DePuy Spine Inc.
a Johnson & Johnson company

never stop moving™

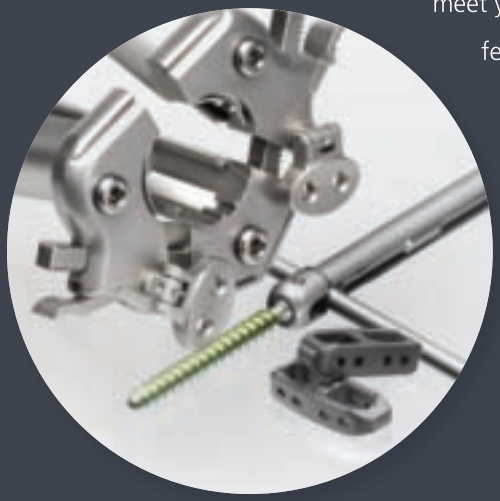
Surgical Technique Guide

MIS Lateral Platform

INTRODUCTION

With the growing prevalence of minimally invasive surgical (MIS) approaches in the spine, the lateral technique has emerged as a MIS procedure that allows for the treatment of spinal disorders while at the same time minimizing the disruption to surrounding structures. Built upon the existing fundamentals of surgery, the surgical technique described herein utilizes a lateral, retroperitoneal approach that allows for clear access to the intervertebral disc while minimizing muscular disruption and trauma to nearby structures (e.g. muscle groups posteriorly or organs and blood vessels anteriorly). This technique can be used to address many degenerative, deformity or other lumbar conditions that may benefit from a minimally invasive approach.

The MIS Lateral Platform leverages DePuy Spine's proven experience in designing products that treat a wide range of pathologies from the simple to the complex. This system was developed in close collaboration with top experts in the fields of neurosurgery and orthopaedic surgery to provide a comprehensive solution to meet your lateral needs. The complete platform features the **PIPELINE® LS Lateral Access System, COUGAR® LS Lateral Cage System, and VIPER®2 System.** Neuromonitoring may be considered when performing a lateral surgical approach. This innovative, integrated platform of products provides controlled access, simplified cage insertion, and versatile posterior fixation options.



Turning MIS on its side
with an integrated lateral platform.

CONTENTS

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INDICATIONS FOR USE

The COUGAR® LS Lateral Cage System is indicated for use in the thoracolumbar spine (i.e., T1 to L5) to replace a diseased vertebral body resected or excised for the treatment of tumors, to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. This system is also indicated for treating fractures of the thoracic and lumbar spine. The system is designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column even in the absence of fusion for a prolonged period. When used as a vertebral body replacement device, this system is intended for use with DePuy Spine supplemental internal fixation.

The COUGAR LS Lateral Cage System is also indicated for intervertebral body fusion with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These implants may be implanted via an open or a minimally invasive lateral approach. When used as an interbody fusion device, this system is intended for use with DePuy Spine supplemental internal fixation.

The COUGAR LS Lateral Cage System is intended for use with DePuy Spine supplemental fixation.

Refer to the COUGAR LS Lateral Cage Package Insert Instructions for complete information on contraindications, warnings, precautions and adverse events associated with the use of the device.

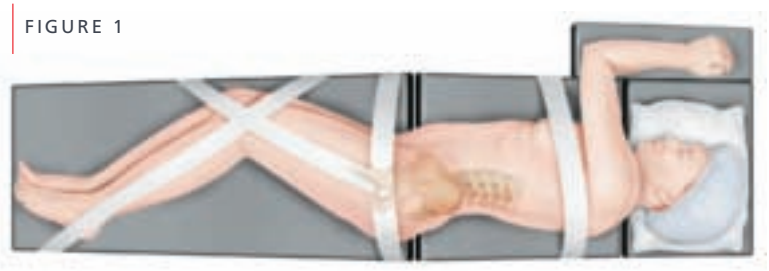
PATIENT POSITIONING

SURGICAL CONSIDERATIONS

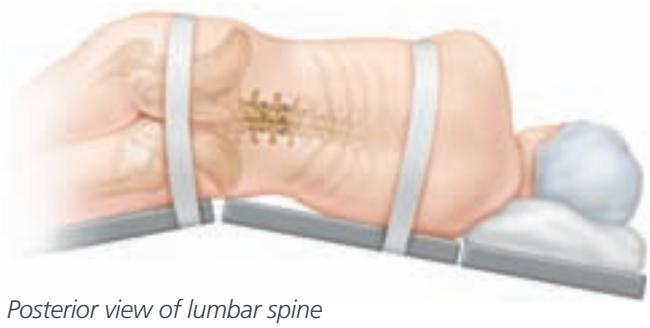
This approach enables the spine to be accessed via a lateral retroperitoneal approach. The anatomic landmarks the surgeon should consider are the iliac crest, the ribs and the lateral border of the erector spinae muscles.

If intraoperative neuromonitoring is to be used, a trained neurophysiologist or technician should apply all desired electrodes prior to patient positioning. The patient is placed on a bendable surgical table in a direct lateral decubitus (90°) position so that the iliac crest is directly over the table break. Flexion of the table can be used to aid in the opening of the space between the 12th rib and the iliac crest. Once the desired position is achieved, secure the patient (Figure 1).

