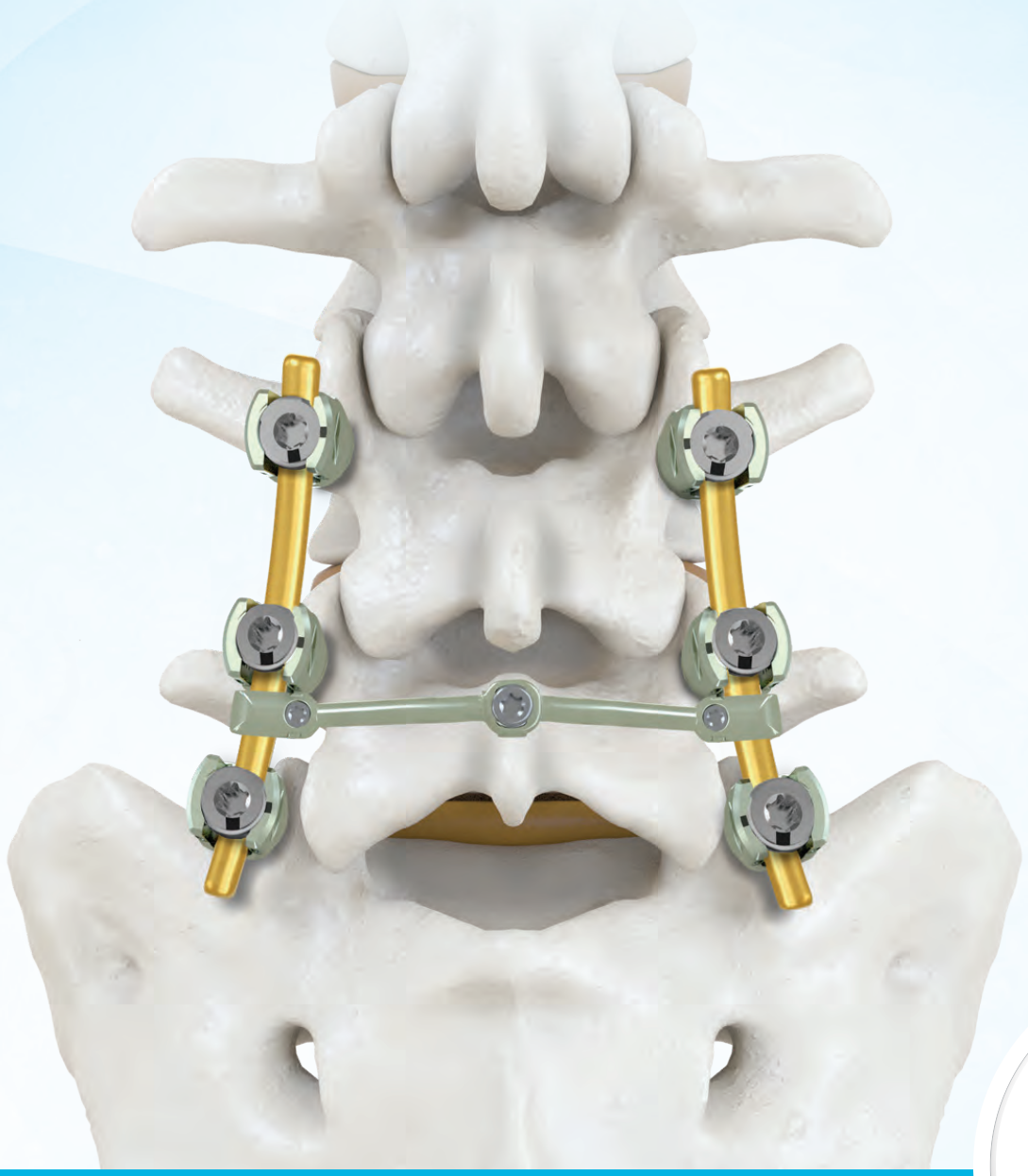
GLOBUS MEDICAL



CREO DLX®

Stabilization System

SURGICAL TECHNIQUE GUIDE

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GLOBUS MEDICAL

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

Life moves us

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

SURGICAL TECHNIQUE GUIDE

CREO DLX®

CREO DLX®

Stabilization System

CREO DLX® Stabilization System is a comprehensive 6.0mm and 6.35mm diameter rod based pedicle screw system that offers a large diameter rod solution for complex spinal deformity, tumor, and trauma pathologies.

Robust implants and instruments provide versatile options for cases requiring stiffer, stronger constructs. This system is designed to deliver reliability, speed, and efficiency in challenging procedures.

DESIGNED FOR STRENGTH

The robust screw head is optimized to withstand correction forces in patients with large, stiff curves. The screw accepts a 6.0mm or 6.35mm rod for increased construct strength and stability.

ENHANCED LOCKING CAP

The CREO DLX® Threaded Locking Cap is designed to decrease cross-threading while requiring fewer revolutions to tighten, which may save time in the operating room.

EFFICIENT REDUCTION OPTIONS

The CREO DLX® Quick-Release Reduction Clip incorporates a secure 4-point connection to the screw head and an instant 1-step release for efficiency. The system offers 6 reduction options ranging from 3mm to 60mm.

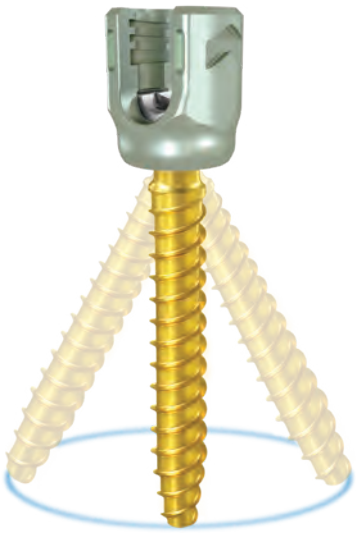
IMPLANT OVERVIEW

DLX Threaded Locking Cap

- 10Nm locking mechanism
- Robust enhanced locking cap is designed to decrease cross-threading
- Single step locking
- Ease of engagement
- DLX Fenestrated Locking Cap (1156.0015) is also available for use with DLX fenestrated procedures

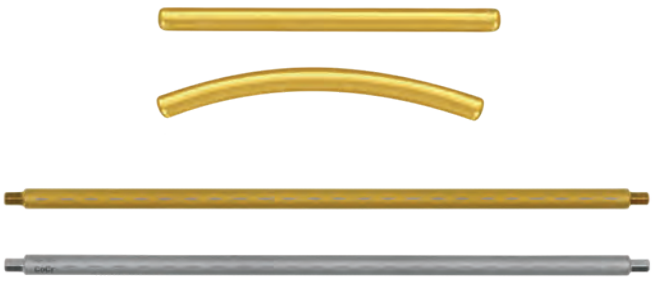
DLX Polyaxial Screw

- 25° angulation (50° total cone of angulation) provides intraoperative versatility
- Self-tapping design
- Double lead thread for rapid insertion
- Blunt tip for bicortical purchase
- Constant minor diameter for maximum bone purchase
- Taps are available, color-coded to screw size
- Accepts 6.0 or 6.35mm diameter rod
- Screw diameters: 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.5, 8.5, 9.5, 10.5, 11.5mm
- Screw lengths: 20-140mm



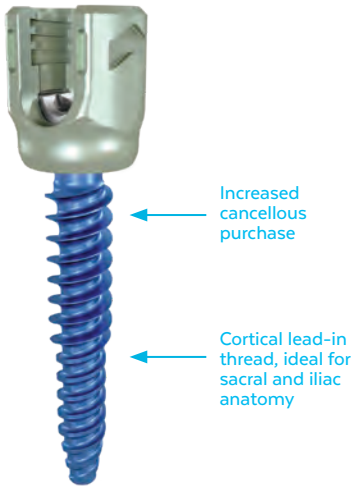
Rods

- 6.0 and 6.35mm diameters available
- Comprehensive selection of straight, curved, and hex-ended rods available in a range of sizes
- Available in titanium alloy (TAV) or cobalt chrome alloy (CoCr)
- Straight and curved rods are available from 20-150mm
- Hex-ended rods available from 200-700mm



DLX Dual Outer Diameter (DOD) Screws

- Designed to maximize purchase in cancellous and cortical bone
- Nominal distal diameter allows for deeper insertion into the sacrum while helping to minimize the risk of perforation
- Designed for enhanced fixation of the sacrum and ilium
- ±25° angulation (50° total cone of angulation)
- Available in proximal/distal outer diameters: 5.5/4.5mm, 6.5/5.0mm, 7.5/6.0mm, 8.0/6.5mm, 8.5/7.0mm, 9.5/8.0mm, 10.5/9.0mm
- Screw lengths: 30-120mm

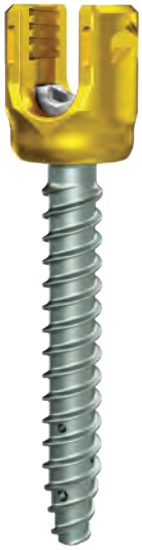


DLX Uniplanar Screw

- Useful for deformity correction
- Combines the versatility of a polyaxial screw with correction capabilities of a monoaxial screw
- Medial-lateral rigidity with cranial-caudal adjustability
- ±20° angulation in the cranial-caudal direction
- Screw diameters: 4.0, 4.5, 5.0, 5.5, 6.5, 7.5mm
- Screw lengths: 25-55mm

DLX Fenestrated Screws

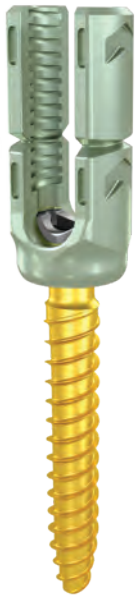
- Designed to enable screw augmentation with bone cement to enhance fixation in patients with advanced stage tumors involving the thoracic and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion
- Dispersed pattern of fenestration allows for even distribution of bone cement
- Screw fenestrations:
  - Four for lengths 25, 30, and 35mm
  - Six for lengths 40mm and longer



IMPLANT OVERVIEW

DLX Reduction Screw

- Allows for 15mm of gradual reduction
- Eliminates the need for reduction instruments
- ±25° angulation (50° total cone of angulation)
- Screw diameters: 4.0, 4.5, 5.0, 5.5, 6.5, 7.5, 8.5mm
- Screw lengths: 20-65mm



DLX Hooks

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

DLX Cross-Connectors

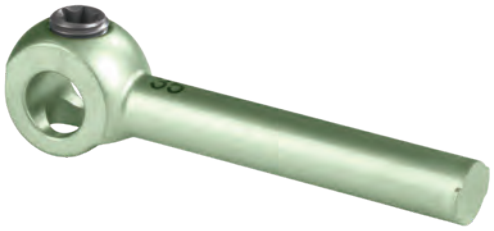
- Designed to enhance construct stability
- Robust profile and strength
- Angular, medial-lateral, cephalad-caudal, and anterior-posterior adjustments to provide secure fit
- Seven overlapping sizes: 29-33mm, 32-40mm, 38-50mm, 48-60mm, 58-70mm, 68-80mm, 78-90mm

DLX Low-Profile Cross-Connectors

- Ideal for use in thoracic spine to help reduce prominence
- 4.5mm profile above rod
- Angular and medial-lateral adjustments to provide secure fit
- Six overlapping sizes: 20-22mm, 21.5-25mm, 24.5-31mm, 30.5-43mm, 42.5-67mm, 66.5-91mm

DLX Threaded Head Offset Connectors

- 15–35mm lengths, in 5mm increments, and 150mm
- DLX Head offset connectors may be used with DLX DOD screws for strong pelvic fixation
- Available in CREO DLX® head, open, and closed offset connectors



INSTRUMENT OVERVIEW

PEDICLE PREPARATION

Pedicle Awl 6067.0001

Pedicle Probe - Straight 602.101

Pedicle Probe - Curved 602.102

Ball Tip Probe 602.105

Ball Tip Probe, Curved 602.106

Ball Tip Probe, Double-Ended 624.110

PEDICLE PREPARATION (CONT'D)

5.5mm Solid Tap, 40mm Threads 6156.0155

SCREW INSERTION

CREO DLX® Rigid Screwdriver Shaft 6156.1080

CREO DLX® Rigid Screwdriver Outer Sleeve 6156.1085

Self-Retaining Driver Shaft, ¼" Quick-Connect 6067.0060

Straight Handle, Ratcheting, ¼"
Quick-Connect 6067.0010

T-Handle, Ratcheting,
¼" Quick-Connect 6067.0020

FENESTRATED SCREW INSERTION INSTRUMENTS

If utilizing CREO DLX® Fenestrated Screw implants, refer to the CREO® Fenestrated System Technique Guide (GMTGD201) for additional instruments needed for fenestrated screw insertion and bone cement preparation.

Cannulated Driver Shaft, CREO® Fenestrated 6192.0040

CREO DLX® Fenestrated Screwdriver Outer Sleeve 6156.0030

CREO DLX® Fenestrated Screwdriver Counter-Torque 6156.0035

ROD INSERTION AND MANIPULATION

Rod Template, 150mm 602.501

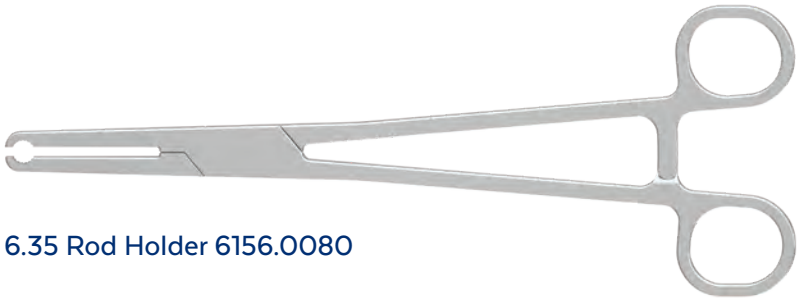
Rod Template, 300mm 602.517

Rod Template, Silicone, 500mm 602.519

Items in gray are additionally available.

