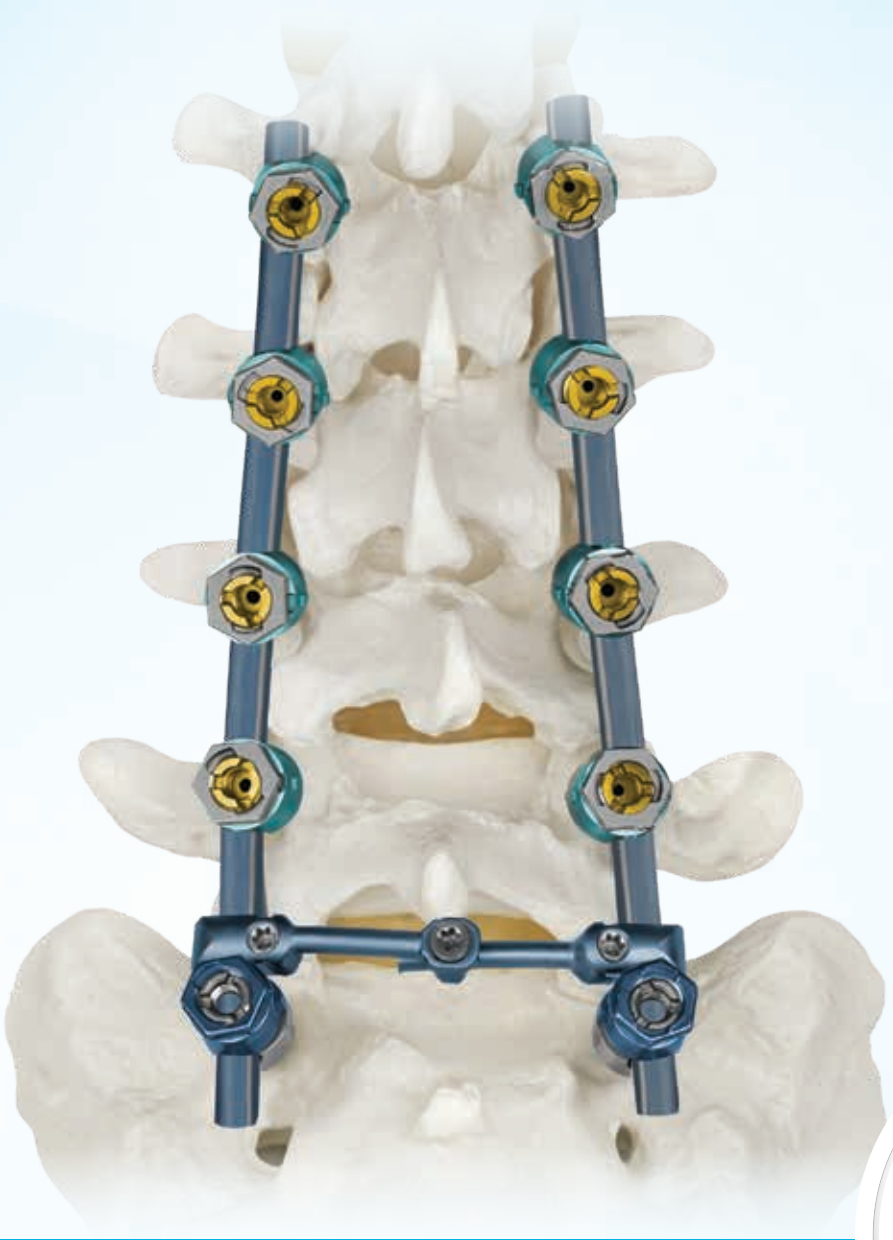
GLOBUS MEDICAL



CREO®
Side-Loading
Stabilization System

SURGICAL TECHNIQUE GUIDE

GLOBUSMEDICAL.COM | *Life moves us*

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

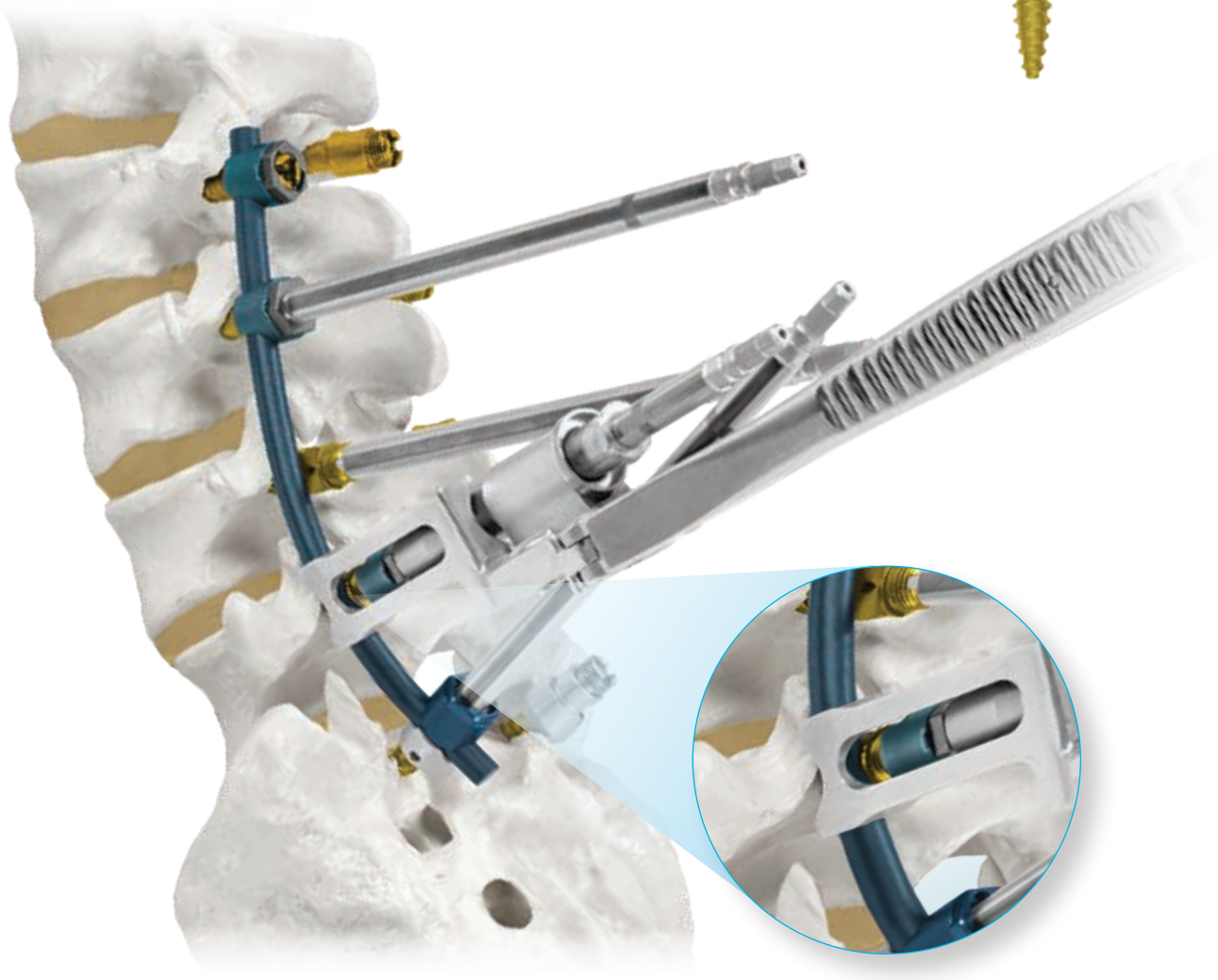
CREO® Side-Loading

CREO® Side-Loading

Stabilization System

CREO® Side-Loading Stabilization System is a comprehensive pedicle screw system designed for complex spinal procedures and challenging patient anatomy.

The system provides the ability to manipulate spinal segments, reduce the rod to the screw laterally, and correct severe deformities while maintaining fixation.



Side-Loading, Simplified.

Integrated Nut and Sleeve

- Locking sleeves allow simultaneous rod capture and provisional tightening
- Loosening the nut releases the sleeve to aid in compression and distraction

Lateral Reducer

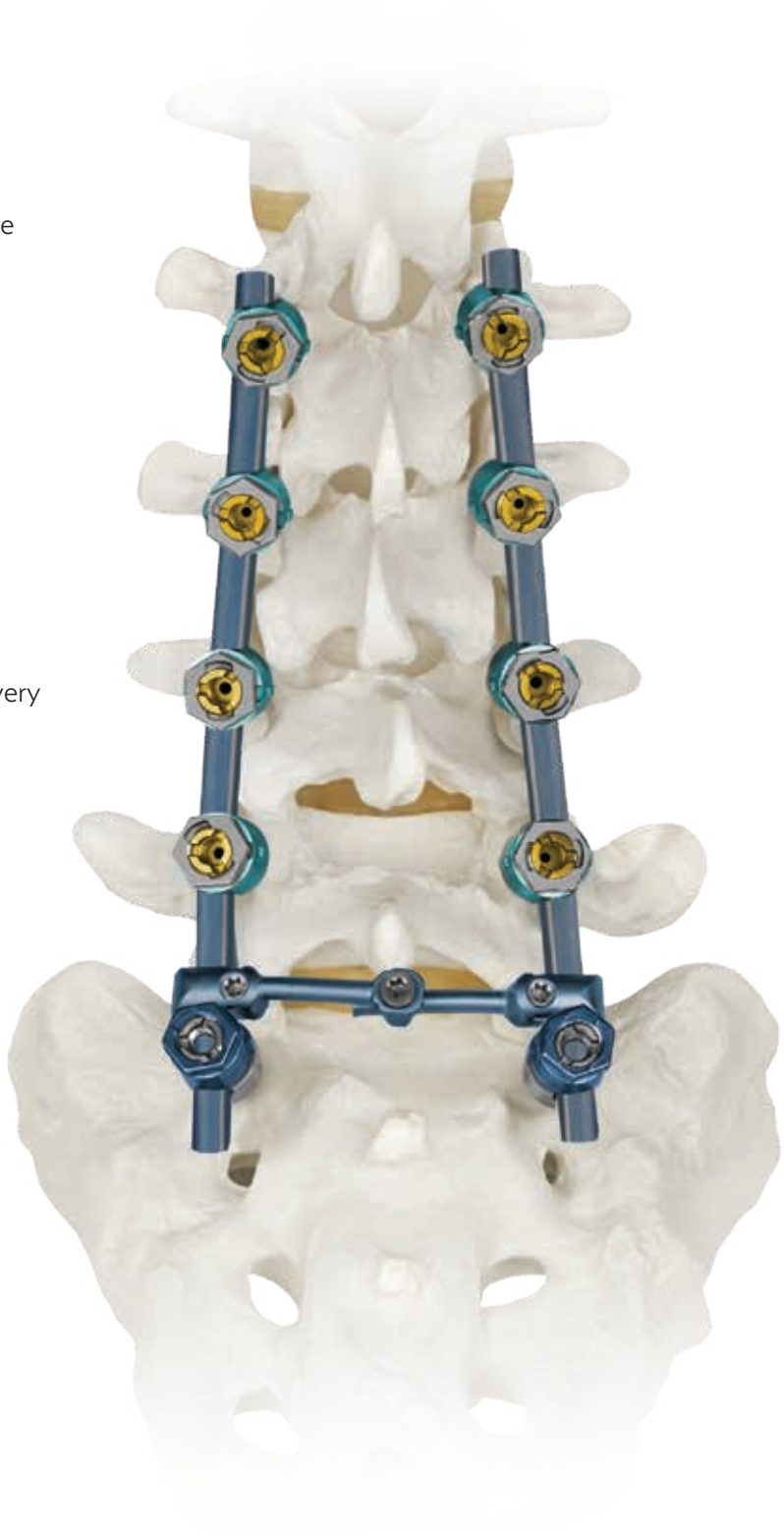
- Offers powerful correction, enabling surgeons to reduce the rod laterally to the implant
- Facilitates rod capture with locking sleeve delivery

Hinged Dorsal Reducer

Provides up to 35mm of gradual reduction with a simple squeeze of the handle

Comprehensive System

Includes monoaxial, polyaxial, uniplanar, cannulated, and dual outer diameter screws



IMPLANT OVERVIEW

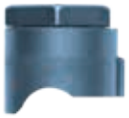
Locking Sleeves

- Integrated nut and sleeve
- Separate locking sleeves for both monoaxial and polyaxial/uniplanar screws
- Sleeves are specific to rod diameter and implant style

Monoaxial Locking Sleeve, 5.5

Monoaxial Locking Sleeve, 6.0

Polyaxial/ Uniplanar Locking Sleeve, 5.5



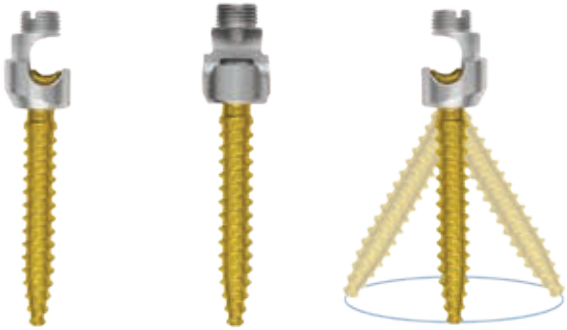
Polyaxial/ Uniplanar Locking Sleeve, 6.0

Monoaxial Screws

- Low profile, side loading screw design
- Double lead thread for rapid insertion
- Blunt tip for bicortical purchase
- Constant outer diameter
- Screw diameters: 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.5, 8.5, 9.5, and 10.5mm
- Screw lengths: 20–120mm
- Accept 5.5mm or 6.0mm diameter rod

Polyaxial Screws

- ±30° angulation (60° total) provides intraoperative versatility
- Self-tapping design
- Double lead thread for rapid insertion (up to 7.5mm in diameter)
- Blunt tip for bicortical purchase
- Constant outer diameter for maximum bone purchase
- Screw diameters: 4.0, 4.5, 5.0, 5.5, 6.5, 7.5, 8.5, 9.5, and 10.5mm
- Screw lengths 20–120mm
- Accept 5.5mm or 6.0mm diameter rod

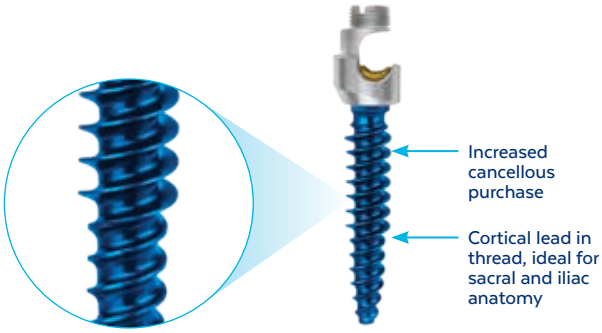


Uniplanar Screws

- Useful for deformity correction
- Combine versatility of a polyaxial screw with correction capabilities of a monoaxial screw
- Medial-lateral rigidity with cranial/caudal adjustability
- ±20° angulation in cranial/caudal direction
- Screw diameters: 4.0, 4.5, 5.0, 5.5, 6.5, 7.5, and 8.5mm
- Screw lengths: 20-65mm
- Accept 5.5mm or 6.0mm diameter rod

