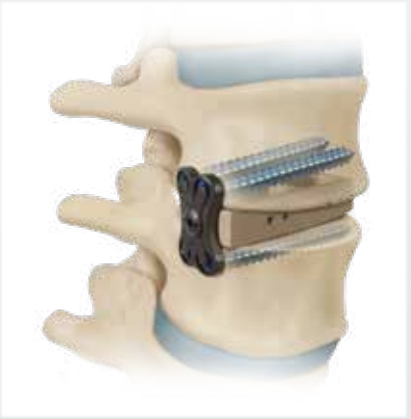
Timberline® MPF

Lateral Modular Plate Fixation System

Surgical Technique Guide



ZimVie

A first-of-its-kind, lateral, modular plate fixation device that easily and accurately accommodates varying plate styles, sizes and positioning.

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ZimVie Spine does not practice medicine. This technique was developed in conjunction with health care professionals. This document is intended for surgeons and is not intended for laypersons. Each surgeon 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 surgeons have received. As with all surgical procedures, the technique used in each case will depend on the surgeon's medical judgment as the best treatment for each patient. Results will vary based on health, weight, activity and other variables. Not all patients are candidates for this product and/or procedure.

Device Description

The Timberline MPF Lateral Modular Plate Fixation 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:

- Low-profile implant design allows for minimal retractor exposure.
- Interchangeable plate and interbody spacer options for intraoperative flexibility.
- 1-, 2- and 4-screw plate designs.
- Variable screws (5.5 mm with 6.0 mm rescue option).
- 15° of cephalad/caudal angulation to avoid adjacent-level pedicle screws.
- Plate design limits A/P screw angulation to avoid undesired screw trajectories.
- Nominal 0° and 5° screw trajectory for optimal cortical bone purchase.
- Single-step lock plate for screw back out prevention.
- Simple mayo stand or in situ threaded assembly options.
- Fixed and variable drill guides to assist in desired screw placement.

Required Equipment

ITEMS	DETAILS
Timberline Implants and Instruments	
Timberline Case 1, 18 mm and 22 mm 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 MPF Implants and Instruments	
Timberline MPF Implants Kit	PCR8600-1101
Timberline MPF Instruments Kit	PCR8600-2101
Timberline MPF Hyperlordotic Kit	PCR8600-3301
Timberline MPF 14° Implants Kit	PCR8600-1401
Timberline Access Kit (single use only)	**8700-9112**
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
Neuromonitoring Equipment Timberline System is compatible with any commercially available system	
Timberline Auxiliary Instrument Kit	Rotating disc cutters, paddle shavers and disc spreaders
Timberline Angled Instrument Kit	PCR8700-7201 *Recommended for L4–L5*

**May not be available in all geographic areas.*

Preoperative and Intraoperative Preparation

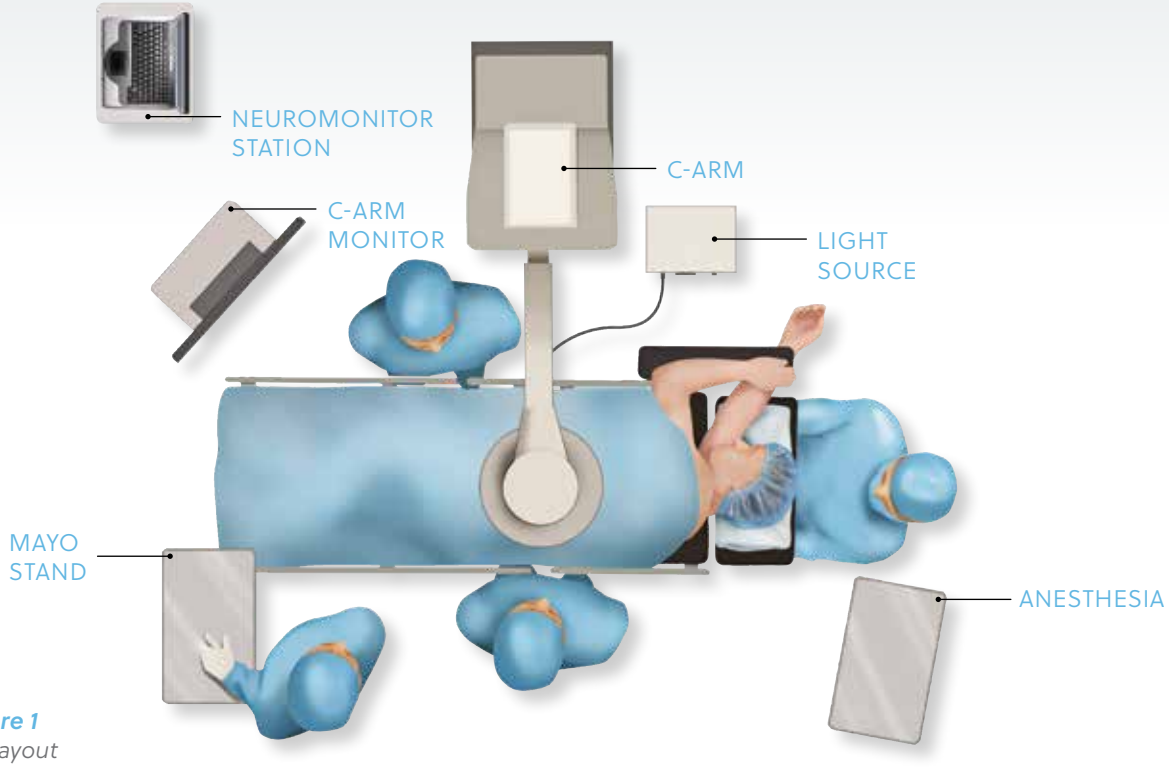


Figure 1
OR layout

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 Lateral Fusion System may be used with most 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.

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 axillary roll under the axilla, and a 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.

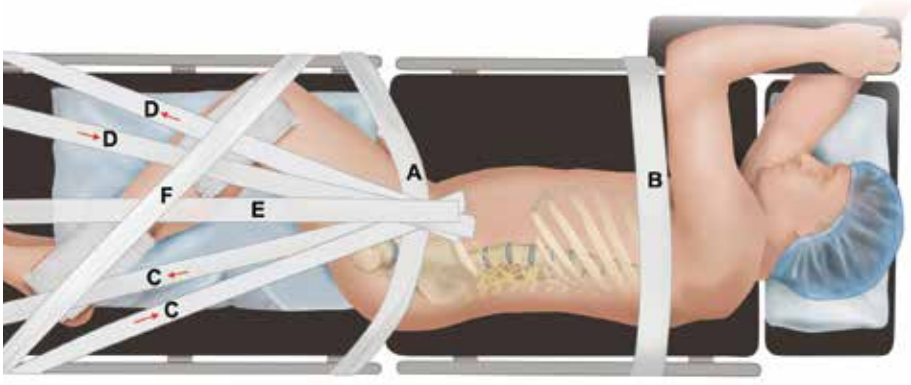


Figure 2
Patient positioning and taping

Surgical Approach Preparation and Retraction

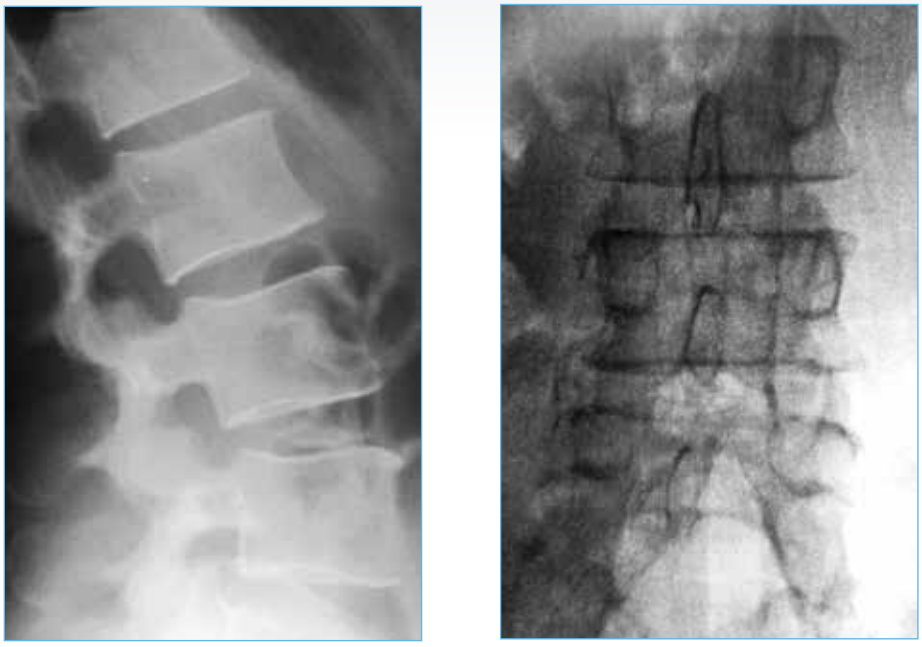


Figure 3
Examples of true lateral and A/P images

STEP 2

- 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.
- 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 **(Figure 3)**.