FIGURE 1



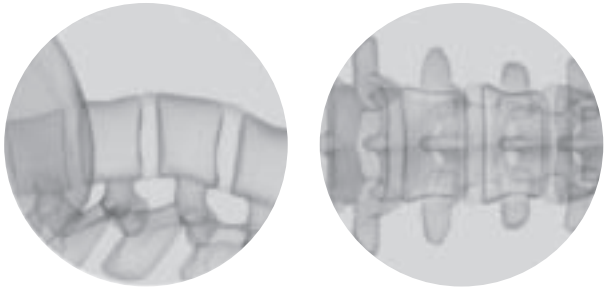
Lateral view of lumbar spine



Posterior view of lumbar spine

Using fluoroscopy to verify location, the surgical table should be flexed to increase the distance between the iliac crest and rib cage in order to gain direct access to the disc (Figure 2). This configuration ensures the pelvis tilts away from the spine allowing access to all lumbar levels, particularly L4–L5.

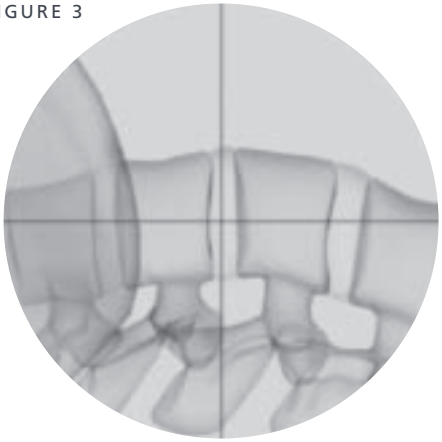
FIGURE 2



ANATOMIC LANDMARK IDENTIFICATION & INITIAL INCISIONS

Following preparation, the disc space is identified using lateral fluoroscopy. Do this by crossing and centering two K-wires over the affected disc space. Mark the skin at the intersection of the K-wires to indicate the location of the skin incision for the operative corridor (Figure 3).

FIGURE 3



APPROACH

To approach the disc space, a vertical to slightly oblique skin incision is made over the target level (Figure 4). A monopolar cautery may be used for hemostatis and a small retractor is used for initial dissection of the skin and subcutaneous tissues.

Visualize the external abdominal oblique fascia and begin blunt dissection through the muscle.

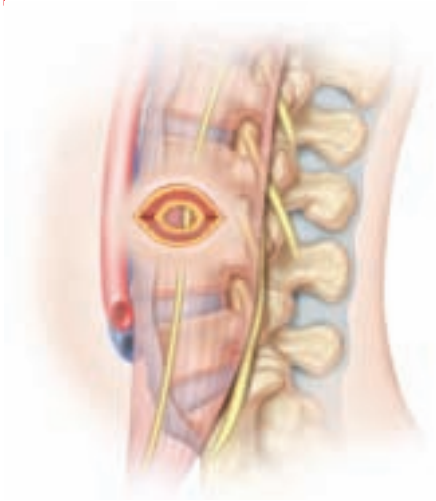
After dissecting through both the external and internal oblique abdominal muscles, bluntly penetrate the transversalis fascia exposing the retroperitoneal fat.

Once inside the retroperitoneal space, palpation or visualization of the psoas muscle is necessary prior to dilator introduction.

TIP:

All dissection should be done in line with the muscle fibers.

FIGURE 4



SEQUENTIAL DILATION

Sequential dilation is performed by passing the next largest dilator over the previously inserted dilator. A twisting motion should be used to advance each dilator. Once all dilators are introduced, fluoroscopy should be used to verify position and that the dilators are flush with the vertebral body (Figure 8).

FIGURE 8

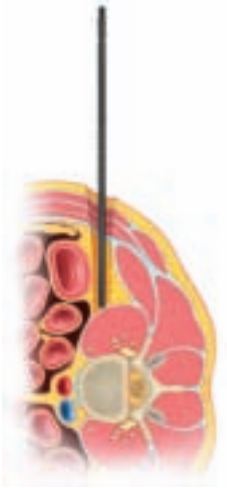
NOTE:

There are four (4) dilators included in the set; 5mm, 10mm, 14mm and 18mm.

Measure the working depth off of the dilator. The depth can be taken at the point where the skin contacts the second, third or fourth dilator.

ACCESS

FIGURE 5



INITIAL AND SEQUENTIAL DILATION

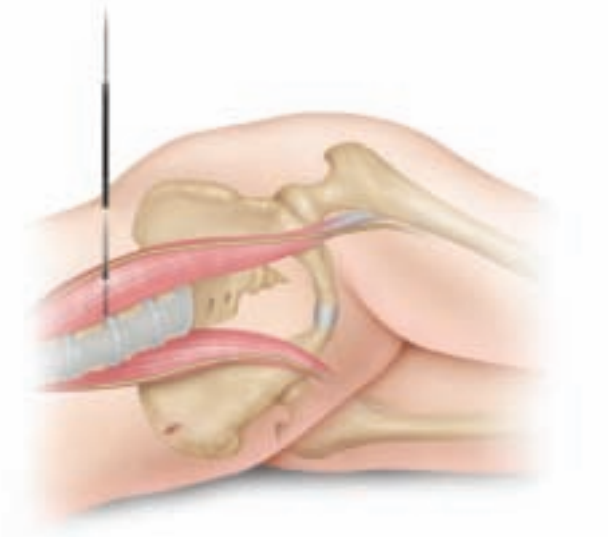
Introduce the first 5mm dilator through the incision to the psoas muscle (Figure 5).