ROD INSERTION AND MANIPULATION (CONT'D)

6.35 Power Bender 6156.0075



6.35 Rod Holder 6156.0080

6.35 Rod Pusher 634.513

6.35 Power Rod Grip 6156.0085

6.35 Vise-Style Rod Grip 6156.3020

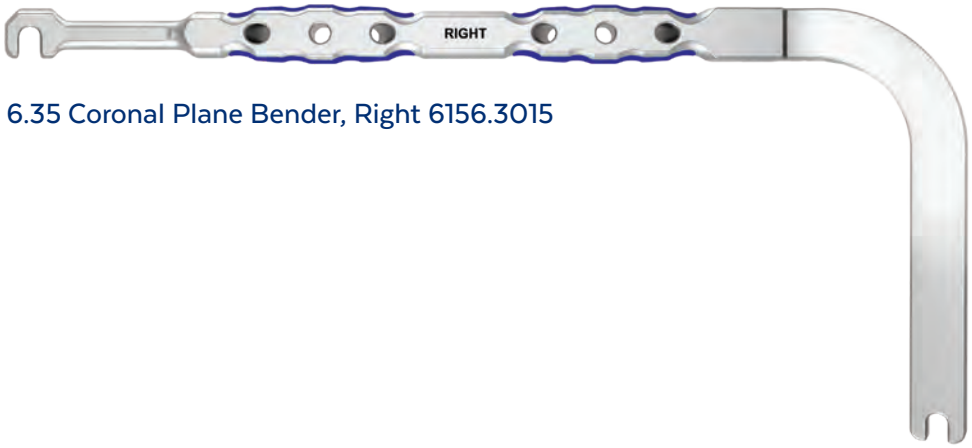
ROD INSERTION AND MANIPULATION (CONT'D)

Rod Wrench 6067.3025

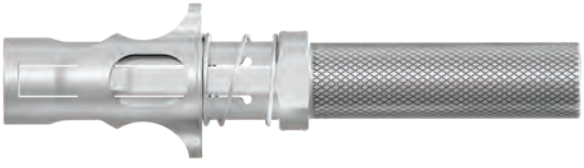
6.35 *In Situ* Bender, Left 6156.3000

6.35 *In Situ* Bender, Right 6156.3005

6.35 Coronal Plane Bender, Left 6156.3010



6.35 Coronal Plane Bender, Right 6156.3015



Quick-Release Derotation Attachment Tube 6156.3100

Wide Derotator Coupling Clamp, Short 6156.3105

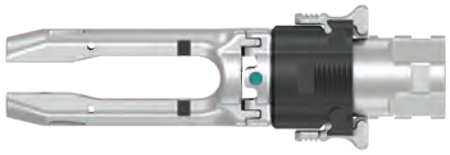
ROD REDUCTION INSTRUMENTS

CREO DLX® Reduction Fork 6156.2030

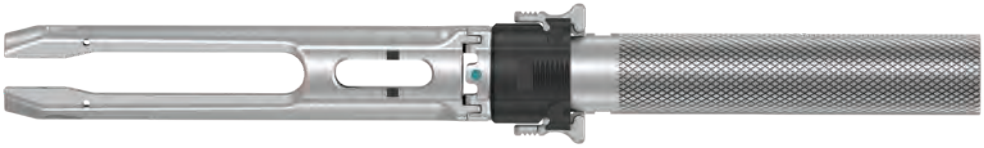
CREO DLX® Overhead Reducer 6156.2010

CREO DLX® Pistol Grip Reducer 6156.2015

ROD REDUCTION INSTRUMENTS (CONT'D)



CREO DLX® Quick-Release Reduction Clip 6156.2040

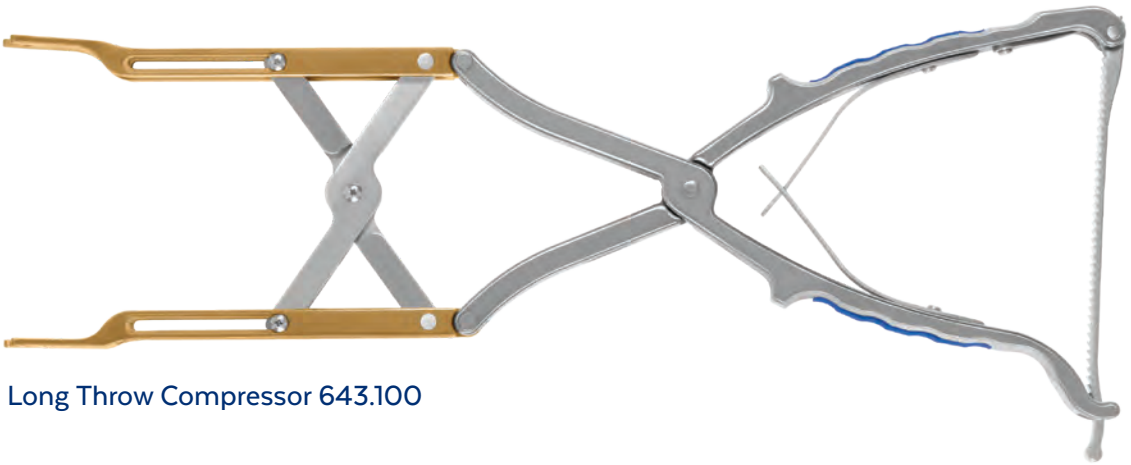


CREO DLX® Quick-Release Reduction Clip, Long 6156.2041

CREO DLX® Quick-Release Reduction Clip Pusher 6156.2045

CREO DLX® Quick-Release Reduction Clip Pusher, Long 6156.2046

SCREW LOCKING INSTRUMENTS



Long Throw Compressor 643.100

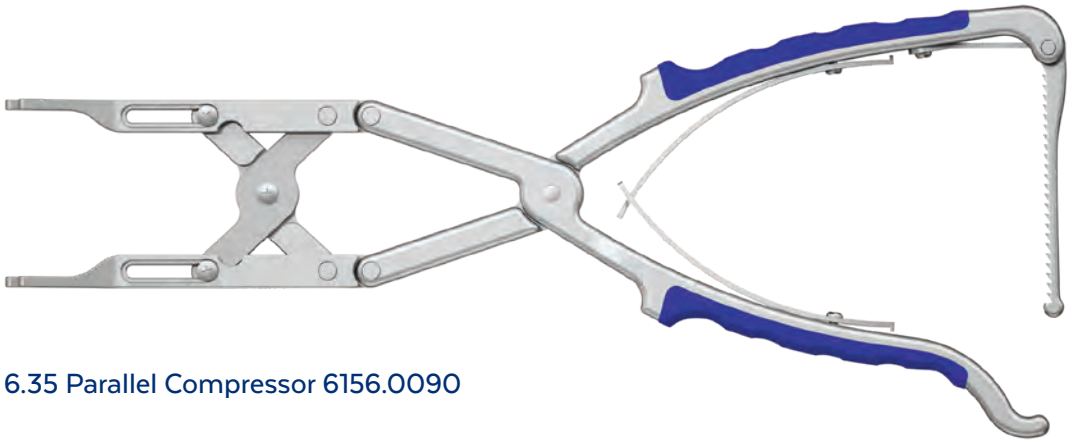
Torque-Limiting T-Handle, Ratcheting, 10Nm, ¼" Quick-Connect 6120.0040

Final Locking Driver Shaft, T27, ¼" Quick-Connect 6156.0050

Final Locking Driver Shaft, T27, ¼" Quick-Connect, Long 6156.0055

Threaded Locking Cap Driver 6156.5000

SCREW LOCKING INSTRUMENTS (CONT'D)



6.35 Parallel Compressor 6156.0090

6.35 Parallel Distractor 6156.0095

CREO DLX® Counter-Torque 6156.1030

SURGICAL TECHNIQUE

CREO DLX®

Refer to the package insert for information on the indications, device description, contraindications, precautions, warnings, and potential risks associated with this system. The CREO® product insert is printed at the back of this surgical technique guide for reference.

STEP 1 APPROACH

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

Preoperative planning is recommended to estimate screw and/or hook location and sizes. 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.

Preparing pedicle pathway

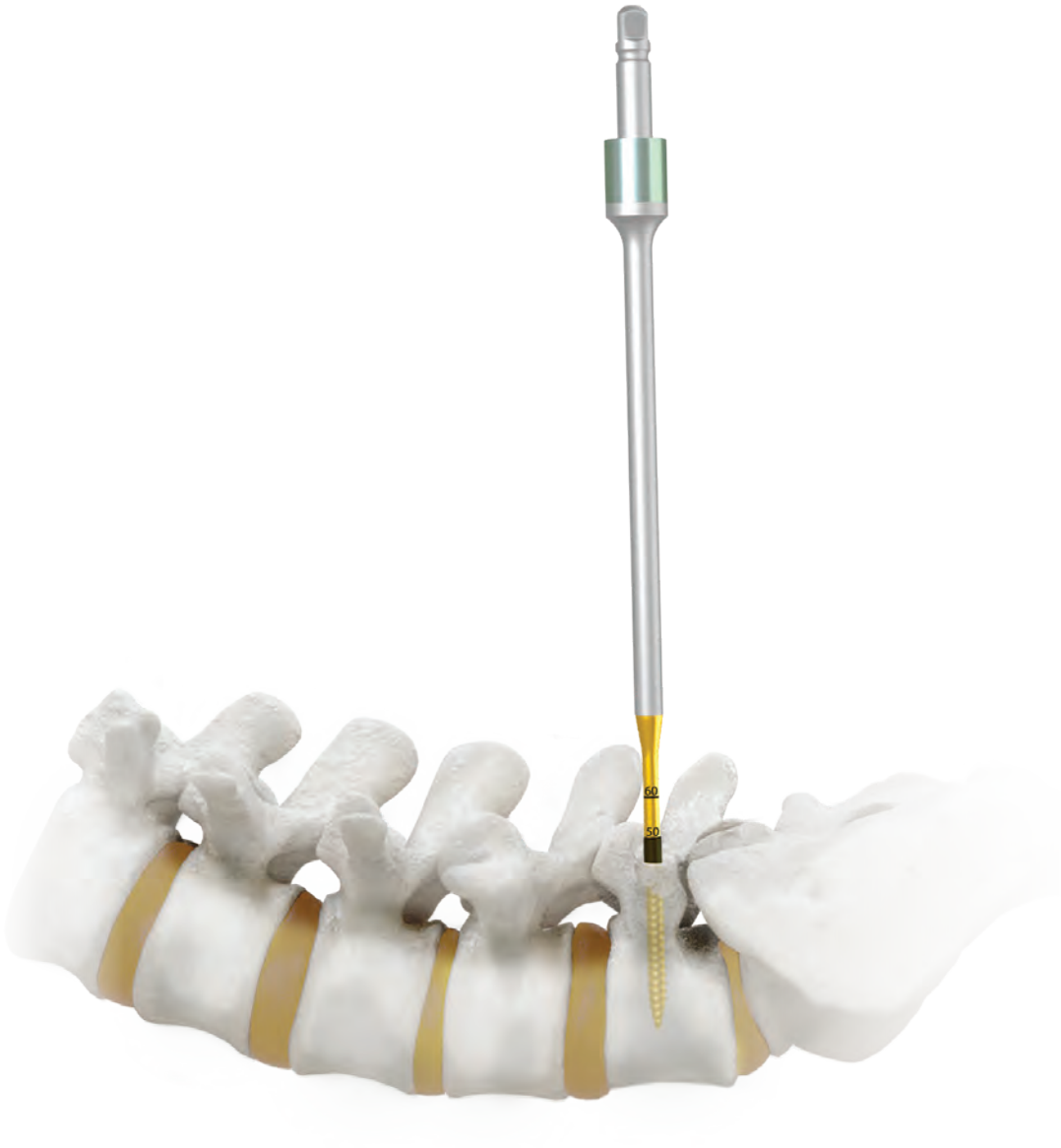
STEP 2 SCREW INSERTION

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

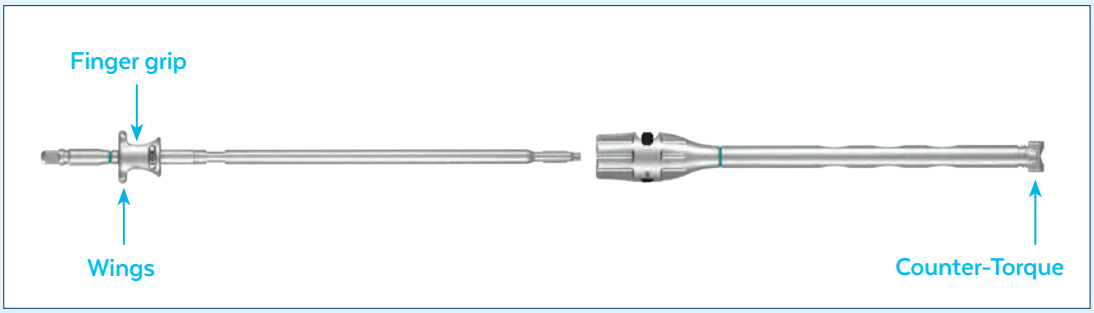
CREO DLX® screws are self-tapping. However, if additional tapping is desired, select the appropriate size **Solid Tap, 40mm Threads** and thread into the pedicle.



