ZIMMER BIOMET

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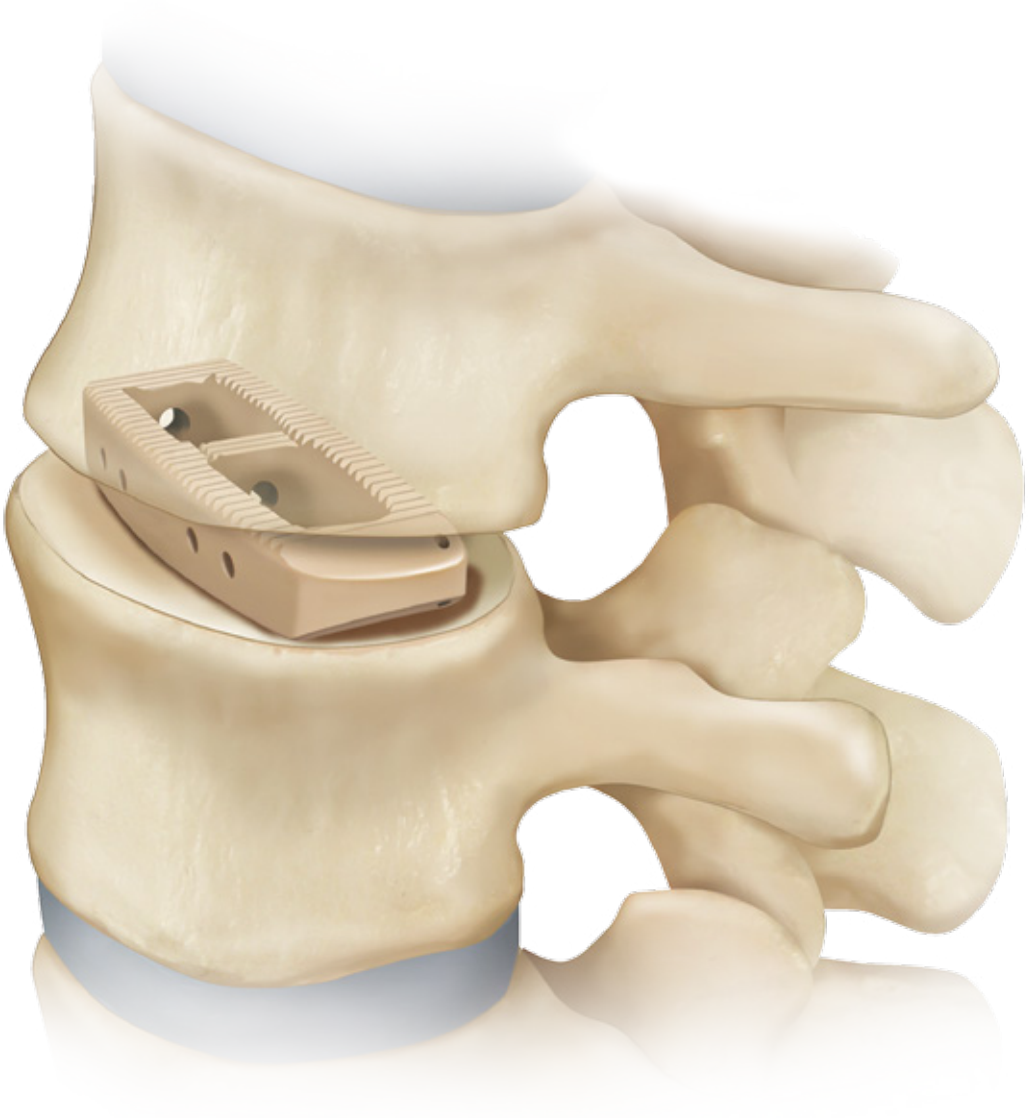
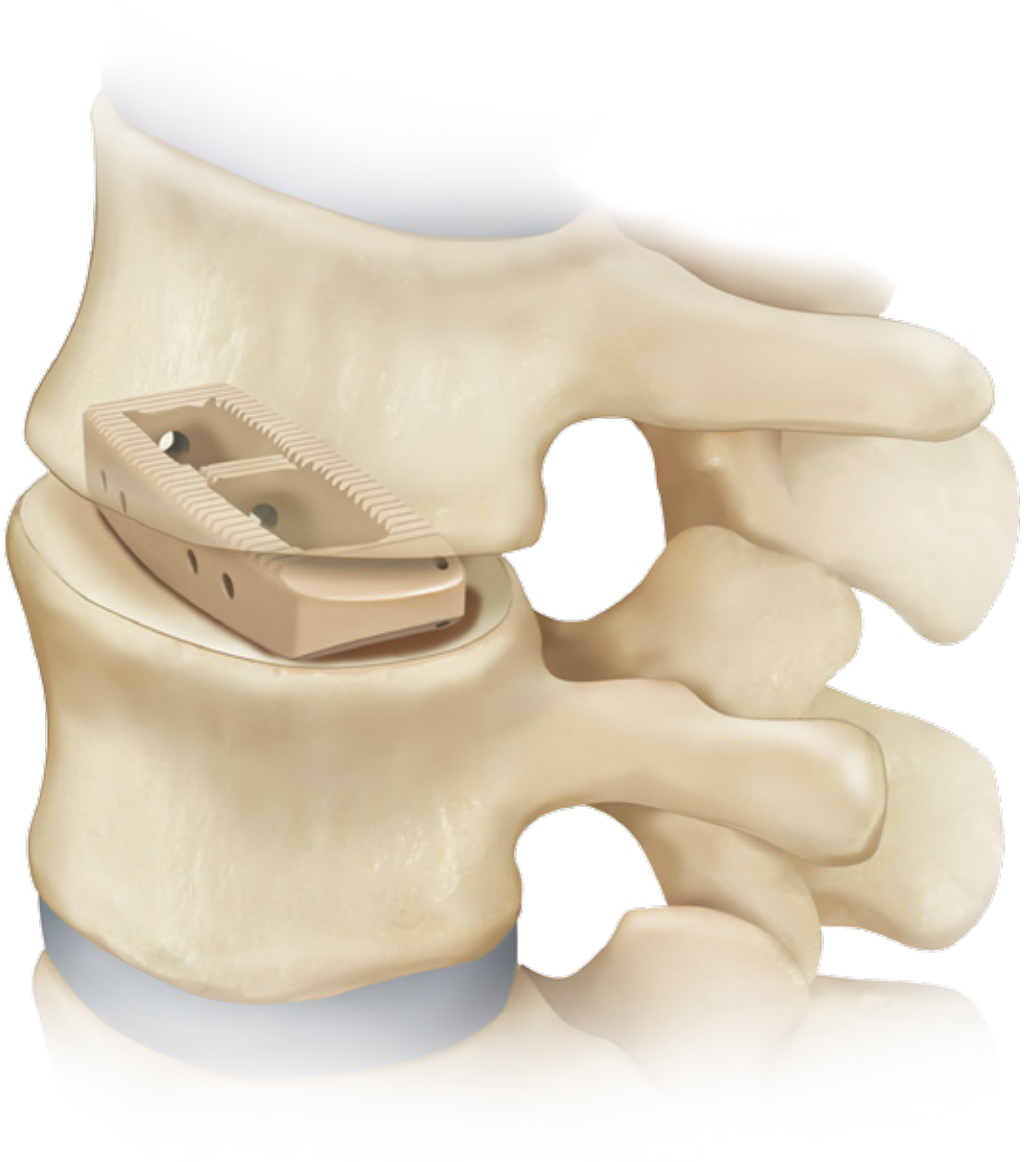


Thoracolumbar Solutions

Timberline®
Lateral Fusion System

Surgical Technique Guide



A complete and comprehensive minimally invasive lateral system consisting of an innovative retraction system, implants and instruments.

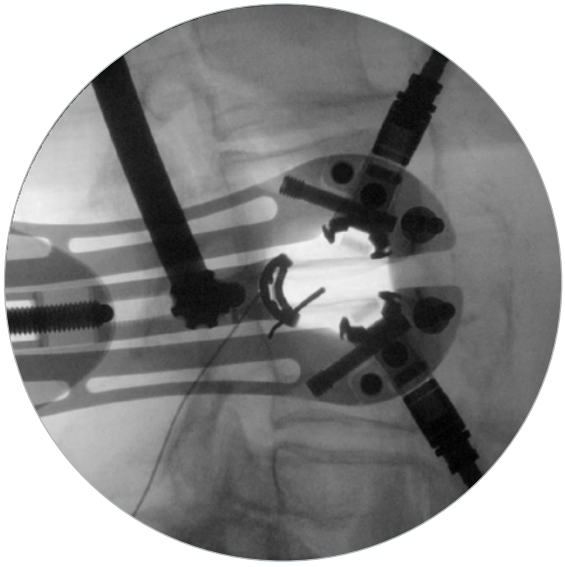
TABLE OF CONTENTS

Zimmer Biomet Spine does not practice medicine. Each physician should exercise his or her own independent judgment in the diagnosis and treatment of an individual patient, and this information does not purport to replace the comprehensive training physicians have received.

The following general Surgical Technique Guide is for illustrative purposes only. As with all surgical procedures, the technique used in each case will depend on the surgeon's medical judgment as to the best treatment for each patient. Only those individuals with specialized training and experience in spinal surgery should attempt to use the Timberline Lateral Fusion System. Detailed preoperative clinical and diagnostic evaluation followed by carefully executed surgical technique is essential.

Refer to the Instructions for Use (IFU) for a complete list of prescribing information. This technique guide was developed in conjunction with health care professionals.

DEVICE DESCRIPTION



The **Timberline Lateral Fusion System** is a complete lateral access fusion system, including an intuitive, low-profile modular retractor system, fiber optic lighting, PEEK-OPTIMA® LT1 interbody spacers and thoughtfully designed instruments to aid in access and implantation. The system is designed for the treatment of degenerative traumatic and pathologic conditions and deformities of the thoracic and lumbar spine.

System highlights include:

- PEEK-OPTIMA LT1 implants.
- Modular, lateral retractor system.
- Fiber optic lighting system.
- Lateral-specific disc preparation instruments.
- Optional neuromonitoring and access disposables.

Key features of the retractor system include:

- Integrated posterior shim for reduced retractor migration.
- Radiolucence for optimized visualization.
- Low-profile, modular design.
- Three blades plus optional fourth blade attachment.
- Controlled, non-ratcheting, infinite resolution retraction.
- Independent cranial/caudal blade toeing and posterior blade retraction.
- Various blade lengths with 20° toeing capability.
- Intradiscal, blade-lengthening and fixation shims.
- Easily attachable, advanced fiber optic lighting.

Required Equipment

ITEMS	DETAILS
Timberline Implants and Instruments	Kit listings *(see page 38–43)*
Timberline Case 1, 18mm and 22mm Implant Kit	PCR8700-1201
Timberline Case 2, Retractor Kit I	PCR8700-2301
Timberline Case 3, Retractor Kit II	PCR8700-3301
Timberline Case 4, Disc Preparation Kit	PCR8700-4201
Timberline Case 5, Rongeur and Implantation Instruments	PCR8700-5301
Timberline Access Kit (single use only)	8700-9112 *(see page 47)*
Light Source	300 Watts with an ACMI connection
Radiolucent Breakable Table	AMSCO 3085 or equivalent

Recommended and Optional Equipment

ITEMS	DETAILS
Timberline Monitoring Kit (single use only)*	8700-9112 *(see page 47–48)*
Neuromonitoring Equipment	Compatible with any commercially available system
Timberline Auxiliary Instrument Kit	PCR8700-6201 *(see page 44)* *Rotating disc cutters, paddle shavers and disc spreaders*
Timberline Angled Instrument Kit	PCR8700-7201 *(see page 45–46)* *Recommended for L4–L5*
Timberline Implants—16mm	PCR8700-0011 *(see page 35)*
Timberline Implants—26mm	PCR8700-0021 *(see page 35)*
Timberline Implants—Coronal Taper	PCR8700-0031 *(see page 35)*
Additional Non-Standard Implants Available	*(see page 36)*

*May not be available in all geographic areas.

PREOPERATIVE AND INTRAOPERATIVE PREPARATION

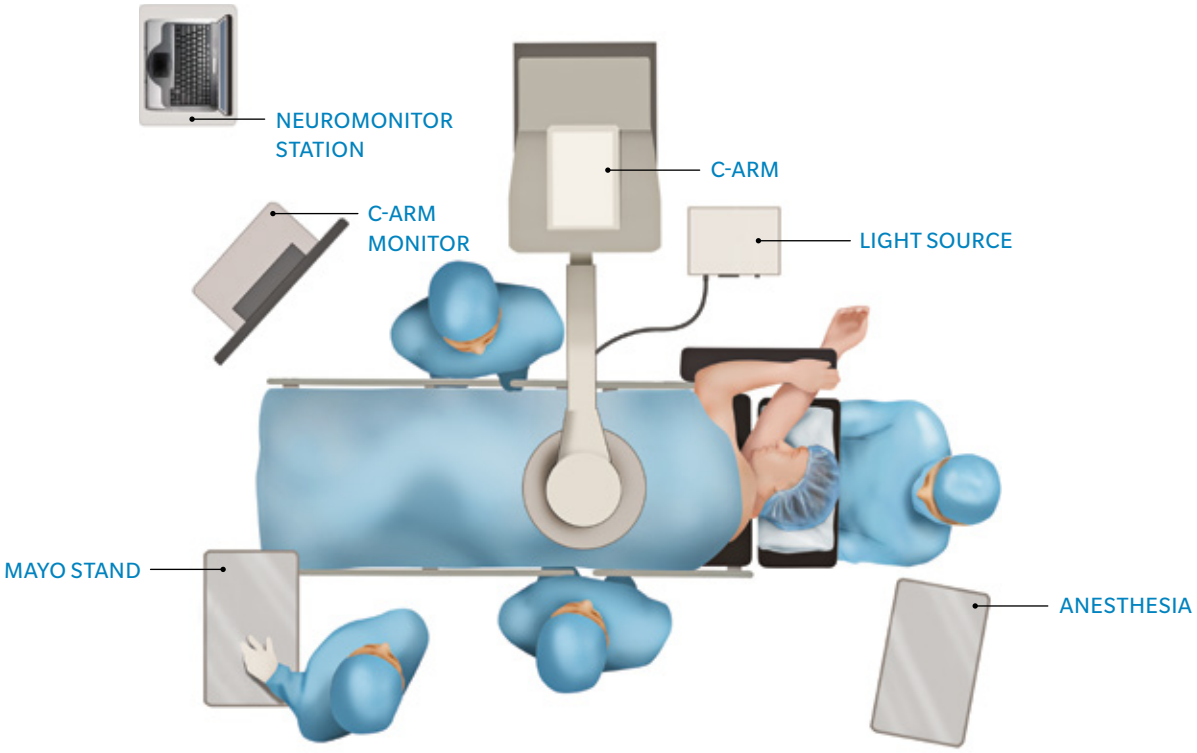


Figure 1
OR layout

Preoperative Preparation

- Review and inspect all instrumentation and implants prior to sterilization.
- The primary surgeon must be fully experienced with the required spinal fusion techniques, as well as the lateral surgical approach to the spine.
- Please read the Instructions for Use for a complete list of prescribing instructions.
- Surgical site access is dependent upon the level and indication(s) being treated. Adequate planning should be done to ensure safe and proper access to the surgical site.
- Preoperative imaging studies of the anatomy should be examined to:
  - Ensure that the range of implant sizes is appropriate for the patient's anatomy at the proposed operative levels.
  - Give special consideration to L4–L5, ensuring that height of the iliac crest will not prevent access to the L4–L5 disc space.
  - Review anatomy and determine the best approach (i.e., left or right, concave vs. convex side of deformity).

