Surgical Technique
Guide
With the growing prevalence of minimally invasive surgical (MIS) approaches in the spine, the lateral technique has emerged as an 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.
Device Description

The COUGAR® LS Lateral Cage System consists of the PEEK/carbon fiber composite cages (CFRP). Cages are available in parallel or lordotic configurations and are available in various sizes to match patient anatomy. The cage structure is radiolucent with tantalum x-ray wire so that healing can be assessed by normal radiographic methods. The cages have teeth that resist rotation and migration and have cavities to accept packing of autogenous bone graft.

The implants may be utilized in either an open or minimally invasive surgical approach. The implants are placed using a lateral surgical approach.
Patient Positioning

Surgical Considerations

A lateral, retroperitoneal approach will be used to access the spine and perform a minimally invasive lateral interbody fusion. The anatomic landmarks the surgeon should consider are the iliac crest, the ribs and the lateral border of the erector spinae muscles.

Adequate consideration should be given to proper patient positioning. 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 right lateral decubitus (90°) position. 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).

NOTE: Position the patient so that the table break is located between the top of the iliac crest and greater trochanter. This helps to ensure the pelvis tilts away from the spine when the table is bent and facilitates access to all lumbar levels, particularly L4–L5.
Patient Positioning

Once the patient is secured, adjust the table to ensure true AP and Lateral fluoro images of the desired levels (Figure 2).

Anatomic Landmark Identification & Initial Incisions

Following preparation, the disc space is identified using lateral fluoroscopy. Use K wires to locate and mark the following anatomic landmarks: midline of the disc space plane, anterior margin of the disc space and posterior margin of the disc space (Figure 3).

NOTE: It is recommended to extend the skin marking for the midline of the disc space plane to facilitate alignment of the c-arm.
Approach

To approach the disc space, a transverse incision is made over the target level (Figure 4). A monopolar cautery may be used for hemostasis 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.
**Initial and Sequential Dilation**

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

Once through the psoas, confirm the initial dilator position using lateral fluoroscopy. The preferred position on the lateral disc is midline to the vertebral body (Figure 6). Use AP fluoroscopy to confirm that the initial dilator is flush with the annulus.

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).

**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.
Sequential Dilation

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

Measure the working depth off of the dilator. The depth can be taken at the highest level of skin around the dilators.

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

Retractor Assembly

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

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 9).

Assemble the retractor by placing each of the racks into the slots of the corresponding sections by lining them up and sliding together (Figure 10). Depress the release buttons during these steps in order to disengage the ratchet feature (Figure 11).
Access

Setting Retractor Depth

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).

NOTE: Confirm that the retractor blades are fully closed and rigid, forming a complete tubular circle before setting the depth and inserting the retractor over the dilators. This will maintain the shape as the retractor is passed through the tissue.
Access

Retractor Insertion

Insert the retractor over the dilators, with the V-shaped section to the back. Gently rotate 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.

Place the retractor in the final position by orientating the section of the retractor containing the racks facing posteriorly as shown (Figure 15). Ensure that the retractor is perpendicular and centered within the disc space.
Access

Rigid Arm Attachment

On the anterior side of the patient, position a bed rail clamp on the table rail out of the way of the c-arm (Figure 16). 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 posterior rail of the retractor using the universal connection slot.

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 17). The guidewire should remain in place.
Access

**Initial Expansion and Toeing**

Expand the retractor by rotating the skate keys as indicated by the etchings on the top of the retractor (Figure 18). Both sections can be opened in 1 mm increments independently of each other. The skate keys can be folded out of the way anytime during the procedure to facilitate visualization.

Prior to beginning interbody preparation, care should be taken to ensure that no nerve roots are in the area. Additionally, soft tissue can be cleared using a Penfield or laproscopic kitners.

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 19).

Once the retractor is in position the fixation pin may be placed (Figure 20).

**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.
Access

**Telescoping Blade Adjustment**

After the retractor is expanded, the telescoping blades can be adjusted further to prevent soft tissue creep in the working space.

In order to adjust the length of 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.

**Shortening the Retractor Blades**

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 21). Release the trigger to unlock the two items.

**Lengthening the Retractor Blades**

The blade adjuster instrument can be used to push the telescoping blade along the blade track. Engagement of the ratchet mechanism with the blade adjustment tool is only needed to pull back on or shorten the retractor blade.

The tissue sweeper, or an equivalent instrument, may be utilized to retract the soft tissue while deploying the telescoping blades.
Access

**Light Source Attachment**

A light source may also be attached to any one of the telescoping blade tracks as shown (Figure 22).

**Anterior Blade**

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

Open the retractor to a position wide enough to accommodate the anterior blade.
Annulotomy and Disc Space Preparation

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. Under fluoroscopy, carefully pass the Cobb elevator along both endplates completely through to the contralateral annulus.

Use pituitaries, curettes, disc cutters, scrapers, rasps and other discectomy instruments to thoroughly remove the disc and prepare the endplates for fusion. Care should be taken to ensure all instruments are used in a fashion parallel to the endplate, which can be checked under AP fluoroscopy.

