Medtronic

CD HORIZON® SOLERA™

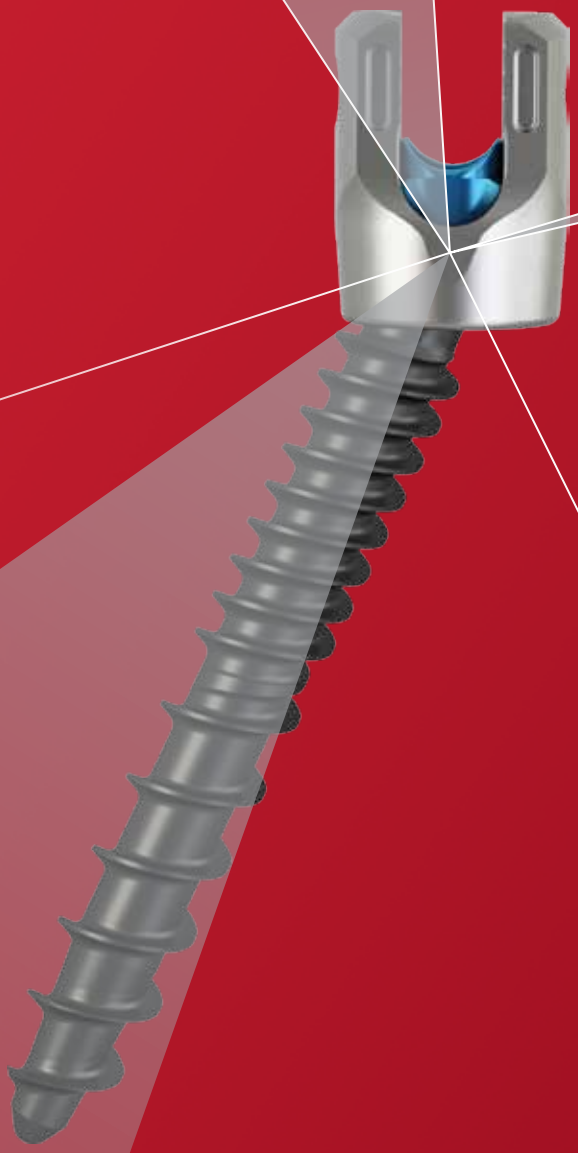
Spinal System

Surgical Technique

Profile. Performance. Efficiency.

CAPSTONE® PEEK Spinal System, CLYDESDALE™ Spinal System, and SOVEREIGN™ Spinal System incorporate technology developed by Gary K. Michelson, MD.

MICHELSON TECHNOLOGY AT WORK



Profile. Performance. Efficiency.

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 profile without compromising implant integrity, as compared to CD HORIZON® LEGACY™ 5.5mm Systems as seen in mechanical testing.[1] Risks associated with these spinal implants include loosening, disassembly, bending, and/or breakage of components. 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.

[1]Based on internal testing of a CHROMALOY™ and CHROMALOY™ Plus rod construct per ASTM F1798. Testing not indicative of human clinical outcome.

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CD HORIZON® SOLERA™

Spinal System

Surgical Technique

Enabling Spinal Technology

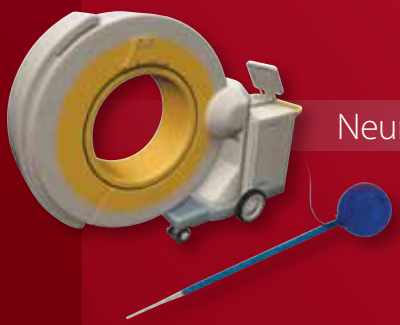
Low Profile Implants

Rod Material Choices

Advanced Instrumentation

Implant Traceability

Minimally Invasive Approach Options



Neuromonitoring and Navigation Enabled

Implant Features

Multi-Axial Screw

- 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
- OSTEOGRIP® dual lead threadform
- Cobalt Chrome tulip is designed to be compatible with CHROMALOY™, 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[1]
  NOTE: The CD HORIZON® Spinal System has not been evaluated for safety, heating, migration or compatibility in the magnetic resonance environment.
- Saddle is color-coded by bone screw diameter

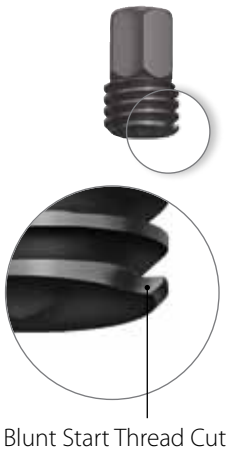
Fixed Angle Screw

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

Screw Color-coding Size Reference

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

Break-off Set Screw



Blunt Start Thread Cut

- Features a blunt start thread, reducing the chances of the set screw starting off-axis to the tulip
- The thread pattern on the set screw and the geometry of the tulip head forces the set screw to start in "one way."
- The reverse angle threadform maximizes the surface contact of the set screw threads with the tulip head
- Testing shows increased mechanical performance with an average of 17% reduction in locking torque versus the CD HORIZON® Spinal System[2]

[1]Results based on internal imaging study. MRI and CT images were taken of three different materials: Stainless Steel, Titanium, and Cobalt Chrome. Images were reviewed by seven technical experts for clarity in regions of interest.

[2]Based on internal testing per ASTM F1798 as compared to CD HORIZON® LEGACY™ 5.5mm Ti CP. Testing not indicative of human clinical outcome.

Implant Features *continued*

Rod Spectrum

CHROMALOY™ Pre-bent Rod

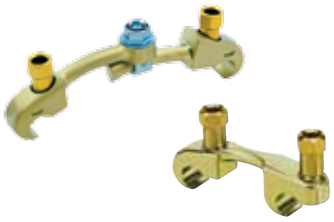
CHROMALOY™ Rod

CHROMALOY™ Plus Rod

Titanium Alloy Rod*
*(can be ordered as an extra implant)

- Multiple material types for construct tailoring and intraoperative flexibility
- Available rods
  - Precontoured and Precut CHROMALOY™ Rods
  - Straight CHROMALOY™ and CHROMALOY™ Plus Rods
  - Straight Titanium Alloy Lined Rod

CD HORIZON® X10 CROSSLINK® Plate



- Reduced profile of arches of the implant when compared to the 5.5mm CD HORIZON® X10 CROSSLINK® Plate Spinal System
- Compatible with CHROMALOY™, CHROMALOY™ Plus, and Titanium Rods
- Adjustable or fixed length options
- Attaches to the rod in the coronal, sagittal, or transverse planes in any orientation for adjustable length options

Hooks

- Compatible with CHROMALOY™, CHROMALOY™ Plus, and Titanium Rods
- Anatomic design to mimic the posterior spinal elements

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

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

*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	» Can be used to medialize or lateralize the rod in supralaminar or infralaminar position. » Can back up a pedicle screw at the same level.
		Transverse Process	↕	T1 – L5	
	Total Anatomical Pedicle Hook	Articular Process	↑	T1 – T10	» Centralized head for balance. » Lipped design can improve hook stability.
	Total Anatomical Transverse Process Hook	Transverse Process	↕	T1 – L5	» Centralized head for balance. » Lipped design can improve hook stability.

Color-coding Size Reference

Extra Small	Small	Medium	Large
●	●	●	●

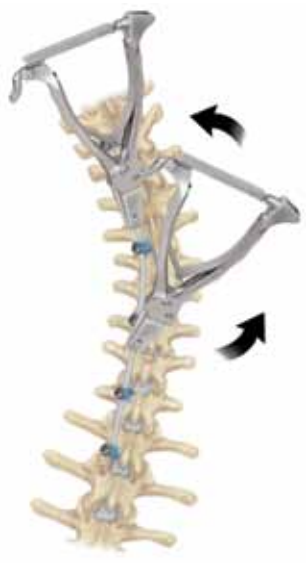
Improper positioning and placement of implants may cause damage.

Instrument Overview

Hinged Translator

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

Rod Gripper



Attaches firmly to the rod for controlled rod manipulation.

Sequential Reducer

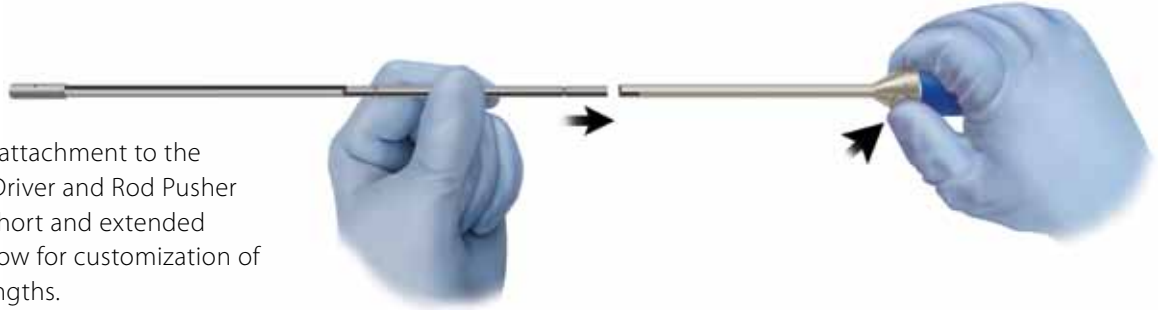
Allows controlled and sequential rod reduction.

Dual Ended Set Screw Starter

Securely engages the outer hex of the set screw to allow more control when tightening the set screw.

Adjustable Handle

Allows easy attachment to the Provisional Driver and Rod Pusher shafts. The short and extended positions allow for customization of preferred lengths.



Instrument Set

Screw Preparation

In-Line Handle Round Awl
7480104

Thoracic Probe
8350294

Lumbar Probe
8350293

Quick Connect Ratcheting Handle
G900000

Quick Connect
Ratcheting T-Handle
7579000

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)

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 Screw Lock Sleeve Driver
5484334

Lock Sleeve Multi-Axial Screwdriver
5484306

Multi-Axial Screwdriver*
5484305

*May be ordered as an extra instrument.

Instrument Set *continued*

Screw Placement *continued*

Self-Retaining Driver
5484113

Screw Confirmation Tool
5584007

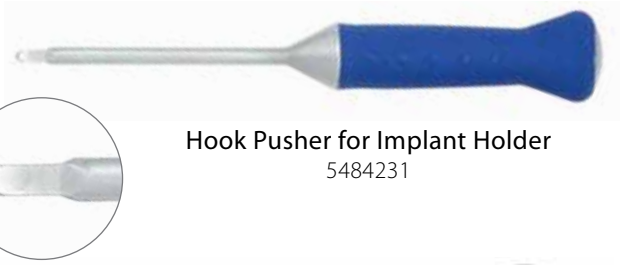
Hook Preparation

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

Instrument Set *continued*

Hook Placement *continued*

Straight Implant Holder
5484216

Self-Retaining
Hook Pusher
5484317

Rod Contouring

50cm Rod Template
5484510

20cm Rod Template
5484520

4.75mm Rod Cutter
RC404022-E

French Bender
7480162

Rod Insertion

Rod Introducer
5484318

Instrument Set *continued*

Rod Reduction

Beale Rod Reducer, Slots
5484307

Forceps Rocker
7480142

Sequential Reducer Inner Sleeve
5484304

Push Button Rocker*
5484319

Sequential Reducer Outer Sleeve
5484328

Rod Pusher
5484235
Shown with Adjustable Driver Handle

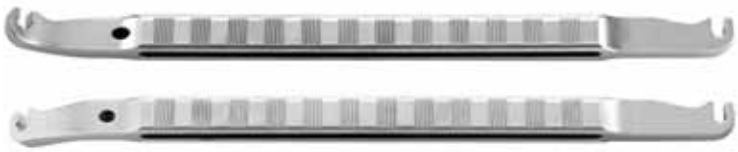
Sequential Reducer
(Assembled)

*May be ordered as an extra instrument.

Instrument Set *continued*

Rod Correction

Coronal Benders
Left 5484315
Right 5484316



***In Situ* Benders**
Left 5484313
Right 5484314

Dual Action Rod Gripper
5484303

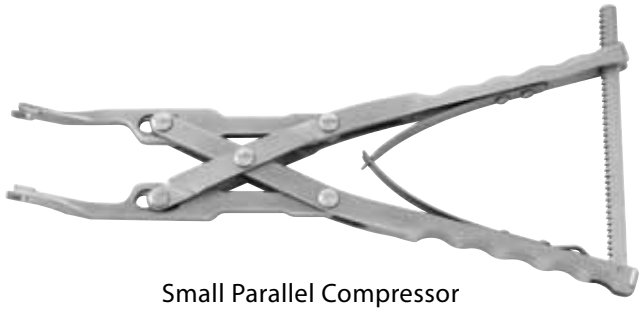
Rod Rotation Wrench
5484285

Instrument Set *continued*

Compression and Distraction

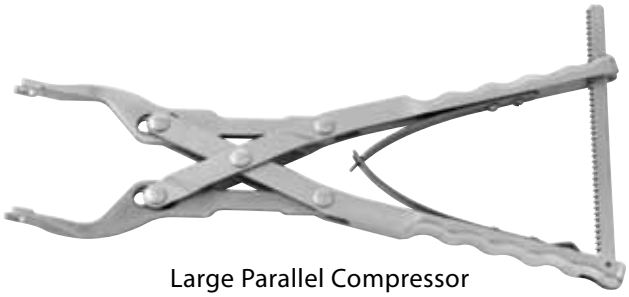
Curved Compressor
5484309

Multilevel Hook Compressor*
808-503

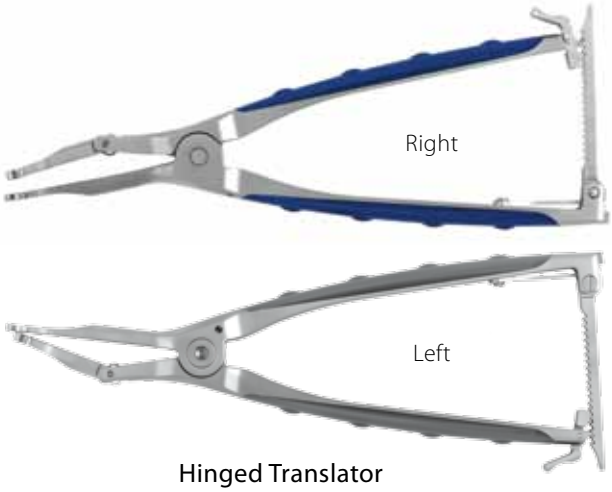


Small Parallel Compressor
7480165

Distractor Pliers
5484171

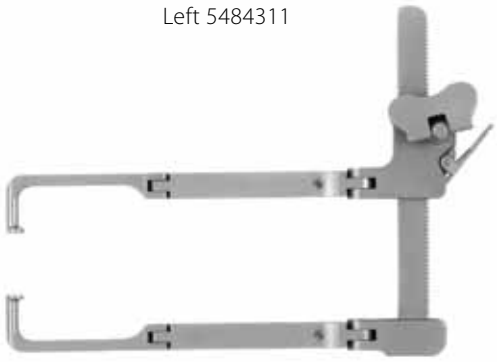


Large Parallel Compressor
7480166



Hinged Translator
Right 5484310
Left 5484311

Parallel Distractor
7480170



TLIF Distractor
5484327

*May be ordered as an extra instrument.