  Tip: *The Timberline angled instrument kit is available upon request. This kit may facilitate access to L4–L5 and other obstructed levels.*
- Confer with the surgeon to ensure you have all of the needed implants (widths, lengths and heights) for the surgery.

Intraoperative Preparation

- All imaging studies should be available for both planning and intraoperative review of the patient's anatomy.
- The Timberline System may be used alone or, at the surgeon's discretion, in conjunction with a neuromonitoring system. The Timberline System may be used with most other commercially available neuromonitoring systems.
- The operative suite should be laid out such that it is conducive to the lateral approach procedure ***(Figure 1)***.

PATIENT PREPARATION

Neuromonitoring may be selected at the surgeon's discretion. If neuromonitoring is to be used, a neurophysiologist or neuromonitoring technician should apply electrodes to the patient prior to patient positioning.

Tip: *If neuromonitoring is selected, it is important to discuss with the anesthesiologist that the patient is not to be administered paralytics during the procedure. A "train of four" test will help ensure an absence of paralytics.*

STEP 1

- Place the patient in a lateral decubitus (90°) position on a breakable surgical table such that the patient's greater trochanter is directly over the break in the table. The surgical table should be reversed prior to positioning the patient so that fluoroscopy may be used ***(Figure 2)***.

Tips:

- Considerations for left- vs. right-side positioning:
  - When anatomy allows, a left-sided approach is preferred.
  - Previous surgeries or anatomical factors may dictate approaching from the patient's right side.
- Use an auxiliary roll and hip bump underneath the patient's greater trochanter.
- Place pillows under the head, between the knees and under the upper arm.
- Cover sensitive areas as needed with a towel prior to taping. 3-inch silk surgical tape is recommended.
- Secure the patient to the table using surgical tape per the following ***(Figure 2):***
  - A. Directly across the table just below the tip of the iliac crest and below table break.
  - B. Directly across the table, over the thoracic region just underneath the arm.
  - C. Just superior and anterior to tip of the iliac crest, down to the foot of the table (posterior), around the corner of the table and back to the tip of the iliac crest.
  - D. Just superior and posterior to tip of the iliac crest, down to the foot of the table (anterior), around the corner of the table and back to the tip of the iliac crest.
  - E. From the tip of the iliac crest, straight down to the end of the table.
  - F. From the anterior edge of the table, over the knee and along the lower leg to the posterior, inferior corner of the table.
- The pelvis should now be tilted away from the spine by lowering the table's "foot" end or the patient's legs.

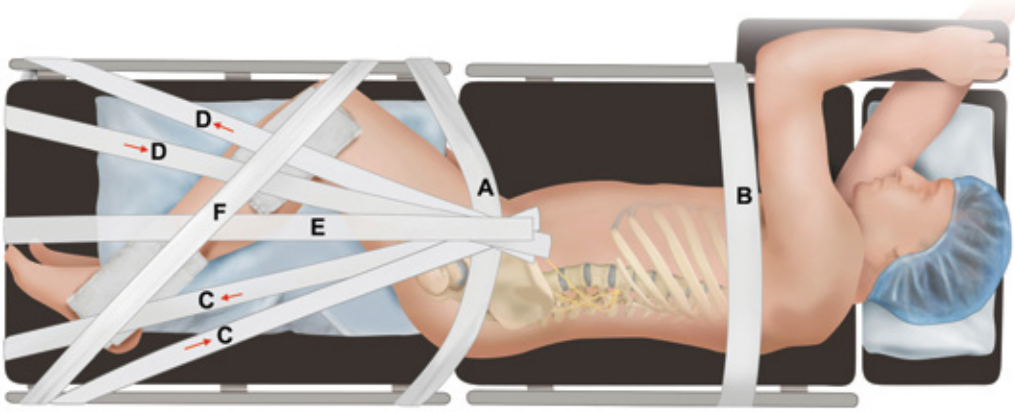


Figure 2
Patient positioning and taping

NEUROMONITORING PREPARATION *(if utilized)*

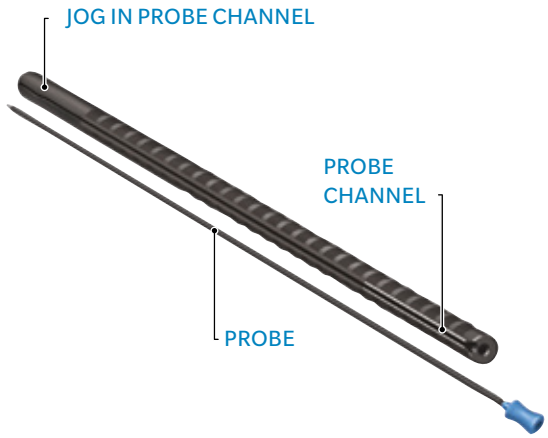


Figure 3a
Monopolar probe and initial dilator

Figure 3b
Monopolar probe fully advanced in initial dilator

STEP 2

- If neuromonitoring is selected by the surgeon, tape the blue end of the extension cable to the drape to keep it in the sterile field.
- Ensure that at least two feet of the extension cable's blue end is free for attachment to the stimulator probes.
- Connect the black end of the extension cable to the neuromonitoring system.

STEP 3

- If neuromonitoring is selected by the surgeon, insert a **monopolar probe,** or equivalent, into the exterior groove of the **initial dilator**.
- A jog in the initial dilator's probe channel provides resistance as the monopolar probe is advanced. This will keep the monopolar probe from backing out of the dilator as it passes through the soft tissue ***(Figure 3a)***.

STEP 4

- A hard stop will indicate when the monopolar probe is fully advanced.
- Verify that the monopolar probe tip is fully advanced by ensuring that the distal tip is exposed ***(Figure 3b)***.

  Tip: *It may be helpful to bend the proximal end of the monopolar probe out of the way to minimize interference with the K-wire and other instrumentation.*

RETRACTOR PREPARATION

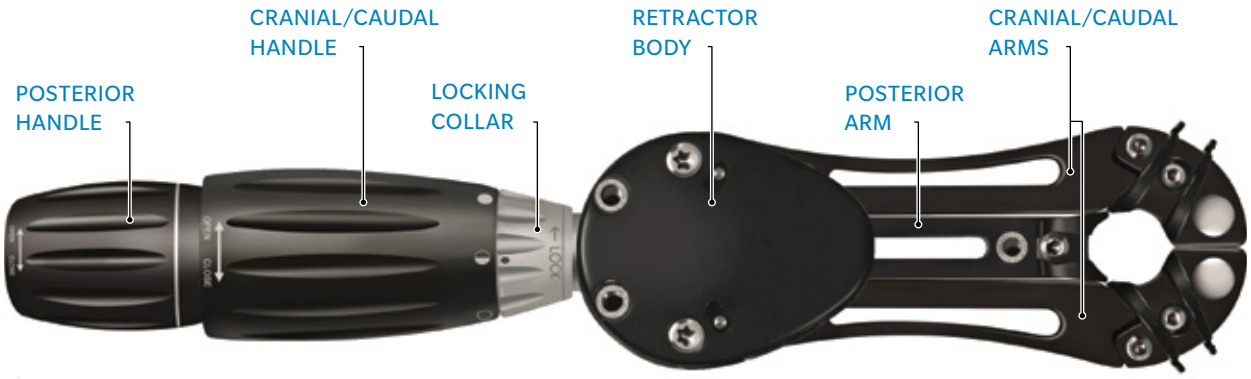


Figure 4
Retractor components

Figure 5
Handle assembly

STEP 5

- Attach the **bedrail clamp** to the bedrail on the anterior side of the patient.
- The bedrail clamp should be placed approximately one foot from the incision site, towards the head, ensuring that it is snug on the bedrail.

STEP 6

- After draping the patient, insert the **articulating arm** rod into the bedrail clamp.
- Ensure that enough of the articulating arm rod is exposed above the bedrail clamp for subsequent attachment of the articulating arm assembly to the retractor.

STEP 7

- Insert the **posterior handle** into the **cranial/caudal handle.** Ensure the posterior handle is pressed all the way into the cranial/caudal handle such that the second indicator line is flush with the cranial/caudal handle ***(Figure 5)***.

RETRACTOR PREPARATION *(continued)*

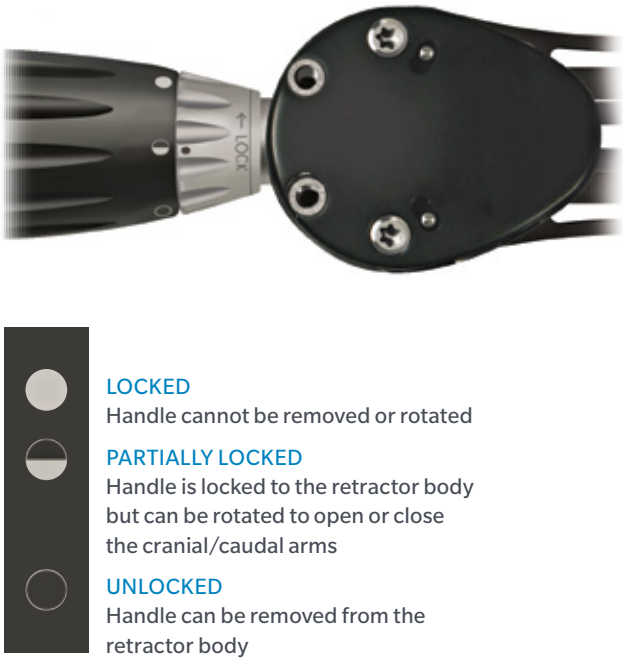


Figure 6
Locking collar positions

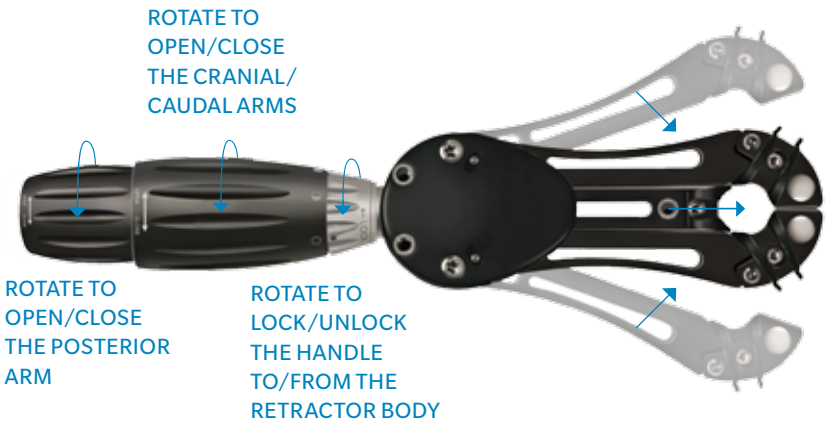


Figure 7
Retractor handle actuation

STEP 8

- Attach the **handle assembly** to the **retractor body**. You may need to twist the handle assembly while applying inward pressure to seat the handle assembly into the retractor body.
- Rotate the **locking collar** counterclockwise to secure the handle to the retractor body.
- There are alignment markings on the locking collar and cranial/caudal handle to indicate the partially locked position (as well as fully locked and unlocked positions) for locking the handle assembly to the retractor body ***(Figure 6)***.

STEP 9

- Rotate the cranial/caudal handle clockwise to close the **cranial/caudal arms**. Rotate the posterior handle clockwise to close the posterior arm ***(Figure 7)***.

TOEING PAD IN TOED POSITION

TOEING PAD IN ZERO POSITION

Figure 8
Toeing pad position

STEP 10

- Ensure that both **toeing pads** (on the cranial/caudal arms) are all the way down at the zero position.
- Using the **ball-tip driver** or the second posterior handle provided in the kit, loosen the kit screws until the toeing pads are completely flush against the retractor body ***(Figure 8)***.

  Note: *The toeing pads are adjusted via their respective 3.5mm hex kit screws. Similarly, the blades are attached with a 3.5mm hex kit screw. 3.5mm hex drivers are available on the ball-tip driver or the posterior handle. When the toeing pads are in the zero position, the cranial/caudal blades will not be in contact with each other, but rather will be slightly spaced apart.*

SURGICAL APPROACH PREPARATION

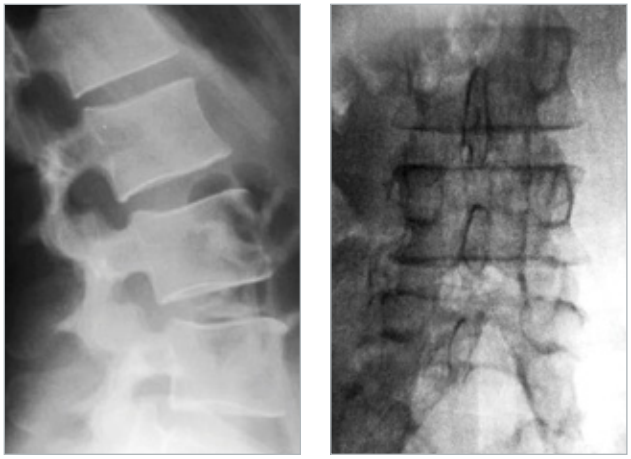


Figure 9
Examples of true lateral and A/P images

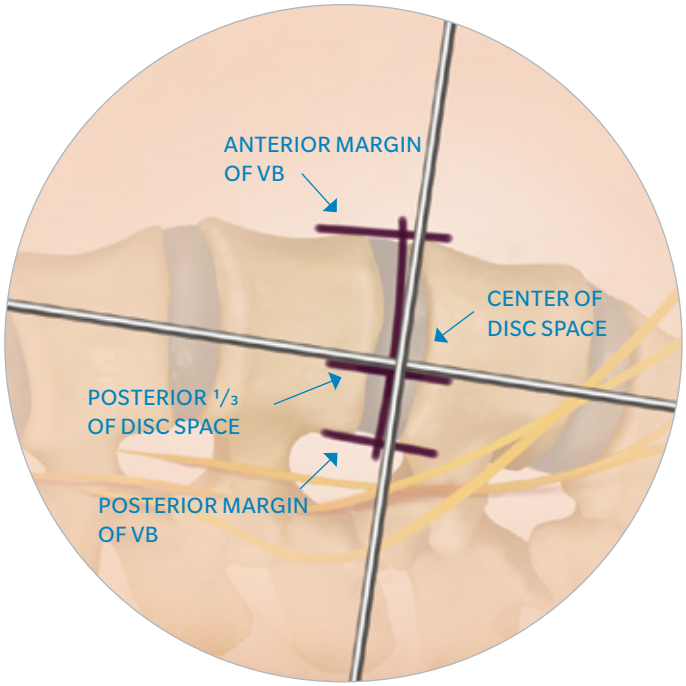


Figure 10
Localization and incision site marking

STEP 11

- Now that the patient has been secured to the table, adjust the table so that true lateral and anterior-posterior (A/P) images may be obtained when the C-arm is set at 90° and 0° respectively.

