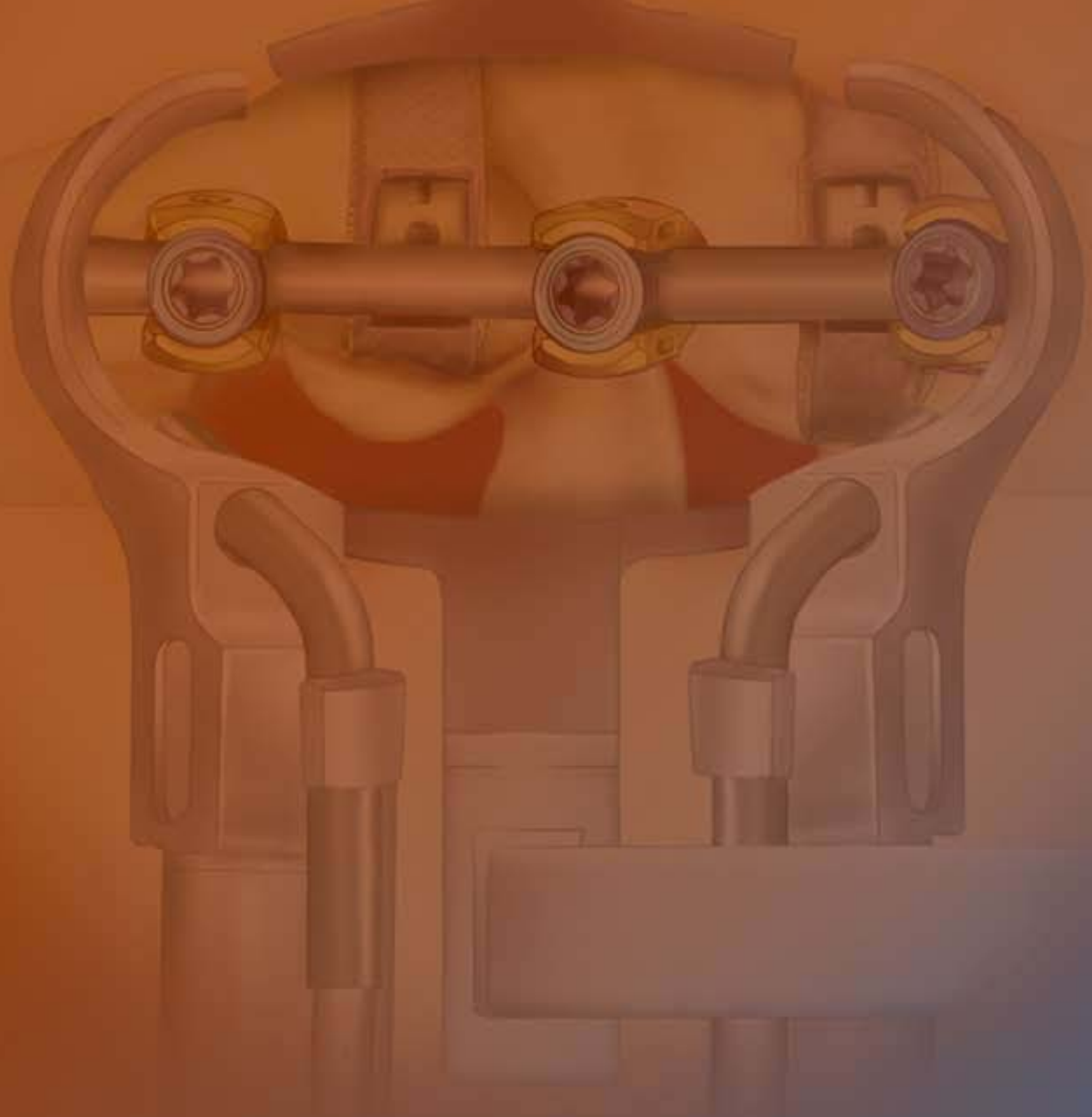
Figure 26b

MAST QUADRANT™

Retractor System

SURGICAL STEPS FOR

Fixation



The MAST QUADRANT™ Retractor may be further translated or articulated to gain pedicle access (Figure 27).

A NIM Pedicle Access Needle (PAK) can be used to gain access to the pedicle. Place the NIM PAK Needle at the intersection of the facet and the transverse process; the Needle may be advanced partially through the pedicle (Figure 28). EMG monitoring may now be performed to ensure proper placement of the Needle in the pedicle. An AP image should show the Needle tip at the lateral margin of the pedicle initially. As the NIM PAK Needle advances towards the base of the pedicle, on the lateral image, it should approach the pedicle center on the AP image.

AP Fluoroscopy view shows the NIM PAK with a radiolucent handle (Figures 29 and 30).

