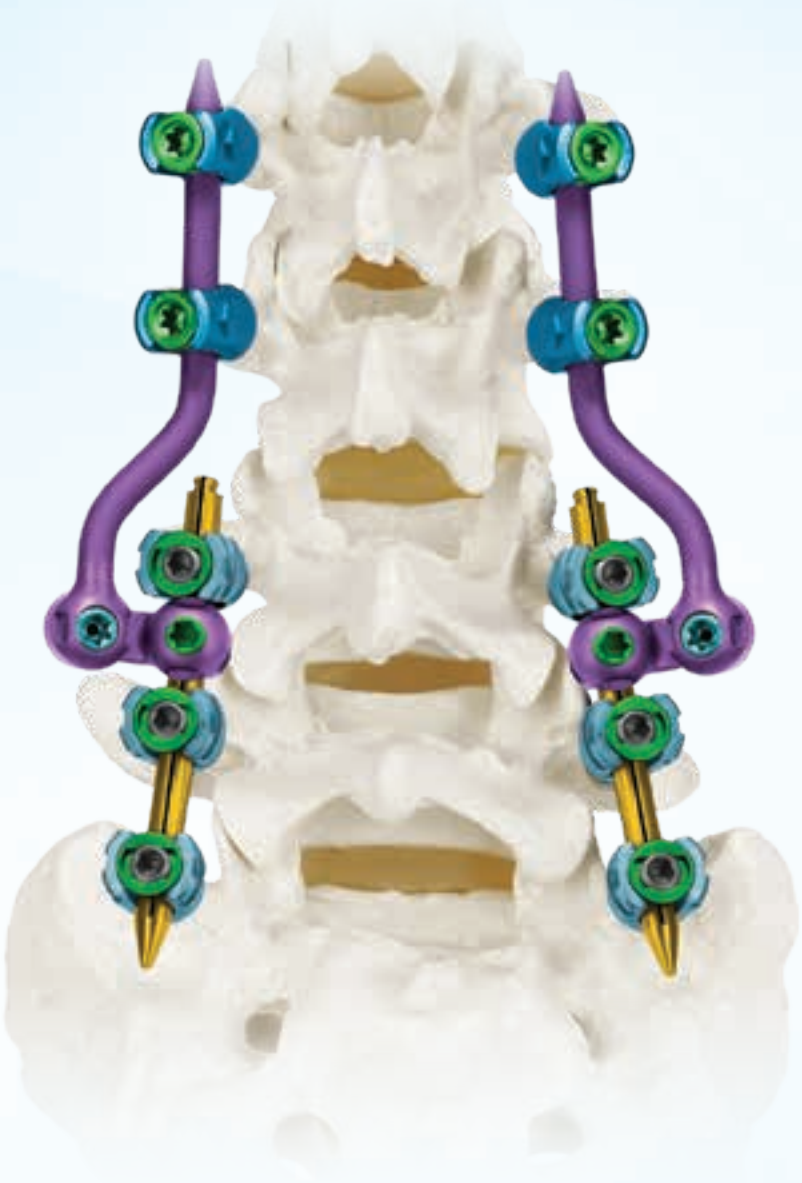


CREO ADDITION®

MIS Revision Fixation

GLOBUS MEDICAL

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

Life moves us

SURGICAL TECHNIQUE GUIDE

CREO ADDITION®

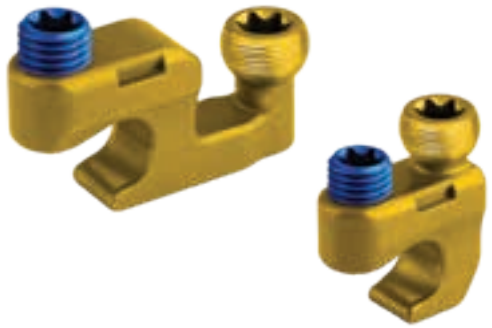
CREO ADDITION®

MIS Revision Fixation

CREO ADDITION® is a comprehensive connector set designed to revise and extend existing thoracolumbar constructs using a minimally invasive approach, eliminating the need to remove existing implants.

Comprehensive Implant Options

Modular Connectors



- Unique design allows polyaxial rotation and is compatible with Headed Rods and the CREO AMP® platform
- Lateral and superior connector options for securing to existing rod constructs
- Compatible with 5.5–6.35mm diameter rod systems

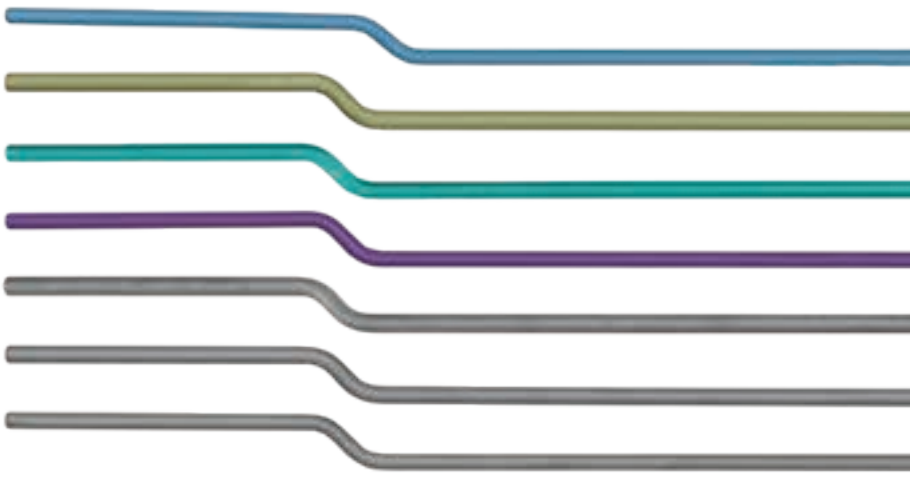
Top Loading Connectors

- Allows for easy insertion onto the existing rod
- Accepts 5.5mm diameter rods

Headed Rods

- Polyaxial head with integrated 5.5mm diameter rod
- Allows for ±25° of angulation to aid alignment
- Offerings to accommodate various anatomies:
  - Straight Headed Rods
  - Lateral Headed Rods with left and right lateral bends
  - Superior Headed Rods with half and full offset bends

Z Rods



- Pre-contoured rod enables realignment to the new construct
- Available in 4.75, 5.5, 6.0, and 6.35mm rod diameters
- Available in titanium alloy (TAV) or cobalt chrome (CoCr)

IMPLANT OVERVIEW

CREO® Threaded Locking Cap

- Low torque (8Nm) locking mechanism
- Easy engagement

Lateral Connectors

Closed-Closed Lateral Connector

- Securely couples two parallel rods
- Engages with holder for secure insertion
- Options to accept 4.75–6.35mm diameter rods

Open-Closed Lateral Connector

- Securely couples two parallel rods
- Open style clamp in parallel with closed clamp
- Engages with holder for secure insertion
- Options to accept 4.75–6.35mm diameter rods

Double Head Lateral Connector

- Securely couples two parallel rods
- Uses CREO® Threaded Locking Cap
- Engages with holder for secure insertion
- Options to accept 4.75–6.0mm diameter rods

Single Head - Open Lateral Connector

- Securely couples two parallel rods
- Uses CREO® Threaded Locking Cap
- Engages with holder for secure insertion
- Options to accept 4.75–6.0mm (Head) and 4.75–6.35mm (Open) diameter rods

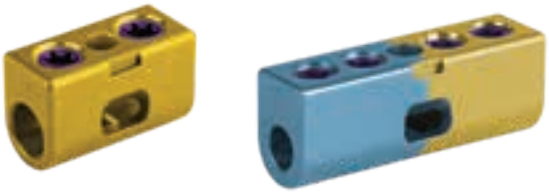
Single Head - Top Loading Lateral Connector

- Securely couples two parallel rods
- Attaches to existing rod from above
- Uses CREO® Threaded Locking Cap
- Engages with holder for secure insertion
- Options to accept 5.5–6.0mm (head) and 5.5mm (top loading) diameter rods

In-line Connectors

In-line Closed Connector

- Securely couples two rods end-to-end
- Built-in stop and visualization windows indicate if rod is fully seated
- Engages with holder for secure insertion
- Options to accept 4.75–6.35mm diameter rods



Double Head In-line Connector

- Securely couples two rods end-to-end
- Uses CREO® Threaded Locking Cap
- Allows for attachment of rod reduction instruments
- Engages with holder for secure insertion
- Accepts 4.75–6.0mm diameter rods

In-line Closed Connector with Integrated Rod

- Securely attaches to end of the existing rod
- Provides direct in-line connection with a 400mm rod
- Built-in stop and visualization windows indicate if rod is fully seated
- Engages with holder for secure insertion
- Accepts 5.5–6.35mm diameter rods
- Available in 5.5, 6.0, and 6.35mm rod diameters

Modular Connectors

Modular Head - Open Lateral Connector

- Securely attaches to the existing rod
- Allows for connection of Headed Rod or CREO AMP® platform
- Navigates around existing rod constructs
- Engages with holder for secure insertion
- Accepts 5.5–6.35mm diameter rods

Modular Head - Open Superior Connector

- Securely attaches to the existing rod
- Allows for connection of Headed Rod or CREO AMP® platform
- Navigates above existing rod constructs
- Engages with holder for secure insertion
- Accepts 5.5-6.35mm diameter rods

Modular Head - Top Loading Lateral Connector

- Securely attaches to the existing rod from above
- Allows for connection of Headed Rod or CREO AMP® platform
- Navigates around existing rod constructs
- Engages with holder for secure insertion
- Accepts 5.5mm diameter rod

Headed Rods

Straight Headed Rod

- Polyaxial head with integrated 5.5mm diameter rod
- Allows for ±25° of angulation to aid in alignment
- Available in 40, 45, 50, and 200mm lengths

Lateral Headed Rod

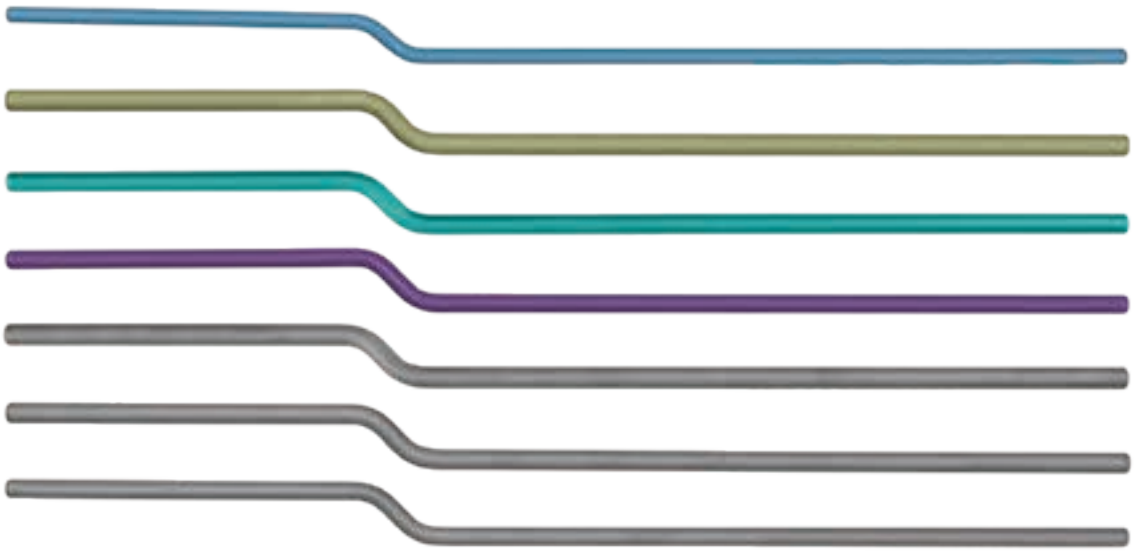
- Polyaxial head with integrated pre-bent 5.5mm diameter rod
- Allows for ±25° of angulation to aid in alignment
- Left or right lateral bends
- Available in 75, 80, 85, and 230mm lengths

Superior Headed Rod

- Polyaxial head with integrated pre-bent 5.5mm diameter rod
- Allows for ±25° of angulation to aid in alignment
- Full or half offset bends
- Available in 75, 80, 85, and 230mm lengths

Z Rods

- Pre-contoured 300mm rod with 12mm offset for construct alignment
- Available in 4.75, 5.5, 6.0, and 6.35mm rod diameters
- Titanium alloy (TAV) or cobalt chrome (CoCr)



