



Rethinking Possibilities, Reshaping Lives

Surgical Technique Guide



primaLOK™ SP
Interspinous Fusion System



Description

The OsteoMed Spine PrimaLOK™ SP Interspinous Fusion System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion of the thoracic, lumbar and/or sacral spine. PrimaLOK SP is a bilateral locking plate system which attaches to the posterior non-cervical spine at the spinous processes. It is available in various heights and widths to accommodate differing anatomic requirements.

Surgical procedures appropriate for use with PrimaLOK SP include, but are not limited to:

- Supplemental fixation for Anterior Lumbar Interbody Fusion (ALIF), Transforaminal Lumbar Interbody Fusion (TLIF), Lateral Lumbar Interbody Fusion (LLIF), Posterior Lumbar Interbody Fusion (PLIF), Posterior Lateral Fusion (PLF) and lumbar facet screw procedures.
- Supplemental fixation for failed fusion revision and hybrid constructs

Indications for Use

The PrimaLOK SP Interspinous Fusion System is a posterior, non-pedicle supplemental fixation device, intended for use in the non-cervical spine (T1-S1). It is intended for plate fixation/attachment to the spinous process for the purpose of achieving supplemental fusion in the following conditions: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), and/or tumor. The PrimaLOK SP Interspinous Fusion System is intended for use at one level, with bone graft material, and not intended for stand-alone use.

For additional information, warnings and contraindications, please refer to the Product Insert.

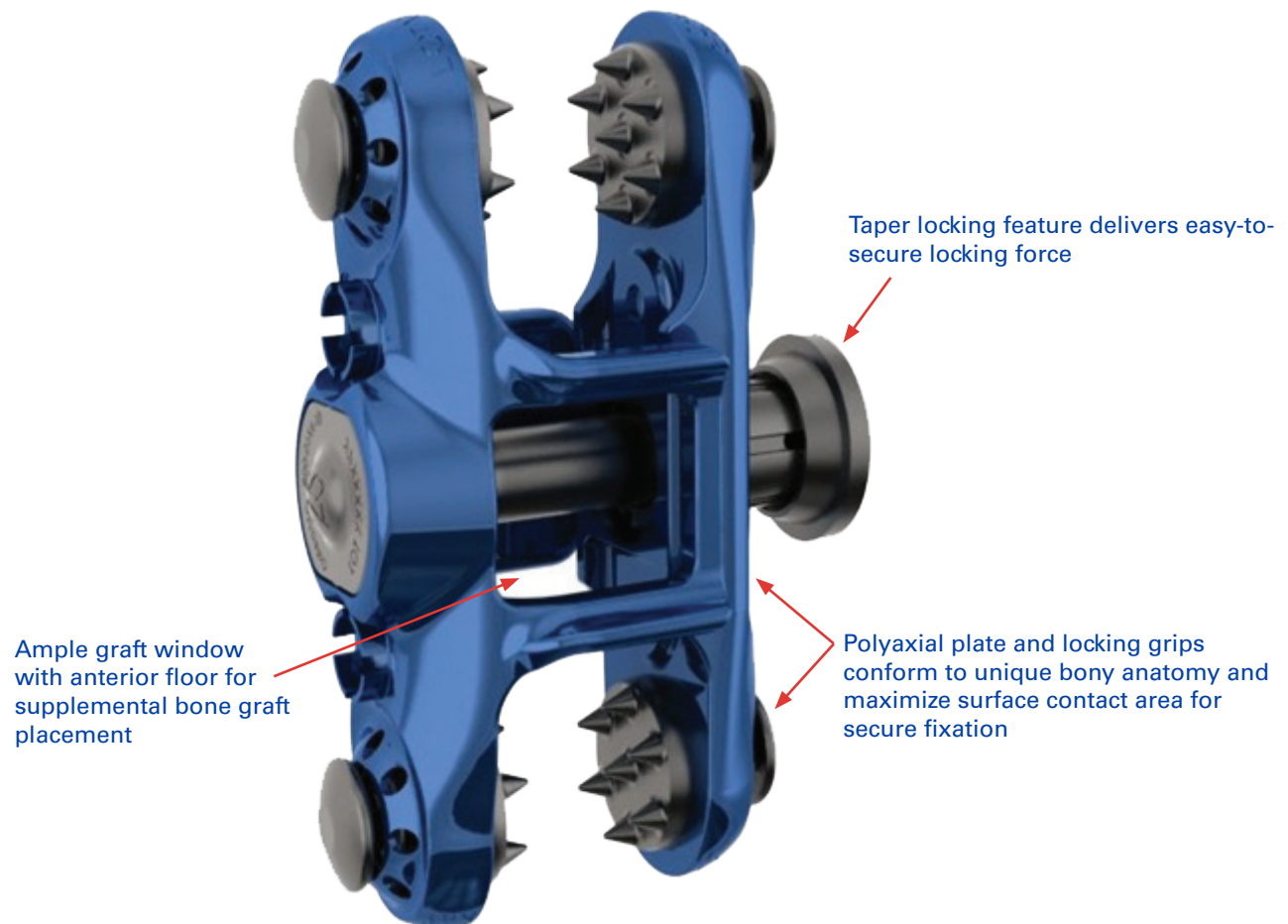
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DESIGN RATIONALE

RETHINKING FIXATION

Rethinking lumbar fixation in a fresh new way inspired the design of the OsteoMed Spine PrimaLOK™ SP Interspinous Fusion System. PrimaLOK SP is a next generation posterior lumbar spinous process fixation device. Patent-pending polyaxial technology provides for optimal placement and enhanced fixation to accommodate anatomic variations with minimal disruption to anatomy. These unique features, combined with easy-to-use instrument options for a variety of surgical approaches, result in a streamlined fixation solution tailored to the needs of surgeons and patients.



