LOW PROFILE PEDICULAR SCREW SYSTEM WITH VERTEBRAL COLUMN DEROTATION FOR CORRECTING THREE DIMENSIONAL SPINAL ALIGNMENT

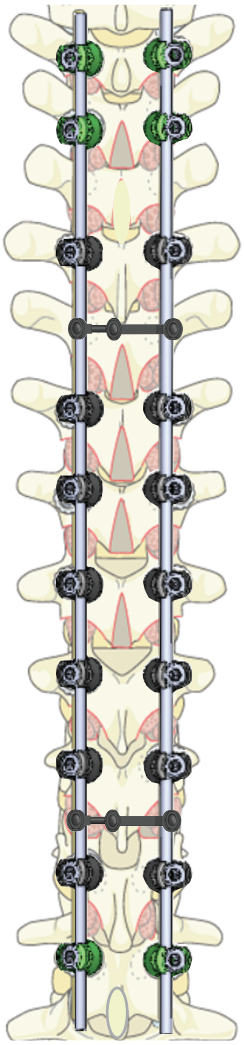
G SURGICAL PEDICLE SYSTEM

G SURGICAL

MARKSMAN

SPINAL DEFORMITY SYSTEM





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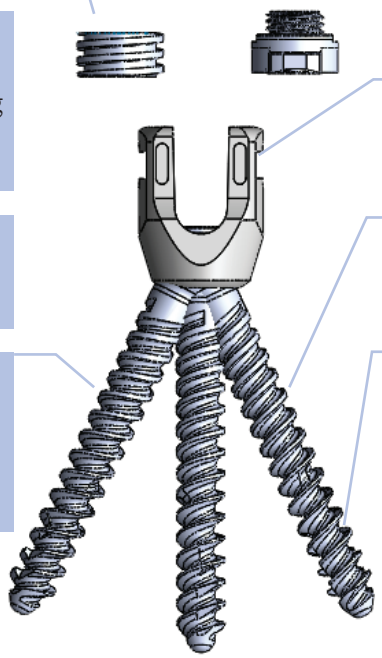
SCOLIOSIS MARKSMAN
Polyaxial Product Features

Set Screw design prevents cross threading or slippage

Internal 4 mm hex, utilizes same instruments as the pedicle screw reducing instruments and time required to secure

Color coded tulips for easy screw diameter identification

Double lead thread for faster insertion
Tapered inner core for maximum bone purchase



Locking collar design reduces torque loading and assistin vertebral derotation before final tightening

Minimum tulip profile reduces muscle dead space scar tissue

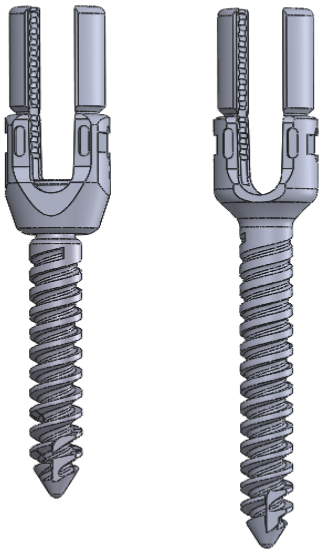
Polyaxial, top loading locks angle when final torque is applied

Two self tapping flutes 180° apart allow balanced self-centering insertion

Scoliosis
Monoaxial (Fixed Head)
same features as Polyaxial
except has fixed head



Reduction Screws
Product Features



Extended Head aids in rod capture particularly suitable for severe scoliotic curves.

IMPLANTS, SCOLIOSIS

ROD

TR-155200	5.5 mm x 200 mm Titanium Rod
TR-155300	5.5 mm x 300 mm Titanium Rod
TR-155400	5.5 mm x 400 mm Titanium Rod
TR-155500	5.5 mm x 500 mm Titanium Rod
TR-155600	5.5 mm x 600 mm Titanium Rod

MONOAXIAL

MA-4525-55H	4.5 mm x 25 mm Monoaxial Screw, Marksman
MA-4530-55H	4.5 mm x 30 mm Monoaxial Screw, Marksman
MA-4535-55H	4.5 mm x 35 mm Monoaxial Screw, Marksman
MA-4540-55H	4.5 mm x 40 mm Monoaxial Screw, Marksman
MA-4545-55H	4.5 mm x 45 mm Monoaxial Screw, Marksman
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IMPLANTS, SCOLIOSIS

CROSSILINK

CL-4050	Crosslink Assembly 40 mm-50 mm
CL-5060	Crosslink Assembly 50 mm-60 mm
CL-6070	Crosslink Assembly 60 mm-70 mm
CL-7080	Crosslink Assembly 70 mm-80 mm

SET SCREW

PA-4000	Set Screw

POLYAXIAL

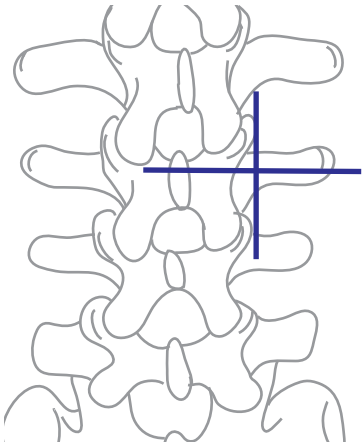
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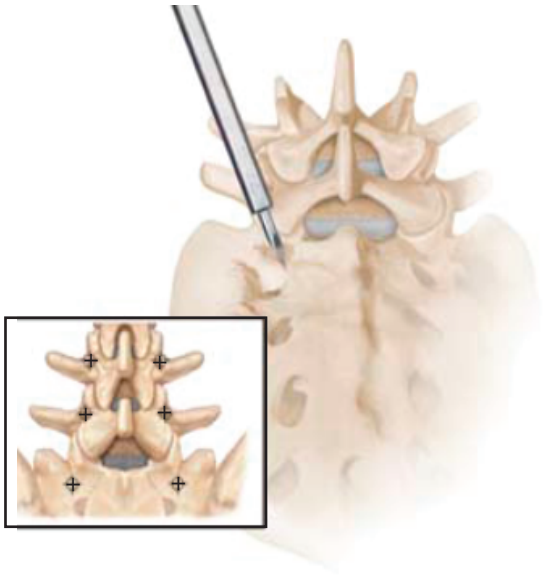
Approach and Preparation:

The procedure is performed with the patient in a prone position. The incision length dependent on preoperatively planning, based on x-rays and prior review.



