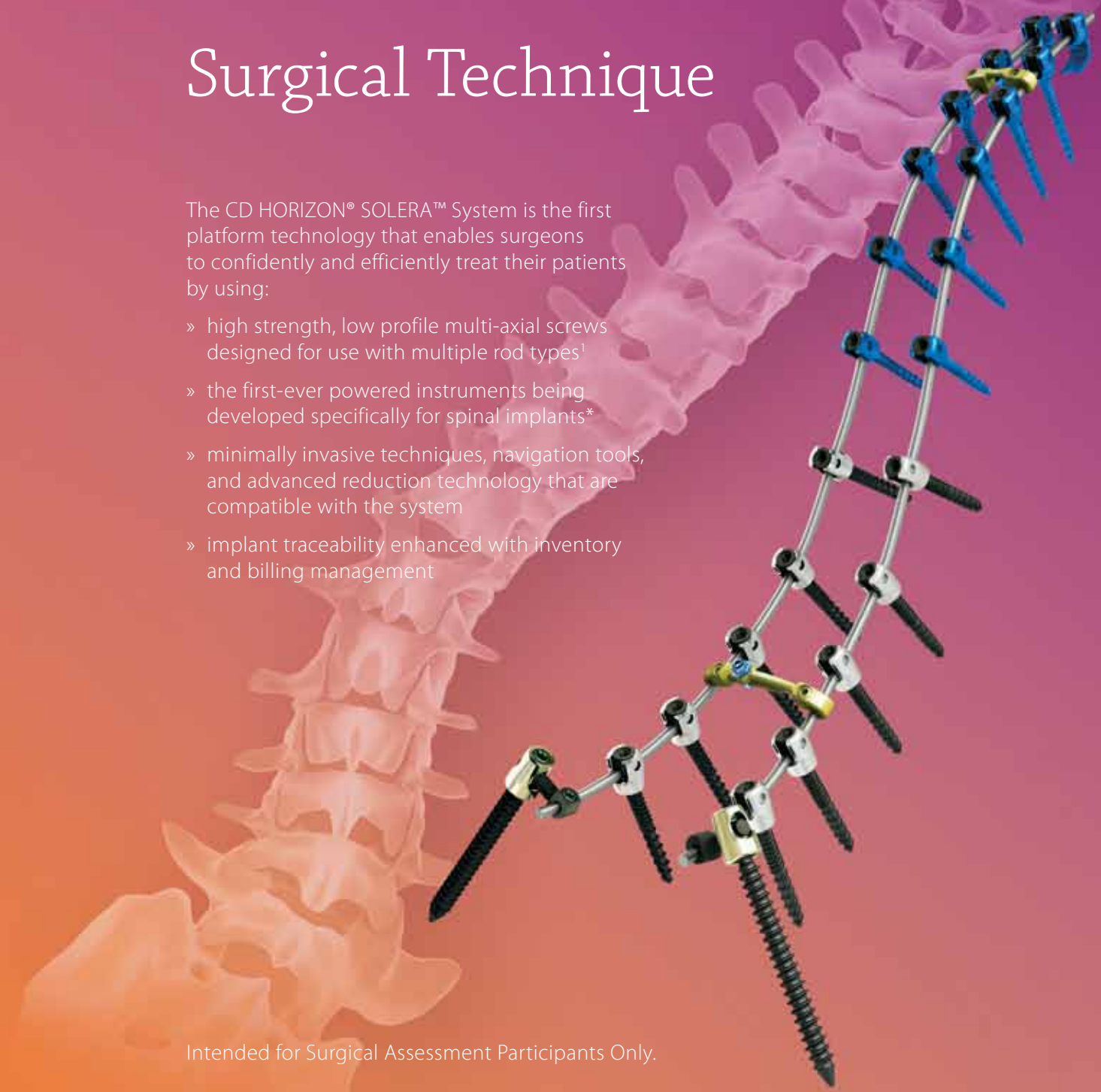
Medtronic

CD HORIZON® SOLERA™
Spinal System

Surgical Technique



The CD HORIZON® SOLERA™ System is the first platform technology that enables surgeons to confidently and efficiently treat their patients by using:

- high strength, low profile multi-axial screws designed for use with multiple rod types[1]
- the first-ever powered instruments being developed specifically for spinal implants*
- minimally invasive techniques, navigation tools, and advanced reduction technology that are compatible with the system
- implant traceability enhanced with inventory and billing management

Intended for Surgical Assessment Participants Only.

[1]Based on internal testing per ASTM F1798 (internal test report TR09-312). Test not indicative of human clinical outcome.
*POWEREASE™ Powered Instruments are designed for procedural steps like rod and post cutting and final construct tightening and are not currently available.

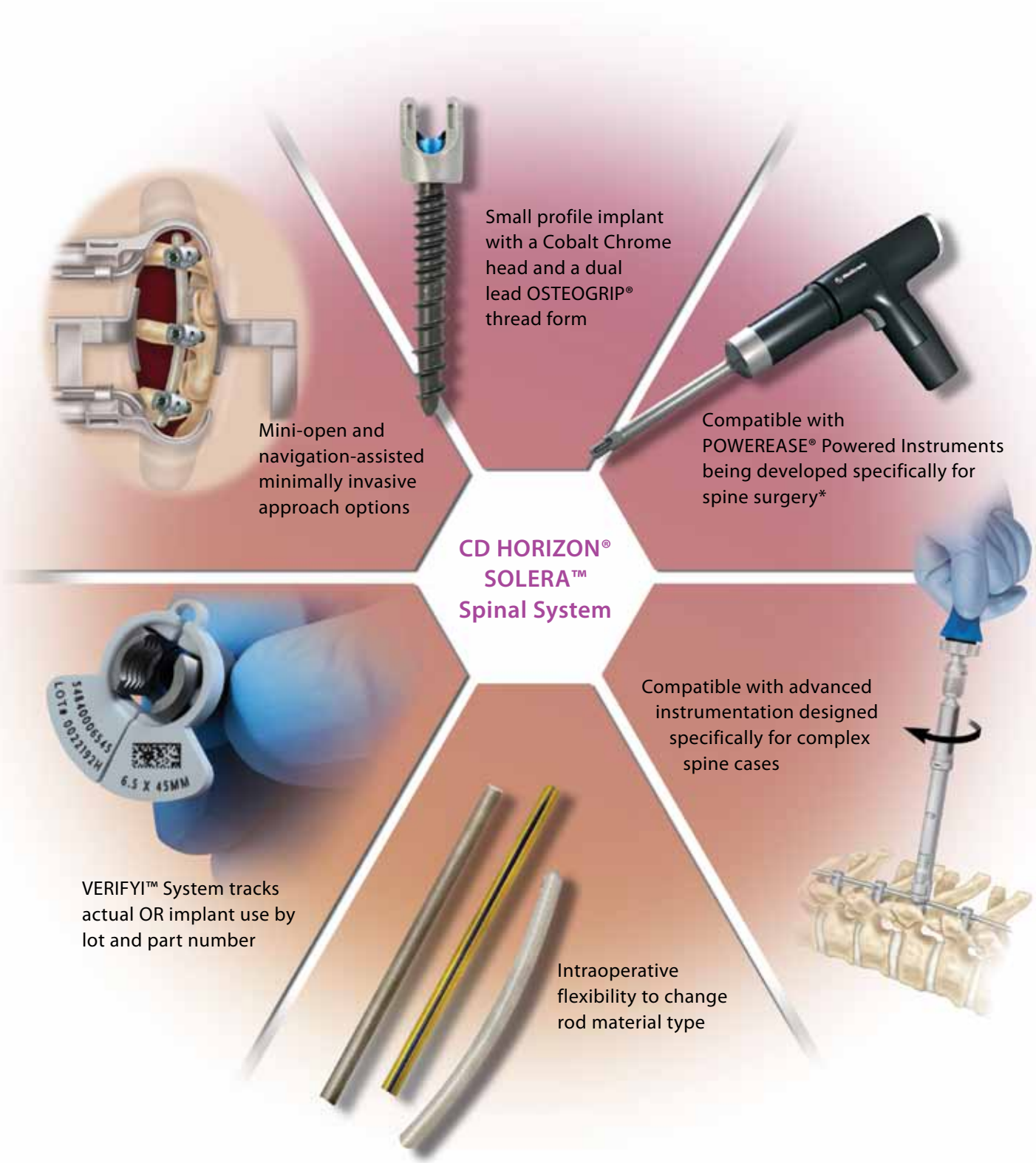
Medtronic

CD HORIZON® SOLERA™

Spinal System

Surgical Technique

Technology Overview



*POWEREASE™ Powered Instruments are designed for procedural steps like rod and post cutting and final construct tightening and are not currently available.

Implant Features

"Experience the Power of One."

From the thoracic spine to the ilium, the CD HORIZON® SOLERA™ Spinal System facilitates surgeon choice and flexibility across patient types with a variety of implant options for treating multiple spinal pathologies with one system. With its 4.75mm rod diameter, the system offers the opportunity to reduce the overall metal mass and implant profile without compromising construct integrity, as compared to CD HORIZON® LEGACY™ System 5.5mm Stainless Steel constructs.[1] The technology platform offered with this system is backed by more than 25 years and 400,000 cases of CD HORIZON® clinical experience and Medtronic expertise.

Multi-Axial Screw

- Dual lead OSTEOGRIP® thread form
- Smaller Profile—26% reduction in overall volume than CD HORIZON® LEGACY™ 5.5mm Multi-Axial Screw and 12% smaller than CD HORIZON® LEGACY™ 4.5mm Multi-Axial Screw
- Cobalt Chrome head is compatible with CD HORIZON® CHROMALOY™, CD HORIZON® CHROMALOY™ Plus, and Titanium Rods, allowing real-time rod choices in the OR to customize the stiffness and strength of the construct
- Imaging comparable to Titanium screw heads[2]
- Color-coded by bone screw diameter

Fixed Angle Screw

- Dual lead OSTEOGRIP® thread form
- Smaller Profile—21% smaller than CD HORIZON® LEGACY™ System 5.5mm Fixed Angle Screw
- Color-coded by bone screw diameter
- Compatible with CD HORIZON® CHROMALOY™, CD HORIZON® CHROMALOY™ Plus, and Titanium Rods, allowing real-time rod choices in the OR to customize the stiffness and strength of the construct

Break-off Set Screw

- Internal TORX for secure instrument engagement
- Features a quick start thread with a blunt start cut
- Design does not allow for misaligned set screws to fully engage or provide break-off feedback when used in multi-axial screws[3]

[1]Based on internal testing of a CD HORIZON® CHROMALOY™ Plus rod construct, per ASTM F1717 (internal test report TR04-269 and TR09-313). Testing not indicative of human clinical outcome.

[2]Results based on internal testing in a cadaveric model (internal test report TR10-184). MRI and CT images were taken of constructs of three different materials: Stainless Steel, Titanium, and Cobalt Chrome. Images were reviewed by seven technical experts for clarity in regions of interest.

[3]Based on internal testing (internal test report TR10-219).

Implant Features *continued*

Rod Spectrum

CD HORIZON® CHROMALOY™ Plus Rod

Titanium Alloy Rod

CD HORIZON® CHROMALOY™ Rod

- Multiple material types for intraoperative flexibility
- Available rods
  - Straight, lined Titanium Alloy Rod
  - Straight CD HORIZON® CHROMALOY™ and CD HORIZON® CHROMALOY™ Plus Rod
  - Precontoured and Precut CD HORIZON® CHROMALOY™ Rod

CD HORIZON® X10 CROSSLINK® Plate

- Compatible with CD HORIZON® CHROMALOY™, CD HORIZON® CHROMALOY™ Plus, and Titanium Rods
- Adjustable or fixed length and angulation
- Attaches to the rod in the coronal, sagittal, or transverse planes in any orientation

Hooks

- Compatible with CD HORIZON® CHROMALOY™, CD HORIZON® CHROMALOY™ Plus, and Titanium Rods
- Anatomic angulation to mimic the posterior spinal elements
- Centralized head for balance

Lateral Connectors

- Compatible with CD HORIZON® CHROMALOY™, CD HORIZON® CHROMALOY™ Plus, and Titanium Rods
- Medial/lateral adjustability may prevent the need for coronal rod bending

Iliac Screws*

- Closed fixed head iliac screws available in 0°, 10°, and 20° angles
- Closed Multi-Axial Screws (CMAS) provide flexibility to position the screw head

*Lateral Connectors must be used with CD HORIZON® System Iliac Screws.

Hook Implants

	Hook Type	Vertebral Posterior Element Placement	Blade Direction	Region of Spine	Design Features
	Pedicle Hook	Articular Process	↑	T1 – T10	» Bifid blade grasps thoracic pedicle for stability.
	Wide Blade Hook	Lamina	↕	T1 – L5	» Wider blade width distributes forces evenly over a wider aspect of bone.
		Transverse Process	↕	T1 – L5	
	Narrow Blade Hook	Lamina	↕	T1 – L5	» Narrower blade width minimizes metal volume in the spinal canal.
		Transverse Process	↕	T1 – L5	
	Wide Blade Ramped Hook	Lamina	↕	T1 – L5	» Ramp reduces intra-canal intrusion.
		Transverse Process	↕	T1 – L5	
	Narrow Blade Ramped Hook	Lamina	↕	T1 – L5	» Ramp reduces intra-canal intrusion.
		Transverse Process	↕	T1 – L5	
	Extended Body Hook	Lamina	↕	T1 – L5	» Can correct anatomic misalignment between two laminae in the dorso-ventral plane.
		Transverse Process	↕	T1 – L5	
	Offset Hook	Lamina	↕	T1 – L5	» Centralized head for balance. » Anatomic angulation to mimic the posterior spinal elements.
		Transverse Process	↕	T1 – L5	
	Total Anatomical Pedicle Hook	Articular Process	↑	T1 – T10	» Centralized head for balance. » Lipped design can improve hook stability. » Anatomic angulation to mimic the posterior spinal elements.
	Total Anatomical Transverse Process Hook	Transverse Process	↕	T1 – L5	» Centralized head for balance. » Lipped design can improve hook stability. » Anatomic angulation to mimic the posterior spinal elements.

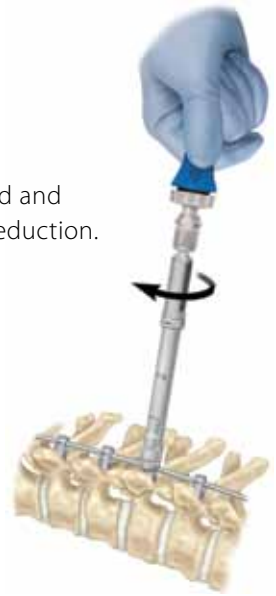
Color-coding Size Reference

Extra Small	Small	Medium	Large
●	●	●	●

Instrument Overview

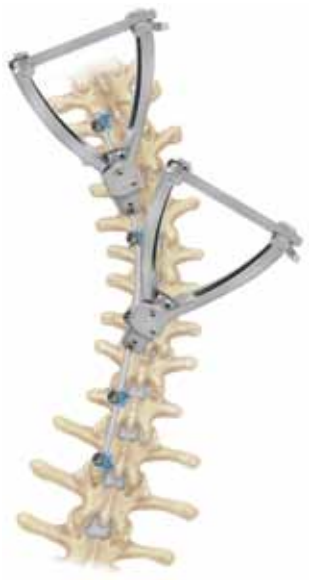
Sequential Reducer

Allows controlled and sequential rod reduction.



Rod Gripper

Attaches firmly to the rod for controlled rod manipulation.



Hinged Translator

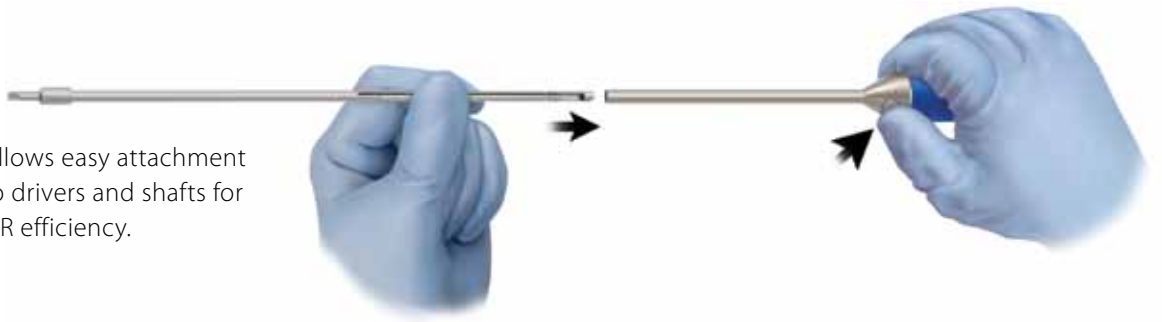
Compresses and distracts off of the rod, not the implant.

Dual Ended Set Screw Starter

Engages inner set screw torx for better visualization, and the knurled grip enhances tactile feel compared to previous designs.

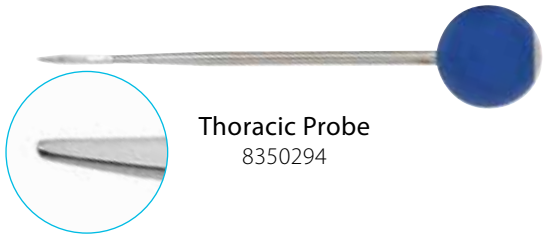
Adjustable Handle

Allows easy attachment to drivers and shafts for OR efficiency.



