

Surgical Technique

PIPELINE[™]
EXPANDABLE
Access System

CONCORDE[™]



MIS T.L.I.F.[®] Technique Guide featuring
the PIPELINE[™] Expandable Retractor
and CONCORDE[™] Instrumentation

DESIGNING SURGEONS

J. Patrick Johnson, MD
Cedars Sinai Medical Center
Los Angeles, CA

Peter O. Newton, MD
Pediatric Orthopedic & Scoliosis Center
San Diego, CA

Ferran Pellisé, MD
Hospital Vall d'Hebron
Barcelona, Spain

Frank M. Phillips, MD
Rush University Medical Center
Chicago, IL

John Regan, MD
California Spine Group
Beverly Hills, CA

Gary Schneiderman, MD
Sutter Neuroscience Institute
Sacramento, CA

Todd Albert, MD
Thomas Jefferson University Hospital
Philadelphia, PA

Michael Groff, MD
Indiana University Medical Center
Indianapolis, IN

Larry Khoo, MD
UCLA, Los Angeles, CA

Palou Caceras, MD
Hospital Del Mar
Barcelona, Spain

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I N T R O D U C T I O N

The Transforaminal Lumbar Interbody Fusion (T.L.I.F.[®]) technique to spinal fusion has proven to be a safe and efficacious approach for the treatment of the lumbar spine. As the prevalence of Minimally Invasive Surgery in spine has grown in recent years, the T.L.I.F. approach has emerged as a technique conducive to less invasive approaches where access is limited.

This surgical technique describes a Minimally Invasive T.L.I.F. approach featuring the PIPELINE[™] Expandable Retractor and CONCORDE[™] Instruments.

Designed to simplify tubular access, the PIPELINE Expandable Retractor is well suited for posterior lumbar decompression and fusion procedures. Offering the flexibility to adjust to a variety of anatomical and surgical conditions, this state-of-the-art retraction system includes three-directional expansion capabilities, individually telescoping blades, and microadjustability up to two levels. Complemented by a comprehensive set of minimally invasive instruments, the PIPELINE Expandable Retraction System delivers on its promise to simplify minimally invasive access.

CONCORDE Instruments represent the very latest in minimally invasive T.L.I.F. technology. Optimized for use with the PIPELINE Access System, CONCORDE Instruments simplify tubular placement of a unilateral allograft spacer with ease, control, and confidence.

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NOTE: Any operating room table used for image procedures will suffice, though the Jackson Table offers an optimal amount of unrestricted fluoroscopic visualization.

Step 1 - Patient Positioning

- Position patient in the prone position. The use of a Jackson Table will provide an unrestricted view for imaging and an optional Wilson Frame will assist in achieving the proper patient position.



- On the contralateral side to the planned incision, position a Clark Socket (■) on the table rail lateral to the mid or upper thigh to facilitate subsequent placement of the Rigid Arm Assembly.
- Once the surgical preparation and draping are completed, the sterile Rigid Arm Assembly is attached to the table via the Clark Socket with the aid of the circulating nurse.

Step 2 – Anatomical Landmarks



- Dilation of the multifidus and longissimus muscles that run parallel to the spine is the primary objective. Fluoroscopy is used to accurately locate the desired level and close attention is made to keep the targeted surgical site at the center of the fluoroscopic view. A C-arm with AP and Lateral views provide proper imaging.
- For a transforaminal lumbar interbody fusion the center of the target is generally the medial border of the facet joint of the desired disc level.

NOTE: The AP imaging of this anatomy is optional and may be eliminated to avoid the need to rotate the C-Arm, which can lead to breaks in the sterile technique.

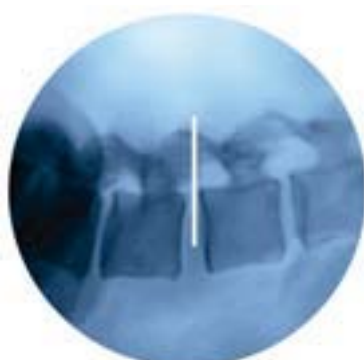
Step 3 – Targeting



- An Incision Template may be used with fluoroscopic guidance to locate the incision's center over the disc space of the proper level to be operated on.
- A longitudinal incision slightly larger than the Retractor is made, usually through skin only, since the Dilators will pierce and dilate the fascia.

