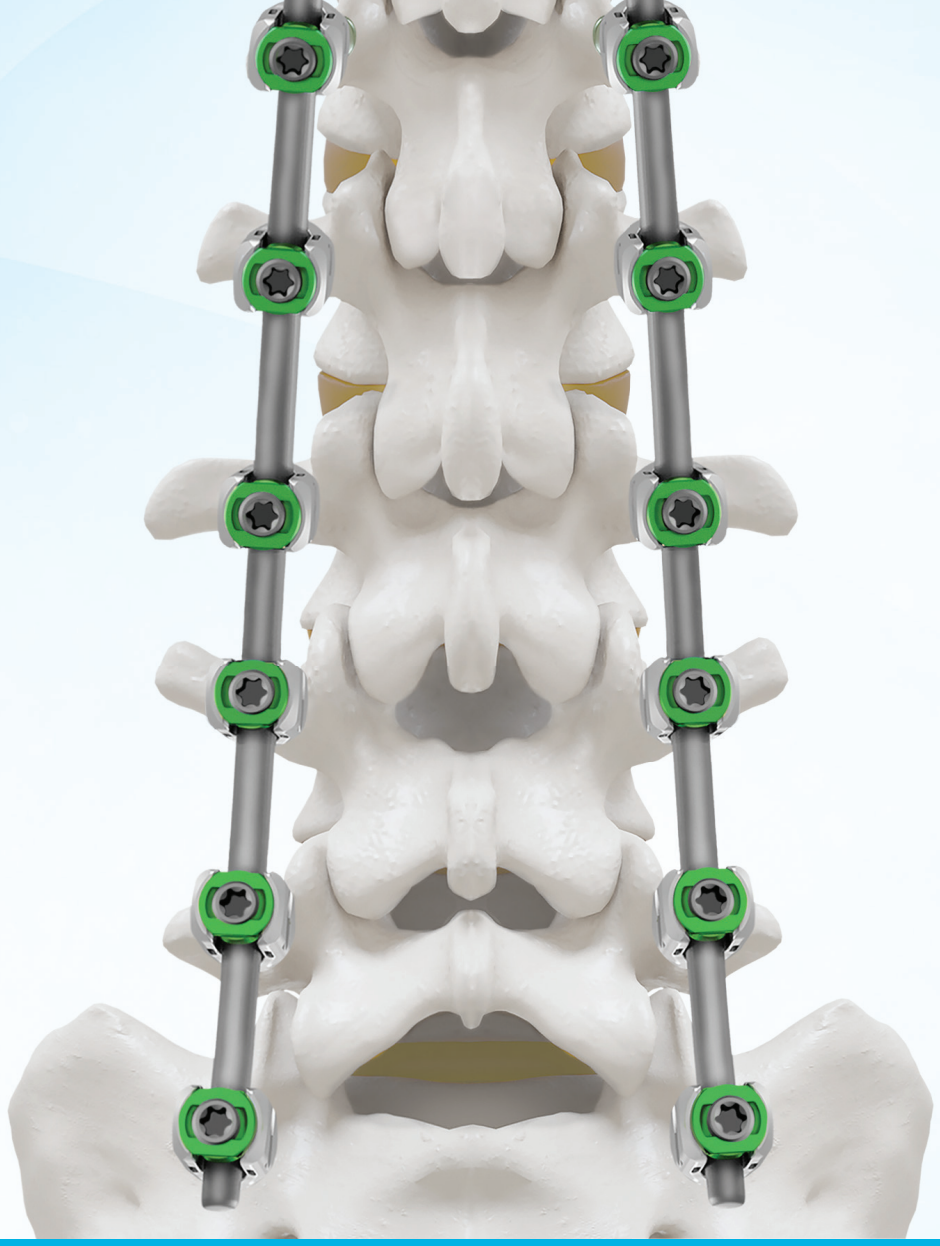

CREO NXT™

Stabilization System

SURGICAL TECHNIQUE GUIDE

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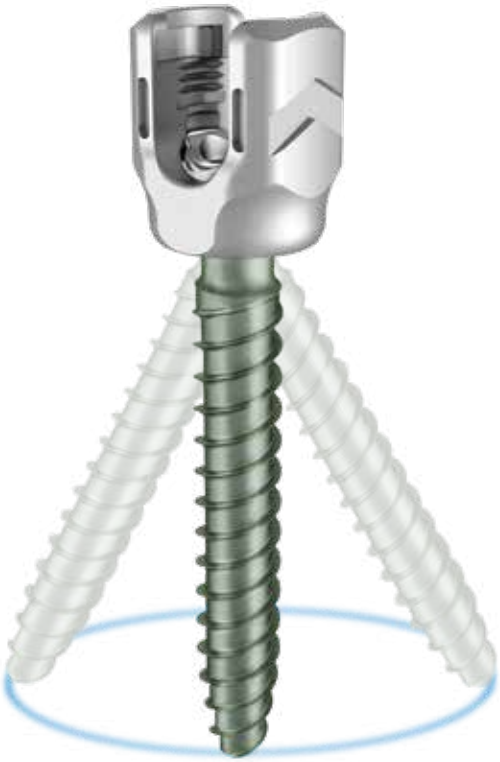
SURGICAL TECHNIQUE GUIDE

CREO NXT™

CREO NXT™

Stabilization System

CREO NXT™ is a non-threaded cobalt chrome pedicle screw system that redefines Globus Medical's deformity portfolio with robust implants and advanced deformity instruments.



Non-Threaded Locking Cap

- Eliminates cross-threading while securing the rod within the screw head with a quarter-turn
- Provides clearance for the rod to translate within the screw head with minimal resistance in corrective maneuvers

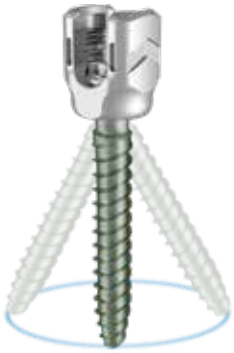
CoCr Screw Head

- Designed to handle high deformity loads
- Four-point interface with reduction and derotation instruments provides a rigid and secure connection for correction maneuvers
- Dependent locking allows the screw to return to polyaxial state after the locking cap is loosened, eliminating the need for remobilization
- Robust screw head accepts a 5.5 or 6.0mm diameter rod

IMPLANT OVERVIEW

Polyaxial Screw

- ±25° of conical angulation (50° total)
- Provides versatility and ease of alignment to address difficult pedicle trajectories and complex deformities



Uniplanar Screw

- Combines the versatility of a polyaxial screw with correction capabilities of a monoaxial screw
- Medial-lateral rigidity with cranial-caudal adjustability

Dual Outer Diameter (DOD) Screw

- Designed to optimize purchase in cancellous and cortical bone
- Nominal distal diameter allows for deeper insertion into sacrum without perforation
- Designed for enhanced fixation of the sacrum and ilium

Hooks

- Small, medium, and large profiles
- 41 different hook configurations for the lamina, pedicle, and transverse process
- Narrow, standard, and wide blades

CREO® 5.5 Cross Connector

- Enhances construct stability
- Angular and medial-lateral adjustments provide a secure, optimized fit

CREO® 5.5 Low Profile Cross Connector

- Ideal for use in thoracic spine to help reduce prominence

Offset Connectors

- Available in lengths of 15-35mm and 150mm
- Recommended for use with DOD screws for pelvic fixation
- Available in headed, open, and closed varieties
- CREO® Head Offset Connectors compatible with CREO NXT™ reduction instruments

Rods

- Available in 5.5mm and 6.0mm diameters
- Straight, curved, hex-ended and tapered rods
- Titanium alloy (TAV), commercially pure titanium (CP), cobalt chrome alloy (CoCr), or ESR cobalt chrome

INSTRUMENT OVERVIEW

PEDICLE PREPARATION

6067.0001 Pedicle Awl

602.101 Pedicle Probe-Straight

602.102 Pedicle Probe-Curved

602.109 Pedicle Probe

6156.0155 40mm Solid Tap

602.105 Ball Tip Probe

PEDICLE PREPARATION (CONT'D)

602.106 Ball Tip Probe, Curved

624.110 Ball Tip Probe, Double Ended

SCREW INSERTION

6067.0010 Straight Handle, Ratcheting, ¼" Quick-connect

6067.0020 T-Handle, Ratcheting ¼" Quick-connect

6067.0050 Driver Shaft, ¼" Quick-connect, Short

6067.0056 Driver Shaft, ¼" Quick-connect, Extra Long

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

6200.0050 CREO NXT™ Self-Centering Driver. ¼" Quick-connect

SCREW INSERTION (CONT'D)

6200.1080 CREO NXT™ Rigid Screw Driver Shaft

6200.1085 CREO NXT™ Rigid Screw Driver Outer Sleeve

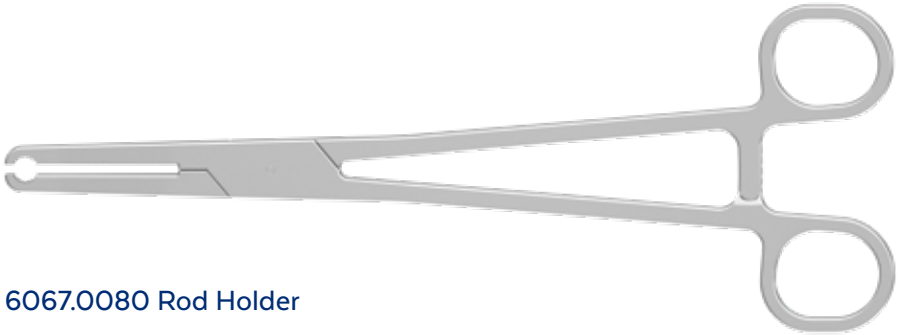
ROD MANIPULATION AND INSERTION

602.501 Rod Template, 150mm

602.517 Rod Template, 300mm

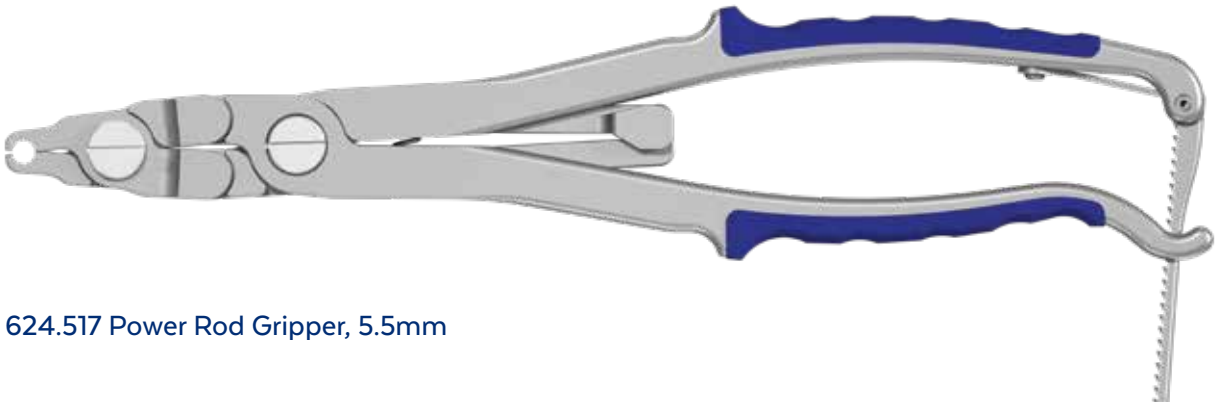
602.519 Rod Template, Silicone, 500mm

6067.0075 Power Bender



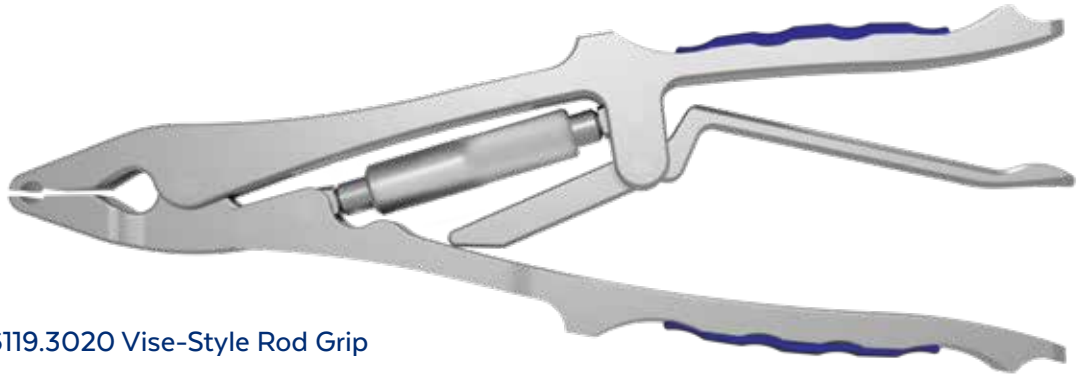
6067.0080 Rod Holder

ROD MANIPULATION AND INSERTION (CONT'D)