INSTRUMENT OVERVIEW

PREPARATION INSTRUMENTS

Bone Hook, 5.5mm 6175.0031
Bone Hook, 6.0mm 6175.0032

Straight Osteotome, 12.7mm (1/2") 643.052

IMPLANT INSERTION INSTRUMENTS

Implant Holder, Straight 6175.0010

Implant Holder, Offset 6175.0020

IMPLANT INSERTION INSTRUMENTS (CONT'D)

Headed Rod Calipers 6175.2000

Modular Connector Inserter, Threaded 6175.2011

Headed Rod Inserter Driver 6175.2030

Headed Rod Inserter, Threaded 6175.2040

Headed Rod Inserter Fork 6175.2041

Headed Rod Inserter, Threaded 6175.2040
Headed Rod Inserter Fork 6175.2041
(Assembled)

Headed Rod Inserter Handle 6175.2050

Modular Connector Inserter Guide 6175.2060

LOCKING INSTRUMENTS

Double Head Lateral Counter Torque, 4.75
6175.9930
Double Head Lateral Counter Torque, 5.5-6.0
6175.9933

Double Head In-Line Counter Torque, 4.75
6175.9910
Double Head In-Line Counter Torque, 5.5-6.0
6175.9913

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

Connector Counter Torque 6119.6015

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

4.75 Threaded Locking Cap Driver 6067.5000

Threaded Locking Cap Driver 6120.5000

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

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

ADDITIONALLY AVAILABLE INSTRUMENTS

Rod Bender, Left 652.690
Rod Bender, Right 652.691

4.75 Coronal Plane Bender, Left 6067.3010
4.75 Coronal Plane Bender, Right 6067.3015
Coronal Plane Bender, Left 6119.3010
Coronal Plane Bender, Right 6119.3015

4.75 *In situ* Bender, Left 6067.3000
4.75 *In situ* Bender, Right 6067.3005
In situ Bender, Left 6119.3000
In situ Bender, Right 6119.3005

Rod Holder 6067.0080

Fixed Dissector 685.150

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

Modular Connector Inserter 6175.2010

RECOMMENDED SETS FOR CREO ADDITION®

For CREO ADDITION® 5.5-6.35 Cases	
9175.9001 CREO ADDITION® MIS Revision Implant Set	**REQUIRED**
9175.9002 CREO ADDITION® MIS Revision Instrument Set	**REQUIRED**
954.910 REVERE® ADDITION® Revision Fixation Set	**OPTIONAL**
954.930 Universal Implant Removal Set	**OPTIONAL**

For CREO ADDITION® 4.75 Cases	
9175.9002 CREO ADDITION® MIS Revision Instrument Set	**REQUIRED**
9175.9003 CREO ADDITION® 4.75 Implant and Instrument Set	**REQUIRED**
954.910 REVERE® ADDITION® Revision Fixation Set	**OPTIONAL**
954.930 Universal Implant Removal Set	**OPTIONAL**

For MIS Revision Cases
9134.9001 CREO MIS® Implant Set
9134.9002 CREO MIS® Instrument Set I
9134.9003 CREO MIS® Instrument Set II
OR
985.901 REVOLVE® Implant Set
985.902 REVOLVE® Instrument Set

For Open Revision Cases - 4.75mm Rod Systems
CREO® 4.75 implant and instrument sets

For Open Revision Cases - 5.5mm or 6.0mm Rod Systems
CREO® implant and instrument sets
OR
924.931 REVERE® Expanded Implant Set
924.902 REVERE® Instrument I Set
924.903 REVERE® Instrument II Set

For Open Revision Cases - 6.35mm Rod Systems
CREO DLX™ implant and instrument sets
OR
934.901 REVERE® 6.35 Implant Set
934.902 REVERE® 6.35 Instrument I Set
934.903 REVERE® 6.35 Instrument II Set

SURGICAL TECHNIQUE

MIS Revision

Please refer to the product insert printed at the back of this technique guide for complete description, indications, contraindications, precautions and warnings.

Pedicle screws are inserted into adjacent levels. Refer to the CREO MIS® Surgical Technique Guide (GMTGD138) or REVOLVE® Surgical Technique Guide (GMTGD44) for instructions on pedicle screw insertion, rod insertion, etc. This technique provides instructions on connector insertion only.

STEP 1 IMPLANT SELECTION

CREO ADDITION® offers multiple MIS options for hardware connection. Implant selection depends on the following:

- Revision approach (e.g., lateral, superior)
- Number of additional levels
- Available rod spacing
- Surgeon preference

Select the appropriate size connector and insert onto rod with a corresponding holder.

<table>
<tr><th colspan="4">Modular Head Implants</th></tr>
<tr><th>Approach</th><th colspan="2">Modular Connector</th><th>Headed Rod</th></tr>
<tr><td rowspan="6">Lateral</td><td rowspan="3">Modular Head - Open Lateral Connector</td><td rowspan="3">  </td><td>Straight Headed Rod</td></tr>
<tr><td>Lateral Headed Rod, Left</td></tr>
<tr><td>Lateral Headed Rod, Right</td></tr>
<tr><td rowspan="3">Modular Head - Top Loading Lateral Connector</td><td rowspan="3">  </td><td>Straight Headed Rod</td></tr>
<tr><td>Lateral Headed Rod, Left</td></tr>
<tr><td>Lateral Headed Rod, Right</td></tr>
<tr><td colspan="4">Use the Modular Head - Open Lateral Connector or Modular Head - Top Loading Lateral Connector for extending fixation around existing constructs.</td></tr>
<tr><td rowspan="3">Superior</td><td rowspan="3">Modular Head - Open Superior Connector</td><td rowspan="3">  </td><td>Straight Headed Rod</td></tr>
<tr><td>Superior Headed Rod, Half Offset</td></tr>
<tr><td>Superior Headed Rod, Full Offset</td></tr>
<tr><td colspan="4">Use the Modular Head - Open Superior Connector for extending fixation above existing constructs.</td></tr>
</table>

STEP 2 MODULAR CONNECTOR INSERTION

Access the most cephalad level of the existing construct. This is the site of attachment for the CREO ADDITION® modular connector. A **Bone Hook** or **Osteotome** may be used to prepare the rod site for attachment by removing any bone and soft tissue along or below the rod.

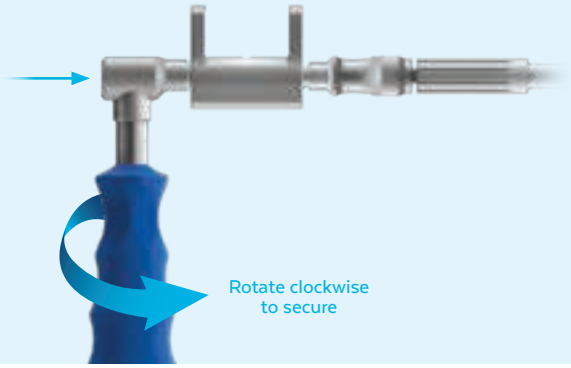
Modular Head Connectors are inserted using the Modular Connector Inserter, Threaded assembly.

MODULAR CONNECTOR INSERTER, THREADED ASSEMBLY

Align the etched flat surface of the **Modular Connector Inserter, Threaded** with the rod slots of the **Modular Connector Inserter Guide** and insert.

Ensure that the handle is in the unlocked position by rotating the handle counterclockwise until it stops. To attach the **Headed Rod Inserter Handle** to the Modular Connector Inserter, Threaded, align the etched flat surface with the etched line on the handle and insert.

Lock the handle to the inserter by rotating the handle clockwise until secure.

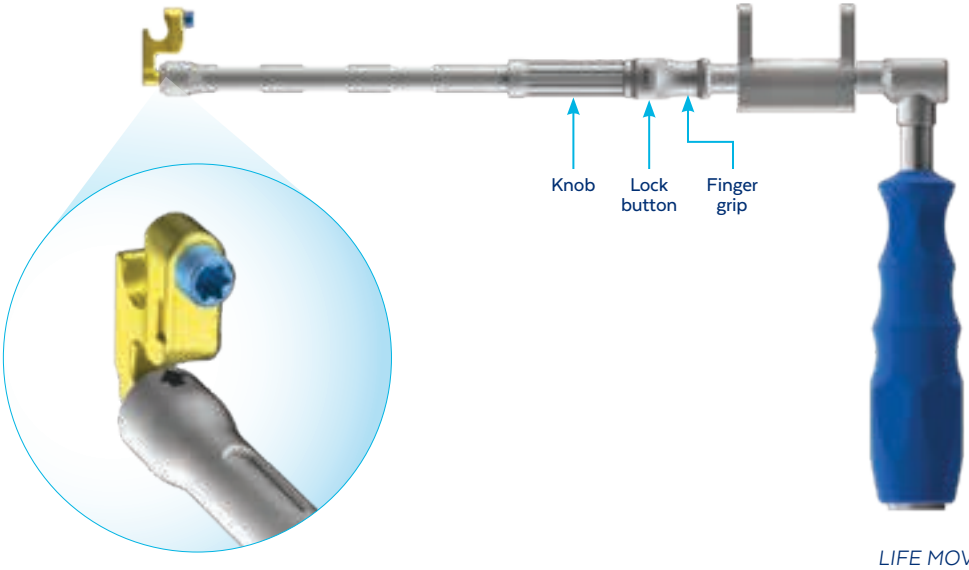


Modular Head - Open Lateral Connector

Connector Attachment

Pull the finger grip back towards the handle and loosen the knob. Engage the inserter tip into the hexalobular feature aligning the implant with the etched arrow on the inserter, as shown below.

Engaging the modular connector



Modular Head - Open Lateral Connector (cont'd)

Connector Attachment

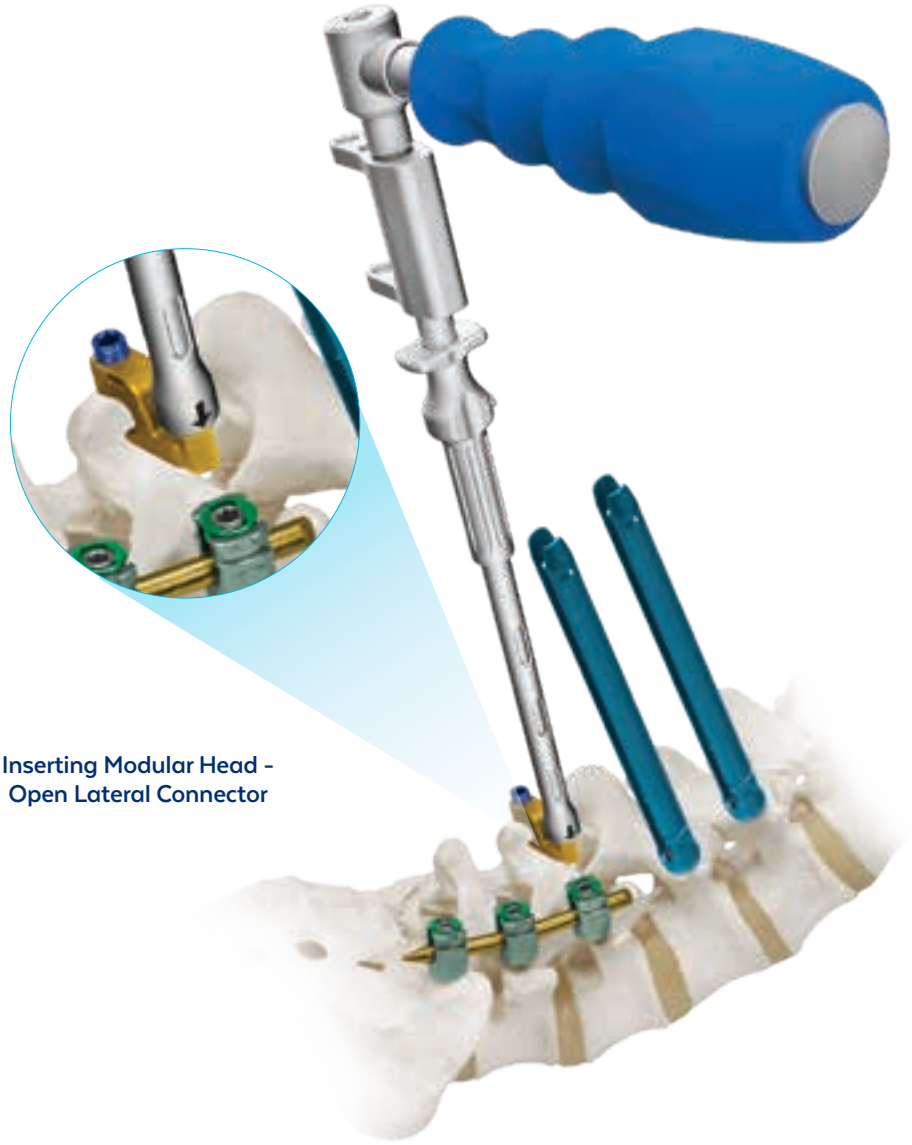
Once the implant is engaged, rotate the knob of the inserter clockwise until tight. Push the lock button above the knob to activate the lock. The lock automatically slides distally, meeting the knob, and securing the modular connector to the inserter. The modular connector is ready for insertion.

