CONCORDE®
Interbody System

for Transforaminal Lumbar Interbody Fusion (TLIF)

Surgical Technique

DePuy Synthes

PART OF THE Johnson&Johnson FAMILY OF COMPANIES

Contents

Image intensifier control

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.

Identify proper pedicle insertion points for guide wires, taps or screws. The optimal insertion point is at the intersection of the transverse process and superior articular process. Consult the EXPEDIUM® Spinal System Surgical Technique, EXPEDIUM VERSE® System Guide, or VIPER® 2 System Guide for additional details on pedicle screw insertion.

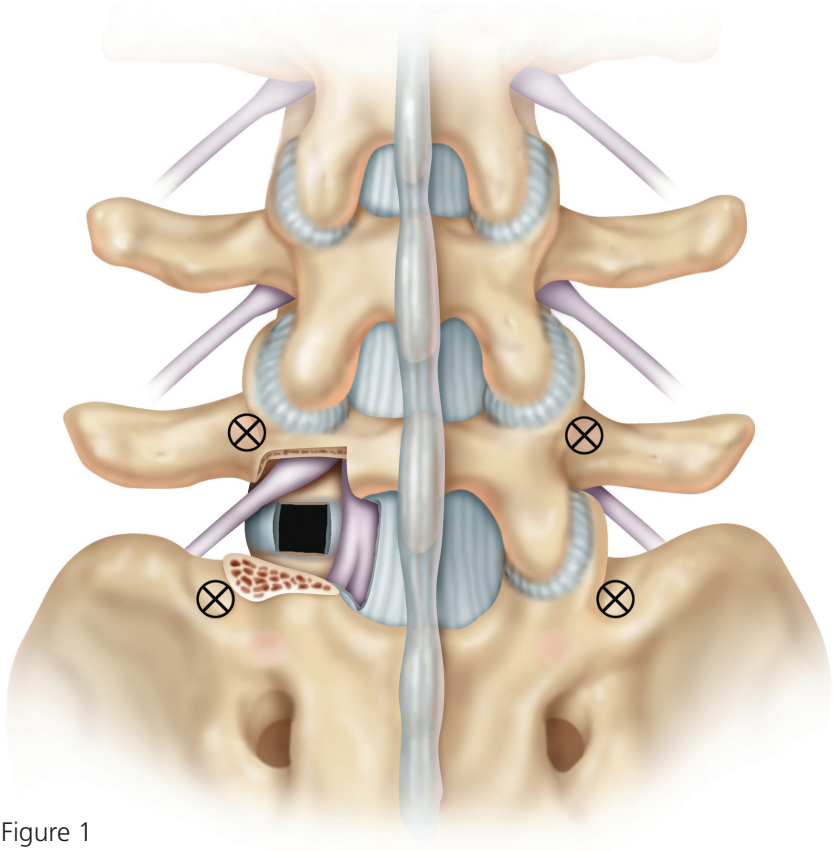


Figure 1

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.

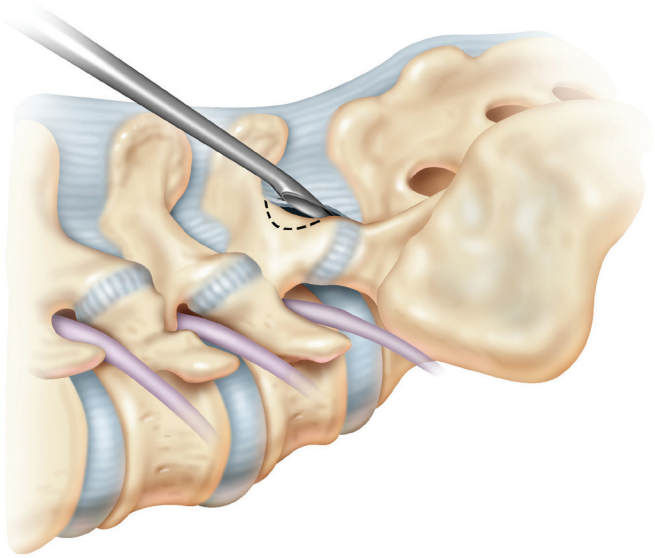


Figure 2

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.

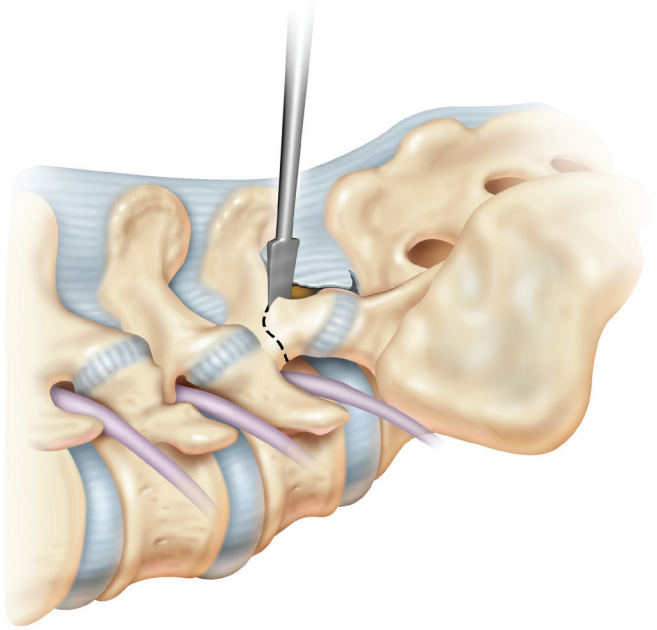


Figure 3

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).

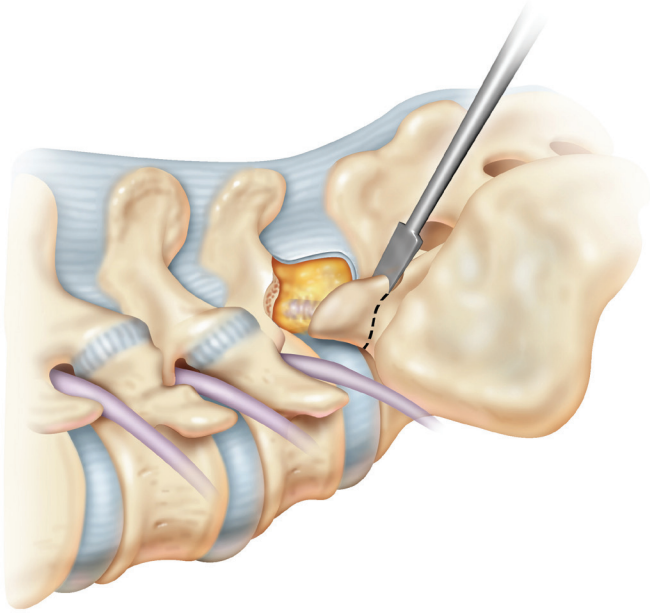


Figure 4

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 coagulate the epidural veins overlying the disc space.

