

Surgical Technique

*for Transforaminal Lumbar
Interbody Fusion (TLIF)*



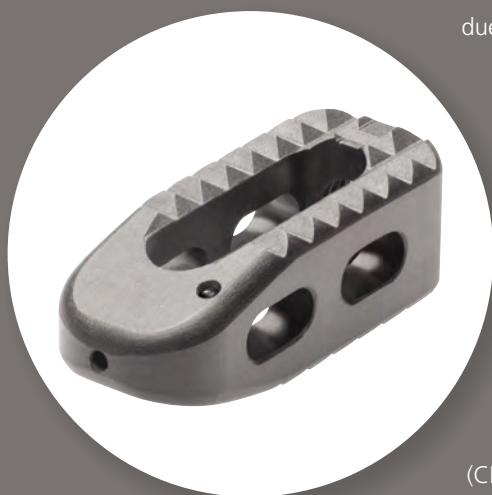


INTRODUCTION

An adaption of the posterior lumbar interbody fusion (PLIF) procedure, the TLIF technique employs a unilateral approach to the discspace through the intervertebral foramen. Requiring only a partial unilateral facet resection, the TLIF procedure when compared to a PLIF:

Preserves the laminar arch and contralateral facet

- Avoids bilateral scarring
- Avoids significant dural retraction which may reduce the risk of intraoperative dural tears
 - Offers a revision strategy that may not exist with a PLIF due to bilateral scarring



The unique unilateral TLIF approach requires specific implants and instrumentation to facilitate thorough disc space preparation and accurate cage placement.

The technique herein describes the use of the CONCORDE® Bullet. The key feature of the CONCORDE Bullet interbody cage is the bulleted nose for ease of insertion into the interbody space. Manufactured from Carbon Fiber Reinforced Polymer (CFRP), CONCORDE Bullet offers optimised area for bone graft and tantalum markers also allow you to visualise the position of the cage insitu. CONCORDE Bullet is designed for surgeons who prefer a straight, oblique placement of the implant and is intended to be used with supplementary posterior instrumentation.



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STEP 1: PEDICLE SCREW INSERTION

Pedicle screws can be placed either before or after the interbody reconstruction. It is often advantageous to have screws as a distraction point during the procedure. Many surgeons place screws before the spinal canal is exposed. If placing screws is done after the facetectomy as shown (Figure 1), take extra care to avoid dural injury during the placement of guide wires, taps or screws.

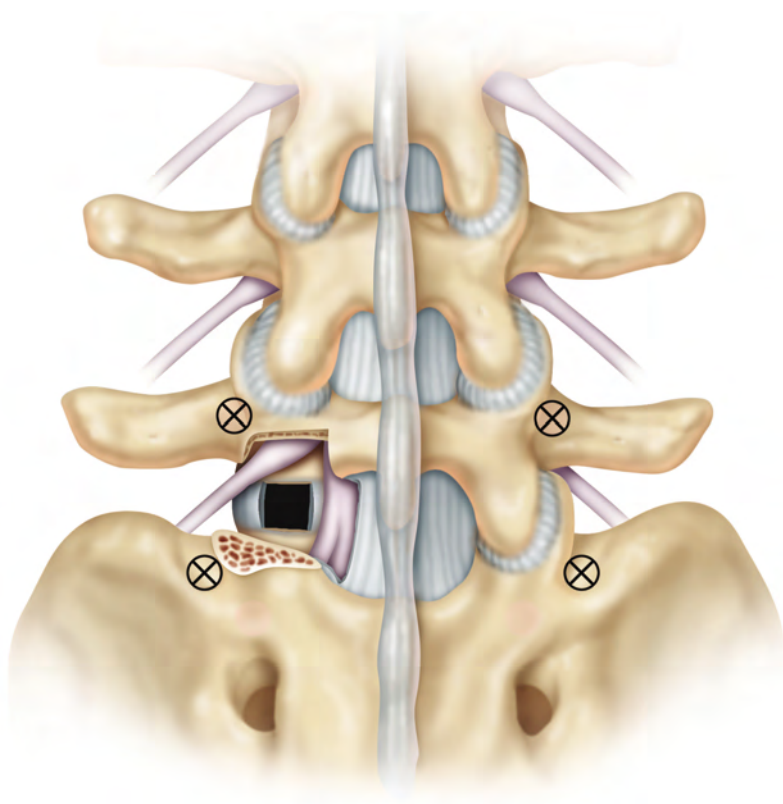


FIGURE 1

Identify pedicle insertion points. The optimal insertion point is at the intersection of the transverse process and pars interarticularis. Consult the EXPEDIUM[®] Spinal System Surgical Technique or VIPER[®] 2 System Guide for additional details on pedicle screw insertion.

STEP 2: FACETECTOMY AND WORKING ZONE PREPARATION (L5/S1)

In order to gain transforaminal access to the disc space, a unilateral facetectomy is performed. The side chosen for the approach is often determined by the location of the pathology or the presence of scar tissue. Resect the ligamentum flavum from the anterior surface of the lamina with a curette. The inferior lamina of L5 can be removed by a Kerrison rongeur illustrated by the dotted line of Figure 2 to improve access to the ligamentum flavum.