Dual Outer Diameter (DOD) Screws

- Designed for optimal purchase in both cancellous and cortical bone
- Nominal diameter at distal end allows for deeper insertion in sacrum without perforation
- Designed for enhanced fixation in the sacrum and ilium
- ±30° angulation (60° total)
- Available in proximal/distal outer diameters: 8.0/6.5, 8.5/7.0, 9.5/8.0, and 10.5/9.0mm
- Screw lengths: 70–120mm



Rods

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

Cross Connector

- Enhances construct stability
- 4.6mm profile above rod
- Optimized profile and strength
- Angular and medial-lateral adjustments provide secure fit
- Seven overlapping sizes: 29-33, 32-40, 38-50, 48-60, 58-70, 68-80, and 78-90mm
- Two types available for a 5.5mm or 6.0mm diameter rod

Low Profile Cross Connector

- Ideal for use in thoracic spine to help reduce prominence
- Six overlapping sizes: 20-22, 21.5-25, 24.5-31, 30.5-43, 42.5-67, and 66.5-91mm
- Two types available for a 5.5mm or 6.0mm diameter rod

Offset Connectors

- 15-35mm lengths in 5mm increments, and 150mm
- Recommended for use with DOD screws for strong pelvic fixation
- Available in open and closed offset connectors

INSTRUMENT OVERVIEW

PEDICLE PREPARATION INSTRUMENTS

Pedicle Awl 6067.0001

Pedicle Probe, Straight 602.101

Pedicle Probe, Curved 602.102

Pedicle Probe, Thoracic 602.109

Ball Tip Probe, Straight 602.105

PEDICLE PREPARATION INSTRUMENTS (CONT'D)

Ball Tip Probe, Curved 602.106

Ball Tip Probe, Double Ended 624.110

4.5mm Tap 655.214

5.5mm Tap 655.215

6.5mm Tap 655.216

7.5mm Tap 655.217

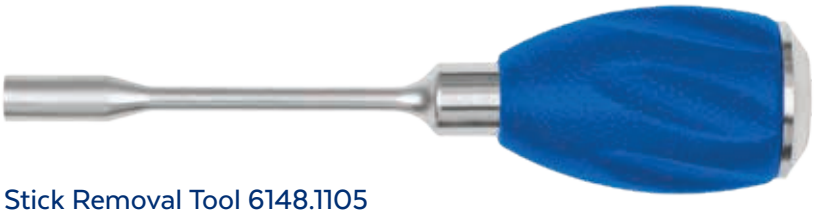
8.5mm Tap 655.218

SCREW INSERTION INSTRUMENTS

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

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

Stick Driver, 1/4" Quick-Connect 6148.1100



Stick Removal Tool 6148.1105

SCREW INSERTION INSTRUMENTS (CONT'D)

Stick Outer Sleeve 6148.1110

Stick Inner Shaft 6148.1111

Monoaxial Stick Attachment Guide, CREO® Side-Loading 6148.1025

Polyaxial Stick Attachment Guide, CREO® Side-Loading 6148.1026

3.5mm Hex Driver, 1/4" Quick-Connect 6148.0050

Rigid Polyaxial Screwdriver, 1/4" Quick-Connect, CREO® Side-Loading 6148.1080

ROD MANIPULATION AND INSERTION INSTRUMENTS

Rod Template, 150mm 602.501

Rod Template, 300mm 602.517

Rod Template, 500mm 6067.1500

Power Bender 6067.0075

Rod Holder 6067.0080

ROD MANIPULATION AND INSERTION INSTRUMENTS (CONT'D)

6.0 Power Rod Gripper 6120.0085
Power Rod Gripper, 5.5mm 624.517*

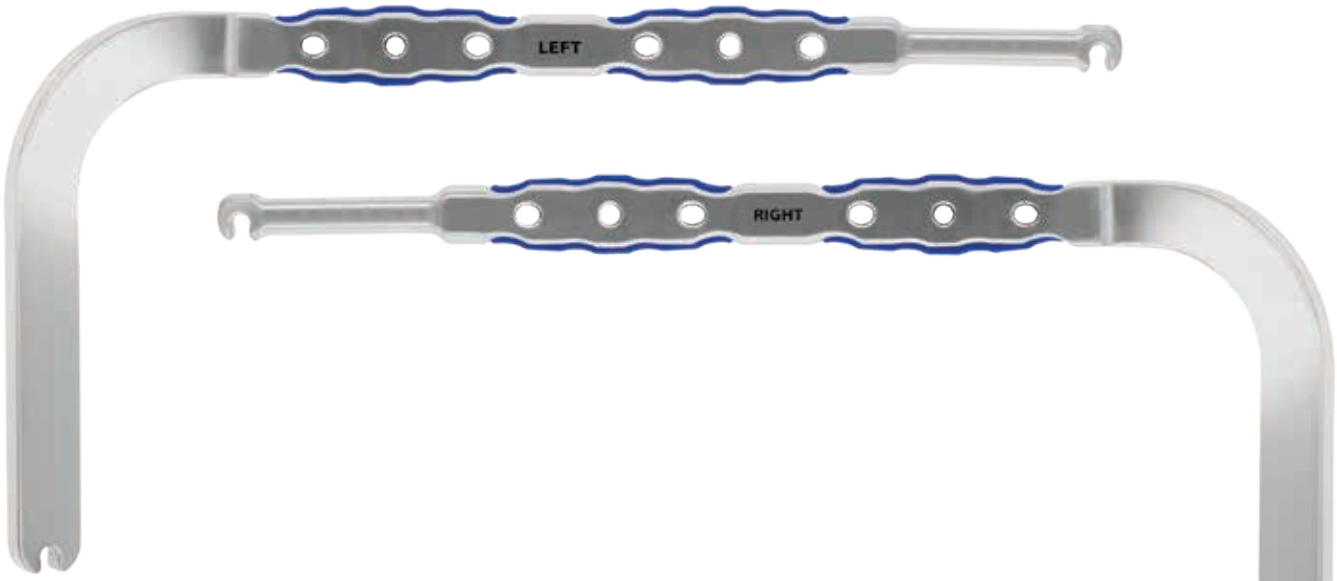
6.0 *In Situ* Bender, Left 6120.3000
5.5 *In Situ* Bender, Left 6119.3000*

6.0 *In Situ* Bender, Right 6120.3005
5.5 *In Situ* Bender, Right 6119.3005*

Rod Wrench 6067.3025

**For use when 5.5mm rods are used instead of 6.0mm rods*

ROD MANIPULATION AND INSERTION INSTRUMENTS (CONT'D)



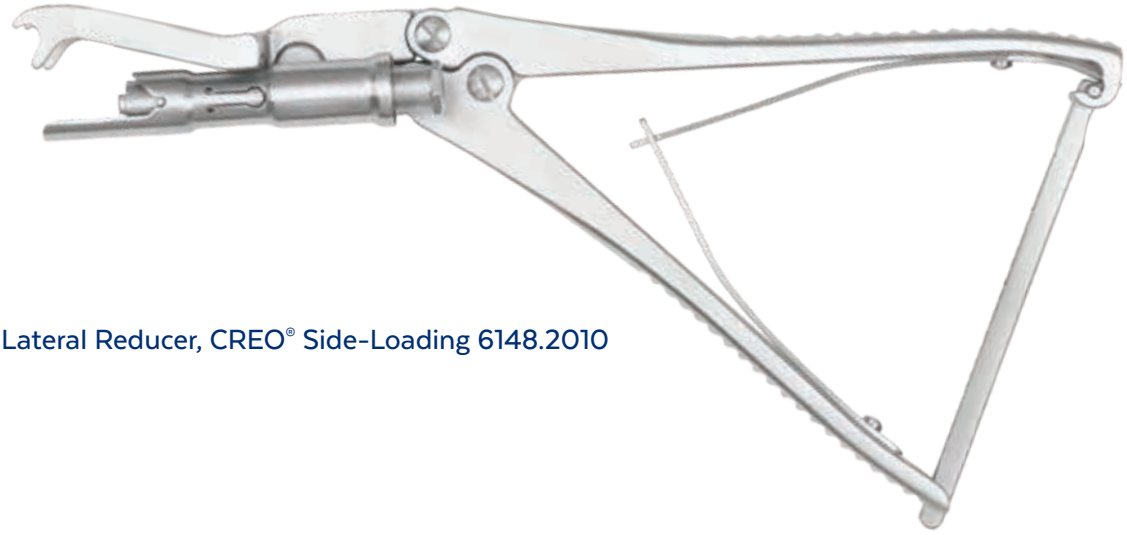
6.0 Coronal Plane Bender, Left 6120.3010
5.5 Coronal Plane Bender, Left 6119.3010*

6.0 Coronal Plane Bender, Right 6120.3015
5.5 Coronal Plane Bender, Right 6119.3015*

6.0 Vise-Style Rod Grip 6120.3020
5.5 Vise-Style Rod Grip 6119.3020*

**For use when 5.5mm rods are used instead of 6.0mm rods*

ROD REDUCTION INSTRUMENTS



Lateral Reducer, CREO® Side-Loading 6148.2010

Dorsal Reducer, Geared, CREO®
Side-Loading 6148.2015

ROD REDUCTION INSTRUMENTS (CONT'D)

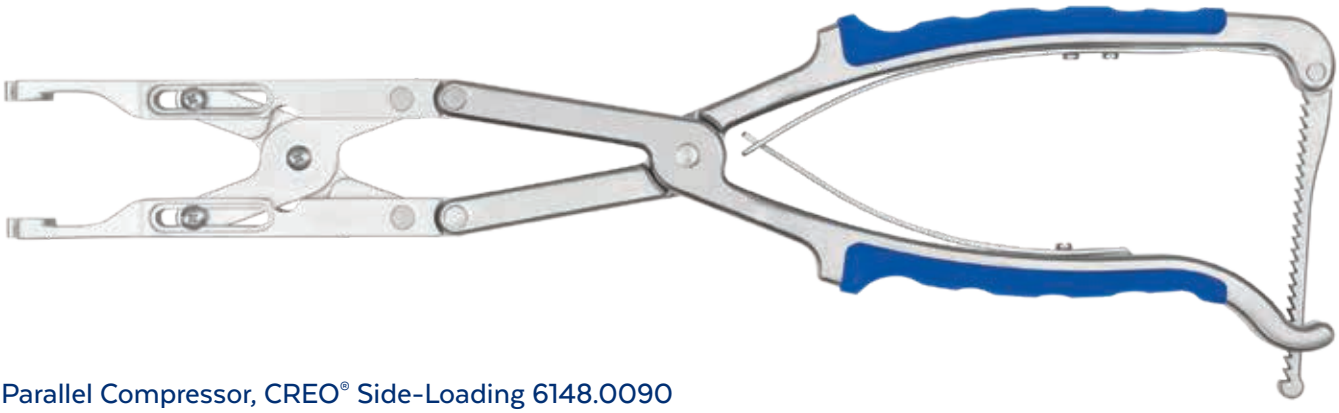
Dorsal Reducer, Hinged, CREO® Side-Loading 6148.2016

SCREW LOCKING INSTRUMENTS

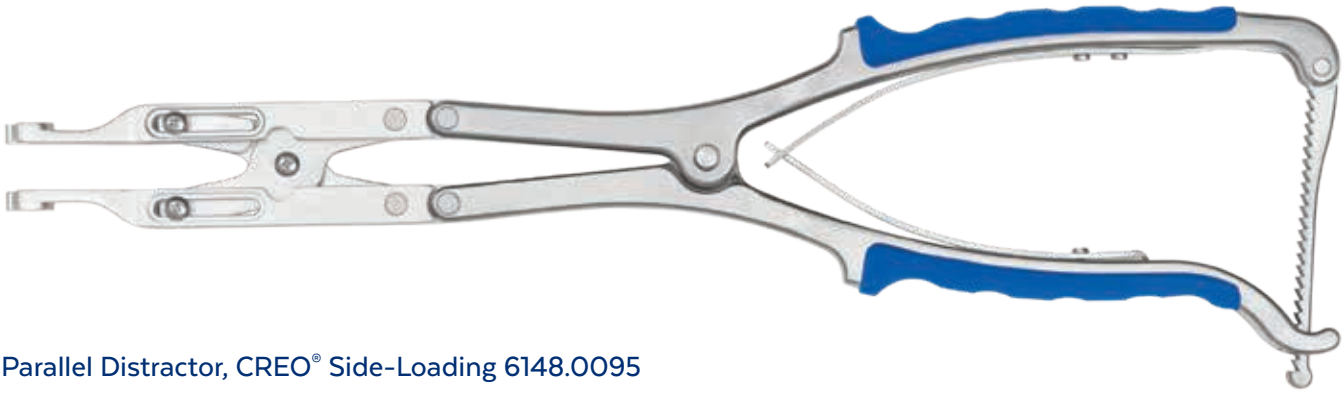
11mm Hex Driver, T-Handle 6148.3050

Locking Sleeve Inserter, T-Handle, CREO®
Side-Loading 6148.5000

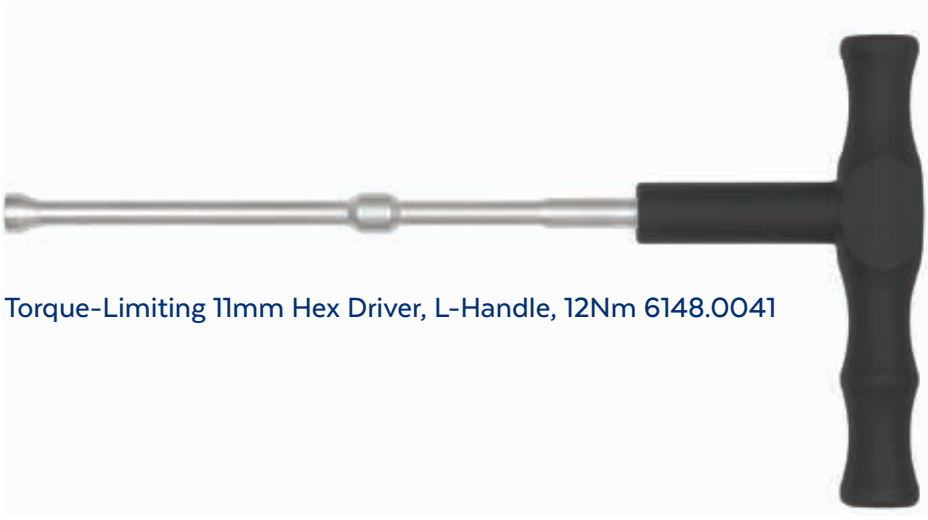
SCREW LOCKING INSTRUMENTS (CONT'D)



Parallel Compressor, CREO® Side-Loading 6148.0090



Parallel Distractor, CREO® Side-Loading 6148.0095



Torque-Limiting 11mm Hex Driver, L-Handle, 12Nm 6148.0041

SCREW LOCKING INSTRUMENTS (CONT'D)

