CREO MIS®

Posterior Stabilization System

SURGICAL TECHNIQUE GUIDE

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

Life moves us

SURGICAL TECHNIQUE GUIDE

CREO MIS®

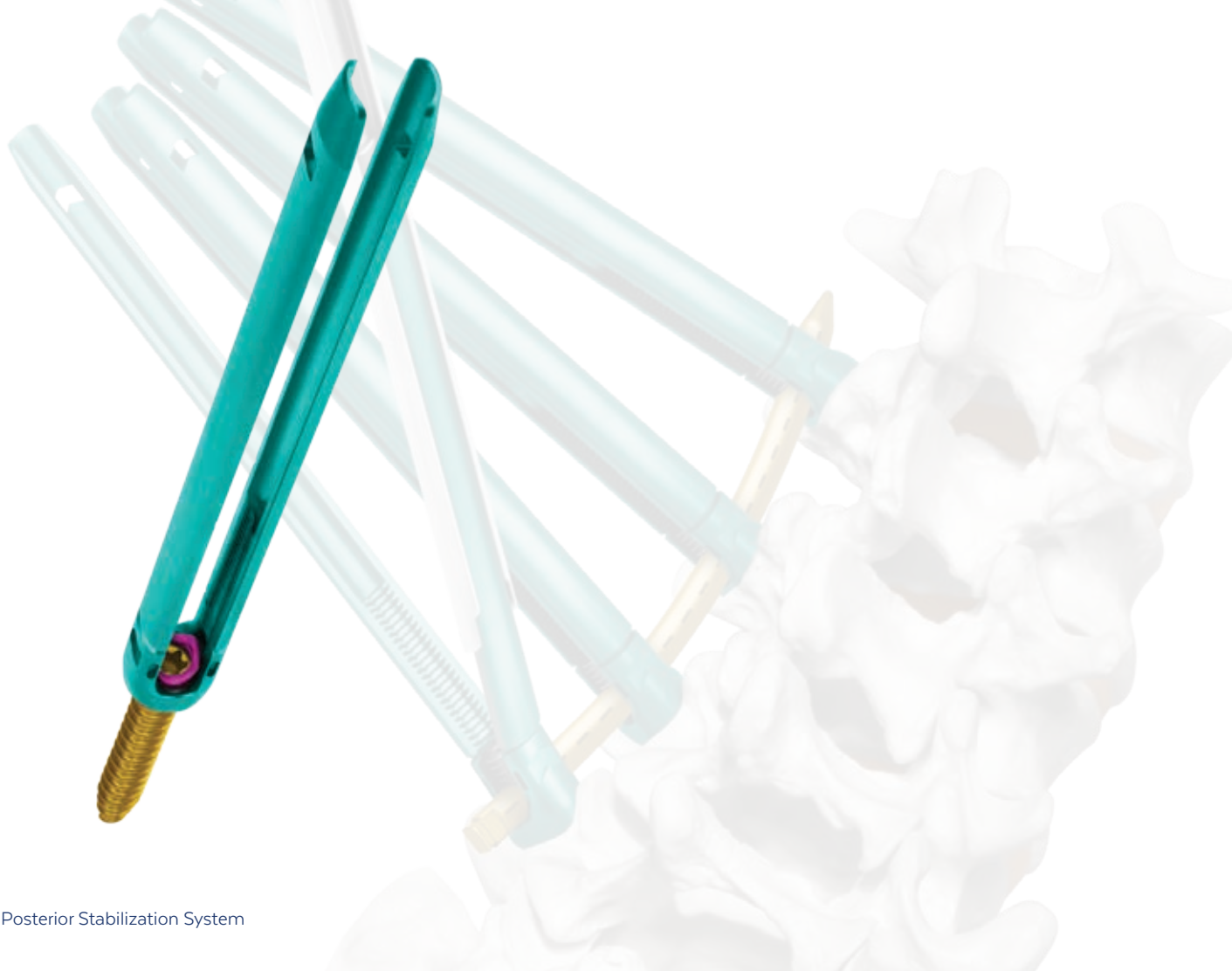
CREO MIS®

Posterior Stabilization System

CREO MIS® is a posterior percutaneous stabilization system featuring extended screw heads for facilitating minimally invasive surgical (MIS) techniques. The extended screw heads feature one of the smallest diameters available on the market to help minimize soft tissue disruption and screw sleeve interference.

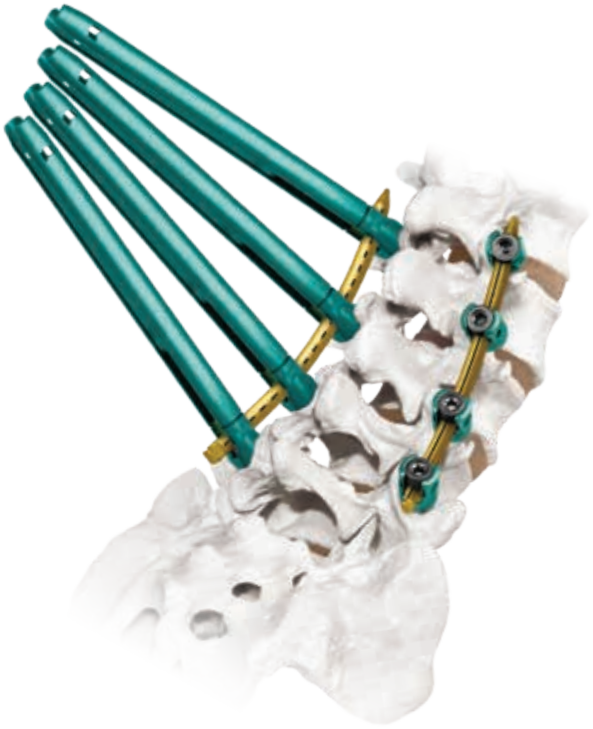
Low in profile, CREO MIS® provides the strength and rigidity of a traditional percutaneous screw system allowing for manipulation and deformity correction. With reduction options up to 30mm and the ability to assemble the extended screw heads to a wide range of screw offerings, CREO MIS® is a comprehensive and customizable solution for cases.

The CREO MIS® system offers the ability to insert a locking cap through the screw head in a controlled, guided manner where the rod is captured, reduced, and locked in one simplified step.



Minimized Soft Tissue Disruption

Extended screw heads provide a small outer diameter to help reduce soft tissue disruption and screw sleeve interference.



Powerful MIS Correction

Deformity Adapters rigidly attach to the extended screw head and allow for screw manipulation and deformity correction.*

Integrated Rod Reduction

Ensures proper thread alignment while capturing, reducing, and locking the rod in one simplified step.

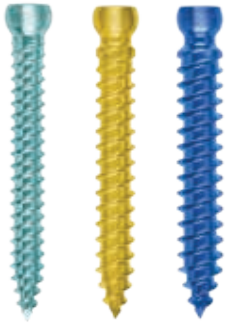
**CREO MIS® Deformity Adapters are compatible with the CREO® Reduction Derotator.*

IMPLANT OVERVIEW

Screw Post

- Cannulated screws
- Self-tapping design
- Double lead thread for rapid insertion
- Blunt tip for bicortical bone purchase
- Constant outer diameter for maximum bone purchase
- Taps are color-coded to screw size
- Screw diameters: 4.5, 5.0, 5.5, 6.5, 7.5, 8.5, 9.5, and 10.5mm
- Screw lengths: 20–120mm

CREO ONE™ Robotic Screw

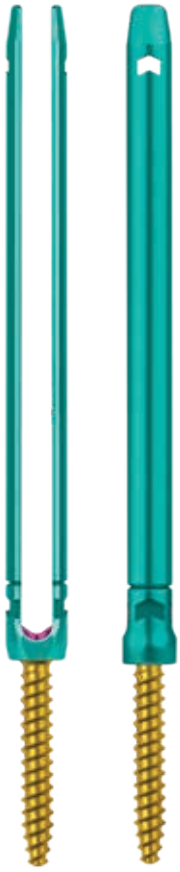


- Designed for use with ExcelsiusGPS®
- Awl-tip, non-cannulated screws
- Pre-drilling a pilot hole is required for insertion
- Double lead thread for rapid insertion
- Constant outer diameter to maximize bone purchase
- Screw diameters: 5.5, 6.5, and 7.5mm
- Screw lengths: 35–55mm

Threaded Locking Cap

- Low torque locking mechanism (8Nm)
- Single-step locking
- Easy to engage

Polyaxial Extended Tabs



- 13mm diameter
- 10mm and 30mm reduction options
- ±30° angulation (60° total) provides intraoperative versatility
- Removal Tool provides fast and easy tab removal with a clean break

Rods

- 5.5mm and 6.0mm diameter
- Titanium alloy and cobalt chrome
- Rod lengths
  - 30-150mm, in 5mm increments
  - 150-300mm, in 10mm increments
  - 300-500mm, in 50mm increments

INSTRUMENT OVERVIEW

PREPARATION INSTRUMENTS

Bone Access Needle, Trocar Tip, 8G 685.027S

1.6mm K-Wire, 500mm, Blunt, Threaded Tip 685.005

4.5mm Cannulated Tap 6134.0045

5.0mm Cannulated Tap 6134.0050

5.5mm Cannulated Tap 6134.0055

6.5mm Cannulated Tap 6134.0065

7.5mm Cannulated Tap 6134.0075

8.5mm Cannulated Tap 6134.0085

SCREW INSERTION INSTRUMENTS

PEEK Cannula A 6134.0110

Cannula A 6134.0100

PEEK Cannula B 6134.0111

Cannula B 6134.0101

PEEK Cannula C 6134.0112

Screw Measuring Instrument 6134.0130

Screwdriver, 30mm 6134.0140

Screwdriver, 10mm 6134.0145

Head Inserter 6134.1000

Head Positioner 6134.0435

SCREW INSERTION INSTRUMENTS – CREO ONE™ ROBOTIC SCREW

CREO MIS® Cannulated Screwdriver, 30mm 6143.2680

CREO MIS® Cannulated Screwdriver, 30mm 6143.2681

CREO AMP® Cannulated Modular Screwdriver, GPS 6143.2659

Driver Array, CREO MIS®, 15mm 6143.2536

Driver Array, 15mm 6143.2535

Screwdriver, GI1, 30mm 6134.1440

Screwdriver, GI1, 10mm 6134.1445

GLOBUS POWER®, GPS

Handpiece, Twin Trigger
6205.1000

Reamer Head Attachment, 1/4” Quick-Connect 6205.3002

Drill Head Attachment, AO Quick-Connect 6205.3005

Drill Head Attachment, Jacobs 6205.3006

GLOBUS POWER®, GPS (CONT'D)

Chuck Key 6205.3013

Wrench 6205.3017

High Speed Drill Array, GPS 6143.2541

High Speed Drill Attachment, GPS 6205.3007

High Speed Drill Array Sleeve, 15mm, GPS 6143.2551

High Speed Drill Array Sleeve, 17mm, GPS 6143.2552*

High Speed Drill Guard, GPS 6143.2550

Drill Head Attachment, 1/4" Quick-Connect 6205.3001*

CHARGER & BATTERIES SET

Battery, Sterilizable Li-Ion, 13.2V 6205.2001

Battery Charger, Single Bay 6205.2000

*Additionally available

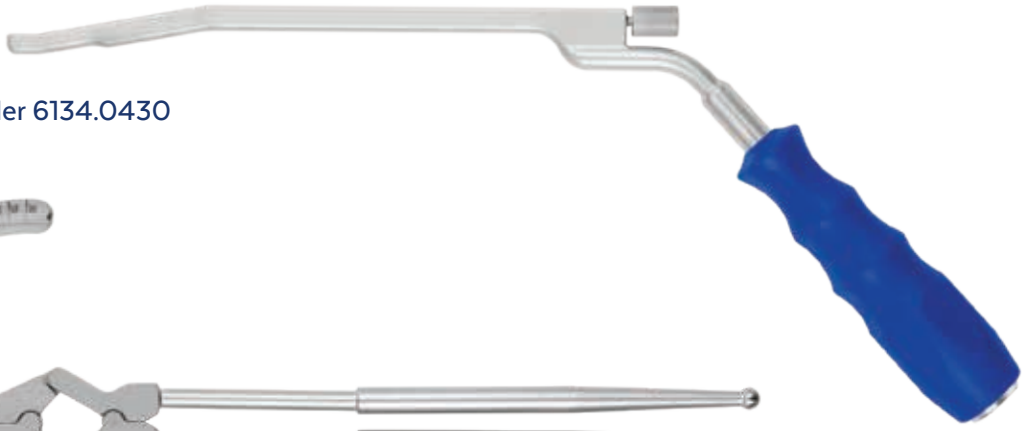
DISPOSABLE DRILL BITS

High Speed Drill Bit, 2.5mm, GPS 6143.2580S

High Speed Drill Bit, 3.5mm, GPS 6143.2582S

High Speed Drill Bit, 4.5mm, GPS 6143.2584S

ROD INTRODUCTION INSTRUMENTS



Fixed Rod Holder 6134.0430

Calipers, Small 6134.0420

Rod Holder, Forcep Style 6067.0080

Counter-Torque 6134.0220

Compressor 6134.0400

Rod Indicator 6134.0205

*Additionally available

ROD INTRODUCTION INSTRUMENTS (CONT'D)

Locking Cap Driver 6134.0185

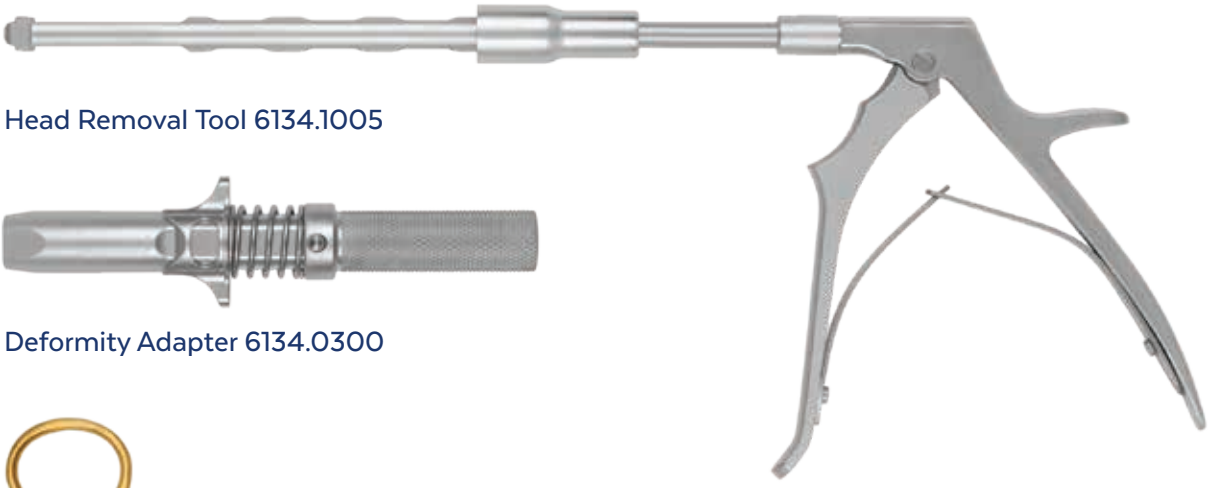
Compressor/Distractor Cuff 6134.0150

Stabilizer Cuff 6134.0155

Fixed Dissector 685.150

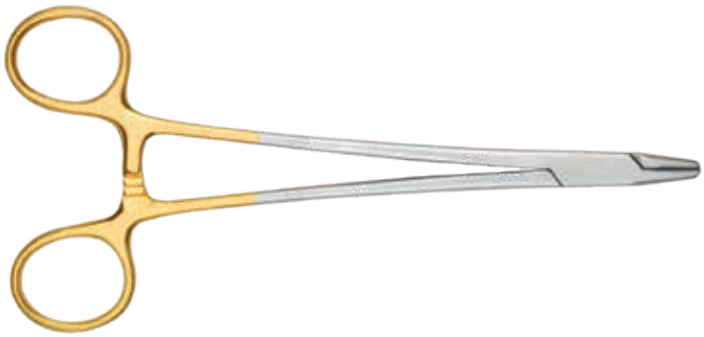
Tab Remover 6134.0160

ADDITIONAL INSTRUMENTS



Head Removal Tool 6134.1005

Deformity Adapter 6134.0300



K-Wire Gripper 623.003

Reduction Clip Driver 6119.3111

Rescue Sleeve 6134.0135

Reduction Fork 6120.2030

Power Bender 6067.0075

Driver Shaft, 1/4” Quick-Connect, Long 6067.0055

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

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

Torque-Limiting T-Handle, Ratcheting, 8.0Nm, 1/4” Connect, Black 634.611

SURGICAL TECHNIQUE

CREO MIS®

Please refer to the product information at the end of this technique manual for complete description, indications, contraindications, and warnings associated with this system.

