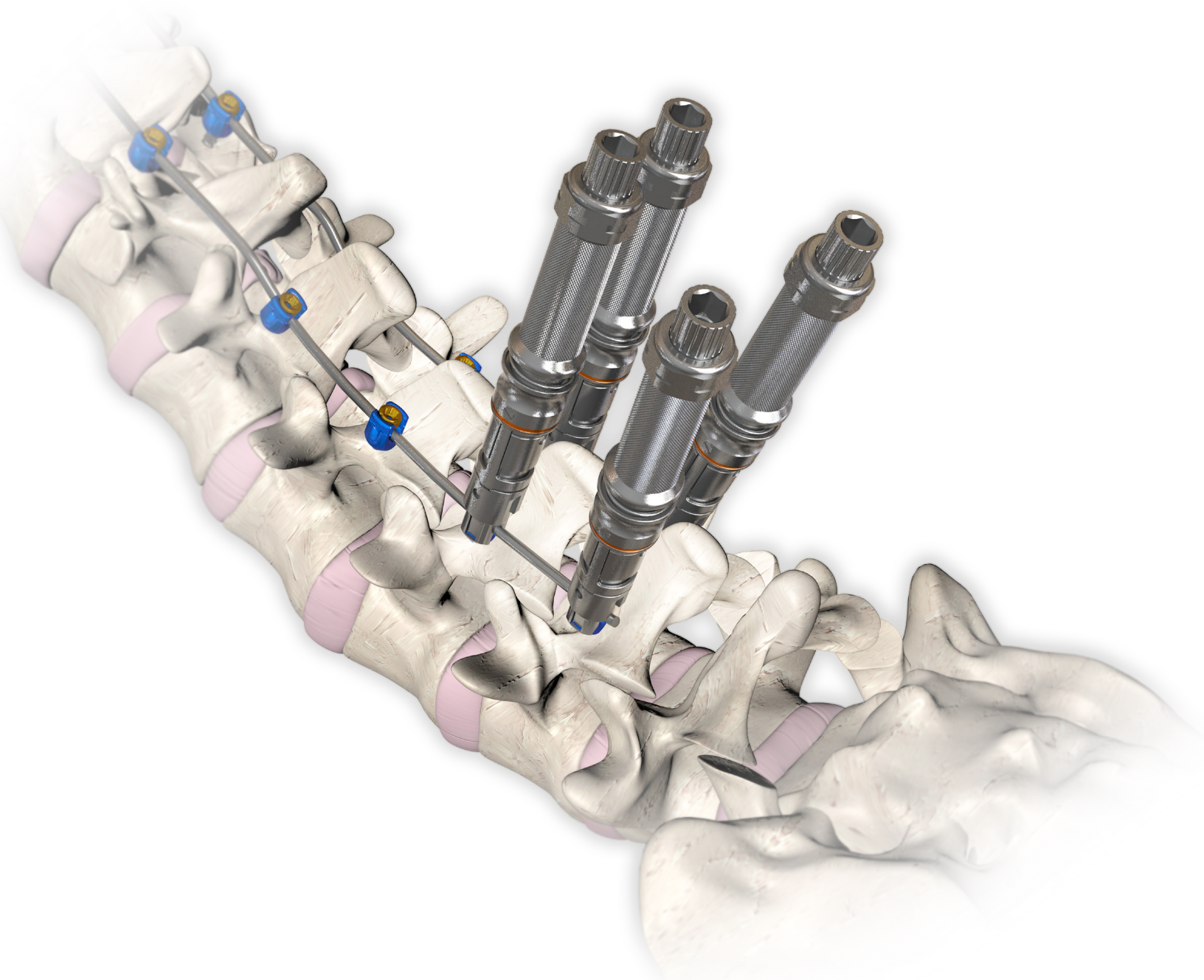
RESPONSE™ 4.5/5.0mm System

SURGICAL TECHNIQUE



OrthoPediatrics®
Leading Innovation in Pediatric Orthopedics

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INDICATIONS

Outside of the United States - When used for posterior non-cervical pedicle screw fixation in pediatric patients, the RESPONSE 4.5/5.0 Spine System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The RESPONSE 4.5/5.0 Spine System is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

NOTE: the RESPONSE 4.5/5.0 System may not be available in all markets; please contact your OP representative for availability.

Inside the United States - The ***RESPONSE™ 4.5/5.0 Spine System*** is intended for immobilization and stabilization of the posterior, non-cervical spine in skeletally mature patients as an adjunct to fusion for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, curvatures (i.e., scoliosis, kyphosis, or lordosis), tumor, pseudarthrosis, and/or failed previous fusion.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the RESPONSE 4.5/5.0 Spine System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis, neuromuscual scoliosis and congenital scoliosis. The RESPONSE 4.5/5.0 Spine System is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

Brazil: The RESPONSE™ 4.5/5.0 Spine System is intended for immobilization and stabilization of the posterior, non-cervical spine in skeletally mature patients as an adjunct to fusion for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e.., fracture or dislocation), spinal stenosis, curvatures (i.e., scoliosis, kyphosis, or lordosis), tumor, pseudarthrosis, and/or failed previous fusion.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the ***Response 4.5/5.0 Spine System implants*** are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The Response 4.5/5.0 Spine System is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

SYSTEM FEATURES

The ***RESPONSE™ 4.5/5.0 Spine System*** includes a selection of biocompatible material and various implant designs, configurations and sizes to accommodate various surgical techniques. The primary features of the RESPONSE 4.5/5.0 Spine System include the following:

- **unique set screw design** with proprietar square threads for better fixation and easy insertion to help reduce the ability to cross thread
- one of the **lowest profile** 4.5/5.0mm pedicle screws on the market
- unique one step, snap-on **rod reduction** instruments that complement the versatile rod reduction and coupled derotation options
- **versatility** in using 4.5mm or 5.0mm rod option in same low profile screw
- 7.0mm screw option for **sacral fixation**

4.5/5.0 Implant Classification

The **RESPONSE™ 4.5/5.0 Spine System** features the following pedicle screws:

- Polyaxial and Polyaxial Reduction Pedicle Screws
- Uniaxial and Uniaxial Reduction Pedicle Screws

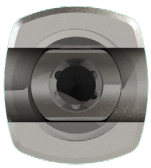
Screw diameter and length is indicated on the lateral surface of the screw.

Each pedicle screw size is designed with a unique color identifier as shown in the illustrations below.

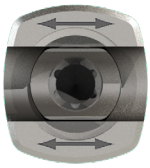


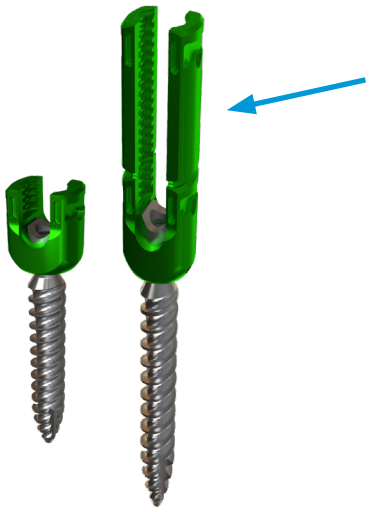
4.0mm 4.5mm 5.0mm 5.5mm 6.0mm 7.0mm

Polyaxial Screws are designated by an absence of arrows or divots on the proximal surface of the screw.



Uniaxial Screws are designated by two arrows on the proximal surface of the screw.





Polyaxial Reduction and **Uniaxial Reduction** Screws are designated by extended tabs which are removed following rod reduction.

4.5/5.0mm IMPLANTS

Polyaxial Pedicle Screws

Polyaxial Screws	
00-1600-2420	4.0mm x 20mm
00-1600-2425	4.0mm x 25mm
00-1600-2430	4.0mm x 30mm
00-1600-2435	4.0mm x 35mm
00-1600-2440	4.0mm x 40mm
00-1600-7420	4.5mm x 20mm
00-1600-7425	4.5mm x 25mm
00-1600-7430	4.5mm x 30mm
00-1600-7435	4.5mm x 35mm
00-1600-7440	4.5mm x 40mm
00-1600-7445	4.5mm x 45mm
00-1600-2520	5.0mm x 20mm
00-1600-2525	5.0mm x 25mm
00-1600-2530	5.0mm x 30mm
00-1600-2535	5.0mm x 35mm
00-1600-2540	5.0mm x 40mm
00-1600-2545	5.0mm x 45mm
00-1600-2550	5.0mm x 50mm
00-1600-7520	5.5mm x 20mm
00-1600-7525	5.5mm x 25mm
00-1600-7530	5.5mm x 30mm
00-1600-7535	5.5mm x 35mm
00-1600-7540	5.5mm x 40mm
00-1600-7545	5.5mm x 45mm
00-1600-7550	5.5mm x 50mm
00-1600-2620	6.0mm x 20mm
00-1600-2625	6.0mm x 25mm
00-1600-2630	6.0mm x 30mm
00-1600-2635	6.0mm x 35mm
00-1600-2640	6.0mm x 40mm
00-1600-2645	6.0mm x 45mm
00-1600-2650	6.0mm x 50mm
00-1600-2655	6.0mm x 55mm
00-1600-2660	6.0mm x 60mm
00-1600-2670	6.0mm x 70mm
00-1600-2680	6.0mm x 80mm

Polyaxial Screws	
00-1600-2730	7.0mm x 30mm
00-1600-2735	7.0mm x 35mm
00-1600-2740	7.0mm x 40mm
00-1600-2745	7.0mm x 45mm
00-1600-2750	7.0mm x 50mm
00-1600-2760	7.0mm x 60mm
00-1600-2770	7.0mm x 70mm
00-1600-2780	7.0mm x 80mm

***Additional screw sizes may be available by special order**

4.5/5.0mm IMPLANTS

Polyaxial Reduction Screws

Polyaxial Reduction Screws	
00-1600-3420	4.0mm x 20mm
00-1600-3425	4.0mm x 25mm
00-1600-3430	4.0mm x 30mm
00-1600-3435	4.0mm x 35mm
00-1600-3440	4.0mm x 40mm
00-1600-9420	4.5mm x 20mm
00-1600-9425	4.5mm x 25mm
00-1600-9430	4.5mm x 30mm
00-1600-9435	4.5mm x 35mm
00-1600-9440	4.5mm x 40mm
00-1600-9445	4.5mm x 45mm
00-1600-3520	5.0mm x 20mm
00-1600-3525	5.0mm x 25mm
00-1600-3530	5.0mm x 30mm
00-1600-3535	5.0mm x 35mm
00-1600-3540	5.0mm x 40mm
00-1600-3545	5.0mm x 45mm
00-1600-3550	5.0mm x 50mm
00-1600-9520	5.5mm x 20mm
00-1600-9525	5.5mm x 25mm
00-1600-9530	5.5mm x 30mm
00-1600-9535	5.5mm x 35mm
00-1600-9540	5.5mm x 40mm
00-1600-9545	5.5mm x 45mm
00-1600-9550	5.5mm x 50mm
00-1600-3620	6.0mm x 20mm
00-1600-3625	6.0mm x 25mm
00-1600-3630	6.0mm x 30mm
00-1600-3635	6.0mm x 35mm
00-1600-3640	6.0mm x 40mm
00-1600-3645	6.0mm x 45mm
00-1600-3650	6.0mm x 50mm
00-1600-3655	6.0mm x 55mm
00-1600-3660	6.0mm x 60mm
00-1600-3670	6.0mm x 70mm
00-1600-3680	6.0mm x 80mm

Polyaxial Reduction Screws	
00-1600-3730	7.0mm x 30mm
00-1600-3735	7.0mm x 35mm
00-1600-3740	7.0mm x 40mm
00-1600-3745	7.0mm x 45mm
00-1600-3750	7.0mm x 50mm
00-1600-3760	7.0mm x 60mm
00-1600-3770	7.0mm x 70mm
00-1600-3780	7.0mm x 80mm

***Additional screw sizes may be available by special order**

4.5/5.0mm IMPLANTS

Uniaxial Pedicle Screws

Uniaxial Screws	
00-1650-0420	4.0mm x 20mm
00-1650-0425	4.0mm x 25mm
00-1650-0430	4.0mm x 30mm
00-1650-0435	4.0mm x 35mm
00-1650-0440	4.0mm x 40mm
00-1650-6420	4.5mm x 20mm
00-1650-6425	4.5mm x 25mm
00-1650-6430	4.5mm x 30mm
00-1650-6435	4.5mm x 35mm
00-1650-6440	4.5mm x 40mm
00-1650-6445	4.5mm x 45mm
00-1650-0520	5.0mm x 20mm
00-1650-0525	5.0mm x 25mm
00-1650-0530	5.0mm x 30mm
00-1650-0535	5.0mm x 35mm
00-1650-0540	5.0mm x 40mm
00-1650-0545	5.0mm x 45mm
00-1650-0550	5.0mm x 50mm
00-1650-6520	5.5mm x 20mm
00-1650-6525	5.5mm x 25mm
00-1650-6530	5.5mm x 30mm
00-1650-6535	5.5mm x 35mm
00-1650-6540	5.5mm x 40mm
00-1650-6545	5.5mm x 45mm
00-1650-6550	5.5mm x 50mm
00-1650-0620	6.0mm x 20mm
00-1650-0625	6.0mm x 25mm
00-1650-0630	6.0mm x 30mm
00-1650-0635	6.0mm x 35mm
00-1650-0640	6.0mm x 40mm
00-1650-0645	6.0mm x 45mm
00-1650-0650	6.0mm x 50mm
00-1650-0655	6.0mm x 55mm
00-1650-0660	6.0mm x 60mm
00-1650-0670	6.0mm x 70mm
00-1650-0680	6.0mm x 80mm

Uniaxial Screws	
00-1650-0730	7.0mm x 30mm
00-1650-0735	7.0mm x 35mm
00-1650-0740	7.0mm x 40mm
00-1650-0745	7.0mm x 45mm
00-1650-0750	7.0mm x 50mm
00-1650-0760	7.0mm x 60mm
00-1650-0770	7.0mm x 70mm
00-1650-0780	7.0mm x 80mm

***Additional screw sizes may be available by special order**

4.5/5.0mm IMPLANTS

Uniaxial Pedicle Screws

Uniaxial Screws	
00-1650-1420	4.0mm x 20mm
00-1650-1425	4.0mm x 25mm
00-1650-1430	4.0mm x 30mm
00-1650-1435	4.0mm x 35mm
00-1650-1440	4.0mm x 40mm
00-1650-8420	4.5mm x 20mm
00-1650-8425	4.5mm x 25mm
00-1650-8430	4.5mm x 30mm
00-1650-8435	4.5mm x 35mm
00-1650-8440	4.5mm x 40mm
00-1650-8445	4.5mm x 45mm
00-1650-1520	5.0mm x 20mm
00-1650-1525	5.0mm x 25mm
00-1650-1530	5.0mm x 30mm
00-1650-1535	5.0mm x 35mm
00-1650-1540	5.0mm x 40mm
00-1650-1545	5.0mm x 45mm
00-1650-1550	5.0mm x 50mm
00-1650-8520	5.5mm x 20mm
00-1650-8525	5.5mm x 25mm
00-1650-8530	5.5mm x 30mm
00-1650-8535	5.5mm x 35mm
00-1650-8540	5.5mm x 40mm
00-1650-8545	5.5mm x 45mm
00-1650-8550	5.5mm x 50mm
00-1650-1620	6.0mm x 20mm
00-1650-1625	6.0mm x 25mm
00-1650-1630	6.0mm x 30mm
00-1650-1635	6.0mm x 35mm
00-1650-1640	6.0mm x 40mm
00-1650-1645	6.0mm x 45mm
00-1650-1650	6.0mm x 50mm
00-1650-1655	6.0mm x 55mm
00-1650-1660	6.0mm x 60mm
00-1650-1670	6.0mm x 70mm
00-1650-1680	6.0mm x 80mm

