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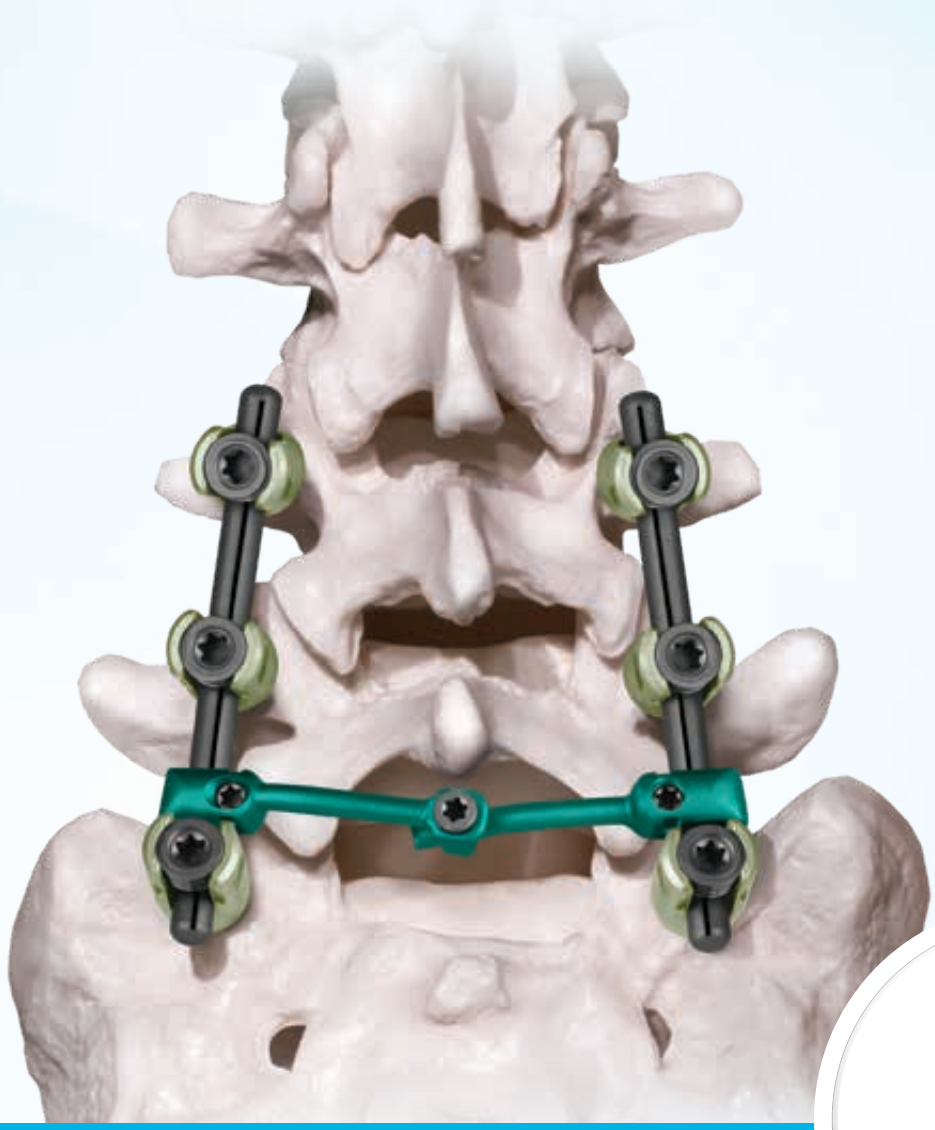

CREO AMP® Threaded

Stabilization System

SURGICAL TECHNIQUE GUIDE

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GLOBUS MEDICAL

Our mission is to deliver cutting-edge technology, research, and innovative solutions to promote healing in patients with musculoskeletal disorders.

Life moves us

The Surgical Technique shown is for illustrative purposes only. The technique(s) actually employed in each case always depends on the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient. Additionally, as instruments may occasionally be updated, the instruments depicted in this Surgical Technique may not be exactly the same as the instruments currently available. Please consult with your sales representative or contact Globus directly for more information.

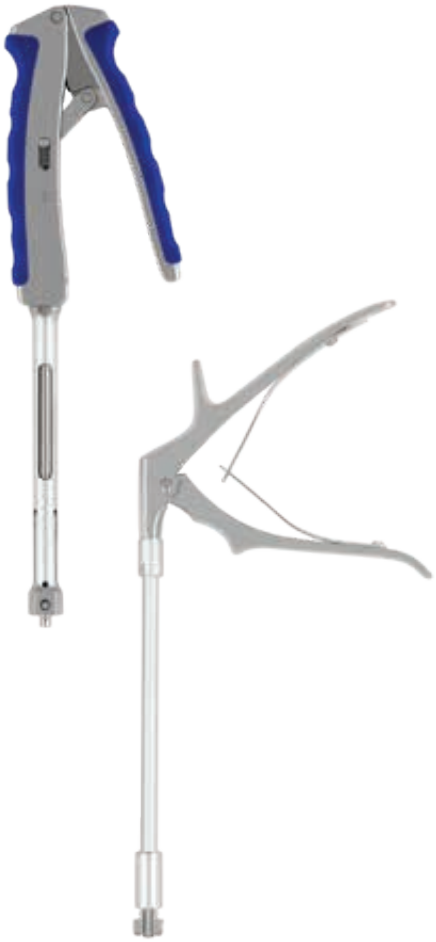
SURGICAL TECHNIQUE GUIDE

CREO AMP® Threaded

CREO AMP® Threaded

Stabilization System

CREO AMP® Threaded, an Advanced Modular Platform for thoracolumbar stabilization, features unmatched ease of use and intraoperative versatility by providing intuitively designed implants and instruments to maximize construct stability. The system provides comprehensive and customizable solutions for degenerative, complex deformity, and tumor/trauma cases by allowing a multitude of connector head options to be placed and exchanged *in situ*.



Optimized Visualization

CREO AMP® Threaded implants are designed with a low profile. Inserting the screw posts prior to the screw heads allows for decortication and access in TLIF cases.

Confidence in Construct Stability

The Head Inserter is designed for component assembly, incorporating a handle lock/release indicator to ensure that the screw head is secured onto the screw post. Testing shows the intraoperatively assembled CREO AMP® Threaded screw construct is as strong as the CREO® Threaded preassembled screw construct.*

Solutions for Complex Spinal Pathologies

The system offers an extensive array of connector options, including polyaxial and closed screw heads, various offset connectors, sacral plates, and lamina clamps. Multiple reduction options allow up to 30mm of gradual reduction and can be coupled for derotation techniques.

*Testing on file at Globus Medical

IMPLANT OVERVIEW

Threaded Locking Cap

- Low torque locking mechanism (8Nm)
- Single-step locking
- Ease of engagement

Threaded Polyaxial Screw Head

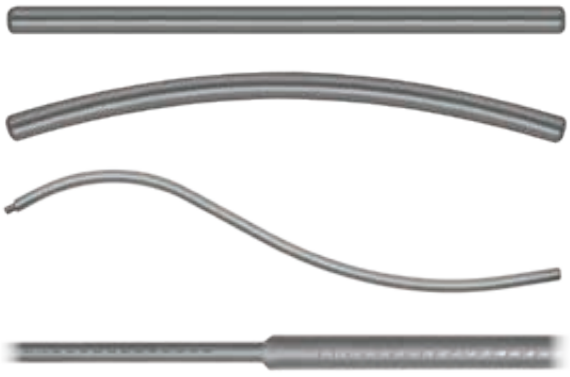
- ±30° angulation (60° total) provides intraoperative versatility
- Available in titanium alloy or cobalt chrome alloy (CoCr)

Screw Post

- Self-tapping design
- Double lead thread for rapid insertion (up to 7.5mm in diameter)
- Blunt tip for bicortical purchase
- Constant outer diameter for maximum bone purchase
- Taps are available, color-coded to screw size
- Screw diameters: 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.5, 8.5, 9.5, 10.5mm
- Screw lengths: 20–120mm

Rods

- 5.5 and 6.0mm diameters available
- Comprehensive selection of straight, curved, pre-contoured, and tapered rods available in a range of sizes
- Hex-ended and tapered rods available from 200–600mm (4.0mm hex on both ends)
- Available in titanium alloy, commercially pure titanium (CP), or CoCr



Double Screw Head Connector (CREO AMP QUAD®)

- Ideal for use in a 4-rod construct
- Increases construct stiffness
- Available in titanium alloy or CoCr

Closed Screw Head

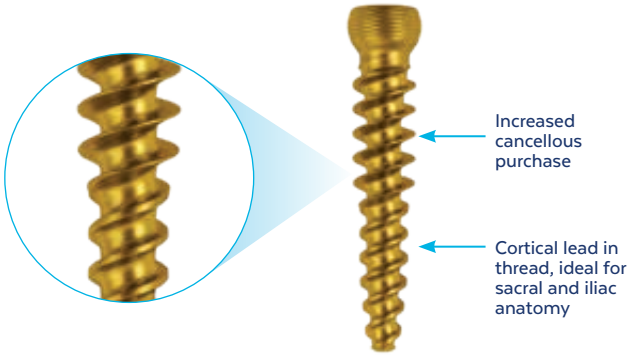
- Eliminates locking cap insertion step
- Completely enclosed connection point

Reduction Screw Head

- Allows for 20mm of gradual reduction
- Eliminates the need for reduction instruments
- Compatible with the Coupled Derotator to perform derotation maneuvers
- Available in titanium alloy or CoCr

Dual Outer Diameter (DOD) Screw Post

- Designed to optimize purchase in both cancellous and cortical bone
- Nominal diameter at distal end allows for deeper insertion in sacrum without perforation
- Designed for enhanced fixation in the sacrum and ilium
- ±30° angulation (60° total)
- Available in proximal/distal outer diameters of 5.5/4.5, 6.5/5.0, 7.5/6.0, 8.0/6.5, 8.5/7.0, 9.5/8.0, 10.5/9.0mm
- Screw lengths: 30–120mm



DOD screws designated by distal diameter

Threaded Monoaxial Screw

- Low profile, top-loading screw design
- Double lead thread for rapid insertion
- Blunt tip for bicortical purchase
- Constant outer diameter
- Screw diameters: 4.0, 4.5, 5.0, 5.5, 6.5, 7.5, 8.5mm
- Screw lengths: 20–90mm

HA Coated Screw Post

- Hydroxyapatite (HA) coating on screw shank is designed to increase resistance to screw pullout
- Screw diameters: 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.5, 8.5, 9.5, 10.5mm
- Screw lengths: 25-120mm

Cross Connector

- 4.6mm profile above the rod
- Optimized profile and strength
- Angular and medial-lateral adjustments provide secure fit
- Seven overlapping sizes: 29–33, 32–40, 38–50, 48–60, 58–70, 68–80, 78–90mm

Low Profile Cross Connector

- Ideal for use in the thoracic spine to help reduce prominence
- Six overlapping sizes: 20–22, 21.5–25, 24.5–31, 30.5–43, 42.5–67, 66.5–91mm

Threaded Offset Connectors

- 15–35mm lengths, in 2.5mm increments, and 150mm
- Head offset connectors are recommended for use with DOD screws for strong pelvic fixation
- Compatible with CREO® reduction instruments
- Available in CREO® head, open, and closed offset connectors

Sacral Plates

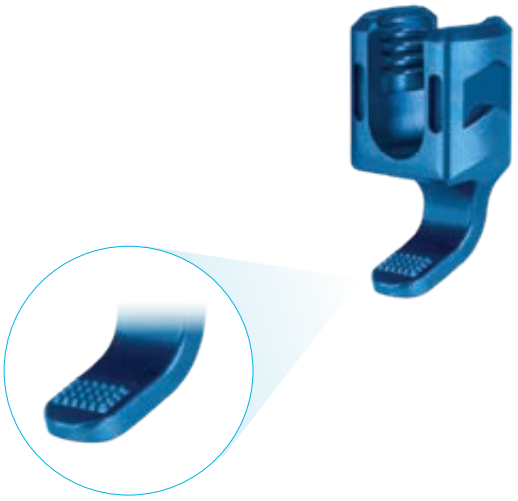
- Designed for divergent S1 and ala bone screw placement for rigid fixation
- Multiple fixation points intended to minimize plate loosening
- Short central spike for initial positioning
- Modular screw heads can be easily attached for rod placement and reduction
- Contoured to match patient anatomy

Lamina Clamps

- Ideal for use at the top of the construct as an alternative to a claw construct
- One-level (25mm) and two-level (60mm) implants
- Small, medium, and large throat heights

Threaded Hooks

- Low profile, top-loading hook design
- Various hook configurations for the lamina, pedicle, or transverse process
- Unique lamina hooks for thoracic or lumbar applications
- Small, medium, and large profiles
- Narrow, standard, and wide blade widths
- Serrations on hook blades to aid in positioning