  Note: *True A/P orientation of the surgical level has been achieved when the spinous process is centered directly between the pedicles, the pedicles appear round and the endplates are distinguished as a solid line on the A/P radiograph/fluoro.*

  True lateral and A/P images may require adjusting the bed position separately for each level ***(Figure 9)****.*

  True lateral orientation is noted by observing a sharp view of the endplates at the operative level and when the neural foramina align perfectly on the lateral radiograph/fluoro.

STEP 12

- Identify the level to be fused by laying two crossed **K-wires** on the skin above the proposed surgical site.
- Confirm the position using fluoroscopy.
- The incision point for a single level should be centered over the disc of the level to be fused.
- For two levels, the incision point should be centered over the vertebral body, separating the two discs to be resected.
- Mark the incision point by marking the angle of the disc space, the anterior margin, posterior margin and midpoint to the posterior third of the disc space ***(Figure 10)***.

SURGICAL APPROACH

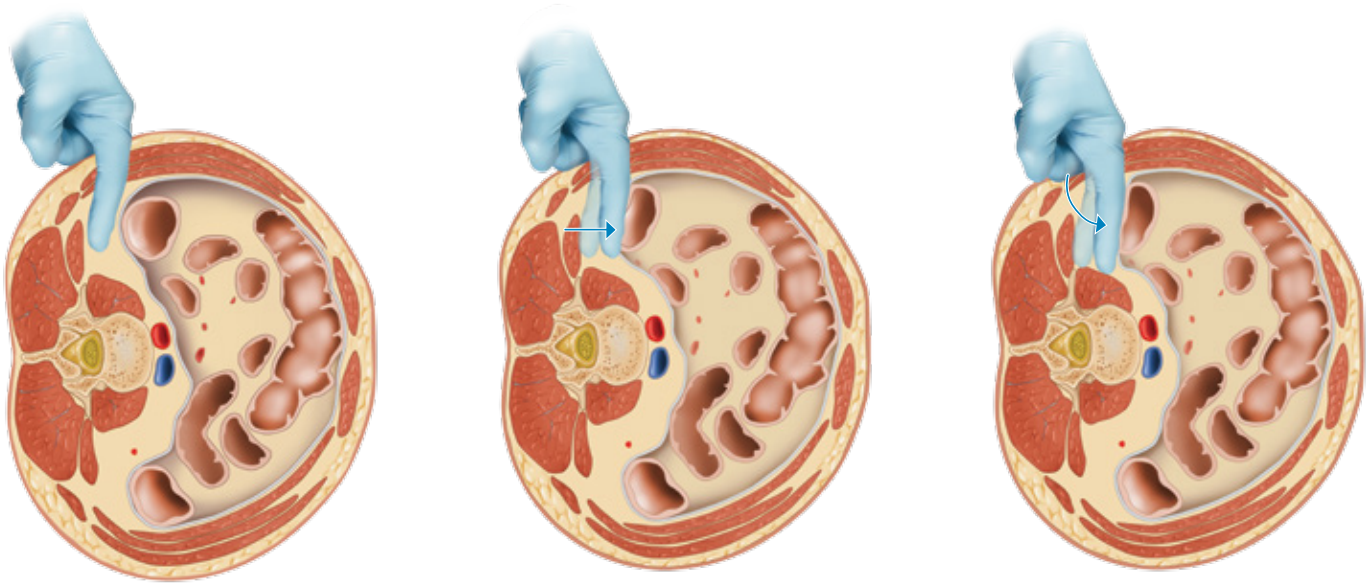


Figure 11
Approach to the spine

STEP 13

- After making the skin incision and dividing the subcutaneous tissue, the oblique muscles of the abdomen should be visible.
- Separate the fibers using blunt dissection.
- Once the retroperitoneal space has been entered, one should feel the tissue give way ("pop") into the free space of the retroperitoneum.
- Move the peritoneum anteriorly with the forefinger and continue blunt dissection to palpate to the transverse process posteriorly.
- Slide the finger forward to the retro-psoas recess and over the dome of the psoas to ensure the retroperitoneal viscera have been safely retracted anteriorly ***(Figure 11)***.

INITIAL DILATOR INSERTION

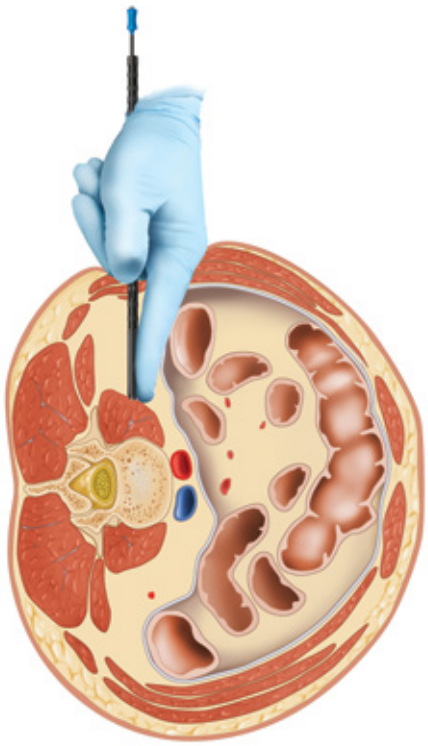


Figure 12
Dilator insertion

STEP 14

- If neuromonitoring is selected by the surgeon, connect the blue end of the extension cable to the monopolar probe previously inserted into the initial dilator.

STEP 15

- While holding the index finger on the surface of the psoas muscle with the palm of the hand facing posteriorly, carefully guide the initial dilator down the palm of the hand and into the retroperitoneal space until the tip of the dilator is at the lateral margin of the psoas muscle ***(Figure 12)***.
- Remove the non-dominant hand and verify the position of the dilator using lateral fluoroscopy.

  Note: *The dilator can be held in place with the* ***initial dilator holder*** *while using lateral fluoroscopy.*

  Tip: *The cranial/caudal position of the dilator should be the center of the disc space. The A/P position of the dilator should be between the posterior third and center of the disc space.*

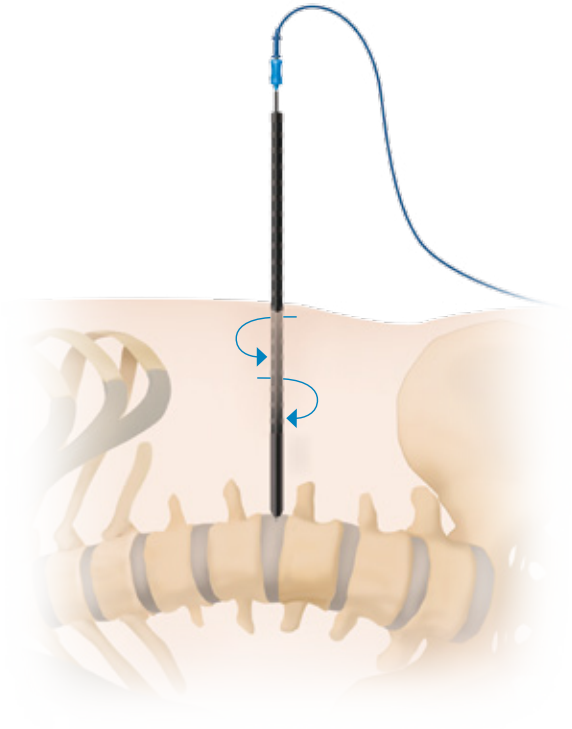


Figure 13a
Initial dilator placement

STEP 16

- Carefully advance the dilator through the psoas muscle using a rotating motion to ensure the dilator is all the way down to the disc, and to ensure there are no muscle fibers underneath the dilator ***(Figure 13a)***.
- Use the initial dilator holder to maintain the position of the dilator; confirm the dilator is still in an acceptable position using lateral fluoroscopy ***(Figures 13b, c, d)***.
- If the surgeon has elected to use neuromonitoring, the technician can initiate the EMG stimulation. The surgeon can then determine if the initial dilator is in a safe position relative to the nerves.

  Note: *The initial dilator holder is designed with radiolucent tips to limit radiographic interference.*

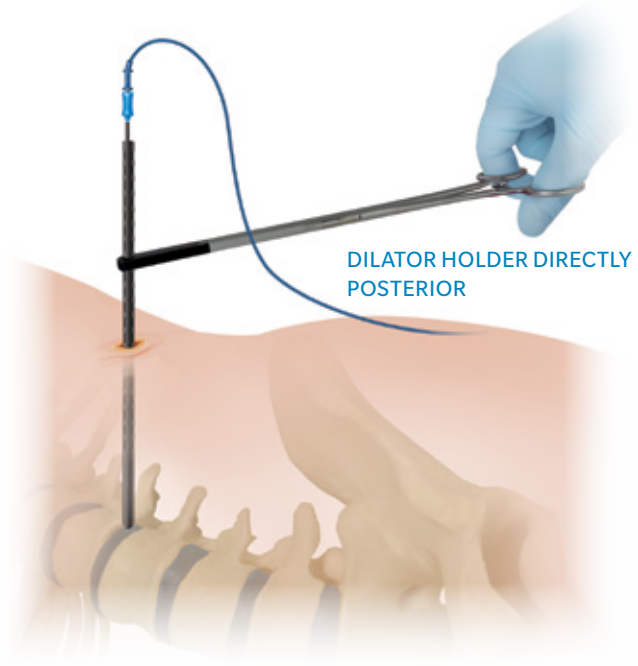


Figure 13b
Initial dilator holder

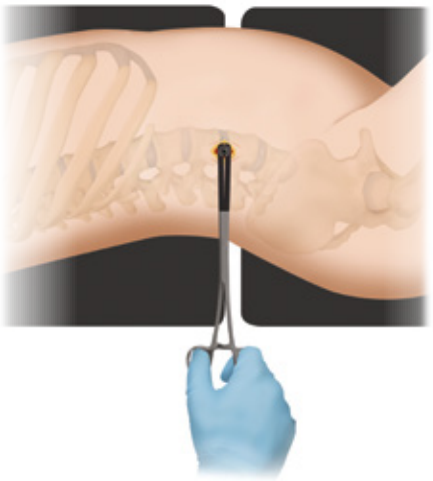


Figure 13c
Initial dilator holder—lateral view

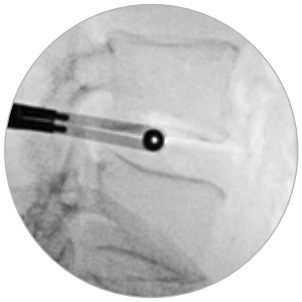


Figure 13d
Initial dilator holder—lateral fluoro view

K-WIRE INSERTION

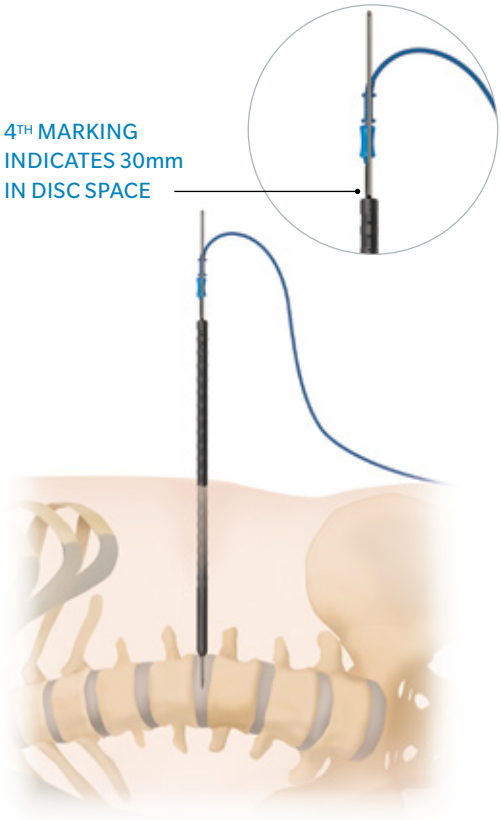


Figure 14
Initial dilator and K-wire positioning

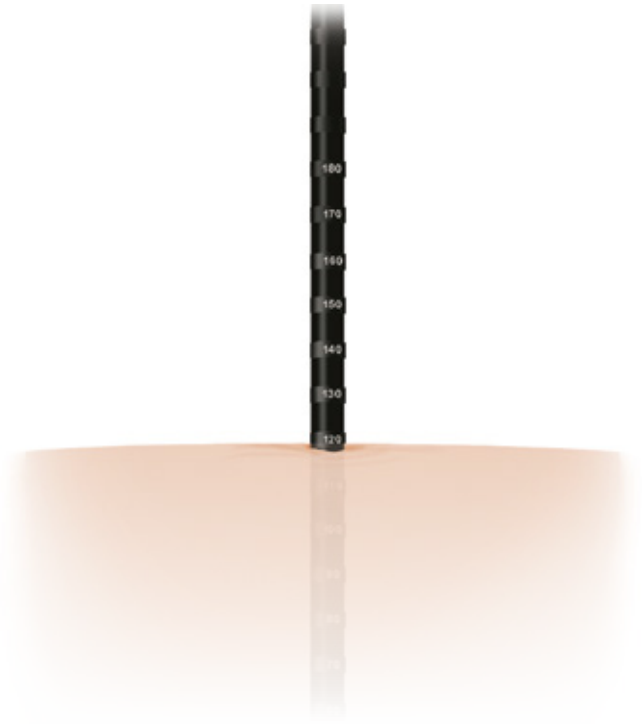


Figure 15
Dilator depth measurement

STEP 17

- Once the initial dilator is in an acceptable position, insert a K-wire through the center of the initial dilator and into the disc space.
- The K-wire should be inserted approximately halfway across the disc space to assist in securing the access entry point.
- Verify the position of the K-wire and initial dilator using A/P and lateral fluoroscopy ***(Figure 14)***.