Uniaxial Screws	
00-1650-1730	7.0mm x 30mm
00-1650-1735	7.0mm x 35mm
00-1650-1740	7.0mm x 40mm
00-1650-1745	7.0mm x 45mm
00-1650-1750	7.0mm x 50mm
00-1650-1760	7.0mm x 60mm
00-1650-1770	7.0mm x 70mm
00-1650-1780	7.0mm x 80mm

***Additional screw sizes may be available by special order**

4.5/5.0mm IMPLANTS

Rod Options

Cobalt Chrome rod material is indicated in two ways:

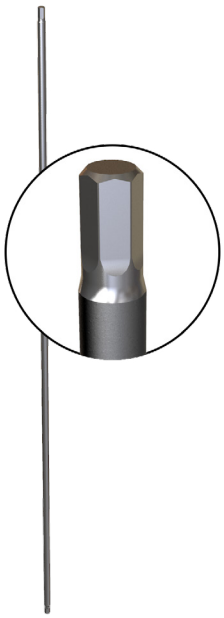
- etched dashed lines which run along the length of the rod
- etching opposite from the hex feature

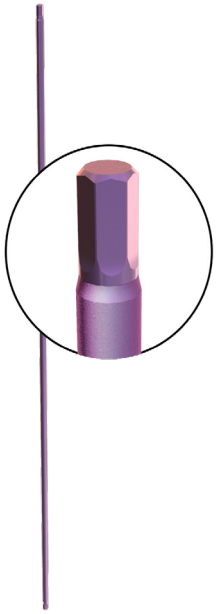
Cobalt Chrome Rod (CoCr)	
4.5mm x 500mm	00-1600-4555
5.0mm x 500mm	00-1600-5055
4.5mm x 5.5mm x 500mm	00-1650-8451
4.5mm x 6.0mm x 500mm	00-1650-8461
5.0mm x 5.5mm x 500mm	00-1650-8551
5.0mm x 6.0mm x 500mm	00-1650-8561

Titanium Alloy rod material is indicated in three ways:

- etched straight line which runs along the length of the rod
- unique color identifier
- etching opposite from the hex feature

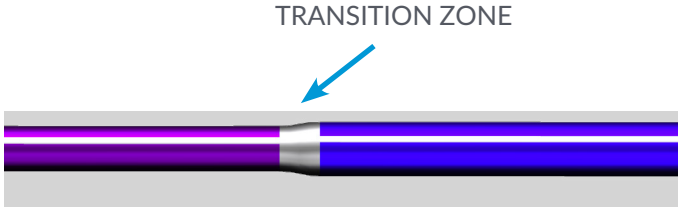
Titanium Rod (Ti)	
5.0mm x 500mm	00-1600-5056
5.0mm x 5.5mm x 500mm	00-1650-9551
5.0mm x 6.0mm x 500mm	00-1650-9561







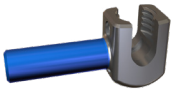
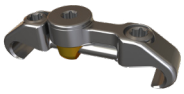
Cobalt Chrome (CoCr) Transition Rod



Titanium (Ti) Transition Rod

4.5/5.0mm IMPLANTS

CONNECTORS AND SET SCREWS

Product	Description	Item Number
	Inline Connector, 40mm	00-1600-5740
	Inline Connector, 60mm	00-1600-5760
	Inline Connector, 80mm	00-1600-5780
	Wedding Band Connector, 4.5/5.0	00-1600-6900
	Wedding Band Connector, 4.5/6.0	00-1650-6900
	Domino Connector, 20mm (4.5/5.0)	00-1600-6820
	Domino Connector, 20mm (4.5/6.0)	00-1650-6820
	Large Set Screw Used in: All 4.5/5.0 Pedicle Screws & Hooks	00-1600-4001
	Open Lateral Connector, 5.0mm shaft, 20mm	00-1600-7020
	Open Lateral Connector, 5.0mm shaft, 40mm	00-1600-7040
	Open Lateral Connector, 5.0mm shaft, 80mm	00-1600-7080
	Open Lateral Connector, 6.0mm shaft, 20mm	00-1650-7020
	Open Lateral Connector, 6.0mm shaft,40mm	00-1650-7040
	Open Lateral Connector, 6.0mm shaft, 80mm	00-1650-7080
	Adjustable Cross Connector, Small	00-1600-3041
	Adjustable Cross Connector, Medium	00-1600-3043
	Adjustable Cross Connector, Large	00-1600-3045
	Adjustable Cross Connector, X-Large	00-1600-3047
	Fixed Cross Connector, 14mm	00-1600-5014
	Fixed Cross Connector, 16mm	00-1600-5016
	Fixed Cross Connector, 18mm	00-1600-5018
	Fixed Cross Connector, 20mm	00-1600-5020
	Fixed Cross Connector, 22mm	00-1600-5022
	Fixed Cross Connector, 24mm	00-1600-5024
	Fixed Cross Connector, 26mm	00-1600-5026
	Fixed Cross Connector, 28mm	00-1600-5028
	Fixed Cross Connector, 30mm	00-1600-5030
	Fixed Cross Connector, 32mm	00-1600-5032
	Fixed Cross Connector, 34mm	00-1600-5034
	Fixed Cross Connector, 36mm	00-1600-5036

4.5/5.0mm IMPLANTS

HOOKS

Product	Description	Item Number
	Open Pedicle Hook, 5.0mm	00-1600-3149
	Open Pedicle Hook, 6.5mm	00-1600-3150
	Open Pedicle Hook, 8.0mm	00-1600-3151
	Open Laminar Hook, 5.0mm, Narrow	00-1600-3249
	Open Laminar Hook, 6.5mm, Narrow	00-1600-3250
	Open Laminar Hook, 8mm, Narrow	00-1600-3251
	Open Laminar Hook, 5.0mm, Wide	00-1600-3253
	Open Laminar Hook, 6.5mm, Wide	00-1600-3254
	Open Laminar Hook, 8mm, Wide	00-1600-3255
	Open Thoracic Hook, 5.0mm, Narrow	00-1600-3259
	Open Thoracic Hook, 6.5mm, Narrow	00-1600-3260
	Open Thoracic Hook, 8.0mm, Narrow	00-1600-3261
	Open Thoracic Hook, 5.0mm, Wide	00-1600-3263
	Open Thoracic Hook, 6.5mm, Wide	00-1600-3264
	Open Thoracic Hook, 8.0mm, Wide	00-1600-3265
	Open Thoracic Hook, 10.0mm, Wide	00-1600-3266
	Open Left Offset Lumbar Hook, 5.0mm	00-1600-3302
	Open Right Offset Lumbar Hook, 5.0mm	00-1600-3303
	Open Left Offset Lumbar Hook, 6.5mm	00-1600-3312
	Open Right Offset Lumbar Hook, 6.5mm	00-1600-3313
	Open Left 40 Degree Offset Hook, 5.0mm	00-1600-3304
	Open RIght 40 Degree Offset Hook, 5.0mm	00-1600-3305
	Open Left 40 Degree Offset Hook, 6.5mm	00-1600-3314
	Open RIght 40 Degree Offset Hook, 6.5mm	00-1600-3315
	Open Left 40 Degree Offset Hook, 8.0mm	00-1600-3324
	Open RIght 40 Degree Offset Hook, 8.0mm	00-1600-3325

INSTRUMENTS

Pedicle Prep/Screw Insertion



Pedicle Awl
01-1003-6020



Lenke Probe, 2mm Straight
01-1003-6021



Lenke Probe, 2mm Curved
01-1003-6022



Thoracic Lenke Probe, 2mm Curved
01-1003-6016



Uniaxial (Single Lead)



Polyaxial (Double Lead)

Taps

Size	Uniaxial Tap	Polyaxial Tap
3.0MM	01-1300-3130	01-1300-1030
3.5MM	01-1300-3135	01-1300-1035
4.0MM	01-1300-3140	01-1300-1040
4.5MM	01-1300-3145	01-1300-1045
5.0MM	01-1300-3150	01-1300-1050
6.0MM	01-1300-3160	01-1300-1060



Feeler Probe, Large: 01-1003-6025

INSTRUMENTS

Pedicle Prep/Screw Insertion



Pedicle Screw Driver (**blue** handle)	01-1600-6035
Reduction Pedicle Screw Driver (**green** handle)	01-1600-6036



Axial Handle, Fixed
01-1003-6299



Large Hudson Power Adapter
01-1003-5102



Axial Handle, Ratcheting
01-1003-6033



Screw Head Positioner
01-1600-6276



Palm Handle, Ratcheting
01-1003-6034



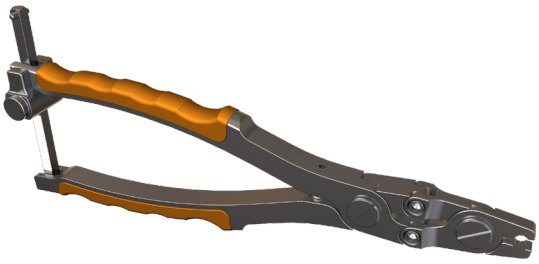
Fixed Ratcheting T-Handle
01-1600-0027

INTRUMENTS

Pedicle Prep/Screw Insertion



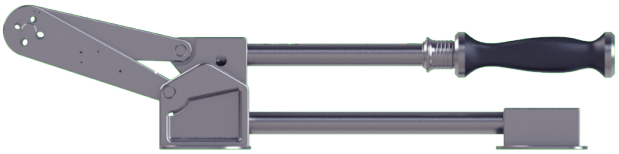
Rod Template, 500mm
01-1003-6059



Dual Action Rod Grippers
01-1600-0016



French Bender
01-1003-6055



Rod Cutter
01-1300-0015

INTRUMENTS

Pedicle Prep/Screw Insertion



In-Situ Benders

4.5mm, Left	01-1600-0012
4.5mm, Right	01-1600-0009
5.0mm, Left*	01-1600-0014
5.0mm, Right*	01-1600-0011

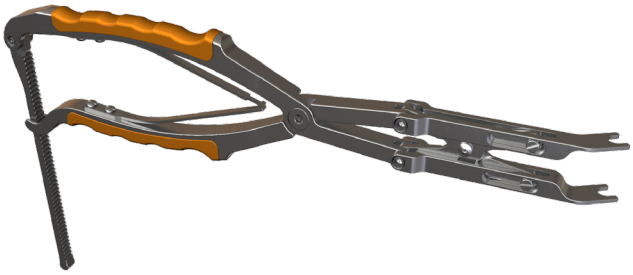
*5.0mm In-Situ Benders feature **purple** handles



Coronal Benders

4.5mm, Left	01-1600-0006
4.5mm, Right	01-1600-0003
5.0mm, Left*	01-1600-0008
5.0mm, Right*	01-1600-0005

*5.0mm Coronal Benders feature **purple** handles



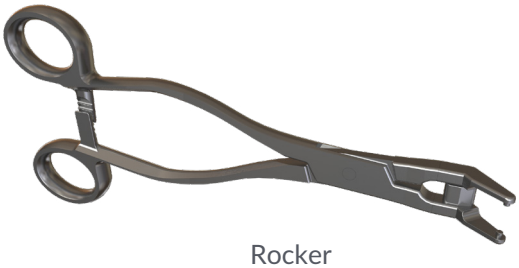
Compressors
01-1600-6078



Distractor
01-1600-6079



Rod Pusher
01-1003-6069



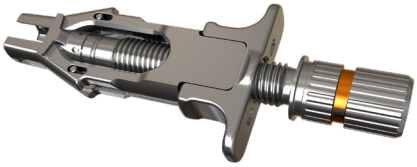
Rocker
01-1600-6071

INTRUMENTS

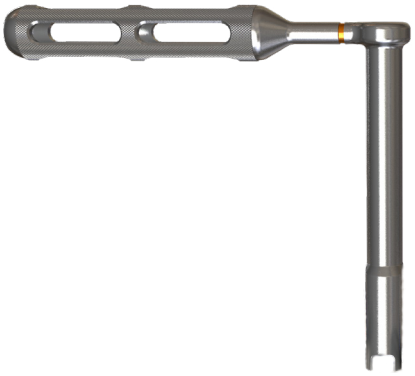
Rod Reduction & Screw Tightening



Driver, Short: 01-1300-5100
Driver, Medium: 01-1300-5102
Driver, Long: 01-1300-5101



Mini Rod Reducer
01-1600-5000



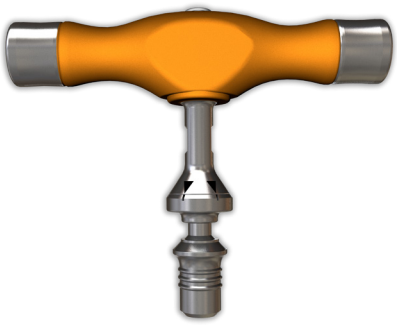
Counter Torque Tube, Short
Counter Torque
01-1600-6140



Final Torque Large Set Screw Driver
01-1600-9100



T-27 Large Set Screw Driver
01-1600-9130



Set Screw Torque Limiter
Orange T-Handle, 11 N-m [100 in-lbs]*
01-1600-0026



Manual Single Use Set Screw Torque Limiter
Light Grey Sleeve; 12N-m
803-002



Manual Single Use Torque Limiter
Blue Sleeve; 7N-m
803-001

INTRUMENTS

X-Link



X-Link Counter Torque Tube
01-1003-6166



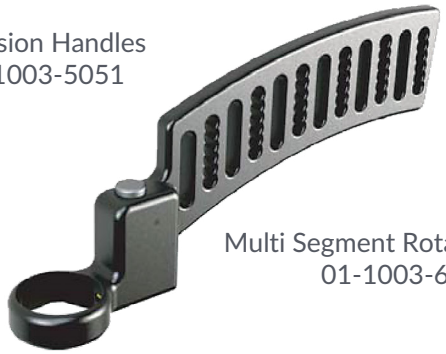
X-Link Torque Limiter
Green T-Handle, 58 in-lbs*
01-1003-6167

*a sleeve is included on each t-handle indicating the date in which recalibration is required.