Instrument Set

Screw Preparation



Thoracic Probe
8350294

Lumbar Probe
8350293

In-Line Handle Round Awl
7480104

Modified Quick Connect Ratcheting Handle
9339082

Taps

8350420 (3.75mm)	8350425 (6.0mm)
8350421 (4.0mm)	8350426 (6.5mm)
8350422 (4.5mm)	8350428 (7.5mm)
8350423 (5.0mm)	8350430 (8.5mm)
8350424 (5.5mm)	8350432 (9.5mm)

Quick Connect Ratcheting T-Handle
7579000

Dual Ended Feeler Probe
7480100

Sounding/Feeler Probe, 2mm
8572102

Straight Holt Probe
803-292

T-handle Holt Probe
803-290

Screw Placement

Fixed Angle Screwdriver
5484280

Lock Sleeve Multi-Axial Screwdriver
5484111

Multi-Axial Screwdriver
5484109

Self-Retaining Driver
5484113

Instrument Set *continued*

Hook Preparation

Laminar Elevator
7480220

Pedicle Finder
7480225

Transverse Process Elevator
7480222

Hook Placement

Hook Pusher for Implant Holder
5484231

Self-Retaining Implant Holder
5484217

Lateral Implant Holder
5484211

Offset Hook Holder
5484219

Straight Implant Holder
5484216

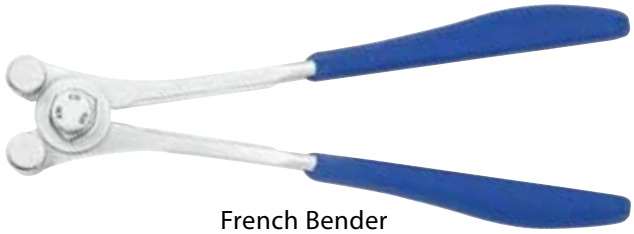
Total Anatomical
Hook Instrument
5484317

Instrument Set *continued*

Rod Contouring

Rod Template
5484510

4.75mm Rod Cutter
RC404022-E



French Bender
7480162

Rod Insertion

Rod Pusher*
5484235
*Shown with Adjustable Driver Handle

Rod Rotation Wrench
5484285

Rod Holder
8350312

Instrument Set *continued*

Rod Reduction

Beale Rod Reducer, Slots
5484134

Forceps Rocker
7480142

Beale Rod Reducer, Rocker
5484136

European Rocker
7480141

Quick Connect Reduction
Nut Driver
5484011

Set Screw Confirmation Tool
5484010

Inner Sleeve
5484008

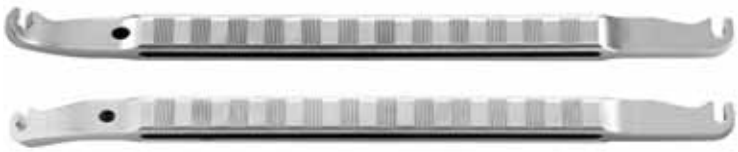
Outer Sleeve
5484009

Sequential Reducer

Instrument Set *continued*

Correction

Coronal Benders
Left 5484265
Right 5484270



***In Situ* Benders**
Left 5484255
Right 5484260

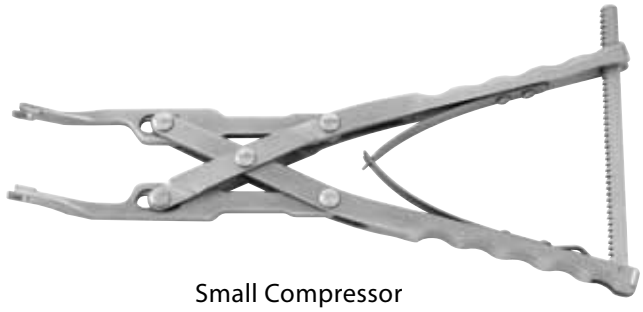
Dual Action Rod Gripper
5484006

Instrument Set *continued*

Compression and Distraction

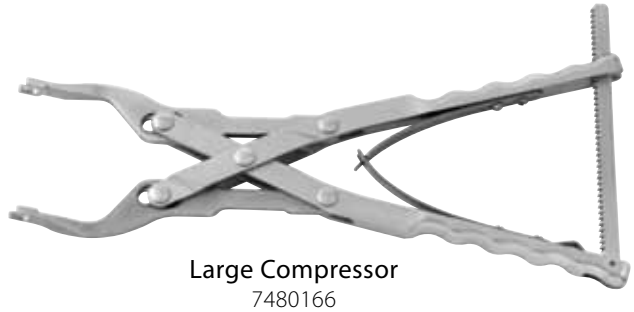
Curved Compressor
5484165

Multilevel Hook Compressor
808-503



Small Compressor
7480165

Distractor Pliers
5484171



Large Compressor
7480166

Hinged Translator
5484172

Parallel Distractor
7480170

Instrument Set *continued*

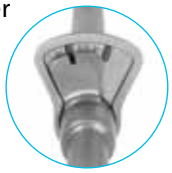
Final Tightening/Set Screws

Dual Ended Twisted Set Screw Starter
5484004

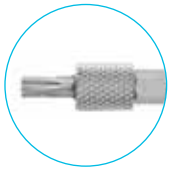
Set Screw Breakoff Driver
8350316

Counter Torque
5484150

Torque Indicating Driver
5484147



Set Screw Obturator
8350322



Instrument Set *continued*

Additional Instruments

6.35mm Hex Shaft
Provisional Driver*
5480131V
*Shown with Adjustable Driver Handle

Torx 20 Shaft
815-517

T27 Obturator
7480154

Adjustable Driver Handle
5480140V

Screw Head
Positioner Shaft
5484003

Removal Instruments

Ball-ended T25 Screw
Removal Driver
5480004V

Self-Retaining 3.5mm Hex Driver
7480114

Instrument Set *continued*

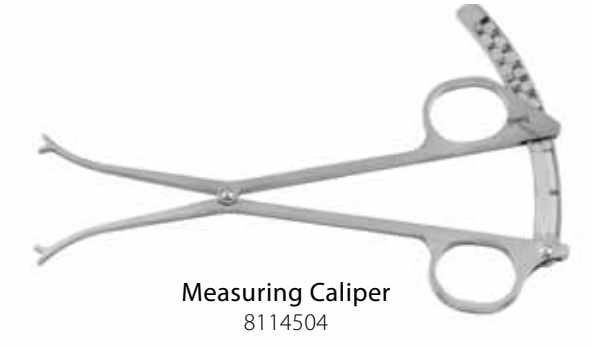
CD HORIZON® X10 CROSSLINK® Plate Implants and Instrument Set

CD HORIZON® X10 CROSSLINK®
Multi-Span® Plate

CD HORIZON® X10 CROSSLINK®
Fixed Plate

Measuring Card
8114506

T-bolt Implant Positioners
808-545



Measuring Caliper
8114504

7/32" Torque-Limiting Set Screwdriver
8110535

Counter Torque
8110540

In-line Plate Holder
8110511

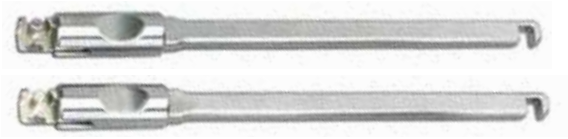


Plate Benders Bending Irons
8114505

3.0mm Hex Head Shaft, Removal Driver
8110530

Pedicle Screw Surgical Technique

Thoracic Facetectomy and Starting Points

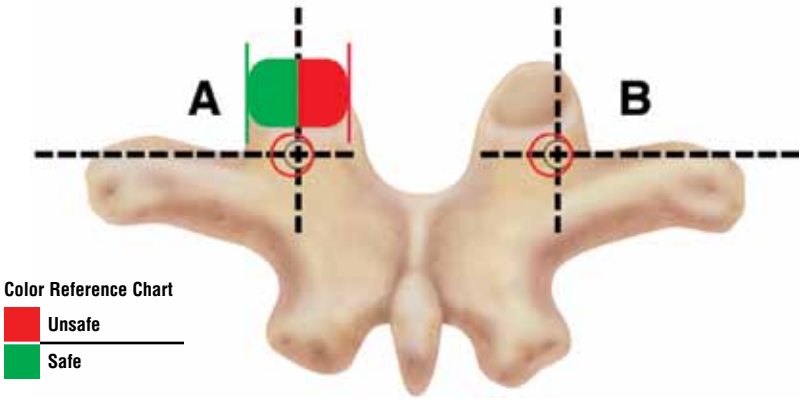
Clean the facet joints and perform a partial inferior articular process osteotomy to enhance visualization and fusion. Remove 3mm to 5mm of the inferior facet and denude the articular cartilage on the superior facet, except for the lowest vertebra to be instrumented. This will allow for the intraoperative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

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.

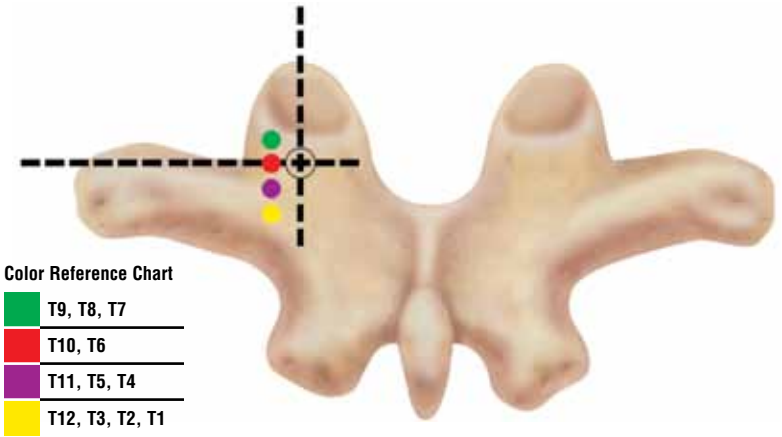
After a thorough exposure, use as much anatomic information as possible by starting with a neutral, non-rotated vertebra. The lateral and posterior views shown on the following page can be used as a guide for starting points and screw trajectory.

The first and extremely critical step to performing advanced deformity techniques is the safe and secure placement of segmental pedicle screws. Knowledge of the Superior Facet Rule (A) to direct the medial/lateral and the Cephalocaudal Starting Points (B) is a helpful reference to accomplish this.

Superior Facet Rule (A)



Cephalocaudal Starting Points (B)

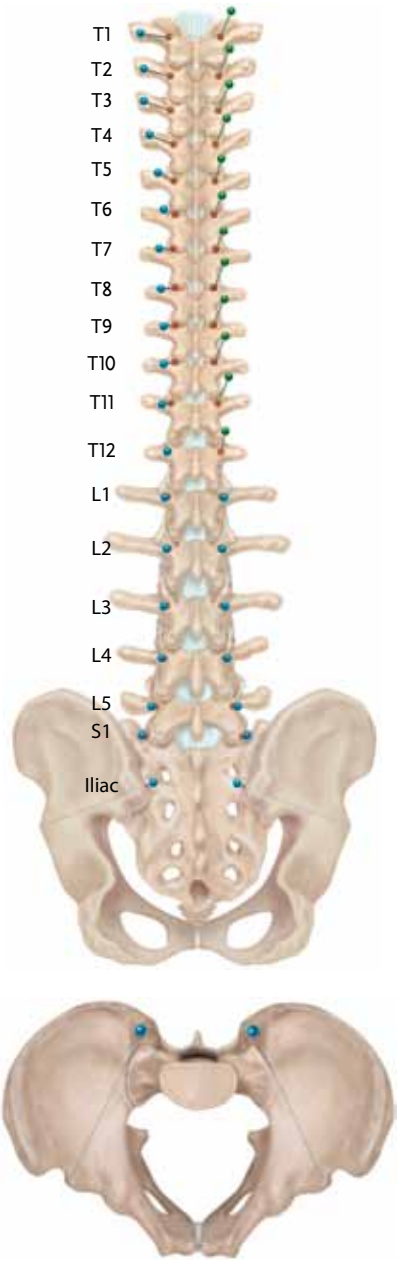


Important

Do not start medial to the midpoint of the superior facet.

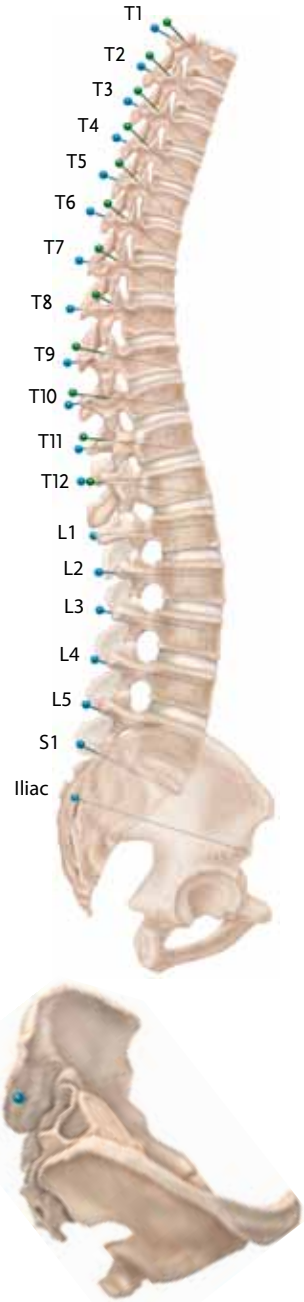
Screw Starting Points

Use Fixed Angle or Multi-Axial Screws for the straightforward approach (Blue Pins).
Use Multi-Axial Screws only for the anatomic approach (Green Pins).



Axial View

Level	Cephalad-Caudad Starting Point	Medial-Lateral Starting Point
T1	Midpoint Transverse Process (TP)	Junction: TP-Lamina
T2	Midpoint TP	Junction: TP-Lamina
T3	Midpoint TP	Junction: TP-Lamina
T4	Junction: Proximal Third-Midpoint TP	Junction: TP-Lamina
T5	Proximal Third TP	Junction: TP-Lamina
T6	Junction: Proximal Edge-Proximal Third TP	Junction: TP-Lamina-Facet
T7	Proximal TP	Midpoint Facet
T8	Proximal TP	Midpoint Facet
T9	Proximal TP	Midpoint Facet
T10	Junction: Proximal Edge-Proximal Third TP	Junction: TP-Lamina-Facet
T11	Proximal Third TP	Just medial to lateral pars
T12	Midpoint TP	At the level of lateral pars
L1	Midpoint TP	Junction: Lateral pars and superior facet
L2	Midpoint TP	Junction: Lateral pars and superior facet
L3	Midpoint TP	Junction: Lateral pars and superior facet
L4	Midpoint TP	Junction: Lateral pars and superior facet
L5	Midpoint TP	Junction: Lateral pars and superior facet
S1	Midpoint Sacral Ala	Junction: Sacral ala and superior facet
Iliac	1cm Cephalad to Distal Posterior Superior Iliac Spine (PSIS)	1cm inferior to the superior PSIS on the medial slope



Oblique View

Pedicle Preparation

Create a 3mm-deep posterior cortical breach with a high-speed burr. 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 Thoracic Probe to search in the burred 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 **(Figure 1)**.

Grip the side of the handle to avoid applying too much ventral pressure. Insert the tip approximately 20mm to 25mm **(Figure 2)**, and then remove the probe to reorient it so that the tip points medially. Carefully place the probe into the base of the prior hole and use the instrument markings to advance the probe to the desired depth **(Figure 3)**. Rotate the probe 180° to ensure adequate room for the screw.

Figure 1

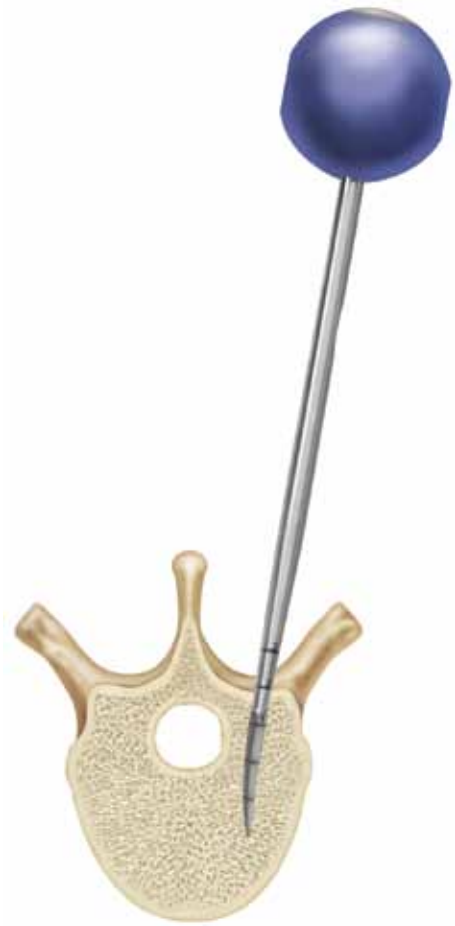


Figure 2

Figure 3

Pedicle Preparation *continued*

Check to ensure that only blood is coming out of the pedicle and that the bleeding is not excessive. Using a flexible ball-tipped Sounding/Feeler Probe, advance the instrument to the base (floor) of the hole to confirm five distinct bony borders: a floor and four walls (medial, lateral, superior, and inferior) **(Figure 4)**. Give special care to the first 10mm to 15mm of the tract. Cortically breached pedicles may be salvageable. When necessary, place bone wax in the pedicle hole to limit bleeding, then reposition the probe with a more appropriate trajectory.

Next, undertap the pedicle by 0.5mm to 1.0mm of the final screw diameter **(Figure 5)**. Palpate the tapped pedicle tract with a flexible Sounding/Feeler Probe. Clamp a hemostat to the exposed Sounding/Feeler Probe and measure the length of the hole **(Figure 6)**. Select the appropriate screw diameter and length by both preoperative measurement and intraoperative observation.