Surgical Approach—Retraction and Discectomy

Figure 4a
Retractor components

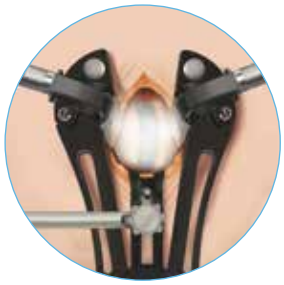


Figure 4b
Wave guide attachment

Figure 4c
Monopolar probe insertion

STEP 3

- The Timberline retractor is utilized to create the desired exposure for implanting the Timberline MPF implant. Refer to the Timberline Surgical Technique Guide for instructions on using the Timberline retractor **(Figures 4a, b, c)**.

  Tip: *The Timberline MPF plate trial may be placed into the working space to verify adequate access has been achieved to allow room for the plate. These are optional instruments and must be ordered separately.*

STEP 4

- Refer to the Timberline Surgical Technique Guide for instructions on performing the discectomy, and for information regarding available Timberline disc preparation instruments.

Implant Sizing and Insertion

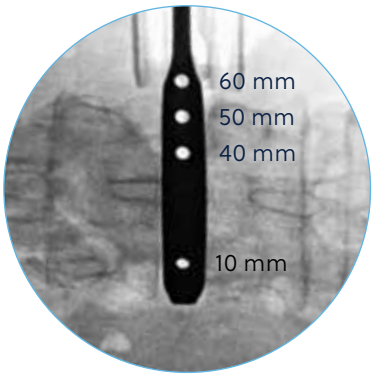


Figure 5a
Implant trialing

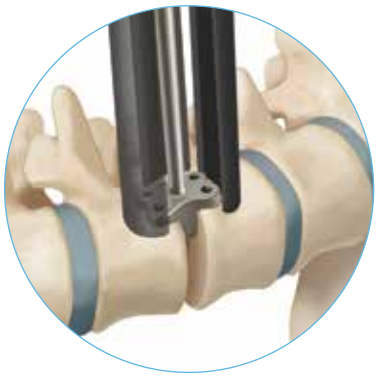


Figure 5b
Plate trialing

Figure 5c
Hyperlordotic spacer

STEP 5

- Use the Timberline implant trials to determine the correct length and height of the interbody implant.

  Note: Trials for each implant width, lordotic angle and height are provided in the kit. Trial fit should be snug, but not extremely tight. Use caution to avoid over distracting the disc space.

- Confirm correct placement of the trial using fluoroscopy.
- The trial should be centered across the disc space (medial/lateral), and appropriately centered in the anterior/posterior plane.
- Implant length can be determined using the holes in the trial. Holes are placed 10 mm, 40 mm, 50 mm and 60 mm from the tip of the trial. The slap hammer may be used to assist with removal of spreaders or trials **(Figure 5a)**.

Note: *Timberline trial heights correlate directly to implant heights to accurately replicate implant fit.*

Tip: *The surgeon should take a lateral fluoroscopic image to verify that the trial is positioned appropriately in the A/P plane. The trial and subsequent implant should be centered in the disc space anterior to posterior.*

Note: *Plate trials are available upon request to confirm plate sizing and adequate exposure if desired* **(Figure 5b).**

Note: *If using hyperlordotic spacers* **(Figure 5c)**, *please refer to appendix A on page 23. This appendix will cover ALL resection, hyperlordotic sizing and implant construct placement.*

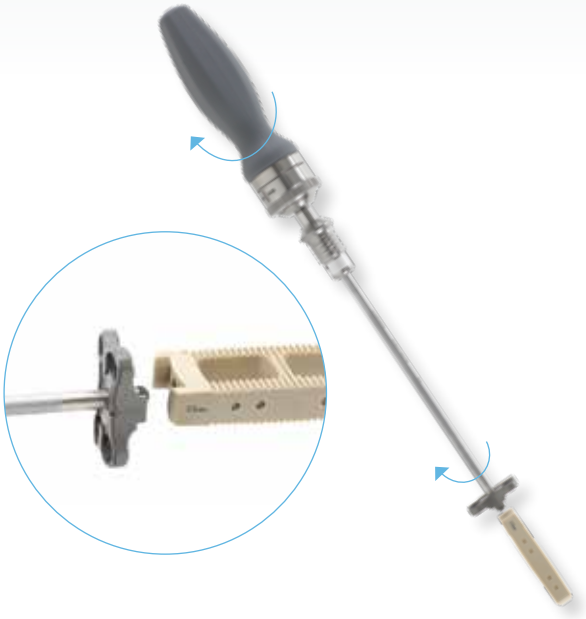


Figure 6
Plate and interbody assembly

Figure 7
Inserter attachment

STEP 6

- Assemble the device by selecting the appropriate size PEEK-OPTIMA interbody and the corresponding plate. Plate options include 1-, 2- and 4-hole plate configurations as determined by the patient's fixation needs.
- Assemble the plate and interbody spacer using the kit screw driver and torque limiting handle until it clicks (12in-lb) **(Figure 6)**.

  Note: *The 1-hole plate caddy is available in hyperlordotic or 14° kits or separate.*

STEP 7

- Attach the implant inserter to the implant assembly by threading the draw rod into the center of the plate **(Figure 7)**.
- The draw rod is advanced by turning the thumb wheel of the inserter.
- Attach the desired handle to the inserter.

Note: *If the matching plate size is used, the full variable bone screw cephalad/caudal angulation may be utilized (4-hole plate: 0°–15°, 1- and 2-hole plate: 5°–20°). The 4-hole plate may by undersized by up to two sizes and the 1- and 2-hole plates may be undersized by one size. When undersizing the plate, care must be taken to avoid vertebral endplate damage and to allow proper clearance between the bone screw and PEEK-OPTIMA interbody. When undersizing the 4-hole plate by one size the bone screw should be inserted at a minimum cephalad/caudal angulation of 3° and if undersizing the 4-hole plate by two sizes a minimum cephalad/caudal angulation of 5° should be used. When undersizing the 2-hole plate by one size the bone screw should be inserted at a minimum cephalad/caudal angulation of 10°. Do not oversize the plate.*

Screw Hole Preparation

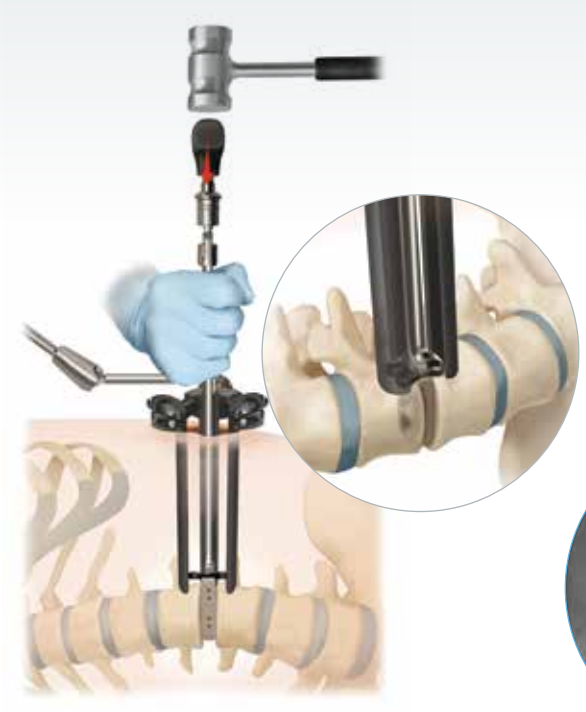


Figure 8
Implant insertion

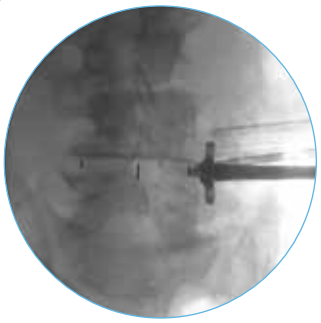


Figure 9
Fluoroscopy confirmation

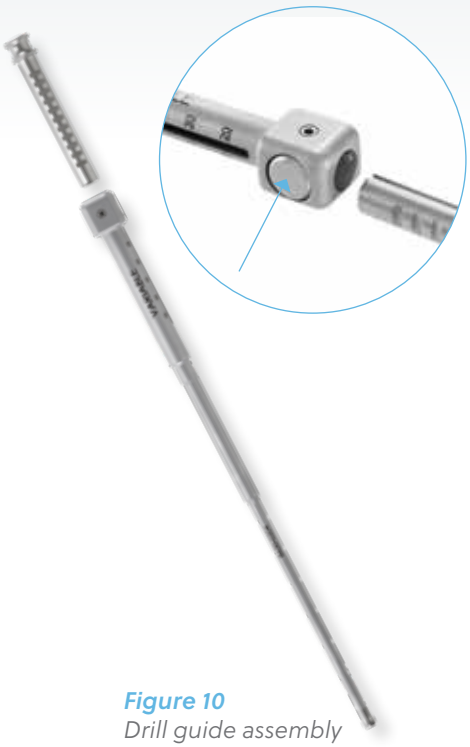


Figure 10
Drill guide assembly

STEP 8

- Impact the implant assembly into the disc space until the plate is resting against the vertebral body **(Figure 8)**.

  Note: *Care should be taken to avoid damaging the vertebral endplates.*

- Confirm correct position using fluoroscopy **(Figure 9)**.

  Note: *The implant should be centered across the disc space, with the plate resting against the ipsilateral vertebral body and situated near the center of the disc space, anterior to posterior.*

- Ensure that no graft material has extruded out of the implant's graft chamber.
- Adjust with the implant tamp as necessary.