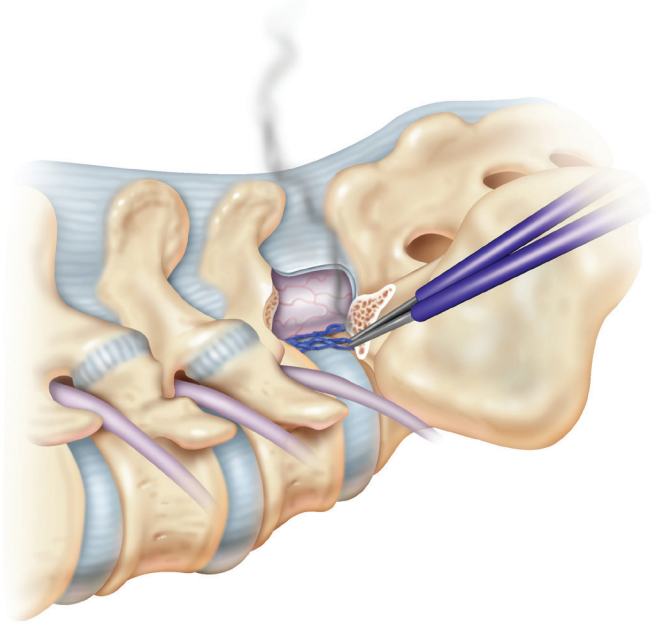


Figure 5

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). The epidural veins have now been ligated to afford a corridor of approach to the disc space.

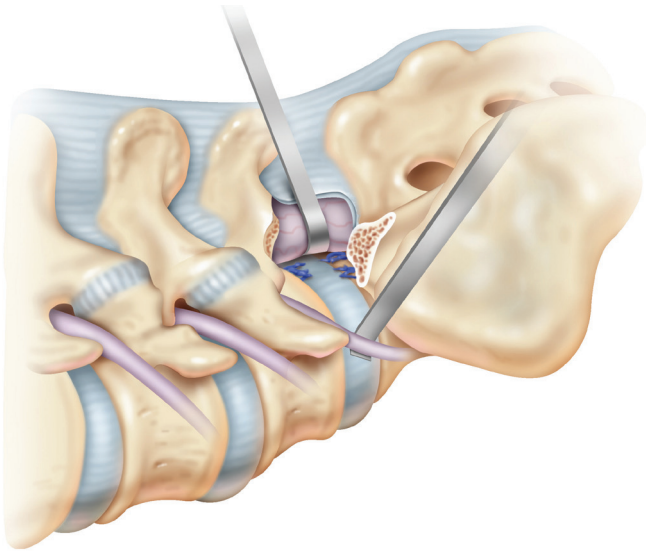


Figure 6

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).

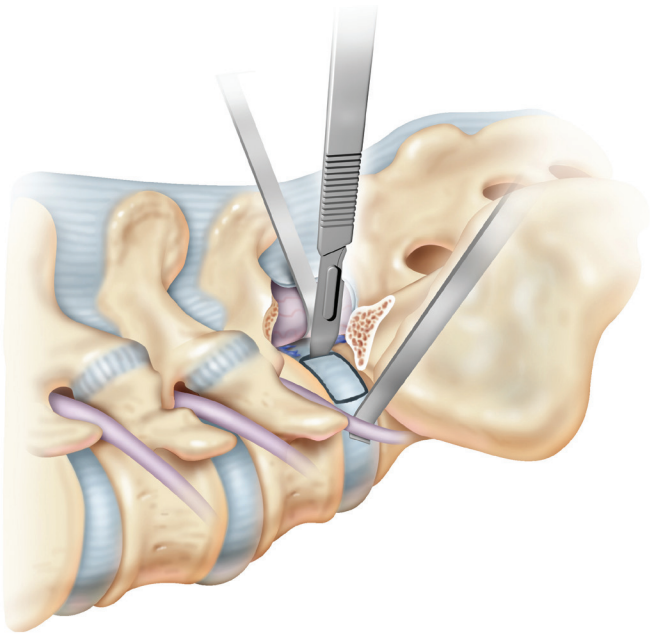


Figure 7

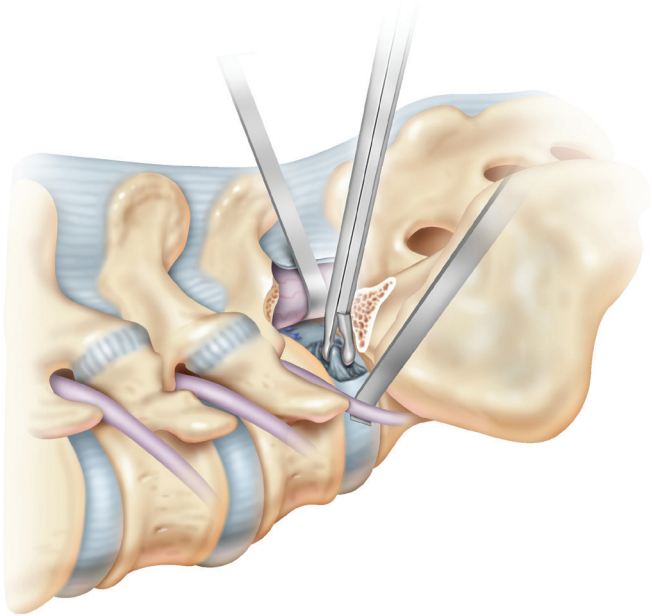


Figure 8

4

Initial Distraction and Preparation of Disc Space

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.