STEP 1 APPROACH

The patient is placed under anesthesia and positioned prone. The operative area is carefully cleaned. Lateral C-arm fluoroscopy or other radiographic methods are required throughout surgery to ensure correct screw placement.

There are various techniques for pedicle screw and rod insertion. For the purposes of this surgical technique, a Wiltse paramedial approach and building of a three-level construct are shown.

STEP 2 SCREW INSERTION

Pedicle Access

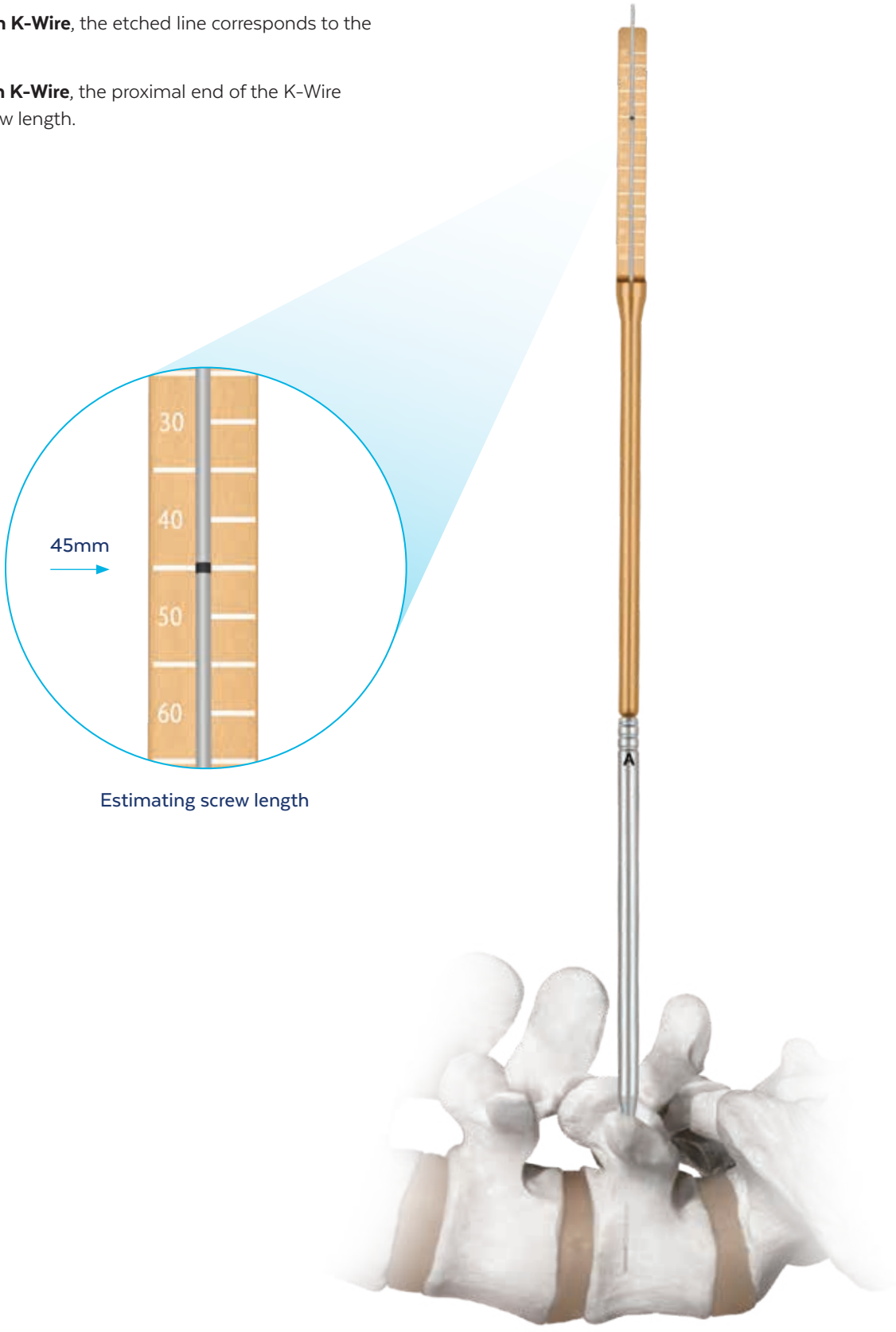
Using C-arm fluoroscopy or other radiographic methods, access the pedicle with a **Bone Access Needle, Trocar Tip, 8G**.

Remove the handle from the needle and insert a K-Wire. The **K-Wire Gripper** can be used to aid K-Wire insertion. Verify K-Wire position with fluoroscopy.

Create an incision around the K-Wire. Dilate the incision by placing **Cannula A** over the K-Wire. Locate the **Screw Measuring Instrument** on the proximal end of the cannula to approximate the length of pedicle screw needed.

If using the **500mm K-Wire**, the etched line corresponds to the length of screw.

If using the **450mm K-Wire**, the proximal end of the K-Wire corresponds to screw length.



Estimating screw length

SCREW INSERTION (CONT'D)

Tissue Dilation

Remove the Screw Measuring Instrument and progressively dilate the incision using **Cannula B**.

Remove the cannulas ensuring that the K-Wire does not become displaced as the cannulas are removed.

*Note: **PEEK Cannula C** is an over-dilator through which a CREO MIS® screw can be inserted. The cannula insulates the screw for neuromonitoring.*

Pedicle Preparation

CREO MIS® pedicle screws are self-tapping; however, pedicles may be tapped if desired. Attach the **Cannulated Tap** of the desired diameter to the **Straight Handle, Ratcheting, 1/4" Quick-Connect**. Tap the pedicle to the determined depth. All taps indicate screw length based on alignment with the proximal end of Cannula B.

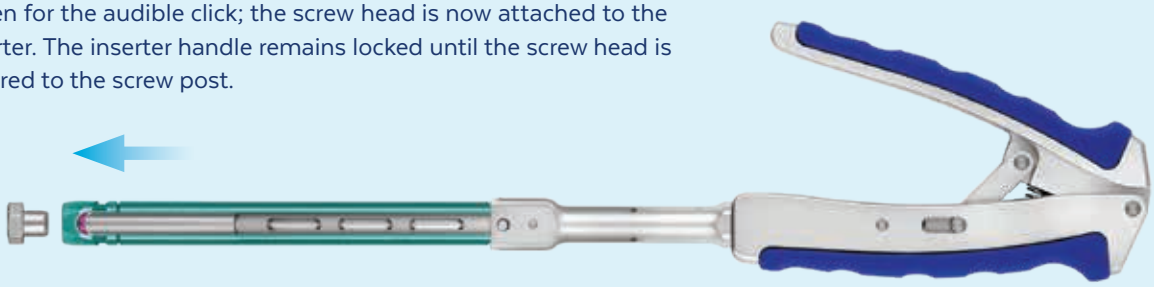
Note: Ensure the K-Wire does not advance while tapping.

Dilating incision

SCREW ASSEMBLY

Loading the Head Inserter

Align the flats on the **Head Inserter** with the open sides of the screw head. Lower the inserter directly onto the screw head and apply light pressure. Listen for the audible click; the screw head is now attached to the inserter. The inserter handle remains locked until the screw head is secured to the screw post.



Loading the Screw Post

Hold the inserter with the screw head attached over the selected screw post. Lower the screw head onto the screw post and apply axial force. Listen for the audible click; the screw head is now attached to the screw post. At this point, the screw head is not yet locked to the screw post.

To securely lock the screw head onto the screw post, compress the inserter handle. The screw head is now locked onto the screw post, creating an assembled screw. Release the inserter handle, pull the inserter upward, and rotate slightly to confirm the screw head is attached and has polyaxial motion. Engagement of the screw head to the screw post is confirmed through tactile feedback. The inserter does not detach at this point.

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

ENGAGE

Lowering screw head to top of screw post

COMPRESS

Screw head attached to screw post

RELEASE

Screw head locked to screw post; screw is fully assembled

SCREW INSERTION (CONT'D)

Exchanging Screw Head Style with Head Inserter

If the selected screw head loaded onto the Head Inserter needs to be exchanged for a different style, the Screw Head Unloader can be used to unload or load the instrument.

There are four silver pins located in the CREO MIS® Implant Case. Choose one of the pins and using the inserter, press the screw head over the silver pin until an audible click is heard. Lock and release the screw head onto the pin by compressing the inserter handle. Load the next implant onto the inserter as desired.

Use the **Head Removal Tool** to remove the screw head from the Screw Head Unloader.

Resetting/Unloading a Locked Screw Head

If a screw head does not attach to a screw post:

- The screw post may be inserted too far into the bone. Use a screwdriver to adjust the height, or clear the bone using the decortication tool.
- There may be bone or other material in the way. Remove this material.
- The screw head may already be locked. This can occur if the screw head placement is attempted too far off angle, or if projecting bone/material allows the Head Inserter handle to compress.

If the locked screw head is NOT in the inserter, DO NOT PUT IT BACK IN THE INSERTER.

Use the Head Removal Tool to unlock the screw head. Once unlocked, insert the screw head into the Head Inserter. Complete screw head application and locking to a screw post with the Head Inserter.

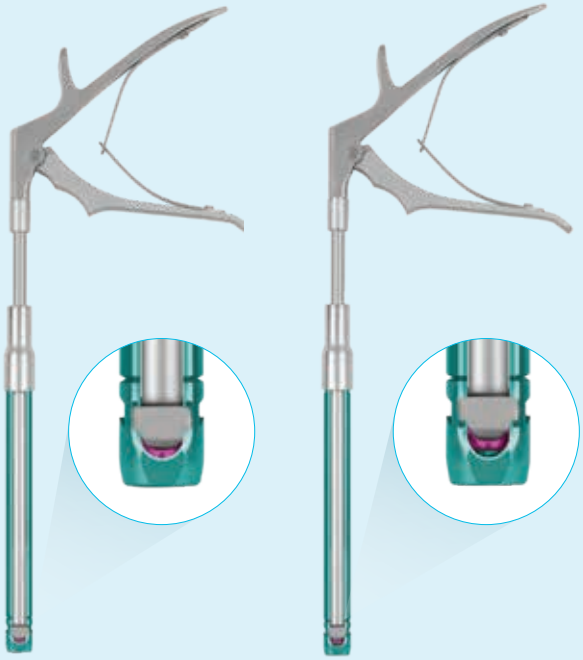
If the locked screw head is IN the inserter, use the silver pins located in the CREO MIS® Implant Set.

With the inserter handle open, place the screw head down over the pin and then compress the handle to release the LOCKED screw head. Use the Head Removal Tool to unlock the screw head. Complete screw head application and locking to a screw post with the Head Inserter.

USING A TOOL

Press on post | Compress to release

Note: Screw post located in CREO MIS® Implant Set 9134.9001



Locked screw head | Unlocked screw head

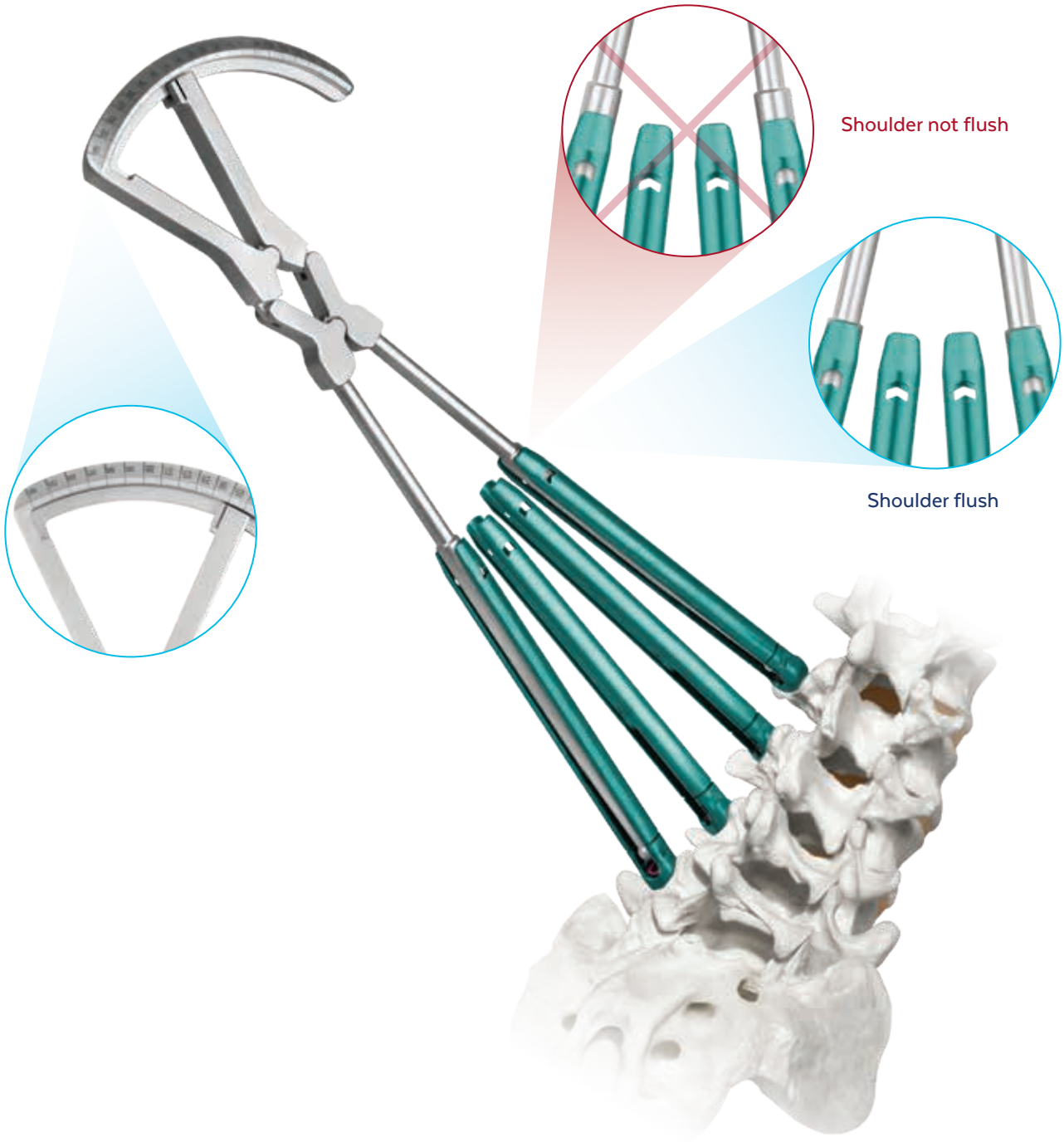
Drive the screw assembly over the K-Wire into the prepared pedicle using the screwdriver. Use fluoroscopy to monitor screw insertion and placement. Do not allow advancement of the K-Wire.