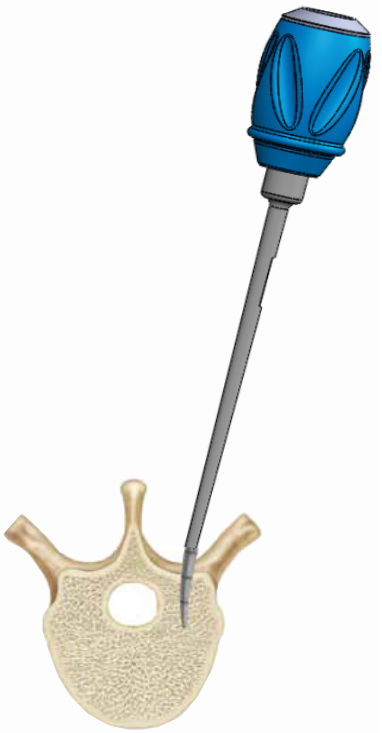
Pedicle Preparation:

Proper entry point is critical. Knowledge of the Superior Facet Rule to direct the medial/lateral and the Cephalo/ Caudal starting points is a helpful reference to accomplish this. The cortical surface can be removed using a burr or rongeur. An Awl is provided in the instrument set for penetrating the cortex and creating a pilot hole. A Curved Probe and Tester are available to complete preparation for screw insertion.



Screw insertion trajectory should follow the angle of the pedicle canal.





Pedicle Screw Insertion:

Any bone structures that may obstruct screw insertion or exposure for the instrumentation or fusion should be removed. There are several options for the surgeon of typical thoracic idiopathic scoliosis including screw volume, with less screws used on smaller curves and more screws used on larger and or stiffer curves up to utilizing at every level and contralateral locations for maximum derotational ability.

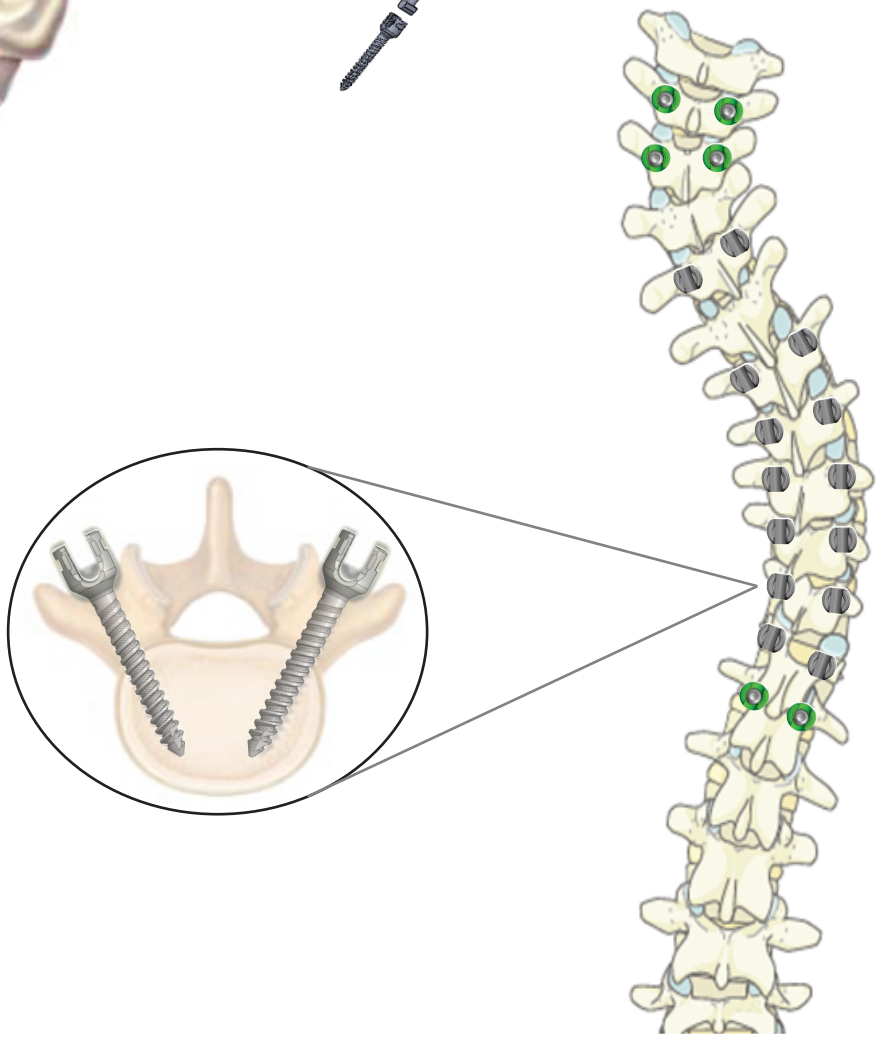


Screw insertion:

Polyaxial, Monoaxial Screws and Reduction Screws may be utilized but generally fixed head (Monoaxial Screws) are used where apical forces are performed to maximize derotation applied force and Polyaxial Screws are used at the construct ends.