  Note: *The K-wire has four markings. The distal-most marking indicates when the K-wire is flush with the tip of the initial dilator. Each proximal marking thereafter indicates a distance of 10mm.*

STEP 18

- With the initial dilator fully advanced to the ipsilateral annulus of the disc, the retractor blade length can be chosen by noting the depth marked on the initial dilator at the skin edge ***(Figure 15)***.

  Tip: *The blade length is measured from the bottom side of the retractor. Use the blade length one size longer than that indicated by the skin edge mark. The surgeon should immediately communicate the desired blade length to the technician to allow adequate time to assemble the blades onto the retractor before it is needed.*

SECOND DILATOR INSERTION

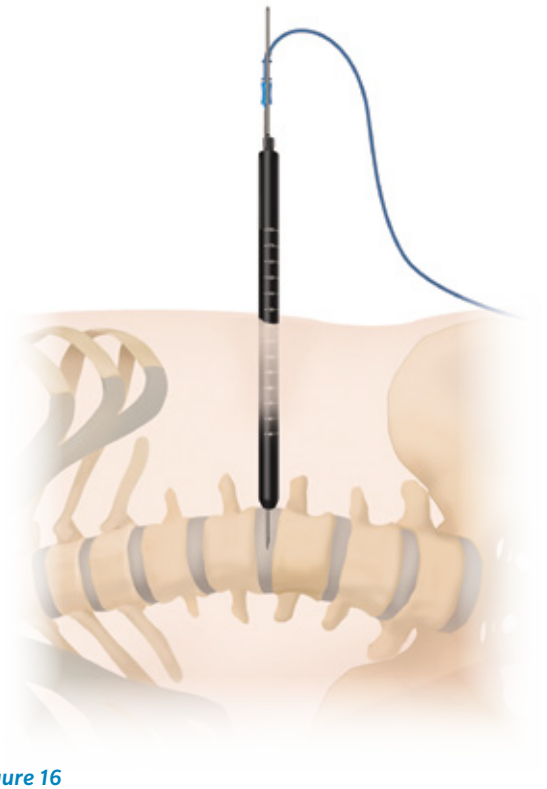


Figure 16
Second dilator placement

STEP 19

- If neuromonitoring is selected by the surgeon, keep the monopolar probe attached to the extension cable and remove the monopolar probe from the initial dilator.
- If desired by the surgeon, the monopolar probe may be inserted into the exterior groove of the **second dilator**.

STEP 20

- Carefully advance the second dilator over the initial dilator.
- Use a slow rotating motion to ensure the dilator has advanced all the way through the psoas and is down against the disc ***(Figure 16)***.
- If neuromonitoring is selected by the surgeon, and if desired, re-stimulate after the second dilator has been completely inserted to check for nearby nerves and help ensure the femoral nerve remains posterior to the dilators.

RETRACTOR ASSEMBLY

Figure 17a
Retractor assembly

Figure 17b
Retractor assembly

Figure 18
Blades attached to retractor

STEP 21

- With the retractor arms just slightly open, attach the posterior blade onto the posterior arm of the retractor using the ball-tip driver ***(Figure 17)***.

  Note: *Retractor assembly should be performed on the back table while the surgeon is inserting the second dilator. To help ensure that the retractor is assembled when the surgeon is ready for it, assembly should begin immediately after determining the appropriate blade lengths (step 19).*

  Tip: *The cranial/caudal blades are identical and are not provided with any shims attached. The posterior blade is different, and is identified by a "P" marked on the side of the blade as well as by its integral and non-removable intradiscal shim.*

STEP 22

- Next, attach the cranial/caudal blades onto the cranial/caudal arms of the retractor using the ball-tip driver ***(Figure 18)***.

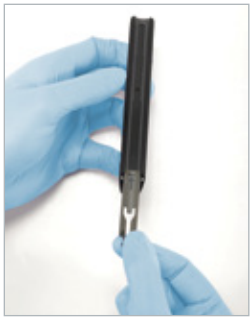


Figure 19a
Shim insertion

Figure 19b
Shim insertion

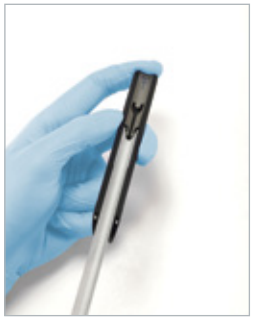


Figure 19c
Shim insertion

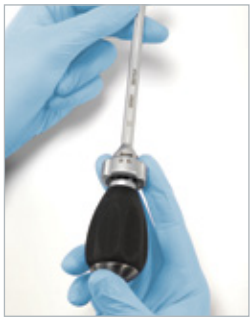


Figure 20a
Shim adjustment and removal

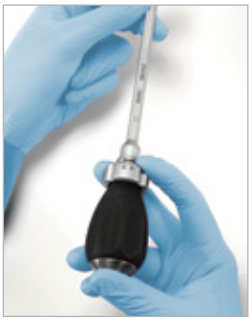


Figure 20b
Shim adjustment and removal

Figure 20c
Shim adjustment and removal

Figure 20d
Shim adjustment and removal

STEP 23

- If desired, manually load the **lengthening shims** into the cranial/caudal blades. Advance the shims using the **shim impactor** until they are flush with the tips of the blades.

  Tip: *To ensure proper shim placement, place a finger at the end of the blade while inserting the shims into the cranial/caudal blades.* ***The shim remover*** *may be used to readjust the shims to the proper height. As described previously, the* ***posterior blade*** *is provided with an integrated intradiscal shim. Prior to handing the assembled retractor to the surgeon, ensure the posterior intradiscal shim is fully retracted and the blades are closed tightly* ***(Figures 19, 20)****.*

RETRACTOR INSERTION

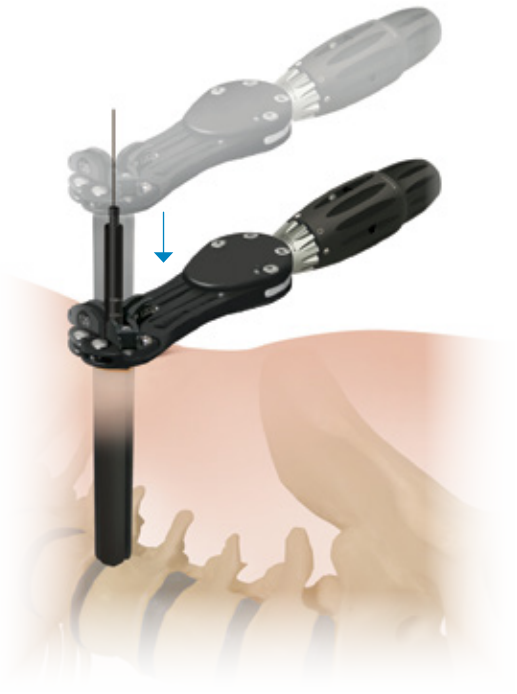


Figure 21
Retractor insertion

Figure 22a
Articulating arm attachment

Figure 22b
Articulating arm attachment points

STEP 24

- Carefully slide the retractor assembly over the second dilator using downward pressure and a gentle rotating motion.
- Align the retractor with the C-arm and verify the blades of the retractor are in line with the disc space using fluoroscopy. The retractor handle should be parallel to the disc space, and unless ribs or the iliac crest prevent it, the retractor working channel should be aligned with the disc space ***(Figure 21)***.
- Confirm correct positioning of the retractor using A/P and lateral fluoroscopy.

STEP 25

- Once the retractor is properly positioned, while maintaining downward pressure on the retractor, attach the articulating arm to the retractor body or posterior arm.
- The attachment choice will depend on the location of the dilator/K-wire in the disc space.
- To retract posteriorly with respect to the dilator, the articulating arm is attached to the retractor body; to retract anteriorly with respect to the dilator, the articulating arm is attached to the posterior arm ***(Figure 22)***.
- Verify the top surface of the retractor is parallel to the floor.

  Note: *Attach the articulating arm in a triangular configuration, with the bend toward the ceiling, so that the assembly applies a downward force on the retractor. The black knob of the articulating arm should be above the level of the retractor.*

Figure 23a
Articulating arm knob

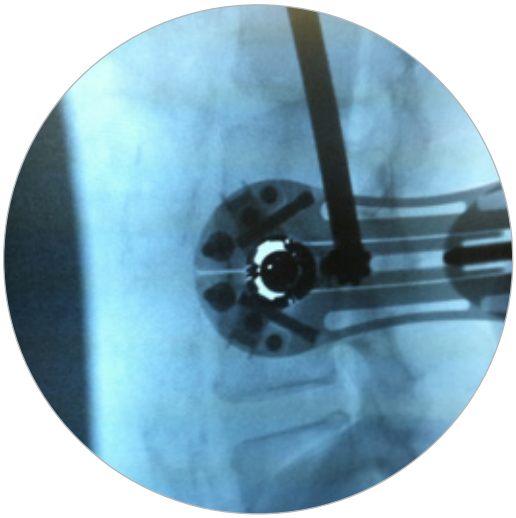


Figure 23b
Lateral fluoroscopy

- While applying downward pressure to the retractor, lock the articulating arm in the desired position.
- The **articulating arm knob** instrument may be used to tighten the articulating arm to the retractor ***(Figure 23a)***.

  Tip: *It is helpful to support the weight of the articulating arm when attaching it to the retractor.*

  Tip: *Lateral fluoroscopy* ***(Figure 23b)*** *can be used to verify the retractor is positioned correctly. The fluoro image should allow the surgeon to see monopolar probe channels directly down the blades. The monopolar probe slots should be visible if the retractor is positioned parallel to the disc and in line with the C-arm.*

INTRADISCAL SHIM EXTENSION—OPTION 1

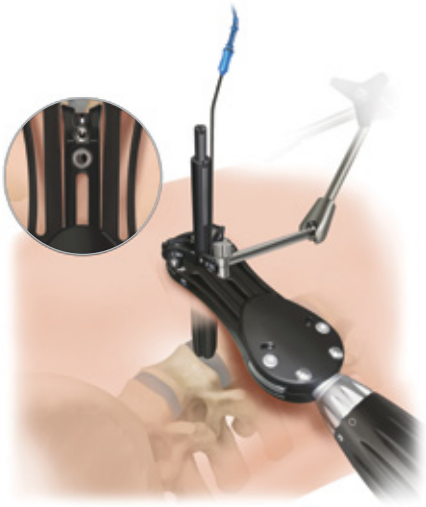


Figure 24a
Monopolar probe in posterior blade

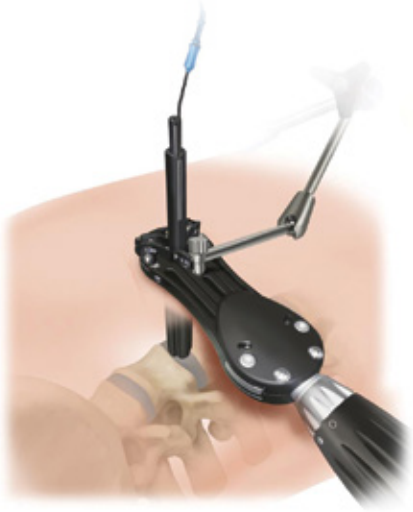


Figure 24b
Monopolar probe in second dilator

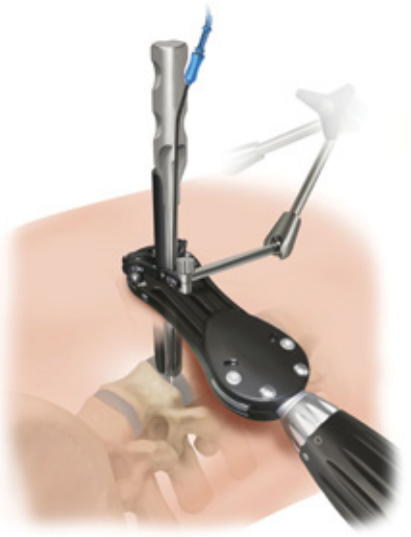


Figure 24c
Shim insertion

STEP 26 (INTRADISCAL SHIM INSERTION—OPTION 1)

The Timberline retractor system design allows the surgeon to advance the intradiscal shim while the dilators are still in place. This helps to prevent the retractor from moving prior to fixing the position of the retractor relative to the spine using the shim. The surgeon may elect to confirm that the retractor is a safe distance from any neurological structures and deploy the intradiscal shim.

- Insert the monopolar probe into the groove in the posterior blade. Stimulate to determine relative proximity to nearby nerve roots ***(Figure 24a)***.
- Insert the monopolar probe back into the second dilator. Stimulate to determine to confirm the nerve is now farther away ***(Figure 24b)***.
- If the stimulation threshold increases, and the surgeon determines that the nerve is situated a safe distance from the posterior blade, the shim can now be deployed.
- Insert the shim impactor into the posterior blade. While confirming with A/P fluoroscopy, advance the intradiscal shim into the disc space until it bottoms out in the blade channel ***(Figure 24c)***.

  Tip: *The force required to advance the shim is not significant. In many instances, this can be done by hand. If a mallet is required, the surgeon should refrain from impacting the shim with excessive force.*

RETRACTION

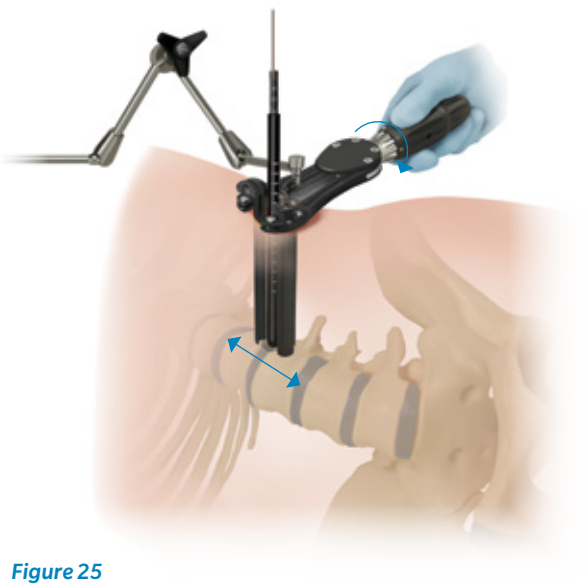


Figure 25
Cranial/caudal retraction

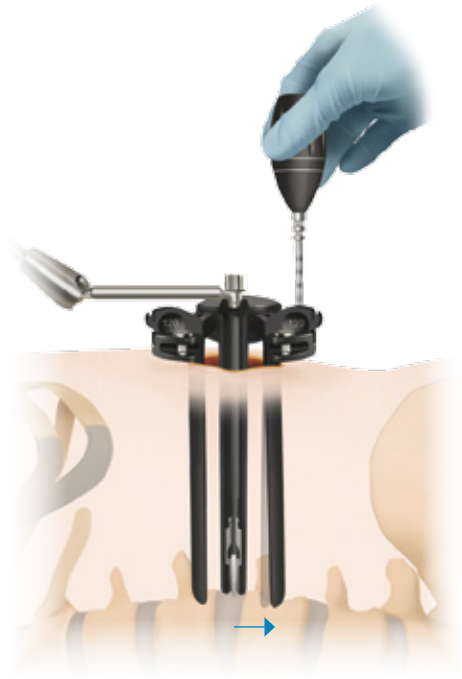


Figure 26
Plate toeing

STEP 27

- Ensure that the locking collar is in the partially locked position so that the handle can be rotated *(Refer to **Figure 6** on page 10)*.
- Open the cranial/caudal blades by rotating the cranial/caudal handle counterclockwise approximately 180° ***(Figure 25)***.