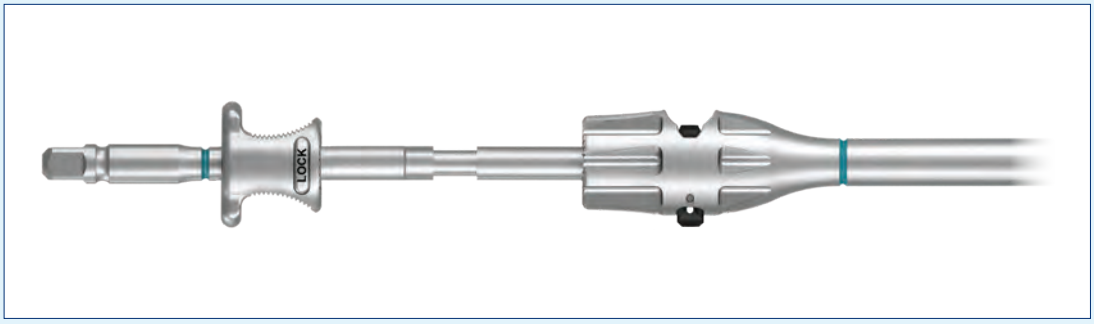
Tapping screw pathway

RIGID SCREWDRIVER ASSEMBLY

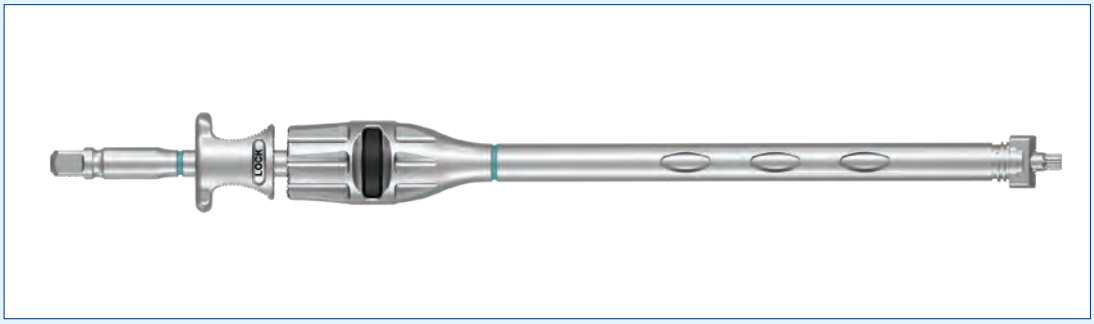
Ensure the finger grip on the **CREO DLX® Rigid Screwdriver Shaft** is pulled back toward the ¼" quick-connect end. Align the wings of the finger grip with the Counter-Torque end of the **CREO DLX® Rigid Screwdriver Outer Sleeve**.



Press the black button on the outer sleeve and insert the driver shaft until it bottoms out and the black button clicks back into place.



When properly assembled, the screwdriver shaft is retained within the outer sleeve and rotates freely.



SCREW INSERTION (CONT'D)

Loading the Screwdriver and Screw Insertion

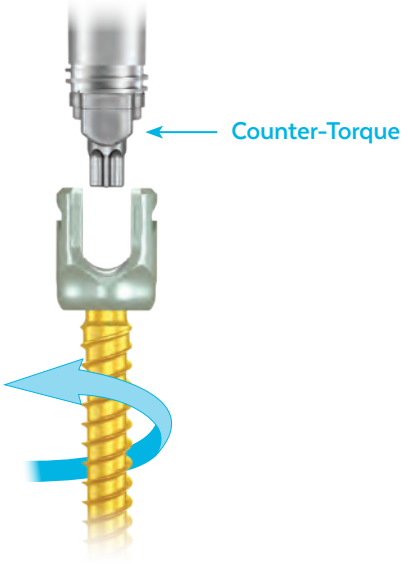
Attach the Rigid Screwdriver assembly to the **Straight Handle, Ratcheting, ¼" Quick-Connect** or **T-Handle, Ratcheting, ¼" Quick-Connect**.

Ensure the finger grip is pulled back toward the handle so the knob can rotate freely.

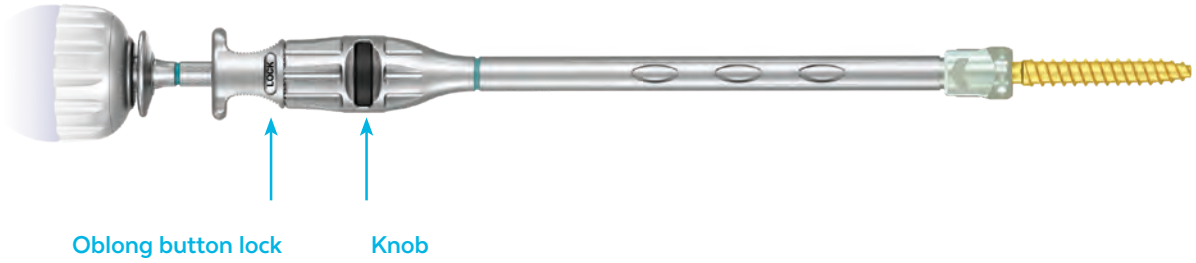
Holding the shank of the selected screw straight, align the Counter-Torque with the rod slot and insert the driver tip into the screw head. Rotate the screw shank until the driver tip fully engages the screw head. Slide the knob toward the screw and rotate clockwise until tight.

Press the oblong button above the knob to activate the lock. The lock automatically slides distally, meeting the knob and locking the internal shaft to the external sleeve. The screw is now ready to be driven into the prepared pedicles. Insert screws at the desired levels.

To disengage, grasp the finger grips on the lock and pull back toward the handle until the button clicks and releases. Rotate the knob counterclockwise to unthread and disengage the screwdriver from the screw.



Engaging screw



Screw loaded on driver

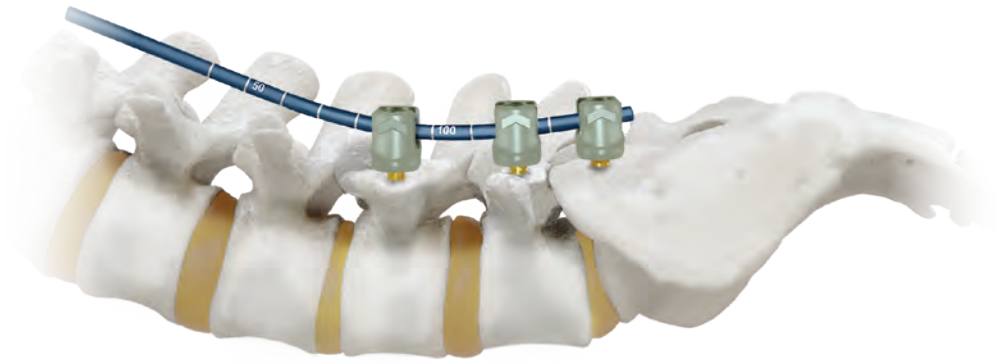
Disengaging screw

If using CREO DLX® Fenestrated Screw implants, refer to the CREO® Fenestrated Screw System Technique Guide (GMTGD201) for steps involving fenestrated screwdriver assembly, screw engagement, screw insertion, cement preparation, cement injection, and screwdriver disassembly utilizing the DLX appropriate instruments.

STEP 3 ROD INSERTION AND THREADED LOCKING CAP DELIVERY

Rod Preparation

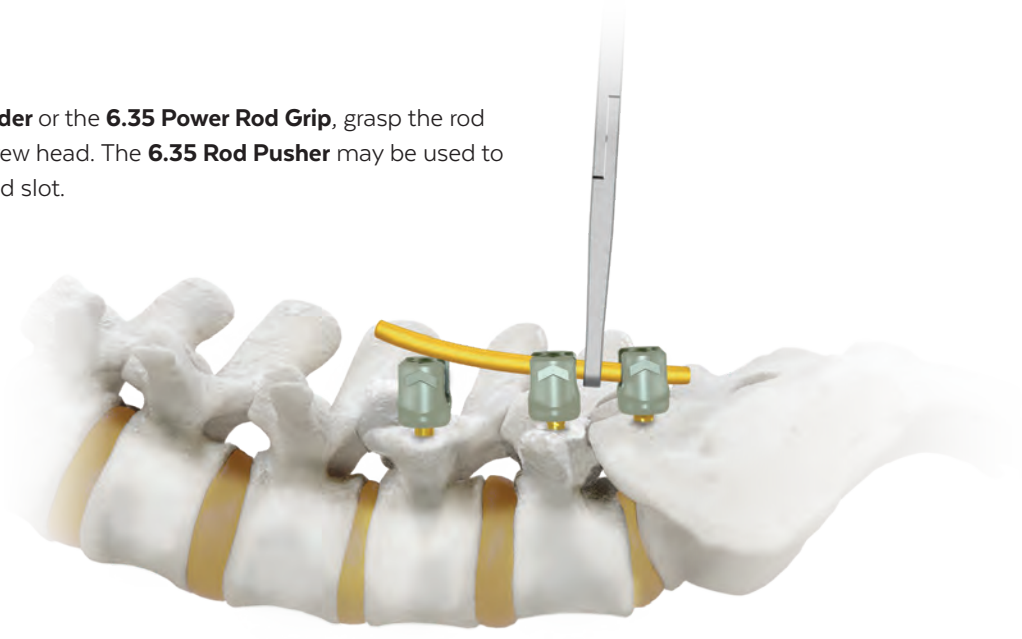
Determine the appropriate length and contour of the rod using the **Rod Template**. Rods may be contoured using the **6.35 Power Bender**.



Using Rod Template

Rod Insertion

Using the **6.35 Rod Holder** or the **6.35 Power Rod Grip**, grasp the rod and insert it into the screw head. The **6.35 Rod Pusher** may be used to push the rod into the rod slot.

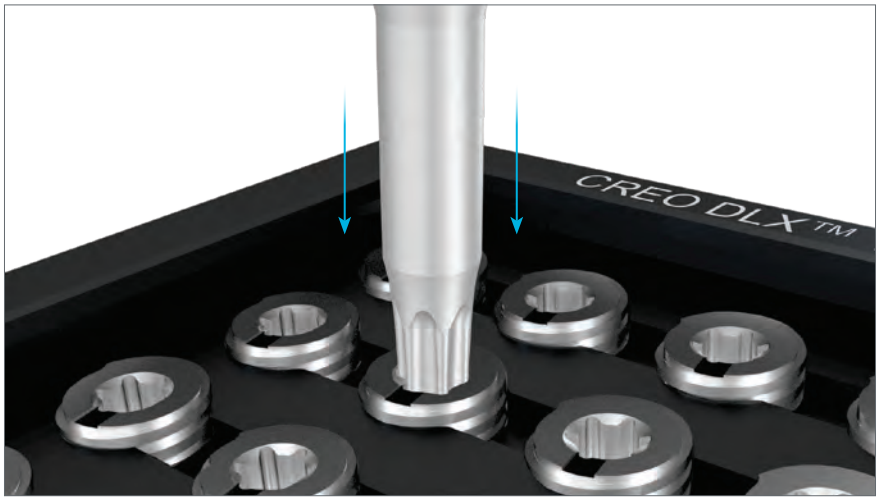


Rod insertion using 6.35 Rod Holder

ROD INSERTION AND THREADED LOCKING CAP DELIVERY (CONT'D)

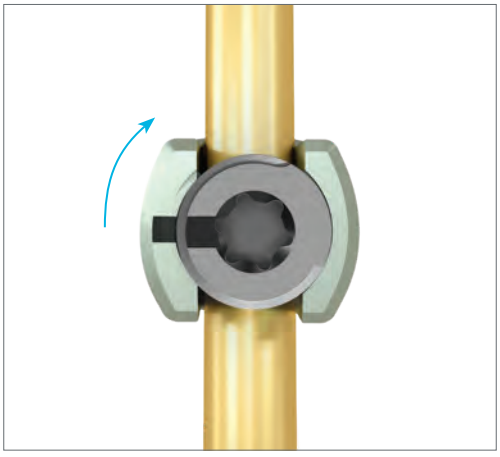
Threaded Locking Cap Delivery

Insert the tip of the **CREO DLX® Threaded Locking Cap Driver** into the locking cap and press down. The locking cap driver retains the locking cap.



Loading locking cap driver

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



Rod provisionally captured

STEP 4 ROD REDUCTION

The CREO DLX® Stabilization System has six options for rod reduction:

A. CREO DLX® Counter-Torque (3mm)

B. CREO DLX® Reduction Fork (5mm)

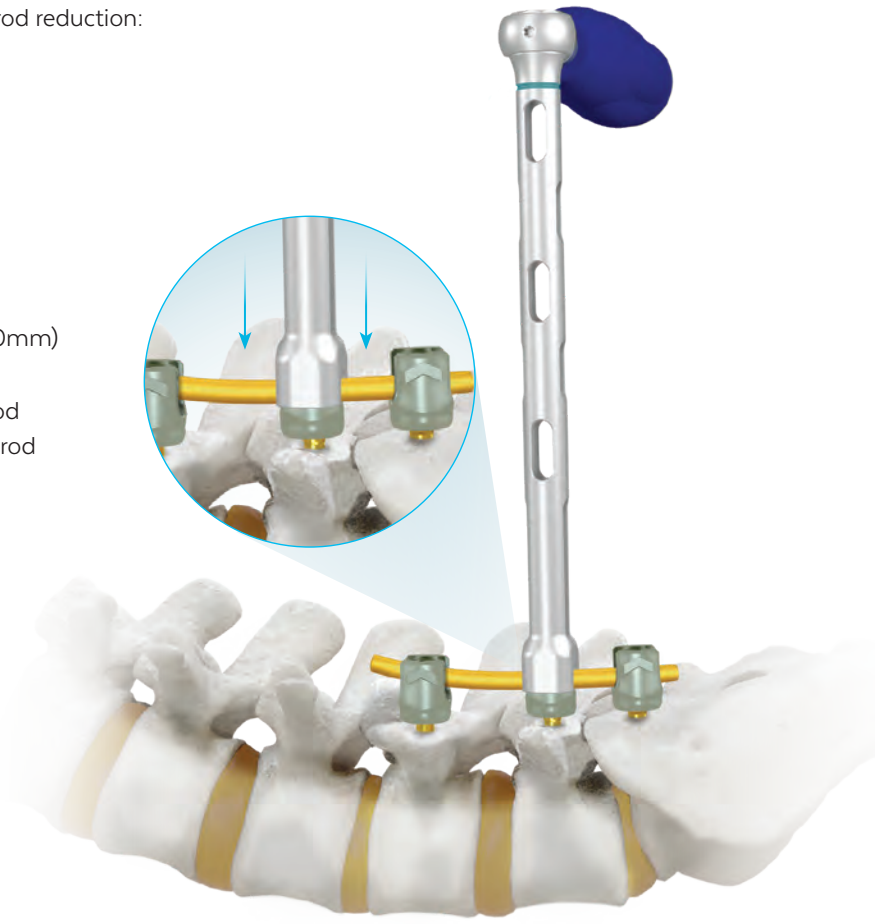
C. CREO DLX® Overhead Reducer (10mm)