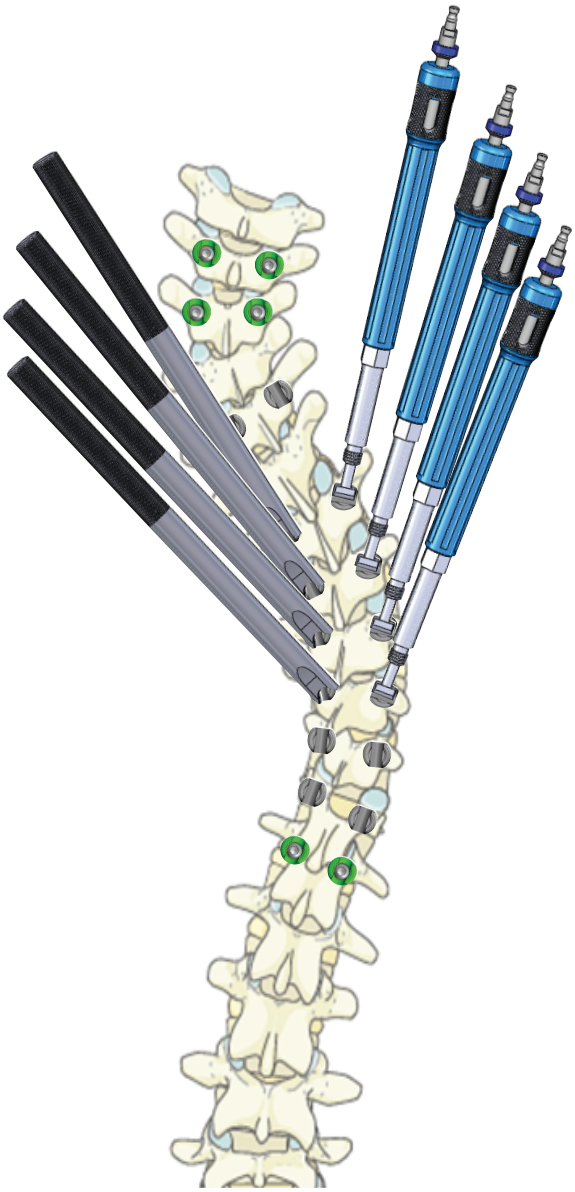
Instrument attachment for derotation:

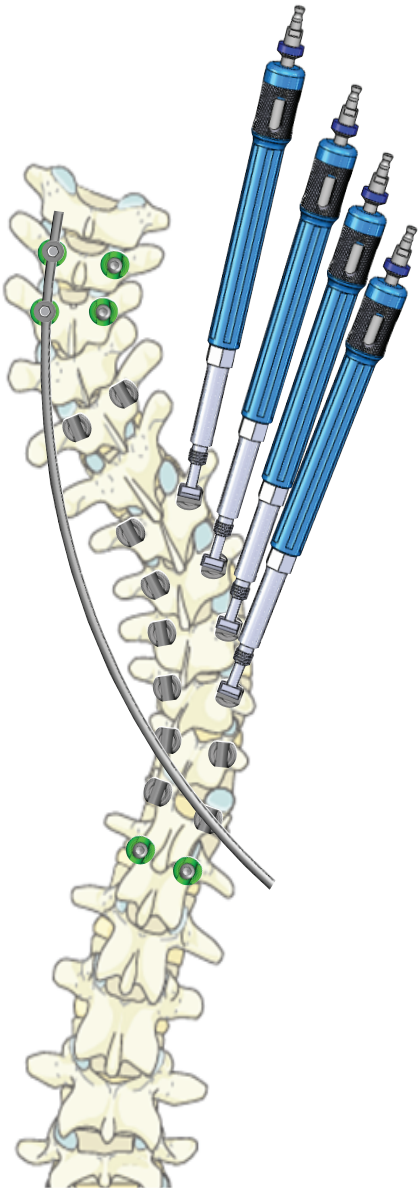
After all screws have been inserted, attach the Monoaxial Screw Drivers to vertebral segments of the convex side and the Derotator Tubes to the adjacent apical vertebra on the concave side.

By applying force on the convex implants with the Monoaxial Drivers and the concave Derotation Tubes, a periapical derotation maneuver can be made. The degree of derotational corrective forces can be accessed to quantify the degree of safe and effective derotational corrective forces to be generated.

Concave Rod Insertion:

The pre-contoured rod, contoured in the sagittal plane only, is inserted in the most cephalad pedicle screw on the concave side and set screws loosely inserted on to the pedicle screw. For large deformities, the apical screws may not fully seat into the pedicle screw and the additional lower cephalad screws may also need to be provisionally tightened.



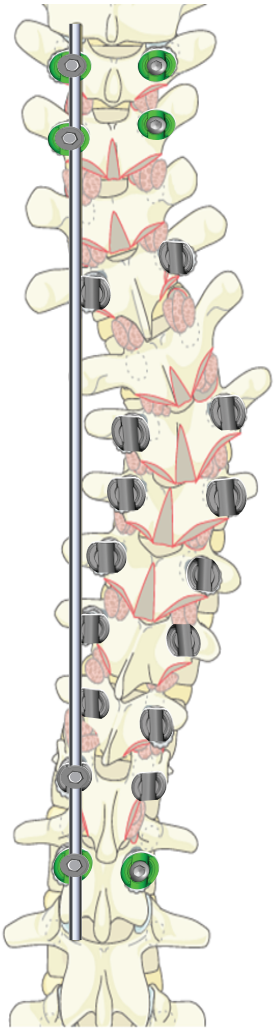


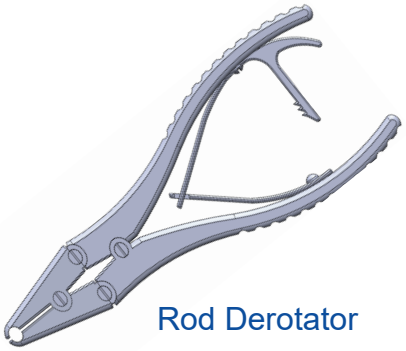
Anatomical Alignment via Derotation

The rod can now be rotated 180 degrees into the correct sagittal position using a Rod Derotator and the distal pedicle screws provisionally tightened with set screws. The rod is now captured cephalad and caudal but only locked into the caudal screws.

Starting caudad and moving sequentially cephalad, the apical segments on the concave rod are captured. The Rod Derotator, Rod Fork and or Rod Pusher can be used for seating the rod into the pedicle screw heads. The convex side, using the Monoaxial Drivers is used to assist in derotation while capturing the concave pedicle screws.

The cephalad screws should still remain loose capturing the rod only.