624.517 Power Rod Gripper, 5.5mm

6120.0003 Rod Pusher



6119.3020 Vise-Style Rod Grip

6067.3025 Rod Wrench

6119.3000 *In-situ* Bender, Left

6119.3005 *In-situ* Bender, Right

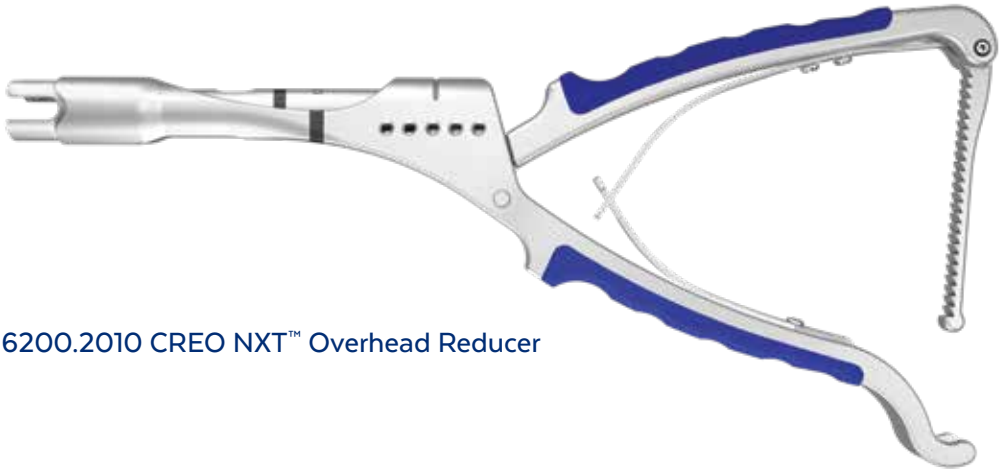
ROD MANIPULATION AND INSERTION (CONT'D)

6119.3010 Coronal Plane Bender, Left

6119.3015 Coronal Plane Bender, Right

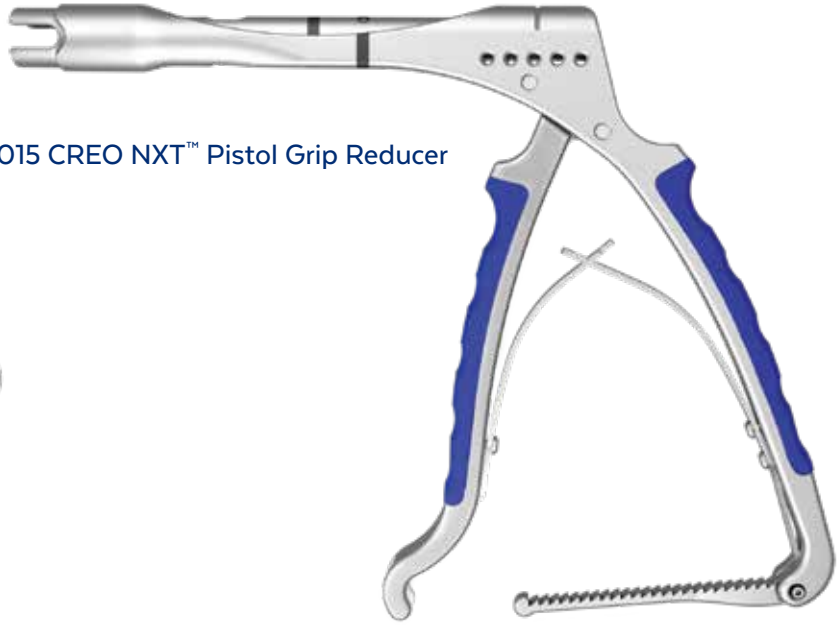
ROD REDUCTION

6200.2030 CREO NXT™ Reduction Fork



6200.2010 CREO NXT™ Overhead Reducer

ROD REDUCTION (CONT'D)



6200.2015 CREO NXT™ Pistol Grip Reducer

6156.3115 Quick-Release Reduction T-Handle

6200.2040 CREO NXT™ Quick-Release Reduction Clip

6200.2045 CREO NXT™ Quick-Release Reduction Clip, Pusher

6200.2041 CREO NXT™ Quick-Release Reduction Clip, Long

6200.2046 CREO NXT™ Quick-Release Reduction Clip, Pusher, Long

ROD REDUCTION (CONT'D)

6200.3110 11.65mm Hex Driver, Long

6200.3111 11.65mm Hex Driver

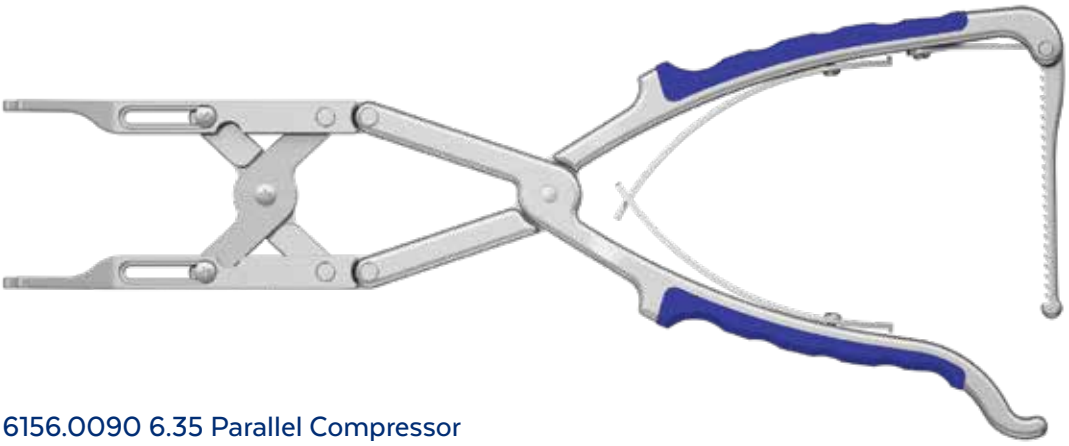
LOCKING CAP INSERTION AND SCREW LOCKING

6200.1010 CREO NXT™ Locking Cap Driver

6200.1025 CREO NXT™ Locking Cap Guide

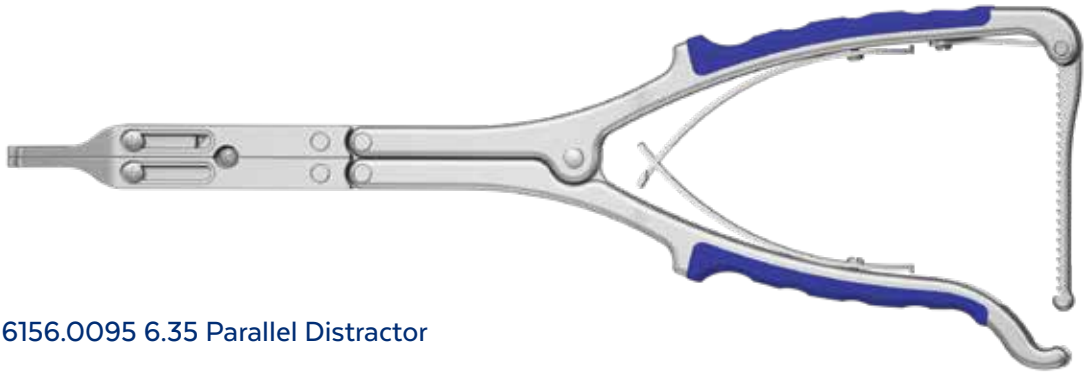
SCREW LOCKING INSTRUMENTS

6200.1030 CREO NXT™ Counter Torque

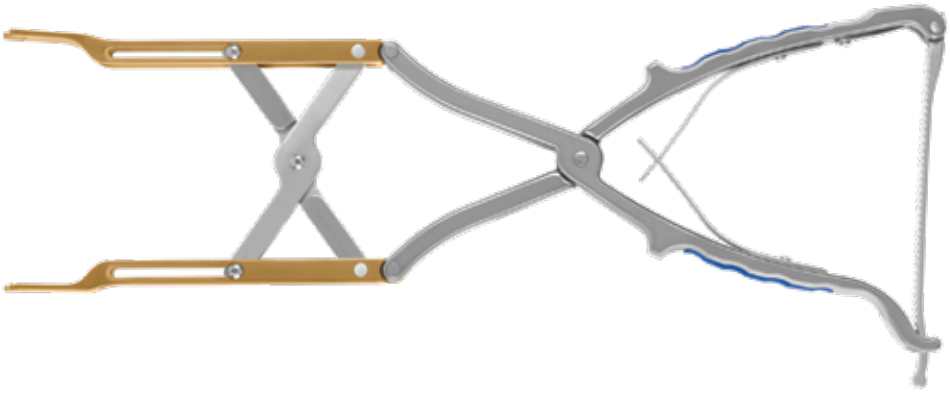


6156.0090 6.35 Parallel Compressor

SCREW LOCKING INSTRUMENTS (CONT'D)



6156.0095 6.35 Parallel Distractor



643.100 Long Throw Compressor

6200.0050 Self Centering Driver, 1/4" Quick-connect

634.611 Ratcheting, Torque Limiting Handle, 1/4" Quick-connect

SURGICAL TECHNIQUE

CREO NXT™

Refer to the package insert printed in the back of this technique guide for information on the intended use/indications, device description, contraindications, precautions, warnings, and potential risks associated with this system.

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. For the purposes of this technique guide, a Wiltse paramedial approach and building of an L4-L5-S1 construct are shown.

STEP 2 PEDICLE PREPARATION

Locate the pedicles and remove bone and/or soft tissue as needed. Use the **Pedicle Awl** to perforate the pedicle cortex. Use the **Pedicle Probe, Straight** to open the pedicle pathway. Use a **Ball Tip Probe** to verify that the walls of the prepared pedicle pathway are not violated. Demarcations every 10mm on the probes indicate the depth of the pathway and may also help determine screw length.

While CREO NXT™ screws are self-tapping, taps are available if additional tapping is needed.