D. CREO DLX® Pistol Grip Reducer (10mm)

E. CREO DLX® Quick-Release Reduction Clip (40mm)

F. CREO DLX® Quick-Release Reduction Clip, Long (60mm)

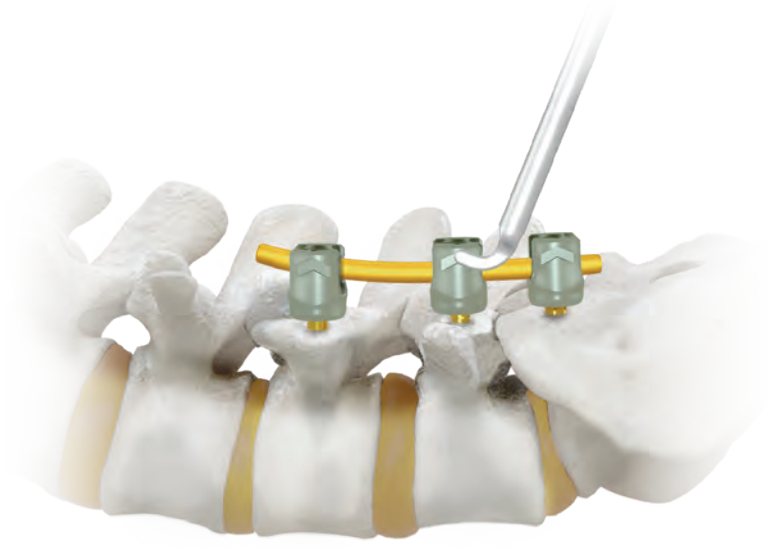
The rod reduction instruments are designed to seat the rod into the screw head, not to bend the rod. Ensure that the rod is properly contoured prior to reduction.



Rod reduction using CREO DLX® Counter-Torque

Option A: CREO DLX® Counter-Torque

The **CREO DLX® Counter-Torque** may be used for small adjustments of the rod into the screw head. Place the Counter-Torque over the rod and screw head and apply downward pressure.



Rod reduction using CREO DLX® Reduction Fork

Option B: CREO DLX® Reduction Fork

The **CREO DLX® Reduction Fork** may be used to reduce the rod. The instrument provides 5mm of reduction and is useful when the rod is slightly above the screw.

Slide the fork into the indented reduction slots on both sides of the screw head. Press the handle down to reduce the rod into the screw head.

ROD REDUCTION (CONT'D)

Option C: CREO DLX® Overhead Reducer

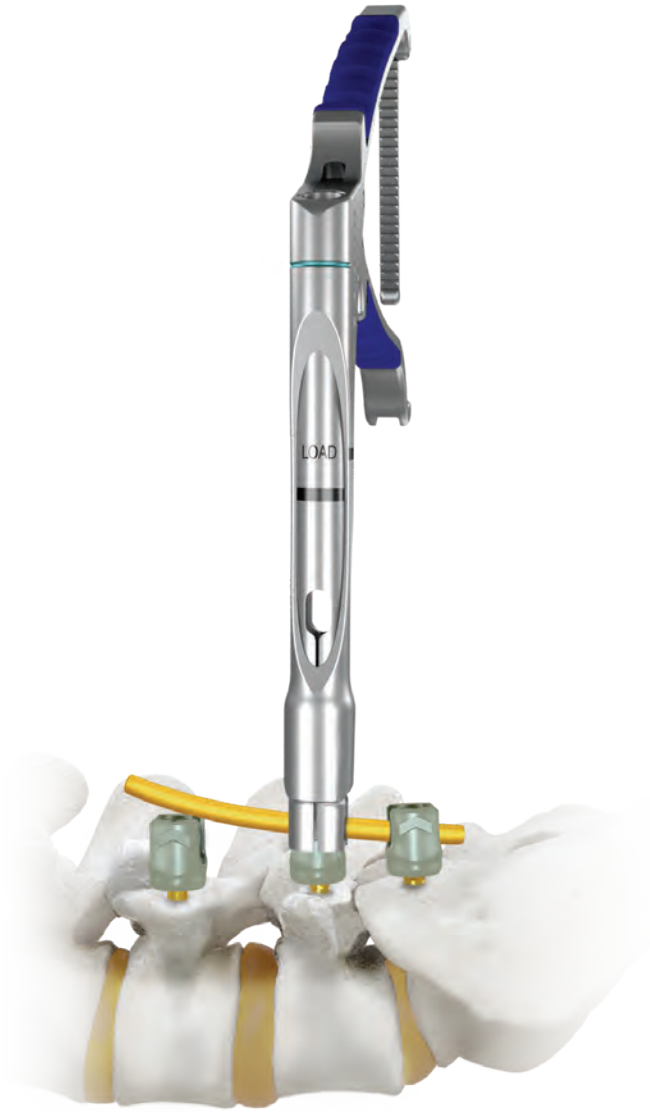
The **CREO DLX® Overhead Reducer** provides up to 10mm of reduction. Ensure the reducer is fully open by releasing the ratcheting latch; the LOAD indicator on the inner shaft aligns with the etched black ring on the outer shaft.

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

When the rod is fully reduced to 10mm, the etched black ring on the inner shaft aligns with the etched black ring on the outer shaft.

The CREO DLX® Threaded Locking Cap Driver may be inserted through the reducer to capture the rod.

Rod reduction using CREO DLX® Overhead Reducer



Rod reduction using CREO DLX® Pistol Grip Reducer

Option D: CREO DLX® Pistol Grip Reducer

The **CREO DLX® Pistol Grip Reducer** provides up to 10mm of reduction. Ensure the reducer is fully open by releasing the ratcheting latch; 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 press down until it is fully seated. Compress the handles to engage the screw and reduce the rod.

When the rod is fully reduced to 10mm, the etched black ring on the inner shaft aligns with the etched black ring on the outer shaft.

The CREO DLX® Threaded Locking Cap Driver may be inserted through the reducer to capture the rod.

Option E : CREO DLX® Quick-Release Reduction Clip

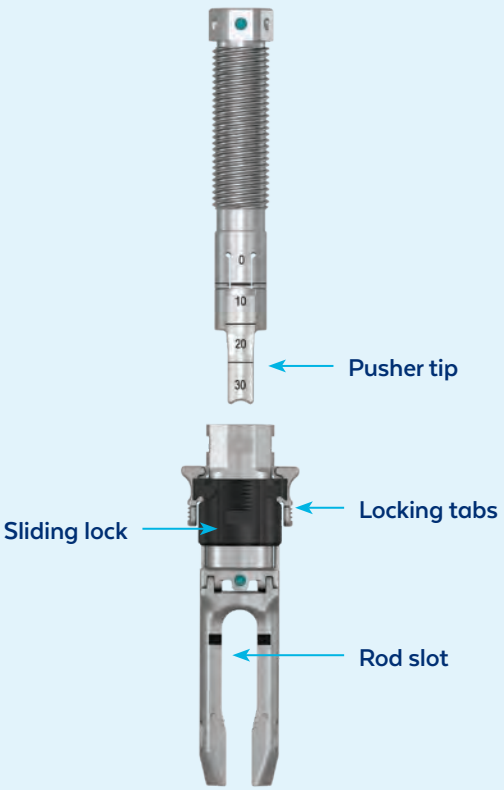
The **CREO DLX® Quick-Release Reduction Clip** provides up to 40mm of continuous gradual reduction.
The **CREO DLX® Quick-Release Reduction Clip, Long** provides up to 60mm of continuous gradual reduction.

Ensure the CREO DLX® Quick-Release Reduction Clip is in the unlocked position by depressing the two silver locking tabs and pulling the black sliding lock away from the instrument tip. Align the **CREO DLX® Quick-Release Reduction Clip Pusher** tip with the rod slot of the Reduction Clip. Insert the Reduction Clip Pusher into the Reduction Clip and thread to the desired starting reduction amount using the demarcations on the clip. Place the Reduction Clip over the rod, align squarely over the screw head and press down until completely flush with the screw head. Press the black sliding lock down until it clicks into place. The silver locking tabs do not need to be pressed to engage the lock. Verify the connection by pulling up on the reducer.

Reduce the rod by placing the **Reduction T-Handle** onto the Reduction Clip Pusher and rotating clockwise until it is fully threaded into the Reduction Clip. If reducing over multiple levels, use the **Reduction Clip Driver** or **Reduction Clip Driver, Short** attached to a Straight Ratcheting Handle to minimize interference with adjacent reducers.

Once reduction is achieved, insert the Threaded Locking Cap using the Threaded Locking Cap Driver. Remove the Reduction Clip by depressing the two silver locking tabs and pulling up on the instrument.

CREO DLX® QUICK-RELEASE REDUCTION CLIP ASSEMBLY



Rod reduction using CREO DLX®
Quick-Release Reduction Clip

STEP 5 DEFORMITY CORRECTION

Global Derotation

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

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

To rotate the rod, the **6.35 Power Rod Grip** or **6.35 Vise-Style Rod Grip** can be used. Position two 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 6.35 Power Rod Grip

Hooks may be prepared and placed as described on page 34. If using hooks, it is important to monitor their position during derotation to verify they are not displaced. Once the rod is rotated into final position, the locking caps are provisionally tightened to maintain rod position.

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. If using hooks, verify the positions and make any necessary adjustments.

Final tighten the locking caps to completely lock the construct.

Final tightening after deformity correction

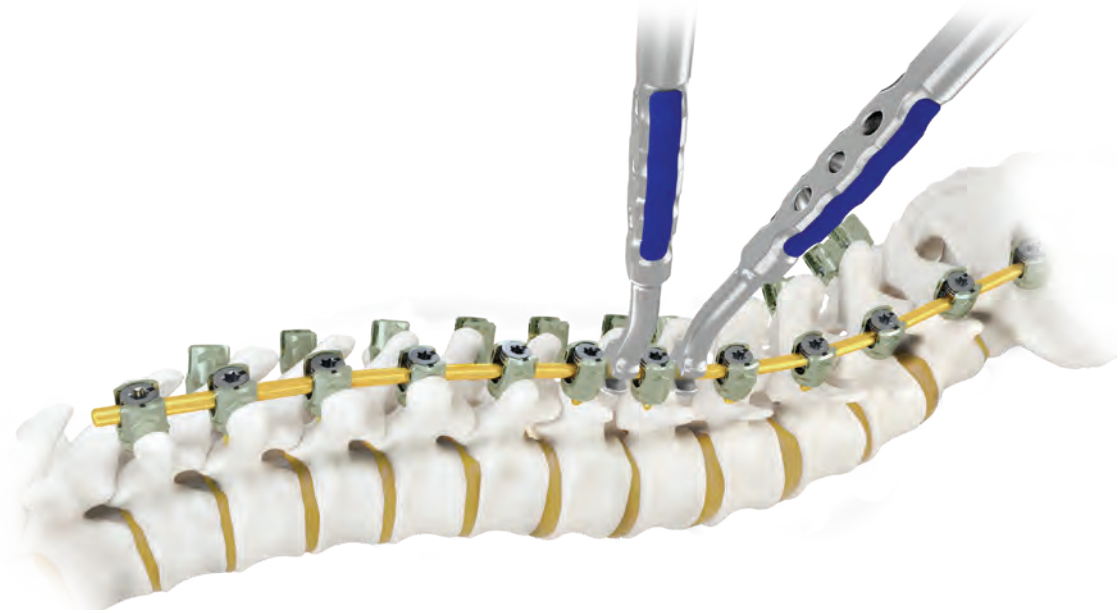
DEFORMITY CORRECTION (CONT'D)

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.

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

In Situ Benders are used to make corrections to 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 and/or distraction may be performed.



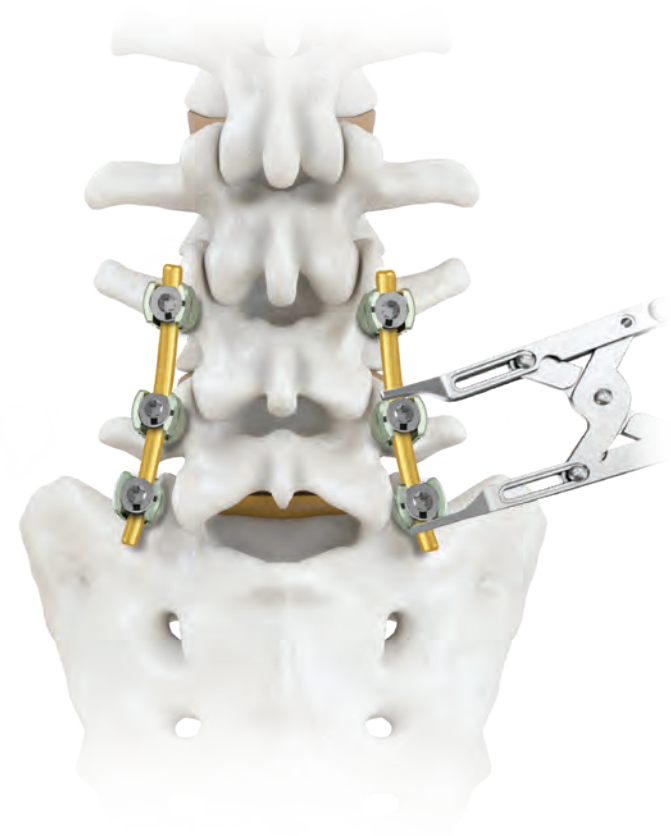
The Coronal Plane Benders are used to make corrections to rod curvature in the coronal plane. Rod bending is accomplished with two benders (left and right), positioned close to one another. Position the benders so the grooves on the inside of the left bender engage the grooves on the inside of the right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

Once rod bending is complete, compression or distraction may be performed.