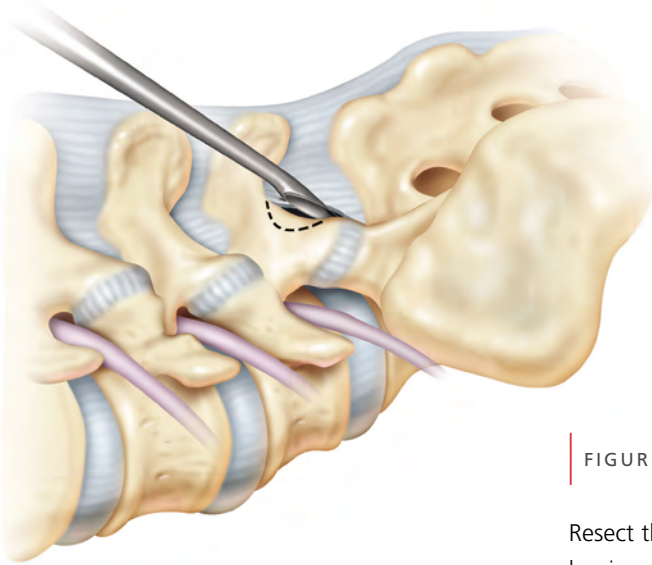


FIGURE 2

Resect the inferior articular process of L5 with a straight osteotome or a Kerrison (Figure 3). The osteotomy exits laterally just below the L5 pedicle. The lateral capsular part of the ligamentum flavum is now visible and can be resected. Unless the pathology mandates excessive spinous process removal, it is recommended to preserve it as a place for the intervertebral distraction should it be required at a later time.

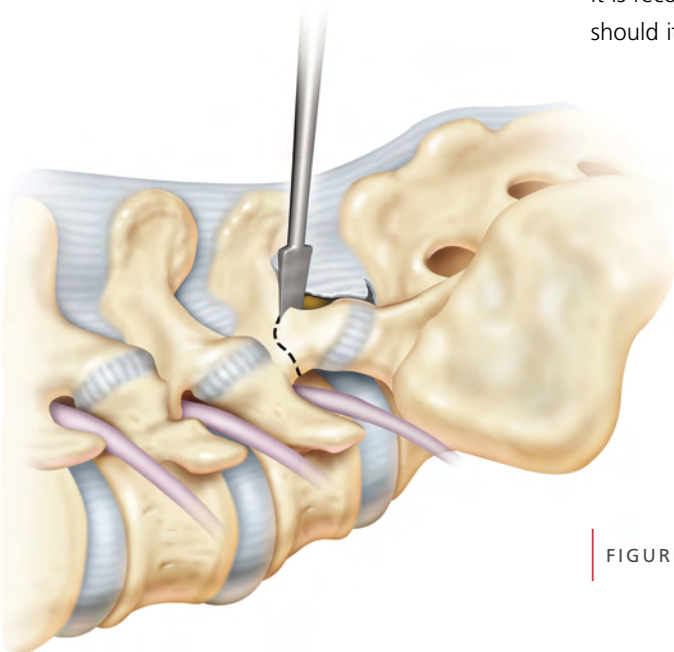


FIGURE 3

Resect the superior articular process of S1 with a straight osteotome or a kerrison while protecting the traversing nerve root to expose the intervertebral foramen (Figure 4).

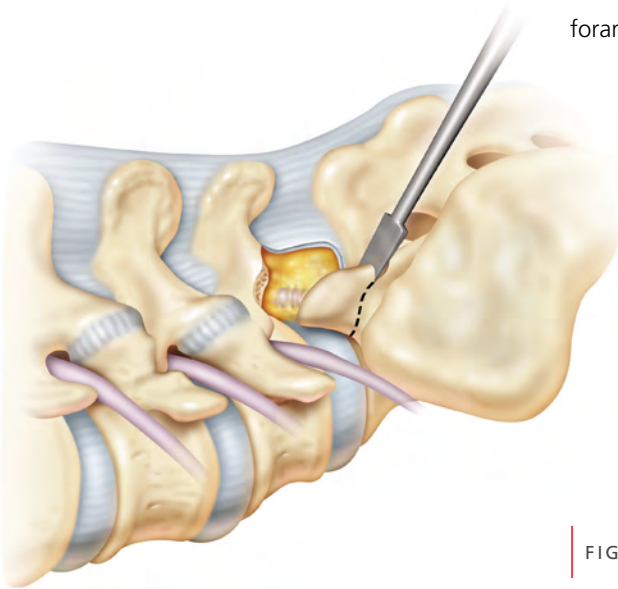


FIGURE 4

Expose the medial and cephalad margin of the S1 pedicle by removing the overhanging superior articular process with a kerrison punch to gain final exposure of the L5/S1 disc. Complete thorough hemostasis over the exposed disc space with the use of bipolar cautery (Figure 5). It is essential at this point to have a dry exposure of the floor of the spinal canal before proceeding into the disc space.

