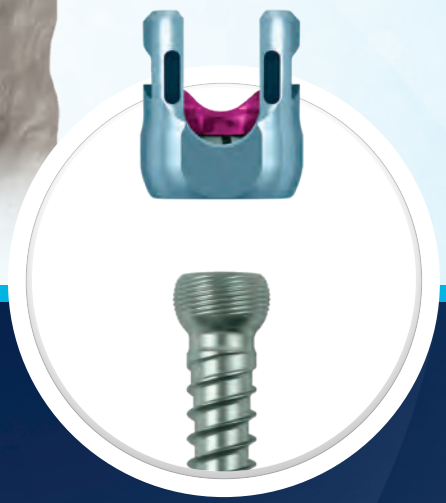




CREO AMP® 5.5

Stabilization System

Outside the US Only

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® 5.5

Overview 4
Implant Overview 5
Instrument Overview 9
Surgical Technique
1. Planning. 24
2. Approach 24
3. Screw Insertion 25
4. Screw Post Distraction for Interbody 27
5. Screw Head Insertion/Removal 28
Loading the Head Inserter. 28
Exchanging/Resetting/Unloading a Screw Head 32
6. Rod Insertion and Locking Cap Delivery 33
Option A: Locking Cap Driver, Short 34
Option B: Semi-Automatic Locking Cap Driver 36
7. Rod Reduction. 38
Option A: Locking Cap Guide 38
Option B: Reduction Fork 38
Option C: Geared Reducer, Pistol Grip 39
Option D: Geared Reducer, Overhead 39
Option E: Tower Reducer 40
Option F: Reduction Clip. 41
8. Deformity Correction 42
9. Compression or Distraction 45
10. Final Tightening. 46
Final Construct 47
Optional Technique: CREO® Cross Connector. 48
Optional Technique: Sacral Plate. 49
Optional Technique: Hooks. 51
Optional Technique: Lamina Clamp 54
Optional Technique: Iliac Screws and Offset Connectors. 55
Optional Technique: Revision/Removal 56
Optional Technique: Cross Connector Removal. 56
Optional Technique: Remobilization. 56
Optional Technique: Derotation. 56
Available Sets. 56

CREO AMP® 5.5

Stabilization System



CREO AMP® 5.5, an Advanced Modular Platform for thoracolumbar stabilization, features unmatched ease of use and intraoperative versatility by providing intuitively designed implants and instruments that maximize security and 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*.

CREO AMP® 5.5 optimizes efficiency and visibility at the operative site with intuitive and ergonomic instruments. It allows for convenient decortication and screw post distraction.



Optimized Visualization

CREO AMP® 5.5 implants are designed with a low profile of 14.95mm. Inserting the screw posts prior to the screw heads allows for superior decortication and access in TLIF cases. Reduction instruments are designed with minimal bulk for improved visualization in the surgical field.

Confidence in Construct Stability

The Head Inserter is designed for component assembly, incorporating a handle lock/release indicator that ensures a screw head is secured onto the screw post. Testing shows the intraoperatively assembled CREO AMP® 5.5 screw construct is equally as strong as the CREO® 5.5 preassembled screw construct.*

Solutions for Complex Spinal Pathologies

The system offers an extensive array of connector options, including polyaxial screw heads, various offset connectors, sacral plates, and lamina clamps. All connectors can be exchanged *in situ,* offering versatility for challenging patient anatomy.

The compact CREO® Reduction Clip allows up to 30mm of gradual reduction and can be coupled for derotation techniques as needed.

*Data on file at Globus Medical

IMPLANT OVERVIEW

Non-Threaded Locking Cap

- Non-threaded design eliminates cross-threading
- Low-torque mechanism (5.5Nm)
- Set screw pre-torqued in place to prevent unintentional movement in shipping or handling
- Allows direct placement with the driver for easier assembly
- Rod can be rotated within screw head before final tightening, allowing for better manipulation for curve correction



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



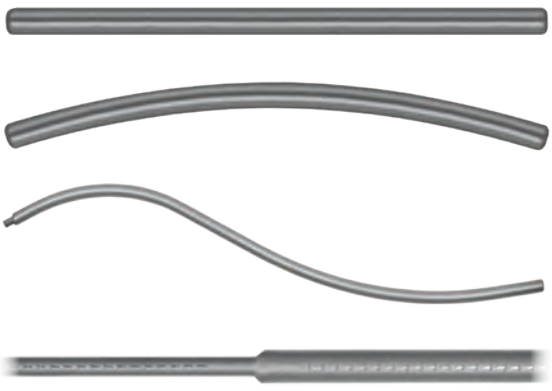
Polyaxial Screw Head

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



Rods

- 5.5mm diameter 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 (TAV), commercially pure titanium (CP), or cobalt chrome (CoCr)



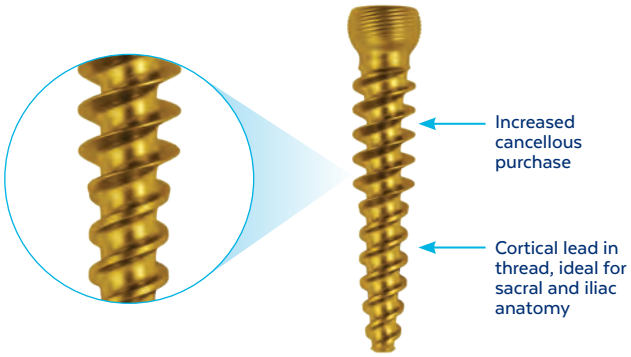
Double Screw Head Connector (CREO AMP QUAD®)

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



Dual Outer Diameter (DOD) Screw Post

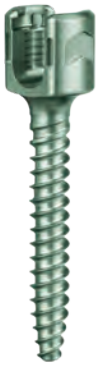
- Designed to optimize purchase in both cancellous and cortical bone
- Nominal diameter at distal end allows for deeper insertion in sacrum without perforation
- Designed for enhanced fixation in the sacrum and ilium
- ±30° angulation (60° total)
- Available in proximal/distal outer diameters of 5.5/4.5, 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

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, 5.0, 5.5, 6.5, 7.5, 8.5mm
- Screw lengths: 20–90mm



HA Coated Screw Post

- Hydroxyapatite (HA) coating on screw post 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 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