  Note: *A 180° turn of the cranial/caudal handle results in approximately 17mm of blade retraction.*

STEP 28

- Toeing of the cranial/caudal blades may be accomplished using the posterior handle ***(Figure 26)***.
- To toe the blades outward, the handle is rotated clockwise.

  Tip: *The cranial/caudal blades can be toed up to 20°. Care should be taken to avoid trauma to the psoas and the radicular vessels located at the midpoint of the vertebral body. Blades should not be extended past the midpoint of either vertebral body.*

STEP 29

- Retract anteriorly or posteriorly by rotating the posterior handle counterclockwise.

STEP 30

- Once the retractor has been opened to the desired position, remove the initial dilator and second dilator, leaving the K-wire in place.

WORKING CHANNEL PREPARATION

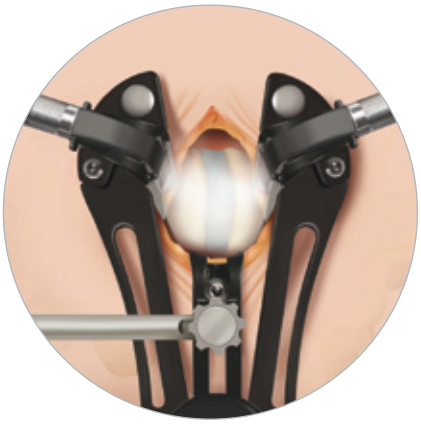


Figure 27a
Wave guide attachment

Figure 27b
Wave guide cover alignment

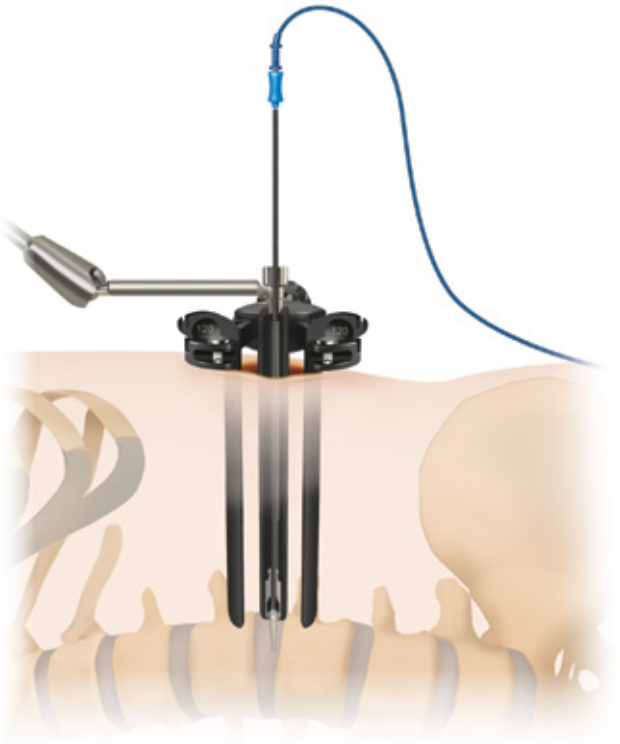


Figure 28
Monopolar probe insertion

STEP 31

- Attach the **wave guide(s)** to the light cable.
- Attach the wave guide(s) to the desired cranial/caudal blades ***(Figure 27a)***.
- Turn on the light source and adjust the light intensity as needed.

  Tip: *To ensure proper seating of the wave guide, place the wave guide onto the blade going straight down, ensuring the black cover sits inside the black channel* ***(Figure 27b)***.

STEP 32

- If desired, and at the surgeon's discretion, the monopolar probe may be positioned into retractor blades to check for proximity to the neural elements.
- The cranial/caudal blades are designed with two channels in which the monopolar probe, or a similar probe, can be inserted ***(Figure 28)***.
- The posterior blade is designed with one center channel in which the monopolar probe, or a similar probe, can be inserted.

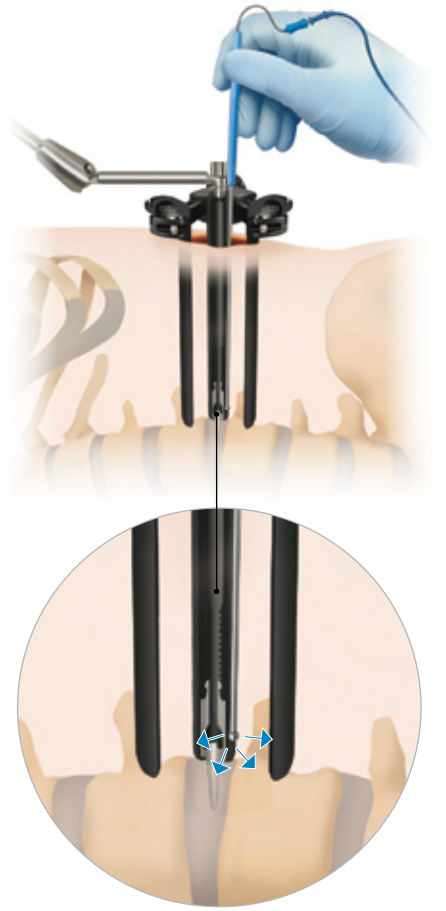


Figure 29
Ball-tip probe

Figure 30
Blade lengthening and widening shims

STEP 33

- Visualize and probe using the ball-tip probe to verify that the working area is clear of neural elements ***(Figure 29)***.

STEP 34

- A **psoas retractor** or **Penfield** may be used to sweep away any tissue from the working channel.
- Long **suction instruments** and **bipolar forceps** are available for this portion of the operation.

  Tip: Blade lengthening shims *or* ***widening shims*** *may be utilized to extend the effective reach of the cranial and/or caudal blades and ensure tissues remain clear of the working area. Shims are loaded into the cranial/caudal blades with the shim inserter. Insert the shims down the center channel of the cranial and/or caudal blades. The posterior blade has a preloaded, non-removable intradiscal shim.*

INTRADISCAL SHIM EXTENSION—OPTION 2

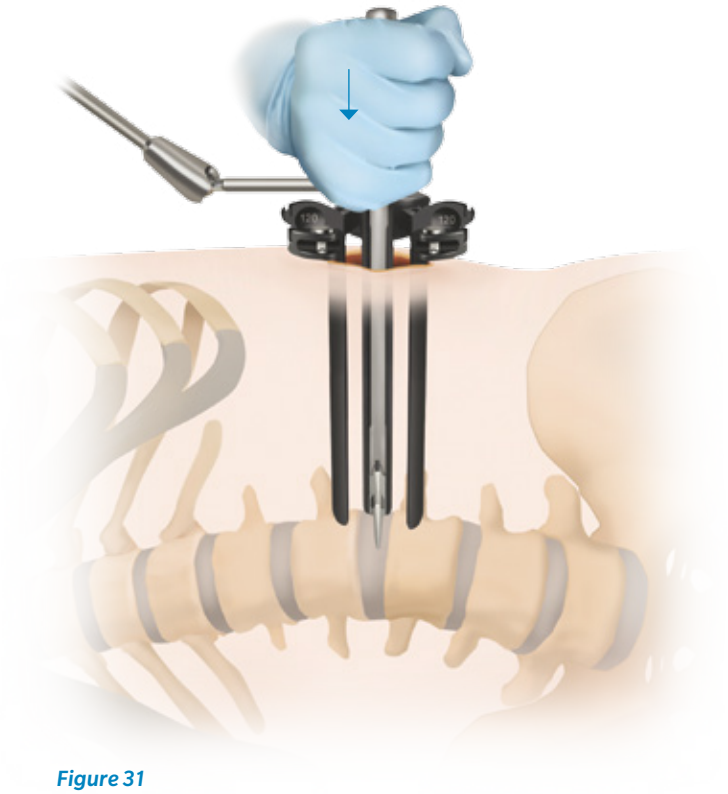


Figure 31
Advance shim

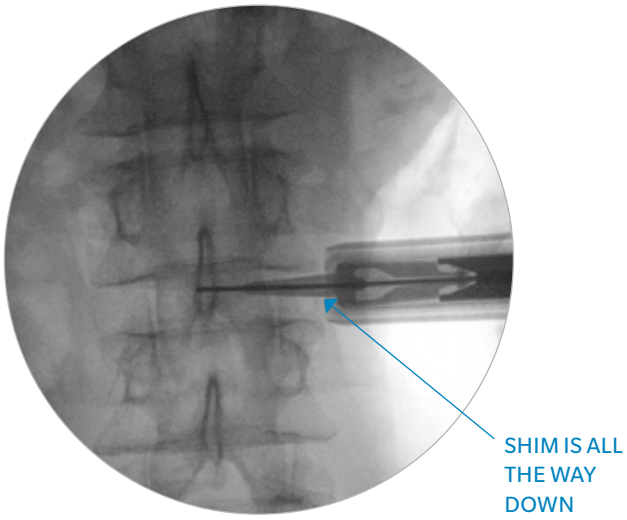


Figure 32
Intradiscal shim position

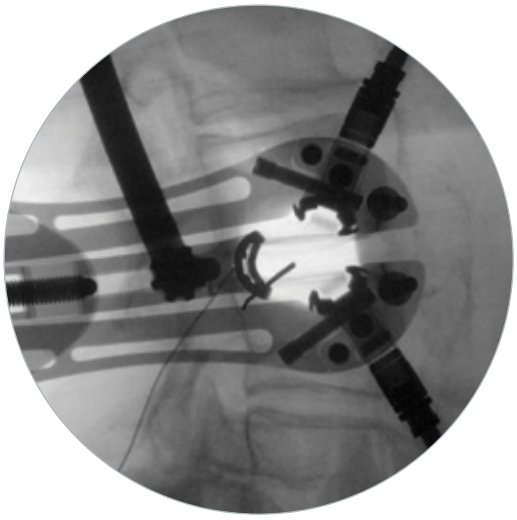
STEP 35 (INTRADISCAL SHIM INSERTION—OPTION 2)

If the surgeon selects to open the retractor prior to shim insertion with the dilators still in place *(step 26 on page 22)* do the following:

- Extend the intradiscal shim of the posterior blade into the intervertebral disc space from its initial position using the shim inserter ***(Figure 31)***.
- As needed, impact the shim inserter until the intradiscal shim bottoms out in the blade channel.
- When fully seated, the intradiscal shim will be protruding 20mm past the blade tip.
- Verify the intradiscal shim location using anterior/posterior fluoroscopy ***(Figure 32)***.
- Remove the K-wire.

  Tip: *The force required to advance the shim is not significant. In many instances, this can be done by hand. If a mallet is required, the surgeon should refrain from impacting the shim with excessive force.*

CORRECT ACCESS CONFIRMATION AND ANTERIOR BLADE ATTACHMENT



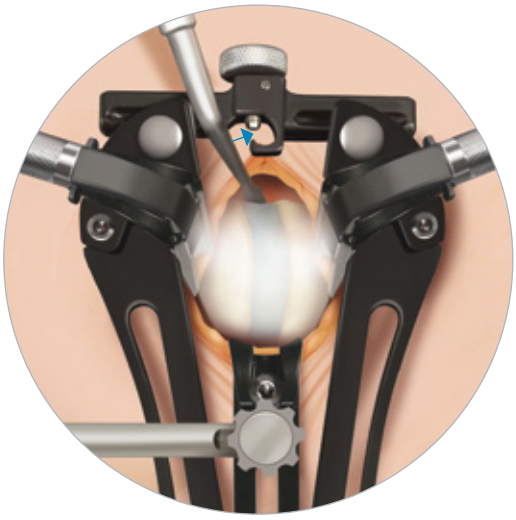


Figure 33
Scoville with crossbar

STEP 36

- Confirm that the retractor has been opened to the desired exposure.

  Tip: *An* ***implant trial*** *or* ***box cutter*** *may be placed into the working channel to verify there is adequate room for the procedure. Lateral fluoroscopy can be used to confirm proper alignment of the templating instrument with the disc space.*
- If desired, unlock the retractor handle and remove it from the retractor body.

STEP 37

- The surgeon has the option to utilize a soft tissue retractor to help retract soft tissue between the cranial/caudal blades, anteriorly. This soft tissue retractor also helps to identify the location of the anterior margin of the vertebral body.
- Place the tip of the soft tissue retractor just anterior to the anterior longitudinal ligament under direct visualization. Clip the anterior bar into the front of the retractor.
- Place the shaft of the soft tissue retractor within the hook of the anterior bar and tighten the thumb wheel such that it holds the soft tissue retractor shaft firmly.

  Note: *There are five variations of soft tissue retractors with varying lengths, blade curvatures and blade widths in the Timberline System kit.*

ANNULOTOMY AND DISCECTOMY

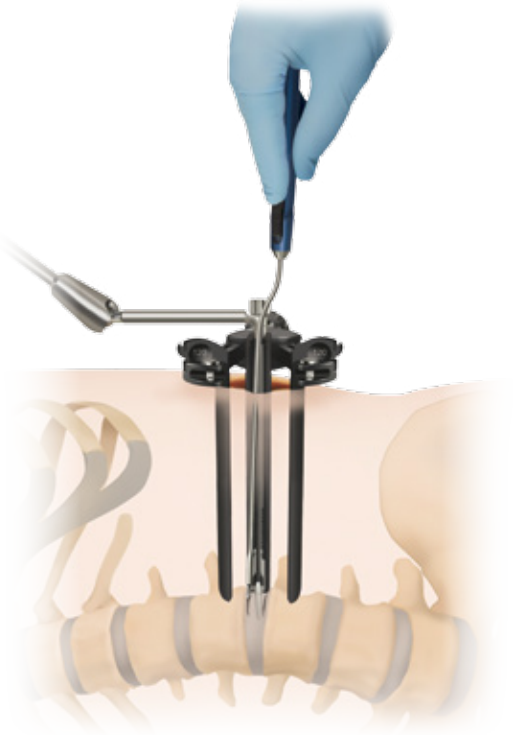


Figure 34
Annulotomy

Figure 35a
Cobb elevator

STEP 38

- Having first defined the anterior border of the disc space, use the **bayoneted annulotomy knife** to cut the annulus ***(Figure 34)***.
- Care is taken to avoid traversing the anterior longitudinal ligament and the anteriorly situated vessels.
- The annulotomy should be at least as long as the width of the implant to be used (i.e., 16mm, 18mm, 22mm, 26mm).