Monoaxial Counter-Torque, CREO® Side-Loading 6148.3000

Polyaxial Counter-Torque, CREO® Side-Loading 6148.3001

CROSS CONNECTOR INSTRUMENTS

Cross Connector Driver, Torque-Limiting 6067.1050

Cross Connector Inserter 6067.1055

Cross Connector Caliper 6067.1060

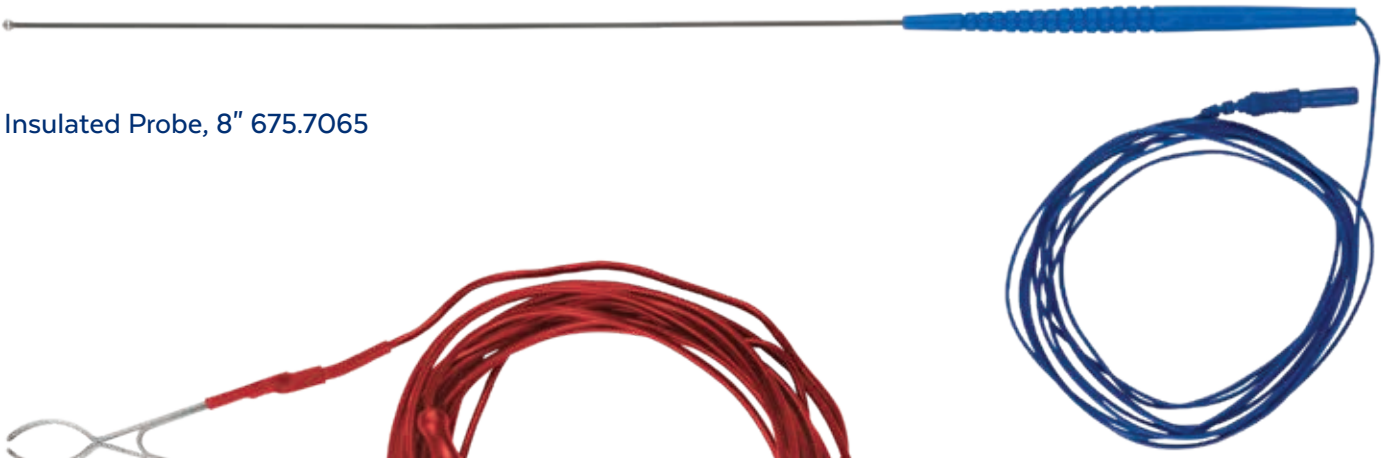
Cross Connector Measurement Card 6067.1065

ADDITIONALLY AVAILABLE INSTRUMENTS

Pedicle Probe, Thoracic Curved 624.113

Pedicle Probe, Thoracic Straight 624.114

PEDICLE ACCESS KIT 624.0275



Insulated Probe, 8" 675.7065

Spring Clip 675.7055

ADDITIONALLY AVAILABLE INSTRUMENTS (CONT'D)

Stick Driver, Power 6148.1101

Torque-Limiting L-Handle, 12Nm, 1/4" Quick-Connect 6148.0040

Locking Sleeve Inserter, Palm Handle, CREO® Side-Loading 6148.5001

Rod Cutter 602.508

SURGICAL TECHNIQUE

CREO® Side-Loading

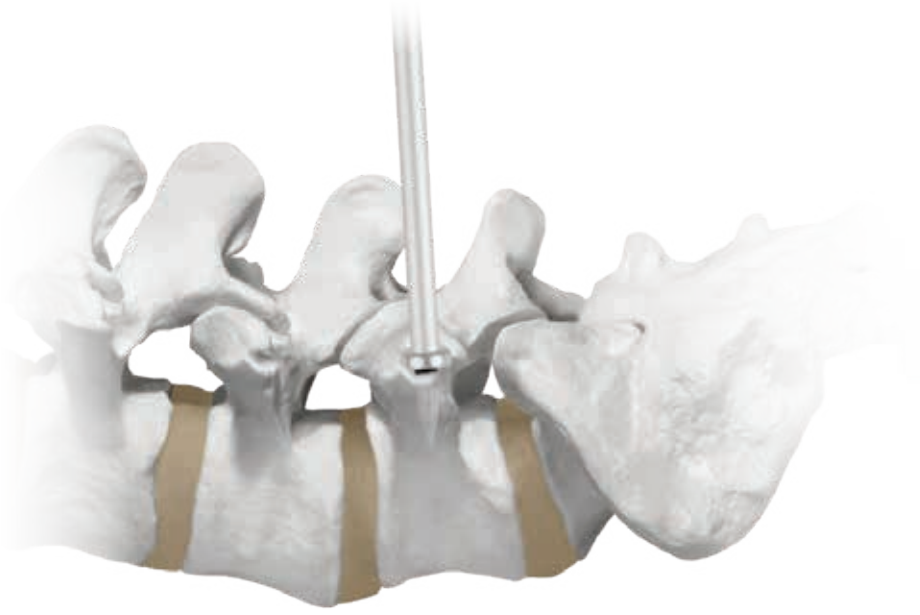
Please refer to the product insert (also printed in the back of this manual) for a complete description, indications, contraindications, warnings, and precautions.

STEP 1 PLANNING

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 posterior approach and building of an L2 to S1 construct is shown.

STEP 2 APPROACH

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



Preparing pedicle pathway

STEP 3 SCREW INSERTION

Pedicle Preparation

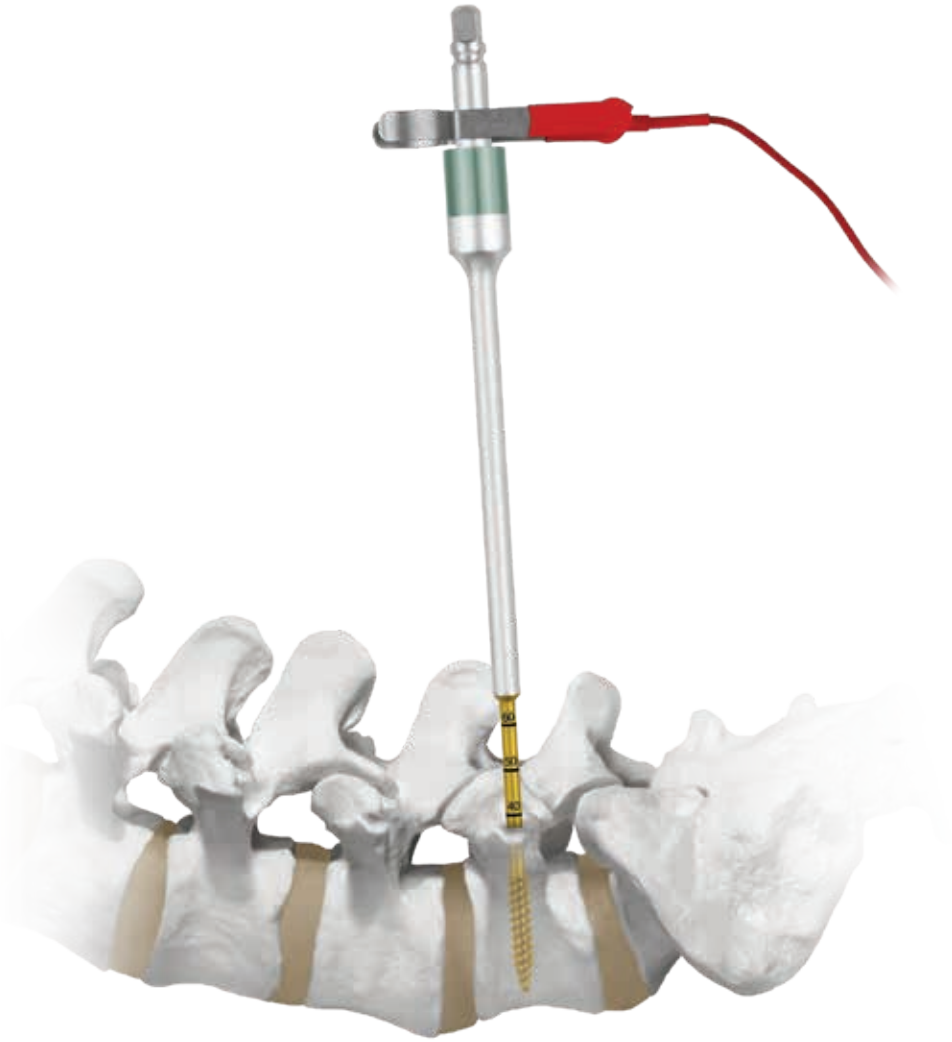
Locate the pedicles and remove bone and/or soft tissue as needed using standard instruments. Use the **Pedicle Awl** to perforate the pedicle cortex.

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

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

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

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



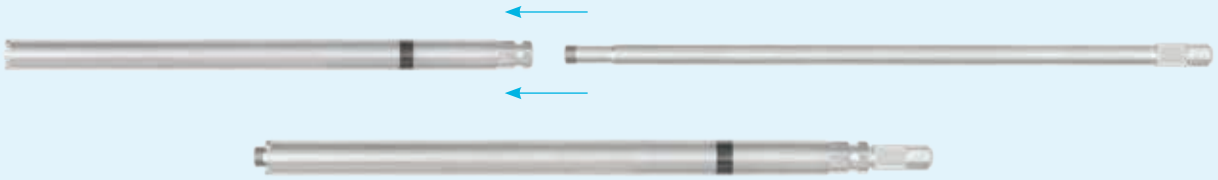
Using Spring Clip

**Globus Medical does not provide intraoperative neurophysiological monitoring equipment.*

SCREW INSERTION (CONT'D)

LOADING THE MONOAXIAL SCREWDRIVER

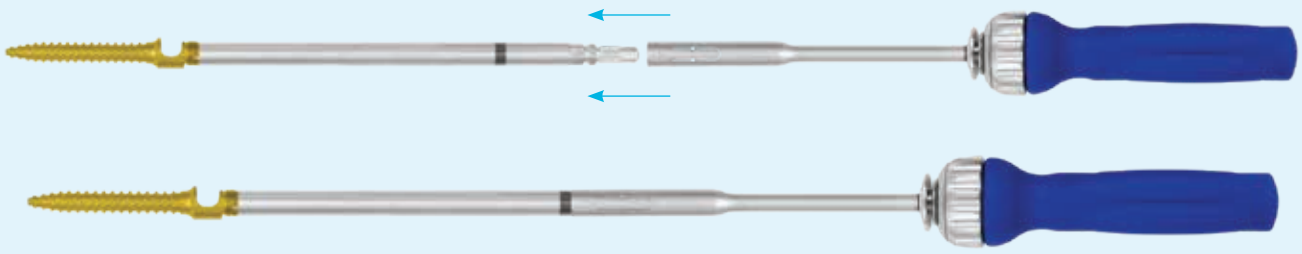
Insert the **Stick Inner Shaft** into the **Stick Outer Sleeve** and thread until the inner shaft floats within the outer sleeve.



Attach the **Straight Handle, Ratcheting, ¼" Quick-Connect** to the **Stick Driver ¼" Quick-Connect**.

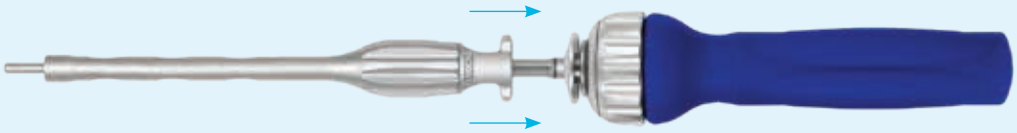
Select the appropriate pedicle screw diameter and length. Align the tri-lobe of the Stick Outer Sleeve with the tri-lobe of the monaxial screw head and thread the Stick Inner Shaft clockwise until finger tight.

Insert the Stick Driver over the stick assembly until an audible click is heard. The screw is now ready to be inserted.

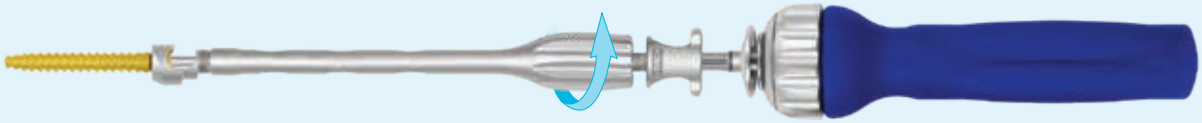


LOADING THE POLYAXIAL SCREWDRIVER

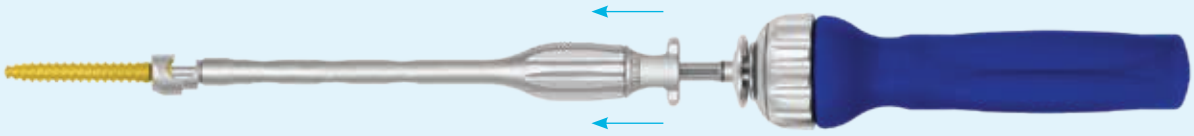
Assemble the **Rigid Polyaxial Screwdriver, 1/4" Quick-Connect** to the Straight Handle, Ratcheting, 1/4" Quick-Connect or **T-Handle, Ratcheting, 1/4" Quick-Connect**. Pull the finger grip toward the handle and ensure the knob is fully loosened.



Select the appropriate pedicle screw diameter and length. Insert the driver tip through the screw head and into the drive feature. Rotate to engage the tri-lobe driver tip into the tri-lobe of the screw head. Rotate the knob of the screwdriver clockwise until tight to engage the external screw head threads.



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



Note: Rotate the knob clockwise for increased rigidity. The lock prevents the screwdriver from unthreading and disengaging the screw.

SCREW INSERTION (CONT'D)

Monoaxial Screw Insertion

Drive the screws into prepared pedicles using the Straight Handle, Ratcheting, 1/4" Quick-Connect and Stick Driver. Disengage the screwdriver from the stick by pulling the Stick Driver away from the stick assembly.

If desired, use the **Monoaxial Decortication Tool, CREO® Side-Loading** and **T-Handle, Ratcheting, 1/4" Quick-Connect** to remove surrounding tissue and bone around the screw head.

Screw insertion into the prepared pedicle may be neuromonitored. Use the **Insulated Probe, 8"** for triggered EMG monitoring while introducing the screw into the pedicle. Locate the probe in the screw head to monitor access.

Monoaxial screw insertion

Polyaxial and Uniplanar Screw Insertion

Drive the screws into the prepared pedicles using the **Rigid Polyaxial Screwdriver, 1/4" Quick-Connect**. Disengage the screwdriver from the screw by grasping the lock by the finger grips on each side. To release, pull the lock back toward the screwdriver handle until an audible click is heard. Rotate the knob counterclockwise to unthread and disengage the screwdriver.

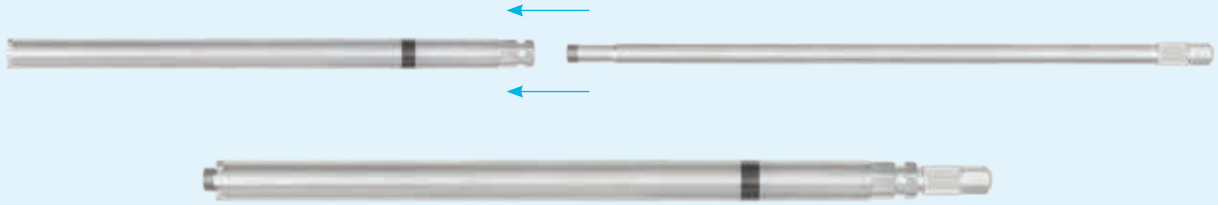
Screw insertion into the prepared pedicle may be neuromonitored. Use the Insulated Probe, 8" for triggered EMG monitoring while introducing the screw into the pedicle. Locate the probe in the screw head to monitor access.