NOTE: Proper targeting is very important to maximize ease of surgery and minimize the need to enlarge the incision.

Tip: The Retractor measures 25mm in outer diameter and can be used as a guide when determining the length of the initial incision.



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Step 4 – Initial Dilation

NOTE: *The Retractor can also be used for an open Wiltse approach where the natural muscle plane is located through a mobilized midline or paramedian incision. For open surgery, the dilation steps would not be required except for a single Dilator to identify the proper Retractor depth.*



- Once the incision is made, the first Dilator is inserted into the incision, bluntly piercing the fascia to dilate the paravertebral muscle tissue down to the laminar level. If desired, the fascia can be incised prior to the insertion of the first Dilator.
- The first Dilator's position is confirmed fluoroscopically. With careful tactile sensation, the paravertebral muscles are swept free from the lamina, base of the spinous process and over the facet joint with a gentle wandering motion to facilitate visualization and ensure the subsequent Dilators and Retractor are fully seated against the facet.
- The amount of subperiosteal dissection is minimal and thus there is little muscle that is denervated or robbed of its blood supply during these dilation steps which may reduce postoperative patient pain.

Step 5 – Serial Dilation and Depth Measurement



- Sequential dilation is performed by passing the next largest Dilator over the previously inserted Dilator.
- It is recommended that the depth measurement is taken from the second or third Dilators as they will be flush to the bone and produce the most accurate measurement. The depth should be taken at the point where the skin contacts the Dilator.



- Select the proper Retractor size based on the measured depth. The Retractor is available in two sizes that range from 35mm to 95mm depths.
Small Retractor = 35mm-55mm
Large Retractor = 55mm-95mm
- Continue serial dilation until all four Dilators have reached the facet.



TIP: An Introducer can be utilized to insert the largest Dilators. This may be required to overcome the tension of the fascia and to ensure the Dilators have reached the facet.

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Step 6 – Retractor Assembly



- The Retractor comes in four individual quadrants with four individual Telescoping Blades that must be assembled prior to surgery. It is important to identify the small (S) and large (L) designations on the components to ensure the Retractor is assembled properly.



- Assemble the Retractor by placing the quadrant with the short rack into the slot of a quadrant with a long rack. Repeat this until the two halves are assembled. Next, line up the long racks with the remaining slots in the opposing quadrants and slide them together. Depress the Release Buttons during these steps in order to disengage the ratchet feature.



- The Telescoping Blades can now be inserted into the four quadrants of the Retractor. Ensure the blades are properly seated by engaging one tooth of the ratcheting mechanism. This can be confirmed with both tactile and audible feedback.



Step 7 – Setting Retractor Depth



- With the aid of the surgical assistant, the Telescoping Blades of the Retractor can be deployed to the measured depth using the Blade Depth Tower.

- Rotate the ring on the Blade Depth Tower until the top surface of the ring corresponds to the desired depth.



- Align the Telescoping Blades with the teeth on the top of the Blade Depth Tower and press downward to deploy the blades. Additional alignment can be achieved by aligning the etched lines on the base of the Tower with the quadrants of the Retractor.

- Alternatively, the Blade Depth Tower can be set to the measured depth and held in one hand while it is inserted into the Retractor to deploy the Telescoping Blades.



TIP: The Retractor is available in a small and large size. Ensure the proper scale is used by matching the S for the Small Retractor and the L for the Large Retractor.

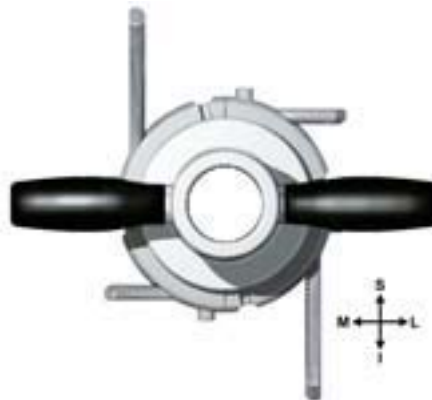
TIP: Ensure the Retractor is in the fully-closed position and held together when deploying the Telescoping Blades, so that all four Blades are deployed uniformly.