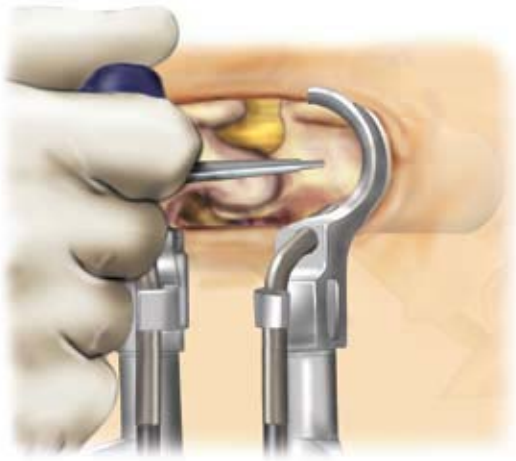


Figure 27

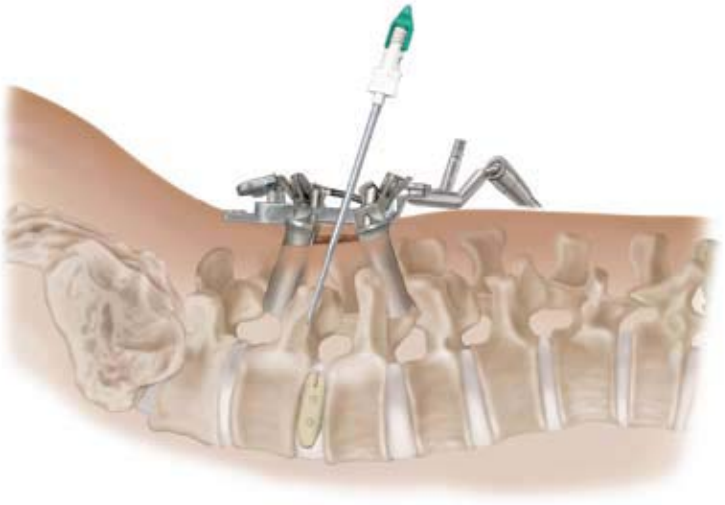


Figure 28

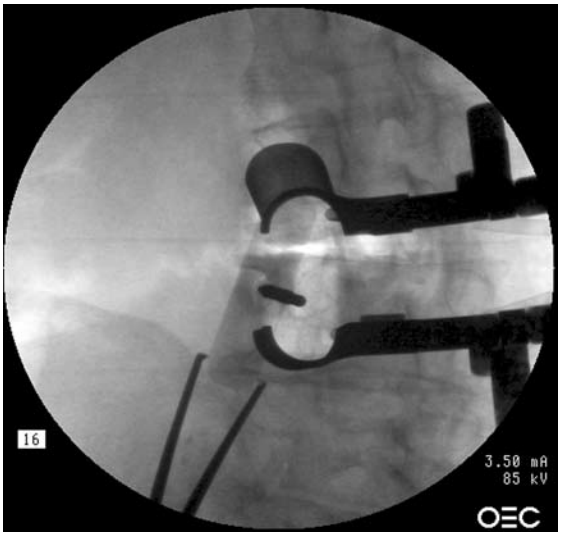


Figure 29

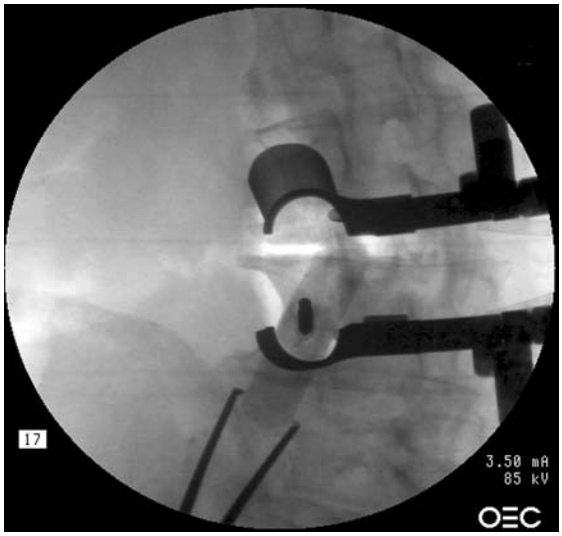


Figure 30

The NIM-ECLIPSE™ Spinal System can be utilized to evaluate positioning within the pedicle through the use of free-running and triggered EMG nerve monitoring* (Figure 31). The NIM-ECLIPSE™ Spinal System Connection Procedure and Electrode Placement Guide provide detailed instructions for system setup and implementation.

The NIM PAK Needle includes an electrified Handle and insulated Cannula that enable electrification of the bone cutting portion of the device (Figure 32). The electrified Needle can then be utilized to generate triggered EMG feedback during initial entry into the pedicle. Prior to insertion into the pedicle, the NIM PAK Needle should be electrified to 5mA to 6mA. The surgeon should stop Needle insertion and investigate positioning within the pedicle if a triggered EMG response is generated during insertion.

Figure 31

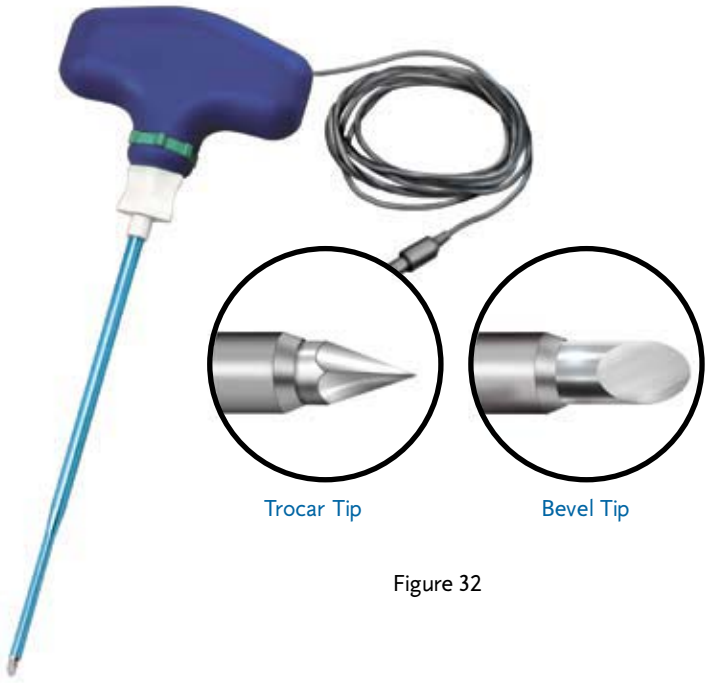


Figure 32

*Please see the NIM-ECLIPSE™ Spinal System package insert and user's manual for complete instructions and list of warnings, precautions, and other medical information.

