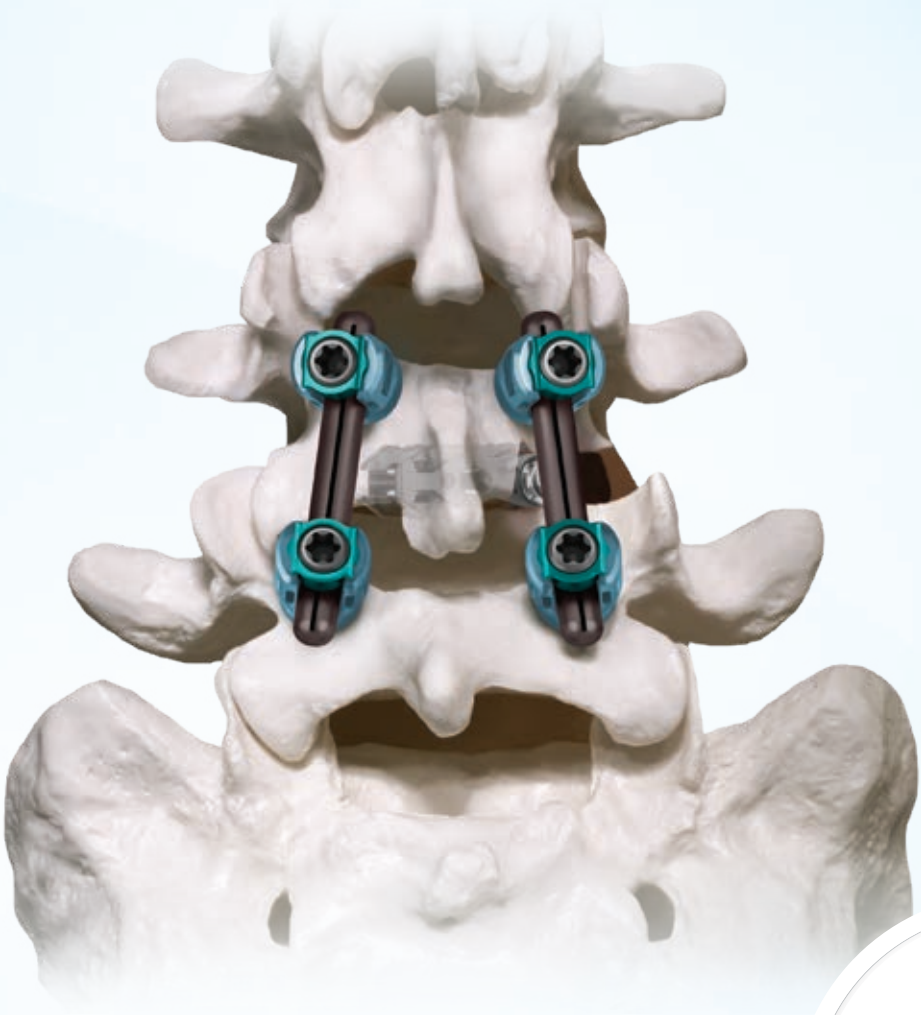


CREO MCS®

Midline Cortical Screw System

SURGICAL TECHNIQUE GUIDE

GLOBUSMEDICAL.COM | *Life moves us*

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

SURGICAL TECHNIQUE GUIDE

CREO MCS®

Distinguishing Characteristics 4
Implant Overview 7
Instrument Overview 8
Surgical Technique
1. Approach 18
2. Screw Trajectory 18
3. Site Preparation 20
4. Screw Insertion 20
Option A: CREO MCS® Modular Screw 20
Option B: CREO MCS® Preassembled 27
5. Rod Insertion and Locking Cap Delivery 29
Option A: Locking Cap Driver, Short 32
Option B: Semi-Automatic Locking Cap Driver 30
6. Rod Reduction 34
Option A: Locking Cap Guide 34
Option B: Reduction Fork 34
Option C: Geared Reducer, Pistol Grip 35
Option D: Geared Reducer, Overhead 35
Option E: Tower Reducer 36
7. Compression or Distraction 37
8. Final Tightening 38
Final Construct 39
CREO MCS® CORE Instrument Set 40
CREO MCS® 5.5 Instrument 42
CREO MCS® 5.5 Implant Set 44
Important Information 46

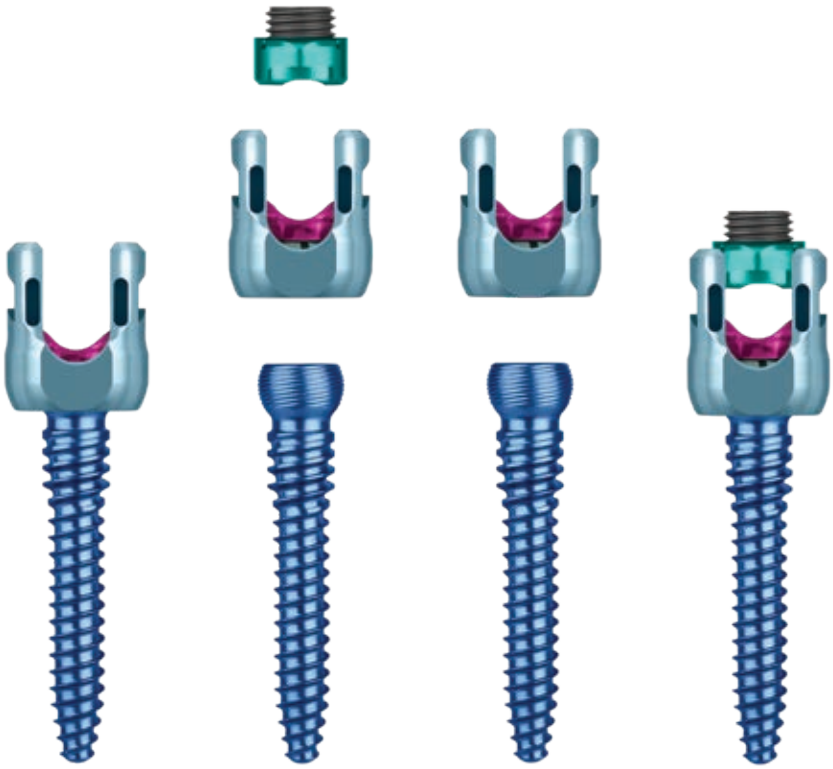
CREO MCS®

Midline Cortical Screw System

The CREO MCS® system revolutionizes patient care by providing enhanced cortical screw fixation paired with advanced interbody technology through a simple minimally invasive midline surgical approach.

CREO MCS® is a comprehensive screw fixation platform available in preassembled and modular constructs. Modular screws enhance visibility at the operative site and access for decompression. Additional distraction of the disc space can be performed directly off of the screw posts, facilitating interbody spacer placement prior to rod insertion.

The system features multiple options to fit varying patient anatomy. Preassembled and modular screws accept 5.5mm rods. CREO® modular screw shanks are also compatible with any CREO AMP® screw head and corresponding rods.*



*Refer to the corresponding CREO AMP® Technique Guide (GMTGD104 or GMTGD123) .

Minimally Invasive Surgical Approach

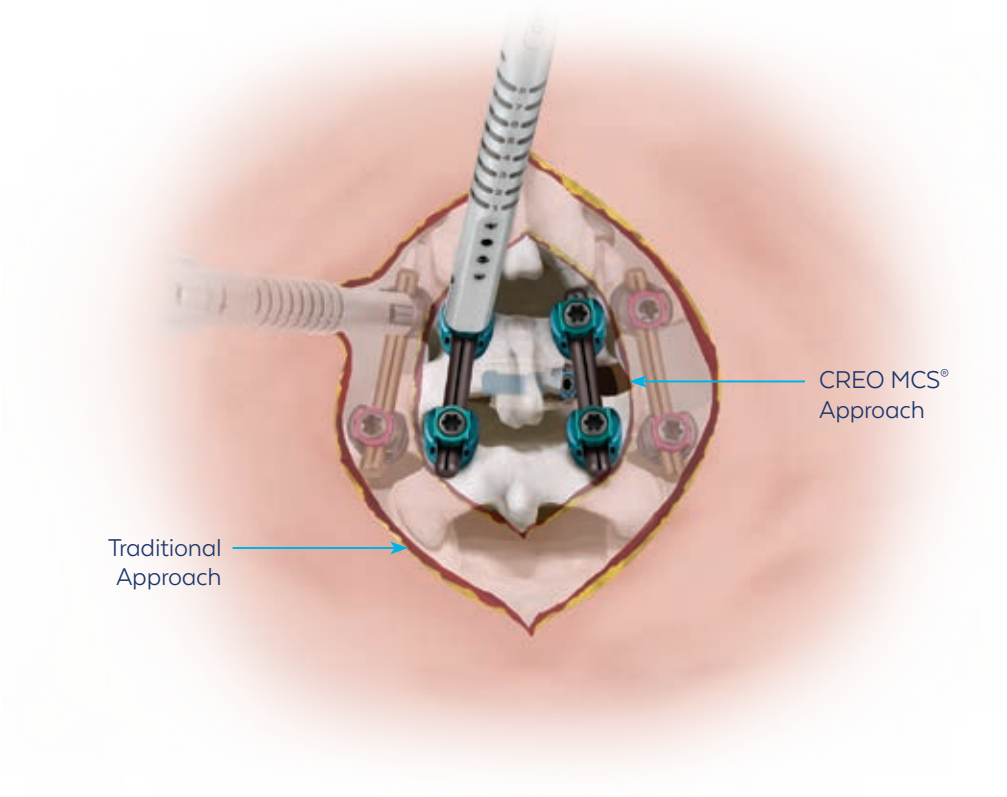
CREO MCS® utilizes a minimally invasive midline surgical approach, allowing for minimal tissue and muscle retraction.

Cortical Fixation

CREO MCS® screws feature a Dual Outer Diameter (DOD) and cortical thread pitch to provide a better anatomical fit and enhanced fixation.

Maximized Modularity

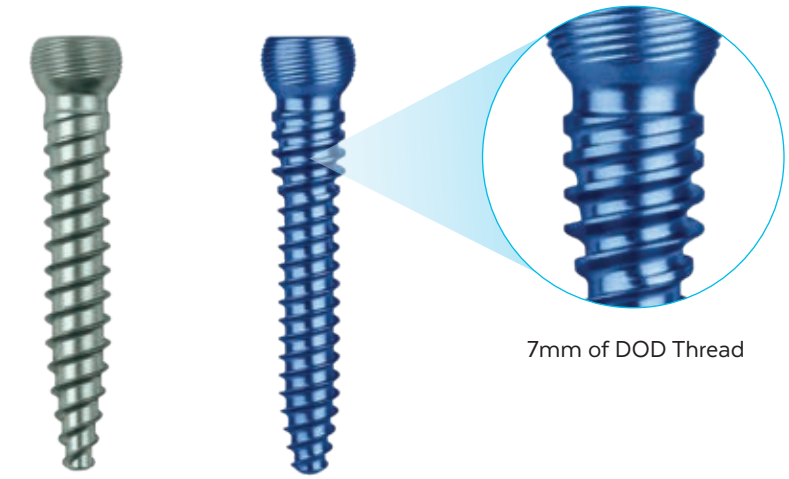
CREO MCS® allows screw heads to be attached *in situ* following decompression for improved visualization in the surgical field.



Enhanced Fixation

CREO MCS® screws are designed based on morphometry and the cortical trajectory. The screws provide enhanced pullout strength compared to traditional screws.