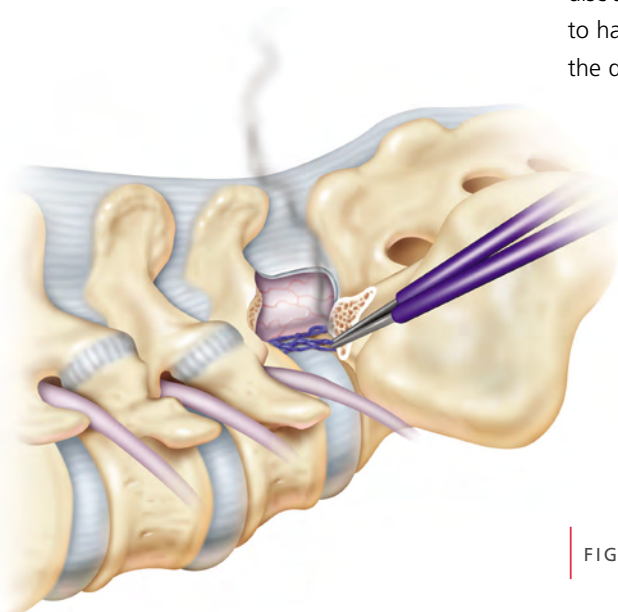


FIGURE 5

STEP 3: ANNULOTOMY AND INITIAL DISC DISSECTION

Care should be taken to gently retract and protect the exiting L5 nerve root and lateral part of the central dural sac. A dissector or nerve root retractor is used to ensure the protection of these structures at every step of the procedure (Figure 6).

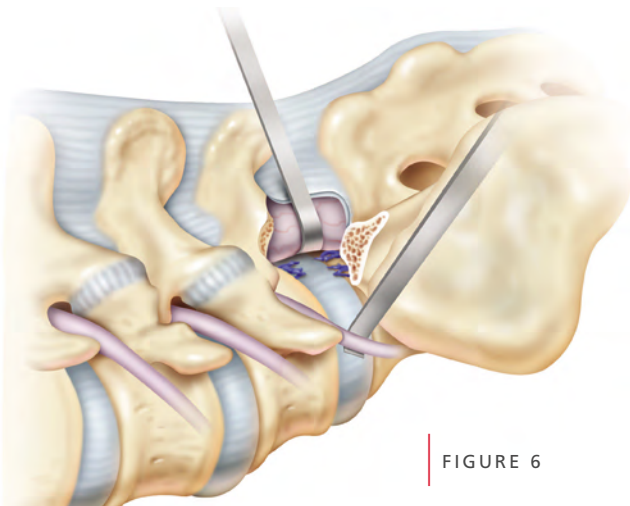


FIGURE 6

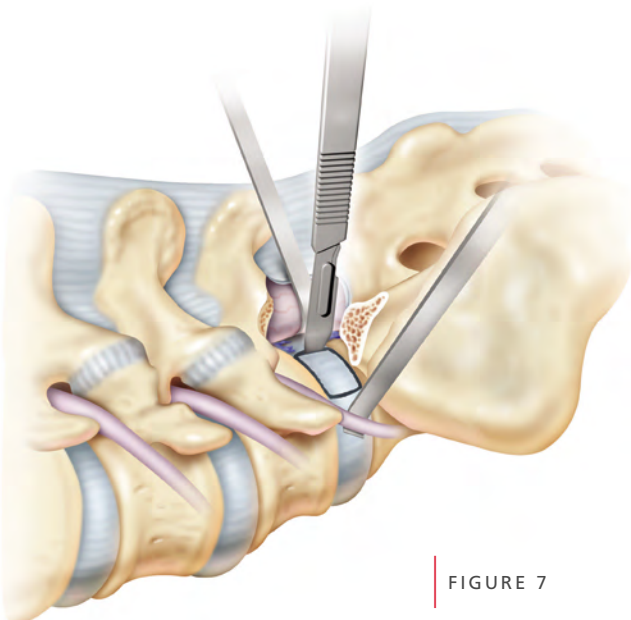


FIGURE 7

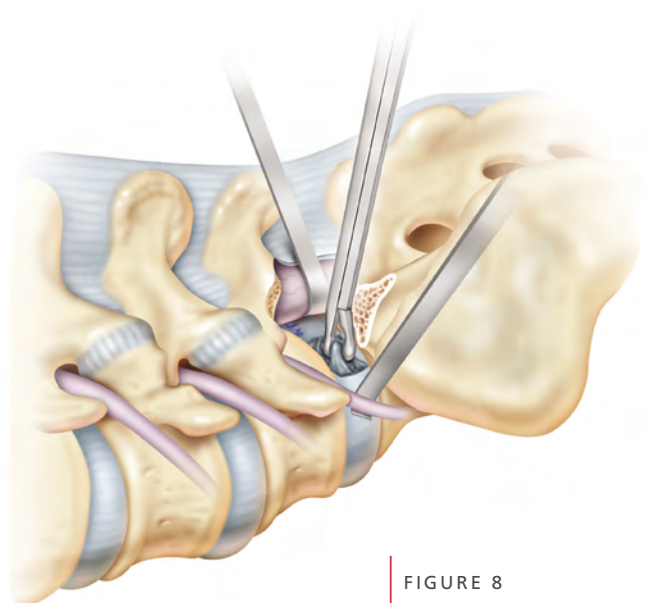
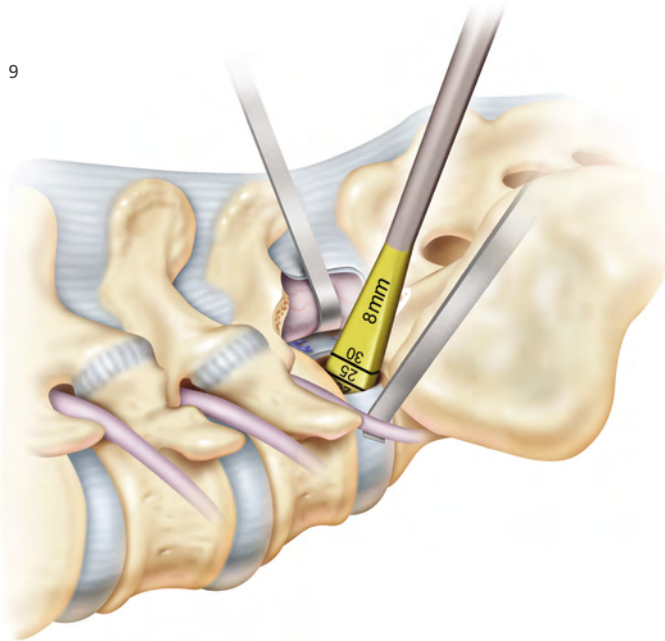


FIGURE 8

Perform a box annulotomy to create a window into the disc space (Figure 7). After the box annulotomy, a pituitary rongeur is used to initially remove loose nuclear tissue in order to clear an initial space for the distractors (Figure 8).