The inner stylet of the NIM PAK Needle is removed to allow the Guidewire to be inserted into the pedicle (Figure 33). Be extremely careful with regards to the position of the Guidewire. Unintentional advancement of the wire can potentially be very dangerous. Once the Guidewire is inserted, the NIM PAK Needle may be removed.

In dense bone, where the Screw may be difficult to advance, ensure that the pedicle is fully prepared by using a Tap the same size as the inserted Screw (Figure 34). Fluoroscopy should be used to verify the position of the Guidewire and the Tap during this step. The threaded portion of the Tap is 45mm in length.

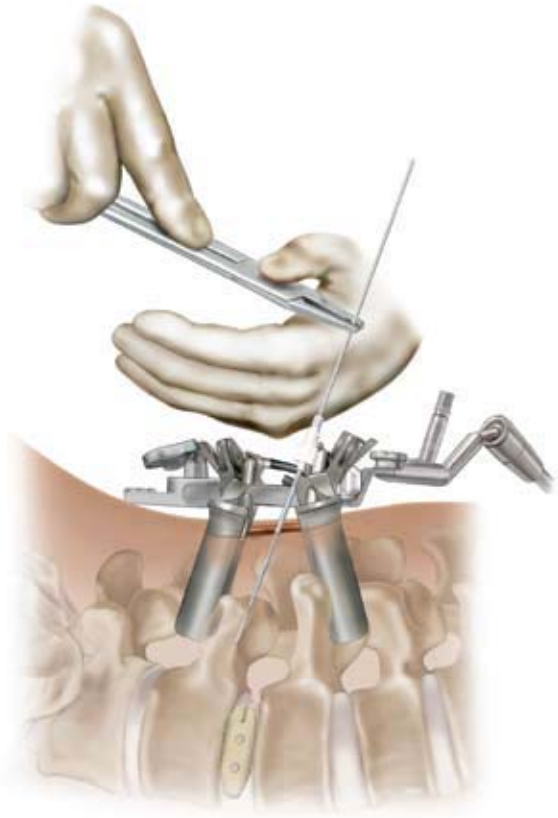


Figure 33

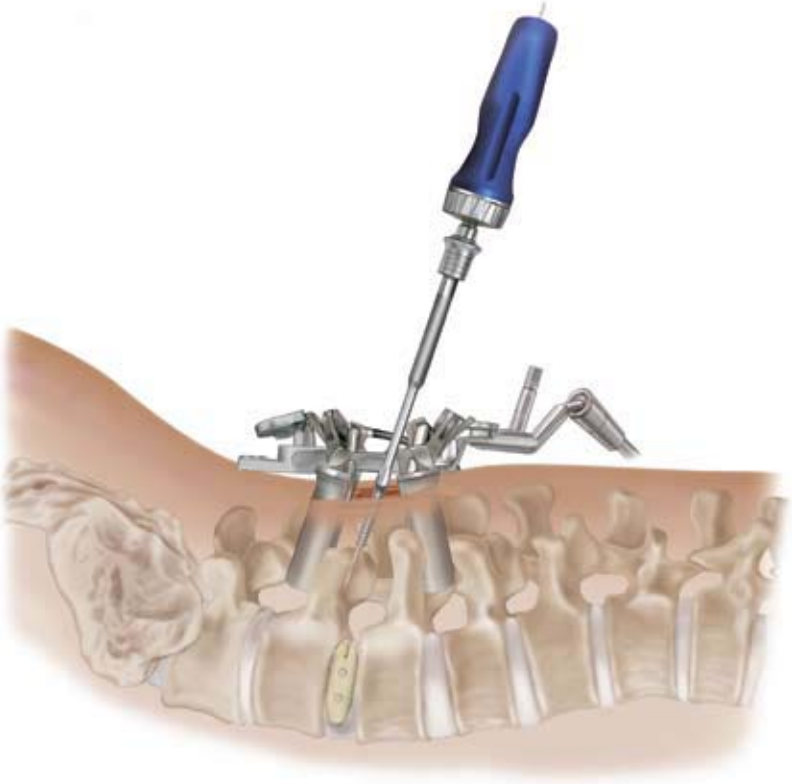


Figure 34

With the pedicles prepared and the proper Screw lengths determined, fully insert the hex end of the Multi-Axial Screwdriver into the Screw head (Figure 35). Next thread the Screwdriver Sleeve into the Screw head (Figure 36). The combination of the hex head and the threaded sleeve provide a stable insertion instrument for inserting the Multi-Axial Screws bilaterally (Figure 37). The Screw and Screwdriver are now placed over the Guidewire and inserted into the pedicle. Once your Screw has interfaced with bone, you may remove the Guidewire.