Offset Connectors

- 15–35mm lengths, in 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



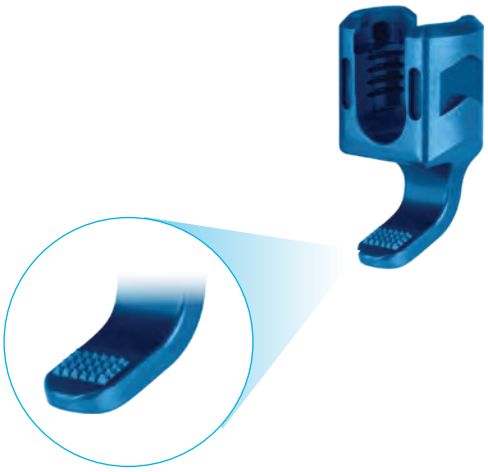
Lamina Clamps

- 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



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

PEDICLE PREPARATION INSTRUMENTS (CONT'D)



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, 1/4” Quick-Connect 6119.3030



Self-Retaining Monoaxial Screwdriver, 1/4” Quick-Connect 6119.3035



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 6119.1000



Head Release 6119.1005



Screw Head Positioner, Internal 6119.1070



Screw Head Positioner, External 6119.1075

ROD MANIPULATION AND INSERTION INSTRUMENTS



Rod Template, 150mm 602.501



Rod Template, 300mm 602.517



Rod Template, 500mm 6067.1500



Power Bender 6067.0075



Rod Holder 6067.0080



Power Rod Gripper 6067.0085

ROD MANIPULATION AND INSERTION INSTRUMENTS (CONT'D)



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 6119.2000



Tower Reducer Attachment, 1/4” Quick-Connect 6119.2005



Geared Reducer, Overhead 6119.2010



Geared Reducer, Pistol Grip 6119.2015

ROD REDUCTION INSTRUMENTS (CONT'D)



Reduction Clip, Short 6119.2020



Reduction Clip Driver, 1/4" Quick-Connect 6119.3110



Reduction Clip Driver, Short 6119.3111



Reduction Fork 6119.2030

SCREW LOCKING INSTRUMENTS



Ratcheting Torque-Limiting Handle, 1/4" Quick-Connect 6067.0040



Locking Cap Driver, Short 6119.1010



Locking Cap Guide 6119.1025



Adjustable Counter-Torque, Short
6119.1030

COMPRESSION/DISTRACTION INSTRUMENTS



Parallel Compressor 6067.0090



Parallel Distractor 6067.0095

COMPRESSION/DISTRACTION INSTRUMENTS (CONT'D)

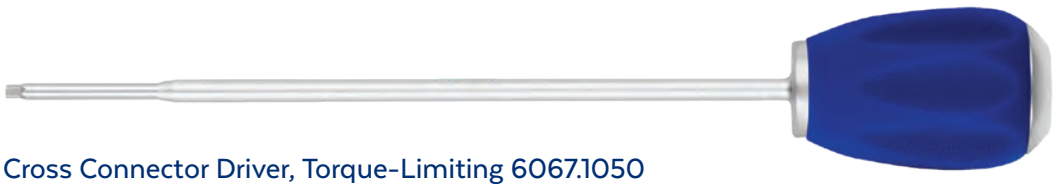


Parallel Head Distractor 6067.7005

CROSS CONNECTOR INSTRUMENTS



Cross Connector Caliper 6067.1060



Cross Connector Driver, Torque-Limiting 6067.1050



Cross Connector Inserter 6067.1055

HOOK PLACEMENT INSTRUMENTS



Lamina Finder 6067.8000



Pedicle Finder 6067.8005



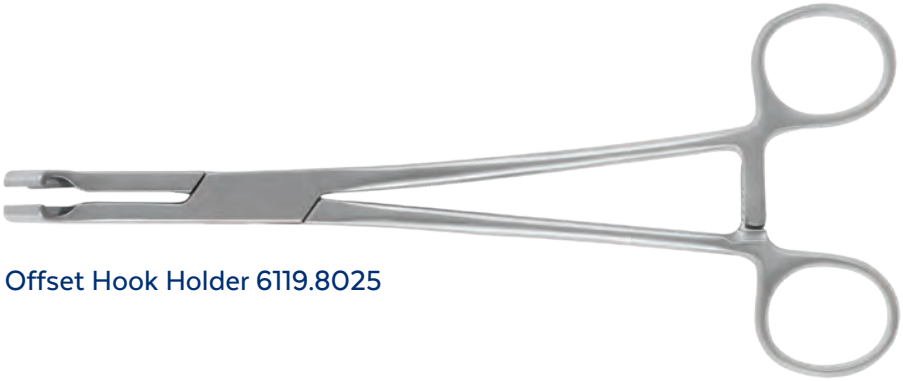
Hook Holder 6119.8010



Hook Positioner 6119.8015



Lateral Hook Holder 6119.8020



Offset Hook Holder 6119.8025

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



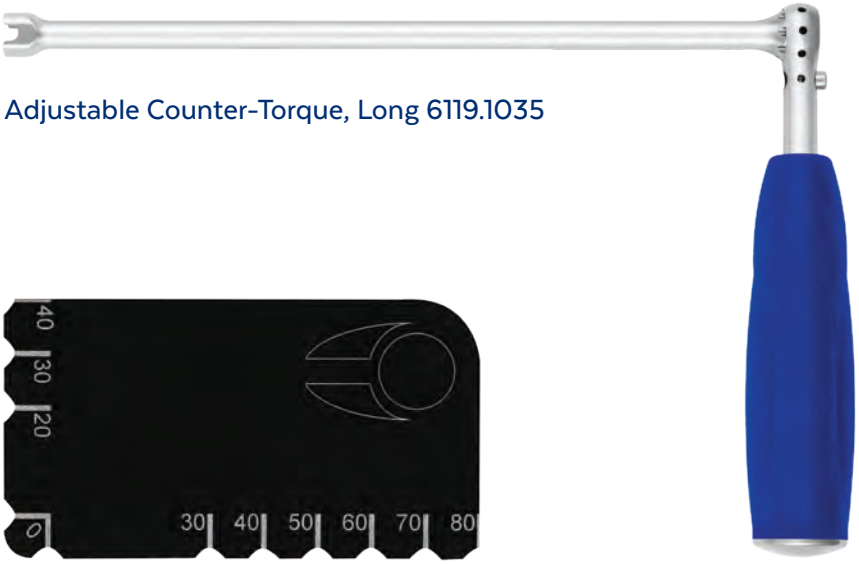
10.5mm Solid Tap 6067.0100



Locking Cap Driver, Long 6119.1015



Semi-Automatic Locking Cap Driver 6119.1020



Adjustable Counter-Torque, Long 6119.1035

Cross Connector Measurement Card 6067.1065



Reduction Forceps 6119.2035



CREO® Screw Head Distractor 6120.0001



Torque-Limiting Hexalobe Driver 6067.0041

SURGICAL TECHNIQUE

CREO AMP® 5.5 Stabilization System

Please refer to the product insert for complete description, indications, contraindications, warnings, and precautions.