Polyaxial and uniplanar screw insertion

SCREW INSERTION (CONT'D)

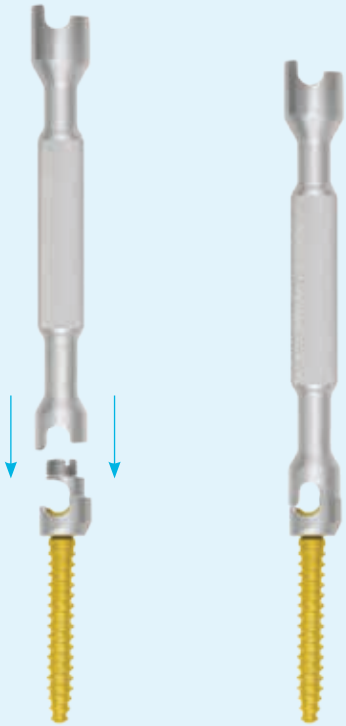
STICK ATTACHMENT

Insert the Stick Inner Shaft into the Stick Outer Sleeve and thread until the inner shaft floats within the outer sleeve to create the stick assembly.



Place the **Stick Attachment Guide** with the end etched "HEAD" over the screw head.

Insert the stick assembly into the Stick Attachment Guide and align the tri-lobe of the Stick Outer Sleeve to the tri-lobe of the polyaxial, uniplanar, or monoaxial screw head. Rotate the Stick Inner Shaft clockwise until finger tight. Remove the Stick Attachment Guide.



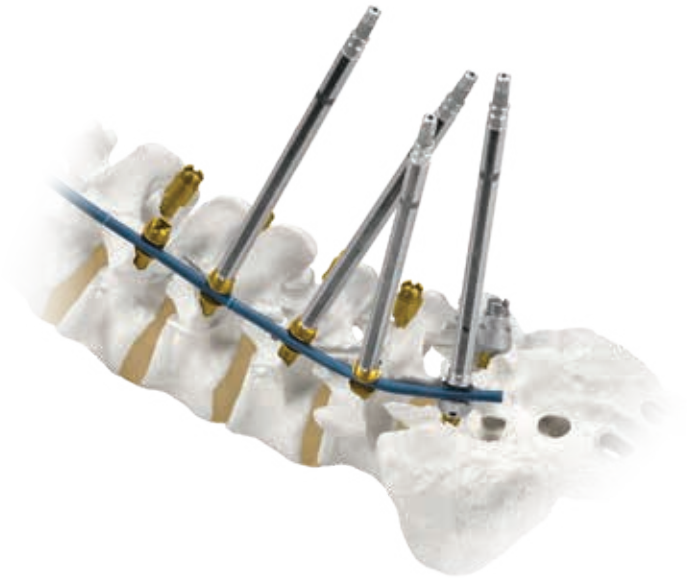
The end of the Stick Attachment Guide marked "SLEEVE" can be used to re-attach sticks after a locking sleeve has been inserted.

The Polyaxial Stick Attachment Guide is shown.

STEP 4 ROD INSERTION AND LOCKING SLEEVE DELIVERY

Rod Preparation

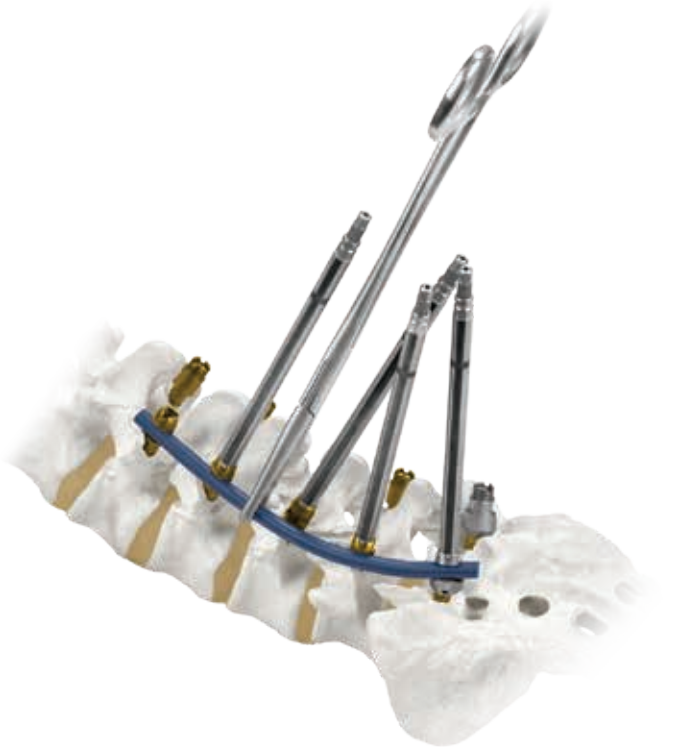
Determine the appropriate length and contour of the rod using the **Rod Template**. It is recommended to oversize the rod to allow at least 5mm of proximal and distal rod overhang following anticipated compression and distraction. Cut rods to the desired length using the **Rod Cutter**. Contour the rods using the **Power Bender**, if necessary.



Using Rod Template

Rod Insertion

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

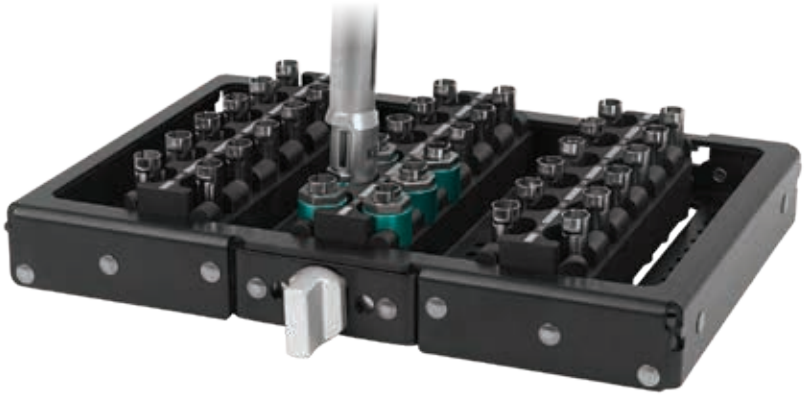


Rod insertion

ROD INSERTION AND LOCKING SLEEVE DELIVERY (CONT'D)

Loading Locking Sleeves

Align the tongs of the **Locking Sleeve Inserter, T-Handle** with the Alignment Key on the back of the locking sleeves. Push the Locking Sleeve Inserter over the locking sleeve and rotate until it clicks into the drive feature, so that it is secure. Pull up to release from the module.



To re-load a locking sleeve into the module, align the locking sleeves and the rod slot with the ridges in the module. Rotate each nut until the tabs click into the drive feature.

Inserting Locking Sleeve

Using the Locking Sleeve Inserter, insert the locking sleeve over the stick assembly. Align the rod slot with the rod and insert over the rod and screw head. Rotate the handle clockwise to engage the nut with the screw head.

Pull upwards on the Locking Sleeve Inserter to disengage from the Locking Sleeve and stick assembly.

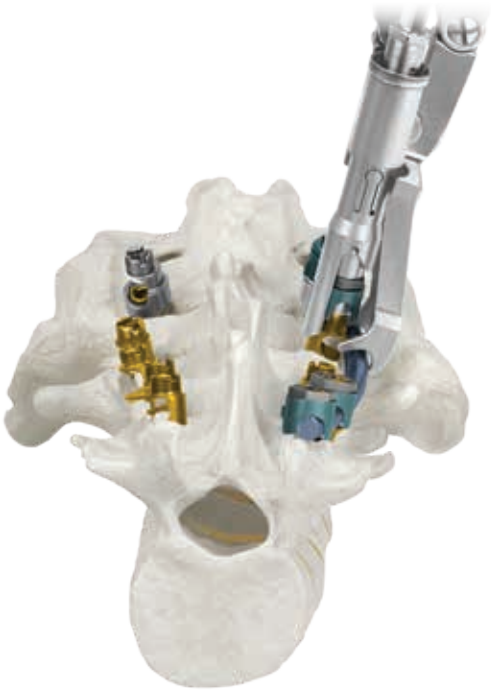
STEP 5 ROD REDUCTION

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

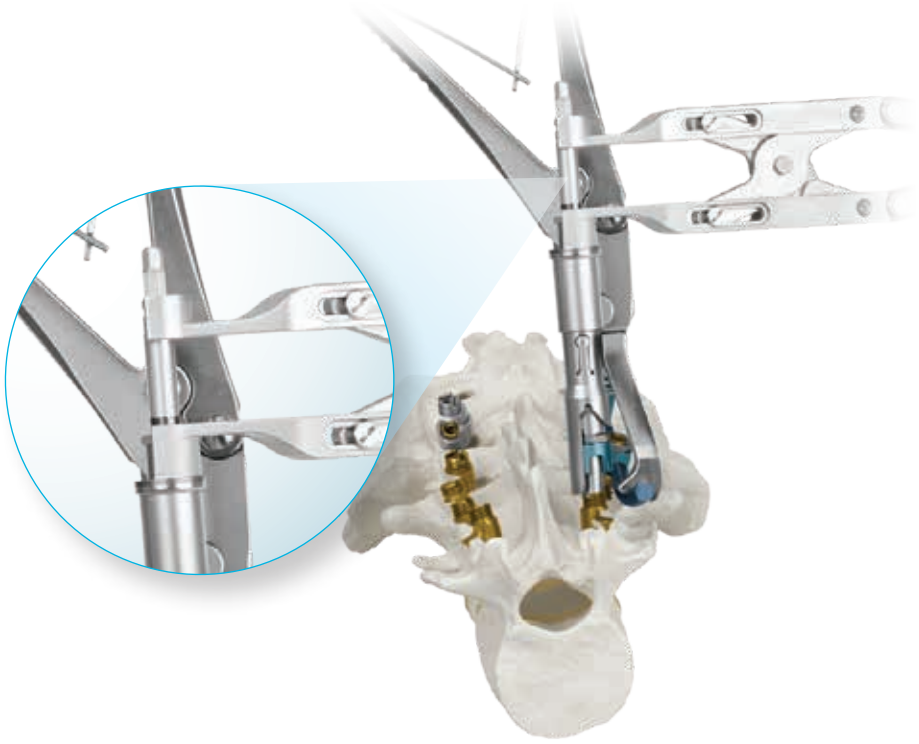
If coronal rod reduction is required, the Lateral Reducer can be used to reduce the rod in the coronal plane. If sagittal rod reduction is necessary, dorsal reducers can be used to reduce the rod dorsally with the Lateral Reducer.

Engaging the Lateral Reducer

Insert the **Lateral Reducer, CREO® Side-Loading** over the stick assembly. Compress the Ratcheting Handles to allow the reduction arm to engage the rod.



ROD REDUCTION (CONT'D)



Dorsal Reducer, Geared

Insert the **Dorsal Reducer, Geared** over the stick assembly and compress the handles until sufficiently reduced.

Dorsal Reducer, Hinged

Place the **Dorsal Reducer, Hinged** on the stick assembly and engage the retaining groove on the Dorsal Reducer, Hinged with the corresponding grooves on the Lateral Reducer and Stick Outer Sleeve. Compress the handles until sufficiently reduced.

Completing Reduction

Compress the handles of the Lateral Reducer until the rod is fully seated. Remove the dorsal reducer by releasing the ratchet. Insert the **11mm Hex Driver, 1/4" Quick-Connect** over the stick assembly and press down on the hex of the Lateral Reducer until the locking sleeve engages the screw and rod. Rotate clockwise to tighten.

STEP 6 DEFORMITY CORRECTION

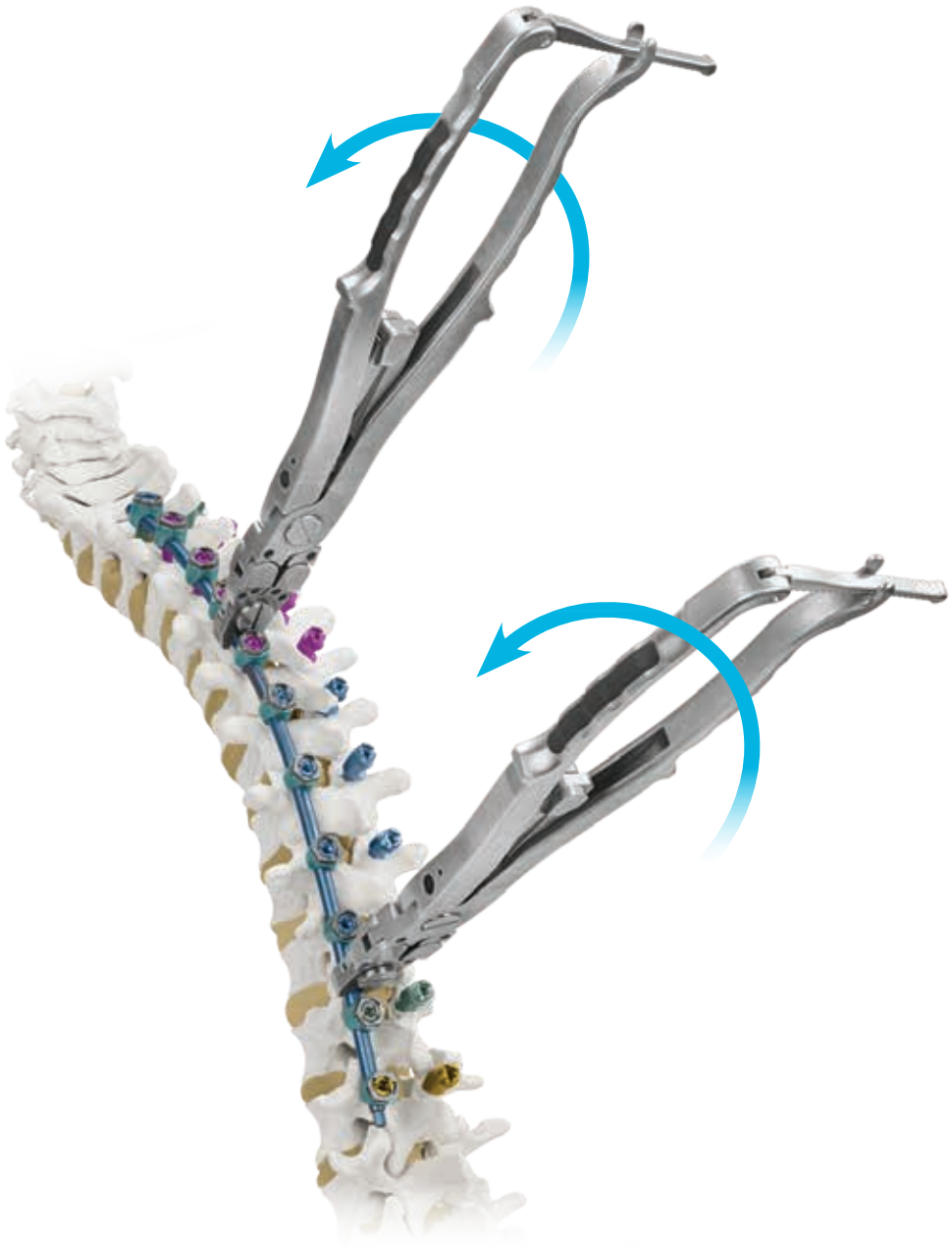
Global Derotation

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

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

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

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



Derotation with Power Rod Grippers

DEFORMITY CORRECTION (CONT'D)

Monitor hook positions during the derotation process to verify that they are not displaced. Once the rod is rotated into its final position, provisionally tighten the locking sleeves.