Figure 35

Figure 36

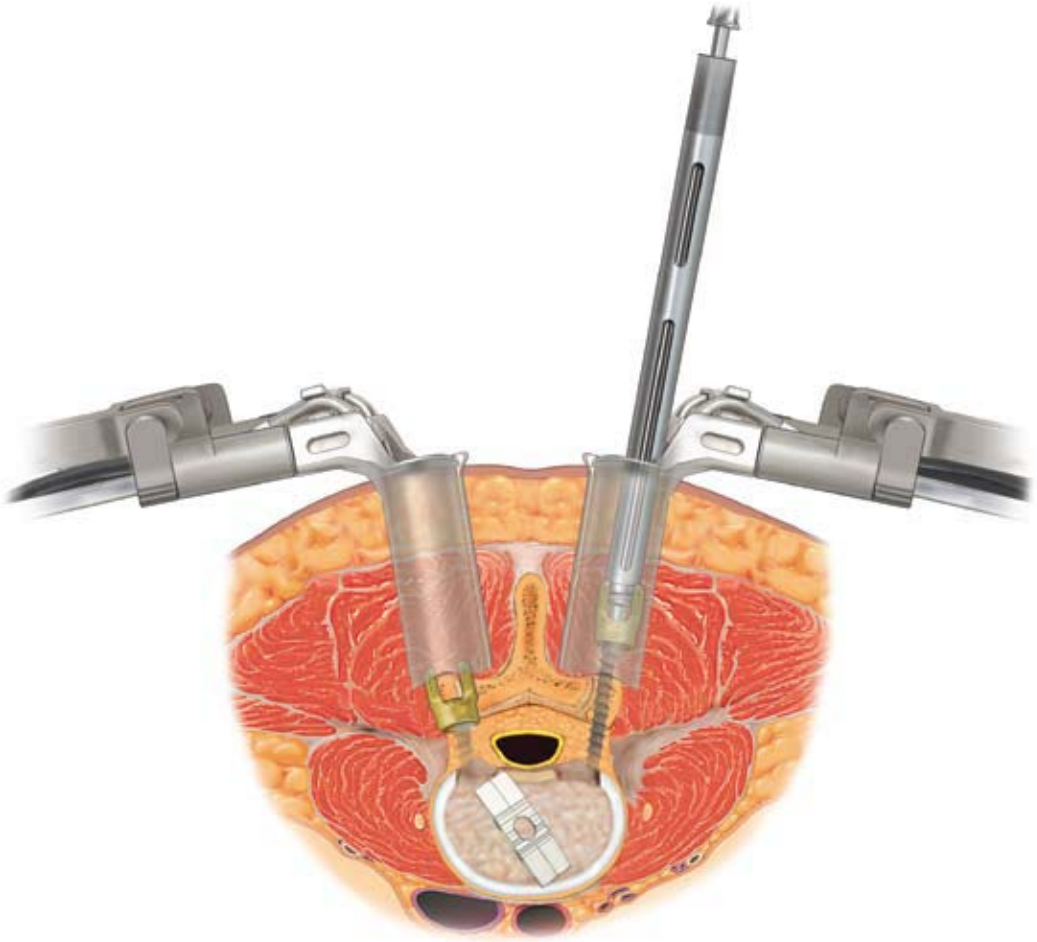
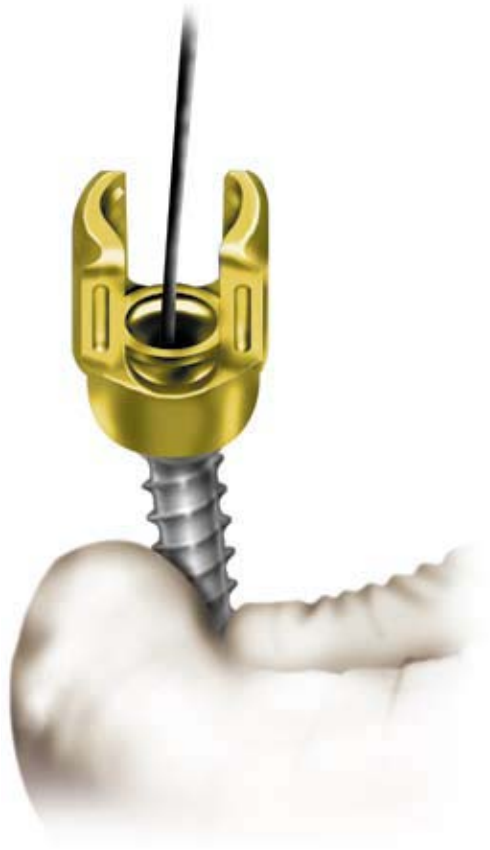


Figure 37

After final Screw placement, Screw positioning can be verified with EMG monitoring by direct stimulation of the Screw. Triggered EMG monitoring should be used to verify positioning of the Screw within the pedicle* (Figure 38).

Surgeon-directed Ball-tip Probe



EMG Monitoring

Figure 38

*Please see the NIM-ECLIPSE™ Spinal System package insert and user's manual for complete instructions and list of warnings, precautions, and other medical information.

To place the Rod into the MAST™ Rod Inserter, press the thumbswitch to the right and insert the Rod into the Inserter, then press the thumbswitch to the left to grip the Rod (Figure 39).

Lower the Rod Inserter into the Retractor and squeeze the Rod Inserter handles to rotate the Rod from the vertical to the horizontal position (Figure 40). Place the Rod into the Screw heads. Then, with the Rod seated in the Screw heads, move the thumbswitch to the right to release the Rod.