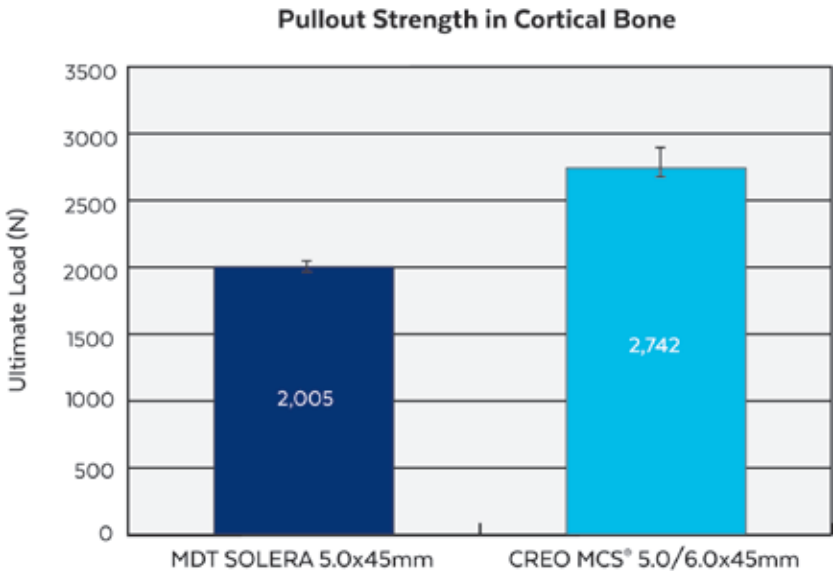
- DOD thread profile for posterior anatomy
- 33% more threads per inch to maximize purchase in dense cortical bone
- Increased core diameter to optimize strength for use in the midline cortical trajectory



Traditional Pedicle Screw

CREO MCS® Cortical Screw

CREO MCS® testing demonstrates a 37% increase in pullout strength compared to that of traditional pedicle screws*

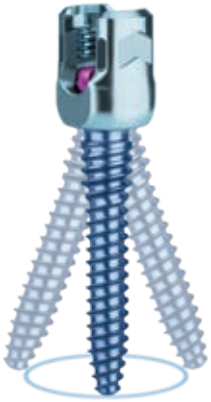


*Data on file at Globus Medical

IMPLANT OVERVIEW

Polyaxial Screw

- ±30° angulation (60° total) provides intraoperative versatility
- Double lead thread for rapid insertion
- 7mm DOD thread profile at the proximal end for enhanced cortical purchase and increased strength
- Screw pitch designed to maintain cortical purchase
- Drills and taps are color-coded to screw size
- Screw diameters: 5.0/4.0, 5.5/4.5, 6.0/5.0, 6.5/5.5mm
- Screw lengths: 20–45mm



Screw Post

- Double lead thread for rapid insertion
- 7mm DOD thread profile at the proximal end for enhanced cortical purchase and increased strength
- Screw pitch designed to maintain cortical purchase
- Compatible with all CREO AMP® screw heads
- Drills and taps are color-coded to screw size
- Screw diameters: 5.0/4.0, 5.5/4.5, 6.0/5.0, 6.5/5.5, 7.5/6.5mm
- Screw lengths: 20–45mm

Modular Screw Head

- ±30° angulation (60° total) provides intraoperative versatility

Rods

- 5.5mm diameter
- Available in titanium alloy (TAV) and cobalt chrome (CoCr)
- Comprehensive selection of straight and curved rods: 35–150mm

INSTRUMENT OVERVIEW

PREPARATION INSTRUMENTS

Pedicle Awl 6067.0001

Pedicle Probe, Straight 602.101

Ball Tip Probe, Curved 602.106

Ball Tipped Probe, Double Ended 624.110

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

Cortical Drill 5.0/4.0 6119.0022*

Cortical Drill 6.0/5.0 6119.0032

Cortical Drill 6.5/5.5 6119.0052

Cortical Drill 7.5/6.5 6119.0062

Cortical Power Drill, 5.0/4.0 6119.0026

Cortical Power Drill, 6.0/5.0 6119.0036

Cortical Power Drill, 6.5/5.5 6119.0056

Cortical Power Drill, 7.5/6.5 6119.0066

**The 5.0/4.0 drill was designed to be used with both the 5.0/4.0 and 5.5/4.5 screws.*

PREPARATION INSTRUMENTS (CONT'D)

Dual Outer Diameter Tap 5.0-4.0x20mm 6119.0023

Dual Outer Diameter Tap 5.5-4.5x20mm 6119.0033

Dual Outer Diameter Tap 6.0-5.0x20mm 6119.0043

Dual Outer Diameter Tap 6.5-5.5x20mm 6119.0053

Dual Outer Diameter Tap 7.5-6.5x20mm 6119.0063

Drill Guide with Adjustable Stop, 10–50mm 6119.0099

SCREW INSERTION INSTRUMENTS

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

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

Rigid Screwdriver, 1/4” Quick-Connect 6119.1080

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

Head Inserter 6119.1000

Head Release 6119.1005

Internal Screw Head Positioner 6119.1070

ROD MANIPULATION AND INSERTION INSTRUMENTS

Rod Template, 150mm 602.501

Rod Template, 300mm 602.517

Power Bender 6067.0075

Rod Holder 6067.0080

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

Reduction Fork 6119.2030

SCREW LOCKING INSTRUMENTS

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

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

Parallel Compressor 6067.0090

Parallel Distractor 6067.0095

Parallel Head Distractor 6067.7005

Locking Cap Driver, Short 6119.1010

Locking Cap Guide 6119.1025

Adjustable Counter-Torque, Short 6119.1030

SIZING INSTRUMENTS

Cross Connector Measurement Card 6067.1065

ADDITIONALLY AVAILABLE

Pedicle Probe, Curved 602.102

Cortical Tap 5.0/4.0 6119.0020

Cortical Tap 5.5/4.5 6119.0030

Cortical Tap 6.0/5.0 6119.0040

Cortical Tap 6.5/5.5 6119.0050

Cortical Tap 7.5/6.5 6119.0060

Dual Outer Diameter Tap 5.0-4.0x35mm 6119.0024

Dual Outer Diameter Tap 5.5-4.5x35mm 6119.0034

Dual Outer Diameter Tap 6.0-5.0x20mm 6119.0044

Dual Outer Diameter Tap 6.5-5.5x35mm 6119.0054

Dual Outer Diameter Tap 7.5-6.5x35mm 6119.0064

2.4mm K-Wire, Sharp 450mm 639.002

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

Semi-Automatic Locking Cap Driver 6119.1020

SURGICAL TECHNIQUE

CREO MCS®

STEP 1 APPROACH

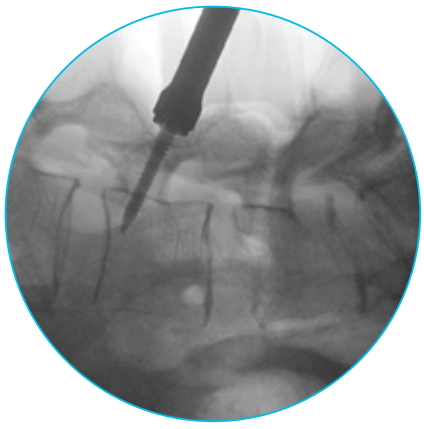
The patient is placed under anesthesia, and positioned prone and in flexion. The operative area is cleaned, and a midline incision is made over the appropriate level(s). Lateral C-arm fluoroscopy or other radiographic methods should be utilized throughout surgery to ensure correct screw placement. The incision is retracted bilaterally, exposing both sides of the spinous processes, the pars interarticularis, and the facet capsules. Dissection of the pars and facets is not required.

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

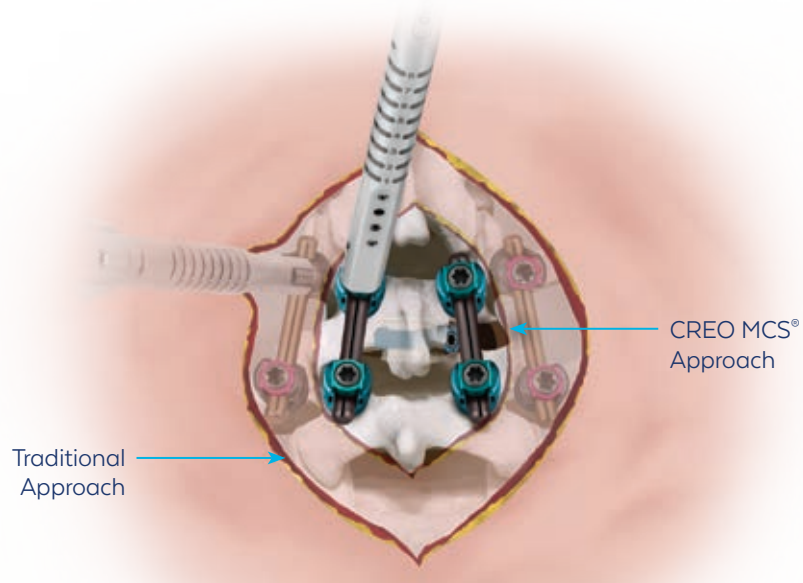
STEP 2 SCREW TRAJECTORY

CREO MCS® features a medial starting point, in contrast to the lateral starting point of traditional pedicle screws. The cortical approach captures the cortical areas of the vertebral body. Breaching of the lateral mass should be avoided.

Note: Drilling and tapping of cortical bone is required. A two-handed approach is recommended during pedicle preparation.



Cortical Screw Trajectory (Lateral View)

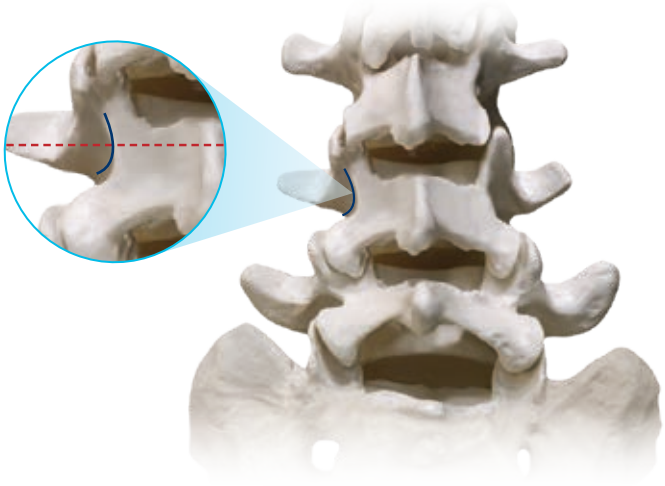


Cortical Screw Trajectory Guide

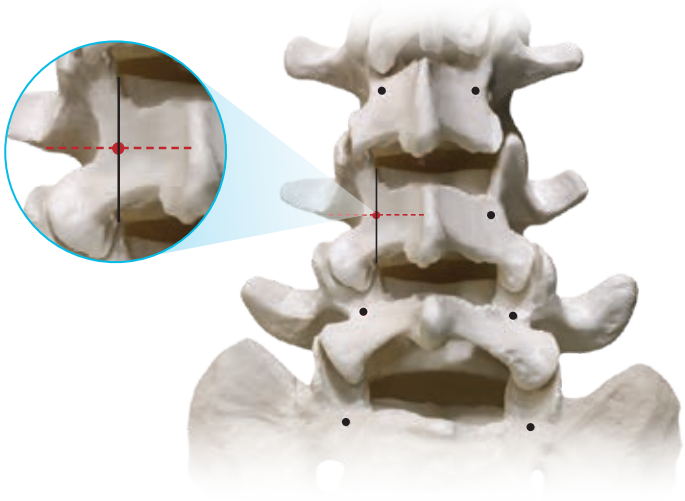
CREO MCS® Trajectory

Determining the cortical trajectory is crucial for accurate screw placement. To determine the starting point, follow the steps below:

