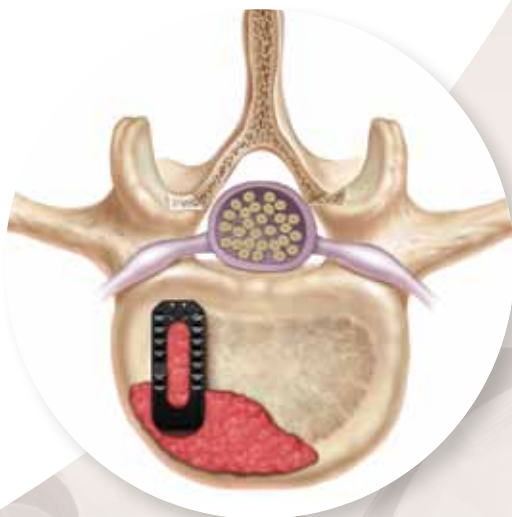


Surgical Technique

*for Posterior Lumbar
Interbody Fusion (PLIF)*



never stop moving®

DePuy
Spine Inc.
a Johnson & Johnson company



TABLE OF CONTENTS

SURGICAL TECHNIQUE	2
Step 1: Patient Positioning & Exposure	2
Step 2: Laminectomy	2
Step 3: Initial Disc Resection	4
Step 4: Disc Height Restoration	4
Step 5: Final Disc Removal & Endplate Decortication	5
Step 6: Trial & Cage Insertion	6
Step 7: Cage Insertion	6
Step 8: Compression	7
Cage Removal	8

Surgical Technique

STEP 1: PATIENT POSITIONING & EXPOSURE

- The Patient is placed in a frame or table that allows the abdomen to hang freely taking care to protect patient pressure points. Positioning should provide for maintenance of lordosis by appropriate hip positioning.
- Localizing x-ray or image intensification is made to verify the appropriate spinal level, and one should ensure that clear intra-operative imaging can be obtained before prep and drape.
- Routine posterior approach is made preserving facet capsules above and below the operative level.