Figure 39

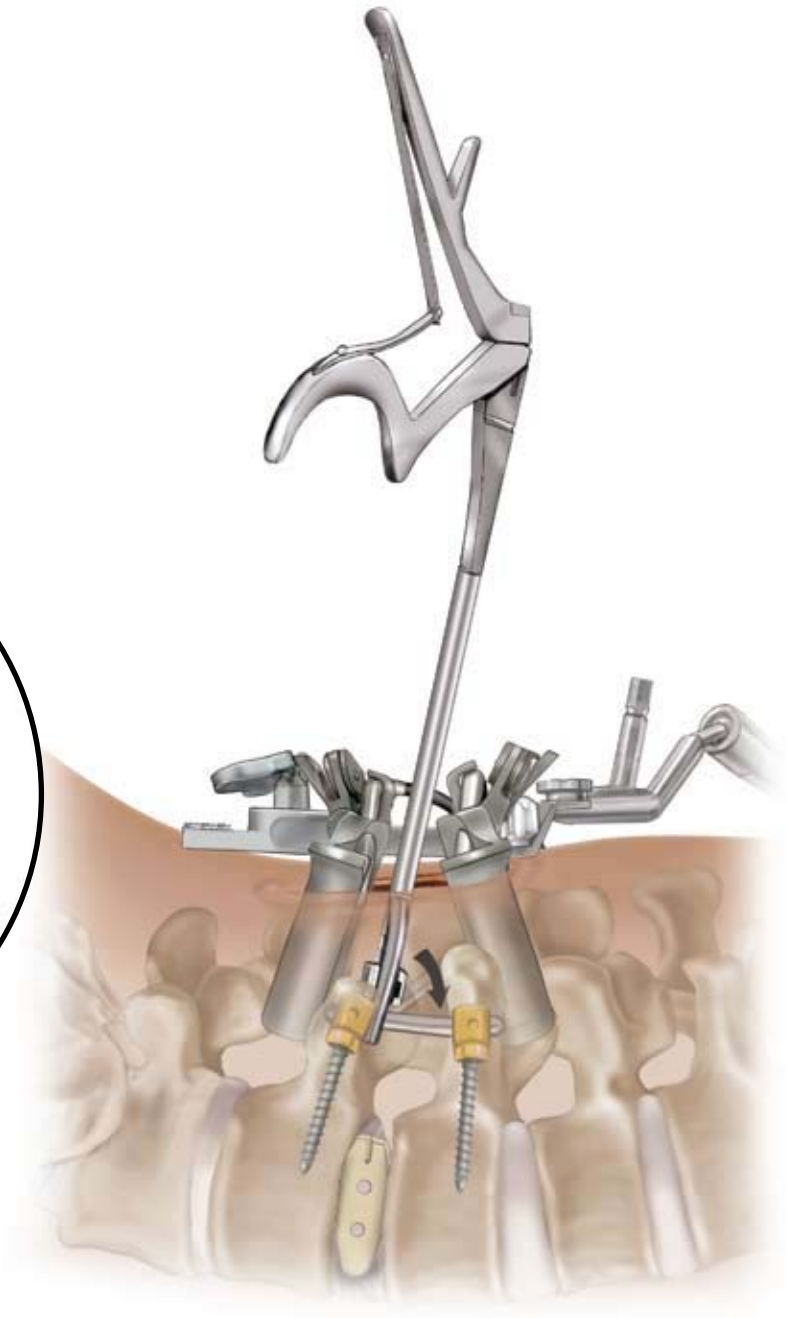


Figure 40

If the Rod is not fully seated into the bottom of the Screw head, the Beale Rod Reducer can be used to fully seat the Rod and simplify the Set Screw insertion process.

The Beale Rod Reducer is the preferred method for reduction when the Rod is lying even to the top of the implant head. To use the Rod Reducer, position the Reducer so that the handles are parallel to the Rod and grasp the Screw head from above (Figure 41). The Reducer handles are slowly compressed allowing the sleeve to slide down and seat the Rod. The Provisional Driver is then inserted through the Rod Reducer to insert the Set Screw into the head of the Pedicle Screw (Figure 42).

Note: Care should be taken with any Rod reduction maneuver. Improper instrument use may dislodge the implants or damage the bony or neurologic anatomy.