STEP 39

- Use a straight **cobb elevator** to disrupt the disc from both vertebral endplates and release the contralateral annulus. This will allow for an implant to sit on the contralateral apophyseal ring.
- Confirm under radiographic evaluation.
- Box cutters, **pituitary rongeurs, curettes, ring curettes** and **rasps** can be used to resect the disc material and prepare the bony endplates for fusion.

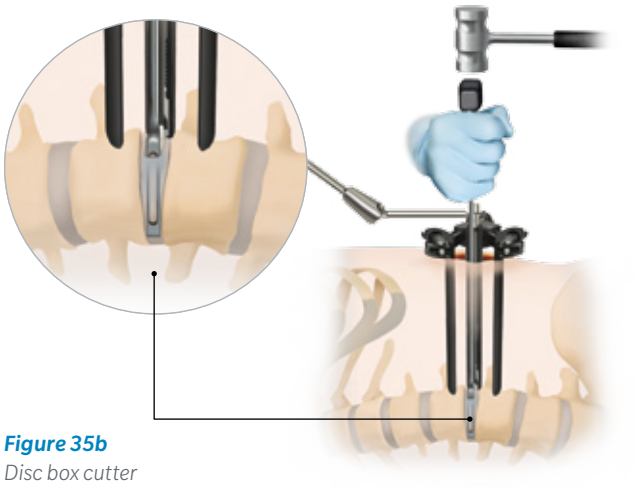


Figure 35b
Disc box cutter

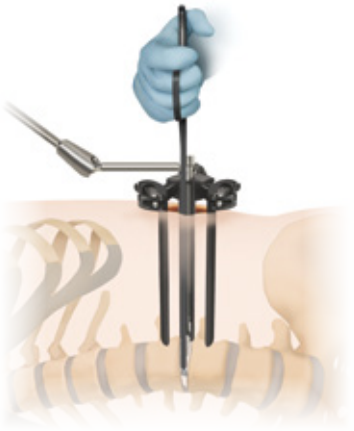


Figure 35c
Pituitary rongeur

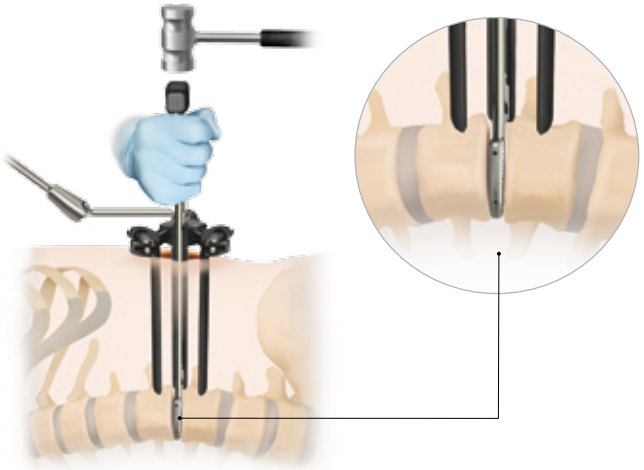


Figure 35d
Trial rasp

- If needed, use disc spreaders (with the **straight modular handle** or the **T-handle**) to distract the vertebral bodies.

  Note: *Avoid unintentional resection of the anterior longitudinal ligament or violation of the bony endplate* ***(Figure 35)****.*

  Note: *The rongeurs and implantation instruments kit is equipped with a* ***slap hammer*** *which may be used in conjunction with any modular or handled instrument.*

IMPLANT SIZING AND INSERTION

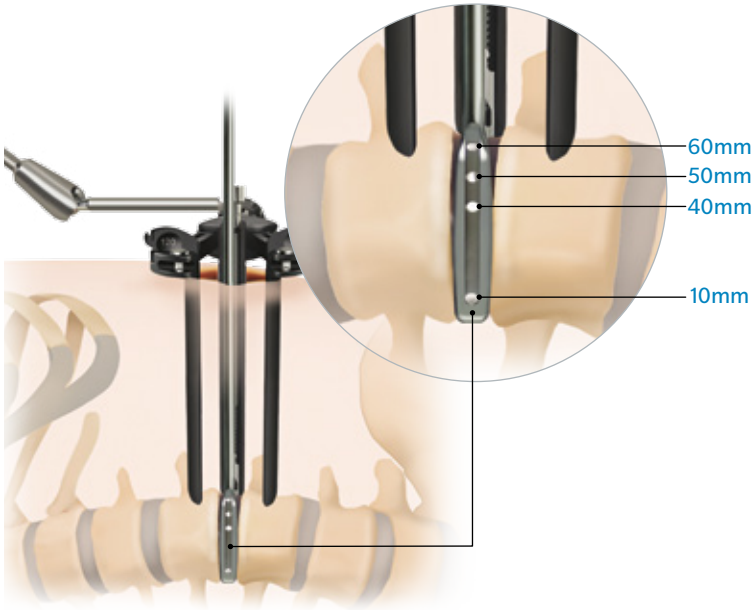


Figure 36a
Trial placement

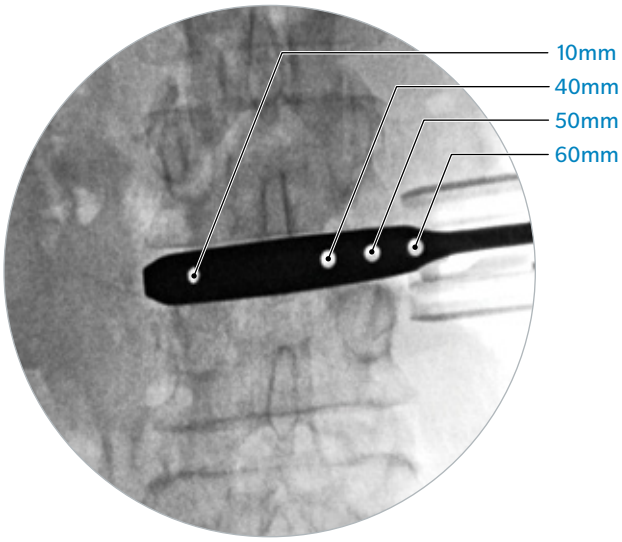


Figure 36b
Implant sizing

STEP 40

- Use trials to determine the correct implant size.

  Note: *Trials for each implant width, lordotic angle and height are provided in the kit. Start with the smallest size trial and move up in size as needed.*
- Confirm correct placement of the trial using lateral and A/P fluoroscopy.
- The trial should be centered across the disc space and appropriately centered in the anterior/posterior plane.
- Implant length can be determined using the holes in the trial.
- Holes are placed 10mm, 40mm, 50mm and 60mm from the tip of the trial ***(Figures 36a, b)***.
- The slap hammer may be used to assist with removal of spreaders or trials.

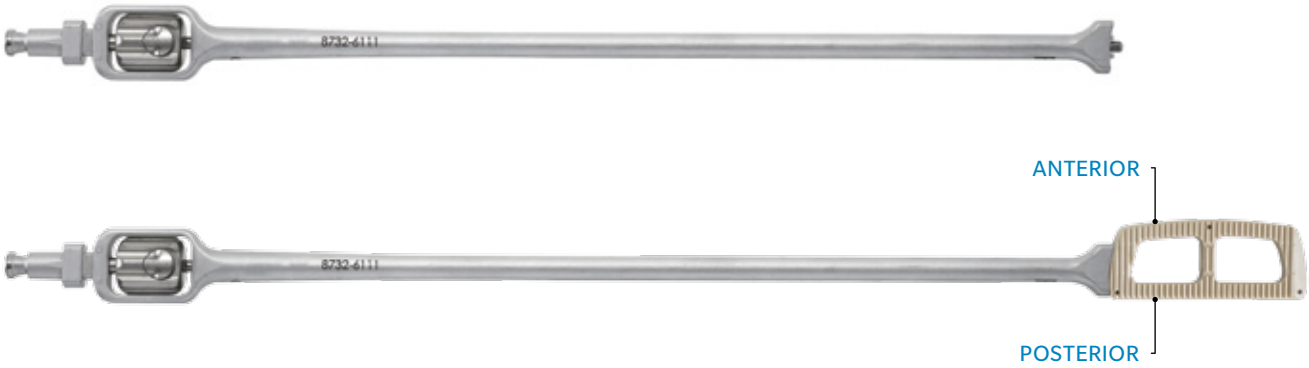


Figure 37
Implant and inserter

STEP 41

- Select the corresponding size Timberline implant.
- Pack the implant with bone graft, being careful not to over pack the implant.
- Attach the implant to the **inserter**.
- There are two locating pins that help center the inserter draw rod over the insertion hole of the implant.
- Rotate the thumb wheel clockwise until the implant is securely attached to the inserter ***(Figure 37)***.
- Attach the inserter to a modular T-handle.

Note: *Standard implants are available in 18mm or 22mm widths, 40mm–60mm lengths and 0° or 8° lordotic configurations (see pages 34–36 for additional implant size options).*

Note: *The implant inserter and implant trials are marked with the letter "P" to designate the posterior position as it relates to the posterior aspect of the implant.*

IMPLANT SIZING AND INSERTION *(continued)*

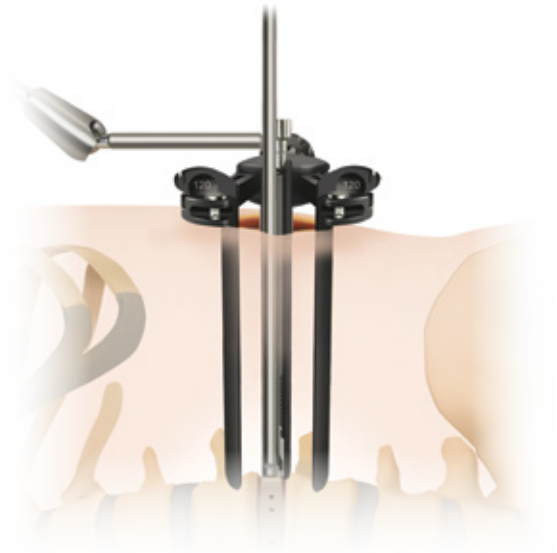


Figure 38a
Implant insertion

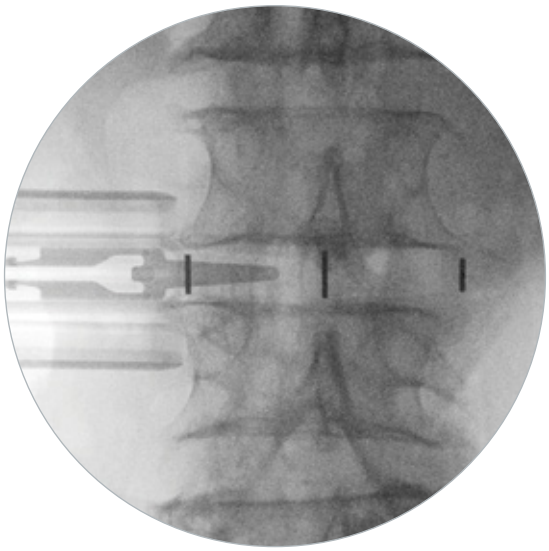


Figure 38b
Implant placement

Figure 38c
Lateral view, implant placement confirmation

STEP 42

- Carefully impact the implant into the disc space.
- Fluoroscopy should be used to confirm correct implant placement.
- The implant should traverse the apophyseal ring and be centered within the disc space ***(Figure 38)***.

  Tip: *If between lengths, it is always better to size up to ensure the implant spans the apophyseal ring.*

STEP 43

- Remove the inserter from the implant and verify the final position of implant with fluoroscopy.
- Ensure that no graft material has extruded out of the implant's graft chamber.
- Adjust with the implant impactor as necessary.

INSTRUMENT REMOVAL AND CLOSURE

STEP 44

- Retract the intradiscal shim into the posterior blade using the shim remover/retractor.
- Remove the scoville retractor and anterior crossbar attachment.
- Remove the light wave guides.
- Remove all other shims in the cranial/caudal blades.
- If the cranial/caudal blades were toed, return them to the zero position.
- Attach the handle assembly to the retractor body if previously detached.
- Close the retractor.
- Loosen the black articulating arm knob and disconnect the arm from the retractor by loosening the thumb screw.
- Carefully remove the retractor while watching to ensure there is no excess bleeding.

The Timberline System is indicated for use with supplemental fixation.

STEP 45

- The wound is closed using standard techniques.

REMOVAL OR REVISION PROCEDURE OF THE TIMBERLINE IMPLANT (*if necessary*)

1. Attach the implant inserter or implant remover to remove the implant.
2. Attach a slap hammer to the instrument or use a mallet to tap the instrument until the implant is removed from the disc space.