STEP 9

- Assemble the depth guide onto the fixed or variable drill guide.
- Depress the button and align the tongue on the depth guide with the groove on the drill guide before advancing to the desired depth **(Figure 10)**.

Figure 11
Awl/drill and guide assembly

Figure 12
Awl/drill insertion

Figure 13a, b
Awl/drill insertion

STEP 10

- The drills and awls are available in both straight and angled configurations, and the guides are available in both fixed and variable configurations to ensure the appropriate trajectory.
- Assemble the appropriate combination of the drill or awl and the appropriate guide (fixed or variable) **(Figure 11)**.
- Place the desired modular handle onto either the awl or drill.

Precaution: *The use of guides is required to help ensure appropriate screw trajectory. The kit includes both fixed and variable guides. Variable guides allow for cephalad/caudal angulation of the screws.*

STEP 11

- Prepare the screw holes by using either an awl or drill.
- Place the drill or awl, and guide assembly into the desired screw hole **(Figure 12)**.
- Ensure the tip of the guide is properly seated in the screw hole of the plate.
- Advance the awl or drill to the desired depth **(Figures 13a, b)**.
- Taps are available if desired.
- Confirm using fluoroscopy.

Note: *The variable drill guide allows for 15° of angulation in the cephalad or caudal directions only. The fixed drill guide has unique geometry at the tip that creates the fixed screw trajectory of 0° for the 4-hole and 5° for the 1- and 2-hole when engaged with the plate.*

- Prepare the remaining screw holes using the same technique.

Screw Insertion

Figure 14
Screw/driver assembly

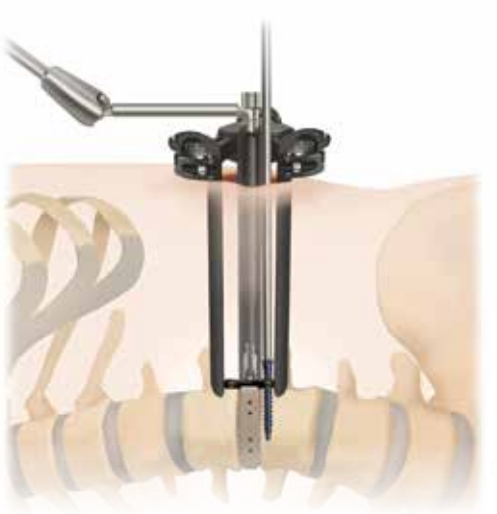


Figure 15
Screw insertion

STEP 12

- Assemble the desired screw onto the screw driver such that the driver hex is fully seated in the screw.
- Attach the screw driver to the desired fixed or ratcheting modular handle **(Figure 14)**.

  Note: *The Timberline MPF System includes variable screws in 5.5 mm and 6.0 mm diameters. Fixed guides can help ensure a good trajectory, but the system does not include fixed screws.*

STEP 13

- Advance the screw into the vertebral body through the appropriate screw hole in the plate following the path previously prepared in the bone **(Figure 15)**.
- Use fluoroscopy to ensure appropriate screw placement.
- Insert the remaining screws.
- Tighten all screws until the screws sit just below the top surface of the plate.
- Confirm using A/P and lateral fluoroscopy.

  Tip: *For 4-hole plates, a cross-wise screw placement pattern is suggested to optimize plate seating.*

  Note: *Use of the integrated screws with interbody spacer angles of 14° and above is mandatory.*

Cover Plate Assembly

Figure 16
Cover plate

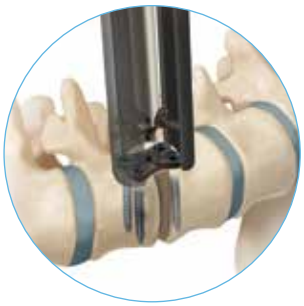


Figure 17a
Cover plate attachment

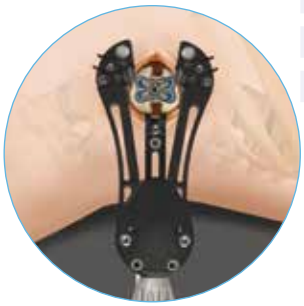


Figure 17b
Final assembly looking down retractor

STEP 14

- Select the cover plate that corresponds to the plate used.
- Attach the torque handle to the cover plate driver.
- Assemble the cover plate onto the cover plate driver by inserting the tip of the cover plate driver into the set screw so that the flanges of the driver align with the slots in the face of the cover plate **(Figure 16)**.

  Note: *1-, 2-, and 4-hole standard cover plates will work for multiple plate sizes within that configuration. The size 6 4-hole plate and size 18 1-hole plate have a unique cover plate. The cover plate to be used with the size 6 4-hole plate is marked "6". The size 18 1-hole plate is marked with a black bar in the cover plate recess and is to be paired with the 1-hole large cover plate which contains the same distinguishing marking.*

STEP 15

- Secure the cover plate to the plate by aligning the set screw over the center hole of the plate.
- Ensure the flanges of the cover plate are aligned so that the cover plate seats into the recess of the plate and the flanges cover the screws.
- Tighten the cover plate set screw with the torque handle until the torque handle clicks (12 in-lb) **(Figure 17a)**.

  Precaution: Use of the cover plate to prevent screw back-out is mandatory.
- Inspect final implant for correct position and assembly **(Figure 17b)**.

Optional In Situ Implant Assembly

Figure 18a
Interbody in situ attachment

Figure 18b
Interbody in situ insertion

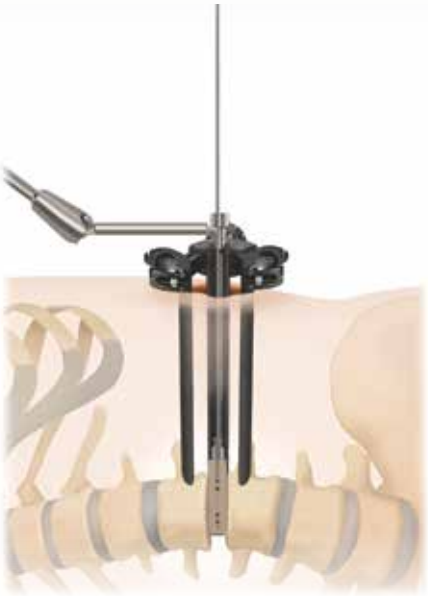


Figure 19
Optional K-wire insertion

STEP 1

The surgeon has the option of inserting the interbody spacer prior to assembly with the plate. This option may be taken in the event that interbody spacer slides are desired for graft containment during insertion.

- The Timberline MPF inserter is used to insert the interbody spacer into the disc space, leaving the ipsilateral end proud of the disc space **(Figures 18a, b)**.

  Note: *This is the same inserter used when inserting the pre-assembled plate and interbody spacer.*

- Confirm position using fluoroscopy.

STEP 2

Optional: *If desired, insert a K-wire through the center of the interbody implant until it has passed through the center of the cage and is resting against the contralateral wall of the implant* **(Figure 19)**.

Figure 20
Plate in situ assembly

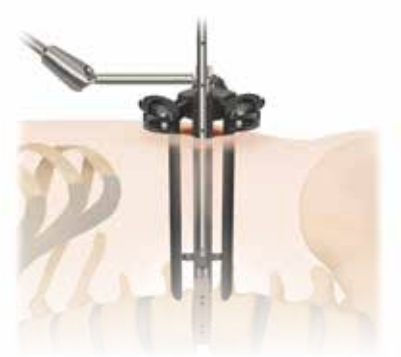


Figure 21
Plate in situ insertion

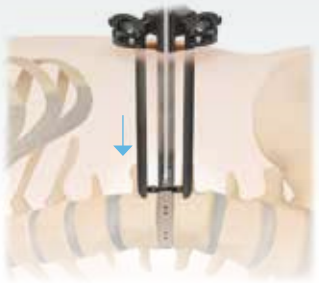


Figure 22a
In situ plate tamp

Figure 22b
Intraoperative fluoro image prior to supplemental posterior fixation. Timberline MPF is indicated for use with supplemental posterior fixation.

STEP 3

- Attach the in situ plate inserter to the plate.
- Insert the in situ plate inserter into the torque handle **(Figure 20**).
- Feed the plate driver assembly and torque handle over the K-wire down onto the interbody implant **(Figure 21)**.

  Note: The in situ p*late inserter and torque handle are cannulated to allow passage over the K-wire.*
- Thread the assembly screw into the interbody spacer and tighten with the torque handle until the handle clicks (12in-lb).

STEP 4

- Remove the plate driver and K-wire, then utilize the implant tamp to advance the implant assembly until the plate is resting against the vertebral body **(Figure 22a)**.
- Confirm correct position using fluoroscopy **(Figure 22b)**.

Optional Angled Instrumentation

Figure 23a
Angled instrument inserter assembly

Figure 23b
Angled insertion

STEP 1

Instruments are provided to accommodate working through the retractor when it is positioned on an angle, such as for working at L4–L5, or near the ribs. The following steps outline the technique when use of angled instruments is required. The system includes instruments for both standard assembly and in situ assembly.

- The Timberline angled disc preparation instruments may be used to perform the discectomy and to prepare the endplates for fusion.
- Use the Timberline angled implant trials to determine the correct length and height of the intervertebral disc space.

STEP 2

- For standard assembly, attach the plate to the interbody implant per the standard procedure referenced above **(page 11 step 6)**.
- Attach the angled plate assembly inserter to the implant assembly **(Figure 23a).**
- Impact the implant assembly into the disc space until the plate rests against the ipsilateral edge of the vertebral body **(Figure 23b)**.