Note: The knob may be tightened further after the lock has been activated by rotating the knob clockwise for increased rigidity. The lock prevents the inserter from loosening and disengaging the modular connector.

Connector Insertion

Before insertion, ensure the set screw is not obstructing the rod slot. Use the driver assembly to rotate the set screw counterclockwise until it stops.

When the attachment site is selected, secure the open end of the connector to the rod by tightening the set screw.



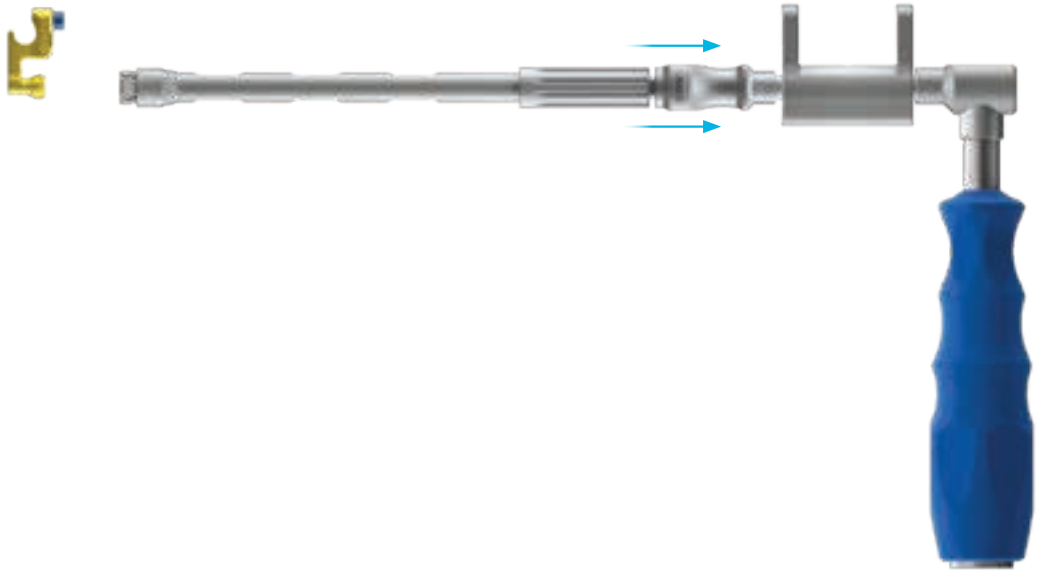
Inserting Modular Head - Open Lateral Connector

Final Tightening

Final tightening is necessary to secure the modular connector. Attach the **Ratcheting Torque-Limiting Handle, ¼" Quick-Connect** to the **Driver Shaft, ¼" Quick-Connect, Long**. Insert the torque-limiting driver assembly through the appropriate guide hole of the inserter assembly and into the set screw. Visually confirm that the driver tip is fully seated in the set screw prior to tightening. Rotate the torque-limiting driver assembly clockwise until it reaches the torque limit (5.5Nm) and two audible clicks are heard.

Securing modular connector to rod

To disengage, grasp the lock by the finger grips on each side and pull the lock back towards the inserter handle. There is an audible click as the button is released. Rotate the knob counterclockwise to loosen and disengage the inserter from the modular connector.



Modular Head - Top Loading Lateral Connector

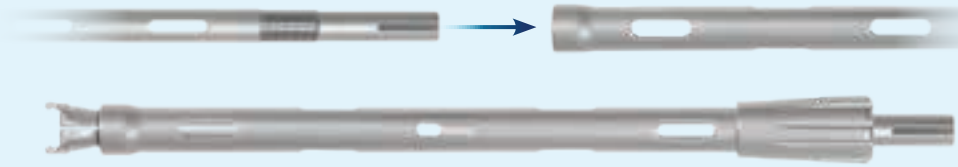
This connector is inserted using the Headed Rod Inserter assembly.

HEADED ROD INSERTER ASSEMBLY

Thread the **Headed Rod Inserter Fork** into the **Headed Rod Inserter, Threaded** until the distal tip of the inserter is flush with the etched line on the fork. Attach the Headed Rod Inserter Handle. Ensure that the handle is in the unlocked position by rotating counterclockwise until it stops. Align the etched flat surface of the fork with the etched line on the handle and insert. Lock the handle to the fork by rotating the handle clockwise until secure.

Headed Rod Inserter, Threaded

Headed Rod Inserter Fork



Headed Rod Inserter Fork and Headed Rod Inserter, Threaded *(assembled)*

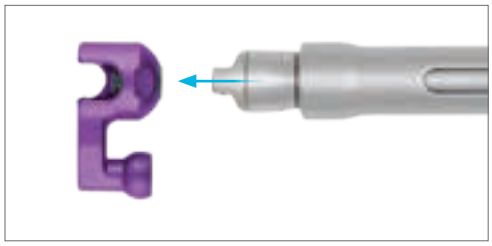
Rotate the handle counterclockwise to unlock

Insert the handle onto the Headed Rod Inserter Fork

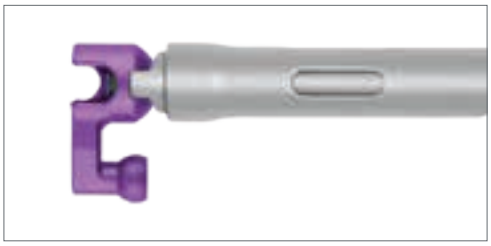
Rotate the handle clockwise to lock

Connector Attachment

Align the tips of the Headed Rod Inserter assembly with the holding slots in the connector. Thread the outer sleeve clockwise until the connector is secure.



Tips aligned with holding slots on the connector



Connector secured to Headed Rod Inserter assembly

Connector Insertion

Before insertion, ensure the set screw is fully loosened. If not, use a driver assembly to rotate the set screw counterclockwise until it stops.

When the attachment site is selected, secure the top loading end of the modular connector onto the rod by placing the implant onto the rod and tightening the set screw.

Inserting Modular Head - Top Loading Lateral Connector

Modular Head - Top Loading Lateral Connector (cont'd)

Provisionally secure the implant by inserting the **Headed Rod Inserter Driver** through the Headed Rod Inserter assembly and into the set screw. Rotate the driver until finger tight.

Provisionally securing connector to rod

Final Tightening

Remove the Headed Rod Inserter assembly by rotating the outer sleeve counterclockwise until the instrument assembly becomes disengaged. Alternatively, the **Spanner Wrench** may be used to loosen the Headed Rod Inserter, Threaded.

Final tightening of the set screw is necessary to secure the modular connector. Attach the Ratcheting Torque-Limiting Handle, ¼" Quick-Connect to the Driver Shaft, ¼" Quick-Connect, Long. Insert the torque-limiting driver assembly into the **Connector Counter Torque**. Insert the driver tip into the set screw and visually confirm that is fully engaged. Slide the counter torque over the modular connector, ensuring it is fully seated. Rotate the torque-limiting driver assembly clockwise until it reaches the torque limit (5.5Nm) and two audible clicks are heard.

STEP 3 HEADED ROD SELECTION

Extending fixation from the existing spinal rod construct to adjacent segments may be achieved by attaching a headed rod to a modular connector.

Headed Rod Selection

Headed Rod Type	Use
Straight Headed Rod 	A Straight Headed Rod may be used when the revision surgery involves a single adjacent level or when the screw trajectory does not require a bend in the new rod.
Lateral Headed Rod 	A Lateral Headed Rod is used to extend fixation to adjacent segments by bending around existing constructs. They may be used when the revision surgery involves multiple adjacent levels and the screw trajectory requires a bend in the new rod. The bend in the Lateral Headed Rod may be positioned medially or laterally.
Superior Headed Rod, Half Offset 	A Superior Headed, Half Offset is used to extend fixation to adjacent segments by bending above existing constructs. The half offset option may be used when the revision surgery involves adjacent level(s) that are offset to the revision connection site.
Superior Headed Rod, Full Offset 	The Superior Headed Rod, Full Offset may be used when a larger offset is needed.

STEP 4 HEADED ROD SIZING

Use the **Headed Rod Calipers** to determine the correct implant length. Place a leg of the caliper into the engaged set screw on the modular connector. Place the other leg of the caliper into the most cephalad adjacent screw head.

The caliper indicates the distance between the modular connector and the screw head. Select the appropriate implant length based on this measurement. If the reading is between two lengths, select the larger value.

Caliper leg inserted into the set screw on the modular connector

Caliper leg inserted into the most cephalad adjacent screw head

Headed Rod Calipers measuring for implant length

STEP 5 HEADED ROD INSERTION

Muscle Dissection

Use the **Fixed Dissector*** to facilitate headed rod insertion into adjacent screw sleeves. Verify advancement of the dissector using fluoroscopy. If needed, use a scalpel through the sleeve to separate the fascia.

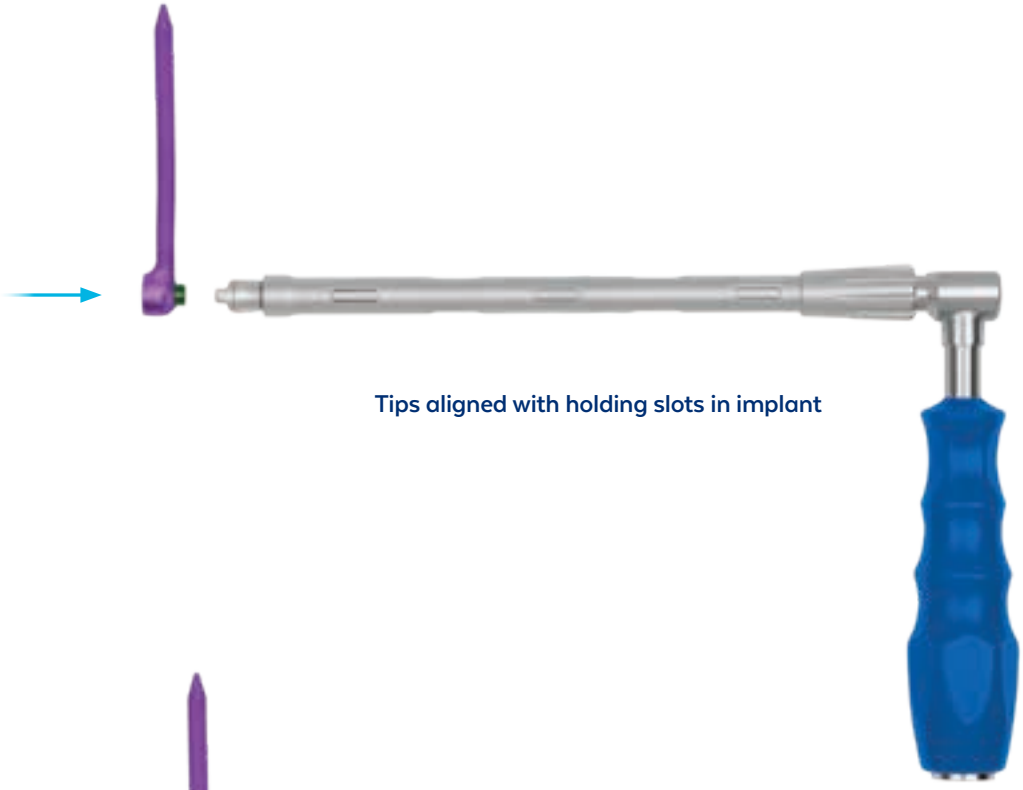
Facilitating headed rod insertion

*Available in CREO MIS® Instrument Set II

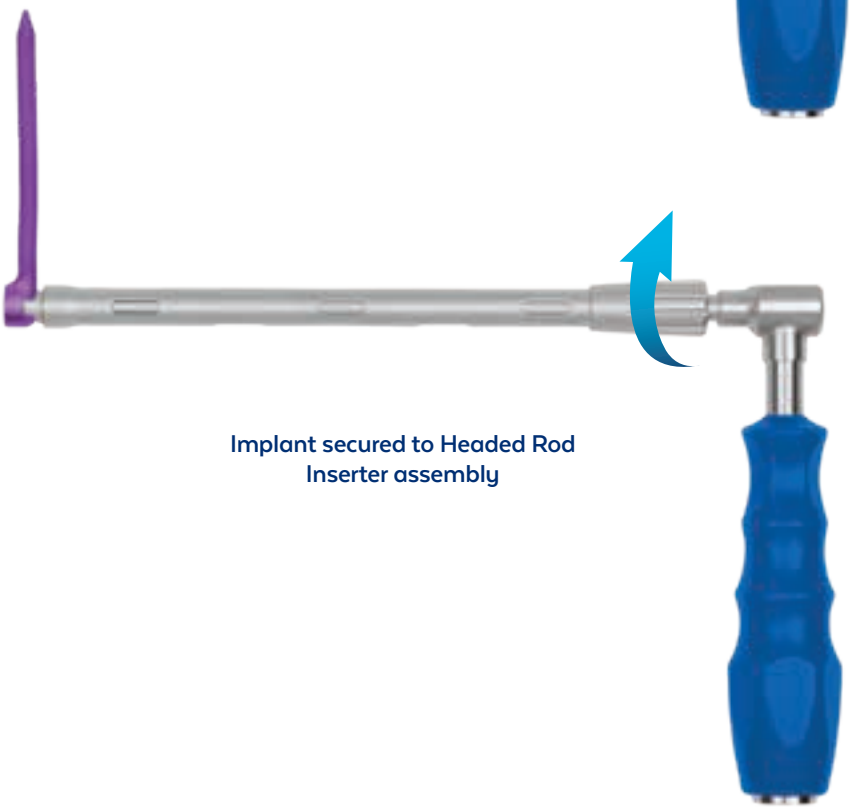
HEADED ROD INSERTION (CONT'D)

Implant Attachment

Align the tips of the Headed Rod Inserter assembly (see page 18) with the holding slots in the implant. Thread the outer sleeve clockwise until the implant is secure.