Multi Segment Derotation Instruments



Extension Handles
01-1003-5051



Multi Segment Rotation Handle
01-1003-6100



Multi Segment Rotation Pin, Long
01-1003-6116



Multi Segment Rotation Pin, Short
01-1003-6117



Multi Segment Rotation Pin, Extra Long
01-1003-6305

INTRUMENTS

Hooks



Straight Hook Holder
01-1600-6150



Lateral Hook Holder
01-1600-6297



Straight Offset Hook Holder
01-1600-6298



Hook Pusher, Hook Mating
01-1600-6158



Hook Pusher, C-shaped
01-1600-6159



T-15 Small Set Screw Driver
01-1600-9135



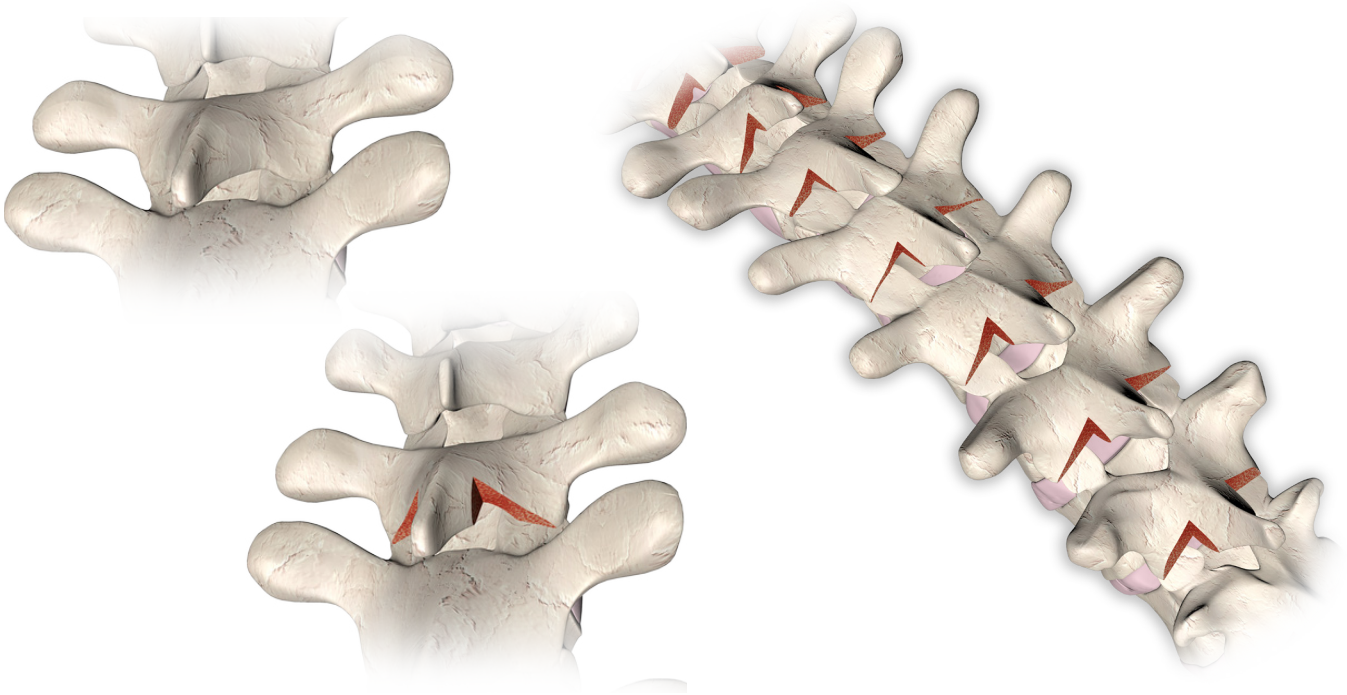
Straight Transverse Hook Trial
01-1300-6154



Straight Laminar Hook Trial
01-1300-6155



Straight Pedicle Hook Trial
01-1300-6156



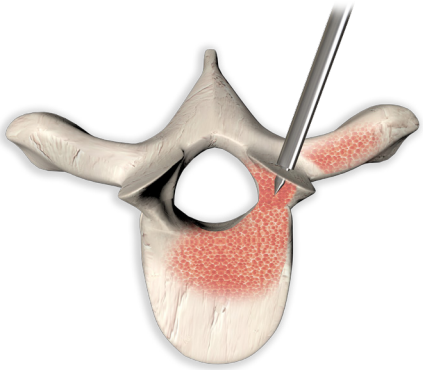
Perform Thoracic Facetectomy

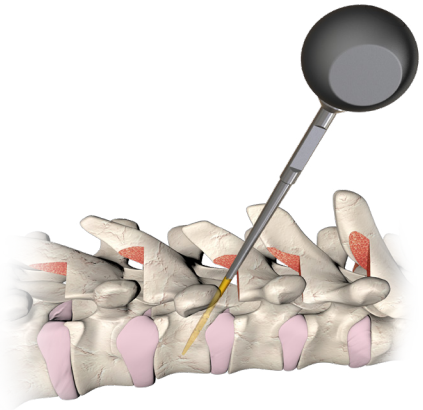
Clean the facet joints and use rongeurs, chisels or bone scalpels to perform a partial inferior articular process osteotomy to enhance visualization.

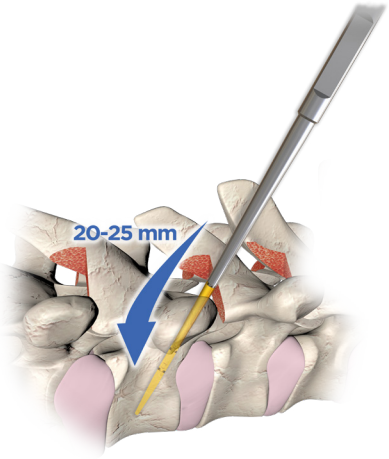
Remove 3mm to 5mm of the inferior facet and denude the articular cartilage on the superior facet, except for the lowest vertebra to be instrumented. This will allow for the intraoperative localization of the thoracic pedicle screw starting points and enhance fusion.

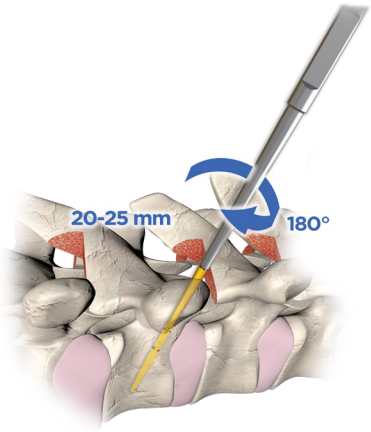
Anatomic starting points vary by the posterior elements that can be observed intraoperatively. These include the transverse process, the lateral portion of the pars interarticularis, and the base of the superior articular process.

After a thorough exposure, use as much anatomic information as possible by starting with a neutral, non-rotated vertebra.









Screw Size	Minor Diameter
4mm Screw	2.5mm
4.5mm Screw	2.75mm
5mm Screw	3.5mm
5.5mm Screw	3.9mm
6mm Screw	4.2mm
6.5mm Screw	4.3mm
7mm Screw	4.5mm

Prepare Pedicles

Create a 3mm deep posterior cortical breach with the Pedicle Awl or burr. Gentle twisting of the handle with light pressure is the safest way to advance the awl. A pedicle blush may be visualized suggesting entrance into the cancellous bone at the base of the pedicle.

Occasionally when preparing small pedicles located at the apex of the curve, the blush will not be evident due to the limited intrapedicular cancellous bone. In this case, use the straight or curved Lenke Probe to search in the cortical breach for the soft, funnel-shaped cancellous bone, which indicates the entrance to the pedicle. The tip should be pointed laterally to avoid perforation of the medial cortex. The feeler probe can be used to find the pedicle with minimal risk of wall penetration. Small taps, like a pile driver can safely advance the probe.

Grip the side of the handle to avoid applying too much ventral pressure. Insert the tip approximately 20mm to 25mm. Orient the probe so that the flat surface of the probe is in the same plane as the curve of the pedicle, then remove the probe to reorient it so that the tip points medially.

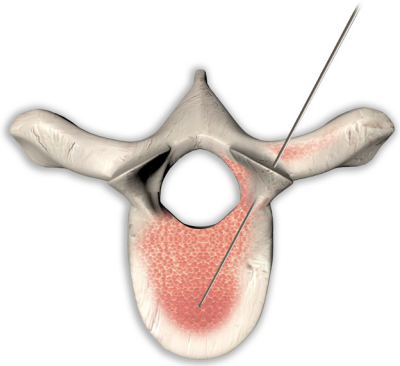
NOTE: Take care to ensure the orientation of the probe is correct in order to avoid damage to the pedicle

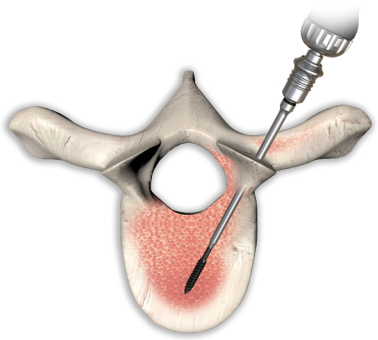
Carefully place the probe into the base of the prior hole and use the instrument markings to advance the probe to the desired depth. Rotate the probe 180° to ensure adequate room for the screw.

At each of these three steps, remove the awl and confirm intrapedicular position with the feeler probe.

CAUTION: The Small Lenke Probe is intended for use in pediatric cases where an exceptionally small pedicle is present. Due to the narrow shaft of the instrument, the probe should be introduced with care to ensure that the tip is not fractured. If additional force is required, it is recommended to use the standard probe.

WARNING: Ensure any tool used to prepare the pedicle (probe, awl, drill, burr, etc.) creates a pilot hole smaller than the minor diameter of the intended screw.







Screw Size	Tap Size
4.0mm	3.0mm Tap
4.5mm	3.5mm Tap
5.0mm	4.0mm Tap
5.5mm	4.5mm Tap
6.0mm	5.0mm Tap
7.0mm	6.0mm Tap



Prepare Pedicles (cont.)

Check to ensure that only blood is coming out of the pedicle and maintain proper hemostasis. Advance the Feeler Probe to the base (floor) of the hole to confirm five distinct bony borders: a floor and four walls (medial, lateral, superior, and inferior). Give special care to the first 10 to 15mm of the tract. When necessary, place bone wax or other hemostatic agent in the pedicle hole to limit bleeding, then reposition the probe with a more appropriate trajectory. Utilize fluorscopy to verify correct pedicle preparation.

WARNING: Insufficient room for the screw will violate spinal cord space.

WARNING: Use CAUTION when utilizing power throughout surgery. Ensure the drill or reamer is on a low rate of speed to maintain control.

Next, undertap the pedicle 1mm less than desired screw size using a handle or power. Taps are marked according to their actual dimensions to aid in the selection of the proper size. Palpate the tapped pedicle tract with a flexible Feeler Probe to feel for the presence of threads after tapping.

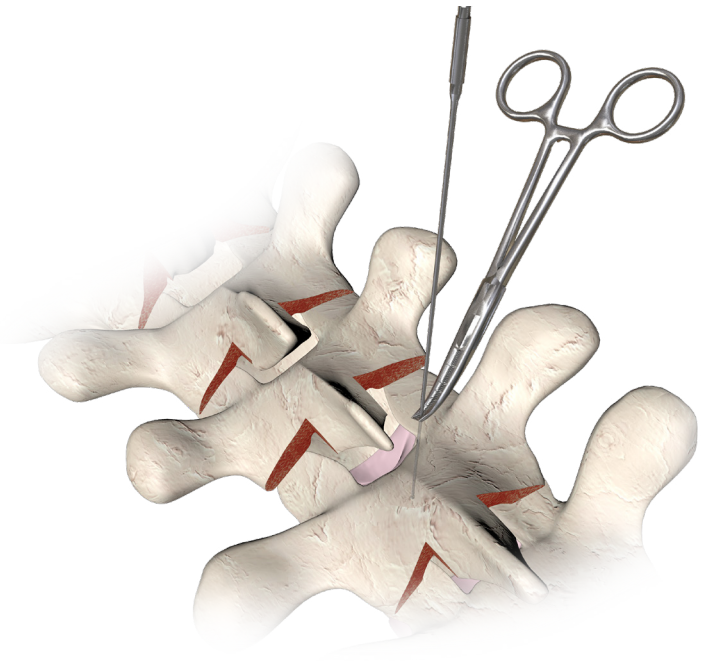
CAUTION: Ensure appropriate size screw is selected prior to tapping. Selection of incorrect screw size can lead to damage to pedicle.

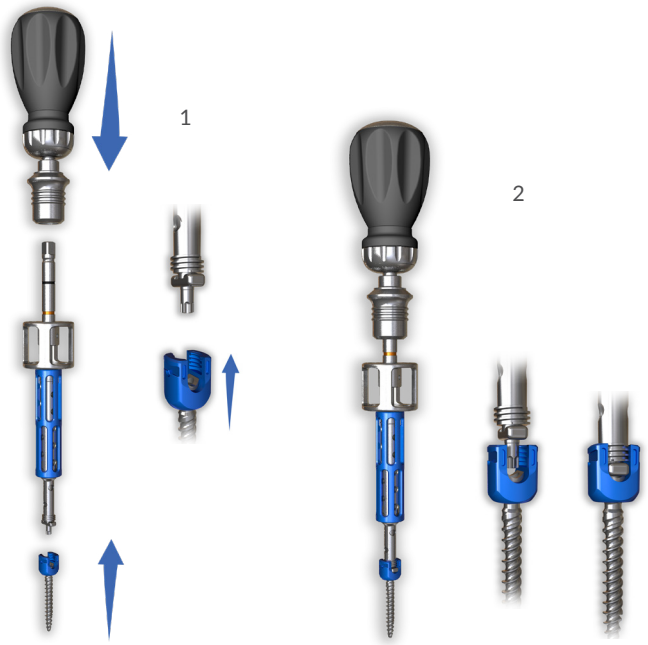
CAUTION: Use care when utilizing Taps to avoid injury to both patient and physician.

NOTE: When assembling Taps to the handle, ensure that the tap is fully seated in the handle. The black line on the shaft will be fully covered when properly seated.

NOTE: Etching on the taps indicate the screw size and corresponding Tap sizes.

NOTE: When utilizing guide wires with cannulated Taps, ensure there is no damage to the wire. Damage may result in complications with the patient or interactions with other mating devices.



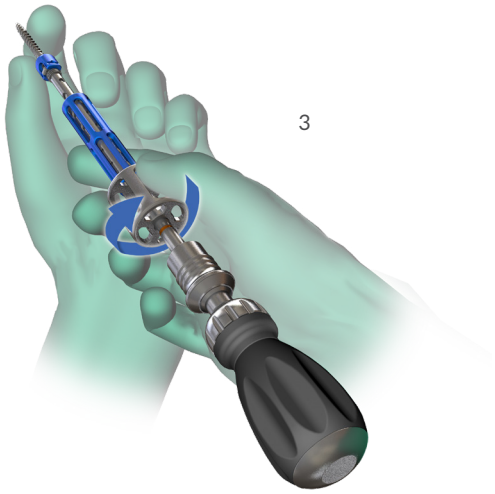


Prepare Pedicles (cont.)

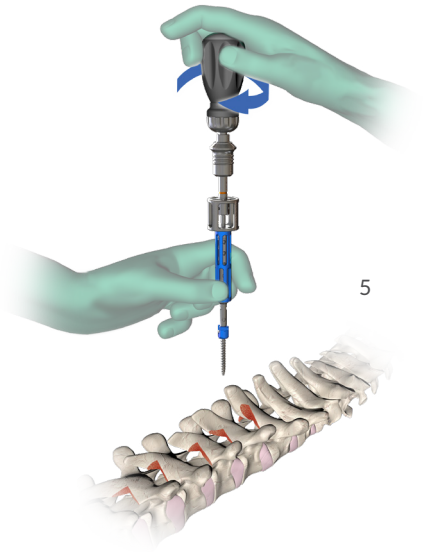
Clamp a hemostat to the exposed Feeler Probe to measure the length of the hole. Select the appropriate screw length by both preoperative measurement and intraoperative observation.

Pedicle Screw Driver Application

1. Attach handle to Poly Driver, select screw for insertion.
2. Place the hexalobe tip of the driver into the screw. Engage the hex with the driver tip.







Pedicle Screw Driver Application (cont.)

3. Turn the threading knob to thread the driver to the screw.

4. Engage the rotation sleeve by pushing it down into the head of the screw.

   The tab feature keeps the screw from disengaging from the driver during screw insertion.