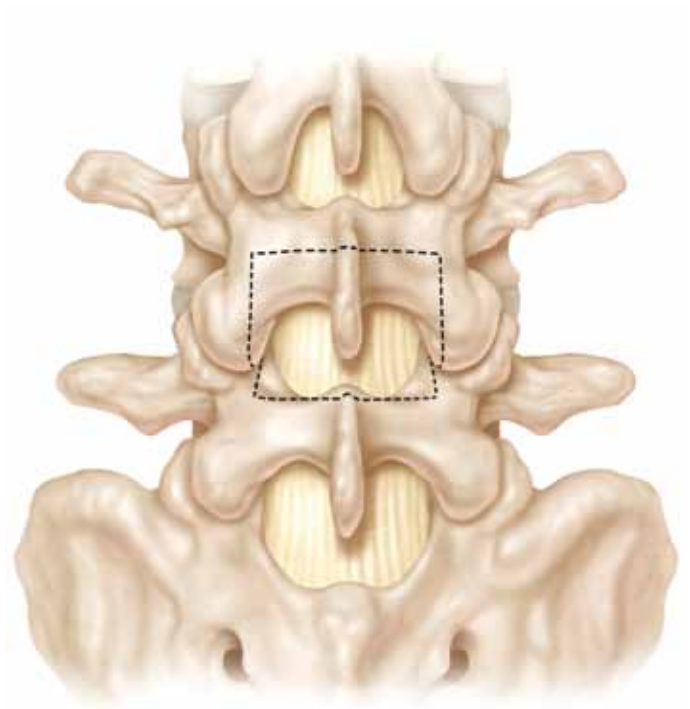


FIGURE 1

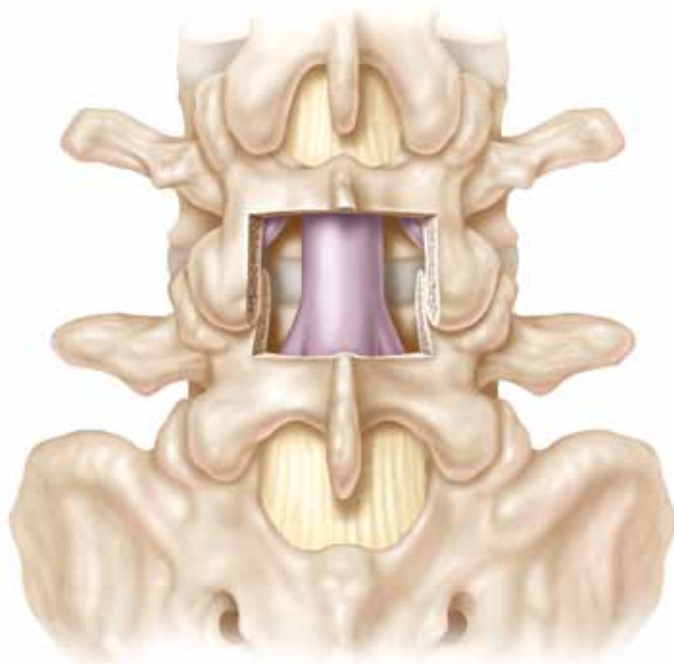


FIGURE 2

STEP 2: LAMINECTOMY

- A symmetric partial bilateral laminectomy of the cranial and caudal level is made to expose the medial wall of the pedicles and the origin and insertion of the ligamentum flavum (Figure 1). The ligamentum flavum must be completely removed during decompression while carefully protecting the dura.
- The laminectomy can be performed with a small osteotome, chisel, or Kerrison type rongeur.
- Excised bone can be carefully cleaned and saved as graft material later in the PLIF procedure.
- Care is taken to preserve the spinous processes to minimize disruption to adjacent segment ligamentous structures (Figure 2). The pars and adjacent facets should be preserved.

- Most of the time pedicle screws are inserted before laminotomy and exposure of neural structures is done. This is to minimize the risk of inadvertent injury to the dura when passing probes or taps during screw insertion. If screws are to be inserted in circumstances where the dura and nerve roots are exposed, great care should be taken to protect these at risk structures.

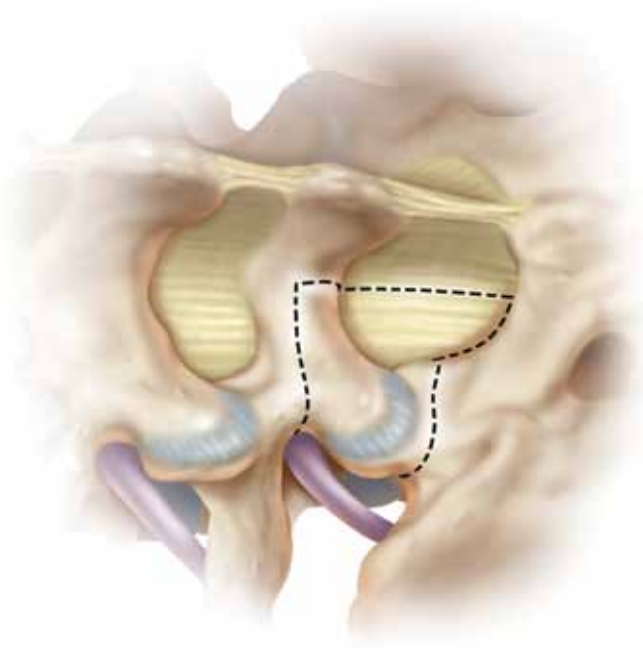


FIGURE 3

- Some surgeons may prefer access through a bilateral facetectomy which in effect is performing a bi-lateral TLIF not PLIF (Figure 3). The PLIF procedure preserves some portion of the facet bi-laterally in hopes of retaining some component of stability. However, this does require slightly more medial retraction of the central dura to fully expose the disc.
- Once the lamina is removed bi-laterally, the axilla of the exiting and traversing nerve root over the disc space must be visualized and mobilized since this creates a safe working area for the PLIF technique. Carefully release any adhesions from the dura over the disc space with a freer or Penfield elevator.
- Bi-polar coagulation, packing, or various hemostatic agents can help control epidural bleeding. It is essential to have excellent control of the epidural veins on the floor of the canal to allow safe and thorough retraction of neural structures. Throughout the PLIF procedure nerve root retraction should be gentle and intermittent, and particularly vigilant when instruments are being passed in and out of the disc space (Figure 4).

Surgical Technique

STEP 3: INITIAL DISC RESECTION

- Once the dura is mobilized bi-laterally and the floor of the canal is well exposed, annulotomy is performed on the left and right sides. The initial left side disc resection should be made fairly close towards the midline and the dura protected with retractors throughout the dissection (Figure 4). Normally partial disc removal of both sides is carried out before thorough final cleaning of endplates is done.
- It often proves helpful to resect posterior rim osteophytes particularly on the cephalad edge of the inferior vertebra to optimize access into the disc and improve ease of cage insertion (Figure 5).



