Medtronic
SOFAMOR DANEK

CD HORIZON® LEGACY™ 5.5

Spinal System–Deformity Surgical Technique

Hook technique described by:

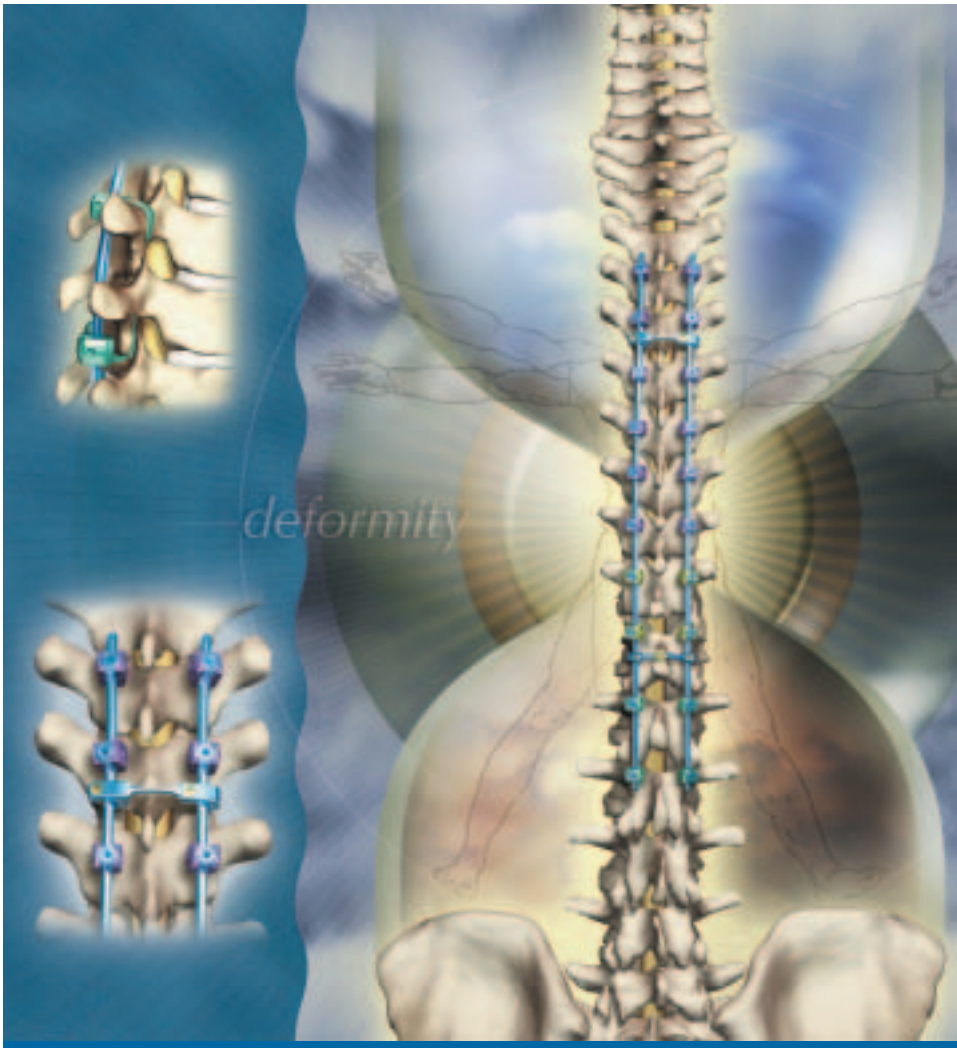
Pierre Lascombes, M.D.
Professor at the Nancy
University School of Medicine

Orthopaedic Pediatric Surgery
Chief, Pediatric Surgery Service
Children's Hospital, CHU of
Nancy, France

Screw technique described by:

Lawrence G. Lenke, M.D.
The Jerome J. Gilden Professor
of Orthopaedic Surgery
Co-chief Adult/Pediatric Spine
Washington University
School of Medicine

Chief, Spinal Service
Shriners Hospital for Children
St. Louis, Missouri



A Masterpiece In Medical Device Design

C4 TECHNOLOGY
REVERSE-ANGLE THREAD FORM

Table of Contents

Introduction

Dear Colleagues:

The CD HORIZON LEGACY 5.5 Spinal System is the next generation in top-loading, top-tightening systems that support a spine surgeon's quest for optimal deformity correction. Since the introduction of the original CD instrumentation, surgeon-driven technologic advances have been partner to superior correction.

Deformity correction requires a comprehensive selection of implants and well-designed instruments. The CD HORIZON LEGACY 5.5 Spinal System has a wide choice of implants that support posterior corrective techniques.

Evolving from our CD heritage, CD HORIZON LEGACY 5.5 Spinal System hooks come in sizes and blade geometries to optimize fit to each patient's anatomy.

The CD HORIZON LEGACY 5.5 Spinal System allows for different philosophies of rod reduction, from patented, state-of-the-art rod reducers to reduction implants, multi axial screws, and hooks.

The CD HORIZON LEGACY 5.5 Spinal System is a complete and comprehensive universal system that offers significant performance and ease of use benefits and brings innovation, versatility, and reliability to every surgical case.

Sincerely,

Lawrence G. Lenke, M.D.

Pierre Lascombes, M.D.

Implants

G4 Technology is the fourth generation closure technology for CD HORIZON instrumentation. The set screw has been designed to thread easier and hold stronger. The reverse-angle thread locking mechanism reverses the force vectors a set screw normally exerts on the side walls of implants during final tightening.

Titanium screws are color-coded by screw diameter.

LEGACY 5.5mm
Fixed Angle Screw
(6.0mm)

Color-Coding Reference
NOTE: Color-coding available for titanium implants only.