DESIGN FEATURES

CLINICAL BENEFITS

Full Polyaxial Design

- 4 independent grips/feet
- Multi-directional polyaxial plate
- 45 degrees of combined grip/plate range of motion
- Accommodates natural variations in anatomy and challenging anatomy
- Enables ideal anterior placement where bone quality is best at spinous process/lamina junction
- Ideal for placement at L5-S1

Gripping Spikes

- 4 grips that independently orient to anatomy
- Total of 28 conical spikes (7 per grip)
- 1.6mm spike length
- Greater load distribution across each spike provides enhanced fixation while minimizing disruption to spinous process (SP) and reducing fracture risk
- Optimal length and number of spikes designed to minimize force concentrations and avoid SP fracture, especially where SP thickness varies

Locking Mechanism

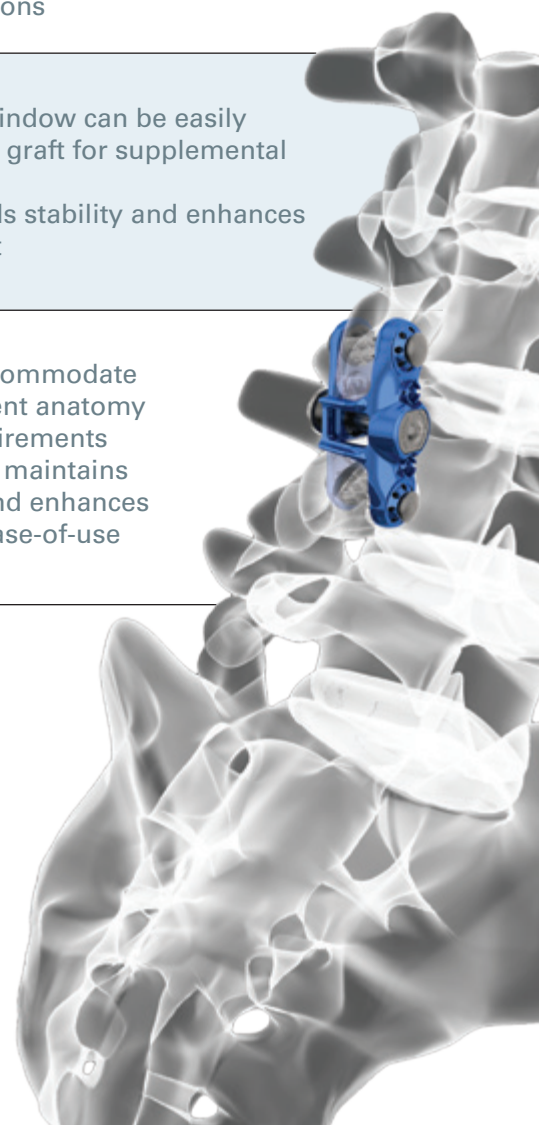
- 6 Morse taper locks
- Provisional and final locking steps
- 300 pounds of compressive force applied to the implant at final lock
- Ability to reposition if necessary before final locking
- Locking features designed to minimize risk of implant malfunctions

Graft Window

- Integrated window contains approximately .5 – 2+cc of graft material
- Anterior window floor
- Generous graft window can be easily packed with bone graft for supplemental SP fusion
- Window floor adds stability and enhances graft containment

Implant Sizes and Sterile Packaging

- 7 sizes from 4mm to 18mm
- Central post comes in 2 sizes: 25mm standard, 30mm optional
- Implants supplied in double peel-pack sterile package that serves as implant loading caddy and allows for placement of the inner tray into the sterile field
- Multiple sizes accommodate variations in patient anatomy and surgical requirements
- Sterile packaging maintains implant quality and enhances O.R. speed and ease-of-use

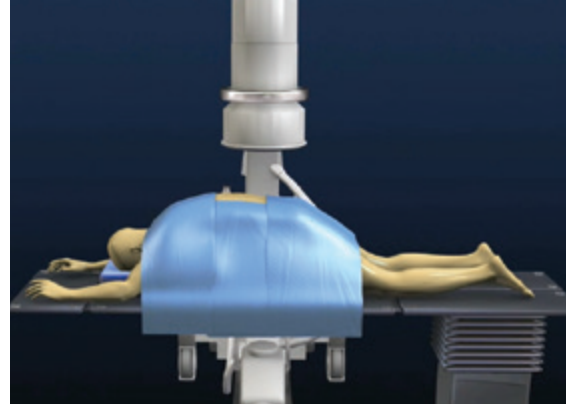


SURGICAL TECHNIQUE

ACCESS AND PREPARATION

Patient Positioning

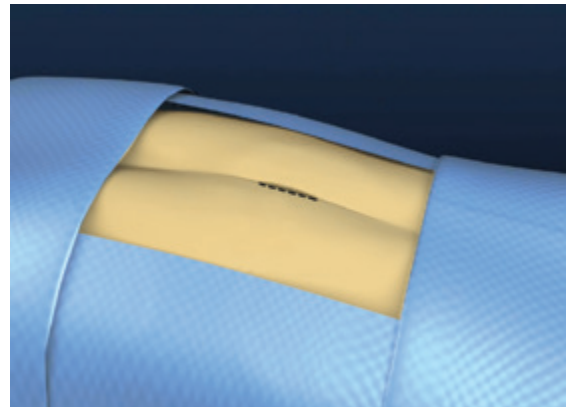
Position the patient in a prone position on a radiolucent table. Ensure adequate clearance around the surgical table for movement of the fluoroscopic C-arm.



Identify the spinous process at the desired level through manual palpation and intraoperative imaging. Make a midline incision approximately 3-5 cm in length to expose the spinous processes at the operative level.

Elevate the paraspinous musculature and adjoining soft tissue to expose the spinous processes and lamina. Removal of the supraspinous ligament is recommended to allow for sizing, distraction, and placement of the implant.

Removing excess soft tissue and osteophytes on the lateral aspects of the spinous processes may be necessary to allow for optimal placement and fixation of the implant grips to the spinous processes.

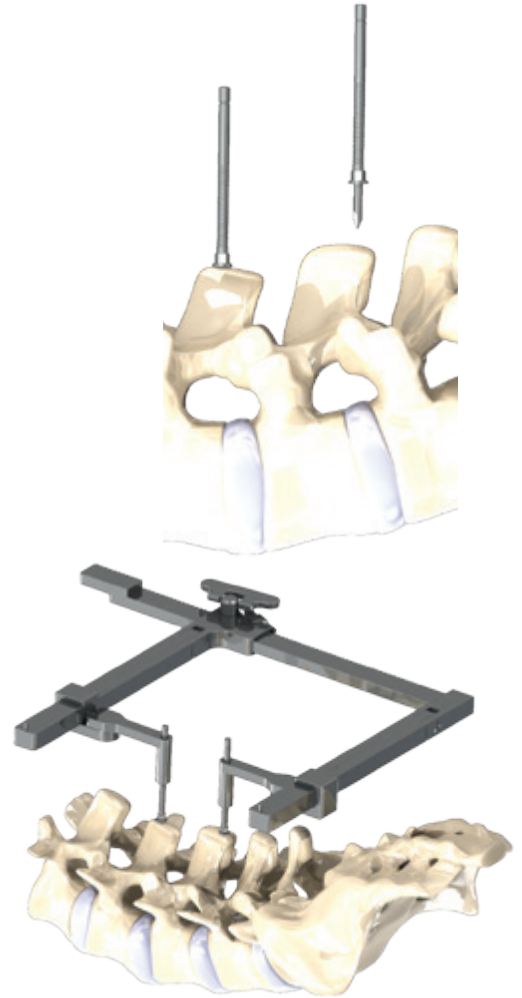


Caution: *If performing a decompression, be careful to avoid removing excessive bone that may compromise the integrity of the spinous processes at the operative level.*

Distraction with Frame

Place Caspar-style distractor screws into the spinous processes, 2/3 of the way cephalad and caudal to the operative space. Screw placement too close to the interspinous space may result in instrument interference during site preparation and implant insertion.