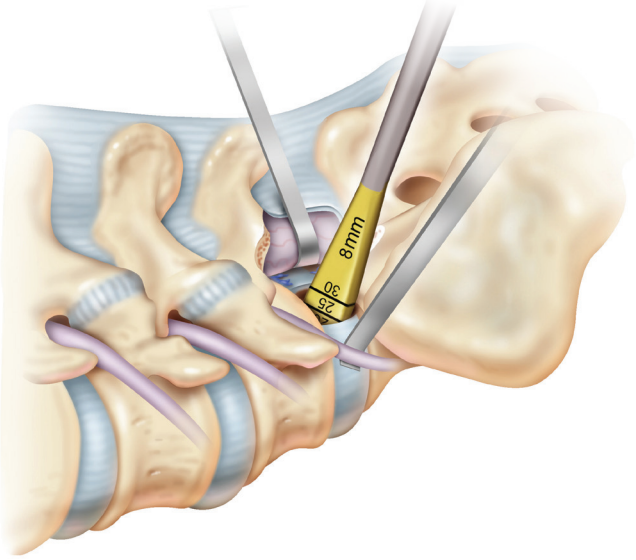


Figure 9

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 endplates are parallel (Figure 11) in order to maximise the posterior opening of the disc space to allow optimal access for disc preparation and reconstruction.

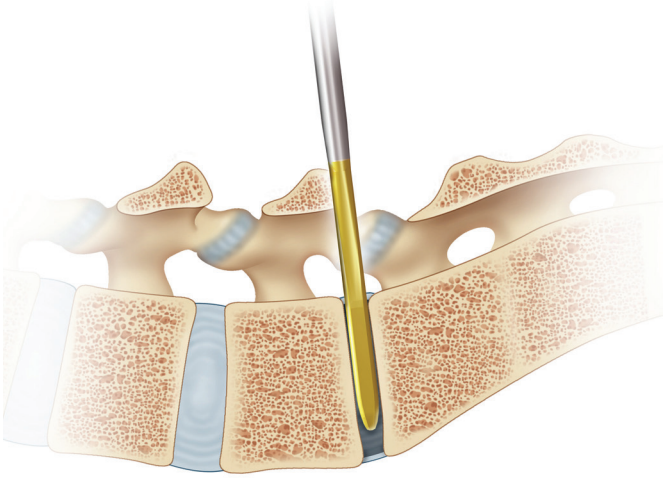


Figure 10

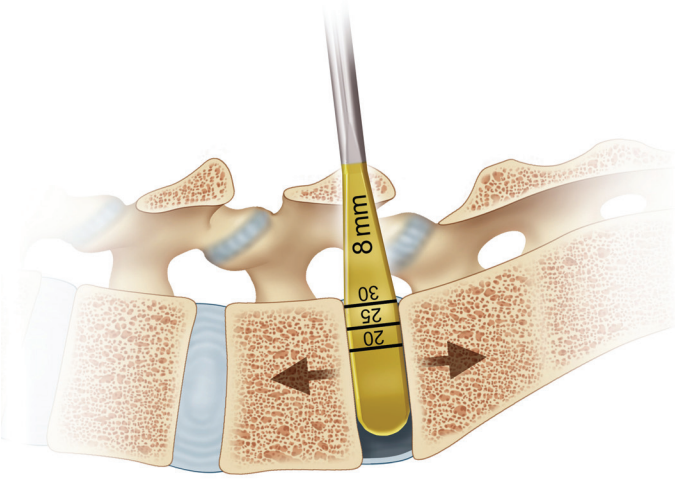


Figure 11

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).

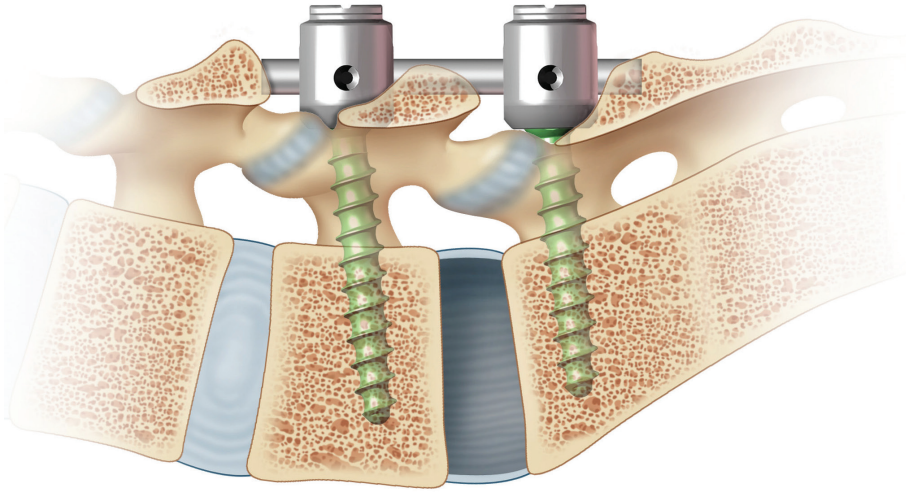


Figure 12

5

Final Disc Preparation and Endplate Cleaning

The final discetomy 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 visualization of the orientation of the endplates.

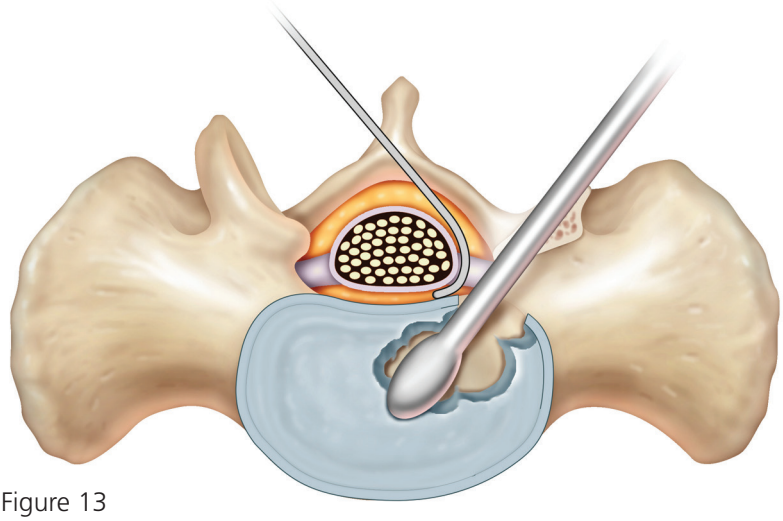


Figure 13

An osteotome can be used to remove the posterior lip of either vertebral body flush to the endplates to optimize visualization 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.