Figure 24a
U-joint awl assembly

Figure 24b
U-joint awl insertion

STEP 3

- Prepare the screw holes using the u-joint awl or drill and the angled drill guide.
- Slide the angled drill guide over the tip of the awl or drill, then advance the assembly into the retractor such that the guide first seats in the screw hole of the plate **(Figure 24a)**.

STEP 4

- Then advance the awl or drill into the bone to the desired depth **(Figure 24b)**.

  Note: *Take care not to advance the awl or drill too far. Full depth insertion is 20 mm past the contralateral surface of the plate.*

Optional Angled Instrumentation (continued)

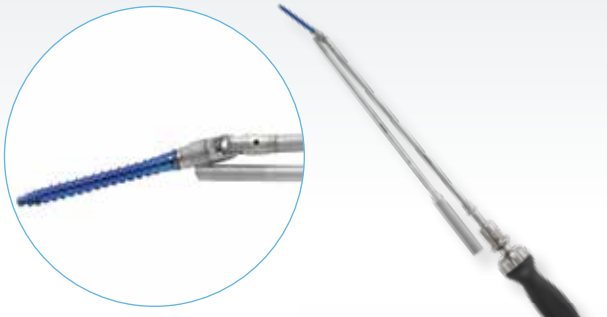


Figure 25a
U-joint screw assembly

Figure 25b
U-joint screw insertion

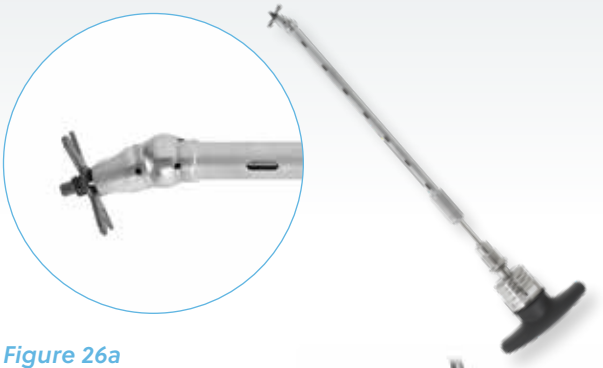


Figure 26a
Angled plate assembly

Figure 26b
Angled plate insertion

STEP 5

- Place the appropriate size screw onto the u-joint driver.
- Then advance the screw through the plate and into the vertebral body **(Figure 25a)**.

  Note: *It is recommended that the screw ring guide be used to help guide the screws into the plate* **(Figure 25b)**.

STEP 6

- Once all of the screws have been inserted and are seated properly, attach the cover plate to the plate using the angled cover plate inserter **(Figures 26a, b)**.
- Inspect the construct to ensure all screws are seated correctly and the cover plate is securely attached.

Retractor Removal and Closure

STEP 16

- Retract the intradiscal shim into the posterior blade using the shim remover/retractor.
- Remove the scoville retractor and anterior crossbar attachment.
- 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.
- Remove the light wave guides.

STEP 17

- The wound is closed using standard techniques.

REMOVAL OR REVISION PROCEDURE OF THE TIMBERLINE MPF IMPLANT (IF NECESSARY)

Timberline MPF Lateral Modular Plate Fixation System is intended to be used with supplemental fixation. Surgeons should follow standard surgical techniques for implantation of FDA- cleared supplemental internal spinal fixation.

1. Attach the cover plate inserter to the cover plate. Disengage the cover plate by turning the cover plate set screw counter-clockwise using the cover plate inserter.
2. Attach the bone screw driver to the bone screw. Remove the screw by rotating the screwdriver counter-clockwise. Remove each bone screw in the same manner.
3. Attach the Timberline MPF inserter to the implant assembly.
4. Attach slap hammer to the inserter or use a mallet to tap the inserter and implant assembly outward until the implant is removed from disc space.

Appendix A—Hyperlordotic Considerations

Anterior Longitudinal Ligament (ALL) Resection

If the surgeon elects to partially or completely release the ALL, follow the steps below:

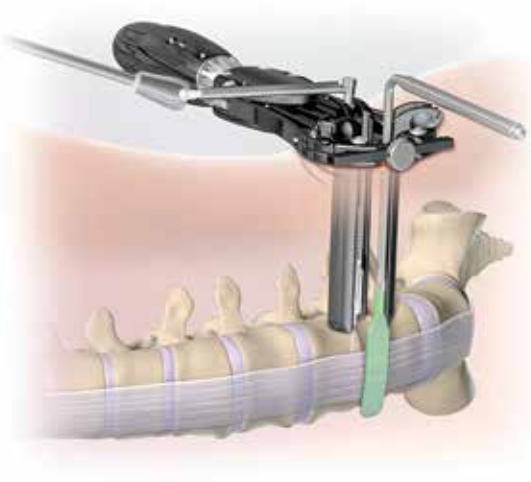


Figure 27
Anterior soft tissue protection

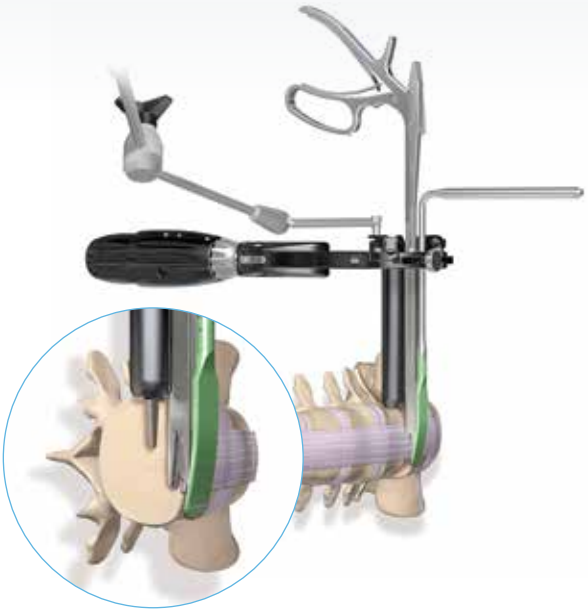


Figure 28
ALL incision

STEP A1

- Utilize a handheld soft tissue retractor to retract soft tissue directly anterior to the ALL by first identifying the ALL, and then carefully advancing the soft tissue retractor anterior to the ALL but posterior to the great vessels. The retractor should extend past the full width of the ALL. With the soft tissue retractor in place, it can be secured to the retractor body with the anterior crossbar **(Figure 27)**.

  Note: *If calcification of the ALL is present, resection should not be attempted in order to mitigate damage to the vessels. If ALL release is not feasible or deemed to be too risky for any reason, proceed with an alternative approach.*

  Tip: *Radiolucent soft tissue retractors are provided in the hyperlordotic kit. This instrument has a tantalum marker 5 mm from the end of the instrument tip and two additional markers to identify the width of the instrument. This marker may be used to help with appropriate placement of the retractor.*

- With the handheld soft tissue retractor in position to protect the anterior soft tissues, use the cutting instrument under direct visualization to incise the ALL. Fluoroscopy may be used to ensure that the cutting instrument is not advanced farther than the soft tissue retractor **(Figure 28).**

Note: *The Zimmer Biomet Ligament Cutter provides a recessed cutting area, which minimizes the chances of any unwanted soft tissue from coming in contact with the cutting surface.*

Appendix A—Implant Sizing and Insertion

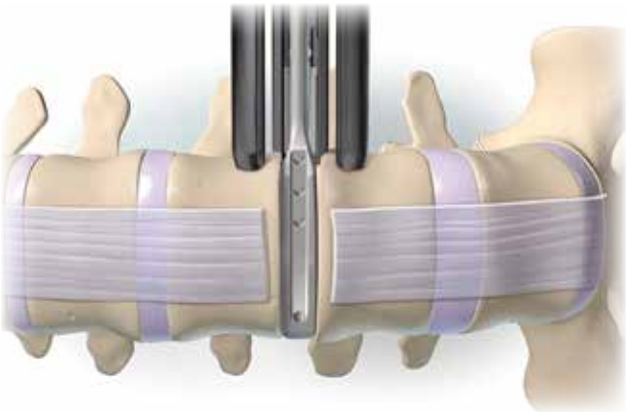


Figure 29
Hyperlordotic trial insertion

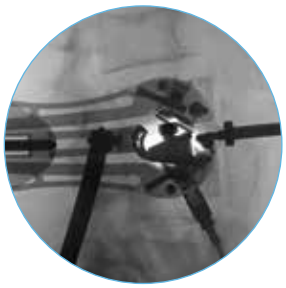


Figure 30a
Hyperlordotic Trialing—Lateral Fluoroscopy

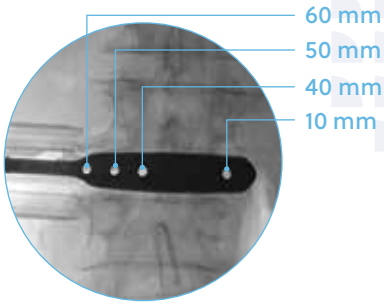


Figure 30b
Hyperlordotic Trialing—A/P Fluoroscopy

STEP A2

- Use the Timberline hyperlordotic implant trials to determine the correct length and height of the interbody implant, starting with the smallest available size. Trials for each implant width, lordotic angle and height are provided in the Timberline hyperlordotic kit **(Figure 29)**.