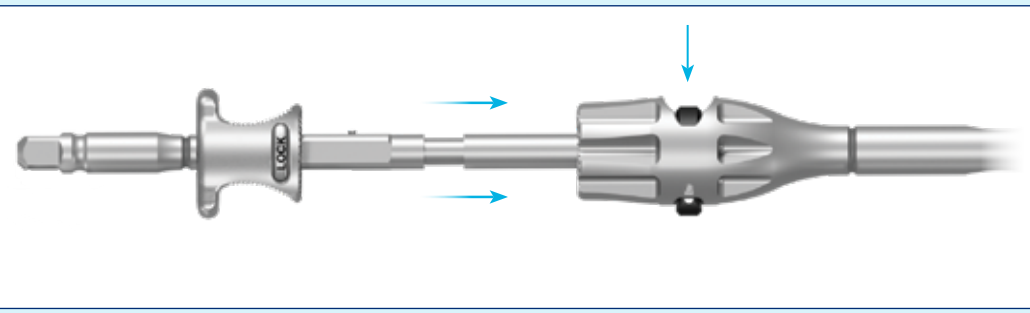
Preparing the pedicle pathway

STEP 3 SCREW INSERTION

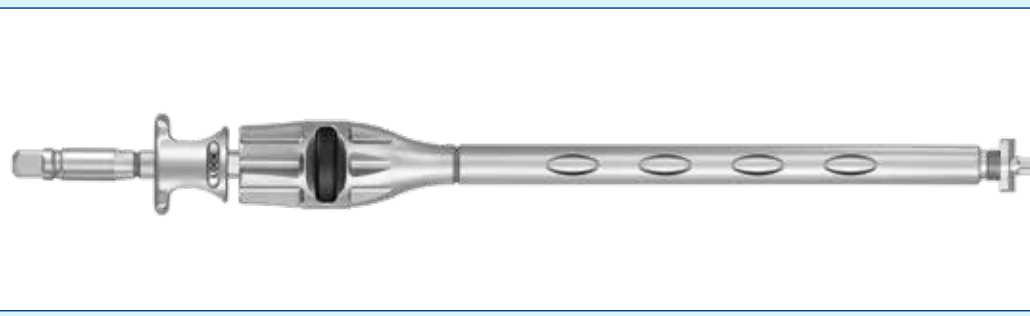
RIGID SCREWDRIVER ASSEMBLY

Ensure the finger grip on the **CREO NXT™ Rigid Screw Driver Shaft** is pulled back toward the ¼" Quick-connect end. Align the wings of the finger grip with the rotating tip of the **CREO NXT™ Rigid Screw Driver Outer Sleeve**.

Depress 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.



Loading Screwdriver and Inserting Screw

Attach the 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 and the knob rotates freely.

Holding the shank of the selected screw straight, align the distal wings of the outer sleeve with the rod slot and insert the driver tip into the screw head. Toggle the screw shank until the driver tip fully engages the screw head. Slide the knurled knob toward the screw and rotate clockwise until tight.

Engaging the screw

Press the lock button on the finger grip to lock the outer sleeve in place. The screw is now ready to be inserted.

Lock button Knurled knob

Screw loaded on driver

Drive the screw into the prepared pedicle using the Rigid Screwdriver assembly and Straight Handle or T-Handle. Ensure that the screw head is freely mobile and free of bone obstruction. For an anterior construct, insert screws anterolaterally into the vertebral body.

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

Finger grips

Disengaging the screw

Repeat for all screws in the construct. If screw removal or repositioning is required, the **Self-Retaining Driver Shaft, ¼" Quick-connect** attached to the Straight Handle or T-Handle may be used.

STEP 4 ROD PREPARATION AND INSERTION

Determine the appropriate length and contour of the rod using the **Rod Template**. Rods may be contoured using the **Power Bender**. Using the **Rod Holder** or **Power Rod Gripper**, grasp the rod and insert it into the screw head. Additionally, the **Rod Pusher** may be used to push the rod into the screw head. The **Rod Cutter** (602.508), additionally available in the Protex Degen Instruments Set, may be used to cut rods to the desired length.

Using Rod Template

Rod insertion

STEP 5 ROD REDUCTION

The rod reduction instruments allow for 3-60mm of continuous reduction and 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.

CREO NXT™ REDUCTION INSTRUMENTS (mm)

60
Quick-Release Reduction Clip, Long

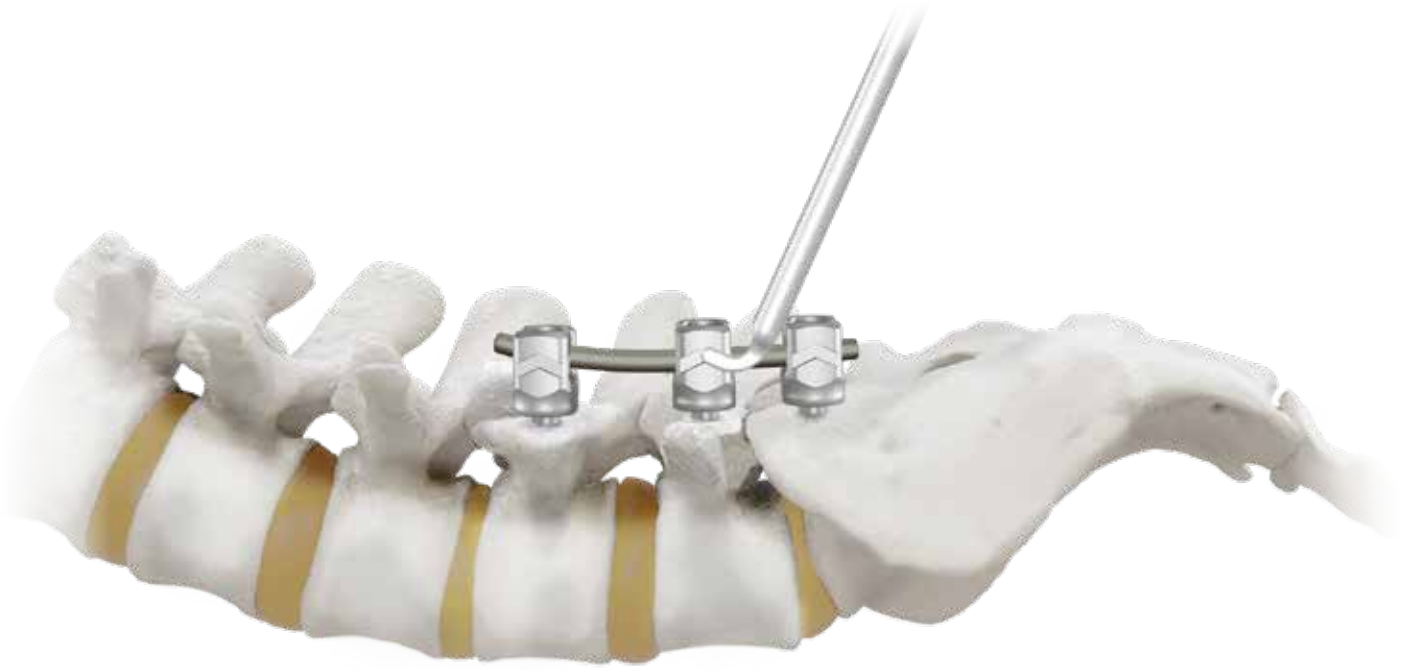
40
Quick-Release Reduction Clip

10
Pistol Grip Reducer

10
Overhead Reducer

05
Reduction Fork

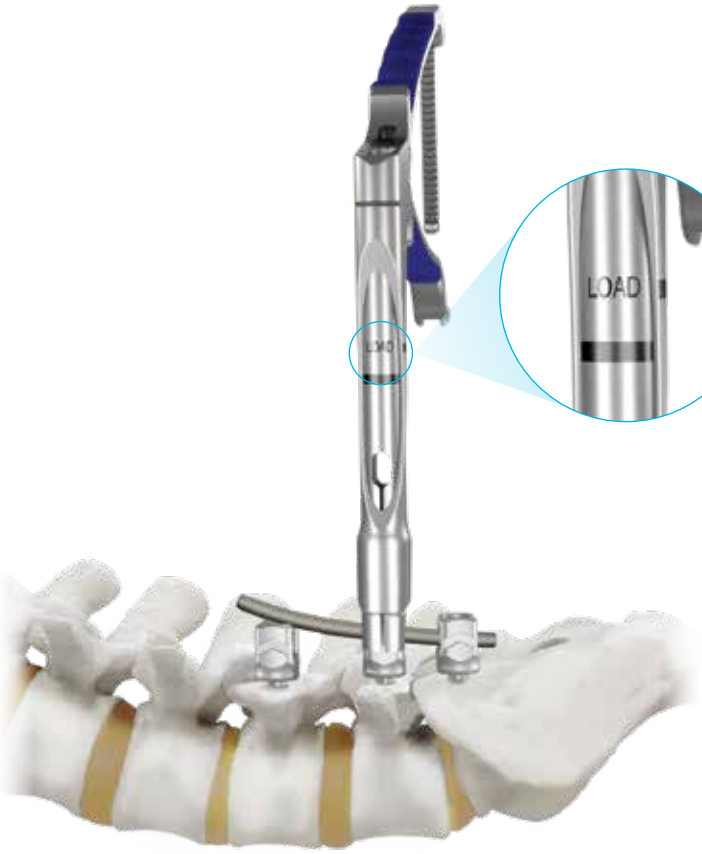
The **CREO NXT™ Reduction Fork** may be used to maneuver the rod into position. The instrument provides 5mm of reduction and is useful when the rod is positioned slightly above the screw head.



USING THE PISTOL GRIP REDUCER AND OVERHEAD REDUCER

Ensure the reducer is fully open by aligning the “LOAD” etching on the inner shaft with the etched black ring on the outer shaft, as shown below. When fully reduced, the horizontal etched line on the inner shaft aligns with the etched black ring on the outer shaft.

The **CREO NXT™ Locking Cap Driver** may be inserted through the **Overhead Reducer** or **Pistol Grip Reducer**.



Pistol Grip Reducer in unloaded position

Pistol Grip Reducer fully reduced

USING THE QUICK RELEASE REDUCTION CLIP

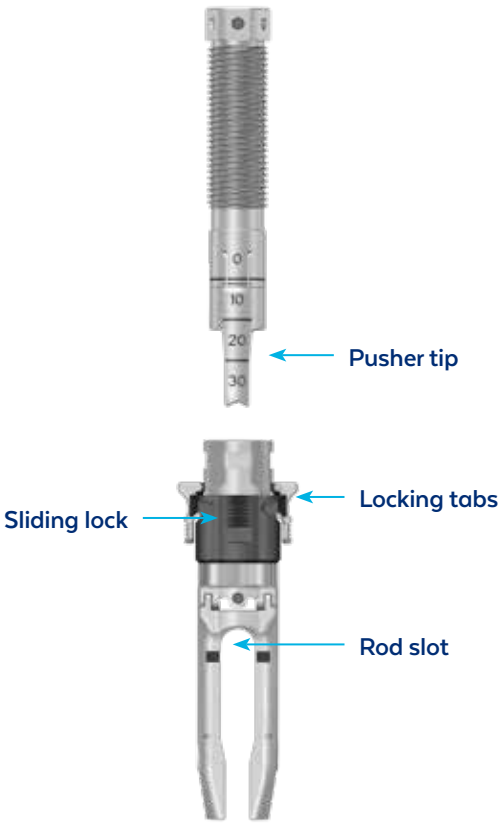
The **CREO NXT™ Quick Release-Reduction Clip, Long** provides up to 60mm of continuous reduction. The **CREO NXT™ Quick-Release Reduction Clip** provides up to 40mm of continuous reduction.

Ensure the 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 NXT™ Quick-Release Reduction Clip, Pusher** tip with the rod slot of the Reduction Clip. Insert the pusher into the clip and thread to the desired starting reduction amount using the demarcations on the Reduction Clip.

Capture the rod within the rod slot, align squarely over the screw head and push down until completely flush. Depress the black sliding lock until it clicks into place. The silver locking tabs do not need to be pressed to engage the lock. Verify rigid connection by pulling up on the reducer.

Reduce the rod by placing the **Quick-Release Reduction T-Handle** onto the Reduction Clip Pusher and rotating clockwise until it bottoms out on the top of the Reduction Clip. If reducing over multiple levels, use the **11.65mm Hex Driver** or **11.65mm Hex Driver, Long** attached to the straight ratcheting handle to minimize interference with adjacent reducers.

Once reduction is achieved, insert the locking cap using the Locking Cap Driver. Remove the Reduction Clip by depressing the two silver locking tabs and pulling up on the instrument. In some cases, one counterclockwise rotation may be needed before removal.