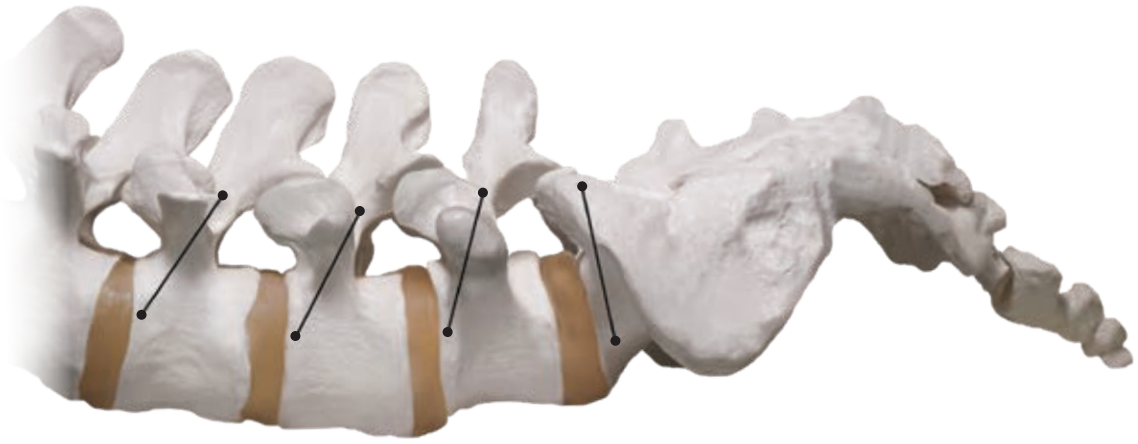
Locate the lateral border of the pars.



Move medially 2–5mm from the lateral border.



Examples of cortical trajectories are illustrated below. Patient anatomy determines the specific cortical trajectories.



STEP 3 SITE PREPARATION

After the incision has been retracted bilaterally and both sides of the spinous processes, pars interarticularis, and facets are exposed, removal of excess soft tissue and bone may be required using standard instruments. Dissection of the pars and facets is not necessary.

A **Pedicle Awl** or a high-speed burr may be used to perforate the pedicle cortex. Once the pedicle cortex has been perforated, set the **Drill Guide with Adjustable Stop, 10-50mm** to the appropriate depth. Pull the silver knob back and slide the gold tube until the desired depth aligns with the etched lines in the window. Place the Drill Guide over the pedicle. Attach the desired **Drill** to either a quick-connect handle or power drill.

Note: Drilling and tapping of bone should be performed prior to decompression as this provides the best visualization.

Drilling

Create a pilot hole using the appropriate size drill. Once the pilot hole has been created, reorient the drill in the final cortical trajectory utilizing the medial approach, ensuring that the drill avoids neurovascular structures. Drilling should be performed slowly to help prevent pars fractures. A two-handed approach is recommended. Fluoroscopic guidance is suggested to ensure correct trajectories.

Tapping

Connect the appropriate sized **Tap** to the desired quick-connect handle. Insert the tap into the drilled pathway and tap to the desired depth. When using a DOD tap, ensure that the large proximal diameter of the DOD tap is not inserted past the pars to avoid overtapping. Under-tapping is not recommended as this could result in fracture. Once the desired length is tapped, use the incremental markings on the tap to determine the proper screw length.

Pedicle Preparation

A **Ball Tip Probe** may be used to ensure that the walls of the pedicle are not violated. Demarcations on the probe indicate depth in 10mm increments for determining screw length.

STEP 4 SCREW INSERTION

Option A: CREO MCS® Modular Screw

Loading the Screwdriver

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

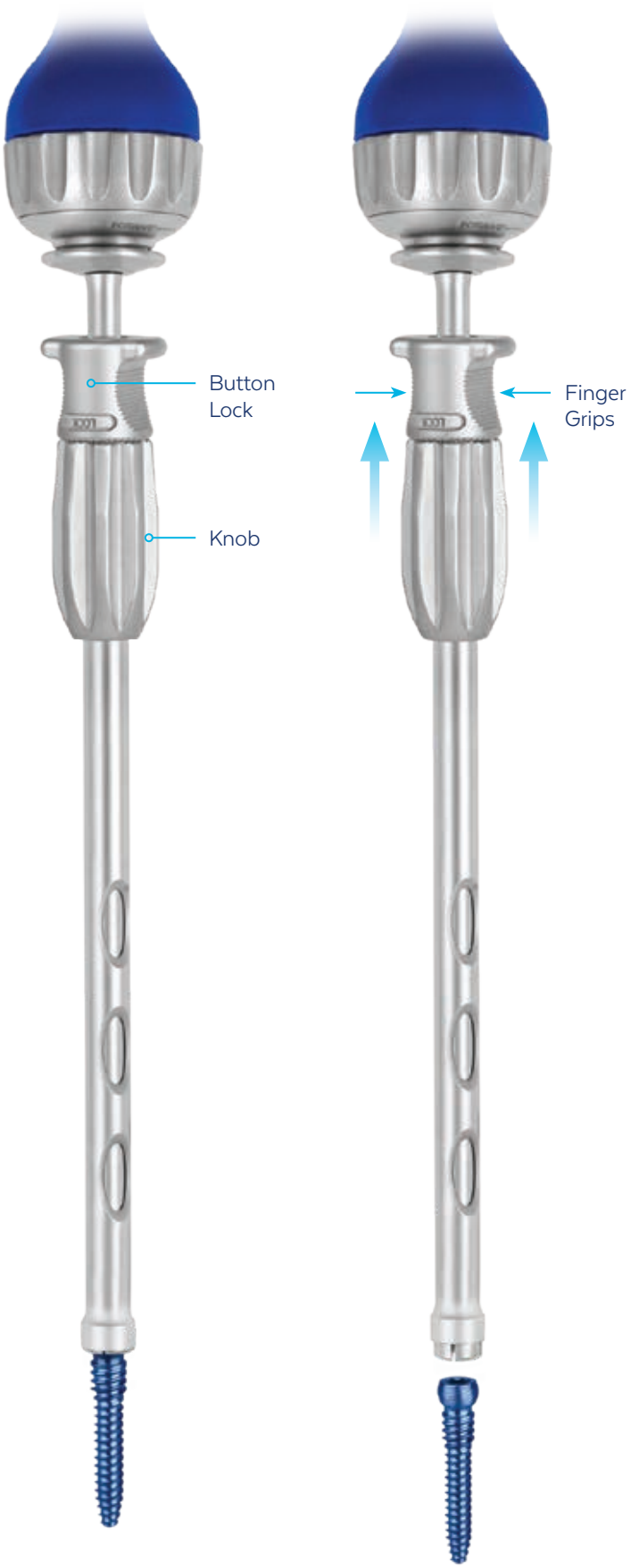
Ensure that the finger grip is pulled back towards the handle and the knob is rotated completely counterclockwise. Holding the threaded portion of the selected screw straight, engage the screwdriver tip onto the screw post until fully seated.

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 ready for insertion.

The knob may be further tightened after the lock has been activated; rotate 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.



Screw loaded on screwdriver

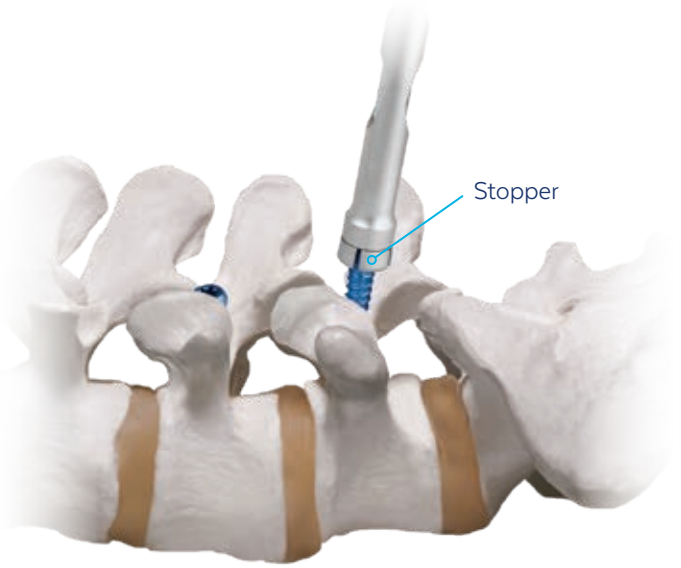
Disengaging screw

SCREW INSERTION (CONT'D)

Inserting Screw Posts

Drive the screw posts into the prepared pedicles using the Modular Screwdriver, 1/4" Quick-Connect, Short assembly. The driver stopper serves to represent the space filled by the screw head when attached. When complete, disengage the screwdriver from the screw. If the screws need to be removed or repositioned, the Self-Retaining Driver Shaft, 1/4" Quick-Connect may be used.

Note: When placing screws, do not back out screws prior to finalizing the construct.



Screw insertion

Screw Head Distraction

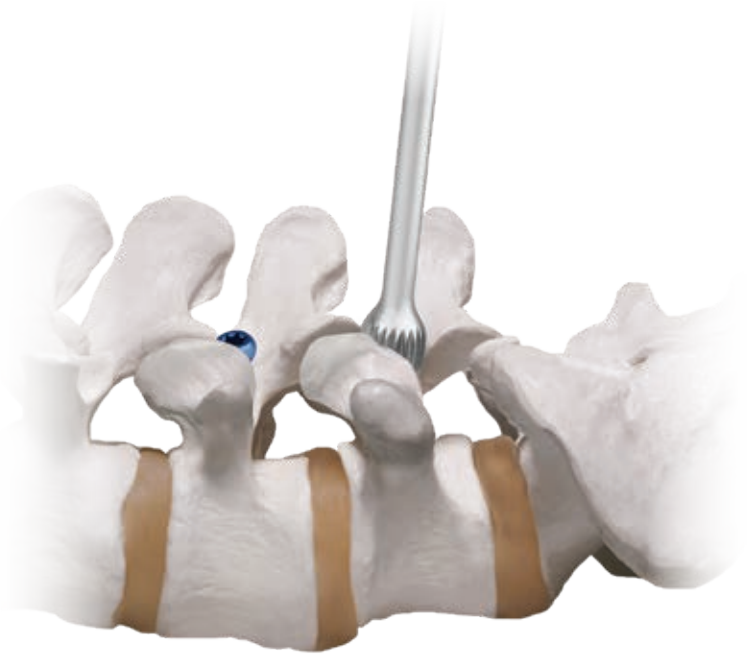
Distraction may be achieved using the screw post heads, prior to screw head application, to accommodate interbody spacer placement.

To distract the screw heads, 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 disc space open.