  Tip: *A slightly anterior-to-posterior initial trajectory when introducing the trial into the disc space may help in preventing anterior migration of the trial.*

  Note: *If the hyperlordotic trial instruments are migrating anteriorly during insertion due to the steep angle of lordosis, guide instruments are available to help prevent this migration.*

- Confirm correct placement of the trial using fluoroscopy. The trial should be centered across the disc space (medial/lateral), and appropriately centered anterior to posterior. Implant length can be determined using the holes in the trial. Holes are placed 10 mm, 40 mm, 50 mm and 60 mm from the tip of the trial. The slap hammer may be used to assist with removal of spreaders or trials **(Figures 30a, b)**.

  Note: *For complete release of the ALL, subsequent distraction of the disc space may be required. In these cases, when full visualization of the ALL is not possible, the cutter is advanced to the visual limits and then removed. A distractor is placed in the disc space and expanded to separate the remaining ligamentous tissue.*

  Note: *The standard Timberline trials can also be sequentially inserted by size to help fully release the ALL.*

  Note: *When selecting the appropriate implant and configuration, consider the subsequent posterior treatment and supplemental fixation. Based upon bench testing, resection of the ALL may facilitate insertion of the implant for greater sagittal correction when used with supplemental fixation per the indications.*

Appendix A—Implant Sizing and Insertion (continued)

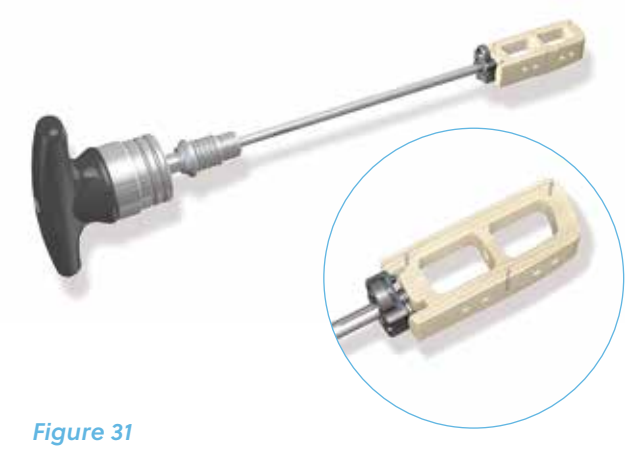


Figure 31
Plate and PEEK spacer assembly

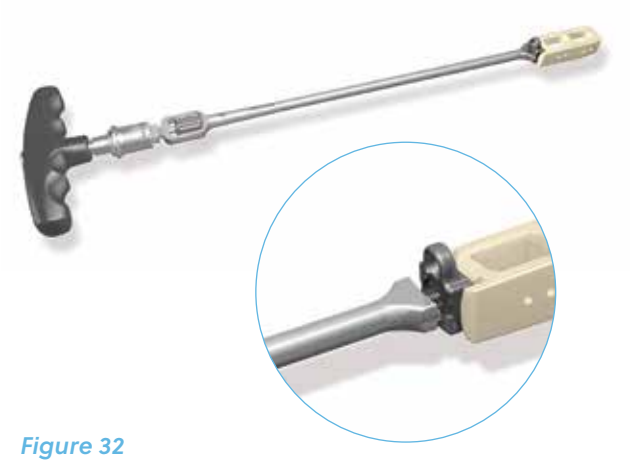


Figure 32
Inserter attachment

STEP A3

- Assemble the device by selecting the appropriate size interbody spacer and plate. Assemble the plate and interbody spacer using the assembly driver and torque limiting handle **(Figure 31)**.
- In general, the 1-hole plate size should be down-sized by one size when using a 20° spacer and two sizes when using a 30° spacer.

  Tip: *When selecting the plate size, ensure the screw holes will appropriately lie over the vertebral body, such that the screws engage the vertebral body and achieve adequate bone purchase.*

  Note: *Each Timberline hyperlordotic spacer can be assembled to any plate size or configuration, giving the surgeon multiple options when selecting the best plate for the given anatomy. Selection of the 1-hole plate in a hyperlordotic procedure may achieve greater lordotic correction by enabling improved endplate contact and compression when using pedicle screws.*

STEP A4

- Attach the implant inserter to the implant assembly by threading the draw rod into the center of the plate **(Figure 32)**. The draw rod is advanced by turning the thumb wheel of the inserter. Attach the desired handle to the inserter.

Appendix A—Insertion and Screw Hole Preparation

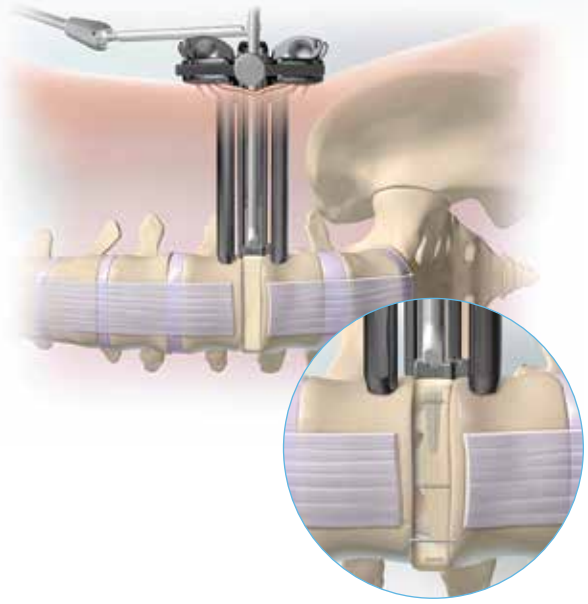


Figure 33
Implant insertion

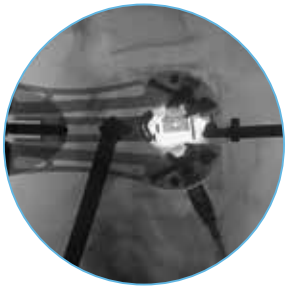


Figure 34a

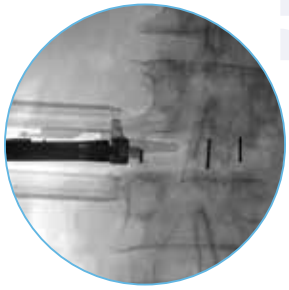


Figure 34b

STEP A5

- Impact the implant assembly into the disc space **(Figure 33)**.

  Note: *Care should be taken to avoid damaging the vertebral endplates.*

  Tip: *An initial anterior-to-posterior trajectory may be required to ensure the implant does not migrate anteriorly.*

- Confirm correct positioning using fluoroscopy.

  Note: *The implant should be centered across the disc space with the plate resting against the ipsilateral vertebral body and situated near the center of the disc space anterior to posterior* **(Figures 34a, b)**.

- Ensure that no graft material has extruded out of the implant graft chamber.

- Adjust with the implant tamp as necessary.

  Note: *Use of the integrated screws with interbody spacer angles of 14° and above is mandatory.*

Appendix A—Screw Insertion

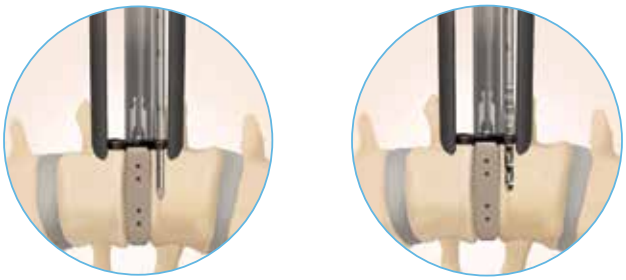


Figure 35a,b
Awl/drill insertion

Figure 36
Screw/driver assembly

STEP A6

- Prepare the screw hole by using either an awl or drill. The drills and awls are available in both straight and angled configurations, and the guides are available in both fixed and variable configurations to ensure the appropriate trajectory **(Figures 35a, b)**.
- Assemble the appropriate combination of drill or awl and guide. Place the desired modular handle onto either the drill or awl.
- Place the instrument assembly into the single screw hole. Ensure the tip of the guide is properly seated in the screw hole of the plate. Advance the awl or drill to the desired depth. Confirm using fluoroscopy.
- Taps are available if desired. Attach the appropriate tap to the desired modular handle. Taps are available in straight and angled configurations. Take and review final fluoroscopy images prior to removing the retractor to ensure good implant placement.

STEP A7

- Assemble the desired screw onto the screw driver. Attach the screw driver to the desired fixed or ratcheting modular handle. Advance the screw into the vertebral body through the single screw hole in the plate following the path previously prepared in the bone. Use fluoroscopy to ensure appropriate screw placement **(Figure 36)**.
- Tighten the screw until it sits just below the top surface of the plate. Confirm using A/P and lateral fluoroscopy.

Appendix A—Cover Plate Assembly, Retractor Removal, and Supplemental Fixation

Figure 38
Attached cover plate

Figure 39
Cover plate inserter

Figure 40
Intraoperative fluoro image prior to supplemental posterior fixation. Timberline MPF is indicated for use with supplemental posterior fixation.

STEP A8

- Select the cover plate that corresponds to the plate used. Attach the torque handle to the cover plate driver. Assemble the cover plate onto the cover plate driver by inserting the tip of the cover plate driver into the set screw such that the flanges of the driver align with the slots in the face of the cover plate.
- Secure the cover plate to the plate/cage assembly by aligning the set screw over the center hole of the plate. Ensure the flanges of the cover plate are aligned such that the cover plate seats into the recess of the plate, and the flanges cover the screws. Tighten the cover plate set screw with the torque handle (12 in-lbs).