Instrument Set *continued*

Final Tightening/Set Screws

Dual Ended Set Screw Starter
5484302

Set Screw Breakoff Driver
8350316

Counter Torque
5484308

Torque Indicating Driver
5484147

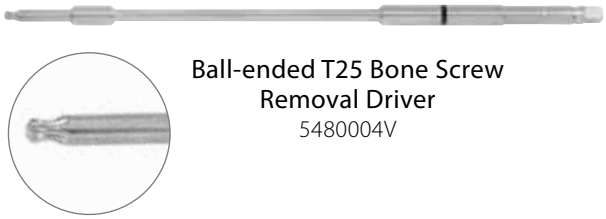
6.35mm Hex Shaft
Provisional Driver
5480131V
Shown with Adjustable Driver Handle

Adjustable Driver Handle
5480140V

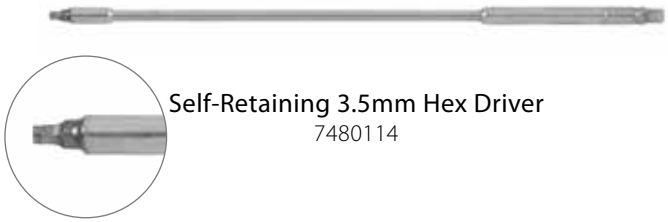
Provisional Driver
7480131

Instrument Set *continued*

Removal Instruments

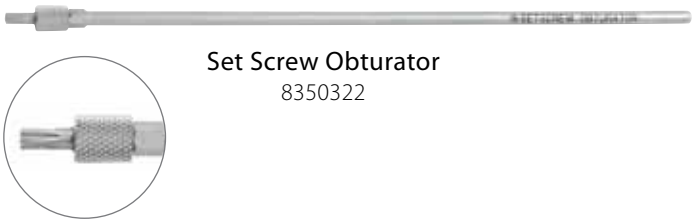


Ball-ended T25 Bone Screw Removal Driver
5480004V



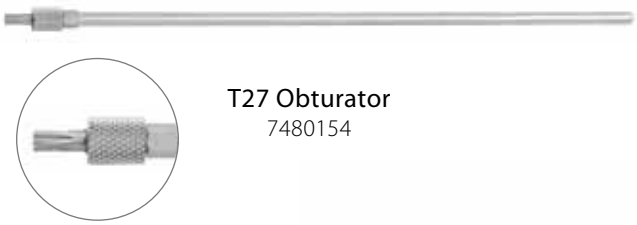
Self-Retaining 3.5mm Hex Driver
7480114

T25 Shaft
815-518



Set Screw Obturator
8350322

Additional Instruments



T27 Obturator
7480154

Torx 20 Shaft
815-517

Screw Head Positioner Shaft
5484301

Pedicle Marker, Cylindrical
8360912

Pedicle Marker with Hex
8360911

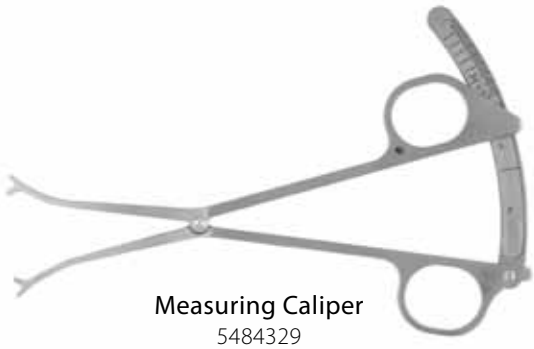
Plate Holding Pin Driver
9790903

Instrument Set *continued*

CD HORIZON® X10 CROSSLINK® Plate Instrument Set

Measuring Card
5484330

T-bolt Implant Positioners
808-545



Measuring Caliper
5484329

7/32" Torque-Limiting Set Screwdriver
8110535

In-line Plate Holder
8110511

Counter Torque
8110540

3.0mm Hex Head Shaft, Removal Driver
8110530

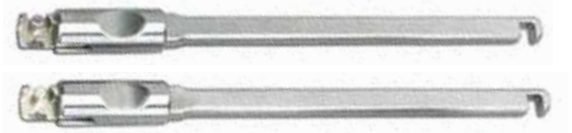


Plate Benders Bending Irons
8114505

Pedicle Screw Surgical Technique

Thoracic Facetectomy and Starting Points

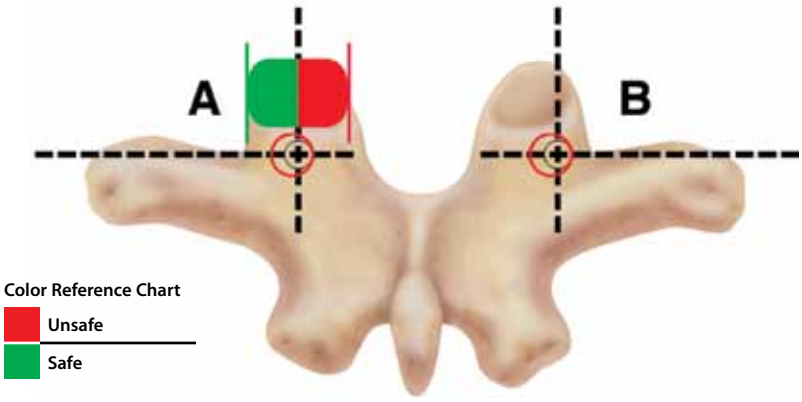
Clean the facet joints and perform a partial inferior articular process osteotomy to enhance visualization and fusion. Remove 3mm to 5mm of the inferior facet and denude the articular cartilage on the superior facet, except for the lowest vertebra to be instrumented. This will allow for the intraoperative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

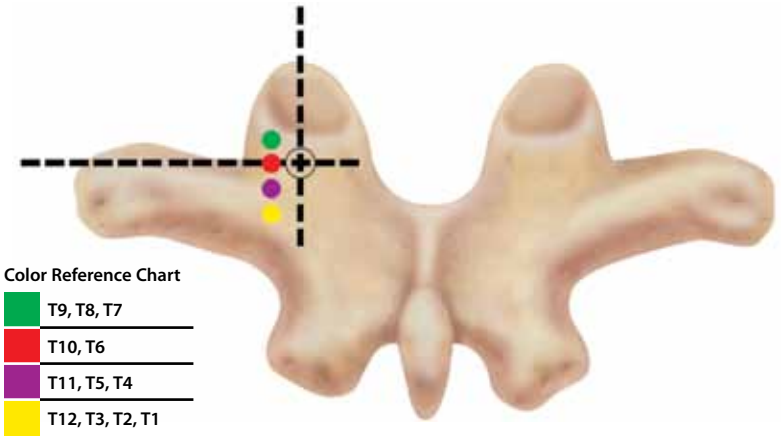
After a thorough exposure, use as much anatomic information as possible by starting with a neutral, non-rotated vertebra. The lateral and posterior views shown on the following page can be used as a guide for starting points and screw trajectory.

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)

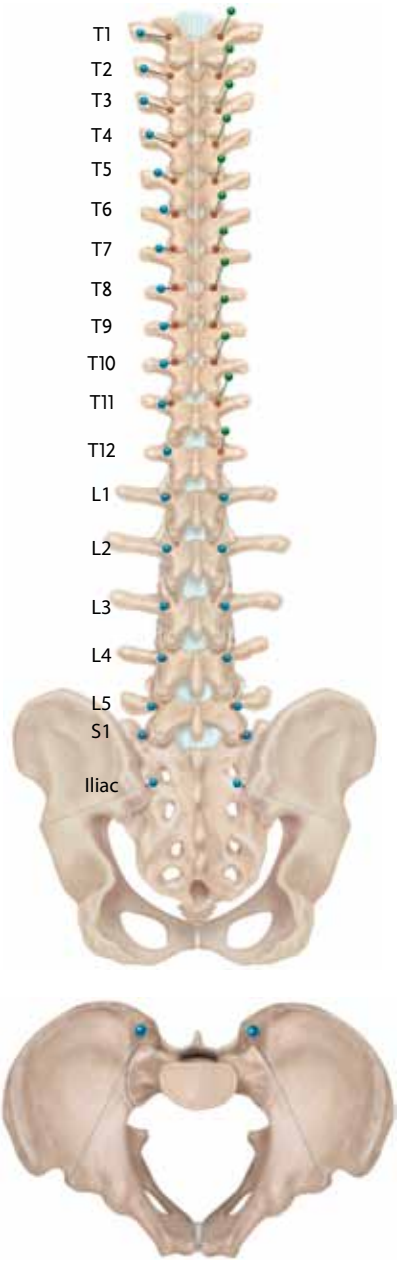


Important

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

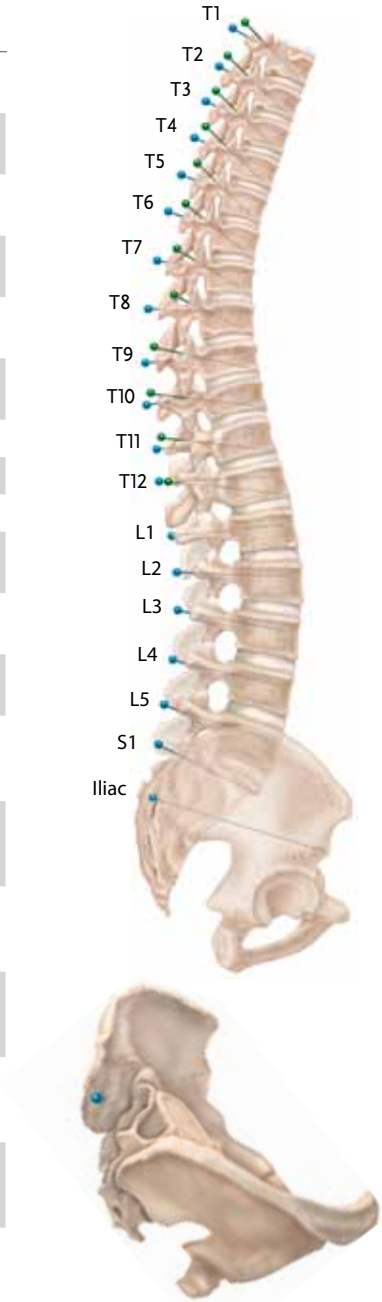
Screw Starting Points

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

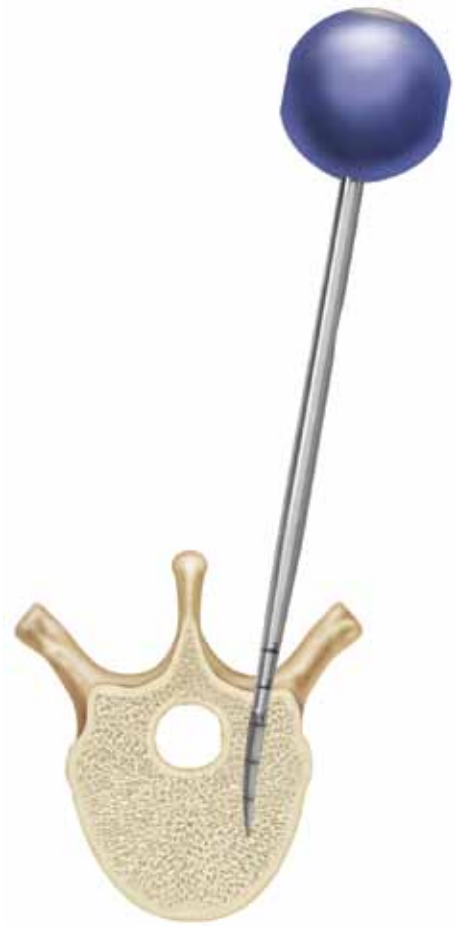


Figure 2

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.

NOTE: Although the OSTEOGRIP® thread design is different than previous designs, you can still select a tapping strategy based upon personal preference. In most instances we recommend under tapping by 1mm. If a pedicle seems particularly tenuous or brittle, then line-to-line tapping might be considered. In addition, due to the untapped second cortical thread, line to line tapping generates a significantly better sense of rigid fixation with the CD HORIZON® SOLERA™ screw as compared to prior systems. For example, you have the flexibility to follow a 5.5mm tap, which feels tight, with a 5.5mm screw and yet not compromise on fixation.

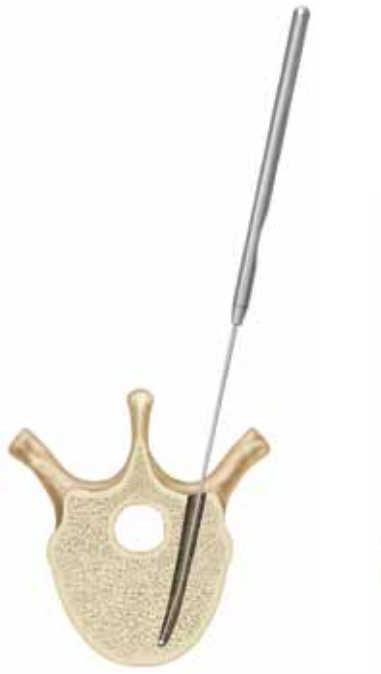


Figure 4

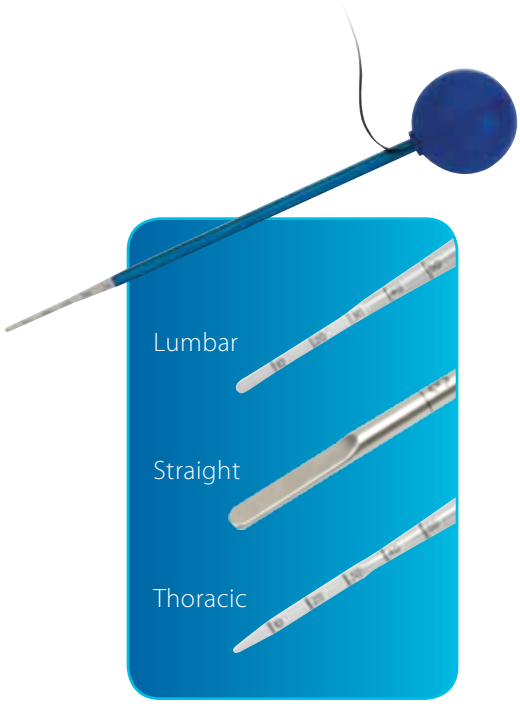
Figure 5

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® Imaging System coupled with the StealthStation® Image Guidance System can also be used to navigate pedicle preparation and screw placement.