Multiple Profiles

Pedicle Hook | Lamina Hook | Thoracic Lamina Hook | Angled Lamina Hook | Upgoing Lamina Hook | Transverse Process Hook | Offset Hook

Throat Heights

Small | Medium | Large

Blade Widths

Narrow | Standard | Wide

INSTRUMENT OVERVIEW

PEDICLE PREPARATION INSTRUMENTS

Pedicle Awl 6067.0001

Pedicle Probe, Straight 602.101

Pedicle Probe, Curved 602.102

Pedicle Probe, Thoracic 602.109

Ball Tip Probe 602.105

Ball Tip Probe, Curved 602.106

Ball Tipped Probe, Double Ended 624.110

4.5mm Tap 655.214

5.5mm Tap 655.215

6.5mm Tap 655.216

7.5mm Tap 655.217

8.5mm Tap 655.218

Straight Handle, Ratcheting, 1/4”
Quick-Connect 6067.0010

T-Handle, Ratcheting, 1/4”
Quick-Connect 6067.0020

SCREW INSERTION INSTRUMENTS

Driver Shaft, 1/4” Quick-Connect, Short 6067.0050

Driver Shaft, 1/4” Quick-Connect, Long 6067.0055

Self-Retaining Driver Shaft, 1/4” Quick-Connect 6067.0060

Rigid Monoaxial Screwdriver, Threaded, 1/4” Quick-Connect 6120.5090

Self-Retaining Monoaxial Screwdriver, Threaded, 1/4” Quick-Connect 6120.3035

Modular Screwdriver, 1/4” Quick-Connect, Short 6067.1041

SCREW HEAD APPLICATION INSTRUMENTS

Decortication Tool, 1/4” Quick-Connect 6067.0065

Decortication Tool, Radial Cutting, 1/4” Quick-Connect 6067.0070

SCREW HEAD APPLICATION INSTRUMENTS (CONT'D)

Head Inserter, Threaded 6120.1000

Head Release, Threaded 6120.1005

Screw Head Positioner, Internal, Threaded 6120.1070

ROD MANIPULATION AND INSERTION INSTRUMENTS

Rod Template, 150mm 602.501

Rod Template, 300mm 602.517

Rod Template, 500mm 6067.1500

ROD MANIPULATION AND INSERTION INSTRUMENTS (CONT'D)

Power Bender 6067.0075

Rod Holder 6067.0080

Power Rod Gripper 624.517

In Situ Bender, Left 6119.3000

In Situ Bender, Right 6119.3005

Rod Wrench 6067.3025

Coronal Plane Bender, Left 6119.3010

Coronal Plane Bender, Right 6119.3015

Vise-Style Rod Grip 6119.3020

ROD REDUCTION INSTRUMENTS

Tower Reducer, Threaded 6120.2000

Tower Reducer Attachment, Threaded, 1/4” Quick-Connect 6120.2005

ROD REDUCTION INSTRUMENTS (CONT'D)

Reduction Clip Driver 6119.3110

Reduction Clip Driver, Short 6119.3111

Reduction Clip, Threaded, Short 6120.2020

Geared Reducer, Overhead, Threaded 6120.2010

Geared Reducer, Pistol Grip, Threaded 6120.2015

Reduction Fork, Threaded 6120.2030

SCREW LOCKING INSTRUMENTS

Torque-Limiting T-Handle, Ratcheting, 8Nm, 1/4” Connect 634.611

Threaded Locking Cap Driver 6120.5000

Locking Cap Guide, Threaded 6120.1025

Counter-Torque, Threaded 6120.1030

COMPRESSION/DISTRACTION INSTRUMENTS

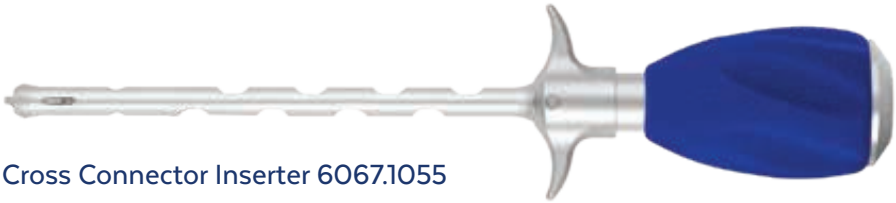
Parallel Compressor, Threaded 6120.0090

Parallel Distractor, Threaded 6120.0095

Parallel Head Distractor 6067.7005

CROSS CONNECTOR INSTRUMENTS

Cross Connector Driver, Torque-Limiting 6067.1050



Cross Connector Inserter 6067.1055

Cross Connector Caliper 6067.1060

HOOK PLACEMENT INSTRUMENTS

Lamina Finder 6067.8000

Pedicle Finder 6067.8005

HOOK PLACEMENT INSTRUMENTS (CONT'D)

Hook Holder, Threaded 6120.8010

Hook Positioner, Threaded 6120.8015

Lateral Hook Holder, Threaded 6120.8020

Offset Hook Holder, Threaded 6120.8025

REDUCTION SCREW HEAD INSTRUMENTS

Reduction Screw Tab Grip 624.555

Reduction Screw Head Inserter 6120.5010

Reduction Screw Sleeve 6120.5030

Reduction Screw Counter-Torque 6120.5050

Reduction Screw Head Release 6120.5015

LAMINA CLAMP INSTRUMENTS

Lamina Clamp Inserter 6067.6040

Lamina Clamp Holder 6067.6041

SACRAL PLATE INSTRUMENTS

3.5mm Hex Screwdriver, Self-Retaining, 1/4” Connection, Shaft 634.408

Sacral Plate Holder 6067.6045

ADDITIONALLY AVAILABLE INSTRUMENTS

Rod Cutter 602.508

Pedicle Probe, Thoracic Curved 624.113

Pedicle Probe, Thoracic Straight 624.114

Pedicle Access Kit 624.027S

Insulated Probe, 8” 675.706S

Spring Clip 675.705S

ADDITIONALLY AVAILABLE INSTRUMENTS (CONT'D)

Straight Handle, Fixed, 1/4" Quick-Connect 6067.0015

Palm Handle, Ratcheting, 1/4" Quick-Connect 6067.0030

Palm Handle, Fixed, 1/4" Quick-Connect 6067.0035

4.0mm Tap 634.213

9.5mm Solid Tap 6067.0900

10.5mm Solid Tap 6067.0100

Cross Connector Measurement Card 6067.1065

CREO® Screw Head Distractor 6120.0001

Screw Head Positioner, External, Threaded 6120.1075

Reduction Forceps, Threaded 6120.2035

SURGICAL TECHNIQUE

CREO AMP® Threaded

Please refer to the product insert (also printed at the back of this manual) for complete description, indications, contraindications, warnings, and precautions.

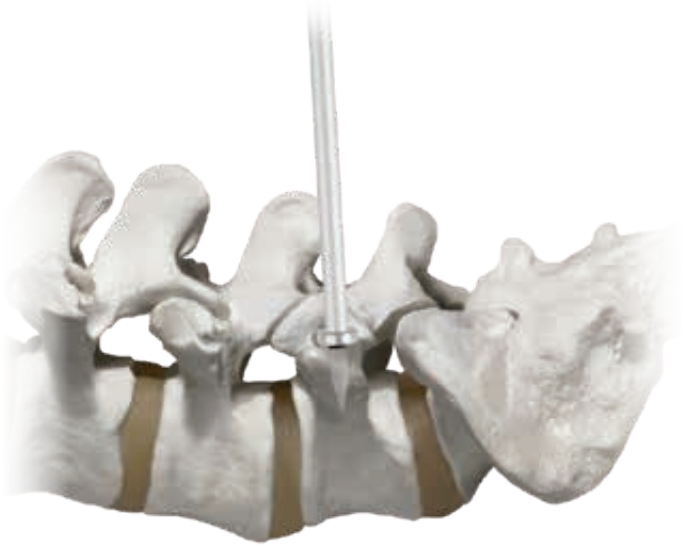
The safety and effectiveness of this device has not been established for use as part of a growing rod construct. This device is only intended to be used when definitive fusion is being performed at all instrumented levels.

STEP 1 PLANNING

Preoperative planning is recommended to estimate screw and/or hook location and sizes. Radiographic evaluations may be completed prior to surgery. There are various techniques for pedicle screw and rod insertion. For the purposes of this technique guide, a Wiltse paramedial approach and building of an L4-L5-S1 construct is shown.

STEP 2 APPROACH

The patient is placed under anesthesia and positioned prone. The operative area is carefully cleaned and an incision is made at the appropriate level(s). Lateral C-arm fluoroscopy or other radiographic methods may be used throughout surgery to ensure correct screw placement. Interbody fusion technique may be completed prior to or following screw insertion.



Preparing pedicle pathway

STEP 3 SCREW INSERTION

Pedicle Preparation

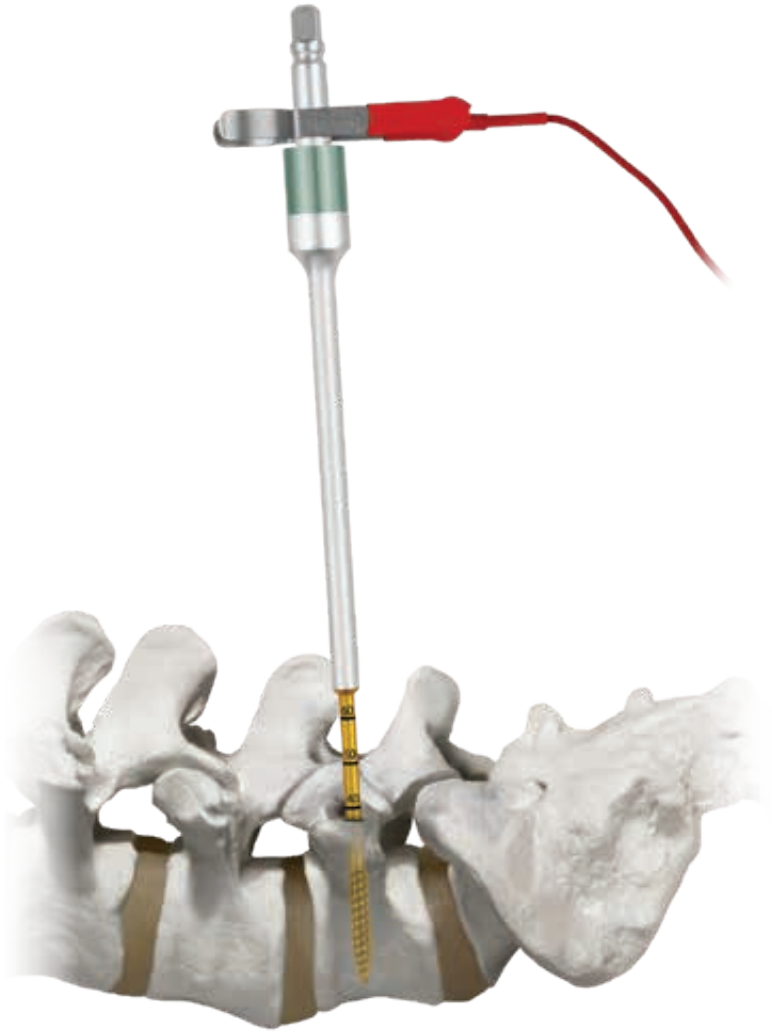
Locate the pedicles and remove bone and/or soft tissue as needed using standard instruments. Use the **Pedicle Awl** to perforate the pedicle cortex.

Use a **Pedicle Probe** to open the pedicle pathway. Demarcations every 10mm on the probe indicate the depth of the pathway and help determine proper screw length.

Use a **Ball Tipped Probe** to verify that the walls of the prepared pedicle pathway are not violated. Demarcations every 10mm on the probe indicate the depth of the pathway and can also help determine proper screw length.

Pedicle access may be monitored for neurophysiological response by attaching the **Spring Clip** on the selected taps.*

CREO AMP® Threaded pedicle screws are self-tapping; however, pedicles may be tapped if desired. Insert the **Tap** of the desired diameter into the **Straight Handle, Ratcheting, 1/4" Quick-Connect** or **T-Handle, Ratcheting, 1/4" Quick-Connect**. Tap the pedicle to the determined depth.



Using Spring Clip

*Globus Medical does not provide intraoperative neurophysiological monitoring equipment.

SCREW INSERTION (CONT'D)

Loading the Screwdriver

Select the appropriate pedicle screw diameter and length. Assemble the **Modular Screwdriver** to the Straight Handle, Ratcheting, 1/4" Quick-Connect or T-Handle, Ratcheting, 1/4" Quick-Connect.

Ensure the finger grip is pulled back towards the handle, and the knob is fully loosened. Holding the threaded portion of the selected screw straight, engage the driver tip into the screw post.

Engaging screw post

Once fully engaged, rotate the knob of the screwdriver clockwise until tight. Push the oblong button above the knob to activate the lock. The lock automatically slides distally, meeting the knob and securing the screw post to the screwdriver. The screw post is now ready for insertion.