Once the screw reaches the posterior aspect of the vertebral body, the K-Wire can be removed. Advance the screw to the desired position. Disconnect the Screwdriver by pulling the lock back and rotating the knurled knob counterclockwise until the thread disengages from the sleeve.

STEP 3 ROD INSERTION

Rod Length Measurement

The **Calipers, Small** are used to determine rod length. Insert the caliper into the CREO MIS® screw head at either end of the construct, as shown below. This ensures the caliper is correctly seated in the screw head to give an accurate reading. The shoulder of the caliper must be flush with the top of the extended screw heads. The reading indicates the desired rod length. If the reading is between two numbers, the larger number should be used. Remove the calipers from the screw heads.



Muscle Dissection

Use the **Fixed Dissector** to facilitate rod insertion between adjacent screw sleeves. Verify advancement of the dissector using frequent fluoroscopy. If needed, a scalpel may be used through the sleeve to separate the fascia.

Facilitating rod insertion

ROD INSERTION (CONT'D)

Rod Introduction

Load the appropriate rod onto the **Fixed Rod Holder** as shown on the next page. Begin by orientating the rod parallel to the screw head with the tip of the rod in the first screw head.

Gently rock the Fixed Rod Holder back toward the handle to pass the rod into the second extended screw head. Verify rod position and advancement with fluoroscopy until fully seated.

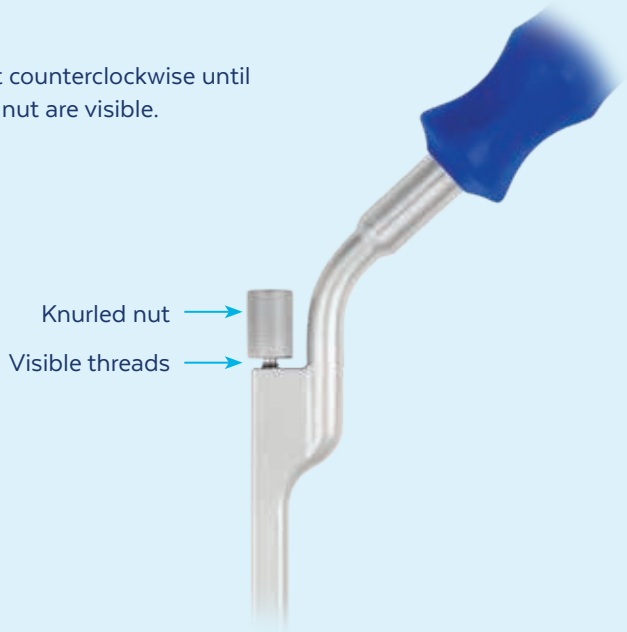
Note: The incision on the first sleeve may need to be extended to allow the Fixed Rod Holder to pass under the skin during final positioning.

Pass the rod through the remaining extended screw heads and verify with fluoroscopy that the rod is properly seated within the extended screw heads.

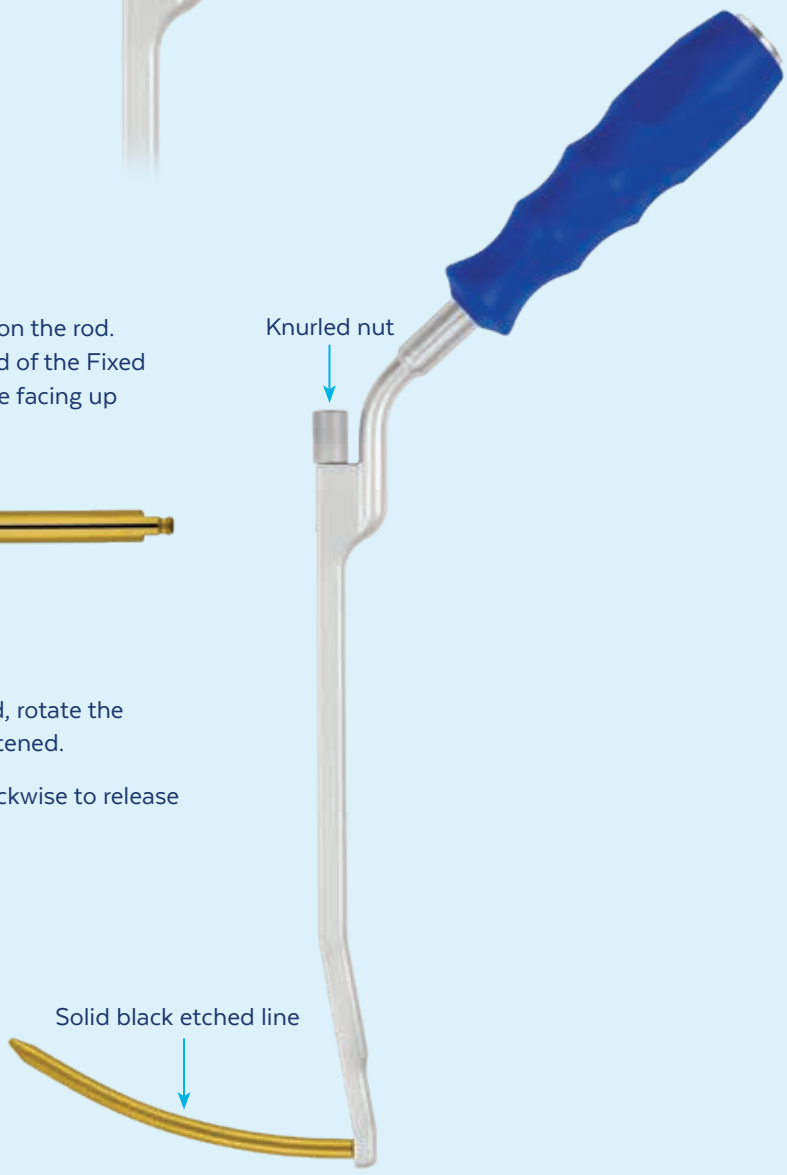
LOADING THE FIXED ROD HOLDER

Insert the rod into the Fixed Rod Holder with the solid black etched line facing up.

Step 1. Loosen the knurled nut counterclockwise until the threads under the knurled nut are visible.



Step 2. Locate the **solid** black etched line on the rod. Insert the rod into the slot at the distal end of the Fixed Rod Holder with the **solid** black etched line facing up toward the knurled nut.



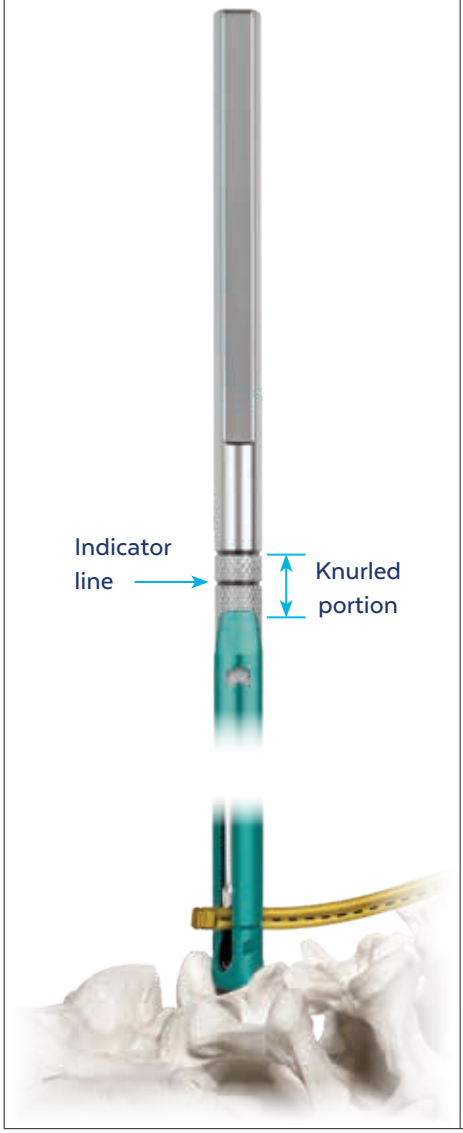
Step 3. Once the rod has been fully seated, rotate the knurled nut clockwise until two finger tightened.

Step 4. Rotate the knurled nut counterclockwise to release the rod from the Fixed Rod Holder.

STEP 4 ROD VERIFICATION

Use the **Rod Indicator** to verify rod location in the extended screw head. Introduce the indicator into each extended screw head, sequentially. The indicator rests on the rod and acts as a gauge for rod location.

Note: Rod placement may also be determined by visual confirmation.

YES	YES	NO
Knurled portion visible	Indicator line flush with extended screw head	No knurled portion visible
Rod located in extended screw head	Rod located in extended screw head	Rod not located in extended screw head
Rod reduction required	Rod seated in screw head	Rod re-introduction required
		

STEP 5 LOCKING CAP INSERTION

Loading the Locking Cap Driver

Place the **Stabilizer Cuff** over the screw head.

Placing Stabilizer Cuff

Push the **Locking Cap Driver** down over the locking cap until it clicks. The click indicates that the locking cap is retained by the driver.

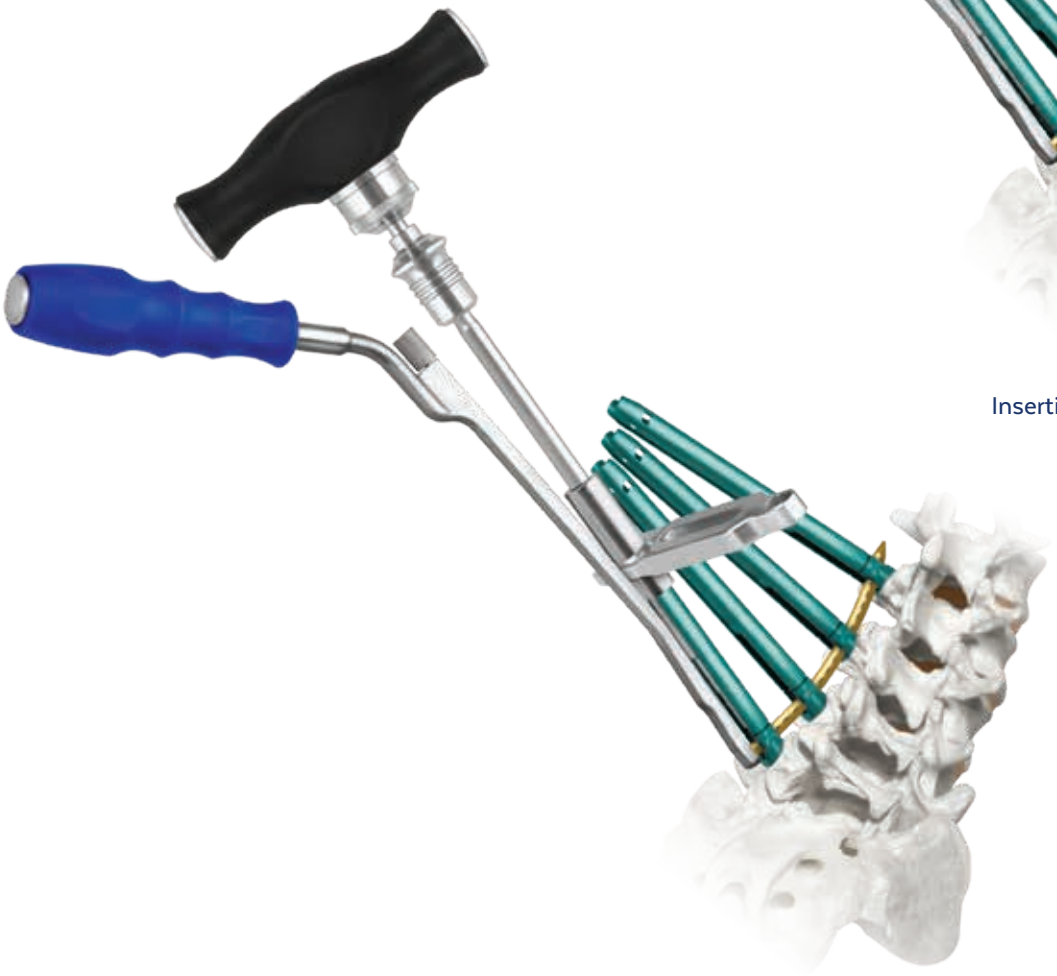
Loading driver

STEP 6 THREADED LOCKING CAP INSERTION/ ROD REDUCTION

Insert the loaded Locking Cap Driver into the screw head. Engage the threads on the locking cap with the screw head by rotating the driver clockwise. Rotate manually until resistance is met.

Place the **Counter-Torque** on the Stabilizer Cuff. Attach the **Ratcheting Torque-Limiting Handle, 1/4" Quick-Connect**. While holding the Counter-Torque, begin to thread the Locking Cap Driver down the screw head.