4.5mm 5.0mm 5.5mm 6.5mm 7.5mm

Axial Connector
(84509HT)

Domino Connector
(84505HT)

5.5mm Rod
(869-021)

Hook Implants

	HOOK TYPE	VERTEBRAL POSTERIOR ELEMENT PLACEMENT	BLADE DIRECTION	REGION OF SPINE	DESIGN FEATURES
 7541103  7541203	PEDICLE HOOK	ARTICULAR PROCESS	↑	T1 - T10	• Bifid blade grasps thoracic pedicle for increased stability. • Lipped design can improve hook stability.
 7541113  7541213	WIDE BLADE HOOK	LAMINA TRANSVERSE PROCESS	↕ ↕	T1 - L5 T1 - L5	• Wider blade width distributes forces evenly over a wider aspect of bone. • Lipped design can improve hook stability on the lamina.
 7541123  7541223	NARROW BLADE HOOK	LAMINA TRANSVERSE PROCESS	↕ ↕	T1 - L5 T1 - L5	• Narrower blade width minimizes metal volume in the spinal canal. • Lipped design can improve stability on the lamina.
 7541143	THORACIC SUPRALAMINAR HOOK	LAMINA TRANSVERSE PROCESS	↓	T1 - T10	• Hook throat ramp prevents blade from pistoning into the spinal canal.
 7541188	THORACIC ANGLED HOOK	LAMINA TRANSVERSE PROCESS	↓	T1 - T3	• Better aligns hook saddles for a pediculo-laminar claw in the upper thoracic spine.
 7541163	LUMBAR INFRALAMINAR HOOK	LAMINA TRANSVERSE PROCESS	↑	T10 - L2	• Blade geometry designed to better fit the lumbar lamina. • May obviate the need to remove the ligamentum.
 7541173	EXTENDED BODY HOOK	LAMINA TRANSVERSE PROCESS	↕ ↕	T1 - L5 T1 - L5	• Can correct anatomic misalignment between two laminae in the dorso-ventral plane.
 7541198	OFFSET HOOK	LAMINA TRANSVERSE PROCESS	↕ ↕	T1 - L5 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.

Instruments

Hook Preparation

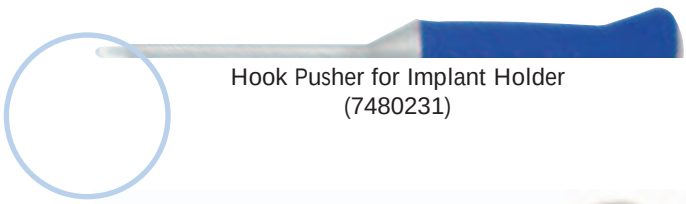
Wide Blade Laminar Elevator
(7480220)

Pedicle Elevator
(7480225)

Narrow Blade Laminar Elevator
(7480221)

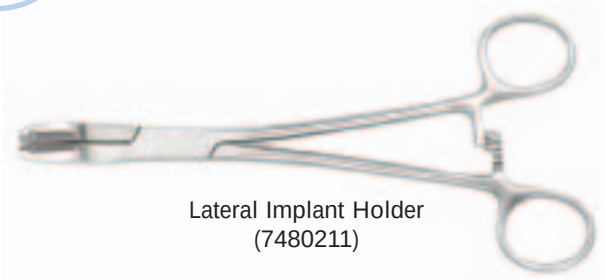
Transverse Process Elevator
(7480222)

Hook Placement

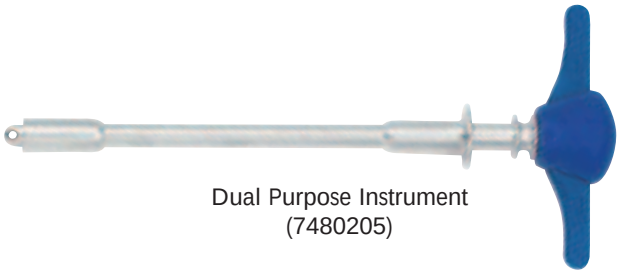


Hook Pusher for Implant Holder
(7480231)

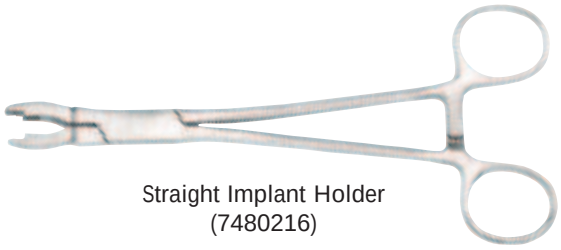
Implant Pusher for Dual Purpose Instrument
(7480230)



Lateral Implant Holder
(7480211)



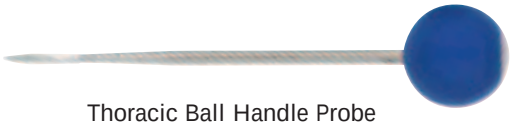
Dual Purpose Instrument
(7480205)



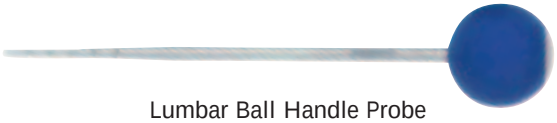
Straight Implant Holder
(7480216)

Instruments

Screw Preparation



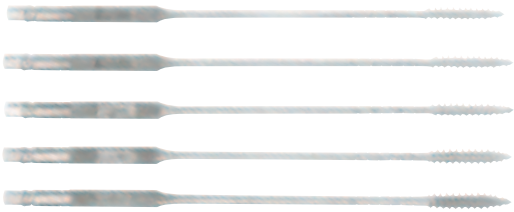
Thoracic Ball Handle Probe
(7480112)



Lumbar Ball Handle Probe
(7480110)

In-Line Round Awl
(7480104)

Quick Connect Ratcheting Handle
(9339082)



4.0mm Tap (8684000)
4.5mm Tap (8684500)
5.5mm Tap (836-015)
6.5mm Tap (836-016)
7.5mm Tap (836-017)

Dual Ended Feeler Probe
(7480100)

Sounding/Feeler Probe
(8572102)

Screw Placement

Fixed Angle Screwdriver
(7480280)

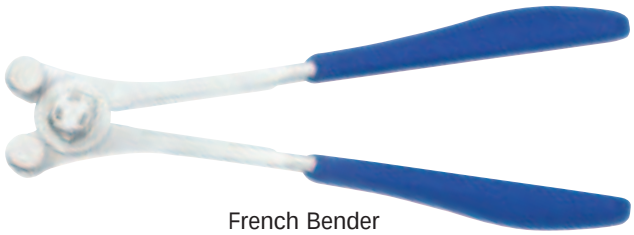
Multi Axial Screwdriver
(7480113)