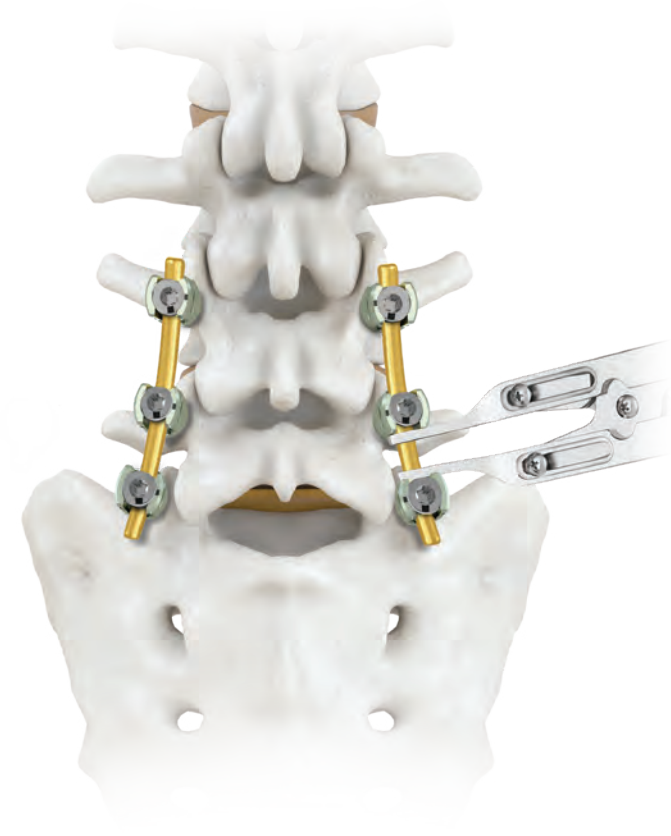
STEP 6 COMPRESSION OR DISTRACTION

CREO DLX® pedicle screws can be compressed or distracted along the rod as necessary using the **6.35 Parallel Compressor** or the **6.35 Parallel Distractor**. Tighten one of the set screws to establish a rigid point for compression or distraction. The **Long Throw Compressor** may be used as an alternative to the 6.35 Parallel Compressor when compression over a larger distance is needed.

Once compression or distraction is complete, provisionally tighten the set screws using either the Straight Handle, Ratcheting, ¼" Quick-Connect or the T-Handle, Ratcheting, ¼" Quick-Connect and the **Threaded Locking Cap Driver**.



Compression

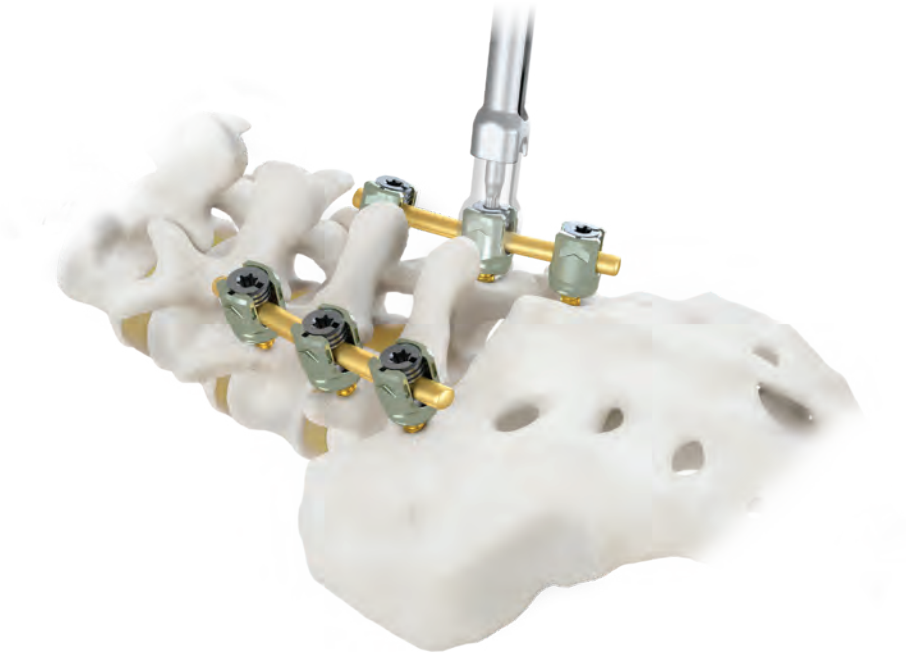


Distraction

STEP 7 FINAL TIGHTENING

Final tightening of all locking caps is necessary to secure the construct. Perform final tightening using the Torque-Limiting T-Handle, Ratcheting, 10Nm, ¼" Quick-Connect and Final Locking Driver Shaft, T27, ¼" Quick-Connect or the **Final Locking Driver Shaft, T27, ¼" Quick-Connect, Long** with the CREO DLX® Counter-Torque.

Attach the torque-limiting handle to the driver shaft and visually confirm the driver tip is fully engaged in the locking cap. Rotate the driver assembly until the torque limit (10Nm) is reached and two audible clicks are heard. Repeat for all locking caps.



OPTIONAL: REVISION OR REMOVAL

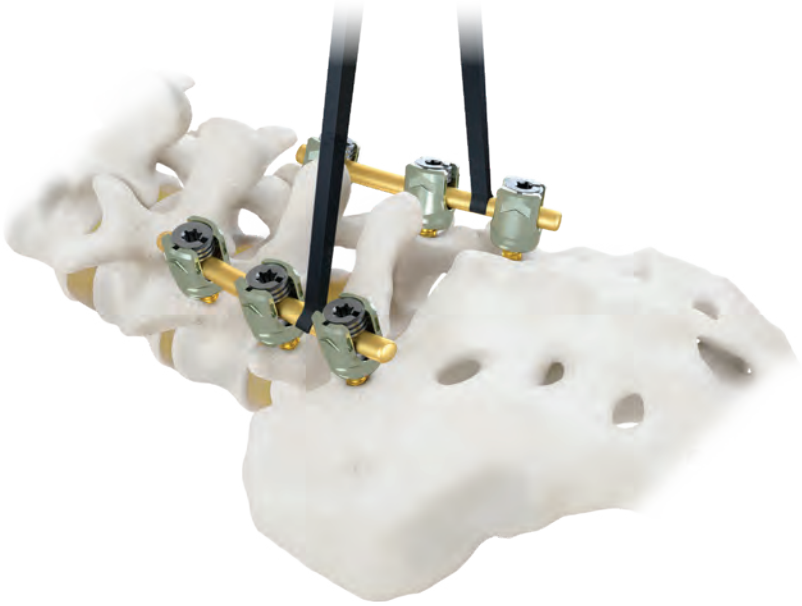
For revision or removal, reverse the insertion steps until the desired implants are removed. Loosen the threaded locking caps using the Final Locking Driver Shaft, T27, ¼" Quick-Connect attached to the desired handle. Remove the threaded locking caps and grasp the rod using a rod holder or rod grip to remove. Remove all screws using the **Self-Retaining Driver Shaft, ¼" Quick-Connect** attached to the straight handle or T-handle. T-connectors and other connectors may remain connected on the rods or may be removed separately.

OPTIONAL: CROSS-CONNECTOR

A cross-connector may be used to connect two rods in a construct to enhance construct stability.

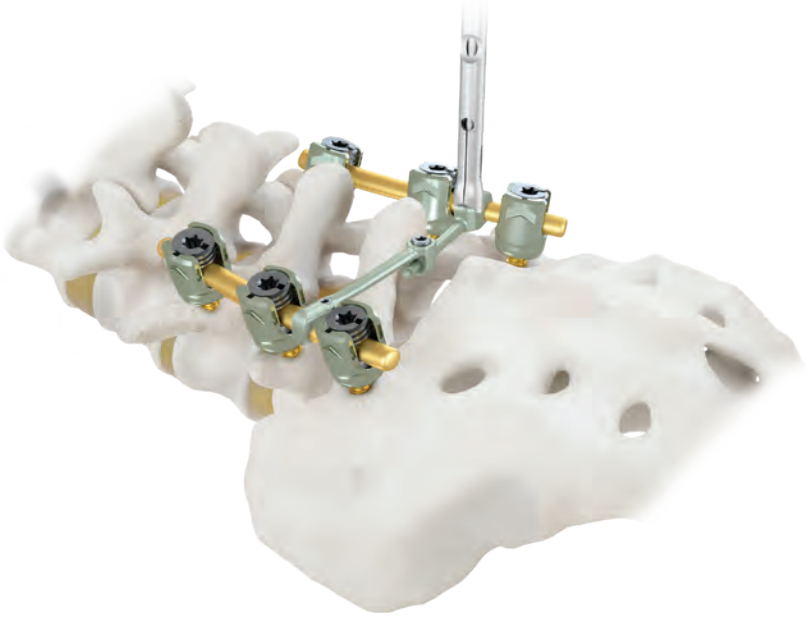
To select the proper length cross-connector, use the **Cross-Connector Caliper, Large Diameter Rod**. Place the caliper between the rods at the desired level. Read the connector length from the etched measurements.

The **Cross-Connector Inserter** can be used to grasp the desired connector. The inserter engages with the slots on either side of the connector. Position the connector between the two rods and provisionally tighten the set screws on each side using the **Cross-Connector Driver, Torque-Limiting**. Adjust the connector to the desired length and tighten the center set screw to lock the two interfacing pieces together. Using the Cross-Connector Driver, final tighten the set screws bearing on the rods.



Using Cross-Connector Caliper

Reading length measurement

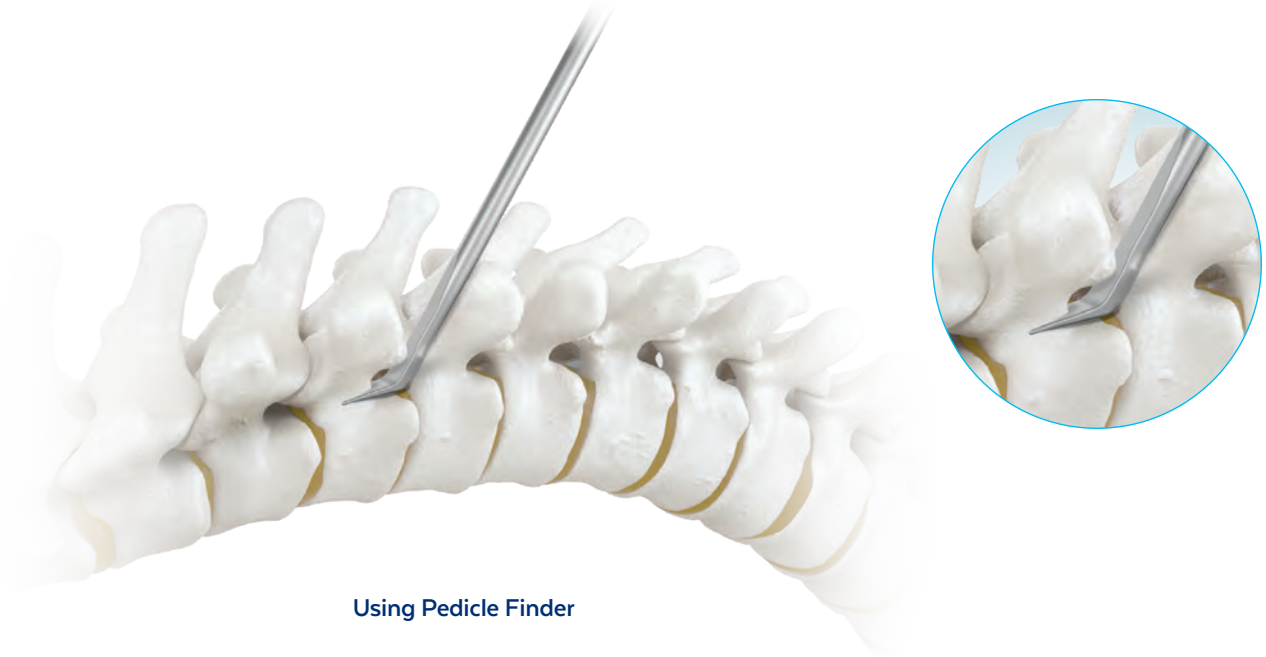


Using Cross-Connector Inserter

OPTIONAL: HOOKS

Preparing the Pedicle

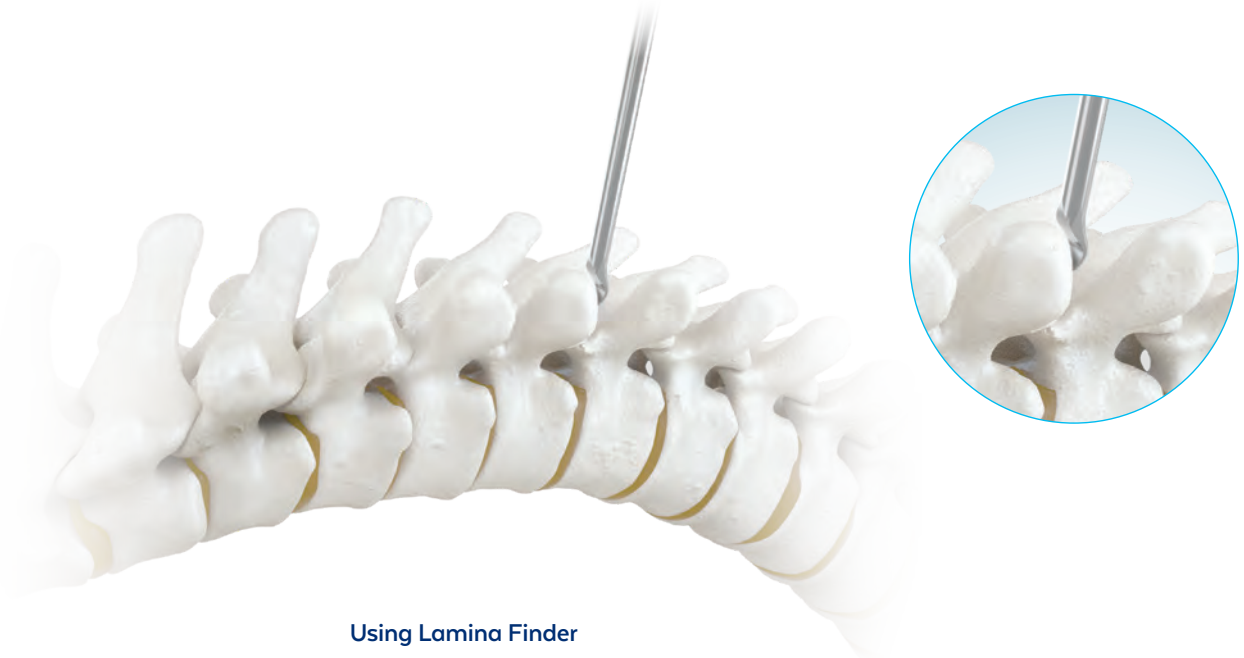
The **Pedicle Finder** is used to prepare the pedicle for hook placement. Use the finder to open the facet capsule and locate the pedicle. If necessary, a portion of the inferior facet may be removed to aid in pedicle hook insertion.