Note: The knob may be further tightened after the lock has been activated by rotating the knob clockwise for increased rigidity. The lock prevents the screwdriver from loosening and disengaging the screw.

To disengage, grasp the lock by the finger grips on each side. Pull the lock back towards the screwdriver handle. There is an audible click as the button is released. Rotate the knob counterclockwise to loosen and disengage the screwdriver from the screw post.

Alternatively, the **Self-Retaining Driver Shaft, 1/4" Quick-Connect** attached to the Straight Handle, Ratcheting, 1/4" Quick-Connect or T-Handle, Ratcheting, 1/4" Quick-Connect may be used.

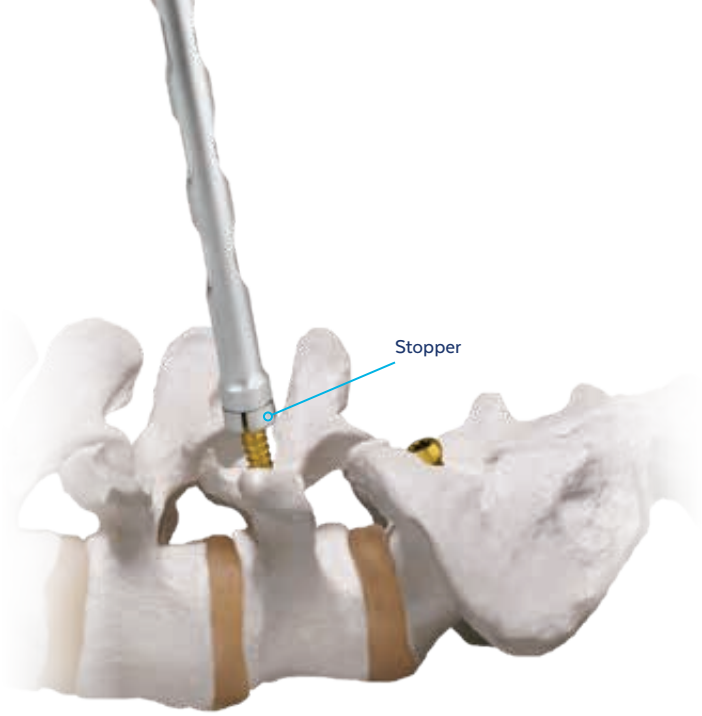
Screw loaded on screwdriver

Disengaging screw

Inserting Screw Posts

Drive the screw posts into the prepared pedicles using the Modular Rigid Driver Assembly. The driver stopper serves as an indicator that the screw is implanted to the desired depth. When complete, disengage the driver from the screw. If the screws need to be removed or repositioned, the Self-Retaining Driver Shaft, 1/4" Quick-Connect may be used.

Screw insertion into the prepared pedicle may also be neuromonitored. The Insulated Probe may be used for triggered EMG monitoring while introducing the screw into the pedicle.*



Screw insertion

STEP 4 SCREW HEAD DISTRACTION

Distraction may be achieved using the screw post heads prior to screw head application to accomodate interbody fusion procedures.

To distract the screw heads, place the feet of the **Parallel Head Distractor** over the screw posts. The hinge on the distractor handles may be adjusted to pivot away from the patient for increased visualization as needed. Compress the distractor handles to distract the screw posts.

Interbody distraction using Parallel Head Distractor

Globus Medical does not provide intraoperative neurophysiological monitoring equipment.

STEP 5 SCREW HEAD INSERTION/REMOVAL

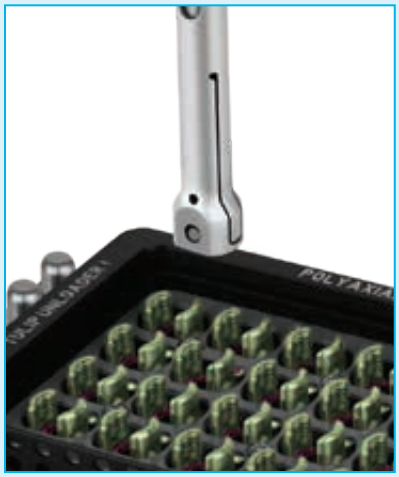
Screw Head Insertion

To ensure optimal clearance for the screw head attachment, use the **Decortication Tool, Radial Cutting, 1/4", Quick-Connect** or **Decortication Tool, 1/4" Quick-Connect** and T-handle, Ratcheting, 1/4", Quick-Connect to remove any surrounding tissue and bone that is immediately adjacent to the head of the screw post.

Using Decortication Tool

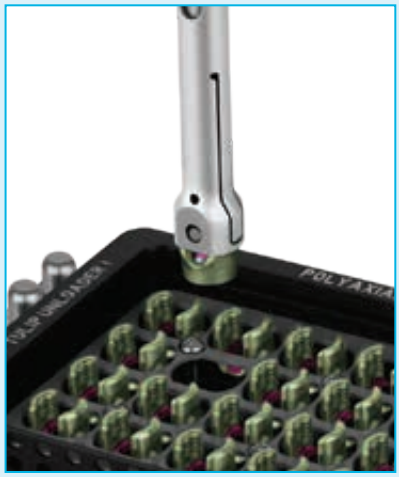
LOADING THE HEAD INSERTER

Hold the **Head Inserter, Threaded** over the screw head module. Align the flats on the inserter with the open sides of the screw head. Lower the inserter directly onto the screw head and apply light pressure. Listen for the audible click; the screw head is now attached to the inserter. Lift up without closing the handle. The inserter handle remains locked until the screw head is secured to the screw post.



Aligning inserter with screw head

Lowering inserter onto screw head



Screw head attached to inserter

CAUTION: The screw head should not be removed from the screw head module and placed on the screw post by hand. This will result in an unsecured screw assembly that will inhibit locking cap insertion.

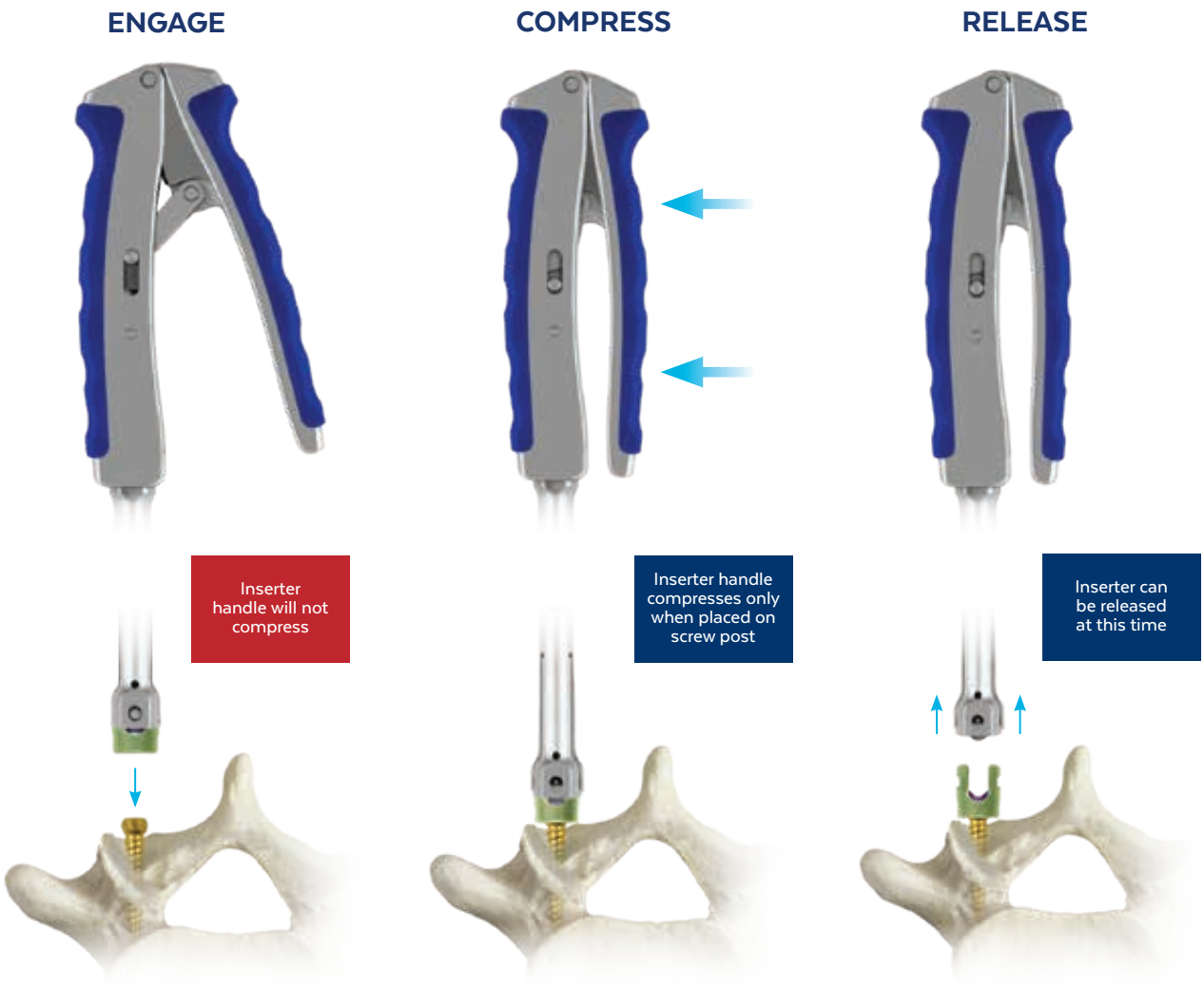
Screw Head Attachment

CAUTION: The inserter is required for screw head attachment. Failing to use the inserter may result in an unlocked screw assembly.

Hold the inserter with the screw head attached over the implanted screw post. Lower the screw head on top of the screw post and apply axial force. Listen for the audible click; the screw head is now attached to the screw post. At this point the screw head is not yet locked to the screw post.

To securely lock the screw head onto the screw post, compress the inserter handle. The screw head is now locked onto the screw post, creating an assembled screw. Release the inserter handle, pull the inserter upward, and rotate slightly to confirm the screw head is attached and has polyaxial motion. Engagement of the screw head to the screw post is confirmed through tactile feedback. The inserter does not detach at this point.

Upon confirmation, compress the inserter handle and simultaneously pull upward. This allows the inserter to release from the screw assembly for the next screw head application. Repeat the screw head insertion steps for the remaining screw posts.



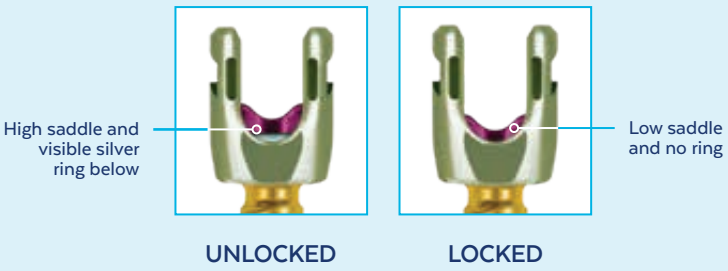
Lowering screw head to top of screw post

Screw head attached to screw post

Screw head locked to screw post; screw is fully assembled

SCREW HEAD INSERTION/REMOVAL (CONT'D)

STANDARD HEAD ATTACHMENT



Screw Head Removal (Optional)

Locked screw heads can be removed *in situ* only by using the **Head Release, Threaded**.

Insert the tip of the release into the center of the screw head by aligning the outer sleeve with the corresponding flats on the screw head. Ensure the instrument is fully seated in the screw head.

Compress the release handle, simultaneously tilting and pulling away from the screw post, to detach the screw head.

Head Release, Threaded inserted into center of screw head

Screw head detached from screw post

To detach the screw head from the Head Release, release the handle.

Note: Once a screw head has been removed from the screw post and detached from the Head Release, the screw head may be inserted onto another screw post in the existing patient only. This can only be performed up to three times by following the screw head insertion technique.

All screw heads and connectors should be inserted and locked down onto the screw posts prior to rod insertion.

EXCHANGING SCREW HEAD STYLE WITH HEAD INSERTER

If the selected screw head loaded onto the Head Inserter needs to be exchanged for a different style, the Screw Head Unloader can be used to unload or load the instrument.

Select one of the four Screw Head Unloaders, and using the inserter, press the screw head over the Screw Head Unloader until there is an audible click. Lock and release the screw head onto the Screw Head Unloader by compressing the inserter handle. Load the next implant onto the inserter as desired.

Use the Head Release to remove the screw head from the Screw Head Unloader.