STEP 4: INITIAL DISTRACTION AND PREPARATION OF DISC SPACE

FIGURE 9



Initial distraction of the disc space is necessary in order to access the disc for a thorough discectomy which is required for good fusion preparation and orientation for optimal cage insertion.

Distraction can be achieved using one of the following methods

- Distraction between pedicle screws
- Distraction between the spinous process

Use of a starter dilator (8 mm) or a disc spreader from the disc preparation set as pictured in Figure 9.

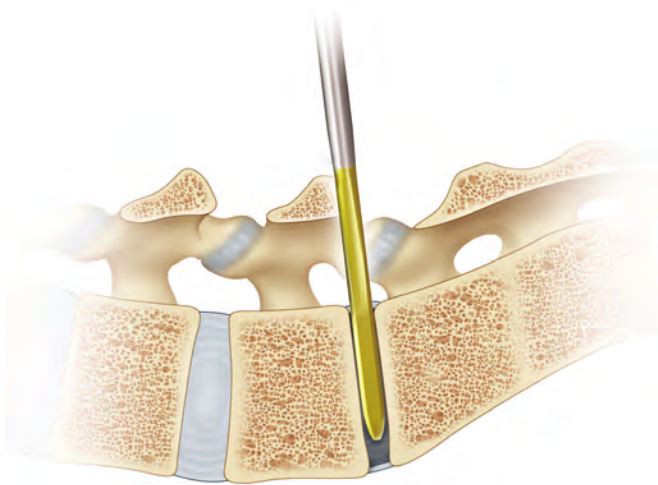


FIGURE 10

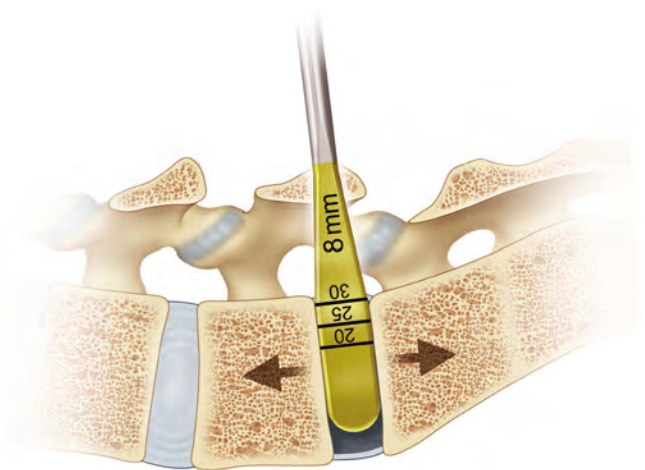
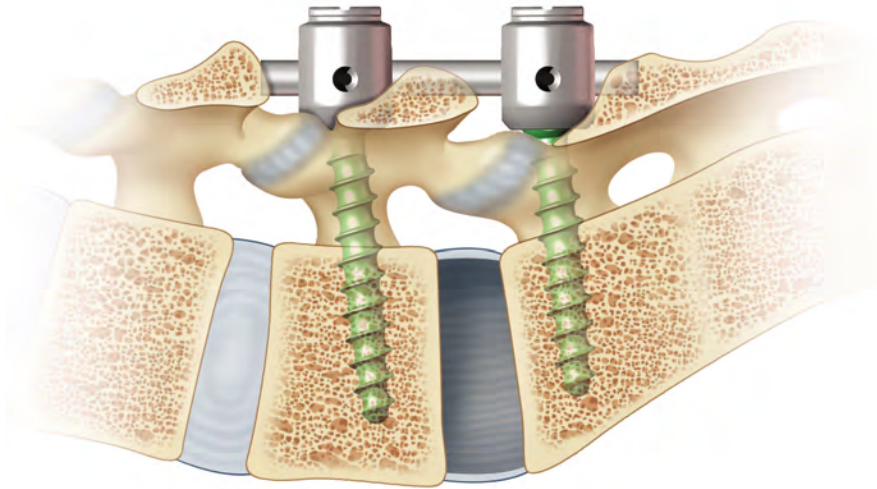


FIGURE 11

After the initial removal of disc tissue, a starter dilator (8 mm) or a spreader from the disc preparation set is inserted horizontally into a collapsed disc space and then rotated 90° to achieve distraction (Figure 10 and 11). Ideally once distraction is complete, the end plates are parallel (Figure 11) in order to maximise the posterior opening of the disc space to allow optimal access for disc preparation and reconstruction.