Assembling Reduction Clip

Reduction Clip, Pusher and Driver

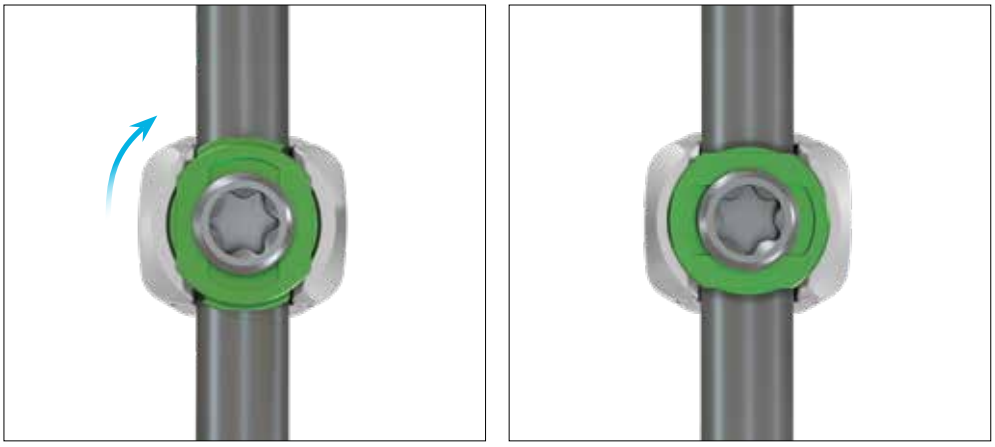
STEP 6 LOCKING CAP INSERTION

Loading the Locking Cap Driver

Align the black etching on the sides of the CREO NXT™ Locking Cap Driver with the corresponding silver lines in the locking cap module. Press the driver down over the locking cap until an audible click is heard, indicating that the locking cap is now retained by the driver. Ensure the locking cap is flush with the end of the driver.

Locking Cap Insertion

Align the tabs of the locking cap with the rod and insert the locking cap into the screw head. Rotate the driver clockwise 90° to capture the rod. Locking cap insertion requires minimal torque. If the locking cap is difficult to rotate, the rod may not be seated properly and further rod reduction and/or contouring may be required. The construct is not completely locked until the center set screw of the locking cap is final tightened.



Unlocked Locked

Provisional tightening may be achieved using the **Driver Shaft, 1/4" Quick-connect, Extra Long**, and a T-Handle inserted through the Locking Cap Driver. Alternatively, the **CREO NXT™ Self-Centering Driver, ¼" Quick-connect** may be used to provisionally tighten the set screw.

STEP 7 DEFORMITY CORRECTION

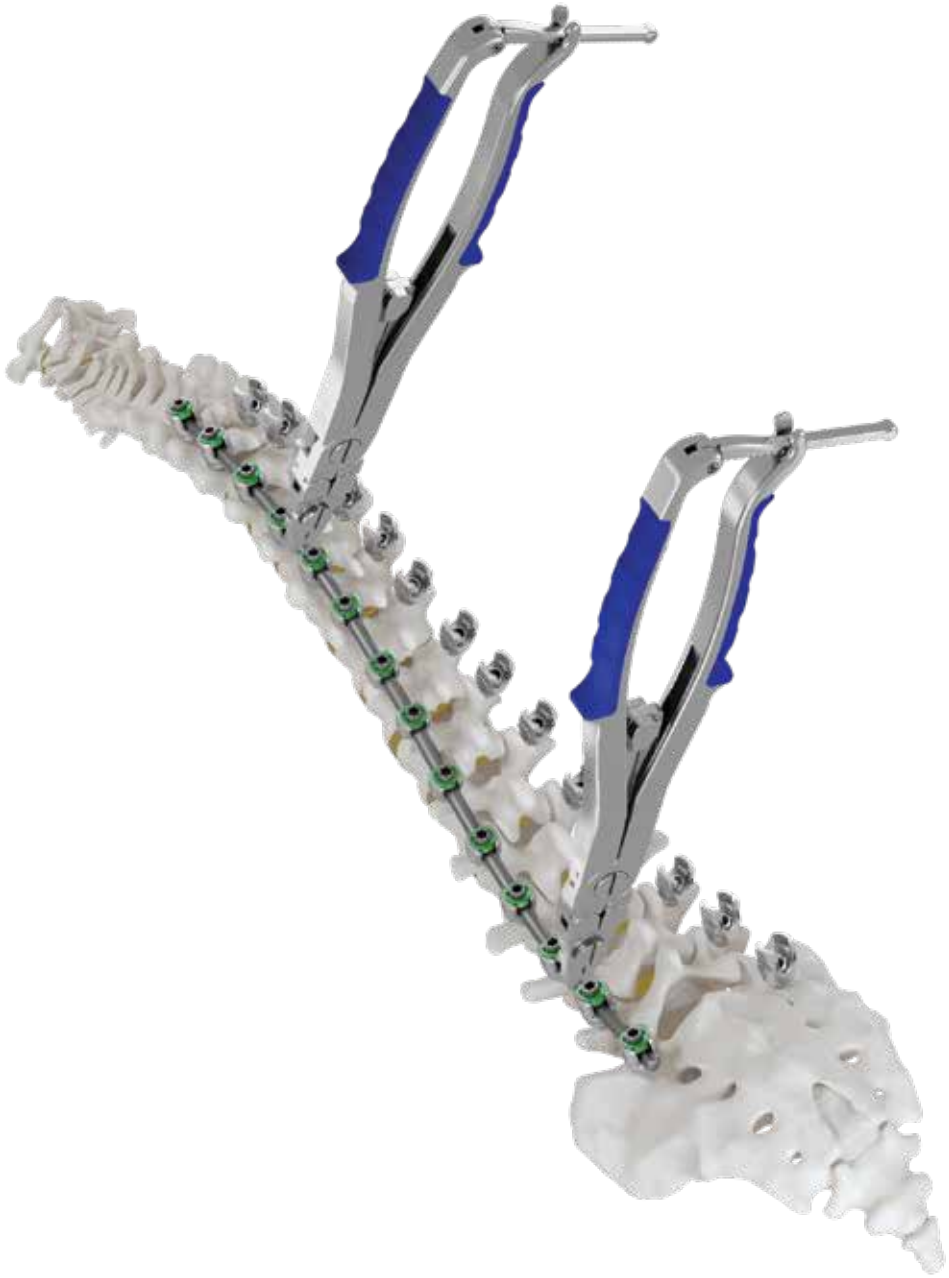
Global Derotation

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

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

To rotate the rod, two **Power Rod Grippers, 5.5mm** or **Vise-Style Rod Grips** may be used. Position the rod grips at the desired locations and rotate counterclockwise. Derotation should be performed gradually to avoid neurological injury and maintain proper rod placement.

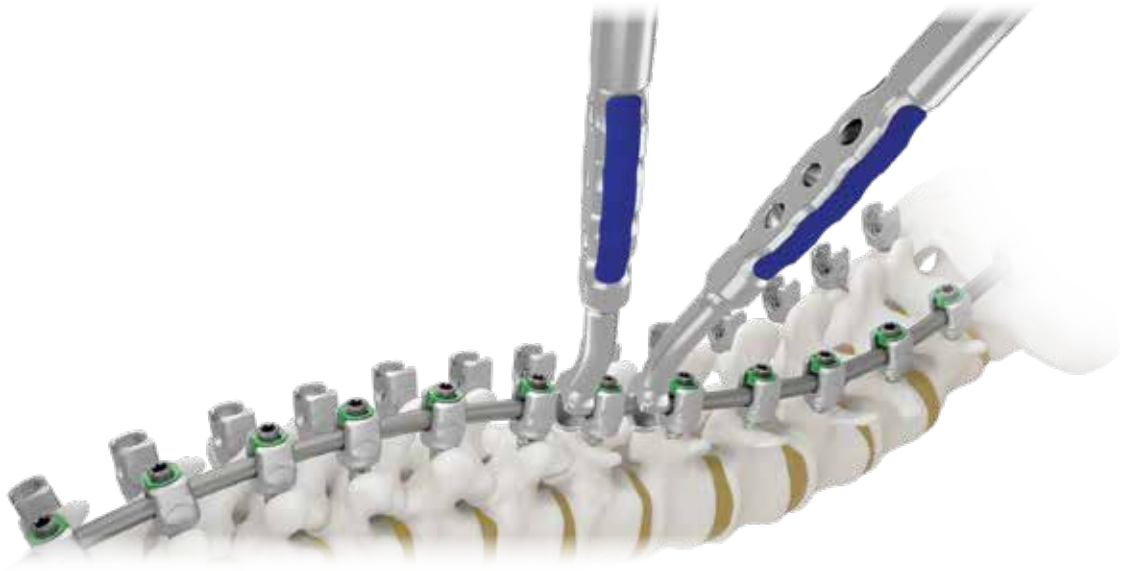
Alternatively, the **Rod Wrench** may be used to aid in rod rotation.



In Situ Rod Bending

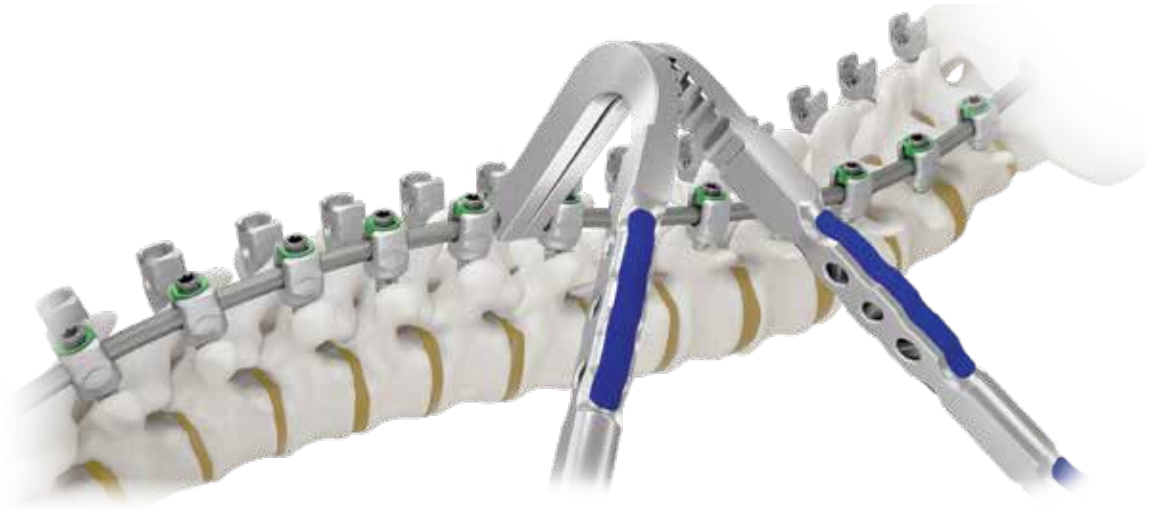
In situ rod bending may be accomplished using the ***In-Situ* Bender** (Left or Right) or **Coronal Plane Bender** (Left or Right). Rod bending may be performed after the rod is fully seated and the locking caps are inserted.

In-Situ Benders are used to make corrections to the rod curvature in the sagittal plane. Position two benders (left and right) close to one another. Bend the rod in small increments to prevent damage to the rod. Once rod bending is complete, compression or distraction may be performed.