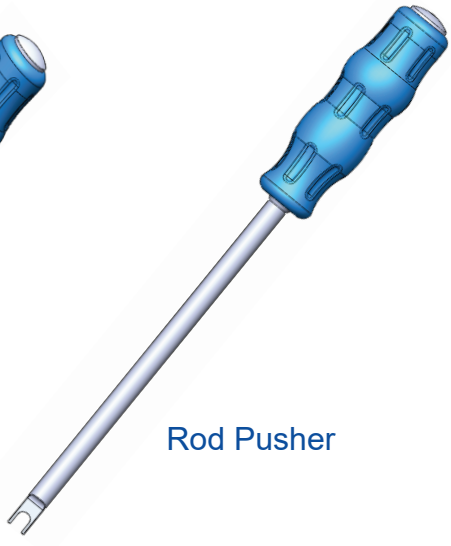




Rod Derotator



Rod Fork



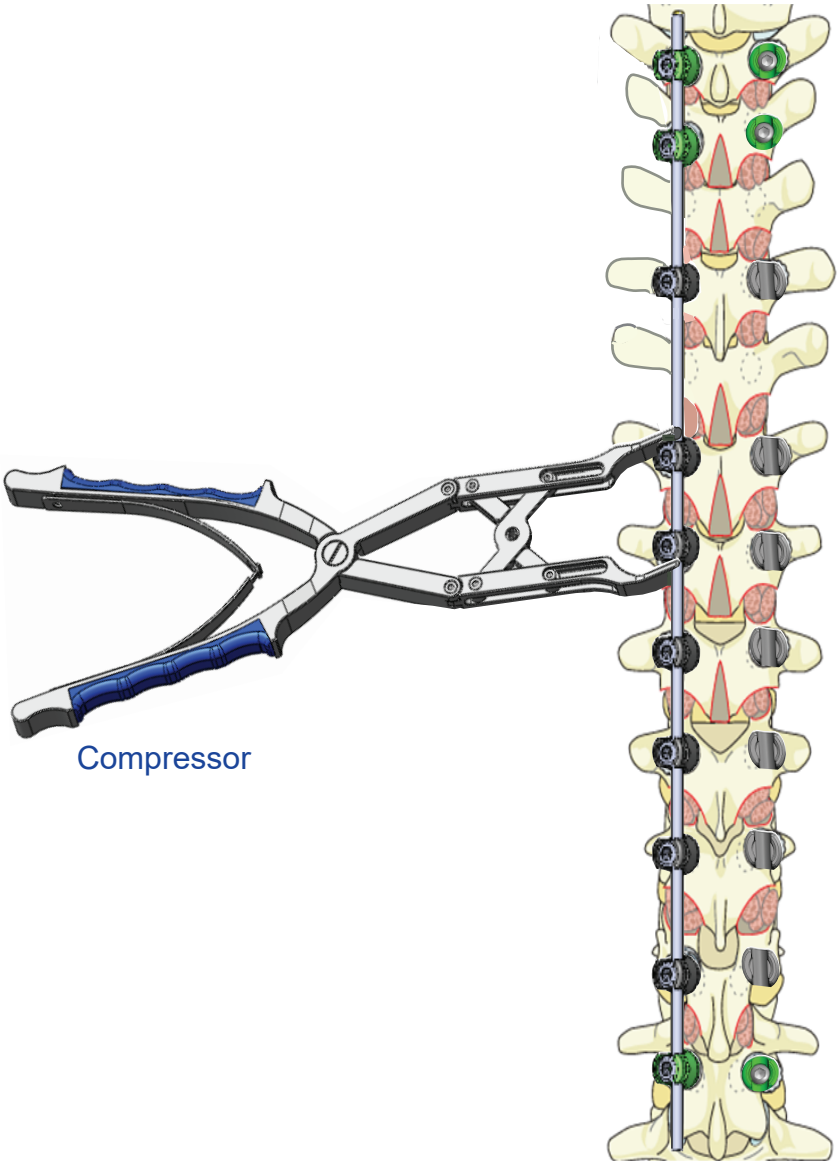
Rod Pusher

Compression/Distraction:

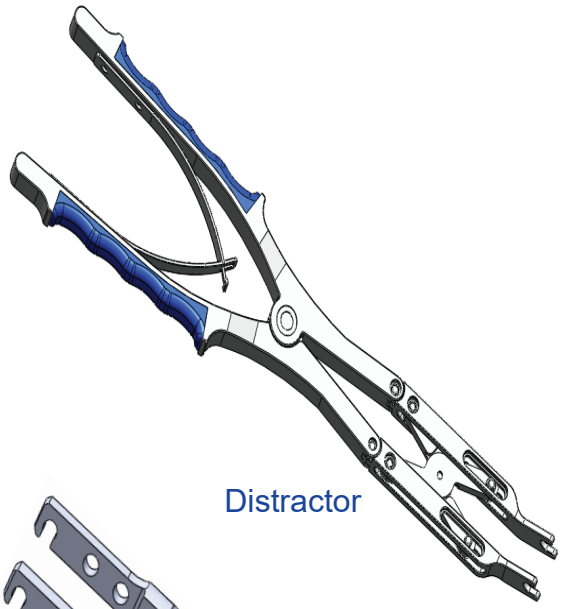
After Monoaxial Screw Drivers are removed, use the In-Situ rod contouring instruments for coronal translation correction. Provisionally tighten the set screws after compression/ distraction but to normalize the rod/screw interface, remove compression prior to final tightening of the set screws.

Final Derotation:

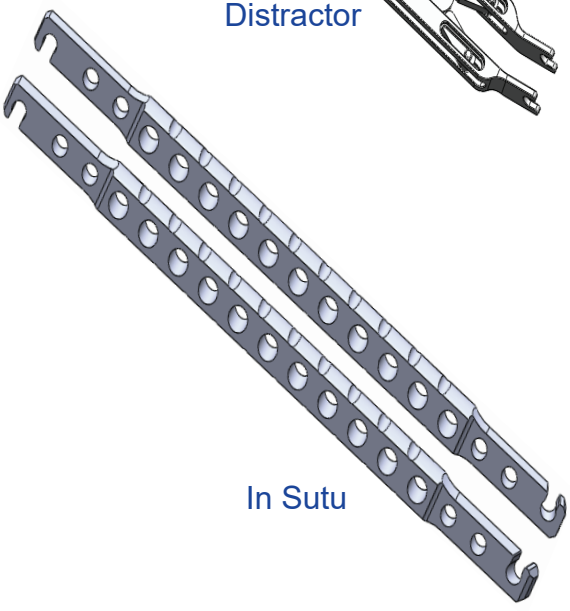
Again, perform bilateral apical vertebral derotation on the concave side while both ends of the construct have been provisionally tightened. Place the Derotator Tubes over the four concave monoaxial screws and the Monoaxial Screw Drivers over the apical convex monoaxial screws, loosen the set screws and derotate the spine and chest wall around the rod and retighten the set screw.