Tips aligned with holding slots in implant



Implant secured to Headed Rod Inserter assembly

Implant Insertion

Orient the rod portion of the headed rod parallel to the adjacent screw heads with the tip of the rod in the first screw head.

Rock the Headed Rod Inserter assembly back toward the handle to pass the rod into the second screw head.

HEADED ROD INSERTION (CONT'D)

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

Attaching headed rod to modular connector

After the rod portion of the headed rod is seated within the adjacent screw heads, position the head portion of the headed rod directly over the modular connector. Place the headed rod onto the modular connector and apply axial force. An audible click confirms that the headed rod is attached to the modular connector.

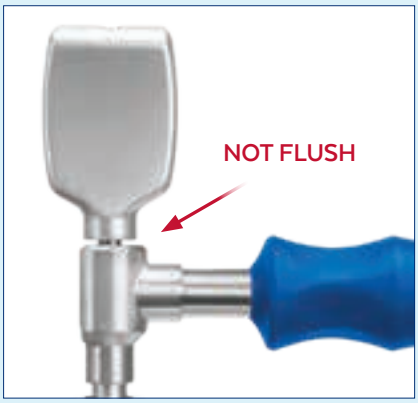
STEP 6 HEADED ROD ATTACHMENT

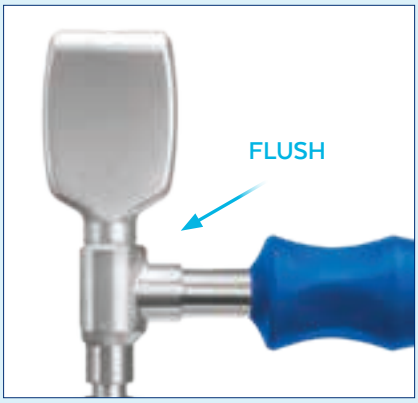
Insert the Headed Rod Inserter Driver through the Headed Rod Inserter assembly. Fully seat the driver into the set screw and provisionally tighten. Rotate the driver clockwise approximately one rotation or until the shoulder on the driver is flush with the back of the handle. Do not advance the set screw further.

Pull upward on the handle to verify that the headed rod is secured to the modular connector.

If the Headed Rod disengages from the Modular Connector, rotate the driver counterclockwise until it stops to back out the set screw. Repeat the previous insertion steps.

Ensure the driver sits flush with the inserter assembly





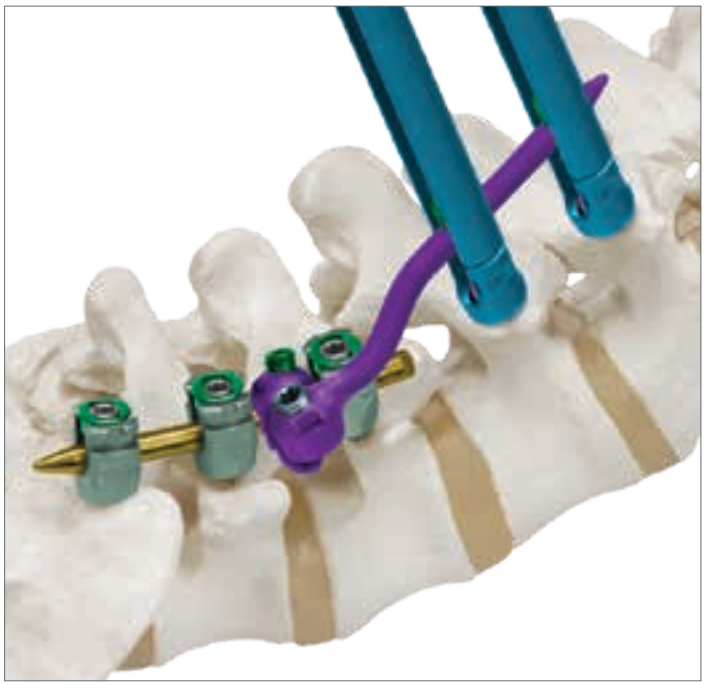
Engaging the driver into the headed rod set screw

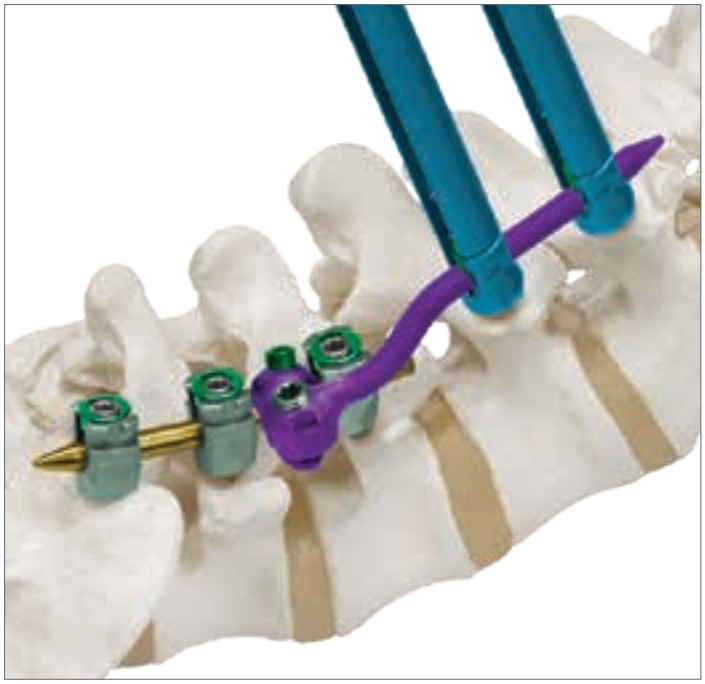
Disengaging the Headed Rod Inserter Assembly

Remove the Headed Rod Inserter assembly by rotating the outer sleeve counterclockwise until the assembly becomes disengaged and pull upward.

STEP 7 ROD CAPTURE

Reduce the rod portion of the headed rod into the adjacent screw heads. Secure the headed rod with locking caps before tightening the head portion of the implant. For rod reduction and locking cap insertion, refer to CREO MIS® or REVOLVE® surgical technique.



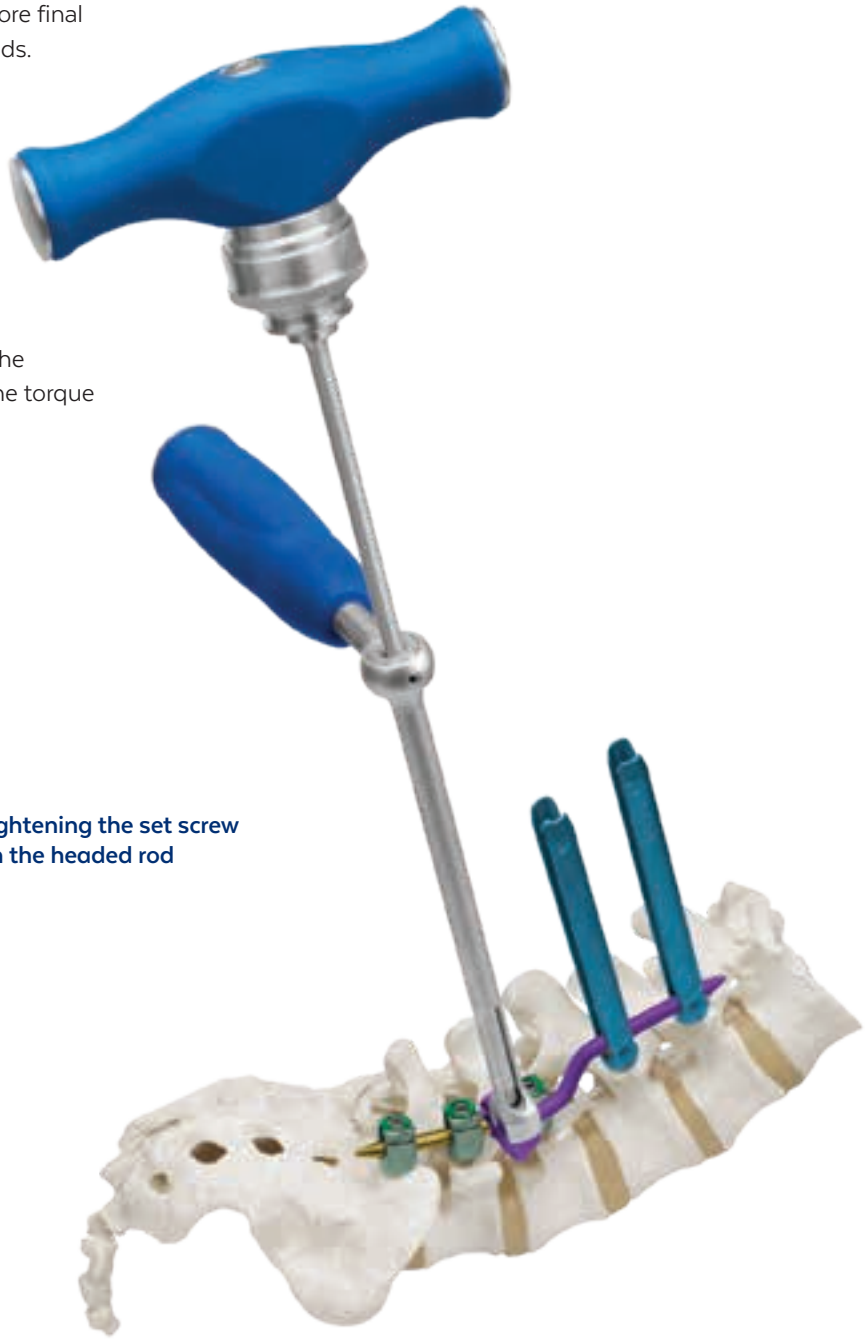


STEP 8 FINAL TIGHTENING

Final tighten the set screw of the headed rod before final tightening the locking caps in adjacent screw heads.

Attach the Driver Shaft, ¼" Quick-Connect, Long, to the Ratcheting Torque-Limiting Handle, ¼" Quick-Connect. Insert the torque-limiting driver assembly into the Connector Counter Torque.

Insert the driver tip into the set screw and visually confirm that it is fully engaged. Slide the counter torque over the headed rod. Rotate the torque-limiting driver assembly until it reaches the torque limit (5.5 Nm) and two audible clicks are heard.



Final tightening the set screw in the headed rod

OPTIONAL: IMPLANT REMOVAL

For revision or removal of connectors, the insertion steps are reversed until the implants can be removed. Connectors may remain on a rod for removal or may be removed separately.

FINAL CONSTRUCTS

Modular Head - Top Loading Lateral Connector with Lateral Headed Rod
AP view

Modular Head - Open Lateral Connector with Straight Headed Rod
AP view

Modular Head - Open Superior Connector
with Superior Headed Rod
AP view

Modular Head - Open Superior Connector
with Superior Headed Rod
Lateral view

SURGICAL TECHNIQUE

Open Revision

Please refer to the product insert printed at the back of this technique guide for complete description, indications, contraindications, precautions and warnings.