Once through the psoas, confirm the initial dilator position using fluoroscopy. The preferred position on the lateral disc is just anterior to the midsection of the vertebral body (Figure 6). A lateral fluoroscopic picture should be taken to confirm position of dilator.

NOTE:

Clear visualization of the psoas and nerves or use of a triggered EMG neuromonitoring device may be used when gaining access to the targeted disc space.

FIGURE 6



Insert the guidewire through the first dilator into the disc space. Confirm that the guidewire is positioned approximately halfway into the disc space fluoroscopically (Figure 7).

FIGURE 7

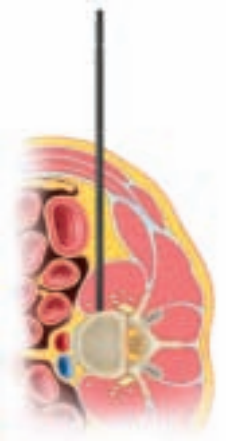


FIGURE 9

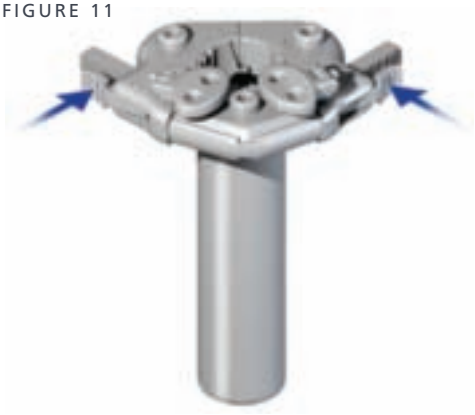
RETRACTOR ASSEMBLY

The retractor comes in three (3) individual sections with three (3) individual telescoping blades (Figure 9).

FIGURE 10

Insert the telescoping blades into the three sections of the retractor. Ensure the blades are properly seated by engaging one tooth of the ratcheting mechanism. This can be confirmed with both tactile and audible feedback (Figure 10).

FIGURE 11



Assemble the retractor by placing each of the racks into the slots of the corresponding sections by lining them up and sliding together. Depress the release buttons during these steps in order to disengage the ratchet feature (Figure 11).

SETTING RETRACTOR DEPTH

FIGURE 12

The retractor can be deployed to the measured working depth using the blade depth tower (Figure 12).

Rotate the ring on the blade depth tower until the top surface of the ring corresponds to the desired depth as etched.

Align the blade depth tower with the telescoping blades of the retractor and press downward to deploy the blades (Figure 13).

FIGURE 13

RETRACTOR INSERTION

The retractor can be inserted over the dilators, with the V-shaped section to the back, by gently rotating the retractor back and forth until the retractor flange reaches the skin surface or the telescoping blades of the retractor reach the spine. Irrigating the outer surfaces of the retractor may assist in inserting the device.

At this time care should be taken to ensure that no nerve roots are in the area prior to beginning interbody preparation. If the retractor needs to be expanded for better visualization, twisting the skate key will open the retractor in 1mm increments.

Use bipolar cautery to clear muscle from the lateral annulus.

Place the retractor in the final position by orientating the section of the retractor containing the racks facing posteriorly as shown (Figure 14).

FIGURE 14

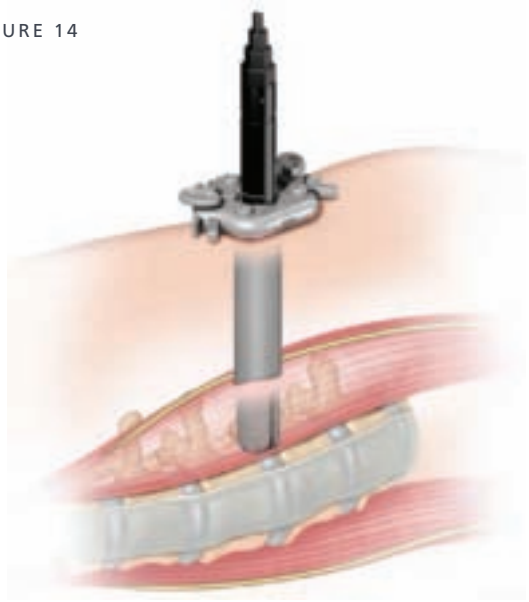
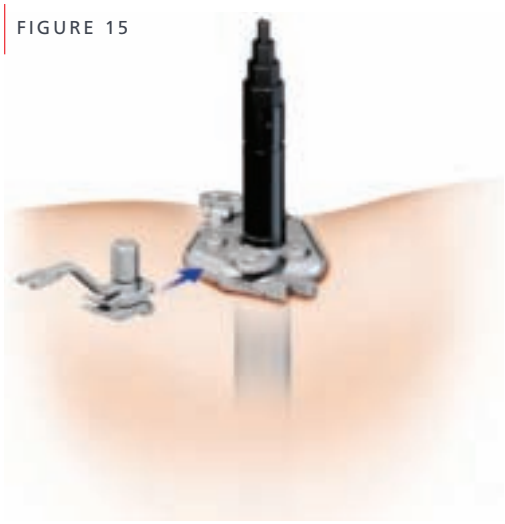