***In-Situ* Benders**

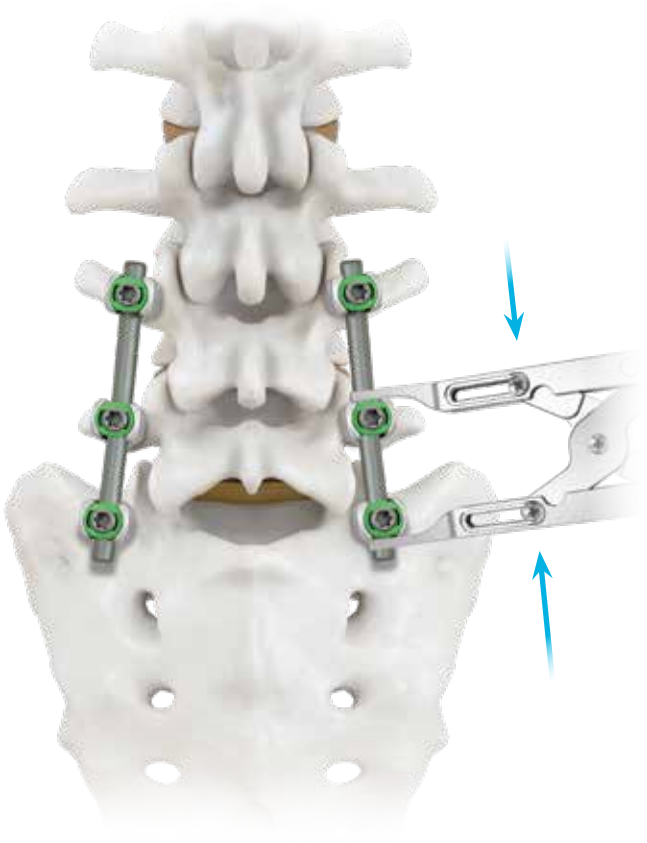
Coronal Plane Benders are used to make corrections to the rod curvature in the coronal plane. Position the benders so the grooves on the inside of the left bender engage with those on the right bender. Bend the rod in small increments to prevent rod damage. Once rod bending is complete, compression or distraction may be performed.



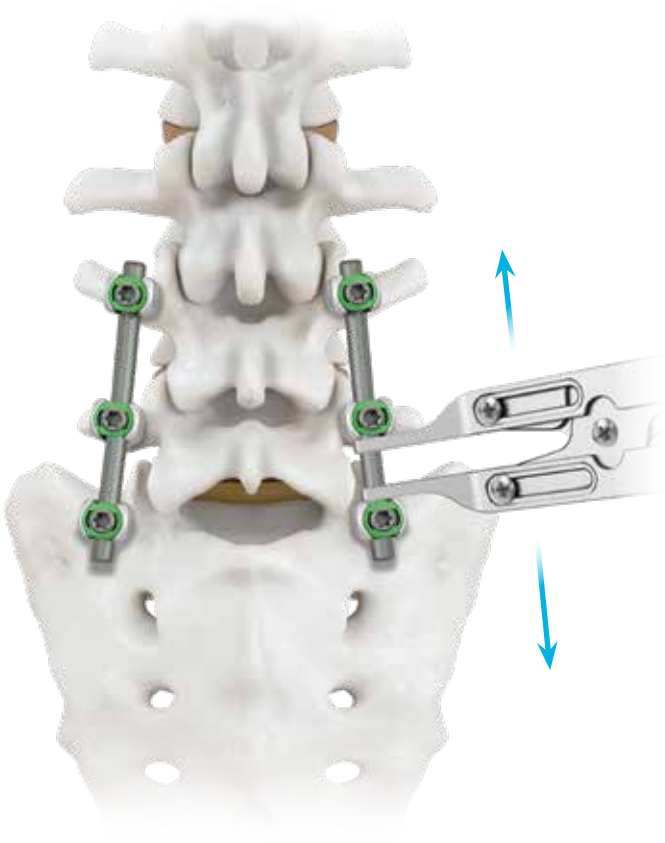
Coronal Plane Benders

STEP 8 COMPRESSION OR DISTRACTION

Pedicle screws may be compressed or distracted along the rod using the **Parallel Compressor** or **Parallel Distractor**. Tighten one set screw to establish a rigid point for compression or distraction. The **Long Throw Compressor** may be used as an alternative to the Parallel Compressor when greater compression force is needed. Once compression or distraction is completed, provisionally tighten the set screws using the T-Handle, Ratcheting, ¼" Quick Connect and **Driver Shaft, ¼" Quick Connect, Short** assembly.



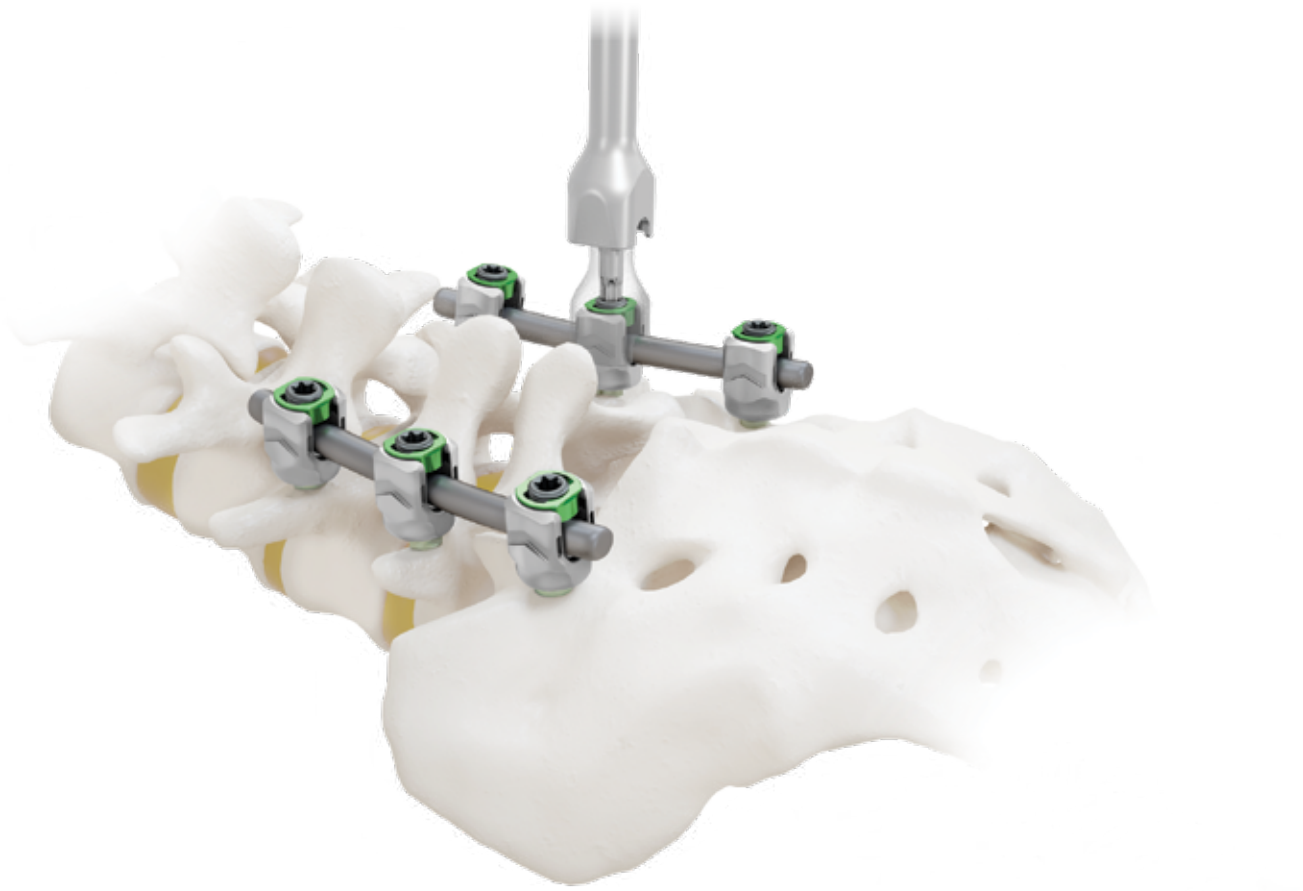
Compression using Parallel Compressor



Distraction using Parallel Distractor

STEP 9 FINAL TIGHTENING

Final tightening is performed using the **Torque Limiting T-Handle, Ratcheting, 8 Nm, ¼" Connect, Black** and **Driver Shaft, ¼' Quick Connect, Short** with the **CREO NXT™ Counter Torque**. Visually confirm that the driver shaft tip is fully engaged in the set screw of the locking cap before seating the counter torque onto the rod. Rotate the assembly clockwise until two audible clicks are heard, indicating that the torque limit of 8Nm is reached. Ensure that all set screws are final tightened after corrective maneuvers are complete.



OPTIONAL: REVISION/REMOVAL

For revision or removal, reverse the insertion steps until the desired implants may be removed. Loosen locking caps or set screws using a driver. Locking cap removal should not be performed with the Counter Torque in place. Once the set screws are loosened and the locking caps are removed, grasp the rod and remove. Remove all screws using a screwdriver. T-connectors and other connectors may remain connected on the rods for removal, or may be removed separately.

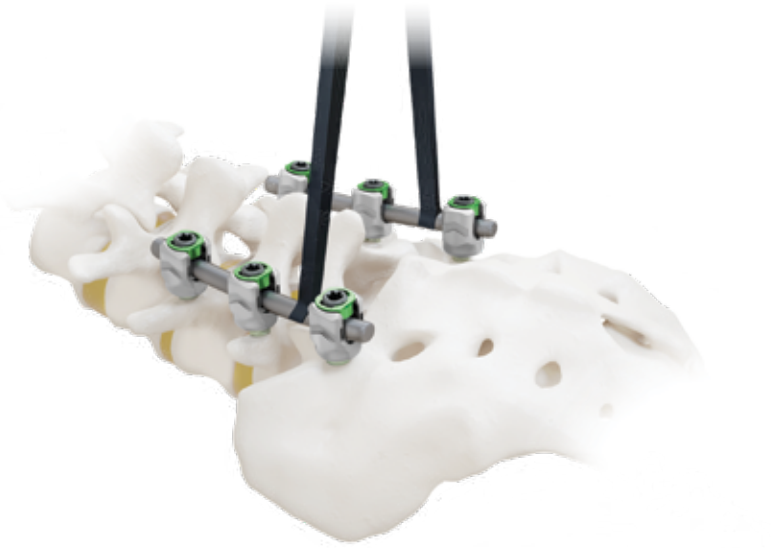
FINAL CONSTRUCT

OPTIONAL: CROSS CONNECTOR

A Cross Connector may be used between rods to enhance construct stability.

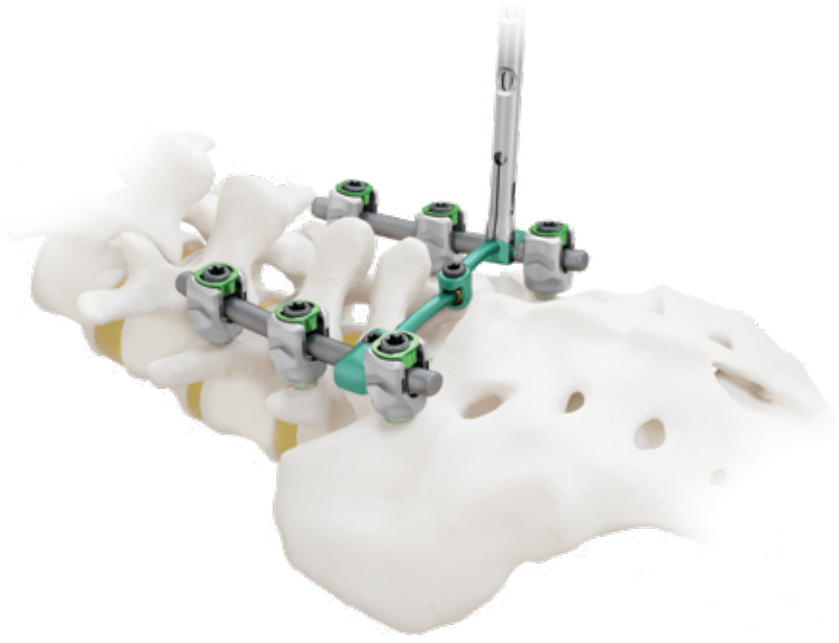
To select the proper length cross connector, place the **Cross Connector Caliper** between the rods at the desired level. Read the cross connector length.