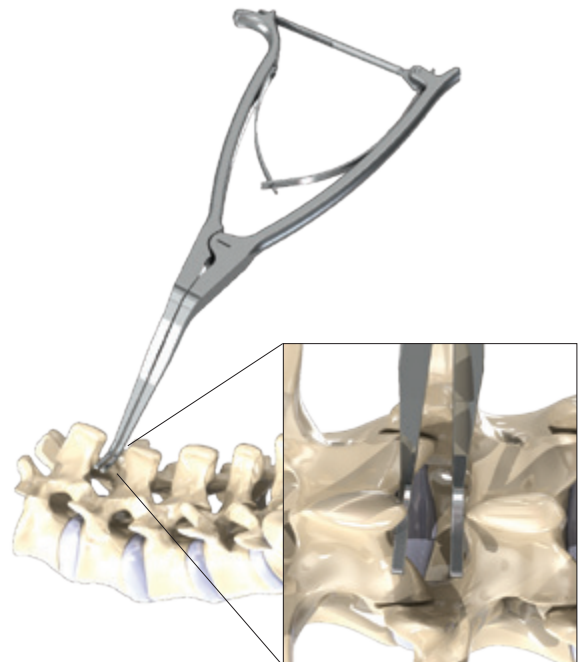
Distract the interspinous space using the lumbar Retractor Frame with the extension arms. Maintain distraction during implant placement.



Distraction with Laminar Spreader

As an alternative to the Retractor Frame, a Laminar Spreader is available. With the Laminar Spreader closed, insert the tips into the anterior portion of the interspinous space where the PrimaLOK SP will be implanted, near the base of the spinous processes or upon the lamina. Engage the ratchet arm and compress the handles of the Laminar Spreader to spread the tips and distract the interspinous space. Maintain distraction during implant placement and locking.

Caution: Distraction of the interspinous space is intended to provide just enough space to slip the PrimaLOK SP implant into place. Over-distraction may cause damage to the spinous process or lamina and affect the successful use of the implant.

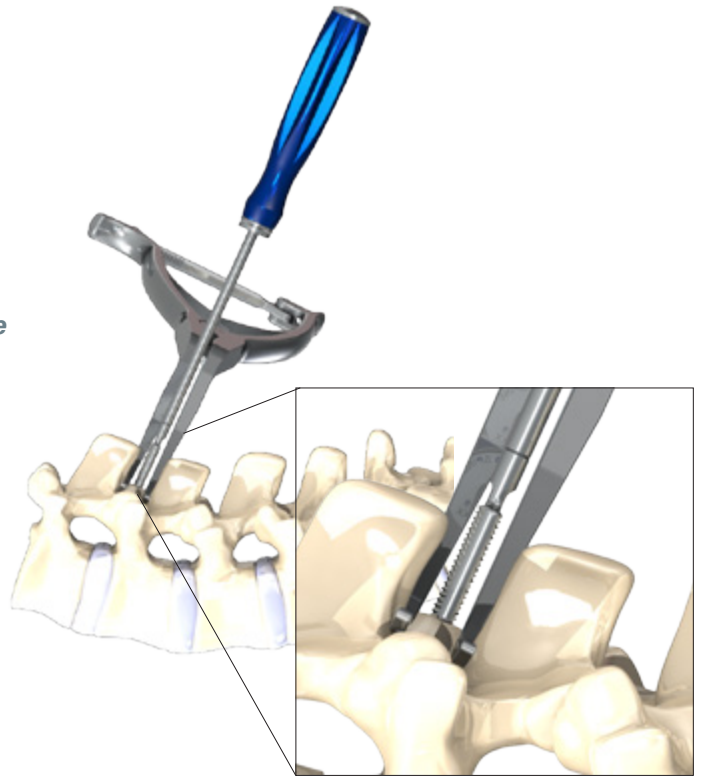


ACCESS AND PREPARATION

Rasping

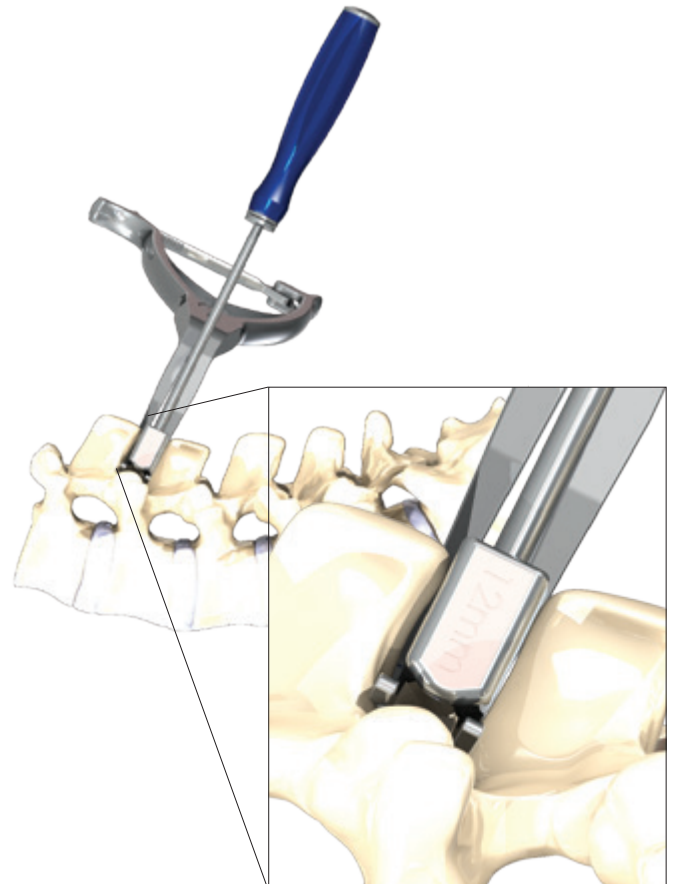
Prepare the fusion site using the Rasp. Depending on the amount of distraction needed, apply the Rasp on the surfaces indicated for the caudal and cephalad spinous processes.