Inserting locking cap

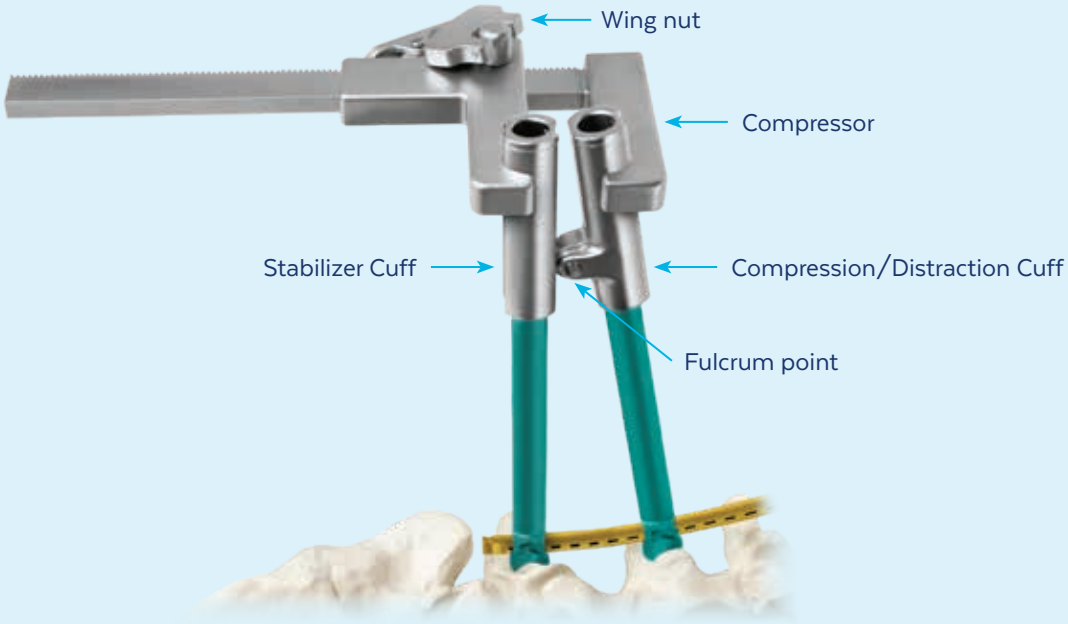


Reducing rod with Counter-Torque

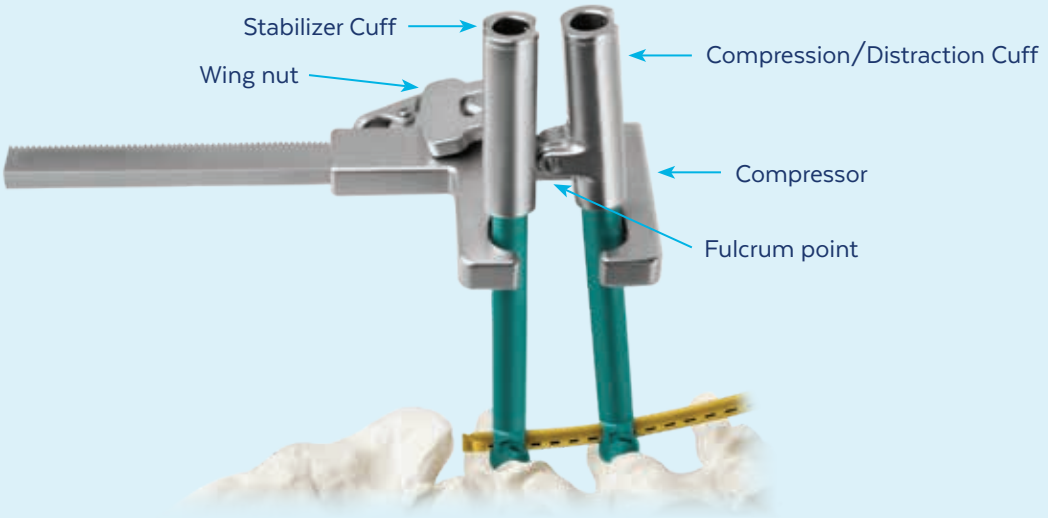
COMPRESSION OR DISTRACTION

If compression or distraction is needed, place the **Compression/Distraction Cuff** over the desired screw head.

To achieve distraction, place the **Compressor** around the two cuffs above the fulcrum point. Rotate the wing nut on the compressor until adequate distraction is achieved.



To achieve compression, place the Compressor around the two sleeves below the fulcrum point. Rotate the wing nut until adequate compression is achieved.



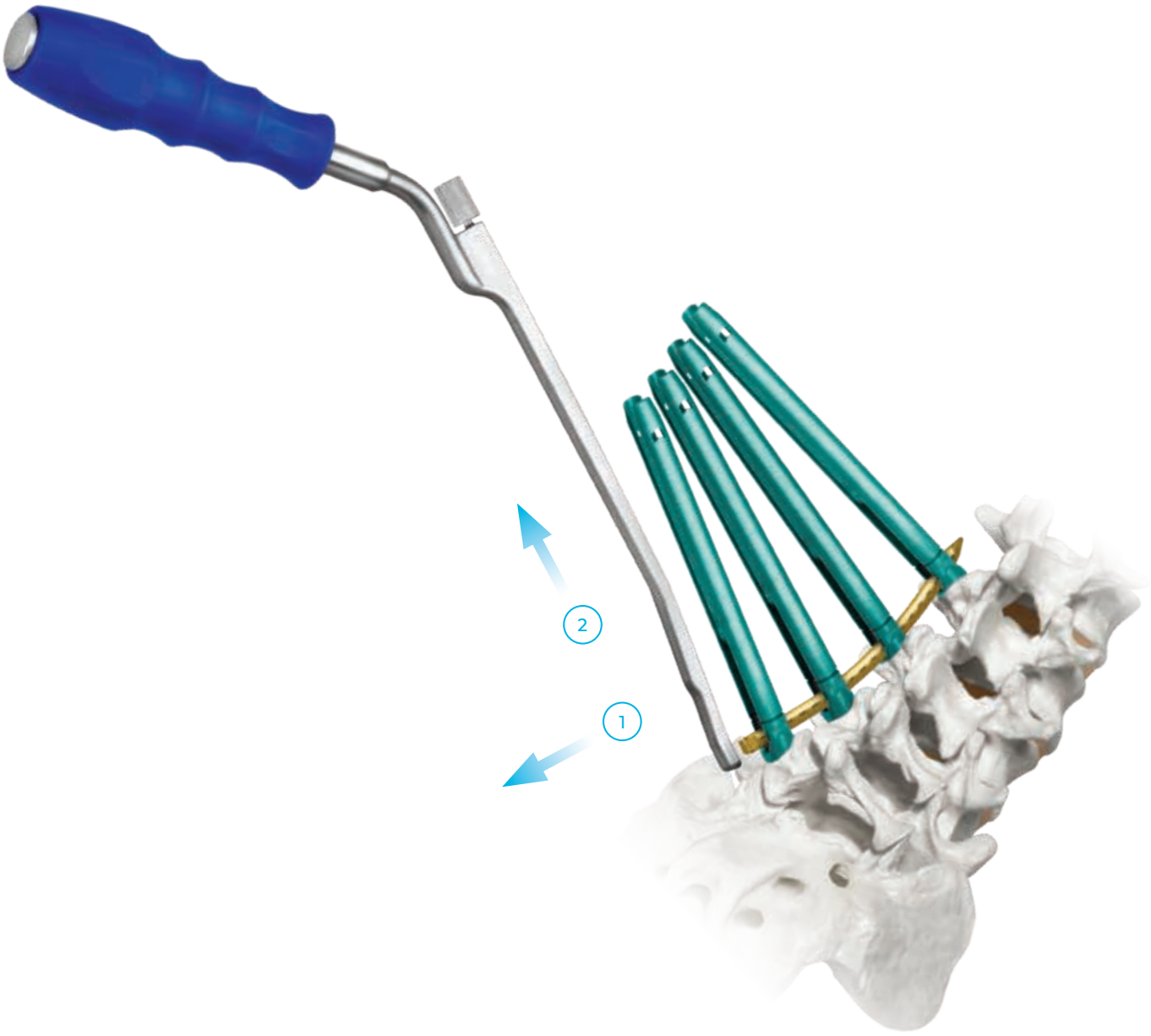
STEP 7 FINAL TIGHTENING

Final tightening of the set screw is necessary to secure the construct and is accomplished using the Locking Cap Driver and Counter-Torque.

Attach the Counter-Torque to the Stabilizer Cuff. Insert the **Driver Shaft, 1/4" Quick-Connect, Long** until it is engaged in the locking cap. Rotate the driver until it reaches the torque limit (8Nm).

STEP 8 ROD HOLDER EXTRACTION

After final tightening all set screws, release the Fixed Rod Holder. First, loosen the knurled nut counterclockwise. Second, gently retract the holder away from the sleeve to release the holder.

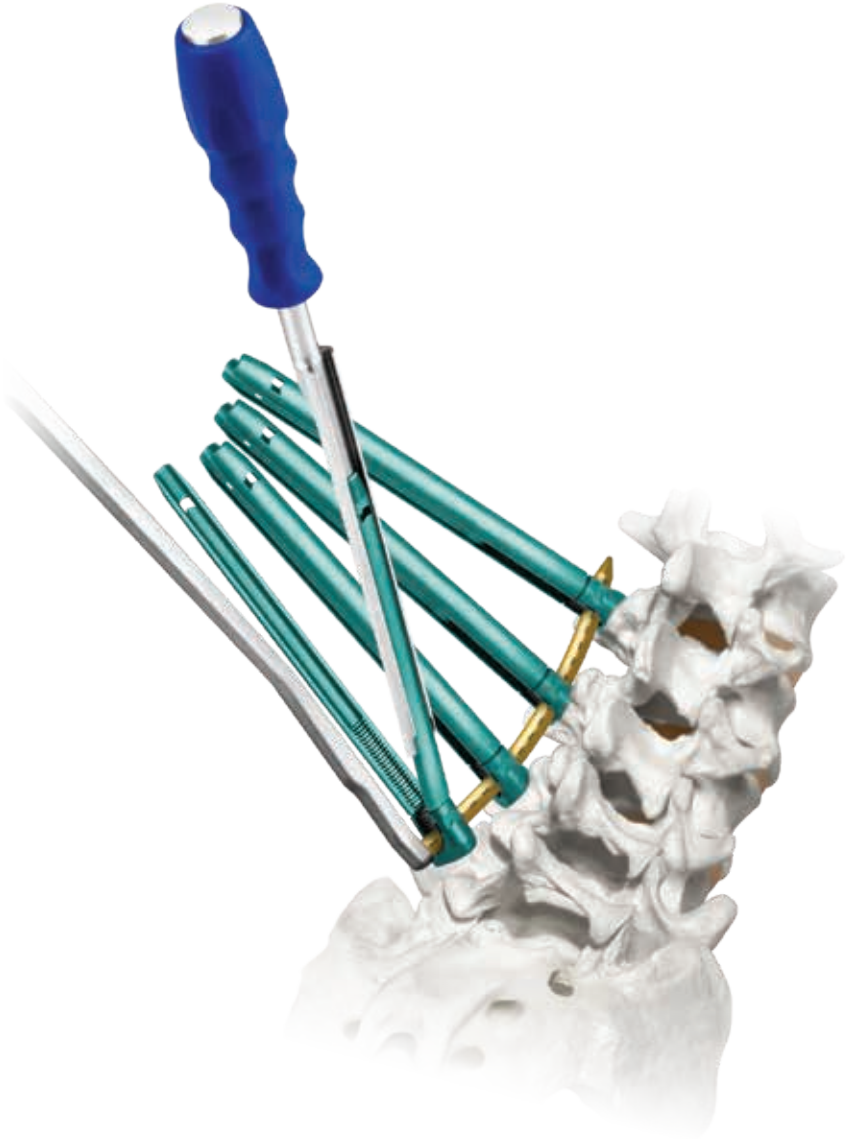


STEP 9 EXTENDED SCREW HEAD REMOVAL

Secure the **Tab Remover** onto the reduction tabs by placing the flat side on the inside of the screw head. Ensure the Tab Remover is fully seated and apply lateral force to break off one tab. Repeat this step to remove the remaining tabs.

Placing Tab Remover on screw head

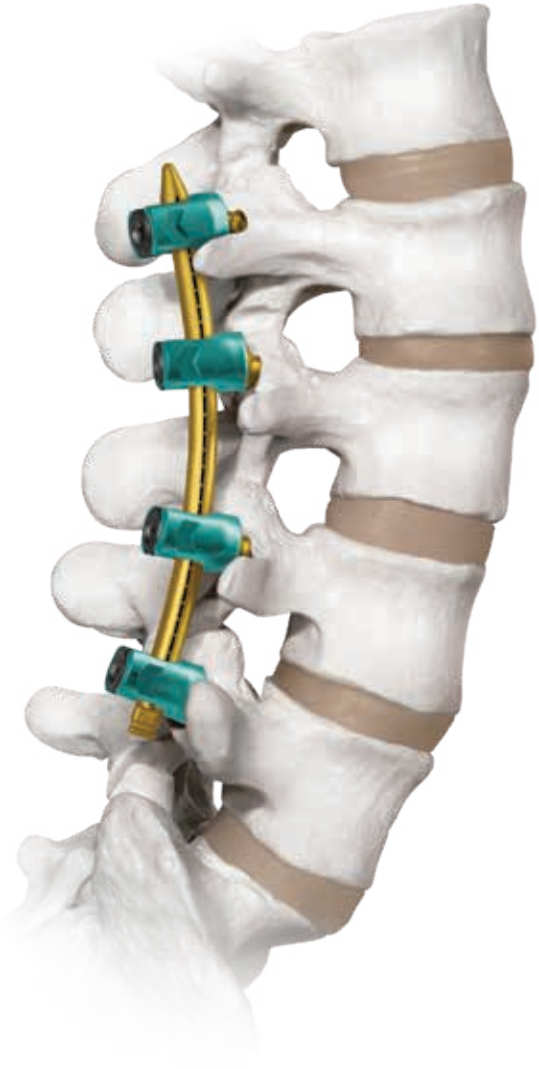
Tab Remover fully seated



Using Tab Remover

FINAL POSITION

AP view



Lateral view

OPTIONAL SURGICAL TECHNIQUE

CREO ONE™

Refer to the device insert for information on the indications, device description, contraindications, precautions, warnings, and potential risks associated with this system.

CREO ONE™ screws are self-tapping, awl-style tip screws. Pre-drilling of a pilot hole is required to break the cortex and avoid skiving. Pedicles may be additionally prepared with an awl and/or tap, if desired.

These screws may be used in conjunction with ExcelsiusGPS® and the Globus Power®, GPS High Speed Drill. Refer to the **ExcelsiusGPS® User Manual (GMUML01)** and **Globus Power®, GPS User Manual (GMUML04)** for system uses, indications, contraindications, warnings, and precautions.

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. Guided Instruments may be used manually or under power, with the Medtronic StealthStation® Navigation System. Refer to the **Guided Instruments Technique Guide (GMTGD158)** for detailed instructions. Select the "Medtronic Solera™" or "Medtronic Legacy™" screw system on the Medtronic StealthStation®.

STEP 1 PLANNING

Preoperative Planning

Radiographic evaluation, including standing AP and lateral films, may be completed prior to surgical intervention. Additional evaluations such as CT scans or MRI may be required. The screw layout may be planned prior to surgery. Interbody fusion techniques may be completed prior to or following screw insertion.

ExcelsiusGPS® Planning

Use the ExcelsiusGPS® system to load patient images and plan screw placement. Determine which screw type (CREO MIS® or CREO AMP®). For the Preoperative CT workflow, screws are planned before image acquisition. For the Intra-op CT or fluoroscopy workflow, screws are planned after image acquisition.

Refer to the **ExcelsiusGPS® User Manual**.

STEP 2 APPROACH

The patient is placed under anesthesia and positioned prone. The operative area is carefully cleaned. Lateral C-arm fluoroscopy or other radiographic methods are required throughout surgery to ensure correct screw placement.

There are various techniques for pedicle screw and rod insertion. For the purposes of this surgical technique, a Wiltse paramedial approach and building of a three-level construct are shown.