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

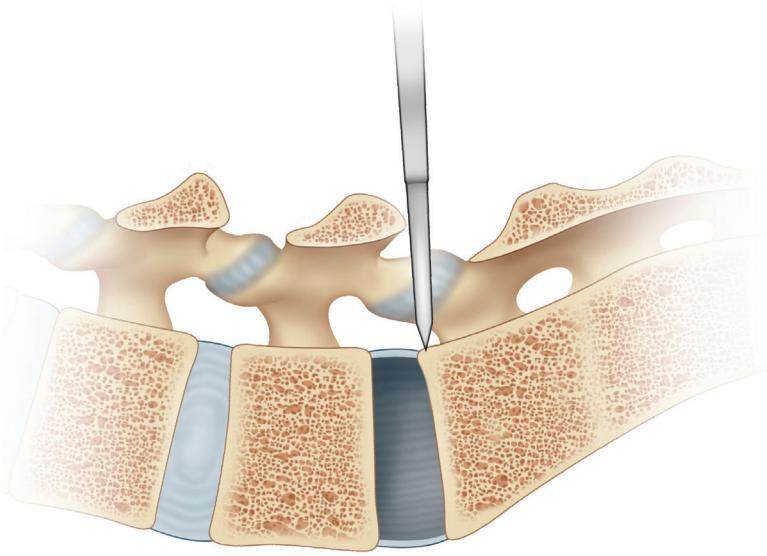


Figure 14

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).

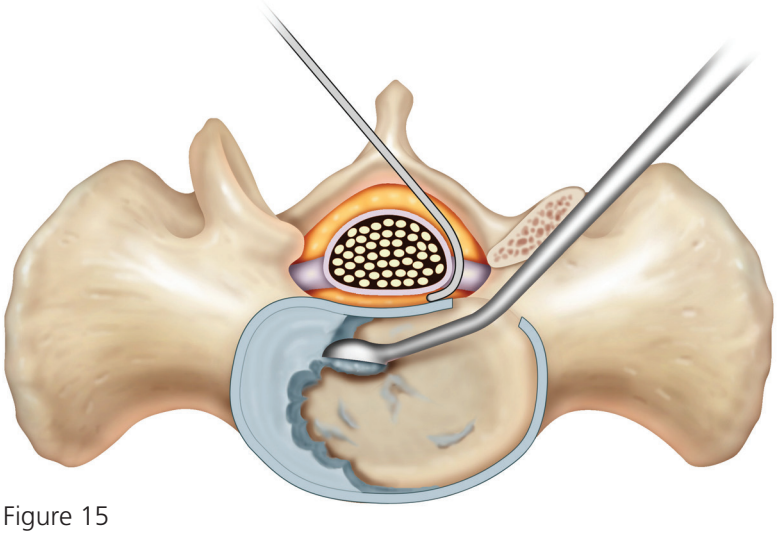


Figure 15

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 utilized 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 utilized to remove disc material from the contralateral side of the disc space; these will specifically address the inferior and superior endplates (Figure 16).

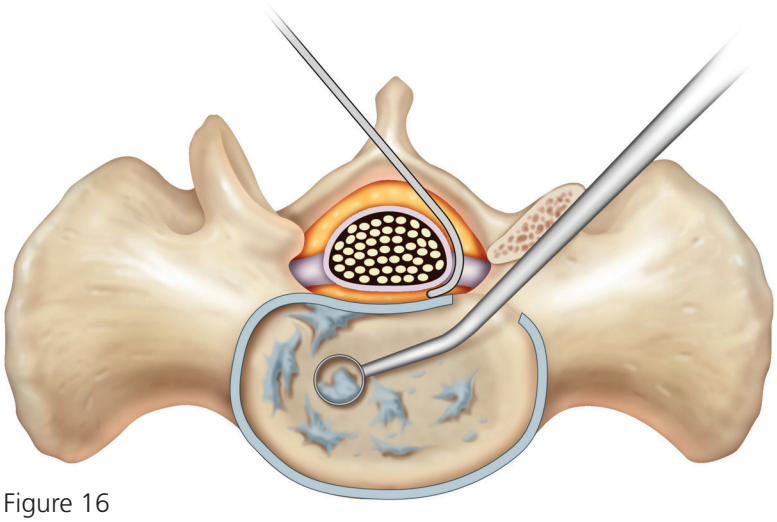


Figure 16

6

Decortication and Placement of Bone Graft

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 contralateral side of the disc space with bone graft using a variety of straight and curved bone tamps from the disc preparation set (Figure 17).

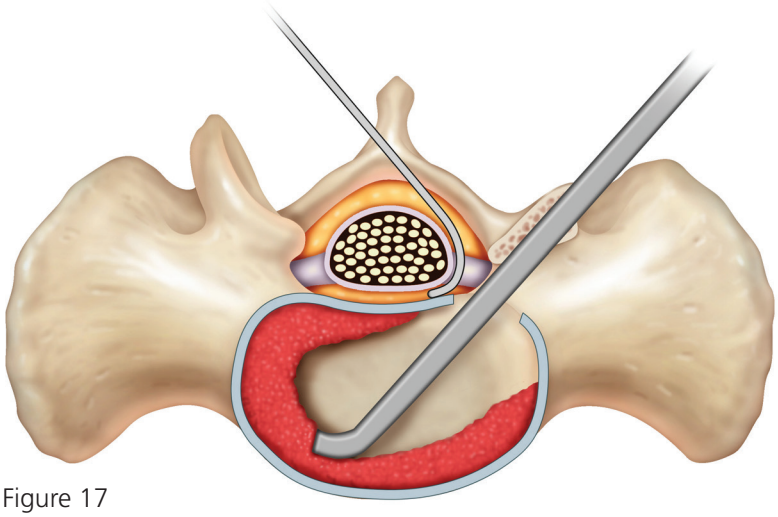


Figure 17

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

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 analyzing disc orientation and ultimate desired lordosis.

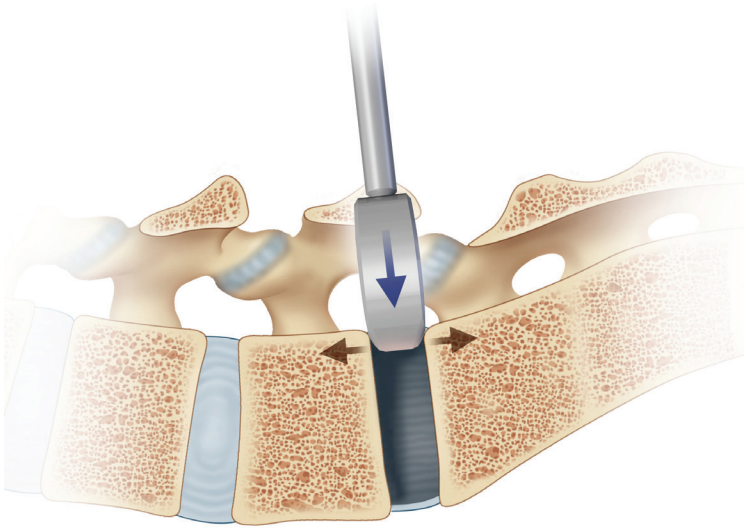


Figure 18

The cage trials match the parallel configuration available with CONCORDE Interbody System Implants. Trials are sized to match the overall height of the corresponding implant, including the teeth of the implant.