The safety and effectiveness of the in-line connector has not been established for use as part of a growing rod construct. The in-line connector 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 can 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 Tip 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® 5.5 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 Rigid Driver** 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

Once fully engaged, rotate the knob of the screwdriver clockwise until tight. Press the oblong button above the knob to activate the lock. The lock will automatically slide 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

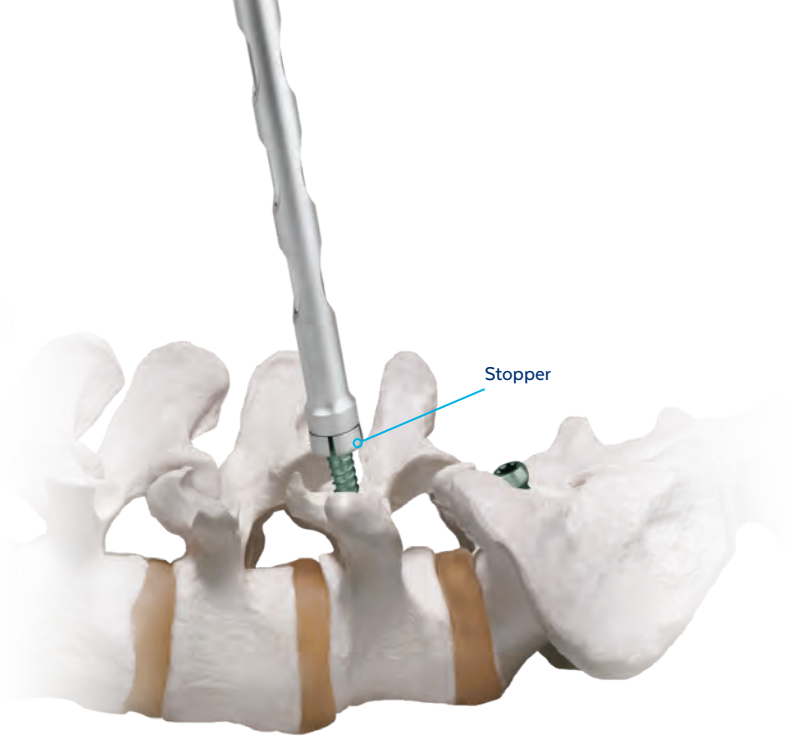


Disengaging screw

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 POST DISTRACTION FOR INTERBODY

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

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



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 screw post.



Using Decortication Tool

LOADING THE HEAD INSERTER

Hold the **Head Inserter** over the screw head module. Align the flats on the side of 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 handles remain 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.

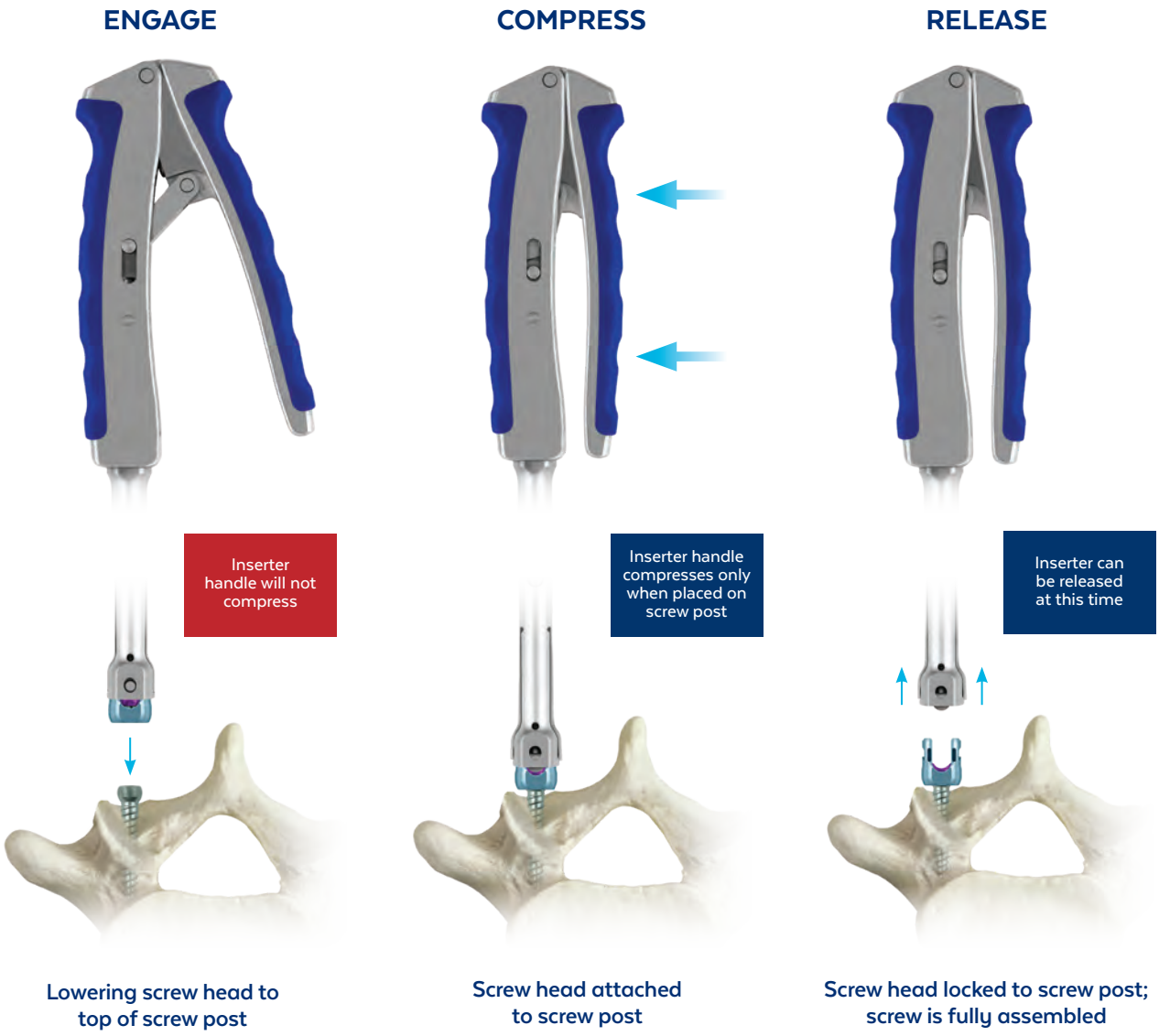
Screw Head Attachment

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 to the 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.