Pedicle screws are inserted into adjacent levels. Refer to the appropriate CREO® or REVERE® surgical technique guide for instructions on pedicle screw insertion, rod insertion, etc. This technique provides instructions for connector insertion.

STEP 1 PREPARATION

Remove interfering bone using the **Straight Osteotome, 12.7mm (½")**. Expose the rod and levels planned for revision.

After exposing the existing rod construct, clear bone along and beneath the rod as needed using the **Bone Hook**. Use the rasp on the hook to prepare the connector site.

STEP 2 IMPLANT SELECTION

CREO ADDITION® offers multiple options for hardware connection. Implant selection depends on the following:

- Revision approach (e.g., in-line, lateral)
- Number of levels
- Available rod spacing
- Surgeon preference

Select the appropriate size connector and insert onto rod with a corresponding holder.

STEP 3 IMPLANT INSERTION

Use the **Implant Holder, Straight** or **Implant Holder, Offset** to insert the selected implant. Rotate the knurled knob counterclockwise until it stops.

Align the instrument tip with the holding slots in the implant. Compress the handle and thread the knurled knob clockwise until the implant is secure.

Lateral Connectors

Ensure the set screws are not obstructing the rod slots of the connector. If needed, use the driver assembly to rotate the set screw counterclockwise until it stops.

Closed - Closed Lateral Connector Insertion

Select a connection point and slide the connector opening onto the end of the existing rod. Provisionally tighten the engaged set screws using the **Ratcheting Torque-Limiting Handle, ¼" Quick-Connect** and **Driver Shaft, ¼" Quick-Connect, Short** assembly.

Use the **Rod Holder*** to insert the new rod. Place one rod end into a free rod slot on the connector and the other end into the adjacent screw heads. Cut and contour the rod as desired using the **Rod Benders, Left and Right***.

Secure the new rod using the Ratcheting Torque-Limiting Handle, ¼" Quick-Connect and Driver Shaft, ¼" Quick-Connect, Short assembly. Provisionally tighten the engaged set screws.

**Additionally available*

Open - Closed Lateral Connector Insertion

Select a connection point and secure the open end onto the existing hardware by placing the connector along the rod between two screw heads. Provisionally tighten the engaged set screw using the Ratcheting Torque-Limiting Handle, ¼" Quick-Connect and Driver Shaft, ¼" Quick-Connect, Short assembly.

Use the Rod Holder* to insert the new rod. Place one rod end into the closed connection point on the connector and place the other end into the adjacent screw heads. Cut and contour the rod as desired using the Rod Benders, Left and Right*.

Secure the new rod using the Ratcheting Torque-Limiting Handle, ¼" Quick-Connect and Driver Shaft, ¼" Quick-Connect, Short assembly. Provisionally tighten the engaged set screw. The construct is not completely locked until final tightening.

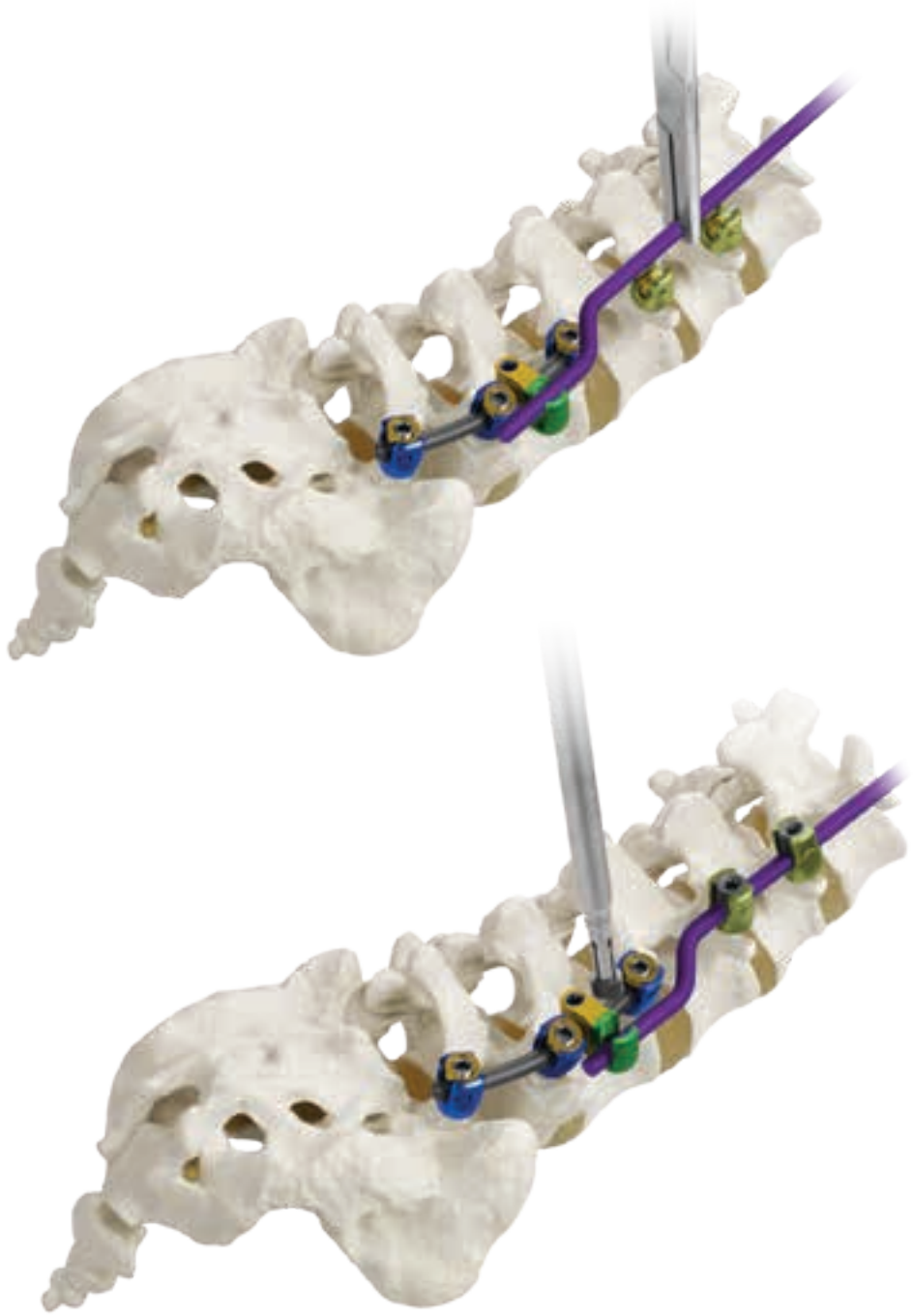
*Additionally available

Single Head - Open Lateral Connector Insertion

Select a connection point and secure the open end onto the existing hardware by placing the connector along the rod between the two screw heads. Provisionally tighten the engaged set screw using the Ratcheting Torque-Limiting Handle, ¼" Quick-Connect and Driver Shaft, ¼" Quick-Connect, Short assembly.

Use the Rod Holder* to insert the new rod. Place one end of the rod into the head on the connector and place the opposite end into the adjacent screw heads. Cut and contour the rod as desired using the Rod Benders, Left and Right*.

Capture the new rod by using the **Straight Handle, Ratcheting, ¼" Quick-Connect*** and **Threaded Locking Cap Driver** assembly to introduce a **CREO® Threaded Locking Cap** into the head on the connector. The construct is not completely locked until final tightening.



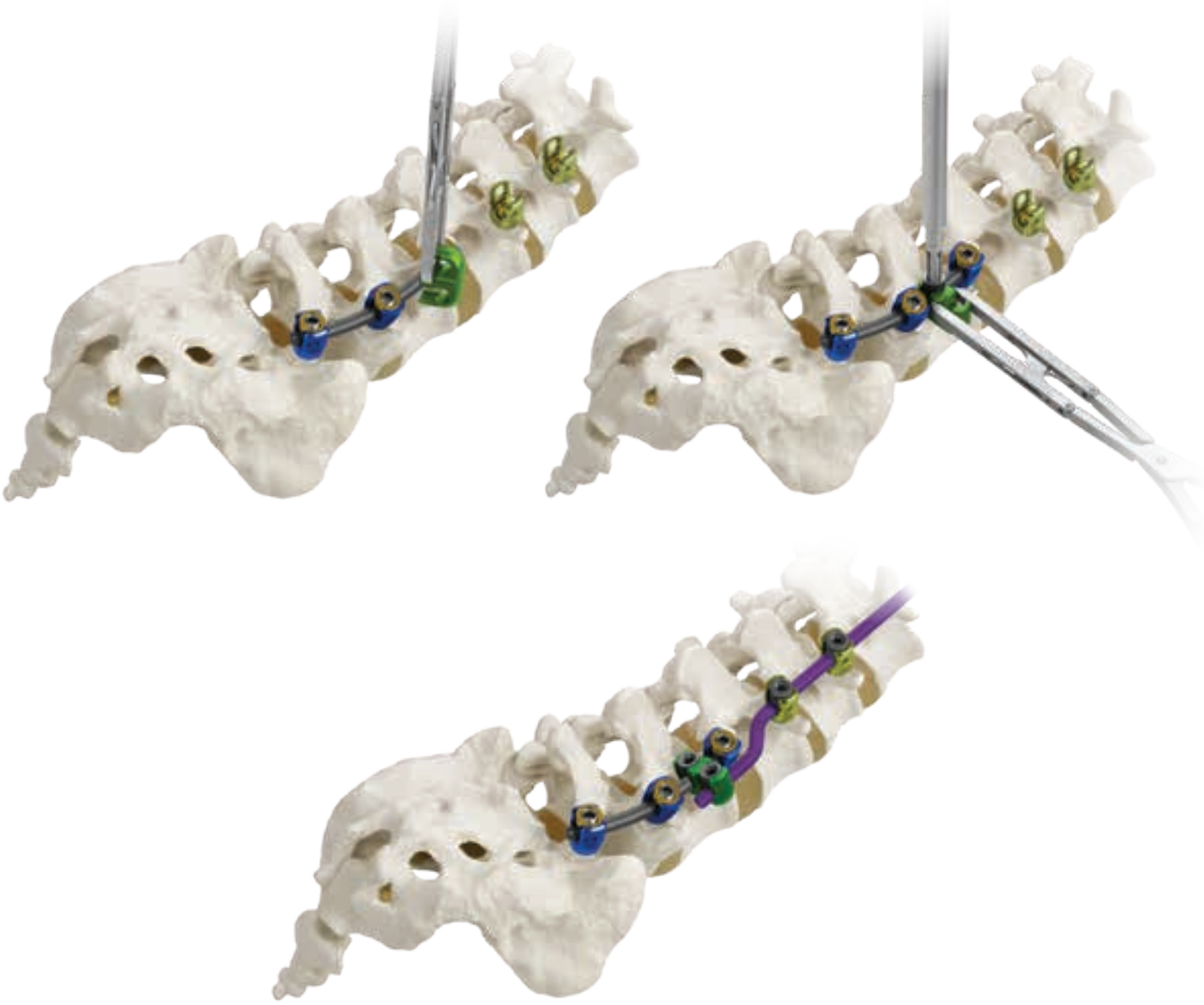
*Additionally available

Double Head Lateral Connector Insertion

Select a connection point and secure the distal head onto the existing hardware by placing the connector along the rod between two screw heads. Secure the existing rod using the Straight Handle, Ratcheting, ¼" Quick-Connect* and Threaded Locking Cap Driver assembly. Introduce a CREO® Threaded Locking Cap into the engaged head on the connector.

Use the Rod Holder* to insert the new rod. Place one rod end into the free head on the connector and place the other end into adjacent screw heads. Cut and contour the rod as desired using the Rod Benders, Left and Right*.

Secure the new rod using the Straight Handle, Ratcheting, ¼" Quick-Connect* and Threaded Locking Cap Driver assembly. Introduce a CREO® Threaded Locking Cap into the head on the connector. The construct is not completely locked until final tightening.



*Additionally available

Single Head - Top Loading Lateral Connector Insertion

Implant Holders, Straight and Offset, or the Headed Rod Inserter assembly may be used to insert these implants.

*Refer to **Page 18** for Headed Rod Inserter assembly instructions.*

Before insertion, ensure the set screw is fully loosened. If not, use a driver assembly to rotate the set screw counterclockwise until it stops.

Select a connection point and secure the top loading connection onto the existing hardware by pressing the connector onto the rod between the two screw heads. Provisionally tighten the set screw using the Headed Rod Inserter Driver. The construct is not completely locked until final tightening.