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

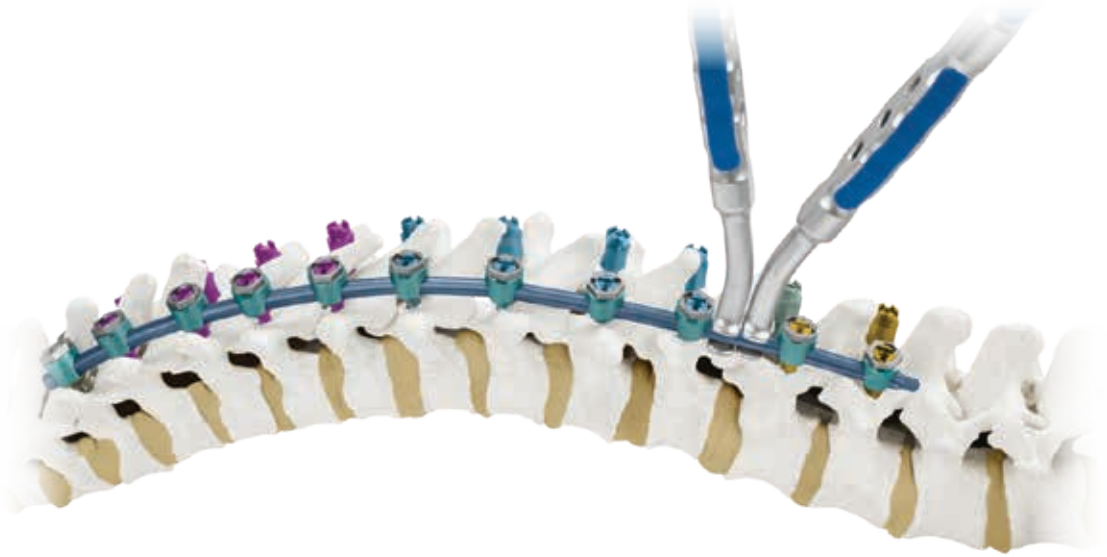
In Situ Bending

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

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

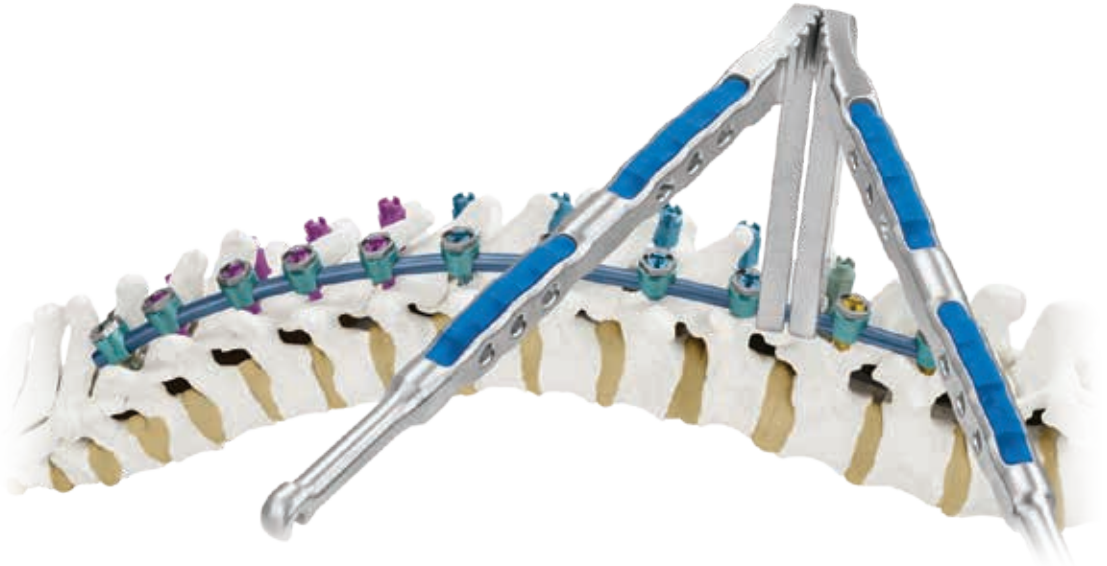
In Situ Rod Bending

In Situ Benders are used to curve a rod 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 to avoid damage to the rod. Once rod bending is complete, compression or distraction may be performed.



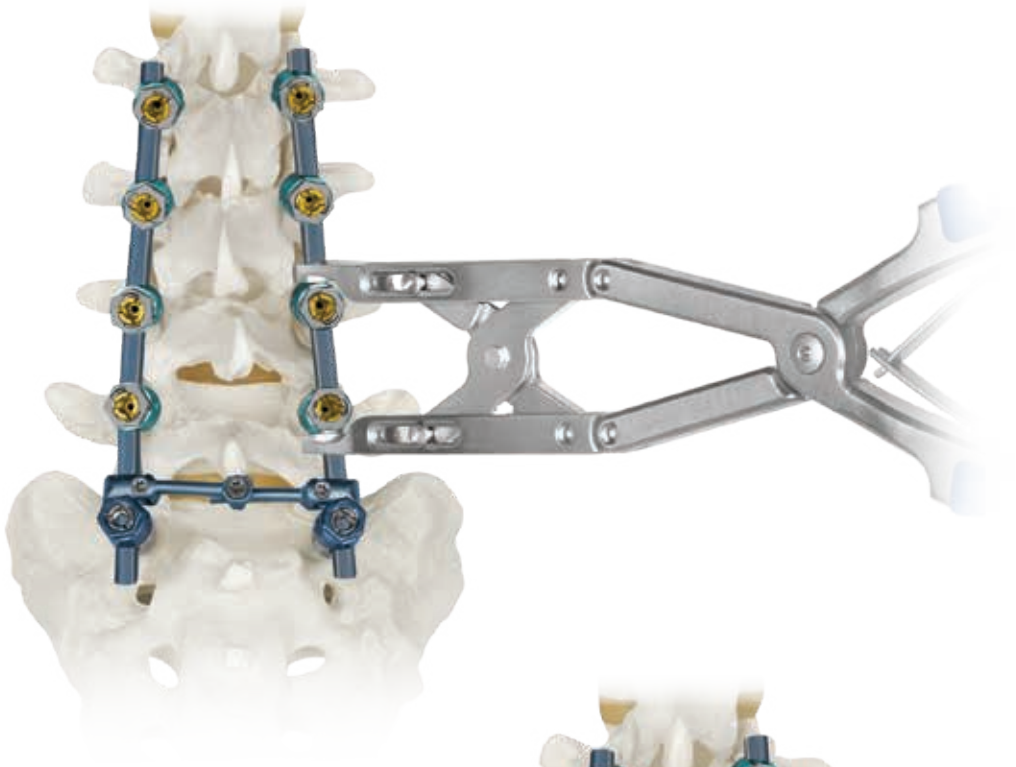
Using Coronal Plane Benders

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

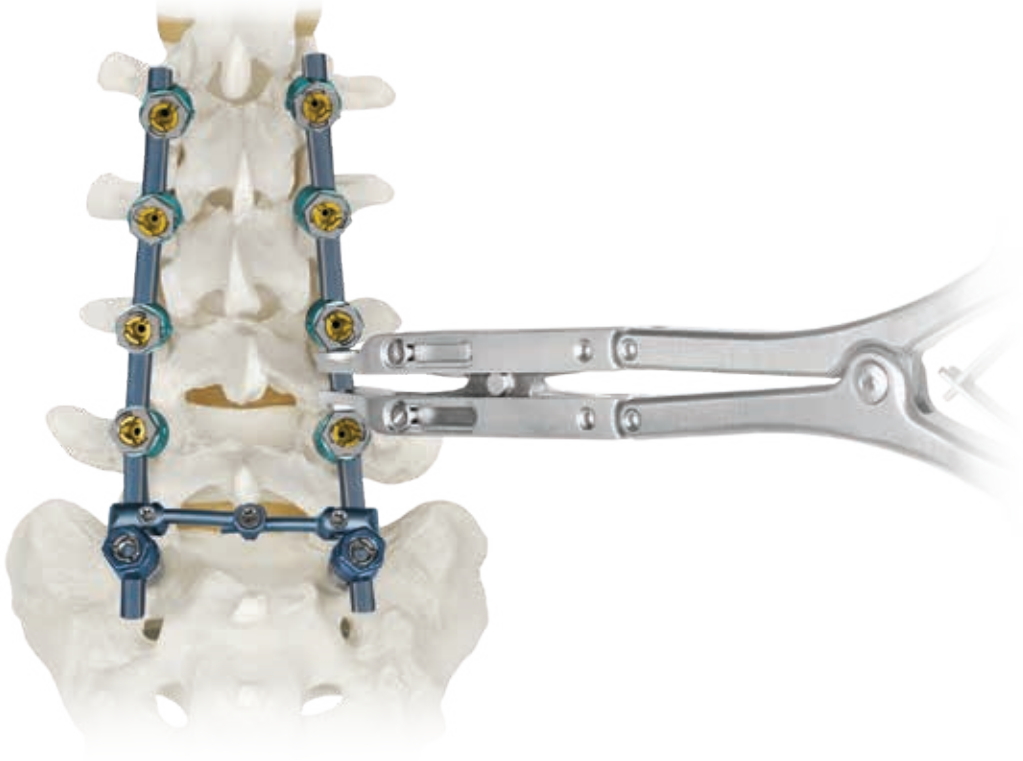


STEP 7 COMPRESSION OR DISTRACTION

CREO® Side-Loading pedicle screws may be compressed or distracted along the rod as necessary using the **Parallel Compressor, Side-Loading** or **Parallel Distractor, Side-Loading**, respectively. Tighten one of the locking sleeves to establish a rigid point for compression or distraction. Once compression or distraction is completed, provisionally tighten the locking sleeves using the 11mm Hex Driver, T-Handle.



Compression



Distraction

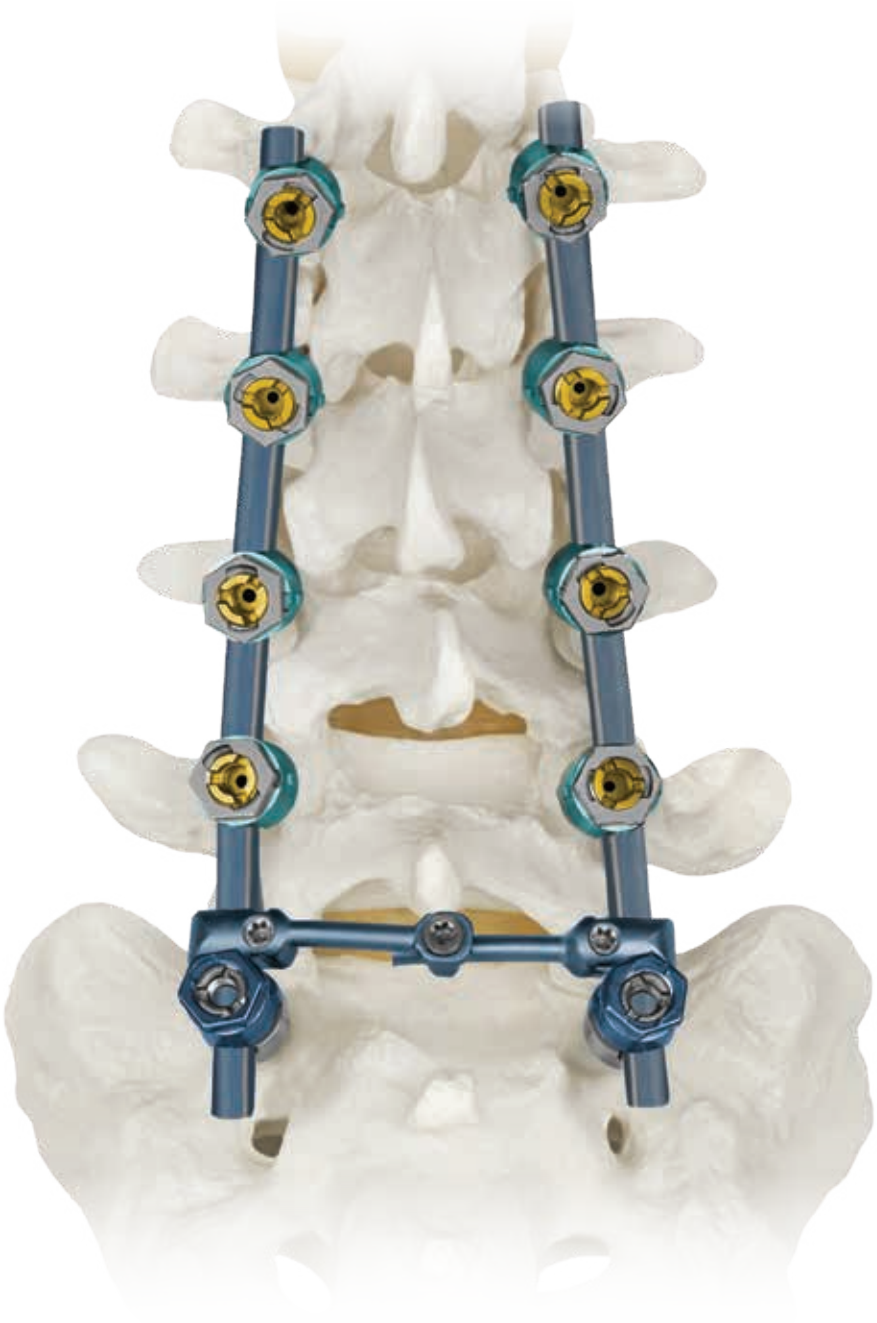
STEP 8 FINAL TIGHTENING

To secure the construct, use the **Torque-Limiting 11mm Hex Driver, L-Handle, 12Nm** or **11mm Hex Driver, 1/4" Quick-Connect** and **Torque-Limiting L-Handle, 12Nm, 1/4" Quick-Connect** for final tightening of the locking sleeves.

Insert the driver assembly into the Counter-Torque. Slide the Counter-Torque over the screw head, ensuring it is fully seated. Rotate the driver assembly clockwise until it reaches the torque limit of 12Nm and rotate to two audible clicks. Repeat for all locking sleeves.

Ensure that locking sleeves are final tightened after corrective maneuvers are complete.

FINAL CONSTRUCT



Final CREO® Side-Loading Construct

OPTIONAL TECHNIQUE: CROSS CONNECTOR

Cross Connector Insertion

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

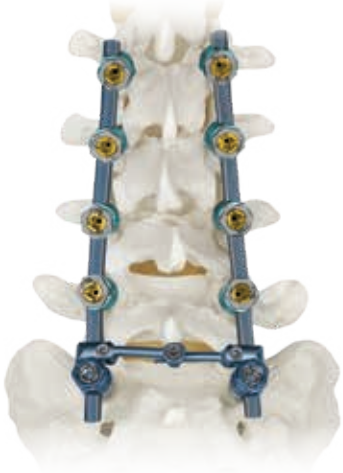
The **Cross Connector Caliper** may be used to estimate the distance between two rods. Place the caliper between the rods at the desired level. Read the cross connector length from the caliper handle.