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Step 8 – Retractor Insertion

TIP: It is important to keep the Dilators fully seated on the facet during the insertion of the Retractor to avoid creep of soft tissue underneath the Dilators.

TIP: The T-Handle should be oriented perpendicular to the longer set of adjustment racks to allow room for your hands.



- The T-Handle Inserter can now be assembled to the top of the Retractor by lining up the pins with the four Universal Connection Slots. Ensure the Retractor is in the fully-closed position prior to assembling the T-Handle.
- The Retractor can be inserted over the Dilators by gently rotating the T-Handle Inserter back and fourth until the Retractor flange reaches the skin surface or the blades of the Retractor reach the spine. Irrigating the outer surfaces of the Retractor may assist in inserting the device.
- Place the Retractor in the final position by orienting the longer adjustment racks in the cephalad/caudal direction.

Step 9 – Universal Connection Slots



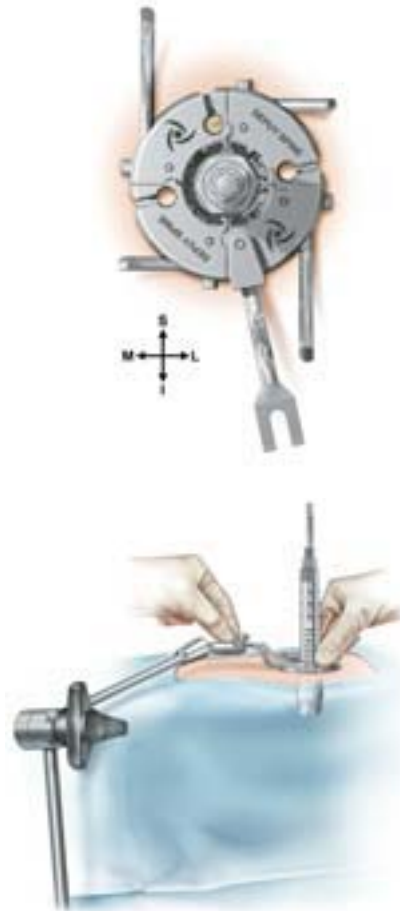
- There are four Universal Connection Slots on the top of the Retractor that can accommodate the Rigid Arm, Light Source and subsequent Retractor Blades.
- It is recommended to place the components in the following Universal Connection Slots to optimize the use of the attachments:
 1. The Rigid Arm Assembly should be placed in the caudal Universal Connection Slot.
 2. The Medial-Lateral Blades should be placed in the Medial-Lateral Universal Connection Slots.
 3. The Light Source should be placed in the cephalad Universal Connection Slot or any unused Medial-Lateral Universal Connection Slots.

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Step 10 – Rigid Arm Attachment

TIP: When attaching or adjusting the Rigid Arm Assembly care should be taken to maintain the Retractor's position up against the lamina and facet to prevent creep of soft tissue.

TIP: It is recommended to leave the medial and lateral Universal Connection Slots free for subsequent blade attachment.



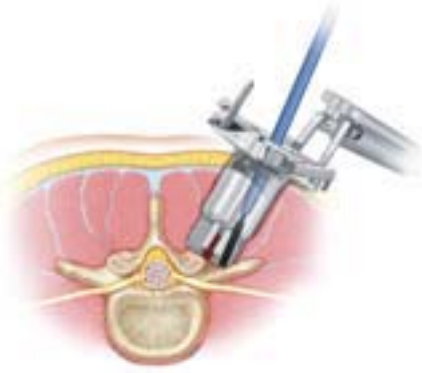
- The Rigid Arm Assembly, which was attached to the surgical table during Step 1, is now connected to the Retractor by attaching the Rigid Arm Attachment to the caudal Universal Connection Slot.
- Once the Rigid Arm Attachment is secure, the Rigid Arm can be connected by inserting the Rigid Arm Attachment fork to the end and tightening the thumb screw. This assembly will hold the Retractor in place for the remainder of the procedure.
- The Rigid Arm Assembly can be loosened at any point during the procedure to allow the Retractor to be angled for an alternate field of view.