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



Using the Cross Connector Caliper

Reading length measurement



Using the Cross Connector Driver

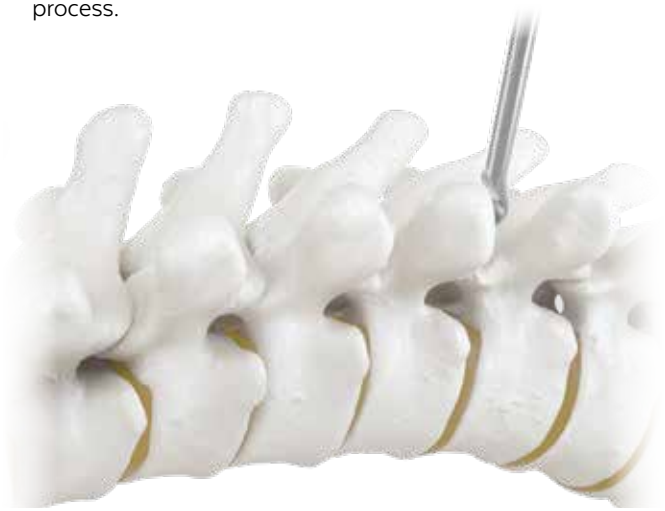
OPTIONAL: HOOKS

Preparing the Pedicle

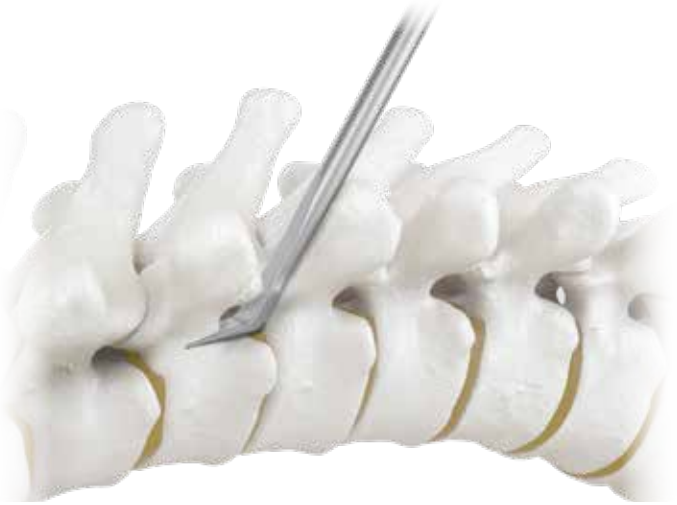
The **Pedicle Finder** is used to prepare the pedicle for hook placement. Use the finder to open the facet capsule and locate the pedicle. If necessary, a portion of the inferior facet process may be removed to aid in pedicle hook insertion.

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 **Lamina Finder** may also be used to locate and prepare the transverse process.



Preparing the lamina



Preparing the pedicle

Pedicle Hook Placement

A pedicle hook is typically used at the T10 level and above. The hook blade is placed upgoing and sits flush against the facet and pedicle.

Lamina Hook Placement

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

Transverse Process Hook Placement

A transverse process hook is typically placed downgoing, at the top of a construct. Transverse process hooks may be used with an upgoing pedicle hook to form a claw construct, either at the same level or one level superior.

CREO NXT™ Hook Placement Instruments

The CREO NXT™ Stabilization System has several instruments to aid in hook placement. The **CREO NXT™ Hook Holder** and the **CREO NXT™ Offset Hook Holder** engage into the reduction slots on both sides of the hook.

The Offset Hook Holder allows for introduction of a cap without disengaging the holder.

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

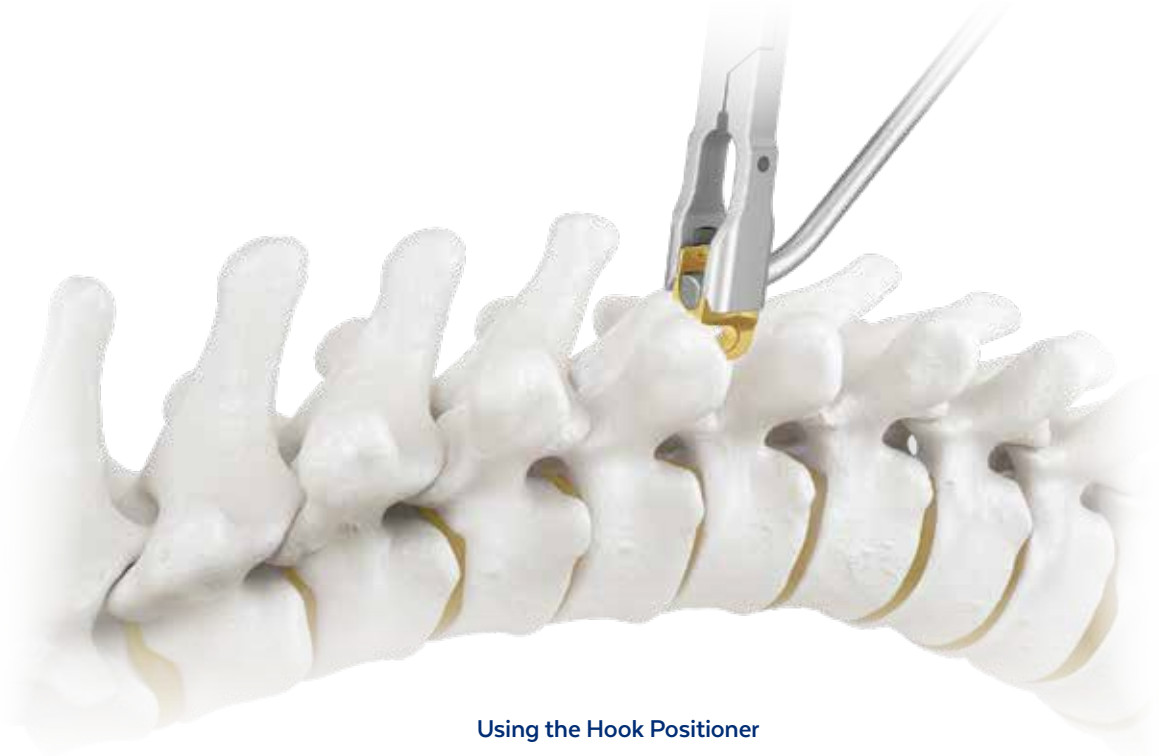
The **Hook Positioner** may be used to aid in inserting and positioning the hooks.

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

Hook Holder

Offset Hook Holder

Lateral Hook Holder



Using the Hook Positioner

CREO DLX-NXT
CORE INSTRUMENT SET 9156.9000

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, 150 mm	1
602.517	Rod Template, 300 mm	1
602.519	Rod Template, Silicone,500mm	1
6067.0001	Pedicle Awl	1
6067.0010	Straight Handle, Ratcheting, 1/4" Quick-connect	2
6067.0015	Straight Handle, Fixed, 1/4" Quick-connect	
6067.0020	T-Handle, Ratcheting, 1/4" Quick-connect	2
6067.0030	Palm Handle, Ratcheting, 1/4" Quick-connect	
6067.0035	Palm Handle, Fixed, 1/4" Quick-connect	
6067.0050	Driver Shaft, 1/4" Quick-connect, Short	1
6067.0060	Self-retaining Driver Shaft, 1/4" 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
624.110	Ball Tipped Probe, Double Ended	1
624.113	Pedicle Probe, Thoracic, Curved	
624.114	Pedicle Probe, Thoracic, Straight	
9156.0000	CREO DLX-NXT Core Instruments Graphic Case	

**Items in gray are additionally available*

CREO NXT™
DEGEN IMPLANT SET 9200.9001

Part No.	Description	QTY
1200.0000	CREO NXT™ Locking Cap	16

CREO® 5.5 Cross Connector

Part No.	Length	QTY
1119.0030	29-33mm	1
1119.0034	32-40mm	1
1119.0039	38-50mm	2
1119.0046	48-60mm	2
1119.0062	58-70mm	1
1119.0075	68-80mm	
1119.0086	78-90mm	

5.5mm Straight Rod, Titanium Alloy

Part No.	Length	QTY
1119.5030	30mm	
1119.5035	35mm	
1119.5040	40mm	
1119.5045	45mm	4
1119.5050	50mm	
1119.5055	55mm	4
1119.5060	60mm	
1119.5065	65mm	4
1119.5070	70mm	
1119.5075	75mm	4
1119.5080	80mm	
1119.5085	85mm	4
1119.5090	90mm	
1119.5095	95mm	
1119.5100	100mm	2
1119.5125	125mm	2
1119.5150	150mm	2

5.5mm Straight Rod, Cobalt Chrome

Part No.	Length	QTY
7119.5030	30mm	
7119.5035	35mm	
7119.5040	40mm	
7119.5045	45mm	

5.5mm Straight Rod, Cobalt Chrome

Part No.	Length	QTY
7119.5050	50mm	
7119.5055	55mm	
7119.5060	60mm	
7119.5065	65mm	
7119.5070	70mm	
7119.5075	75mm	
7119.5080	80mm	
7119.5085	85mm	
7119.5090	90mm	
7119.5095	95mm	
7119.5100	100mm	
7119.5125	125mm	
7119.5150	150mm	

5.5mm Curved Rod, Titanium Alloy

Part No.	Length	QTY
1119.7030	30mm	
1119.7035	35mm	4
1119.7040	40mm	4
1119.7045	45mm	4
1119.7050	50mm	2
1119.7055	55mm	2
1119.7060	60mm	2
1119.7065	65mm	4
1119.7070	70mm	2
1119.7075	75mm	4
1119.7080	80mm	2
1119.7085	85mm	4
1119.7090	90mm	2
1119.7095	95mm	2
1119.7100	100mm	2
1119.7125	125mm	2
1119.7150	150mm	2

*Items in gray are additionally available

5.5mm Curved Rod, Cobalt Chrome

Part No.	Length	QTY
7119.7030	30mm	
7119.7035	35mm	
7119.7040	40mm	
7119.7045	45mm	
7119.7050	50mm	
7119.7055	55mm	
7119.7060	60mm	
7119.7065	65mm	
7119.7070	70mm	
7119.7075	75mm	
7119.7080	80mm	
7119.7085	85mm	
7119.7090	90mm	
7119.7095	95mm	
7119.7100	100mm	
7119.7125	125mm	
7119.7150	150mm	
7119.7200	200mm	

CREO NXT™ Polyaxial Screw, CoCr Head, Ti Shank

Part No.	Diameter/Length	QTY
7200.1130	10.5 x 30mm	
7200.1135	10.5 x 35mm	
7200.1140	10.5 x 40mm	
7200.1145	10.5 x 45mm	
7200.1150	10.5 x 50mm	
7200.1155	10.5 x 55mm	
7200.1160	10.5 x 60mm	
7200.1165	10.5 x 65mm	
7200.1525	5.5 x 25mm	
7200.1530	5.5 x 30mm	8
7200.1535	5.5 x 35mm	8
7200.1540	5.5 x 40mm	8
7200.1545	5.5 x 45mm	8
7200.1550	5.5 x 50mm	6
7200.1555	5.5 x 55mm	6
7200.1560	5.5 x 60mm	