5. Turn the driving knob while holding the shaft of the Poly Driver assembly to advance the screw down the pedicle.

NOTE: Reference the System Overview section to ensure correct screw is selected prior to driver application.

NOTE: Ensure all steps are followed for proper assembly of screw and driver to avoid disengagement during application.

NOTE: Pedicle Screws can be inserted under power by attaching the power adapter (01-1003-5102) to the screwdriver.

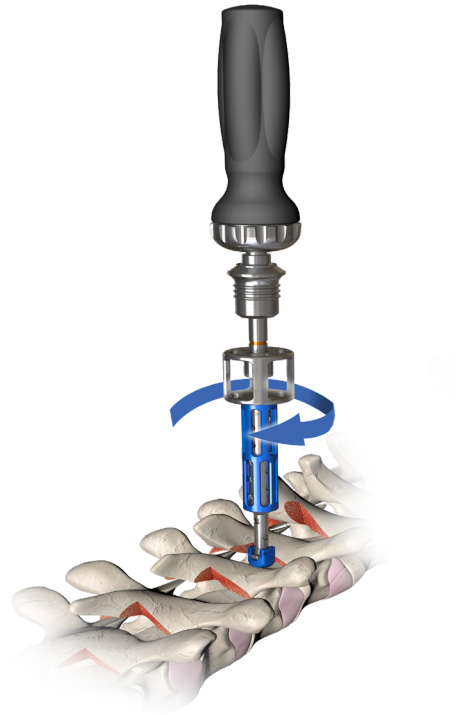


Figure 1: Advance the pedicle screw.

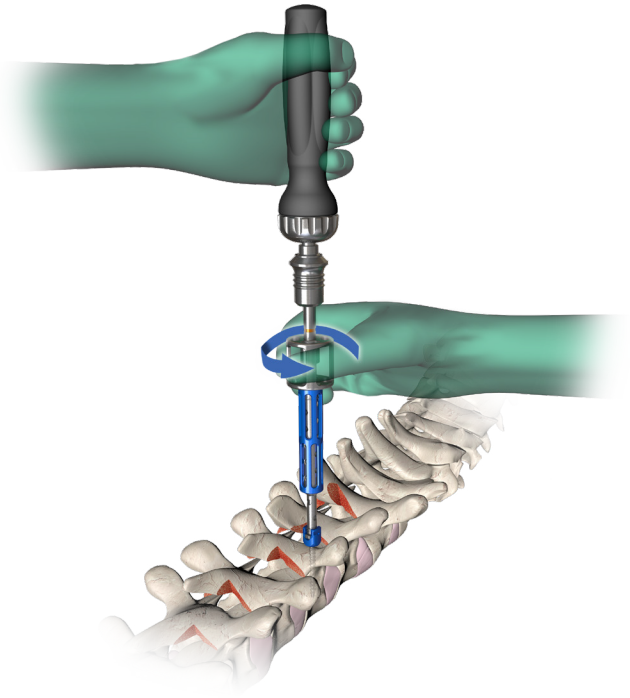


Figure 2: Disengage the driver from the screw.

Place Screws

Slowly advance the screw down the pedicle to ensure proper tracking (Figure 1).

To disengage the driver from the screw, turn the threading knob counterclockwise, then gently rock the driver to disengage the tip of the hex from the screw (Figure 2).

Screws should be placed at every segment, as needed, that allows free passage of a screw on the correction side and every third or fourth level on the supportive side. Insert at least two screws at the proximal and distal end of the supportive side. As needed, more screws are placed for greater construct rigidity. At this time, screws may be interchanged as needed. Screws should be checked radiographically at this time to ensure intraosseous screw placement.

Scoliotic pedicles may be too narrow to cannulate, especially at the concave apex. Alternate fixation such as hooks, wires, bands, or tapes can be used.

NOTE: Following screw insertion, utilize the screw head positioner to ensure proper tulip head alignment in preparation for rod placement.





Contour & Place the First Rod

Before placing rods, confirm screw placement with 2D or 3D fluoroscopy.

Triggered EMG's may be performed at this stage.

Once correct screw placement has been verified radiographically, measure and contour rods in the sagittal and coronal planes. Clamping the rod with Rod Grippers at both ends helps prevent the rod from rotating during contouring.

NOTE: Ensure the appropriate size rod and material is selected. Do not rebend rods.

WARNING: If using Transition Rods, do not place transition zone inside the pedicle screws.



Rocker



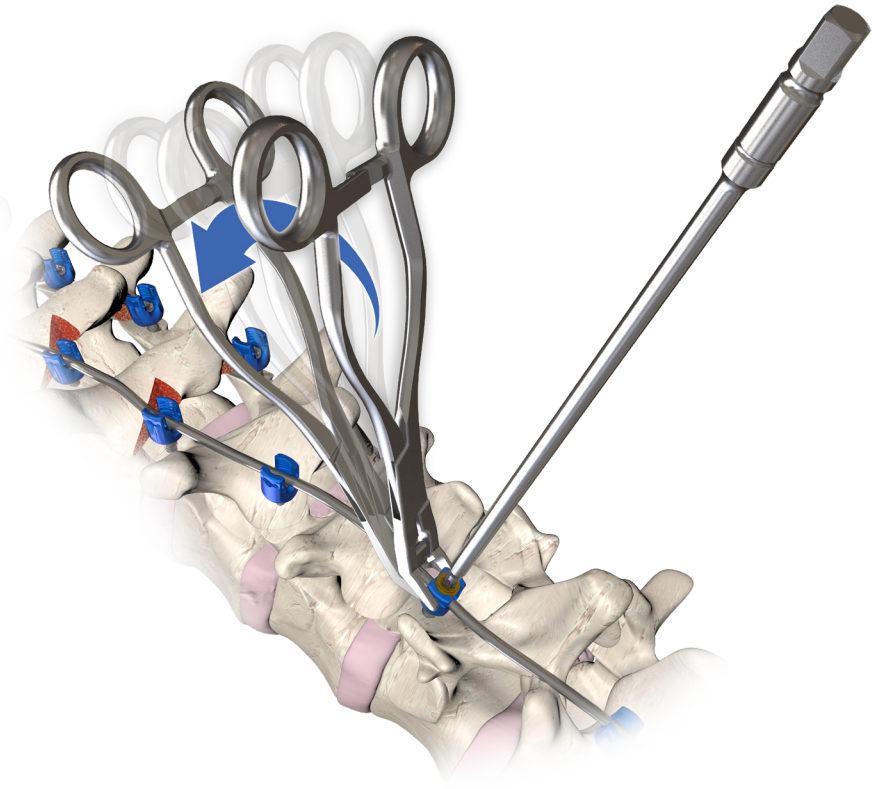
Rod Reduction Tower

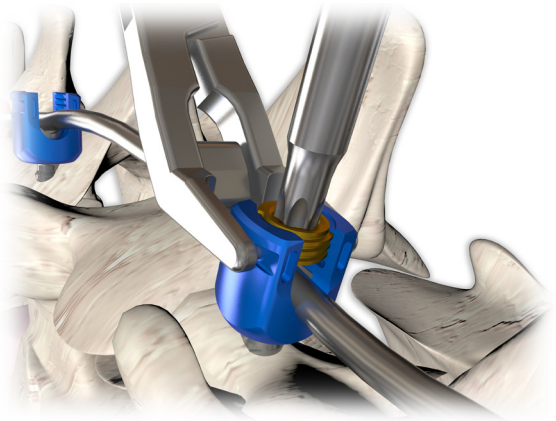
Reduce the First Rod

For non-hyperkyphotic deformities, depending upon surgeon preference, the rod may be placed on the concave side first. The contoured rod is placed into the previously placed screws. There are multiple options and instruments that can facilitate seating the rod into the saddle of the implant.

NOTE: Care should be taken with any of the following reduction methods. Improper instrument use may loosen implants or damage the residual facets and other bony anatomy.

Two instruments are used to facilitate fully seating the rod into the saddle: the Rocker and the Rod Reduction Tower



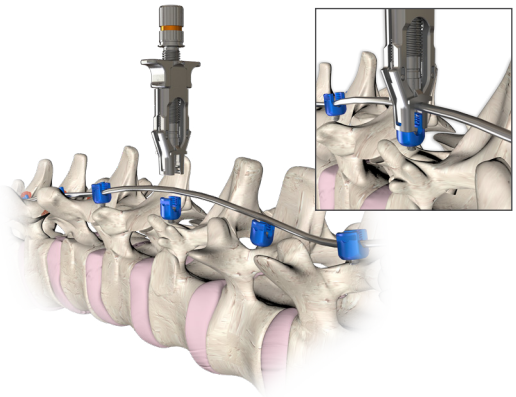


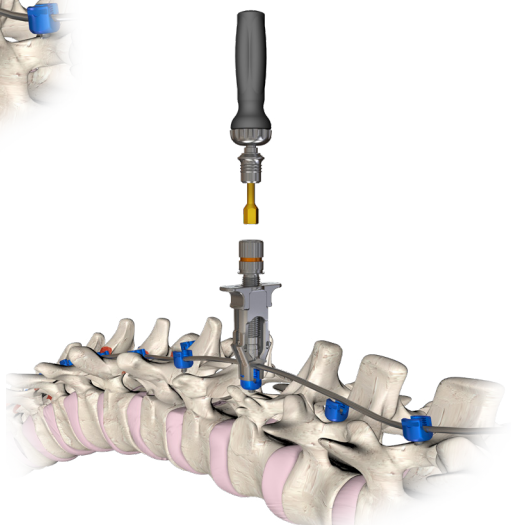
Rod Reduction – Rocker Method

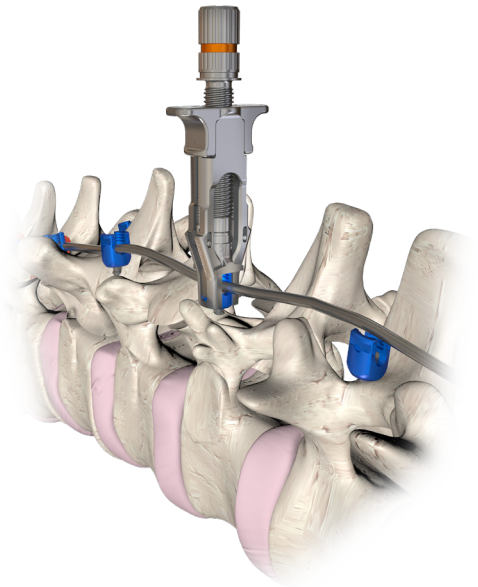
Use of the Rocker is an effective method for reducing (or seating) the rod into the implant when only a slight height difference exists between the rod and the implant saddle.

To reduce the rod using the Rocker method, grasp the sides of the implant with the rocker cam above the rod. Lever the Rocker backwards over the rod to seat the rod into the saddle of the implant. Use the 4.5/5.0 Large Set Screw Driver to place a set screw and provisionally tighten.

NOTE: To avoid cross threading of the set screw, it is advised to turn the set screw counterclockwise until a click is felt, ensuring that the set screw is lined up correctly. Then proceed with clockwise tightening of the set screw.







Rod Reduction – Mini Reducer

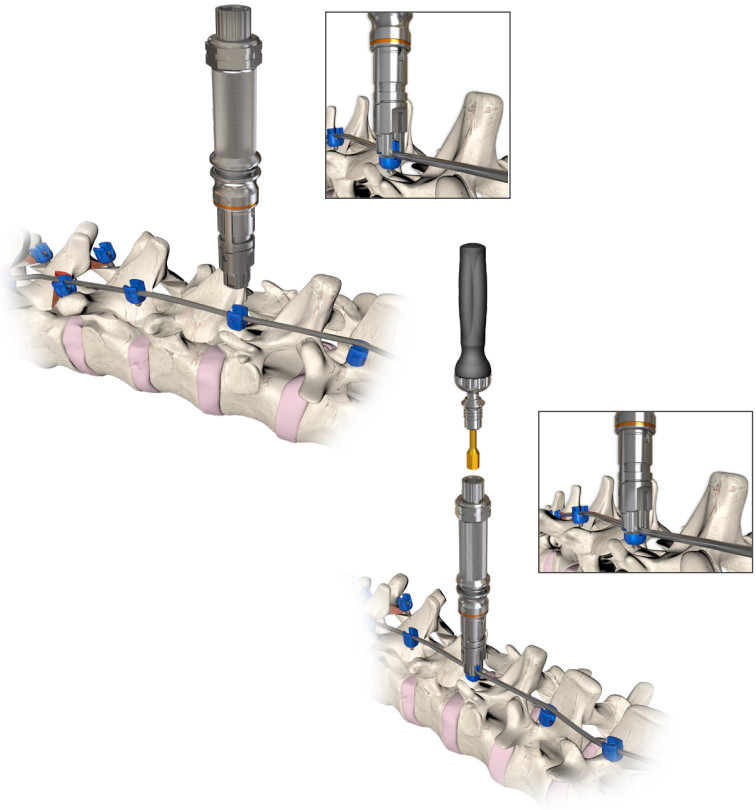
Insert and affix Mini Reducer by pushing down over the top of the screw head.

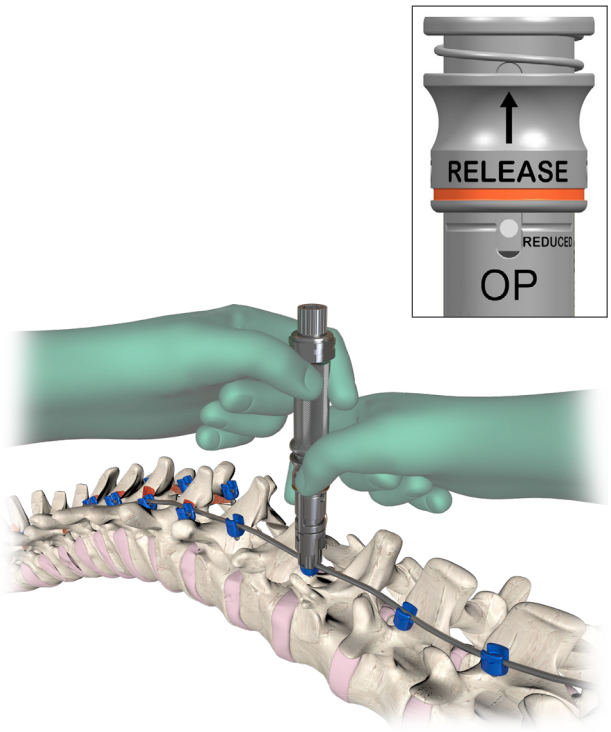
To reduce the Rod, use the short driver and axial ratcheting handle to turn the hexagonal knob clockwise.

Mini Reducer Removal

See page 32 for instructions on provisionally tightening set screws. After the rod has been reduced and the set screw has been provisionally tightened, the Mini Reducer may be removed from the screw head. Turn the hexagonal knob counter clockwise a few turns and then place downward pressure on the hexagonal knob and pull up on the release tabs to disengage from the screw head.

WARNING: The mini reducer does not fully seat the rod.