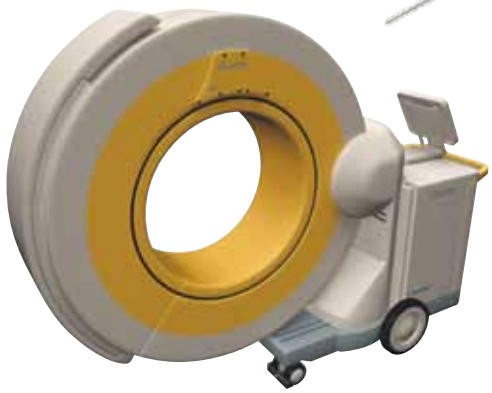
NIM-ECLIPSE® Spinal System



NIM® Pedicle Probes

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

NavLock™ Navigated Instruments



O-arm® Imaging System

O-arm® and StealthStation® System Images

For the complete labeling for the navigation products please contact Medtronic Navigation, General Business at (888) 580-8860 or visit www.medtronicnavigation.com.

VERIFYI™ Implant Tracking System

The CD HORIZON® SOLERA™ Spinal System implants 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 **(Figure 7)**. 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 8)**. Retain all of the implant tags so that they can be scanned at the end of the surgery. A tag sorter is available if the surgeon wants to track the implants by spinal level **(Figure 9)**.

Important

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

Figure 7

Figure 8

Figure 9

Screw Placement

Quick Connect Handle

Attach the Quick Connect Handle to the Multi-Axial Screw Lock Sleeve Driver by snapping into place. A slight rotation of the Quick Connect Handle may be required to fully engage with the driver. To remove the Quick Connect Handle from the driver, press the cap on the handle to disengage the driver **(Figure 10a and 10b)**.

Screw Engagement

After the Quick Connect Handle is assembled on the Lock Sleeve Driver, ensure that the blue locking cap is not engaged with the screwdriver shaft and then thread the driver shaft into the screw from the screw caddy **(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. Break off the VERIFYI™ Implant Tracking Tag as shown **(Figure 13)** and place the tag in the Tag Sorter.

Important

The Multi-Axial Screw Lock Sleeve Driver locking cap must be disengaged while threading it into the threads of the bone screw tulip head. The locking mechanism of the driver may be damaged if it is advanced into the tulip head with the locking cap engaged.

Figure 10a

Figure 10b

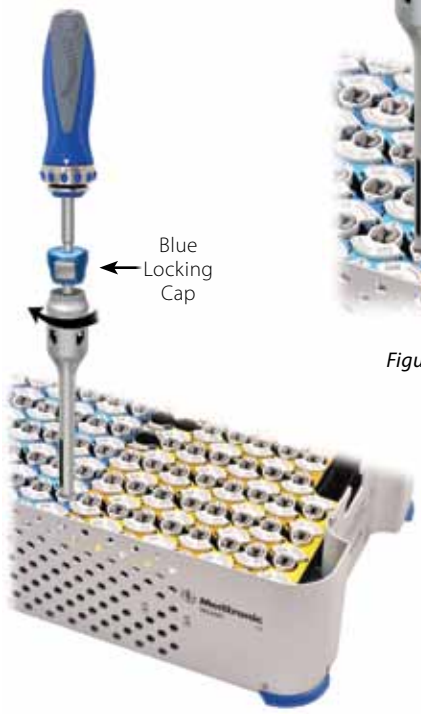


Figure 11

Figure 12

Figure 13

Screw Placement *continued*

The ring on the Quick Connect Handle determines the direction the screw will be driven by the Multi-Axial Screw Lock Sleeve Driver. Turn the ring clockwise to drive the screw into the pedicle **(Figure 14)**. Turning the ring counterclockwise will allow the driver to remove the screw from the pedicle **(Figure 15)**.

Figure 14

Figure 15

Slowly advance the screw down the pedicle to ensure proper tracking while allowing for viscoelastic expansion **(Figure 16)**. Once the screw is inserted, push the button on the blue locking cap and slide it back toward the handle to disengage the driver **(Figure 17)**. Finally, unthread the Lock Sleeve Multi-Axial Screw Driver from the screw.

Important

If the button on the blue cap is locked and the driver is difficult to disengage, hold the screwdriver sleeve and twist the screw driver shaft counterclockwise. This will allow the button on the locking cap to release and disengage the screwdriver shaft from the screw.

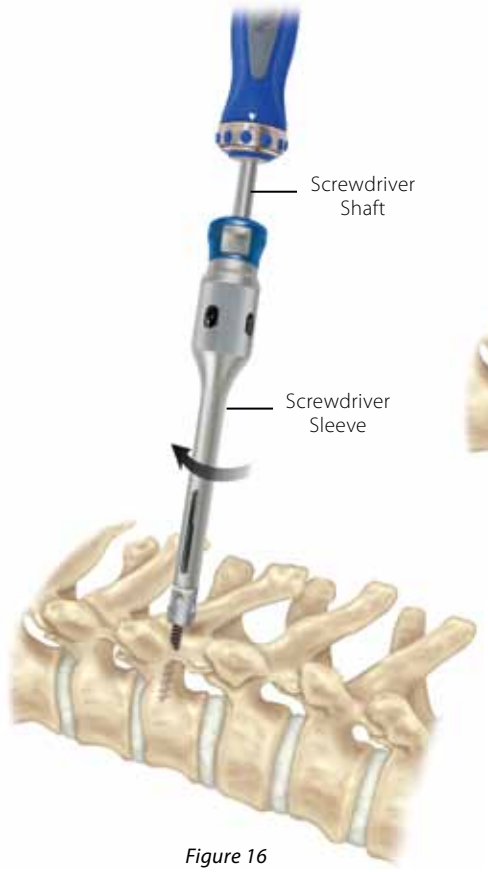


Figure 16

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.

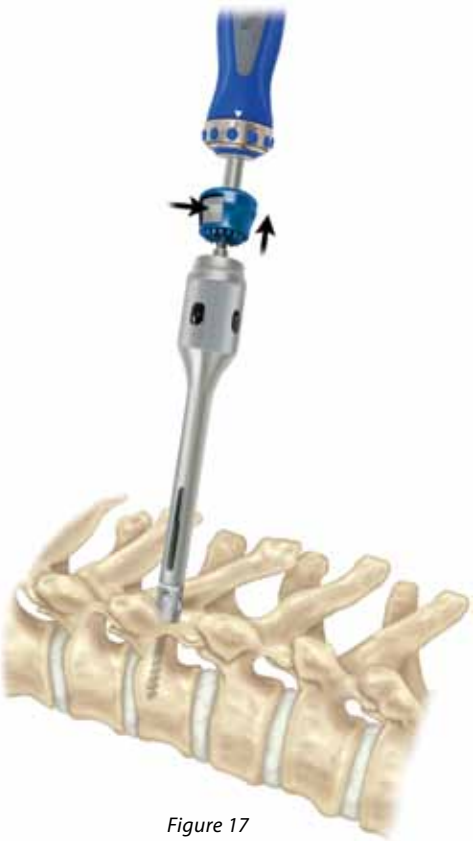
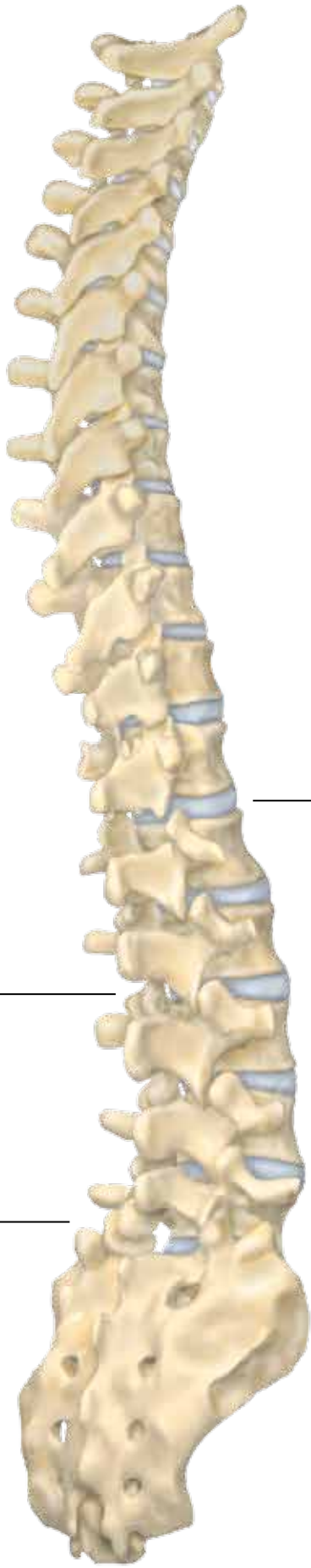


Figure 17

Interbody Options

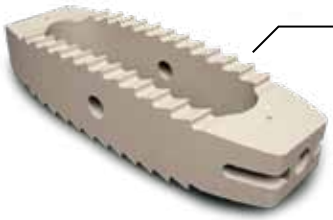
Depending on the type of surgical technique and the patient pathology, a variety of interbody options are available to be used with CD HORIZON® SOLERA™ Spinal System as supplemental fixation instrumentation.



T2 ALTITUDE™
Expandable Corpectomy System

CAPSTONE® PEEK
Spinal System

SOVEREIGN™
Spinal System



CLYDESDALE™
Spinal System

Rod Selection

The CD HORIZON SOLERA™ Spinal System offers a rod spectrum with rods of different material types and lengths to facilitate construct tailoring intraoperative flexibility **(Figure 18)**. The low profile CD HORIZON® SOLERA™ screws are compatible with all three rod material types: Titanium Alloy, CHROMALOY™, and CHROMALOY™ Plus. This spectrum of rod materials allow real-time rod choices in the OR to customize the stiffness and strength of the construct to the patient needs.

Pre-bent CHROMALOY™ Rods

These rods are made of Cobalt Chrome. They range in lengths from 30mm to 120mm in 5mm increments **(Figure 19)**. The pre-bent rods reduce the steps associated with measuring, cutting, and bending straight rods during lumbar fusion surgeries. The pre-bent rods have short lines on each end for alignment during rod placement.

NOTE: Prior to implantation, break off the VERIFYI™ Implant Tracking Tag and retain it in the Tag Sorter so that it can be scanned at the end of the surgery.

500mm Straight Rods

There are three types of 500mm straight rods: Titanium Alloy*, CHROMALOY™, and CHROMALOY™ Plus. Each rod type has different strength characteristics. The choice of the rod material depends upon the patient pathology, bone quality, and construct strength requirements as determined by the surgeon.

Figure 18

Figure 19

*The 500mm straight Titanium Alloy rod is not in the implant set and can be ordered as an extra item.

Rod Contouring and Placement

Once correct screw placement has been verified radiographically, measure and contour the selected rods in the sagittal and coronal planes. A rod template may be used to measure the rod length required for the construct **(Figure 20)**. A rod cutter (handheld or table top) may be used to cut the appropriate rod length.

Figure 20

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 21)**.

Figure 21

NOTE: Prior to implantation of the rod, break off the VERIFYI™ Implant Tracking Tag and retain it in the Tag Sorter so that it can be scanned at the end of the surgery.

Provisional Driver Assembly

The Provisional Driver assembly consists of a handle and a separate insert shaft. The instrument set contains a Provisional Driver insert shaft and a Rod Pusher insert shaft. When assembling either insert shaft, align the black laser markings on the shaft with the black line on the handle and insert the shaft **(Figure 22)**. When the insert shaft stops push the button on the handle and insert until it stops again **(Figure 23)**. Turn the shaft 90° following the black line on the shaft **(Figure 24)**. Push the shaft toward the handle until it locks into place. The driver is now locked in the short position **(Figure 25a)**.

The Provisional Driver has a short and an extended position. The push button on the handle allows the driver to lock in the two different positions. The short position is used for tightening the set screw while the extended position allows use through the Beale Rod Reducer or a Sequential Reducer.

To use the driver in the extended position, push the button and start pulling the insert shaft out from the short position. Release the button and continue pulling the shaft out until the button engages with an audible "click" **(Figure 25b)**.

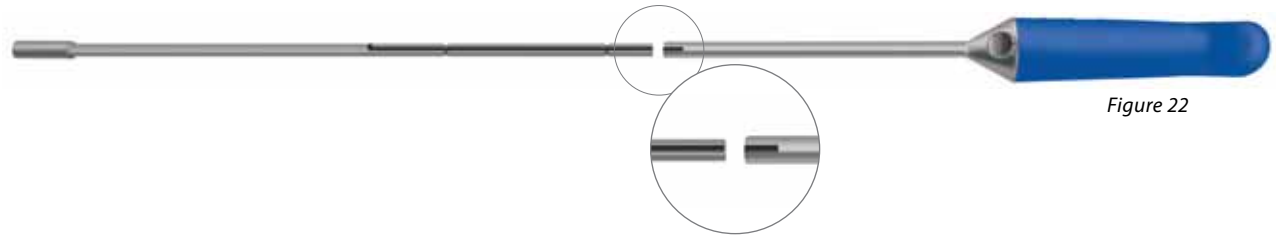


Figure 22

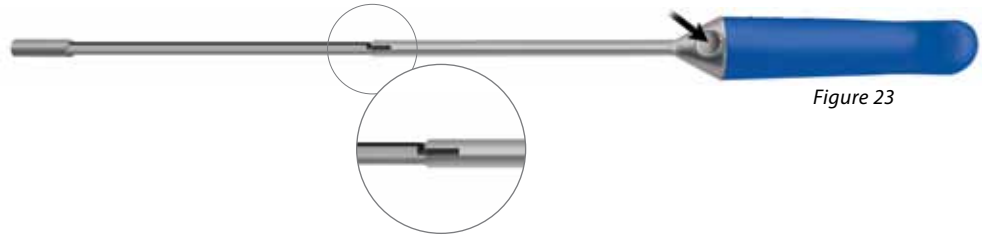


Figure 23

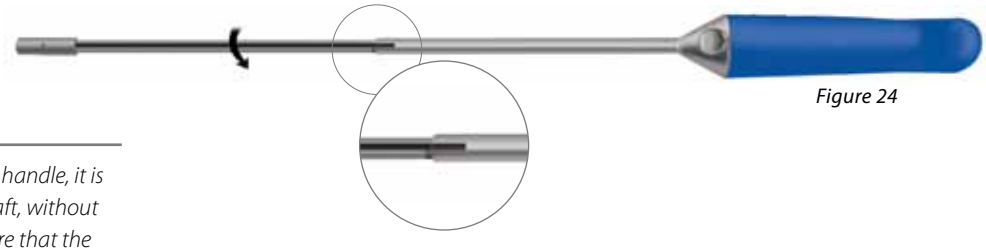


Figure 24

Important

After locking the shaft into the handle, it is advised to pull back on the shaft, without depressing the button, to ensure that the shaft is securely attached to the handle.

Figure 25a

Note

This instrument requires disassembly for proper sterilization after surgery.

Figure 25b

Rod Reduction

For non-hyperkyphotic deformities, place the rod on the concave side first. The contoured rod is introduced into the previously placed screws. There are several methods and instruments that 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.