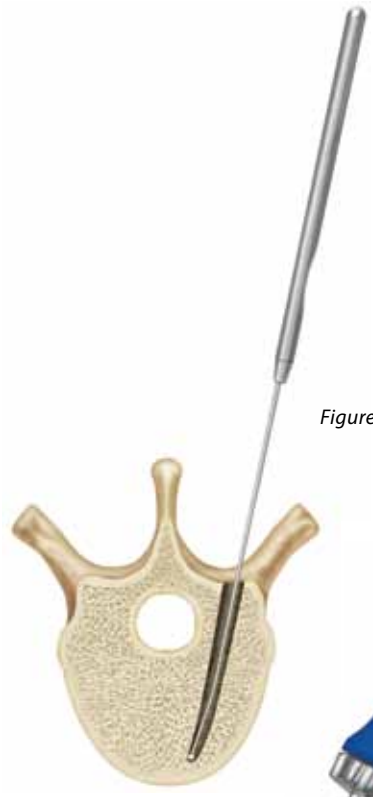


Figure 4

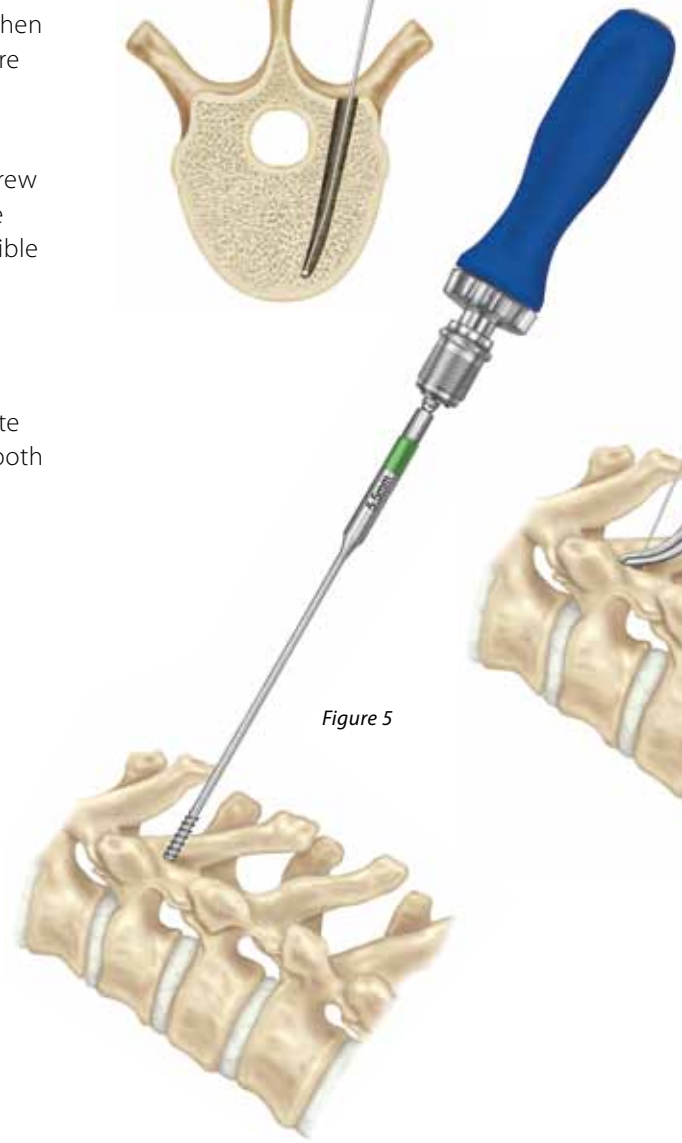


Figure 5

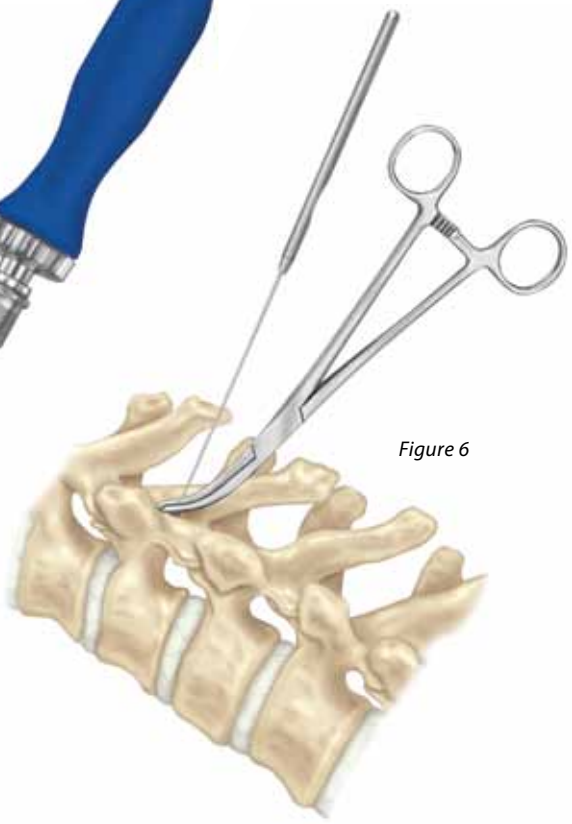
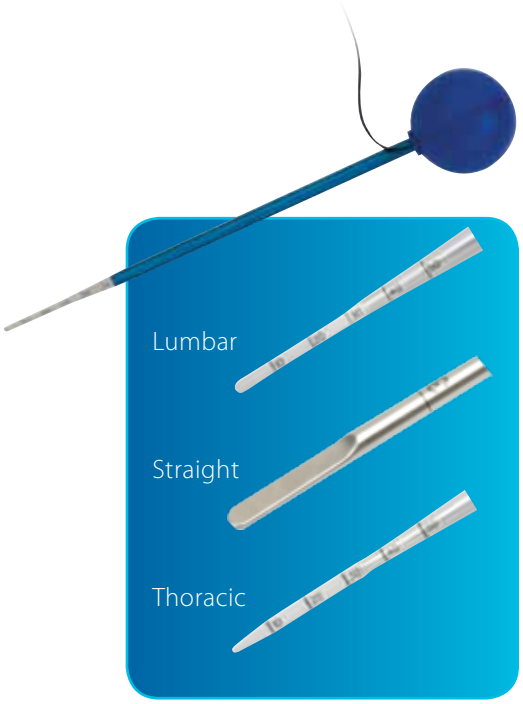


Figure 6

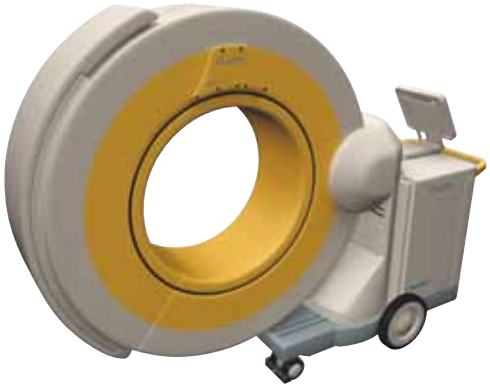
Enabling Technologies

Triggered intraoperative EMG monitoring, such as the NIM-ECLIPSE® Spinal System*, may be used to verify the trajectory within the pedicle. The O-Arm® Intra-operative Imaging System coupled with the STEALTHSTATION® Image Guidance System can also be used to navigate pedicle preparation and screw placement.

NIM-ECLIPSE® Spinal System*



NIM® Pedicle Probes



O-Arm® Imaging System

O-Arm® and STEALTHSTATION® System Images

*The NIM-ECLIPSE® Spinal System is manufactured by Axon Systems, Inc. Distributed by Medtronic.

VERIFYI™ Implant Tracking

The CD HORIZON® SOLERA™ Spinal System implants are the first to feature the VERIFYI™ Implant Tracking System, a patent-pending traceability tool which enables electronic tracking and documentation of implant part and lot numbers to provide data management benefits for surgeons and hospitals. Each implant has a tag attached that is clearly marked with the part number, lot number, implant size, and a barcode. Contact your local Medtronic sales representative for detailed information on using the VERIFYI™ Implant Tracking System.

Prior to implantation remove the tags from the implants **(Figure 7)**. When placing fixed or multi-axial screws, attach a driver to the screw in the screw caddy to remove the screw and then break off the tag **(Figures 8 and 9)**. Retain all of the implant tags so they can be scanned at the end of the surgery. A tag holder is available if the surgeon wants to track the implants by spinal level **(Figure 10)**.

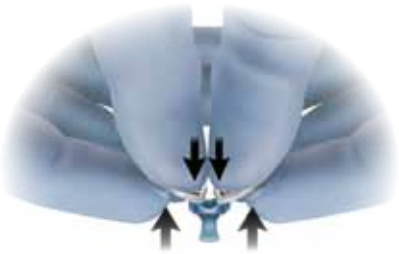


Figure 7

Figure 8

Important

The implant tags must be removed prior to implantation. Do not implant the tags.

Figure 9

Figure 10

Screw Placement

Thread a screw onto either a fixed or multi-axial screwdriver. If the Lock Sleeve Multi-Axial Screw Driver is used, ensure that the blue locking cap is not engaged with the screwdriver shaft, and then thread the screw onto the driver shaft **(Figure 11)**. Slide the blue locking cap toward the screw to engage it with the driver shaft **(Figure 12)**. An audible "click" will confirm engagement.

Slowly advance the screw down the pedicle to ensure proper tracking while allowing for viscoelastic expansion **(Figure 13)**. Once the screw is inserted, push the button on the blue locking cap and slide it back to its original position. Finally, unthread the Lock Sleeve Multi-Axial Screw Driver from the screw.

Screws should be placed at every segment on the correction side and every third or fourth level on the stabilizing side. Insert at least two screws at the proximal and distal ends of the planned construct on the stabilizing side. For some pathologies, such as kyphosis and scoliosis, more screws are placed for greater construct rigidity. Screws should be checked radiographically at this time to ensure intraosseous screw placement.

Figure 11

Figure 12

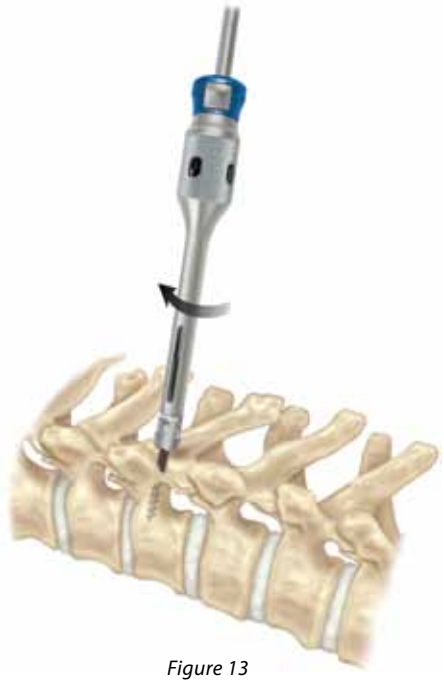


Figure 13

Rod Contouring and Placement

Once correct screw placement has been verified radiographically, measure and contour rods in the sagittal and coronal planes. The titanium alloy rods have an orientation line that serves as a reference point during contouring. Clamping the rod with Dual Action Rod Grippers at both ends helps prevent the rod from rotating during contouring **(Figure 14)**.

Figure 14

Rod Reduction

For non-hyperkyphotic deformities, place the rod on the concavity first. The contoured rod is placed into the previously placed screws. There are several methods and instruments that can facilitate fully seating the rod into the saddle of the implant.

Important

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.

Forceps Rocker Method

Use of the Forceps 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 use the Forceps Rocker, grasp the sides of the implant with the rocker cam above the rod and then lever backward over the rod **(Figure 15)**. The levering action allows the rod to be fully seated into the saddle of the implant. The Dual Ended Twisted Set Screw Starter is then used to introduce the set screw **(Figure 16)**.

European Rocker Method

The European Rocker can also be used to achieve rod reduction. To use this rocker, grasp the sides of the implant with the rocker cam above the rod, squeeze the handle to secure the instrument to the implant, and then lever the instrument backward over the rod **(Figure 17)**. The levering action allows the rod to be fully seated into the implant saddle. To remove the instrument, press the blue button on the top of the instrument.

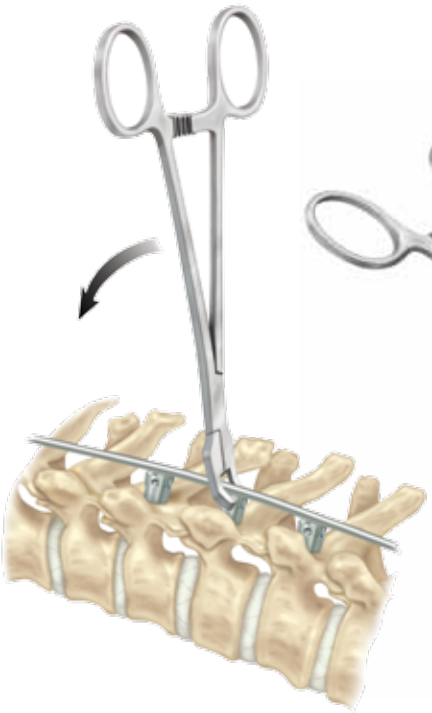


Figure 15

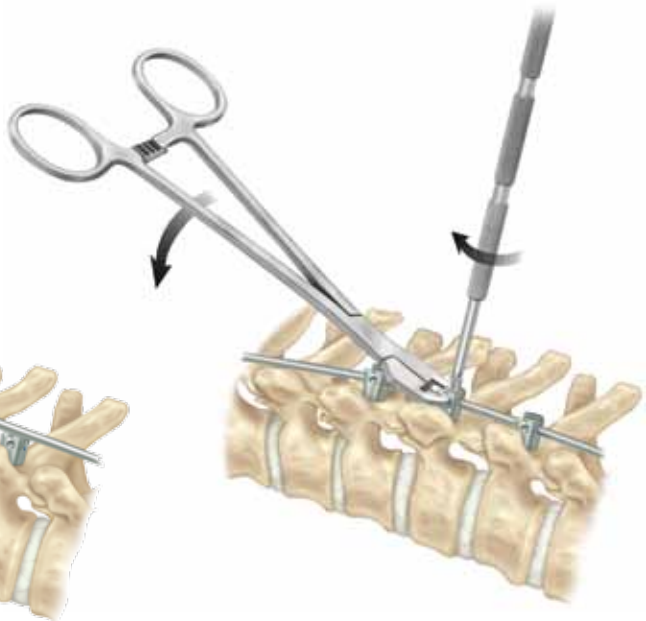


Figure 16

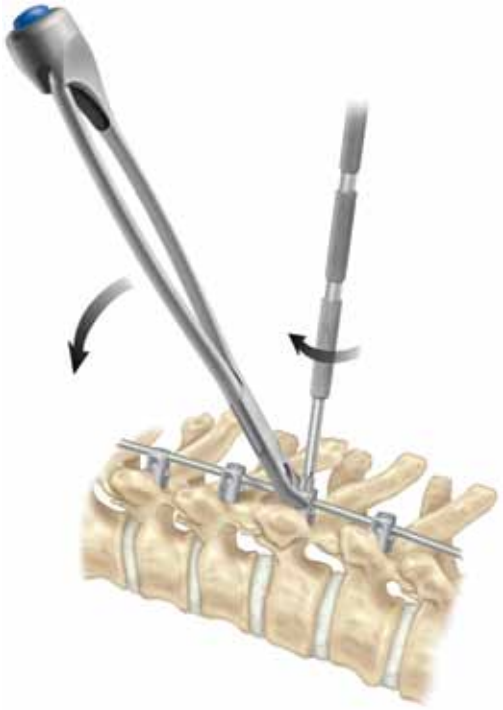


Figure 17

Rod Reduction *continued*

Beale Rod Reducer

In situations where the rod rests at the top of the implant, the Beale Rod Reducer may be used to seat the rod. There are two types of Beale Reducers: the Slot Reducer attaches to the four implant slots **(Figure 18)**, and the Rocker Reducer attaches to the two holes on the sides of the implant **(Figure 19)**, similar to the Forceps Rocker.

Once the Beale Rod Reducer is attached to the implant, squeeze the reducer handles slowly, allowing the sleeve to slide down, and seat the rod into the implant saddle. A set screw is then placed through the reducer tube and into the implant head with the Dual Ended Twisted Set Screw Starter. Provisionally tighten the set screw with the Twisted T25 Provisional Driver **(Figure 20)**.

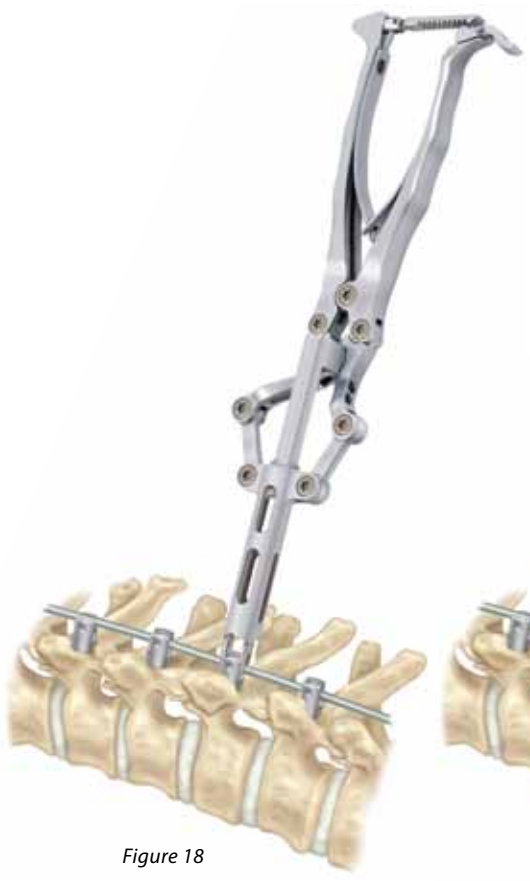


Figure 18

Figure 19

Figure 20

Sequential Reduction

The Sequential Reducer may be used to gradually seat the rod. Insert the Inner Sleeve into the Outer Extender **(Figure 21)** and turn the Reduction Nut clockwise until the word "LOAD" is visible through the oval window on the Outer Extender **(Figure 22)**. Place the Sequential Reducer on the screw head and turn the Reduction Nut until the Sequential Reducer is firmly attached to the screw head **(Figure 23)**.

Figure 21

Figure 22

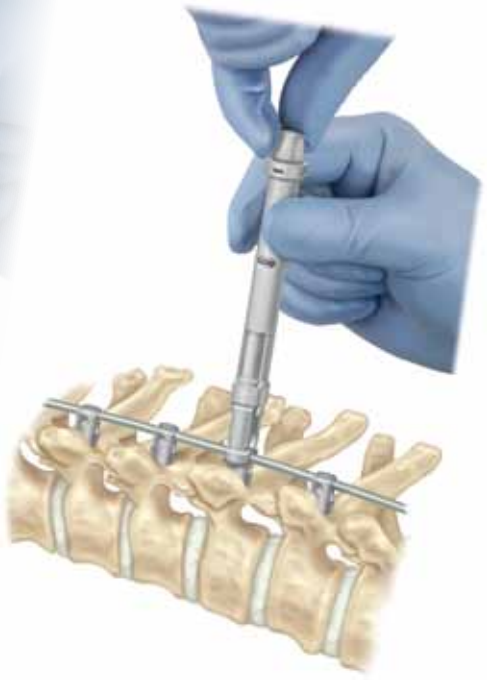


Figure 23

Sequential Reduction *continued*

Attach the Quick Connect Reduction Nut Driver to the Sequential Reducer and then attach the Quick Connect Ratcheting Handle. Turn the handle clockwise until the rod is fully reduced by visual confirmation **(Figure 24)**.

Attach the set screw to the Dual Ended Twisted Set Screw Starter and place it through the cannulation of the reducer **(Figure 25)**. Provisionally tighten the set screw and then remove the set screw starter.

After the set screw has been provisionally tightened, use the Set Screw Confirmation Tool to verify that the set screw is fully seated. Place the Set Screw Confirmation Tool through the cannulation of the reducer; if the black line is visible, the set screw is fully seated.

To remove the Sequential Reducer from the implant, turn the Quick Connect Ratcheting Handle counterclockwise until the word "LOAD" has passed slightly below the bottom of the oval window **(Figure 26)**. An audible "click" may be heard.

Important

Do not continue turning the handle once "LOAD" has passed slightly below the bottom of the oval window, or the Inner Sleeve will detach from the Outer Sleeve.

Figure 24

Figure 25

Figure 26

Deformity Correction

The set screws are kept loose (or only locked at one end); then the concave rod is slowly straightened with the left and right Coronal Benders **(Figure 27)**. Each straightening of the concave rod is performed over a pedicle screw. Several passes may be required in order for viscoelastic relaxation with subsequent curve correction to occur.