8

Cage Insertion—CONCORDE Interbody System

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 Interbody System Implants should only be used with the CONCORDE Interbody System Inserters (2879-01-000 or 2879-01-009).

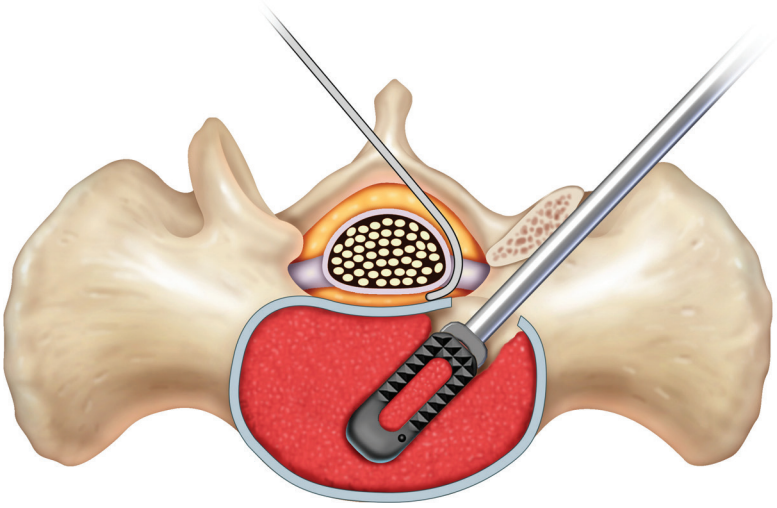


Figure 19: CONCORDE Interbody System

9

Implant Orientation for Lordotic CONCORDE Interbody System

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

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.

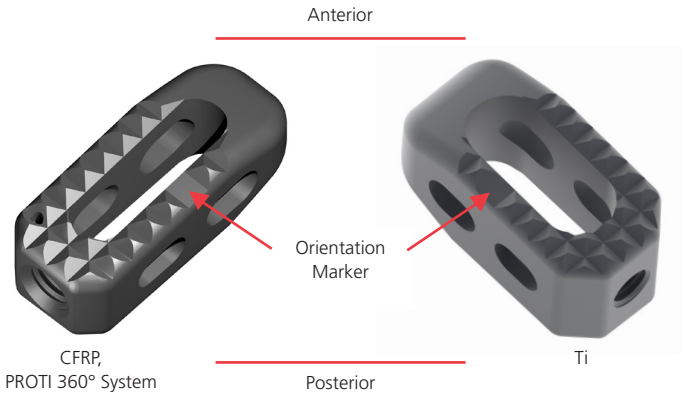


Figure 20

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 selected pedicle 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.

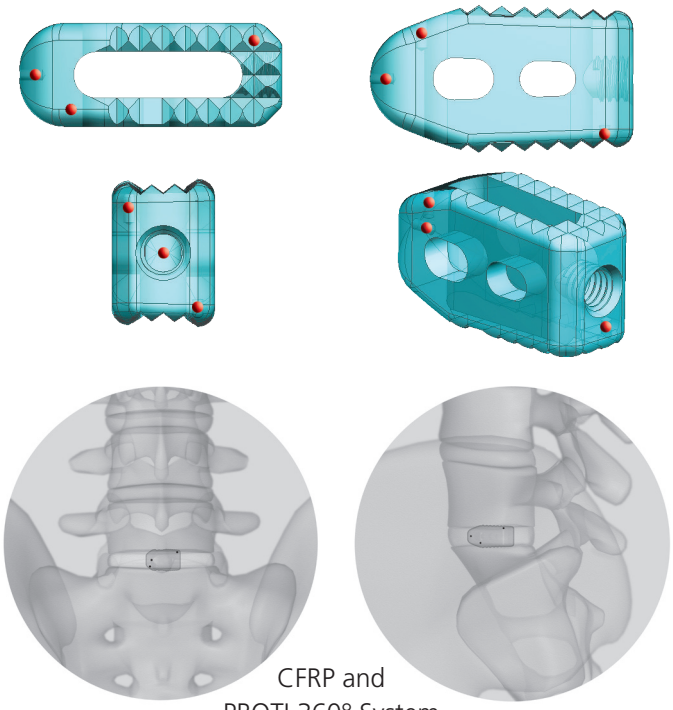
Confirm that the rod does not impinge on the adjacent facets. Once desired lordosis of the segment and positioning of the implant is confirmed, revisit all screws for final tightening.

11

Verification of Final Cage Placement—CONCORDE Interbody System

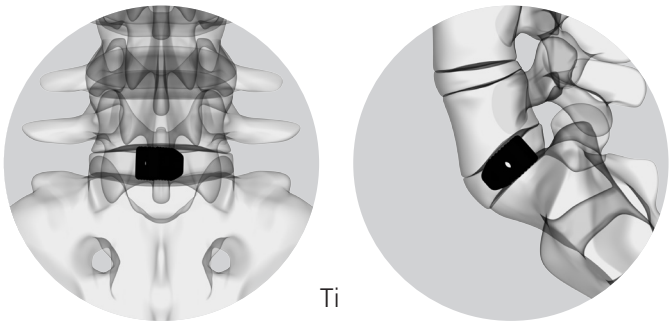
- An X-ray should be taken to verify final cage placement.

In the CFRP and PROTI 360°™ System, the appearance of three tantalum markers will identify the position of the CONCORDE Interbody System Cage in the sagittal, coronal, and axial planes.



CFRP and
PROTI 360° System

In the Ti Spacer, the implant windows will identify the position of the CONCORDE Interbody System Cage in the sagittal plane.



Ti

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 roots, especially where they may be adhesed 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 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. 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 optimized 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.