Important

As the Cobalt Chrome material is stiffer than Titanium material, reduction tools or manual reduction techniques must be used for rod manipulation or to seat the rod into the tulip head. Never use the set screw to reduce a spinal rod because the force applied by a set screw may not be able to fully seat the rod into the saddle of the screw.

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 26)**. The levering action allows the rod to be fully seated into the saddle of the implant. The Dual Ended Set Screw Starter is then used to introduce the set screw **(Figure 27)**.

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 28)**. 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.

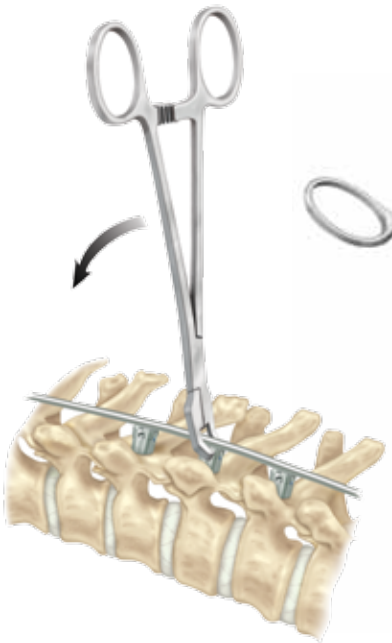


Figure 26

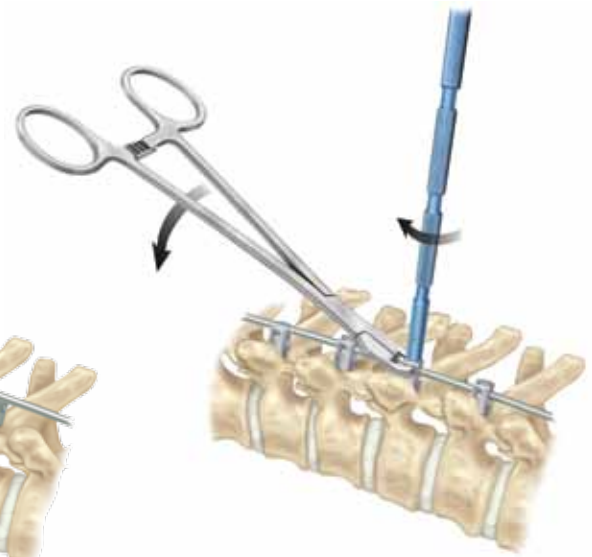


Figure 27

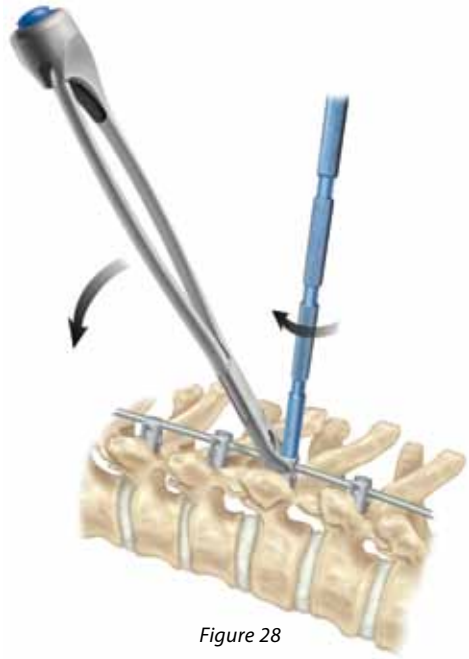


Figure 28

*Can be ordered as an extra instrument.

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. The Beale Rod Reducer attaches to the four implant slots **(Figure 29)**.

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.

NOTE: Prior to implantation of the set screw, break off the VERIFYI™ Implant Tracking Tag and retain it in the Tag Sorter so that it can be scanned at the end of the surgery.

The set screw is then placed through the reducer tube and into the implant head with the Provisional Driver or a Dual Ended Set Screw Starter. Provisionally tighten the set screw with the Provisional Driver in the extended position **(Figure 30)**.

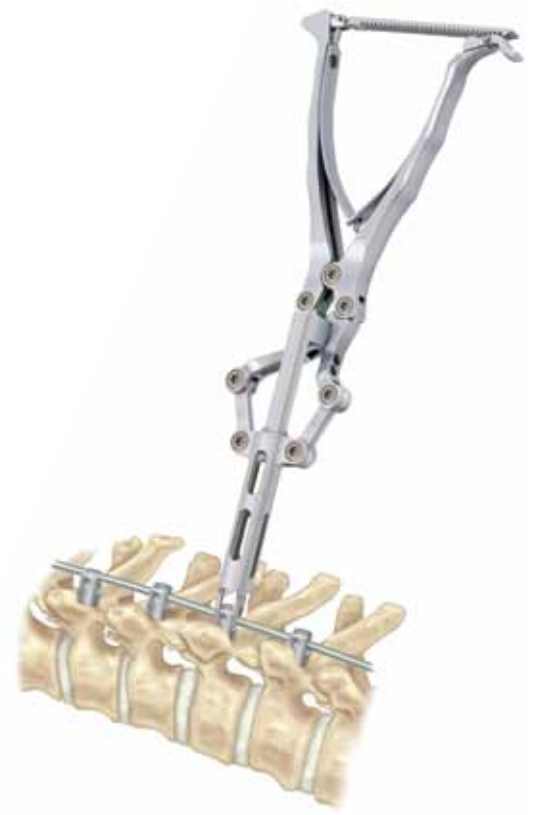


Figure 29

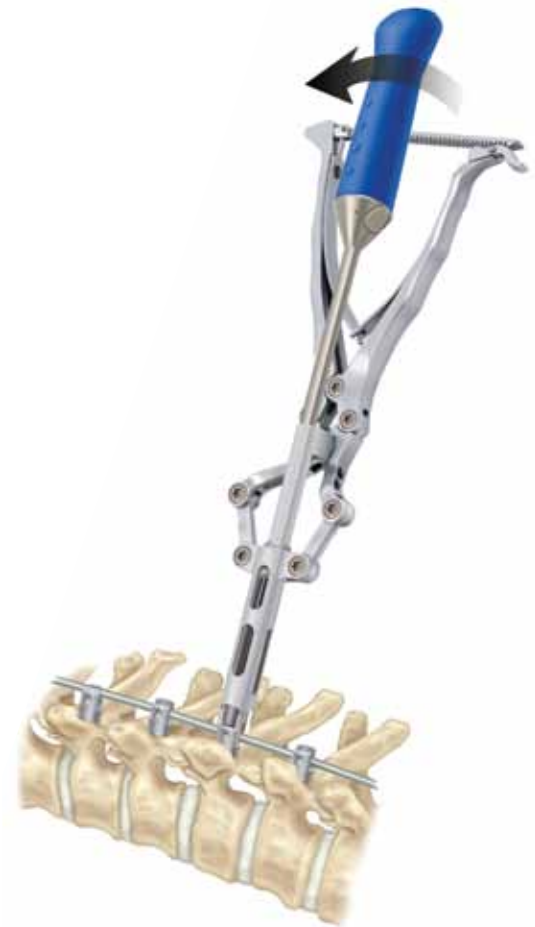


Figure 30

Sequential Rod Reduction

The Sequential Reducer may be used to gradually seat the rod. Insert the Inner Sleeve into the Outer Sleeve **(Figure 31)** and manually turn the wing nut clockwise until the word "LOAD" is visible in the oval window of the Sequential Reducer **(Figure 32)**. Place the Sequential Reducer over the rod and rock the instrument onto the screw head. This will allow it to "pop" into place. Then turn the wing nut until the instrument is firmly attached to the screw head. Once attached to the screw turn the wing nut clockwise until "RD" appears in the oval window and a black line is visible above the wing nut **(Figure 33)**. Ensure that the rod is fully reduced using visual confirmation.

Figure 31

Figure 32

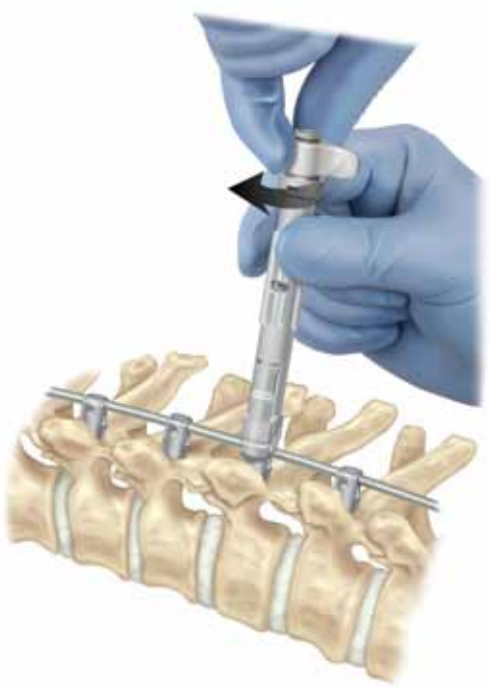


Figure 33

Sequential Rod Reduction *continued*

Attach the set screw to the Dual Ended Set Screw Starter or Provisional Driver and place it through the cannula of the reducer **(Figure 34)**. Provisionally tighten the set screw and then remove the set screw starter.

To remove the Sequential Reducer from the implant turn the wing nut counterclockwise until the word "LOAD" has passed slightly below the bottom of the oval window **(Figure 35)**. An audible "click" may be heard. Turning the wing nut beyond LOAD will allow the instrument to be disassembled.

Note

Stop turning the handle when the "LOAD" sign passes slightly below the oval window to prevent detaching of the Inner Sleeve from the Outer Sleeve.

Important

The Sequential Rod Reducer requires disassembly for proper sterilization after surgery.

Figure 34

Figure 35

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 36)**. 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. Watch the bone-to-screw interface with all correction maneuvers.

Hinged Translator

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. Pay careful attention to the bone-to-screw interface during any correction maneuver.

Prior to placing the Hinged Translator on the rod, disengage the rack so that the hinged leg and straight leg are touching each other **(Figure 37)**. A left and a right translator are included in the set to facilitate the compression and distraction maneuvers around the bony anatomy. The arrow on the rack of the Hinged Translator shows the direction in which the implant will be moved.

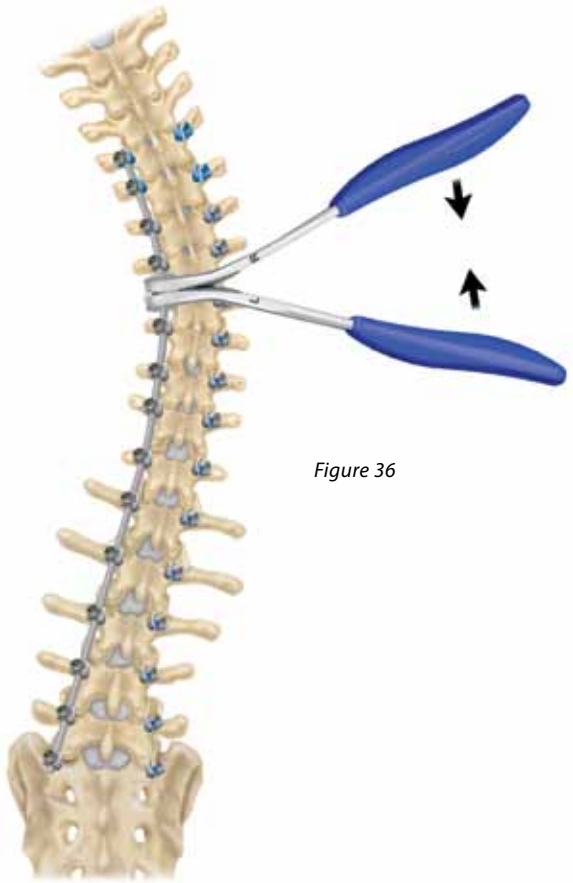


Figure 36

Figure 37

Deformity Correction *continued*

Hinged Translator *continued*

Example for Compressing the T8-T9 Segment: Provisionally tighten the T9 set screw. Prior to squeezing the handles, place the instrument along the rod with the straight leg below and immediately against the T9 screw. **(Figure 38)**. Squeeze the handles to begin compression **(Figure 39)**.

Example for Distracting the T8-T9 Segment: Provisionally tighten the T8 set screw. Prior to squeezing the handles, place the instrument along the rod with the straight leg below and immediately against the T8 screw **(Figure 40)**. Squeeze the handles to begin distraction **(Figure 41)**.

Figure 38

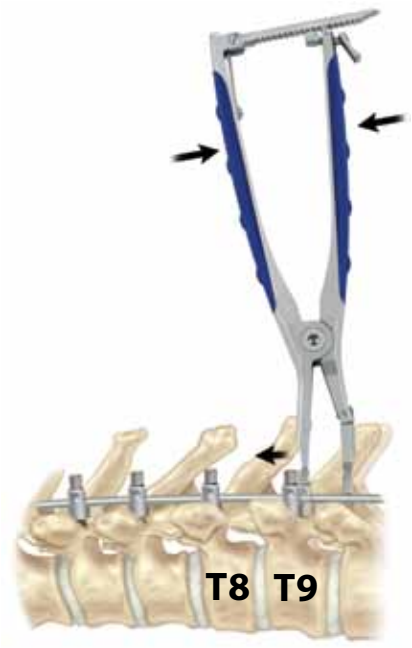


Figure 39

Figure 40

Figure 41

Deformity Correction *continued*

Placing the Stabilizing Rod

Following placement of the second rod and set screws **(Figure 42)**, 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 43)**. 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.

Important

The Dual Ended Set Screw Starter or the Provisional Driver may be used for provisionally tightening the set screws.