Tighten the apical set screws and perform the appropriate compression or distraction. The Hinged Translator can be used in place of either a compressor or a distractor during correction maneuvers. The straight leg of the instrument will push the implant while the hinged leg engages on the rod to act as rod gripper. To use the Hinged Translator as a compressor, place the straight leg against the cephalad screw above the disc space with the hinged leg proximal to the straight leg and squeeze the handles to begin compression **(Figure 28)**. To use the instrument to distract, place the straight leg against the cephalad screw of the disc space and the hinged leg proximal to the straight leg and squeeze the handles to begin distraction **(Figure 29)**. Watch the bone-to-screw interface with all correction maneuvers.

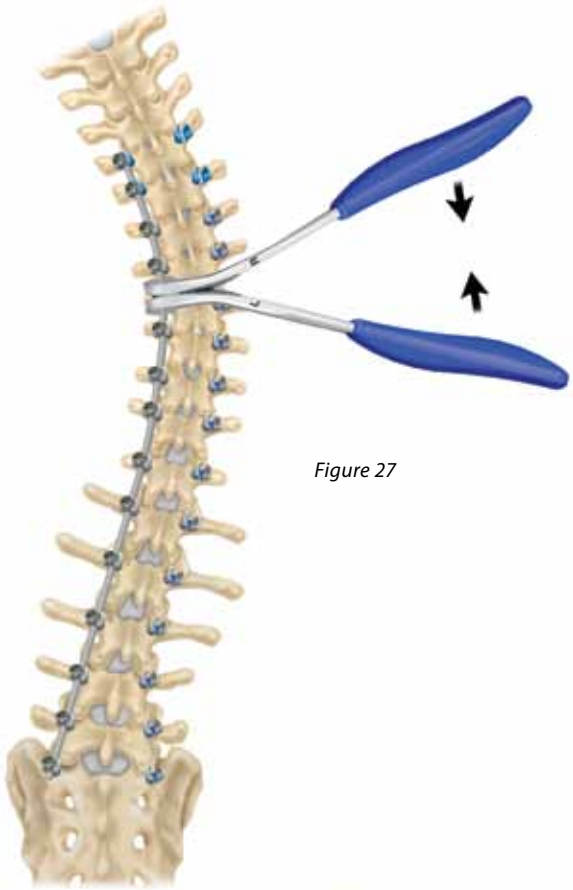


Figure 27

Figure 29

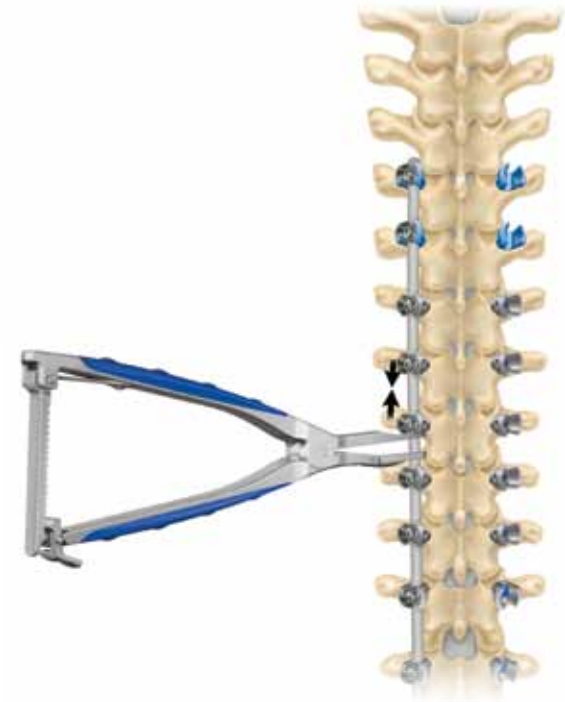


Figure 28

Deformity Correction *continued*

Placing the Stabilizing Rod

Following placement of the second rod and set screws **(Figure 30)**, convex compressive forces are placed on the segments using the Compressor to horizontalize the lowest instrumented vertebra and mildly compress the convexity of the deformity **(Figure 31)**. It is preferred that compression be released just prior to the set screw being broken off or with 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. NMEP and/or SSEP monitoring are performed to detect any potential neurologic deficits. Fixation is verified with AP and lateral x-rays to confirm spinal correction and alignment.

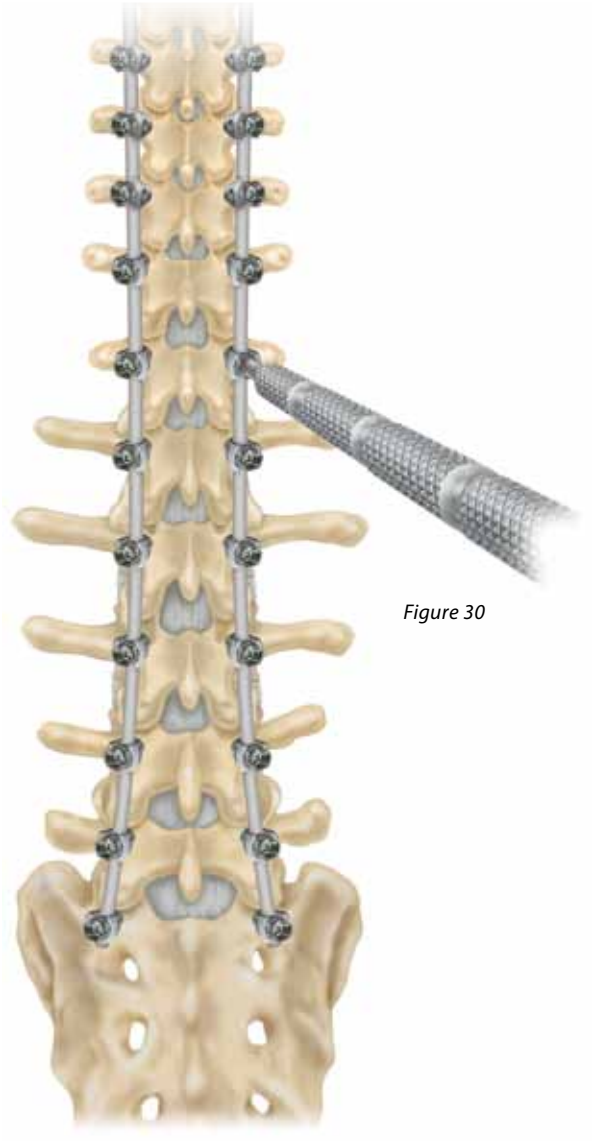


Figure 30

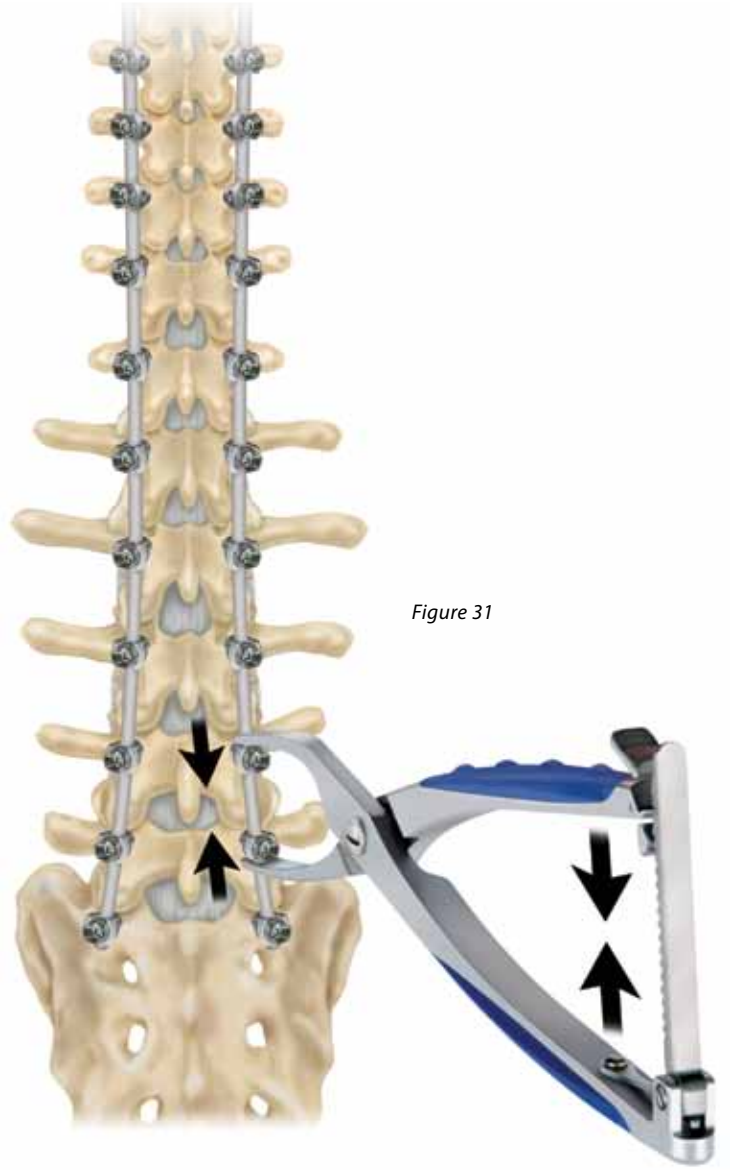


Figure 31

Final Tightening and Decortication

Using the Counter Torque and the Self-Retaining Breakoff Driver, shear off the set screws, which locks the rods into place **(Figure 32)**.

Use the Torque Indicating Driver to verify the correct torque limit has been achieved once the set screws are sheared off. Attach the Quick Connect Handle to the Torque Indicating Driver and pass it through the Counter Torque and into the inner portion of the set screw **(Figure 33)**. Turn the handle until the needle reaches the line on the right side of the scale to ensure the correct torque limit has been achieved **(Figure 34)**. Continuing to tighten the set screw such that the needle passes this line can result in over tightening, which could reduce the effectiveness of the connection.

The posterior elements are decorticated with a burr and the bone graft is placed. The CD HORIZON® X10 CROSSLINK® Plates should be placed at the proximal and distal ends of the construct. Please refer to the next page for detailed instructions on applying the plates.

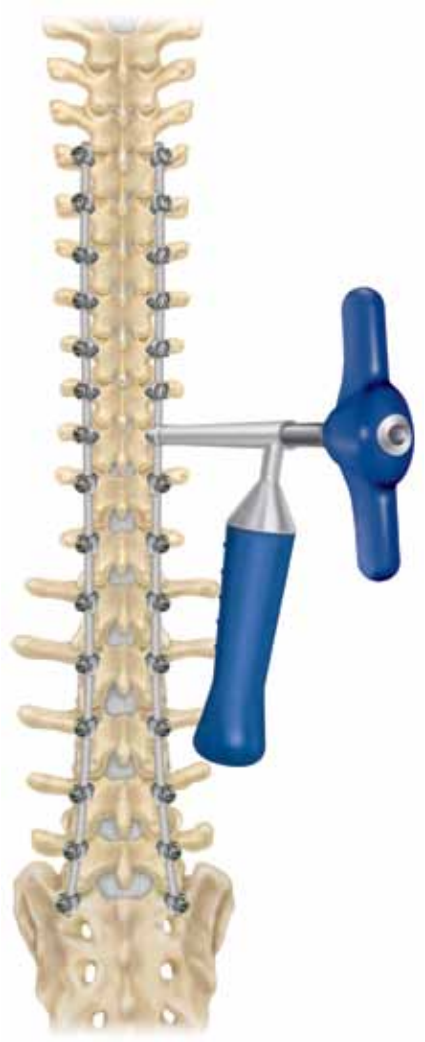


Figure 32

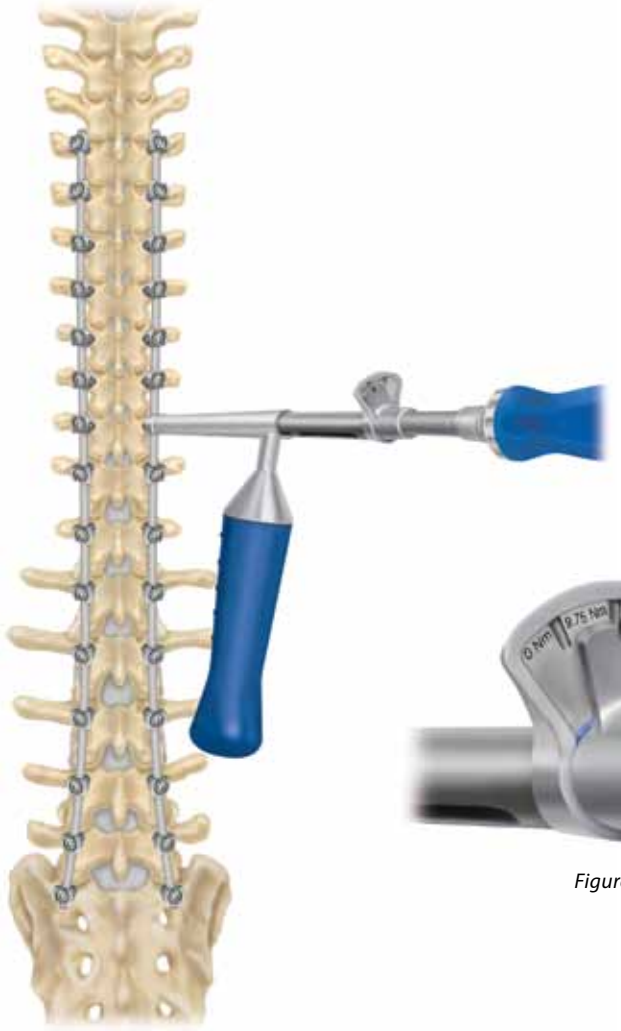


Figure 33

Figure 34

CD HORIZON® X10 CROSSLINK® Plate Placement

The surgeon may choose one of several CD HORIZON® X10 CROSSLINK® Plate placement options.

In-line Plate Holder Method

The midline nut is provisionally tightened to gain control of the CD HORIZON® X10 CROSSLINK® MULTI-SPAN® Plate during placement. With the use of the In-line Plate Holder, the plate is selected, gripped, and positioned to capture the far rod. Following placement of the plate onto one rod, tighten the set screw using the 7/32" Torque-Limiting Set Screwdriver until it is firmly attached to the rod **(Figure 35)**. Next, loosen the midline nut to appreciate the multiaxial flexibility of the plate and seat the opposite end onto the other rod, followed by final tightening of the break-off set screws to 60 in-lbs (6.2-7.3Nm). Finally, tighten the midline nut to 80 in-lbs, remembering that the midline nut is **not** a break-off set screw **(Figure 36)**.

Figure 35

Figure 36

CD HORIZON® X10 CROSSLINK® Plate Placement *continued*

T-Bolt Implant Positioner Method

With the use of the implant positioner instruments, the appropriate CD HORIZON® X10 CROSSLINK® MULTI-SPAN® Plate is selected and gripped **(Figure 37)**. Ensure that both positioners fit securely onto both set screws.

The T-bolt Implant Positioners can be used to sequentially articulate the plate around the rod **(Figure 38)**. If the plate cannot be precisely seated against the rod, the set screw is still too prominently extended into the ventral opening. Keep the plate in the wound and abutting against the rod. By rotating the positioners, the set screw can be manipulated and slightly backed out, allowing the rod to fully seat in the ventral opening. Once precise contact has been achieved between the plate and the rod, the positioners can be used to provisionally tighten the plate to the rod. The same process is carried out for the other side of the plate. Both halves of the plate should precisely articulate with the rod before final tightening and set screw breakoff.

Remove the T-bolt Implant Positioners and provisionally tighten the midline nut using the 7/32" Torque-Limiting Set Screwdriver. A Counter Torque may be placed on the CD HORIZON® X10 CROSSLINK® MULTI-SPAN® Plate to minimize torque transfer to the construct during final tightening. The screwdriver shaft is introduced through the Counter Torque. The set screws are sheared off using the screwdriver. The midline nut then undergoes final tightening with the same screwdriver. The midline nut on the CD HORIZON® X10 CROSSLINK® MULTI-SPAN® Plate is **not** a break-off set screw; the driver will "click" when the appropriate torque is obtained.

Figure 37

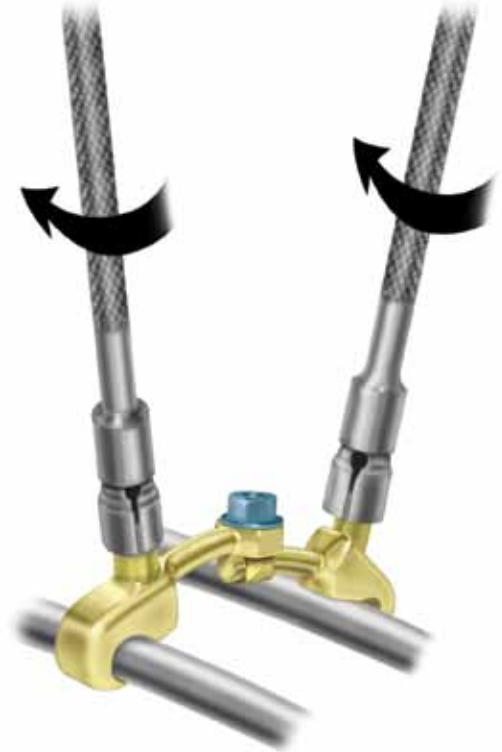


Figure 38

CD HORIZON® X10 CROSSLINK® Plate Placement *continued*

Forceps Plate Holder Method

With the use of the Forceps Plate Holder, the appropriate CD HORIZON® X10 CROSSLINK® MULTI-SPAN® Plate is selected and gripped **(Figure 39)**. The forceps have a notched tip to securely hold both crossbars **(Figure 40)**.

Ensure that both crossbars on the CD HORIZON® X10 CROSSLINK® Plate are gripped. The plate is then placed to capture the far rod (in relation to the surgeon) of the two rods to be stabilized. Using the 7/32" Torque-Limiting Set Screwdriver, the far rod's set screw is provisionally tightened to anchor the device to this rod.

Remove the Forceps Plate Holder from both crossbars. Place the Forceps Plate Holder on the crossbar that is able to move **(Figure 41)**. Anchor the second side of the plate to the rod and provisionally tighten the set screw. Remove the Forceps Plate Holder and provisionally tighten the midline nut.

A Counter Torque may be placed on the CD HORIZON® X10 CROSSLINK® MULTI-SPAN® Plate to minimize torque transfer to the construct during final tightening. The screwdriver shaft is introduced through the Counter Torque. The set screws are sheared off using the 7/32" Torque-Limiting Set Screwdriver. The midline nut then undergoes final tightening with the same screwdriver. The midline nut on the CD HORIZON® X10 CROSSLINK® MULTI-SPAN® Plate is **not** a break-off set screw; the driver will "click" when the appropriate torque is obtained.

Figure 39

Figure 41

Figure 40

Postoperative Care and Mobilization

Prior to closure do a final check to ensure that the set screws are symmetrically seated in the screw heads and sheared off, that the bone graft has not become dislodged during manipulation, and that a proper count of all sheared-off set screw heads is correct **(Figure 42)**.