Step 11 – Removal of the Dilators



- Once the Retractor has been fully positioned to the laminar level, and the Rigid Arm Assembly has been tightened, the Dilators can be removed.
- Care should be taken to ensure the PIPELINE Retractor remains fully seated during this step to prevent creep of soft tissue.

Step 12 – Initial Dissection



- Electrocautery can be used to remove any remaining muscle attached to the bony anatomy inside the Retractor. This prevents bleeding from the tissue. Gently palpate the bone with an inactive, extended length bovie tip to ensure that it is against bone. A pituitary rongeur can be used to pluck the fragments out of the exposure. Irrigation can be used routinely to ensure adequate visualization during these maneuvers.

Step 13 – Distraction



- The Retractor can be expanded in both the cephalad-caudal and medial-lateral directions by inserting the Distractor into the top of the Retractor and expanding to the desired opening. The ratcheted teeth on the racks allow for micro-adjustment and will hold the Retractor in the open position.
- The Distractor should be aligned to open parallel to the curved racks to avoid undue stresses on the Retractor.

NOTE: The Retractor can be expanded in the cephalad-caudal and medial-lateral directions. In addition, each quadrant has a Telescoping Blade to allow for individual Retractor depth adjustment.



Tip: It may be helpful to collapse the Retractor and incise the fascia to alleviate excess tension on the Retractor. Once the fascia is incised the Retractor can be expanded again. If possible, deploy the lateral Telescoping Blades (Step 14) prior to expansion to prevent lateral muscle creep.

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Step 14 – Telescoping Blade Adjustment



- After the Retractor is expanded and the facet joint is clearly visible, the Blade Pusher may be inserted into the Telescoping Blade track and used to deploy the Telescoping Blades further to prevent soft tissue creep in the working space. A small Cobb Elevator or equivalent instrument may be utilized to retract the soft tissue while deploying the Telescoping Blades.



- The Telescoping Blades can also be removed or adjusted upward at any point during surgery. Insert the Blade Remover into the tooth of the Telescoping Blade (1). The handle can gently be moved outward to relieve the ratchet mechanism of the Telescoping Blade (2) and the Telescoping Blade can be removed or adjusted (3).

NOTE: Muscle creep is common on the lateral aspect of the Retractor due to the presence of the multifidus and longissimus muscles.

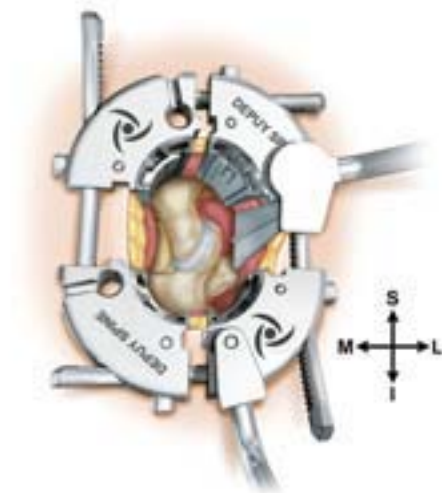
Step 15 – Medial-Lateral Blade Attachment



- If needed Medial-Lateral (ML) Blades may be attached to the Universal Connection Slots on the Retractor to prevent soft tissue creep through the side of the expanded Retractor.

- The ML Blades are available in a variety of different lengths and widths to conform to patient anatomy.

- The tops of the adjustment racks have etched lines indicating when the ML Blades will fit properly. When the lines are visible inside the opening, the respective ML Blades will fit inside the Retractor.