Use the COUGAR LS Lateral cage spreaders to distract the disc space and gauge the appropriately sized trial (Figure 23).

NOTE: Release of the contralateral annulus is critical to facilitate distraction of the disc space.
Implant Sizing

Under AP fluoroscopy, gently impact the appropriately sized trial into the disc space until centered (Figure 24). Verify proper anterior/posterior position using lateral fluoroscopy.

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

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).

FIGURE 26
Implant Placement

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).

Access to L4/5 Level

For patients with an extremely high iliac crest, the COUGAR LS Angled Instrument System is available to facilitate disc space preparation and cage placement (Figure 28).
Implant Placement

**Collapsed Disc Spaces**

The insertion blades can be used to facilitate placement of the cage into collapsed disc spaces.

Once preparation of disc space is complete, the insertion blades can be placed all the way across the disc space so that they cover the entire width of the vertebral body (Figure 29). Next, the implant and insertion instrument can be placed between the blades and impacted down the length of the blades (Figure 30) until fully seated within the disc space (Figure 31).

**Insertion Blade Removal Options**

Once the implant is in the desired location, the insertion blades can be removed either (1) as an assembly by using a slap hammer to remove the entire insertion blade assembly (Figure 32) or (2) in components by disconnecting the modular handle and removing each blade individually (Figure 33).
Implant Placement

Graft Retention

Graft retention clips can be used to facilitate containment of graft material during implant insertion. Select the appropriately sized clip that corresponds to the implant size. Attach the clip to the shaft of the implant insertion device (Figure 34) and slide the clip down over the implant (Figure 35).

Next, the graft retention clip, cage and insertion instrument assembly can be placed through the retractor until the bulleted nose of the cage comes in contact with the vertebral bodies (Figure 36). The cage can then be impacted into position until fully seated within the disc space (Figure 37).
Implant Placement

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 38).

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 for detailed instructions for use, complete information on contraindications, warnings, precautions and adverse events associated with the use of the systems.

NOTE: Prior to removing retractor, remove fixation pin, untie blades and collapse retractor.
Removal/Revision Procedure

In the event that a lateral cage needs to be revised and removed from a patient, the cage may be removed via a lateral approach either through the original side of the incision, or through the contra-lateral side. An anterior approach can also be considered. Pre-operative planning should include scan analysis of cage orientation, the location of any embedded bone graft, and any endplate intrusion. It may be easier to enter the disc space from the contra-lateral side due to lack of scar tissue. However, be aware that the position of the cage may dictate which end is easier to reach. Also, if approaching on the contra-lateral side from initial incision, the leading nose of the cage will not have a threaded hole for engaging the insertion device if necessary.

If approaching laterally, access to the disc space can be achieved using the steps outlined in the APPROACH and ACCESS sections of this surgical technique guide. Once access to the disc space is achieved and nerves are protected, an annulotomy is made to reenter the disc space. Intervertebral distraction is essential to optimize removal. Fine curettes can be used to remove any fibrous tissue surrounding the cage. If large amounts of bone are present, osteotomes may be required to remove bone. Once the perimeter of the cage is clear, osteotomes or chisels can be used to reestablish a cleft between the cage and endplate. Any fibrous tissue or bone passing through the cage into the endplate should be released before removal. Overhanging osteophytes that might impede removal should also be resected.

Once distraction is optimized and encasing fibrous tissue and bone excised, the surgeon can attach the cage removal tool to the cage. Alternately, the surgeon can use the cage inserter and reattach the inserter to the cage by placing the male end of the inserter into the female end of the lateral cage and rethreading the inserter. Next, the slap hammer can be attached to either the cage removal instrument or the cage inserter for removal of the cage from the disc space.

An explanted implant should never be reimplanted. Even though a device appears undamaged, it may have small defects and internal stress patterns that may lead to early breakage. Reuse can compromise device performance and patient safety. Reuse of single use devices can also cause cross-contamination leading to patient infection.
Notes
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 spondylothesis 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.

CONTRAINDICATIONS

1. Use of this system is contraindicated when there is active systemic infection, infection localized to the site of the proposed implantation, or when the patient has demonstrated allergy or foreign body sensitivity to any of the implant materials.
2. Severe osteoporosis may prevent adequate fixation and thus preclude the use of this or any other orthopaedic implant.
3. Conditions that may place excessive stresses on bone and implants, such as severe obesity or degenerative diseases, are relative contraindications. The decision whether to use these devices in such conditions must be made by the physician taking into account the risks versus the benefits to the patient.
4. Prior fusion at the level to be treated is a contraindication for this system when used for interbody vertebroplasty.
5. Use of these implants is relatively contraindicated in patients whose activity, mental capacity, mental illness, alcoholism, drug abuse, occupation, or lifestyle may interfere with their ability to follow postoperative restrictions and who may place undue stresses on the implant during bony healing and may be at a higher risk of implant failure.