Caution: Do not use the Rasp where it could easily fracture the bone.



Sizing

Once the fusion site is prepared, determine the desired implant size starting with the smallest sizer and increasing sequentially until initial sizing is determined. Sizers range from 4mm-18mm.



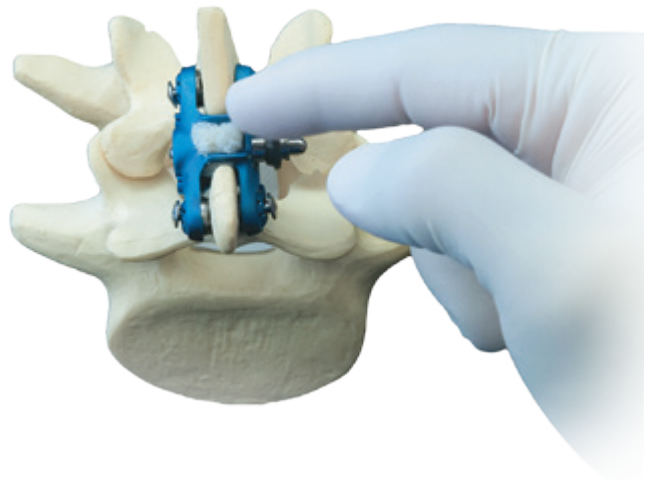
Sterile Packaging

Select the indicated implant size from the sterile package. The sterile pack inner tray is designed to be used as an implant caddy; a Backup Plate Caddy (800-0302) is also available.



Bone Graft

Bone graft can be packed into the graft window of the implant prior to insertion or after placement into the surgical site. Dependent on the size of implant selected, the window contains approximately .5cc — 2+cc of graft material.



INSERTING THE IMPLANT

The technique for using a PrimaLOK SP implant includes these basic steps:

1. Loading the implant onto the instrument
2. Inserting it into the surgical site at the appropriate level
3. Compressing
4. Provisional locking
5. Final locking

Three minimally-disruptive instrument options are available for tailoring the surgical technique to surgeon preferences and unique characteristics of the patient's anatomy.

T1 Technique 1

- An all-in-one instrument option for most steps
- One instrument is used for inserting, compressing, and provisional locking, and a separate instrument is used for final locking
- ***Select this technique when using 4mm and 6mm implants***

T2 Technique 2

- A low-profile version of the all-in-one for inserting and compressing
- Separate instruments are used for provisional locking and final locking
- ***Select this technique when using 4mm and 6mm implants***

T3 Technique 3

- This is the most decoupled version of each instrument and surgical step
- Two insertion instruments are used – one for each side of the implant
- Separate instruments are used for compressing, provisional locking, and final locking
- ***Select this technique in cases requiring extreme angulation of the polyaxial plate (10+ degrees)***

General Notes and Cautions

- The implant can be placed with the tip of the central post on either side of the spinous process
- Do not place the implant where it could easily fracture the bone
- Do not place the implant where it cannot be locked and unlocked. For example, if the post tip of the implant is close to a facet, confirm that there is clearance for using the locking instruments
- When placing the implant into the surgical site, confirm placement with fluoroscopy or visual inspection to ensure that all four polyaxial grips will engage the spinous processes
- If the plates on the implant do not open wide enough to fit over the patient's spinous processes, the 25mm central post can be replaced with an optional 30mm post

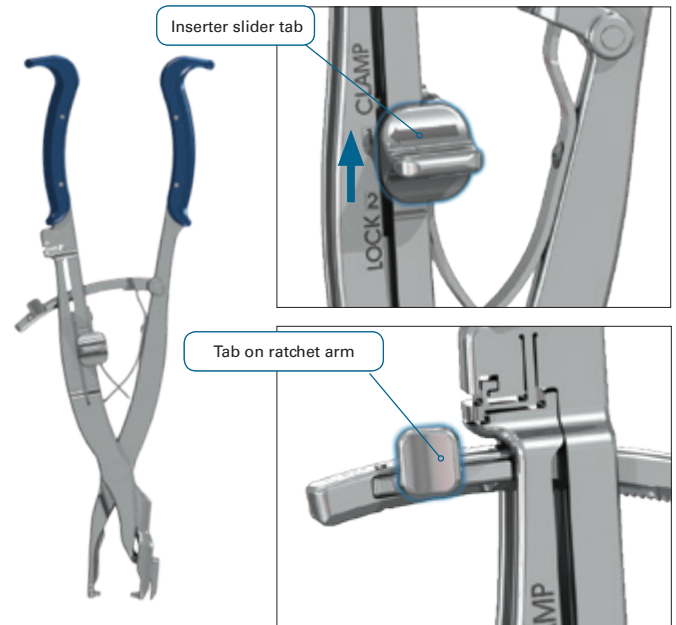
Changing the Central Post

Disengage the implant from the inserter. Slide the lock ring and the plate off the central post. Push on the tip to disengage the base of the post from the plate. Replace with the 30mm post until fully seated and slide the lock ring assembly and plate onto the new post. Place the implant back in the caddy and re-engage the inserter.



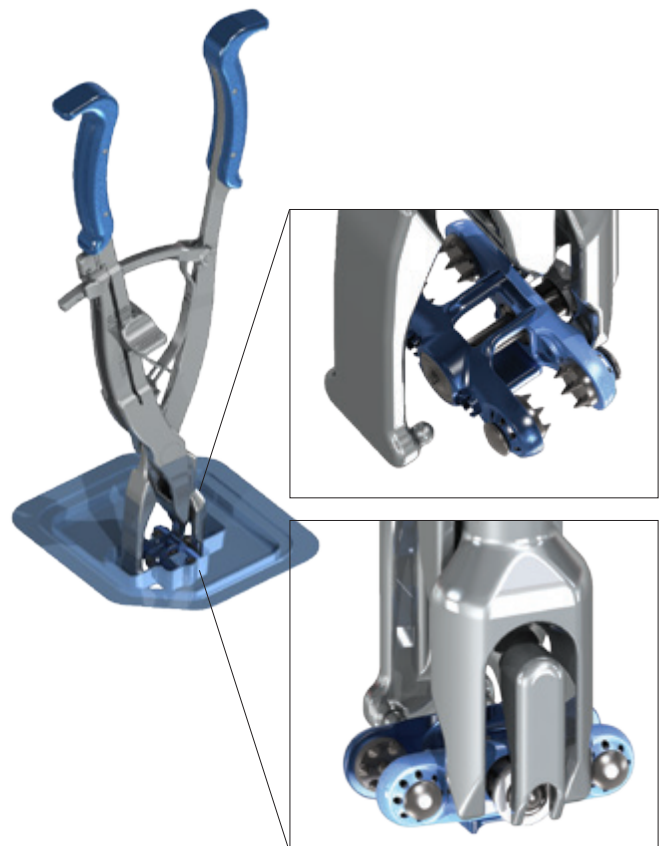
TECHNIQUE 1 T1

Prior to loading the implant, make sure the slider tab on the Inserter is in the CLAMP (1) position. Open the distal jaws of the Inserter by releasing the ratchet arm. If a wider opening is needed, depress the tab on the ratchet arm.