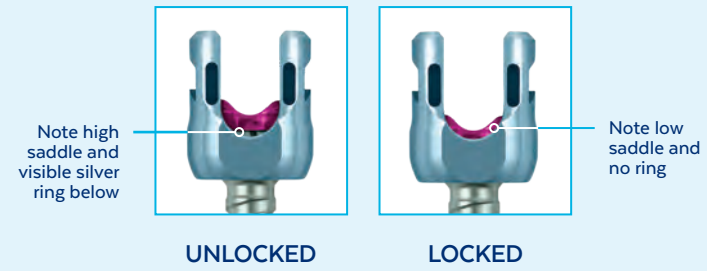
To securely lock the screw head onto the screw post, compress the inserter handle. The screw head is now locked onto the screw post, creating an assembled screw. Release the inserter handle, pull the inserter upward, and rotate slightly to confirm the screw head is attached and has polyaxial motion. 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.



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**.

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 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 can 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.

Choose 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 then 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)

Option A: Locking Cap Driver, Short

Loading the Driver

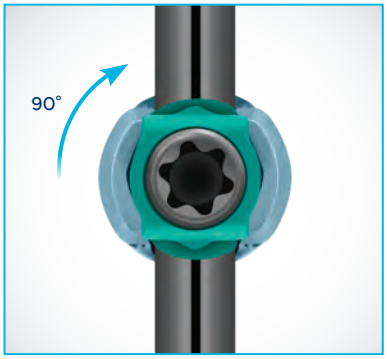
Align the black etching on the sides of the **Locking Cap Driver, Short**, with the curved sides of the cut-out in the locking cap module. Push the driver down over the locking cap until it clicks. The click indicates the locking cap is now retained by the driver.



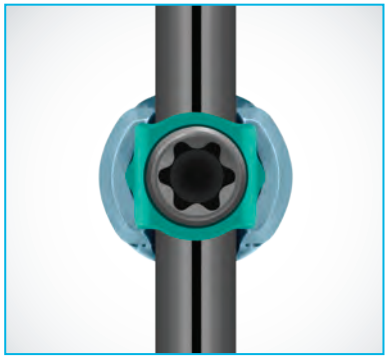
Aligning driver

Locking Cap Insertion

With a loaded driver, insert the locking cap into the screw head and rotate the driver clockwise 90° to capture the rod. Locking cap insertion requires minimal torque. Do not force it. If the locking cap is difficult to rotate, the rod may not be seated properly and further rod reduction and/or rod contouring may be required. The construct is not completely locked until final tightening.



Unlocked

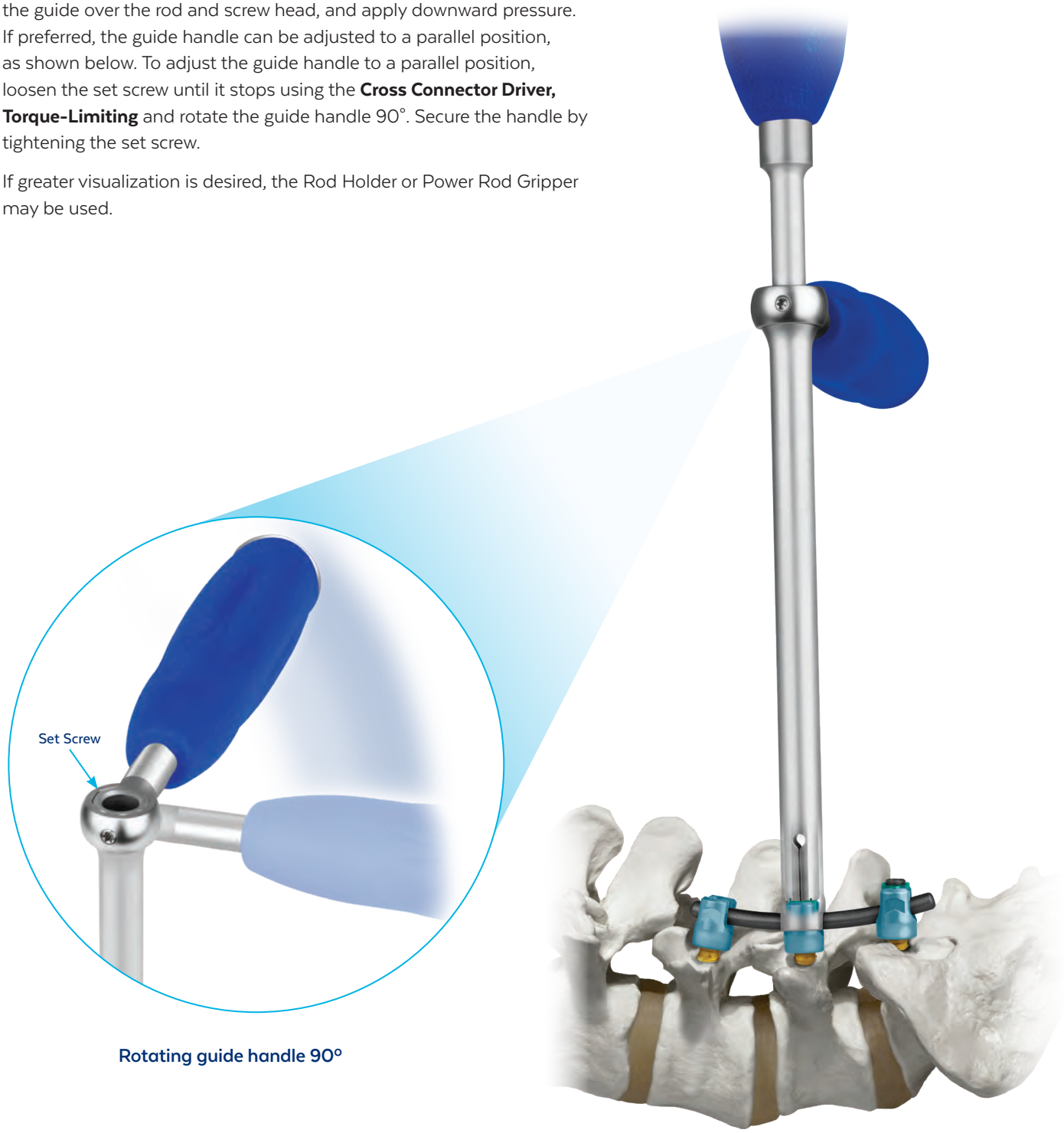


Locked

Locking Cap Guide

The **Locking Cap Guide** 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 can 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

ROD INSERTION AND LOCKING CAP DELIVERY (CONT'D)

Option B: Semi-Automatic Locking Cap Driver

Loading the Driver

Holding the **Semi-Automatic Locking Cap Driver** with the distal end facing down, rotate the knob counterclockwise toward the LOAD position.