Rod Reduction – Rod Reduction Tower

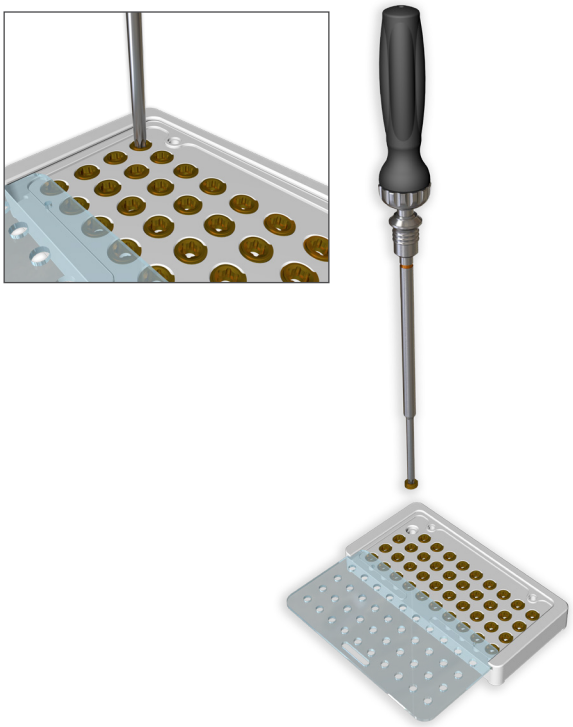
Insert and affix Rod Reduction Tower by pushing down over the top of the screw head.

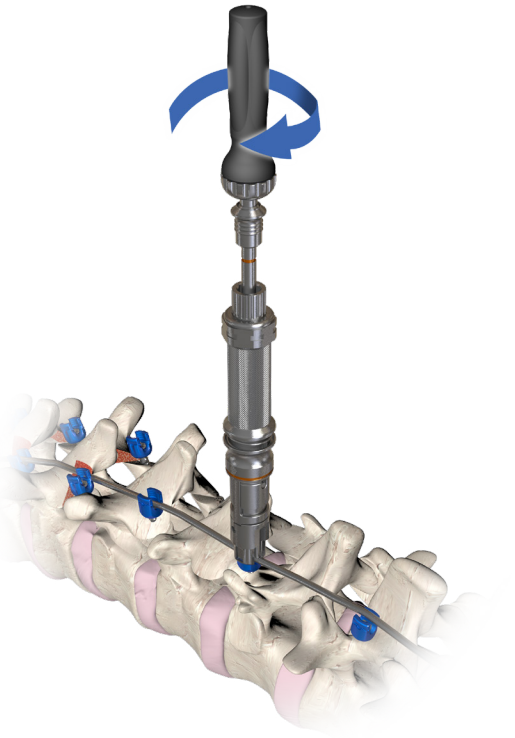
To reduce the Rod, use the hex adapter and axial ratcheting handle to turn the hexagonal knob clockwise.

NOTE: Rod is fully reduced when the pin is in contact with the groove after tightening the hexagonal knob until it stops.

Tower Removal

See page 32 for instructions on provisionally tightening set screws. After the rod has been reduced and the set screw has been provisionally tightened, the Rod Reduction Tower may be removed from the screw head. Turn the hexagonal knob counter clockwise a few turns, then pull up on the medial collar to disengage from the screw head.

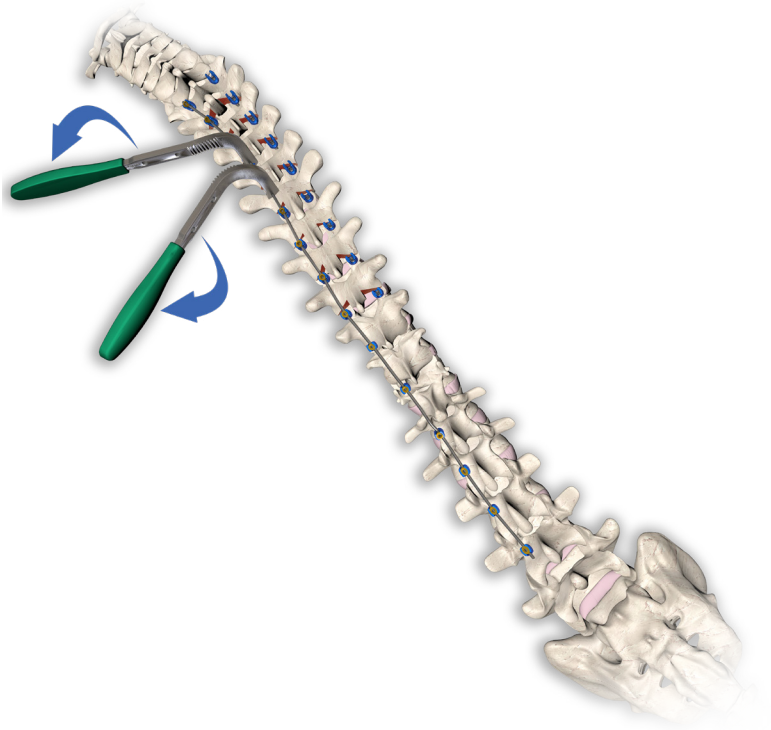




Provisionally Tighten Set Screws

Capture the appropriate set screw onto the hexalobe feature of the Large Set Screw Driver.

Use the 4.5/5.0 Large Set Screw Driver to introduce the Set Screw. Send the Set Screw down the Rod Reducer or Mini Reducer until it bottoms out on the screw threads. To avoid cross threading of the Set Screw, turn the set screw counterclockwise until a click is felt, ensuring that the set screw is lined up correctly. Then proceed with clockwise tightening of the Set Screw.



Deformity Correction – Straighten Rod via Rotation and/or Coronal Bending

Keep the set screws loose (or only locked at one end), then slowly straighten the concave rod with the Coronal Benders. Perform each straightening of the concave rod over a pedicle screw. Several passes may be required.

NOTE: To avoid cross threading of the set screw, it is advised to turn the set screw counter clockwise until a click is felt, ensuring that the set screw is lined up correctly. Then proceed with clockwise tightening of the set screw.

See pages 27-31 to reference rod reduction and contouring. At this point of the surgery part of the correction has been achieved, mainly due to translation maneuvers used when inserting the rod. Further correction can be accomplished with rod rotation and/or coronal bending, depending on the type and stiffness of the curve, and completed with compression/distraction maneuvers.

NOTE: If using a 4.5mm rod, the green-handled Coronal Benders and In-Situ Benders should be used. If using a 5.0mm rod, the purple-handled Coronal Benders and In-Situ Benders should be used.

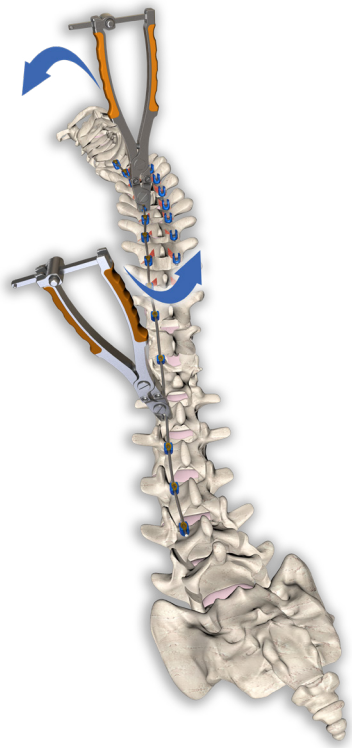


Figure 1: Rod rotation for final positioning

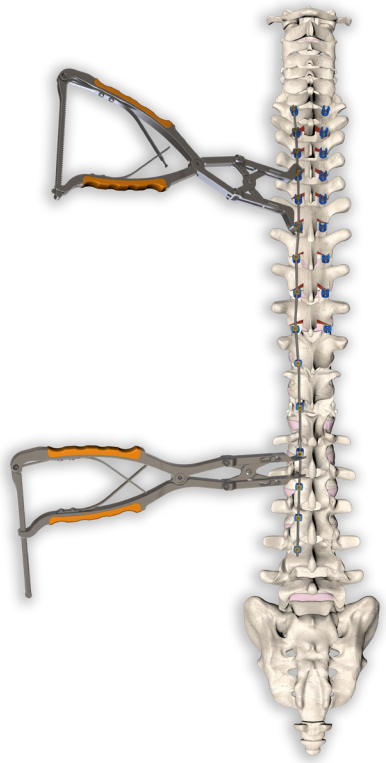


Figure 2: Compression and distriction of rod

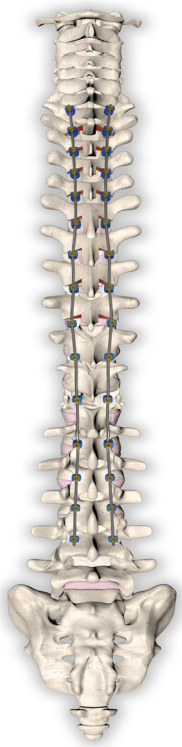
Deformity Correction

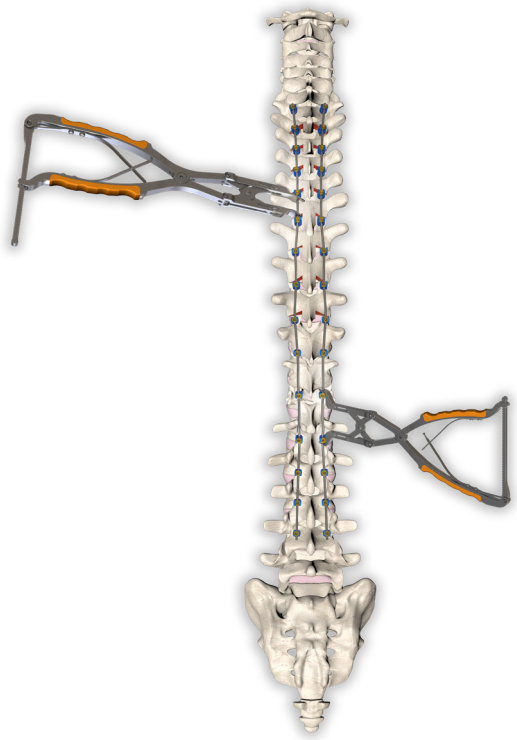
Rod Rotation

Once the contoured rod and all of the set screws have been placed, the rod is ready to be rotated into its final position (Figure 1). The rotation must be done slowly in order to prevent rapid neurologic changes and/or injury to the spinal cord. The rotation is done using two rod-grippers. It is important to monitor the interval hooks, which tend to back out during rod rotation.

Compression & Distraction

Tighten the apical set screws. Compression or distraction may be performed at this time (Figure 2). Watch the screw/bone interface with all correction maneuvers.



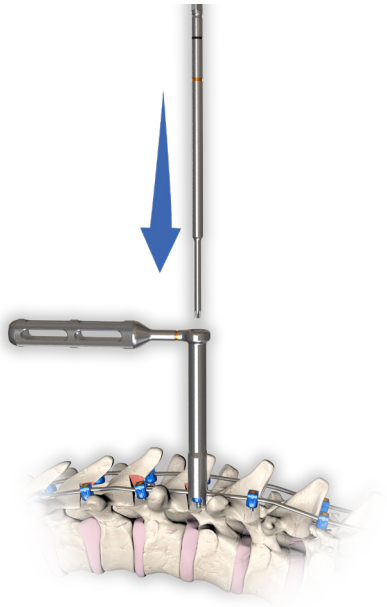


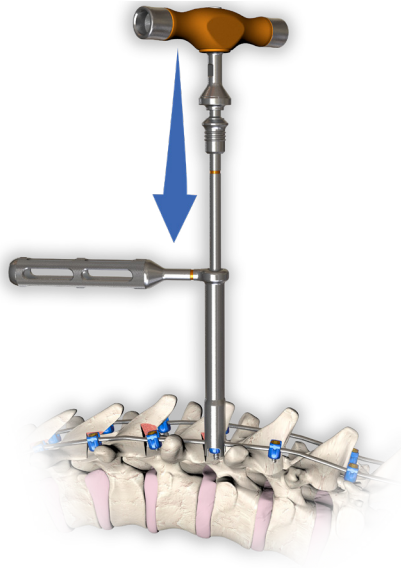
Deformity Correction – Place the Stabilizing Rod

Following placement of the second rod and set screws, convex compressive forces are placed on the segments using the Parallel Compressor to horizontalize the lowest instrumented vertebra and mildly compress the convexity of the deformity. It is preferred that compression be released just prior to final tightening. This technique will help ensure that the implant head and rod are normalized to one another and thus allow for the rod to be fully seated in the implant head during the final tightening step.

Perform sensory and motor evoked potential monitoring for the early detection of a spinal cord deficit during surgical manipulation of the spine.

Verify fixation with A/P and lateral x-rays to confirm spinal correction and alignment.





Final Tightening

To final tighten all open pedicle screw assemblies, seat the Counter Torque Wrench and the Final Set Screw Driver Shaft (01-1600-9100) onto the open screw, saddle, and set screw.

Place the orange Set Screw Torque Limiter T-Handle (11 N-m [100 in-lbs]) on the Driver Shaft, and turn the handle clockwise while firmly holding the Counter Torque Wrench.

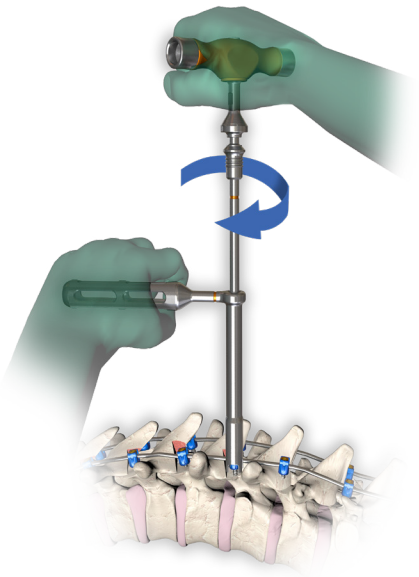
Turn the T-handle until two audible clicks are heard, indicating that proper torque has been met.

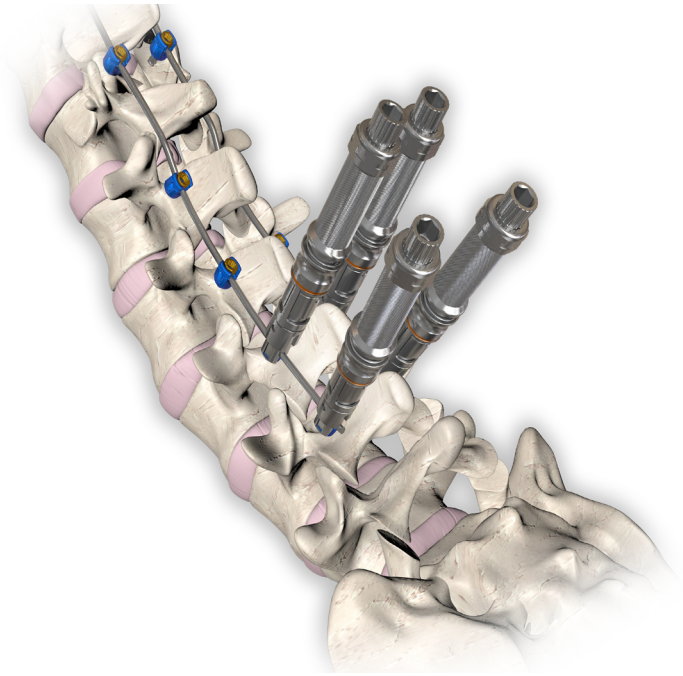
NOTE: The orange T-handle (11 N-m) or the 12 N-m (Light Gray Collar) Single Use Torque Limiter is only to be used with the large set screw driver for large set screws.

WARNING: Ensure set screw is properly tightened with provided Orange Set Screw Torque Limiter T-Handle, or with the 12 N-m (Light Gray Collar) Single Use Torque Limiter attached to Fixed / Ratcheting T-Handle. Failure to fully seat the torque driver in the set screw can lead to damage or disassociation of set screw postoperatively.