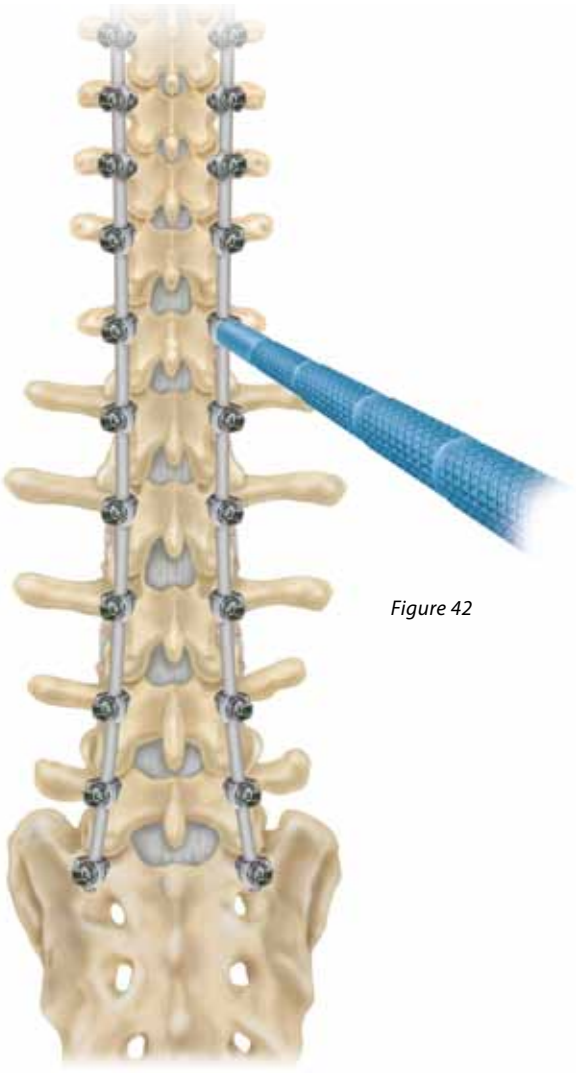


Figure 42

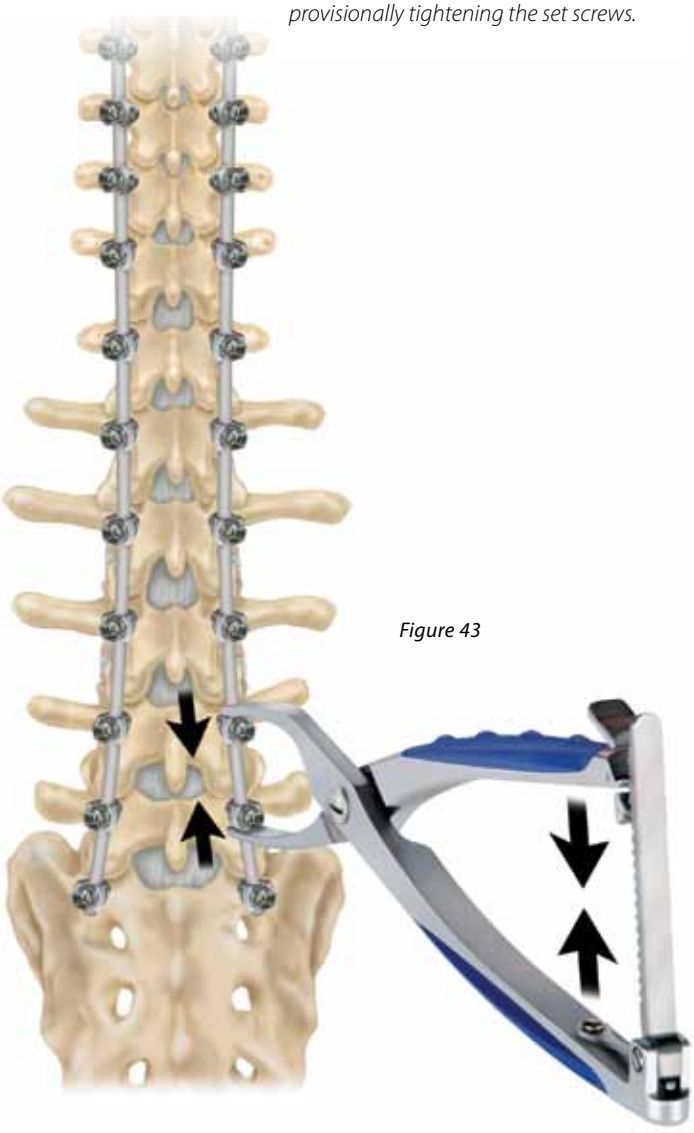


Figure 43

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 44)**. The break off set screw has the appropriate locking torque built into it and should not require additional tightening. Final tightening torque range is 9-10.5Nm or 80-93 in-lbs. If additional manipulation of the set screw is desired after the break off is achieved, the Torque Indicating Driver should be used to prevent over tightening of the set screw which could reduce the strength of the connection.

To use the Torque Indicating Driver, attach the Quick Connect T-Handle to the Torque Indicating Driver and pass it through the Counter Torque and into the inner portion of the set screw **(Figure 45)**. Turn the handle until the slot reaches the line on the right side of the scale to ensure the Correct Torque limit has been achieved **(Figure 46)**. The posterior elements are decorticated with a burr and the bone graft is placed.

Important

A Counter Torque should be used when using the Torque Indicating Driver.

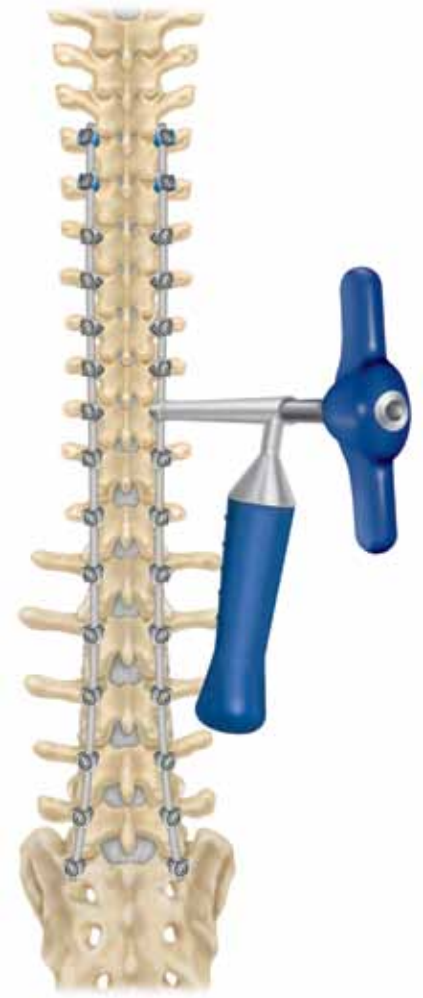


Figure 44

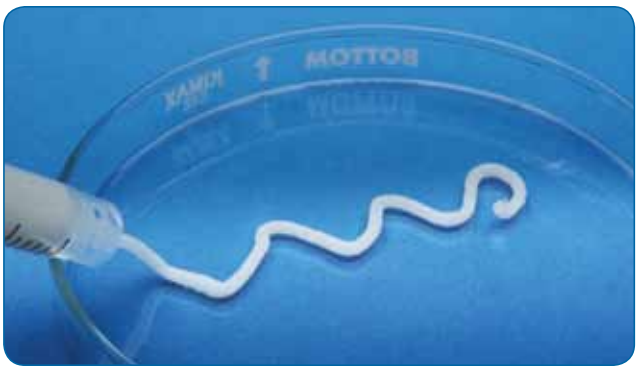
Figure 45

Figure 46

Bone Graft Options

Precise placement of the bone graft (autograft or allograft bone) on the decorticated surface is essential to facilitate fusion. A number of Medtronic bone graft substitutes, such as MASTERGRAFT® Ceramic Scaffolds, PROGENIX® Putty, and PROGENIX® Plus, are available as fillers for voids or gaps that are not intrinsic to the stability of the bony structure.

MASTERGRAFT® Ceramic Scaffolds



PROGENIX® Putty

PROGENIX® Plus

CD HORIZON® X10 CROSSLINK® Plate Placement

It has been shown that a CROSSLINK® Plate provides resistance against both axial and torsional loads by converting a two rod construct into an unitized quadrilateral frame (Johnston, Ashman, Allard: Effect of Spinal Construct Stiffness on Early Fusion Mass Incorporation. Spine 15: 908-912, 1990). In long constructs, the CROSSLINK® Plate should be placed on the upper one-third of the construct and another one in the lower one-third of the construct.

To determine the appropriate CROSSLINK® Plate, use the measuring credit card or the measuring caliper **(Figure 47)**.

In-line Plate Holder Method

NOTE: Prior to implantation of the CROSSLINK® Plate, break off the VERIFYI™ Implant Tracking Tag and retain it in the tag sorter so that it can be scanned at the end of the surgery.

The midline nut is provisionally tightened to gain control of the CD HORIZON® X10 CROSSLINK® Multi-Span Plate. The rod set screws are backed out such that they do not obstruct rod introduction. With the use of the In-line plate holder, the plate is gripped and positioned to capture the far rod of the two rods. The far rod set screw is provisionally tightened using the 7/32" Torque-Limiting Set Screw Driver to firmly anchor the device to the rod **(Figure 48)**. Next, loosen the midline nut to allow the multi-axial flexibility of the CD HORIZON® CROSSLINK® Plate and assemble the plate to the other rod and provisionally tighten the set screw. Retighten the midline nut to secure the overall device **(Figure 49)**.

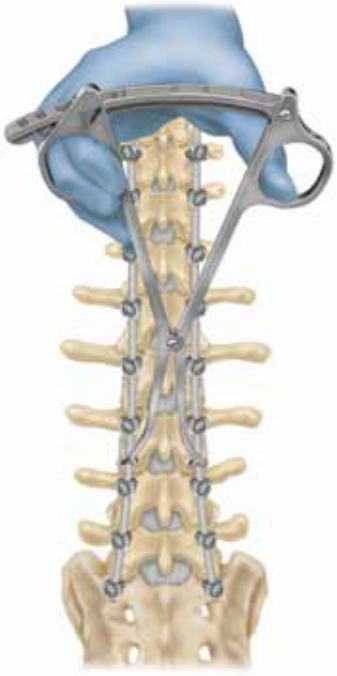


Figure 47

Figure 48

Figure 49

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 50)**. 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 51)**. If the plate cannot be precisely seated against the rod, the set screw is still too prominently extended into the claw 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 claw 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 Screw Driver.

Figure 50

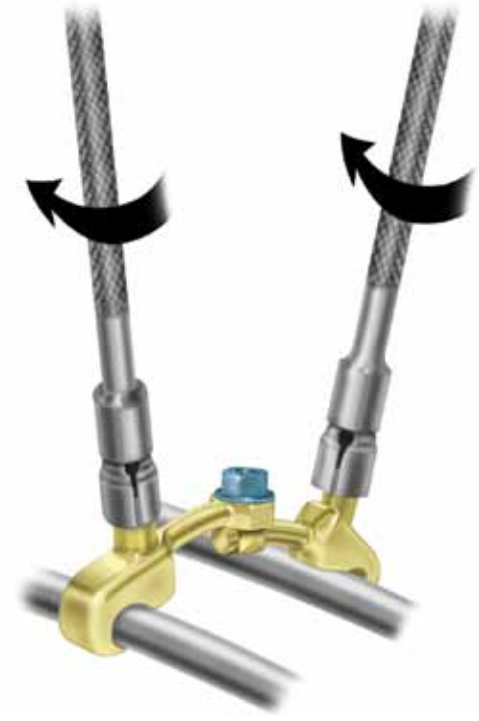


Figure 51

Final Tightening of the Plate

Finally tighten the midline nut to 80in-lbs (9Nm) using the Counter Torque to minimize torque transfer and the 7/32" Torque-Limiting Set Screw Driver **(Figure 52)**. The 7/32" Torque-Limiting Set Screw Driver should be fully seated on the midline nut during the final tightening. The midline nut is not a Break-off set screw. An audible "click" from the handle will confirm that the midline nut is adequately tightened to the appropriate torque.

Advance the break off set screws using the Counter Torque and the 7/32" Torque-Limiting Set Screw Driver and tighten the set screws to break off at 55-65 in-lbs (6.2-7.3Nm) **(Figure 53)**. The sheared off sections of the set screws can remain housed in the shaft of the driver until removal is convenient. To remove the sheared-off sections of the set screws from the driver, hold the handle horizontally and the broken off sections will easily fall from the oblong window in the shaft **(Figure 54)**.

Figure 52

Figure 53

Figure 54

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 55)**.

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.

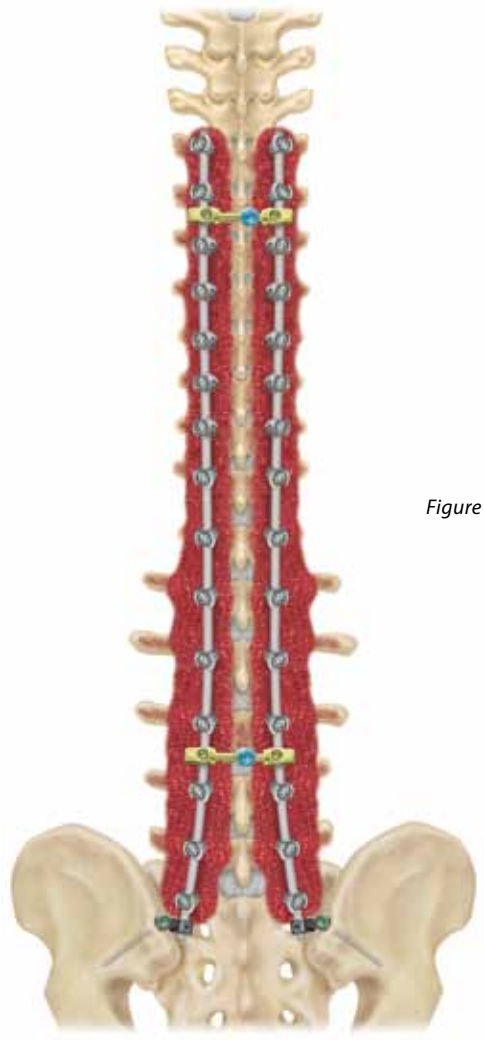


Figure 55

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 56** 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 57** shows a construct treating neuromuscular scoliosis from T2 to L5.

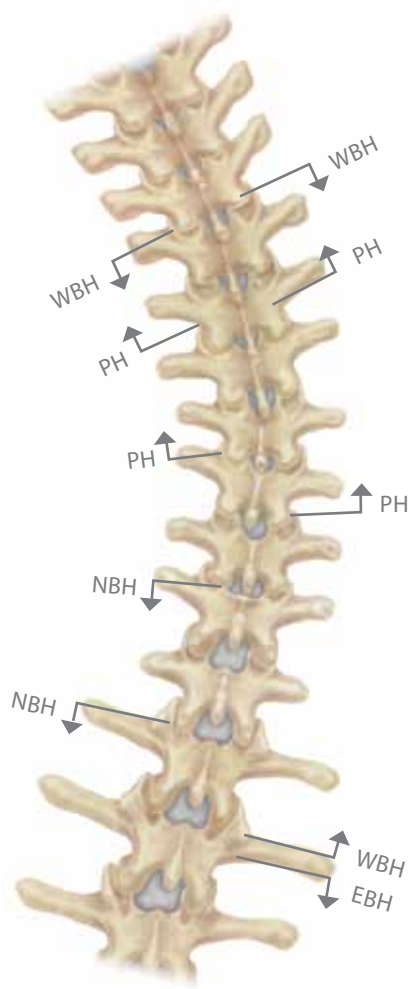


Figure 56

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

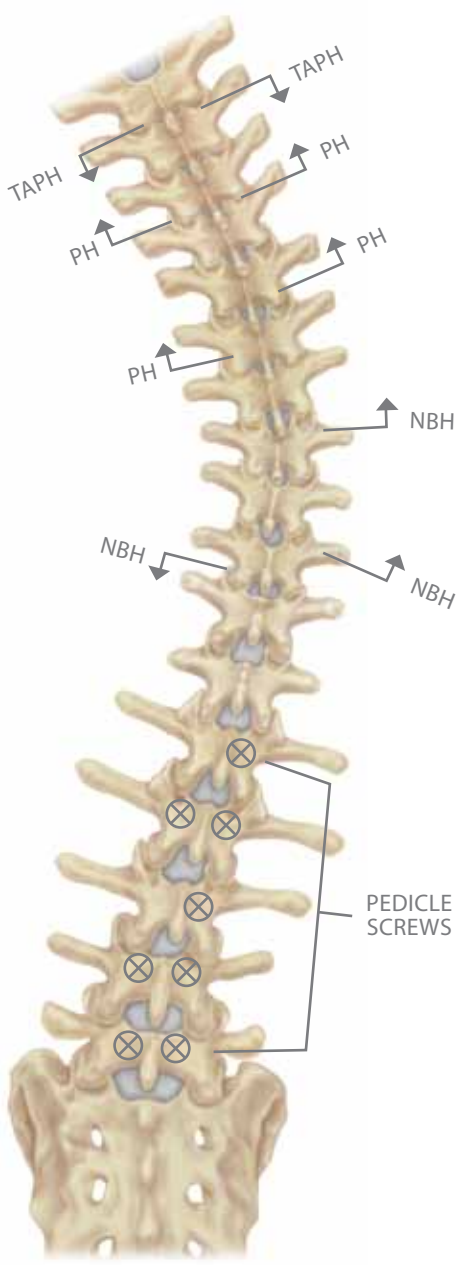


Figure 57

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). 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.