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

Using Cross Connector Caliper

Reading length measurement

Inserting Cross Connector



Final CREO® Side-Loading Construct with Cross Connector

OPTIONAL TECHNIQUE: REVISION OR REMOVAL

For revision or removal, reverse the insertion steps until the desired implants are removed. Loosen the locking sleeves using the 11mm Hex Driver and remove using the Locking Sleeve Inserter. Grasp the rod and remove. Remove all screws using the appropriate driver. T-connectors and other connectors may remain connected on the rods for removal, or may be removed separately.

CREO® SIDE-LOADING
CORE INSTRUMENT I SET 9148.9000

	Part No.	Description	Qty
1	602.101	Pedicle Probe, Straight	1
2	602.102	Pedicle Probe, Curved	1
3	602.105	Ball Tip Probe	1
4	602.106	Ball Tip Probe, Curved	1
5	602.109	Pedicle Probe, Thoracic	1
6	602.501	Rod Template, 150mm	1
7	602.517	Rod Template, 300mm	1
8	624.110	Ball Tipped Probe, Double Ended	1
9	655.214	4.5mm Tap	1
10	655.215	5.5mm Tap	1
11	655.216	6.5mm Tap	1
12	655.217	7.5mm Tap	1
13	655.218	8.5mm Tap	1
14	6067.0001	Pedicle Awl	1
15	6067.0010	Straight Handle, Ratcheting, 1/4" Quick-Connect	2
16	6067.0020	T-Handle, Ratcheting, 1/4" Quick-Connect	1
17	6067.0075	Power Bender	1
18	6067.1050	Cross Connector Driver, Torque-Limiting	1
19	6067.1055	Cross Connector Inserter	1
20	6067.1060	Cross Connector Caliper	1
21	6067.1065	Cross Connector Measurement Card	1
22	6067.1500	Rod Template, 500mm	1
23	6148.0090	Parallel Compressor, CREO® Side-Loading	1
24	6148.0095	Parallel Distractor, CREO® Side-Loading	1

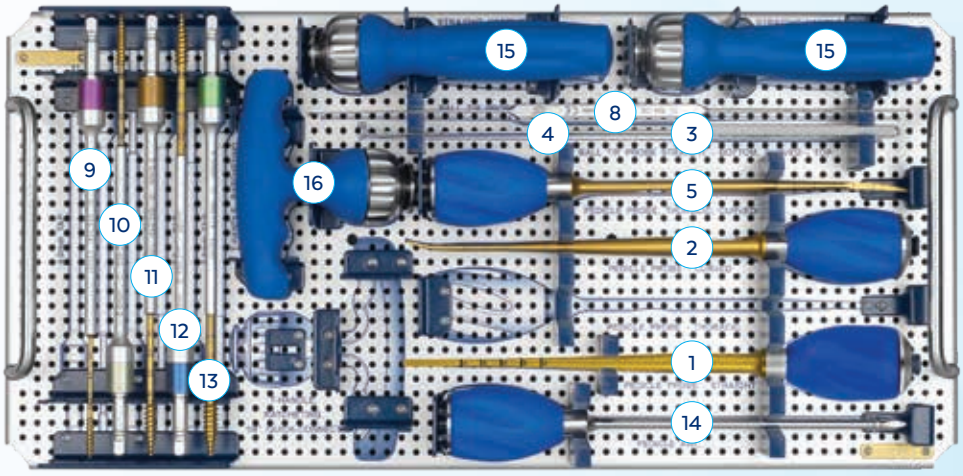
Module/Case

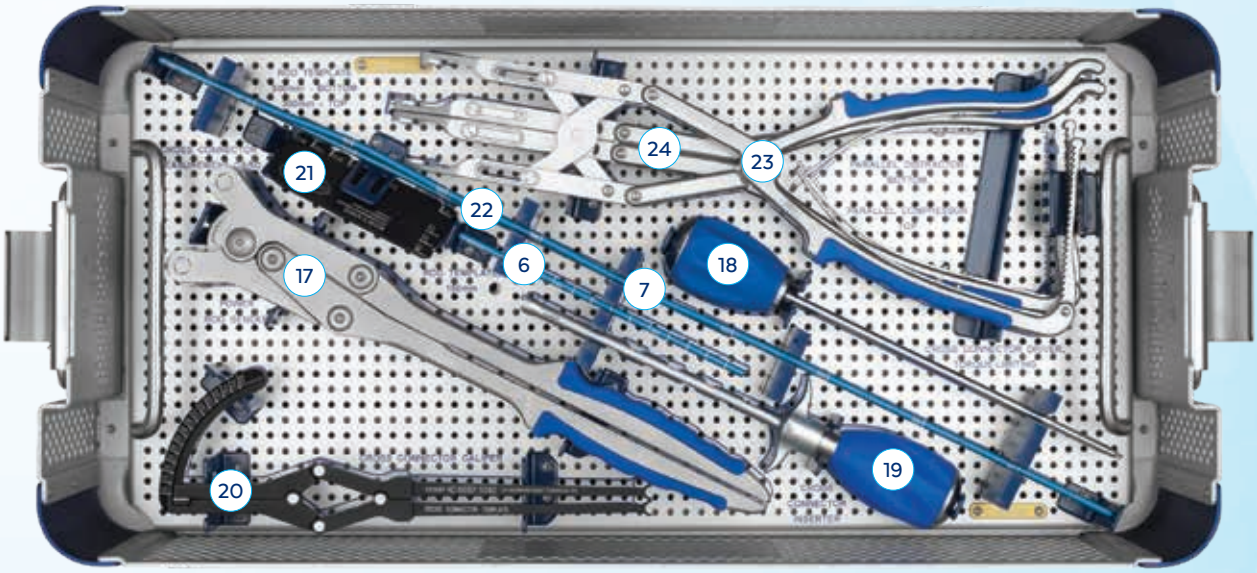
9148.0000	CREO® Side-Loading Core Instruments-I Graphic Case

Additionally Available

Part No.	Description	Qty
624.113	Pedicle Probe, Thoracic, Curved	0
624.114	Pedicle Probe, Thoracic, Straight	0
634.213	4.0mm Tap	0
6067.0100	10.5mm Solid Tap	0
6067.0900	9.5mm Solid Tap	0

CREO® SIDE-LOADING
CORE INSTRUMENT I SET 9148.9000





CREO® SIDE-LOADING
CORE INSTRUMENT II SET 9148.9001

	Part No.	Description	Qty
1	6067.0080	Rod Holder	1
2	6148.0041	Torque-Limiting 11mm Hex Driver, L-Handle, 12Nm	1
3	6148.0045	11mm Hex Driver, 1/4" Quick-Connect	1
4	6148.1105	Stick Removal Tool	1
5	6148.1110	Stick Outer Sleeve	16
6	6148.1111	Stick Inner Shaft	16
7	6148.2010	Lateral Reducer, CREO® Side-Loading	2
8	6148.2015	Dorsal Reducer, Geared, CREO® Side-Loading	1
9	6148.2016	Dorsal Reducer, Hinged, CREO® Side-Loading	1
10	6148.3050	11mm Hex Driver, T-Handle	1
11	6148.5000	Locking Sleeve Inserter, T-Handle, CREO® Side-Loading	2

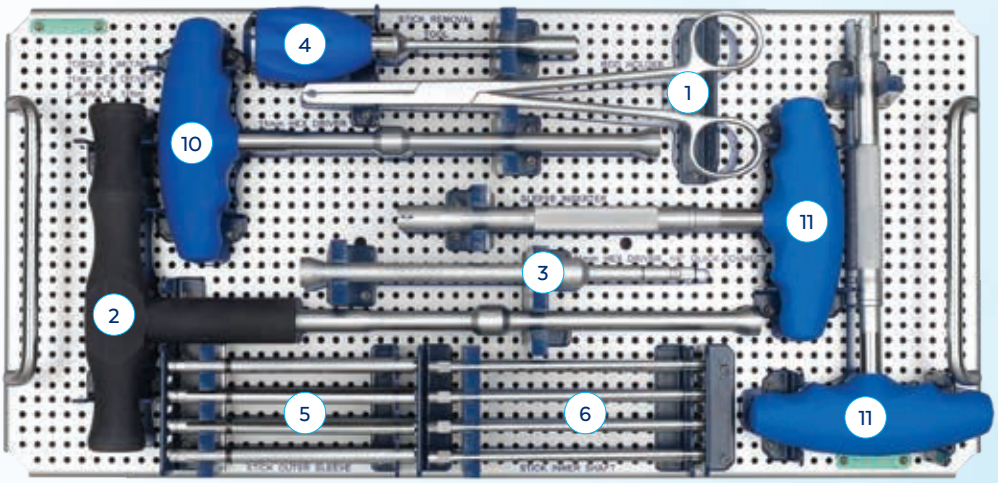
Module/Case

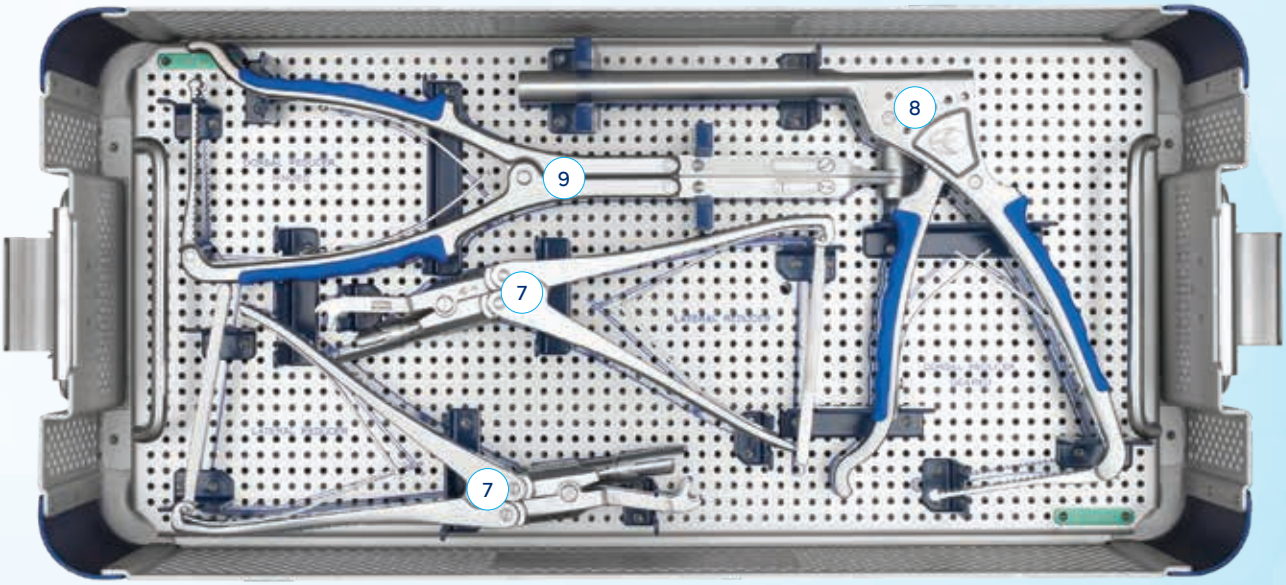
9148.0001	CREO® Side-Loading Core Instruments - II Graphic Case

Additionally Available

Part No.	Description	Qty
6148.0040	Torque-Limiting L-Handle, 12Nm, 1/4" Quick-Connect	0
6148.5001	Locking Sleeve Inserter, Palm Holder, CREO® Side-Loading	0

CREO® SIDE-LOADING
CORE INSTRUMENT II SET 9148.9001





CREO® SIDE-LOADING 6.0mm
IMPLANT AND INSTRUMENT SET 9148.9003

6.0mm Straight Rod, Titanium Alloy

Part No.	Length	Qty
1120.1020	20mm	0
1120.1025	25mm	0
1120.1030	30mm	0
1120.1035	35mm	0
1120.1040	40mm	0
1120.1045	45mm	4
1120.1050	50mm	0
1120.1055	55mm	4
1120.1060	60mm	0
1120.1065	65mm	4
1120.1070	70mm	0
1120.1075	75mm	4
1120.1080	80mm	0
1120.1085	85mm	4
1120.1090	90mm	0
1120.1095	95mm	0
1120.1100	100mm	2
1120.1125	125mm	2
1120.1150	150mm	2

6.0mm Straight Rod, Cobalt Chrome

Part No.	Length	Qty
7120.1020	20mm	0
7120.1025	25mm	0
7120.1030	30mm	0
7120.1035	35mm	0
7120.1040	40mm	0
7120.1045	45mm	0
7120.1050	50mm	0
7120.1055	55mm	0
7120.1060	60mm	0
7120.1065	65mm	0
7120.1070	70mm	0
7120.1075	75mm	0
7120.1080	80mm	0
7120.1085	85mm	0
7120.1090	90mm	0
7120.1095	95mm	0
7120.1100	100mm	0
7120.1125	125mm	0
7120.1150	150mm	0

6.0mm Curved Rod, Titanium Alloy

Part No.	Length	Qty
1120.3020	20mm	0
1120.3025	25mm	0
1120.3030	30mm	0
1120.3035	35mm	4
1120.3040	40mm	4
1120.3045	45mm	4
1120.3050	50mm	2
1120.3055	55mm	2
1120.3060	60mm	2
1120.3065	65mm	4
1120.3070	70mm	2
1120.3075	75mm	4
1120.3080	80mm	2
1120.3085	85mm	4
1120.3090	90mm	2
1120.3095	95mm	2
1120.3100	100mm	2
1120.3125	125mm	2
1120.3150	150mm	2

6.0mm Curved Rod, Cobalt Chrome

Part No.	Length	Qty
7120.3020	20mm	0
7120.3025	25mm	0
7120.3030	30mm	0
7120.3035	35mm	0
7120.3040	40mm	0
7120.3045	45mm	0
7120.3050	50mm	0
7120.3055	55mm	0

Items in gray are additionally available.