Align screw head over Screw Head Unloader with Head Inserter

Press screw head over Screw Head Unloader; compress and release handle to lock screw head to Screw Head Unloader

RESETTING/UNLOADING A LOCKED SCREW HEAD

If the screw head does not attach to a screw post, it may be due to one of the following:

- The screw post may be inserted too far into the bone. Use a screwdriver to adjust the height, or clear the surrounding bone using the Decortication Tool.
- There may be tissue or other material in the way. Remove this material.
- The screw head may already be locked. This can occur if the screw head placement is attempted too far off angle or if projecting bone or tissue allows the Head Inserter handle to compress.

If the locked screw head is NOT in the inserter, DO NOT PUT IT BACK IN THE INSERTER. Use the Head Release to unlock the screw head. Once unlocked, insert the screw head into the Head Inserter. Complete screw head application and locking to a screw post with the Head Inserter.

If the screw head is IN the inserter, the Screw Head Unloader can be used to unload the instrument. With the inserter handle open, place the screw head down over the Screw Head Unloader and compress the handle to release the LOCKED screw head. Use the Head Release to unlock the screw head. Complete screw head application and lock to a screw post with the Head Inserter.

STEP 6 ROD INSERTION AND LOCKING CAP DELIVERY

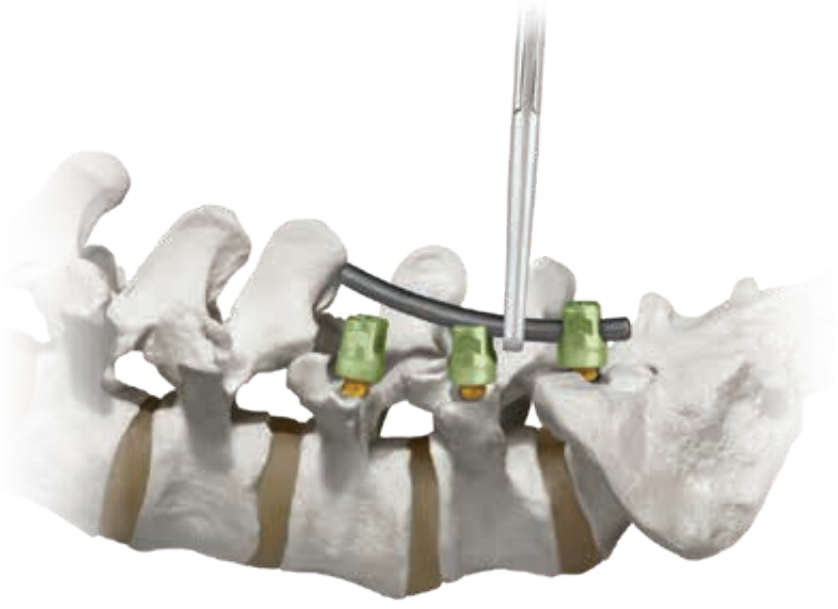
Rod Preparation

Determine the appropriate length and contour of the rod using a **Rod Template**. It is recommended to oversize the rod to allow at least 5mm of proximal and distal rod overhang after anticipated compression and distraction. Straight and curved rods are available in a variety of lengths. Alternatively, rods may be cut to length using the **Rod Cutter**. Rods may also be contoured using the **Power Bender**.

Using Rod Template

Rod Insertion

Using the **Rod Holder**, grasp the rod and insert it into the pedicle screws. Alternatively, the **Power Rod Gripper** may be used.



Rod insertion

ROD INSERTION AND LOCKING CAP DELIVERY (CONT'D)

Threaded Locking Cap Driver

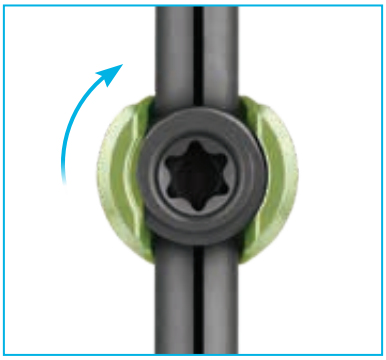
Loading the Driver

Assemble the Threaded Locking Cap Driver to the Straight Handle, Ratcheting 1/4" Quick-Connect or T-Handle, Ratcheting 1/4" Quick-Connect. Push the Threaded Locking Cap Driver down over the locking cap until it clicks. The click indicates that the locking cap is retained by the driver.

Loading driver

Locking Cap Insertion

With a loaded locking cap driver, engage the threads on the locking cap with the screw head by rotating the driver clockwise. The rod is provisionally captured when one thread of the locking cap is engaged with the screw head. The locking cap and cap driver may be used to reduce the rod into the saddle of the screw head. Remove the cap driver by pulling it straight up. The construct is not completely locked until final tightening.

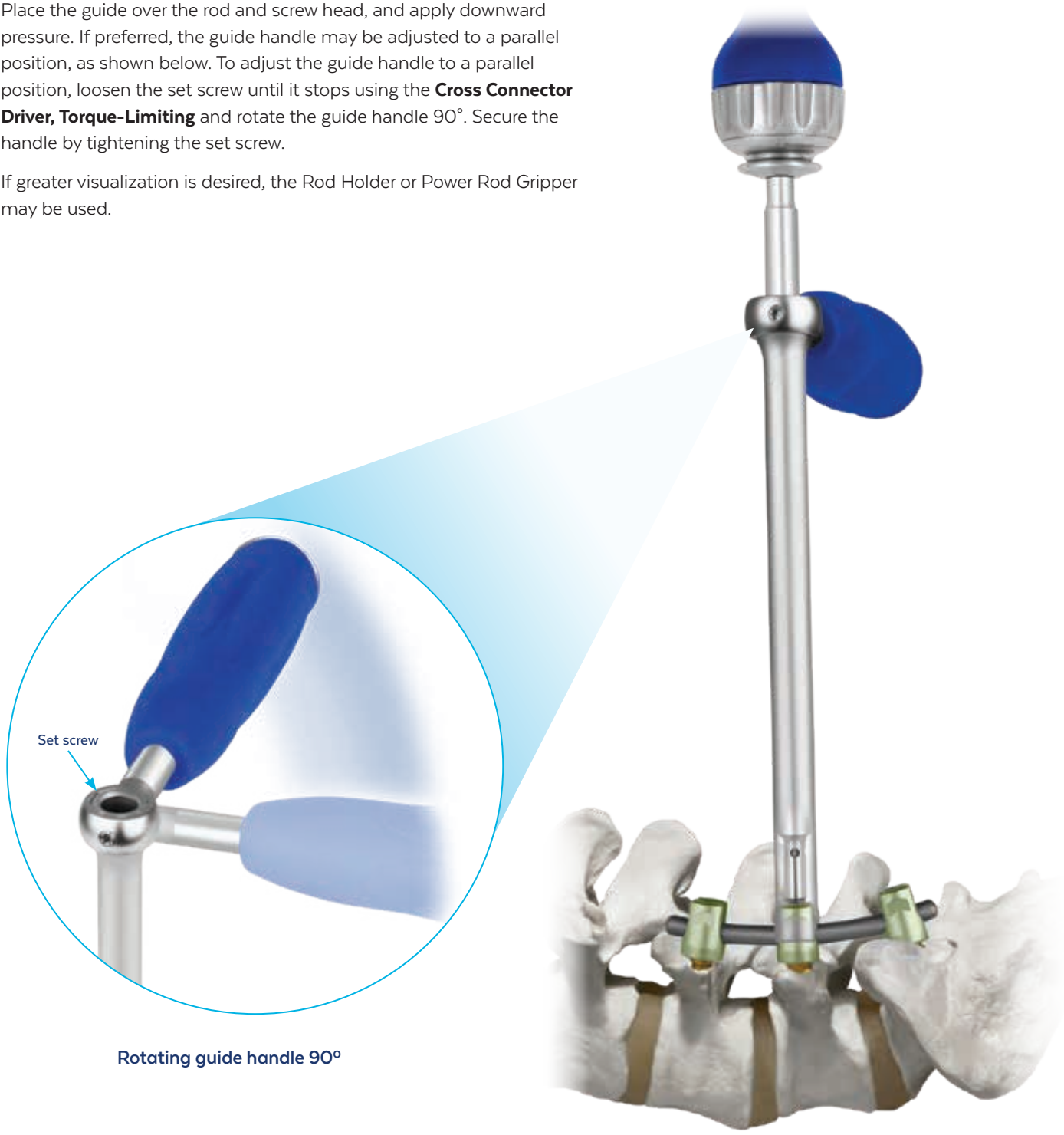


Rod provisionally captured

Locking Cap Guide

The **Locking Cap Guide, Threaded** is used to aid in small adjustments of the rod into the screw head and acts as a guide for the locking cap driver. Place the guide over the rod and screw head, and apply downward pressure. If preferred, the guide handle may be adjusted to a parallel position, as shown below. To adjust the guide handle to a parallel position, loosen the set screw until it stops using the **Cross Connector Driver, Torque-Limiting** and rotate the guide handle 90°. Secure the handle by tightening the set screw.

If greater visualization is desired, the Rod Holder or Power Rod Gripper may be used.



Rotating guide handle 90°

Locking cap insertion through Locking Cap Guide, Threaded

STEP 7 ROD REDUCTION

The CREO AMP® Threaded Stabilization System has six options for rod reduction (max reduction):

A. Locking Cap Guide, Threaded (3mm)
B. Reduction Fork, Threaded (5mm)
C. Geared Reducer, Pistol Grip, Threaded (10mm)
D. Geared Reducer, Overhead, Threaded (10mm)
E. Tower Reducer, Threaded (20mm)
F. Reduction Clip, Threaded (30mm)

The rod reduction instruments are designed to seat the rod into the screw head. Ensure that the rod is properly contoured prior to reduction.

Option A: Locking Cap Guide, Threaded

The Locking Cap Guide, Threaded may be employed for small adjustments around the rod. Place the locking cap guide over the rod and screw head and apply downward pressure.

Rod reduction using Locking Cap Guide, Threaded

Option B: Reduction Fork, Threaded

The **Reduction Fork, Threaded** may be used to maneuver the rod into position. The instrument is useful when the rod is slightly above the screw. Slide the fork into the reduction slots on the screw head. Push the rod down, sliding it into the screw head.

Rod reduction using Reduction Fork, Threaded

Option C: Geared Reducer, Pistol Grip, Threaded

The **Geared Reducer, Pistol Grip, Threaded** provides up to 10mm of reduction. Ensure the reducer is fully open; the LOAD indicator on the inner shaft aligns with the etched black ring on the outer shaft.

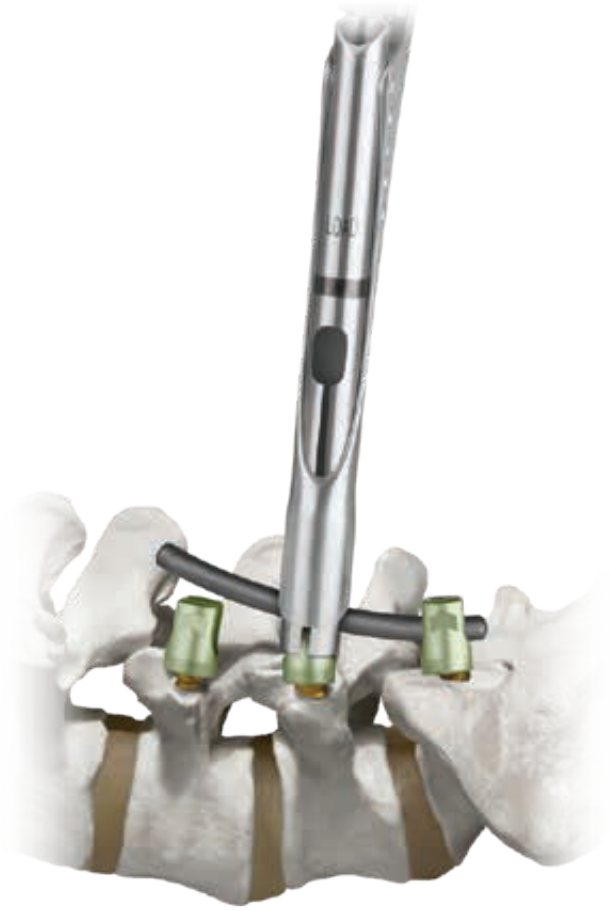
Place the reducer squarely over the screw head and press down until it is fully seated. Compress the handles to engage the screw and reduce the rod.

When fully reduced, the horizontal etching on the inner shaft aligns with the etched black ring on the outer shaft.

The locking cap driver is inserted through the reducer.

Remove the reducer by unlocking the hinged ratchet on the handle.

Rod reduction using Geared Reducer, Pistol Grip, Threaded



Rod reduction using Geared Reducer, Overhead, Threaded

Option D: Geared Reducer, Overhead, Threaded

The **Geared Reducer, Overhead, Threaded** provides up to 10mm of reduction and may be used to reduce the rod into position. Ensure the reducer is fully open; the LOAD indicator on the inner shaft aligns with the etched black ring on the outer shaft.

Place the reducer over the screw head and push down until it is fully seated. Compress the handles to engage the screws and reduce the rod.