FIGURE 12

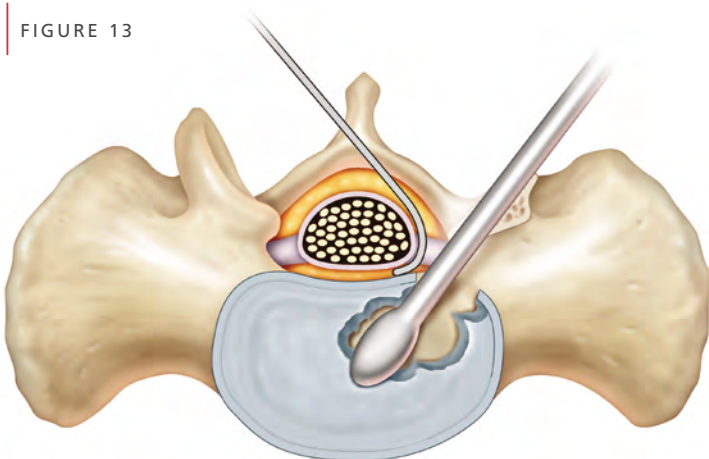
Once distraction is obtained, the opening of the disc space can be maintained with either a temporary rod or the use of a laminar spreader between the spinous processes (Figure 12).



STEP 5: FINAL DISC PREPARATION AND ENDPLATE CLEANING

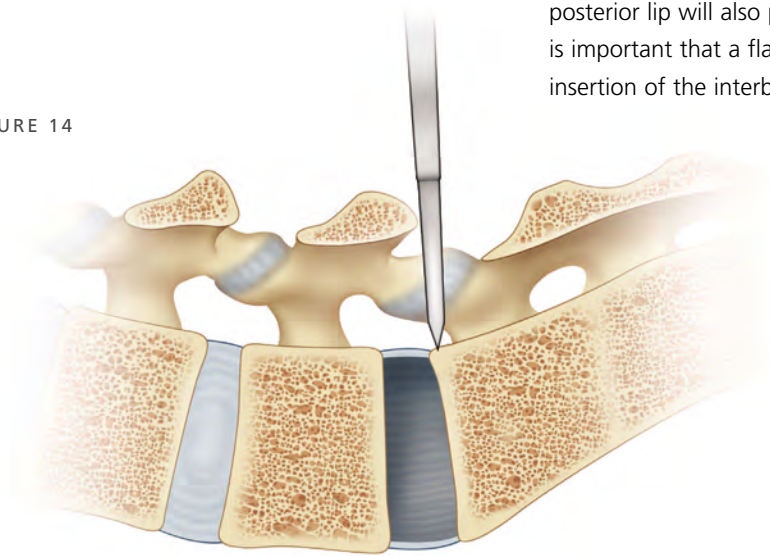
The final discectomy is performed using a combination of curettes, osteotomes, rongeurs and shavers (Figure 13). Care should be taken to maintain the integrity of the endplates and to protect the dura with appropriate retractors wherever instruments are passed in and out of the disc space. Once the initial central portion of the disc has been removed, there is improved visualisation of the orientation of the endplates.

FIGURE 13



An osteotome can be used to remove the posterior lip of either vertebral body flush to the endplates to optimise visualisation and access for the anterior contralateral aspect of the disc (Figure 14). The resection of the posterior lip will also provide a smooth path for insertion of the cage. It is important that a flat, parallel surface is achieved in preparation for the insertion of the interbody device.

FIGURE 14



NOTE: Care should be taken to preserve the integrity of the endplates when resecting the posterior lips.

In order to ensure the disc material is removed from the contralateral posterior corner of the disc space, an offset down-biting curette can be used (Figure 15).

FIGURE 15

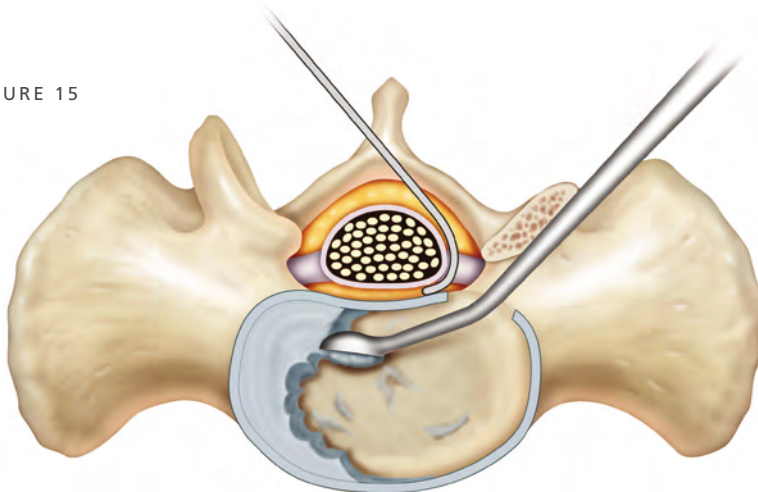
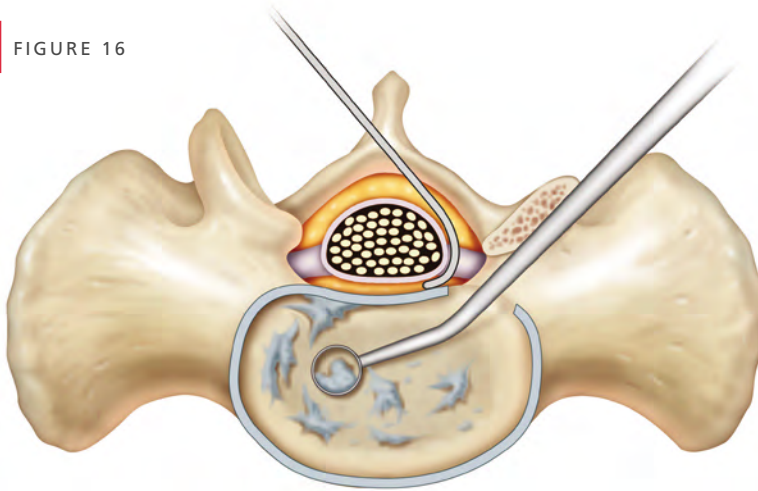