FIGURE 15



RIGID ARM ATTACHMENT

On the anterior side of the patient, position a bed rail clamp on the table rail approximate to the mid or upper thigh to facilitate subsequent placement of the rigid arm assembly (Figure 15). Once the surgical preparation and draping are completed, the sterile rigid arm assembly is attached to the table via the bed rail clamp with the aid of the circulating nurse.

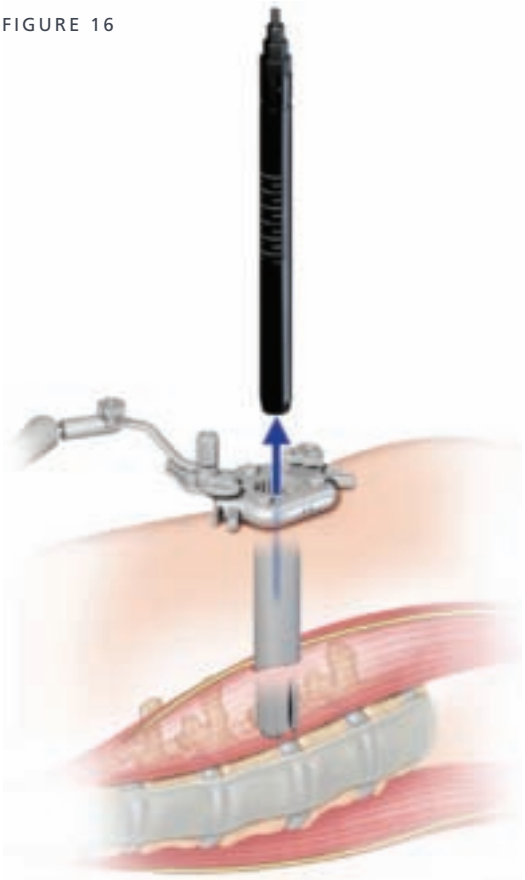
Connect the rigid arm attachment to the retractor using the universal connection slot. Note that there are two (2) universal connection slots available, anterior or posterior, depending on anatomical limitations or surgeon preference.

Once the rigid arm attachment is secure, the rigid arm can be connected by inserting the rigid arm attachment fork to the end and tightening the thumb lever. This assembly will hold the retractor in place for the remainder of the procedure.

The rigid arm assembly can be loosened at any point during the procedure to allow the retractor to be angled for an alternative field of view.

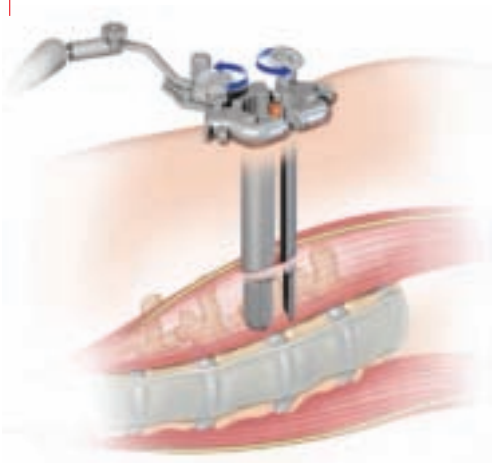
Once the retractor has been fully positioned and the rigid arm assembly has been tightened, the dilators can be removed (Figure 16).

FIGURE 16



INITIAL EXPANSION AND TOEING

FIGURE 17



Expand the retractor by rotating the skate keys as indicated by the etchings on the top of the retractor to open (Figure 17). Both sections can be opened independently of each other. Depress the locking buttons to release the sections.

The skate keys can be folded out of the way anytime during the procedure to facilitate visualization.

Toeing of the blades can be performed with the blade toe driver. Place the driver into the drive gears within the section to toe and rotate clockwise to toe outward and counter-clockwise to toe back to the origin (Figure 18).

Once the retractor is in position the fixation pin may be placed (Figure 19).