When final torque is complete a squeaking sound is often heard. This is by design and part of the science of the RESPONSE Spine System thread technology. This squeaking is caused by an effect called “galling” or cold welding. By utilizing this science, the large

*See Page 39 for Final Tightening – Alternate Instruments





set screw and tulip head interface self-locks upon final torque.

Ensure set screw is properly seated within the pedicle screw following final torque (Figure 3). When utilizing a 5.0mm rod, the set screw will be flush with the pedicle screw head. When utilizing a 4.5mm rod, the set screw will be slightly recessed within the pedicle screw head.



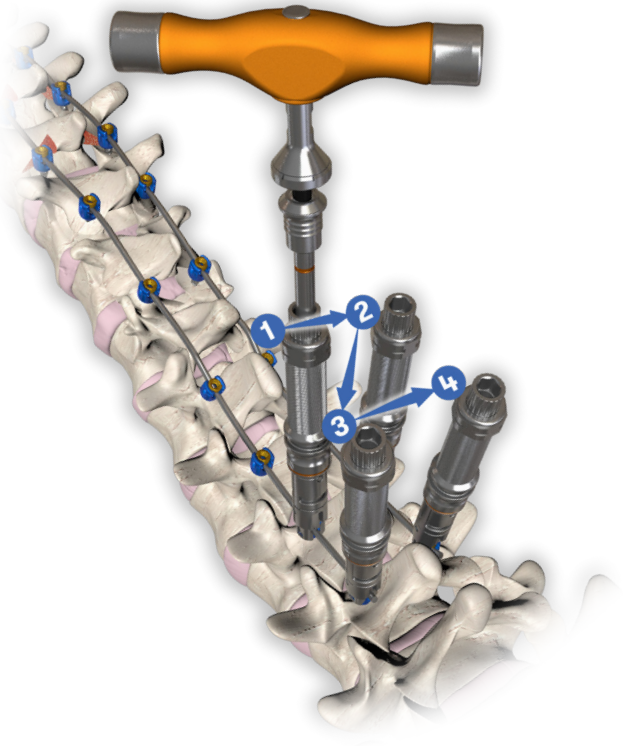
WARNING: If using Transition Rods, do not place transition zone inside the pedicle screws.

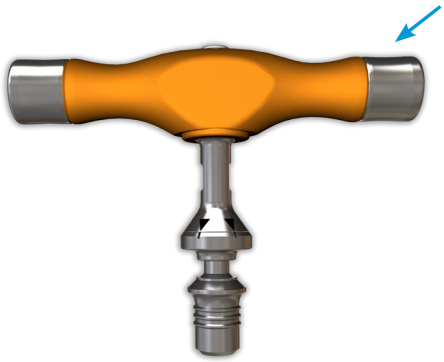
FIGURE 3: Proper seating of set screw within pedicle screw

*See Page 39 for Final Tightening – Alternate Instruments

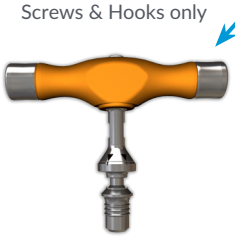
Final Tightening at the Bottom of the Construct

In the context of the OrthoPediatrics RESPONSE system, use the towers in the lower two levels, as shown below. This will ensure that the rod is fully seated.



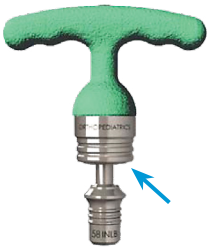


RESPONSE 4.5/5.0 Pedicle Screws & Hooks only



Set Screw Torque Limiter Orange T-Handle, 11 N-m [100 in-lbs]
01-1600-0026

RESPONSE 4.5/5.0 Connectors



X-Link Torque Limiter Green T-Handle, 58 in-lbs
01-1003-6167

Final Tightening at the Bottom of the Construct (cont.)

Tighten the towers sequentially to ensure that the rod is properly seated in the tulip head.

Tighten the set screws utilizing the orange T-handle (11 N-m [100 in-lbs]) in the sequence shown to the left at the last two levels sequentially from cephalad to caudal.

Turn the orange T-handle (11 N-m [100 in-lbs]) until two audible clicks are heard, indicating that proper torque has been met.

Final Tightening Summary

When completing final tightening, it is important to remember these key points.

Verify the expiration date on the torque limiter. The area where the expiration date can be found is designated by the red arrows shown below.

Utilize the correct Torque Limiter.

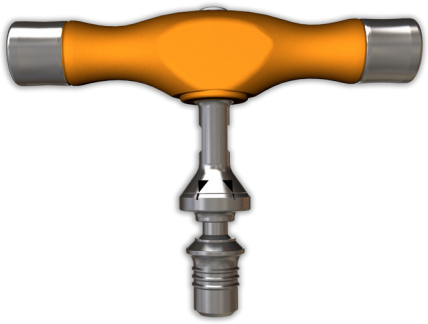
*See Page 39 for Final Tightening – Alternate Instruments

Final Tightening - Alternate Instruments

Fixed Ratcheting T-Handle
01-1600-0027







Manual Single Use Set Screw Torque Limiter
Light Grey Sleeve; 12N-m
803-002

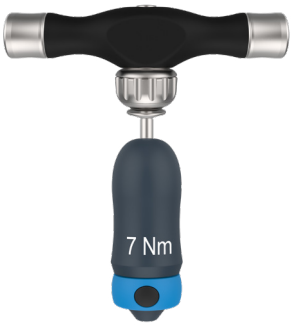
Set Screw Torque Limiter
Orange T-Handle, 11 N-m [100 in-lbs]*
01-1600-0026

NOTE: Fixed Ratcheting T-Handle attached to 12 N-m Single Use Torque Limiter(Light Grey Sleeve) Can be used in place of the Orange T-Handle 11 N-m Set Screw Torque Limiter at any step of this surgical technique

Two clicks are required with either instrument to lock construct.

Both the 12 N-m Single Use Torque Limiter and the 11 N-m Orange T-Handle Torque Limiter have been tested with torque limiting ranges that effectively lock the implant construct.

Fixed Ratcheting T-Handle
01-1600-0027





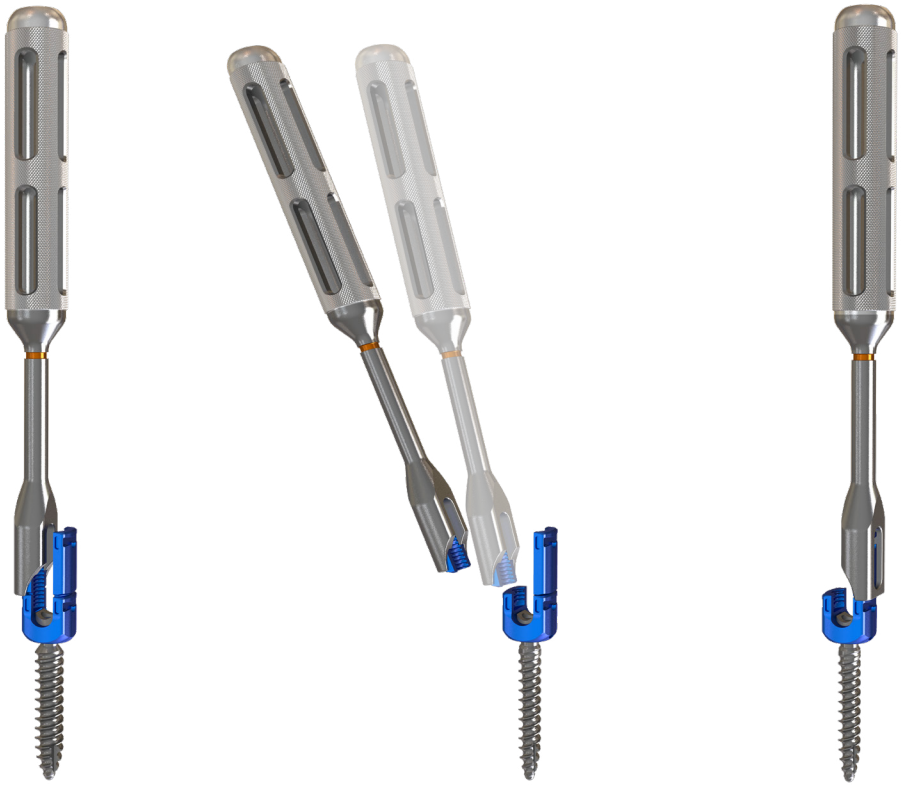


Manual Single Use Torque Limiter
Blue Sleeve; 7N-m
803-001

X-Link Torque Limiter
Green T-Handle, 58 in-lbs*
01-1003-6167

NOTE: Fixed Ratcheting T-Handle attached to 7 N-m Single Use Torque Limiter (Blue Sleeve) can be used in place of the Green T-Handle 58in-lb X-Link Torque LImiter at any step of this surgical technique.

Both the 7 N-m Single Use Torque Limiter (Blue Sleeve) and the 58in-lb Green X-Link T-Handle Torque Limiter have been tested with torque limiting ranges that effectively lock the implant construct.

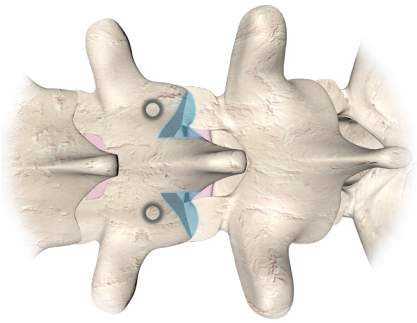


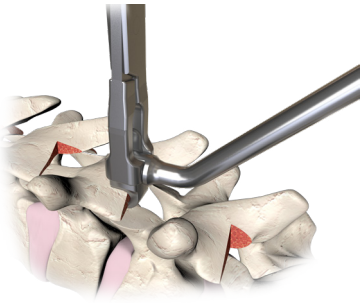
Reduction Screws

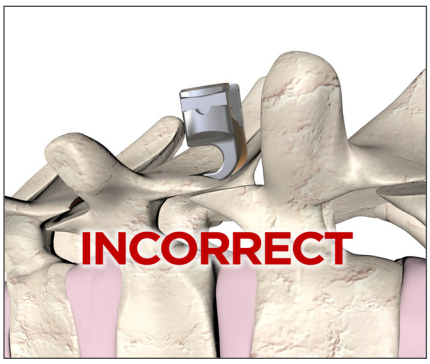
If reduction screws or reduction hooks are being utilized within the construct, use the Tab Breaker at this time to remove the extended tab on each pedicle screw and reduction hook.

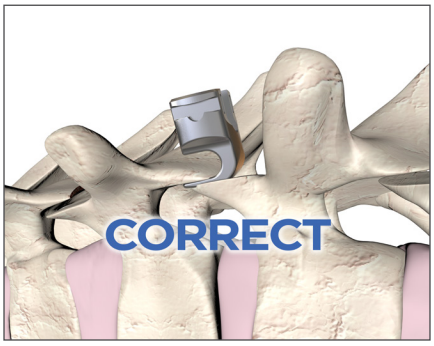
CAUTION: Use care when using the Tab Breaker to avoid injury to both patient and physician.

HOOK SURGICAL TECHNIQUE









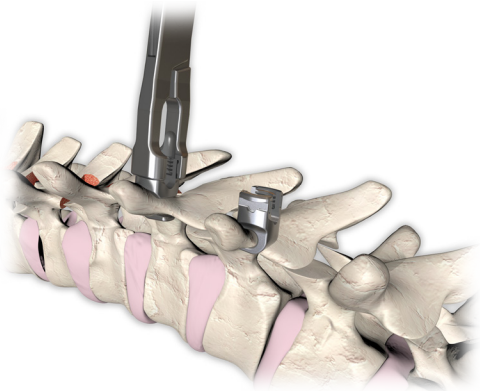
Hook Site Preparation – Pedicle Hook

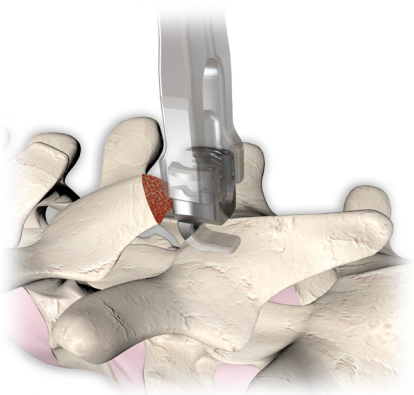
The facet capsule is divided; a portion of the inferior facet process may be removed to facilitate insertion of the hook.

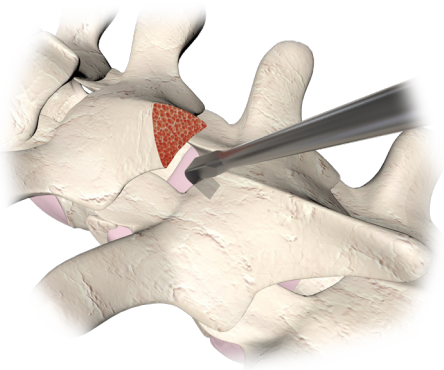
Clearly identify the pedicle with the help of the Pedicle Elevator and insert the hook. The Pedicle Hook may be used from T1 to T10. Place the hook blade cephalad (up-going) and in the infralaminar position.

The facet capsule is divided; a portion of the inferior facet process may be removed to facilitate insertion of the hook. If necessary, use a Hook Pusher on the Pedicle Hook. The Pedicle Hook must be placed into the joint cavity and must not split the inferior articular process.

> **NOTE:** Use care when inserting hook with the hook holder, avoiding excessive force so as to not break the pedicle or disengage the holder.







Hook Placement

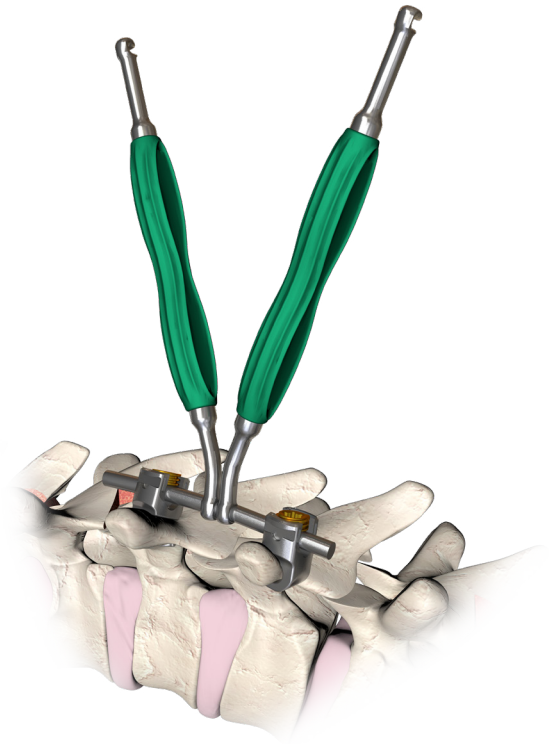
Hook Placement at the Transverse Process

A Wide Blade Hook is typically used in a pedicle transverse claw construct as a caudal (down-going) hook. Laminar Hook Trials may be used to separate the ligamentous attachment between the under-surface of the transverse process and the posterior arch of the rib medial to the rib-transverse joint. Use a Hook Holder to insert these hooks.

Thoracic Hooks

A partial or total division of the spinous process directly above the vertebra to be instrumented (thoracic vertebra) may be performed. A division and/or partial removal of the ligamentum flavum and a small laminotomy are carried out on the superior lamina. The amount of bone removed from the lamina may vary depending on the size of the hook blade and throat angle chosen. The upper edge of the lamina below or the lower edge of the lamina above may be resected to ease the placement of this hook. The Laminar Hook Trial may be used to check the space between laminar and peridural structures. Two widths of Laminar Hook Trials are available depending on the size of the lamina: Narrow or Wide Blade. Use a Hook Holder to insert the hook when placed on the superior lamina.