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.

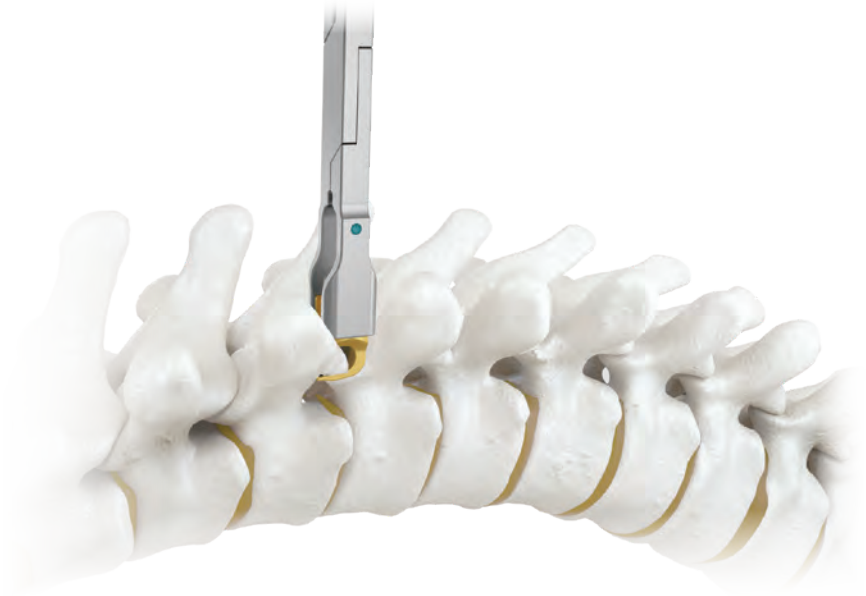


Using Lamina Finder

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 **CREO DLX® Hook Holder**. Insert the hook into the holder and place in the desired position.

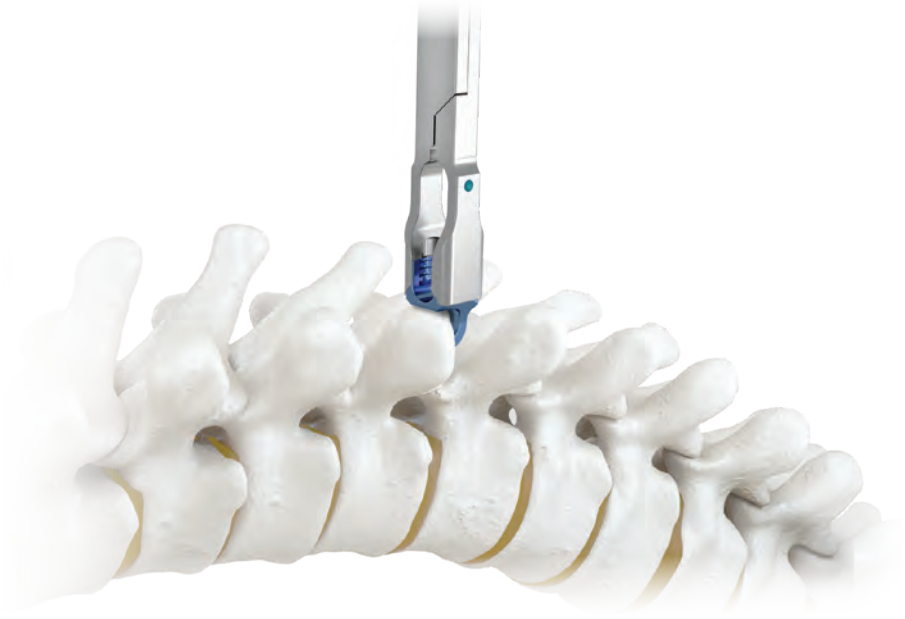
Alternatively, the **CREO DLX® Lateral Hook Holder** or the **CREO DLX® Offset Hook Holder** may be used to insert pedicle hooks.



Lamina Hook Placement

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

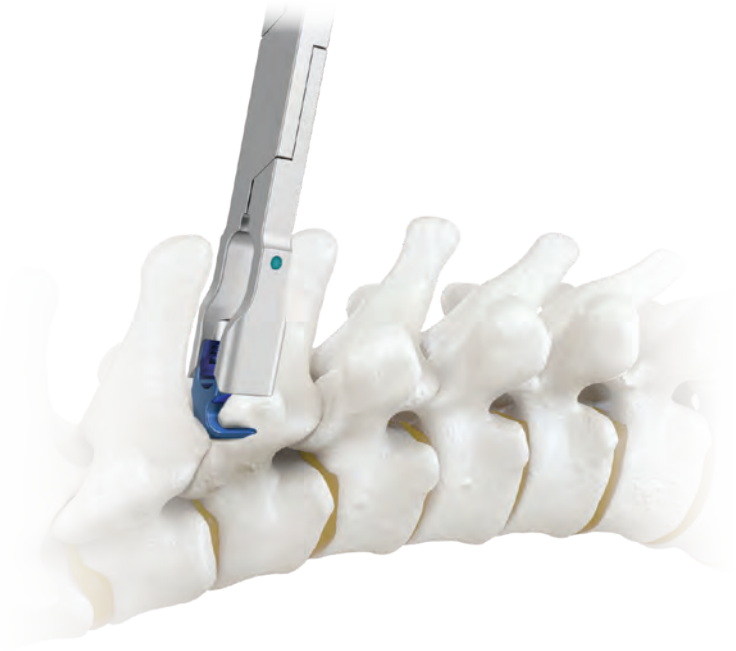


OPTIONAL: HOOKS (CONT'D)

Transverse Process Hook Placement

A transverse process hook is usually placed down-going and typically 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 **6.35 Hook Positioner** to seat the hook. Repeat hook insertion for each desired location.



Transverse process hook placement

CREO DLX® Hook Placement Instruments

NOTE: Check hook position frequently to ensure that the hooks remain in the correct position throughout the procedure.

The CREO DLX® 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 Offset Hook Holder allows for introduction of a locking cap without disengaging the holder.

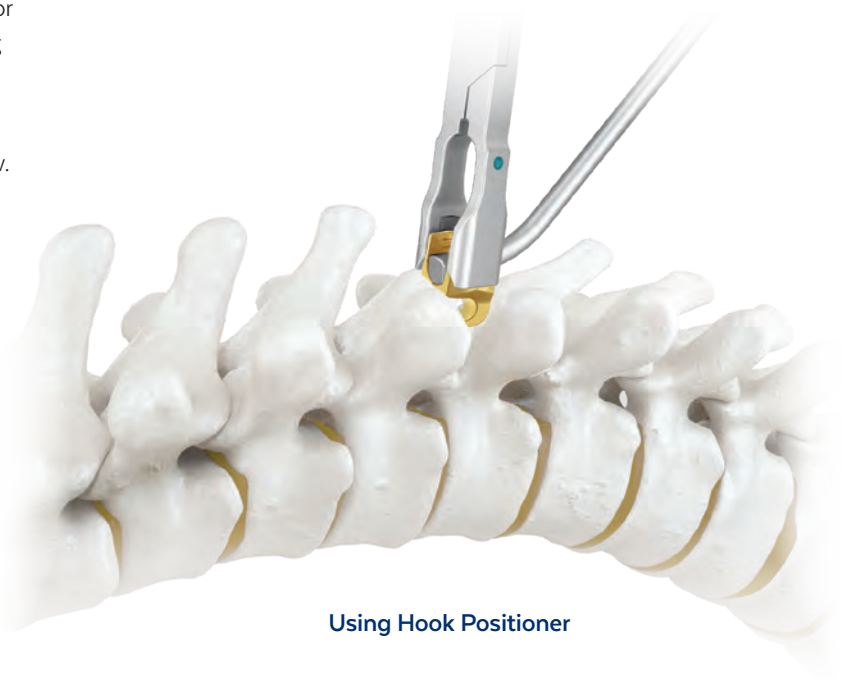
Alternatively, the Lateral Hook Holder may be used for insertion. This holder engages into the slots on the cephalad and caudal sides of the hook and allows for introduction of the rod and cap without disengaging the holder.

The 6.35 Hook Positioner may be used to aid in inserting and positioning the hooks, as shown below.

CREO DLX® Hook Holder

CREO DLX® Offset Hook Holder

CREO DLX® Lateral Hook Holder



Using Hook Positioner

CREO DLX-NXT
9156.9000 CORE INSTRUMENTS SET

Part No.	Description	Qty
602.101	Pedicle Probe - Straight	1
602.102	Pedicle Probe - Curved	1
602.105	Ball Tip Probe	1
602.106	Ball Tip Probe, Curved	1
602.109	Pedicle Probe - Thoracic	1
602.501	Rod Template, 150mm	1
602.517	Rod Template, 300mm	1
602.519	Rod Template, Silicone, 500mm	1
624.110	Ball Tipped Probe, Double-Ended	1
624.113	Pedicle Probe, Thoracic, Curved	
624.114	Pedicle Probe, Thoracic, Straight	
6067.0001	Pedicle Awl	1
6067.0010	Straight Handle, Ratcheting, ¼" Quick-Connect	2
6067.0015	Straight Handle, Fixed, ¼" Quick-Connect	
6067.0020	T-Handle, Ratcheting, ¼" Quick-Connect	2
6067.0030	Palm Handle, Ratcheting, ¼" Quick-Connect	
6067.0035	Palm Handle, Fixed, ¼" Quick-Connect	
6067.0050	Driver Shaft, ¼" Quick-Connect, Short	1
6067.0060	Self-Retaining Driver Shaft, ¼" Quick-Connect	2
6067.1050	Cross-Connector Driver, Torque-Limiting	1
6067.1055	Cross-Connector Inserter	1
6067.1065	Cross-Connector Measurement Card	
6120.0001	CREO® Screw Head Distractor	
6156.0090	6.35 Parallel Compressor	1
6156.0095	6.35 Parallel Distractor	1
6156.0105	10.5mm Solid Tap, 40mm Threads	
6156.0115	11.5mm Solid Tap, 40mm Threads	
6156.0125	12.5mm Solid Tap, 40mm Threads	
6156.0140	4.0mm Solid Tap, 40mm Threads	
6156.0145	4.5mm Solid Tap, 40mm Threads	1
6156.0150	5.0mm Solid Tap, 40mm Threads	
6156.0155	5.5mm Solid Tap, 40mm Threads	1
6156.0160	6.0mm Solid Tap, 40mm Threads	
6156.0165	6.5mm Solid Tap, 40mm Threads	1
6156.0175	7.5mm Solid Tap, 40mm Threads	1
6156.0185	8.5mm Solid Tap, 40mm Threads	1
6156.0195	9.5mm Solid Tap, 40mm Threads	
6156.1060	Cross-Connector Caliper, Large Diameter Rod	1
6156.3115	Quick-Release Reduction T-Handle	1
9156.0000	CREO DLX-NXT Core Instruments Graphic Case	

Items in gray are additionally available.