Distraction using Parallel Head Distractor

Screw Head Insertion

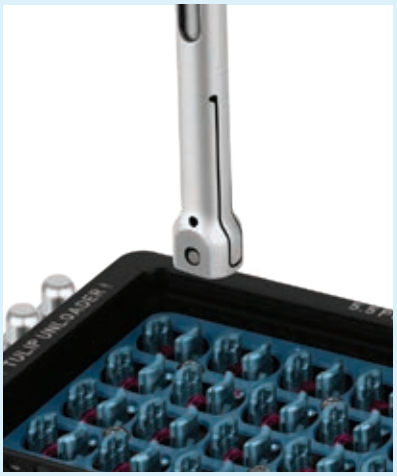
To ensure optimal clearance for screw head attachment, use the **Decortication Tool, Radial Cutting, 1/4", Quick-Connect** or **Decortication Tool, 1/4" Quick-Connect** and **T-handle, Ratcheting, 1/4", Quick-Connect** to remove any surrounding tissue and bone.



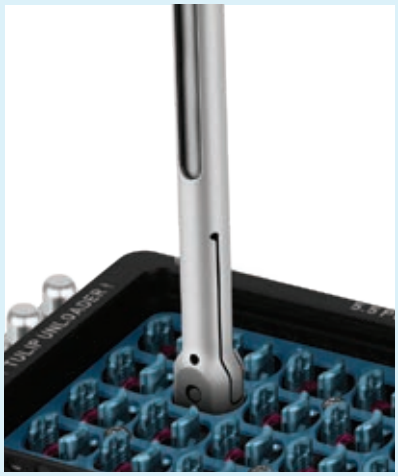
Using Decortication Tool

LOADING THE HEAD INSERTER

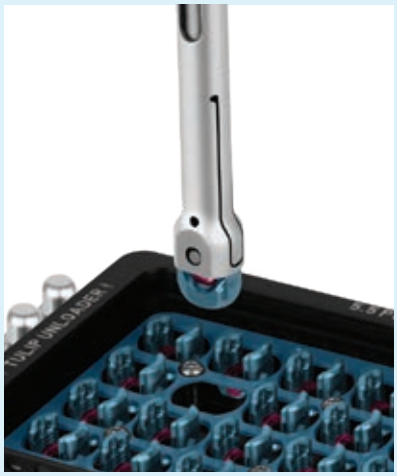
Hold the **Head Inserter** over the screw head module. Align the flats on the inserter with the open sides of the screw head. Lower the inserter directly onto the screw head and apply light pressure. Listen for the audible click; the screw head is attached to the inserter. The inserter handle remains 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 manually. This may result in an unsecured screw assembly. Always use the Head Inserter.

SCREW INSERTION (CONT'D)

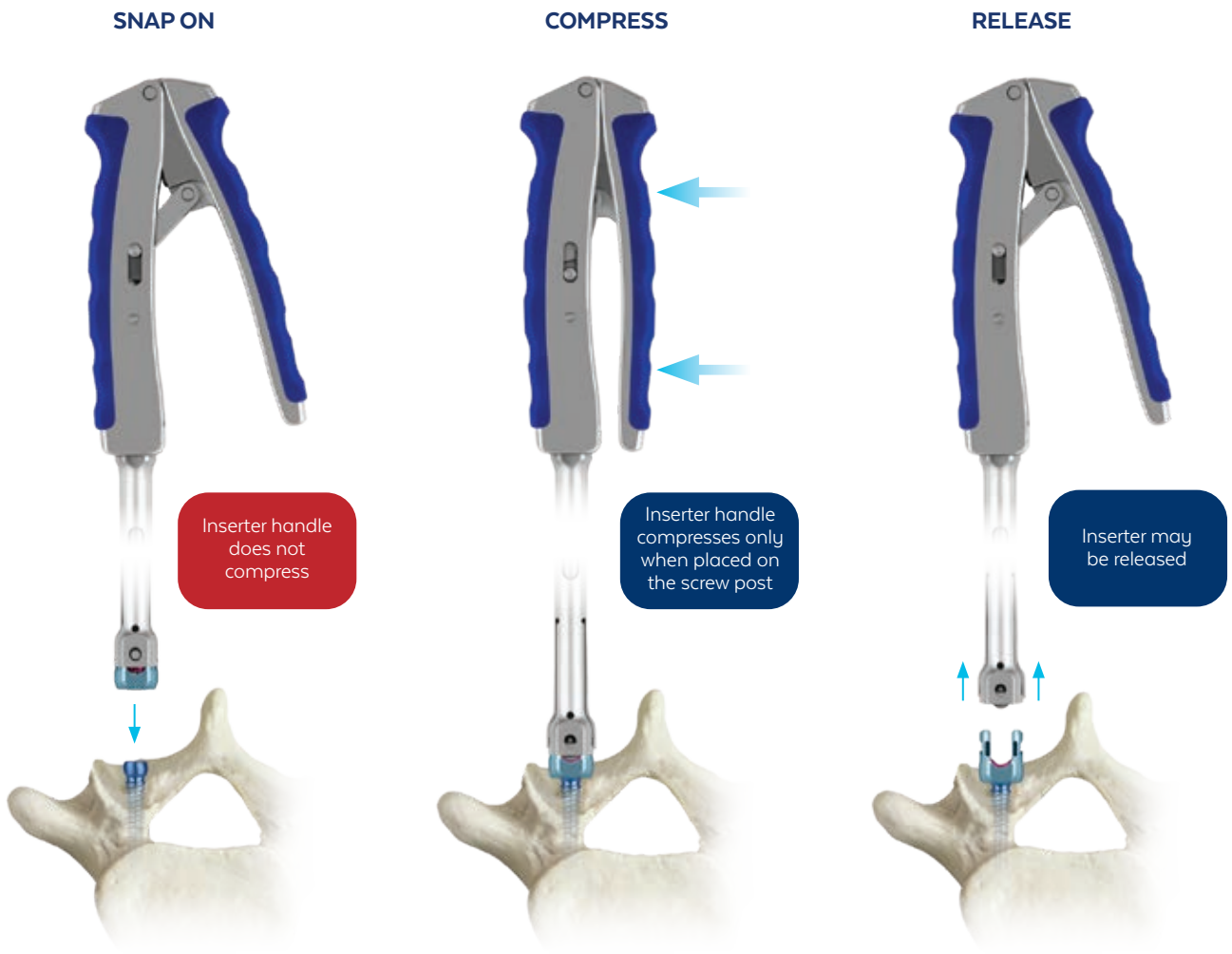
Screw Head Insertion (Cont'd)

CAUTION: The inserter is required for screw head attachment. Failure 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 screw post and apply axial force. Listen for the audible click that indicates that the screw head is attached to the screw post. At this point, the screw head is not yet locked onto 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 (while still attached to the screw head), pull the inserter upward, and rotate slightly to confirm that the screw head is attached and has polyaxial motion. Confirm screw head attachment.

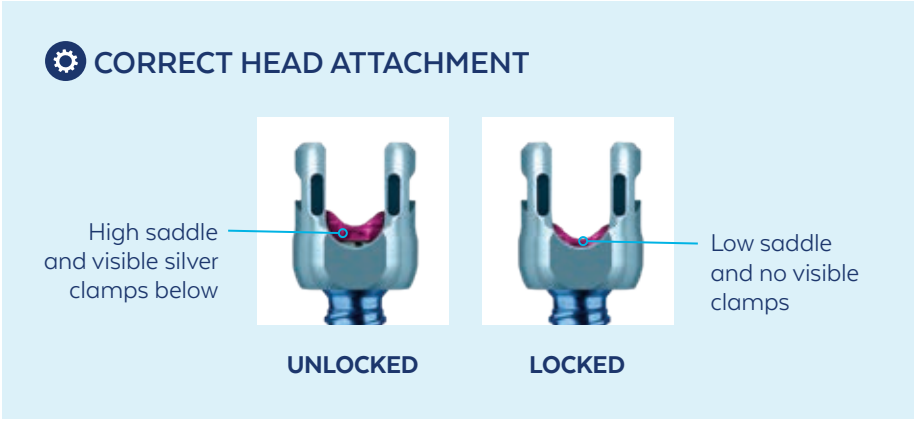
Upon confirmation, compress the inserter handle and simultaneously pull upward. This allows the inserter to release from the screw assembly for the next screw head application. Repeat steps for the remaining screw posts.



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 Removal (Optional)

Locked screw heads can only be removed *in situ* 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 that the instrument is bottomed out in the screw head and aligned to the same axis as the screw post.

Compress the release handle and simultaneously pull away from the screw posts 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 same patient only. This can 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.

SCREW INSERTION (CONT'D)

Exchanging Screw Head Style with Inserter

If the selected screw head loaded onto the Head Inserter needs to be exchanged for a different style, the Screw Head Unloader may be used.

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 screw head onto the inserter as desired.

Use the Head Release to remove the screw head from the 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 pin 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 locking to a screw post with the Head Inserter.

Applying screw head to screw head unloader using Head Inserter

Releasing screw head from screw head unloader using Head Release

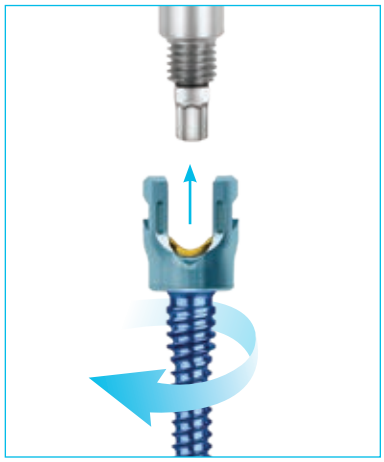
Unloading locked screw head from Head Inserter

Option B: CREO MCS® Preassembled

Loading the Screwdriver

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

Ensure that 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 screwdriver tip into the screw head. Rotate the knob of the screwdriver clockwise until tight to engage the internal tulip threads.



Engaging screw

Press the oblong button above the knob to activate the lock. The lock automatically slides distally, meeting the knob and securing the screw to the screwdriver. The screw is ready for use.

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 unthreading and disengaging the screw.*

To disengage, grasp the lock by the finger grips on each side. Pull the lock back towards the screwdriver handle. The button will click and release. Rotate the knob counterclockwise to unthread and disengage the screwdriver from the screw.