Compressor



Distractor



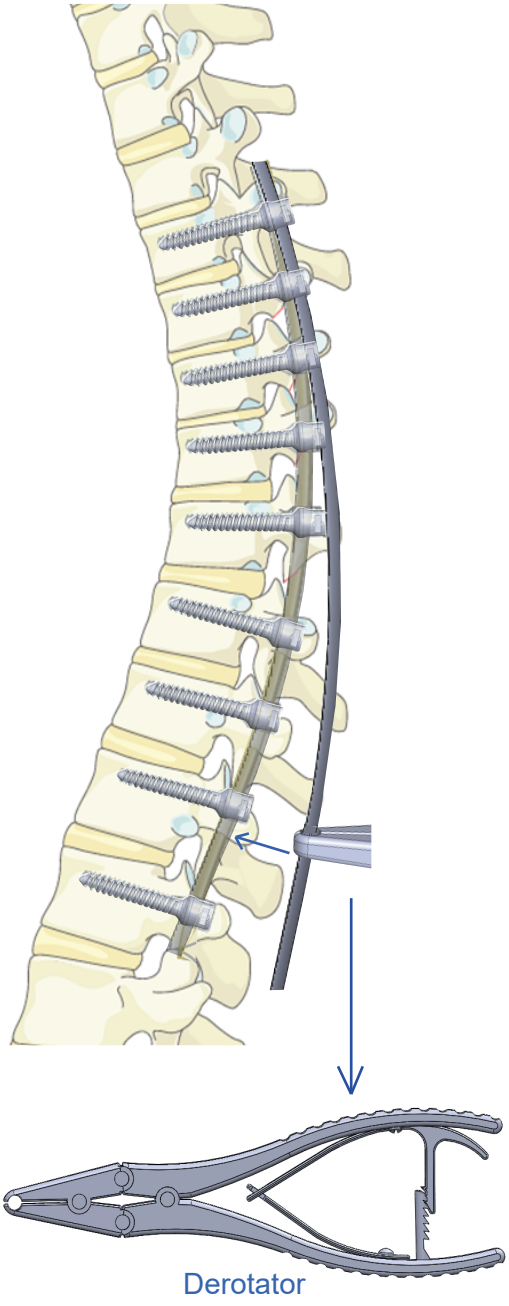
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Second Rod Placement:

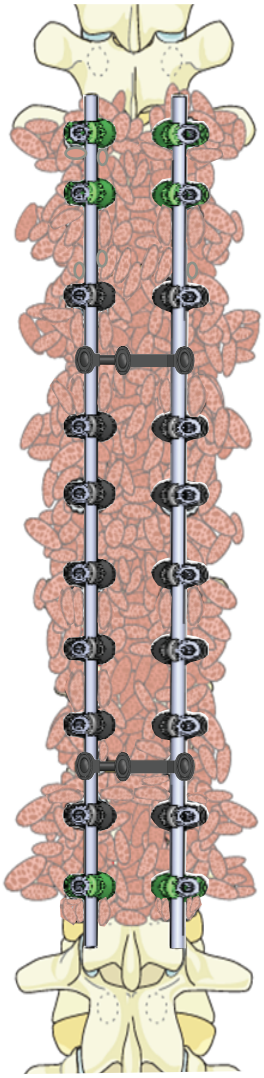
The rod on the convex side can be contoured and inserted cephalad to caudad. Set screws are inserted and provisionally tightened. Compression and or distraction to further align and stress relieve each vertebral segments can be performed. Once alignment is completed and each end of the construct has been normalized, all set screws are sequentially tightened using a Power Holder and Final Torque Instrument provided in the instrument set.

Cross-Links, to increase stability, can be attached to the bilateral rods in multiple locations and posterior grafting can be performed after decortication.

Fluoroscopy imaging is made to check coronal and sagittal correction, screw position and assure the rods are fully seated into the pedicle screw saddles.



Derotator



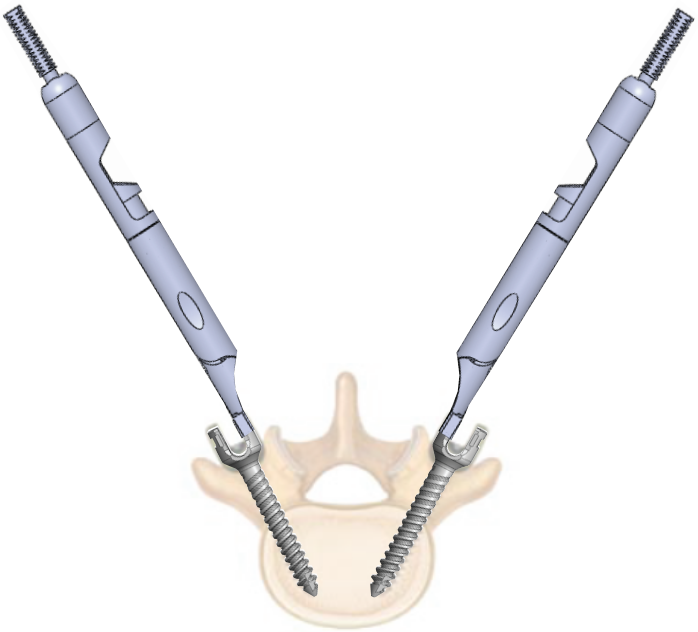
Following cross connector placement, wound closure is performed in the customary manner.