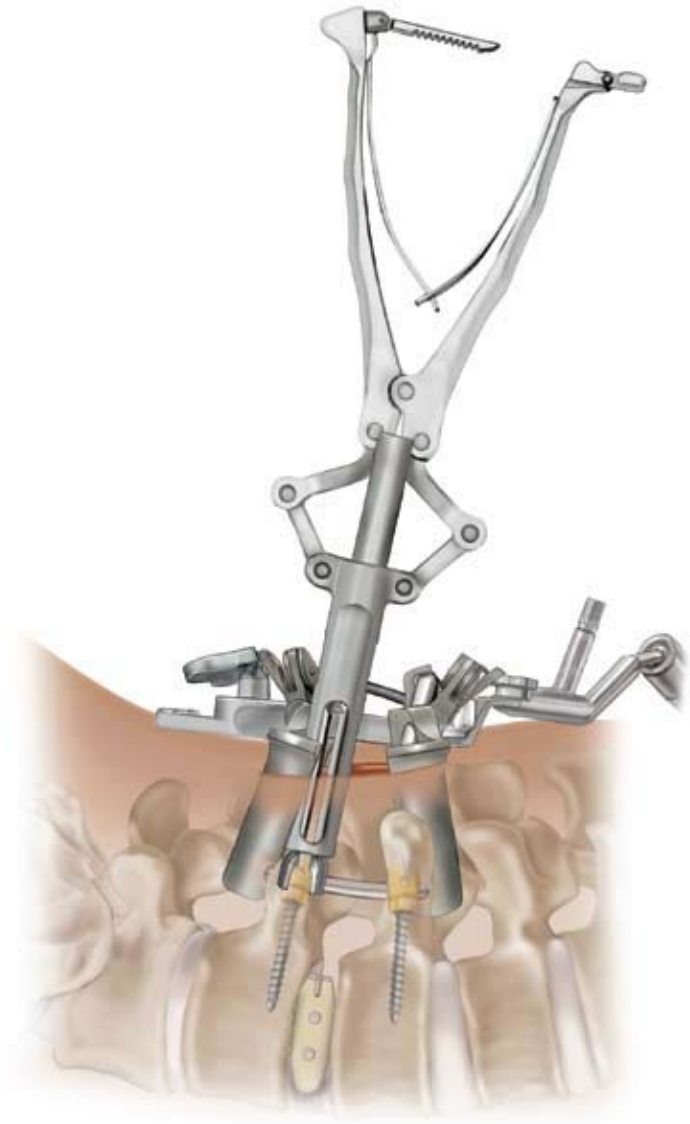


Figure 41

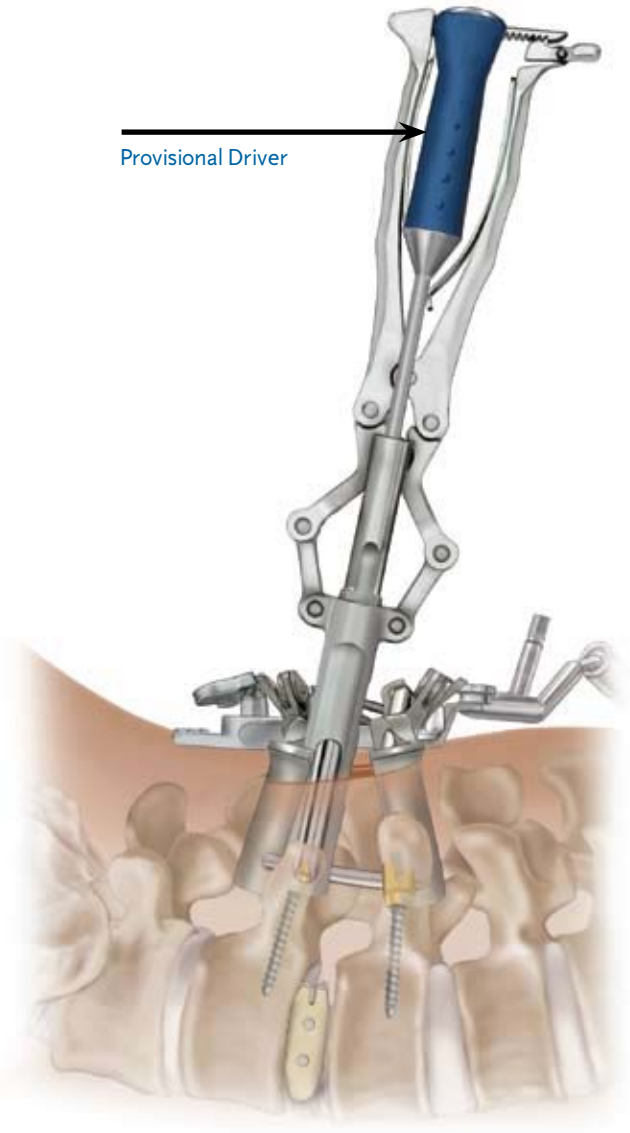


Figure 42

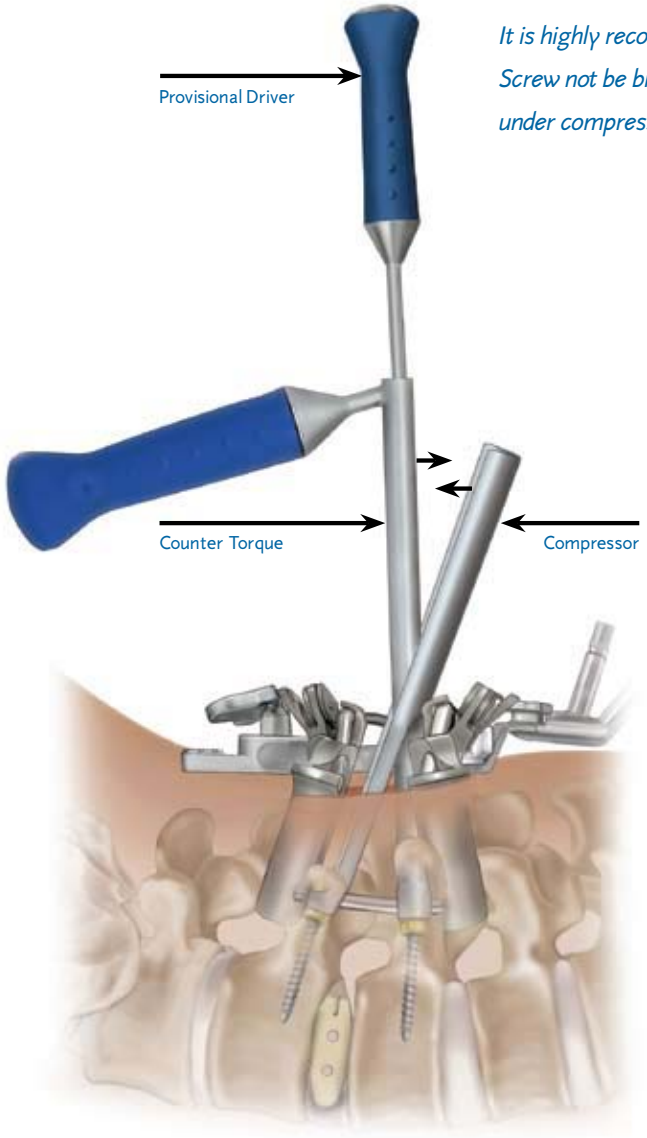
If either compression or distraction is needed, it should be performed at this time. In either maneuver, the Set Screw on one side of the motion segment should be provisionally tightened, with the Set Screw loose on the implant to be compressed or distracted. Compression or distraction will occur against the provisionally tightened implant.

The Provisional Driver may be used to temporarily lock and secure the Rod and implant construct. Usually, temporary fixation of the implant may be performed numerous times without damage to either the set screw or the implant threads. However, if the Set Screw has been cross-threaded, it must be replaced.

Care should be taken with all Set Screws to ensure that the feet of either the Compressor or the Distractor are placed securely against the implant body and not against the Set Screw (Figure 43).

Once satisfactory compression or distraction has been achieved, final tightening may be performed.

It is preferred that compression be released just prior to the Set Screws being broken off or final tightening. This technique will help ensure that the implant head and rod are normalized to one another and, thus, allow for the rod to be fully seated in the implant head during the final tightening step.



It is highly recommended that the Set Screw not be broken off or final tightened under compression.

Figure 43

When all implants are securely in place, final tightening and breakoff of the Set Screw head are done. Insert the Self-Retaining Break-Off Driver into the cannulated portion of the Counter Torque which should be positioned over the implant and Rod (Figure 44). The T-handle on the Driver provides adequate leverage for the breakoff of the Set Screw head (between 88 in-lb to 106 in-lb). The handle of the Counter Torque device should be held firmly to prevent torquing of the construct while the Set Screw is secured and sheared off.