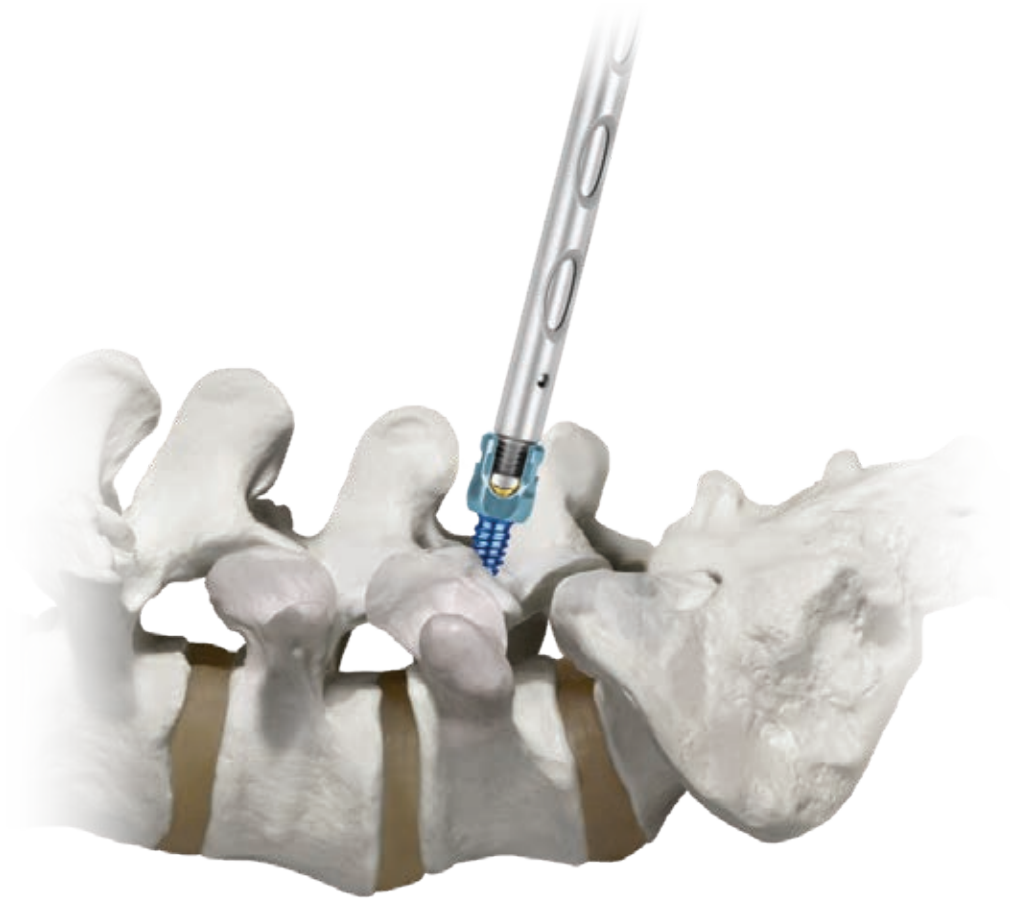
Screw loaded on screwdriver

Disengaging screw

SCREW INSERTION (CONT'D)

Inserting Screws

Drive the screw into the drilled and tapped holes using the Rigid Screwdriver, 1/4" Quick-Connect and straight handle or T-handle. When complete, disengage the screwdriver from the screw. If screw removal or repositioning is required, the self-retaining driver shaft may be used.

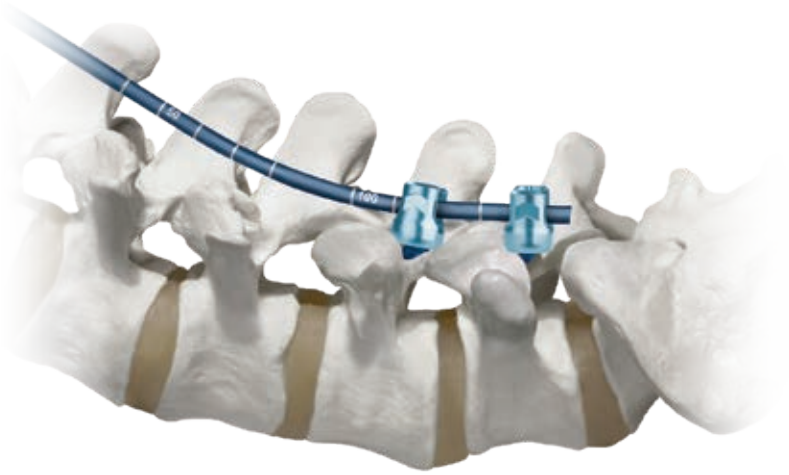


Screw insertion

STEP 5 ROD INSERTION AND LOCKING CAP DELIVERY

Rod Preparation

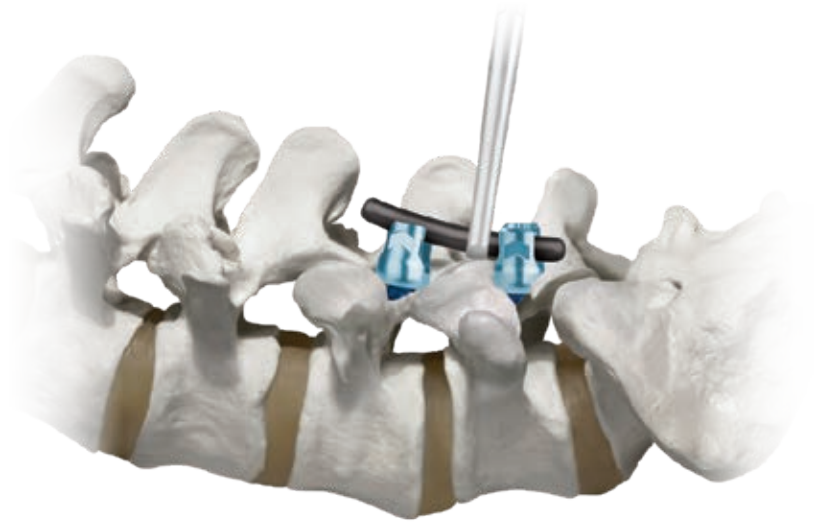
Determine the appropriate length and contour of the rod using the **Rod Template**. Straight and curved rods are available in a variety of lengths. Rods may be contoured using the **Power Bender**.



Using Rod Template

Rod Insertion

Using the **Rod Holder**, grasp the rod and insert it into the cortical screws.



Rod insertion

Option A: Locking Cap Driver, Short

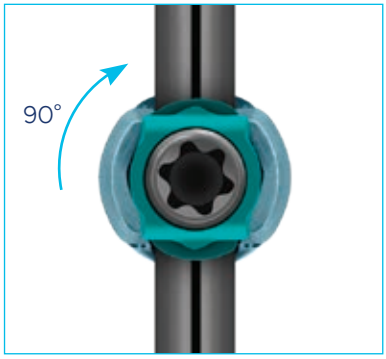
Loading the Driver

Align the black etching on the sides of the Locking Cap Driver, Short, with the curved sides of the cutout in the locking cap module. Push the locking cap driver down over the locking cap until fully seated.

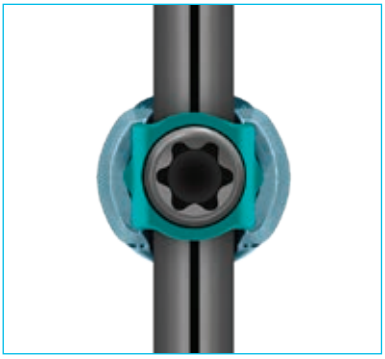
Aligning driver

Locking Cap Insertion

With a loaded locking cap 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 the driver. 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 may be used.

Note: The Cross Connector Driver, Torque-Limiting is additionally available upon request.

Rotating guide handle 90º

Locking cap insertion through Locking Cap Guide

Option B: Semi-Automatic Locking Cap Driver

Loading the Locking Cap 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 locking cap driver with the flats on the locking cap module. Push the locking cap driver down over the locking cap until fully seated. Repeat these steps for up to a total of eight locking caps.

Note: This driver must be loaded from the locking cap module.

View the yellow indicator and etchings numbered 1–8 on the distal end of the locking cap 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

Driver in locked position

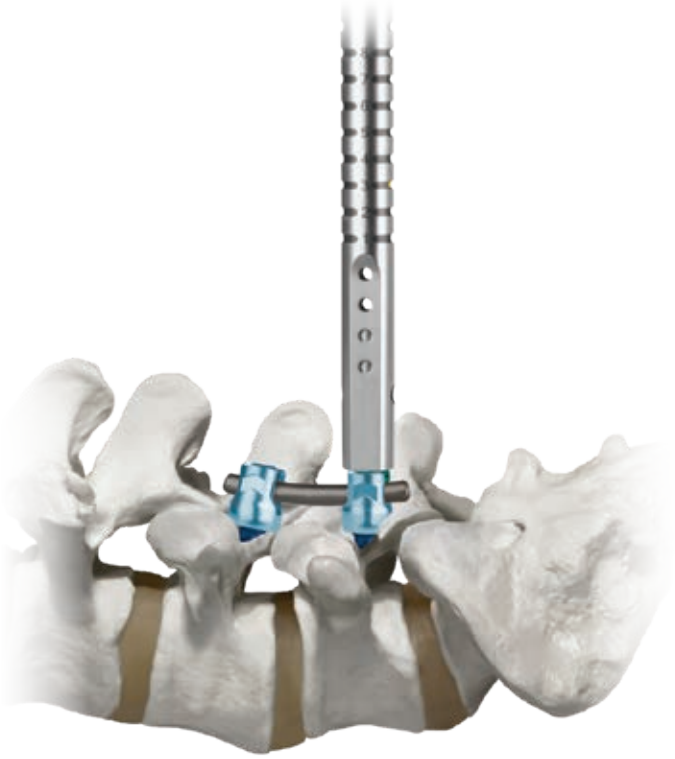
Locking Cap Insertion

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 driver cephalad or caudal along the rod and lift to release the locking cap, allowing the next locking cap to automatically advance in the driver.

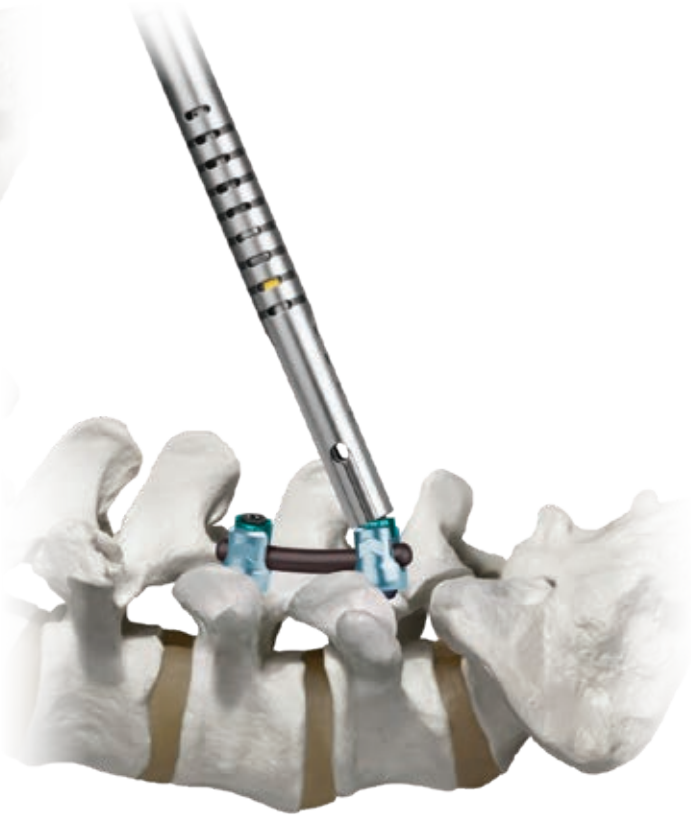
Locking cap insertion requires minimal effort. Do not force the driver. If the locking cap is difficult to rotate, the rod may not be seated properly and further rod reduction and/or rod contouring may be required.