WARNING: If using Transition Rods, do not place hooks on the transition zone.



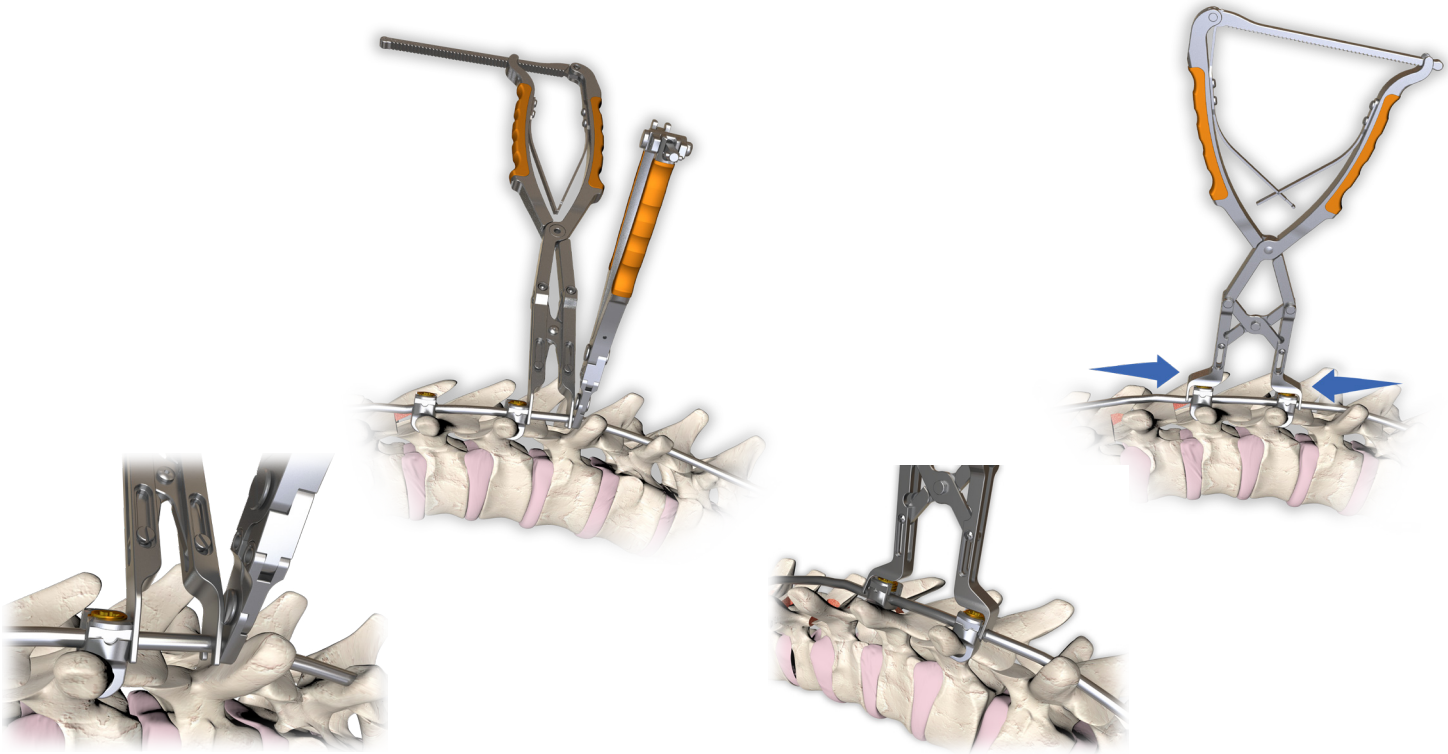
In-Situ Bending

Once the rotation of the rod is complete and the position of the hooks is verified, provisionally tighten the set screws in the interval hooks to prevent rod derotation. Provisionally tighten the set screws using the T-27 Large Set Screw Driver for Large Set Screws and the T-20 Small Set Screw Driver for Small Set Screws.

Check the hooks following all rotation maneuvers and make necessary adjustments to ensure that proper placement is maintained.

At this point, the rod should be fully seated into the saddle of all of the implants.

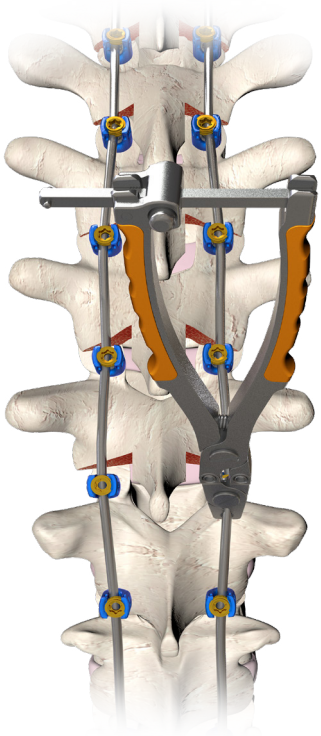
The in-situ benders may be used for correction and final adjustment of the rod in the sagittal and/or coronal plane. The rod is bent in small incremental steps using the two bender tips positioned near each other on the rod.



Compression/Distraction

Once the rod is secured in the implants, perform distraction and/or compression to place the hooks in their final position. The Compressor, Distractor, and Rod Gripper are used to carry out these maneuvers. It is recommended to use the Rod Gripper as a stop for distraction maneuvers rather than the implant.

Care should be taken to ensure that the foot of either instrument is placed against the implant body and not against the set screw. It is preferred that compression be released just prior to the set screw being final tightened. This technique will help ensure that the implant head and rod are normalized to one another and thus allow for the rod to be fully seated in the implant head during the final tightening step. After these maneuvers are complete, the set screw is tightened with the orange Torque Limiter T-Handle (100 in-lbs) for open hooks.



Stabilization Rod Placement

With the completion of the deformity correction and the seating of the correction rod, the opposite side of the construct is prepared. Measure the length for the stabilizing rod, then cut.

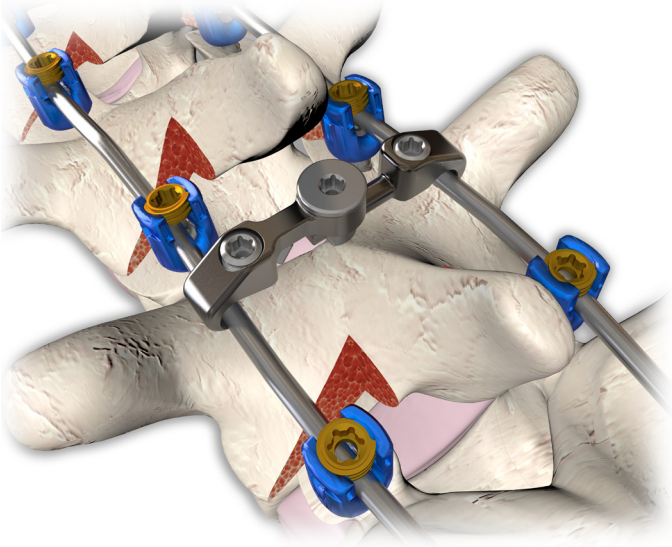
Using the French Bender, contour the rod according to the curvature of the spine and the residual position of alignment from the correction rod.

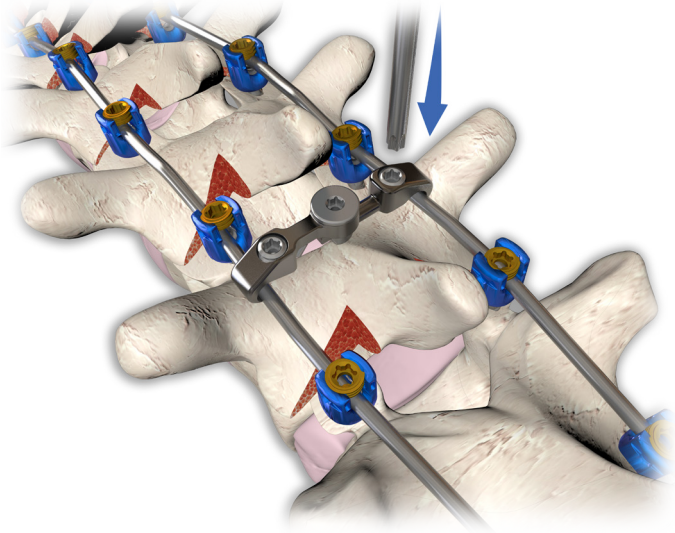
Place the contoured rod into the hooks with rod gripper or by hand and provisionally secure the rod with set screws. Once the rod is secured to the implants, perform distraction and/or compression to place the hooks in their final position. Refer to Page 41 to ensure the appropriate steps are followed. Do not final tighten set screw under compression.

NOTE: The spine may be decorticated to carry out the bone fusion and morselized cancellous bone placed along the decorticated spine, extending out over the transverse processes.

This technique uses Set Screws. The Set Screw Driving Shaft placed in the Torque Limiter T-Handle avoids torquing of the construct; the orange Set Screw Torque Limiter T-Handle (11 N-m [100in-lbs]) is used with open hooks.

WARNING: Ensure set screw is properly tightened with provided orange Set Screw Torque Limiter T-Handle. Use of incorrect torque driver can lead to dissociation of set screw postoperatively.





X-Link Placement

After final tightening of the set screws, it is critical to place cross connectors. These links provide rotational stability to the construct. A framed construct resists rotational forces. Ideally, the cross connectors should be placed close to the proximal or distal end of the construct.

Cross Connectors:

> **NOTE:** Ensure correct size of cross connector is selected by using the X-Link Selector.

Capture both rods and confirm placement. Place Small Set Screws using the Small Set Screw Starter. Provisionally tighten using the Small Set Screw Driver to secure the connector to the rods.

Provisionally tighten the midline nut to gain control of the linkage device during placement.

Capture the far rod (in relation to the surgeon) of the two rods to be stabilized. Use the Small Set Screw Driver to provisionally tighten to anchor the device to this rod.

Loosen the midline nut to allow the linkage to capture the other rod, then anchor the linkage by seating the set screw to the rod. Re-tighten the midline nut to secure the link.

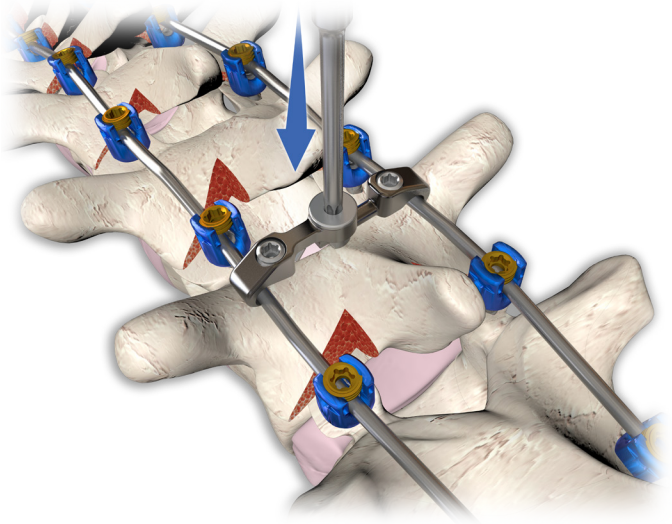
For final tightening, Seat the Counter Torque Tube and the Small Set Screw Driver onto the connector, rod, and set screw.

Then turn the green T-handle (58 in-lbs) of the Driver Shaft while firmly holding the Counter Torque Wrench.

Turn the T-handle until an audible click is heard, indicating that proper torque has been met.

Repeat the tightening procedure on the remaining Small Set Screw.

*See Page 39 for Final Tightening – Alternate Instruments



X-Link Placement (cont.)

Final tighten the midline screw. Seat the Small Set Screw Driver over the midline screw, then turn the green T-handle (58 in-lbs) until an audible click is heard, indicating that proper torque has been met.

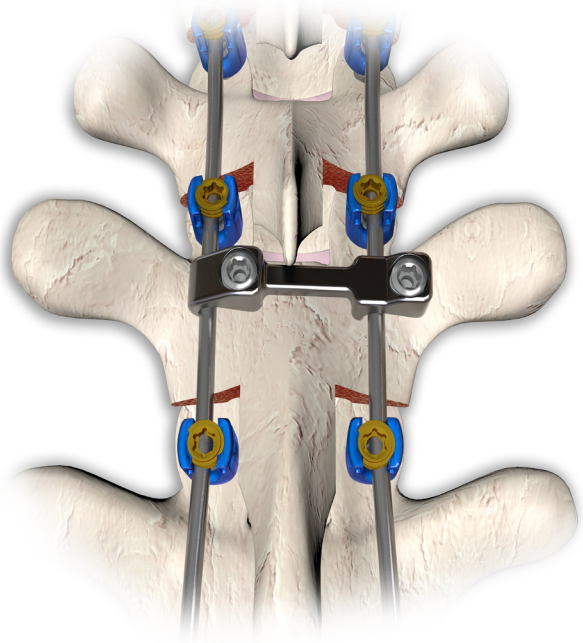
NOTE: For insertion of Inline Dual Diameter Connectors, Domino Inline Dual Diameter Connectors, Wedding Band Inline Dual Diameter Connectors, and the Closed Lateral Connectors, Place Small Set Screws with the Small Set Screw Starter, provisionally tighten using the Small Set Screw Driver.

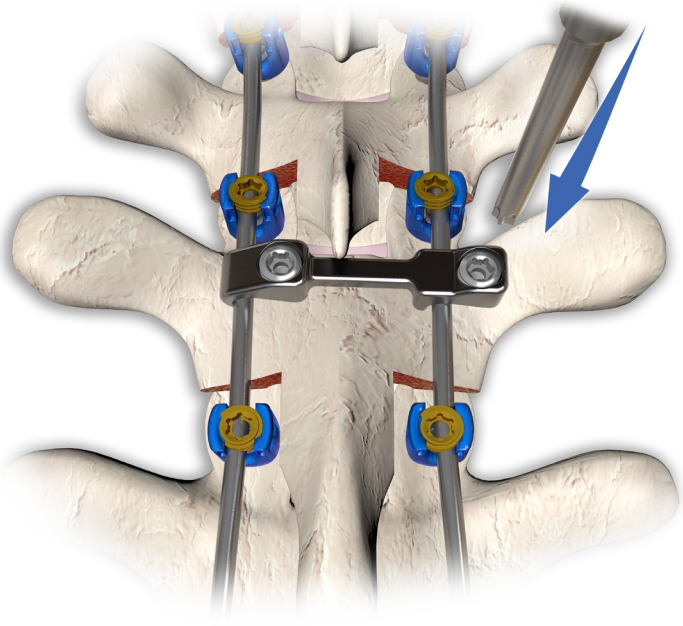
CAUTION: Final tighten with the Small Set Screw Driver mounted on the green T-handle (58 in-lbs). Turn the T-handle until an audible click is heard, indicating that proper torque has been met.

WARNING: If using Transition Rods, do not place cross-connectors on the transition zone.

*See Page 39 for Final Tightening – Alternate Instruments

CROSS CONNECTOR TECHNIQUE





Fixed Cross Connector

Capture both rods and confirm placement. Provisionally tighten using the X-Link Screw Driver Shaft to secure the connector to the rods.

For final tightening, Seat the Counter Torque Tube and the X-Link Screw Driver Shaft onto the connector, rod, and set screw.