  Note: *Use of the cover plate to prevent back-out of the screws is mandatory.*

  Note: *The 18 mm 1-hole plate has a unique cover plate. The 18 mm 1-hole plate is marked with a black bar in the cover plate recess and is to be paired with the 1-hole large cover plate which contains the same distinguishing marking.*

STEP A9

- Inspect final implant for correct position and assembly.
- Compress vertebral bodies on the implant and secure with supplemental fixation.

Timberline MPF Implant Sizes and Graft Volumes

MPF Implant Sizes

18 mm width, 0° lordosis

DESCRIPTION	HEIGHT	cc	PART NUMBER
18 mm × 45 mm × 0°	8 mm	2.4	8601-4508
	10 mm	3.0	8601-4510
	12 mm	3.6	8601-4512
	14 mm	4.2	8601-4514
18 mm × 50 mm × 0°	8 mm	2.5	8601-5008
	10 mm	3.1	8601-5010
	12 mm	3.7	8601-5012
	14 mm	4.4	8601-5014
18 mm × 55 mm × 0°	8 mm	2.7	8601-5508
	10 mm	3.4	8601-5510
	12 mm	4.1	8601-5512
	14 mm	4.8	8601-5514
18 mm × 60 mm × 0°	8 mm	3.0	8601-6008
	10 mm	3.8	8601-6010
	12 mm	4.6	8601-6012
	14 mm	5.4	8601-6014

22 mm width, 0° lordosis

DESCRIPTION	HEIGHT	cc	PART NUMBER
22 mm × 45 mm × 0°	8 mm	2.9	8603-4508
	10 mm	3.7	8603-4510
	12 mm	4.4	8603-4512
	14 mm	5.2	8603-4514
22 mm × 50 mm × 0°	8 mm	3.0	8603-5008
	10 mm	3.8	8603-5010
	12 mm	4.6	8603-5012
	14 mm	5.4	8603-5014
22 mm × 55 mm × 0°	8 mm	3.5	8603-5508
	10 mm	4.4	8603-5510
	12 mm	5.3	8603-5512
	14 mm	6.2	8603-5514
22 mm × 60 mm × 0°	8 mm	4.0	8603-6008
	10 mm	5.0	8603-6010
	12 mm	6.0	8603-6012
	14 mm	7.0	8603-6014

18 mm width, 8° lordosis

DESCRIPTION	HEIGHT	cc	PART NUMBER
18 mm × 45 mm × 8°	8 mm	2.0	8602-4508
	10 mm	2.6	8602-4510
	12 mm	3.2	8602-4512
	14 mm	3.8	8602-4514
18 mm × 50 mm × 8°	8 mm	2.1	8602-5008
	10 mm	2.7	8602-5010
	12 mm	3.3	8602-5012
	14 mm	4.0	8602-5014
18 mm × 55 mm × 8°	8 mm	2.3	8602-5508
	10 mm	3.0	8602-5510
	12 mm	3.7	8602-5512
	14 mm	4.4	8602-5514
18 mm × 60 mm × 8°	8 mm	2.6	8602-6008
	10 mm	3.4	8602-6010
	12 mm	4.2	8602-6012
	14 mm	5.0	8602-6014

22 mm width, 8° lordosis

DESCRIPTION	HEIGHT	cc	PART NUMBER
22 mm × 45 mm × 8°	8 mm	2.4	8604-4508
	10 mm	3.1	8604-4510
	12 mm	3.9	8604-4512
	14 mm	4.6	8604-4514
22 mm × 50 mm × 8°	8 mm	2.5	8604-5008
	10 mm	3.2	8604-5010
	12 mm	4.0	8604-5012
	14 mm	4.8	8604-5014
22 mm × 55 mm × 8°	8 mm	2.9	8604-5508
	10 mm	3.8	8604-5510
	12 mm	4.7	8604-5512
	14 mm	5.6	8604-5514
22 mm × 60 mm × 8°	8 mm	3.4	8604-6008
	10 mm	4.4	8604-6010
	12 mm	5.4	8604-6012
	14 mm	6.4	8604-6014

Hyperlordotic Implant Sizes and Quantities

18 mm width, 14° lordosis

DESCRIPTION	HEIGHT	cc	QTY	PART NUMBER
18 mm × 45 mm × 14°	10 mm	2.3	2	8621-4510
	12 mm	2.9	2	8621-4512
	14 mm	3.5	2	8621-4514
18 mm × 50 mm × 14°	10 mm	2.0	2	8621-5010
	12 mm	2.5	2	8621-5012
	14 mm	3.1	2	8621-5014
	16 mm	3.6	1	8621-5016
18 mm × 55 mm × 14°	10 mm	2.3	2	8621-5510
	12 mm	2.9	2	8621-5512
	14 mm	3.5	2	8621-5514
	16 mm	4.0	1	8621-5516
18 mm × 60 mm × 14°	10 mm	2.6	2	8621-6010
	12 mm	3.3	2	8621-6012
	14 mm	4.0	2	8621-6014
	16 mm	4.6	1	8621-6016

22 mm width, 14° lordosis

DESCRIPTION	HEIGHT	cc	QTY	PART NUMBER
22 mm × 45 mm × 14°	10 mm	2.6	2	8622-4510
	12 mm	3.3	2	8622-4512
	14 mm	4.1	2	8622-4514
22 mm × 50 mm × 14°	10 mm	2.6	2	8622-5010
	12 mm	3.3	2	8622-5012
	14 mm	4.1	2	8622-5014
	16 mm	4.9	1	8622-5016
22 mm × 55 mm × 14°	10 mm	3.0	2	8622-5510
	12 mm	3.9	2	8622-5512
	14 mm	4.8	2	8622-5514
	16 mm	5.7	1	8622-5516
22 mm × 60 mm × 14°	10 mm	3.4	2	8622-6010
	12 mm	4.4	2	8622-6012
	14 mm	5.4	2	8622-6014
	16 mm	6.4	1	8622-6016

22 mm width, 20° lordosis

DESCRIPTION	HEIGHT	cc	QTY	PART NUMBER
22 mm × 45 mm × 20°	12 mm	3.0	2	8613-4512
	14 mm	3.7	2	8613-4514
	16 mm	4.5	2	8613-4516
	18 mm	5.2	2	8613-4518
22 mm × 50 mm × 20°	12 mm	3.1	2	8613-5012
	14 mm	3.9	2	8613-5014
	16 mm	4.6	2	8613-5016
	18 mm	5.4	2	8613-5018
22 mm × 55 mm × 20°	12 mm	3.5	2	8613-5512
	14 mm	4.4	2	8613-5514
	16 mm	5.3	2	8613-5516
	18 mm	6.2	2	8613-5518
22 mm × 60 mm × 20°	12 mm	4.0	2	8613-6012
	14 mm	5.0	2	8613-6014
	16 mm	6.0	2	8613-6016
	18 mm	7.0	2	8613-6018

22 mm width, 30° lordosis

DESCRIPTION	HEIGHT	cc	QTY	PART NUMBER
22 mm × 45 mm × 30°	14 mm	3.0	2	8614-4514
	16 mm	3.7	2	8614-4516
	18 mm	4.5	2	8614-4518
	20 mm	5.2	2	8614-4520
22 mm × 50 mm × 30°	14 mm	3.1	2	8614-5014
	16 mm	3.8	2	8614-5016
	18 mm	4.6	2	8614-5018
	20 mm	5.4	2	8614-5020
22 mm × 55 mm × 30°	14 mm	3.5	2	8614-5514
	16 mm	4.4	2	8614-5516
	18 mm	5.3	2	8614-5518
	20 mm	6.2	2	8614-5520
22 mm × 60 mm × 30°	14 mm	4.0	2	8614-6014
	16 mm	5.0	2	8614-6016
	18 mm	6.0	2	8614-6018
	20 mm	7.0	2	8614-6020

Timberline MPF Implant Dizes and Graft Volumes

Plates

1-Hole

SIZE	LENGTH	PART NUMBER
8	13.5 mm	8605-0108
10	15.5 mm	8605-0110
12	17.5 mm	8605-0112
14	19.5 mm	8605-0114
16	21.5 mm	8605-0116
18	23.5 mm	8605-0118

2-Hole

SIZE	LENGTH	PART NUMBER
8	21 mm	8605-0208
10	23 mm	8605-0210
12	25 mm	8605-0212
14	27 mm	8605-0214

4-Hole

SIZE	LENGTH	PART NUMBER
6	26.5 mm	8605-0406
8	28.5 mm	8605-0408
10	30.5 mm	8605-0410
12	32.5 mm	8605-0412
14	34.5 mm	8605-0414

Cover Plate

TYPE	PLATE SIZE PAIRING	PART NUMBER
1-hole	8–16	8606-0100
1-hole Tall	18	8606-0118
2-hole	8–14	8606-0200
4-hole	8–14	8606-0400
4-hole Short	6	8606-0406