FIGURE 16

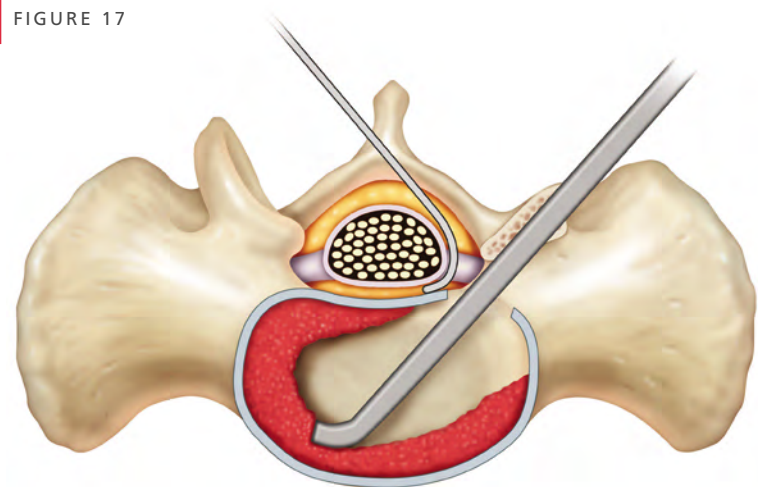


A curette or a rasp can be used in a scraping fashion to separate and remove any remaining disc and cartilage from the bony endplates. Straight or angled rongeurs are utilised to remove any remaining loose disc material.

A variety of straight, angled, and offset cup, ring, and down biting curettes are available from the disc preparation set to facilitate further disc removal. Double angled cup curettes (left and right) can also be utilised to remove disc material from the contralateral side of the disc space; these will specifically address the inferior and superior endplates (Figure 16).

STEP 6: DECORTICATION AND PLACEMENT OF BONE GRAFT

FIGURE 17



Final decortication is done with sharp curettes and osteotomes and should be deep enough to stimulate punctate endplate bleeding.

In order to achieve a solid interbody fusion, the disc space should be filled with as much bone graft as possible. Fill the anterior third and contra-lateral side of the disc space with bone graft using a variety of straight and curved bone tamps from the disc preparation set (Figure 17).

The quality of the disc preparation and endplate decortication is as important as the volume of the graft inserted.

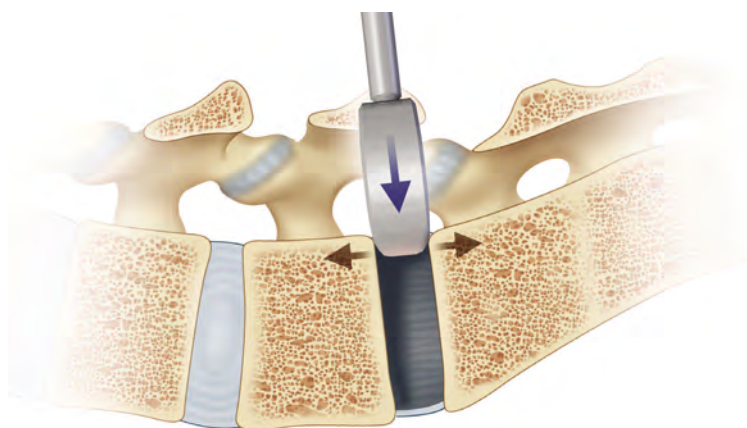
STEP 7: CAGE TRIALING

Trialing to aid in correct selection of the implant is extremely important.

A cage trial should be used prior to insertion of the implant to evaluate potential cage placement and determine the optimal implant fit (Figure 18).

Lateral fluoroscopy may be useful in analysing disc orientation and ultimate desired lordosis.

FIGURE 18



The cage trials match the parallel or lordotic configurations available with CONCORDE Bullet Implants.

Trials are sized to match the overall height of the corresponding implant, including the teeth of the implant.

STEP 8: CAGE INSERTION – CONCORDE BULLET

Align threaded hole of cage with threaded tip. Tighten the knob clockwise until cage is secure. Take care not to cross thread or overtighten the inserter (Figure 19).

CONCORDE Bullet implants should only be used with the CONCORDE Bullet inserters (2879-01-000 or 2879-01-009).

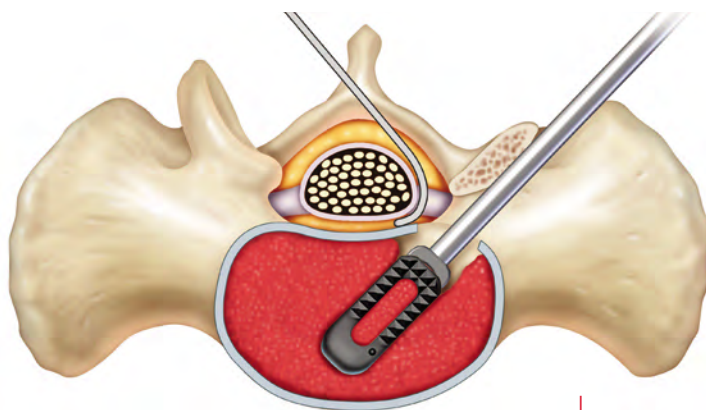


FIGURE 19: CONCORDE BULLET

STEP 9: IMPLANT ORIENTATION FOR LORDOTIC CONCORDE BULLET

In order to provide the desired 5 degrees of lordotic angulation, confirm that the orientation marker is located on the poster-medial side of the implant before insertion (Figure 20). Once the implant is loaded on to the inserter, pack the cage with bone graft using the filler block.