Appropriate postoperative monitoring following evaluation of the extent of the surgical procedure and the patient's overall medical status is essential. Deep vein anti-embolic treatment should be considered for all patients, along with active pulmonary toilet, fluid balance, nutritional status, and monitoring of neurologic function. Prophylactic antibiotics may be continued for a brief duration following surgery until the wound seals. Finally, postoperative bracing may be considered for longer fusions depending upon individual surgeon preference.

A structured, progressive physical therapy program is essential to mobilize the patient in order to diminish postoperative complications and to rehabilitate the patient sufficiently for discharge. During the inpatient rehabilitation period, patients should be carefully instructed in the appropriate methods of getting in and out of bed, stair climbing, and brace application, as well as how long to sit and various other activities of daily living. Patients who lag behind a normal recovery period proportional to the extent of their surgery should be expediently considered for transfer to a rehabilitation inpatient facility.

Finally, postoperative follow-up for a minimum of two years is crucial to assess the progression of fusion and, equally important, the patient's clinical improvement.

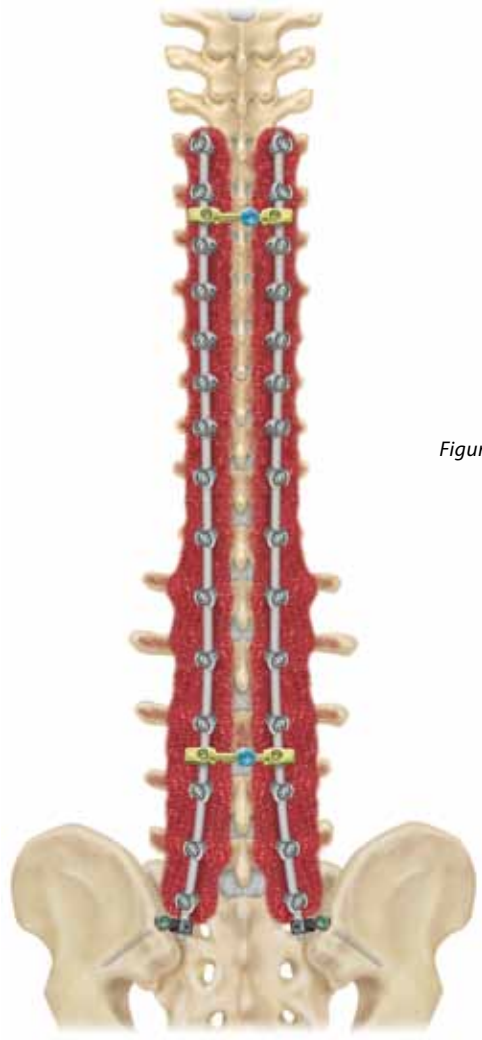


Figure 42

Explantation

The CD HORIZON® SOLERA™ set screws (plugs) may be removed using the T25 Obturator and the Self-retaining Breakoff Driver. The T25 Obturator is inserted into the working end of the Self-retaining Break-off Driver, so that the knurled portion of the T25 Obturator is flush with the driver. Insert the obturator tip through the Counter Torque, which should be seated on the screw and into the plug, turning counterclockwise until the plug has been removed. The pedicle screws may be removed using either the Multi-Axial Screwdriver or the Self-retaining Screwdriver in conjunction with the Ratcheting Handle. First, attach the Ratcheting Handle to the modular end of the driver. Next, fully engage the T25 end of the screwdriver into the screw head; then, if utilizing the Multi-Axial Screwdriver, thread the instrument sleeve into the screw head. Turn counterclockwise until the pedicle screws have been removed.

If removal of a CD HORIZON® X10 CROSSLINK® MULTI-SPAN® Plate is necessary, place the 7/32" Torque-Limiting Set Screwdriver over the midline nut and turn counterclockwise to loosen. Place the 3.0mm Hex Removal Driver into a standard Medtronic Quick Connect Handle. Place the tip of the 3.0mm internal hex driver into the set screw and confirm that the 3.0mm tip is completely inserted and seated in the set screw so that the tip does not strip the hex. Turn the driver counterclockwise to loosen the set screw from the rod.

Hook Surgical Technique

Surgical Strategy

Preoperatively, any spinal surgery should be studied and a scheme of the construct defined.

Shown below are examples of some typical hook constructs for a T4-L1 idiopathic scoliosis and a T2-S1 neuromuscular scoliosis.

These schemes, which are strictly for illustrative purposes, are examples of how to treat these types of scoliosis. **Figure 43** shows a standard right thoracic curve (Lenke Type 1AN/King Type III) instrumented with hooks from T4 to L1. This case can also be treated using a hybrid construct consisting of hooks and pedicle screws. **Figure 44** shows a construct treating neuromuscular scoliosis from T2 to L5.

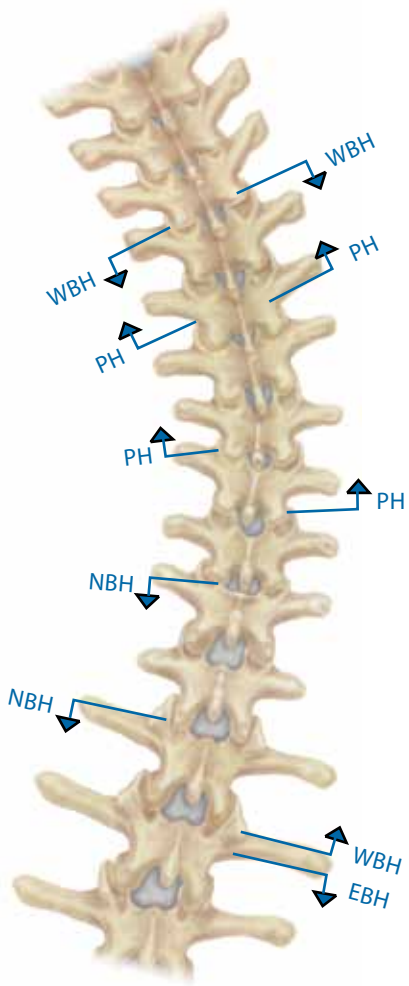


Figure 43

Hook Construct Legend	
NBH	= Narrow Blade Hook
OH	= Offset Hook
PH	= Pedicle Hook
⊗	= Pedicle Screw
WBH	= Wide Blade Hook
	= Up-Going Hook
	= Down-Going Hook
TAPH	= Total Anatomical Pedicle Hook
TATP	= Total Anatomical Transverse Process Hook
EBH	= Extended Body Hook

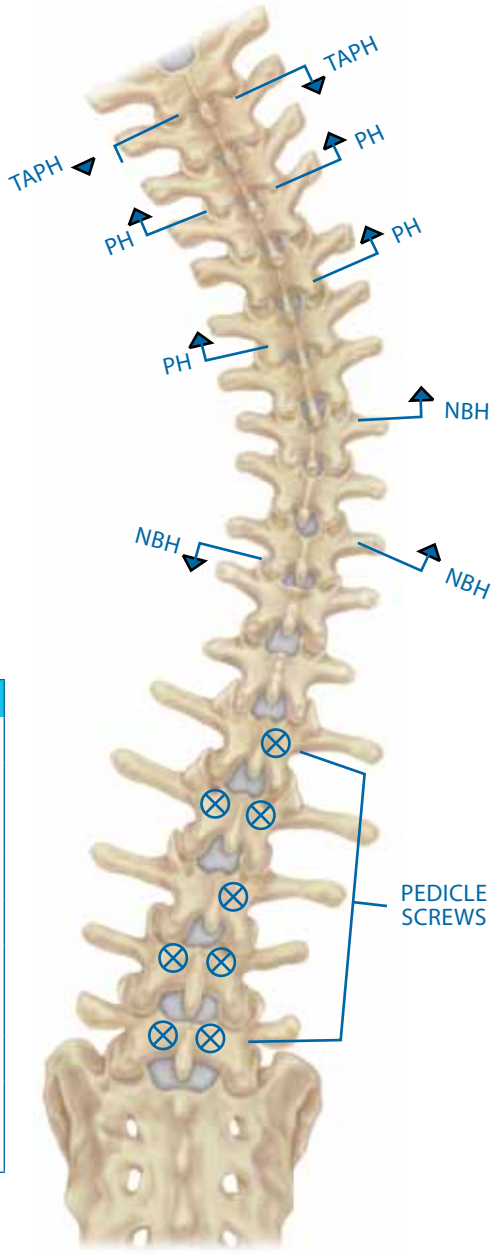


Figure 44

Hook Site Preparation, Options, and Insertion

The CD HORIZON® SOLERA™ Spinal System offers a number of top-loading hooks of different anatomic shapes and sizes (see hook implants chart, page 5). Any CD HORIZON® SOLERA™ Spinal System hook may be treated as a closed hook by placing the set screw into the hook prior to insertion of the rod. The surgeon must choose the appropriate hook based on the individual patient's anatomy, deformity degree and type, method of correction chosen, and amount of compression/distraction that will be needed to provide proper and stable purchase of the implants.

Several different instruments can be used for hook insertion. The Straight or Lateral Implant Holder combined with the Hook Pusher **(Figure 45)**.

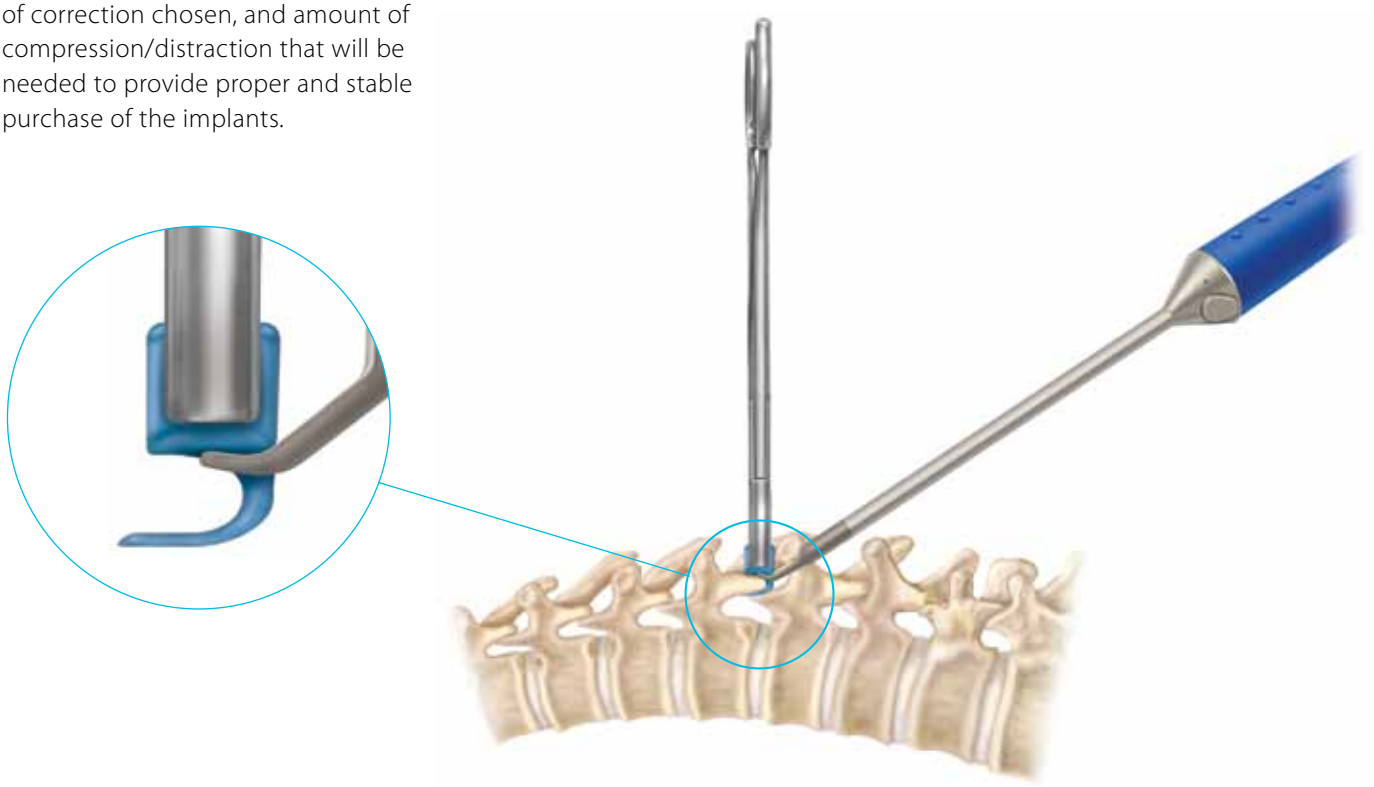


Figure 45

Hook Site Preparation, Options, and Placement

Pedicle Hook

The Pedicle Hook may be used from T1 to T10. The hook blade is always cephalad (up-going) and is in the infralaminar position. The facet capsule is divided, and a portion of the inferior facet process may be removed to facilitate insertion of the hook **(Figure 46)**. Once the pedicle has been clearly identified with the help of the Pedicle finder **(Figure 47)**, the hook may be inserted.

If needed, a mallet can be used to impact the Pedicle Hook. It is important that the Pedicle Hook is placed into the joint cavity and is not splitting the inferior articular process **(Figures 48 and 49)**.

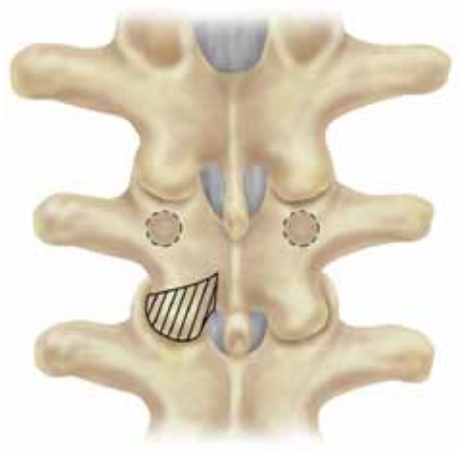


Figure 46

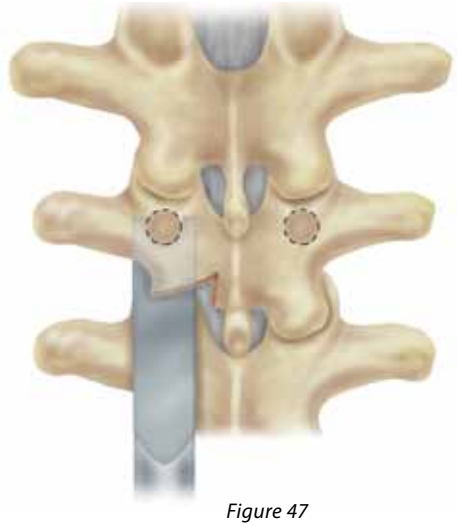
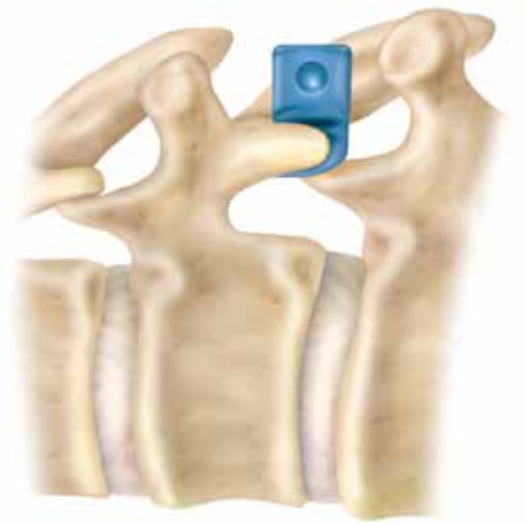


Figure 47



CORRECT

Figure 48

INCORRECT

Figure 49

Hook Site Preparation, Options, and Placement *continued*

Transverse Process Hook

This is generally a wide blade hook and is typically used in a pedicle-transverse claw construct as a caudal (down-going) hook **(Figure 50)**. The Transverse Process Elevator or the wide blade Laminar Elevator may be used to separate the ligamentous attachment between the undersurface of the transverse process and the posterior arch of the rib medial to the rib-transverse joint. An Implant Holder is used to insert this hook.

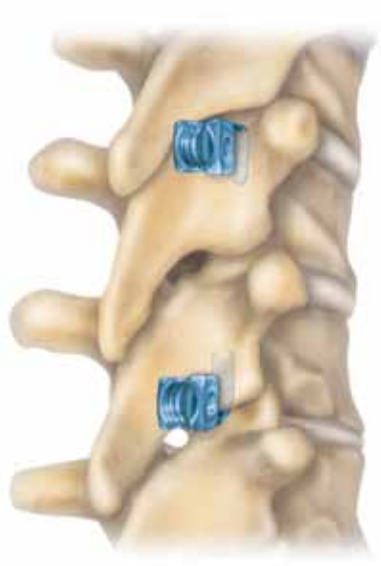


Figure 50

Hook Site Preparation, Options, and Placement *continued*

Total Anatomical Hooks

TAH™ Total Anatomical Hooks have a small shelf designed to enhance their stability. The combination of the shelf and the close fit of the throat of these hooks demands that the angle of insertion is less vertical than required by other implants. To achieve this angle of insertion without violating the cut surface of the superior articular facet, a small amount of the adjacent inferior tranverse process and lamina may need to be removed.

The TAH Pedicle Hook may be used from T1 to T10. The hook blade is always cephalad (upgoing) and is in the infralaminar position. The facet capsule is divided, and a portion of the inferior facet process may be removed to facilitate insertion of the hook **(Figure 51)**. Once the pedicle has been clearly identified with the help of the Pedicle Elevator **(Figure 52)**, the hook may be inserted.

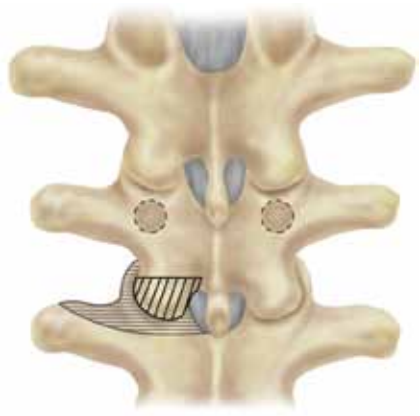


Figure 51

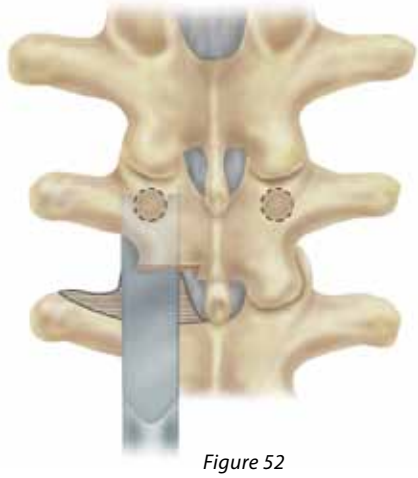


Figure 52

Hook Site Preparation, Options, and Placement *continued*

TAH Transverse Process Hook

This hook is typically used in a transverse process/pedicle claw construct as a caudal (down-going) hook **(Figure 53)**. The Transverse Process Elevator or the Laminar Elevator may be used to separate the ligamentous attachment between the undersurface of the transverse process and the posterior arch of the rib medial to the rib/transverse process joint. An Implant Holder is used to insert this hook.