Direct Vertebral Column Rotation Technique

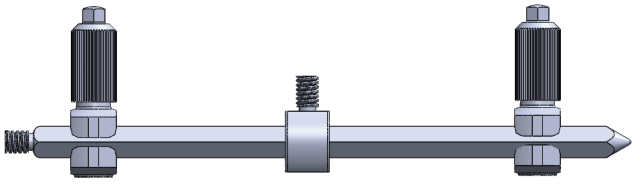
Both Monoaxial, Polyaxial and Reduction screws may be used for correction in the sagittal and coronal planes through rod rotation and in-situ rod contouring.

Surgical approach, pedicle preparation and pedicle screw insertion should follow the same procedures as described earlier. Placement and screw lengths should be confirmed using fluoroscopy before rod insertion.

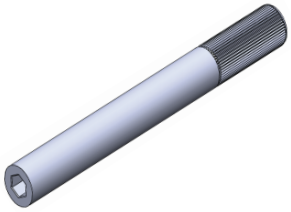
After pedicle screws have been inserted, attach Implant Holders to the pedicle screw slotted portion of the head and repeat for the contralateral side. Implant Holders should be attached to the medial side of the screw head.



Three Bridge lengths are available to span the contralateral implant holders and can be attached using Bridge Nuts secured to the Implant Holders and Bridge.

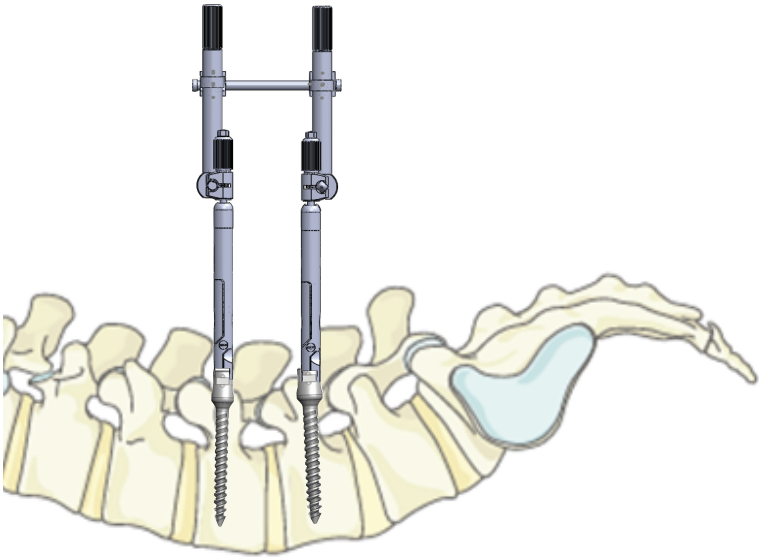


Bridge lengths 115, 170 mm , 224 mm

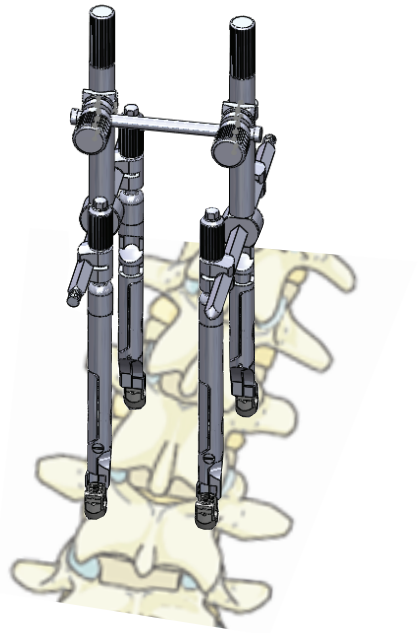


Assemble the 2 bridge nuts to the appropriate bridge length and slide in position to attach to the top of the implant holder and corresponding implant holder on the contralateral side. Tighten the bridge nuts to secure using the hex end of the Extension Handle to insert onto the Bridge Nut.

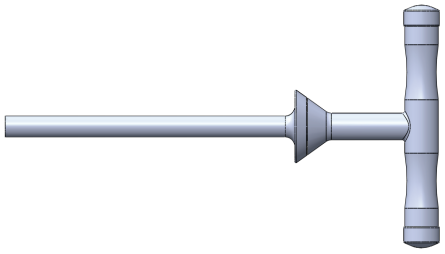
Adjacent levels are attached using a bridge connector by loosening the knurl knobs sliding over the bridge handles at two adjacent levels and tightening the knurl knobs of the bridge nut.



With the ridged superstructure attached to adjacent levels, bilateral apical vertebral derotation can be performed as described at the beginning of the technique.



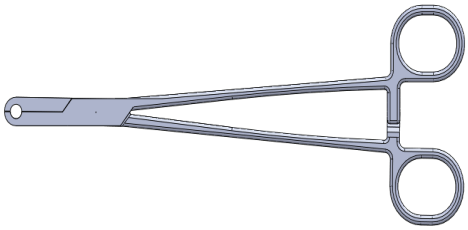
G Surgical Scoliosis System Marksman Instruments are provided in autoclavable cases. All instruments are manufactured from surgical grade stainless steel, with laser engraved markings for easy identification and have silkscreened graphics for placement of instruments in the autoclavable case. Anatomical silicone handles are provided for ease of use.