It is important to protect the central dura and traversing and exiting nerve roots during insertion and manipulation of the implant.

Excessive torque or impaction force, when applied to long-handled insertion tools, can cause splitting or fracture of implants.

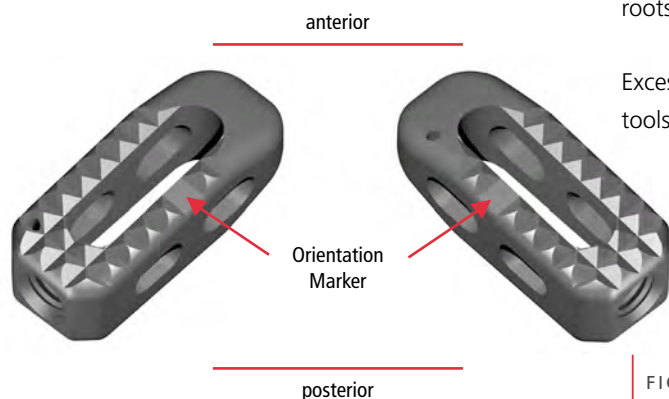


FIGURE 20

STEP 10: FINAL COMPRESSION

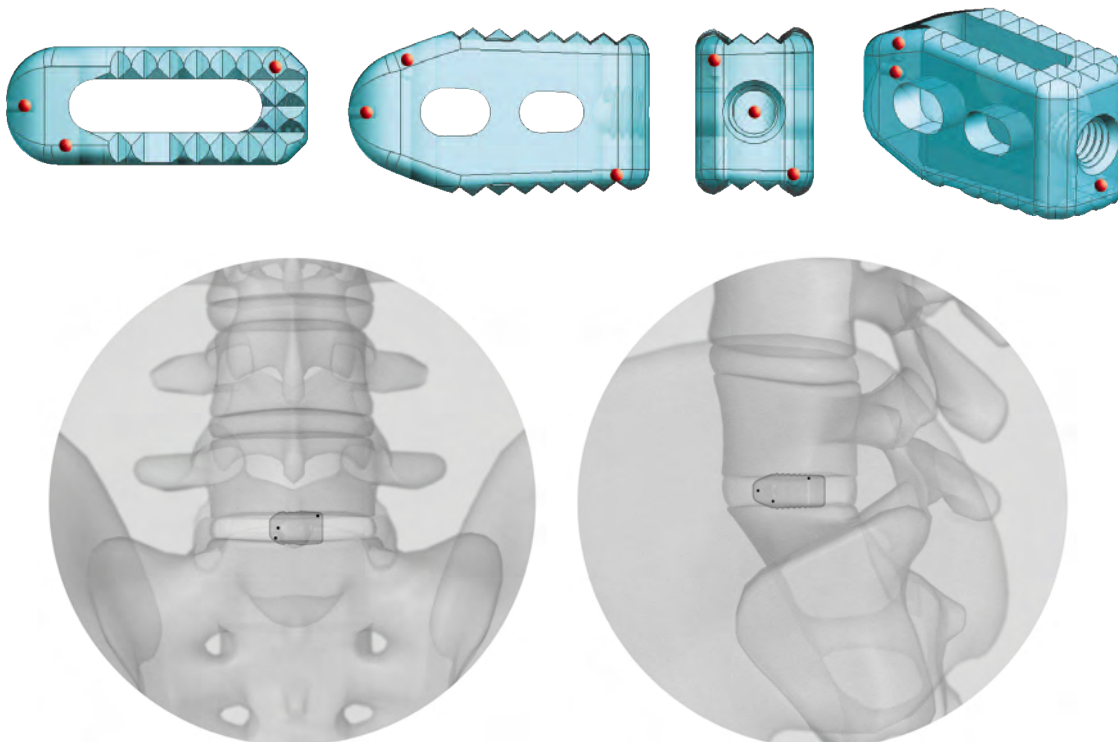
The appropriate length pre-cut, prelordosed rod is selected to match the lordosis of the patient's spine. Rods are seated into the screw heads and active compression is applied to the EXPEDIUM Screw System. To achieve this, tighten either the caudal or cranial set screws to securely lock one end of the rod in place and provide an anchor point for the compression. With the remaining set screw loosened, use the compressor to perform final compression. Lock the compression in place by tightening the remaining set screw. The same maneuver can then be repeated on the contralateral side. Following compression, normal segmental lordosis and foraminal height should be maintained.

Confirm that the rod does not impinge on the adjacent facets. Once desired lordosis of the segment and positioning of the implant is confirmed, revisit all screws for final tightening.

STEP 11: VERIFICATION OF FINAL CAGE PLACEMENT – CONCORDE BULLET

An X-ray should be taken to verify final cage placement.

The appearance of three tantalum beads will identify the position of the CONCORDE Bullet cage in the sagittal, coronal and axial planes.