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



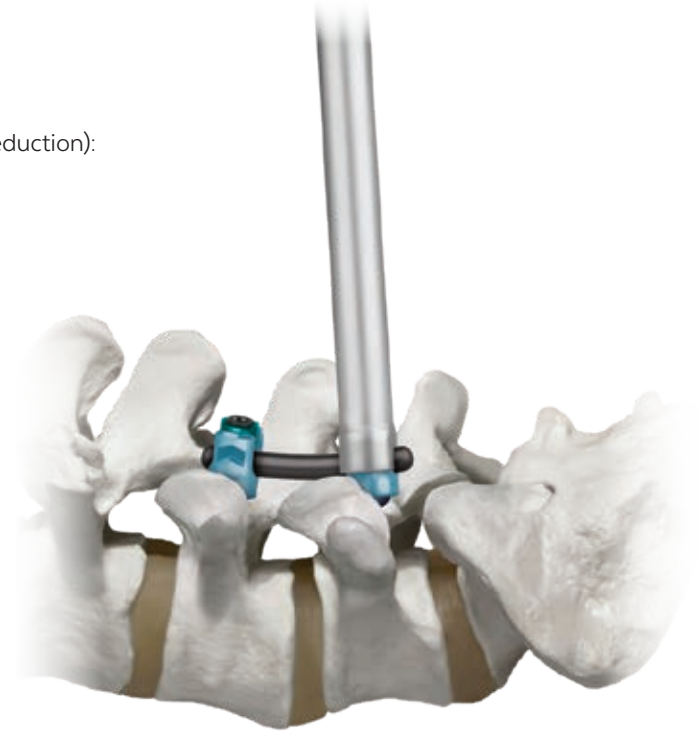
Tilting driver along rod

STEP 6 ROD REDUCTION

The CREO MCS® system has five 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)

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



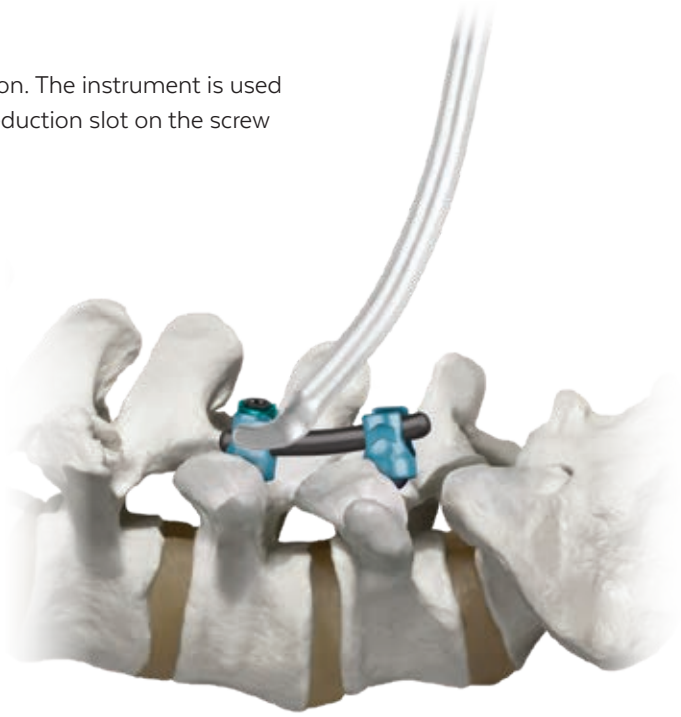
Rod reduction using Locking Cap Guide

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.

Option B: Reduction Fork

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



Rod reduction using Reduction Fork

Option C: Geared Reducer, Pistol Grip

The **Geared Reducer, Pistol Grip** provides up to 10mm of reduction. Ensure that 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 head 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, Short is inserted through the reducer.

Remove the reducer by unlocking the ratchet on the back and pull up.

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 that 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 screw head 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, Short is inserted through the reducer.

Remove the reducer by unlocking the ratchet on the back and pull up.

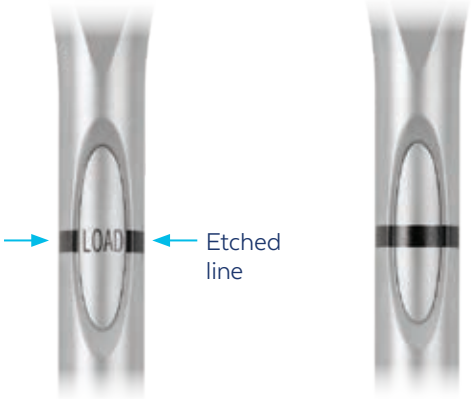
Option E: Tower Reducer

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

Ensure that the reducer is in the starting position by fully backing it up counterclockwise until the LOAD marking 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, Short into the reducer. Rotate the locking cap driver 90° clockwise to engage the locking cap.



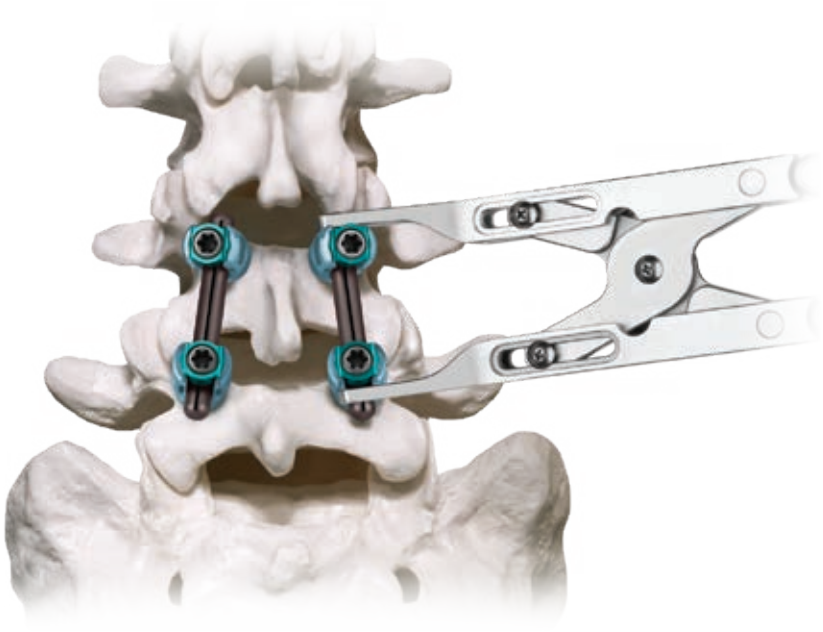
LOAD position

Fully reduced

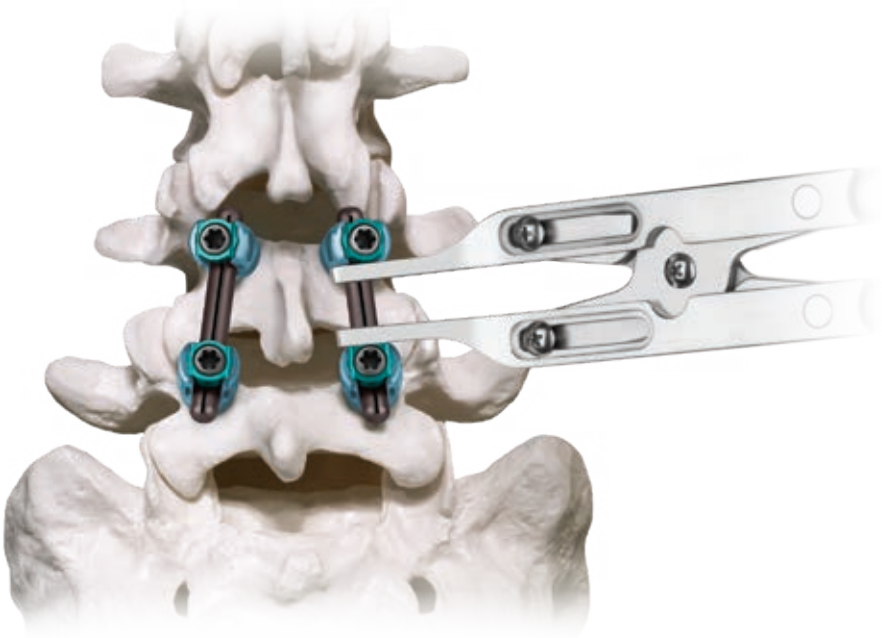
Rod reduction using Tower Reducer with optional tower reducer attachment

STEP 7 COMPRESSION OR DISTRACTION

CREO MCS® cortical 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 complete, provisionally tighten the set screws using the **Ratcheting Torque-Limiting Handle, 1/4" Quick-Connect** and **Driver Shaft, 1/4" Quick-Connect, Short**.



Compression

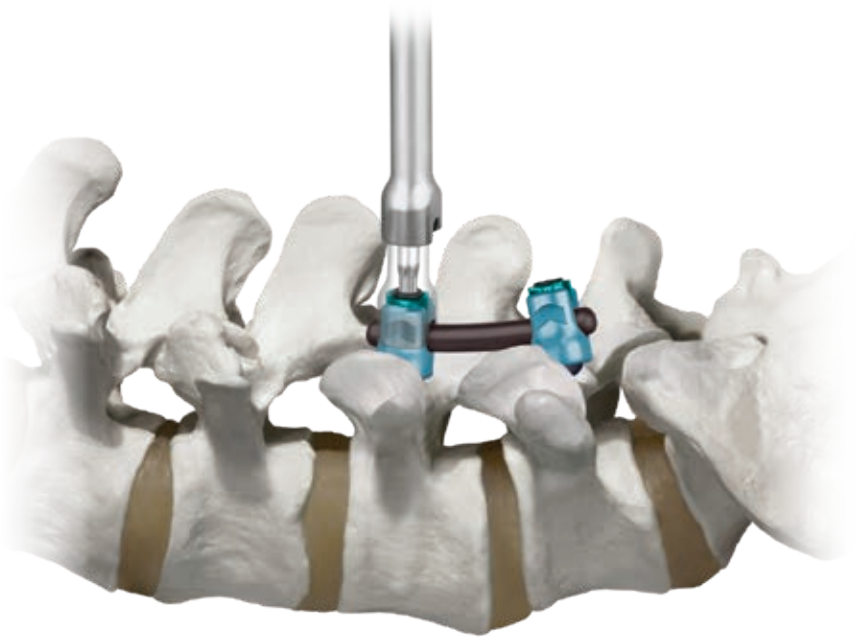


Distraction

STEP 8 FINAL TIGHTENING

Final tightening of the 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 that the driver tip is fully engaged in the set screw. Slide the counter-torque over the screw head, ensuring that 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.