T1 Loading

Place the Inserter over the implant and gently squeeze until the spherical tabs engage the mating holes on the lateral sides of the implant. It will only fit in one direction; rotate the inserter 180 degrees if it is not engaging.



INSERTING THE IMPLANT

T1 Inserting

Place the implant into the operative site, as far anterior and as close to the lamina as possible. The tip of the central post can go on either side of the spinous process. Confirm placement with fluoroscopy or visual inspection, ensuring that all four polyaxial grips are properly positioned to engage the spinous processes.



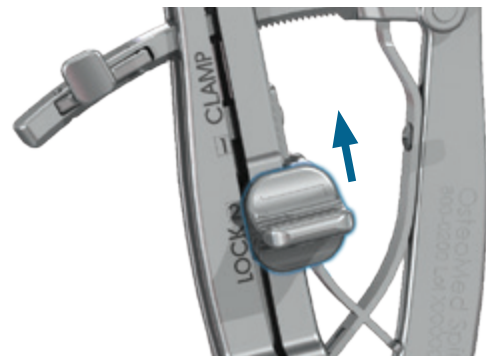
T1 Compressing and Provisional Locking

Gently squeeze the Inserter to partially seat the teeth into the bone. Confirm that each grip has engaged the spinous processes and has no polyaxial motion by gently attempting to move the implant with the inserter or a probe.

Slightly release pressure on the handles, then move the slider tab on the implant Inserter from the CLAMP (1) to the LOCK (2) position. Grip and squeeze the Inserter again until it clicks to provisionally lock the implant plates to the spinous processes.

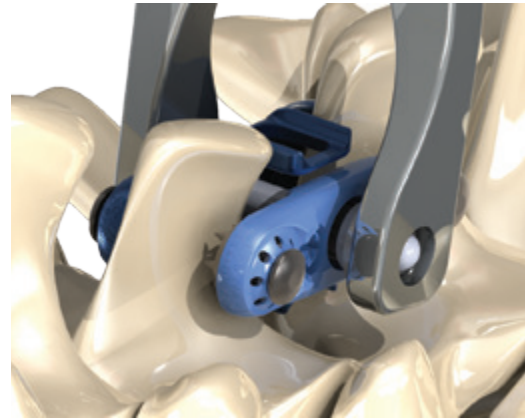


To remove the Inserter from the implant, place the slider tab back into the CLAMP (1) position. Release the ratchet arm by lifting upward. Carefully spread the distal jaws, lightly rocking the Inserter side to side, and disengage the spherical tabs from the implant.



T1 Final Locking

After confirming desired placement, use the Lock Ring Compressor to achieve final locking. Place the circular cut-out over the tip of the central post. Grip and squeeze until an audible click is heard, which indicates that final locking compressive force has been delivered. Remove final locking and distraction tools. Ensure that the implant remains locked.



TECHNIQUE 2 T2

Prior to loading the implant, raise and release the ratchet arm of the Inserter Compressor.



T2 Loading

Place the pivoting leg of the Inserter Compressor over the Polyaxial Plate side of the implant and align the rigid leg with the Post Plate side. Gently squeeze the Inserter Compressor until the tabs engage with the mating holes on both plates.



INSERTING THE IMPLANT

T2 Inserting

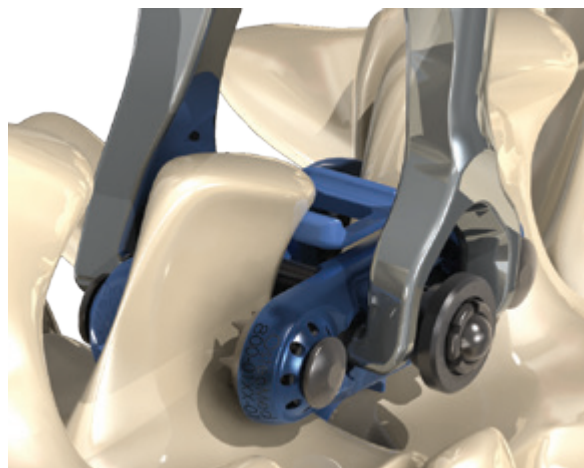
Place the implant into the operative site, as far anterior and as close to the lamina as possible. Confirm placement with fluoroscopy or visual inspection.

- **Note:** *In cases of extreme angulation (10 degrees or more), the pivoting leg of the Inserter Compressor could potentially block the lock ring and prevent sufficient provisional locking. If this occurs, instead use Technique 3 instrumentation.*



T2 Compressing

Gently squeeze the Inserter Compressor to partially seat the teeth into the bone. Confirm that each grip has engaged the spinous processes and has no polyaxial motion by gently attempting to move the implant with the inserter or a probe.



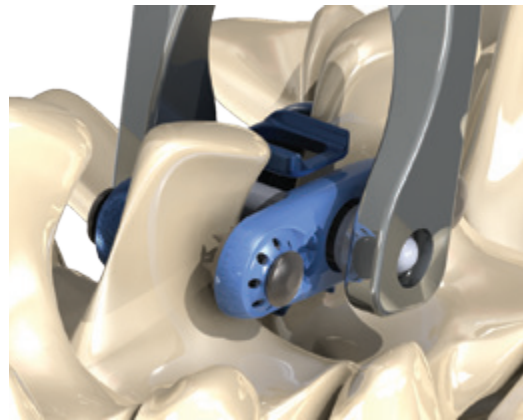
T2 Provisional Locking

Drop and engage the ratchet arm of the Inserter Compressor to maintain compression. Place the Provisional Locker over the implant. The open, horseshoe tip goes over the protruding end of the central post and the opposite tip engages with the mating bump protruding from the rigid leg. Firmly squeeze the Provisional Locker until it clicks.