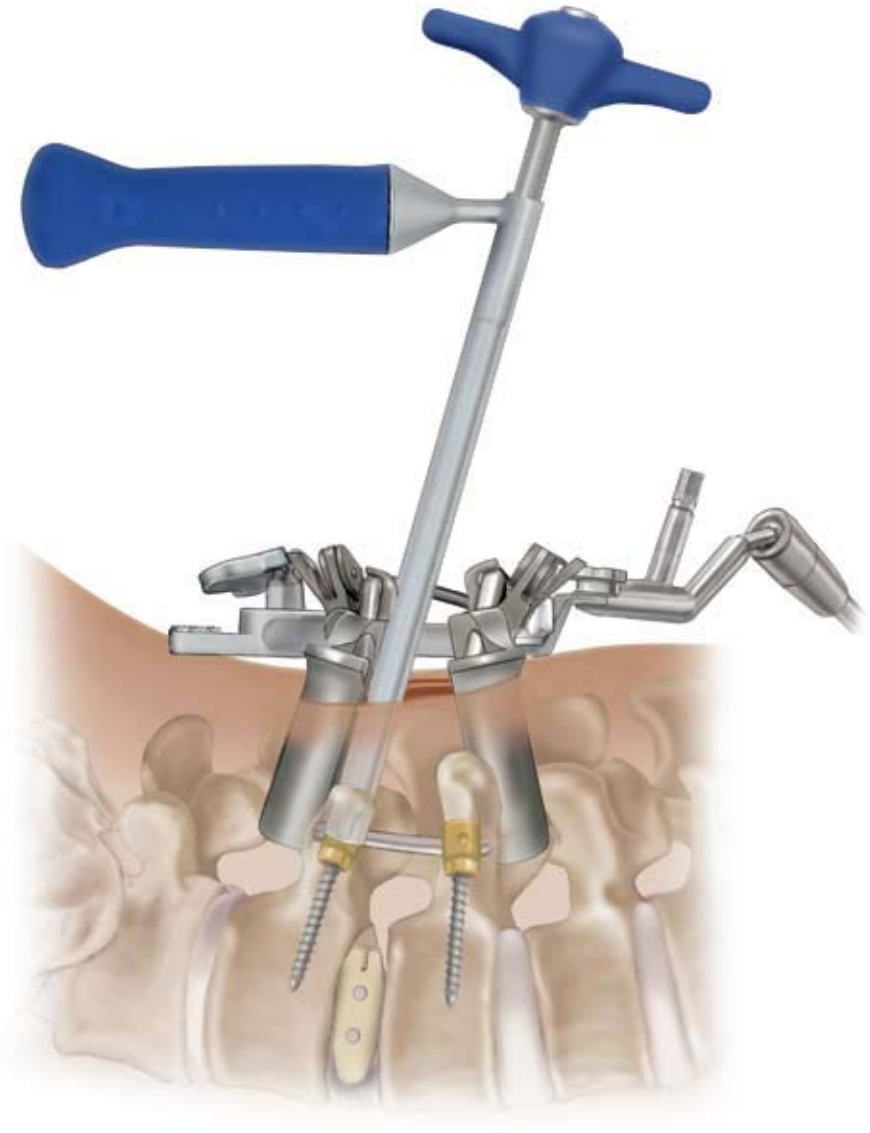


Figure 44

The CD HORIZON® LEGACY™ Set Screws may be removed using the T27 Obturator and the Break-off Driver. The T27 Obturator is inserted into the working end of the Break-off Driver, so that the knurled portion of the T27 Obturator is flush with the Driver. Insert the Obturator tip through the Counter Torque, which should be seated on the Screw, and into the Set Screw, turning counterclockwise until the Set Screw has been removed. The pedicle screws may be removed using the CD HORIZON® LEGACY™ Attachment Driver in connection with the Ratcheting Handle. First, attach the Ratcheting Handle to the modular end of the driver. Next, fully engage the hex end of the screwdriver into the screw head. Turn counterclockwise until the pedicle screws have been removed.

Important Product Information

IMPORTANT INFORMATION ON THE MAST QUADRANT™ RETRACTOR SYSTEM

DESCRIPTION

The MAST QUADRANT™ Retractor System is a tubular-based retraction system, designed to provide surgeons with the freedom to retract tissue through any combination of distracting or articulating the blades. The MAST QUADRANT™ System includes instruments used to access the spine by dilating the overlying tissues, as well serving as a retracting device to maintain the access. The system may be used in conjunction with microscopes, light sources, cameras, or other visualization aids. No warranties, express or implied, are made. Implied warranties of merchantability and fitness for a particular purpose or use are specifically excluded. See the MSD Catalog or price list for further information about warranties and limitations of liability.

INDICATIONS

The MAST QUADRANT™ Retractor System is intended to provide surgeons with instruments such as dilators, retractors, light sources and pedicle access needles used to perform a variety of spinal fixation procedures utilizing a minimally invasive approach.

The MAST QUADRANT™ Retractor System is indicated for visualization of the surgical field in any area of the body cut open during a surgical procedure. When used in the cervical, thoracic, or lumbar spine either from an anterior or posterior direction, for example, the MAST QUADRANT™ Retractors and accessories are intended to aid the surgeon's visualization of the surgical area and allow him/her to perform any type of surgical spinal procedure such as herniated disc repair, visualization of the circumferential decompression of the nerve roots, aiding in the search and removal of nucleus material, spinal fusion, or insertion of spinal implants.

CONTRAINDICATIONS

The MAST QUADRANT™ Retractor System has no known contraindications intrinsic to the device. No part of the device should ever be used in a cutting or tearing action. The device should not be inserted into body cavities, hollow organs, or natural body openings. There are no other known risks associated with the use of the device outside of the normal and expected risks of surgery.