FIGURE 18

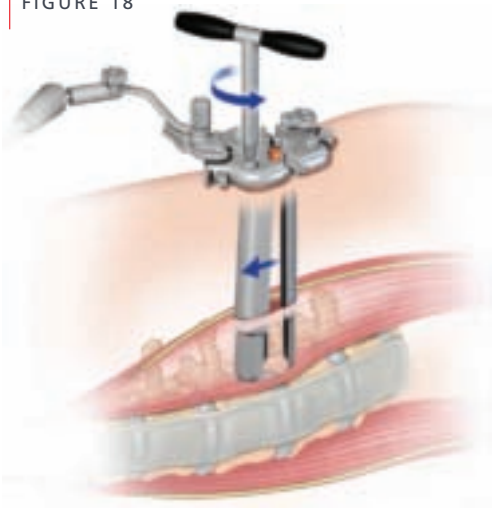
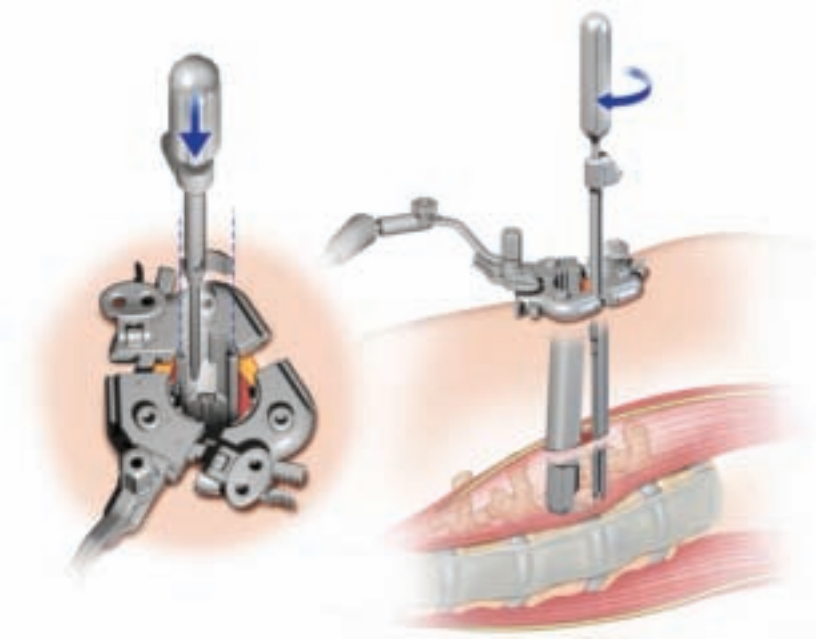


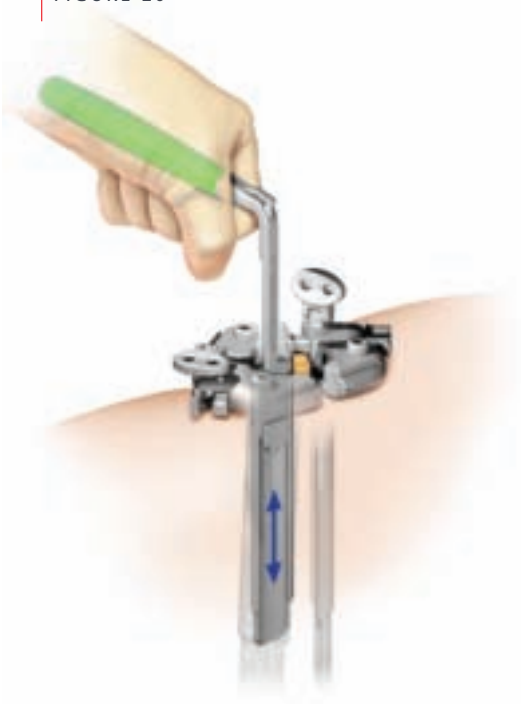
FIGURE 19



NOTE:

Return the toeing blades to original position at the end of the procedure to facilitate removal of the retractor from the working space and ensure no muscle or other tissues are caught between the collapsed blades.

FIGURE 20



TELESCOPING BLADE ADJUSTMENT

After the retractor is expanded the blade adjuster may be inserted into the telescoping blade track and used to deploy the telescoping blades further to prevent soft tissue creep in the working space. A small cobb elevator or equivalent instrument may be utilized to retract the soft tissue while deploying the telescoping blades.

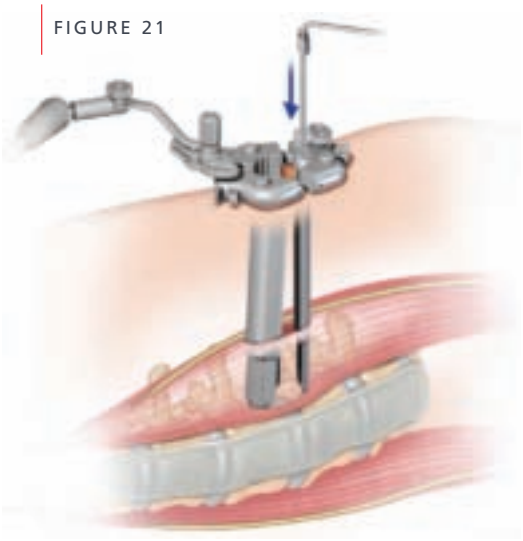
Insert the blade adjuster instrument into the telescoping blade track until the instrument tip is flush with the top of the telescoping blade.

Squeeze and hold the trigger of the blade adjuster instrument to relieve the ratchet mechanism and lock the blade adjuster instrument to the telescoping blade.

Once the two items are locked together the blade adjuster instrument may be pulled or pushed along the telescoping blade track to position the telescoping blade (Figure 20). Release the trigger to unlock the two items.

The telescoping blades can also be removed or adjusted upward at any point during the surgery.

FIGURE 21



LIGHT SOURCE ATTACHMENT

A light source may also be attached to any one of the telescoping blade tracks as shown (Figure 21).