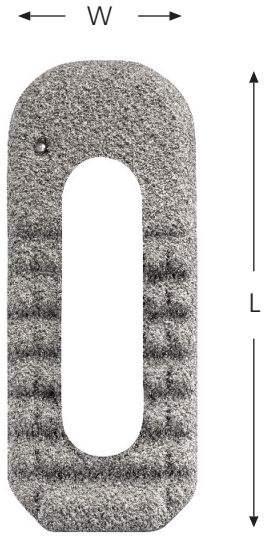
CONCORDE™ Interbody System Product Catalog

Parallel Implants Width (mm) x Height (mm) x Length (mm)

CFRP	Ti	Description
187823107	196923007	CONCORDE Bullet Parallel, 9x7x23
187823108	196923008	CONCORDE Bullet Parallel, 9x8x23
187823109	196923009	CONCORDE Bullet Parallel, 9x9x23
187823110	196923010	CONCORDE Bullet Parallel, 9x10x23
187823111	196923011	CONCORDE Bullet Parallel, 9x11x23
187823212	196923212	CONCORDE Bullet Parallel, 11x12x23
187823213	196923213	CONCORDE Bullet Parallel, 11x13x23
187827107	196927017	CONCORDE Bullet Parallel, 9x7x27
187827108	196927018	CONCORDE Bullet Parallel, 9x8x27
187827109	196927019	CONCORDE Bullet Parallel, 9x9x27
187827110	196927010	CONCORDE Bullet Parallel, 9x10x27
187827111	196927011	CONCORDE Bullet Parallel, 9x11x27
187827212	196927212	CONCORDE Bullet Parallel,11x12x27
187827213	196927213	CONCORDE Bullet Parallel,11x13x27

Lordotic Implants Width (mm) x Height (mm) x Length (mm)

CFRP	Ti	Description
187823408	196923508	CONCORDE Bullet 5° Lordotic, 9x8x23
187823409	196923509	CONCORDE Bullet 5° Lordotic, 9x9x23
187823410	196923510	CONCORDE Bullet 5° Lordotic, 9x10x23
187823411	196923511	CONCORDE Bullet 5° Lordotic, 9x11x23
187823512	196923612	CONCORDE Bullet 5° Lordotic, 11x12x23
187823513	196923613	CONCORDE Bullet 5° Lordotic, 11x13x23
187827408	196927518	CONCORDE Bullet 5° Lordotic, 9x8x27
187827409	196927519	CONCORDE Bullet 5° Lordotic, 9x9x27
187827410	196927510	CONCORDE Bullet 5° Lordotic, 9x10x27
187827411	196927511	CONCORDE Bullet 5° Lordotic, 9x11x27
187827512	196927712	CONCORDE Bullet 5° Lordotic, 11x12x27
187827513	196927713	CONCORDE Bullet 5° Lordotic, 11x13x27



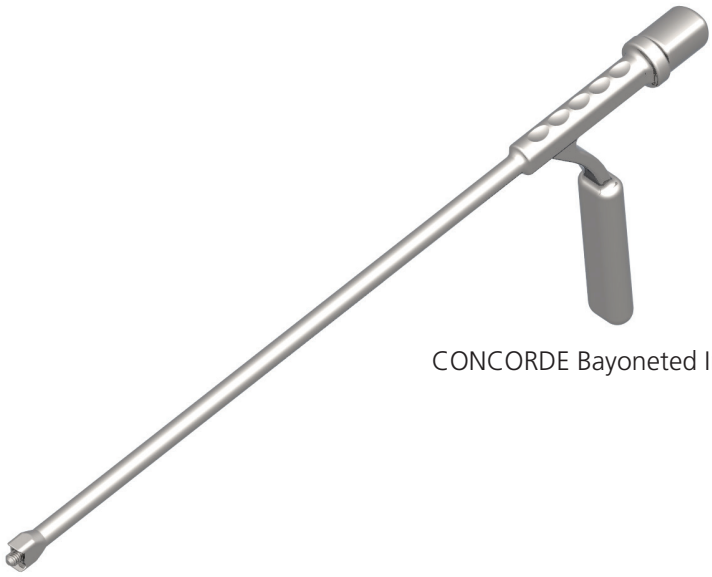
CONCORDE ProTi 360°™ Interbody System Parallel Implants

Short 9 mm x 23 mm	Description
188823107	CONCORDE ProTi P, 9x7x23 mm
188823108	CONCORDE ProTi P, 9x8x23 mm
188823109	CONCORDE ProTi P, 9x9x23 mm
188823110	CONCORDE ProTi P, 9x10x23 mm
188823111	CONCORDE ProTi P, 9x11x23 mm
188823112	CONCORDE ProTi P, 9x12x23 mm
188823113	CONCORDE ProTi P, 9x13x23 mm
188823114	CONCORDE ProTi P, 9x14x23 mm
188823115	CONCORDE ProTi P, 9x15x23 mm
Long 9 mm x 27 mm	
188827107	CONCORDE ProTi P, 9x7x27 mm
188827108	CONCORDE ProTi P, 9x8x27 mm
188827109	CONCORDE ProTi P, 9x9x27 mm
188827110	CONCORDE ProTi P, 9x10x27 mm
188827111	CONCORDE ProTi P, 9x11x27 mm
188827112	CONCORDE ProTi P, 9x12x27 mm
188827113	CONCORDE ProTi P, 9x13x27 mm
188827114	CONCORDE ProTi P, 9x14x27 mm
188827115	CONCORDE ProTi P, 9x15x27 mm

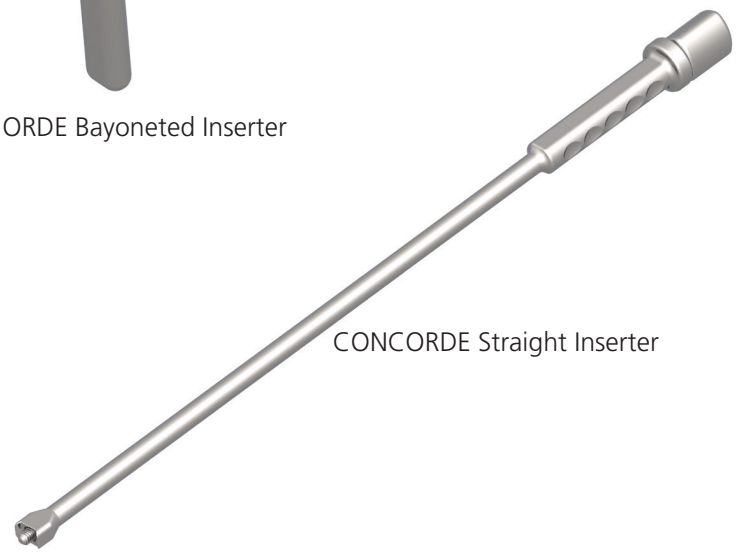
CONCORDE ProTi 360°™ Interbody System Lordotic Implants