FIGURE 4

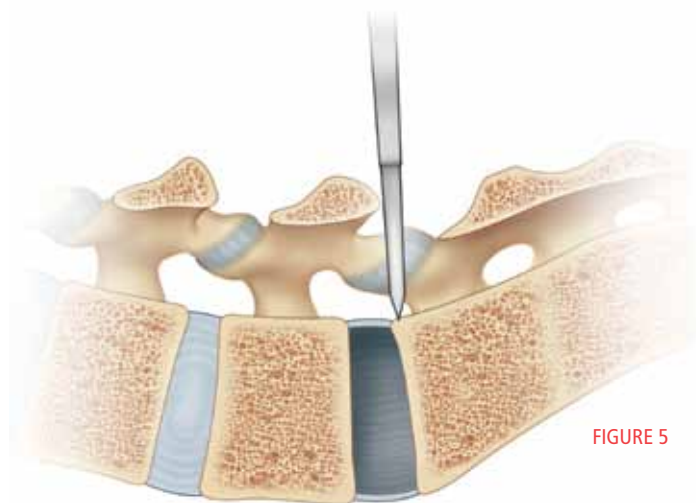


FIGURE 5

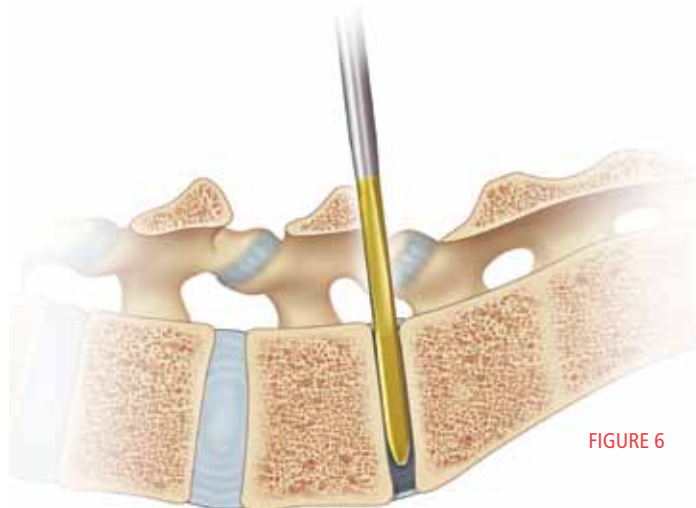


FIGURE 6

STEP 4: DISC HEIGHT RESTORATION

- Options for distraction include intradiscal distracters as well as supplementary distraction via the screws or laminar spreader.
- Blunt tipped intradiscal distractors are inserted into the disc with the paddle blade horizontal in the disc space (Figure 6). In the case of very narrow disc space, a starter dilator may be used prior to inserting the first spreader.
- Depth marks are located on the disc distractor to avoid penetrating the front wall of the annulus. In most cases, it should be inserted to a depth of 25-30mm.

- The intradiscal distractors come in sequential heights starting at 9mm and increasing by 2mm increments to 15mm.
- Once successfully inserted, the disc spreader is gently rotated 90° to elevate the disc space to the height of the disc spreader size (Figure 7).
- A second disc spreader of the same size can be inserted on the opposite side and the first disc spreader is removed. The next size disc spreader is then inserted in the original site and the process repeated until maximum disc height is restored and the parallel distraction is achieved.
- Motion segment positioning should be checked by x-ray or image intensification. It is essential to be monitoring both disc height as well as segmental lordosis. Ultimately the cage height, cage geometry, and posterior compression with the instrumentation combine to determine final lordosis. PLIF technique can be kyphogenic if attention is not directed to all three of these components.