STEP 3 PATIENT REGISTRATION

Once the patient has been prepped, a patient attachment instrument is secured to rigid bony anatomy neighboring the surgical site. The Dynamic Reference Base (DRB) is attached to the patient attachment instrument. A surveillance marker is inserted into rigid bony anatomy to identify unwanted shifts in the DRB. Use the fluoroscopy registration fixture or Intra-op CT registration fixture to register the patient location relative to patient images.

Refer to the **ExcelsiusGPS® User Manual**.

STEP 4 INSTRUMENT PREPARATION

The High Speed Drill may be used through the ExcelsiusGPS® End Effector to create a pilot hole for the CREO ONE™ screws. The High Speed Drill is used under power and can ***only*** be used with ExcelsiusGPS®. Assemble the High Speed Drill, Array, and Array Sleeve.

Refer to the **Globus Power® Surgical Technique (GMTGD204)** for detailed instructions on assembling the High Speed Drill

Assemble and attach the drill assembly to the Globus Power Drill and slide a charged battery into the hand piece.

High Speed Drill

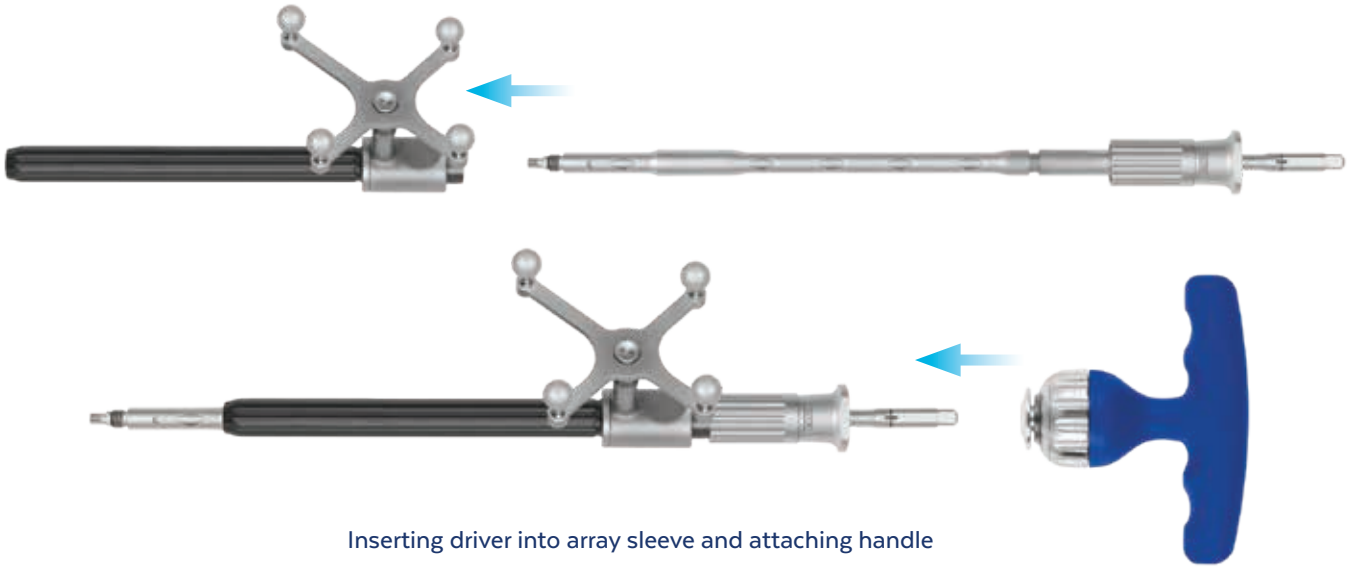
INSTRUMENT PREPARATION (CONT'D)

Determine which CREO MIS® or CREO AMP® screw heads will be attached to the CREO ONE™ screw shanks. Select the corresponding ExcelsiusGPS® driver as listed below. Identify the screw type and driver in the ExcelsiusGPS® software.

Screw Head	Driver
CREO MIS®	CREO MIS® Screwdriver, 10mm, GPS
	CREO MIS® Screwdriver, 30mm, GPS
	CREO MIS® Driver Outer Sleeve, 10mm, GPS & CREO MIS® Driver Shaft, GPS
	CREO MIS® Driver Outer Sleeve, 10mm, GPS & CREO MIS® Driver Shaft, GPS
CREO AMP®*	CREO AMP® Cannulated Modular Screwdriver, GPS*

*Refer to the **CREO AMP® Technique Guide (GMTGD104)**

ExcelsiusGPS® array sleeves are assembled to the selected driver for navigation and guidance. Press the release button on the array sleeve and insert the instrument shaft into the sleeve. Slide the shaft through the sleeve until it clicks into place. Gently pull up on the instrument shaft to confirm it is secured.



Inserting driver into array sleeve and attaching handle

STEP 5 INSTRUMENT VERIFICATION

The assembled driver and assembled High Speed Drill must be verified through the ExcelsiusGPS® system to ensure they have not been damaged during handling, cleaning, and sterilization. Refer to the **ExcelsiusGPS® User Manual** and the **Globus Power®, GPS User Manual** for detailed steps for instrument verification.

STEP 6 SCREW INSERTION

Pedicle Access

CREO ONE™ screws are self-tapping and have an awl-style tip. Pre-drilling a pilot hole is required to break the cortex and avoid skiving. Pedicles may be additionally prepared with an awl and/or tap, if desired. Perform instrument verification for any other desired instrument arrays as needed.

Ensure that all screw trajectories are planned in the ExcelsiusGPS® System and saved prior to drilling.

Set the hand piece to High Speed Mode by depressing the Mode Selector on the side displaying a drill.

Align the robotic arm on the selected trajectory. The screw plan is active when the screw label is highlighted and the robotic arm can be moved by the bracelet or pressing the foot pedal.

Once the robotic arm is aligned on the selected trajectory, insert the High Speed Drill into the End Effector, ensuring the array is facing the camera. Verify the High Speed Drill model is displayed in real time on the monitor.

Use the bottom trigger to advance the drill and use the top trigger to reverse the drill. Advance the drill through the End Effector. Remove by reversing the drill.

High Speed Drill in End Effector

Screw Insertion

Determine the desired screw diameter and length and screw head reduction option based on screw planning. Assemble the screw to screw head as directed by the Screw Assembly steps on pages 17 and 18. Attach the desired screw to the screwdriver.

If using CREO AMP® Cannulated Modular Screwdriver, GPS refer to the **CREO AMP® Technique Guide** for instructions on assembling the screw to screw head as directed by the Screw Assembly steps.

Insert the driver assembly through the End Effector, ensuring the array is facing the camera. Verify the driver model is displayed in real time on the monitor. Insert a CREO ONE™ pedicle screw into the pedicle.

Disconnect the screwdriver from the screw. Ensure the screw head is freely mobile and free of bone obstruction.

Repeat steps for additional screws. Insert the rod and locking cap as described in step 3-9 (pages 20-31) for construct assembly and final tightening.

Inserting CREO ONE™ Screw

CREO MIS®
IMPLANT SET 9134.9001

CREO® Cannulated Modular Screw

Part No.	Diameter/Length	Qty
1067.4325	4.5x25mm	–
1067.4330	4.5x30mm	–
1067.4335	4.5x35mm	–
1067.4340	4.5x40mm	–
1067.4345	4.5x45mm	–
1067.4350	4.5x50mm	–
1067.4355	4.5x55mm	–
1067.4425	5.0x25mm	–
1067.4430	5.0x30mm	–
1067.4435	5.0x35mm	–
1067.4440	5.0x40mm	–
1067.4445	5.0x45mm	–
1067.4450	5.0x50mm	–
1067.4455	5.0x55mm	–
1067.4525	5.5x25mm	–
1067.4530	5.5x30mm	–
1067.4535	5.5x35mm	2
1067.4540	5.5x40mm	2
1067.4545	5.5x45mm	2
1067.4550	5.5x50mm	2
1067.4555	5.5x55mm	–
1067.4625	6.5x25mm	–
1067.4630	6.5x30mm	–
1067.4635	6.5x35mm	6
1067.4640	6.5x40mm	8
1067.4645	6.5x45mm	8
1067.4650	6.5x50mm	4
1067.4655	6.5x55mm	2
1067.4660	6.5x60mm	2
1067.4665	6.5x65mm	–
1067.4670	6.5x70mm	–
1067.4675	6.5x75mm	–
1067.4680	6.5x80mm	–
1067.4685	6.5x85mm	–
1067.4690	6.5x90mm	–
1067.4695	6.5x95mm	–
1067.4610	6.5x100mm	–
1067.4611	6.5x110mm	–
1067.4612	6.5x120mm	–

CREO® Cannulated Modular Screw (Cont'd)

Part No.	Diameter/Length	Qty
1067.4720	7.5x20mm	–
1067.4725	7.5x25mm	–
1067.4730	7.5x30mm	–
1067.4735	7.5x35mm	4
1067.4740	7.5x40mm	6
1067.4745	7.5x45mm	6
1067.4750	7.5x50mm	4
1067.4755	7.5x55mm	2
1067.4760	7.5x60mm	2
1067.4765	7.5x65mm	–
1067.4820	8.5x20mm	–
1067.4825	8.5x25mm	–
1067.4830	8.5x30mm	–
1067.4835	8.5x35mm	–
1067.4840	8.5x40mm	–
1067.4845	8.5x45mm	–
1067.4850	8.5x50mm	–
1067.4855	8.5x55mm	–
1067.4860	8.5x60mm	–
1067.4865	8.5x65mm	–
1067.4940	9.5x40mm	–
1067.4945	9.5x45mm	–
1067.4950	9.5x50mm	–
1067.4955	9.5x55mm	–
1067.4960	9.5x60mm	–
1067.4965	9.5x65mm	–
1067.1040	10.5x40mm	–
1067.1045	10.5x45mm	–
1067.1050	10.5x50mm	–
1067.1055	10.5x55mm	–
1067.1060	10.5x60mm	–
1067.1065	10.5x65mm	–

**Items in gray are additionally available.*

5.5mm Curved Rod, Titanium Alloy

Part No.	Length	Qty
1134.7030	30mm	–
1134.7035	35mm	–
1134.7040	40mm	2
1134.7045	45mm	2
1134.7050	50mm	2
1134.7055	55mm	2
1134.7060	60mm	2
1134.7065	65mm	2
1134.7070	70mm	2
1134.7075	75mm	2
1134.7080	80mm	2
1134.7085	85mm	2
1134.7090	90mm	2
1134.7095	95mm	2
1134.7100	100mm	2
1134.7105	105mm	–
1134.7110	110mm	2
1134.7115	115mm	–
1134.7120	120mm	2
1134.7125	125mm	–
1134.7130	130mm	2
1134.7135	135mm	–
1134.7140	140mm	2
1134.7145	145mm	–
1134.7150	150mm	2

5.5mm Straight Rod, Titanium Alloy

Part No.	Length	Qty
1134.5030	30mm	–
1134.5035	35mm	–
1134.5040	40mm	2
1134.5045	45mm	2
1134.5050	50mm	2
1134.5055	55mm	2
1134.5060	60mm	2
1134.5065	65mm	2
1134.5070	70mm	2
1134.5075	75mm	2
1134.5080	80mm	2
1134.5085	85mm	2
1134.5090	90mm	2
1134.5095	95mm	2
1134.5100	100mm	2
1134.5105	105mm	–
1134.5110	110mm	2
1134.5115	115mm	–
1134.5120	120mm	2
1134.5125	125mm	–
1134.5130	130mm	2
1134.5135	135mm	–
1134.5140	140mm	2
1134.5145	145mm	–
1134.5150	150mm	2

5.5mm Straight Rod, Titanium Alloy (Cont'd)

Part No.	Length	Qty
1134.5160	160mm	2
1134.5170	170mm	–
1134.5180	180mm	2
1134.5190	190mm	–
1134.5200	200mm	2
1134.5210	210mm	–
1134.5220	220mm	–
1134.5230	230mm	–
1134.5240	240mm	–
1134.5250	250mm	2
1134.5260	260mm	–
1134.5270	270mm	–
1134.5280	280mm	–
1134.5290	290mm	–
1134.5300	300mm	2
1134.5350	350mm	–
1134.5400	400mm	–
1134.5450	450mm	–
1134.5500	500mm	–

Part No.	Description	Qty
1134.0010	CREO MIS® Locking Cap	20
1134.0100	CREO MIS® Modular Polyaxial Screw Head, 30mm	14
1134.0110	CREO MIS® Modular Polyaxial Screw Head, 10mm	6
6134.1000	Head Inserter	2
6134.1005	Head Removal Tool	1
9134.0001	CREO MIS® Implant Set Graphic Case	
9120.0610	CREO® Threaded Locking Cap Module	
9134.0610	CREO MIS® 5.5mm Titanium Straight and Curved Rod Module	

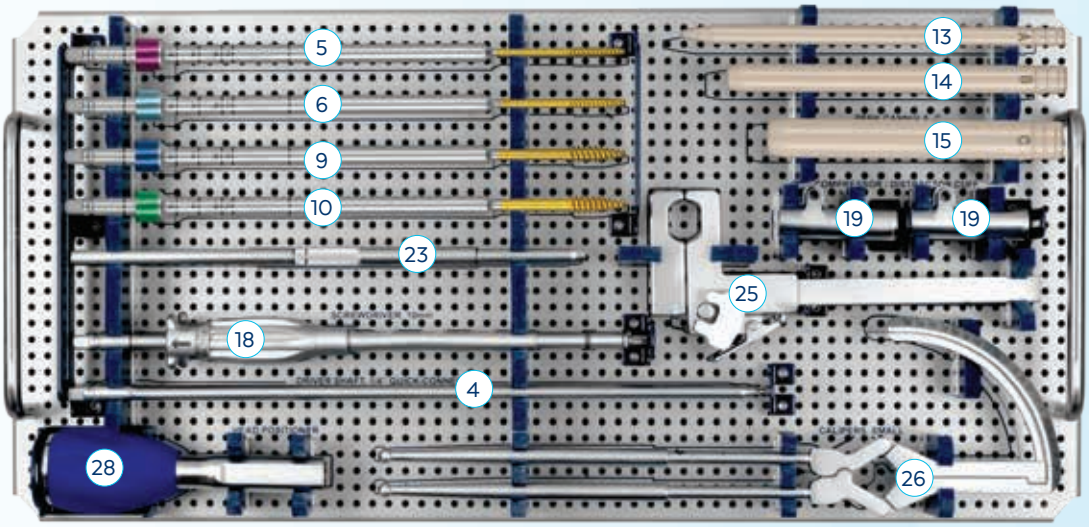
**Items in gray are additionally available.*