Self-Retaining Screwdriver
(7480117)

Instruments

Rod Contouring

Rod Template
(808-575)



French Bender
(7480162)

Rod Insertion

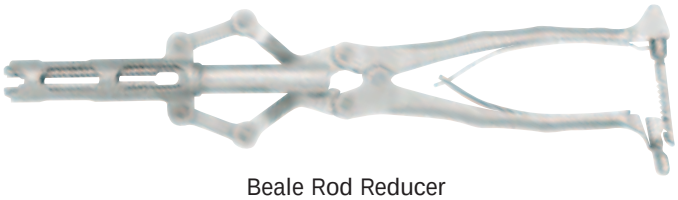
Rod Pusher
(7480235)

C-Shaped Rod Pusher
(7480236)

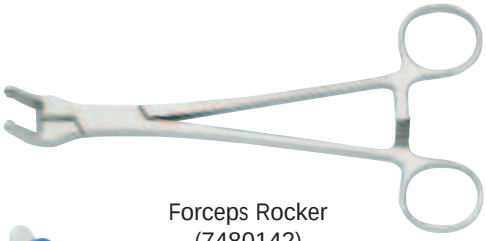
Rod Inserter
(7480126)

Instruments

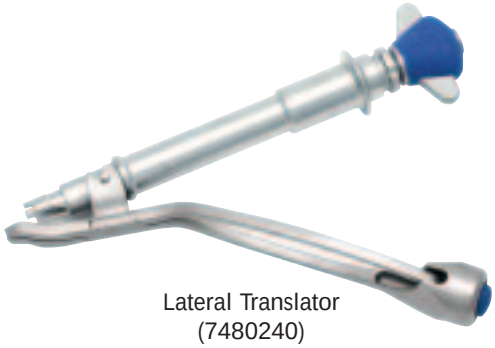
Rod Reduction



Beale Rod Reducer
(7480134)

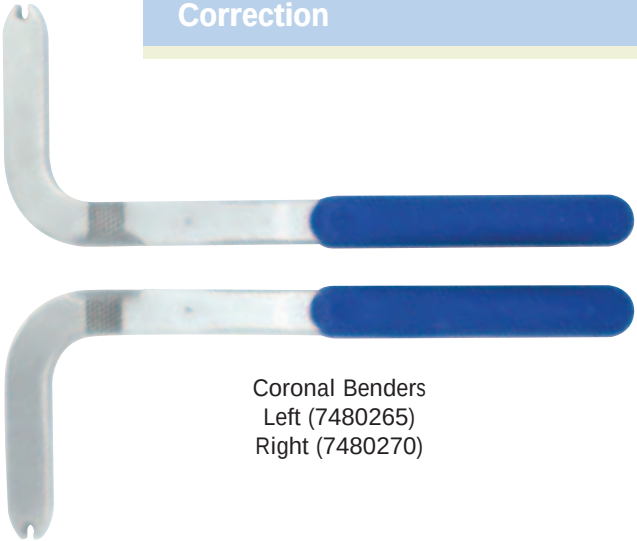


Forceps Rocker
(7480142)



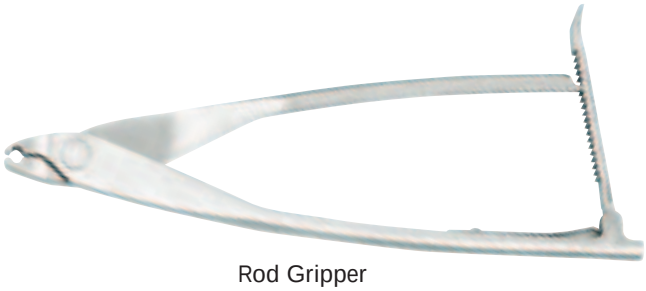
Lateral Translator
(7480240)
(7480245)

Correction



Coronal Benders
Left (7480265)
Right (7480270)

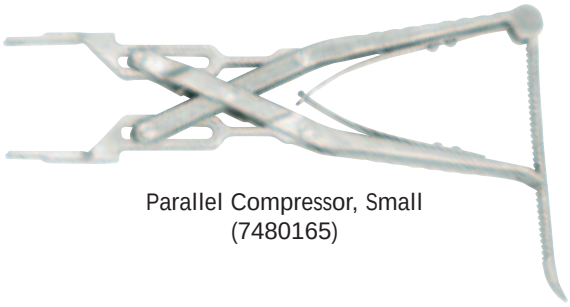
In-Situ Benders
Left (7480255)
Right (7480260)



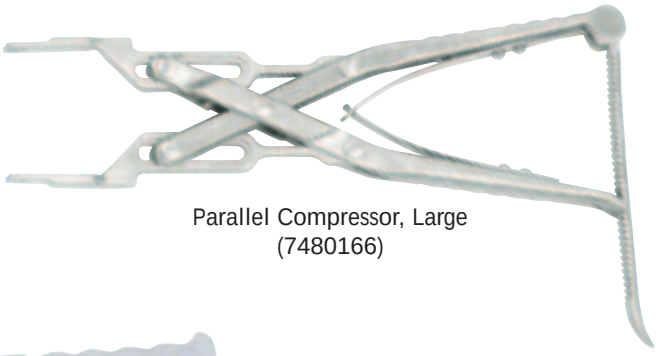
Rod Gripper
(7480175)

Instruments

Compression and Distraction



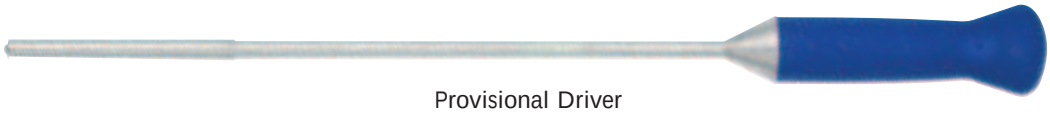
Parallel Compressor, Small
(7480165)