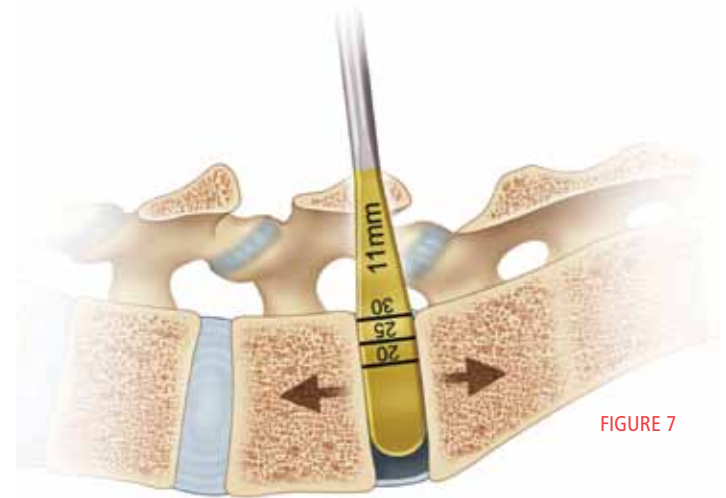


FIGURE 7

STEP 5: FINAL DISC REMOVAL & ENDPLATE DECORTICATION

- Thorough removal of all disc material and cartilaginous endplates must be performed in order to expose the bleeding sub-chondral bone of the vertebral endplates. A combination of rasps, cup and ring curettes can be used protecting the dura during each step. Care must always be taken not to penetrate the endplates which can lead to subsidence of the interbody device into the vertebral body.
- Anatomic disc shavers can also be used to aid in complete disc removal and decortication. These are cutting instruments that shave disc material away from the endplates. Begin with 8mm disc shaver. Larger shavers are sequentially inserted until the size that corresponds to the distraction height of the disc space is achieved. The shavers are rotated back and forth, medial to lateral, in order to remove all disc material.
- Final endplate decortication should expose punctate bleeding while not extending so deep that cage subsidence is at risk.

Surgical Technique

STEP 6: TRIAL & CAGE INSERTION

- The appropriate trial spacer is selected to ensure proper cage size and placement. Cages and their corresponding trials come in 0, 5, and 10° Lordotic options.
- The size on each trial corresponds to the full cage height including the teeth.
- Using the appropriate nerve root retractor, the trial is gently tapped into the disc space with a mallet and should be recessed 3-5mm deep to the posterior vertebral margin. It is critical to remain aware of the potential to kyphose the motion segment with over distraction if a cage is too tall, particularly posteriorly (Figure 8).
- **At this point radiographic confirmation of motion segment reduction, height and lordosis may be helpful.**

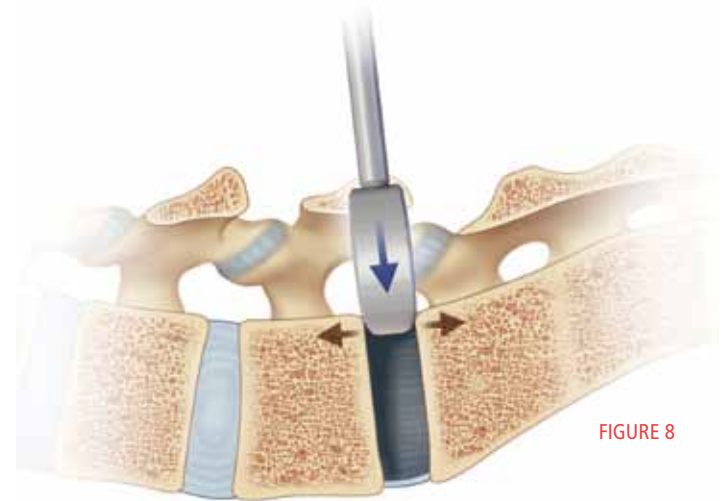


FIGURE 8

STEP 7: CAGE INSERTION

- Prior to insertion, the surgeon may prefer to place additional fusion materials in the anterior aspect of the disc space to supplement fusion material that is placed inside the cage.
- The cage inserter threads directly into the cage.
- Once proper cage size and lordosis have been determined, the selected cage can be filled with osteoinductive and osteoconductive material as needed.
- While distraction is maintained and the nerve roots carefully protected, the cage is gently tapped into position under direct vision and fluoroscopic control.
- The cage should be counter-sunk at least 3-4mm deep to the posterior rim of the vertebral body (Figure 9). Once a cage has engaged the endplates, it cannot be easily removed.
- The same procedure is carried out on the opposite side while distraction is still maintained.