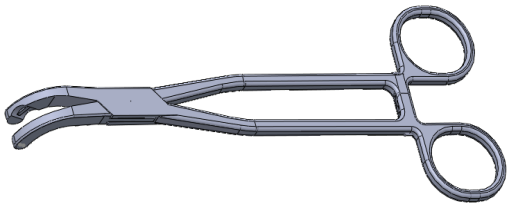
SSG0021 Torque Instrument for Cross Link



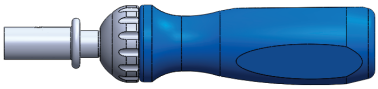
SSG0006L Tester



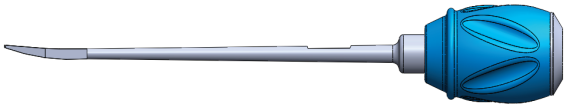
SSG0012 Rod Holder



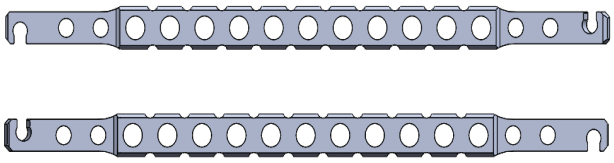
SSP0009 Housing Holder



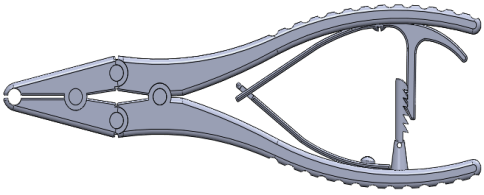
SSP0205C Quick Connect Inline Handle Cannulated



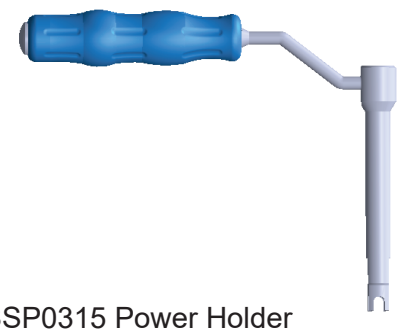
SSG0207C Lenke Probe, Curved



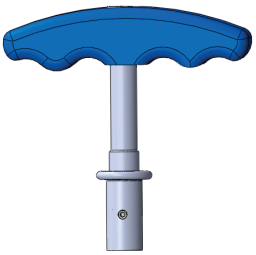
SSP0013L In-Situ Rod Bender, Left
SSP0013R In-Situ Rod Bender, Right



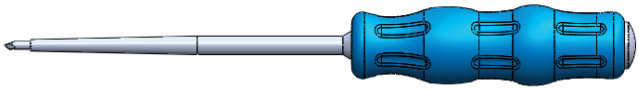
SSG0019-55 Rod Derotator, Marksman 55



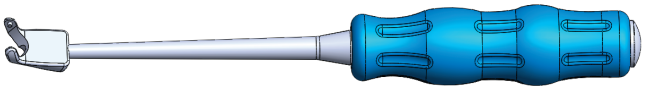
SSP0315 Power Holder



SSP0118 Quick Connect T-Handle



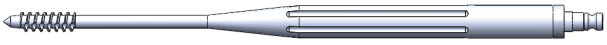
SSG0001 Awl



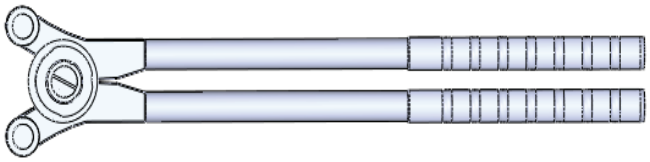
SSP0204 Rod Fork For Slot Marksman 55



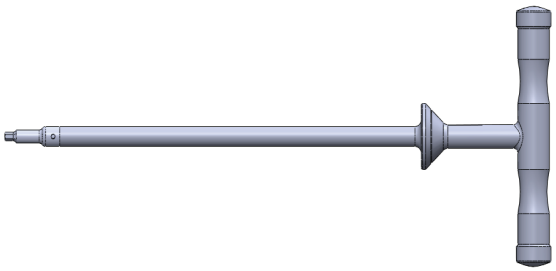
SSP0214 Rod Pusher Marksman 55



SSP0208-55 Tap, Marksman 55, 5.5 mm
SSP0208-65 Tap, Marksman 55, 6.5 mm
SSP0208-75 Tap, Marksman 55, 7.5 mm
SSP0208-85 Tap, Marksman 55, 8.5 mm

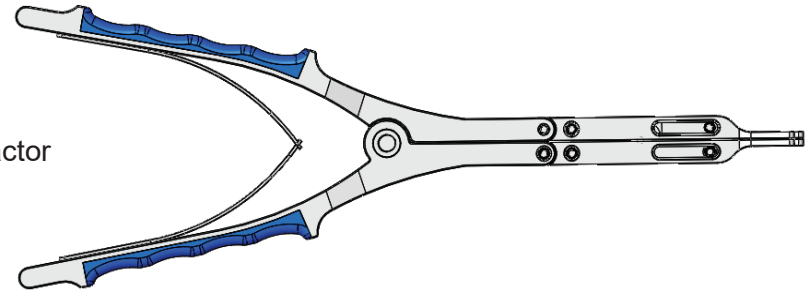


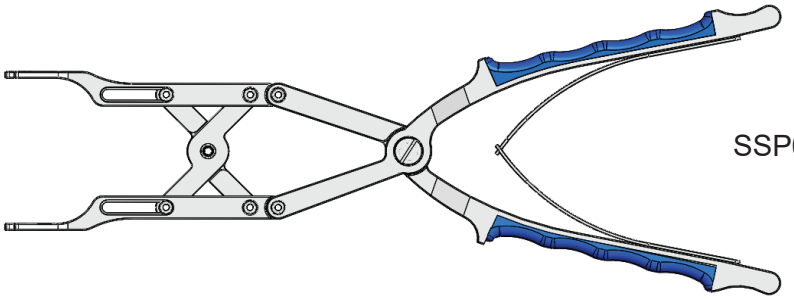
SSG0011 Rod Bender



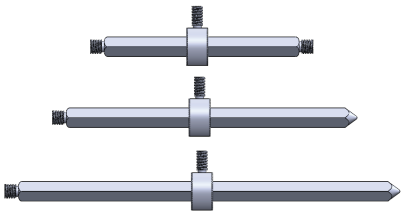
SSG0020M Torque Measuring Device 4 mm

SSP0211 Distractor





SSP0212 Compressor



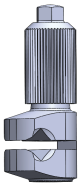
SSP4018 Brodge 115 mm, Scoliosis
SSP4020 Brodge 170 mm, Scoliosis
SSP4023 Brodge 224 mm, Scoliosis



SSP4025 Derotator Tube



SSP4014 Bridge Connector, Scoliosis



SSP4011 Bridge Net



SSP4015 Extension Handle, Scoliosis



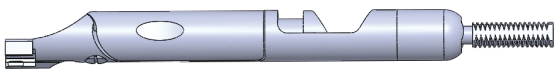
SSP4012 Implant Holder Handle, Scoliosis