WARNINGS, PRECAUTIONS AND ADVERSE EFFECTS CONCERNING SPINAL FIXATION IMPLANTS

Following are specific warnings, precautions and adverse effects that should be understood by the surgeon and explained to the patient. These warnings do not include all adverse effects that can occur with surgery in general, but are important considerations particular to the COUGAR® LS implants. General surgical risks should be explained to the patient prior to surgery.

The COUGAR® LS implants are intended for use either as an intervertebral body fusion device or as a vertebral body replacement. These implants are intended to be permanent. The following recommendations for removal of hardware apply to the supplemental internal fixation implants used in this procedure. Neuromonitoring may be considered when performing a lateral surgical approach.

WARNINGS

1. CORRECT SELECTION OF THE IMPLANT IS EXTREMELY IMPORTANT. The potential for satisfactory intervertebral body fusion or vertebral body replacement is increased by the selection of the proper size device. While proper selection can help minimize risks, the size and shape of human bones present limitations on the size, shape and strength of implants. Internal fixation devices cannot withstand activity levels equal to those placed on normal healthy bone. No implant can be expected to withstand indefinitely the unsupported stress of full weight bearing.

When using the COUGAR® LS Lateral Cage System, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact on the performance of this system.

2. IMPLANTS CAN BREAK WHEN SUBJECTED TO THE INCREASED ASSOCIATED WITH DELAYED UNION OR NONUNION. Internal fixation appliances are load-sharing devices that are used to obtain an alignment until normal healing (fusion) occurs. If healing is delayed, or does not occur, the implant may eventually break due to material fatigue. The degree of success of union, loads produced by weight bearing, and activity levels will, among other conditions, dictate the longevity of the implant. Netches, scratches or bending of the implant during the course of surgery may also contribute to early failure. Patients should be fully informed of the risks of implant failure.

3. COMPONENTS OF THIS SYSTEM SHOULD NOT BE USED WITH COMPONENTS OF ANY OTHER SYSTEM OR MANUFACTURER.

4.  MIXING METALS CAN CAUSE CORROSION. There are many forms of corrosion damage and several of these occur on metals surgically implanted in humans. General or uniform corrosion is present on all implanted metals and alloys. The rate of corrosive attack on metal implant devices is usually very low due to the presence of passive surface films. DiSSimilar metals in contact, such as titanium and stainless steel, accelerate the corrosion process of stainless steel and more rapid attack occurs. The presence of corrosion often accelerates fatigue fracture of implants. The amount of metal compounds released into the body system will also increase. Internal fixation devices, such as rods, hooks, wires, etc., which come into contact with other metal objects, must be made from like or compatible metals. Avoid coupling of stainless steel with these implants.

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

PRECAUTIONS

1. SURGICAL IMPLANTS MUST NEVER BE REUSED. An explanted implant should never be reimplanted. Even though a device appears undamaged, it may have small defects and internal stress patterns that may lead to early breakage. Reuse of device performance and patient safety. Reuse of single use devices can also cause cross-contamination leading to patient infection.

2. CORRECT HANDLING OF THE IMPLANT IS EXTREMELY IMPORTANT. Polymer/carbon-fiber implants are designed to support physiologic loads. Excessive torque, when applied to long-handle insertion tools, can cause splitting or fracture of the carbon-fiber implants. When a carbon-fiber implant is impacted or hammered into place, the broad surface of the insertion tool should be carefully seated fully against the carbon-fiber implant. Impaction forces applied directly to a small surface of the implant could cause fracture of the implant. Split or fractured implants should be removed and replaced.

3. REMOVAL OF SUPPLEMENTAL FIXATION AFTER HEALING. If the supplemental fixation is not removed following the completion of its intended use, any of the following complications may occur: (1) Corrosion, with localized tissue reaction or pain; (2) Migration of implant position resulting in injury; (3) Risk of additional injury from postoperative trauma; (4) Bending, loosening, and/or breakage, which could make removal impractical or difficult; (5) Pain, discomfort, or abnormal sensations due to the presence of the device; (6) Possible increased risk of infection; and (7) Bone loss due to stress shielding. The surgeon should weigh the risks versus benefits when deciding whether to remove the implant. Removal implant should be followed by adequate postoperative management. If, for example, the patient is older and has a low activity level, the surgeon may choose not to remove the implant, thus eliminating the risks involved with a second surgery.

4. ADEQUATELY INSTRUCT THE PATIENT. Postoperative care and the patient’s ability and willingness to follow instructions are among the most important aspects of successful bone healing. The patient must be made aware of the limitations of the implants. The patient should be encouraged to ambulate to tolerance as soon as possible after surgery, and instructed to limit and restrict lifting and twisting motions and any type of sports participation until the bone fusion is complete. The patient should understand that implants are not as strong as normal healthy bone and could loosen, bend and/or break if excessive demands are placed on it, especially in the absence of complete bone healing. Implants displaced or damaged by improper activities may experience migration to the devices and damage to nerves or blood vessels.

5. ANY CONDITION NOT DESCRIBED IN THE INDICATIONS FOR USE HAS NOT BEEN STUDIED. The safety and effectiveness of these implants for conditions not listed in the indications for use has not been established.

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