Parallel Compressor, Large
(7480166)

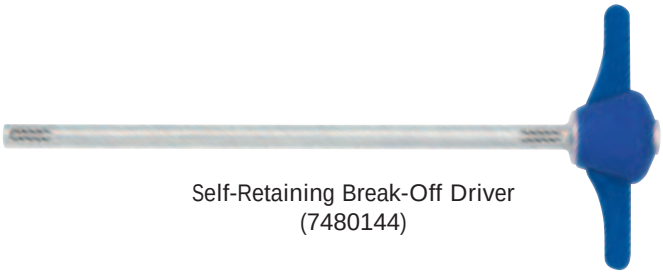
Distractor
(7480171)

Final Tightening/Set Screws



Provisional Driver
(7480131)

Counter Torque
(7480150)



Self-Retaining Break-Off Driver
(7480144)

T27 Obturator
(7480154)

Dual Ended Plug Starter
(7480122)

Instruments

X10 CROSSLINK® Plate Implants and Instruments

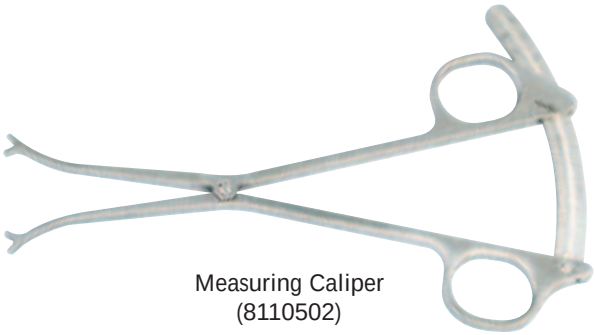
X10 CROSSLINK® Multi-Span™ Plate

X10 CROSSLINK® Fixed Plate

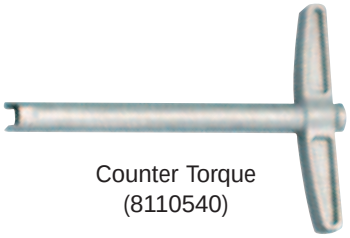
Measuring Credit Card
(8110501)

Implant Positioners
(808-545) (optional)

7/32" Torque-Limiting Set Screwdriver
(8110535)



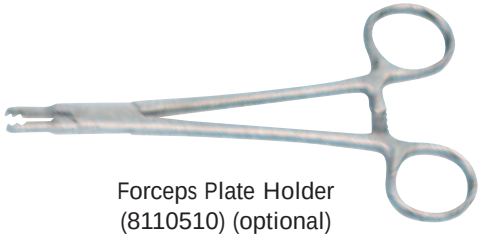
Measuring Caliper
(8110502)



Counter Torque
(8110540)

45° In Line Plate Holder
(8110511)

Plate Benders
(8110525)



Forceps Plate Holder
(8110510) (optional)

3.0mm Hex Head Shaft, Removal Driver
(8110530)

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 adolescent 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 1** 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 2**). **Figure 3** shows a construct treating neuromuscular scoliosis from T2 to S1.

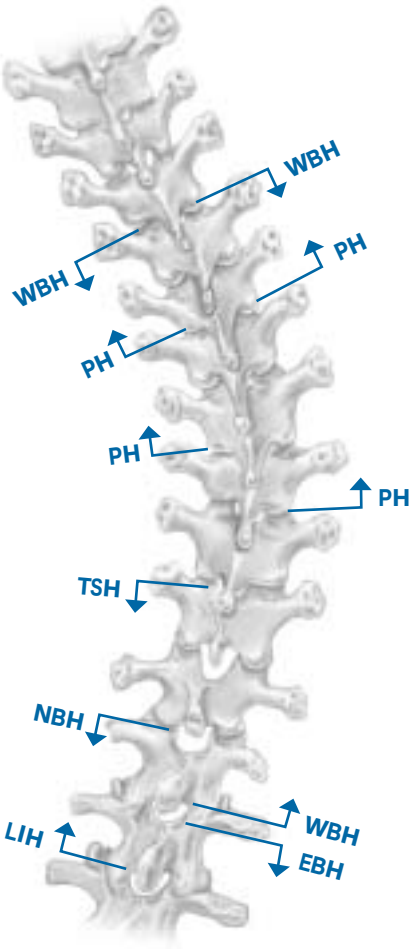


Figure 1

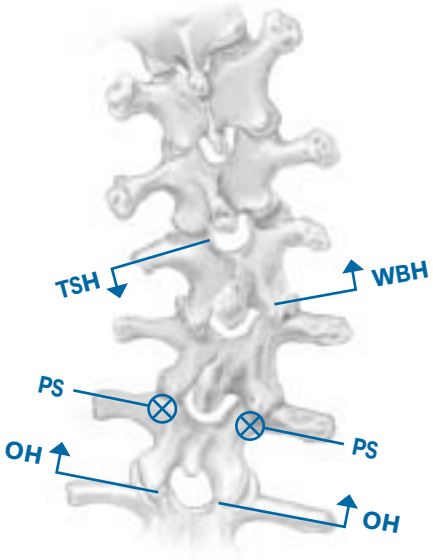


Figure 2

Hook Construct Legend	
EBH	= Extended Body Hook
LIH	= Lumbar Infralaminar Hook
NBH	= Narrow Blade Hook
OH	= Offset Hook
PH	= Pedicle Hook
PS ⊗	= Pedicle Screw
TAH	= Thoracic Angled Hook
TSH	= Thoracic Supralaminar Hook
WBH	= Wide Blade Hook
↓	= Up-Going Hook