Align the flats on the driver with the flats on the locking cap module. Push the driver down over the locking cap until fully seated. Slightly twist back and forth while applying axial force. Repeat these steps for a total of up to eight locking caps.

Note: The Semi-Automatic Locking Cap Driver must be loaded from the locking cap module.

View the yellow indicator and etching numbered 1–8 on the distal end of the driver to confirm the number of locking caps that are loaded.

When all caps are loaded, rotate the knob clockwise to secure them into the driver for use.



Loading Semi-Automatic Locking Cap Driver (driver in LOAD position)



Locking caps loaded



Rotating driver to locked position

Locking Cap Insertion

Using the loaded Semi-Automatic Locking Cap Driver, insert the locking cap into the screw head and rotate the driver clockwise 90° to capture the rod. Slightly tilt the instrument cephalad or caudal along the rod and lift to release the locking cap, allowing the next locking cap to automatically advance in the driver for the next application.

Locking cap insertion requires minimal effort. Do not force it. If the locking cap is difficult to rotate, the rod may not be seated properly and further rod reduction and/or rod contouring may be required.

Note: The Semi-Automatic Locking Cap Driver is only compatible with the Reduction Fork option for rod reduction. All other reduction options can be accomplished using the standard Locking Cap Driver, Short.



Inserting locking cap



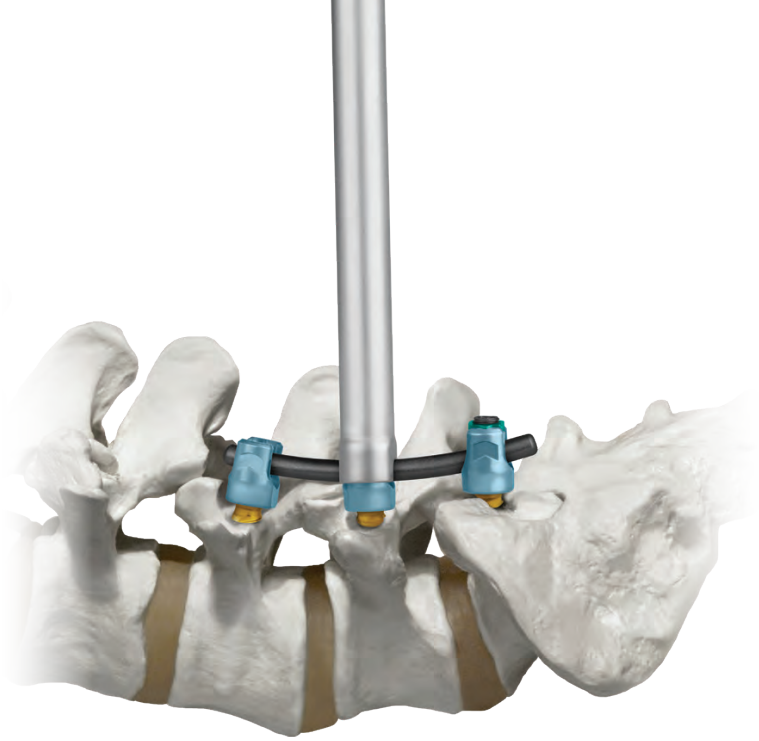
Tilting driver along rod to release locking cap

STEP 7 ROD REDUCTION

The CREO AMP® 5.5 Stabilization System has six options for rod reduction (max reduction):

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



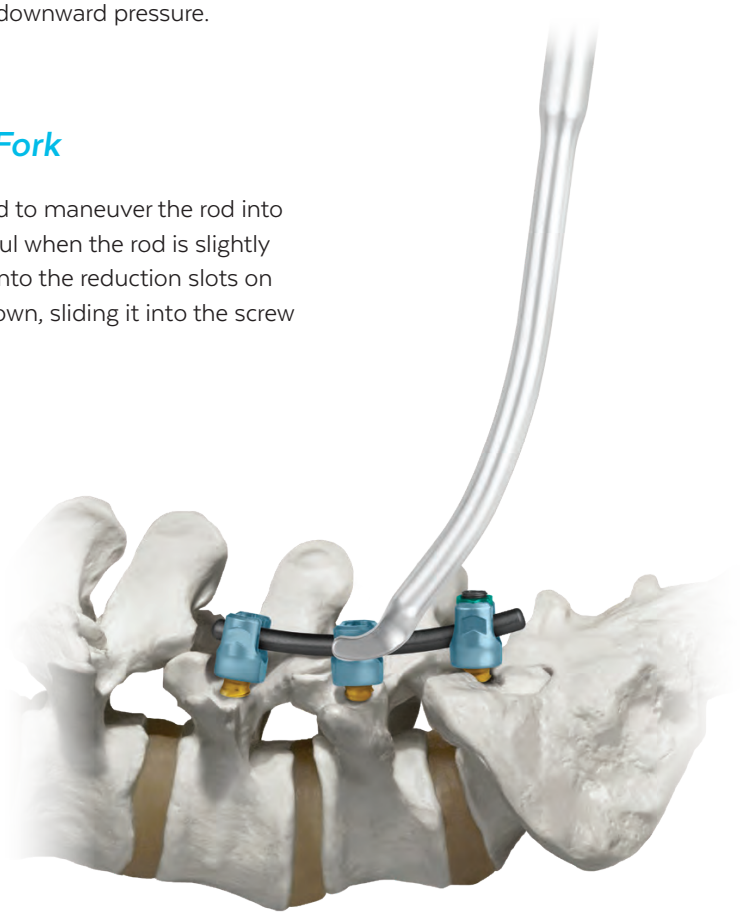
Rod reduction using Locking Cap Guide

Option A: Locking Cap Guide

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

Option B: Reduction Fork

The **Reduction Fork** can 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. Remove the fork.