CREO MIS®
INSTRUMENT SET I 9134.9002

	Instruments		Qty
	623.050	Reamer	–
1	634.611	3.5mm Torque-Limiting Driver Ratcheting, 1/4" Connect, 8.0Nm	1
	685.003	1.6mm K-Wire, 450mm, Blunt Tip	–
	685.004	1.6mm K-Wire, 450mm, Sharp Tip	–
2	685.005	1.6mm K-Wire, 500mm, Blunt, Threaded Tip	12
	685.006	1.6mm K-Wire, 500mm, Sharp, Threaded Tip	–
	685.007	1.6mm Nitinol K-Wire, 500mm, Blunt	–
	685.008	1.6mm Nitinol K-Wire, 500mm, Sharp	–
3	6067.0010	Straight Handle, Ratcheting, 1/4" Quick-Connect	2
4	6067.0055	Driver Shaft, 1/4" Quick-Connect, Long	2
	6120.1025	Locking Cap Guide, Threaded	–
	6120.1030	Counter-Torque, Threaded	–
	6120.2010	Geared Reducer, Overhead, Threaded	–
5	6134.0045	4.5mm Cannulated Tap	1
6	6134.0050	5.0mm Cannulated Tap	1
7	6134.0055	5.5mm Cannulated Tap	1
8	6134.0065	6.5mm Cannulated Tap	1
9	6134.0075	7.5mm Cannulated Tap	1
10	6134.0085	8.5mm Cannulated Tap	1
11	6134.0100	Cannula A	1
12	6134.0101	Cannula B	1
13	6134.0110	Peek Cannula A	1
14	6134.0111	Peek Cannula B	1
15	6134.0112	Peek Cannula C	1
16	6134.0130	Screw Measuring Instrument	1
17	6134.0140	Screwdriver, 30mm	2
18	6134.0145	Screwdriver, 10mm	2
	6134.1440	Screwdriver, GI-I, 30mm	–
	6134.1445	Screwdriver GI-I, 10mm	–
19	6134.0150	Compressor/Distractor Cuff	2
	6134.0151	Locking Stabilizer Cuff	–

	Instruments		Qty
20	6134.0155	Stabilizer Cuff	6
	6134.0157	Long Stabilizer Cuff	–
21	6134.0160	Tab Remover	1
22	6134.0185	Locking Cap Driver	4
23	6134.0205	Rod Indicator	1
24	6134.0220	Counter-Torque	1
25	6134.0400	Compressor	1
26	6134.0420	Calipers, Small	1
	6134.0421	Calipers, Large	–
27	6134.0430	Fixed Rod Holder	1
	6134.0431	Fixed Rod Holder, Straight	–
	6134.0432	Fixed Rod Holder, Reverse Angle	–
28	6134.0435	Head Positioner	1
	685.027S	Bone Access Needle, Trocar Tip, 8G	6
	685.028S	Bone Access Needle, Bevel Tip, 8G	–
	685.030S	Bone Access Needle, Trocar Tip, 11G	–
	685.031S	Bone Access Needle, Bevel Tip, 11G	–
	9134.0002	CREO MIS® Instruments I Graphic Case	

*Items in gray are additionally available.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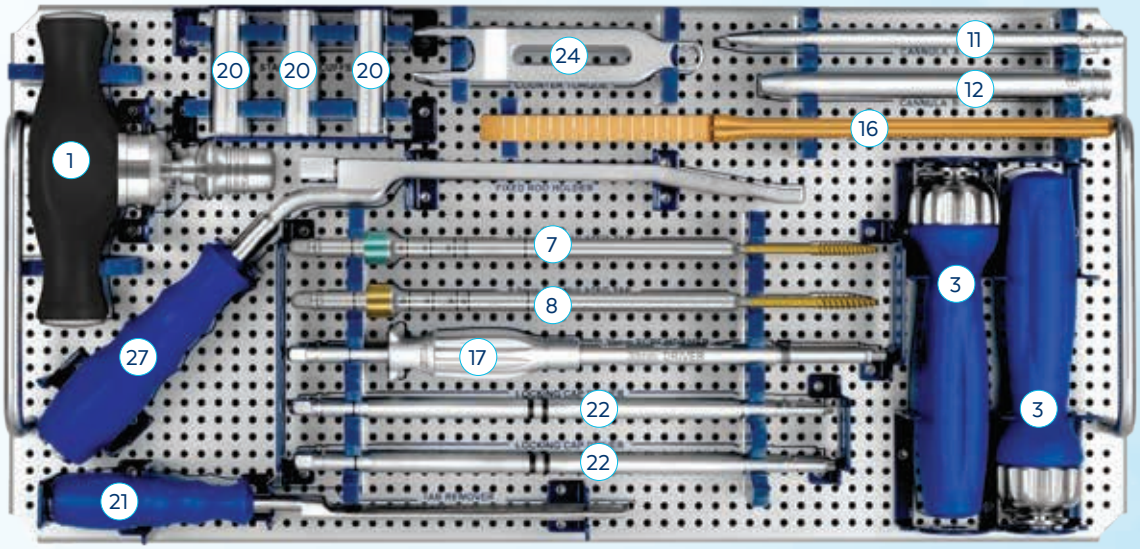
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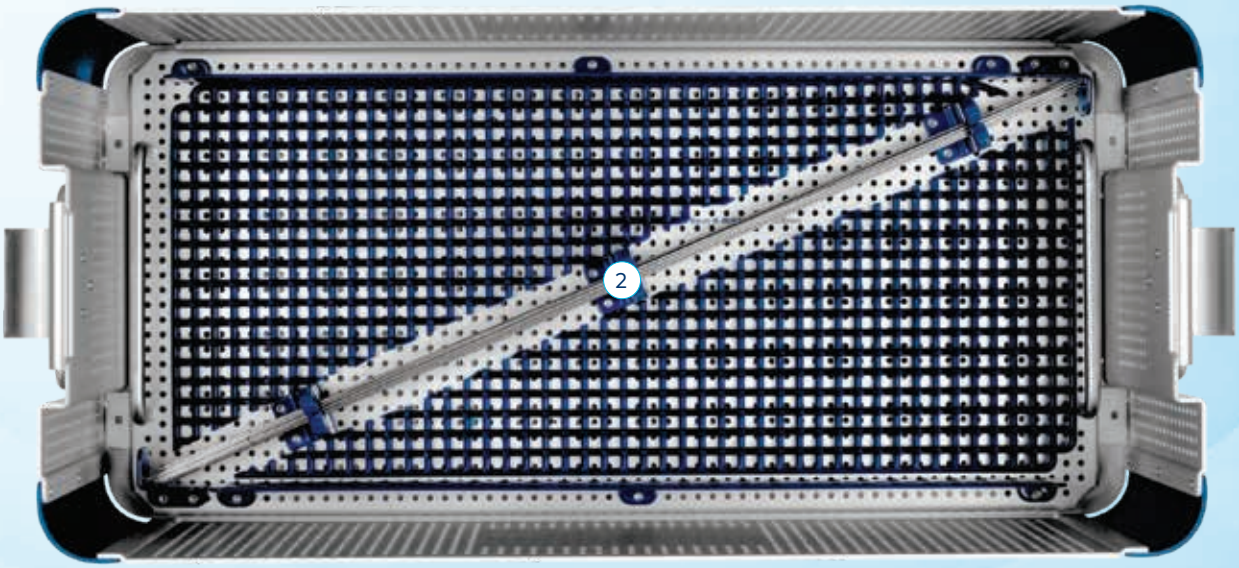
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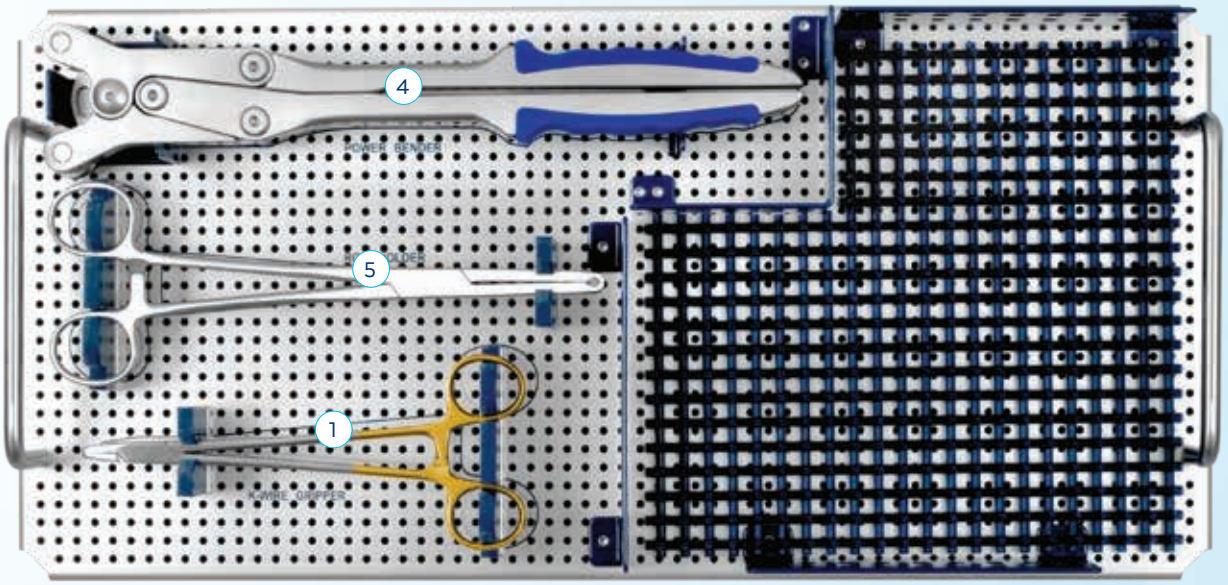
CREO MIS®
INSTRUMENT SET II 9134.9003

	Instrument		Qty
1	623.003	K-Wire Gripper	1
2	685.150	Fixed Dissector	1
3	6067.0020	T-Handle, Ratcheting, 1/4” Quick-Connect	1
4	6067.0075	Power Bender	1
5	6067.0080	Rod Holder, Forcep style	1
6	6119.3111	Reduction Clip Driver	1
7	6120.2030	Reduction Fork	1
8	6134.0135	Rescue Sleeve	3
9	6134.0430	Fixed Rod Holder	1
	9134.0003	CREO MIS® Instruments II Graphic Case	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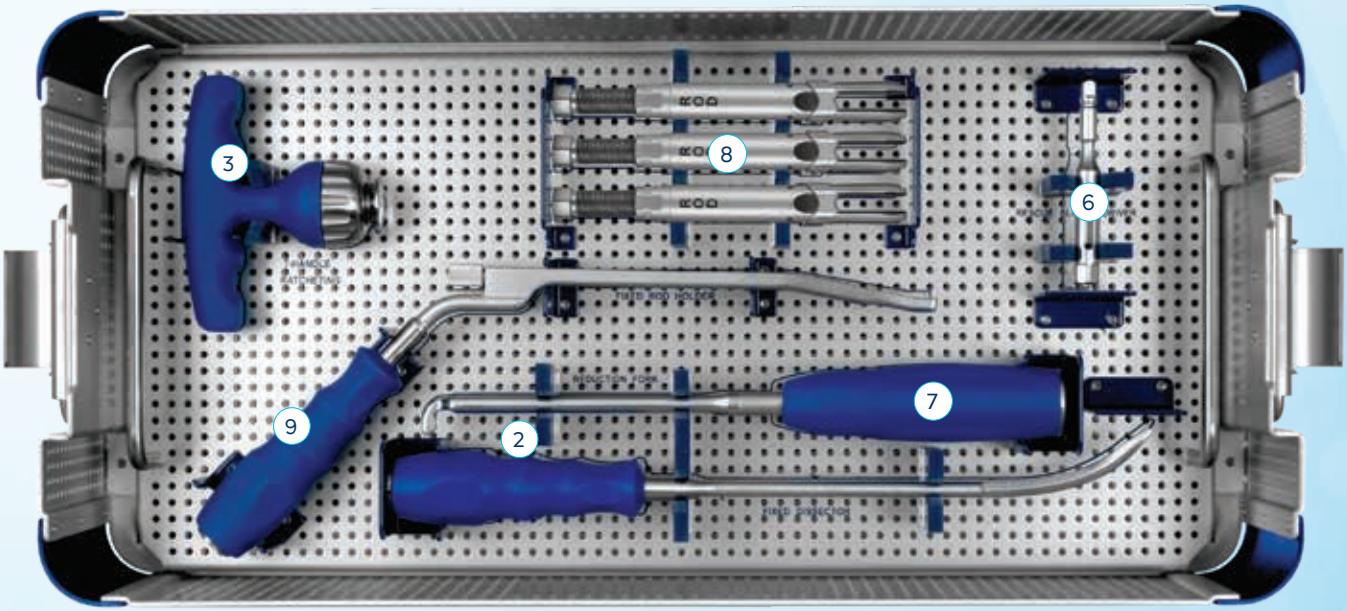
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CREO MIS®
ADDITIONAL RODS SET 9134.9004

5.5mm Straight Rod, Cobalt Chrome

Part No.	Description	Qty
7134.5040	40mm	2
7134.5045	45mm	2
7134.5050	50mm	2
7134.5055	55mm	2
7134.5060	60mm	2
7134.5065	65mm	2
7134.5070	70mm	2
7134.5075	75mm	2
7134.5080	80mm	2
7134.5085	85mm	2
7134.5090	90mm	2
7134.5095	95mm	2
7134.5100	100mm	2
7134.5105	105mm	-
7134.5110	110mm	2
7134.5115	115mm	-
7134.5120	120mm	2
7134.5125	125mm	-
7134.5130	130mm	2
7134.5135	135mm	-
7134.5140	140mm	2
7134.5145	145mm	-
7134.5150	150mm	2

5.5mm Curved Rod, Cobalt Chrome

Part No.	Description	Qty
7134.7040	40mm	2
7134.7045	45mm	2
7134.7050	50mm	2
7134.7055	55mm	2
7134.7060	60mm	2
7134.7065	65mm	2
7134.7070	70mm	2
7134.7075	75mm	2
7134.7080	80mm	2
7134.7085	85mm	2
7134.7090	90mm	2
7134.7095	95mm	2
7134.7100	100mm	2
7134.7105	105mm	-
7134.7110	110mm	2
7134.7115	115mm	-
7134.7120	120mm	2
7134.7125	125mm	-
7134.7130	130mm	2
7134.7135	135mm	-
7134.7140	140mm	2
7134.7145	145mm	-
7134.7150	150mm	2

**Items in gray are additionally available.*

6.0mm Straight Rod, Titanium Alloy

Part No.	Description	Qty
1134.6040	40mm	2
1134.6045	45mm	2
1134.6050	50mm	2
1134.6055	55mm	2
1134.6060	60mm	2
1134.6065	65mm	2
1134.6070	70mm	2
1134.6075	75mm	2
1134.6080	80mm	2
1134.6085	85mm	2
1134.6090	90mm	2
1134.6095	95mm	2
1134.6100	100mm	2
1134.6105	105mm	–
1134.6110	110mm	2
1134.6115	115mm	–
1134.6120	120mm	2
1134.6125	125mm	–
1134.6130	130mm	2
1134.6135	135mm	–
1134.6140	140mm	2
1134.6145	145mm	–
1134.6150	150mm	2

6.0mm Curved Rod, Titanium Alloy

Part No.	Description	Qty
1134.8040	40mm	2
1134.8045	45mm	2
1134.8050	50mm	2
1134.8055	55mm	2
1134.8060	60mm	2
1134.8065	65mm	2
1134.8070	70mm	2
1134.8075	75mm	2
1134.8080	80mm	2
1134.8085	85mm	2
1134.8090	90mm	2
1134.8095	95mm	2
1134.8100	100mm	2
1134.8105	105mm	–
1134.8110	110mm	2
1134.8115	115mm	–
1134.8120	120mm	2
1134.8125	125mm	–
1134.8130	130mm	2
1134.8135	135mm	–
1134.8140	140mm	2
1134.8145	145mm	–
1134.8150	150mm	2