Note: *Plates over 16 must use tall cover plate.*

Screws

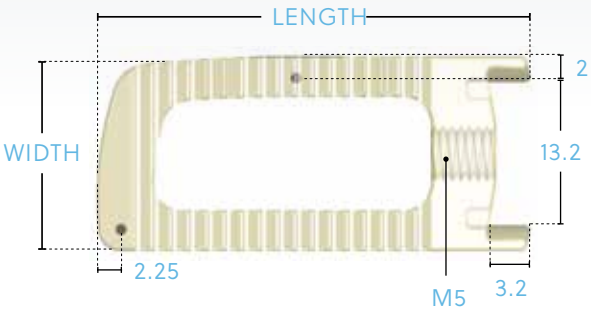
Self-Tapping Screws

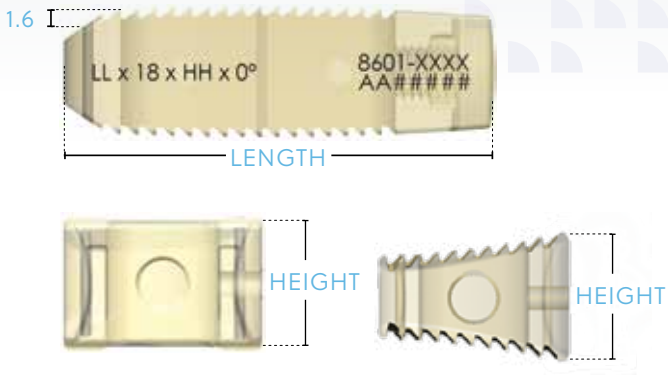
SIZE	LENGTH	PART NUMBER
ø5.5 mm	30 mm	8607-5530
ø5.5 mm	35 mm	8607-5535
ø5.5 mm	40 mm	8607-5540
ø5.5 mm	45 mm	8607-5545
ø5.5 mm	50 mm	8607-5550
ø5.5 mm	55 mm	8607-5555
ø5.5 mm	60 mm	8607-5560
ø6 mm	30 mm	8607-6030
ø6 mm	35 mm	8607-6035
ø6 mm	40 mm	8607-6040
ø6 mm	45 mm	8607-6045
ø6 mm	50 mm	8607-6050
ø6 mm	55 mm	8607-6055
ø6 mm	60 mm	8607-6060

Bi-Cortical Screws

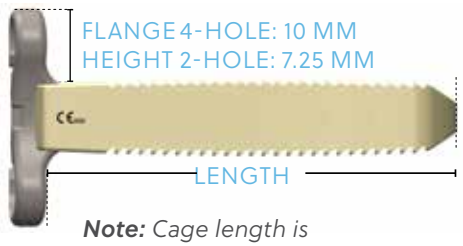
SIZE	LENGTH	PART NUMBER
ø5.5 mm	45 mm	8609-5545
ø5.5 mm	50 mm	8609-5550
ø5.5 mm	55 mm	8609-5555
ø5.5 mm	60 mm	8609-5560
ø6 mm	45 mm	8609-6045
ø6 mm	50 mm	8609-6050
ø6 mm	55 mm	8609-6055
ø6 mm	60 mm	8609-6060

Implant Design Features

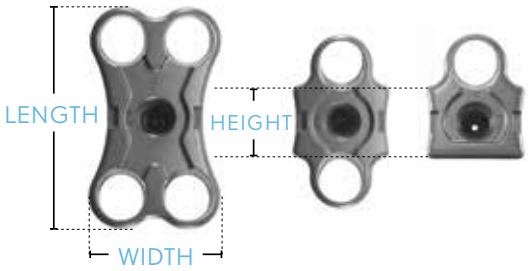




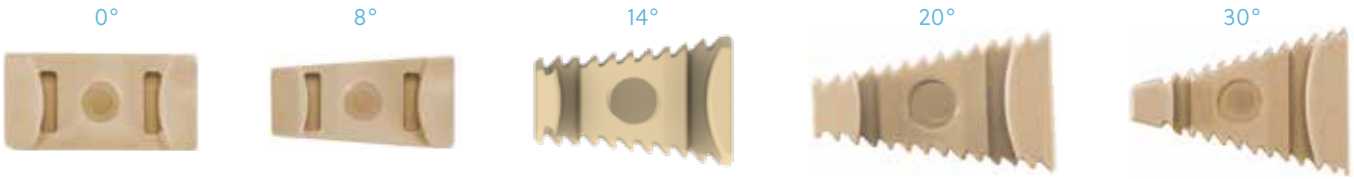
Note: *Height is taken from the anterior portion of the implant on non-parallel implants*



Note: *Cage length is measured to the inside edge of the plate*



Lordotic Options



Note: *Any plate style may be assembled to the hyperlordotic spacers. The tantalum marker nearest the plate assembly side will align with the tip of the plate set screw when the plate is assembled properly.*

Kit Overview

Timberline MPF Implant and Instrument Kits

DESCRIPTION	KIT NUMBER
Timberline MPF Implants	PCR8600-1101
Timberline MPF Instruments	PCR8600-2101
Timberline MPF Hyperlordotic Implants and Instruments	PCR8600-3301
Timberline MPF 14° Implants	PCR8600-1401

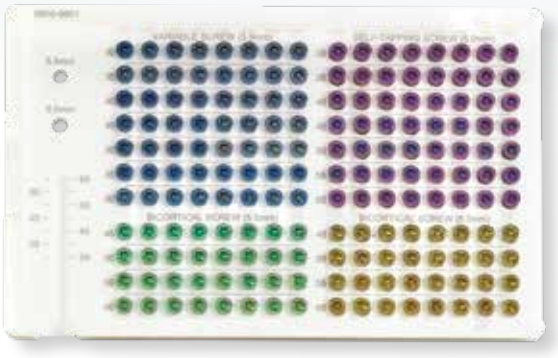
Note: *Both MPF kits (implants and instruments) must be ordered to support a hyperlordotic implant and 14° implant surgery.*

	DESCRIPTION	KIT NUMBER
Standard Implant and Instrument Kits	Timberline MPF Case 1, 18 mm and 22 mm 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	PCR8700-5301
	Instruments Timberline Access Kit	8700-9112
	Timberline Monitoring Kit*	8700-9122
	Special Order MEP Electrode Kit	8735-1013
Optional Implant and Instrument Kits	Timberline MPF 1-hole Plate Caddy	PCR8600-9906
	Timberline Case 6, Auxiliary Instruments	PCR8700-6201
	Timberline Case 7, Angled Instruments	PCR8700-7201

*May not be available in all geographic areas.

Timberline MPF Implant and Instrument Kits

Timberline MPF Case 1: Implants, Kit Number: PCR8600-1101



Screw Caddy	PART NUMBER
	8600-9901

Plate Caddy	PART NUMBER
	8600-9903

18 mm Implant Caddy	PART NUMBER
	8600-9904

22 mm Implant Caddy	PART NUMBER
	8600-9905

Optional Timberline MPF Implant and Instrument Kits

Optional 1-Hole Plate Caddy, PCR8600-9906 (must be ordered separately)

1-Hole Plate Caddy	PART NUMBER
	8600-9906

Optional Plate Trials (must be ordered separately)

2-Hole Plate Trial	PART NUMBER
8 mm	8632-0208
10 mm	8632-0210
12 mm	8632-0212
14 mm	8632-0214

4-Hole Plate Trial	PART NUMBER
8 mm	8632-0408
10 mm	8632-0410
12 mm	8632-0412
14 mm	8632-0414

Angled 2-Hole Plate Trial	PART NUMBER
8 mm	8632-1208
10 mm	8632-1210
12 mm	8632-1212
14 mm	8632-1214

Angled 4-Hole Plate Trial	PART NUMBER
8 mm	8632-1408
10 mm	8632-1410
12 mm	8632-1412
14 mm	8632-1414

Timberline MPF Standard Implant and Instrument Kits

Timberline MPF Case 2: Instruments, Kit Number: PCR8600-2101

Awl U-Joint	PART NUMBER
	8630-0001

Drill U-Joint	PART NUMBER
	8630-0002

Tap U-Joint	PART NUMBER
	8630-0003

Variable Angled Guide	PART NUMBER
	8630-0201

Fixed Angled Guide	PART NUMBER
	8630-0202

Angled Driver Guide	PART NUMBER
	8630-0203

Driver U-Joint	PART NUMBER
	8630-0004

Retractable Awl	PART NUMBER
Point	8630-0101
Beveled	8640-0004

Retractable Straight Drill	PART NUMBER
	8630-0102

Straight Tap, 5.5 mm	PART NUMBER
	8630-0103

Retractable Sleeve Depth Guide	PART NUMBER
	8630-0206

Variable Retractable Sleeve	PART NUMBER
	8630-0204

Fixed Retractable Sleeve	PART NUMBER
	8630-0205

Driver Straight Split Tip	PART NUMBER
	8630-0107 or 8630-0105

Timberline MPF Standard Implant and Instrument Kits

Timberline MPF Case 2: Instruments, Kit Number: PCR8600-2101

T-Handle Non-Ratchet	PART NUMBER
	9801-0009

¼ Hex Axial Ratchet	PART NUMBER
	9801-0003

Hudson T-Handle Ratchet	PART NUMBER
	9801-0011

Hudson Torque Limiting T-Handle	PART NUMBER
	8630-0304

Hudson Axial Torque Limiting	PART NUMBER
	8531-0700

Timberline MPF Case 2: Instruments, Kit Number: PCR8600-2101 (continued)