1 line = Small ML Blade

2 lines = Medium ML Blade

3 lines = Large ML Blade

Solid Etch Zone = Retractor fully expanded

ML Blade Sizes:

Small, Medium and Large Widths

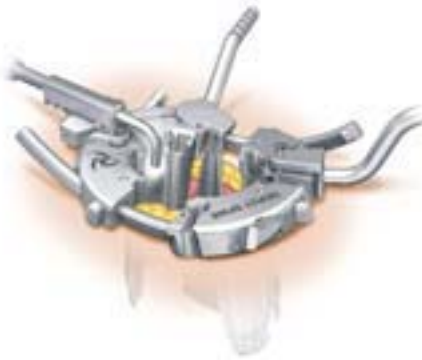
35, 55, 75 & 95mm Lengths



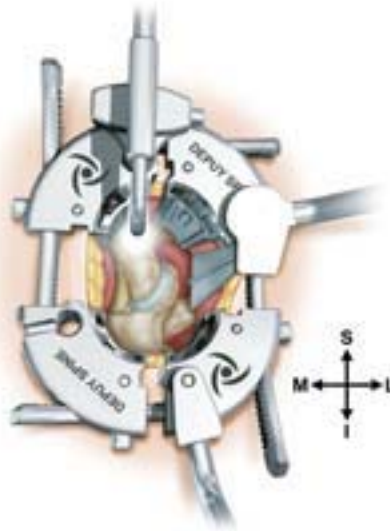
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Step 16 – Light Source Attachment

NOTE: The Light Source is compatible with most standard light boxes in the operating room. The Light Source cable comes with two adapters preassembled. The outermost adapter will accommodate a Karl Storz light source, the second adapter will accommodate the Richard Wolf light sources and the last adapter will accommodate the ACMI light source.



- A Light Source may also be attached to one of the remaining Universal Connections.
- If desired, the Light Source can be adjusted inward or outward depending on the amount of expansion of the Retractor.



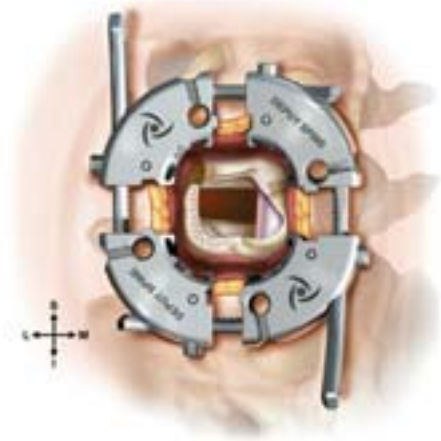
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Step 17 – Facetectomy and Discectomy



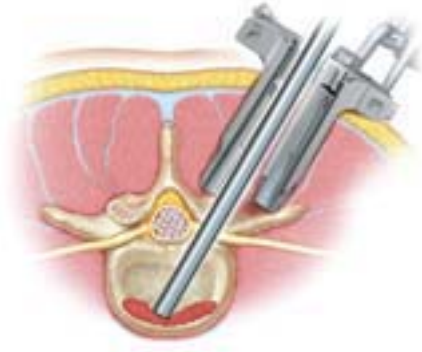
- A facetectomy and annulotomy are performed in order to gain access to the disc space. A complete discectomy is then performed and the vertebral body endplates are prepared.



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Step 18 – Bone Graft Placement



- Once the disc space is prepared the CONCORDE Bone Funnel is used to pre-pack autologous bone graft in the anterior portion of disc space, as well as medial and lateral to the planned spacer placement.
- A CONCORDE Distractor Guide may be used at this point to loosen the disc space in order to facilitate disc removal, endplate preparation and graft placement.



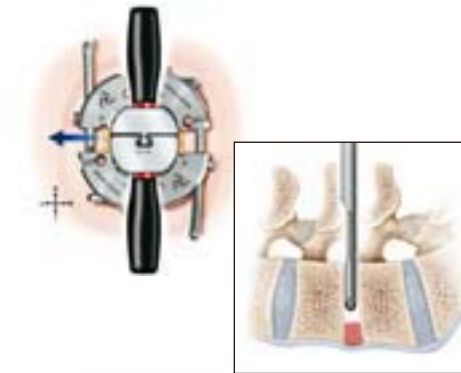
- The CONCORDE Bone Funnel has a graft material reservoir to allow for efficient graft placement without having to repeatedly re-load the funnel. Volume etchings give the surgeon an indication of the amount of graft material that has been placed.