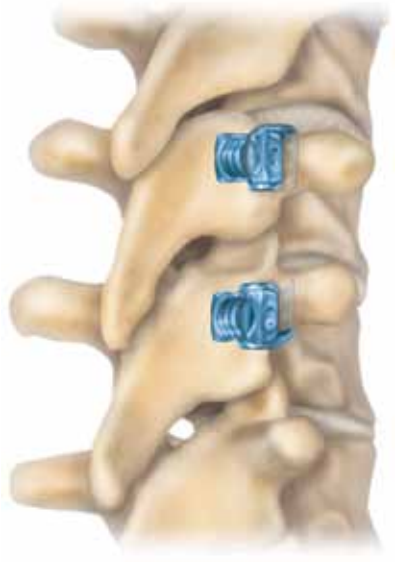


Figure 53

Decortication

Once inserted, laminar hooks are not very stable prior to rod insertion. Therefore, it is recommended to remove them to decorticate.

At this point in the surgery, bilateral partial facetectomies are carried out **(Figure 54)**. The intervening cartilage is denuded to allow exposure of the subchondral bone assisting in bone fusion.

Decortication of the laminae, spinous processes, and transverse processes, along with bone graft placement, will be done at the end of the surgery to avoid intraoperative bleeding. Laminar hooks are placed back into their position.

Figure 54

Rod Contouring

Once the hooks on the correction side of the deformity (concave in the thoracic area, convex in the lumbar area of the spine) are tested for fit and placement, a rod template may be used to determine the length and the curve. The correction rod is cut to the appropriate length (1cm to 2cm longer than the overall hook-to-hook length). To achieve the correct sagittal plane contour, the rod is bent in small incremental steps using a French Bender **(Figure 55)**. It is important to maintain a same plane orientation of the rod to prevent a spiral-type bend down the rod.

In the case of a reducible scoliosis, the rod is bent according to the final postoperative planned correction to obtain a nice postoperative thoracic kyphosis and lumbar lordosis.

In a case of stiff scoliosis, the rod is placed along the spine to check for proper correction, hook fit, and contouring. This type of scoliosis correction will be mainly obtained with *in situ* bending.

Figure 55

Rod Insertion

The contoured rod is placed into the top-loading implants beginning from either the upper or lower part of the construct, there is no particular rule for rod insertion. One can start with the implants in which the rod seems to best position and facilitate the continuation of the insertion **(Figures 56 and 57)**. A Rod Holder may be used to assist in placing the rod. Using the Dual Ended Twisted Set Screw Starter, set screws are placed into the first implants where the rod seats perfectly. The Rod Pusher may be used to push the rod down in order to place a set screw and/or, due to its C-shape, to push the hook into its correct position **(Figure 58)**.

There are several methods and instruments that may be used to facilitate rod reduction and to fully seat the rod into the saddle of the implants. Refer to the Rod Reduction steps on pages 25 through 28 of the pedicle screw section of this technique for method options.

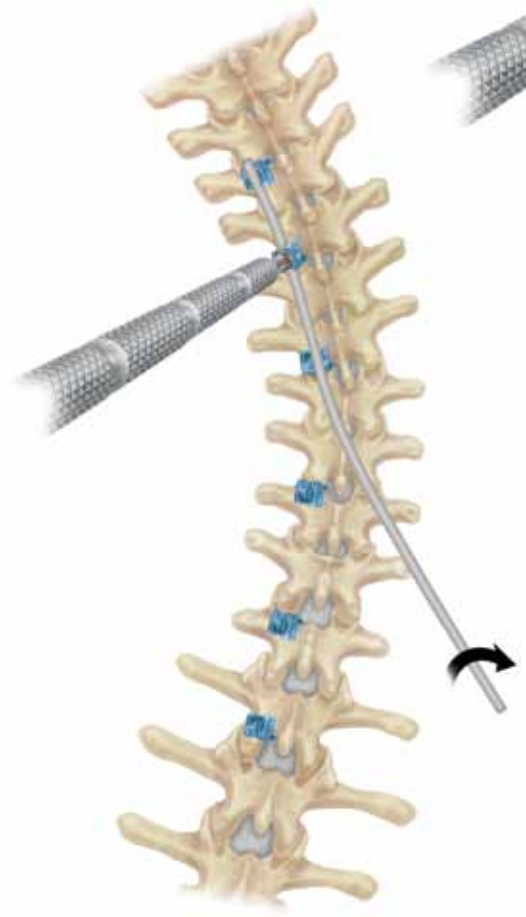


Figure 56

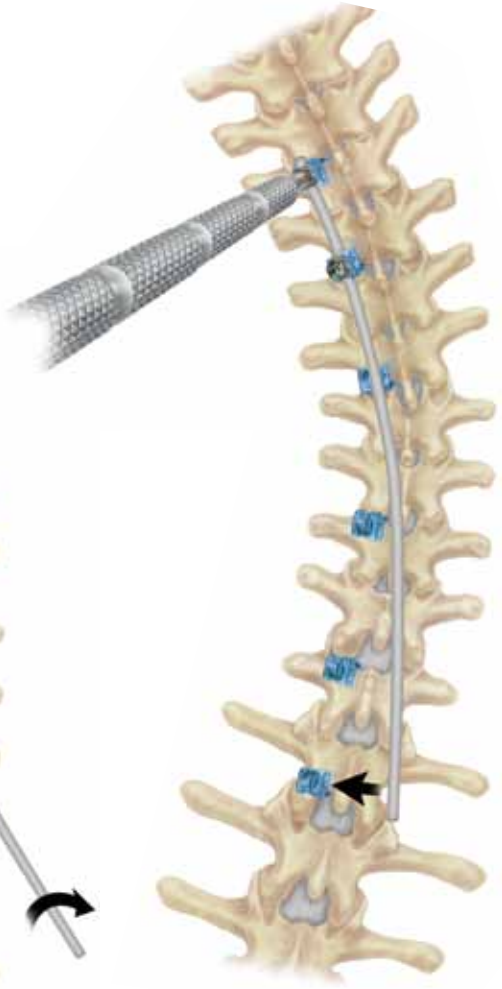


Figure 57

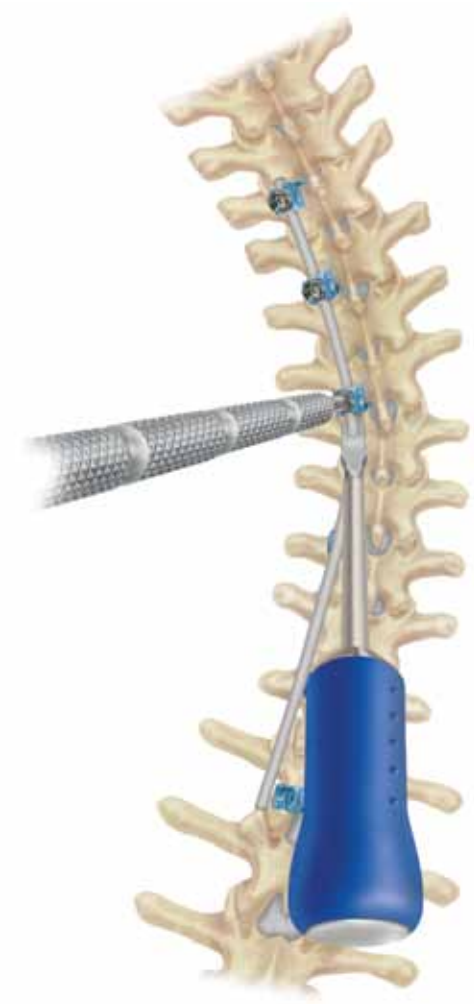


Figure 58

Deformity Correction

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 *in situ* bending, depending on the type and stiffness of the curve, and completed with compression/ distraction maneuvers.

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. The rotation must be done slowly in order to prevent rapid neurologic changes and/or partial pullout or hook dislodgement. The rotation is done using two Dual Action Rod Grippers **(Figure 59)**. It is important to monitor the interval hooks, which tend to back out during rod rotation. Several methods are proposed: use of the C-Shaped Rod Pusher, the placement of C-rings on the rod prior to rotation, placement of the Rod Gripper on the rod just below the hook to buttress it, or the use of a hook stabilizer instrument, which is available upon special ordering request.

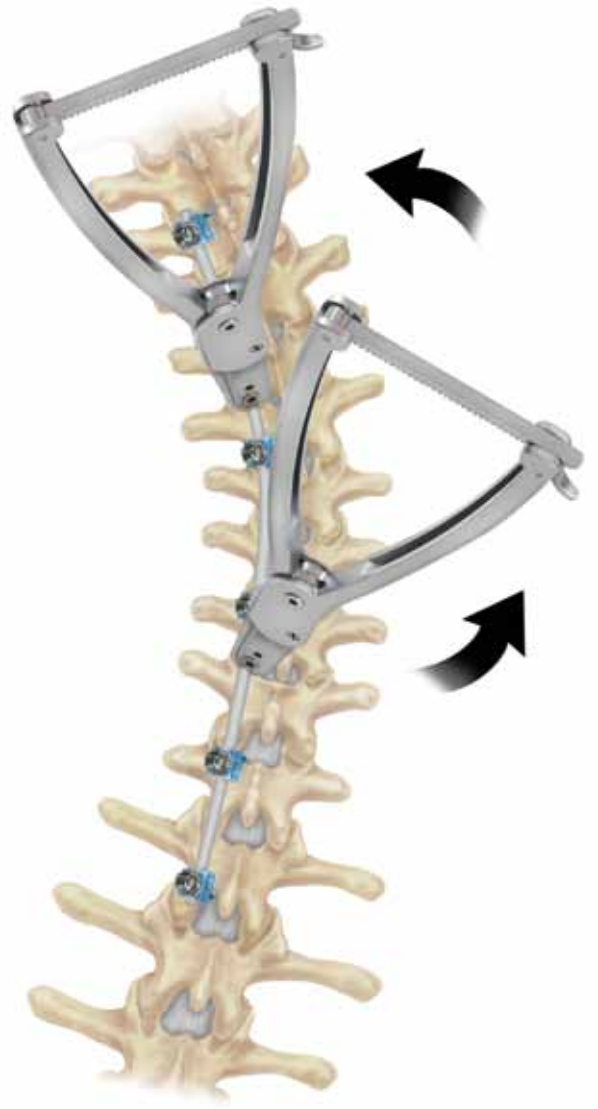


Figure 59

Deformity Correction *continued*

Once the rotation of the rod is complete and the position of the hooks is verified, the interval hooks' set screws are provisionally tightened to prevent rod derotation. The hooks should be checked following all rotation maneuvers and the necessary adjustments made to ensure that proper placement is maintained. At this point, the rod should be fully seated into the saddle of all of the implants.

In Situ Bending

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 **(Figure 60)**.

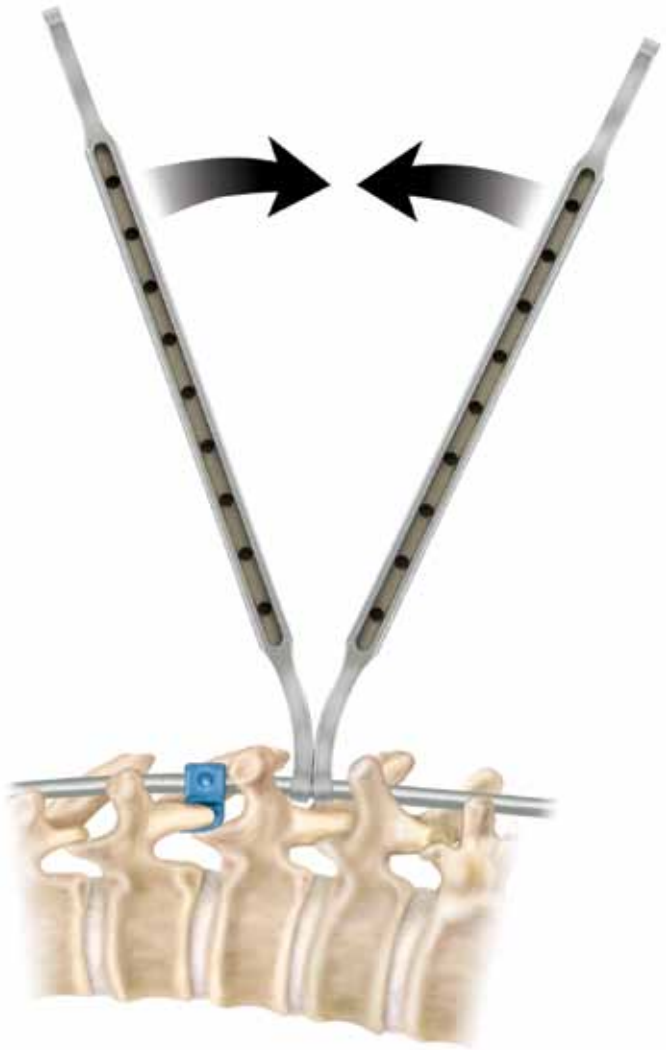


Figure 60

Compression and Distraction

Once the rod is secured in the implants, distraction and/or compression are performed to place the hooks in their final position. The Multilevel Hook Compressor, Distractor, Hex Shaft Provisional Driver, 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 **(Figure 61)**, with the exception of the inverted claw. Compression maneuvers are most often carried out directly on two hooks **(Figure 62)**. 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 broken off or final tightened. This technique will help ensure that the implant head and rod are normalized to one another, and thus, allows 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 Hex Shaft Provisional Driver.

Figure 61

Important

It is highly recommended that the set screw not be broken off or final tightened under compression.

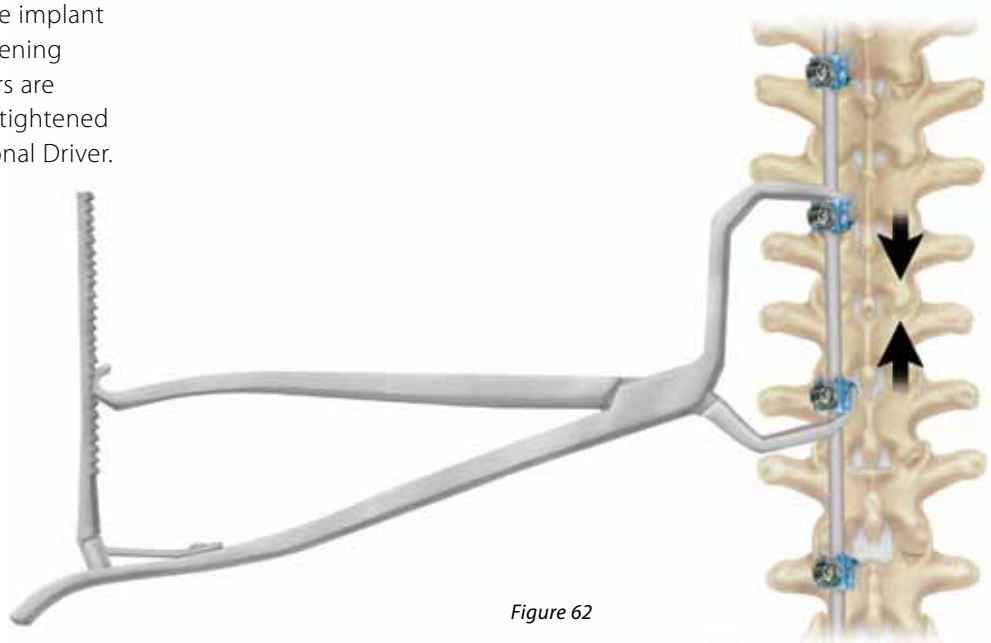


Figure 62

Stabilization and Holding 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 and provisionally secure the rod with set screws **(Figure 63)**. Once the rod is secured to the implants, distraction and/or compression are performed to place the hooks in their final position. Refer to the previously described instructions to ensure the appropriate steps are followed. It is highly recommended that the set screw not be broken off or final tightened under compression.

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.

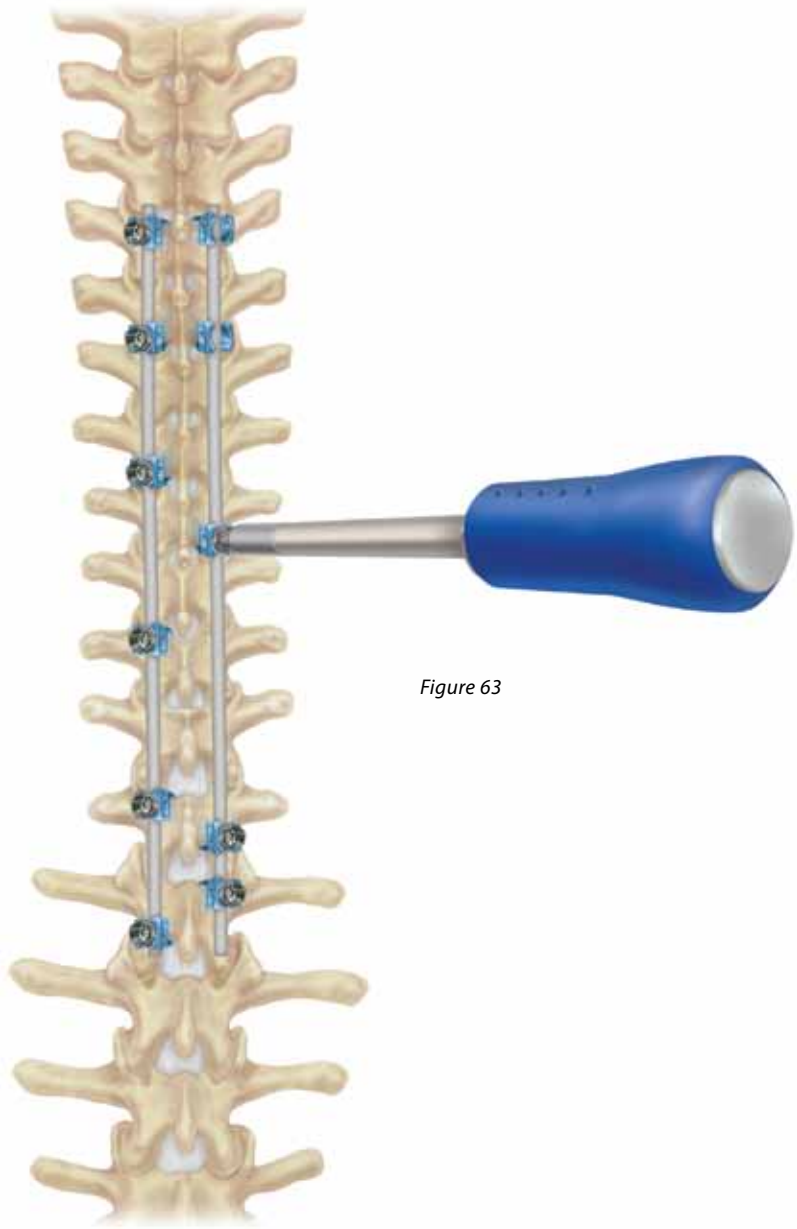


Figure 63

Final Tightening

When all implants are securely in place and the rod fully seated, final tightening and/or break-off of the set screw heads is performed.