Short 9 mm x 23 mm	Description
188823408	CONCORDE ProTi 5°, 9x8x23 mm
188823409	CONCORDE ProTi 5°, 9x9x23 mm
188823410	CONCORDE ProTi 5°, 9x10x23 mm
188823411	CONCORDE ProTi 5°, 9x11x23 mm
188823412	CONCORDE ProTi 5°, 9x12x23 mm
188823413	CONCORDE ProTi 5°, 9x13x23 mm
188823414	CONCORDE ProTi 5°, 9x14x23 mm
188823415	CONCORDE ProTi 5°, 9x15x23 mm
Long 9 mm x 27 mm	
188827408	CONCORDE ProTi 5°, 9x8x27 mm
188827409	CONCORDE ProTi 5°, 9x9x27 mm
188827410	CONCORDE ProTi 5°, 9x10x27 mm
188827411	CONCORDE ProTi 5°, 9x11x27 mm
188827412	CONCORDE ProTi 5°, 9x12x27 mm
188827413	CONCORDE ProTi 5°, 9x13x27 mm
188827414	CONCORDE ProTi 5°, 9x14x27 mm
188827415	CONCORDE ProTi 5°, 9x15x27 mm

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, 9x12 (Width mm x Height mm)
2878-04-013	CONCORDE Bullet Trial, 9x13 (Width mm x Height mm)
2864-10-019	CONCORDE Bullet In-Line Slap-Hammer
2879-01-009	CONCORDE Bayoneted Inserter, 9 mm
2879-01-000	CONCORDE Straight Inserter, 9 mm
2878-20-200	CONCORDE Bullet Tray
2878-20-001	CONCORDE Bullet Lid
2878-20-500	CONCORDE Bullet Caddy



CONCORDE Bayoneted Inserter



CONCORDE Straight Inserter

CONCORDE Interbody System Instrument and Implant Set (CONBLC)

Graphic Case	
2878-20-200	CONCORDE Bullet Tray
2878-20-001	CONCORDE Bullet Tray Lid
2878-20-500	CONCORDE Bullet Caddy Set

Instruments	
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, 9 mm
2879-01-000	CONCORDE Straight Inserter, 9 mm

Implants

Parallel

CONCORDE Bullet 9x23	
1878-23-107	7 mm Height, 2 ea.
1878-23-108	8 mm Height, 2 ea.
1878-23-109	9 mm Height, 2 ea.
1878-23-110	10 mm Height, 2 ea.
1878-23-111	11 mm Height, 2 ea.
CONCORDE Bullet 11x23	
1878-23-212	12 mm Height
1878-23-213	13 mm Height
CONCORDE Bullet 9x27	
1878-27-107	7 mm Height, 2 ea.
1878-27-108	8 mm Height, 2 ea.
1878-27-109	9 mm Height, 2 ea.
1878-27-110	10 mm Height, 2 ea.
1878-27-111	11 mm Height, 2 ea.
CONCORDE Bullet 11x27	
1878-27-212	12 mm Height
1878-27-213	13 mm Height

Lordotic (5°)

CONCORDE Bullet 9x23	
1878-23-408	8 mm Height, 2 ea.
1878-23-409	9 mm Height, 2 ea.
1878-23-410	10 mm Height, 2 ea.
1878-23-411	11 mm Height, 2 ea.
CONCORDE Bullet 11x23	
1878-23-512	12 mm Height
1878-23-513	13 mm Height
CONCORDE Bullet 9x27	
1878-27-408	8 mm Height, 2 ea.
1878-27-409	9 mm Height, 2 ea.
1878-27-410	10 mm Height, 2 ea.
1878-27-411	11 mm Height, 2 ea.
CONCORDE Bullet 11x27	
1878-27-512	12 mm Height
1878-27-513	13 mm Height

CONCORDE Interbody System Ti Implant Only Set (CONBTA)

Graphic Case

2797-26-521	Graphic Case
2878-20-500	CONCORDE Bullet Caddy Set

Implants

Parallel

CONCORDE Bullet Ti 9x23	
1969-23-007	7 mm Height, 2 ea.
1969-23-008	8 mm Height, 2 ea.
1969-23-009	9 mm Height, 2 ea.
1969-23-010	10 mm Height, 2 ea.
1969-23-011	11 mm Height, 2 ea.
CONCORDE Bullet Ti 11x23	
1969-23-212	12 mm Height
1969-23-213	13 mm Height
CONCORDE Bullet Ti 9x27	
1969-27-017	7 mm Height, 2 ea.
1969-27-018	8 mm Height, 2 ea.
1969-27-019	9 mm Height, 2 ea.
1969-27-010	10 mm Height, 2 ea.
1969-27-011	11 mm Height, 2 ea.
CONCORDE Bullet Ti 11x27	
1969-27-212	12 mm Height
1969-27-213	13 mm Height

Lordotic (5°)

CONCORDE Bullet Ti 9x23	
1969-23-508	8 mm Height, 2 ea.
1969-23-509	9 mm Height, 2 ea.
1969-23-510	10 mm Height, 2 ea.
1969-23-511	11 mm Height, 2 ea.
CONCORDE Bullet Ti 11x23	
1969-23-612	12 mm Height
1969-23-613	13 mm Height
CONCORDE Bullet Ti 9x27	
1969-27-518	8 mm Height, 2 ea.
1969-27-519	9 mm Height, 2 ea.
1969-27-510	10 mm Height, 2 ea.
1969-27-511	11 mm Height, 2 ea.
CONCORDE Bullet Ti 11x27	
1969-27-712	12 mm Height
1969-27-713	13 mm Height

CONCORDE® ProTi 360°™ System Implant Only Set
Parallel (CONPPA)
Lordotic (CONPLA)

Implants

Parallel

CONCORDE ProTi 360° System 9x23	
188823107	7 mm Height, 2 ea.
188823108	8 mm Height, 2 ea.
188823109	9 mm Height, 2 ea.
188823110	10 mm Height, 2 ea.
188823111	11 mm Height, 2 ea.
188823112	12 mm Height, 2 ea.
188823113	13 mm Height, 2 ea
188823114	14 mm Height, 1 ea.
188823115	15 mm Height, 1 ea.
CONCORDE ProTi 360° System 9x27	
188827107	7 mm Height, 2 ea.
188827108	8 mm Height, 2 ea.
188827109	9 mm Height, 2 ea.
188827110	10 mm Height, 2 ea.
188827111	11 mm Height, 2 ea.
188827112	12 mm Height, 2 ea.
188827113	13 mm Height, 2 ea.
188827114	14 mm Height, 1 ea.
188827115	15 mm Height, 1 ea.