CREO® SIDE-LOADING 6.0mm
IMPLANT AND INSTRUMENT SET 9148.9003

6.0mm Curved Rod, Cobalt Chrome

Part No.	Length	Qty
7120.3060	60mm	0
7120.3065	65mm	0
7120.3070	70mm	0
7120.3075	75mm	0
7120.3080	80mm	0
7120.3085	85mm	0
7120.3090	90mm	0
7120.3095	95mm	0
7120.3100	100mm	0
7120.3125	125mm	0
7120.3150	150mm	0

6.0mm Hex-Ended Rod, Titanium Alloy

Part No.	Length	Qty
1120.2200	200mm	2
1120.2300	300mm	2
1120.2400	400mm	0
1120.2500	500mm	4
1120.2600	600mm	0

6.0mm Hex-Ended Rod, Cobalt Chrome

Part No.	Length	Qty
7120.2200	200mm	2
7120.2300	300mm	2
7120.2400	400mm	0
7120.2500	500mm	4
7120.2600	600mm	0

CREO® 6.0 Cross Connector

Part No.	Length	Qty
1119.0029	29-33mm	1
1119.0032	32-40mm	1
1119.0038	38-50mm	2
1119.0048	48-60mm	2
1119.0058	58-70mm	1
1119.0068	68-80mm	0
1119.0078	78-90mm	0

CREO® 6.0 Low Profile Cross Connector

Part No.	Length	Qty
1119.0222	20-22mm	0
1119.0225	21.5-25mm	2
1119.0231	24.5-31mm	2
1119.0243	30.5-43mm	2
1119.0267	42.5-67mm	2
1119.0291	66.5-91mm	0

Instruments

Part No.	Description	Qty
6067.3025	Rod Wrench	1
6120.0085	6.0mm Power Rod Gripper	2
6120.3000	6.0mm *In Situ* Bender, Left	1
6120.3005	6.0mm *In Situ* Bender, Right	1
6120.3010	6.0mm Coronal Plane Bender, Left	1
6120.3015	6.0mm Coronal Plane Bender, Right	1

Module/Case

9120.0303	CREO® 6.0 Low Profile Cross Connector Module
9120.0710	CREO® 6.0 Variable Cross Connector Module
9120.0810	CREO® 6.0 Rod Module
9148.0003	CREO® Side-Loading 6.0mm Implants & Instruments Graphic Case

Items in gray are additionally available.

CREO® SIDE-LOADING MONOAXIAL
IMPLANT AND INSTRUMENT SET 9148.9004

Locking Mechanism

Part No.	Description	Qty
1148.0000	CREO® Side-Loading Monoaxial Locking Sleevel, 6.0	36
1148.0005	CREO® Side-Loading Monoaxial Locking Sleeve, 5.5	0

CREO® Side-Loading Monoaxial Screw

Part No.	Diameter/Length	Qty
5148.0220	4.0x20mm	2
5148.0225	4.0x25mm	4
5148.0230	4.0x30mm	6
5148.0235	4.0x35mm	6
5148.0240	4.0x40mm	6
5148.0245	4.0x45mm	2
5148.0320	4.5x20mm	2
5148.0325	4.5x25mm	4
5148.0330	4.5x30mm	6
5148.0335	4.5x35mm	6
5148.0340	4.5x40mm	6
5148.0345	4.5x45mm	2
5148.0350	4.5x50mm	0
5148.0420	5.0x20mm	0
5148.0425	5.0x25mm	4
5148.0430	5.0x30mm	6
5148.0435	5.0x35mm	6
5148.0440	5.0x40mm	6
5148.0445	5.0x45mm	6
5148.0450	5.0x50mm	4
5148.0455	5.0x55mm	4
5148.0525	5.5x25mm	2
5148.0530	5.5x30mm	4
5148.0535	5.5x35mm	6
5148.0540	5.5x40mm	6
5148.0545	5.5x45mm	6
5148.0550	5.5x50mm	6
5148.0555	5.5x55mm	4
5148.0560	5.5x60mm	2
5148.0025	6.0x25mm	2

CREO® Side-Loading Monoaxial Screw

Part No.	Diameter/Length	Qty
5148.0030	6.0x30mm	4
5148.0035	6.0x35mm	6
5148.0040	6.0x40mm	6
5148.0045	6.0x45mm	6
5148.0050	6.0x50mm	6
5148.0055	6.0x55mm	4
5148.0060	6.0x60mm	2
5148.0625	6.5x25mm	2
5148.0630	6.5x30mm	4
5148.0635	6.5x35mm	6
5148.0640	6.5x40mm	8
5148.0645	6.5x45mm	8
5148.0650	6.5x50mm	6
5148.0655	6.5x55mm	4
5148.0660	6.5x60mm	2
5148.0665	6.5x65mm	0
5148.0725	7.5x25mm	2
5148.0730	7.5x30mm	4
5148.0735	7.5x35mm	4
5148.0740	7.5x40mm	4
5148.0745	7.5x45mm	6
5148.0750	7.5x50mm	4
5148.0755	7.5x55mm	2
5148.0760	7.5x60mm	2
5148.0765	7.5x65mm	2
5148.0825	8.5x25mm	2
5148.0830	8.5x30mm	2
5148.0835	8.5x35mm	2
5148.0840	8.5x40mm	2
5148.0845	8.5x45mm	2
5148.0850	8.5x50mm	2
5148.0855	8.5x55mm	2
5148.0860	8.5x60mm	2
5148.0865	8.5x65mm	2
5148.0930	9.5x30mm	0
5148.0935	9.5x35mm	0
5148.0940	9.5x40mm	0

Items in gray are additionally available.

CREO® SIDE-LOADING MONOAXIAL
IMPLANT AND INSTRUMENT SET 9148.9004

CREO® Side-Loading Monoaxial Screw

Part No.	Diameter/Length	Qty
5148.0945	9.5x45mm	0
5148.0950	9.5x50mm	0
5148.0955	9.5x55mm	0
5148.0960	9.5x60mm	0
5148.0965	9.5x65mm	0
5148.0130	10.5x30mm	0
5148.0135	10.5x35mm	0
5148.0140	10.5x40mm	0
5148.0145	10.5x45mm	0
5148.0150	10.5x50mm	0
5148.0155	10.5x55mm	0
5148.0160	10.5x60mm	0
5148.0165	10.5x65mm	0

CREO® Side-Loading Monoaxial Screw, Cannulated

Part No.	Diameter/Length	Qty
5148.0322	4.5x20mm	0
5148.0327	4.5x25mm	0
5148.0332	4.5x30mm	0
5148.0337	4.5x35mm	0
5148.0342	4.5x40mm	0
5148.0347	4.5x45mm	0
5148.0352	4.5x50mm	0
5148.0422	5.0x20mm	0
5148.0427	5.0x25mm	0
5148.0432	5.0x30mm	0
5148.0437	5.0x35mm	0
5148.0442	5.0x40mm	0
5148.0447	5.0x45mm	0
5148.0452	5.0x50mm	0
5148.0457	5.0x55mm	0
5148.0527	5.5x25mm	0
5148.0532	5.5x30mm	0
5148.0537	5.5x35mm	0
5148.0542	5.5x40mm	0
5148.0547	5.5x45mm	0
5148.0552	5.5x50mm	0

CREO® Side-Loading Monoaxial Screw, Cannulated

Part No.	Diameter/Length	Qty
5148.0557	5.5x55mm	0
5148.0562	5.5x60mm	0
5148.0027	6.0x25mm	0
5148.0032	6.0x30mm	0
5148.0037	6.0x35mm	0
5148.0042	6.0x40mm	0
5148.0047	6.0x45mm	0
5148.0052	6.0x50mm	0
5148.0057	6.0x55mm	0
5148.0062	6.0x60mm	0
5148.0627	6.5x25mm	0
5148.0632	6.5x30mm	0
5148.0637	6.5x35mm	0
5148.0642	6.5x40mm	0
5148.0647	6.5x45mm	0
5148.0652	6.5x50mm	0
5148.0657	6.5x55mm	0
5148.0662	6.5x60mm	0
5148.0667	6.5x65mm	0
5148.0727	7.5x25mm	0
5148.0732	7.5x30mm	0
5148.0737	7.5x35mm	0
5148.0742	7.5x40mm	0
5148.0747	7.5x45mm	0
5148.0752	7.5x50mm	0
5148.0757	7.5x55mm	0
5148.0762	7.5x60mm	0
5148.0767	7.5x65mm	0
5148.0827	8.5x25mm	0
5148.0832	8.5x30mm	0
5148.0837	8.5x35mm	0
5148.0842	8.5x40mm	0
5148.0847	8.5x45mm	0
5148.0852	8.5x50mm	0
5148.0857	8.5x55mm	0
5148.0862	8.5x60mm	0

Items in gray are additionally available.

CREO® SIDE-LOADING MONOAXIAL IMPLANT AND INSTRUMENT SET 9148.9004

CREO® Side-Loading Monoaxial Screw, Cannulated

Part No.	Diameter/Length	Qty
5148.0867	8.5x65mm	0
5148.0932	9.5x30mm	0
5148.0937	9.5x35mm	0
5148.0942	9.5x40mm	0
5148.0947	9.5x45mm	0
5148.0952	9.5x50mm	0
5148.0957	9.5x55mm	0
5148.0962	9.5x60mm	0
5148.0967	9.5x65mm	0

Instruments

Part No.	Description	Qty
6067.0402	5.0mm Cannulated Tap	0
6067.0502	5.5mm Cannulated Tap	0
6067.0602	6.5mm Cannulated Tap	0
6067.0702	7.5mm Cannulated Tap	0
6067.0802	8.5mm Cannulated Tap	0
6148.0070	Monoaxial Decortication Tool, CREO® Side-Loading	1
6148.1025	Monoaxial Stick Attachment Guide, CREO® Side-Loading	1
6148.1100	Stick Driver, 1/4” Quick-connect	2
6148.1101	Stick Driver, Power	0
6148.3000	Monoaxial Counter-Torque, CREO® Side-Loading	1
685.003	1.6mm K-Wire, 450mm, Blunt Tip	0

Module/Case

9148.0004	CREO® Side-Loading Monoaxial Implants and Instruments Graphic Case
9148.0100	CREO® Side-Loading Monoaxial Screw Module
9148.0101	CREO® Side-Loading Monoaxial Locking Sleeve Module
9148.0105	CREO® Side-Loading Monoaxial Locking Sleeve Module, 5.5

Items in gray are additionally available.

CREO® SIDE-LOADING POLYAXIAL & UNIPLANAR
IMPLANT AND INSTRUMENT SET 9148.9005

Locking Mechanism

Part No.	Description	Qty
1148.0010	CREO® Side-Loading Polyaxial Locking Sleeve, 5.5	0
1148.0011	CREO® Side-Loading Polyaxial Locking Sleeve, 6.0	36

CREO® Side-Loading Polyaxial Screw, CoCr Head, Ti Shank

Part No.	Diameter/Length	Qty
5148.1220	4.0x20mm	2
5148.1225	4.0x25mm	2
5148.1230	4.0x30mm	4
5148.1235	4.0x35mm	4
5148.1240	4.0x40mm	2
5148.1245	4.0x45mm	2
5148.1320	4.5x20mm	0
5148.1325	4.5x25mm	4
5148.1330	4.5x30mm	6
5148.1335	4.5x35mm	8
5148.1340	4.5x40mm	6
5148.1345	4.5x45mm	6
5148.1350	4.5x50mm	0
5148.1420	5.0x20mm	0
5148.1425	5.0x25mm	4
5148.1430	5.0x30mm	6
5148.1435	5.0x35mm	6
5148.1440	5.0x40mm	6
5148.1445	5.0x45mm	6
5148.1450	5.0x50mm	2
5148.1455	5.0x55mm	2
5148.1525	5.5x25mm	6
5148.1530	5.5x30mm	4
5148.1535	5.5x35mm	4
5148.1540	5.5x40mm	4
5148.1545	5.5x45mm	2
5148.1550	5.5x50mm	0
5148.1555	5.5x55mm	0
5148.1560	5.5x60mm	0
5148.1625	6.5x25mm	6

CREO® Side-Loading Polyaxial Screw, CoCr Head, Ti Shank

Part No.	Diameter/Length	Qty
5148.1630	6.5x30mm	6
5148.1635	6.5x35mm	6
5148.1640	6.5x40mm	6
5148.1645	6.5x45mm	6
5148.1650	6.5x50mm	6
5148.1655	6.5x55mm	0
5148.1660	6.5x60mm	0
5148.1665	6.5x65mm	0
5148.1725	7.5x25mm	0
5148.1730	7.5x30mm	0
5148.1735	7.5x35mm	0
5148.1740	7.5x40mm	0
5148.1745	7.5x45mm	0
5148.1750	7.5x50mm	0
5148.1755	7.5x55mm	0
5148.1760	7.5x60mm	0
5148.1765	7.5x65mm	0
5148.1830	8.5x30mm	0
5148.1835	8.5x35mm	0
5148.1840	8.5x40mm	0
5148.1845	8.5x45mm	0
5148.1850	8.5x50mm	0
5148.1855	8.5x55mm	0
5148.1860	8.5x60mm	0
5148.1865	8.5x65mm	0

CREO® Side-Loading Uniplanar Screw, CoCr Head, Ti Shank

Part No.	Diameter/Length	Qty
5148.5220	4.0x20mm	0
5148.5225	4.0x25mm	0
5148.5230	4.0x30mm	0
5148.5235	4.0x35mm	0
5148.5240	4.0x40mm	0
5148.5245	4.0x45mm	0
5148.5320	4.5x20mm	0
5148.5325	4.5x25mm	0
5148.5330	4.5x30mm	0

Items in gray are additionally available.

CREO® SIDE-LOADING POLYAXIAL & UNIPLANAR
IMPLANT AND INSTRUMENT SET 9148.9005

CREO® Side-Loading Uniplanar Screw, CoCr Head, Ti Shank

Part No.	Diameter/Length	Qty
5148.5335	4.5x35mm	0
5148.5340	4.5x40mm	0
5148.5345	4.5x45mm	0
5148.5350	4.5x50mm	0
5148.5420	5.0x20mm	0
5148.5425	5.0x25mm	0
5148.5430	5.0x30mm	0
5148.5435	5.0x35mm	0
5148.5440	5.0x40mm	0
5148.5445	5.0x45mm	0
5148.5450	5.0x50mm	0
5148.5455	5.0x55mm	0
5148.5525	5.5x25mm	0
5148.5530	5.5x30mm	0
5148.5535	5.5x35mm	0
5148.5540	5.5x40mm	0
5148.5545	5.5x45mm	0
5148.5550	5.5x50mm	0
5148.5555	5.5x55mm	0
5148.5560	5.5x60mm	0
5148.5625	6.5x25mm	0
5148.5630	6.5x30mm	0
5148.5635	6.5x35mm	0
5148.5640	6.5x40mm	0
5148.5645	6.5x45mm	0
5148.5650	6.5x50mm	0
5148.5655	6.5x55mm	0
5148.5660	6.5x60mm	0
5148.5665	6.5x65mm	0
5148.5725	7.5x25mm	0
5148.5730	7.5x30mm	0
5148.5735	7.5x35mm	0
5148.5740	7.5x40mm	0
5148.5745	7.5x45mm	0
5148.5750	7.5x50mm	0
5148.5755	7.5x55mm	0
5148.5760	7.5x60mm	0

CREO® Side-Loading Uniplanar Screw, CoCr Head, Ti Shank

Part No.	Diameter/Length	Qty
5148.5765	7.5x65mm	0
5148.5825	8.5x25mm	0
5148.5830	8.5x30mm	0
5148.5835	8.5x35mm	0
5148.5840	8.5x40mm	0
5148.5845	8.5x45mm	0
5148.5850	8.5x50mm	0
5148.5855	8.5x55mm	0
5148.5860	8.5x60mm	0
5148.5865	8.5x65mm	0

Instruments

Part No.	Description	Qty
6148.0050	3.5mm Hex Driver, 1/4" Quick-Connect	1
6148.1026	Polyaxial Stick Attachment Guide, CREO® Side-Loading	1
6148.1080	Rigid Polyaxial Screwdriver, 1/4" Quick-Connect, CREO® Side-Loading	2
6148.3001	Polyaxial Counter-Torque, CREO® Side-Loading	1

Module/Case

9148.0005	CREO® Side-Loading Polyaxial/Uniplanar Implants and Instruments Graphic Case
9148.0200	CREO® Side-Loading Polyaxial/Uniplanar Screw Module
9148.0301	CREO® Side-Loading 6.0mm Polyaxial Locking Sleeve Module
9148.0201	CREO® Side-Loading 5.5mm Polyaxial Locking Sleeve Module

Items in gray are additionally available.