REVISION INSTRUCTIONS

In the event of a revision, the cage may be removed from an anterior or posterior approach. Preoperative 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. It may be easier to enter the canal from the contralateral side due to lack of scar tissue. However, be aware that the position of the cage may dictate which end is easier to reach once revision annulotomy is done. Also, if approaching on the contralateral side from initial insertion, the leading nose of the cage will not have a threaded hole for engaging the insertion device if necessary.

Once the nerves are protected, an annulotomy is made to reenter the disk space. Intervertebral distraction is essential to optimise 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. Once the perimeter of the cage is clear, osteotomes or chisels are used to reestablish a cleft between the cage and endplate. 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 optimised and encasing fibrous tissue and bone excised, the cage can be grasped in the sidewalls with the removal tool and backed out. A curved curette or the threaded insertion tool can also be used to engage the cage and provide additional removal force if necessary.

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.

CONCORDE BULLET PRODUCT CATALOG



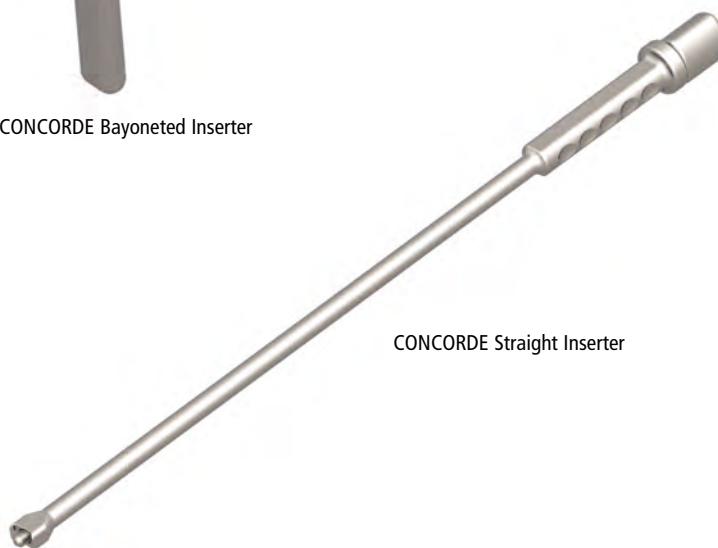
Product Code	Description
Parallel Implants	Width (mm) x Height (mm) x Length (mm)
187823107	CONCORDE Bullet Parallel, 9x7x23
187823108	CONCORDE Bullet Parallel, 9x8x23
187823109	CONCORDE Bullet Parallel, 9x9x23
187823110	CONCORDE Bullet Parallel, 9x10x23
187823111	CONCORDE Bullet Parallel, 9x11x23
187823212	CONCORDE Bullet Parallel, 11x12x23
187823213	CONCORDE Bullet Parallel, 11x13x23
187827107	CONCORDE Bullet Parallel, 9x7x27
187827108	CONCORDE Bullet Parallel, 9x8x27
187827109	CONCORDE Bullet Parallel, 9x9x27
187827110	CONCORDE Bullet Parallel, 9x10x27
187827111	CONCORDE Bullet Parallel, 9x11x27
187827212	CONCORDE Bullet Parallel, 11x12x27
187827213	CONCORDE Bullet Parallel, 11x13x27

Product Code	Description
Lordotic Implants	Width (mm) x Height (mm) x Length (mm)
187823408	CONCORDE Bullet 5° Lordotic, 9x8x23
187823409	CONCORDE Bullet 5° Lordotic, 9x9x23
187823410	CONCORDE Bullet 5° Lordotic, 9x10x23
187823411	CONCORDE Bullet 5° Lordotic, 9x11x23
187823512	CONCORDE Bullet 5° Lordotic, 11x12x23
187823513	CONCORDE Bullet 5° Lordotic, 11x13x23
187827408	CONCORDE Bullet 5° Lordotic, 9x8x27
187827409	CONCORDE Bullet 5° Lordotic, 9x9x27
187827410	CONCORDE Bullet 5° Lordotic, 9x10x27
187827411	CONCORDE Bullet 5° Lordotic, 9x11x27
187827512	CONCORDE Bullet 5° Lordotic, 11x12x27
187827513	CONCORDE Bullet 5° Lordotic, 11x13x27

Product Code	Description
2878-04-007	CONCORDE Bullet Trial, 9x7 (Width mm x Height mm)
2878-04-008	CONCORDE Bullet Trial, 9x8 (Width mm x Height mm)
2878-04-009	CONCORDE Bullet Trial, 9x9 (Width mm x Height mm)
2878-04-010	CONCORDE Bullet Trial, 9x10 (Width mm x Height mm)
2878-04-011	CONCORDE Bullet Trial, 9x11 (Width mm x Height mm)
2878-04-012	CONCORDE Bullet Trial, 11x12 (Width mm x Height mm)
2878-04-013	CONCORDE Bullet Trial, 11x13 (Width mm x Height mm)
2864-10-019	CONCORDE Bullet In-Line Slap-Hammer
2879-01-009	CONCORDE Bayoneted Inserter, 9mm
2879-01-000	CONCORDE Straight Inserter, 9mm
2878-20-200	CONCORDE Bullet Tray
2878-20-001	CONCORDE Bullet Lid
2878-20-500	CONCORDE Bullet Caddy



CONCORDE Bayoneted Inserter



CONCORDE Straight Inserter

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 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), TLIF (CONCORDE, CONCORDE Bullet, 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 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.
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.

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