Lordotic (5°)

CONCORDE ProTi 360° System 9x23	
188823408	8 mm Height, 2 ea.
188823409	9 mm Height, 2 ea.
188823410	10 mm Height, 2 ea.
188823411	11 mm Height, 2 ea.
188823412	12 mm Height, 2 ea.
188823413	13 mm Height, 2 ea.
188823414	14 mm Height, 1 ea.
188823415	15 mm Height, 1 ea.
CONCORDE ProTi 360° System 9x27	
188827408	8 mm Height, 2 ea.
188827409	9 mm Height, 2 ea.
188827410	10 mm Height, 2 ea.
188827411	11 mm Height, 2 ea.
188827412	12 mm Height, 2 ea.
188827413	13 mm Height, 2 ea.
188827414	14 mm Height, 1 ea.
188827415	15 mm Height, 1 ea.

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.

CONCORDE Bullet Ti and CFRP

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 issues, 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 ixaion 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

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.

For detailed cleaning and sterilization instructions, please refer to:
www.synthes.com/cleaning-sterilization
In Canada, the cleaning and sterilization instructions will be provided with the Loaner shipments.

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.

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.

CONCORDE ProTi 360° System

The ProTi360° 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 posterior or transforaminal approach using autogenous bone. When used as interbody fusion devices these implants are intended for use with supplemental fixation systems cleared for use in the thoracolumbar spine.

Contraindications

- Acute or chronic infections or severe defects of the osseous structures of the vertebral bodies, which need to be sound for the stable implantation of the devices
- Bone tumors in the region of the implant anchoring
- Unwillingness or inability of the patient to follow the instructions for postoperative treatment
- Any medical or surgical condition that could preclude the potential success of the implantation
- Pregnancy
- Osteoporosis or similar bone density loss
- Systemic or metabolic illnesses
- Drug abuse or alcoholism
- Generally poor condition of the patient
- Adiposity
- Psychosocial issues; lack of co-operation by the patient

Warnings

WARNINGS AND POTENTIAL RISKS

The surgeon should be aware of the following:

1. The correct selection of the implant is extremely important. The potential for success is increased by the selection of the proper size, shape and design of the implant. The size and shape of the human spine presents limiting restrictions of the size and strength of implants. No implant can be expected to withstand the unsupported stresses of full weight bearing.
2. The surgeon must ensure that all necessary implants and instruments are on hand prior to surgery. The device must be handled and stored carefully, protected from damage, including from corrosive environments. They should be carefully unpacked and inspected for damage prior to use.
3. All instruments must be cleaned and sterilized prior to surgery.
4. As with all orthopaedic implants, DePuy Synthes Spine Interbody Systems should never be reused under any circumstances.
5. The DePuy Synthes Spine Interbody System should never be used with dissimilar materials.
6. Proper implant selection and patient compliance to postoperative precautions will greatly affect surgical outcomes. Patients who smoke have been shown to have an increased incidence of nonunion. Therefore, these patients should be advised of this fact and warned of the potential consequences.
7. Postoperative care is important. The patient should be instructed in the limitations of his/her implant and should be cautioned regarding weight bearing and body stress on the appliance prior to secure bone healing.

Precautions

Federal law restricts this device to sale by or on the order of a physician.

PREOPERATIVE:

1. Only patients that meet the criteria described in the indications should be selected.
2. Patient conditions and/or pre-dispositions such as those addressed in the contraindications section should be avoided.
3. Care should be used in the handling and storage of the implant components. The implants should not be scratched or otherwise damaged. Implants and instruments should be protected during storage especially from corrosive environments.
4. All instruments should be cleaned and sterilized before use.

INTRAOPERATIVE:

1. Any instruction manuals should be carefully followed.
2. At all times, extreme caution should be used around the spinal cord and nerve roots. Damage to nerves may occur resulting in a loss of neurological functions.
3. Autograft may be placed in the area to be fused.

POSTOPERATIVE:

1. The physician's postoperative directions and warnings to the patient and the corresponding patient compliance are extremely important.
2. Detailed instructions on the use and limitations of the device should be given to the patient. The risk of bending, loosening, or breakage of an internal fixation device during postoperative rehabilitation may be increased if the patient is active, or if the patient is debilitated or demented. The patient should be warned to avoid falls or sudden jolts in spinal position.
3. To allow maximum chances for a successful surgical result, the patient or device should not be exposed to mechanical vibrations that may loosen the device construct. The patient should be warned of this possibility and instructed to limit and restrict physical activities, especially lifting, twisting motions and any type of sport participation. The patient should be advised not to smoke or consume alcohol during the healing process.
4. If a nonunion develops or if the components loosen, bend, and/or break, the device(s) should be revised and/or removed immediately before serious injury occurs. Failure to immobilize a delayed union or nonunion of bone will result in excessive and repeated stresses on the implant. By the mechanism of fatigue these stresses can cause eventual bending, loosening, or breakage of the device(s). It is important that immobilization of the spinal surgical site be maintained until firm bony union is established and confirmed by radiographic examination. The patient must be adequately warned of these hazards and closely supervised to ensure cooperation until bony union is confirmed.
5. Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopaedic implants, none of the DePuy Synthes Spine Interbody Systems device components should ever be reused under any circumstances.

Limited Warranty and Disclaimer: DePuy Synthes 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.

Please also refer to the package insert(s) or other labeling associated with the devices identified in this surgical technique for additional information.

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

Some devices listed in this surgical technique may not have been licensed in accordance with Canadian law and may not be for sale in Canada. Please contact your sales consultant for items approved for sale in Canada.

Not all products may currently be available in all markets.

DePuy Synthes

PART OF THE Johnson & Johnson FAMILY OF COMPANIES

For recognized manufacturer, refer to product label.

CONCORDE® Bullet CFRP and Ti
Manufactured and Distributed by:
Synthes USA, LLC
1101 Synthes Avenue
Monument, Co 80132
USA

CONCORDE® ProTi 360°™ System
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83 South Commerce Way, Suite 310
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DSUS/SPN/0116/1141 Rev 1 4/18 SCDS