DIRECTIONS FOR USE

Specific instructions for use depend on patient considerations. Therefore, Medtronic Sofamor Danek cannot provide a surgical procedure that will be applicable to all situations. Any available surgical procedure brochure or manual for the MAST QUADRANT™ Retractor System and for all instruments should be reviewed prior to use. The only critical directions for use are to insert the cannula or dilators and position them in the surgical wound prior to insertion of the device. Once visualization assistance is obtained, the surgeon can then complete the planned surgical procedure.

POSSIBLE ADVERSE EVENTS

Risks possibly associated with the use of the MAST QUADRANT™ Retractor System are similar to those associated with any surgery to the planned area of Retractor use. The most frequently stated risks are bleeding, neurological damage, damage to the surrounding soft tissue, and infection. Each of these risks has also been used to describe the risks associated with conventional surgical intervention. Additional risks associated with the use of the MAST QUADRANT™ Retractors, other than those described for spinal surgery in general, may be instrument malfunction, such as bending, fragmentation, loosening, and/or breakage (whole or partial). Also, the surgery may not be effective. Similar risks are associated with the system use in other parts of the body.

Additional risks are attendant to surgery and the use of anesthesia, etc., and are not directly related to the use of the instruments. These include, but are not limited to, pneumonia, phlebitis, embolism, wound infection, blood loss with or without anemia.

WARNINGS AND PRECAUTIONS

A successful result is not always achieved in every surgical case. This fact is especially true in orthopaedic or neuro-surgery cases where many extenuating circumstances may compromise the results.

In the event of technical complications, the surgical technique can be converted to an open procedure and the surgery completed.

Preoperative and operating procedures, including knowledge of surgical techniques are important considerations in the successful utilization of the system by the surgeon. Further, the proper selection of the patient and the compliance of the patient will greatly affect the results.

In addition, the following should be considered:

1. This device is a delicate instrument. It should **NOT** be dropped, bent at a sharp angle, or exposed to any type of gamma radiation.
2. Additional accessories should be available at the time of surgery in case of possible contamination due to mishandling or removing the devices from the sterile field.
3. Components of the system should be thoroughly inspected during cleaning prior to surgery for possible damage.
4. Proper, secure component connections must be made to assure proper functioning of the optical, irrigation, and aspiration aspects of the device.

CAUTION – High Temperature

Typically, a light source is used in conjunction with the MAST QUADRANT™ Retractors. The recommended light source utilizes 100W light sources and 5mm fiber optic cables. Use of larger cables and/or higher wattage light sources may result in high temperatures on the metal connection to the light cable, which may result in injury to patient or staff and damage to product. Reduce intensity levels on high watt light sources/large light cables and take precautions to protect patient and staff from injury.

!USA For US Audiences Only

CAUTION: FEDERAL LAW (USA) RESTRICTS THESE DEVICES TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

Cleaning Procedure: Exterior cleaning is essential prior to any sterilization procedure. Dry thoroughly. Without the removal of all contaminants from the surface, the sterilization medium will not contact the surfaces.

WARNING: DO NOT USE ULTRASONIC CLEANER OR ABRASIVES DURING THE CLEANING PROCESS.

STERILIZATION

The non-sterile instruments and instruments which are re-usable are recommended to be steam sterilized by the hospital using one of the following methods:

If the products described in this document are sterilized by the hospital in a tray or case, it must be sterilized in a tray or case provided by Medtronic Sofamor Danek.

Some accessories and Retractors are supplied sterile and non-reusable. Sterile product will be clearly labeled as such on the package label. The sterility of the product supplied sterile can only be assured if the packaging is intact.

NOTE: The following note applies to the process parameter identified with the * below: For use of this product and Retractors outside the United States, some non-U.S. Health Care Authorities recommend sterilization according to these parameters so as to minimize the potential risk of transmission of Creutzfeldt-Jakob disease, especially of surgical Retractors that could come onto contact with the central nervous system

Method:	Steam	Steam	Steam
Cycle:	Pre-vacuum	Gravity	Gravity*
Temperature:	270°F (132°C)	250°F (121°C)	273°F (134°C)*
Exposure Time:	4 minutes	60 minutes	20 minutes*

The MAST QUADRANT™ Retractors should be thoroughly cleaned prior to sterilization.
CAUTION: Do not immerse or rinse light sources used with these instruments in cold water or any other liquid to accelerate cooling.

PRODUCT COMPLAINT

Any Health Care Professional (e.g., customer or user of this system of products), who has any complaints or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify the distributor, Medtronic Sofamor Danek. Further, if this system ever "malfunctions," (i.e., does not meet any of its performance specifications or otherwise does not perform as intended), or is suspected of doing so, the distributor should be notified immediately. If any Medtronic Sofamor Danek product ever "malfunctions" and may have caused or contributed to the death or serious injury of a patient, the distributor should be notified immediately by telephone, fax, or written correspondence. When filing a complaint, please provide the component(s) name and number, lot number(s), your name and address, the nature of the complaint, and notification of whether a written report from the distributor is requested.

Please contact Customer Service or your Medtronic Sales Representative for the most up-to-date version of the package insert.

EC REP

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Please contact your Medtronic Sales Representative for package inserts for other products described in this surgical technique.

listen. respond. deliver.

The surgical technique shown is for illustrative purposes only. The technique(s) actually employed in each case will always depend upon the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient. Please see the package insert for the complete list of indications, warnings, precautions, and other medical information.

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IRN2889/066 REVIRN7822-2.0-03/128

NIM-ECLIPSE™ Spinal System is manufactured by Axon Systems, Inc.
Distributed by Medtronic's Spinal and Biologics Business.

Reference:

[1] Fessler R, Khoo L. Minimally Invasive Cervical Microendoscopic Foraminotomy: An Initial Clinical Experience. *Neurosurgery Focus*. 13(2): Article 5, 2002.

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