Step 19 – Disc Space Distraction



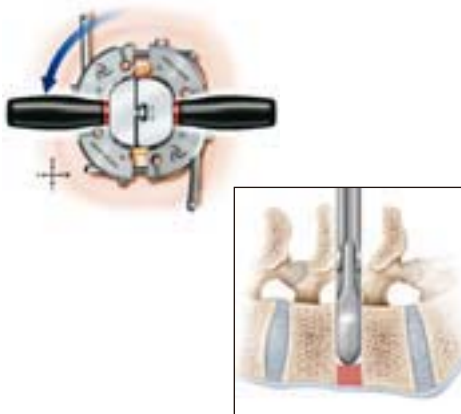
- Sequential Distractor Guides are now used to distract the disc space to the proper height and annular tension, in preparation for placement of a spacer.

NOTE: The **CONCORDE** System comes with a complete set of sequential 2-piece Distractor Guides. Unlike traditional intradiscal spreader paddles, the 2-piece **CONCORDE** Distractor Guides are specifically designed for 1 piece to be left in place to both maintain disc space distraction during spacer placement, and to guide the spacer into position. This eliminates the need for pedicle screws to maintain disc space distraction, and aids the surgeon in placing the spacer through a small access window.



- Insert the final Distractor Guide horizontally into the disc space placing the Distractor Guide as far laterally as possible. Turn the Distractor Guide 90° taking care to orient the removable distractor piece (with 2-way arrow) medially. (This piece will be removed prior to spacer placement.) The angle of the Distractor should reflect the desired trajectory of the spacer.

Tip: If added medial angulation is desired for the spacer, use the optional Curved Distractor Guide.

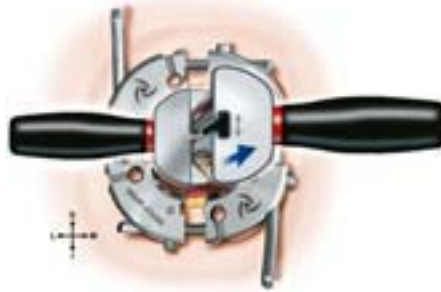


- For optional medial Distractor Guide placement or optional Curved Distractor Guide use, refer to Optional Distractor Guide Use (Step 25).

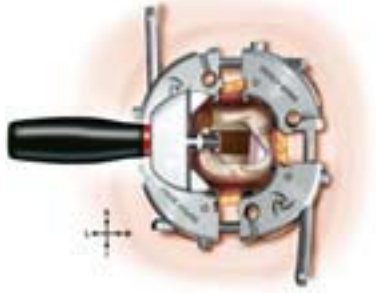
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Step 19 – Disc Space Distraction (cont.)



- To remove the medial half of the Distractor Guide, pull up on the medial handle, while holding the lateral Distractor Guide handle stationary. Confirm that the Distractor Guide placement allows space for medial placement of the spacer. If not, repeat the previous step until the desired placement is achieved.



Step 20 – Depth Gauge Use

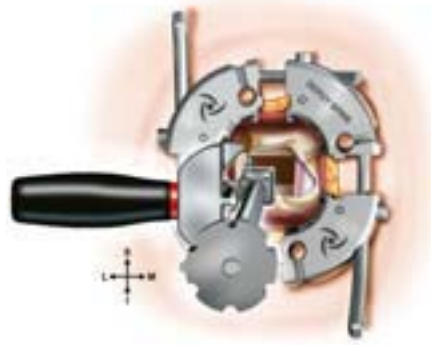


- In preparation for spacer placement, the CONCORDE Depth Gauge may be used to determine the oblique distance across the disc space, or to help determine if a sufficient amount of graft has been placed anteriorly.
- The Depth Gauge's distal shoulder is designed to abut the edge of the vertebral body while the inner shaft is extended.