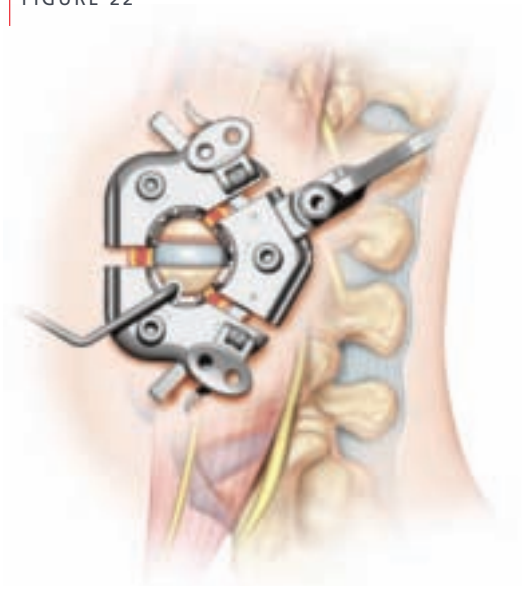
ANTERIOR BLADE

If needed, an anterior blade may be attached to the retractor to prevent soft tissue creep though the anterior side of the retractor.

Open the retractor to a position wide enough to accommodate the anterior blade as indicated by etchings on the racks of the retractor.

ANNULOTOMY AND DISC SPACE PREPARATION

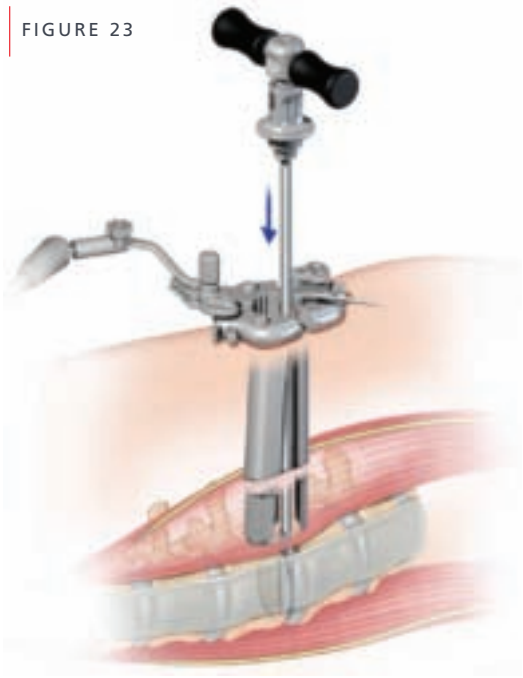
FIGURE 22



Once appropriate access to the disc space has been established and no neurovascular structures are seen in the bottom of the retractor an annulotomy can be made with the annulotomy knife. Pass the cobb elevator along both endplates completely through the contralateral annulus. This step is critical to facilitate distraction of the disc space (Figure 22).

Use pituitaries, curettes, disc cutters, scrapers, rasps and other discectomy instruments to thoroughly remove the disc and prepare the endplates for fusion.

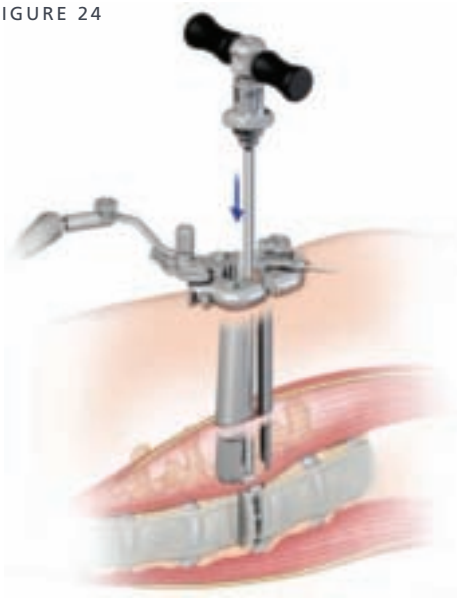
FIGURE 23



Care should be taken to make sure all instruments are used in a fashion parallel to the endplate (Figure 23), which can be checked by fluoroscope in the A/P plane of the patient.

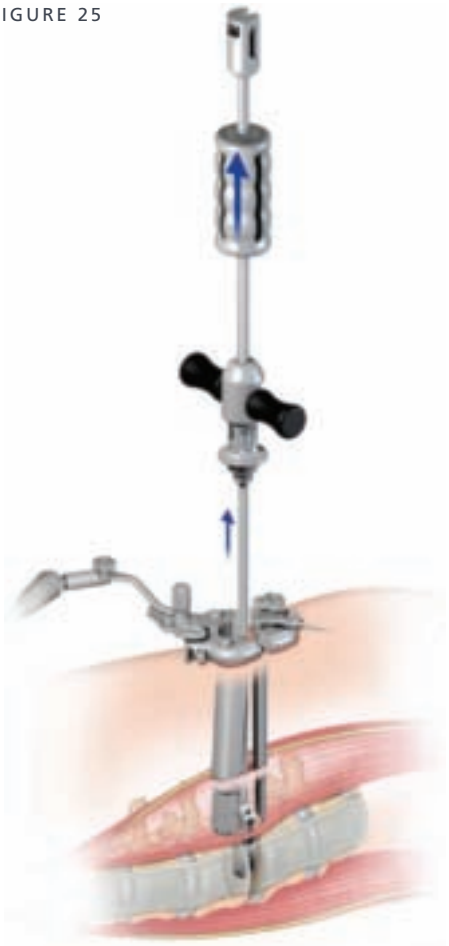
IMPLANT SIZING

FIGURE 24



Use the COUGAR LS Lateral cage spreaders to distract the disc space and gauge the appropriately sized trial. Choose the appropriately sized trial. Under AP fluoroscopy, gently impact the trial into the disc space until centered. Verify proper anterior / posterior position using lateral fluoroscopy (Figure 24).