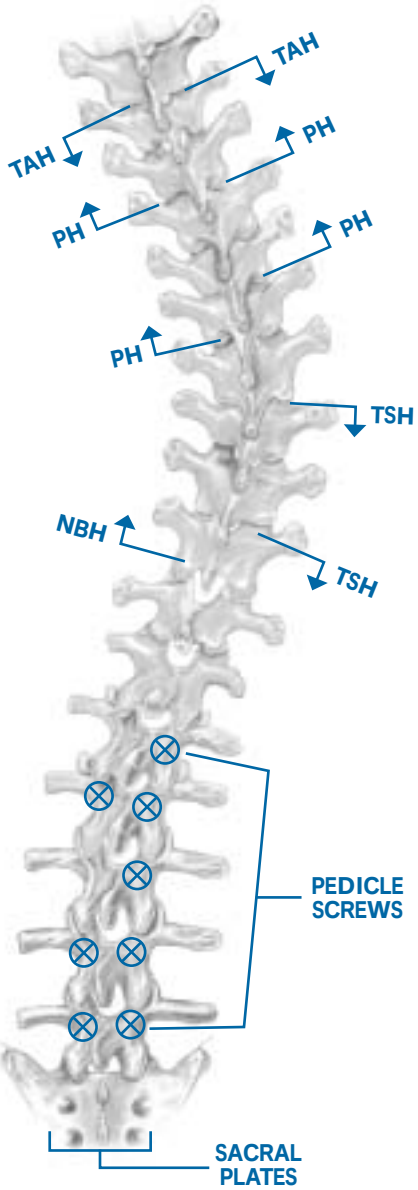


Figure 3

Hook Site Preparation/Options/Insertion

The CD HORIZON LEGACY 5.5mm Spinal System offers a number of top-loading hooks of different anatomic shapes and sizes (see hook implants chart, page 4). Any CD HORIZON LEGACY 5.5mm Spinal System hook may be treated as a closed hook by simply placing the set screw into the hook prior to insertion of the rod. The surgeon must choose the appropriate hook based on the individual patient's anatomy, deformity degree and type, method of correction chosen, and amount of compression/distraction that will be needed to provide proper and stable purchase of the implants.

Several different instruments can be used for hook insertion: for example, the Dual Purpose Instrument combined with the Hook Pusher (**Figure 4**) or the Straight or Lateral Hook Holder combined with the captive Hook Pusher (**Figure 5**).

Figure 4

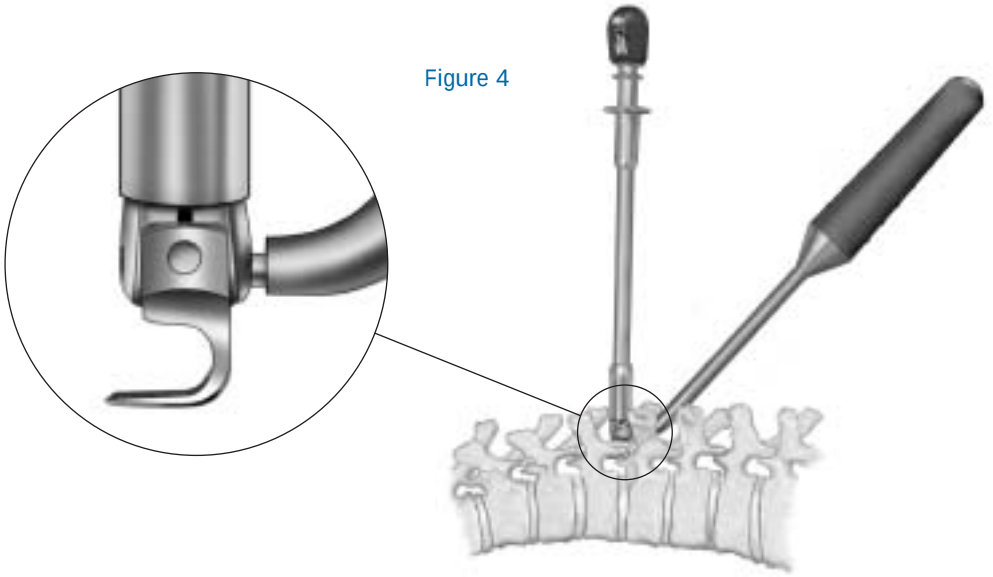
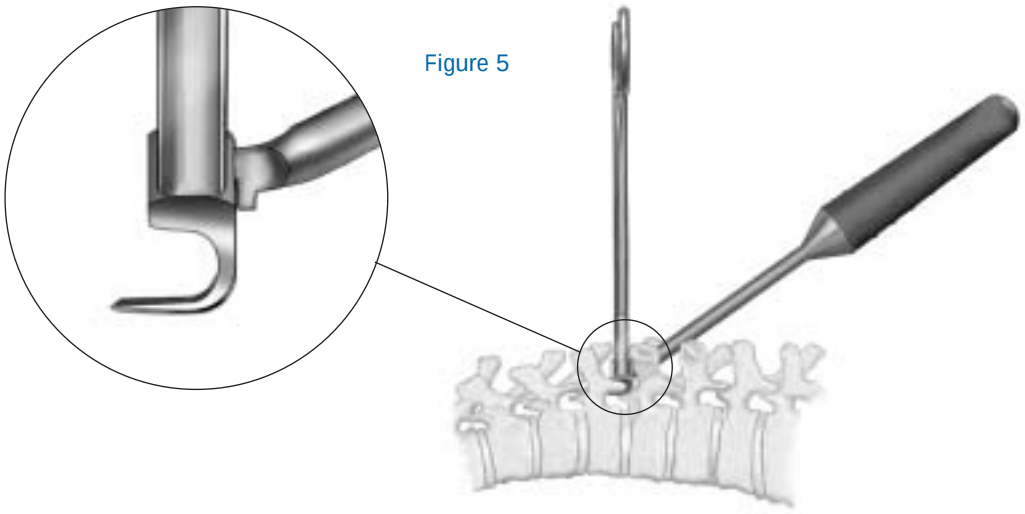


Figure 5



Hook Site Preparation/Options/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 6**). Once the pedicle has been clearly identified with the help of the Pedicle Elevator (**Figure 7**), the hook may be inserted.

If needed, a mallet can be used to impact the Pedicle Hook. It is important that the Pedicle Hook is placed into the joint cavity and is not splitting the inferior articular process (**Figures 8a and 8b**).