When fully reduced, the horizontal etching on the inner shaft aligns with the etched black ring on the outer shaft.

The locking cap driver is inserted through the reducer.

Remove the reducer by unlocking the hinged ratchet on the handle.

ROD REDUCTION (CONT'D)

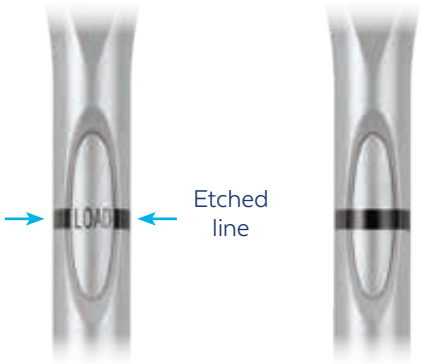
Option E: Tower Reducer, Threaded

The **Tower Reducer, Threaded** provides up to 20mm of continuous gradual reduction to reduce the rod into position.

Ensure the reducer is in the starting position by fully backing it up counterclockwise until the LOAD indicator aligns with the etched black ring. The reducer can now be attached to the screw assembly by placing the reducer squarely over the screw head and pushing down until it is completely flush with the screw head. Rotate the reducer handle clockwise and continue until the horizontal etching aligns with the ring on the outer sleeve of the instrument.

For added leverage, use the **Tower Reducer Attachment, Threaded, 1/4" Quick-Connect** to rotate the handle. Insert the loaded locking cap driver into the reducer. Rotate the locking cap clockwise to engage the locking cap.

Remove the driver and reducer by rotating counterclockwise until back in the LOAD position.



LOAD position **Fully reduced**

Rod reduction using Tower Reducer, Threaded with optional tower reducer attachment

Option F: Reduction Clip, Threaded

The **Reduction Clip, Threaded** allows up to 30mm of continuous gradual reduction to reduce the rod into the screw head.

Press the clip onto the screw head and secure by rotating the knurled knob clockwise one full rotation. Attach the T-Handle, Ratcheting, 1/4" Quick-Connect and insert the **Reduction Clip Driver** into the hex on the inner shaft of the clip. Rotate the T-handle clockwise until the rod is fully reduced into the screw head, and the threads on the inner shaft of the clip are no longer visible.

Remove the Reduction Clip Driver. Insert a loaded Threaded Locking Cap Driver through the Reduction Clip, Threaded and rotate the locking cap clockwise to engage the locking cap and secure the rod.

Remove the Reduction Clip, Threaded by rotating the inner shaft counterclockwise until it is fully unthreaded.

Rod reduction using Reduction Clip, Threaded with Reduction Clip Driver

STEP 8 DEFORMITY CORRECTION

Global Derotation

Global derotation maneuvers are used to translate a coronal plane deformity into the naturally curved sagittal plane by rotating the rod 90° in the construct.

The rod is contoured to the proper sagittal alignment and positioned into the implants. After the rod is positioned in the implants and the locking caps are inserted, but not final tightened, the rod is rotated into its final position.

To rotate the rod, two Power Rod Grippers or **Vise-Style Rod Grips** are used. Position the rod grips at the desired locations and rotate the rod. Derotation should be performed gradually to avoid neurological injury and maintain proper rod placement.

Alternatively, the **Rod Wrench** may be used to aid in rod rotation.

Derotation with Power Rod Grippers

It is important to monitor the position of the hooks during the derotation process to verify that they are not displaced. Once the rod is rotated into its final position, the locking caps are provisionally tightened to maintain rod positioning.

After the first rod is secured in its final position, compression and/or distraction may be performed. A second rod is inserted to stabilize the construct. Further compression and/or distraction may be performed if necessary. Verify the hook positions and make necessary adjustments, then final tighten the locking caps to completely lock the rod.

DEFORMITY CORRECTION (CONT'D)

In Situ Bending

In situ rod bending may be accomplished using ***In Situ* Benders** or **Coronal Plane Benders**. Rod bending may be performed after the rod is fully seated into the implants and locking caps are provisionally tightened.

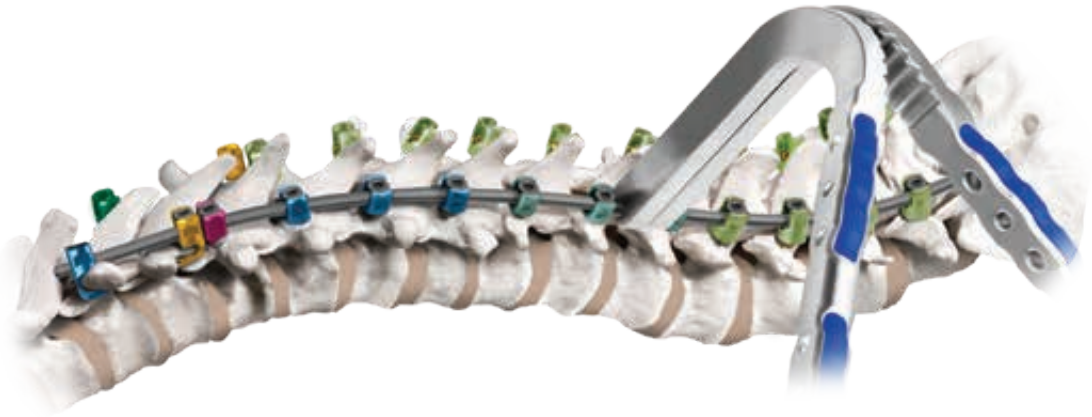
Note: In Situ *and Coronal Plane Benders are powerful instruments; carefully perform bending and ensure that implant fixation is not disrupted.*

In Situ Rod Bending

In Situ Benders are used to make corrections to the rod curvature in the sagittal plane. Rod bending is accomplished with two benders (left and right), positioned close to one another. Bend the rod in small increments so as not to cause damage. Once rod bending is complete, compression or distraction may be performed.

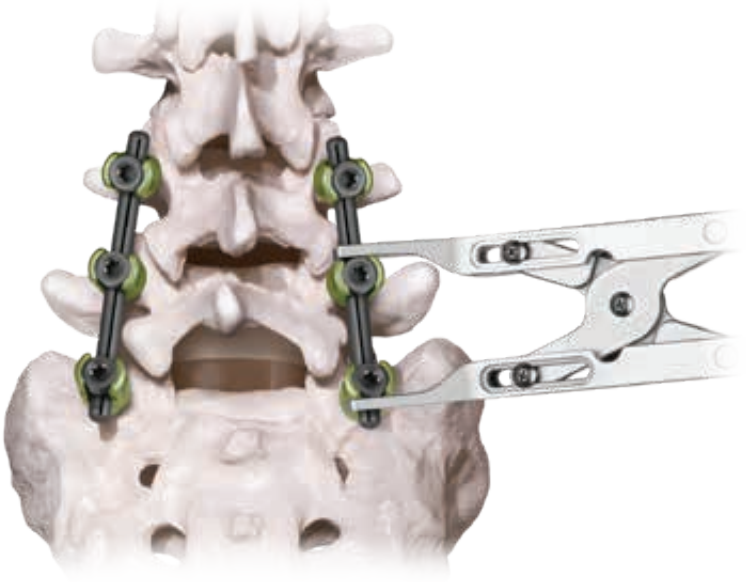
Using Coronal Plane Benders

The Coronal Plane Benders are used to make corrections to the rod curvature in the coronal plane. Rod bending is accomplished with two benders (left and right), positioned close to one another. Position the benders so the grooves on the inside of the left bender engage the grooves on the inside of the right bender. Bend the rod in small increments to avoid damage to the rod. Once rod bending is complete, compression or distraction may be performed.

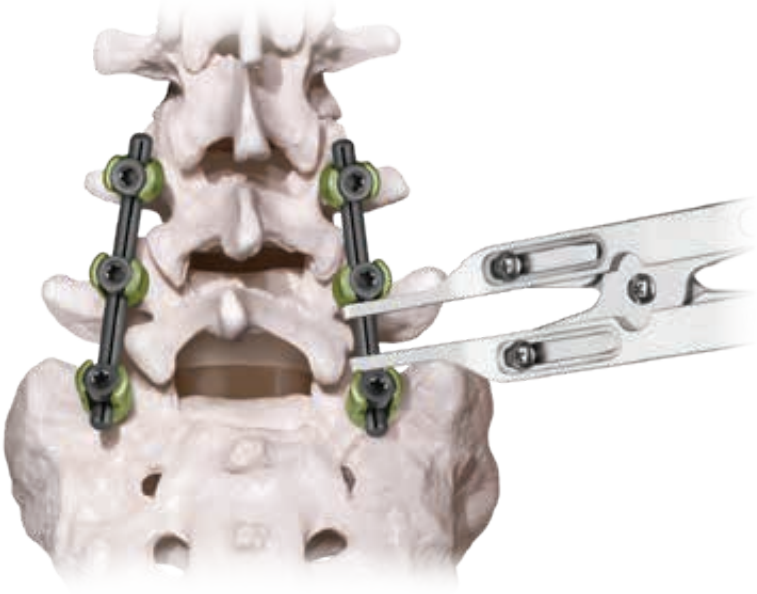


STEP 9 COMPRESSION OR DISTRACTION

CREO AMP® Threaded pedicle screws may be compressed or distracted along the rod as necessary using the **Parallel Compressor, Threaded** or **Parallel Distractor, Threaded**, respectively. Tighten one of the locking caps to establish a rigid point for compression or distraction. Once compression or distraction is completed, provisionally tighten the locking caps using the **Torque-Limiting T-Handle, Ratcheting, 1/4" Connect** and **Driver Shaft, 1/4" Quick-Connect, Short**. If remobilization of the screw head is required, refer to page 56.

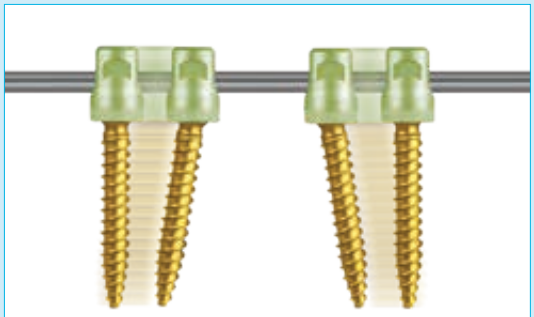


Compression



Distraction

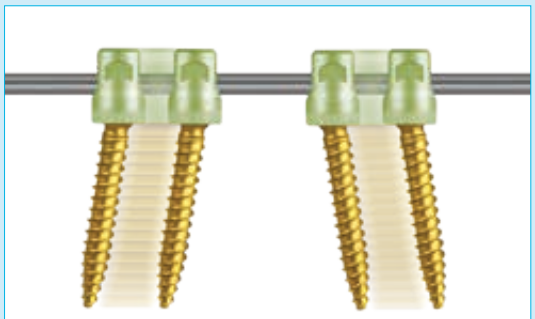
Free Angulation



Compression with free angulation

For free angulation, compress or distract screws after locking cap insertion.

Locked Angulation



Compression with locked angulation

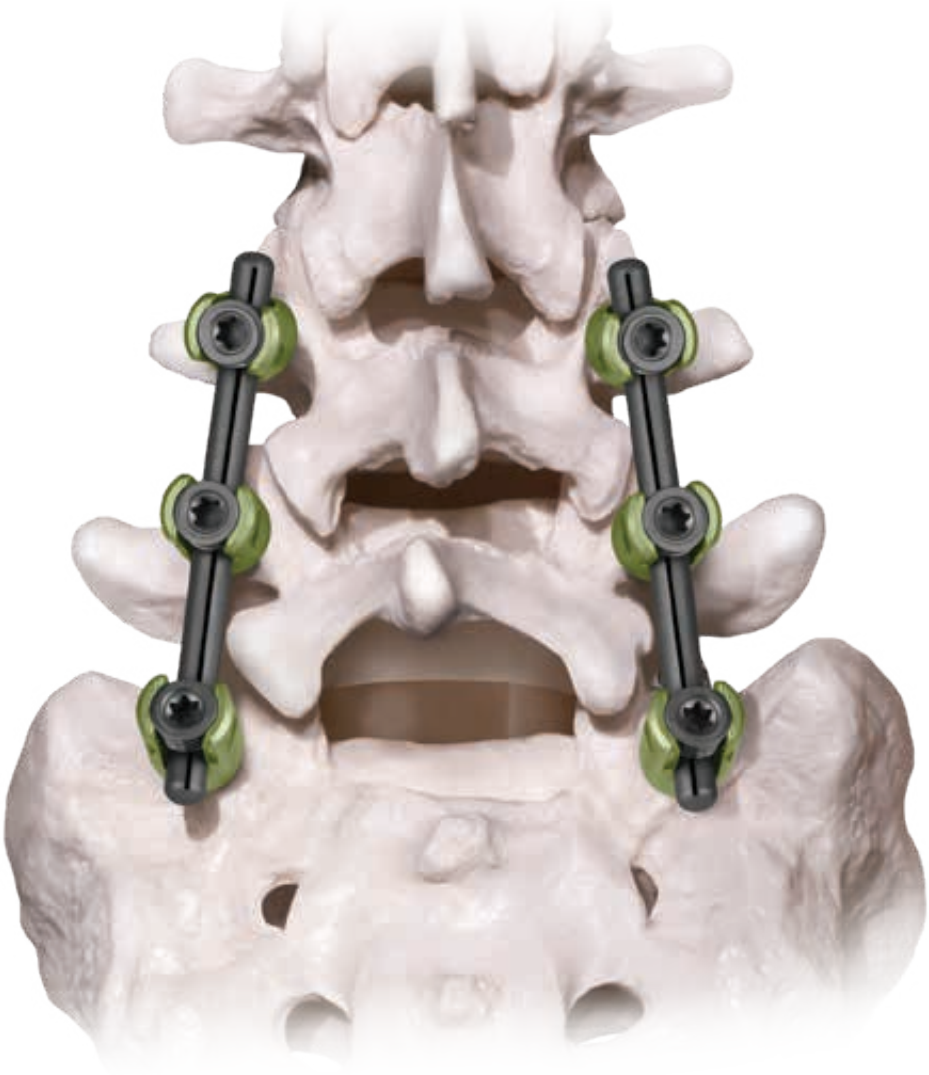
To lock the angulation of the screw and obtain parallel distraction, provisionally tighten the set screw(s) using the Torque-Limiting T-Handle, Ratcheting, 1/4" Connect and Driver Shaft, 1/4" Quick-Connect, Short. Loosen at least one set screw by approximately one full rotation to allow the screw to slide along the rod without changing the polyaxial feature. Compress or distract the screws. Proceed to final tightening.