T2 Final Locking

After confirming desired placement, use the Lock Ring Compressor to achieve final locking. Place the circular cut-out over the tip of the central post. Grip and squeeze until an audible click is heard, which indicates that final locking compressive force has been delivered. Remove final locking and distraction tools. Ensure that the implant remains locked.



INSERTING THE IMPLANT

TECHNIQUE 3

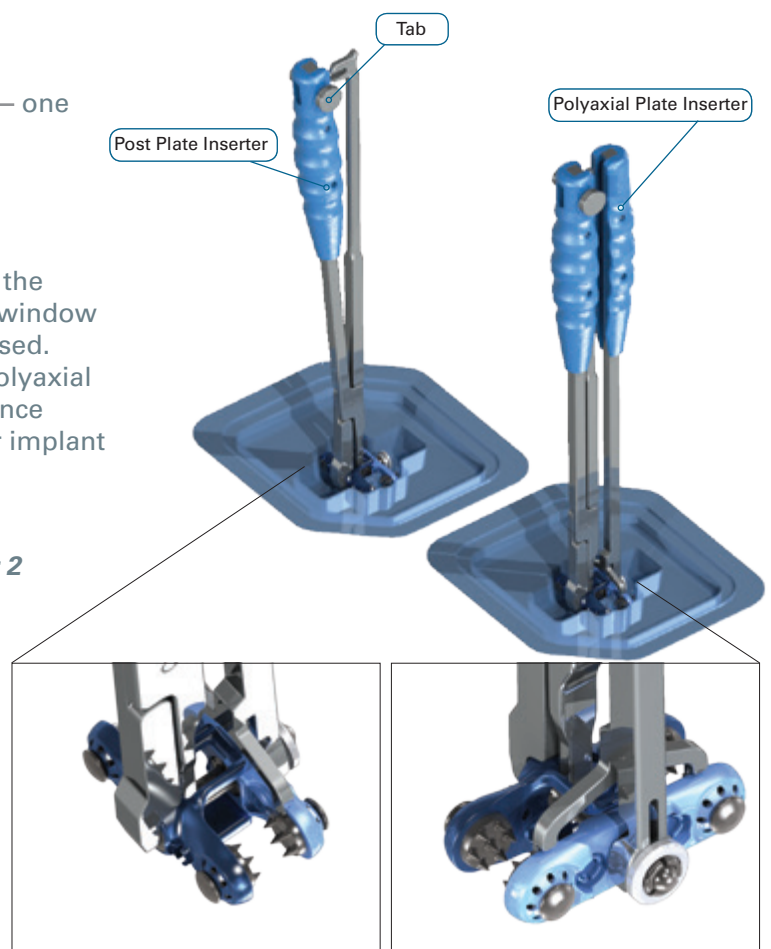
T3

This technique uses a decoupled, two-piece inserter — one for each side of the implant.

T3 Loading

Open the leg of the Post Plate Inserter by depressing the larger tab. Place the opened leg down over the graft window of the implant, then squeeze the leg until it snaps closed. Place the Polyaxial Plate Inserter over the opposite polyaxial plate and press down until it snaps onto the collet. Once secured, lift the implant from the sterile packaging or implant caddy.

Note: Technique 3 instruments will not work with 4mm and 6mm implants. Instead, use Technique 1 or 2 instrumentation.



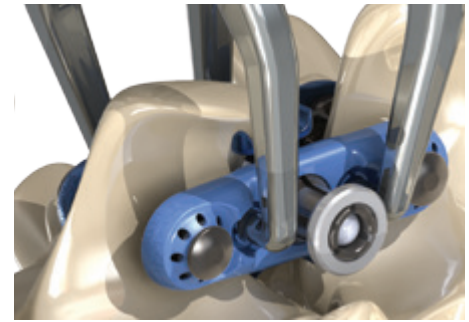
T3 Inserting

Place the implant into the operative site, as far anterior and as close to the lamina as possible. Confirm placement with fluoroscopy or visual inspection.



T3 Compressing

Place the tips of the two Plate Compressors into the spherical mating pockets on the implant, then loosely compress. Remove the Polyaxial Plate Inserter before fully compressing.

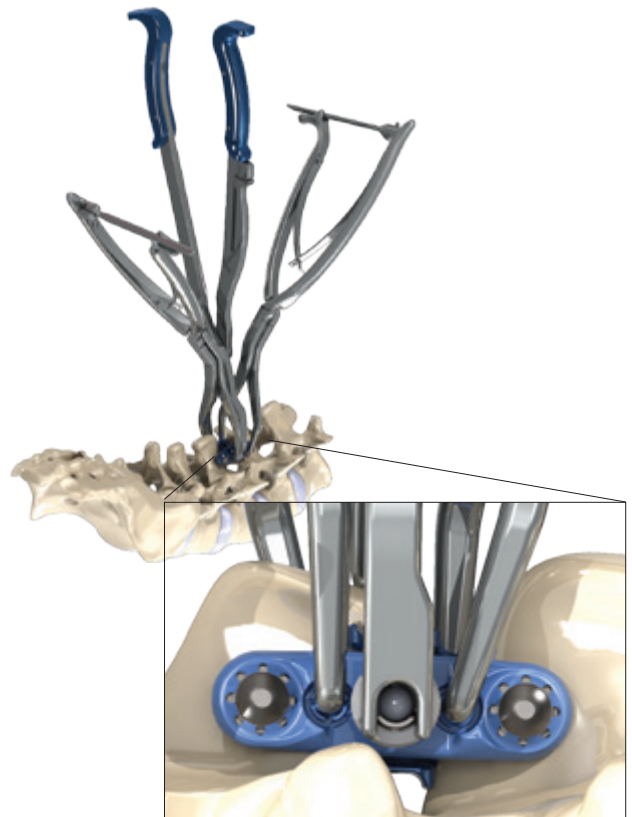


Firmly squeeze the Plate Compressors, fully seating the teeth of the polyaxial grips into the bone. Confirm that each grip has engaged the spinous processes and has no polyaxial motion by gently attempting to move the implant with the inserter or a probe. Remove the Post Plate Inserter by depressing the larger tab and releasing it from the implant.