Rod reduction using Reduction Fork

Option C: Geared Reducer, Pistol Grip

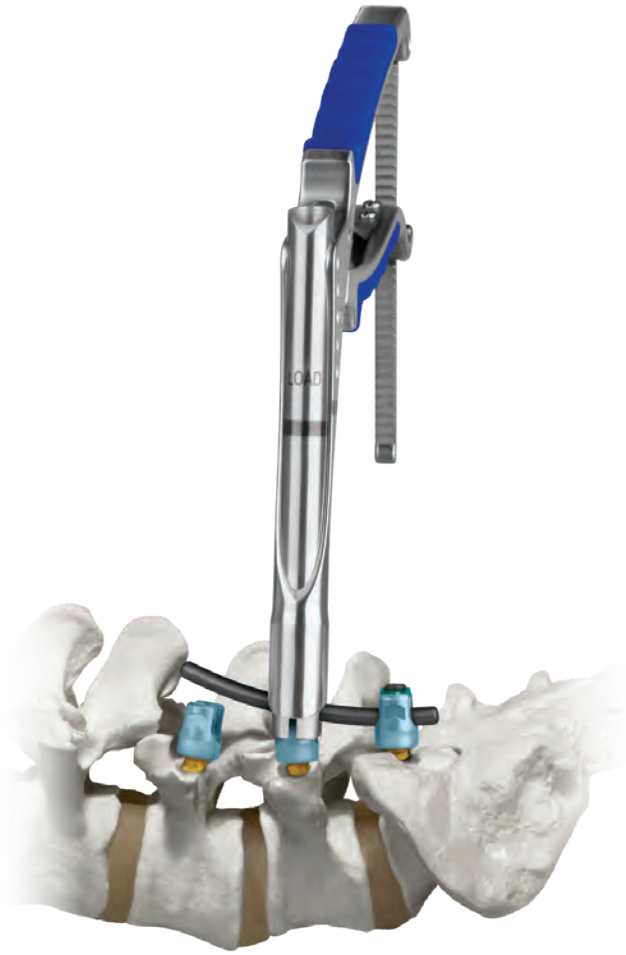
The **Geared Reducer, Pistol Grip** provides up to 10mm of reduction. Ensure the reducer is fully open; the LOAD indicator on the inner shaft aligns with the etched black ring on the outer shaft.

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 and pulling up on the reducer.



Rod reduction using Geared Reducer, Pistol Grip



Rod reduction using Geared Reducer, Overhead

Option D: Geared Reducer, Overhead

The **Geared Reducer, Overhead** 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 squarely over the screw head and push 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 and pull up.

ROD REDUCTION (CONT'D)

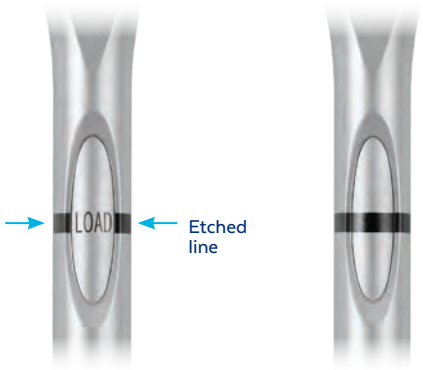
Option E: Tower Reducer

The **Tower Reducer** 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, 1/4" Quick-Connect** to rotate the handle. Insert the loaded locking cap driver into the reducer. Rotate the driver 90° clockwise to engage the locking cap.

Remove the reducer by rotating the handle counterclockwise into the LOAD position and pull up.



LOAD position

Fully reduced



Rod reduction using Tower Reducer with optional tower reducer attachment

Option F: Reduction Clip

The **Reduction Clip** 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.

Remove the Reduction Clip Driver. Insert a loaded Locking Cap Driver, Short through the Reduction Clip and rotate the locking cap clockwise 90° to engage the locking cap and secure the rod.

Remove the Reduction Clip by fully unthreading the inner shaft and pulling up.



Rod reduction using Reduction Clip with Reduction Clip Driver

STEP 8 DEFORMITY CORRECTION

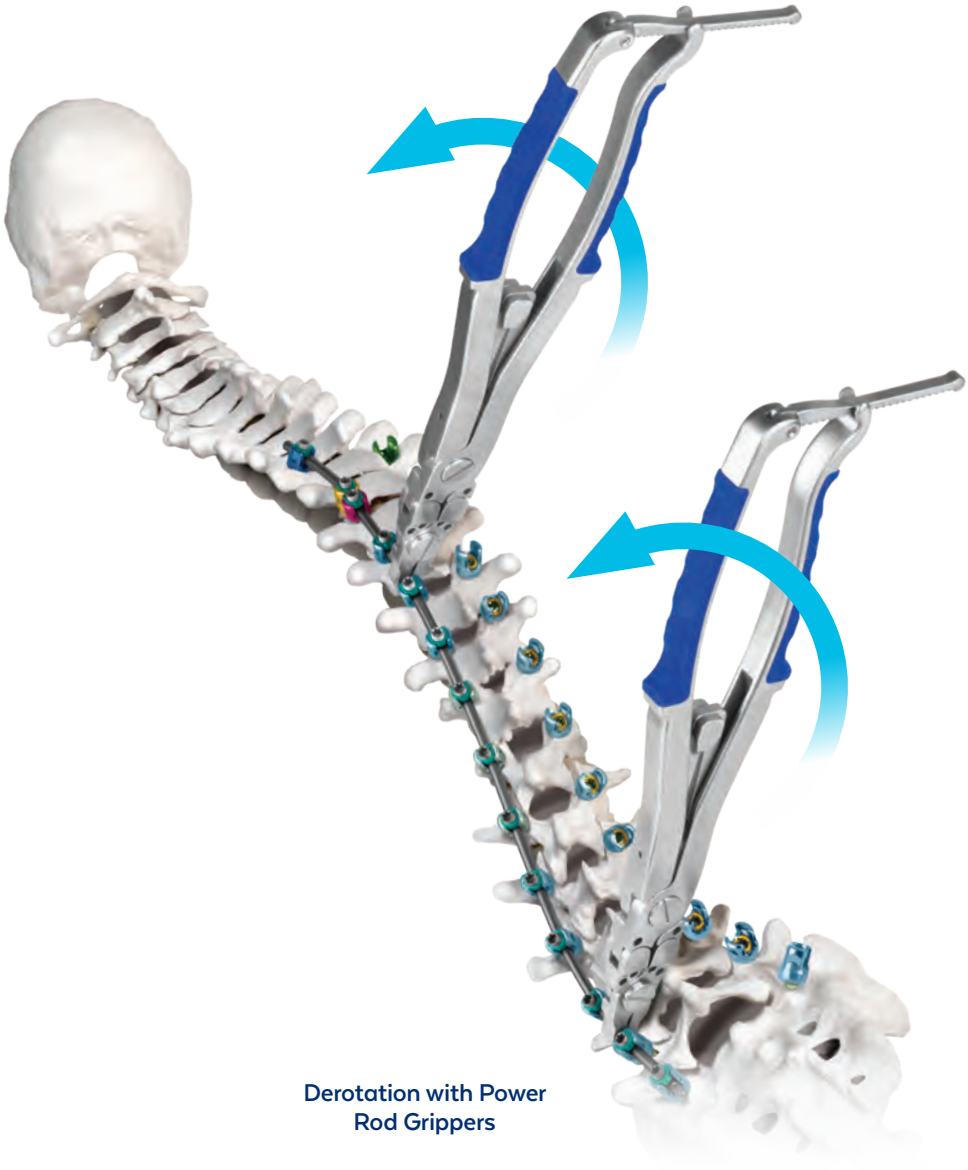
Global Derotation

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 in 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 any hooks during the derotation process to verify that they are not displaced. Once the rod is rotated into its final position, the set screws 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 then 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 set screws 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

The *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.