CREO DLX®
9156.9001 DEGEN IMPLANTS SET

CREO DLX® Polyaxial Screw

Part No.	Diameter/Length	Qty
5156.1030	11.5 x 30mm	
5156.1035	11.5 x 35mm	
5156.1040	11.5 x 40mm	
5156.1045	11.5 x 45mm	
5156.1050	11.5 x 50mm	
5156.1055	11.5 x 55mm	
5156.1060	11.5 x 60mm	
5156.1065	11.5 x 65mm	
5156.1130	10.5x30mm	
5156.1135	10.5x35mm	
5156.1140	10.5x40mm	
5156.1145	10.5x45mm	
5156.1150	10.5x50mm	
5156.1155	10.5x55mm	
5156.1160	10.5x60mm	
5156.1165	10.5x65mm	
5156.1525	5.5x25mm	
5156.1530	5.5x30mm	8
5156.1535	5.5x35mm	8
5156.1540	5.5x40mm	8
5156.1545	5.5x45mm	8
5156.1550	5.5x50mm	6
5156.1555	5.5x55mm	6
5156.1560	5.5x60mm	
5156.1625	6.5x25mm	
5156.1630	6.5x30mm	4
5156.1635	6.5x35mm	6
5156.1640	6.5x40mm	8
5156.1645	6.5x45mm	8
5156.1650	6.5x50mm	8
5156.1655	6.5x55mm	6
5156.1660	6.5x60mm	6
5156.1665	6.5x65mm	
5156.1725	7.5x25mm	

Part No.	Diameter/Length	Qty
5156.1730	7.5x30mm	2
5156.1735	7.5x35mm	6
5156.1740	7.5x40mm	6
5156.1745	7.5x45mm	6
5156.1750	7.5x50mm	6
5156.1755	7.5x55mm	6
5156.1760	7.5x60mm	
5156.1765	7.5x65mm	
5156.1825	8.5x25mm	
5156.1830	8.5x30mm	
5156.1835	8.5x35mm	
5156.1840	8.5x40mm	4
5156.1845	8.5x45mm	4
5156.1850	8.5x50mm	6
5156.1855	8.5x55mm	
5156.1860	8.5x60mm	
5156.1865	8.5x65mm	
5156.1930	9.5x30mm	
5156.1935	9.5x35mm	
5156.1940	9.5x40mm	
5156.1945	9.5x45mm	
5156.1950	9.5x50mm	
5156.1955	9.5x55mm	
5156.1960	9.5x60mm	
5156.1965	9.5x65mm	
5156.2025	6.0x25mm	
5156.2030	6.0x30mm	
5156.2035	6.0x35mm	
5156.2040	6.0x40mm	
5156.2045	6.0x45mm	
5156.2050	6.0x50mm	
5156.2055	6.0x55mm	
5156.2060	6.0x60mm	
5156.2065	6.0x65mm	

Items in gray are additionally available.

CREO DLX®
9156.9001 DEGEN IMPLANTS SET

6.0-6.35 Cross-Connector

Part No.	Diameter/Length	Qty
1156.0030	29-33mm	1
1156.0034	32-40mm	1
1156.0039	38-50mm	2
1156.0046	48-60mm	2
1156.0062	58-70mm	1
1156.0075	68-80mm	
1156.0086	78-90mm	

6.35mm Straight Rod, Titanium Alloy

Part No.	Length	Qty
1120.5020	20mm	
1120.5025	25mm	
1120.5030	30mm	
1120.5035	35mm	
1120.5040	40mm	
1120.5045	45mm	4
1120.5050	50mm	
1120.5055	55mm	4
1120.5060	60mm	
1120.5065	65mm	4
1120.5070	70mm	
1120.5075	75mm	4
1120.5080	80mm	
1120.5085	85mm	4
1120.5090	90mm	
1120.5095	95mm	
1120.5100	100mm	2
1120.5125	125mm	2
1120.5150	150mm	2

6.35mm Curved Rod, Titanium Alloy

Part No.	Length	Qty
1120.7020	20mm	
1120.7025	25mm	
1120.7030	30mm	
1120.7035	35mm	4
1120.7040	40mm	4
1120.7045	45mm	4
1120.7050	50mm	2
1120.7055	55mm	2
1120.7060	60mm	2
1120.7065	65mm	4
1120.7070	70mm	2
1120.7075	75mm	4
1120.7080	80mm	2
1120.7085	85mm	4
1120.7090	90mm	2
1120.7095	95mm	2
1120.7100	100mm	2
1120.7125	125mm	2
1120.7150	150mm	2

9156.0001	CREO DLX® Degen Implants Graphic Case
9156.0101	CREO DLX® Polyaxial Screw Module
9156.0610	CREO DLX® Threaded Locking Cap Module
9156.0710	6.0-6.35 Cross-Connector Module
9156.0810	6.35 Rod Module

Items in gray are additionally available.

CREO DLX®
9156.9002 POLYAXIAL DOD SCREW SET

CREO DLX® Polyaxial DOD Screw

Part No.	Diameter/Length	Qty
5156.2130	10.5-9.0x30mm	
5156.2135	10.5-9.0x35mm	
5156.2140	10.5-9.0x40mm	
5156.2145	10.5-9.0x45mm	
5156.2150	10.5-9.0x50mm	
5156.2155	10.5-9.0x55mm	
5156.2160	10.5-9.0x60mm	
5156.2165	10.5-9.0x65mm	
5156.2230	8.0-6.5x30mm	2
5156.2235	8.0-6.5x35mm	4
5156.2240	8.0-6.5x40mm	4
5156.2245	8.0-6.5x45mm	4
5156.2250	8.0-6.5x50mm	4
5156.2255	8.0-6.5x55mm	4
5156.2260	8.0-6.5x60mm	4
5156.2265	8.0-6.5x65mm	2
5156.2530	5.5-4.5x30mm	
5156.2535	5.5-4.5x35mm	
5156.2540	5.5-4.5x40mm	
5156.2545	5.5-4.5x45mm	
5156.2550	5.5-4.5x50mm	
5156.2555	5.5-4.5x55mm	
5156.2560	5.5-4.5x60mm	
5156.2630	6.5-5.0x30mm	2
5156.2635	6.5-5.0x35mm	2
5156.2640	6.5-5.0x40mm	2
5156.2645	6.5-5.0x45mm	2
5156.2650	6.5-5.0x50mm	2
5156.2655	6.5-5.0x55mm	2
5156.2660	6.5-5.0x60mm	2
5156.2665	6.5-5.0x65mm	2
5156.2730	7.5-6.0x30mm	4
5156.2735	7.5-6.0x35mm	4
5156.2740	7.5-6.0x40mm	4

Part No.	Diameter/Length	Qty
5156.2745	7.5-6.0x45mm	4
5156.2750	7.5-6.0x50mm	4
5156.2755	7.5-6.0x55mm	4
5156.2760	7.5-6.0x60mm	2
5156.2765	7.5-6.0x65mm	2
5156.2830	8.5-7.0x30mm	2
5156.2835	8.5-7.0x35mm	2
5156.2840	8.5-7.0x40mm	2
5156.2845	8.5-7.0x45mm	2
5156.2850	8.5-7.0x50mm	2
5156.2855	8.5-7.0x55mm	2
5156.2860	8.5-7.0x60mm	2
5156.2865	8.5-7.0x65mm	2
5156.2930	9.5-8.0x30mm	
5156.2935	9.5-8.0x35mm	
5156.2940	9.5-8.0x40mm	
5156.2945	9.5-8.0x45mm	
5156.2950	9.5-8.0x50mm	
5156.2955	9.5-8.0x55mm	
5156.2960	9.5-8.0x60mm	
5156.2965	9.5-8.0x65mm	

9156.0002	CREO DLX® Polyaxial DOD Screw Graphic Case
9156.0022	CREO DLX® Polyaxial DOD Screw Module

Items in gray are additionally available.

CREO DLX®
9156.9003 DEFORMITY IMPLANTS SET

CREO DLX® Polyaxial Screw

Part No.	Diameter/Length	Qty
5156.1220	4.0x20mm	4
5156.1225	4.0x25mm	4
5156.1230	4.0x30mm	4
5156.1235	4.0x35mm	8
5156.1240	4.0x40mm	8
5156.1245	4.0x45mm	8
5156.1250	4.0x50mm	
5156.1255	4.0x55mm	
5156.1320	4.5x20mm	
5156.1325	4.5x25mm	4
5156.1330	4.5x30mm	10
5156.1335	4.5x35mm	12
5156.1340	4.5x40mm	10
5156.1345	4.5x45mm	10
5156.1350	4.5x50mm	
5156.1355	4.5x55mm	
5156.1420	5.0x20mm	
5156.1425	5.0x25mm	4
5156.1430	5.0x30mm	12
5156.1435	5.0x35mm	14
5156.1440	5.0x40mm	12
5156.1445	5.0x45mm	10
5156.1450	5.0x50mm	2
5156.1455	5.0x55mm	2
5156.1460	5.0x60mm	
5156.1525	5.5x25mm	10
5156.1530	5.5x30mm	10
5156.1535	5.5x35mm	10
5156.1540	5.5x40mm	10
5156.1545	5.5x45mm	10
5156.1550	5.5x50mm	12
5156.1555	5.5x55mm	2
5156.1560	5.5x60mm	
5156.1625	6.5x25mm	4

CREO DLX® Polyaxial Screw (Cont'd)

Part No.	Diameter/Length	Qty
5156.1630	6.5x30mm	10
5156.1635	6.5x35mm	10
5156.1640	6.5x40mm	12
5156.1645	6.5x45mm	12
5156.1650	6.5x50mm	12
5156.1655	6.5x55mm	4
5156.1660	6.5x60mm	4
5156.1665	6.5x65mm	2

6.35mm Hex-Ended Rod, Titanium Alloy

Part No.	Length	Qty
1120.6200	200mm	2
1120.6300	300mm	2
1120.6400	400mm	
1120.6500	500mm	2
1120.6600	600mm	
1120.6700	700mm	

Implant

Part No.	Description	Qty
1156.0010	CREO DLX® Threaded Locking Cap	24

Low Profile Cross-Connector

Part No.	Length	Qty
1156.0220	20-22mm	
1156.0221	21.5-25mm	2
1156.0224	24.5-31mm	2
1156.0230	30.5-43mm	2
1156.0242	42.5-67mm	2
1156.0266	66.5-91mm	

9156.0003	CREO DLX® Deformity Implants Graphic Case
9156.0103	CREO DLX® Small Diameter Screw Module
9156.0303	6.0-6.35 Low Profile Cross-Connector Module
9156.0610	CREO DLX® Threaded Locking Cap Module

Items in gray are additionally available.

CREO DLX®
9156.9004 UNIPLANAR SCREW SET

CREO DLX® Uniplanar Screw

Part No.	Diameter/Length	Qty
5156.5325	4.5x25mm	4
5156.5330	4.5x30mm	6
5156.5335	4.5x35mm	6
5156.5340	4.5x40mm	6
5156.5345	4.5x45mm	
5156.5350	4.5x50mm	
5156.5355	4.5x55mm	
5156.5425	5.0x25mm	2
5156.5430	5.0x30mm	6
5156.5435	5.0x35mm	6
5156.5440	5.0x40mm	4
5156.5445	5.0x45mm	
5156.5450	5.0x50mm	
5156.5455	5.0x55mm	
5156.5525	5.5x25mm	4
5156.5530	5.5x30mm	14
5156.5535	5.5x35mm	12
5156.5540	5.5x40mm	12
5156.5545	5.5x45mm	2
5156.5550	5.5x50mm	4
5156.5555	5.5x55mm	
5156.5625	6.5x25mm	
5156.5630	6.5x30mm	10
5156.5635	6.5x35mm	10
5156.5640	6.5x40mm	10
5156.5645	6.5x45mm	8
5156.5650	6.5x50mm	2
5156.5655	6.5x55mm	2

Part No.	Diameter/Length	Qty
5156.5730	7.5x30mm	
5156.5735	7.5x35mm	
5156.5740	7.5x40mm	
5156.5745	7.5x45mm	
5156.5750	7.5x50mm	

9156.0004	CREO DLX® Uniplanar Screw Graphic Case
9156.0104	CREO DLX® Uniplanar Screw Module

Items in gray are additionally available.

CREO DLX®
9156.9006 HOOKS AND INSTRUMENTS SET

Thoracic Lamina Hook, Narrow

Part No.	Size	Qty
1156.9901	Small	2
1156.9902	Medium	2

Thoracic Lamina Hook

Part No.	Size	Qty
1156.9904	Small	2
1156.9905	Medium	2

Lamina Hook, Up-Going

Part No.	Size	Qty
1156.9907	Medium	2
1156.9908	Large	2

Transverse Process Hook

Part No.	Side/Size	Qty
1156.9922	Right, Large	
1156.9923	Left, Large	
1156.9924	Right, Medium	2
1156.9925	Left, Medium	2

Pedicle Hook

Part No.	Size	Qty
1156.9927	Small	2
1156.9928	Medium	6
1156.9929	Large	2

Lamina Hook, Narrow

Part No.	Size	Qty
1156.9940	Small	2
1156.9941	Medium	2
1156.9942	Large	2

Lamina Hook

Part No.	Size	Qty
1156.9944	Small	4
1156.9945	Medium	8
1156.9946	Large	4

Lamina Hook, Wide

Part No.	Size	Qty
1156.9948	Small	2
1156.9949	Medium	2
1156.9950	Large	2

Lamina Hook, Tall Body

Part No.	Size	Qty
1156.9952	Small	2
1156.9953	Medium	2
1156.9954	Large	2

Angled Lamina Hook

Part No.	Size	Qty
1156.9955	Small	2
1156.9956	Medium	2
1156.9957	Large	2

Items in gray are additionally available.

CREO DLX®
9156.9006 HOOKS AND INSTRUMENTS SET (CONT'D)

Lamina Hook, Extra Wide

Part No.	Size	Qty
1156.9960	Small	
1156.9961	Medium	
1156.9962	Large	

Lamina Hook, Offset Right, Extra Wide

Part No.	Size	Qty
1156.9970	Small	
1156.9971	Medium	
1156.9972	Large	

Lamina Hook, Offset Left, Extra Wide

Part No.	Size	Qty
1156.9973	Small	
1156.9974	Medium	
1156.9975	Large	

Lamina Hook, Medium

Part No.	Description	Qty
1156.9981	Offset Right	2
1156.9984	Offset Left	2
1156.9991	30° Offset, Right	
1156.9995	30° Offset, Left	

Instruments

Part No.	Description	Qty
6067.8000	Lamina Finder	1
6067.8005	Pedicle Finder	1
6156.8010	CREO DLX® Hook Holder	2
6156.8015	6.35 Hook Positioner	1
6156.8020	CREO DLX® Lateral Hook Holder	1
6156.8025	CREO DLX® Offset Hook Holder	1
9156.0006	CREO DLX® Hooks and Instruments Graphic Case	
9156.0206	CREO DLX® Hook Module	

Items in gray are additionally available.