Assembly Driver	PART NUMBER
	8630-0303

Straight Tamp	PART NUMBER
	8631-0020

K-wire Dispenser	PART NUMBER
	7706-1007

Straight Cover Plate Inserter	PART NUMBER
	8630-0302

Interbody Removal Tool	PART NUMBER
	8631-0030

Interbody Angled Inserter	PART NUMBER
	8631-0012

Interbody Straight Inserter	PART NUMBER
	8631-0000

Angled Cover Plate Inserter	PART NUMBER
	8630-0300

Straight Draw Rod	PART NUMBER
	8631-0000-002

Angled *In Situ* Plate Inserter	PART NUMBER
	8631-0011

Straight *In Situ* Plate Inserter	PART NUMBER
	8631-0001

Angled Tamp	PART NUMBER
	8631-0021

Timberline MPF Hyperlordotic Implants and Instrument

Kit Number: PCR8600-330

Ligament Cutter	PART NUMBER
	8633-0003

Ligament Distractor	PART NUMBER
	8633-0005

Soft Tissue Retractor	PART NUMBER
Grooved	8633-0023
Insulated	8633-0031

Trial	PART NUMBER
Trial, 20°, 12 mm	8632-2312
Trial, 20°, 14 mm	8632-2314
Trial, 20°, 16 mm	8632-2316
Trial, 20°, 18 mm	8632-2318
Trial, 30°, 14 mm	8632-2414
Trial, 30°, 16 mm	8632-2416
Trial, 30°, 18 mm	8632-2418
Trial, 30°, 20 mm	8632-2420

Guides	PART NUMBER
Inserter Guide	8633-0100
Fixed Inserter Guide	8633-0101

20° Caddy	PART NUMBER
	8600-9911

30° Caddy	PART NUMBER
	8600-9912

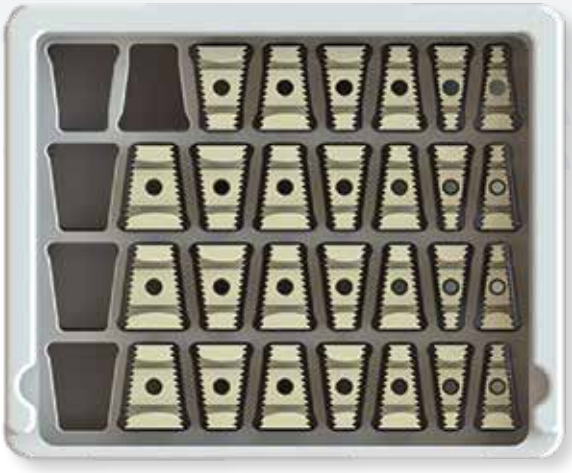
Timberline MPF 14° Implant Kit

Kit Number: PCR8600-1401

14° Trial

DESCRIPTION (HEIGHT × WIDTH × ANGLE)	PART NUMBER
10 mm × 18 mm × 14°	8632-3010
12 mm × 18 mm × 14°	8632-3012
14 mm × 18 mm × 14°	8632-3014
16 mm × 18 mm × 14°	8632-3016
10 mm × 22 mm × 14°	8632-3110
12 mm × 22 mm × 14°	8632-3112
14 mm × 22 mm × 14°	8632-3114
16 mm × 22 mm × 14°	8632-3116

18 mm 14° Implant Caddy	PART NUMBER
	8600-9914



22 mm 14° Implant Caddy	PART NUMBER
	8600-9915

Important Information on the Timberline MPF Lateral Modular Plate Fixation System

Purpose

The Timberline MPF System is a lumbar intervertebral body fusion device which is part of the ZimVie Spinal Fusion System.

Device Description

The Timberline MPF device is an intervertebral body fusion device consisting of a PEEK-OPTIMA® polymer intervertebral spacer, titanium plate and screws. The interbody spacer has a generally rounded shape with various heights and footprints and 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 titanium plate has holes for receiving bone screws and a central hole for receiving a cover plate to prevent screw back-out. The Timberline MPF System is available in a variety of sizes and configurations to approximate anatomical variation in different vertebral levels and/or patient anatomy. The Timberline MPF System is provided non-sterile.

Indications for Use

When used as a lumbar intervertebral body fusion device, the Timberline MPF 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). Implants with 14° lordosis or greater are only indicated from levels L2–L5 and are to be used with at least one integrated fixation screw. The Timberline MPF implants are to be used with supplemental fixation. Approved supplemental fixation systems include the ZimVie Spinal Fixation System.

Contraindications

Contraindications may be relative or absolute. The choice of a particular device must be carefully weighed against the patient's overall evaluation. Circumstances listed below may reduce the chance of a successful outcome. Contraindications include, but are not limited to:

- Allergy to PEEK, titanium or cobalt chrome alloys, or foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made prior to implantation.
- Known or suspected infection/immune system incompetence. Acute or chronic infectious diseases of any etiology or localization.
- Any abnormality present which affects the normal process of bone remodeling including, but not limited to, severe osteoporosis involving the spine, bone absorption, osteopenia, active infection at the site or certain metabolic disorders affecting osteogenesis.
- Morbid Obesity. An overweight or obese patient can produce loads on the spinal system, which can lead to failure of the fixation of the device or failure of the device itself.
- Any neuromuscular deficit which places an unusually heavy load on the device during the healing period.
- Open wounds.
- Pregnancy.
- Any other medical or surgical condition which would preclude the potential benefit of spinal surgery, such as the presence of congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of the white blood count (WBC) or a marked left shift in the WBC differential count.
- Any case requiring the mixing of components from two different systems.
- Any case requiring the mixture of stainless steel with titanium, or stainless steel with cobalt chrome implant components.
- Fever or leukocytosis.
- Signs of local infection or inflammation.
- Previous history of infection.
- Prior fusion at the level to be treated.
- Alcoholism or heavy smoking.
- Senility, mental illness or substance abuse, of a severity that the patient may ignore certain necessary limitations and precautions in the use of the implant, leading to failure or other complications.

- Any patient unwilling to follow postoperative instructions.

Inadequate tissue coverage over the operative site.

Possible Complications

- Possible complications specific to the device may include:
  - Early or late implant bending, breakage, failure, loosening or movement/migration.
  - Bone fracture.
  - Allergic reaction to implant material.

Other general complications associated with any spinal surgical procedure may include: Non-union or delayed union, pseudoarthrosis; pain; second surgery; bleeding; infection, early and late; tissue or nerve damage, including dural tears or other neurological problems; incisional complications; scar formation; damage to blood vessels and cardiovascular system compromise; changes in mental status; damage to internal organs and connective tissue; complications due to the use of bone grafting, including graft donor site complications; respiratory problems; reactions to anesthesia and/or death.

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 integrated fixation screws or supplemental fixation.

Precautions

The Timberline MPF implants are for single use only. Never reuse any implant even if it appears unmarked or undamaged. Reuse of the implant components may result in reduced mechanical performance, malfunction, or failure of the device. Any implant implanted and then removed must be discarded. Use only new implants for each case.

Only experienced spinal surgeons should perform the implantation of this system with specific training in the use of vertebral implants. The surgical procedure is technically demanding and presents a risk of serious injury to the patient.

The Timberline MPF System 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.

Based on the fatigue testing results, the physician/surgeon must consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact on the performance of the system.

Risks associated with neurosurgery, general surgery, orthopedic 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, as well as alternative treatment methods, are explained to the patient.

Preoperatively: The surgeon must be fully conversant with all aspects of the surgical technique and know the indications and contraindications of this type of implant. The surgeon must have acquainted himself before the operation with the specific technique for insertion of the product, which is available from the manufacturer. As part of the preoperative examination, the surgeon must check that no biological, biomechanical or other factors will affect the correct conduct of the operation and the postoperative period. An appropriate range of implant sizes must be available at the time of the operation.

Intraoperatively: The correct selection of the type and size of implant appropriate to the patient and the positioning of the implant are extremely important.

Postoperatively: Patients must be informed of the precautions to be taken in their everyday life to guarantee a maximum implant service life. It is recommended that regular postoperative follow-up is undertaken to detect early signs of failure of the implants and to consider the action to be taken. Deterioration of the device after bone consolidation cannot be considered to constitute a dysfunction or deterioration in the characteristics of the implants.

The use of guides is required to help ensure appropriate screw trajectory.

Important Information on the Timberline MPF Lateral Modular Plate Fixation System (continued)

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.

When using the soft tissue retractor, care must be taken to ensure it is correctly and safely placed.

Proper handling of the implant before and during the operation is crucial.

Use of the cover plate to prevent back-out of the screws is mandatory. Use of the integrated screws with lordotic angles of 14° and above is mandatory. If a cover plate is disassembled from a plate, it must be discarded and not reused. If a plate is disassembled from an interbody spacer, it must be discarded and not reused.

The Timberline MPF device must not be used with vertebral components or instruments from other manufacturers.

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 ZimVie Spine representative or distributor 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.

Do not apply excessive force or stress. Misuse can damage instruments or implants.

Perform a careful preoperative review to be sure that all necessary implant components are available and that the instrument set is complete and in working order prior to initiating surgery.

The Timberline MPF System has not been tested for safety and compatibility in the magnetic resonance (MR) environment. The Timberline MPF System has not been tested for heating or migration in the MR environment.

Mixing of dissimilar metals can accelerate or initiate the corrosion process. Titanium components must NOT be used together in building a construct that involves other implant materials. Titanium and cobalt chrome may be used together within the same construct.

For more information, visit ZimVie.com

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