Use the Rod Holder* to insert the new rod. Place one rod end into the head on the connector and place the other end into adjacent screw heads. Cut and contour the rod as desired using the Rod Benders, Left and Right*.

Secure the new rod by using the Straight Handle, Ratcheting, ¼" Quick-Connect* and Threaded Locking Cap Driver assembly. Introduce a CREO® Threaded Locking Cap into the head on the connector. The construct is not completely locked until final tightening.

*Additionally available

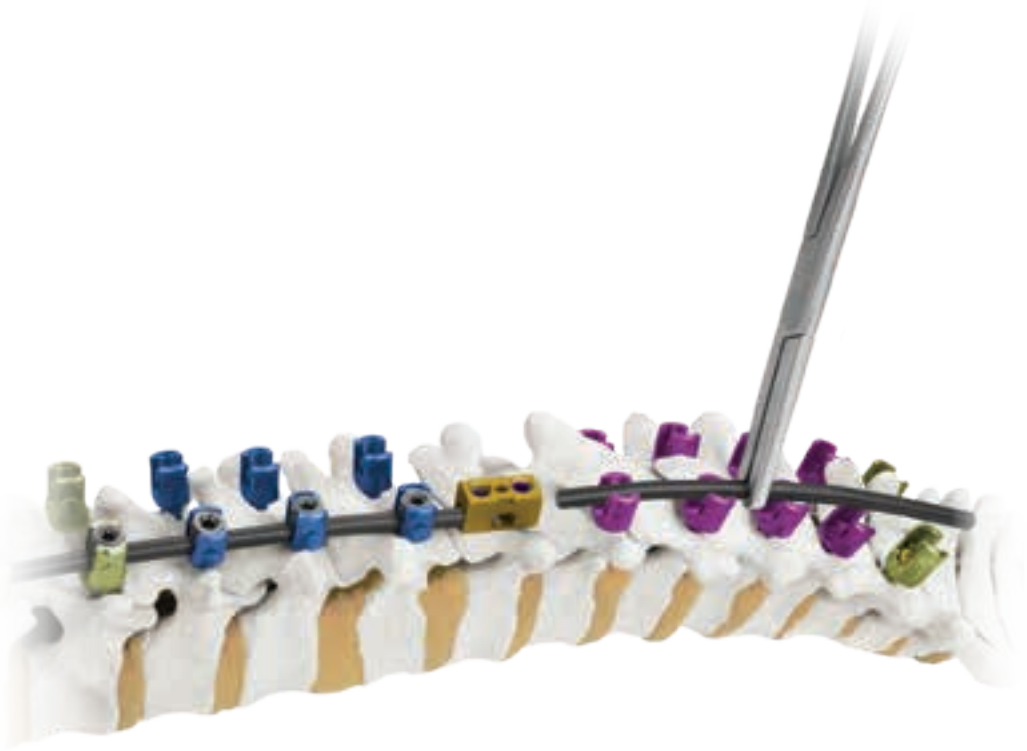
In-line Connectors

Ensure the set screws are not obstructing the rod slots of the connector. If needed, use a driver assembly to rotate the set screw counter clockwise until it stops.

In-line Closed Connector Insertion

Select a connection point and slide the connector opening onto the end of the existing rod. Provisionally tighten the engaged set screw using the Ratcheting Torque-Limiting Handle, ¼" Quick-Connect and Driver Shaft, ¼" Quick-Connect, Short assembly.

Use the Rod Holder* to insert the new rod. Slide one rod end into the free rod slot on the connector and place the other end into adjacent screw heads. Cut and contour the rod as desired using the Rod Benders, Left and Right*.

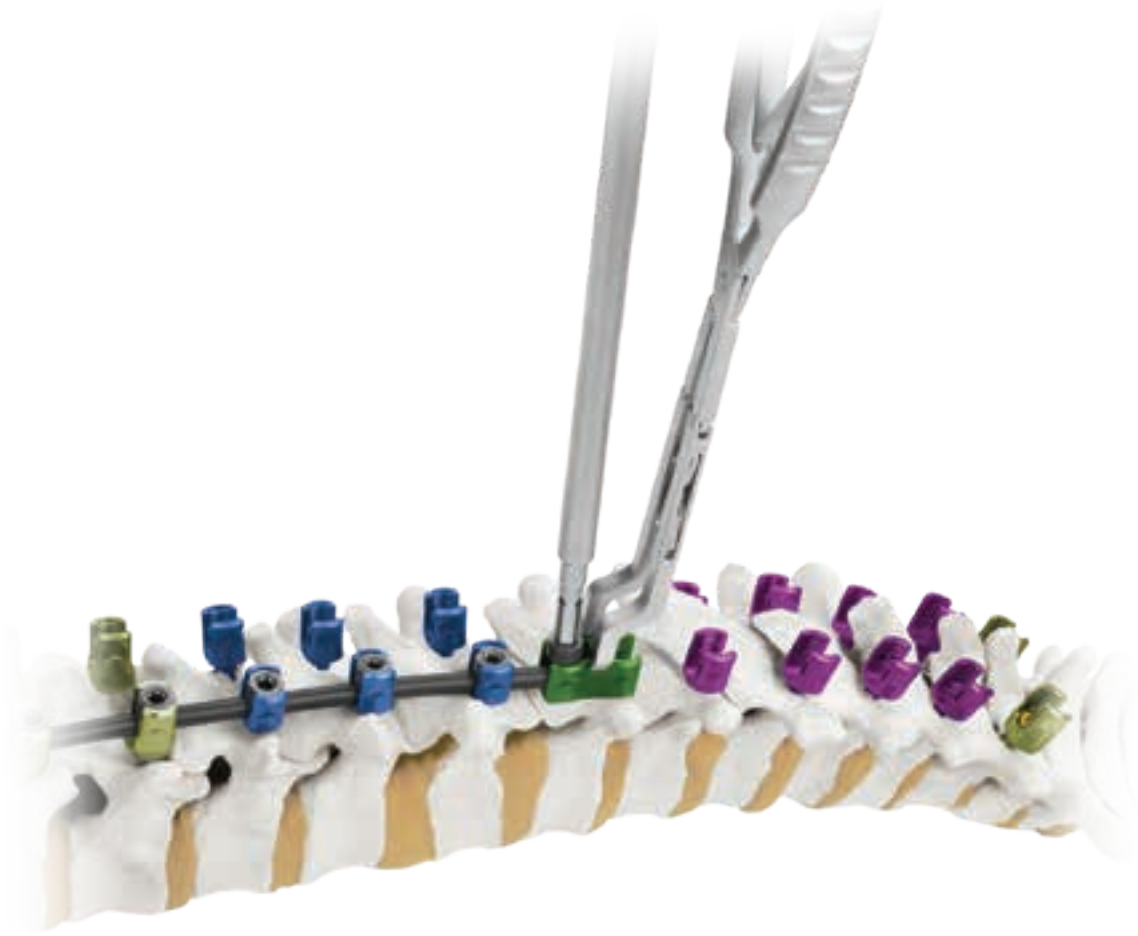


Secure the new rod by using the assembled Ratcheting Torque-Limiting Handle, ¼" Quick-Connect and Driver Shaft, ¼" Quick-Connect, Short to provisionally tighten the engaged set screw. The construct is not completely locked until final tightening.

*Additionally available

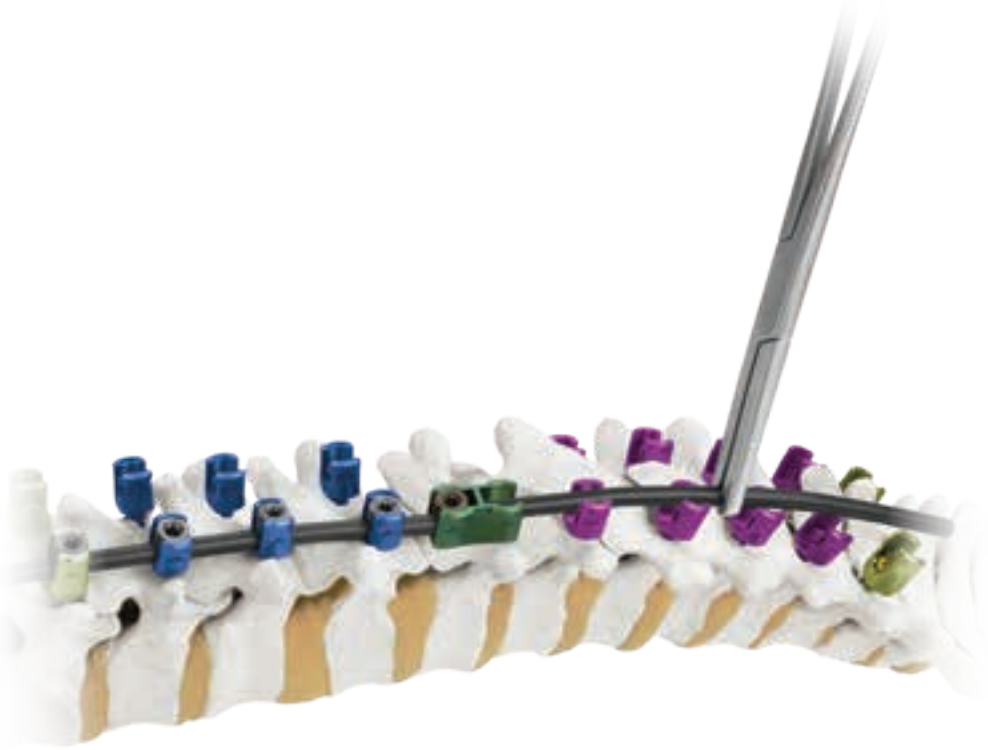
Double Head In-line Connector

Select a connection point and slide the first connector head onto the end of the existing rod. Secure the existing rod by using the Straight Handle, Ratcheting, ¼" Quick-Connect* and Threaded Locking Cap Driver assembly. Introduce a CREO® Threaded Locking Cap into the engaged head on the connector.



*Additionally available

Use the Rod Holder* to insert the new rod. Place one rod end into the free head on the connector and place the other end into the adjacent screw heads. Cut and contour the rod as desired using the Rod Benders, Left and Right*.



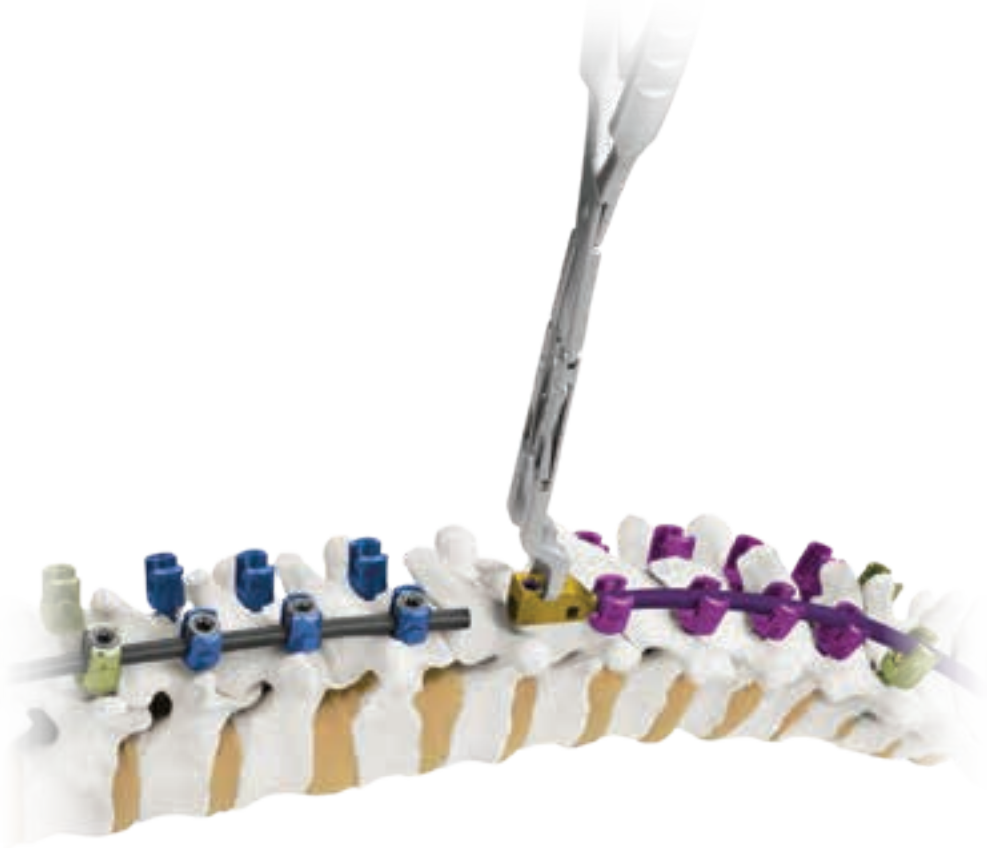
Secure the new rod by using the Straight Handle, Ratcheting, ¼" Quick-Connect* and Threaded Locking Cap Driver assembly. Introduce a CREO® Threaded Locking Cap into the engaged head on the connector. The construct is not completely locked until final tightening

*Additionally available

In-line Connectors (cont'd)

In-line Closed Connector with Integrated Rod Insertion

Select a connection point and slide the connector opening onto the end of the existing rod. Place the rod portion of the implant into adjacent screw heads.