The Counter Torque instrument is placed over the implant and the rod **(Figure 64)**. The Set Screw Breakoff Driver is then placed through the cannulated Counter Torque. The Self-Retaining Break-Off Driver provides adequate leverage for breaking the set screw heads. The handle of the Counter Torque device should be held firmly to prevent torquing of the construct while the set screw is secured and sheared off **(Figure 65)**. The broken-off part of the set screw is captured in the cannulated portion of the Self-Retaining Break-Off Driver. Following final tightening, the sheared-off portions of the set screws accumulated in the driver are removed using the T27 Obturator shaft **(Figure 66)**.

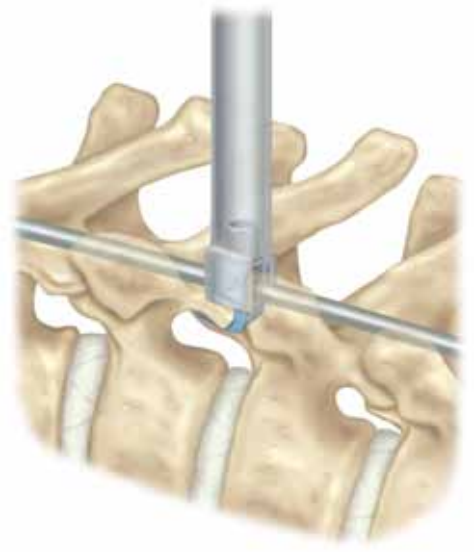


Figure 64

Figure 65

Figure 66

CD HORIZON® X10 CROSSLINK® Plate Placement, Closure, and Explantation

Once final tightening of the set screws is completed, it is mandatory that transverse links be placed to provide rotational stability to the construct. A framed construct resists rotational forces. Refer to the previously described instructions for placing CD HORIZON® X10 CROSSLINK® Plates in the pedicle screw section of this technique. The posterior elements should be decorticated with a burr followed by bone graft placement **(Figure 67)**. Wound closure is performed in the customary manner.

Explantation

The CD HORIZON® SOLERA™ set screws (plugs) may be removed using the T25 Obturator and the Self-retaining Breakoff Driver. The T25 Obturator is inserted into the working end of the Self-retaining Break-off Driver, so that that knurled portion of the T25 Obturator is flush with the driver. Insert the obturator tip through the Counter Torque, which should be seated on the screw and into the plug, turning clockwise until the plug has been removed. The hooks may be removed using the Self-Retaining Implant Holder. Attach the Self-Retaining Implant Holder to the implant and remove the hook.

If removal of a CD HORIZON® X10 CROSSLINK® MULTI-SPAN® Plate is necessary, place the 7/32" Torque-Limiting Set Screwdriver over the midline nut and turn counterclockwise to loosen. Place the 3.0mm Hex Removal Driver into a standard Medtronic Quick Connect Handle. Place the tip of the 3.0mm internal hex driver into the set screw and confirm that the 3.0mm tip is completely inserted and seated in the set screw so that the tip does not strip the hex. Turn the driver counterclockwise to loosen the set screw from the rod.

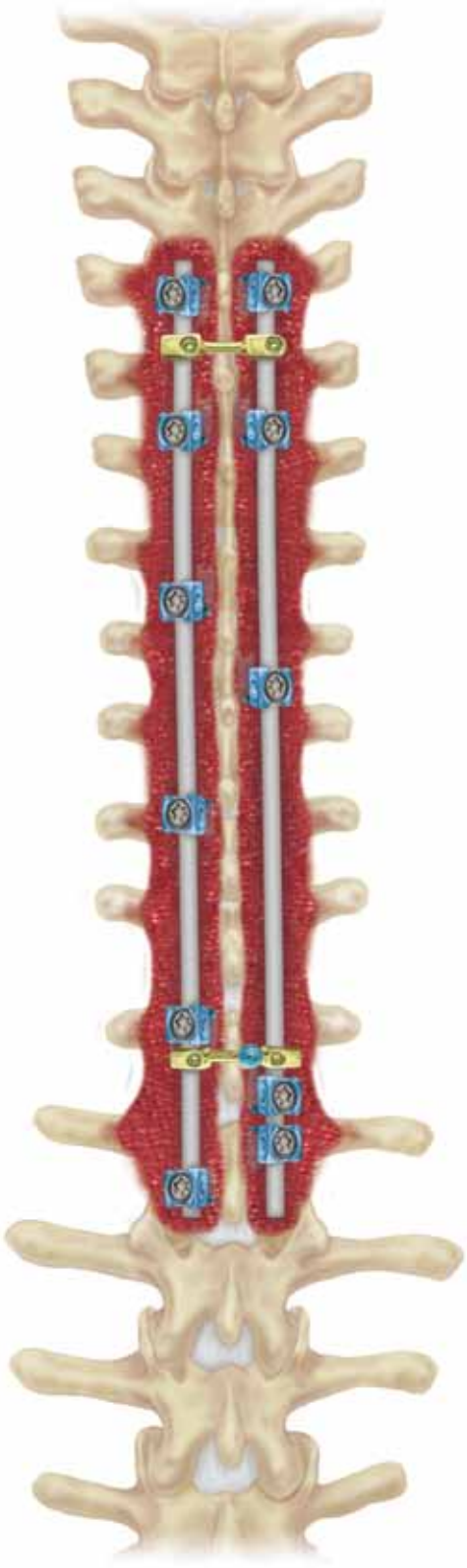


Figure 67

Product Ordering Information

4.75mm Cobalt Chrome/Titanium Multi-Axial Screws

Catalog Number	Description
54840004020	4.0mm × 20mm
54840004030	4.0mm × 30mm
54840004035	4.0mm × 35mm
54840004040	4.0mm × 40mm
54840004045	4.0mm × 45mm
54840004050	4.0mm × 50mm
54840004520	4.5mm × 20mm
54840004525	4.5mm × 25mm
54840004530	4.5mm × 30mm
54840004535	4.5mm × 35mm
54840004540	4.5mm × 40mm
54840004545	4.5mm × 45mm
54840004550	4.5mm × 50mm
54840005020	5.0mm × 20mm
54840005025	5.0mm × 25mm
54840005030	5.0mm × 30mm
54840005035	5.0mm × 35mm
54840005040	5.0mm × 40mm
54840005045	5.0mm × 45mm
54840005050	5.0mm × 50mm
54840005055	5.0mm × 55mm
54840005520	5.5mm × 20mm
54840005525	5.5mm × 25mm
54840005530	5.5mm × 30mm
54840005535	5.5mm × 35mm
54840005540	5.5mm × 40mm
54840005545	5.5mm × 45mm
54840005550	5.5mm × 50mm
54840005555	5.5mm × 55mm
54840005560	5.5mm × 60mm
54840006020	6.0mm × 20mm
54840006025	6.0mm × 25mm
54840006030	6.0mm × 30mm
54840006035	6.0mm × 35mm
54840006040	6.0mm × 40mm
54840006045	6.0mm × 45mm
54840006050	6.0mm × 50mm
54840006055	6.0mm × 55mm
54840006060	6.0mm × 60mm

Catalog Number	Description
54840006520	6.5mm × 20mm
54840006525	6.5mm × 25mm
54840006530	6.5mm × 30mm
54840006535	6.5mm × 35mm
54840006540	6.5mm × 40mm
54840006545	6.5mm × 45mm
54840006550	6.5mm × 50mm
54840006555	6.5mm × 55mm
54840006560	6.5mm × 60mm
54840006565	6.5mm × 65mm
54840007525	7.5mm × 25mm
54840007530	7.5mm × 30mm
54840007535	7.5mm × 35mm
54840007540	7.5mm × 40mm
54840007545	7.5mm × 45mm
54840007550	7.5mm × 50mm
54840007555	7.5mm × 55mm
54840007560	7.5mm × 60mm
54840008525	8.5mm × 25mm
54840008530	8.5mm × 30mm
54840008535	8.5mm × 35mm
54840008540	8.5mm × 40mm
54840008545	8.5mm × 45mm
54840008550	8.5mm × 50mm
54840008555	8.5mm × 55mm
54840008560	8.5mm × 60mm
54840008565	8.5mm × 65mm
54840009550	9.5mm × 50mm
54840009555	9.5mm × 55mm
54840009560	9.5mm × 60mm

Screw Color-coding Size Reference

4.0mm	4.5mm	5.0mm	5.5mm	6.0mm	6.5mm	7.5mm	8.5mm	9.5mm

Product Ordering Information *continued*

4.75mm Cobalt Chrome/Titanium Cannulated Multi-Axial Screws

Catalog Number	Description
54840015535	5.5mm × 35mm
54840015540	5.5mm × 40mm
54840015545	5.5mm × 45mm
54840015550	5.5mm × 50mm
54840016535	6.5mm × 35mm
54840016540	6.5mm × 40mm
54840016545	6.5mm × 45mm
54840016550	6.5mm × 50mm
54840016555	6.5mm × 55mm
54840017530	7.5mm × 30mm
54840017535	7.5mm × 35mm
54840017540	7.5mm × 40mm
54840017545	7.5mm × 45mm

4.75mm Titanium Set Screws

Catalog Number	Description
5440020	Break-off Set Screws

4.75mm Titanium Fixed Angle Screws

Catalog Number	Description
54410004020	4.0mm × 20mm
54410004025	4.0mm × 25mm
54410004030	4.0mm × 30mm
54410004035	4.0mm × 35mm
54410004040	4.0mm × 40mm
54410004045	4.0mm × 45mm
54410004520	4.5mm × 20mm
54410004525	4.5mm × 25mm
54410004530	4.5mm × 30mm
54410004535	4.5mm × 35mm
54410004540	4.5mm × 40mm
54410004545	4.5mm × 45mm
54410004550	4.5mm × 50mm
54410005020	5.0mm × 20mm
54410005030	5.0mm × 30mm
54410005035	5.0mm × 35mm
54410005040	5.0mm × 40mm
54410005045	5.0mm × 45mm
54410005050	5.0mm × 50mm
54410005055	5.0mm × 55mm
54410005520	5.5mm × 20mm
54410005525	5.5mm × 25mm
54410005530	5.5mm × 30mm
54410005535	5.5mm × 35mm
54410005540	5.5mm × 40mm
54410005550	5.5mm × 50mm
54410005555	5.5mm × 55mm
54410005560	5.5mm × 60mm
54410006025	6.0mm × 25mm
54410006030	6.0mm × 30mm
54410006035	6.0mm × 35mm
54410006040	6.0mm × 40mm
54410006045	6.0mm × 45mm
54410006050	6.0mm × 50mm
54410006055	6.0mm × 55mm
54410006525	6.5mm × 25mm
54410006530	6.5mm × 30mm
54410006535	6.5mm × 35mm
54410006540	6.5mm × 40mm
54410006545	6.5mm × 45mm
54410006550	6.5mm × 50mm
54410006555	6.5mm × 55mm
54410006560	6.5mm × 60mm
54410007530	7.5mm × 30mm
54410007535	7.5mm × 35mm
54410007540	7.5mm × 40mm
54410007545	7.5mm × 45mm
54410007550	7.5mm × 50mm
54410007555	7.5mm × 55mm
54410007560	7.5mm × 60mm
54410007565	7.5mm × 65mm

Screw Color-coding Size Reference

4.0mm	4.5mm	5.0mm	5.5mm	6.0mm	6.5mm	7.5mm	8.5mm	9.5mm

Product Ordering Information *continued*

4.75mm Titanium Hooks

Catalog Number	Description	
5441101	Pedicle Hook, Extra Small	
5441102	Pedicle Hook, Small	
5441103	Pedicle Hook, Medium	
5441104	Pedicle Hook, Large	
5441112	Wide Blade Hook, Small	
5441113	Wide Blade Hook, Medium	
5441114	Wide Blade Hook, Large	
5441122	Narrow Blade Hook, Small	
5441123	Narrow Blade Hook, Medium	
5441124	Narrow Blade Hook, Large	
5441133	Ramped, Wide Blade, Medium	
5441142	Ramped, Narrow Blade, Small	

Catalog Number	Description	
5441143	Ramped, Narrow Blade, Medium	
5441172	Extended Body Hook, Small	
5441173	Extended Body Hook, Medium	
5441174	Extended Body Hook, Large	
5441196	Right Offset Hook, Small	
5441197	Left Offset Hook, Small	
5441198	Right Offset Hook, Large	
5441199	Left Offset Hook, Large	
5441302	Total Anatomical Pedicle Hook, Small	
5441303	Total Anatomical Pedicle Hook, Medium	
5441342	Total Anatomical Transverse Process Hook, Small	
5441343	Total Anatomical Transverse Process Hook, Medium	

4.75mm Rods

Catalog Number	Description
1475001030	30mm Pre-bent Cobalt Chrome
1475001040	40mm Pre-bent Cobalt Chrome
1475001050	50mm Pre-bent Cobalt Chrome
1475001060	60mm Pre-bent Cobalt Chrome
1475001070	70mm Pre-bent Cobalt Chrome
1475001080	80mm Pre-bent Cobalt Chrome
1475001090	90mm Pre-bent Cobalt Chrome

Catalog Number	Description
1475001100	100mm Pre-bent Cobalt Chrome
1475001110	110mm Pre-bent Cobalt Chrome
1475001120	120mm Pre-bent Cobalt Chrome
1475000500	500mm Straight Cobalt Chrome
1476000500	500mm Straight Cobalt Chrome Plus
1474000500	500mm Straight Titanium, Lined

4.75mm CD HORIZON® X10 CROSSLINK® Plates, Titanium

Catalog Number	Description
5442016	16mm Fixed
5442019	19mm Fixed
5442022	22mm Fixed
5442025	25mm Fixed
5442028	28mm Fixed
5442031	31mm Fixed
5442034	34mm Fixed
5442037	37mm Fixed

Catalog Number	Description
5442136	36mm-38mm MULTISPAN
5442138	38mm-41mm MULTISPAN
5442141	41mm-45mm MULTISPAN
5442144	44mm-48mm MULTISPAN
5442147	47mm-53mm MULTISPAN
5442152	52mm-64mm MULTISPAN
5442160	60mm-80mm MULTISPAN
8110855	Set Screw

Hook Color-coding Size Reference

Extra Small	Small	Medium	Large

Product Ordering Information *continued*

Titanium Closed Multi-Axial Iliac Screws*

Catalog Number	Description	Catalog Number	Description
70465540	5.5mm × 40mm	70467560	7.5mm × 60mm
70465550	5.5mm × 50mm	70467570	7.5mm × 70mm
70465560	5.5mm × 60mm	70467580	7.5mm × 80mm
70466550	6.5mm × 50mm	70468570	8.5mm × 70mm
70466560	6.5mm × 60mm	70468580	8.5mm × 80mm
70466570	6.5mm × 70mm	70468590	8.5mm × 90mm

Titanium Iliac Screws*

Catalog Number	Description	Catalog Number	Description
7040650	6.5mm × 50mm, 0°	7041780	7.5mm × 80mm, 10°
7040660	6.5mm × 60mm, 0°	7041870	8.5mm × 70mm, 10°
7040670	6.5mm × 70mm, 0°	7041880	8.5mm × 80mm, 10°
7040760	7.5mm × 60mm, 0°	7041890	8.5mm × 90mm, 10°
7040770	7.5mm × 70mm, 0°	7042650	6.5mm × 50mm, 20°
7040780	7.5mm × 80mm, 0°	7042660	6.5mm × 60mm, 20°
7040870	8.5mm × 70mm, 0°	7042670	6.5mm × 70mm, 20°
7040880	8.5mm × 80mm, 0°	7042760	7.5mm × 60mm, 20°
7040890	8.5mm × 90mm, 0°	7042770	7.5mm × 70mm, 20°
7041650	6.5mm × 50mm, 10°	7042780	7.5mm × 80mm, 20°
7041660	6.5mm × 60mm, 10°	7042870	8.5mm × 70mm, 20°
7041670	6.5mm × 70mm, 10°	7042880	8.5mm × 80mm, 20°
7041760	7.5mm × 60mm, 10°	7042890	8.5mm × 90mm, 20°
7041770	7.5mm × 70mm, 10°		

Titanium Iliac Set Screws

Catalog Number	Description
7049855	Hex Break-off Set Screws

Titanium Iliac Lateral Connectors (May be ordered as extras.)

Catalog Number	Description
5443120	4.75mm/6.35mm Closed, 20mm
5443130	4.75mm/6.35mm Closed, 30mm
5443160	4.75mm/6.35mm Closed, 60mm

*Lateral Connectors must be used with CD HORIZON® System Iliac Screws.

Important Product Information

IMPORTANT INFORMATION ON THE CD HORIZON® Spinal System

PURPOSE

The CD HORIZON® Spinal System is intended to help provide immobilization and stabilization of spinal segments as an adjunct to fusion of the thoracic, lumbar, and/or sacral spine.

DESCRIPTION

The CD HORIZON® Spinal System consists of a variety of shapes and sizes of rods, hooks, screws, CROSSLINK® Plates, staples and connecting components, as well as implant components from other Medtronic spinal systems, which can be rigidly locked into a variety of configurations, with each construct being tailor-made for the individual case.

Certain implant components from other Medtronic spinal systems can be used with the CD HORIZON® Spinal System. These components include TSRH® rods, hooks, screws, plates, CROSSLINK® plates, connectors, staples and washer, GDLH® rods, hooks, connectors and CROSSLINK® bar and connectors; LIBERTY® rods and screws; DYNALOK® PLUS and DYNALOK CLASSIC® bolts along with rod/bolt connectors; and Medtronic Multi-Axial rods and screws. Please note that certain components are specifically designed to connect to Ø3.5mm, Ø4.5mm, Ø5.5mm rods or Ø6.35mm rods, while other components can connect to both Ø5.5mm rods and Ø6.35mm rods. Care should be taken so that the correct components are used in the spinal construct.

CD HORIZON® hooks are intended for posterior use only. CD HORIZON® staples and CD HORIZON® ECLIPSE® rods and associated screws are intended for anterior use only. However, for patients of smaller stature, CD HORIZON® 4.5mm rods and associated components may be used posteriorly.