CREO NXT™ Polyaxial Screw, CoCr Head, Ti Shank

Part No.	Diameter/Length	QTY
7200.1625	6.5 x 25mm	
7200.1630	6.5 x 30mm	4
7200.1635	6.5 x 35mm	6
7200.1640	6.5 x 40mm	8
7200.1645	6.5 x 45mm	8
7200.1650	6.5 x 50mm	8
7200.1655	6.5 x 55mm	6
7200.1660	6.5 x 60mm	6
7200.1665	6.5 x 65mm	
7200.1725	7.5 x 25mm	
7200.1730	7.5 x 30mm	2
7200.1735	7.5 x 35mm	6
7200.1740	7.5 x 40mm	6
7200.1745	7.5 x 45mm	6
7200.1750	7.5 x 50mm	6
7200.1755	7.5 x 55mm	6
7200.1760	7.5 x 60mm	
7200.1765	7.5 x 65mm	
7200.1825	8.5 x 25mm	
7200.1830	8.5 x 30mm	
7200.1835	8.5 x 35mm	
7200.1840	8.5 x 40mm	4
7200.1845	8.5 x 45mm	4
7200.1850	8.5 x 50mm	6
7200.1855	8.5 x 55mm	
7200.1860	8.5 x 60mm	
7200.1865	8.5 x 65mm	
7200.1930	9.5 x 30mm	
7200.1935	9.5 x 35mm	
7200.1940	9.5 x 40mm	
7200.1945	9.5 x 45mm	
7200.1950	9.5 x 50mm	
7200.1955	9.5 x 55mm	
7200.1960	9.5 x 60mm	
7200.1965	9.5 x 65mm	
7200.2025	6.0 x 25mm	

**Items in gray are additionally available*

CREO NXT™
DEGEN IMPLANT SET 9200.9001 (CONT'D)

CREO NXT™ Polyaxial Screw, CoCr Head, Ti Shank

Part No.	Diameter/Length	QTY
7200.2030	6.0 x 30mm	
7200.2035	6.0 x 35mm	
7200.2040	6.0 x 40mm	
7200.2045	6.0 x 45mm	
7200.2050	6.0 x 50mm	
7200.2055	6.0 x 55mm	
7200.2060	6.0 x 60mm	
7200.2065	6.0 x 65mm	

9119.0710	CREO 5.5 Variable Cross Connector Module
9119.0810	CREO 5.5 Rod Module
9200.0001	CREO NXT™ Degen Implants Graphic Case
9200.0101	CREO NXT™ Degen Screw Module
9200.0610	CREO NXT™ Locking Cap Module

**Items in gray are additionally available*

CREO NXT™
DUAL OUTER DIAMETER SCREW SET 9200.9002

CREO NXT™ Polyaxial DOD Screw, CoCr Head, Ti Shank

Part No.	Diameter/Length	QTY
7200.2130	10.5 - 9.0 x 30mm	
7200.2135	10.5 - 9.0 x 35mm	
7200.2140	10.5 - 9.0 x 40mm	
7200.2145	10.5 - 9.0 x 45mm	
7200.2150	10.5 - 9.0 x 50mm	
7200.2155	10.5 - 9.0 x 55mm	
7200.2160	10.5 - 9.0 x 60mm	
7200.2165	10.5 - 9.0 x 65mm	
7200.2230	8.0 - 6.5 x 30mm	2
7200.2235	8.0 - 6.5 x 35mm	4
7200.2240	8.0 - 6.5 x 40mm	4
7200.2245	8.0 - 6.5 x 45mm	4
7200.2250	8.0 - 6.5 x 50mm	4
7200.2255	8.0 - 6.5 x 55mm	4
7200.2260	8.0 - 6.5 x 60mm	4
7200.2265	8.0 - 6.5 x 65mm	
7200.2530	5.5 - 4.5 x 30mm	
7200.2535	5.5 - 4.5 x 35mm	
7200.2540	5.5 - 4.5 x 40mm	
7200.2545	5.5 - 4.5 x 45mm	
7200.2550	5.5 - 4.5 x 50mm	
7200.2555	5.5 - 4.5 x 55mm	
7200.2560	5.5 - 4.5 x 60mm	
7200.2630	6.5 - 5.0 x 30mm	2
7200.2635	6.5 - 5.0 x 35mm	2
7200.2640	6.5 - 5.0 x 40mm	2
7200.2645	6.5 - 5.0 x 45mm	2
7200.2650	6.5 - 5.0 x 50mm	2
7200.2655	6.5 - 5.0 x 55mm	2
7200.2660	6.5 - 5.0 x 60mm	2
7200.2665	6.5 - 5.0 x 65mm	2
7200.2730	7.5 - 6.0 x 30mm	4
7200.2735	7.5 - 6.0 x 35mm	4
7200.2740	7.5 - 6.0 x 40mm	4
7200.2745	7.5 - 6.0 x 45mm	4
7200.2750	7.5 - 6.0 x 50mm	4

CREO NXT™ Polyaxial DOD Screw, CoCr Head, Ti Shank

Part No.	Diameter/Length	QTY
7200.2755	7.5 - 6.0 x 55mm	4
7200.2760	7.5 - 6.0 x 60mm	2
7200.2765	7.5 - 6.0 x 65mm	2
7200.2830	8.5 - 7.0 x 30mm	2
7200.2835	8.5 - 7.0 x 35mm	2
7200.2840	8.5 - 7.0 x 40mm	2
7200.2845	8.5 - 7.0 x 45mm	2
7200.2850	8.5 - 7.0 x 50mm	2
7200.2855	8.5 - 7.0 x 55mm	2
7200.2860	8.5 - 7.0 x 60mm	2
7200.2865	8.5 - 7.0 x 65mm	2
7200.2930	9.5 - 8.0 x 30mm	
7200.2935	9.5 - 8.0 x 35mm	
7200.2940	9.5 - 8.0 x 40mm	
7200.2950	9.5 - 8.0 x 50mm	
7200.2955	9.5 - 8.0 x 55mm	
7200.2960	9.5 - 8.0 x 60mm	
7200.2965	9.5 - 8.0 x 65mm	

9200.0002	CREO NXT™ Dual Outer Diameter Screw Graphic Case
9200.0102	CREO NXT™ Dual Outer Diameter Screw Module

**Items in gray are additionally available*

CREO NXT™
DEFORMITY IMPLANT SET 9200.9003

Part No.	Description	QTY
7119.8935	3.5 (150mm) - 5.5 (650mm) Tapered Rod, Cobalt Chrome, 800mm Length	
1119.8935	3.5 (150mm) - 5.5 (650mm) Tapered Rod, Titanium, 800mm Length	
1200.0000	CREO NXT™ Locking Cap	24

CREO® 5.5 Low Profile Cross Connector, Long

Part No.	Length	QTY
1119.0220	20 - 22mm	
1119.0221	21.5 - 25mm	2
1119.0224	24.5 - 31mm	2
1119.0230	30.5 - 43mm	2
1119.0242	42.5 - 67mm	2
1119.0266	66.5 - 91mm	

5.5mm Hex-ended Rod, Titanium Alloy

Part No.	Length	QTY
1119.6200	200mm	2
1119.6300	300mm	2
1119.6400	400mm	
1119.6500	500mm	2
1119.6600	600mm	

5.5mm ESR Straight Rod, Cobalt Chrome

Part No.	Length	QTY
7119.5201	200mm	
7119.5301	300mm	
7119.5500	500mm	
7119.5501	500mm	
7119.5601	600mm	
7119.6200	200mm	2

5.5mm ESR Single Hex-ended Rod, Cobalt Chrome

Part No.	Length	QTY
7119.6203	200mm	
7119.6303	300mm	
7119.6503	500mm	
7119.6603	600mm	

5.5mm Hex-ended Rod, Cobalt Chrome

Part No.	Length	QTY
7119.6300	300mm	2
7119.6400	400mm	
7119.6500	500mm	2
7119.6600	600mm	

5.5mm Curved Rod, Cobalt Chrome

Part No.	Length	QTY
7119.7100	100mm	
7119.7125	125mm	
7119.7150	150mm	
7119.7200	200mm	

CREO NXT™ Polyaxial Screw, CoCr Head, Ti Shank

Part No.	Length	QTY
7200.1220	4.0 x 20mm	4
7200.1225	4.0 x 25mm	4
7200.1230	4.0 x 30mm	4
7200.1235	4.0 x 35mm	8
7200.1240	4.0 x 40mm	8
7200.1245	4.0 x 45mm	8
7200.1250	4.0 x 50mm	
7200.1255	4.0 x 55mm	
7200.1320	4.5 x 20mm	
7200.1325	4.5 x 25mm	4
7200.1330	4.5 x 30mm	10
7200.1335	4.5 x 35mm	12
7200.1340	4.5 x 40mm	10
7200.1345	4.5 x 45mm	10
7200.1350	4.5 x 50mm	
7200.1355	4.5 x 55mm	
7200.1420	5.0 x 20mm	
7200.1425	5.0 x 25mm	4
7200.1430	5.0 x 30mm	12
7200.1435	5.0 x 35mm	14
7200.1440	5.0 x 40mm	12
7200.1445	5.0 x 45mm	10
7200.1450	5.0 x 50mm	2

*Items in gray are additionally available

CREO NXT™ Polyaxial Screw, CoCr Head, Ti Shank

Part No.	Length	QTY
7200.1455	5.0 x 55mm	2
7200.1460	5.0 x 60mm	
7200.1525	5.5 x 25mm	10
7200.1530	5.5x30mm	10
7200.1535	5.5 x 35mm	10
7200.1540	5.5 x 40mm	10
7200.1545	5.5 x 45mm	10
7200.1550	5.5 x 50mm	12
7200.1555	5.5 x 55mm	2
7200.1560	5.5 x 60mm	
7200.1625	6.5 x 25mm	4
7200.1630	6.5 x 30mm	10
7200.1635	6.5 x 35mm	10
7200.1640	6.5 x 40mm	12
7200.1645	6.5 x 45mm	12
7200.1650	6.5 x 50mm	12
7200.1655	6.5 x 55mm	4
7200.1660	6.5 x 60mm	4
7200.1665	6.5 x 65mm	2

9119.0303	CREO® 5.5 Low-Profile Cross Connector Module
9200.0003	CREO NXT™ Deformity Implants and Instruments Graphic Case
9200.0103	CREO NXT™ Small Diameter Screw Module
9200.0610	CREO NXT™ Locking Cap Module

**Items in gray are additionally available*

CREO NXT™
UNIPLANAR SCREW SET 9200.9004

CREO NXT™ Uniplanar Screw, CoCr Head, Ti Shank

Part No.	Diameter/Length	QTY
7200.5325	4.5 x 25mm	4
7200.5330	4.5 x 30mm	6
7200.5335	4.5 x 35mm	6
7200.5340	4.5 x 40mm	6
7200.5345	4.5 x 45mm	
7200.5350	4.5 x 50mm	
7200.5355	4.5 x 55mm	
7200.5425	5.0 x 25mm	2
7200.5430	5.0 x 30mm	6
7200.5435	5.0 x 35mm	6
7200.5440	5.0 x 40mm	4
7200.5445	5.0 x 45mm	
7200.5450	5.0 x 50mm	
7200.5455	5.0 x 55mm	
7200.5525	5.5 x 25mm	4
7200.5530	5.5 x 30mm	14
7200.5535	5.5 x 35mm	12
7200.5540	5.5 x 40mm	12
7200.5545	5.5 x 45mm	2
7200.5550	5.5 x 50mm	4
7200.5555	5.5 x 55mm	
7200.5625	6.5 x 25mm	
7200.5630	6.5 x 30mm	10
7200.5635	6.5 x 35mm	10
7200.5640	6.5 x 40mm	10
7200.5645	6.5 x 45mm	8
7200.5650	6.5 x 50mm	2
7200.5655	6.5 x 55mm	2
7200.5730	7.5 x 30mm	
7200.5735	7.5 x 35mm	
7200.5740	7.5 x 40mm	
7200.5745	7.5 x 45mm	
7200.5750	7.5 x 50mm	