Provisionally tighten the engaged set screws using the Ratcheting Torque-Limiting Handle, ¼" Quick-Connect and Driver Shaft, ¼" Quick-Connect, Short assembly. The construct is not completely locked until final tightening.

STEP 4 FINAL TIGHTENING

Final tightening of all set screws and threaded locking caps is necessary to secure the construct. Follow the guide below for each implant type.

Final Tightening	
Connectors with Set Screws	Attach the Ratcheting Torque-Limiting Handle, ¼" Quick-Connect to the Driver Shaft, ¼" Quick-Connect, Short. Secure the implant with the Implant Holder, Straight. Slide the Connector Counter Torque over the connector and ensure it is fully seated. Insert the driver tip through the counter torque into the set screw. Visually confirm that it is fully engaged. Rotate the torque-limiting driver assembly clockwise until it reaches the torque limit (5.5Nm) and two audible clicks are heard.
Double Head Lateral Connectors **Single Head - Open Lateral Connectors** **Single Head - Top Loading Lateral Connectors**	Attach the Ratcheting Torque-Limiting Handle, ¼" Quick-Connect to the Driver Shaft, ¼" Quick-Connect, Short. Insert the Torque-Limiting Driver Assembly in the Double Head Lateral Counter Torque. Insert the driver tip into the threaded locking cap. Visually confirm that it is fully engaged. Slide the Double Head Lateral Counter Torque over the connector and ensure it is fully seated. Rotate the final tightening assembly clockwise until it reaches the torque limit (8.0Nm) and two audible clicks are heard.
Double Head In-line Connectors	Attach the Ratcheting Torque-Limiting Handle, ¼" Quick-Connect to the Driver Shaft, ¼" Quick-Connect, Short. Insert the Torque-Limiting Driver Assembly into the Double Head In-line Counter Torque. Insert the driver tip into the threaded locking cap. Visually confirm it is fully engaged. Slide the Double Head In-line Counter Torque over the connector and ensure that it is fully seated. Rotate the torque-limiting driver assembly clockwise until it reaches the torque limit (8.0Nm) and two audible clicks are heard.

Torque Limit - 5.5Nm
Closed - Closed Lateral Connector
Open - Closed Lateral Connector
Single Head - Open Lateral Connector *(Open side only)*
Single Head - Top Loading Lateral Connector *(Top loading side only)*
In-line Closed Connector
In-line Closed Connector with Integrated Rod

Torque Limit - 8.0Nm
Double Head Lateral Connector
Single Head - Open Lateral Connector *(Head side only)*
Single Head - Top Loading Lateral Connector *(Head side only)*
Double Head In-line Connector

OPTIONAL: IMPLANT REMOVAL

For revision or removal of connectors, the insertion steps are reversed until the implants can be removed. Connectors may remain on a rod for removal or may be removed separately.

LATERAL CONNECTOR FINAL CONSTRUCTS

Double Head Lateral Connector with Z Rod

Open - Closed Lateral Connector with Z Rod

Single Head - Open Lateral Connector with Z Rod

Single Head - Top Loading Lateral Connector with Z Rod

IN-LINE CONNECTOR FINAL CONSTRUCTS

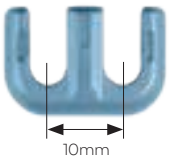
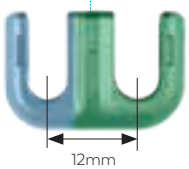
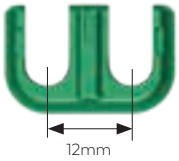
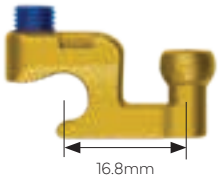
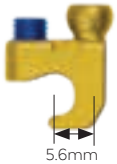
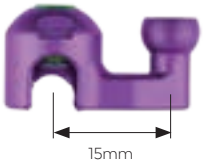
Double Head In-line Connector

In-line Closed Connector

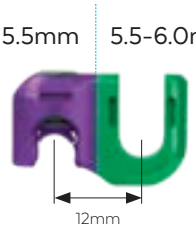
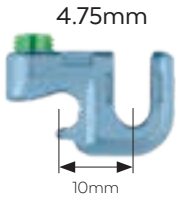
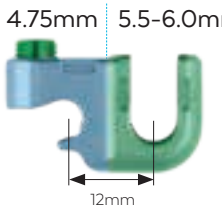
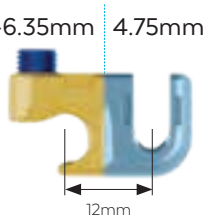
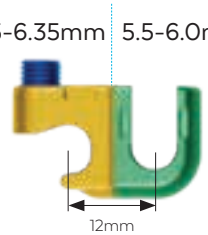
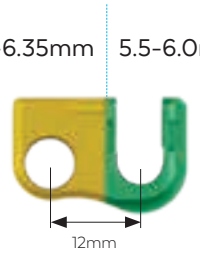
In-line Closed Connector with Integrated Rod

CONNECTOR GUIDE

Double Head Lateral and Modular Connectors

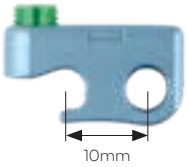
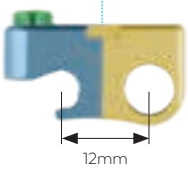
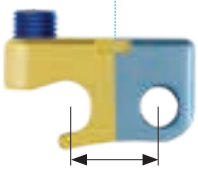
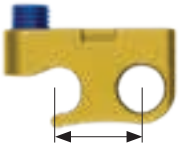
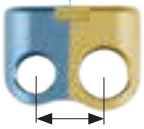
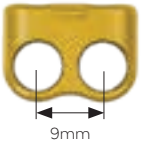
Part Number	Description	Compatible Rod Diameter
1175.9930	Double Head Lateral Connector, 4.75 to 4.75, 10mm Wide	4.75mm 
1175.9931	Double Head Lateral Connector, 4.75 to 5.5-6.0, 12mm Wide	4.75mm | 5.5-6.0mm 
1175.9933	Double Head Lateral Connector, 5.5-6.0 to 5.5-6.0, 12mm Wide	5.5mm-6.0mm 
1175.6255	Modular Head-Open Lateral Connector, 5.5-6.35	5.5mm-6.35mm 
1175.6355	Modular Head-Open Superior Connector, 5.5-6.35	5.5mm-6.35mm 
1175.7202	Modular Head-Top Loading Lateral Connector, 5.5 Top Loading	5.5mm 

Single Head Lateral Connectors

Part Number	Description	Compatible Rod Diameter
1175.7952	Single Head-Top Loading Lateral Connector, 5.5-6.0 Head to 5.5 Top Loading	
1175.9210	Single Head-Open Lateral Connector, 4.75 to 4.75, 10mm Wide	
1175.9211	Single Head-Open Lateral Connector, 5.5-6.0 Head to 4.75 Open, 12mm Wide	
1175.9213	Single Head-Open Lateral Connector, 4.75 Head to 5.5-6.35 Open, 12mm Wide	
1175.9214	Single Head-Open Lateral Connector, 5.5-6.0 Head to 5.5-6.35 Open, 12mm Wide	
1175.9822	Single Head-Closed Lateral Connector, 5.5-6.0 Head to 5.5-6.35 Closed, 12mm Wide	

CONNECTOR GUIDE (CONT'D)

Lateral Connectors

Part Number	Description	Compatible Rod Diameter
1175.4422	Open-Closed Lateral Connector, 4.75 to 4.75, 2 Set Screws, 10mm Wide	4.75mm 
1175.3422	Open-Closed Lateral Connector, 4.75 Open to 5.5-6.35 Closed, 2 Set Screws, 12mm Wide	4.75mm 5.5-6.35mm 
1175.6422	Open-Closed Lateral Connector, 5.5-6.35 Open to 4.75 Closed, 2 Set Screws, 12mm Wide	5.5-6.35mm 4.75mm 
1175.5422	Open-Closed Lateral Connector, 5.5—6.35 to 5.5—6.35, 2 Set Screws, 12mm Wide	5.5-6.35mm 
1175.4841	Closed-Closed Lateral Connector, 4.75 to 4.75, 4 Set Screws, 8mm Wide	4.75mm 
1175.3841	Closed-Closed Lateral Connector, 4.75 to 5.5-6.35, 4 Set Screws, 9mm Wide	4.75mm 5.5-6.35mm 
1175.5841	Closed-Closed Lateral Connector, 5.5—6.35 to 5.5—6.35, 4 Set Screws, 9mm wide	5.5mm—6.35mm 

In-line Connectors

Part Number	Description	Compatible Rod Diameter
1175.1144	In-line Closed Connector, 4.75 to 4.75, 4 Set Screws	4.75mm 
1175.1134	In-line Closed Connector, 4.75 to 5.5-6.35, 4 Set Screws	4.75mm  5.5-6.35mm 
1175.1152	In-line Closed Connector, 5.5-6.35 to 5.5-6.35, 2 Set Screws	5.5mm—6.35mm 
1175.1554	In-line Closed Connector with Integrated 5.5 Rod, 5.5—6.35, 400mm	5.5mm—6.35mm 
1175.1604	In-line Closed Connector with Integrated 6.0 Rod, 5.5-6.35, 400mm	5.5mm—6.35mm 
1175.1634	In-line Closed Connector with Integrated 6.35 Rod, 5.5-6.35, 400mm	5.5mm—6.35mm 
1175.9910	Double Head In-line Connector, 4.75 to 4.75	4.75mm 
1175.9911	Double Head In-line Connector, 4.75 to 5.5-6.0	4.75mm  5.5-6.0mm 
1175.9913	Double Head In-line Connector, 5.5-6.0 to 5.5-6.0	5.5mm—6.0mm 

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IMPLANT SET 9175.9001

Part No.	Description	Qty
1119.0010	CREO® Threaded Locking Cap	10
1175.1152	In-line Closed Connector, 5.5-6.35 to 5.5-6.35, 2 Set Screws	2
1175.1554	In-line Closed Connector with Integrated 5.5 Rod, 5.5-6.35, 400mm	2
1175.1604	In-line Closed Connector with Integrated 6.0 Rod, 5.5-6.35,400mm	2
1175.1634	In-line Closed Connector with Integrated 6.35 Rod, 5.5-6.35, 400mm	2
1175.5510	Straight Headed Rod, 5.5, 40mm	2
1175.5511	Straight Headed Rod, 5.5, 45mm	2
1175.5512	Straight Headed Rod, 5.5, 50mm	2
1175.5514	Straight Headed Rod, 5.5, 200mm	2
1175.5520	Lateral Headed Rod, Right, 5.5, 75mm	2
1175.5521	Lateral Headed Rod, Right, 5.5, 80mm	2
1175.5522	Lateral Headed Rod, Right, 5.5, 85mm	2
1175.5524	Lateral Headed Rod, Right, 5.5, 230mm	2
1175.5525	Lateral Headed Rod, Left, 5.5, 75mm	2
1175.5526	Lateral Headed Rod, Left, 5.5, 80mm	2
1175.5527	Lateral Headed Rod, Left, 5.5, 85mm	2
1175.5529	Lateral Headed Rod, Left, 5.5, 230mm	2
1175.5530	Superior Headed Rod, Full Offset, 5.5, 75mm	2
1175.5531	Superior Headed Rod, Full Offset, 5.5, 80mm	2
1175.5532	Superior Headed Rod, Full Offset, 5.5, 85mm	2
1175.5534	Superior Headed Rod, Full Offset, 5.5, 230mm	2
1175.5535	Superior Headed Rod, Half Offset, 5.5, 75mm	2
1175.5536	Superior Headed Rod, Half Offset, 5.5, 80mm	2
1175.5537	Superior Headed Rod, Half Offset, 5.5, 85mm	2
1175.5539	Superior Headed Rod, Half Offset, 5.5, 230mm	2
1175.5422	Open-Closed Lateral Connector, 5.5-6.35 to 5.5-6.35, 2 Set Screws, 12mm Wide	4
1175.5841	Closed-Closed Lateral Connector, 5.5-6.35 to 5.5-6.35, 4 Set Screws, 9mm Wide	2