T3 Provisional Locking

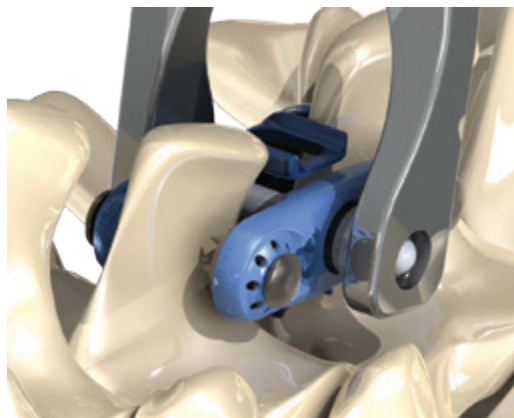
With the Plate Compressors maintaining compression, place the Provisional Locker over the implant. The open, horseshoe tip goes over the protruding end of the central post and the opposite tip engages with the mating bump protruding from the head of the central post. Firmly squeeze the Provisional Locker until it clicks. Remove Plate Compressors before final locking.



INSERTING THE IMPLANT

T3 Final Locking

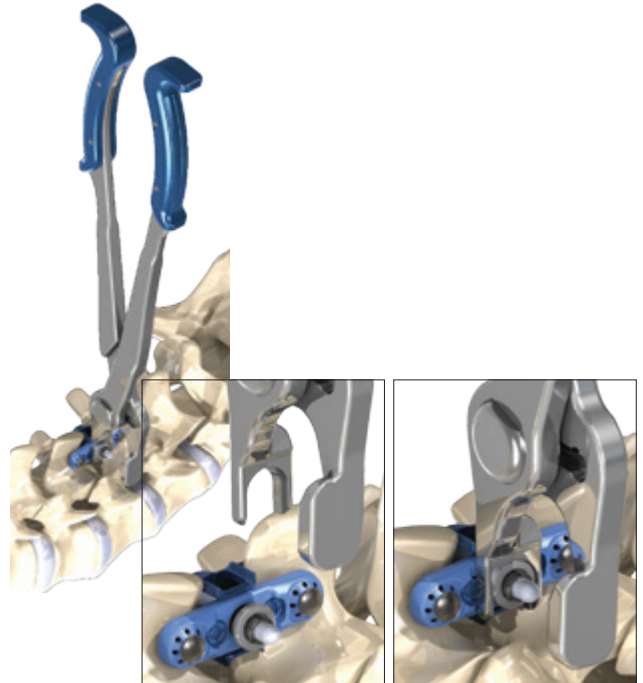
After confirming desired placement, use the Lock Ring Compressor to achieve final locking. Place the circular cut-out over the tip of the central post. Grip and squeeze until an audible click is heard, which indicates that final locking compressive force has been delivered. Remove final locking and distraction tools. Ensure that the implant remains locked.



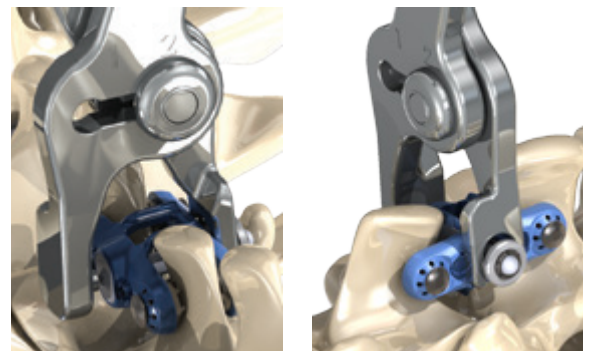
Removal

If it becomes necessary to remove the implant, use the Removal Tool.

Set the Removal Tool to Position 1. Place the forked end between the lock ring and the lateral side of the plate, with the paddle end engaging the tip of the central post. Squeeze the Removal Tool to disengage the lock ring. The implant plates can then be grasped, disassembled and separated, and subsequently removed from the spinous processes.



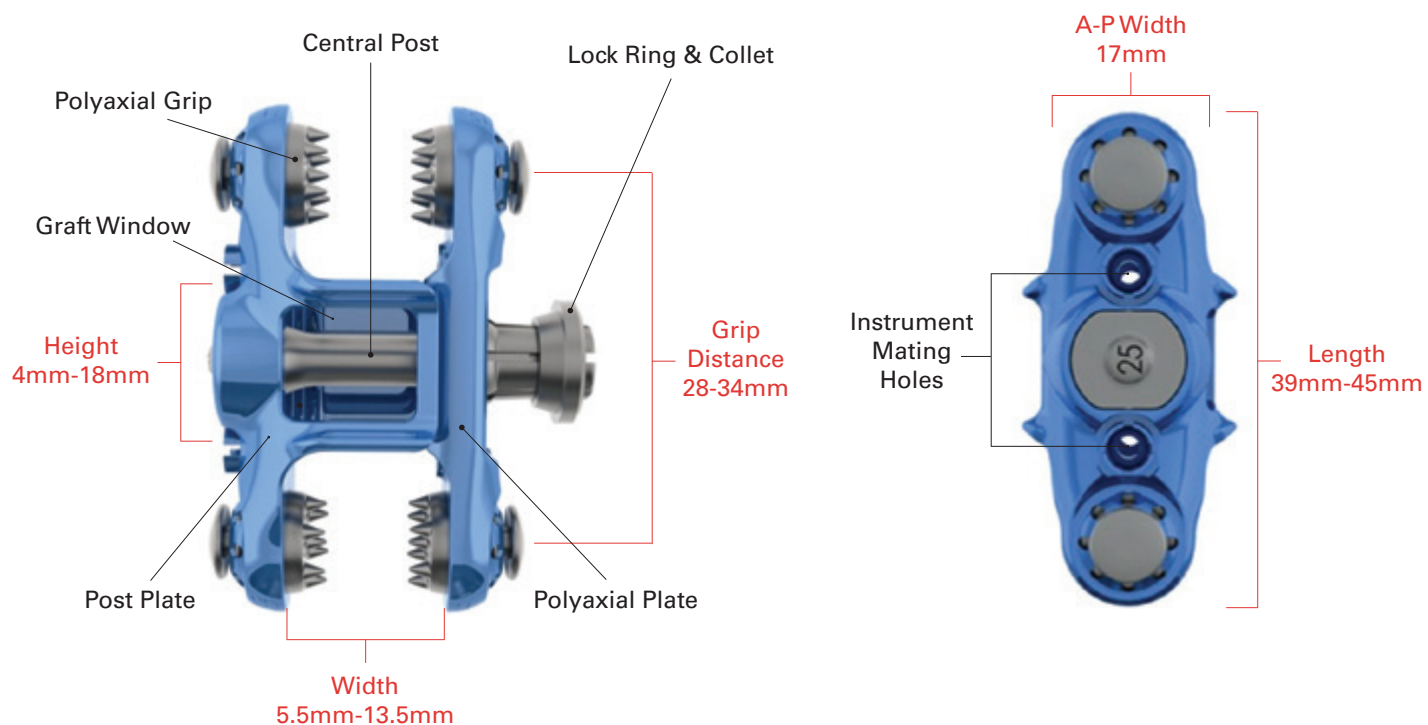
If the spiked teeth are still seated against the spinous processes, preventing removal, put the Removal Tool into Position 2 to loosen the polyaxial collet. Again, place the forked end between the ring and the lateral side of the plate, but with the paddle end engaging the head, rather than the tip, of the post. Squeeze the Removal Tool to disengage the collet. Slightly twist or rock the implant and remove.