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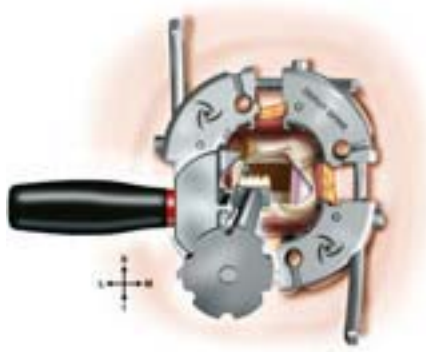
Step 21 – Trial Use



- In order to determine the width and length of the allograft spacer, load the appropriate trial onto the CONCORDE Inserter. Use the trial height that matches the anticipated spacer height and width, and Distractor Guide height.
- The CONCORDE Trial can now be inserted taking care not to impinge any nervous tissue upon insertion.



Step 22 – Spacer Placement



- Load the selected spacer onto the CONCORDE Inserter. The illustrations depict a spacer being placed while guided by the CONCORDE Inserter and Distractor Guide. Proceed with the insertion of the spacer taking care not to impinge any nervous tissue. Special retractors are provided in the CONCORDE System to help with nervous tissue retraction.



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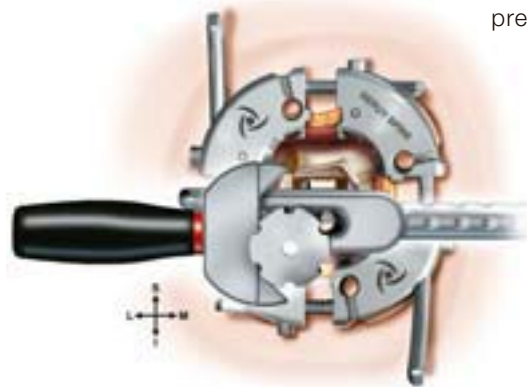
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Step 23 – Distractor Removal



- Once the spacer is in its final position, the CONCORDE Slap Hammer may be used to remove the Distractor Guide in a controlled manner while maintaining downward pressure on the Inserter. Once the Distractor Guide is removed, disengage the Inserter from the spacer and remove the Inserter.

- The Inserter is designed to place the spacer into final position. An Impactor is also available if preferred.



Slap Hammer

Step 24 – Final Spacer Placement



- The ideal spacer placement should cross the midline. If using a lordotic spacer, the angle should be approximately 30-40°. Additional autologous bone graft may be placed as desired.



- It is recommended that posterior fixation be used to supplement the interbody fusion. See the DePuy Spine VIPER™ Surgical Technique Guide for full description of the percutaneous posterior fixation technique using the VIPER System.

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Step 25 – Optional Disc Space Distraction – (Medial)



- If additional medial angulation is desired, the CONCORDE System provides a Curved Distractor Guide to help facilitate proper placement of the spacer. The Curved Distractor Guide provides an additional 20° of angulation to help achieve the desired final spacer position.



- If medial placement of the Distractor Guide is desired, the same sequence and technique should be followed, with the exception of placing the Distractor Guide as far medial as possible when in a horizontal position, and taking care to orient the removable Distractor piece (with 2-way arrow) lateral once the Distractor Guide is rotated 90°.

PIPELINE

Ordering Information

PRODUCT CODE	DESCRIPTION
2882-10-001	1st Dilator, 5mm
2882-10-002	2nd Dilator, 10mm
2882-10-003	3rd Dilator, 14mm
2882-10-004	4th Dilator, 18mm
2882-10-005	5th Dilator, 21mm
2882-10-006	6th Dilator, 25mm
2882-10-007	Introducer
2882-10-008	Insertor T-Handle
2882-10-009	Blade Depth Tower
2882-10-010	Small Retractor
2882-10-011	Large Retractor
2882-10-012	Small Blades
2882-10-013	Large Blades
2882-10-014	Rigid Arm Attachment
2882-10-015	Light Source Attachment
2882-10-016	Light Source
2882-10-017	Distractor
2882-10-018	Blade Pusher
2882-10-019	Blade Remover
2882-10-020	35mm, #1 ML Blade
2882-10-021	55mm, #1 ML Blade
2882-10-022	75mm, #1 ML Blade
2882-10-023	95mm, #1 ML Blade
2882-10-024	35mm, #2 ML Blade
2882-10-025	55mm, #2 ML Blade
2882-10-026	75mm, #2 ML Blade
2882-10-027	95mm, #2 ML Blade
2882-10-028	35mm, #3 ML Blade
2882-10-029	55mm, #3 ML Blade
2882-10-030	75mm, #3 ML Blade
2882-10-031	95mm, #3 ML Blade
2882-10-032	PIPELINE Expandable Case & Tray
2882-10-033	PIPELINE Expandable Case & Tray
2882-01-004	Incision Template
2882-01-040	Rigid Arm