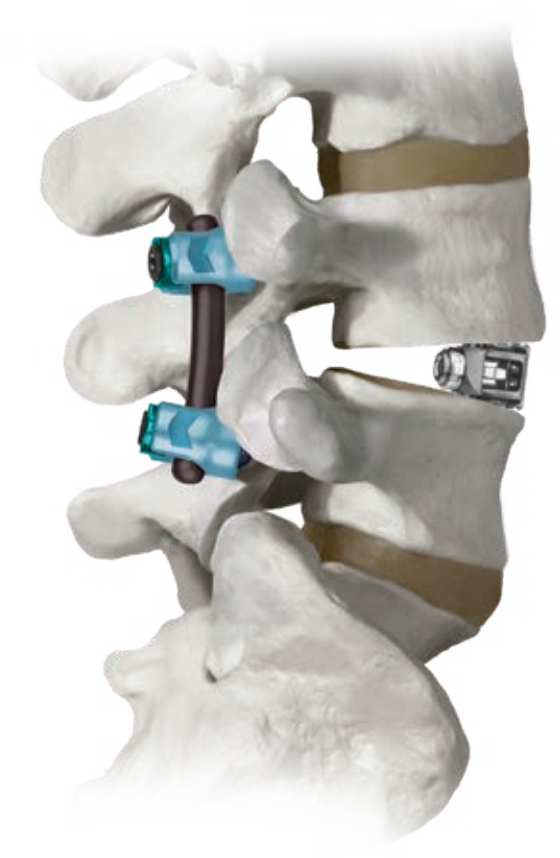


USING THE ADJUSTABLE COUNTER-TORQUE HANDLE

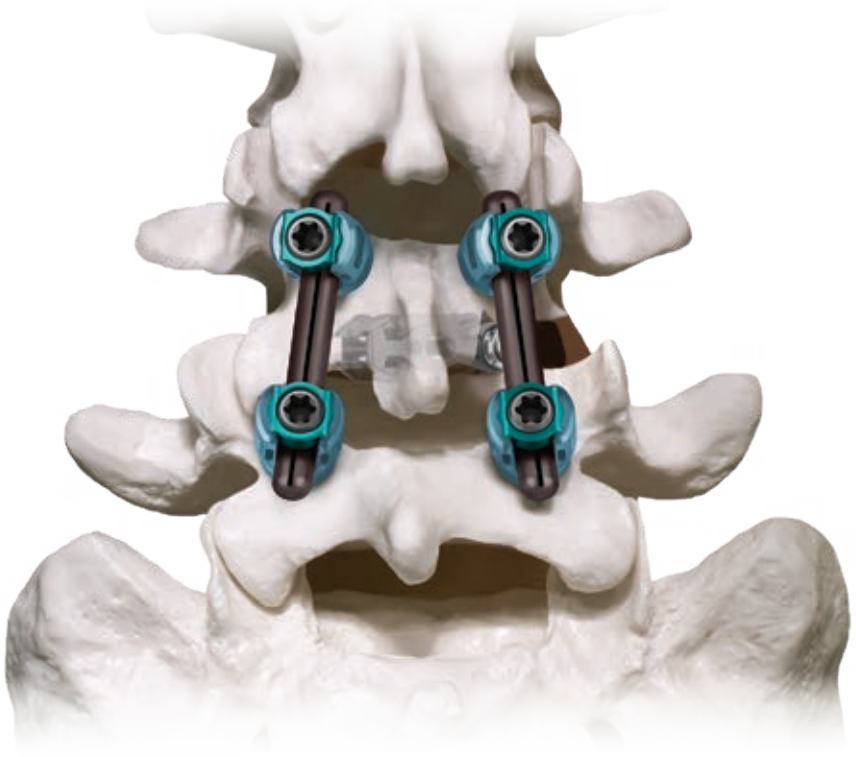
To adjust the orientation of the adjustable counter-torque, press and hold the button on the top of the instrument to rotate the handle in 45° increments. Secure the handle by releasing the button.

Adjusting handle

FINAL CONSTRUCT



Final CREO MCS® and ALTERA® construct, lateral view*



Final CREO MCS® and ALTERA® construct, posterior view*

**For a complete description of the ALTERA® technique, refer to the ALTERA® Technique Guide (GMTGD126).*

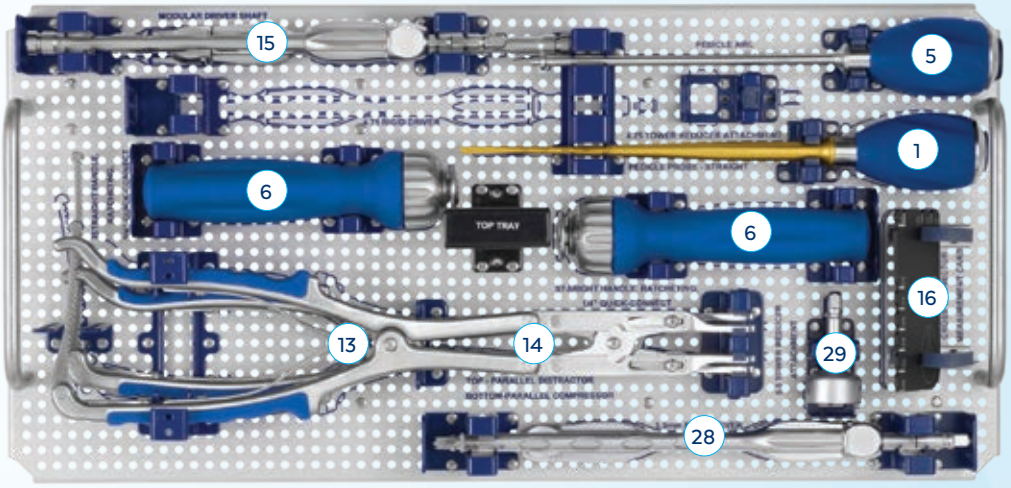
CREO MCS®
CORE INSTRUMENT SET 9119.9501

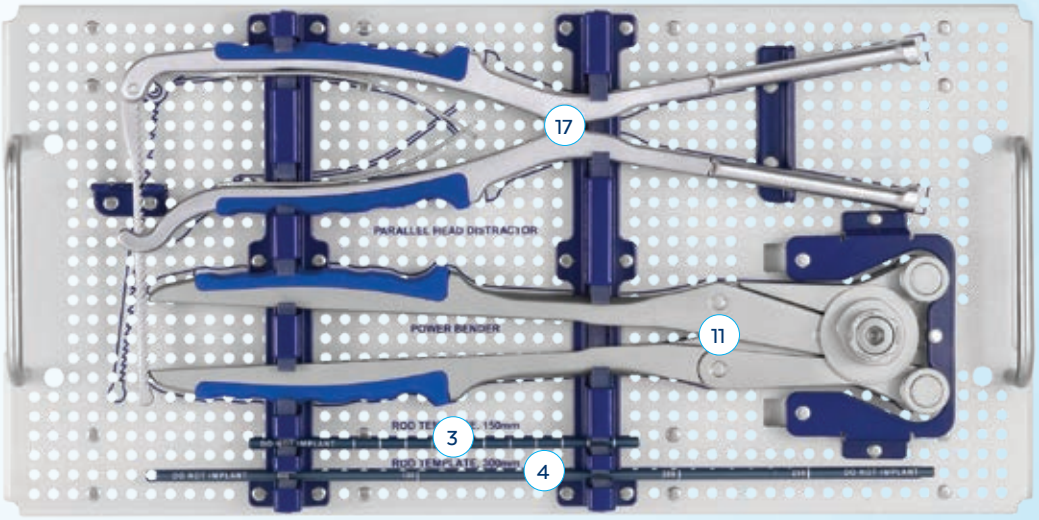
	Part No.	Description	Qty
1	602.101	Pedicle Probe, Straight	1
	602.102	Pedicle Probe, Curved	0
2	602.106	Ball Tip Probe, Curved	1
3	602.501	Rod Template, 150mm	1
4	602.517	Rod Template, 300mm	1
5	6067.0001	Pedicle Awl	1
6	6067.0010	Straight Handle, Ratcheting, 1/4" Quick-Connect	2
	6067.0020	T-Handle, Ratcheting, 1/4" Quick-Connect	0
7	6067.0040	Ratcheting Torque-Limiting Driver, 1/4" Quick-Connect	1
8	6067.0050	Driver Shaft, 1/4" Quick-Connect, Short	1
9	6067.0060	Self-retaining Driver Shaft, 1/4" Quick-Connect	1
10	6067.0070	Decortication Tool, Radial Cutting, 1/4" Quick-Connect	1
11	6067.0075	Power Bender	1
12	6067.0080	Rod Holder	1
13	6067.0090	Parallel Compressor	1
14	6067.0095	Parallel Distractor	1
15	6067.1041	Modular Screwdriver, 1/4" Quick-Connect, Short	2
16	6067.1065	Cross Connector Measurement Card	1
17	6067.7005	Parallel Head Distractor	1
18	6119.0020	Cortical Tap, 5.0/4.0	0
19	6119.0022	Cortical Drill, 5.0/4.0	1
	6119.0023	Dual Outer Diameter Tap 5.0-4.0x20mm	1
	6119.0024	Dual Outer Diameter Tap 5.0-4.0x35mm	0
	6119.0026	Cortical Power Drill, 5.0/4.0	1
20	6119.0030	Cortical Tap, 5.5/4.5	0
21	6119.0032	Cortical Drill, 6.0/5.0	1
	6119.0033	Dual Outer Diameter Tap 5.5-4.5x20mm	1
	6119.0034	Dual Outer Diameter Tap 5.5-4.5x35mm	0

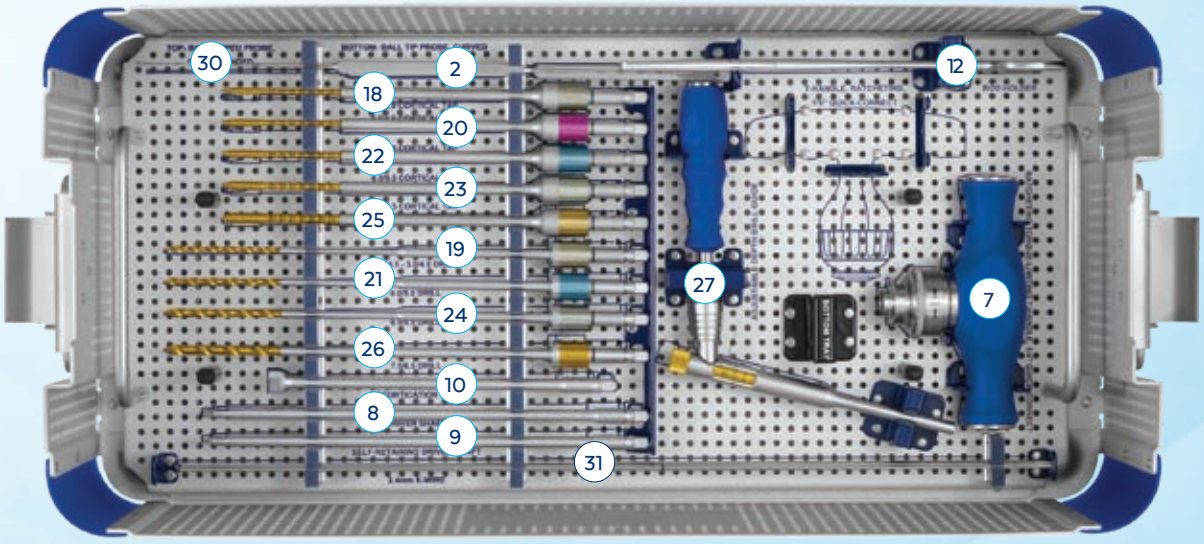
	Part No.	Description	Qty
	6119.0036	Cortical Power Drill, 6.0/5.0	1
22	6119.0040	Cortical Tap, 6.0/5.0	0
	6119.0043	Dual Outer Diameter Tap 6.0-5.0x20mm	1
	6119.0044	Dual Outer Diameter Tap 6.0-5.0x35mm	0
23	6119.0050	Cortical Tap, 6.5/5.5	0
24	6119.0052	Cortical Drill, 6.5/5.5	1
	6119.0053	Dual Outer Diameter Tap 6.5-5.5x20mm	1
	6119.0054	Dual Outer Diameter Tap 6.5-5.5x35mm	0
	6119.0056	Cortical Power Drill, 6.5/5.5	1
25	6119.0060	Cortical Tap, 7.5/6.5	0
26	6119.0062	Cortical Drill, 7.5/6.5	1
	6119.0063	Dual Outer Diameter Tap 7.5-6.5x20mm	1
	6119.0064	Dual Outer Diameter Tap 7.5-6.5x35mm	0
	6119.0066	Cortical Power Drill, 7.5/6.5	1
27	6119.0099	Drill Guide with Adjustable Stop, 10-50mm	1
28	6119.1080	Rigid Screwdriver, 1/4" Quick-Connect	2
29	6119.2005	Tower Reducer Attachment, 1/4" Quick-Connect	1
30	624.110	Ball Tipped Probe, Double Ended	1
31	639.002	2.4mm K-Wire, Sharp 450mm	0
	9119.0501	CREO MCS® CORE Instrument Graphic Case	

*Items in gray are additionally available.