NOTE: Prior to implantation of the hooks, break off the VERIFYI™ Implant Tracking tag and retain it in the Tag Sorter so that it can be scanned at the end of the surgery.

Several different instruments can be used for hook insertion. For instance, the Straight or Lateral Implant Holder combined with the Hook Pusher **(Figure 58)**.

Figure 58

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 59)**. Once the pedicle has been clearly identified with the help of the Pedicle finder **(Figure 60)**, the hook may be inserted.

If needed, a mallet can be used to impact the Hook Pusher to drive the Pedicle Hook. It is important that the Pedicle Hook is placed into the joint cavity **(Figure 61)** and is not splitting the inferior articular process **(Figure 62)**.

Pedicle Hook

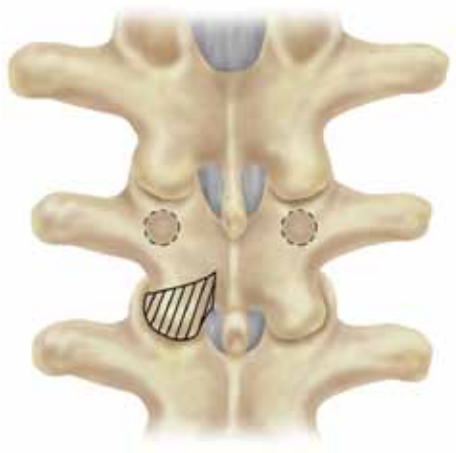


Figure 59

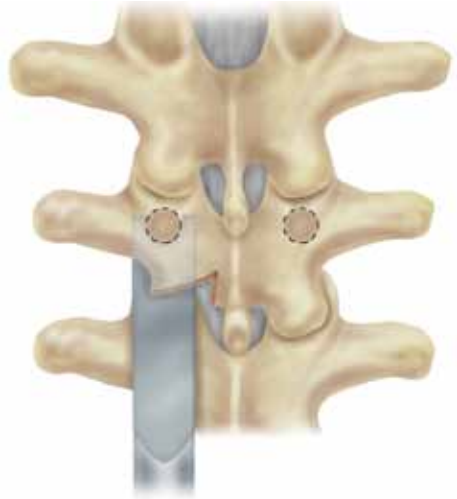
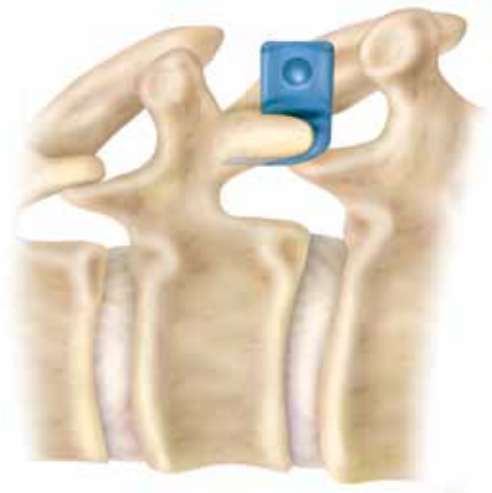
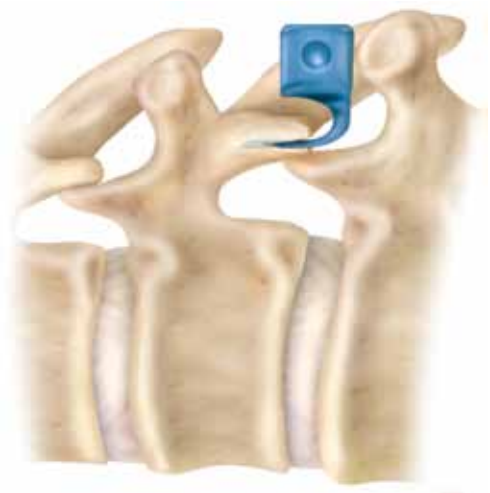


Figure 60



CORRECT

Figure 61



INCORRECT

Figure 62

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) as well as cephalad (up-going) hook **(Figure 63)**. 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.

Wide Blade Hook

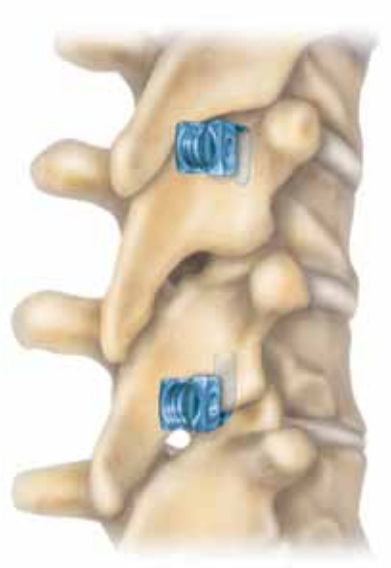


Figure 63

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 transverse 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 (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 64)**. Once the pedicle has been clearly identified with the help of the Pedicle Elevator **(Figure 65)**, the hook may be inserted.

Total Anatomical Hook

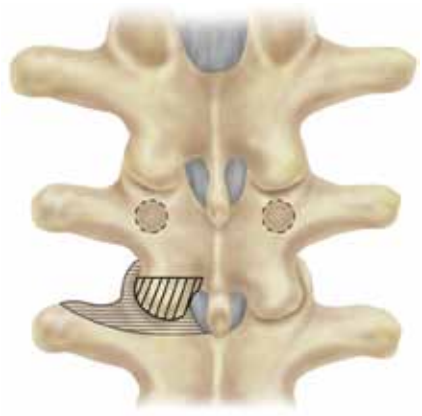


Figure 64

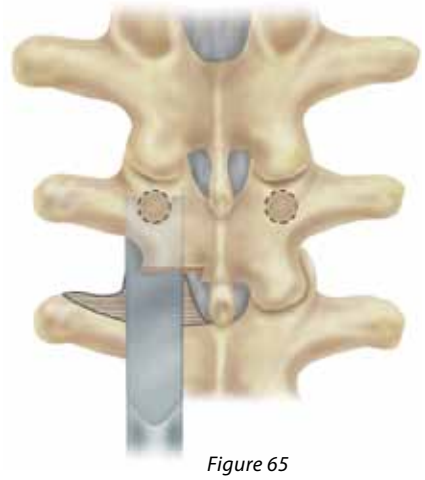


Figure 65

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) as well as cephalad (up-going) hook **(Figure 66)**. 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.

Total Anatomical
Transverse Process Hook

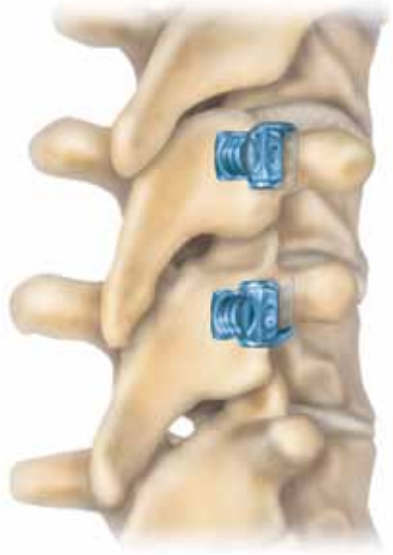


Figure 66

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 67)**. 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.

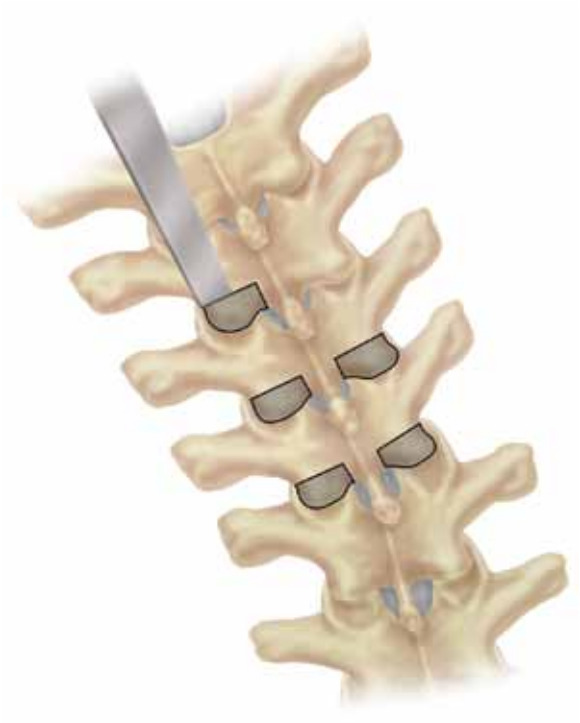


Figure 67

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 68)**. 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.

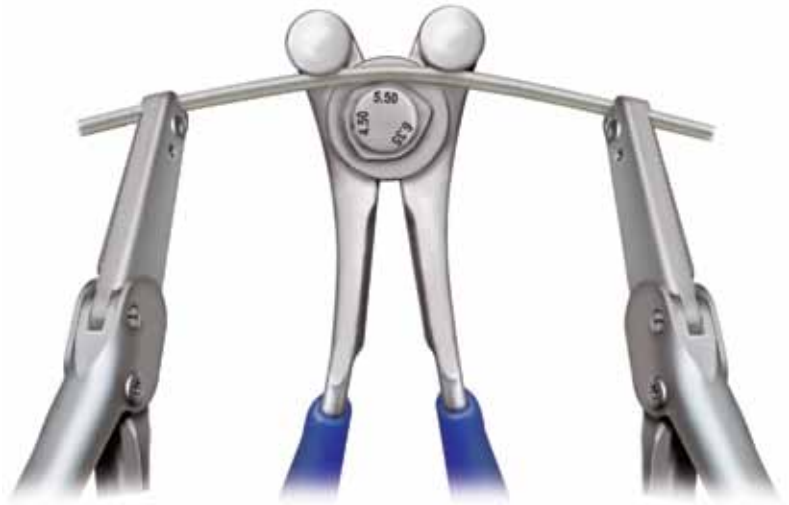


Figure 68

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 69 and 70)**.

A Rod Holder may be used to assist in placing the rod. Using the Dual Ended Set Screw Starter or Provisional Driver, 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 **(Figure 71)**.

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 29 through 32 of the pedicle screw section of this technique for method options.

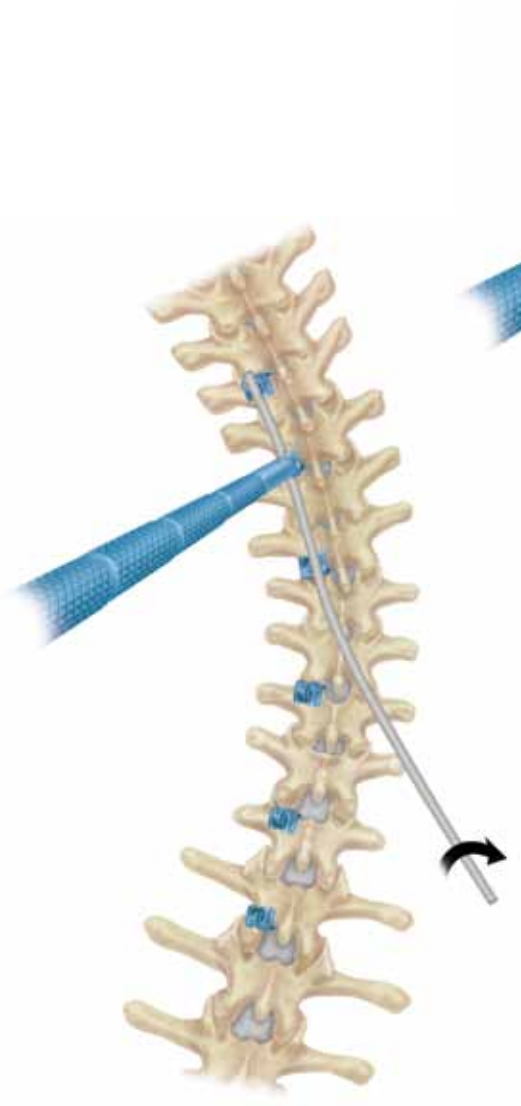


Figure 69

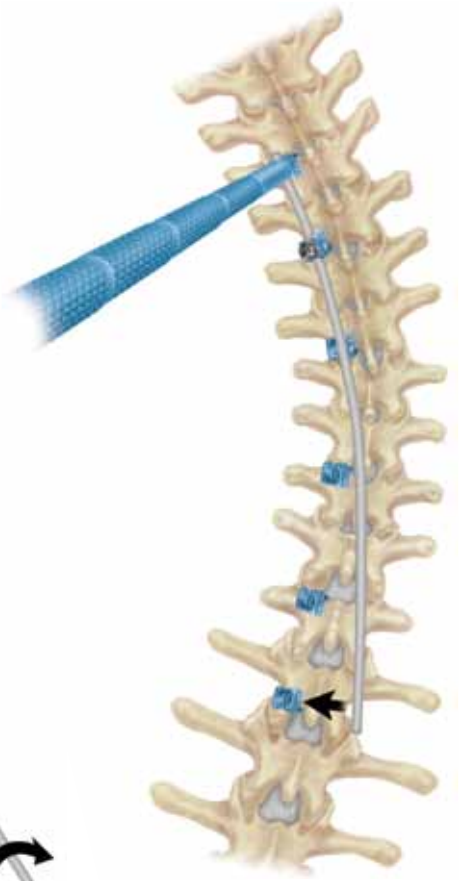


Figure 70

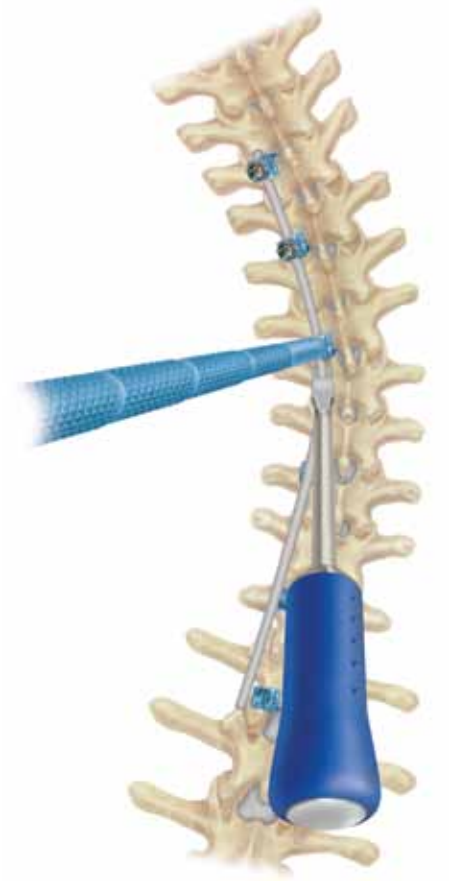


Figure 71

Deformity Correction

At this point of the surgery some 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 72)**. It is important to monitor the interval hooks, which can 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.