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Ordering Information

INSTRUMENTS

PRODUCT CODE

DESCRIPTION

2879-00-007	CONCORDE Distractor Guide 7H Straight
2879-00-008	CONCORDE Distractor Guide 8H Straight
2879-00-009	CONCORDE Distractor Guide 9H Straight
2879-00-010	CONCORDE Distractor Guide 10H Straight
2879-00-011	CONCORDE Distractor Guide 11H Straight
2879-00-012	CONCORDE Distractor Guide 12H Straight
2879-00-013	CONCORDE Distractor Guide 13H Straight
2879-00-107	CONCORDE Distractor Guide 7H Curved
2879-00-108	CONCORDE Distractor Guide 8H Curved
2879-00-109	CONCORDE Distractor Guide 9H Curved
2879-00-110	CONCORDE Distractor Guide 10H Curved
2879-00-111	CONCORDE Distractor Guide 11H Curved
2879-00-112	CONCORDE Distractor Guide 12H Curved
2879-00-113	CONCORDE Distractor Guide 13H Curved
2879-01-000	CONCORDE Inserter Straight
2879-01-009	CONCORDE Inserter Bayoneted
2879-02-000	CONCORDE Impactor Straight
2879-03-000	CONCORDE Rasp Straight
2879-03-001	CONCORDE Rasp Bayoneted
2879-03-002	CONCORDE Rasp Left Angle
2879-03-003	CONCORDE Rasp Right Angle
2879-04-107	CONCORDE Trial 9 x 7 x 27
2879-04-108	CONCORDE Trial 9 x 8 x 27
2879-04-109	CONCORDE Trial 9 x 9 x 27
2879-04-110	CONCORDE Trial 9 x 10 x 27
2879-04-111	CONCORDE Trial 9 x 11 x 27
2879-04-112	CONCORDE Trial 9 x 12 x 27
2879-04-113	CONCORDE Trial 9 x 13 x 27
2879-04-209	CONCORDE Trial 11 x 9 x 27
2879-04-210	CONCORDE Trial 11 x 10 x 27
2879-04-211	CONCORDE Trial 11 x 11 x 27
2879-04-212	CONCORDE Trial 11 x 12 x 27
2879-04-213	CONCORDE Trial 11 x 13 x 27
2879-05-000	CONCORDE Slap Hammer
2879-06-000	CONCORDE Filler Block
2879-07-000	CONCORDE Depth Gauge
2879-08-008	CONCORDE Bone Funnel 8 mm
2879-10-010	CONCORDE Retractor 10 mm
2879-10-015	CONCORDE Retractor 15 mm
2879-20-000	CONCORDE Case and Trays
2879-20-500	CONCORDE Implant Caddy



MIS for Spine.

Product Family Portfolio

PIPELINE™ Access System



Minimally Invasive
Access Systems

CONCORDE™



Minimally Invasive
Interbody Instruments

VIPER™



Minimally Invasive
Percutaneous Posterior
Fixation

INDICATIONS

PIPELINE™ Access System

To provide the surgeon with minimally invasive surgical access to the spine by ensuring the placement/positioning of the retractor, down to the lamina, with its attachment to a flexible arm to provide a self-locking method of access to the spinal site through which a microscope and surgical instruments can be manipulated.

Fiber Optic Cables

The Fiber Optic Cables are indicated for use in surgery where the need for light is warranted. Fiber Optic Cables should be used only by physicians who have been extensively trained and are experienced in the required surgical procedures.

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.

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325 Paramount Drive
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USA
Tel: +1 (800) 227-6633