9200.0004	CREO NXT™ Uniplanar Screws Graphic Case
9200.0104	CREO NXT™ Uniplanar Screws Module

*Items in gray are additionally available

CREO NXT™
HOOKS AND INSTRUMENT SET 9200.9006

CREO NXT™ Hook

Part No.	Description	QTY
1200.9901	Thoracic Lamina, Narrow, Small	2
1200.9902	Thoracic Lamina, Narrow, Medium	2
1200.9904	Thoracic Lamina, Small	2
1200.9905	Thoracic Lamina, Medium	2
1200.9907	Lamina, Upgoing, Medium	2
1200.9908	Lamina, Upgoing, Large	2
1200.9922	Transverse Process, Right, Large	
1200.9923	Transverse Process, Left, Large	
1200.9924	Transverse Process, Right, Medium	2
1200.9925	Transverse Process, Left, Medium	2
1200.9927	Pedicle, Small	2
1200.9928	Pedicle, Medium	6
1200.9929	Pedicle, Large	2
1200.9940	Lamina, Narrow, Small	2
1200.9941	Lamina, Narrow, Medium	2
1200.9942	Lamina, Narrow, Large	2
1200.9944	Lamina, Small	4
1200.9945	Lamina, Medium	8
1200.9946	Lamina, Large	4
1200.9948	Lamina, Wide, Small	2
1200.9949	Lamina, Wide, Medium	2
1200.9950	Lamina, Wide, Large	2
1200.9952	Lamina, Tall Body, Small	2
1200.9953	Lamina, Tall Body, Medium	2
1200.9954	Lamina, Tall Body, Large	2
1200.9955	Angled Lamina, Small	2
1200.9956	Angled Lamina, Medium	2
1200.9957	Angled Lamina, Large	2
1200.9960	Lamina, Extra Wide, Small	
1200.9961	Lamina, Extra Wide, Medium	
1200.9962	Lamina, Extra Wide, Large	
1200.9970	Lamina, Offset Right, Extra Wide, Small	
1200.9971	Lamina, Offset Right, Extra Wide, Medium	
1200.9972	Lamina, Offset Right, Extra Wide, Large	
1200.9973	Lamina, Offset Left, Extra Wide, Small	

CREO NXT™ Hook

Part No.	Description	QTY
1200.9974	Lamina, Offset Left, Extra Wide, Medium	
1200.9975	Lamina, Offset Left, Extra Wide, Large	
1200.9981	Lamina, Offset Right, Medium	2
1200.9984	Lamina, Offset Left, Medium	2
1200.9991	Lamina, 30° Offset, Right, Medium	
1200.9994	Lamina, 30° Offset, Left, Small	

Part No.	Description	QTY
6067.8000	Lamina Finder	1
6067.8005	Pedicle Finder	1
6120.8015	Hook Positioner, Threaded	1
6200.8010	CREO NXT™ Hook Holder	2
6200.8020	CREO NXT™ Lateral Hook Holder	1
6200.8025	CREO NXT™ Offset Hook Holder	1

9200.0006	CREO NXT™ Hook and Instrument Graphic Case
9200.0206	CREO NXT™ Hook Module

**Items in gray are additionally available*

CREO NXT™
DEGEN INSTRUMENT SET 9200.9007

Part No.	Description	QTY
6067.0056	Driver Shaft, 1/4” Quick-connect, Extra Long	1
6067.0075	Power Bender	1
6067.0080	Rod Holder	1
6120.0003	Rod Pusher	1
6200.0050	CREO NXT™ Self-Centering Driver, 1/4” Quick-connect	1
6200.1010	CREO NXT™ Locking Cap Driver	2
6200.1025	CREO NXT™ Locking Cap Guide	1
6200.1030	CREO NXT™ Counter Torque	1
6200.1070	CREO NXT™ Internal Head Positioner	1
6200.1075	CREO NXT™ External Head Positioner	
6200.1080	CREO NXT™ Rigid Screw Driver Shaft	2
6200.1085	CREO NXT™ Rigid Screw Driver Outer Sleeve	2
6200.2010	CREO NXT™ Overhead Reducer	1
6200.2015	CREO NXT™ Pistol Grip Reducer	
6200.2030	CREO NXT™ Reduction Fork	1
6200.2041	CREO NXT™ Quick-Release Reduction Clip, Long	2
6200.2046	CREO NXT™ Quick-Release Reduction Clip, Pusher, Long	2
6200.3111	11.65mm Hex Driver	1
624.517	Power Rod Gripper, 5.5mm	1
634.611	Torque Limiting T-Handle, Ratcheting, 8Nm, 1/4” Connect, Black	1
9200.0007	CREO NXT™ Degen Instruments Graphic Case	

**Items in gray are additionally available*

CREO NXT™
ILIAC IMPLANT AND INSTRUMENT SET 9200.9008

Part No.	Description	QTY
6067.0040	Ratcheting Torque-limiting Driver, 1/4" Quick-connect	1
6200.1037	CREO NXT™ Offset Connector Counter Torque	1
654.401	Sacral Probe, Straight	1

5.5 Offset Rod

Part No.	Description	QTY
1119.0815	Closed, 150mm	
1119.0820	Closed, 15mm	2
1119.0825	Closed, 20mm	2
1119.0830	Closed, 25mm	2
1119.0835	Closed, 30mm	2
1119.0840	Closed, 35mm	2
1119.0915	Open, 150mm	
1119.0960	Open, 15mm	2
1119.0965	Open, 20mm	2
1119.0970	Open, 25mm	2
1119.0975	Open, 30mm	2
1119.0980	Open, 35mm	2

CREO NXT™ Head Offset Connector

Part No.	Length	QTY
1200.0710	150mm	
1200.0715	15mm	2
1200.0720	20mm	2
1200.0725	25mm	2
1200.0730	30mm	2
1200.0735	35mm	2

Cannulated Tap

Part No.	Length	QTY
6156.0205	10.5mm, 40mm Threads	1
6156.0295	9.5mm, 40mm Threads	1

CREO NXT™ Polyaxial Screw, CoCr Head, Ti Shank

Part No.	Diameter/Length	QTY
7200.1100	10.5 x 100mm	2
7200.1101	10.5 x 110mm	2
7200.1102	10.5 x 120mm	2
7200.1170	10.5 x 70mm	2
7200.1175	10.5 x 75mm	2
7200.1180	10.5 x 80mm	2
7200.1185	10.5 x 85mm	2
7200.1190	10.5 x 90mm	2
7200.1195	10.5 x 95mm	2
7200.1700	7.5 x 100mm	2
7200.1701	7.5 x 110mm	2
7200.1702	7.5 x 120mm	2
7200.1770	7.5 x 70mm	2
7200.1775	7.5 x 75mm	2
7200.1780	7.5 x 80mm	2
7200.1785	7.5 x 85mm	2
7200.1790	7.5 x 90mm	2
7200.1795	7.5 x 95mm	2
7200.1800	8.5 x 100mm	2
7200.1801	8.5 x 110mm	2
7200.1802	8.5 x 120mm	2
7200.1870	8.5 x 70mm	2
7200.1875	8.5 x 75mm	2
7200.1880	8.5 x 80mm	2
7200.1885	8.5 x 85mm	2
7200.1890	8.5 x 90mm	2
7200.1895	8.5 x 95mm	2
7200.1900	9.5 x 100mm	2
7200.1901	9.5 x 110mm	2
7200.1902	9.5 x 120mm	2
7200.1970	9.5 x 70mm	2
7200.1975	9.5 x 75mm	2
7200.1980	9.5 x 80mm	2
7200.1985	9.5 x 85mm	2
7200.1990	9.5 x 90mm	2
7200.1995	9.5 x 95mm	2

**Items in gray are additionally available*

CREO NXT™

ILIAC IMPLANT AND INSTRUMENT SET 9200.9008 (CONT'D)

CREO NXT™ Polyaxial DOD Screw, CoCr Head, Ti Shank

Part No.	Diameter/Length	QTY
7200.2100	10.5 - 9.0 x 100mm	2
7200.2101	10.5 - 9.0 x 110mm	2
7200.2102	10.5 - 9.0 x 120mm	2
7200.2170	10.5 - 9.0 x 70mm	2
7200.2175	10.5 - 9.0 x 75mm	2
7200.2180	10.5 - 9.0 x 80mm	2
7200.2185	10.5 - 9.0 x 85mm	2
7200.2190	10.5 - 9.0 x 90mm	2
7200.2195	10.5 - 9.0 x 95mm	2
7200.2200	8.0 - 6.5 x 100mm	2
7200.2201	8.0 - 6.5 x 110mm	2
7200.2202	8.0 - 6.5 x 120mm	2
7200.2270	8.0 - 6.5 x 70mm	2
7200.2275	8.0 - 6.5 x 75mm	2
7200.2280	8.0 - 6.5 x 80mm	2
7200.2285	8.0 - 6.5 x 85mm	2
7200.2290	8.0 - 6.5 x 90mm	2
7200.2295	8.0 - 6.5 x 95mm	2
7200.2800	8.5 - 7.0 x 100mm	2
7200.2801	8.5 - 7.0 x 110mm	2
7200.2802	8.5 - 7.0 x 120mm	2
7200.2870	8.5 - 7.0 x 70mm	2
7200.2875	8.5 - 7.0 x 75mm	2
7200.2880	8.5 - 7.0 x 80mm	2
7200.2885	8.5 - 7.0 x 85mm	2
7200.2890	8.5 - 7.0 x 90mm	2
7200.2895	8.5 - 7.0 x 95mm	2
7200.2900	9.5 - 8.0 x 100mm	2
7200.2901	9.5 - 8.0 x 110mm	2
7200.2902	9.5 - 8.0 x 120mm	2
7200.2970	9.5 - 8.0 x 70mm	2
7200.2975	9.5 - 8.0 x 75mm	2
7200.2980	9.5 - 8.0 x 80mm	2
7200.2985	9.5 - 8.0 x 85mm	2
7200.2990	9.5 - 8.0 x 90mm	2
7200.2995	9.5 - 8.0 x 95mm	2

9200.0008	CREO NXT™ Iliac Implant Graphic Case
9200.0108	CREO NXT™ Iliac Screw Module, Short
9200.0208	CREO NXT™ Iliac Screw Module, Long

CREO NXT™
DEFORMITY INSTRUMENT SET 9200.9013

Part No.	Description	QTY
6067.3025	Rod Wrench	1
6119.3000	*In-Situ* Bender, Left	1
6119.3005	*In-Situ* Bender, Right	1
6119.3010	Coronal Plane Bender, Left	1
6119.3015	Coronal Plane Bender, Right	1
6119.3020	Vise-Style Rod Grip	2
6200.2035	CREO NXT™ Reduction Forceps	
624.517	Power Rod Gripper, 5.5mm	1
643.100	Long Throw Compressor	1
9200.0013	CREO NXT™ Deformity Instruments Graphic Case	

**Items in gray are additionally available*

CREO NXT™
REDUCTION AND DEROTATION INSTRUMENTS SET 9200.9024

Part No.	Description	QTY
6156.3100	Quick Release Derotation Attachment Tube	8
6200.0050	CREO NXT™ Self-Centering Driver, 1/4" Quick-connect	2
6200.2040	CREO NXT™ Quick-Release Reduction Clip	8
6200.2041	CREO NXT™ Quick-Release Reduction Clip, Long	6
6200.2045	CREO NXT™ Quick-Release Reduction Clip, Pusher	8
6200.2046	CREO NXT™ Quick-Release Reduction Clip, Pusher, Long	6
6200.3110	11.65mm Hex Driver, Long	1
6200.3111	11.65mm Hex Driver	1
9200.0024	CREO NXT™ Reduction and Derotation Instruments Graphic Case	

CREO DLX-NXT
DEROTATION CORE SET 9156.9025

Part No.	Description	QTY
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	
634.406	Quick Connect, 1/4" Non-Ratcheting, Large Sport Handle	2
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, 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™ implants mate with 5.5mm and 6.0mm rods. CREO DLX™ implants mate with 6.0mm 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.

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,
- changes to spinal curvature,
- 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.

IMPORTANT INFORMATION ON THE CREO® STABILIZATION SYSTEM

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™ 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 anatomicalstructures 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

IMPORTANT INFORMATION ON THE CREO® STABILIZATION SYSTEM

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.
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

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.

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		

Rev L

NOTES

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