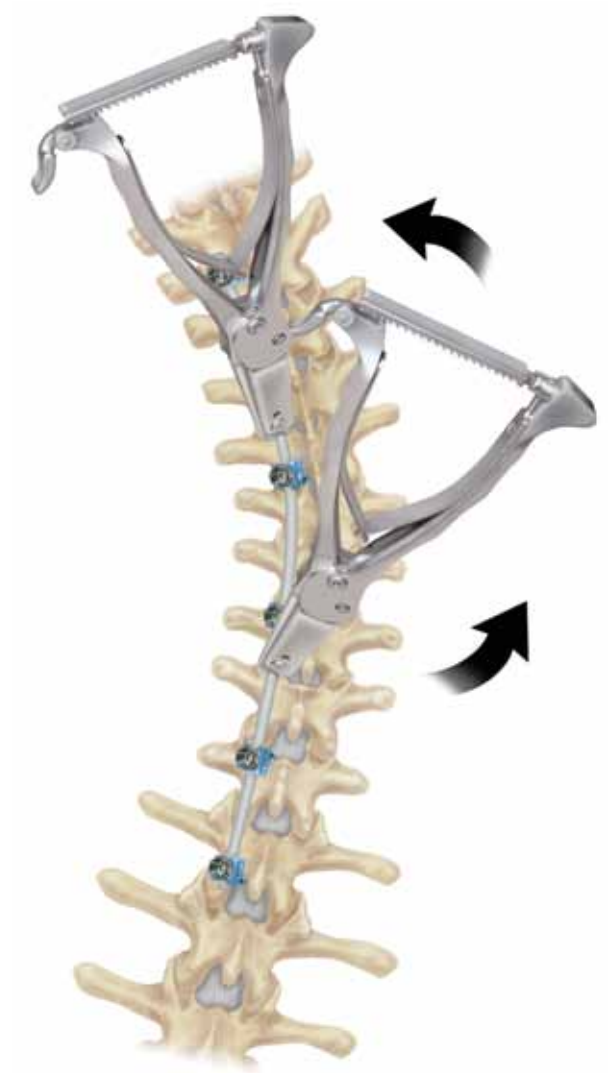


Figure 72

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 plane. The rod is bent in small incremental steps using the two bender tips positioned near each other on the rod **(Figure 73)**.

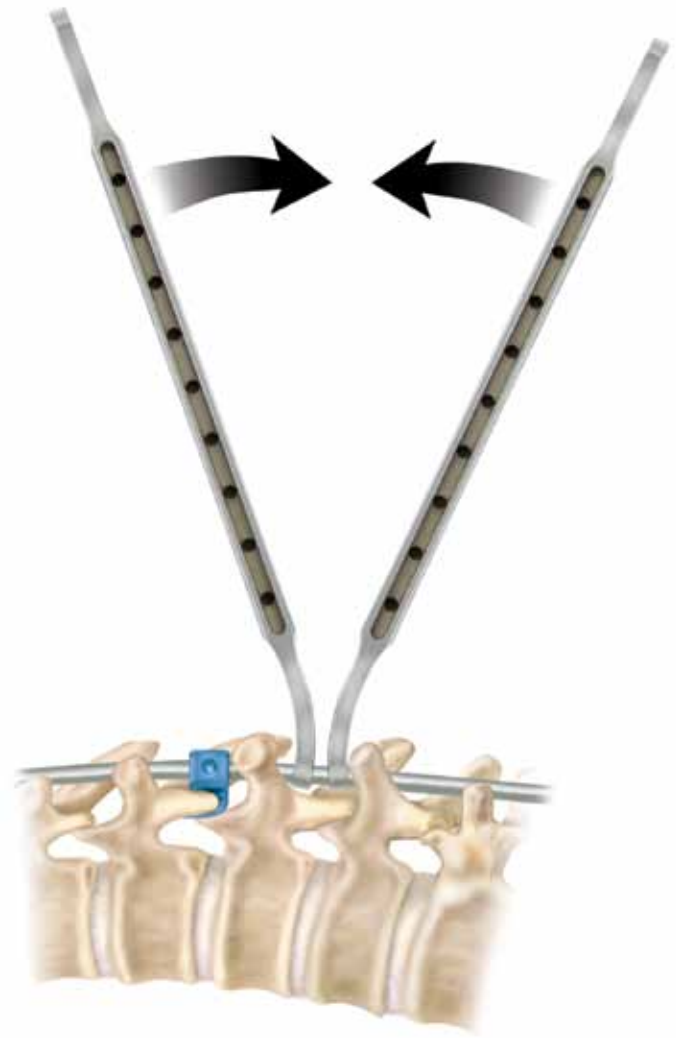


Figure 73

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 Hinged Translator, Multilevel Hook Compressor, Distractor, and Provisional Driver are used to carry out these maneuvers. **(Figure 74)**. Compression maneuvers are most often carried out directly on two hooks **(Figure 75)**. Another option is to use the Hinged Translator for Compression. 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 Provisional Driver.

Figure 74

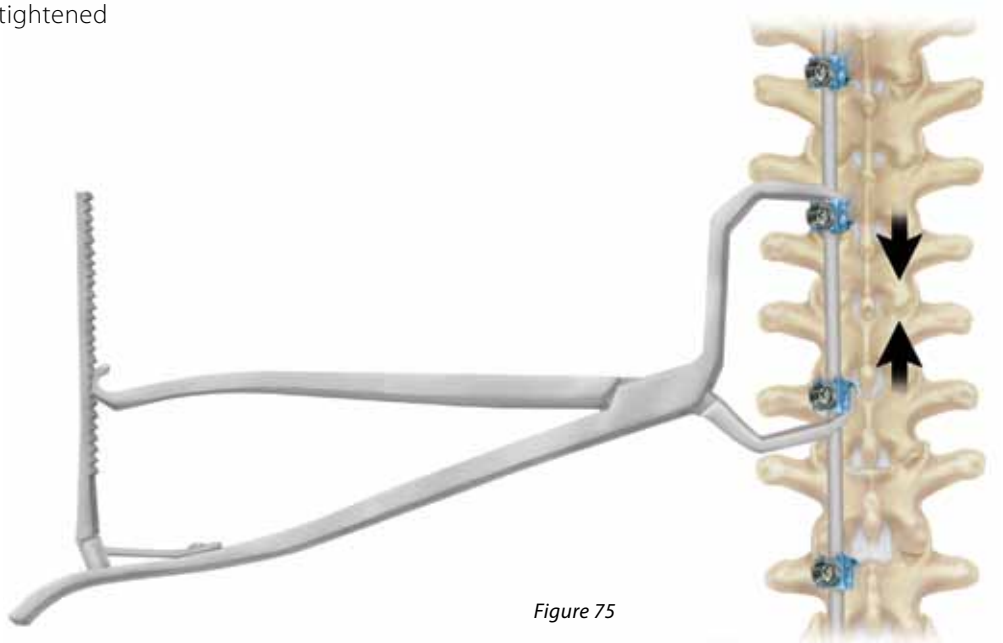


Figure 75

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 76)**. 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.

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.

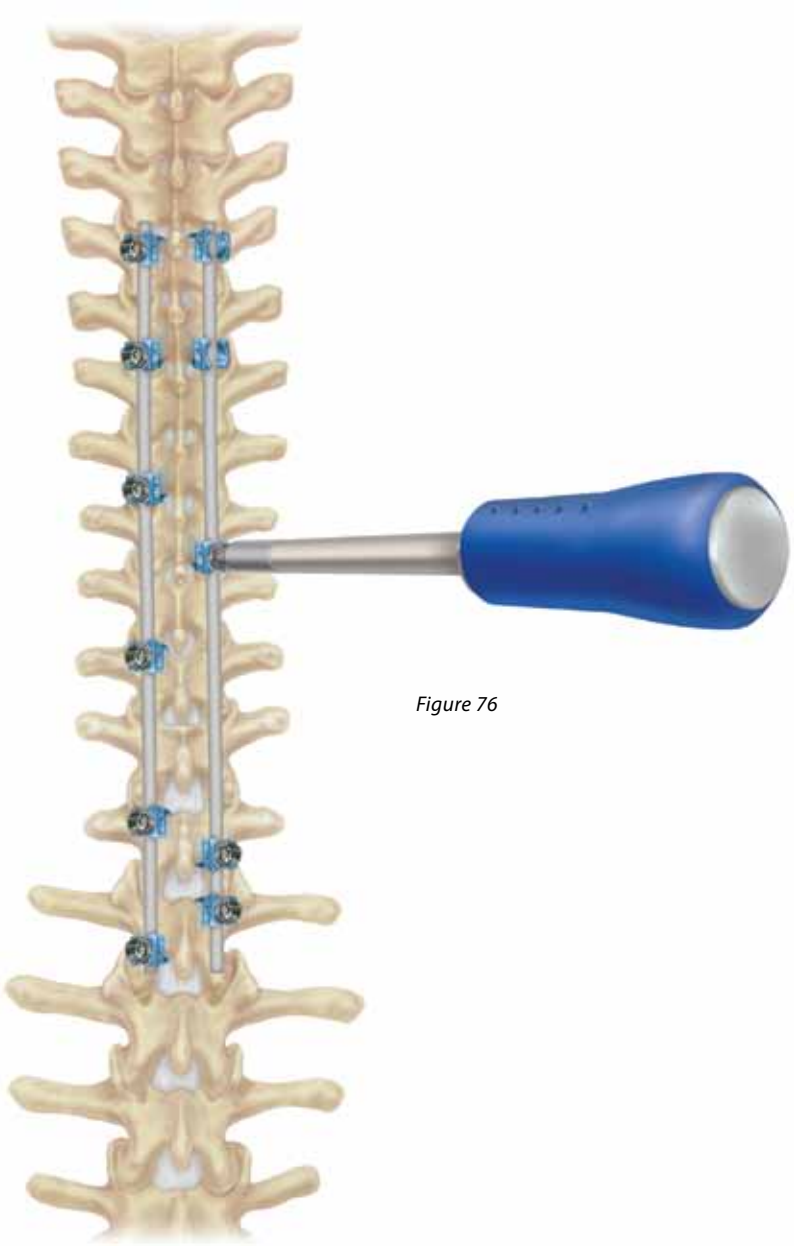


Figure 76

Final Tightening

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

The Counter Torque instrument is placed over the implant and the rod **(Figure 77)**. The Self-Retaining 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 78)**. 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 T25 Obturator shaft **(Figure 79)**.

Important

The set screw should not be broken off or final tightened under compression or distraction due to possible loosening or disassembly.

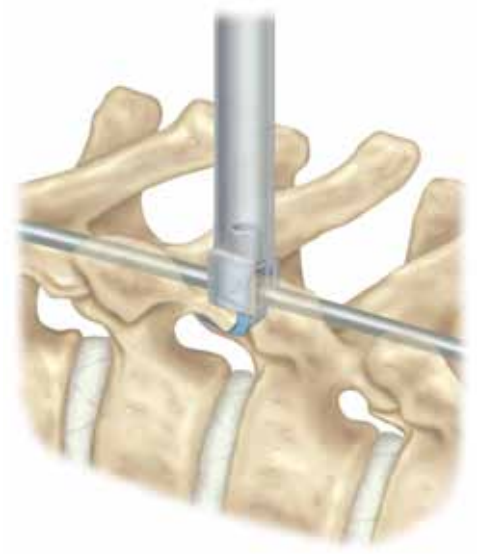


Figure 77

Figure 78

Figure 79

CD HORIZON® X10 CROSSLINK® Plate Placement and Closure

Once final tightening of the set screws is completed, transverse links should be placed if possible 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 80)**. Wound closure is performed in the customary manner.

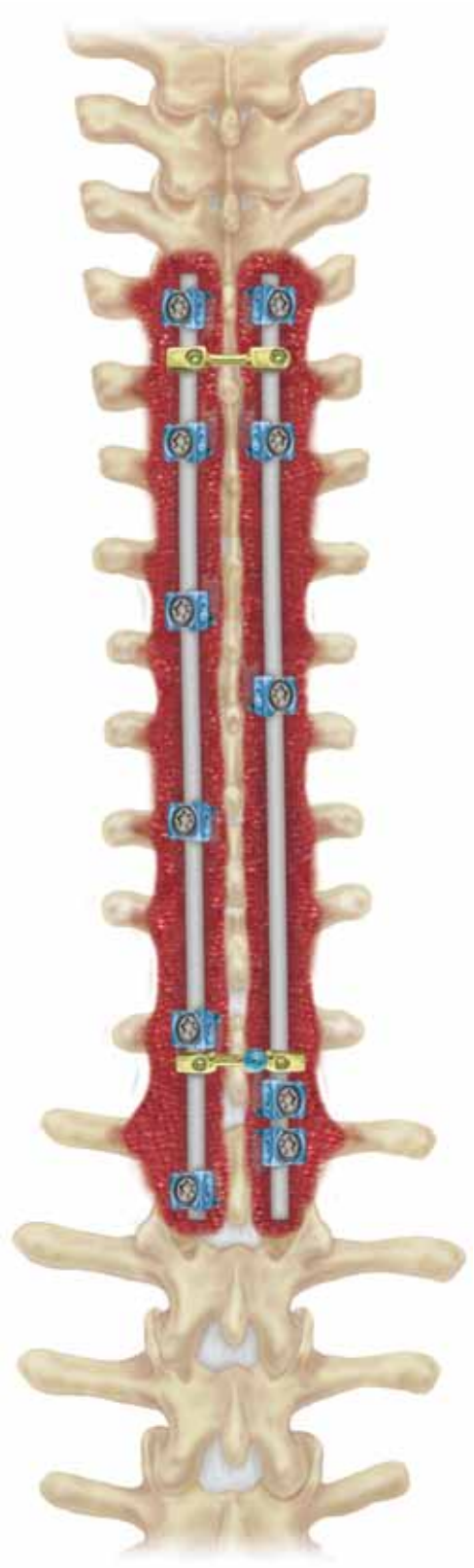


Figure 80

Suggestions to Explant the CD HORIZON® SOLERA™ Spinal System

Set Screws

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.