**Items in gray are additionally available.*

CREO MIS®
ADDITIONAL RODS SET 9134.9004 (CONT'D)

6.0mm Straight Rod, Cobalt Chrome

Part No.	Length	Qty
7134.6040	40mm	2
7134.6045	45mm	2
7134.6050	50mm	2
7134.6055	55mm	2
7134.6060	60mm	2
7134.6065	65mm	2
7134.6070	70mm	2
7134.6075	75mm	2
7134.6080	80mm	2
7134.6085	85mm	2
7134.6090	90mm	2
7134.6095	95mm	2
7134.6100	100mm	2
7134.6105	105mm	–
7134.6110	110mm	2
7134.6115	115mm	–
7134.6120	120mm	2
7134.6125	125mm	–
7134.6130	130mm	2
7134.6135	135mm	–
7134.6140	140mm	2
7134.6145	145mm	–
7134.6150	150mm	2

6.0mm Curved Rod, Cobalt Chrome

Part No.	Length	Qty
7134.8040	40mm	2
7134.8045	45mm	2
7134.8050	50mm	2
7134.8055	55mm	2
7134.8060	60mm	2
7134.8065	65mm	2
7134.8070	70mm	2
7134.8075	75mm	2
7134.8080	80mm	2
7134.8085	85mm	2
7134.8090	90mm	2
7134.8095	95mm	2
7134.8100	100mm	2
7134.8105	105mm	–
7134.8110	110mm	2
7134.8115	115mm	–
7134.8120	120mm	2
7134.8125	125mm	–
7134.8130	130mm	2
7134.8135	135mm	–
7134.8140	140mm	2
7134.8145	145mm	–
7134.8150	150mm	2

Part No.	Description
9134.0004	CREO MIS® Additional Rods Graphic Case
9134.0710	CREO MIS® 5.5mm CoCr Straight & Curved Rod Module
9134.0810	CREO MIS® 6.0mm Titanium Straight & Curved Rod Module
9134.0910	CREO MIS® 6.0mm CoCr Straight & Curved Rod Module

**Items in gray are additionally available.*

CREO MIS®
CORRECTION SET 9134.9005

6.0mm Straight Rod, Titanium Alloy

Part No.	Length	Qty
1134.6040	40mm	2
1134.6045	45mm	2
1134.6050	50mm	2
1134.6055	55mm	2
1134.6060	60mm	2
1134.6065	65mm	2
1134.6070	70mm	2
1134.6075	75mm	2
1134.6080	80mm	2
1134.6085	85mm	2
1134.6090	90mm	2
1134.6095	95mm	2
1134.6100	100mm	2
1134.6105	105mm	–
1134.6110	110mm	2
1134.6115	115mm	–
1134.6120	120mm	2
1134.6125	125mm	–
1134.6130	130mm	2
1134.6135	135mm	–
1134.6140	140mm	2
1134.6145	145mm	–
1134.6150	150mm	2

6.0mm Straight Rod, Cobalt Chrome

Part No.	Length	Qty
1134.8040	40mm	2
1134.8045	45mm	2
1134.8050	50mm	2
1134.8055	55mm	2
1134.8060	60mm	2
1134.8065	65mm	2
1134.8070	70mm	2
1134.8075	75mm	2
1134.8080	80mm	2
1134.8085	85mm	2
1134.8090	90mm	2
1134.8095	95mm	2
1134.8100	100mm	2
1134.8105	105mm	–
1134.8110	110mm	2
1134.8115	115mm	–
1134.8120	120mm	2
1134.8125	125mm	–
1134.8130	130mm	2
1134.8135	135mm	–
1134.8140	140mm	2
1134.8145	145mm	–
1134.8150	150mm	2

5.5mm Straight Rod, Cobalt Chrome

Part No.	Length	Qty
7134.5160	160mm	2
7134.5170	170mm	–
7134.5180	180mm	2
7134.5190	190mm	–
7134.5200	200mm	2
7134.5210	210mm	–
7134.5220	220mm	–
7134.5230	230mm	–
7134.5240	240mm	–
7134.5250	250mm	2
7134.5260	260mm	–
7134.5270	270mm	–
7134.5280	280mm	–
7134.5290	290mm	–
7134.5300	300mm	2
7134.5350	350mm	–
7134.5400	400mm	–
7134.5450	450mm	–
7134.5500	500mm	–

Part No.	Description	Qty
6134.0300	Deformity Adapter	8
9134.0005	CREO MIS® Correction Graphic Case	

**Items in gray are additionally available.*

CREO MIS®
ILIAC IMPLANTS AND INSTRUMENTS SET 9134.9008

CREO AMP® Modular Cannulated Screw

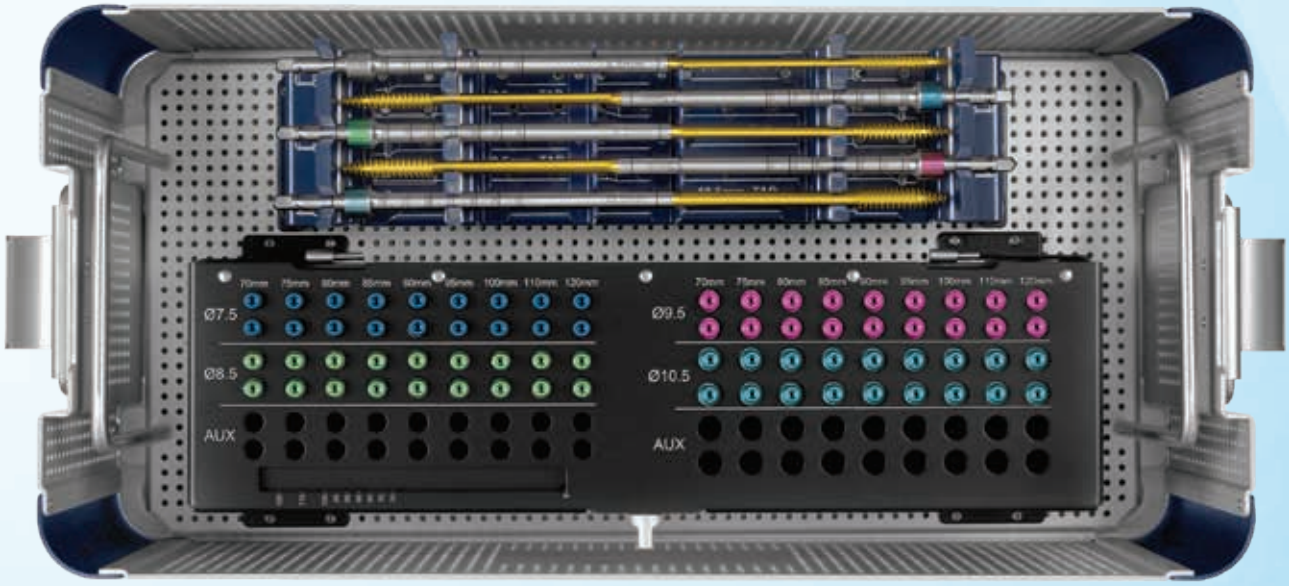
Part No.	Description	Qty
1067.4110	10.5x100mm	2
1067.4111	10.5x110mm	2
1067.4112	10.5x120mm	2
1067.4170	10.5x70mm	2
1067.4175	10.5x75mm	2
1067.4180	10.5x80mm	2
1067.4185	10.5x85mm	2
1067.4190	10.5x90mm	2
1067.4195	10.5x95mm	2
1067.4710	7.5x100mm	2
1067.4711	7.5x110mm	2
1067.4712	7.5x120mm	2
1067.4770	7.5x70mm	2
1067.4775	7.5x75mm	2
1067.4780	7.5x80mm	2
1067.4785	7.5x85mm	2
1067.4790	7.5x90mm	2
1067.4795	7.5x95mm	2

CREO AMP® Modular Cannulated Screw (Cont'd)

Part No.	Description	Qty
1067.4810	8.5x100mm	2
1067.4811	8.5x110mm	2
1067.4812	8.5x120mm	2
1067.4870	8.5x70mm	2
1067.4875	8.5x75mm	2
1067.4880	8.5x80mm	2
1067.4885	8.5x85mm	2
1067.4890	8.5x90mm	2
1067.4895	8.5x95mm	2
1067.4910	9.5x100mm	2
1067.4911	9.5x110mm	2
1067.4912	9.5x120mm	2
1067.4970	9.5x70mm	2
1067.4975	9.5x75mm	2
1067.4980	9.5x80mm	2
1067.4985	9.5x85mm	2
1067.4990	9.5x90mm	2
1067.4995	9.5x95mm	2

Part No.	Description	Qty
6134.8065	6.5mm Cannulated Iliac Tap	1
6134.8075	7.5mm Cannulated Iliac Tap	1
6134.8085	8.5mm Cannulated Iliac Tap	1
6134.8095	9.5mm Cannulated Iliac Tap	1
6134.8105	10.5mm Cannulated Iliac Tap	1

Part No.	Description
9134.0008	CREO MIS® Iliac Implants and Instruments Graphic Case
9134.0108	CREO MIS® Iliac Screw Module



CREO MIS®
HA COATED SCREW SET 9134.9009

CREO AMP® HA Coated Modular Cannulated Screw

Part No.	Description	Qty
1067.4331S	4.5x30mm	2
1067.4336S	4.5x35mm	4
1067.4341S	4.5x40mm	4
1067.4346S	4.5x45mm	4
1067.4431S	5.0x30mm	2
1067.4436S	5.0x35mm	4
1067.4441S	5.0x40mm	4
1067.4446S	5.0x45mm	4
1067.4531S	5.5x30mm	4
1067.4536S	5.5x35mm	4
1067.4541S	5.5x40mm	6
1067.4546S	5.5x45mm	6
1067.4551S	5.5x50mm	4
1067.4556S	5.5x55mm	4
1067.4631S	6.5x30mm	4
1067.4636S	6.5x35mm	4
1067.4641S	6.5x40mm	6
1067.4646S	6.5x45mm	6
1067.4651S	6.5x50mm	4
1067.4656S	6.5x55mm	4

CREO AMP® HA Coated Modular Cannulated Screw (Cont'd)

Part No.	Description	Qty
1067.4661S	6.5x60mm	-
1067.4666S	6.5x65mm	-
1067.4731S	7.5x30mm	2
1067.4736S	7.5x35mm	4
1067.4741S	7.5x40mm	6
1067.4746S	7.5x45mm	6
1067.4751S	7.5x50mm	4
1067.4756S	7.5x55mm	4
1067.4761S	7.5x60mm	-
1067.4766S	7.5x65mm	-
1067.4831S	8.5x30mm	-
1067.4836S	8.5x35mm	-
1067.4841S	8.5x40mm	-
1067.4846S	8.5x45mm	-
1067.4851S	8.5x50mm	-
1067.4856S	8.5x55mm	-
1067.4861S	8.5x60mm	-
1067.4866S	8.5x65mm	-

Part No.	Description
9134.0009	CREO MIS® HA Coated Screw Soft Case

**Items in gray are additionally available.*

CREO MIS®
SMALL DIAMETER SCREW MODULE SET 9134.9010

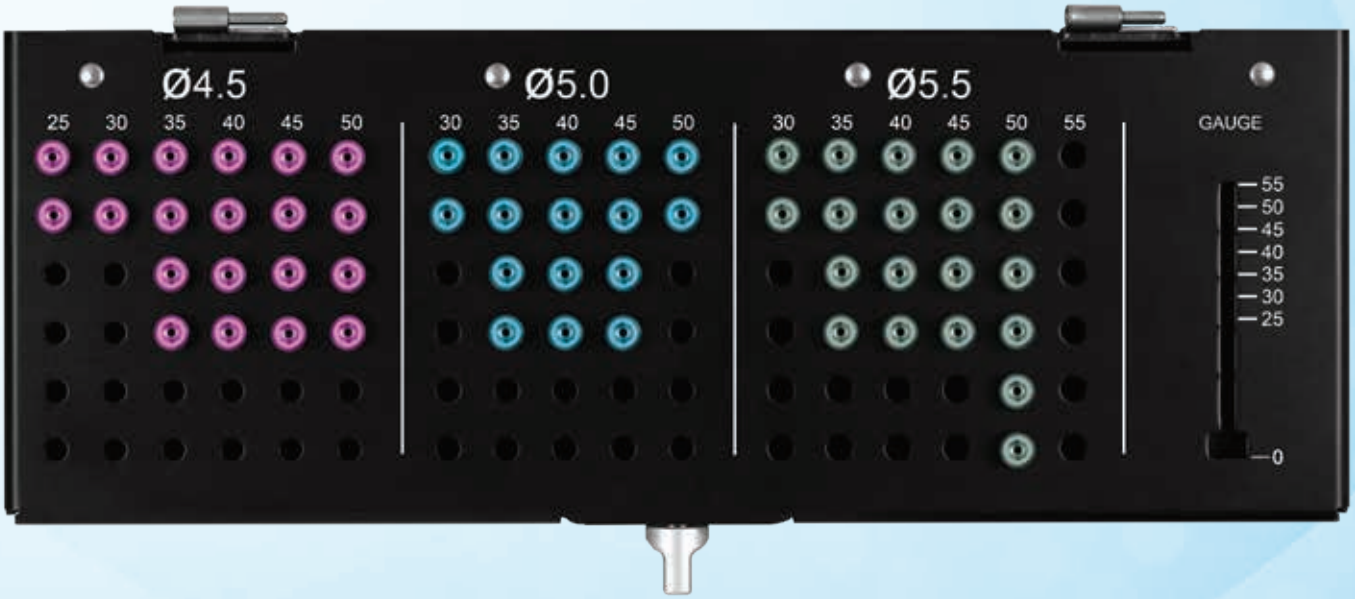
CREO AMP® Modular Cannulated Screw

Part No.	Description	Qty
1067.4320	4.5x20mm	–
1067.4325	4.5x25mm	2
1067.4330	4.5x30mm	2
1067.4335	4.5x35mm	4
1067.4340	4.5x40mm	4
1067.4345	4.5x45mm	4
1067.4350	4.5x50mm	4
1067.4420	5.0x20mm	–
1067.4425	5.0x25mm	–
1067.4430	5.0x30mm	2
1067.4435	5.0x35mm	4
1067.4440	5.0x40mm	4
1067.4445	5.0x45mm	4

CREO AMP® Modular Cannulated Screw (Cont'd)

Part No.	Description	Qty
1067.4450	5.0x50mm	2
1067.4520	5.5x20mm	–
1067.4525	5.5x25mm	–
1067.4530	5.5x30mm	2
1067.4535	5.5x35mm	4
1067.4540	5.5x40mm	4
1067.4545	5.5x45mm	4
1067.455	5.5x50mm	4
1067.4555	5.5x55mm	2

Part No.	Description
9134.0010	CREO MIS® Small Diameter Screw Module



*Items in gray are additionally available.