CREO® SIDE-LOADING MONOAXIAL ILIAC
IMPLANT SET 9148.9009

6.0 Closed Offset Rod

Part No.	Length	Qty
1119.0275	150mm	0
1119.0280	15mm	2
1119.0285	20mm	2
1119.0290	25mm	2
1119.0295	30mm	2
1119.0300	35mm	2

6.0 Open Offset Rod

Part No.	Length	Qty
1119.0345	150mm	0
1119.0360	15mm	2
1119.0365	20mm	2
1119.0370	25mm	2
1119.0375	30mm	2
1119.0380	35mm	2

5.5 Closed Offset Rod

Part No.	Length	Qty
1119.0820	15mm	0
1119.0825	20mm	0
1119.0830	25mm	0
1119.0835	30mm	0
1119.0840	35mm	0

5.5 Open Offset Rod

Part No.	Length	Qty
1119.0960	15mm	0
1119.0965	20mm	0
1119.0970	25mm	0
1119.0975	30mm	0
1119.0980	35mm	0

CREO® Side-Loading Monoaxial Screws

Part No.	Diameter/Length	Qty
5148.0110	10.5x100mm	2
5148.0111	10.5x110mm	2
5148.0112	10.5x120mm	2
5148.0170	10.5x70mm	2
5148.0175	10.5x75mm	2
5148.0180	10.5x80mm	2
5148.0185	10.5x85mm	2
5148.0190	10.5x90mm	2
5148.0195	10.5x95mm	2
5148.0710	7.5x100mm	2
5148.0711	7.5x110mm	2
5148.0712	7.5x120mm	2
5148.0770	7.5x70mm	2
5148.0775	7.5x75mm	2
5148.0780	7.5x80mm	2
5148.0785	7.5x85mm	2
5148.0790	7.5x90mm	2
5148.0795	7.5x95mm	2
5148.0810	8.5x100mm	2
5148.0811	8.5x110mm	2
5148.0812	8.5x120mm	2
5148.0870	8.5x70mm	2
5148.0875	8.5x75mm	2
5148.0880	8.5x80mm	2
5148.0885	8.5x85mm	2
5148.0890	8.5x90mm	2
5148.0895	8.5x95mm	2
5148.0910	9.5x100mm	2
5148.0911	9.5x110mm	2
5148.0912	9.5x120mm	2
5148.0970	9.5x70mm	2
5148.0975	9.5x75mm	2
5148.0980	9.5x80mm	2
5148.0985	9.5x85mm	2
5148.0990	9.5x90mm	2
5148.0995	9.5x95mm	2

Items in gray are additionally available.

CREO® SIDE-LOADING MONOAXIAL ILIAC
IMPLANT SET 9148.9009

CREO® Side-Loading Monoaxial Screws, Cannulated

Part No.	Diameter/Length	Qty
5148.0124	10.5x100mm	0
5148.0134	10.5x110mm	0
5148.0144	10.5x120mm	0
5148.0172	10.5x70mm	0
5148.0177	10.5x75mm	0
5148.0182	10.5x80mm	0
5148.0187	10.5x85mm	0
5148.0192	10.5x90mm	0
5148.0197	10.5x95mm	0
5148.0724	7.5x100mm	0
5148.0734	7.5x110mm	0
5148.0744	7.5x120mm	0
5148.0772	7.5x70mm	0
5148.0777	7.5x75mm	0
5148.0782	7.5x80mm	0
5148.0787	7.5x85mm	0
5148.0792	7.5x90mm	0
5148.0797	7.5x95mm	0
5148.0824	8.5x100mm	0
5148.0834	8.5x110mm	0
5148.0844	8.5x120mm	0
5148.0872	8.5x70mm	0
5148.0877	8.5x75mm	0
5148.0882	8.5x80mm	0
5148.0887	8.5x85mm	0
5148.0892	8.5x90mm	0
5148.0897	8.5x95mm	0
5148.0924	9.5x100mm	0
5148.0934	9.5x110mm	0
5148.0944	9.5x120mm	0
5148.0972	9.5x70mm	0
5148.0977	9.5x75mm	0
5148.0982	9.5x80mm	0
5148.0987	9.5x85mm	0
5148.0992	9.5x90mm	0
5148.0997	9.5x95mm	0

CREO® Side-Loading Monoaxial DOD Screws

Part No.	Diameter/Length	Qty
5148.3110	10.5-9.0x100mm	2
5148.3111	10.5-9.0x110mm	2
5148.3112	10.5-9.0x120mm	2
5148.3170	10.5-9.0x70mm	2
5148.3175	10.5-9.0x75mm	2
5148.3180	10.5-9.0x80mm	2
5148.3185	10.5-9.0x85mm	2
5148.3190	10.5-9.0x90mm	2
5148.3195	10.5-9.0x95mm	2
5148.3210	8.0-6.5x100mm	2
5148.3211	8.0-6.5x110mm	2
5148.3212	8.0-6.5x120mm	2
5148.3270	8.0-6.5x70mm	2
5148.3275	8.0-6.5x75mm	2
5148.3280	8.0-6.5x80mm	2
5148.3285	8.0-6.5x85mm	2
5148.3290	8.0-6.5x90mm	2
5148.3295	8.0-6.5x95mm	2
5148.3810	8.5-7.0x100mm	2
5148.3811	8.5-7.0x110mm	2
5148.3812	8.5-7.0x120mm	2
5148.3870	8.5-7.0x70mm	2
5148.3875	8.5-7.0x75mm	2
5148.3880	8.5-7.0x80mm	2
5148.3885	8.5-7.0x85mm	2
5148.3890	8.5-7.0x90mm	2
5148.3895	8.5-7.0x95mm	2
5148.3910	9.5-8.0x100mm	2
5148.3911	9.5-8.0x110mm	2
5148.3912	9.5-8.0x120mm	2
5148.3970	9.5-8.0x70mm	2
5148.3975	9.5-8.0x75mm	2
5148.3980	9.5-8.0x80mm	2
5148.3985	9.5-8.0x85mm	2
5148.3990	9.5-8.0x90mm	2
5148.3995	9.5-8.0x95mm	2

Items in gray are additionally available.

CREO® SIDE-LOADING MONOAXIAL ILIAC
IMPLANT SET 9148.9009

CREO® Side-Loading Monoaxial DOD Screws, Cannulated

Part No.	Diameter/Length	Qty
5148.3124	10.5-9.0x100mm	0
5148.3134	10.5-9.0x110mm	0
5148.3144	10.5-9.0x120mm	0
5148.3172	10.5-9.0x70mm	0
5148.3177	10.5-9.0x75mm	0
5148.3182	10.5-9.0x80mm	0
5148.3187	10.5-9.0x85mm	0
5148.3192	10.5-9.0x90mm	0
5148.3197	10.5-9.0x95mm	0
5148.3224	8.0-6.5x100mm	0
5148.3234	8.0-6.5x110mm	0
5148.3244	8.0-6.5x120mm	0
5148.3272	8.0-6.5x70mm	0
5148.3277	8.0-6.5x75mm	0
5148.3282	8.0-6.5x80mm	0
5148.3287	8.0-6.5x85mm	0
5148.3292	8.0-6.5x90mm	0
5148.3297	8.0-6.5x95mm	0
5148.3824	8.5-7.0x100mm	0
5148.3834	8.5-7.0x110mm	0
5148.3844	8.5-7.0x120mm	0
5148.3872	8.5-7.0x70mm	0
5148.3877	8.5-7.0x75mm	0
5148.3882	8.5-7.0x80mm	0
5148.3887	8.5-7.0x85mm	0
5148.3892	8.5-7.0x90mm	0
5148.3897	8.5-7.0x95mm	0
5148.3924	9.5-8.0x100mm	0
5148.3934	9.5-8.0x110mm	0
5148.3944	9.5-8.0x120mm	0
5148.3972	9.5-8.0x70mm	0
5148.3977	9.5-8.0x75mm	0
5148.3982	9.5-8.0x80mm	0
5148.3987	9.5-8.0x85mm	0
5148.3992	9.5-8.0x90mm	0
5148.3997	9.5-8.0x95mm	0

Instruments

Part No.	Description	Qty
6067.0040	Torque-Limiting T-Handle, Ratcheting, 5.5Nm, 1/4" Quick-Connect	1
6067.0050	Driver Shaft, 1/4" Quick-Connect, Short	1

Module/Case

9119.0408	CREO® 5.5 Offset Rod Module
9120.0408	CREO® 6.0 Offset Rod Module
9148.0009	CREO® Side-Loading Monoaxial Iliac Implants Graphic Case
9148.0108	CREO® Side-Loading Iliac Screw Module, Short
9148.0208	CREO® Side-Loading Iliac Screw Module, Long

Items in gray are additionally available.

CREO® SIDE-LOADING POLYAXIAL ILIAC IMPLANT SET 9148.9010

6.0 Closed Offset Rod

Part No.	Length	Qty
1119.0275	150mm	0
1119.0280	15mm	2
1119.0285	20mm	2
1119.0290	25mm	2
1119.0295	30mm	2
1119.0300	35mm	2

6.0 Open Offset Rod

Part No.	Length	Qty
1119.0345	150mm	0
1119.0360	15mm	2
1119.0365	20mm	2
1119.0370	25mm	2
1119.0375	30mm	2
1119.0380	35mm	2

5.5 Closed Offset Rod

Part No.	Length	Qty
1119.0820	15mm	0
1119.0825	20mm	0
1119.0830	25mm	0
1119.0835	30mm	0
1119.0840	35mm	0

5.5 Open Offset Rod

Part No.	Length	Qty
1119.0960	15mm	0
1119.0965	20mm	0
1119.0970	25mm	0
1119.0975	30mm	0
1119.0980	35mm	0

CREO® Side-Loading Polyaxial Screws, CoCr Head, Ti Shank

Part No.	Diameter/Length	Qty
5148.1110	10.5x100mm	2
5148.1111	10.5x110mm	2
5148.1112	10.5x120mm	2
5148.1170	10.5x70mm	2
5148.1175	10.5x75mm	2
5148.1180	10.5x80mm	2
5148.1185	10.5x85mm	2
5148.1190	10.5x90mm	2
5148.1195	10.5x95mm	2
5148.1710	7.5x100mm	2
5148.1711	7.5x110mm	2
5148.1712	7.5x120mm	2
5148.1770	7.5x70mm	2
5148.1775	7.5x75mm	2
5148.1780	7.5x80mm	2
5148.1785	7.5x85mm	2
5148.1790	7.5x90mm	2
5148.1795	7.5x95mm	2
5148.1810	8.5x100mm	2
5148.1811	8.5x110mm	2
5148.1812	8.5x120mm	2
5148.1870	8.5x70mm	2
5148.1875	8.5x75mm	2
5148.1880	8.5x80mm	2
5148.1885	8.5x85mm	2
5148.1890	8.5x90mm	2
5148.1895	8.5x95mm	2
5148.1910	9.5x100mm	2
5148.1911	9.5x110mm	2
5148.1912	9.5x120mm	2
5148.1970	9.5x70mm	2
5148.1975	9.5x75mm	2
5148.1980	9.5x80mm	2
5148.1985	9.5x85mm	2
5148.1990	9.5x90mm	2
5148.1995	9.5x95mm	2

Items in gray are additionally available.

CREO® SIDE-LOADING POLYAXIAL ILIAC IMPLANT SET 9148.9010

CREO® Side-Loading Polyaxial DOD Screws, CoCr Head, Ti Shank

Part No.	Diameter/Length	Qty
5148.2110	10.5-9.0x100mm	2
5148.2111	10.5-9.0x110mm	2
5148.2112	10.5-9.0x120mm	2
5148.2170	10.5-9.0x70mm	2
5148.2175	10.5-9.0x75mm	2
5148.2180	10.5-9.0x80mm	2
5148.2185	10.5-9.0x85mm	2
5148.2190	10.5-9.0x90mm	2
5148.2195	10.5-9.0x95mm	2
5148.2210	8.0-6.5x100mm	2
5148.2211	8.0-6.5x110mm	2
5148.2212	8.0-6.5x120mm	2
5148.2270	8.0-6.5x70mm	2
5148.2275	8.0-6.5x75mm	2
5148.2280	8.0-6.5x80mm	2
5148.2285	8.0-6.5x85mm	2
5148.2290	8.0-6.5x90mm	2
5148.2295	8.0-6.5x95mm	2
5148.2810	8.5-7.0x100mm	2
5148.2811	8.5-7.0x110mm	2
5148.2812	8.5-7.0x120mm	2
5148.2870	8.5-7.0x70mm	2
5148.2875	8.5-7.0x75mm	2
5148.2880	8.5-7.0x80mm	2
5148.2885	8.5-7.0x85mm	2
5148.2890	8.5-7.0x90mm	2
5148.2895	8.5-7.0x95mm	2
5148.2910	9.5-8.0x100mm	2
5148.2911	9.5-8.0x110mm	2
5148.2912	9.5-8.0x120mm	2
5148.2970	9.5-8.0x70mm	2
5148.2975	9.5-8.0x75mm	2
5148.2980	9.5-8.0x80mm	2
5148.2985	9.5-8.0x85mm	2
5148.2990	9.5-8.0x90mm	2
5148.2995	9.5-8.0x95mm	2

Instruments

Part No.	Description	Qty
6067.0040	Torque-Limiting T-Handle, Ratcheting, 5.5Nm, 1/4" Quick-Connect	1
6067.0050	Driver Shaft, 1/4" Quick-Connect, Short	1

Module/Case

9119.0408	CREO® 5.5 Offset Rod Module
9120.0408	CREO® 6.0 Offset Rod Module
9148.0010	CREO® Side-Loading Polyaxial Iliac Implants Graphic Case
9148.0110	CREO® Side-Loading Polyaxial Iliac Screw Module, Short
9148.0210	CREO® Side-Loading Polyaxial Iliac Screw Module, Long

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

IMPORTANT INFORMATION ON THE CREO® STABILIZATION SYSTEM

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

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

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

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

Strict adherence to the surgical technique guide is strongly recommended.

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

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

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

ADDITIONAL WARNINGS FOR PEDIATRIC PATIENTS

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

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

PRECAUTIONS

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

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

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

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

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

ADDITIONAL PRECAUTIONS FOR PEDIATRIC PATIENTS

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

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

MRI SAFETY INFORMATION

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

CONTRAINDICATIONS

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

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

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

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

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

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

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

PACKAGING

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

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

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

HANDLING AND USE

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

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

CLEANING

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

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

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

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

CONTACT INFORMATION

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

STERILIZATION

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

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

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

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

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

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

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

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

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

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

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NOTES

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