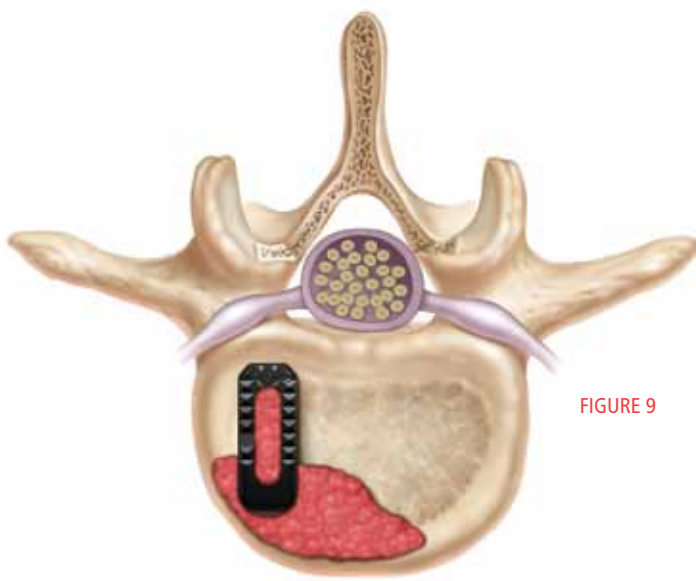


FIGURE 9

STEP 8: COMPRESSION

- Once both cages are in place, final compression is applied symmetrically across the pedicle screw system to appropriately pre-load the cages and establish anatomic segmental lordosis. Care should be taken to be sure there is no loosening of the pedicle screws during compression, particularly at L5 or S1.
- Once compression is complete, final tightening of the pedicle screws is done, and a cross link can be applied if indicated, being careful to guard from any canal intrusion during these steps.
- A thorough inspection of the canal and foramen is then carried out to be sure that no graft material is out of position and that all neural structures are well decompressed.
- Final radiographic confirmation of implant position and segmental alignment should also be done (Figure 10).
- The appearance of three tantalum beads will identify the position of the CONCORDE Inline cage in the sagittal, coronal, and axial planes.