*Items in gray are additionally available

Part No.	Description	Qty
1175.6255	Modular Head-Open Lateral Connector, 5.5-6.35	2
1175.6355	Modular Head-Open Superior Connector, 5.5-6.35	2
1175.9214	Single Head-Open Lateral Connector, 5.5-6.0 Head to 5.5-6.35 Open, 12mm Wide	4
1175.9913	Double Head In-line Connector, 5.5-6.0 to 5.5-6.0	2
1175.9933	Double Head Lateral Connector, 5.5-6.0 to 5.5-6.0, 12mm Wide	4
1175.2551	Z Rod, Titanium Alloy, 5.5 Rod, 12mm Offset, 100-200mm	2
1175.2601	Z Rod, Titanium Alloy, 6.0 Rod, 12mm Offset, 100-200mm	2
1175.2631	Z Rod, Titanium Alloy, 6.35 Rod, 12mm Offset, 100-200mm	2
7175.2551	Z Rod, 5.5 Rod, 12mm Offset, 100-200mm, CoCr	2
7175.2601	Z Rod, 6.0 Rod, 12mm Offset, 100-200mm, CoCr	2
7175.2631	Z Rod, 6.35 Rod, 12mm Offset, 100-200mm, CoCr	2

9175.0001	CREO ADDITION® Implants Graphic Case
9175.0100	CREO ADDITION® Open Revision Connector Module
9175.0200	CREO ADDITION® MIS Revision Connector Module

ADDITIONALLY AVAILABLE

Part No.	Description
1175.7202	Modular Head-Top Loading Lateral Connector, 5.5 Top Loading
1175.7952	Single Head-Top Loading Lateral Connector, 5.5-6.0 Head to 5.5 Top Loading
1175.9822	Single Head-Closed Lateral Connector, 5.5-6.0 Head to 5.5-6.35 Closed, 12mm Wide
2175.3122	Open-Open Lateral Connector, 5.5-6.35 to 6.5, 2 Set Screws, 12mm Wide, SS
2175.3622	Open-Closed Lateral Connector, 6.5 Open to 5.5-6.35 Closed, 2 Set Screws, 12mm Wide, SS
2175.3632	Open-Closed Lateral Connector, 6.5 Open to 5.5-6.35 Closed, 3 Set Screws, 12mm Wide, SS
2175.3941	Closed-Closed Lateral Connector, 5.5-6.35 to 6.5, 4 Set Screws, 9mm Wide, SS

**Items in gray are additionally available*

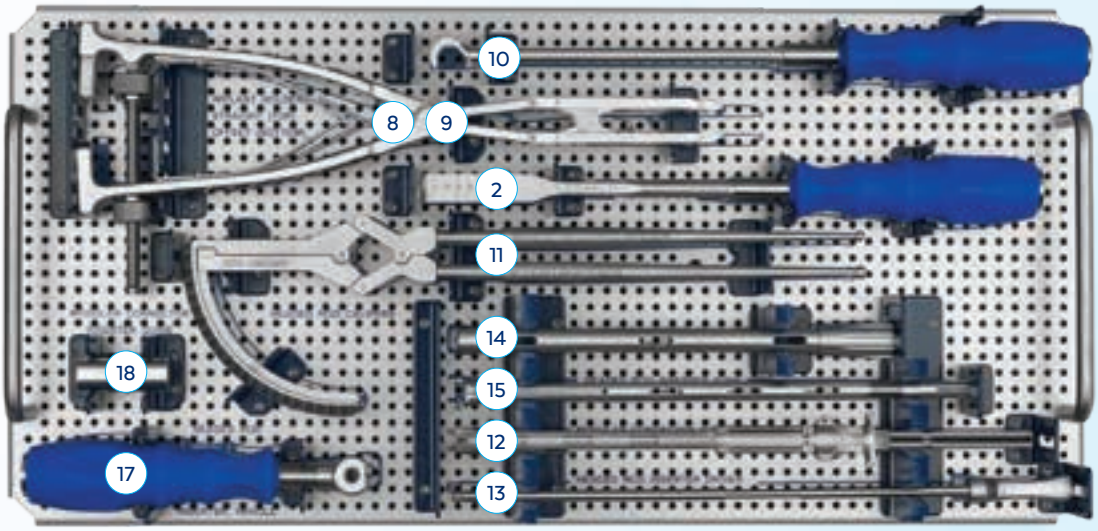
CREO ADDITION® MIS REVISION
INSTRUMENT SET 9175.9002

	Part No.	Description	Qty
1	634.611	Torque Limiting T-Handle, Ratcheting, 8Nm, 1/4" Connect, Black	1
2	643.052	Straight Osteotome, 12.7mm (½")	1
3	6067.0040	Ratcheting Torque-Limiting Handle, ¼" Quick-Connect	1
4	6067.0050	Driver Shaft, ¼" Quick-Connect, Short	1
5	6067.0055	Driver Shaft, ¼" Quick-Connect, Long	2
6	6119.6015	Connector Counter Torque	1
7	6120.5000	Threaded Locking Cap Driver	2
8	6175.0010	Implant Holder, Straight	1
9	6175.0020	Implant Holder, Offset	1
10	6175.0032	Bone Hook, 6.0mm	1
11	6175.2000	Headed Rod Calipers	1
12	6175.2011	Modular Connector Inserter, Threaded	1
13	6175.2030	Headed Rod Inserter Driver	1
14	6175.2040	Headed Rod Inserter, Threaded	1
15	6175.2041	Headed Rod Inserter Fork	1
16	6175.2042	Spanner Wrench	1
17	6175.2050	Headed Rod Inserter Handle	1
18	6175.2060	Modular Connector Inserter Guide	1
19	6175.9913	Double Head In-line Counter Torque, 5.5-6.0	1
20	6175.9933	Double Head Lateral Counter Torque, 5.5-6.0	1

9175.0002	CREO ADDITION® Instruments Graphic Case

ADDITIONALLY AVAILABLE

Part No.	Description
6175.2010	Modular Connector Inserter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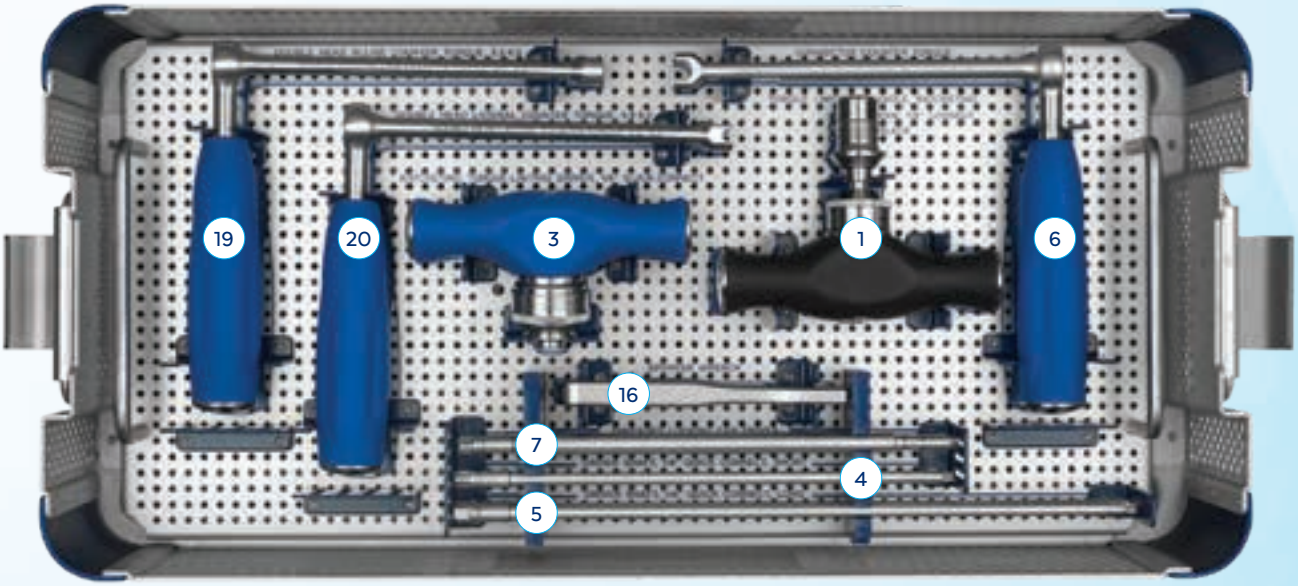
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CREO ADDITION® 4.75
IMPLANT & INSTRUMENT SET 9175.9003

Part No.	Description	Qty
1067.0010	CREO® 4.75 Threaded Locking Cap	10
1119.0010	CREO® Threaded Locking Cap	10
1175.1134	In-line Closed Connector, 4.75 to 5.5-6.35, 4 Set Screws	2
1175.1144	In-line Closed Connector, 4.75 to 4.75, 4 Set Screws	2
1175.3422	Open-Closed Lateral Connector, 4.75 Open to 5.5-6.35 Closed, 2 Set Screws, 12mm Wide	4
1175.4422	Open-Closed Lateral Connector, 4.75 to 4.75, 2 Set Screws, 10mm Wide	4
1175.6422	Open-Closed Lateral Connector, 5.5-6.35 Open to 4.75 Closed, 2 Set Screws, 12mm Wide	4
1175.3841	Closed-Closed Lateral Connector, 4.75 to 5.5-6.35, 4 Set Screws, 9mm Wide	2
1175.4841	Closed-Closed Lateral Connector, 4.75 to 4.75, 4 Set Screws, 8mm Wide	2
1175.9210	Single Head - Open Lateral Connector, 4.75 to 4.75, 10mm Wide	2
1175.9211	Single Head - Open Lateral Connector, 5.5-6.0 Head to 4.75 Open, 12mm Wide	2
1175.9213	Single Head - Open Lateral Connector, 4.75 Head to 5.5-6.35 Open, 12mm Wide	2
1175.9910	Double Head In-line Connector, 4.75 to 4.75	2
1175.9911	Double Head In-line Connector, 4.75 to 5.5-6.0	2
1175.9930	Double Head Lateral Connector, 4.75 to 4.75, 10mm Wide	2
1175.9931	Double Head Lateral Connector, 4.75 to 5.5-6.0, 12mm Wide	2
1175.2471	Z Rod, Titanium Alloy, 4.75 Rod, 10mm Offset, 100mm-200mm	2
1175.2551	Z Rod, Titanium Alloy, 5.5 Rod, 12mm Offset, 100mm-200mm	2
7175.2471	Z Rod, 4.75 Rod, 10mm Offset, 100mm-200mm, CoCr	2
7175.2551	Z Rod, 5.5 Rod, 12mm Offset, 100mm-200mm, CoCr	2
6067.5000	4.75 Threaded Locking Cap Driver	2
6175.0031	Bone Hook, 5.5	1
6175.9910	Double Head In-line Counter Torque, 4.75	1
6175.9930	Double Head Lateral Counter Torque, 4.75	1
9175.0003	CREO ADDITION® 4.75 Implants and Instruments Graphic Case	
9175.0300	CREO ADDITION® 4.75 Connector Module	

IMPORTANT INFORMATION ON CREO® STABILIZATION SYSTEM

DESCRIPTION

The CREO® Stabilization System consists of rods, hooks, monoaxial screws, uniplanar screws, polyaxial screws, reduction screws, fenestrated screws, 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 6.0mm and 6.35mm rods. Implant components can be rigidly locked into a variety of configurations for the individual patient and surgical condition. Polyaxial screws, hooks, and t-connectors are intended for posterior use only. Staples are intended for anterior use only. Rods and monoaxial screws may be used anteriorly or posteriorly. Locking caps are used to connect screws or hooks to the rod and trans iliac connectors.

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

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

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

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

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

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

INDICATIONS

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

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

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

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

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

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

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

WARNINGS

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

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

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

Potential risks when used with bone cement include:

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

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

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

IMPORTANT INFORMATION ON CREO® STABILIZATION SYSTEM

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

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

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

Strict adherence to the surgical technique guide is strongly recommended.

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

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

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

ADDITIONAL WARNINGS FOR PEDIATRIC PATIENTS

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

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

PRECAUTIONS

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

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

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

the products from the packaging using aseptic technique.

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

HANDLING AND USE

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

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

CLEANING

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

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

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

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

CONTACT INFORMATION

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

STERILIZATION

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

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

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

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

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

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

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

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

CAUTION: Federal (U.S.A.) Law 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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