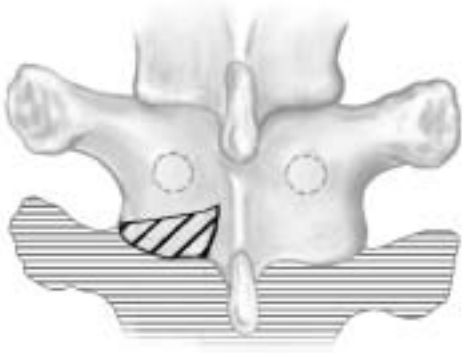


Figure 6

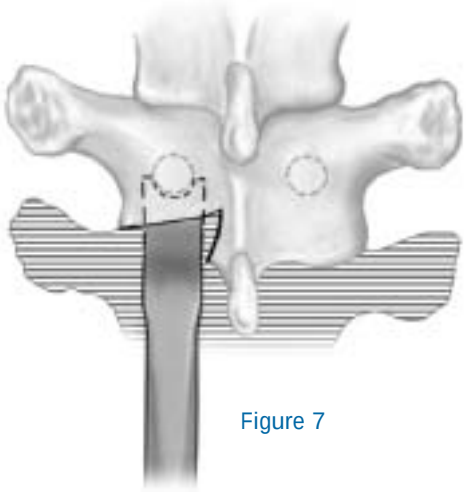
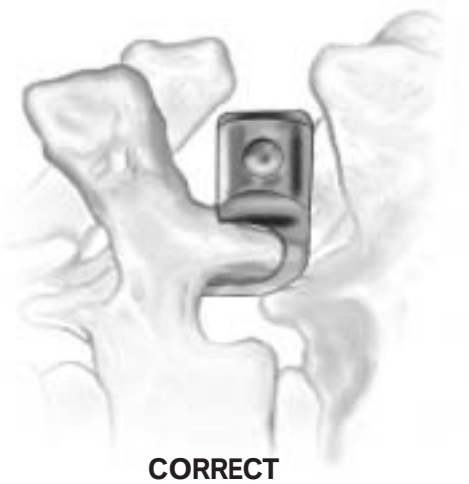
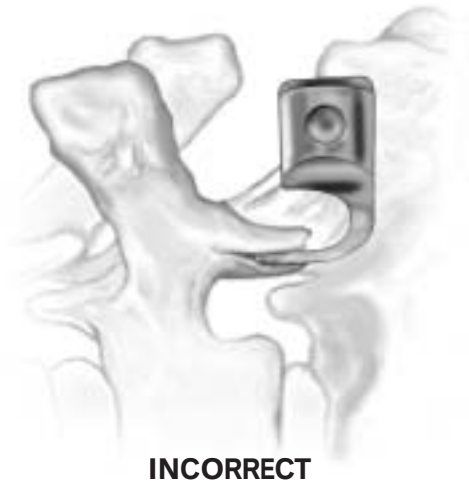


Figure 7



CORRECT

Figure 8a



INCORRECT

Figure 8b

Hook Site Preparation/Options/Placement (cont.)

Transverse Process Hook

This is generally a Wide Blade Hook and is typically used in a pedicle-transverse claw construct as a caudal (down-going) hook (**Figure 9**). 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 joint. An Implant Holder is used to insert this hook.

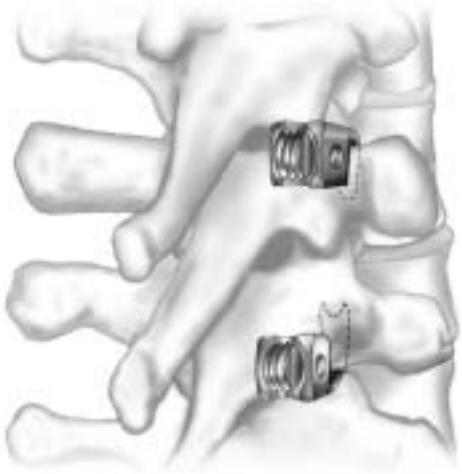


Figure 9

Hook Site Preparation/Options/Placement (cont.)

Laminar Hooks:

Thoracic Supralaminar Hook

The direction of this hook is always caudal (down-going). A partial or total division of the spinous process directly above the vertebra to be instrumented (thoracic vertebra) may be performed. A division and/or partial removal of the ligamentum flavum and a small laminotomy are carried out on the superior lamina. The amount of bone removed from the lamina may vary depending on the size of the hook blade and throat angle chosen. The upper edge of the lamina below may be resected to ease the placement of this hook. The Laminar Elevator may be used to check the space between laminar and peridural structures (**Figure 10**). Two sizes of Laminar Elevators are available depending on the size of the lamina and thus the size of the hook blade: Narrow or Wide Blade. An Implant Holder is typically used to insert the hook (Dual Purpose Instrument or Straight/Lateral Implant Holders) when placed on the superior lamina (**Figure 11**).

Lumbar Infralaminar Hook

This hook is always inserted in the cephalad direction (up-going) and is generally used at T10 or below. With this hook type, the ligamentum flavum is partially removed or separated from the inferior surface of the lamina using the Laminar Elevator, keeping the bone intact, if possible (**Figures 12a and 12b**). An Implant Holder is used to insert the hook.