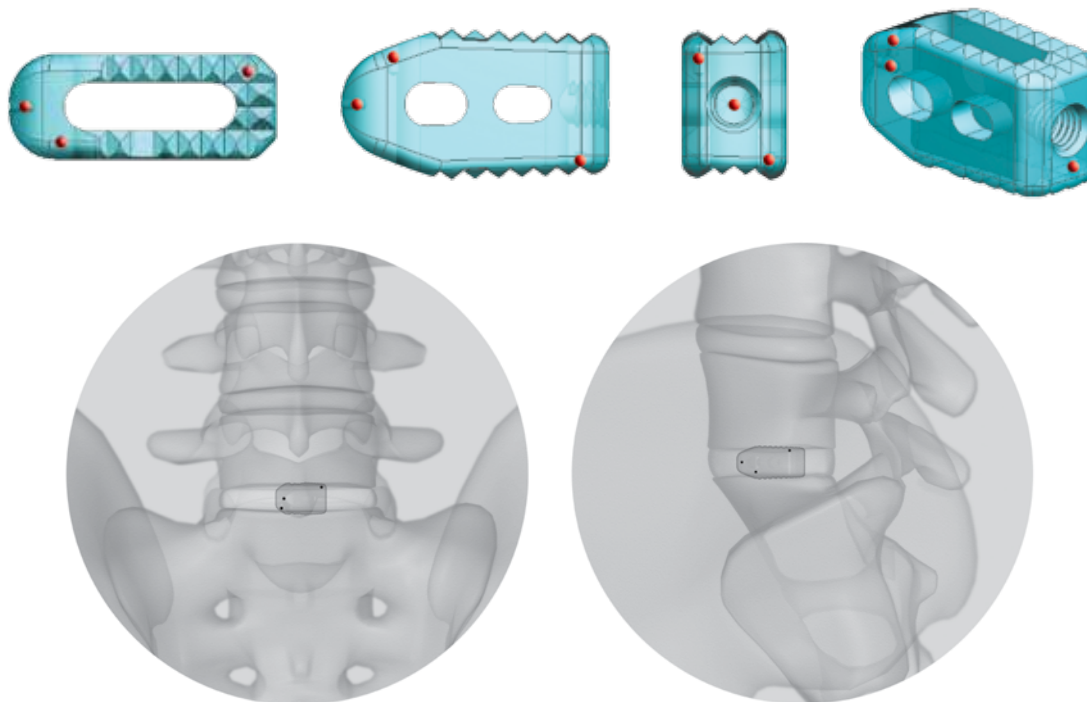


FIGURE 10

Cage Removal

In the event of a revision, the cages may be removed from an anterior or posterior approach. Pre-operative planning should include scan analysis of cage orientation, the location of any embedded bone graft, and any endplate intrusion. If approaching posteriorly it is essential to dissect and protect the exiting and traversing nerve root, especially where they may be adhered from scar. Once the nerves are protected, an extended annulotomy is made to re-enter the disk space. Intervertebral distraction is essential to optimize safe removal. Fine curettes are used to remove any fibrous tissue surrounding the cage. If large amounts of bone are present, osteotomes are required to remove bone from the anterior and posterior walls of the cage. It is important not to attempt cage removal until the majority of encasing fibrous and bony tissue has been removed. Once the perimeter of the cage is clear, osteotomes or chisels are used to reestablish a cleft between the cage and endplate. Slight additional distraction can be helpful at this point. Any fibrous tissue or bone passing through the cage into the endplate must be released before removal. Overhanging osteophytes that might impede removal are also resected. Once distraction is optimized and encasing fibrous tissue and bone excised, the cage can be grasped and backed out. A curved curette can also be used to engage the cage and provide additional removal force if necessary. While it is possible to reengage the CFRP threads with the inserter, this is usually less effective for the removal step. An explanted implant should never be re-implanted. 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.

INDICATIONS AND USAGE

CAUTION: Federal (USA) Law restricts this device to sale by or on the order of a physician (or properly licensed practitioner) who has appropriate training or experience.

The CONCORDE®, CONCORDE Bullet, CONCORDE Inline, CONCORDE Curve, COUGAR®, DEVEX®, and LEOPARD® Systems are indicated for use as intervertebral body fusion devices in skeletally mature patients with degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies) at one or two contiguous levels of the lumbar spine (L2-S1). Patients should have six months of non-operative treatment prior to surgery. These implants are used to facilitate fusion in the lumbar spine and are placed via either a PLIF (CONCORDE, CONCORDE Bullet, CONCORDE Inline), TLIF (CONCORDE, CONCORDE Bullet, CONCORDE Inline, CONCORDE Curve, DEVEX, LEOPARD) or anterior (COUGAR) approach using autogenous bone. When used as interbody fusion devices these implants are intended for use with DePuy Spine supplemental internal fixation products.

The CONCORDE, CONCORDE Bullet, CONCORDE Inline, CONCORDE Curve, COUGAR, DEVEX, and LEOPARD Systems are indicated for use in the thoracolumbar spine (i.e., T1-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. These systems are also indicated for treating fractures of the thoracic and lumbar spine. These systems are 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 these systems are intended for use with DePuy Spine supplemental internal fixation products.

CONTRAINDICATIONS:

1. Use of these systems 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 or osteopenia may prevent adequate fixation and thus preclude the use of these or any other orthopedic implants.
3. Conditions that may place excessive stresses on bone and implants, such as severe obesity, pregnancy or degenerative diseases, are relative contraindications. The decision 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. 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.
5. Prior fusion at the level(s) to be treated.
6. Any condition not described in the Indications for Use.

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

1. CORRECT SELECTION OF THE IMPLANT IS EXTREMELY IMPORTANT. The potential for satisfactory anterior column support 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.

2. IMPLANTS CAN BREAK WHEN SUBJECTED TO THE INCREASED LOADING ASSOCIATED WITH DELAYED UNION OR NONUNION. Internal fixation appliances are load-sharing devices that are used to obtain an alignment until normal healing occurs. If healing is delayed, or does not occur, the implant may eventually break due to material fatigue. The degree or success of union, loads produced by weight bearing, and activity levels will, among other conditions, dictate the longevity of the implant. Notches, 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.

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.

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

Not all products are currently available in all markets

DePuy Spine, Inc.

325 Paramount Drive
Raynham, MA 02767
USA

Tel: +1 (800) 227-6633

www.depuy.com

©DePuy Spine, Inc. 2011
All rights reserved.

IF30-20-000 9/11 ADDB/RPI

3. 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.

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 can compromise 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.

A. *Composite Implants:* 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 polymer/carbon-fiber implants. When a polymer/carbon-fiber implant is impacted or hammered into place, the broad surface of the insertion tool should be carefully seated fully against the 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. Implants can break when subjected to the increased loading associated with delayed union or nonunion.

B. *Metal Implants:* Contouring of metal implants should only be done with proper equipment. The operating surgeon should avoid notching, scratching or reverse bending of the implants when contouring.

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 carefully weigh the risks versus benefits when deciding whether to remove the implants. Implant removal should be followed by adequate postoperative management to avoid refracture. 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 is healed. 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 and damage nerves or blood vessels.

5. Cauterization Near the Implant: When performing cauterization around an implant, care should be taken to avoid contact with the implant.

6. Patients with Previous Surgery. Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.

never stop moving®


DePuy
Spine Inc.
a Johnson & Johnson company