CREO MCS®
CORE INSTRUMENT SET 9119.9501





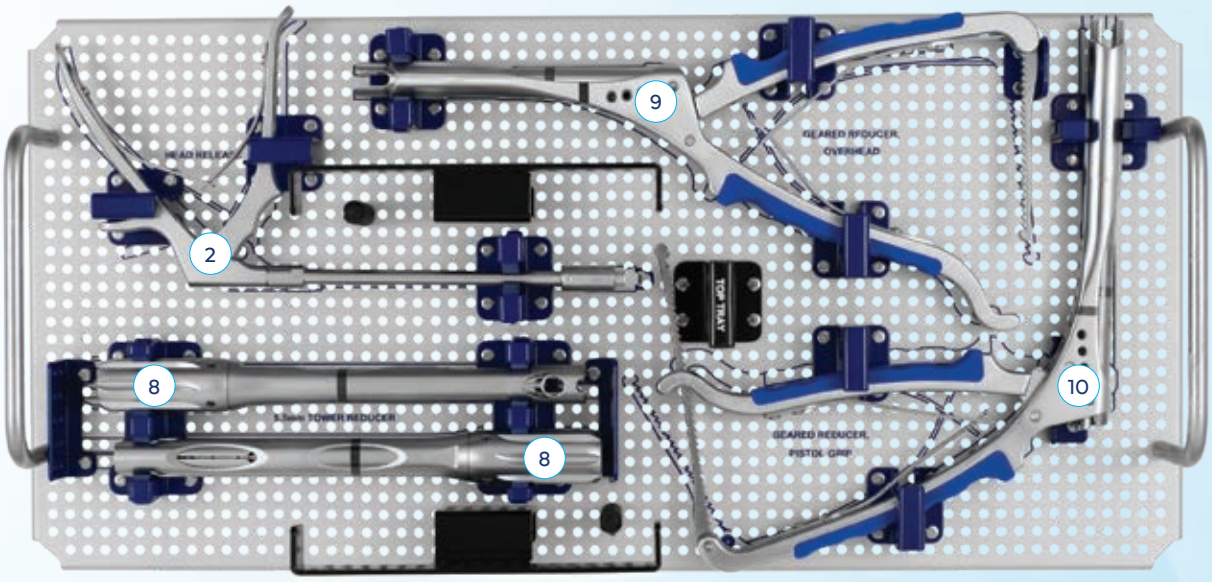


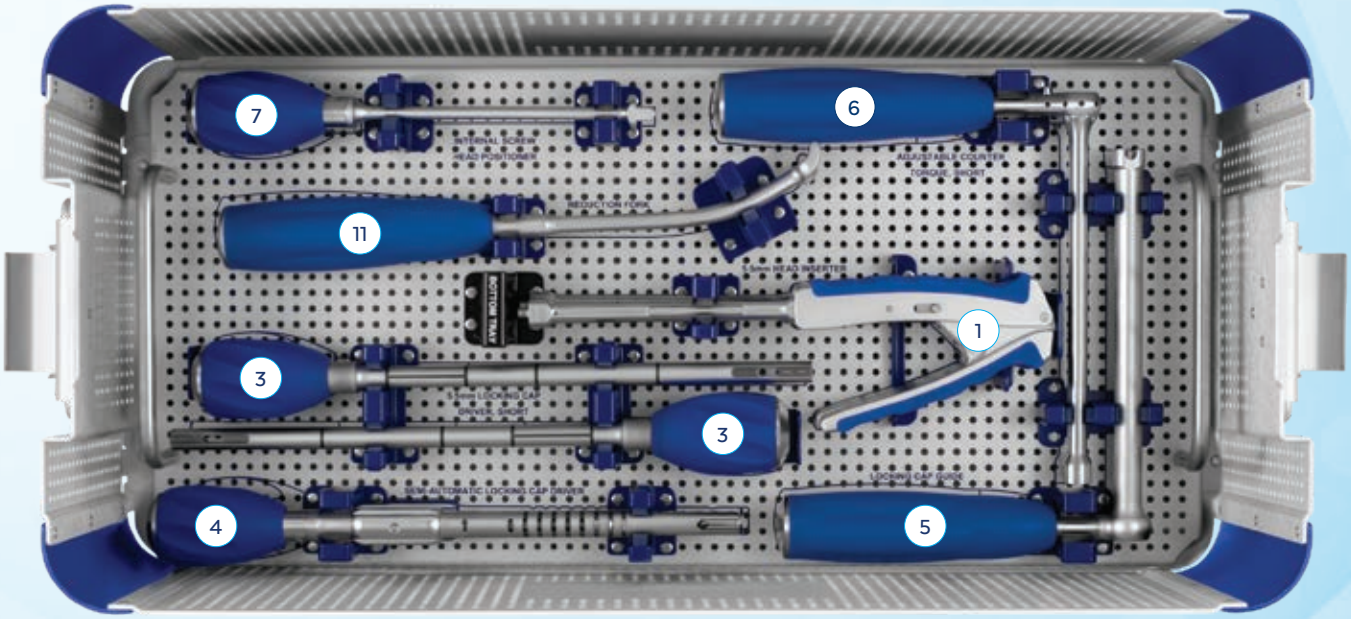
CREO MCS® 5.5
INSTRUMENT SET 9119.9502

	Part No.	Description	Qty
1	6119.1000	Head Inserter	2
2	6119.1005	Head Release	1
3	6119.1010	Locking Cap Driver, Short	2
4	6119.1020	Semi-Automatic Locking Cap Driver	0
5	6119.1025	Locking Cap Guide	1
6	6119.1030	Adjustable Counter-Torque, Short	1
7	6119.1070	Screw Head Positioner, Internal	1
8	6119.2000	Tower Reducer	2
9	6119.2010	Geared Reducer, Overhead	1
10	6119.2015	Geared Reducer, Pistol Grip	1
11	6119.2030	Reduction Fork	1
	9119.0502	CREO MCS® 5.5 Instrument Graphic Case	

**Items in gray are additionally available.*

CREO MCS® 5.5
INSTRUMENT SET 9119.9502





CREO MCS® 5.5
IMPLANT SET 9119.9503

CREO AMP® Cortical Screw, Modular

Part No.	Diameter/Length	Qty
1119.1220	5.0-4.0x20mm	4
1119.1225	5.0-4.0x25mm	6
1119.1230	5.0-4.0x30mm	6
1119.1235	5.0-4.0x35mm	4
1119.1240	5.0-4.0x40mm	0
1119.1245	5.0-4.0x45mm	0
1119.1320	5.5-4.5x20mm	4
1119.1325	5.5-4.5x25mm	6
1119.1330	5.5-4.5x30mm	6
1119.1335	5.5-4.5x35mm	4
1119.1340	5.5-4.5x40mm	0
1119.1345	5.5-4.5x45mm	0
1119.1420	6.0-5.0x20mm	4
1119.1425	6.0-5.0x25mm	6
1119.1430	6.0-5.0x30mm	6
1119.1435	6.0-5.0x35mm	6
1119.1440	6.0-5.0x40mm	4
1119.1445	6.0-5.0x45mm	0
1119.1520	6.5-5.5x20mm	4
1119.1525	6.5-5.5x25mm	6
1119.1530	6.5-5.5x30mm	6
1119.1535	6.5-5.5x35mm	6
1119.1540	6.5-5.5x40mm	6
1119.1545	6.5-5.5x45mm	4
1119.1550	6.5-5.5x50mm	0
1119.1555	6.5-5.5x55mm	0
1119.1625	7.5-6.5x25mm	2
1119.1630	7.5-6.5x30mm	2
1119.1635	7.5-6.5x35mm	4
1119.1640	7.5-6.5x40mm	4
1119.1645	7.5-6.5x45mm	4
1119.1650	7.5-6.5x50mm	0
1119.1655	7.5-6.5x55mm	0

CREO® 5.5 Cortical Screw

Part No.	Diameter/Length	Qty
5119.3222	5.0-4.0x20mm	4
5119.3227	5.0-4.0x25mm	6
5119.3232	5.0-4.0x30mm	6
5119.3237	5.0-4.0x35mm	4
5119.3322	5.5-4.5x20mm	4
5119.3327	5.5-4.5x25mm	6
5119.3332	5.5-4.5x30mm	6
5119.3337	5.5-4.5x35mm	4
5119.3422	6.0-5.0x20mm	4
5119.3427	6.0-5.0x25mm	6
5119.3432	6.0-5.0x30mm	6
5119.3437	6.0-5.0x35mm	6
5119.3442	6.0-5.0x40mm	4
5119.3522	6.5-5.5x20mm	4
5119.3527	6.5-5.5x25mm	6
5119.3532	6.5-5.5x30mm	6
5119.3537	6.5-5.5x35mm	6
5119.3542	6.5-5.5x40mm	4
5119.3547	6.5-5.5x45mm	4

5.5mm Straight Rod, Titanium Alloy

Part No.	Length	Qty
1119.5035	35mm	4
1119.5045	45mm	4
1119.5055	55mm	4
1119.5065	65mm	4
1119.5075	75mm	4
1119.5100	100mm	2
1119.5150	150mm	2

**Items in gray are additionally available.*

CREO MCS® 5.5
IMPLANT SET 9119.9503

5.5mm Curved Rod, Titanium Alloy

Part No.	Length	Qty
1119.7035	35mm	2
1119.7040	40mm	2
1119.7045	45mm	2
1119.7050	50mm	2
1119.7055	55mm	2
1119.7060	60mm	2
1119.7065	65mm	2
1119.7070	70mm	2
1119.7075	75mm	2
1119.7100	100mm	2
1119.7150	150mm	2

5.5mm Curved Rod, CoCr

Part No.	Length	Qty
7119.7035	35mm	0
7119.7040	40mm	0
7119.7045	45mm	0
7119.7050	50mm	0
7119.7055	55mm	0
7119.7060	60mm	0
7119.7065	65mm	0
7119.7070	70mm	0
7119.7075	75mm	0
7119.7100	100mm	0
7119.7150	150mm	0

5.5mm Straight Rod, CoCr

Part No.	Length	Qty
7119.5035	35mm	0
7119.5045	45mm	0
7119.5055	55mm	0
7119.5065	65mm	0
7119.5075	75mm	0
7119.5100	100mm	0
7119.5150	150mm	0

Locking Mechanism

Part No.	Description	Qty
1119.0000	CREO® 5.5 Locking Cap	16
1119.0100	CREO AMP® 5.5 Polyaxial Tulip	16
9119.0503	CREO MCS® 5.5 Implant Graphic Case	
9119.0504	CREO MCS® 5.5 Locking Cap Module	
9119.0506	CREO MCS® 5.5 Rod Module	
9119.0509	CREO MCS® 5.5 Screw Module	
9119.0511	CREO MCS® 5.5 Polyaxial Tulip Module	

**Items in gray are additionally available.*

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		

DI179A REV P

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)

CE 0297

GMTGD120
06.21 Rev E