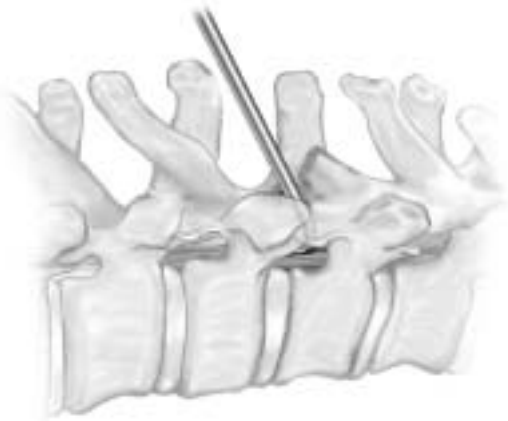


Figure 10

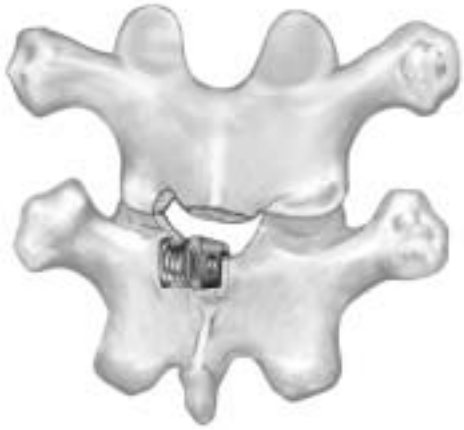


Figure 11

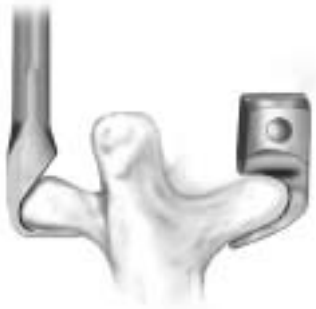


Figure 12a

Figure 12b

Decortication

Once inserted, laminar hooks are not very stable prior to rod insertion. Therefore, it is recommended to remove them and keep them on the staging module (**Figure 13**).

At this point in the surgery, bilateral partial facetectomies are carried out (**Figure 14**). 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.

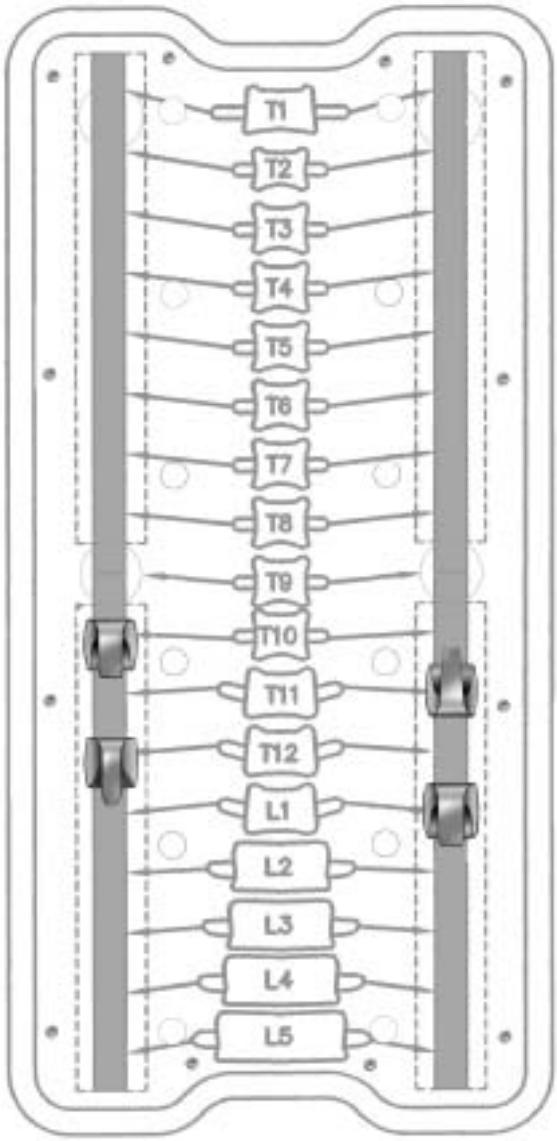


Figure 13

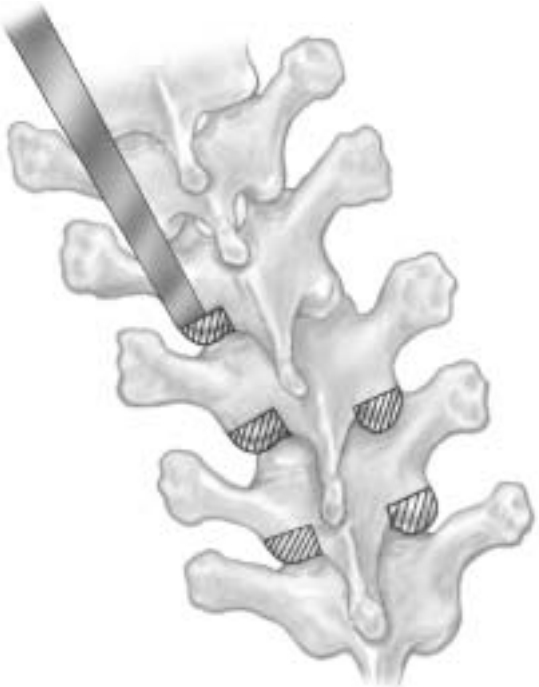


Figure 14

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 (2 to 3cm 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 15**). 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.

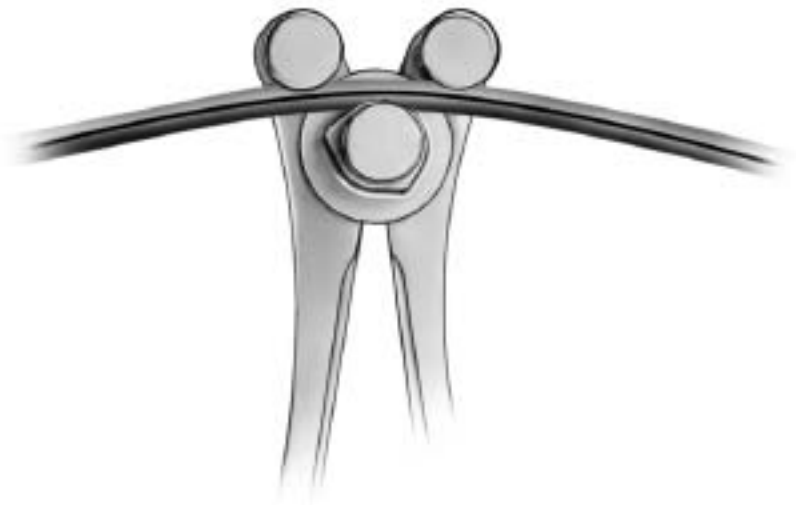


Figure 15

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 16a and 16b**). A rod holder may be used to assist in placing the rod. Using the Dual Ended Plug Starter, set screws are placed into the first implants where the rod seats perfectly. The Rod Pusher may be used to push the rod down in order to place a set screw and/or, due to its C-shape, to push the hook into its correct position (**Figure 17**).