Note: Do not reuse an implant that has been previously locked and unlocked.

PRODUCT INFORMATION

IMPLANT ANATOMY



IMPLANT CATALOG



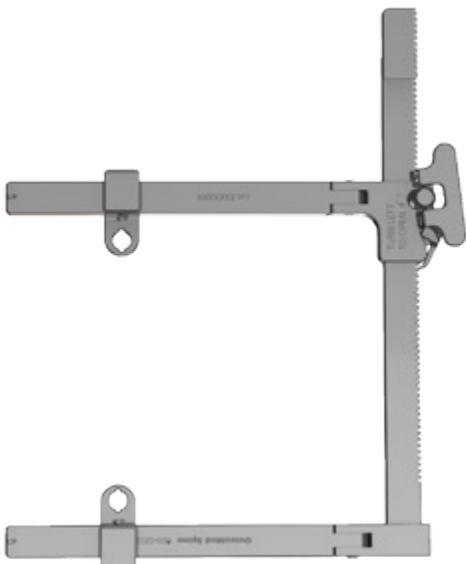
Part No.	Size (Height)	Description	Implant Color
800-0104-SP	4mm	4mm Implant, Sterile	Light Blue
800-0106-SP	6mm	6mm Implant, Sterile	Gold
800-0108-SP	8mm	8mm Implant, Sterile	Magenta
800-0110-SP	10mm	10mm Implant, Sterile	Blue
800-0112-SP	12mm	12mm Implant, Sterile	Green
800-0115-SP	15mm	15mm Implant, Sterile	Bronze
800-0118-SP	18mm	18mm Implant, Sterile	Gray
800-0130-SP	30mm	30mm Central Locking Post, Sterile	

INSTRUMENTS

PRIMALOK SP ACCESS INSTRUMENTS



800-0207 Distractor Screw Driver



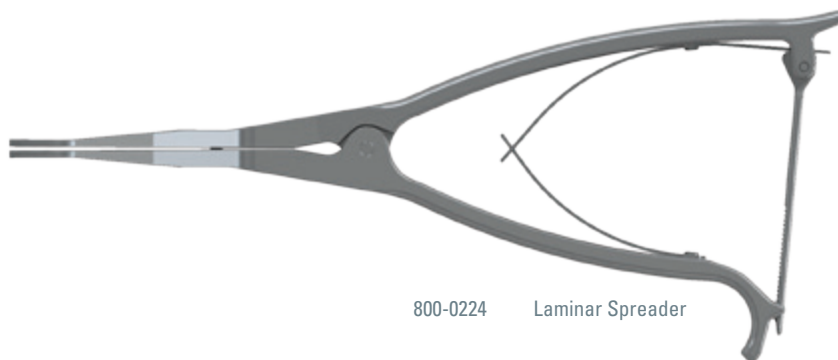
800-0202 Retractor Frame



800-0206-SP 14mm Distractor Screws,
2 Pack Sterile (Disposable)



800-0221 Retractor Extensions (2)

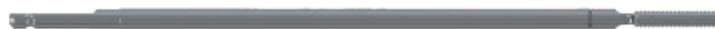


800-0224 Laminar Spreader

PRIMALOK SP PREPARATION INSTRUMENTS



800-0219 Implant Sizer Handle



800-0402 4mm Rasp



800-0304 4mm Implant Sizer
800-0306 6mm Implant Sizer
800-0308 8mm Implant Sizer
800-0310 10mm Implant Sizer
800-0312 12mm Implant Sizer
800-0315 15mm Implant Sizer
800-0318 18mm Implant Sizer

INSTRUMENTS

PRIMALOK SP INSERTION INSTRUMENTS



800-0200

Implant Inserter

T1

T1 Used in Technique 1



800-0227

Inserter Compressor II

T2

T2 Used in Technique 2



800-0233

Post Plate Inserter Assembly

T3

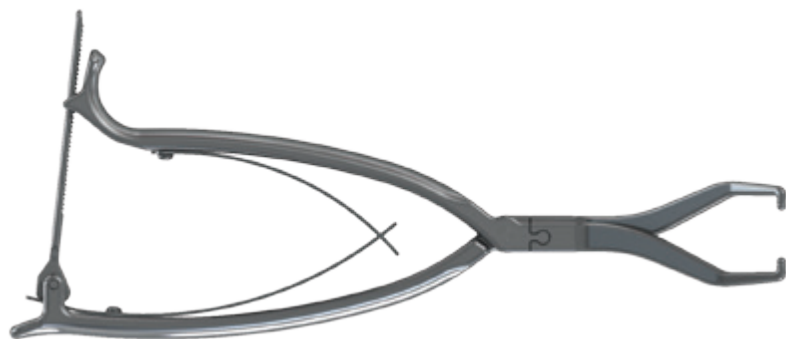
T3 Used in Technique 3



800-0234

Polyaxial Plate Inserter Assembly

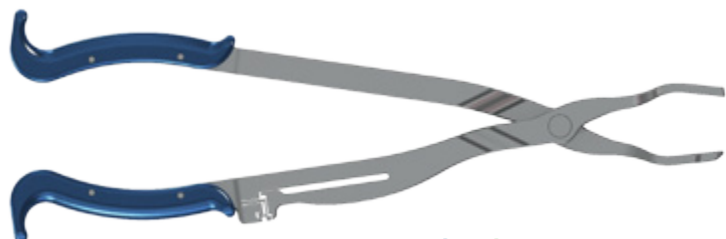
T3



800-0235

Plate Compressor (x2)

T3



800-0228

Offset Provisional Locker

T2

T3



800-0201 Lock Ring Compressor (Final Locker) **T1** **T2** **T3**



800-0203 Removal Tool **T1** **T2** **T3**



Rethinking Possibilities, Reshaping Lives

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