TIMBERLINE IMPLANT SIZES AND GRAFT VOLUMES

Standard Sizes, PCR8700-1201

18mm width, 0° lordosis	HEIGHT	cc	PART NUMBER
18mm × 40mm × 0°	8mm	2.0	8711-4008
	10mm	2.5	8711-4010
18mm × 45mm × 0°	8mm	2.3	8711-4508
	10mm	2.9	8711-4510
	12mm	3.5	8711-4512
18mm × 50mm × 0°	8mm	2.6	8711-5008
	10mm	3.2	8711-5010
	12mm	3.9	8711-5012
18mm × 55mm × 0°	8mm	2.7	8711-5508
	10mm	3.4	8711-5510
	12mm	4.1	8711-5512
18mm × 60mm × 0°	8mm	2.9	8711-6008
	10mm	3.8	8711-6010
	12mm	4.6	8711-6012

18mm width, 8° lordosis	HEIGHT	cc	PART NUMBER
18mm × 45mm × 8°	8mm	2.0	8712-4508
	10mm	2.6	8712-4510
	12mm	3.2	8712-4512
18mm × 50mm × 8°	8mm	2.2	8712-5008
	10mm	2.9	8712-5010
	12mm	3.6	8712-5012
	14mm	4.3	8712-5014
	16mm	5.0	8712-5016
18mm × 55mm × 8°	8mm	2.3	8712-5508
	10mm	3.0	8712-5510
	12mm	3.8	8712-5512
18mm × 60mm × 8°	8mm	2.5	8712-6008
	10mm	3.3	8712-6010
	12mm	4.1	8712-6012

22mm width, 0° lordosis	HEIGHT	cc	PART NUMBER
22mm × 45mm × 0°	8mm	2.8	8721-4508
	10mm	3.5	8721-4510
	12mm	4.2	8721-4512
22mm × 50mm × 0°	8mm	3.2	8721-5008
	10mm	4.0	8721-5010
	12mm	4.8	8721-5012
22mm × 55mm × 0°	8mm	3.5	8721-5508
	10mm	4.4	8721-5510
	12mm	5.4	8721-5512
22mm × 60mm × 0°	8mm	3.8	8721-5508
	10mm	4.9	8721-5510
	12mm	5.9	8721-5512

22mm width, 8° lordosis	HEIGHT	cc	PART NUMBER
22mm × 45mm × 8°	8mm	2.3	8722-4508
	10mm	3.0	8722-4510
	12mm	3.8	8728-4512
22mm × 50mm × 8°	8mm	2.6	8722-5008
	10mm	3.4	8722-5010
	12mm	4.3	8722-5012
	14mm	5.2	8722-5014
	16mm	6.1	8722-5016
22mm × 55mm × 8°	8mm	3.5	8722-5508
	10mm	4.4	8722-5510
	12mm	5.4	8722-5512
22mm × 60mm × 8°	8mm	3.2	8722-6008
	10mm	4.2	8722-6010
	12mm	5.2	8722-6012

PCR8700-0011

16mm width, 0° lordosis	HEIGHT	cc	PART NUMBER
16mm × 25mm × 0°	6mm	0.6	8701-2506
	8mm	0.8	8701-2508
	10mm	1.0	8701-2510
16mm × 30mm × 0°	6mm	0.9	8701-3006
	8mm	1.2	8701-3008
	10mm	1.4	8701-3010
16mm × 35mm × 0°	6mm	1.1	8701-3506
	8mm	1.5	8701-3508
	10mm	1.8	8701-3510
	12mm	2.2	8701-3512
16mm × 40mm × 0°	6mm	1.3	8701-4006
	8mm	1.8	8701-4008
	10mm	2.2	8701-4010

PCR8700-0021

26mm width, 0° lordosis	HEIGHT	cc	PART NUMBER
26mm × 45mm × 0°	8mm	3.6	8705-4508
	10mm	4.6	8705-4510
	12mm	5.5	8705-4512
26mm × 50mm × 0°	8mm	4.2	8705-5008
	10mm	5.3	8705-5010
	12mm	6.4	8705-5012
26mm × 55mm × 0°	8mm	4.8	8705-5508
	10mm	6.0	8705-5510
	12mm	7.2	8705-5512
26mm × 60mm × 0°	8mm	5.4	8705-6008
	10mm	6.8	8705-6010
	12mm	8.1	8705-6012

26mm width, 8° lordosis	HEIGHT	cc	PART NUMBER
26mm × 45mm × 8°	8mm	3.1	8706-4508
	10mm	4.1	8706-4510
	12mm	5.0	8706-4512
26mm × 50mm × 8°	8mm	3.6	8706-5008
	10mm	4.7	8706-5010
	12mm	5.8	8706-5012
	14mm	6.8	8706-5014
	16mm	7.9	8706-5016
26mm × 55mm × 8°	8mm	4.1	8706-5508
	10mm	5.3	8706-5510
	12mm	6.5	8706-5512
26mm × 60mm × 8°	8mm	4.7	8706-6008
	10mm	6.1	8706-6010
	12mm	7.4	8706-6012

PCR8700-0031

18mm width, 0° lordosis, coronal taper 4°	HEIGHT	cc	PART NUMBER
18mm × 45mm × 0°, CT	10mm	2.8	8713-4510
	12mm	3.3	8713-4512
	14mm	3.9	8713-4514
18mm × 50mm × 0°, CT	10mm	3.1	8713-5010
	12mm	3.8	8713-5012
	14mm	4.5	8713-5014
18mm × 55mm × 0°, CT	10mm	3.3	8713-5510
	12mm	4.0	8713-5512
	14mm	4.8	8713-5514
18mm × 60mm × 0°, CT	10mm	3.7	8713-6010
	12mm	4.5	8713-6012
	14mm	5.3	8713-6014

18mm width, 8° lordosis, coronal taper 4°	HEIGHT	cc	PART NUMBER
18mm × 45mm × 8°, CT	10mm	2.5	8714-4510
	12mm	3.1	8714-4512
	14mm	3.6	8714-4514
18mm × 50mm × 8°, CT	10mm	2.8	8714-5010
	12mm	3.5	8714-5012
	14mm	4.1	8714-5014
	16mm	4.8	8714-5016
18mm × 55mm × 8°, CT	10mm	2.9	8714-5510
	12mm	3.7	8714-5512
	14mm	4.4	8714-5514
18mm × 60mm × 8°, CT	10mm	3.2	8714-6010
	12mm	4.1	8714-6012
	14mm	4.9	8714-6014

TIMBERLINE IMPLANT SIZES AND GRAFT VOLUMES *(continued)*

Non-Standard Sizes

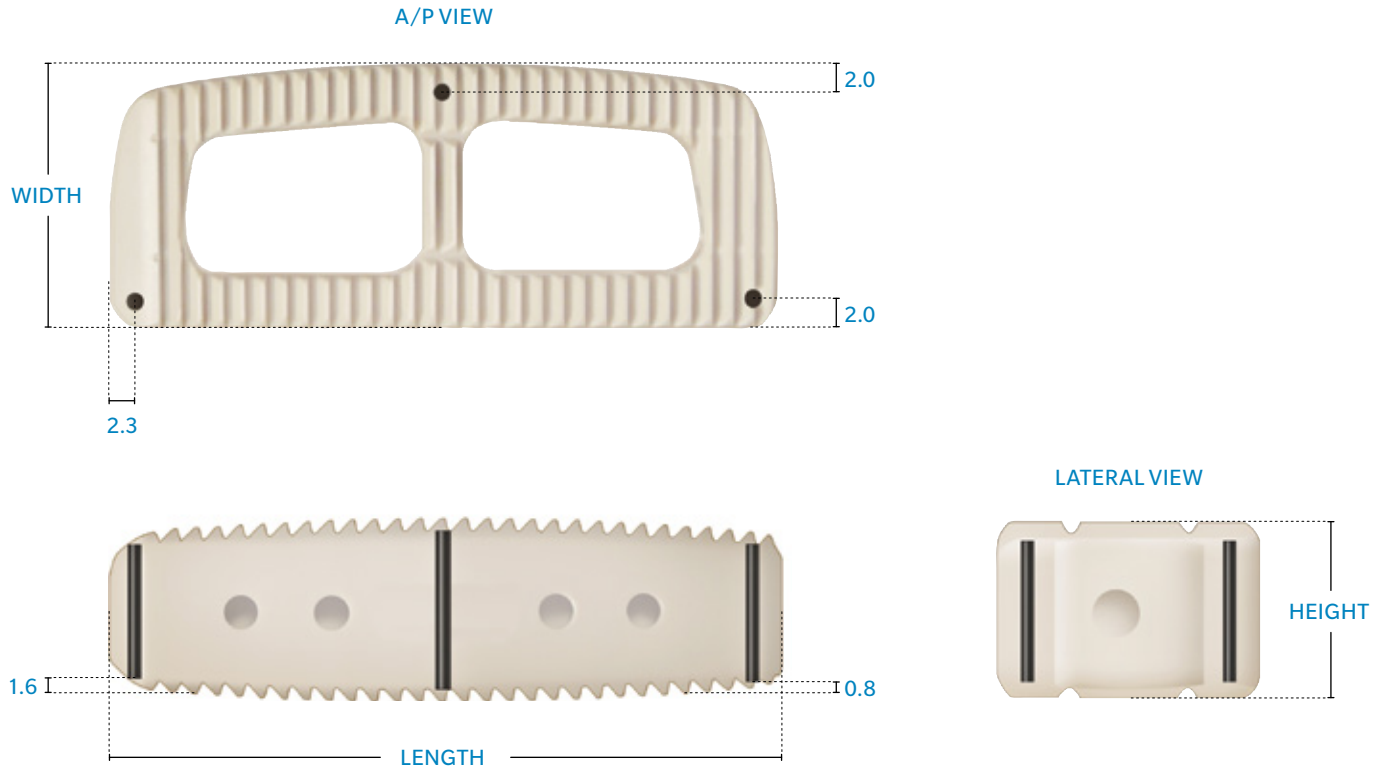
18mm width, 0° lordosis	HEIGHT	cc	PART NUMBER
18mm × 40mm × 0°	12mm	3.0	8711-4012
	14mm	3.5	8711-4014
	16mm	4.0	8711-4016
18mm × 45mm × 0°	14mm	4.1	8711-4514
	16mm	4.6	8711-4516
18mm × 50mm × 0°	14mm	4.5	8711-5014
	16mm	5.2	8711-5016
18mm × 55mm × 0°	14mm	4.9	8711-5514
	16mm	5.6	8711-5516
18mm × 60mm × 0°	14mm	5.4	8711-6014
	16mm	6.2	8711-6016

18mm width, 8° lordosis	HEIGHT	cc	PART NUMBER
18mm × 40mm × 8°	8mm	1.7	8712-4008
	10mm	2.2	8712-4010
	12mm	2.7	8712-4012
	14mm	3.2	8712-4014
	16mm	3.7	8712-4016
18mm × 45mm × 8°	14mm	3.7	8712-4514
	16mm	4.3	8712-4516
18mm × 55mm × 8°	14mm	4.5	8712-5514
	16mm	5.2	8712-5516
18mm × 60mm × 0°	14mm	5.0	8712-6014
	16mm	5.8	8712-6016

22mm width, 0° lordosis	HEIGHT	cc	PART NUMBER
22mm × 45mm × 0°	14mm	4.9	8721-4514
	16mm	5.7	8721-4516
22mm × 50mm × 0°	14mm	5.6	8721-5014
	16mm	6.4	8721-5016
22mm × 55mm × 0°	14mm	6.3	8721-5514
	16mm	7.3	8721-5516
22mm × 60mm × 0°	14mm	7.0	8721-6014
	16mm	8.0	8721-6016

22mm width, 8° lordosis	HEIGHT	cc	PART NUMBER
22mm × 45mm × 8°	14mm	4.5	8722-4514
	16mm	5.2	8722-4516
22mm × 55mm × 8°	14mm	5.7	8722-5514
	16mm	6.6	8722-5516
22mm × 60mm × 8°	14mm	6.3	8722-6014
	16mm	7.3	8722-6016

RADIOGRAPHIC MARKER POSITIONS AND KIT OVERVIEW



	DESCRIPTION	PART NUMBER
Standard Implant and Instrument Kits	Timberline Case 1, 18mm and 22mm Implant Kit	PCR8700-1201
	Timberline Case 2, Retractor Kit I	PCR8700-2301
	Timberline Case 3, Retractor Kit II	PCR8700-3301
	Timberline Case 4, Disc Preparation Kit	PCR8700-4201
	Timberline Case 5, Rongeur and Implantation Instruments	PCR8700-5301
Auxiliary Implant and Instrument Kits	Timberline Case 6, Auxiliary Instruments	PCR8700-6201
	Timberline Case 7, Angled Instruments	PCR8700-7201
	Timberline 16mm Implant Kit	PCR8700-0011
	Timberline 26mm Implant Kit	PCR8700-0021
	Timberline Coronal Taper Implant Kit	PCR8700-0031
Disposable Kits	Timberline Access Kit	8700-9112
	Timberline Monitoring Kit*	8700-9122
	Special Order MEP Electrode Kit	8735-1013

*May not be available in all geographic areas.

STANDARD IMPLANT AND INSTRUMENT KITS

Timberline Case 1: 18mm and 22mm Implant Kit, PCR8700-1201

Trial	PART NUMBER
	8732-2112

18mm width, 0° lordosis	PART NUMBER
8mm	8734-4134
10mm	8732-1110
12mm	8732-1112

22mm width, 0° lordosis	PART NUMBER
8mm	8732-2108
10mm	8732-2110
12mm	8732-2112

18mm width, 8° lordosis	PART NUMBER
8mm	8732-1208
10mm	8732-1210
12mm	8732-1112
14mm	8732-1214

22mm width, 8° lordosis	PART NUMBER
8mm	8732-2208
10mm	8732-2210
12mm	8732-2212
14mm	8732-2214

Timberline Case 2: Retractor Kit I, PCR8700-2201

Retractor	PART NUMBER
	8734-0010

Cranial/Caudal Handle	PART NUMBER
	8734-0060

Posterior Handle	PART NUMBER
	8734-0070

Cranial/Caudal Blades			PART NUMBER
50mm	8734-2050	120mm	8734-2120
60mm	8734-2060	130mm	8734-2130
70mm	8734-2070	140mm	8734-2140
80mm	8734-2080	150mm	8734-2150
90mm	8734-2090	160mm	8734-2160
100mm	8734-2100	170mm	8734-2170
110mm	8734-2110	180mm	8734-2180

Posterior Blades			PART NUMBER
50mm	8734-5050	120mm	8734-5120
60mm	8734-5060	130mm	8734-5130
70mm	8734-5070	140mm	8734-5140
80mm	8734-5080	150mm	8734-5150
90mm	8734-5090	160mm	8734-5160
100mm	8734-5100	170mm	8734-5170
110mm	8734-5110	180mm	8734-5180

Timberline Case 2: Retractor Kit I, PCR8700-2201 *(continued)*

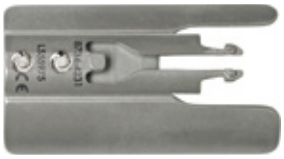
Anterior Bar	PART NUMBER
	8734-4134

Soft Tissue Retractor, Reverse	PART NUMBER
140mm	8733-2305
180mm	8733-2307

Soft Tissue Retractor, Narrow Reverse	PART NUMBER
140mm	8733-2315
180mm	8733-2317

Soft Tissue Retractor, Long	PART NUMBER
	8733-2110

Lengthening Shim	PART NUMBER
	8734-4220



Widening Shims	PART NUMBER
Right	8733-4231
Left	8733-4232

Shim Inserter/Impactor	PART NUMBER
	8734-0090

Shim Remover	PART NUMBER
	8734-0080

Threaded Shim Extended, 5mm	PART NUMBER
	8734-4261

Anchoring Screw	PART NUMBER
	8734-1005

Threaded Shim Driver	PART NUMBER
	8734-4270

Threaded Shim Sleeve	PART NUMBER
	8734-4271

Ball-Tip Driver	PART NUMBER
	8734-6118

Top Handle	PART NUMBER
Inner	8734-4120-010
Outer	8734-4120-020

STANDARD IMPLANT AND INSTRUMENT KITS *(continued)*

Timberline Case 3: Retractor Kit II, PCR8700-3201

Initial Dilator	PART NUMBER
	8734-0025

Second Dilator	PART NUMBER
	8734-0035

Initial Dilator Holder	PART NUMBER
	8734-1006

Blunt K-wire	PART NUMBER
	8734-1001
Chamfered K-wire	PART NUMBER
	8734-1003

K-wire Dispenser	PART NUMBER
	8734-1002

Bipolar Forceps	PART NUMBER
	8733-2200

Table Clamp	PART NUMBER
	8738-0022

Suction Instrument	PART NUMBER
12FR Short	8733-2512
12FR Long	8733-2612

Blunt Bayoneted Dissector, Penfield	PART NUMBER
4mm	8732-6108
Reverse 4mm	8732-6109