CREO DLX®
9156.9007 DEGEN INSTRUMENTS SET

Part No.	Description	Qty
634.513	6.35 Rod Pusher	1
6119.3111	Reduction Clip Driver, Short	1
6120.0040	Torque-Limiting T-Handle, Ratcheting, 10Nm, ¼" Quick-Connect	1
6120.0045	Torque-Limiting L-Handle, 10Nm, ¼" Quick-Connect	
6156.0041	Static Torque-Limiting Hexalobe Driver, 10Nm	
6156.0050	Final Locking Driver Shaft, T27, ¼" Quick-Connect	2
6156.0055	Final Locking Driver Shaft, T27, ¼" Quick-Connect, Long	1
6156.0075	6.35 Power Bender	1
6156.0080	6.35 Rod Holder	1
6156.0085	6.35 Power Rod Grip	1
6156.1030	CREO DLX® Counter-Torque	1
6156.1070	CREO DLX® Internal Head Positioner	1
6156.1075	CREO DLX® External Head Positioner	
6156.1080	CREO DLX® Rigid Screwdriver Shaft	2
6156.1085	CREO DLX® Rigid Screwdriver Outer Sleeve	2
6156.2010	CREO DLX® Overhead Reducer	1
6156.2015	CREO DLX® Pistol Grip Reducer	1
6156.2030	CREO DLX® Reduction Fork	1
6156.2041	CREO DLX® Quick-Release Reduction Clip, Long	2
6156.2046	CREO DLX® Quick-Release Reduction Clip Pusher, Long	2
6156.5000	CREO DLX® Threaded Locking Cap Driver	2
6156.5003	CREO DLX® Threaded Locking Cap Driver, Double-Ended	
9156.0007	CREO DLX® Degen Instruments Graphic Case	

Items in gray are additionally available.

CREO DLX®
9156.9008 ILIAC IMPLANTS AND INSTRUMENTS SET

CREO DLX® Polyaxial Screw

Part No.	Diameter/Length	Qty	Part No.	Diameter/Length	Qty
5156.1000	11.5x100mm		5156.1900	9.5x100mm	2
5156.1001	11.5x110mm		5156.1901	9.5x110mm	2
5156.1002	11.5x120mm		5156.1902	9.5x120mm	2
5156.1070	11.5x70mm		5156.1970	9.5x70mm	2
5156.1075	11.5x75mm		5156.1975	9.5x75mm	2
5156.1080	11.5x80mm		5156.1980	9.5x80mm	2
5156.1085	11.5x85mm		5156.1985	9.5x85mm	2
5156.1090	11.5x90mm		5156.1990	9.5x90mm	2
5156.1095	11.5x95mm		5156.1995	9.5x95mm	2
5156.1100	10.5x100mm	2	5156.2100	10.5-9.0x100mm	2
5156.1101	10.5x110mm	2	5156.2101	10.5-9.0x110mm	2
5156.1102	10.5x120mm	2	5156.2102	10.5-9.0x120mm	2
5156.1170	10.5x70mm	2	5156.2170	10.5-9.0x70mm	2
5156.1175	10.5x75mm	2	5156.2175	10.5-9.0x75mm	2
5156.1180	10.5x80mm	2	5156.2180	10.5-9.0x80mm	2
5156.1185	10.5x85mm	2	5156.2185	10.5-9.0x85mm	2
5156.1190	10.5x90mm	2	5156.2190	10.5-9.0x90mm	2
5156.1195	10.5x95mm	2	5156.2195	10.5-9.0x95mm	2
5156.1700	7.5x100mm	2	5156.2200	8.0-6.5x100mm	2
5156.1701	7.5x110mm	2	5156.2201	8.0-6.5x110mm	2
5156.1702	7.5x120mm	2	5156.2202	8.0-6.5x120mm	2
5156.1770	7.5x70mm	2	5156.2270	8.0-6.5x70mm	2
5156.1775	7.5x75mm	2	5156.2275	8.0-6.5x75mm	2
5156.1780	7.5x80mm	2	5156.2280	8.0-6.5x80mm	2
5156.1785	7.5x85mm	2	5156.2285	8.0-6.5x85mm	2
5156.1790	7.5x90mm	2	5156.2290	8.0-6.5x90mm	2
5156.1795	7.5x95mm	2	5156.2295	8.0-6.5x95mm	2
5156.1800	8.5x100mm	2	5156.2800	8.5-7.0x100mm	2
5156.1801	8.5x110mm	2	5156.2801	8.5-7.0x110mm	2
5156.1802	8.5x120mm	2	5156.2802	8.5-7.0x120mm	2
5156.1870	8.5x70mm	2	5156.2870	8.5-7.0x70mm	2
5156.1875	8.5x75mm	2	5156.2875	8.5-7.0x75mm	2
5156.1880	8.5x80mm	2	5156.2880	8.5-7.0x80mm	2
5156.1885	8.5x85mm	2	5156.2885	8.5-7.0x85mm	2
5156.1890	8.5x90mm	2	5156.2890	8.5-7.0x90mm	2
5156.1895	8.5x95mm	2	5156.2895	8.5-7.0x95mm	2

Items in gray are additionally available.

CREO DLX®
9156.9008 ILIAC IMPLANTS AND INSTRUMENTS SET

CREO DLX® Polyaxial Screw (Cont'd)

Part No.	Diameter/Length	Qty
5156.2900	9.5-8.0x100mm	2
5156.2901	9.5-8.0x110mm	2
5156.2902	9.5-8.0x120mm	2
5156.2970	9.5-8.0x70mm	2
5156.2975	9.5-8.0x75mm	2
5156.2980	9.5-8.0x80mm	2
5156.2985	9.5-8.0x85mm	2
5156.2990	9.5-8.0x90mm	2
5156.2995	9.5-8.0x95mm	2

Head Offset Connector

Part No.	Length	Qty
1156.0710	150mm	
1156.0715	15mm	2
1156.0720	20mm	2
1156.0725	25mm	2
1156.0730	30mm	2
1156.0735	35mm	2

6.35mm Closed Offset Connector

Part No.	Length	Qty
1156.0815	150mm	
1156.0820	15mm	2
1156.0822	17.5mm	
1156.0825	20mm	2
1156.0830	25mm	2
1156.0835	30mm	2
1156.0840	35mm	2

6.35mm Open Offset Connector

Part No.	Length	Qty
1156.0915	150mm	
1156.0960	15mm	2
1156.0965	20mm	2
1156.0970	25mm	2
1156.0975	30mm	2
1156.0980	35mm	2

6.35mm Open Offset Connector

Part No.	Length	Qty
5156.1000	11.5x100mm	
5156.1001	11.5x110mm	
5156.1002	11.5x120mm	
5156.1070	11.5x70mm	
5156.1075	11.5x75mm	
5156.1080	11.5x80mm	
5156.1085	11.5x85mm	
5156.1090	11.5x90mm	
5156.1095	11.5x95mm	
5156.1100	10.5x100mm	2

Instruments

Part No.	Description	Qty
534.604	Torque-Limiting T-Handle, Ratcheting, 6.5Nm, ¼" Connect, Red	1
654.401	Sacral Probe, Straight	1
6156.0205	10.5mm Cannulated Tap, 40mm Threads	1
6156.0295	9.5mm Cannulated Tap, 40mm Threads	1
6156.1037	CREO DLX® Offset Connector Counter-Torque	1
9156.0008	CREO DLX® Iliac Implants and Instruments Graphic Case	
9156.0108	CREO DLX® Iliac Screw Module, Short	
9156.0208	CREO DLX® Iliac Screw Module, Long	

Items in gray are additionally available.

CREO DLX®
9156.9009 POLYAXIAL REDUCTION IMPLANTS AND INSTRUMENTS SET

CREO DLX® Polyaxial Reduction Screw

Part No.	Diameter/Length	Qty
5156.6220	4.0x20mm	
5156.6225	4.0x25mm	
5156.6230	4.0x30mm	
5156.6235	4.0x35mm	
5156.6240	4.0x40mm	
5156.6245	4.0x45mm	
5156.6325	4.5x25mm	
5156.6330	4.5x30mm	
5156.6335	4.5x35mm	
5156.6340	4.5x40mm	
5156.6345	4.5x45mm	
5156.6425	5.0x25mm	
5156.6430	5.0x30mm	4
5156.6435	5.0x35mm	4
5156.6440	5.0x40mm	4
5156.6445	5.0x45mm	4
5156.6450	5.0x50mm	
5156.6455	5.0x55mm	
5156.6525	5.5x25mm	
5156.6530	5.5x30mm	4
5156.6535	5.5x35mm	8
5156.6540	5.5x40mm	8
5156.6545	5.5x45mm	4
5156.6550	5.5x50mm	
5156.6555	5.5x55mm	
5156.6625	6.5x25mm	
5156.6630	6.5x30mm	4
5156.6635	6.5x35mm	6
5156.6640	6.5x40mm	8
5156.6645	6.5x45mm	8
5156.6650	6.5x50mm	6
5156.6655	6.5x55mm	4
5156.6660	6.5x60mm	
5156.6665	6.5x65mm	
5156.6725	7.5x25mm	
5156.6730	7.5x30mm	
5156.6735	7.5x35mm	2
5156.6740	7.5x40mm	6
5156.6745	7.5x45mm	6
5156.6750	7.5x50mm	6
5156.6755	7.5x55mm	2
5156.6760	7.5x60mm	
5156.6765	7.5x65mm	
5156.6825	8.5x25mm	
5156.6830	8.5x30mm	
5156.6835	8.5x35mm	
5156.6840	8.5x40mm	
5156.6845	8.5x45mm	
5156.6850	8.5x50mm	
5156.6855	8.5x55mm	
5156.6860	8.5x60mm	
5156.6865	8.5x65mm	

Instruments

Part No.	Description	Qty
5156.5030	CREO DLX® Reduction Screw Counter-Torque	1
6156.5040	CREO DLX® Rigid Reduction Screwdriver Shaft	2
6156.5045	CREO DLX® Rigid Reduction Screwdriver Outer Sleeve	2
6156.5050	CREO DLX® Reduction Screw Sleeve	4
6156.5060	CREO DLX® Reduction Screw Tab Remover	1
9156.0009	CREO DLX® Reduction Implants and Instruments Graphic Case	
9156.0209	CREO DLX® Polyaxial Reduction Screw Module	

Items in gray are additionally available.

CREO DLX®
9156.9010 FENESTRATED IMPLANT AND INSTRUMENT SET

CREO DLX® Fenestrated Threaded Locking Cap

Part No.	Description	Qty
1156.0015	Fenestrated Threaded Locking Cap	16

CREO DLX® Fenestrated Polyaxial Screw

Part No.	Diameter/Length	Qty
5156.2542	5.5x40mm	6
5156.2547	5.5x45mm	6
5156.2552	5.5x50mm	4
5156.2557	5.5x55mm	4
5156.2642	6.5x40mm	8
5156.2647	6.5x45mm	8
5156.2652	6.5x50mm	8
5156.2657	6.5x55mm	6
5156.2742	7.5x40mm	6
5156.2747	7.5x45mm	6
5156.2752	7.5x50mm	6
5156.2757	7.5x55mm	6

Instruments

Part No.	Description	Qty
6156.0030	Fenestrated Screwdriver Outer Sleeve	8
6156.0035	Fenestrated Screwdriver Counter-Torque	
6192.0040	Cannulated Driver Shaft, CREO® Fenestrated	8
685.003	1.6mm K-Wire, 450mm, Blunt Tip	

9156.0102	CREO DLX® Fenestrated Polyaxial Screw Module
9156.0612	CREO DLX® Fenestrated Threaded Locking Cap Module

Items in gray are additionally available.

CREO DLX®
9156.9013 DEFORMITY INSTRUMENTS SET

Part No.	Description	Qty
643.100	Long Throw Compressor	1
6067.3025	Rod Wrench	1
6156.0085	6.35 Power Rod Grip	1
6156.2035	CREO DLX® Reduction Forceps	
6156.3000	6.35 *In Situ* Bender, Left	1
6156.3005	6.35 *In Situ* Bender, Right	1
6156.3010	6.35 Coronal Plane Bender, Left	1
6156.3015	6.35 Coronal Plane Bender, Right	1
6156.3020	6.35 Vise-Style Rod Grip	2
6156.3025	6.35 Flat Bender	
6156.3026	6.35 Tube Bender	
9156.0013	CREO DLX® Deformity Instruments Graphic Case	

Items in gray are additionally available.

CREO DLX®
9156.9024 DEROTATION INSTRUMENTS SET

Part No.	Description	Qty
6119.3110	Reduction Clip Driver	1
6119.3111	Reduction Clip Driver, Short	1
6156.2040	CREO DLX® Quick-Release Reduction Clip	8
6156.2041	CREO DLX® Quick-Release Reduction Clip, Long	6
6156.2045	CREO DLX® Quick-Release Reduction Clip Pusher	8
6156.2046	CREO DLX® Quick-Release Reduction Clip Pusher, Long	6
6156.3100	Quick-Release Derotation Attachment Tube	8
9156.0024	CREO DLX® Derotation Instruments Graphic Case	

Items in gray are additionally available.

CREO DLX-NXT
9156.9025 DEROTATION CORE SET

Part No.	Description	Qty
634.406	Quick-Connect, ¼" Non-Ratcheting, Large Sport Handle	2
6120.3104	Derotation Counter-Torque	1
6120.3108	Derotation Handle Attachment	4
6156.3105	Wide Derotation Coupling Clamp, Short	4
6156.3106	Wide Derotation Coupling Clamp, Medium	4
6156.3107	Wide Derotation Coupling Clamp, Long	
9156.0025	CREO DLX-NXT Derotation Core Set Graphic Case	

Items in gray are additionally available.

IMPORTANT INFORMATION ON THE 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 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.

IMPORTANT INFORMATION ON THE CREO® STABILIZATION SYSTEM

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.

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.

IMPORTANT INFORMATION ON THE CREO® STABILIZATION SYSTEM

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 (U.S.A.) Law restricts this Device to Sale by or on the Order of a Physician.

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

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