CREO MIS®
LARGE DIAMETER SCREW SET 9134.9011

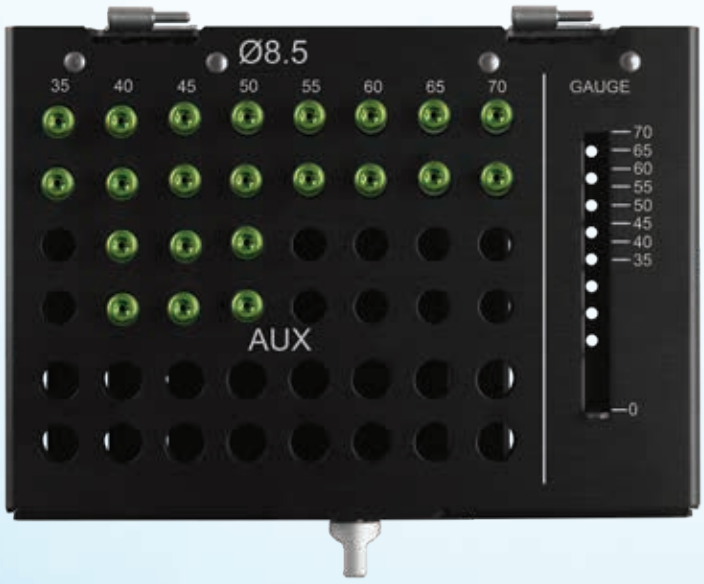
CREO AMP® Modular Cannulated Screw

Part No.	Description	Qty
1067.4140	10.5x40mm	–
1067.4145	10.5x45mm	–
1067.4150	10.5x50mm	–
1067.4155	10.5x55mm	–
1067.4160	10.5x60mm	–
1067.4165	10.5x65mm	–
1067.4170	10.5x70mm	–
1067.4835	8.5x35mm	2
1067.4840	8.5x40mm	4
1067.4845	8.5x45mm	4
1067.4850	8.5x50mm	4
1067.4855	8.5x55mm	2
1067.4860	8.5x60mm	2

CREO AMP® Modular Cannulated Screw (Cont'd)

Part No.	Description	Qty
1067.4865	8.5x65mm	2
1067.4870	8.5x70mm	2
1067.4940	9.5x40mm	–
1067.4945	9.5x45mm	–
1067.4950	9.5x50mm	–
1067.4955	9.5x55mm	–
1067.4960	9.5x60mm	–
1067.4965	9.5x65mm	–
1067.4970	9.5x70mm	–

Part No.	Description
9134.0011	CREO MIS® Large Diameter Screw Module



*Items in gray are additionally available.

CREO ONE™
ROBOTIC SCREW MODULE SET 9134.9017

CREO ONE™ Robotic Screw Module Set

Part No.	Description	Qty
1134.1535	5.5x35mm	4
1134.1540	5.5x40mm	4
1134.1545	5.5x45mm	4
1134.1550	5.5x50mm	4
1134.1635	6.5x35mm	8
1134.1640	6.5x40mm	8
1134.1645	6.5x45mm	8
1134.1650	6.5x50mm	8
1134.1655	6.5x55mm	4

CREO ONE™ Robotic Screw Module Set (Cont'd)

Part No.	Description	Qty
1134.1735	7.5x35mm	4
1134.1740	7.5x40mm	8
1134.1745	7.5x45mm	8
1134.1750	7.5x50mm	4
1134.1755	7.5x55mm	4

Part No.	Description
9134.0017	CREO ONE™ Robotic Screw Module

CREO ONE™
ORDERING GUIDE

For all techniques, order the following CREO MIS® Sets:

CREO MIS® Sets to Order

Set ID	Set Description
9134.9001	CREO MIS® Implant Set
9134.9002	CREO MIS® Instrument Set I
9134.9003	CREO MIS® Instrument Set II
9134.9017	CREO ONE™ Robotic Screw Module Set

For use with ExcelsiusGPS®, order the following, in addition to the CREO MIS® Sets listed above:

ExcelsiusGPS® Sets to Order

Set ID	Set Description
9143.9005	CREO MIS®, GPS Instrument Set
9143.9013	Globus Power®, GPS Instrument Set
9205.9002	Globus Power®, GPS Charger & Batteries Set

GlobusPower®, GPS Disposable Drill Bits

Part No.	Part Description
6143.2580S	High Speed Drill Bit, 2.5mm, GPS
6143.2582S	High Speed Drill Bit, 3.5mm, GPS
6143.2584S	High Speed Drill Bit, 4.5mm, GPS

For use with Medtronic StealthStation®, order the following, in addition to the CREO MIS® Sets listed above:

Drivers to Order

Part No.	Part Description
6134.1440	Screwdriver, GI1, 30mm
6134.1445	Screwdriver, GI1, 10mm

IMPORTANT INFORMATION ON THE CREO® STABILIZATION SYSTEM

DESCRIPTION

The CREO® Stabilization System consists of rods, hooks, monoaxial screws, uniplanar screws, polyaxial screws, reduction screws, fenestrated screws, awl tip screws, locking caps, t-connectors, head offset connectors, trans-iliac connectors, staples, and associated manual surgical instruments. Implants are available in a variety of sizes to accommodate individual patient anatomy. CREO® implants mate with 4.75mm, 5.5mm, and 6.35mm diameter rods. In addition, CREO® 5.5 Threaded screws and locking caps mate with 6.0mm diameter rods. CREO NXT™ and CREO® Preferred Angle implants mate with 5.5mm and 6.0mm rods. CREO DLX™ implants mate with 6.0 and 6.35mm rods. Implant components can be rigidly locked into a variety of configurations for the individual patient and surgical condition. Polyaxial screws, hooks, and t-connectors are intended for posterior use only. Staples are intended for anterior use only. Rods and monoaxial screws may be used anteriorly or posteriorly. Locking caps are used to connect screws or hooks to the rod and trans iliac connectors.

The most common use of this screw, hook, and rod system in the posterior thoracolumbar and sacral spine is two rods, each positioned and attached lateral to the spinous process via pedicle screws and/or lamina, pedicle or transverse process hooks.

The most common use of this screw, hook, and rod system in the anterior thoracolumbar spine is one rod, positioned and attached to the vertebral bodies via monoaxial screws through an appropriate size staple.

Screws and hooks attach to the rods using a locking cap with an inner set screw, or a threaded locking cap. The size and number of screws are dependent on the length and location of the rod. Screws are inserted into a pedicle of the thoracolumbar and/or sacral spine. Screws may be used with a staple. The type and number of hooks are also dependent on the location in the spine needing correction and/or stabilization. Hooks are attached to the laminae, pedicles, or transverse process of the posterior spine.

T-connectors are modular components designed to connect the two rods of a construct and act as a structural cross member. The rod-clamping set screws secure the t-connectors to the rods. Additional set screws secure the adjustable cross members at the desired length. Additional connectors may be used to connect two rods, and are also secured using set screws.

CREO® implants are composed of titanium alloy, cobalt chromium molybdenum alloy, or stainless steel, as specified in ASTM F136, F1295, F1472, F1537 and F138. Rods are also available in commercially pure titanium, as specified in ASTM F67. Screws are also available with hydroxyapatite (HA) coating per ASTM F1185. Due to the risk of galvanic corrosion following implantation, stainless steel implants should not be connected to titanium, titanium alloy, or cobalt chromium-molybdenum alloy implants.

The CREO® System includes manual surgical instruments manufactured from stainless steel, as specified in ASTM F899. Navigation Instruments are nonsterile, reusable instruments that can be operated manually or under power using a power drill such as POWEREASE™, that are intended to be used with the Medtronic StealthStation® System.

CREO ONE™ Robotic Screws are used with ExcelsiusGPS®, Medtronic StealthStation®, or without navigation or guidance assistance. CREO ONE™ Robotic Screws should not be used with any other third-party robotic or navigation system.

INDICATIONS

The CREO® Stabilization System implants are non-cervical spinal fixation devices intended for posterior pedicle screw fixation (T1-S2/ilium), posterior hook fixation (T1-L5), or anterolateral fixation (T8-L5). Pedicle screw fixation is indicated for skeletally mature patients (including small stature) and for pediatric patients. These devices are indicated as an adjunct to fusion for the following indications: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis, Scheuermann's Disease), tumor, stenosis, and failed previous fusion (pseudoarthrosis). When used as an adjunct to fusion, the CREO® Stabilization System is intended to be used with autograft and/or allograft.

In addition, the CREO® Stabilization System is intended for treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft, having implants attached to the lumbosacral spine and/or ilium with removal of the implants after attainment of a solid fusion. Levels of pedicle screw fixation for these patients are L3-sacrum/ilium.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the CREO® Stabilization System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The CREO® Stabilization System is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

In order to achieve additional levels of fixation, the CREO® Stabilization System rods may be connected to the REVERE® Stabilization System (4.5mm, 5.5mm, or 6.35mm rod) or ELLIPSE® Occipito-Cervico-Thoracic Spinal System (3.5mm rod) using corresponding connectors. Refer to the REVERE®, or ELLIPSE® system package insert for instructions and indications of use.

In-Line Connector Growing Rods are indicated in patients under 10 years of age with potential for additional spine growth who require surgical treatment to obtain and maintain correction of severe, progressive, life-threatening, early onset spinal deformities associated with thoracic insufficiency, including early onset scoliosis, as part of a growing rod construct.

Globus Navigation Instruments are intended to be used during the preparation and placement of CREO® screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. These instruments are designed for use with the Medtronic StealthStation® System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a skull, a long bone, or vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

When used for posterior fixation in conjunction with FORTRESS® or FORTRESS-Plus® bone cement, the CREO® Fenestrated Screw System is intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the thoracic and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion. CREO® Fenestrated screws augmented with FORTRESS™ and FORTRESS-Plus™ bone cements are for use at spinal levels where the structural integrity of the spine is not severely compromised.

WARNINGS

The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to degenerative disc disease, degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.

One of the potential risks identified with this system is death. Other potential risks which may require additional surgery, include:

- device component fracture,
- loss of fixation,
- non-union,
- fracture of the vertebrae,
- neurological injury, and
- vascular or visceral injury.

Potential risks when used with bone cement include:

- Hypersensitivity reactions in susceptible persons resulting in anaphylactic response
- Tissue damage, nerve, or circulatory problems caused by cement leakage
- Micromotion of cement against bone surface caused by inadequate fixation

Cement leakage may cause tissue damage, nerve or circulatory problems, and other serious adverse events. These risks may increase with the number of spinal levels where bone cement is utilized, and also with the volume of bone cement used.

Serious adverse events, some with fatal outcome, associated with the use of acrylic bone cements in the spine include myocardial infarction, cardiac arrest, cerebrovascular accident, pulmonary embolism, and cardiac embolism. Although the majority of these adverse events present early within the post-operative period, there have been some reports of diagnoses beyond

a year or more after the procedure.

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

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

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

Strict adherence to the surgical technique guide is strongly recommended.

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

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

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

ADDITIONAL WARNINGS FOR PEDIATRIC PATIENTS

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

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

PRECAUTIONS

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

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

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

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

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

ADDITIONAL PRECAUTIONS FOR PEDIATRIC PATIENTS

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

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

MRI SAFETY INFORMATION

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

CONTRAINDICATIONS

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

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

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

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

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

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

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

PACKAGING

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

The instrument sets are provided nonsterile and are steam sterilized prior to use, as described in the STERILIZATION section below. Following use or

IMPORTANT INFORMATION ON THE CREO® STABILIZATION SYSTEM

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 in2 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:

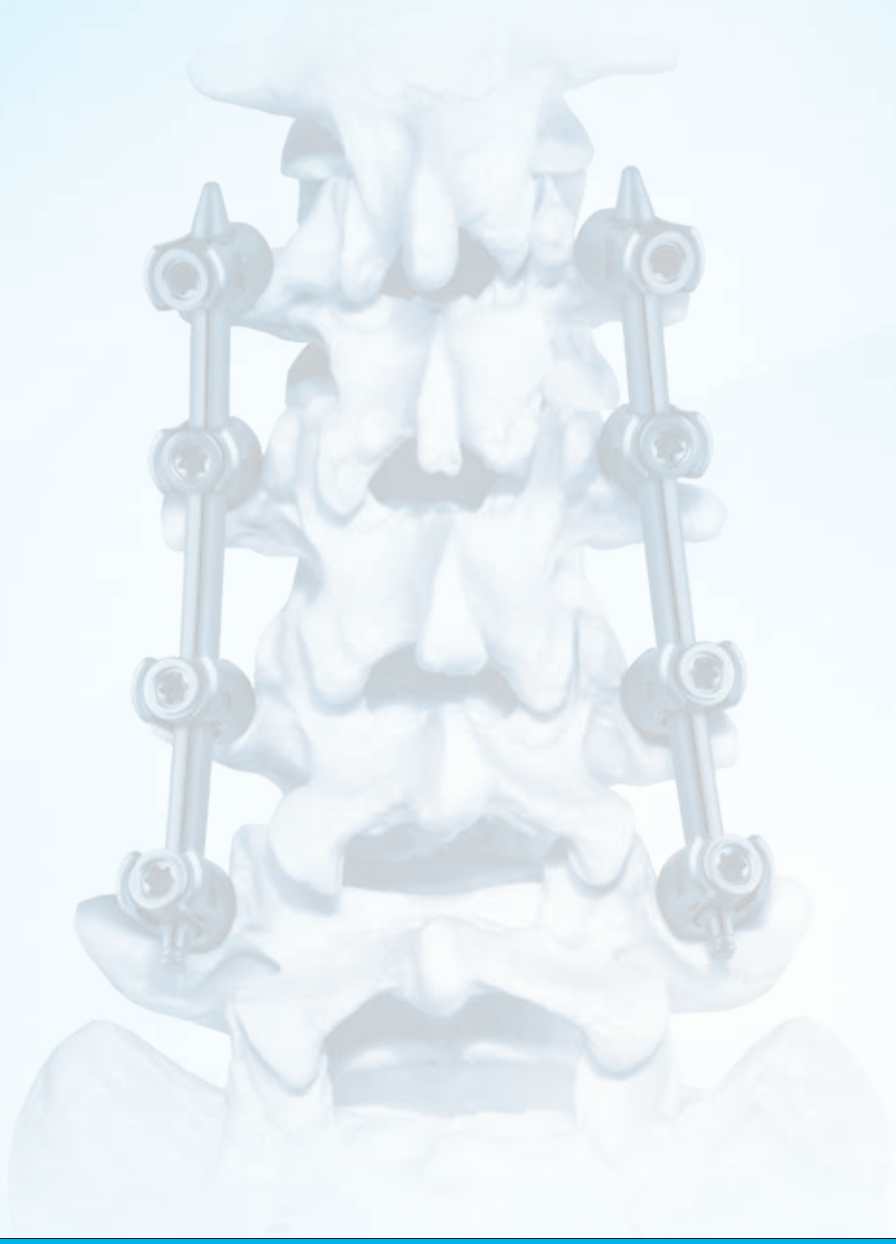
Method	Cycle Type	Temperature	Exposure Time	Drying Time
Steam	Pre-vacuum	132°C (270°F)	4 Minutes	30 Minutes

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		

DI179A Rev N



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

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

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