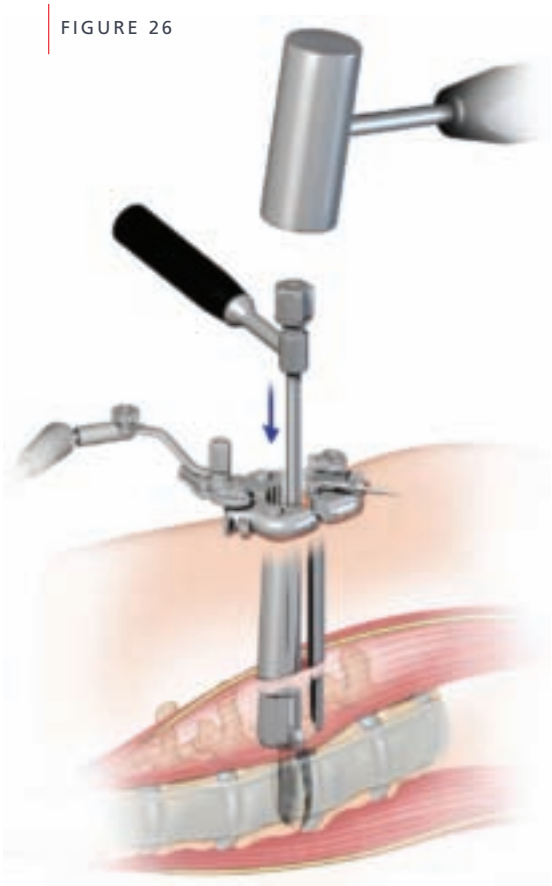
FIGURE 25



If satisfied with placement and fit of trial, remove the trial from the disc space (Figure 25).

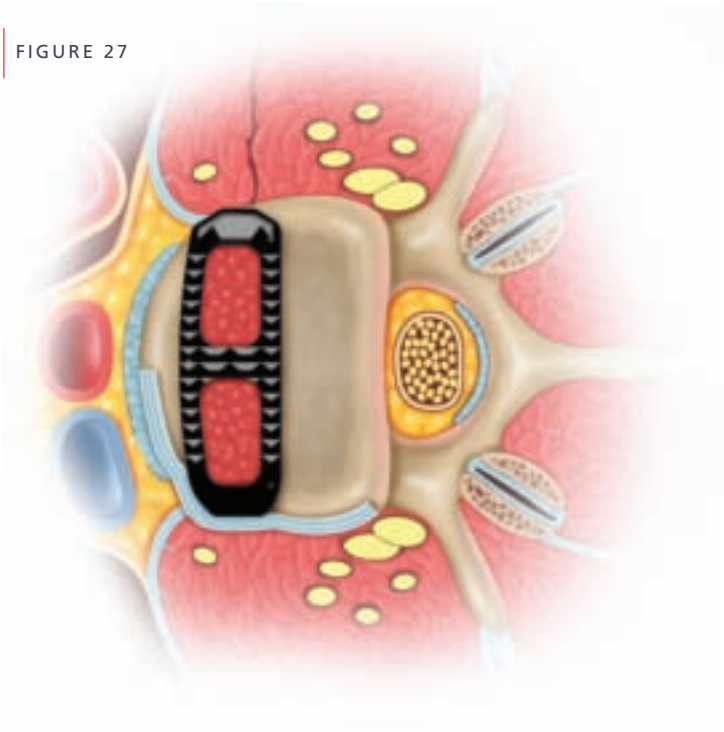
IMPLANT PLACEMENT

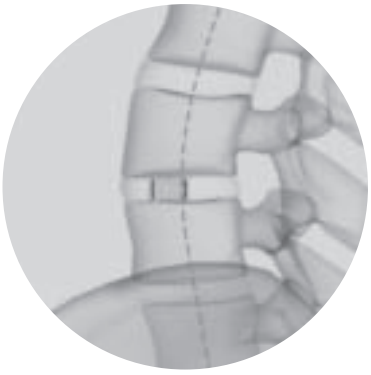
FIGURE 26



Select the corresponding implant, fill the implant with autogenous bone graft material and attach to the inserter. Gently impact the implant into the disc space while monitoring placement under AP fluoroscopy (Figure 26). Ideal placement of the implant is centered across the disc space from a medial lateral perspective and between the anterior third and middle third of the disc space from an anterior/posterior perspective (Figure 27).