The CD HORIZON® Spinal System implant components are fabricated from medical grade stainless steel, medical grade titanium, titanium alloy, medical grade cobalt-chromium-molybdenum alloy, or medical grade PEEK OPTIMA-LT1. Certain CD HORIZON® Spinal System components may be coated with hydroxyapatite. No warranties express, or implied, are made. Implied warranties of merchantability and fitness for a particular purpose or use are specifically excluded. See the MDT Catalog for further information about warranties and limitations of liability

Never use stainless steel and titanium implant components in the same construct.

Medical grade titanium, titanium alloy and/or medical grade cobalt-chromium-molybdenum alloy may be used together. Never use titanium, titanium alloy and/or medical grade cobalt-chromium-molybdenum alloy with stainless steel in the same construct.

The CD HORIZON® Spinal System also includes anterior staples made of Shape Memory Alloy (Nitinol – NiTi). Shape Memory Alloy is compatible with titanium, titanium alloy and cobalt-chromium-molybdenum alloy. Do not use with stainless steel.

PEEK OPTIMA-LT1 implants may be used with stainless steel, titanium or cobalt-chromium-molybdenum alloy implants.

CD HORIZON® PEEK Rods are not to be used with CROSSLINK® Plates.

To achieve best results, do not use any of the CD HORIZON® Spinal System implant components with components from any other system or manufacturer unless specifically allowed to do so in this or another Medtronic document. As with all orthopaedic and neurosurgical implants, none of the CD HORIZON® Spinal System components should ever be reused under any circumstances.

INDICATIONS

The CD HORIZON® Spinal System with or without SEXTANT® instrumentation is intended for posterior, non-cervical fixation 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 and/or lordosis); tumor; pseudarthritis; and/or failed previous fusion.

Except for hooks, when used as an anterolateral thoracic/lumbar system, the CD HORIZON® Spinal System may also be used for the same indications as an adjunct to fusion.

With the exception of degenerative disc disease, the CD HORIZON® LEGACY™ 3.5mm rods and the CD HORIZON® Spinal System PEEK rods and associated components may be used for the aforementioned indications in skeletally mature patients as an adjunct to fusion.

The CD HORIZON SPIRE™ Plate is a posterior, non-pedicle supplemental fixation device intended for use in the non-cervical spine (T1-S1) as an adjunct to fusion. It is intended for plate fixation/attachment to spinous processes for the purpose of achieving supplemental fusion in the following conditions: degenerative disc disease (as previously defined); spondylolisthesis, trauma; and/or tumor.

In order to achieve additional levels of fixation as an adjunct to fusion, the CD HORIZON® Spinal System rods may be connected to the VERTEX® Reconstruction System with the VERTEX® rod connector. Refer to the VERTEX® Reconstruction System Package Insert for a list of the VERTEX® indications of use.

CONTRAINDICATIONS

Contraindications include, but are not limited to:

1. Active infectious process or significant risk of infection (immuno¬compromise).
2. Signs of local inflammation.
3. Fever or leukocytosis.
4. Morbid obesity.
5. Pregnancy.
6. Mental illness.
7. Grossly distorted anatomy caused by congenital abnormalities.
8. Any other medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the presence of congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count.
9. Suspected or documented metal allergy or intolerance.
10. Any case not needing a bone graft and fusion.
11. Any case where the implant components selected for use would be too large or too small to achieve a successful result.
12. Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
13. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
14. Any patient unwilling to follow postoperative instructions.
15. Any case not described in the indications.

NOTA BENE: Although not absolute contraindications, conditions to be considered as potential factors for not using this device include:

1. **Severe bone resorption.**
2. **Osteomalacia.**
3. **Severe osteoporosis.**

POTENTIAL ADVERSE EVENTS

All of the possible adverse events associated with spinal fusion surgery without instrumentation are possible. With instrumentation, a listing of potential adverse events includes, but is not limited to:

1. Early or late loosening of any or all of the components.
2. Disassembly, bending, and/or breakage of any or all of the components.
3. Foreign body (allergic) reaction to implants, debris, corrosion products (from crevice, fretting, and/or general corrosion), including metallosis, staining, tumor formation, and/or autoimmune disease.
4. Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, fibrosis, neurosis, and/or pain. Bursitis. Tissue or nerve damage caused by improper positioning and placement of implants or instruments.
5. Post-operative change in spinal curvature, loss of correction, height, and/or reduction.
6. Infection.
7. Dural tears, pseudomeningocele, fistula, persistent CSF leakage, meningitis.
8. Loss of neurological function (e.g., sensory and/or motor), including paralysis (complete or incomplete), dysesthesias, hyperesthesia, anesthesia, paresthesia, appearance of radiculopathy, and/or the development or continuation of pain, numbness, neuroma, spasms, sensory loss, tingling sensation, and/or visual deficits.
9. Cauda equina syndrome, neuropathy, neurological deficits (transient or permanent), paraplegia, paraparesis, reflex deficits, irritation, arachnoiditis, and/or muscle loss.
10. Urinary retention or loss of bladder control or other types of urological system compromise.
11. Scar formation possibly causing neurological compromise or compression around nerves and/or pain.
12. Fracture, microfracture, resorption, damage, or penetration of any spinal bone (including the sacrum, pedicles, and/or vertebral body) and/or bone graft or bone graft harvest site at, above, and/or below the level of surgery. Retropulsed graft.
13. Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery.
14. Non-union (or pseudarthrosis). Delayed union. Mal-union.
15. Loss of or increase in spinal mobility or function.
16. Inability to perform the activities of daily living.
17. Bone loss or decrease in bone density, possibly caused by stresses shielding.
18. Graft donor site complications including pain, fracture, or wound healing problems.
19. Ileus, gastritis, bowel obstruction or loss of bowel control or other types of gastrointestinal system compromise.
20. Hemorrhage, hematoma, occlusion, seroma, edema, hypertension, embolism, stroke, excessive bleeding, phlebitis, wound necrosis, wound dehiscence, damage to blood vessels, or other types of cardiovascular system compromise.
21. Reproductive system compromise, including sterility, loss of consortium, and sexual dysfunction.
22. Development of respiratory problems, e.g. pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.
23. Change in mental status.
24. Death.

Note: Additional surgery may be necessary to correct some of these potential adverse events.

WARNING

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 spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis). The safety and effectiveness of this device for any other conditions are unknown. The implants are not prostheses.

In the absence of fusion, the instrumentation and/or one or more of its components can be expected to pull out, bend or fracture as a result of exposure to every day mechanical stresses.

PRECAUTION

The implantation of pedicle screw spinal systems should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient.

A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where many extenuating circumstances may compromise the results. This device system is not intended to be the sole means of spinal support. Use of this product without a bone graft or in cases that develop into a non-union will not be successful. No spinal implant can withstand body loads without the support of bone. In this event, bending, loosening, disassembly and/or breakage of the device(s) will eventually occur.

Preoperative and operating procedures, including knowledge of surgical techniques, good reduction, and proper selection and placement of the implants are important considerations in the successful utilization of the system by the surgeon. Further, the proper selection and compliance of the patient will greatly affect the results. Patients who smoke have been shown to have an increased incidence of non-unions. These patients should be advised of this fact and warned of this consequence. Obese,

Important Product Information *continued*

malnourished, and/or alcohol abuse patients are also poor candidates for spine fusion. Patients with poor muscle and bone quality and/or nerve paralysis are also poor candidates for spine fusion.

PHYSICIAN NOTE: Although the physician is the learned intermediary between the company and the patient, the important medical information given in this document should be conveyed to the patient.

!USA For US Audiences Only

CAUTION: FEDERAL LAW (USA) RESTRICTS THESE DEVICES TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

Other preoperative, intraoperative, and postoperative warnings and precautions are as follows:

IMPLANT SELECTION

The selection of the proper size, shape and design of the implant for each patient is crucial to the success of the procedure. Metallic surgical implants are subject to repeated stresses in use, and their strength is limited by the need to adapt the design to the size and shape of human bones. Unless great care is taken in patient selection, proper placement of the implant, and postoperative management to minimize stresses on the implant, such stresses may cause metal fatigue and consequent breakage, bending or loosening of the device before the healing process is complete, which may result in further injury or the need to remove the device prematurely.

DEVICE FIXATION

In cases where a percutaneous posterior approach is used refer to the CD HORIZON® SEXTANT® surgical technique.

MEDTRONIC CD HORIZON® Spinal System instrumentation contains 3.5mm, 4.5 mm, 5.5mm and/or 6.35mm rods and implants, which are intended to be used with device specific instruments.

For self breaking plugs, always hold the assembly with the Counter Torque device. Tighten and break-off the head of the plug to leave the assembly at optimum fixation security. After the upper part of the self breaking plug has been sheared off, further re-tightening is not necessary and not recommended. The head part should not remain in the patient. AFTER THE UPPER PART OF THE SELF BREAKING PLUG HAS BEEN SHEARED OFF, RE-ADJUSTMENT IS NOT POSSIBLE UNLESS THE PLUG IS REMOVED AND REPLACED WITH A NEW ONE.

When using DTT Transverse Links, the M6 plug should be tightened to between 8 and 9 Nm. (70 to 80 inch-lbs).

CD HORIZON® PEEK Rods are not to be used with CROSSLINK® Plates.

PREOPERATIVE

1. Only patients that meet the criteria described in the indications should be selected.
2. Patient conditions and/or pre dispositions such as those addressed in the aforementioned contraindications should be avoided.
3. Care should be used in the handling and storage of the implant components. The implants should not be scratched or otherwise damaged. Implants and instruments should be protected during storage, especially from corrosive environments.
4. An adequate inventory of implants should be available at the time of surgery, normally a quantity in excess of what is expected to be used.
5. Since mechanical parts are involved, the surgeon should be familiar with the various components before using the equipment and should personally assemble the devices to verify that all parts and necessary instruments are present before the surgery begins. The CD HORIZON® Spinal System components (described in the DESCRIPTION section) are not to be combined with the components from another manufacturer.
6. All components and instruments should be cleaned and sterilized before use. Additional sterile components should be available in case of an unexpected need.

INTRAOPERATIVE

1. Extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological functions.
2. Breakage, slippage, or misuse of instruments or implant components may cause injury to the patient or operative personnel.
3. The rods should not be repeatedly or excessively bent. The rods should not be reverse bent in the same location. Use great care to insure that the implant surfaces are not scratched or notched, since such actions may reduce the functional strength of the construct. If the rods are cut to length, they should be cut in such a way as to create a flat, non-sharp surface perpendicular to the midline of the rod. Cut the rods outside the operative field. Whenever possible, use pre-cut rods of the length needed.
4. Utilize an imaging system to facilitate surgery.
5. To insert a screw properly, a guide wire should first be used, followed by a sharp tap. Caution: Be careful that the guide-wire, if used, is not inserted too deep, becomes bent, and/or breaks. Ensure that the guide-ire does not advance during tapping or screw insertion. Remove the guide-wire and make sure it is intact. Failure to do so may cause the guide wire or part of it to advance through the bone and into a location that may cause damage to underlying structures.
6. Caution: Do not overtap or use a screw/bolt that is either too long or too large. Overtapping, using an incorrectly sized screw/bolt, or accidentally advancing the guidewire during tap or screw/bolt insertion, may cause nerve damage, hemorrhage, or the other possible adverse events listed elsewhere in this package insert. If screws/bolts are being inserted into spinal pedicles, use as large a screw/bolt diameter as will fit into each pedicle.
7. Bone graft must be placed in the area to be fused and graft material must extend from the upper to the lower vertebrae being fused.
8. To assure maximum stability, two or more CROSSLINK® plates or DTT Transverse Links on two bilaterally placed, continuous rods, should be used whenever possible.
9. Bone cement should not be used because the safety and effectiveness of bone cement has not been determined for spinal uses, and this material will make removal of the components difficult or impossible. The heat generated from the curing process may also cause neurologic damage and bone necrosis.
10. Before closing the soft tissues, provisionally tighten (finger tighten) all of the nuts or screws, especially screws or nuts that have a break-off feature. Once this is completed go back and firmly tighten all of the screws and nuts. Recheck the tightness of all nuts or screws after finishing to make sure that none loosened during the tightening of the other nuts or screws. Failure to do so may cause loosening of the other components.

POSTOPERATIVE

The physician's postoperative directions and warnings to the patient, and the corresponding patient compliance, are extremely important.

1. Detailed instructions on the use and limitations of the device should be given to the patient. If partial weight-bearing is recommended or required prior to firm bony union, the patient must be warned that bending, loosening and/or breakage of the device(s) are complications which may occur as a result of excessive or early weight-bearing or muscular activity. The risk of bending, loosening, or breakage of a temporary internal fixation device during postoperative rehabilitation may be increased if the patient is active, or if the patient is debilitated or demented. The patient should be warned to avoid falls or sudden jolts in spinal position.
2. To allow the maximum chances for a successful surgical result, the patient or devices should not be exposed to mechanical vibrations or shock that may loosen the device construct. The patient should be warned of this possibility and instructed to limit and restrict physical activities, especially lifting and twisting motions and any type of sport participation. The patient should be advised not to smoke tobacco or utilize nicotine products, or to consume alcohol or non-steroidals or anti-inflammatory medications such as aspirin during the bone graft healing process.
3. The patient should be advised of their inability to bend or rotate at the point of spinal fusion and taught to compensate for this permanent physical restriction in body motion.
4. Failure to immobilize a delayed or non-union of bone will result in excessive and repeated stresses on the implant. By the mechanism of fatigue, these stresses can cause the eventual bending, loosening, or breakage of the device(s). It is important that immobilization of the spinal surgical site be maintained until firm bony union is established and confirmed by roentgenographic examination. If a state of non-union persists or if the components loosen, bend, and/or break, the device(s) should be revised and/or removed immediately before serious injury occurs. The patient must be adequately warned of these hazards and closely supervised to insure cooperation until bony union is confirmed.
5. As a precaution, before patients with implants receive any subsequent surgery (such as dental procedures), prophylactic antibiotics may be considered, especially for high-risk patients.
6. The CD HORIZON® Spinal System implants are temporary internal fixation devices. Internal fixation devices are designed to stabilize the operative site during the normal healing process. After the spine is fused, these devices serve no functional purpose and may be removed. While the final decision on implant removal is, of course, up to the surgeon and patient, in most patients, removal is indicated because the implants are not intended to transfer or support forces developed during normal activities. If the device is not removed following completion of its intended use, one or more of the following complications may occur: (1) Corrosion, with localized tissue reaction or pain; (2) Migration of implant position, possibly resulting in injury; (3) Risk of additional injury from postoperative trauma; (4) Bending, loosening and breakage, which could make removal impractical or difficult; (5) Pain, discomfort, or abnormal sensations due to the presence of the device; (6) Possible increased risk of infection; (7) Bone loss due to stress shielding; and (8) Potential unknown and/or unexpected long term effects such as carcinogenesis. Implant removal should be followed by adequate postoperative management to avoid fracture, re-fracture, or other complications.
7. Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopedic implants, the CD HORIZON® Spinal System components should never be reused under any circumstances.

PACKAGING

Packages for each of the components should be intact upon receipt. If a loaner or consignment system is used, all sets should be carefully checked for completeness and all components including instruments 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 Medtronic.

CLEANING AND DECONTAMINATION

Unless just removed from an unopened Medtronic package, all instruments and implants must be disassembled (if applicable) and cleaned using neutral cleaners before sterilization and introduction into a sterile surgical field or (if applicable) return of the product to Medtronic. 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. Also, many instruments require disassembly before cleaning.

All products should be treated with care. Improper use or handling may lead to damage and/or possible improper functioning of the device.

STERILIZATION

Unless marked sterile and clearly labeled as such in an unopened sterile package provided by the company, all implants and instruments used in surgery must be sterilized by the hospital prior to use. Remove all packaging materials prior to sterilization. Only sterile products should be placed in the operative field. Unless specified elsewhere, these products are recommended to be steam sterilized by the hospital using one of the sets of process parameters below:

METHOD	CYCLE	TEMPERATURE	EXPOSURE TIME
Steam	Pre-Vacuum	270°F (132°C)	4 Minutes
Steam	Gravity	250°F (121°C)	60 Minutes
Steam*	Pre-Vacuum*	273°F (134°C)*	20 Minutes*
Steam*	Gravity*	273°F (134°C)*	20 Minutes*

NOTE: Because of the many variables involved in sterilization, each medical facility should calibrate and verify the sterilization process (e.g. temperatures, times) used for their equipment. *For outside the United States, some non-U.S. Health Care Authorities recommend sterilization according to these parameters so as to minimize the potential risk of transmission of Creutzfeldt-Jakob disease, especially of surgical instruments that could come into contact with the central nervous system.

Important Product Information *continued*

PRODUCT COMPLAINTS

Any Health Care Professional (e.g., customer or user of this system of products), who has any complaints or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify the distributor, Medtronic. Further, if any of the implanted spinal system component(s) ever "malfunctions," (i.e., does not meet any of its performance specifications or otherwise does not perform as intended), or is suspected of doing so, the distributor should be notified immediately. If any Medtronic product ever "malfunctions" and may have caused or contributed to the death or serious injury of a patient, the distributor should be notified immediately by telephone, FAX or written correspondence. When filing a complaint, please provide the component(s) name and number, lot number(s), your name and address, the nature of the complaint and notification of whether a written report from the distributor is requested.

FURTHER INFORMATION

Recommended directions for use of this system (surgical operative techniques) are available at no charge upon request. If further information is needed or required please contact MEDTRONIC.

EC REP

Medtronic B.V.
Earl Bakkenstraat 10
6422 PJ Heerlen
The Netherlands
Tel: + 31 45 566 80 00

Medtronic Sofamor Danek USA, Inc.
1800 Pyramid Place
Memphis, TN 38132
Telephone 800 933 2635 (In U.S.A.)
901 396 3133 (Outside of U.S.A.)
Fax 901 396 0356

©2009 Medtronic Sofamor Danek USA, Inc. All rights reserved.

Contact customer service or your sales representative for the most up-to-date version of the package insert and surgical technique.

Notes

www.medtronic.com

Medtronic
Spinal and Biologics Business
Worldwide Headquarters

2600 Sofamor Danek Drive
Memphis, TN 38132

1800 Pyramid Place
Memphis, TN 38132

(901) 396-3133
(800) 876-3133
Customer Service: (800) 933-2635

For more information visit
www.myspinetools.com

The surgical technique shown is for illustrative purposes only. The technique(s) actually employed in each case will always depend upon the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient.

Please see the package insert for the complete list of indications, warnings, precautions, and other important medical information.

©2009 Medtronic Sofamor Danek USA, Inc. All Rights Reserved. IRN10853-1.0-03/0210