Modulator Instrument	PART NUMBER
	8732-6104

Psoas Retractor	PART NUMBER
4mm, Right Hand	8732-6204
8mm, Right Hand	8732-6208
4mm, Left Hand	8732-6304
8mm, Left Hand	8732-6308

Articulating Arm Knob	PART NUMBER
	8734-4133

Articulating Arm	PART NUMBER
	8734-0020

Timberline Case 4: Disc Preparation Kit, PCR8700-4201

Osteotome	PART NUMBER
10mm	8733-4210

Curved Osteotome	PART NUMBER
10mm	8733-4310

Cobb Elevator	PART NUMBER
18mm	8733-4418
22mm	8733-4422

Angled Cobb Elevator	PART NUMBER
18mm	8733-4518
22mm	8733-4522

Endplate Scraper (Pull)	PART NUMBER
	8733-4613

Box Curette	PART NUMBER
7mm	8733-4707

Serrated Cup Curette, Straight	PART NUMBER
2mm	8733-5102
4mm	8733-5104
6mm	8733-5106

Serrated Cup Curette, Angled Up	PART NUMBER
2mm	8733-5112
4mm	8733-5114

STANDARD IMPLANT AND INSTRUMENT KITS *(continued)*

Timberline Case 5: Rongeur and Implantation Instruments, PCR8700-5201

Ferris Smith Pituitary Rongeur	PART NUMBER
3mm	8733-7153
5mm	8733-7155
7mm	8733-7157

Hodgson-style Rongeur	PART NUMBER
7mm	8733-7177

Kerrison Rongeur	PART NUMBER
3mm	8733-7163
5mm	8733-7165

Slap Hammer	PART NUMBER
	8732-7101

Box Osteotome, 18mm	PART NUMBER
4mm	8733-6104
6mm	8733-6106
8mm	8733-6108

Box Osteotome, 22mm	PART NUMBER
4mm	8733-6204
6mm	8733-6206
8mm	8733-6208

Trial Rasp, 18mm width, 0° lordosis	PART NUMBER
6mm	8732-3106
8mm	8732-3108
10mm	8732-3110
12mm	8732-3112

T-handle	PART NUMBER
	9801-0009

Straight Modular Handle	PART NUMBER
	9801-0111

Timberline Case 5: Rongeur and Implantation Instruments, PCR8700-5201 *(continued)*

Slap Hammer Adaptor	PART NUMBER
	8732-6100

Implant Inserter	PART NUMBER
	8732-6106 or 8732-6111

Draw Rod	PART NUMBER
	87321-6106-005 or 8732-6111-005

Impactor	PART NUMBER
	8732-6103

Implant Remover	PART NUMBER
	8732-6102

Inserter Spanner Wrench	PART NUMBER
	8732-6107

Thin Disc Spreader, 18mm x 4mm	PART NUMBER
	8732-5618

Thick Disc Spreader, 18mm x 6mm	PART NUMBER
	8732-5718

2 Piece Graft Slider	PART NUMBER
	8738-0072

STANDARD IMPLANT AND INSTRUMENT KITS *(continued)*

Timberline Case 6: Auxiliary Instrument Kit, PCR8700-6201

Paddle Shaver	PART NUMBER
6mm	8732-5106
8mm	8732-5108
10mm	8732-5110
12mm	8732-5112
14mm	8732-5114
16mm	8732-5116

Rotating Disc Cutter	PART NUMBER
6mm	8732-5406
8mm	8732-5408
10mm	8732-5410
12mm	8732-5412
14mm	8732-5414
16mm	8732-5416

Disc Spreader	PART NUMBER
6mm	8732-5206
8mm	8732-5208
10mm	8732-5210
12mm	8732-5212
14mm	8732-5214
16mm	8732-5216

Timberline Case 7: Angled Instrument Kit, PCR8700-7201

Ferris Smith Pituitary Rongeur, Angled	PART NUMBER
5mm, Right	8737-7155
5mm, Left	8737-7255
7mm, Right	8737-7157
7mm, Left	8737-7257

Cobb, Angled Up	PART NUMBER
18mm	8737-4418
22mm	8737-4422

Cobb, Angled Down	PART NUMBER
18mm	8737-4518
22mm	8737-4522

Serrated Cup Curette, Angled Up	PART NUMBER
4mm	8737-5104

Serrated Cup Curette, Angled Down	PART NUMBER
4mm	8737-5204

Box Chisel, Angled	PART NUMBER
4mm	8737-6104
6mm	8737-6106
8mm	8737-6108

Trial Rasp, Angled, 18mm	PART NUMBER
6mm	8737-3106
8mm	8737-3108
10mm	8737-3110
12mm	8737-3112

Trial, Angled, 18mm	PART NUMBER
8mm	8737-1108
10mm	8737-1110
12mm	8737-1112
14mm	8737-1114

STANDARD IMPLANT AND INSTRUMENT KITS *(continued)*

Timberline Case 7: Angled Instrument Kit, PCR8700-7201 *(continued)*

Endplate Scraper, Angled	PART NUMBER
	8737-4613

Implant Inserter, Angled	PART NUMBER
Right	8737-1000
Left	8737-1001

Disc Spreader, Angled	PART NUMBER
4mm	8737-5618
6mm	8737-5718

Impactor, Angled	PART NUMBER
	8737-6103

DISPOSABLE KITS

Timberline Access Kit, 8700-9112

PRODUCT DESCRIPTION	QUANTITY	PART NUMBER
Annulotomy Knife	1	8735-2000
Wave Guide	2	8735-0041

Timberline Monitoring Kit, 8700-9122 (May not be available in all geographic areas.)

Note: *8700-9122 includes both 8735-1011 and 8735-1012 (next page). Alternatively, 8735-1011 or 8735-1012 may be ordered individually.*

Probe and Connector Box, 8735-1011

PRODUCT DESCRIPTION	QUANTITY	PART NUMBER
Detachable Monopolar Probes, 275mm	3	8735-1011-001
Probe Extension Cables	2	8735-1011-002
Ball-tip Probe	1	8735-1011-003

DISPOSABLE KITS *(continued)*

Timberline Monitoring Kit, 8700-9122 *(continued)*

EMG/SSEP Electrode Kit, 8735-1012

PRODUCT DESCRIPTION	QUANTITY	PART NUMBER
Lead Wire Parallel Pair Subdermal Needles, 2.5m	8	8735-1012-(001–008)
Lead Wire Pair Surface Electrodes, 2.5m, 1.5cm x 2cm	4	8735-1012-(009–012)
Lead Wire Single Needles, 2.5m	5	8735-1012-(013–017)
Lead Wire, 2.5m, 19mm Single Needle	1	8735-1012-018
Lead Wire Ground Electrode, 2.5m (Single Surface Electrode)	1	8735-1012-019
Lead Wire Return Electrode, 2.5m (Single Surface Electrode)	1	8735-1012-020
Gauze Pads	6	8735-1012-021
Alcohol Pads	6	8735-1012-022
Roll of Tape	1	8735-1012-023
Marking Pen	1	8735-1012-024

Special Order MEP Electrode Kit, 8735-1013

PRODUCT DESCRIPTION	QUANTITY	PART NUMBER
Lead Wire Parallel Pair Subdermal Needles, 2.5m	1	8735-1013-001
Lead Wire Parallel Pair Subdermal Needles, 2.5m	1	8735-1013-002
Corkscrew	1	8735-1013-003
Corkscrew	1	8735-1013-004

IMPORTANT INFORMATION ON THE TIMBERLINE LATERAL FUSION SYSTEM

Device Description

The Timberline Lateral Fusion System is an intervertebral body fusion/vertebral body replacement device generally consisting of a rectangular shape with various lengths, widths, heights and lordotic angles, which may incorporate a measuring function and has uses as described on the label. The device has a hollowed out central area to accommodate autogenous bone graft. The upper and lower surfaces have a series of transverse grooves formed to improve stability and fixation once the device is inserted. The Timberline device is available in a variety of sizes and configurations to approximate anatomical variation in different vertebral levels and/or patient anatomy.

The Timberline System includes disc prep and general instruments, a retractor system and several associated disposables. The Timberline System consists of a comprehensive kit of instruments to perform the surgery. The retractor system consists of three blades with an optional fourth blade attachment. The posterior blade moves independently with respect of the cranial/caudal blades. Multiple blade lengths are available. Other features include toeing blades up to 20°, controlled opening/closing of the arms with infinite resolution, intradiscal docking shims, blade widening and lengthening shims, and fiber optic illumination. Zimmer Biomet Spine provides separate disposable kits for accessing the disc space or for help with neuromonitoring.

Indications for Use

When used as a lumbar intervertebral body fusion device, the Timberline System is intended for spinal fusion procedures to be used with autogenous bone graft in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous spinal levels from L2–S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six months of non-operative treatment. These DDD patients may have had a previous non-fusion spinal surgery at the involved spinal level(s), and may have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). The Timberline System is to be combined with supplemental fixation. Approved supplemental fixation systems include the Zimmer Biomet Spinal Fixation System.

The following devices are indicated to be used as a lumbar intervertebral body fusion device:

Description	Length Range	Width Range	Height Range	Lordotic Angles
Timberline	25mm–60mm	16mm,18mm, 22mm and 26mm	6mm–16mm	0° and 8°

When used as a vertebral body replacement, the Timberline System is indicated for use to replace a vertebral body that has been resected or excised due to tumor or trauma/fracture. The device is intended for use as a vertebral body replacement in the thoracolumbar spine (from T1–L5). The Timberline System may also be used in the thoracolumbar spine (i.e., T1–L5) for partial replacement (i.e., partial vertebrectomy) of a diseased vertebral body resected or excised for the treatment of tumors in order to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The Timberline device is also indicated for treating fractures of the thoracic and lumbar spine. The Timberline System is designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column. For either indication, the system must be used with supplemental internal fixation. Supplemental internal fixation is required to properly utilize this system.

The following devices are indicated to be used as a vertebral body replacement (VBR) device:

Description	Length Range	Width Range	Height Range	Lordotic Angles
Timberline	25mm–60mm	16mm ,18mm, 22mm and 26mm	6mm–50mm	0° and 8°

For any of the above indications, the system must be used with supplemental internal fixation.

Contraindications

Contraindications include, but are not limited to:

- Presence of fever or infection (systemic, spinal or localized).
- Pregnancy.
- Severe osteopenia.
- Prior fusion at the level to be treated.
- Any condition not described in the Indications for Use.
- Any other medical or surgical condition which would preclude the potential benefit of spinal implant surgery.
- Patients with metal sensitivity or allergies to the implant materials.
- Patients unwilling or unable to cooperate with postoperative care instructions.

IMPORTANT INFORMATION ON THE TIMBERLINE LATERAL FUSION SYSTEM *(continued)*

Risks

Potential risks identified with the use of this device system, which may require additional surgery include device component failure (expulsion, loosening or breakage of the implant). Failure may occur as a result of implant stress, loss of fixation, non-union, infection or subsequent fracture of the vertebra. Implant failure may result in neurological injury and vascular or visceral injury. These devices can break when subjected to increased loading associated with delayed union or non-union. Internal fixation appliances are load-sharing devices, which hold a fracture in alignment until healing occurs.

If healing is delayed or does not occur, the implant could eventually break due to material fatigue. The patient's weight, activity level and compliance to weight bearing or activity restrictions can have an effect on the stresses to which the implant is subjected. Such stresses may affect the long-term survival of the implant. The following warnings do not include all possible adverse effects, but are important considerations particular to spinal fixation devices.

Warnings

Patients with previous spinal surgery at the levels to be treated may have different clinical outcomes compared to those without a previous surgery. The risk of a device expulsion and migration is higher without the use of supplemental fixation.

Precautions

- Only experienced spinal surgeons should, with specific training in the use of vertebral implants and lateral approaches to the spine, perform the implantation of this system. The surgical procedure is technically demanding and presents a risk of serious injury to the patient.
- The Timberline device is intended to be used only by surgeons specialized in spinal surgery and having thorough knowledge of vertebral anatomy, regional vertebral morphology and the biomechanical principles of the spine. It is advised that the surgeon also be thoroughly familiar with the surgical techniques relative to the use of the device.
- Risks associated with orthopedic surgery, neurosurgery, general surgery and the use of general anesthesia should be explained to the patient prior to surgery. It is recommended that the advantages and disadvantages of using implants and alternative treatment methods are explained to the patient.
- The surgeon may or may not elect to use neuromonitoring in conjunction with the Timberline System. If neuromonitoring is selected for use by the surgeon, inform the anesthesiologist that EMG monitoring will be used during the procedure to ensure that no neuromuscular blocking agents are administered during monitoring. If necessary, a short-acting neuromuscular agent should be used during intubation.
- Correct selection and placement of the implants is extremely important. Implant selection must be based upon the bone defect to be treated as well as the patient's weight, height, occupation or degree of physical activity.
- Proper handling of the implant before and during the operation is crucial.
- The Timberline device must only be used with appropriate secondary stabilization instrumentation. The Timberline device is not approved for use with vertebral components or instruments from other manufacturers, except for the Avenue® L Lateral Lumbar Cage.
- Before use, inspect all instrumentation for possible damage, wear or non-function. Damaged or defective instruments should not be used or processed. Contact your local Zimmer Biomet Spine representative or dealer for repair or replacement.
- The use of an instrument for tasks other than those for which they are indicated may result in damaged or broken instruments or harm to the patient.
- Do not apply excessive force or stress. Misuse can damage instruments or implants or cause harm to the patient.
- Perform a careful preoperative review to be sure that all necessary implant components are available, and that the instrument kit is complete and in working order prior to initiating surgery.
- The instrument and implant components of the Timberline System should NOT be used with the instrument or implant components from any other system or manufacturer.
- The Timberline device has not been evaluated for safety and compatibility in the magnetic resonance (MR) environment. The Timberline device has not been tested for heating or migration in the MR environment.
- The Timberline lateral fusion device is for single use only. Reuse of the implant components may result in reduced mechanical performance, malfunction or failure of the device.

** The Timberline device is intended to be used with supplemental internal spinal fixation. Surgeons should follow standard surgical techniques for implantation of supplemental internal spinal fixation.*

Disclaimer: *This document is intended exclusively for physicians and is not intended for laypersons. Information on the products and procedures contained in this document is of a general nature and does not represent and does not constitute medical advice or recommendations. Because this information does not purport to constitute any diagnostic or therapeutic statement with regard to any individual medical case, each patient must be examined and advised individually, and this document does not replace the need for such examination and/or advice in whole or in part.*

Caution: *Federal (USA) law restricts this device to sale by or on the order of a physician. Rx Only. Please see the product Instructions for Use for a complete listing of the indications, contraindications, precautions, warnings and adverse effects.*

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