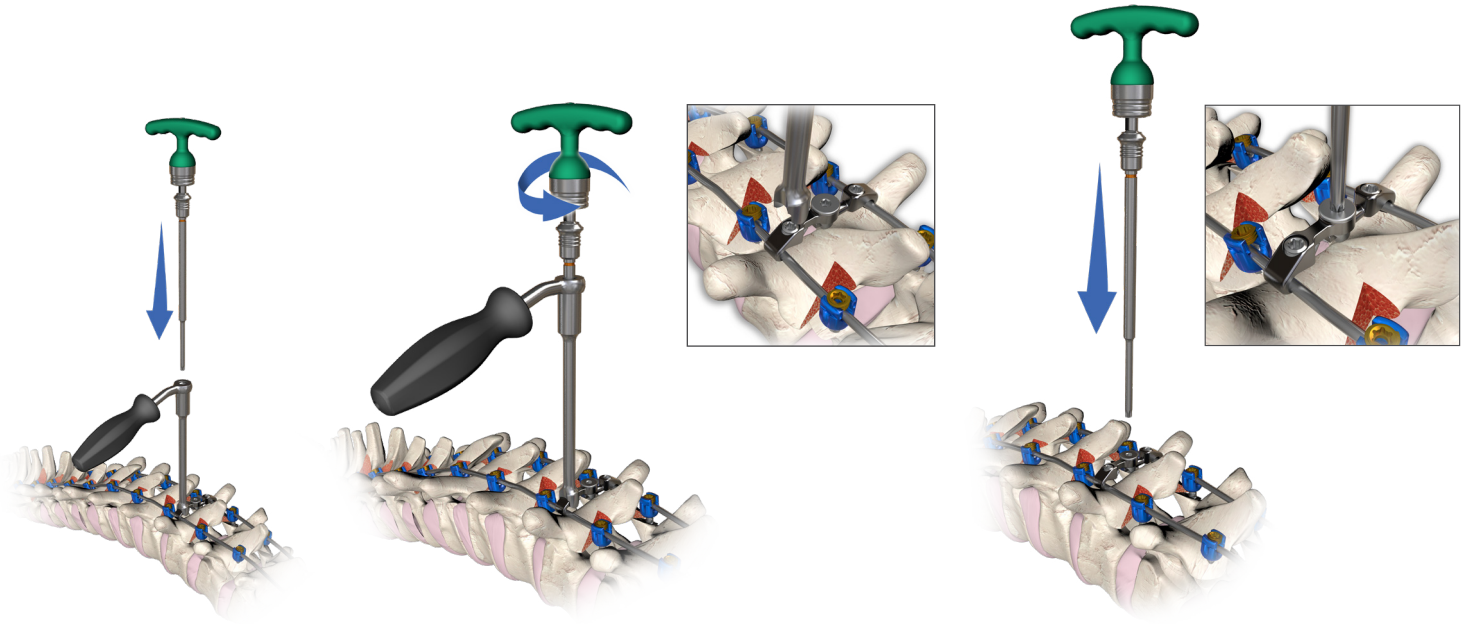
Then turn the green T-handle (58 in-lbs) of the Driver Shaft while firmly holding the Counter Torque Wrench. Repeat for the remaining set screw.

CAUTION: In the event that the cross connector is needing to be contoured, Do not rebend cross connectors.

WARNING: If using Transition Rods, do not place cross-connectors on the transition zone.

*See Page 39 for Final Tightening – Alternate Instruments

REVISION OR REMOVAL TECHNIQUE

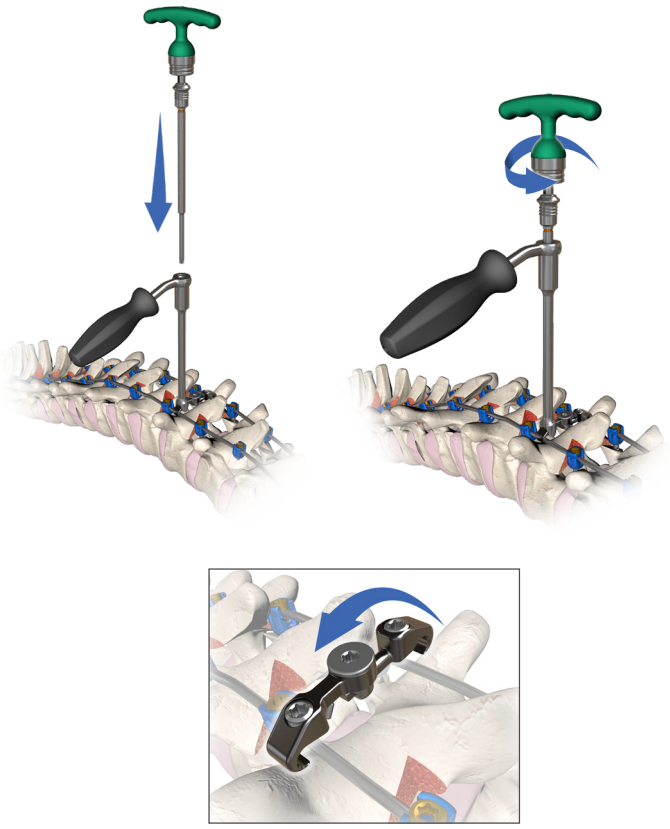


Cross-Connector Removal

Place the X-Link Counter Torque Tube and the Small Set Screw Driver over the connector, rod, and set screw of the rod closest to the surgeon. Use the Small Set Screw Driver and T-handle to remove the set screw while firmly holding the Counter Torque Tube.

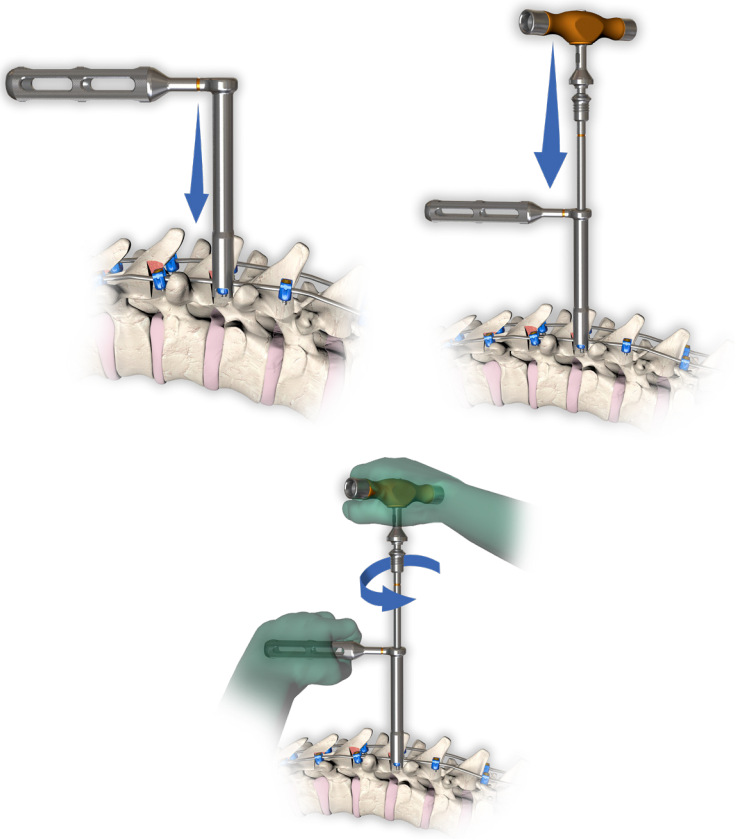
Loosen the midline nut with the Small Set Screw Driver to release the linkage from the rod (disregard this step if releasing a fixed cross connector).

*See Page 39 for Final Tightening – Alternate Instruments



Cross-Connector Removal (cont.)

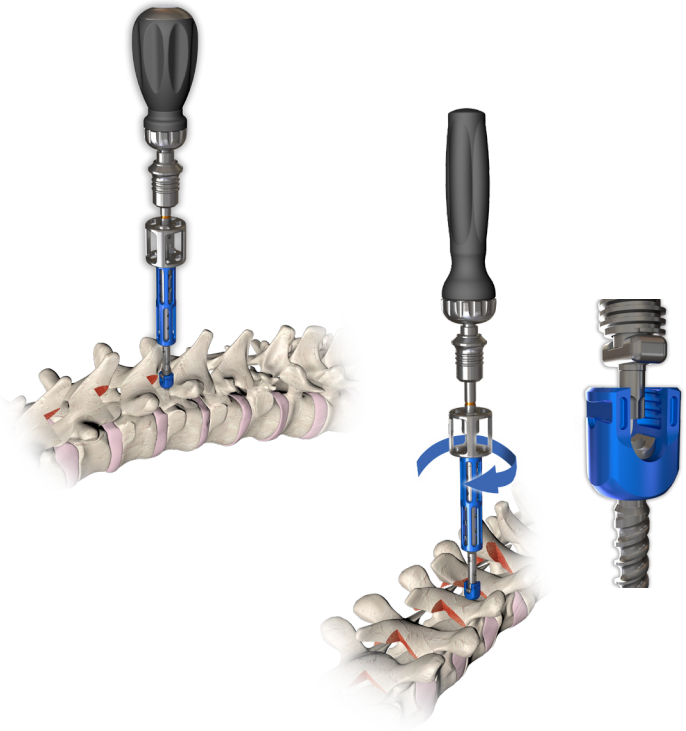
Use the X-Link Counter Torque Tube and the Small Set Screw Driver to remove the set screw from the remaining cross connector, and remove the assembly.

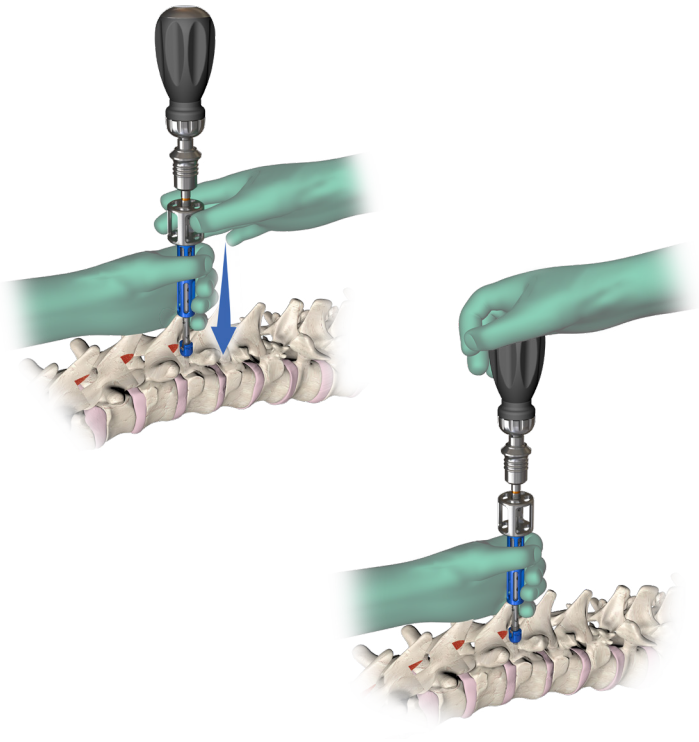


Set Screw Removal

Place the Counter-Torque Wrench over the rod and Pedicle Screw to provide the leverage needed to loosen the Set Screw. Hold the wrench firmly and remove the Set Screw by turning it counter clockwise with the Large Set Screw Driver.

*See Page 39 for Final Tightening – Alternate Instruments



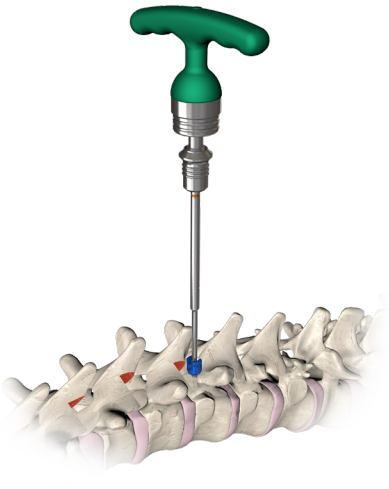


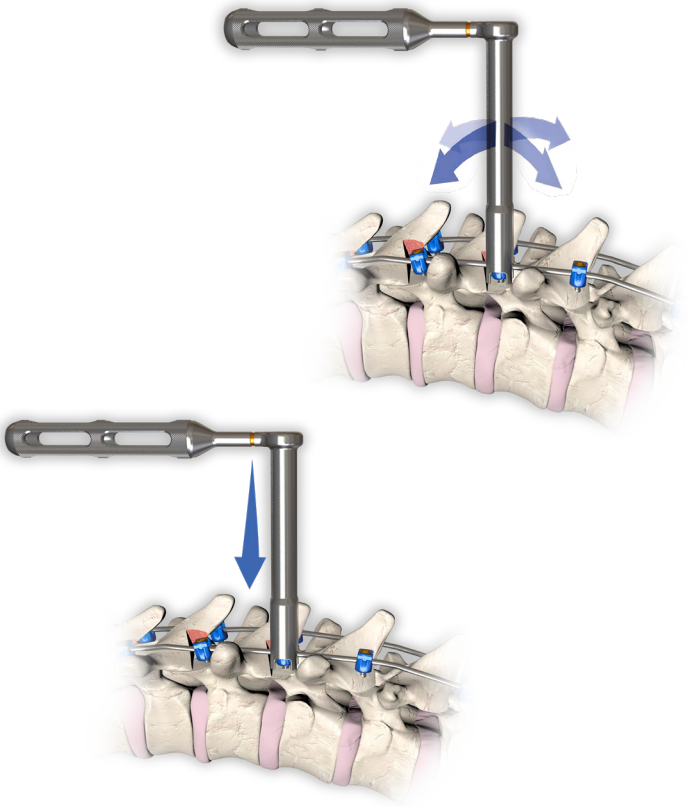
Pedicle Screw Removal

After all Set Screws have been removed, the rod may be removed manually or by using the Rod Gripper.

NOTE: multiple handle options are available for use.

1. Place the hexalobe tip of the driver into the screw until it is seated as shown.
2. Turn the threading knob to thread the driver to the screw.
3. Engage the rotation sleeve by pushing it down into the head of the screw.
4. Turn the driving knob counterclockwise while holding the shaft of the poly driver assembly to remove the screw.





Pedicle Screw Removal (cont.)

Alternate Method

Use the T-15 Pedicle Screw Positioner to remove the Pedicle Screw.

Screw Extraction

If it is necessary to unlock the head of the pedicle screw, place the Counter-Torque Wrench over the screw. Tilt the wrench about 25 degrees. An audible pop may be heard to indicate that the head has been unlocked.

CAUTION: Be aware that the force required to unlock the head of the pedicle screw could damage low quality bone. Use caution during this step. Do not leverage the screw in a direction that could compromise the spinal cord in the event of screw plow.

IMPORTANT MEDICAL INFORMATION

For additional safety information related to the System, refer to the complete eIFU located on the OrthoPediatrics' eIFU website:

http://www.orthopediatrics.com/ifu

Notes

CAUTION: Federal law restricts this device to sale by or the order of a Physician.

CAUTION: Devices are supplied Non-Sterile. Clean and sterilize before use according to instructions.

CAUTION: Implants components are single-use. Do not reuse

CAUTION: Only those instruments and implants contained within this system are recommended for use with this technique. Other instruments or implants used in combination or in place of those contained within this system is not recommended, unless otherwise stated.

NOTE: This technique has been provided by one of our medical advisors only as guidance and it is not intended to limit the methods used by trained and experienced surgeons.

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