FIGURE 27

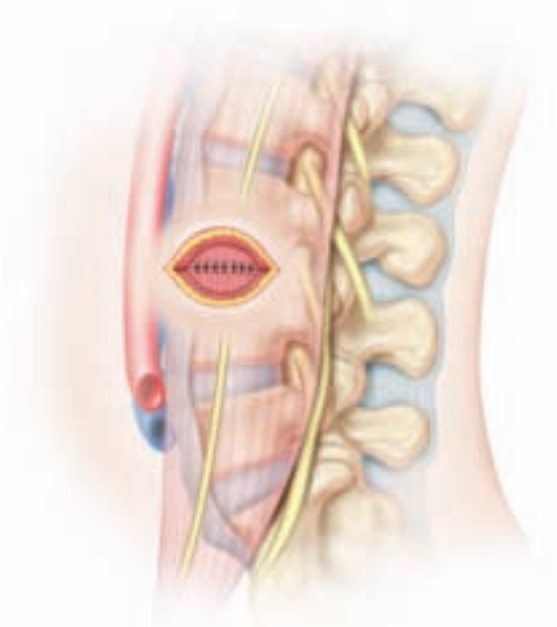




NOTE:

Prior to removing retractor, remove fixation pin, untoe blades and collapse retractor.

FIGURE 28



CLOSURE

Once the procedure is completed, remove the retractor using direct visualization to verify the absence of significant bleeding in the disc space or psoas muscle (Figure 28). The COUGAR LS Lateral Cage System is intended for use with DePuy Spine instrumentation.

- Refer to the Surgical Technique Manuals for VIPER System and EXPEDIUM Spine System and the Package Inserts of the COUGAR LS Lateral Cage System, VIPER System and EXPEDIUM Spine System for detailed instructions for use, complete information on contraindications, warnings, precautions and adverse events associated with the use of the systems.

REVISION

In the event that a lateral cage needs to be revised or removed from a patient, the surgeon should first remove any bone or materials holding the cage to the fusion site. The surgeon should then take the lateral cage inserter and place the male end of the inserter into the female end of the lateral cage and re-thread the inserter. Next, attach the slap hammer to the inserter and remove the cage.

PIPELINE® L.S

Lateral Access System

Independent blades for controlled, distal expansion

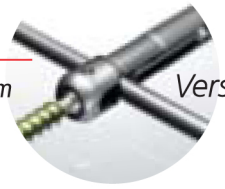
COUGAR® L.S

Lateral Cage System

Self-distracting tip for simplified cage insertion

VIPER® 2

EXPEDIUM® Spine System



Versatile rod insertion options for complex and degenerative pathologies

EXPEDIUM® SPINE SYSTEM

Uncompromising Versatility
Confidence By Design
Redefining Control

INDICATIONS

The COUGAR® LS Lateral Cage System is indicated for use in the thoracolumbar spine (i.e., T1 to L5) to replace a diseased vertebral body resected or excised for the treatment of tumors, to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. This system is also indicated for treating fractures of the thoracic and lumbar spine. The system is designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column even in the absence of fusion for a prolonged period. When used as a vertebral body replacement device, this system is intended for use with DePuy Spine supplemental internal fixation.

The COUGAR LS Lateral Cage System is also indicated for intervertebral body fusion with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These implants may be implanted via an open or a minimally invasive lateral approach. When used as an interbody fusion device, this system is intended for use with DePuy Spine supplemental internal fixation.

The PIPELINE® LS Lateral Access System is intended for use with the COUGAR LS Lateral Cage System, which is indicated for use in the thoracolumbar spine (i.e., T1 to L5) to replace a diseased vertebral body resected or excised for the treatment of tumors, to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The COUGAR LS Lateral Cage System is also indicated for treating fractures of the thoracic and lumbar spine. It is designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column even in the absence of fusion for a prolonged period. When used as a vertebral body replacement device, this system is intended for use with DePuy Spine supplemental internal fixation. The COUGAR LS Lateral Cage System is also indicated for intervertebral body fusion with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These implants may be implanted via an open or a minimally invasive lateral approach. When used as an interbody fusion device, this system is intended for use with DePuy Spine supplemental internal fixation.

The VIPER® and EXPEDIUM® and Spine Systems are intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine.

The VIPER and EXPEDIUM Spine System metallic components are intended for noncervical pedicle fixation and nonpedicle fixation for fusion for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor, pseudoarthrosis; and failed previous fusion in skeletally mature patients.

When used in a posterior percutaneous approach with MIS instrumentation, the VIPER System metallic components are intended for noncervical pedicle fixation and nonpedicle fixation for fusion for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor, pseudoarthrosis; and failed previous fusion in skeletally mature patients.

The VIPER and EXPEDIUM PEEK rods are only indicated for fusion procedures for spinal stenosis with instability (no greater than Grade I spondylolisthesis) from L1-S1 in skeletally mature patients.

Limited Warranty and Disclaimer: DePuy Spine products are sold with a limited warranty to the original purchaser against defects in workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed.

WARNING: In the USA, this product has labeling limitations. See package insert for complete information.

CAUTION: USA Law restricts these devices to sale by or on the order of a physician.

Not all products are currently available in all markets.

To order, call DePuy Spine Customer Service (1-800-227-6633).

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