STEP 10 FINAL TIGHTENING

Final tightening of the locking caps is necessary to secure the construct and is accomplished using the Torque-Limiting T-Handle, Ratcheting, 1/4" Connect and Driver Shaft, 1/4" Quick-Connect, Short, with the **Counter-Torque, Threaded**.

Attach the torque-limiting handle to the driver shaft. Insert the driver assembly into the counter-torque and visually confirm the driver tip is fully engaged in the locking cap. Slide the counter-torque over the screw head, ensuring it is fully seated. Rotate the driver assembly until it reaches the torque limit (8Nm) and then rotate to two audible clicks. Repeat for all locking caps. Ensure that all locking caps are final tightened after corrective maneuvers are complete.

FINAL CONSTRUCT



Final CREO AMP® Threaded construct

OPTIONAL TECHNIQUE: CROSS CONNECTOR

Cross Connector Insertion

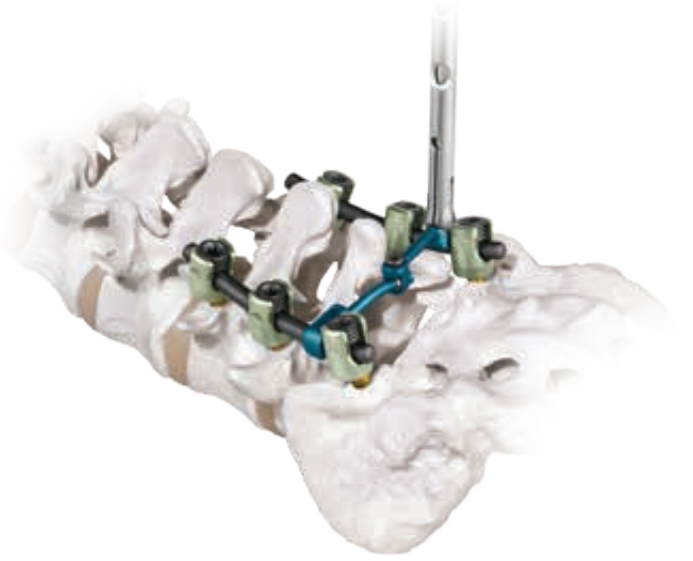
To enhance construct stability, a cross connector may be used as a transverse connector between two rods.

The **Cross Connector Caliper** may be used to estimate the distance between two rods, as shown below. Place the caliper between the rods at the desired level. Read the cross connector length from the caliper handle.

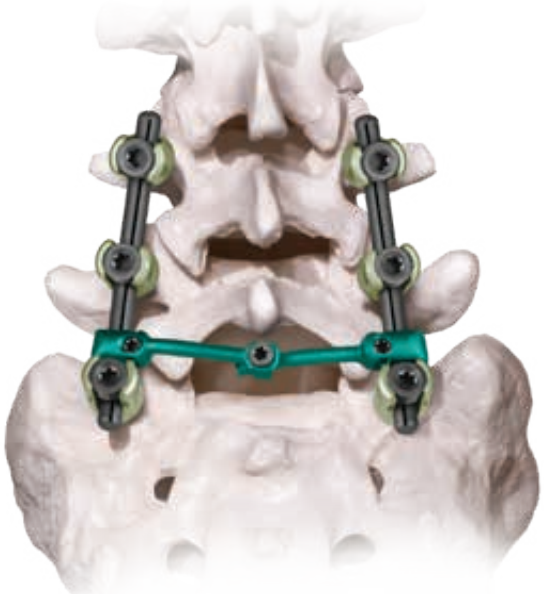
Use the **Cross Connector Inserter** to grasp the desired connector. The inserter engages with the slots on either side of the connector. Position the connector between two rods and provisionally tighten the set screws on each side of the cross connector using the Cross Connector Driver, Torque-Limiting. Adjust the connector position and tighten the center screw. Final tighten the set screws bearing on the rods, using the same driver.

Using Cross Connector Caliper

Reading length measurement



Inserting Cross Connector



Final CREO AMP® Threaded Construct with Cross Connector

OPTIONAL TECHNIQUE: SACRAL PLATE

The CREO® Sacral Plate is designed for screw placement at S1 and the ala.

Locate the sacral pedicle and remove bone and/or soft tissue as needed using the standard preparation instruments. Temporarily place the sacral plate over the sacral pedicle to ensure rod alignment and bony purchase for the ala screw.

Using the Pedicle Awl or burr, perforate the pedicle cortex.

Use the Pedicle Probe to open the pathway. Demarcations every 10mm indicate the depth of the pathway to determine the proper screw length. Use the Ball Tip Probe to verify that the walls of the pedicle pathway are not violated.

Note: The chamfer on the caudal end of the sacral plate aims laterally towards the ala.

Attach the Straight Handle, Ratcheting, 1/4" Quick-Connect to the **Sacral Plate Holder**.

Unlock the holder by lifting the lever toward the proximal end of the plate holder.

Lower the holder onto the head of the sacral plate. Once fully engaged, lift the lever toward the distal end of the holder. The sacral plate is now secured to the holder and ready for use.

Slide the S1 end of the sacral plate over the Ball Tipped Probe shaft. Lower to S1 to position the plate for rod alignment and ala hole location. Press the assembly down to engage the spike into the bone.

Using the pedicle preparation instruments, the ala hole may be created through the plate or after the placement of the S1 screw to ensure that the rod saddle remains aligned with the superior pedicle screws.

Using Pedicle Awl

Using Ball Tip Probe

Sliding S1 end of plate over Ball Tip Probe shaft

OPTIONAL TECHNIQUE: SACRAL PLATE (CONT'D)

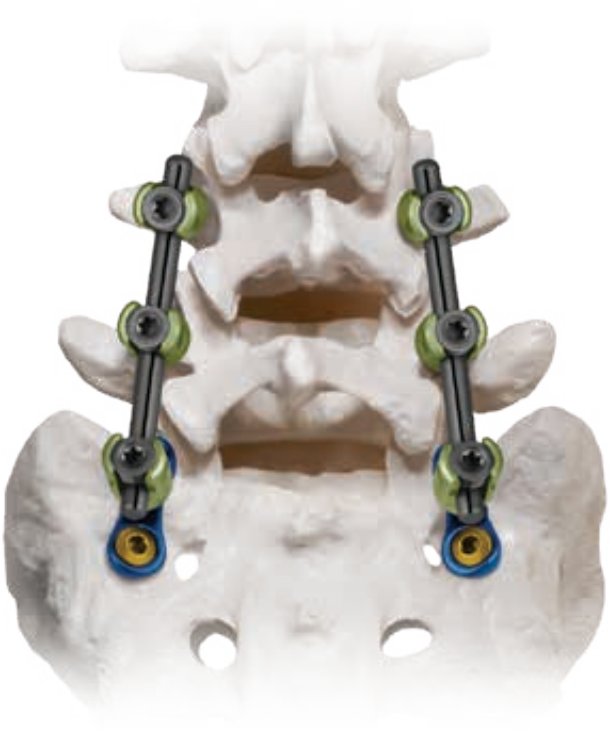
Select the appropriate bone screw and insert the screw through the sacral plate using the **3.5mm Hex Screwdriver, Self-Retaining, 1/4" Connection, Shaft** until the plate is secure. Insert the cephalad/S1 screw first, then repeat for the ala screw.

Note: Bone screws are available in standard and Dual Outer Diameter (DOD) thread styles; DOD screws are specifically designed to aid S1 fixation aimed medially.

To disengage the holder, lift the lever toward the proximal end of the Sacral Plate Holder. Disengage the holder from the plate. Secure a screw head to the head of the sacral plate for rod insertion.

Inserting S1 bone screw

Inserting ala bone screw



Final CREO AMP® Threaded Construct with sacral plates

Securing screw head to sacral plate

OPTIONAL TECHNIQUE: THREADED HOOKS

Preparing the Pedicle for Hook Placement

The **Pedicle Finder** is used to prepare the pedicle for hook placement. Use the finder to open the facet capsule and locate the pedicle. If necessary, a portion of the inferior facet process may be removed to aid in pedicle hook insertion.

Using Pedicle Finder

Preparing the Lamina

The **Lamina Finder** may be used to separate the ligamentous attachment between the transverse process and posterior arch of the rib, medial to the rib-transverse joint. The finder may also be used to locate and prepare the transverse process.

Using Lamina Finder

OPTIONAL TECHNIQUE: THREADED HOOKS (CONT'D)

Pedicle Hook Placement

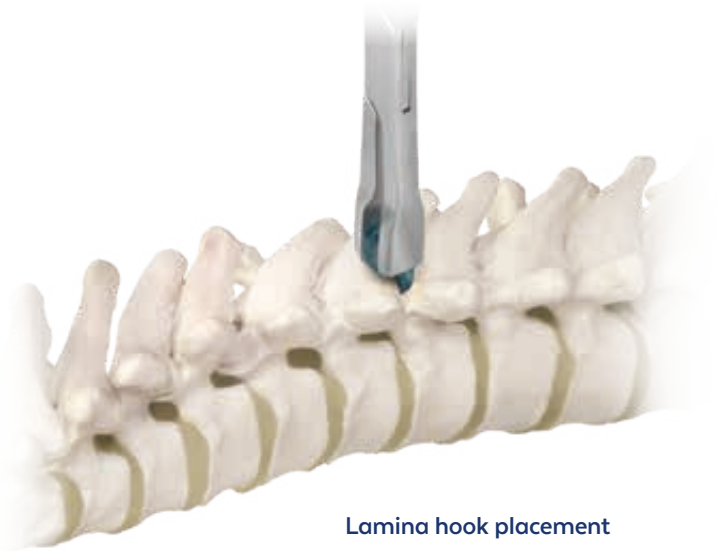
A pedicle hook is typically used at the T10 level and above. The hook blade is placed up-going and sits flush against the facet and pedicle. Once the pedicle is clearly identified, the appropriate hook is inserted using the **Hook Holder, Threaded**. Insert the hook into the holder and place in the desired position.

Alternatively, the **Lateral Hook Holder, Threaded** or the **Offset Hook Holder, Threaded** may be used to insert pedicle hooks.

Pedicle hook placement using Hook Holder, Threaded

Lamina Hook Placement

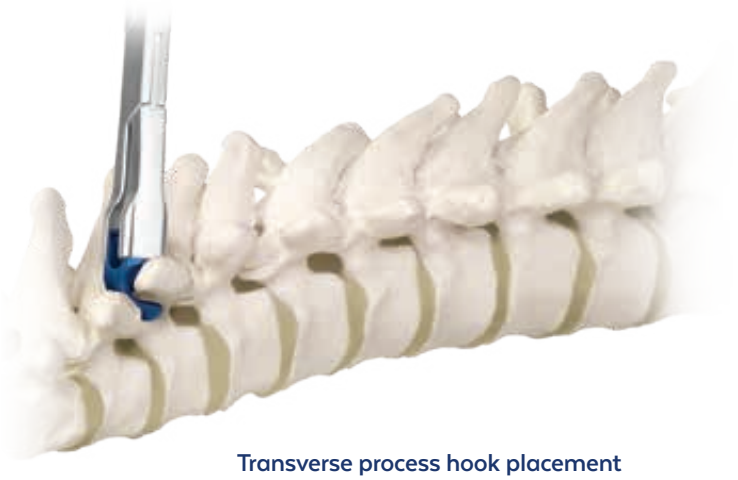
A lamina hook may be up-going or down-going. In the thoracic spine, lamina hooks may be used independently as down-going hooks or in conjunction with an up-going lamina or pedicle hook to form a claw construct. In the lumbar spine, lamina hooks may be used independently as up-going hooks. Alternatively, lamina hooks may be used in conjunction with a transverse process or down-going lamina hook to form a claw construct.