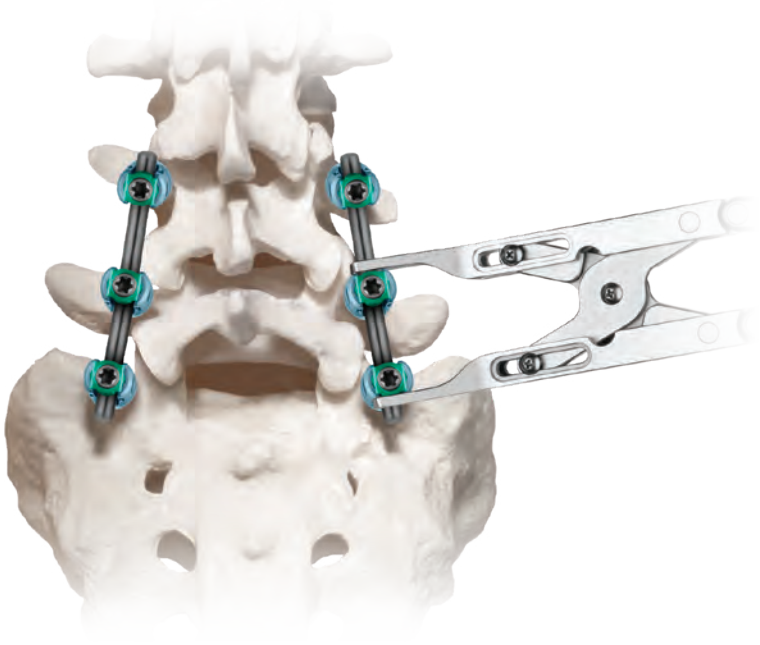
Using Coronal Plane Benders

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 bender 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 so as not to cause damage. Once rod bending is complete, compression or distraction may be performed.

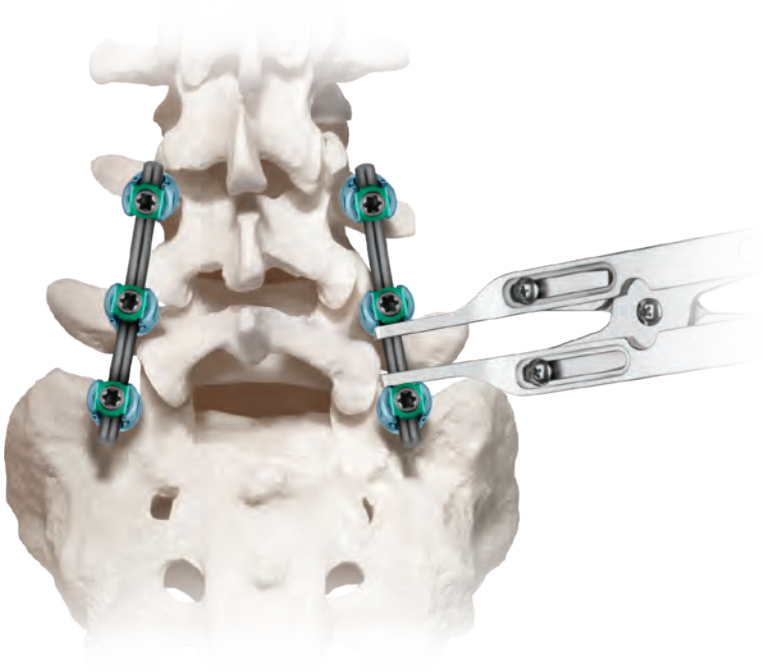


STEP 9 COMPRESSION OR DISTRACTION

CREO AMP® 5.5 pedicle screws can be compressed or distracted along the rod as necessary using the **Parallel Compressor** or **Parallel Distractor**, respectively. Tighten one of the set screws to establish a rigid point for compression or distraction. Once compression or distraction is completed, provisionally tighten the set screws using the **Ratcheting Torque-Limiting Handle, 1/4" Quick-Connect** and **Driver Shaft, 1/4" Quick-Connect, Short**. If remobilization of the screw head is required, refer to page 56.

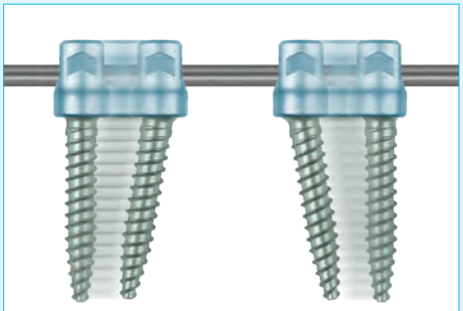


Compression



Distraction

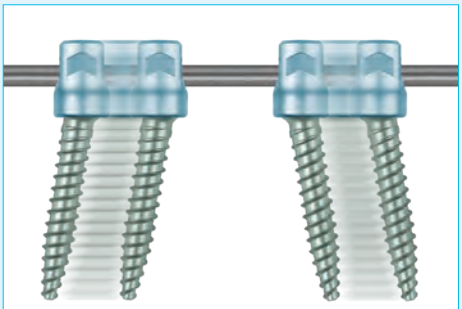
FREE ANGULATION



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 Ratcheting Torque-Limiting Handle and Driver Shaft. Loosen at least one set screw by approximately one full rotation to allow the screw to slide along the rod without changing the polyaxial angle of the screw head. Compress or distract the screws. Proceed to final tightening.

STEP 10 FINAL TIGHTENING

Final tightening of all set screws is necessary to secure the construct and is accomplished using the Ratcheting Torque-Limiting Handle, 1/4" Quick-Connect and Driver Shaft, 1/4" Quick-Connect, Short, with the **Adjustable Counter-Torque, Short**.

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 set screw. Slide the counter-torque over the screw head, ensuring it is fully seated. The counter-torque handle can be adjusted per surgeon preference (see below). Rotate the driver assembly until it reaches the torque limit (5.5Nm) and then rotate to two audible clicks. Repeat for all locking caps. Ensure that locking caps are final tightened after corrective maneuvers are complete.



USING THE ADJUSTABLE COUNTER-TORQUE HANDLE

To adjust the orientation of the counter-torque, press and hold the button on the top of the instrument to rotate the handle in 45° increments. Secure the handle by releasing the button.