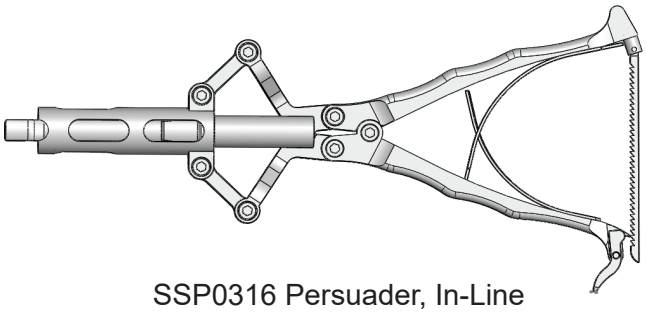
SSP0314 Polyaxial Screw Driver w/Outer Shaft



SSP4026 Screwdriver, Monoaxial Marksman



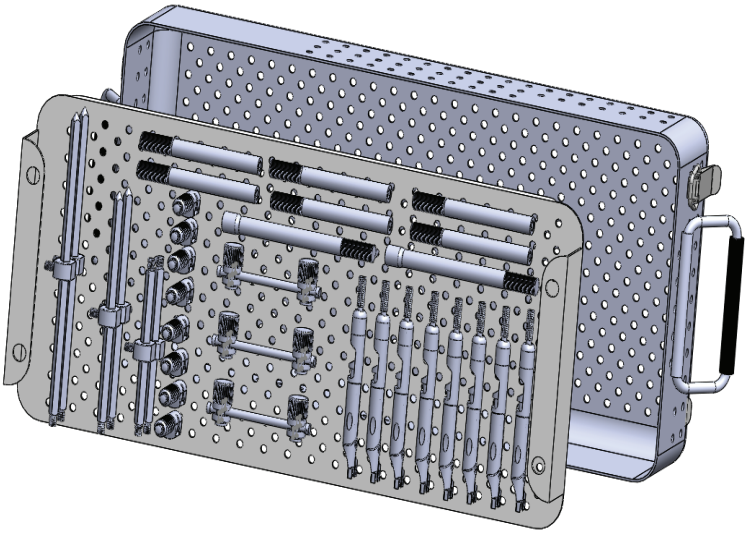
SSP4010 Implant Holder



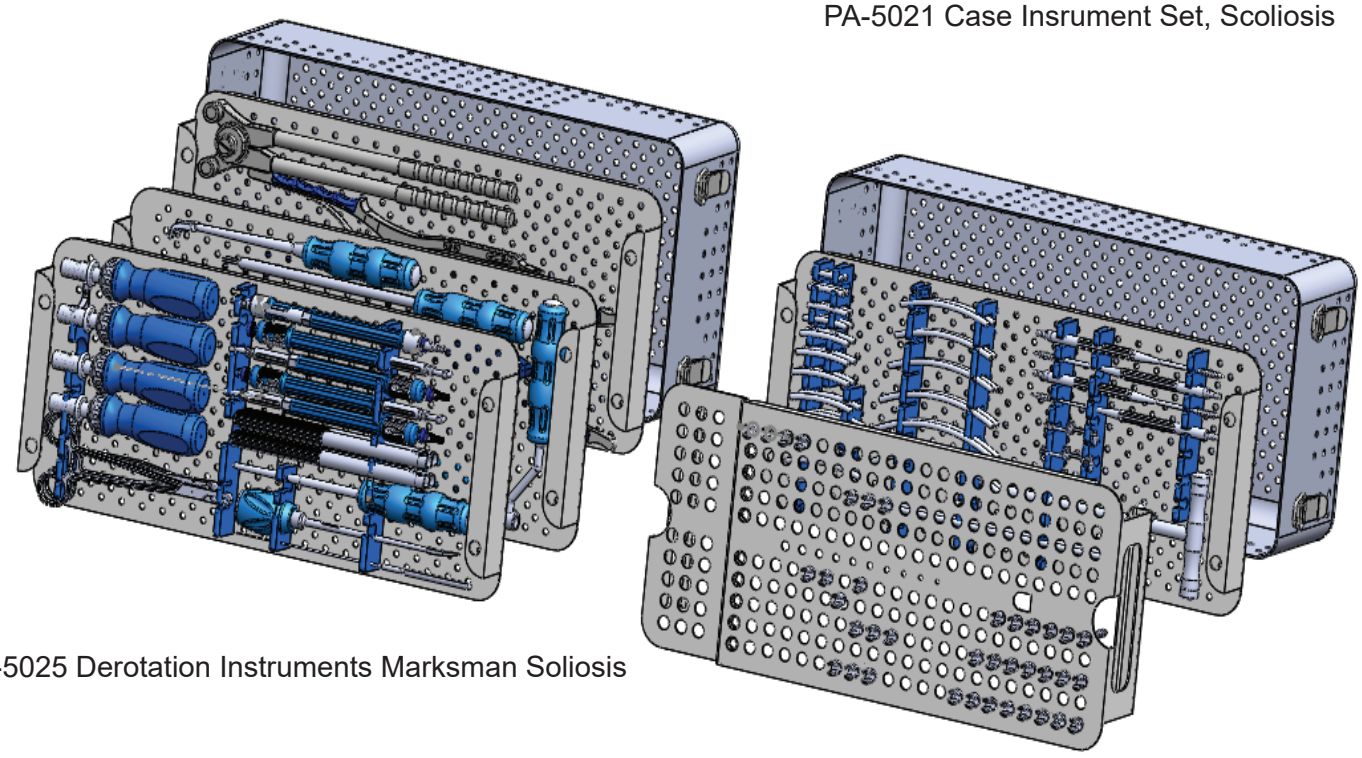
SSP0316 Persuader, In-Line

LOW PROFILE PEDICULAR SCREW SYSTEM WITH VERTEBRAL COLUMN DEROTATION FOR CORRECTING THREE DIMENSIONAL SPINAL ALIGNMENT

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