Lamina hook placement

Transverse Process Hook Placement

A transverse process hook is usually placed down-going. Typically it is used at the top of a construct. Transverse process hooks may be used with an up-going pedicle hook to form a claw construct, either at the same level or one level superior. Insert the appropriate transverse process hook into the Hook Holder and place the hook in the desired location. Use the **Hook Positioner, Threaded** to seat the hook. Repeat hook insertion for each desired location.



Transverse process hook placement

THREADED HOOK PLACEMENT INSTRUMENTS

Note: Hook position should be checked frequently to ensure that the hooks remain in the correct position throughout the procedure.

The CREO AMP® Threaded Stabilization System has several instruments to aid in hook placement. The hook holder and the offset hook holder engage into the reduction slots on the side of the implant. The hook positioner may be used with the standard hook holder to facilitate hook insertion.

The offset hook holder allows for introduction of a cap without disengaging the holder.

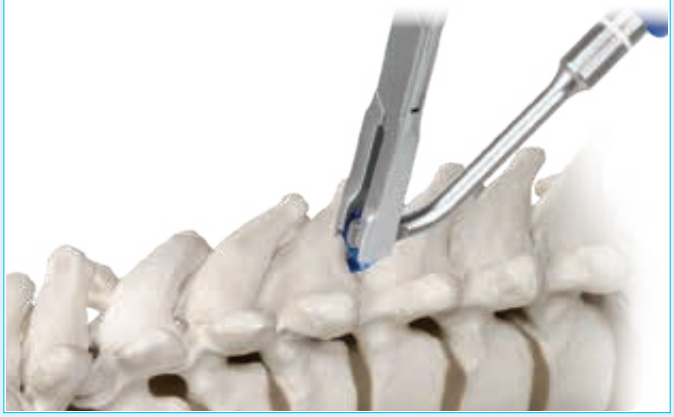
Alternatively, the lateral hook holder may be used for insertion. This holder engages into the slots on the cephalad and caudal sides of the hook and allows for introduction of the rod and cap without disengaging the holder.

A hook positioner may be used to aid in inserting and positioning the hooks, as shown at right.

Hook Holder, Threaded

Offset Hook Holder, Threaded

Lateral Hook Holder, Threaded



OPTIONAL TECHNIQUE: LAMINA CLAMP

CREO® Lamina Clamp

The CREO® Lamina Clamp may be used as an alternative to a claw construct, and is available for a low profile one-level construct or two-level construct.

Trial along the lamina with the assembly in order to determine the appropriate size clamp and rod. The Lamina Finder may be used to separate the ligamentous attachment between the transverse process and posterior arch of the rib, medial to the rib-transverse joint. The finder may also be used to locate and prepare the transverse process.

Insert the female clamp under the inferior portion of the lamina and impact the proximal end of the **Lamina Clamp Inserter** to ensure the clamp is properly seated. Insert the rod portion of the male clamp into the mating hole of the female clamp. Position the male clamp onto the superior portion of the lamina or the transverse process.

Tighten the set screw using the Cross Connector Driver, Torque-Limiting.

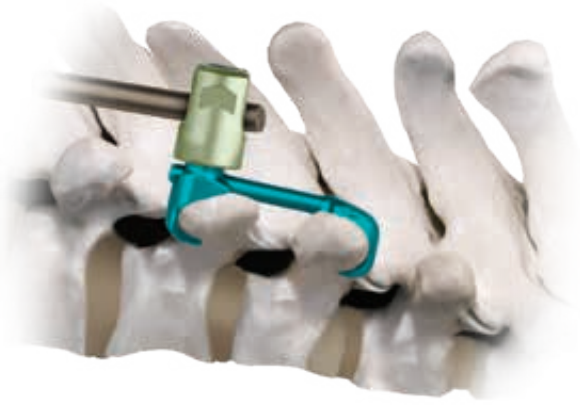
Secure a screw head to the head of the lamina clamp for rod insertion.

Note: Refer to step 5 for screw head insertion technique.

Trialing implant

Inserting female clamp

Inserting male clamp on superior lamina



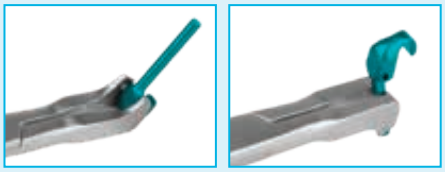
Final construct

LOADING THE LAMINA CLAMP INSTRUMENTS

The Lamina Clamp Inserter engages the head of the female clamp.

The Lamina Clamp Holder engages into the oval slots on the side of the male clamp.

Lamina Clamp Inserter engaged with female clamp



Lamina Clamp Holder engaged with male clamp

OPTIONAL TECHNIQUE: ILIAC SCREWS AND OFFSET CONNECTORS

Iliac Screws

Iliac screws may be used to extend fixation to the pelvis.

Iliac Preparation

Expose the posterior superior iliac spine. Locate the entry point of the iliac screw in the pelvis. Decorticate the entry point with a Pedicle Awl or a bur.

Use a Pedicle Probe to open the screw pathway. Demarcations every 10mm on the probe indicate the depth of the pathway and help determine proper screw length. Use a Ball Tip Probe to verify that the walls of the prepared screw pathway are not violated.

CREO AMP® Threaded pedicle screws are self-tapping; however, pedicles may be tapped if desired. Insert the Tap of the desired diameter into the Straight Handle, Ratcheting or T-Handle, Ratcheting. Tap the pedicle to the determined depth.

Lateral C-arm fluoroscopy or other radiographic methods can be utilized throughout surgery to ensure correct screw placement.

Screw Insertion

Select the appropriate screw diameter and length. Assemble the Modular Screwdriver to the Straight Handle, Ratcheting, 1/4" Quick-Connect or T-Handle, Ratcheting, 1/4" Quick-Connect.

Insert the desired iliac screw into the iliac crest.

Screw insertion

Connector Insertion

Offset Connectors may be used to connect a laterally or medially offset screw head to a rod.

Select the appropriate length of the offset connector and insert it into the screw head using the Rod Holder or Rod Gripper.

Stabilize the offset connector by inserting a locking cap in the offset screw head and provisionally tighten the set screw.

Insertion of Head Offset Connector into screw

OPTIONAL TECHNIQUE: REVISION/REMOVAL

Remove the locking cap by loosening it using the Self-Retaining Driver Shaft. After the locking cap is removed, grasp the rod and remove. The screw head may be removed from the screw post using the Head Release, refer to page 33 for additional details. Remove all screws using the Self-Retaining Driver Shaft. T-connectors and other connectors may remain connected on the rods during removal, or may be removed separately.

OPTIONAL TECHNIQUE: CROSS CONNECTOR REMOVAL

For removal, reverse the insertion steps. Loosen the center screw and the set screws on each side of the cross connector using the Cross Connector Driver, Torque-Limiting. Use the Cross Connector Inserter to grasp and remove the connector.

OPTIONAL TECHNIQUE: REMOBILIZATION

The screw head may be remobilized if the drive feature in the screw is not accessible due to the angle of the screw head. To remobilize the screw head, place the Adjustable Counter-Torque, Short over the screw head, apply downward pressure, and rotate in a circular arc.

OPTIONAL TECHNIQUE: DEROTATION

For detailed instructions on derotation, refer to the **CREO® Derotation Technique Guide (GMTGD157)**.

AVAILABLE SETS

Please refer to the **CREO AMP® Threaded Set List Supplement (GMTGD124)** for a complete description of each instrument or implant set.

IMPORTANT INFORMATION ON CREO® STABILIZATION SYSTEM

DESCRIPTION

The CREO® Stabilization System consists of rods, hooks, monoaxial screws, uniplanar screws, polyaxial screws, reduction screws, fenestrated screws, awl tip screws, locking caps, t-connectors, head offset connectors, trans-iliac connectors, staples, and associated manual surgical instruments. Implants are available in a variety of sizes to accommodate individual patient anatomy. CREO® implants mate with 4.75mm, 5.5mm, and 6.35mm diameter rods. In addition, CREO® 5.5 Threaded screws and locking caps mate with 6.0mm diameter rods. CREO NXT™ and CREO® Preferred Angle implants mate with 5.5mm and 6.0mm rods. CREO DLX™ implants mate with 6.0 and 6.35mm rods. Implant components can be rigidly locked into a variety of configurations for the individual patient and surgical condition. Polyaxial screws, hooks, and t-connectors are intended for posterior use only. Staples are intended for anterior use only. Rods and monoaxial screws may be used anteriorly or posteriorly. Locking caps are used to connect screws or hooks to the rod and trans iliac connectors.

The most common use of this screw, hook, and rod system in the posterior thoracolumbar and sacral spine is two rods, each positioned and attached lateral to the spinous process via pedicle screws and/or lamina, pedicle or transverse process hooks.

The most common use of this screw, hook, and rod system in the anterior thoracolumbar spine is one rod, positioned and attached to the vertebral bodies via monoaxial screws through an appropriate size staple.

Screws and hooks attach to the rods using a locking cap with an inner set screw, or a threaded locking cap. The size and number of screws are dependent on the length and location of the rod. Screws are inserted into a pedicle of the thoracolumbar and/or sacral spine. Screws may be used with a staple. The type and number of hooks are also dependent on the location in the spine needing correction and/or stabilization. Hooks are attached to the laminae, pedicles, or transverse process of the posterior spine.

T-connectors are modular components designed to connect the two rods of a construct and act as a structural cross member. The rod-clamping set screws secure the t-connectors to the rods. Additional set screws secure the adjustable cross members at the desired length. Additional connectors may be used to connect two rods, and are also secured using set screws.

CREO® implants are composed of titanium alloy, cobalt chromium molybdenum alloy, or stainless steel, as specified in ASTM F136, F1295, F1472, F1537 and F138. Rods are also available in commercially pure titanium, as specified in ASTM F67. Screws are also available with hydroxyapatite (HA) coating per ASTM F1185. Due to the risk of galvanic corrosion following implantation, stainless steel implants should not be connected to titanium, titanium alloy, or cobalt chromium-molybdenum alloy implants.

The CREO® System includes manual surgical instruments manufactured from stainless steel, as specified in ASTM F899. Navigation Instruments are nonsterile, reusable instruments that can be operated manually or under power using a power drill such as POWEREASE™, that are intended to be used with the Medtronic StealthStation® System.

CREO ONE™ Robotic Screws are used with ExcelsiusGPS®, Medtronic StealthStation®, or without navigation or guidance assistance. CREO ONE™ Robotic Screws should not be used with any other third-party robotic or navigation system.

INDICATIONS

The CREO® Stabilization System implants are non-cervical spinal fixation devices intended for posterior pedicle screw fixation (T1-S2/ilium), posterior hook fixation (T1-L5), or anterolateral fixation (T8-L5). Pedicle screw fixation is indicated for skeletally mature patients (including small stature) and for pediatric patients. These devices are indicated as an adjunct to fusion for the following indications: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis, Scheuermann's Disease), tumor, stenosis, and failed previous fusion (pseudoarthrosis). When used as an adjunct to fusion, the CREO® Stabilization System is intended to be used with autograft and/or allograft.

In addition, the CREO® Stabilization System is intended for treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft, having implants attached to the lumbosacral spine and/or ilium with removal of the implants after attainment of a solid fusion. Levels of pedicle screw fixation for these patients are L3-sacrum/ilium.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the CREO® Stabilization System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The CREO® Stabilization System is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

In order to achieve additional levels of fixation, the CREO® Stabilization System rods may be connected to the REVERE® Stabilization System (4.5mm, 5.5mm, or 6.35mm rod) or ELLIPSE® Occipito-Cervico-Thoracic Spinal System (3.5mm rod) using corresponding connectors. Refer to the REVERE®, or ELLIPSE® system package insert for instructions and indications of use.

In-Line Connector Growing Rods are indicated in patients under 10 years of age with potential for additional spine growth who require surgical treatment to obtain and maintain correction of severe, progressive, life-threatening, early onset spinal deformities associated with thoracic insufficiency, including early onset scoliosis, as part of a growing rod construct.

Globus Navigation Instruments are intended to be used during the preparation and placement of CREO® screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. These instruments are designed for use with the Medtronic StealthStation® System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a skull, a long bone, or vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

When used for posterior fixation in conjunction with FORTRESS® or FORTRESS-Plus® bone cement, the CREO® Fenestrated Screw System is intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the thoracic and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion. CREO® Fenestrated screws augmented with FORTRESS™ and FORTRESS-Plus™ bone cements are for use at spinal levels where the structural integrity of the spine is not severely compromised.