Adjusting handle

FINAL CONSTRUCT



Final CREO AMP® 5.5 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® 5.5 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 Tip 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.

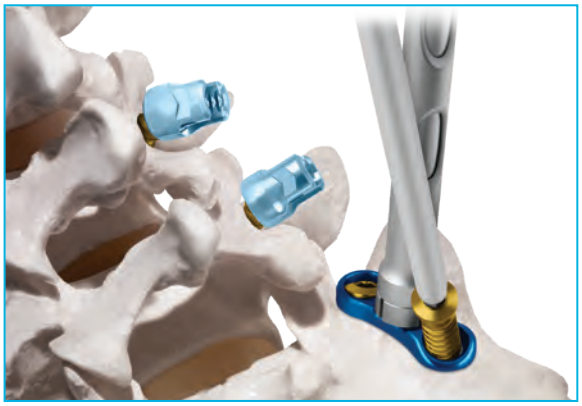
Note: Refer to Step 5 in this guide for screw head insertion technique.



Final CREO AMP® 5.5 construct with Sacral Plates



Inserting S1 bone screw



Inserting ala bone screw

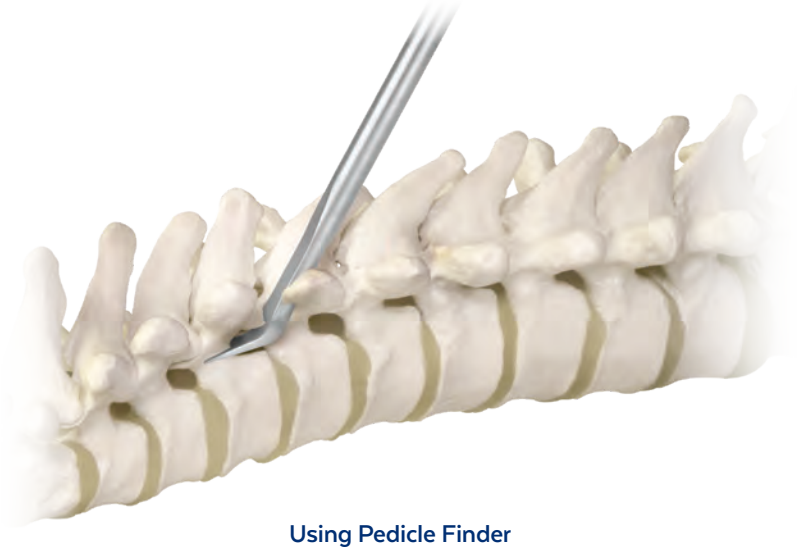


Securing screw head to sacral plate

OPTIONAL TECHNIQUE: 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: 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**. Insert the hook into the holder and place in the desired position.

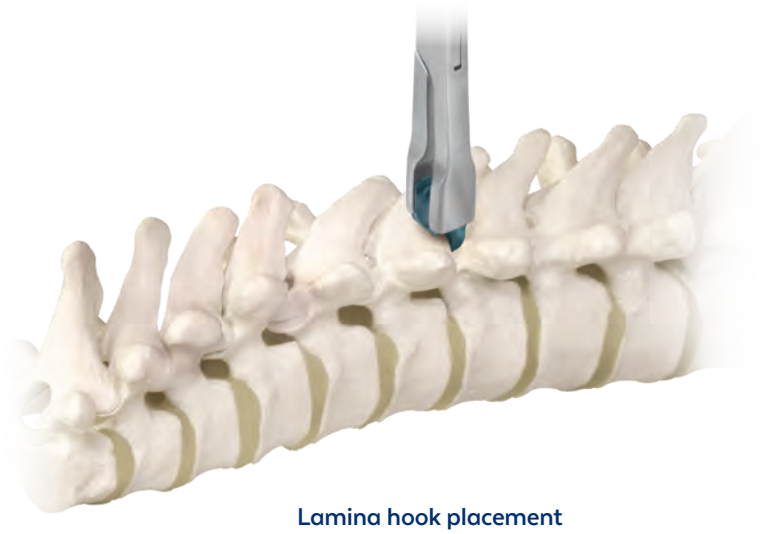
Alternatively, the **Lateral Hook Holder** or the **Offset Hook Holder** may be used to insert the hook. The **Hook Positioner** may also be used to aid in hook placement.



Pedicle hook placement using Hook Holder

Lamina Hook Placement

A lamina hook may be placed 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 to seat the hook. Repeat hook insertion for each desired location.



Transverse process hook placement

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® 5.5 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 instrument.

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 instrument.

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



Hook Holder



Offset Hook Holder



Lateral Hook Holder



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 1-level construct or 2-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 Lamina Clamp Construct

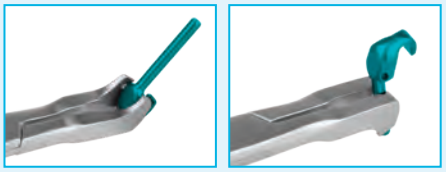
LOADING THE LAMINA CLAMP INSTRUMENTS

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® 5.5 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 Rigid Driver to the Straight Handle, Ratcheting, 1/4" Quick-Connect or T-Handle, Ratcheting, 1/4" Quick-Connect.

Insert the desired iliac screw post 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

Screw Head Removal

The CREO AMP® 5.5 screw head may be removed from the screw. If necessary, remove the locking caps by loosening the set screws using the Self-Retaining Driver Shaft until the locking cap rotates counterclockwise 90°. Grasp the rod and remove it from the screws. Attach the corresponding head release instrument to the screw head and compress the handle to remove the screw head.

Construct Revision/Removal

For revision or removal, reverse the insertion steps until the desired screws are removed. Remove the locking caps by loosening the set screws using the Self-Retaining Driver Shaft until the locking cap rotates counterclockwise 90°. Grasp the rod and remove it from the screws. 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® 5.5 Set List Supplement (GMTGD114)** for a complete description of each instrument or implant set.

NOTES

NOTES

NOTES

Globus Medical
Valley Forge Business Center
2560 General Armistead Avenue
Audubon, PA 19403
www.globusmedical.com

Customer Service:
Phone 1-866-GLOBUS1 (or 1-866-456-2871)
Fax 1-866-GLOBUS3 (or 1-866-456-2873)

©2023 Globus Medical. All rights reserved. Patent www.globusmedical.com/patents.
Life moves us is a registered trademark of Globus Medical. Please refer to package insert for description, indications, contraindications, warnings, precautions and other important information.

CE 0297

EC REP : AJW Technology Consulting GmbH
Breite Straße 3 40213 Düsseldorf, Germany

GMTGD104OU
08.23 Rev D