Pedicle Screws

The pedicle screws may be removed using either the Ball-ended T25 Bone Screw Removal Driver or the Self-retaining Screwdriver in conjunction with the Quick Connect Handle. First, attach the Quick Connect Handle to the modular end of the driver. Next, fully engage the T25 end of the driver 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.

Hooks

The hooks may be removed using the Self-retaining Implant Holder. Attach the Self-retaining Implant Holder to the implant and remove the hook.

CD HORIZON® CROSSLINK® Plates

If removal of a CD HORIZON® X10 CROSSLINK® MULTI-SPAN® Plate is necessary, place the 7/32" Torque-Limiting Set Screw Driver 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.

Product Ordering Information

4.75mm Cobalt Chrome/Titanium Multi-Axial Screws

Catalog Number	Description
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54840004025	4.0mm × 25mm
54840004030	4.0mm × 30mm
54840004035	4.0mm × 35mm
54840004040	4.0mm × 40mm
54840004045	4.0mm × 45mm
54840004050	4.0mm × 50mm
54840004055	4.0mm × 55mm
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
54840004555	4.5mm × 55mm
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54840005555	5.5mm × 55mm
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54840006545	6.5mm × 45mm

Catalog Number	Description
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54840006555	6.5mm × 55mm
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54840006565	6.5mm × 65mm
54840006570	6.5mm × 70mm
54840006580	6.5mm × 80mm
54840006590	6.5mm × 90mm
54840006500	6.5mm × 100mm
54840007520	7.5mm × 20mm
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54840007530	7.5mm × 30mm
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54840009555	9.5mm × 55mm
54840009560	9.5mm × 60mm
54840009565	9.5mm × 65mm
54840009570	9.5mm × 70mm
54840009580	9.5mm × 80mm
54840009590	9.5mm × 90mm
54840009500	9.5mm × 100mm

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 Set Screws

Catalog Number	Description
5440030	Break-off Set Screws

4.75mm Titanium Fixed Angle Screws

Catalog Number	Description
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54410004530	4.5mm × 30mm
54410004535	4.5mm × 35mm
54410004540	4.5mm × 40mm
54410004545	4.5mm × 45mm
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54410005035	5.0mm × 35mm
54410005040	5.0mm × 40mm
54410005045	5.0mm × 45mm
54410005530	5.5mm × 30mm
54410005535	5.5mm × 35mm
54410005540	5.5mm × 40mm
54410005550	5.5mm × 50mm

Catalog Number	Description
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54410006535	6.5mm × 35mm
54410006540	6.5mm × 40mm
54410006545	6.5mm × 45mm
54410006550	6.5mm × 50mm
54410006555	6.5mm × 55mm
54410007535	7.5mm × 35mm
54410007540	7.5mm × 40mm
54410007545	7.5mm × 45mm
54410007550	7.5mm × 50mm
54410007555	7.5mm × 55mm

Screw Color-coding Size Reference

4.5mm	5.0mm	5.5mm	6.5mm	7.5mm

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	●
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	●

Hook Color-coding Size Reference

Extra Small	Small	Medium	Large
●	●	●	●

Product Ordering Information *continued*

4.75mm Rods

CHROMALOY™ Pre-bent Rod

CHROMALOY™ Rod

CHROMALOY™ Plus Rod

Titanium Alloy Rod

Catalog Number	Description
1475501030	30mm Pre-bent Cobalt Chrome
1475501035	35mm Pre-bent Cobalt Chrome
1475501040	40mm Pre-bent Cobalt Chrome
1475501045	45mm Pre-bent Cobalt Chrome
1475501050	50mm Pre-bent Cobalt Chrome
1475501055	55mm Pre-bent Cobalt Chrome
1475501060	60mm Pre-bent Cobalt Chrome
1475501070	70mm Pre-bent Cobalt Chrome
1475501080	80mm Pre-bent Cobalt Chrome
1475501090	90mm Pre-bent Cobalt Chrome
1475501100	100mm Pre-bent Cobalt Chrome
1475501110	110mm Pre-bent Cobalt Chrome
1475501120	120mm Pre-bent Cobalt Chrome
1475000500	500mm Straight Cobalt Chrome
1474000500	500mm Straight Titanium Alloy
1476000500	500mm Straight Cobalt Chrome Plus

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
5442130	30mm-32mm MULTISPAN
5442132	32mm-37mm MULTISPAN
5442136	36mm-38mm MULTISPAN
5442138	38mm-42mm MULTISPAN
5442141	41mm-48mm MULTISPAN
5442144	44mm-54mm MULTISPAN
5442147	47mm-60mm MULTISPAN
5442152	52mm-70mm MULTISPAN
5442160	60mm-86mm MULTISPAN
8110855	Set Screw

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
5443110	4.75mm/6.35mm Closed, 10mm
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.

A subset of CD HORIZON® Spinal System components may be used for posterior pedicle screw fixation in pediatric cases. These constructs may be comprised of a variety of shapes and sizes of rods (ranging in diameter from 3.5mm to 6.35mm), hooks, screws, CROSSLINK® Plates, and connecting components. Similarly to the CD HORIZON® implants used in adult cases, these components can be rigidly locked into a variety of configurations, with each construct being tailor-made for the individual case.

Certain components within the CD HORIZON® Spinal System are specifically excluded for use in pediatric patients. These include PEEK rods, CD HORIZON SPIRE™ spinous process plate device, Shape Memory Alloy Staples, DYNALOK® bolts, and TSRH® screws and washers. All screws used in pediatric cases are only cleared for use via a posterior approach. All of the components used in pediatric cases are fabricated from medical grade stainless steel, medical grade titanium, titanium alloy, and medical grade cobalt-chromium-molybdenum alloy.

Certain implant components from other Medtronic spinal systems can be used with the CD HORIZON® Spinal System in non-pediatric cases. These components include TSRH® rods, hooks, screws, plates, CROSSLINK® plates, connectors, staples, washers, 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 and pediatric patients, 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 expressed 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. These staples are not to be used in pediatric patients.

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 or in pediatric patients.**

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; pseudarthrosis; 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 3.5mm rods may be used for the specific pediatric indications noted below.

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

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

In order to achieve additional levels of fixation, 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:

- Active infectious process or significant risk of infection (immunocompromise).
- Signs of local inflammation.
- Fever or leukocytosis.
- Morbid obesity.
- Pregnancy.
- Mental illness.
- Grossly distorted anatomy caused by congenital abnormalities.
- 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.
- Suspected or documented metal allergy or intolerance.
- Any case not needing a bone graft and fusion.
- Any case where the implant components selected for use would be too large or too small to achieve a successful result.
- Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
- Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
- The CD HORIZON® Spire Plate and the CD HORIZON® PEEK Rods are specifically contraindicated for use in pediatric patients.
- Any patient unwilling to follow postoperative instructions.
- 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:

- **Severe bone resorption.**
- **Osteomalacia.**
- **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:

- Early or late loosening of any or all of the components.
- Disassembly, bending, and/or breakage of any or all of the components.
- 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.
- 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.
- Post-operative change in spinal curvature, loss of correction, height, and/or reduction.
- Infection.
- Dural tears, pseudomeningocele, fistula, persistent CSF leakage, meningitis.
- 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.
- Cauda equina syndrome, neuropathy, neurological deficits (transient or permanent), paraplegia, paraparesis, reflex deficits, irritation, arachnoiditis, and/or muscle loss.
- Urinary retention or loss of bladder control or other types of urological system compromise.
- Scar formation possibly causing neurological compromise or compression around nerves and/or pain.
- 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.
- Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery.
- Non-union (or pseudarthrosis), delayed union, and mal-union.
- Cessation of any potential growth of the operated portion of the spine.
- Loss of or increase in spinal mobility or function.
- Inability to perform the activities of daily living.
- Bone loss or decrease in bone density, possibly caused by stresses shielding.
- Graft donor site complications including pain, fracture, or wound healing problems.
- Ileus, gastritis, bowel obstruction, loss of bowel control, or other types of gastrointestinal system compromise.
- 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.
- Reproductive system compromise, including sterility, loss of consortium, and sexual dysfunction.
- Development of respiratory problems, e.g., pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.
- Change in mental status.
- Death.

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

Additional Potential Adverse Events for Pediatric Patients

- Inability to use pedicle screw fixation due to anatomic limitations (pedicle dimensions, distorted anatomy)
- Pedicle screw malpositioning, with or without neurological or vascular injury
- Proximal or distal junctional kyphosis
- Pancreatitis

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.

Additional Warnings for Pediatric Patients

Warning: The safety and effectiveness of this device has not been established for use as part of a growing rod construct. This device is only intended to be used when definitive fusion is being performed at all instrumented levels.

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

Other adverse events related to pedicle screw fixation, such as screw or rod bending, breakage, or loosening, may also occur in pediatric patients. Pediatric patients may be at increased risk for device-related injury because of their smaller stature.

Precautions

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, 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.

Important Product Information *continued*

Additional Precautions for Pediatric Patients

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

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 in pediatric patients.

The selection of the proper size, shape, and design of the implant for each patient is crucial to the safe use of this device in pediatric patients.

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.

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 between 8 and 9 Nm. (70 to 80 inch-lbs).

CD HORIZON® PEEK Rods are not to be used with CROSSLINK® Plates or in pediatric patients.

PREOPERATIVE

- Only patients that meet the criteria described in the indications should be selected.
- Patient conditions and/or pre dispositions such as those addressed in the aforementioned contraindications should be avoided.
- 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.
- 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.
- 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.
- All components and instruments should be cleaned and sterilized before use. Additional sterile components should be available in case of an unexpected need.

INTRAOPERATIVE

- Extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological functions.
- Breakage, slippage, or misuse of instruments or implant components may cause injury to the patient or operative personnel.
- The rods should not be repeatedly or excessively bent. The rods should not be reverse bent in the same location. Use great care to ensure 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.
- Utilize an imaging system to facilitate surgery.
- 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-wire 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.
- 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.
- 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.
- To ensure maximum stability, two or more CROSSLINK® plates or DTT Transverse Links on two bilaterally placed, continuous rods, should be used whenever possible.
- 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 complete, 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.

- 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.
- 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, utilize nicotine products, or to consume alcohol or non-steroidals or anti-inflammatory medications such as aspirin during the bone graft healing process.
- 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.
- 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 ensure cooperation until bony union is confirmed.
- 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.
- 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.
- 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. Cleaning instructions and associated disassembly instructions (if applicable) can be found at http://manuals.medtronic.com/.

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:

In the United States and its territories:

METHOD	CYCLE	TEMPERATURE	EXPOSURE TIME	DRY TIME
Steam	Pre-Vacuum	270°F (132°C)	4 Minutes	30 Minutes
Steam	Gravity	250°F (121°C)	60 Minutes	30 Minutes

For Medical Facilities Located Outside the United States and its territories: 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.

METHOD	CYCLE	TEMPERATURE	EXPOSURE TIME	DRY TIME
Steam	Pre-Vacuum	273°F (134°C)	20 Minutes	30 Minutes
Steam	Gravity	273°F (134°C)	20 Minutes	30 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. Not all of the sterilization parameters are considered to be standard cycles according to the Food and Drug Administration (FDA). In the United States, use only sterilizer accessories that have been cleared by the FDA for the selected sterilization cycle parameters (time and temperature). Users should only use sterilizer accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared for use in their markets.

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.

Important Product Information *continued*

EC REP

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MRI INFORMATION

The CD HORIZON® Spinal System has not been evaluated for safety, heating, migration, or compatibility in the magnetic resonance environment.
Contact customer service or your sales representative for the most up-to-date version of the package insert.

Summary of Indications

PROGENIX® Putty and PROGENIX® Plus are intended for use as bone graft substitute for voids or gaps that are not intrinsic to the stability of the bony structure (i.e., spine, pelvis, and extremities). It is intended for treatment of surgically or traumatically created osseous defects. Additionally, PROGENIX® Putty and PROGENIX® Plus are intended for the augmentation of deficient maxillary and mandibular alveolar ridges and the treatment of oral/maxillofacial and dental intraosseous defects. Both PROGENIX® Putty and PROGENIX® Plus can be mixed with autograft. When used in spine, PROGENIX® Putty must be mixed with autograft.

MASTERGRAFT® Ceramic Scaffolds are cleared as bone void fillers for bony voids of the skeletal system (i.e., posterolateral spine, pelvis, ilium, and/or extremities). MASTERGRAFT® Granules, MASTERGRAFT® Putty, and MASTERGRAFT® Strip are also cleared as autogenous bone graft extenders. MASTERGRAFT® Granules, MASTERGRAFT® Mini Granules, and MASTERGRAFT® Putty are also cleared for use in bony voids or gaps to fill and/or augment dental oral/maxillofacial bony tissue.

The CAPSTONE® Spinal System is indicated for interbody fusion with autogenous bone graft in patients with Degenerative Disc Disease (DDD) at one or two levels from L2 to S1. These DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These implants may be implanted via an open or a minimally invasive posterior approach. Alternatively, these implants may also be implanted via an anterior and/or transforaminal approach. These implants are to be used with autogenous bone graft. These devices are intended to be used with supplemental fixation instrumentation, which has been cleared by the FDA for use in the lumbar spine.

The CLYDESDALE™ Spinal System is designed to be used with autogenous bone graft to facilitate interbody fusion and is intended for use with supplemental fixation systems cleared for use in the lumbar spine. The CLYDESDALE™ Spinal System is used for patients diagnosed with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These implants may be implanted via a minimally invasive lateral approach.

The SOVEREIGN™ Spinal System is indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These implants may be implanted via a laparoscopic or an open anterior approach. The SOVEREIGN™ device may be used as a stand-alone device or in conjunction with supplemental fixation. When used as a stand-alone device, the device is intended to be used with the three titanium alloy screws and the accompanying cover plate. If the physician chooses to use less than three or none of the provided screws, then additional supplemental fixation which has been cleared by the FDA for use in the lumbar spine must be used to augment stability. The accompanying cover plate MUST be used anytime the device is used with any number of screws.

The T2 ALTITUDE™ Expandable Corpectomy System is a vertebral body replacement system intended for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma (i.e., fracture). The T2 ALTITUDE™ Expandable Centerpiece may be used with or without optional modular endcaps which accommodate individual anatomic requirements. The device is to be used with supplemental fixation. Specifically, the construct is to be used with the VANTAGE® Anterior Fixation System, the TSRH® Spinal System, the CD HORIZON®Spinal System, or their successors. Additionally, the T2 ALTITUDE™ Expandable Corpectomy System is intended to be used with allograft and/or autograft.

Notes

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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.