WARNINGS

The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to degenerative disc disease, degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.

One of the potential risks identified with this system is death. Other potential risks which may require additional surgery, include:

- device component fracture,
- loss of fixation,
- non-union,
- fracture of the vertebrae,
- neurological injury, and
- vascular or visceral injury.

Potential risks when used with bone cement include:

- Hypersensitivity reactions in susceptible persons resulting in anaphylactic response
- Tissue damage, nerve, or circulatory problems caused by cement leakage
- Micromotion of cement against bone surface caused by inadequate fixation

Cement leakage may cause tissue damage, nerve or circulatory problems, and other serious adverse events. These risks may increase with the number of spinal levels where bone cement is utilized, and also with the volume of bone cement used.

Serious adverse events, some with fatal outcome, associated with the use of acrylic bone cements in the spine include myocardial infarction, cardiac arrest, cerebrovascular accident, pulmonary embolism, and cardiac

IMPORTANT INFORMATION ON CREO® STABILIZATION SYSTEM

embolism. Although the majority of these adverse events present early within the post-operative period, there have been some reports of diagnoses beyond a year or more after the procedure.

Other reported adverse events for acrylic bone cements intended for use in the spine include leakage of the bone cement beyond the site of its intended application with introduction into the vascular system resulting in embolism of the lung and/or heart or other clinical sequelae.

If bone cement is seen outside of the vertebral body or in the circulatory system during cement augmentation immediately stop the injection.

There is no clinical data regarding the use of bone cement in pregnant or lactating women.

Strict adherence to the surgical technique guide is strongly recommended.

Cement augmentation is not intended for use in screws placed bicortically.

Components of this system should not be used with components of any other manufacturer.

The components of this system are manufactured from titanium alloy, pure titanium, stainless steel and cobalt chromium-molybdenum alloy. Mixing of stainless steel implant components with different materials is not recommended for metallurgical, mechanical and functional reasons.

ADDITIONAL WARNINGS FOR PEDIATRIC PATIENTS

The use of pedicle screw fixation in the pediatric population may present additional risks when patients are of smaller stature and skeletally immature. Pediatric patients may have smaller spinal structures (pedicle diameter or length) that may preclude the use of pedicle screws or increase the risk of pedicle screw malpositioning and neurological or vascular injury. Patients not skeletally mature that undergo spinal fusion procedures may have reduced longitudinal spinal growth, or may be at risk for rotational spinal deformities ("crankshaft phenomenon") due to continued differential growth of the anterior spine.

Pediatric patients may be at increased risk for device-related injury because of their smaller stature.

PRECAUTIONS

The implantation of screw, hook and rod systems should be performed only by experienced spinal surgeons with specific training in the use of this system because this is a technically demanding procedure presenting a risk of serious injury to the patient. Preoperative planning and patient anatomy should be considered when selecting screw diameter and length, and hook size.

The CREO® Stabilization System includes 4.75 implants intended for use with a 4.75mm rod, 5.5 implants intended for use with a 5.5mm rod, and 6.35 implants intended for use with a 6.35mm rod. CREO® 5.5 Threaded screws and locking caps are also intended for use with a 6.0mm rod. CREO NXT™ and CREO® Preferred Angle implants are intended for use with 5.5mm and 6.0mm rods and CREO DLX™ implants are intended for use with 6.0mm and 6.35mm rods.

Surgical implants are SINGLE USE ONLY and must never be reused. An explanted implant must never be reimplanted. Even though the device appears undamaged, it may have small defects and internal stress patterns which could lead to breakage.

Based on fatigue testing results, when using the CREO® Stabilization System, the surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact on the performance of this system.

When performing cement augmentation, confirm that the pedicle length is sufficient for the most posterior screw fenestration to be located within the vertebral body.

ADDITIONAL PRECAUTIONS FOR PEDIATRIC PATIENTS

The implanting surgeon should consider carefully the size and type of implants most suitable for the pediatric patient's age, size, weight and skeletal maturity.

Since pediatric patients may have additional growth potential following implant surgery, the likelihood of a subsequent removal and/or revision surgery is greater than in adult patients.

MRI SAFETY INFORMATION

CREO® has not been evaluated for safety and compatibility in the MR environment. CREO® has not been tested for heating, migration, or image artifact in the MR environment. The safety of CREO® in the MR environment is unknown. Scanning a patient who has these devices may result in patient injury.

CONTRAINDICATIONS

Certain degenerative diseases or underlying physiological conditions such as diabetes or rheumatoid arthritis may alter the healing process, thereby increasing the risk of implant breakage.

Mental or physical impairment which compromises a patient's ability to comply with necessary limitations or precautions may place that patient at a particular risk during postoperative rehabilitation.

Factors such as the patient's weight, activity level, and adherence to weight bearing or load bearing instructions have an effect on the stresses to which the implant is subjected.

Use of these implants is contraindicated in patients with the following conditions:

1. Active systemic infection, infection or inflammation localized to the site of the proposed implantation, or when the patient has demonstrated allergy or foreign body sensitivity to any of the implant materials.
2. Prior fusion at the level(s) to be treated.
3. Severe osteoporosis, which may prevent adequate fixation.
4. Conditions that may place excessive stresses on bone and implants, such as severe obesity or degenerative diseases, are relative contraindications. The decision whether to use these devices in such conditions must be made by the physician taking into account the risks versus the benefits to the patient.
5. Patients whose activity, mental capacity, mental illness, alcoholism, drug abuse, occupation, or lifestyle may interfere with their ability to follow postoperative restrictions and who may place undue stresses on the implant during bony healing and may be at a higher risk of implant failure.
6. Any patient not willing to cooperate with postoperative instruction.
7. Any condition not described in the indications for use.
8. Fever or leukocytosis.
9. Pregnancy.
10. Any other condition which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors or congenital abnormalities, fracture local to the operating site, 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.
11. Patients with a known hereditary or acquired bone friability or calcification problem should not be considered for this type of surgery.
12. Any case where the implant components selected for use would be too large or too small to achieve a successful result.
13. Any case that requires the mixing of metals from two different components or systems.
14. Any patient having inadequate tissue coverage at the operative site or inadequate bone stock or quality.
15. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.

Use of these implants is contraindicated when used with bone cement in patients with the following conditions:

1. Poor visibility under fluoroscopy
2. Patients with thrombophilia
3. Patients with severe cardiac and/or pulmonary insufficiency
4. Patients with known sensitivity to any of the components of bone cement
5. Any patient with a T-score of > -2.5

PACKAGING

These implants and instruments may be supplied pre-packaged and sterile, using gamma irradiation. The integrity of the sterile packaging should be checked to ensure that sterility of the contents is not compromised. Packaging should be carefully checked for completeness and all components should be carefully checked to ensure that there is no damage prior to use. Damaged packages or products should not be used, and should be returned to Globus Medical. During surgery, after the correct size has been determined, remove the products from the packaging using aseptic technique.

IMPORTANT INFORMATION ON CREO® STABILIZATION SYSTEM (CONT'D)

The instrument sets are provided nonsterile and are steam sterilized prior to use, as described in the STERILIZATION section below. Following use or exposure to soil, instruments must be cleaned, as described in the CLEANING section below.

HANDLING AND USE

All instruments and implants should be treated with care. Improper use or handling may lead to damage and/or possible malfunction. Products should be checked to ensure that they are in working order prior to surgery. All products should be inspected prior to use to ensure that there is no unacceptable deterioration such as corrosion (i.e. rust, pitting), discoloration, excessive scratches, notches, debris, residue, flaking, wear, cracks, cracked seals, etc. Non-working or damaged instruments should not be used, and should be returned to Globus Medical.

Any implant that has not been used, but has become soiled, should be handled according to hospital protocol. Any implant with evidence of damage, residue, debris, or other defects should not be used, and should be returned to Globus Medical.

CLEANING

All instruments that can be disassembled must be disassembled for cleaning. All handles must be detached. Instruments may be reassembled following sterilization. The instruments should be cleaned using neutral cleaners before sterilization and introduction into a sterile surgical field or (if applicable) return of the product to Globus Medical.

Cleaning and disinfecting of instruments can be performed with aldehyde-free solvents at higher temperatures. Cleaning and decontamination must include the use of neutral cleaners followed by a deionized water rinse. Note: certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used.

The following cleaning methods should be observed when cleaning instruments after use or exposure to soil, and prior to sterilization:

1. Immediately following use, ensure that the instruments are wiped down to remove all visible soil and kept from drying by submerging or covering with a wet towel.
2. Disassemble all instruments that can be disassembled.
3. Rinse the instruments under running tap water to remove all visible soil. Flush the lumens a minimum of 3 times, until the lumens flush clean.
4. Prepare Enzol® (or a similar enzymatic detergent) per manufacturer's recommendations.
5. Immerse the instruments in the detergent and allow them to soak for a minimum of 2 minutes.
6. Use a soft bristled brush to thoroughly clean the instruments. Use a pipe cleaner for any lumens. Pay close attention to hard to reach areas.
7. Using a sterile syringe, draw up the enzymatic detergent solution. Flush any lumens and hard to reach areas until no soil is seen exiting the area.
8. Remove the instruments from the detergent and rinse them in running warm tap water.
9. Prepare Enzol® (or a similar enzymatic detergent) per manufacturer's recommendations in an ultrasonic cleaner.
10. Completely immerse the instruments in the ultrasonic cleaner and ensure detergent is in lumens by flushing the lumens. Sonicate for a minimum of 3 minutes.
11. Remove the instruments from the detergent and rinse them in running deionized water or reverse osmosis water for a minimum of 2 minutes.
12. Dry instruments using a clean soft cloth and filtered pressurized air.
13. Visually inspect each instrument for visible soil. If visible soil is present, then repeat cleaning process starting with Step 3.

CONTACT INFORMATION

Globus Medical may be contacted at 1-866-GLOBUS1 (456-2871). A surgical technique manual may be obtained by contacting Globus Medical

STERILIZATION

These implants and instruments may be available sterile or nonsterile. HA-coated implants are only available sterile.

Sterile implants and instruments are sterilized by gamma radiation, validated to ensure a Sterility Assurance Level (SAL) of 10^{-6}. Sterile products are packaged in a heat sealed double pouch or container/pouch. The expiration date is provided in the package label. These products are considered sterile unless the packaging has been opened or damaged. Sterile implants and instruments that become nonsterile or have expired packaging are considered nonsterile and may be sterilized according to instructions for nonsterile implants and instruments below, with the exception of HA-coated implants, which cannot be resterilized and should be disposed of according to hospital protocol. Sterile implants meet pyrogen limit specifications.

Nonsterile implants and instruments have been validated to ensure an SAL of 10^{-6}. The use of an FDA-cleared wrap is recommended, per the Association for the Advancement of Medical Instrumentation (AAMI) ST79, *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities*. It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the FDA for the selected sterilization cycle specifications (time and temperature).

When using a rigid sterilization container, the following must be taken into consideration for proper sterilization of Globus devices and loaded graphic cases:

- Recommended sterilization parameters are listed in the table below.
- Only FDA-cleared rigid sterilization containers for use with pre-vacuum steam sterilization may be used.
- When selecting a rigid sterilization container, it must have a minimum filter area of 176 in^2 total, or a minimum of four (4) 7.5in diameter filters.
- No more than one (1) loaded graphic case or its contents can be placed directly into a rigid sterilization container.
- Stand-alone modules/racks or single devices must be placed, without stacking, in a container basket to ensure optimal ventilation.
- The rigid sterilization container manufacturer's instructions for use are to be followed; if questions arise, contact the manufacturer of the specific container for guidance.
- Refer to AAMI ST79 for additional information concerning the use of rigid sterilization containers.

For implants and instruments provided NONSTERILE, sterilization is recommended (wrapped or containerized) as follows:

Method	Cycle Type	Temperature	Exposure Time	Drying Time
Steam	Pre-vacuum	132°C (270°F)	4 Minutes	30 Minutes
Steam	Pre-vacuum	134°C (273°F)	3 Minutes	30 Minutes

These parameters are validated to sterilize only this device. If other products are added to the sterilizer, the recommended parameters are not valid and new cycle parameters must be established by the user. The sterilizer must be properly installed, maintained, and calibrated. Ongoing testing must be performed to confirm inactivation of all forms of viable microorganisms.

CAUTION: Federal Law (USA) Restricts this Device to Sale by or on the order of a Physician.

REF	CATALOGUE NUMBER	STERILE R	STERILIZED BY IRRADIATION
LOT	LOT NUMBER	EC REP	AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
⚠	CAUTION		MANUFACTURER
	SINGLE USE ONLY		USE BY (YYYY-MM-DD)
QTY	QUANTITY		

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