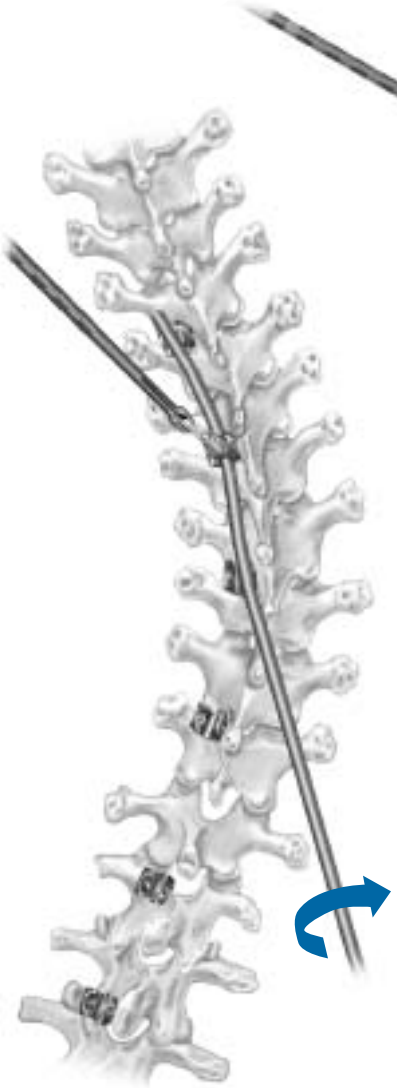


Figure 16a

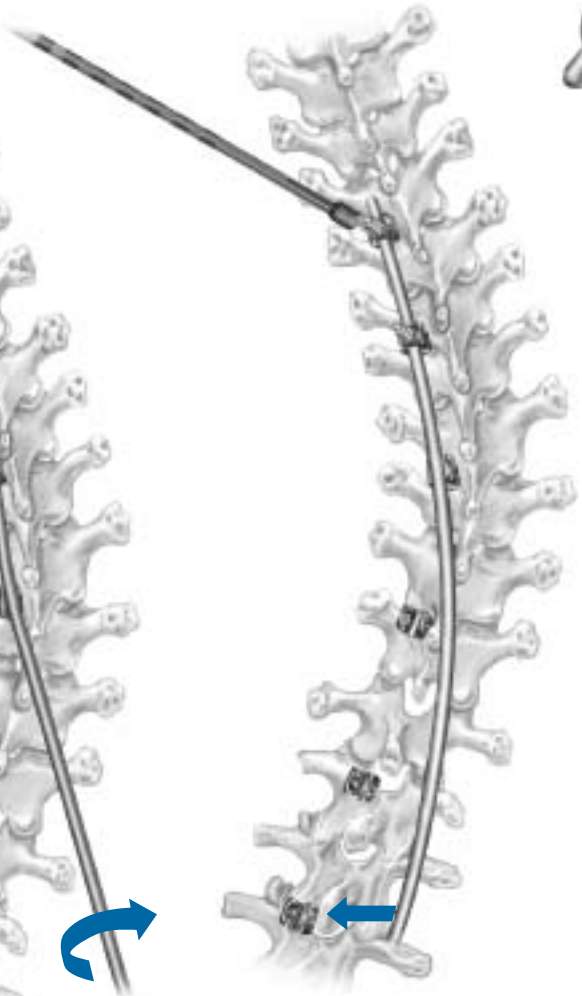


Figure 16b

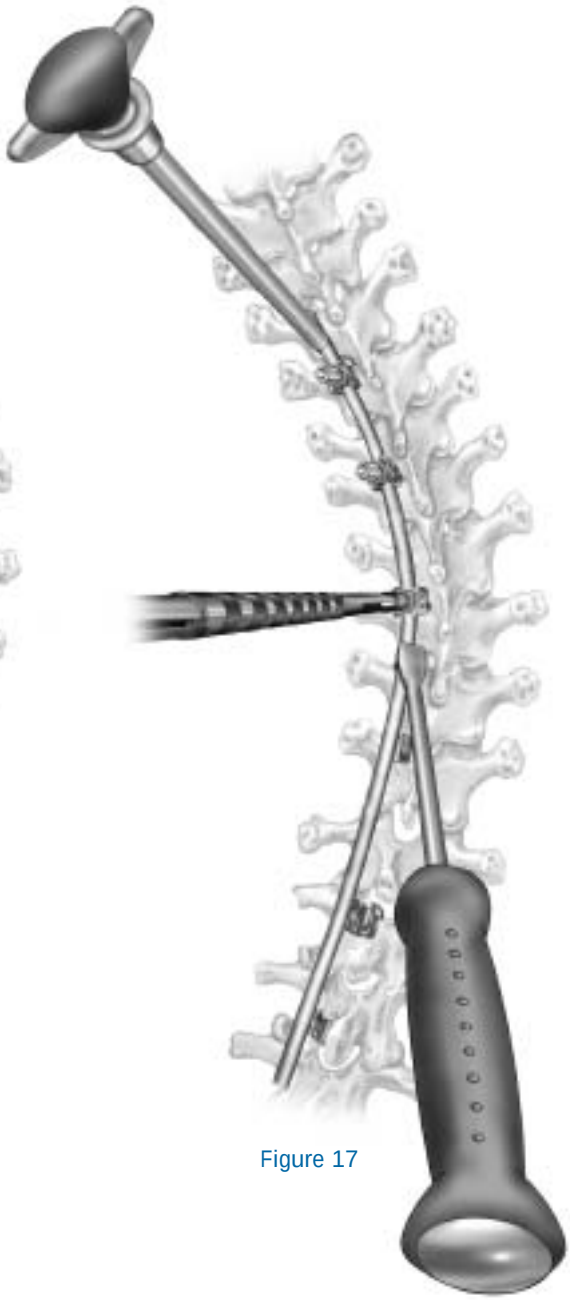


Figure 17

Rod Reduction

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. Depending on the method and instruments used to reduce the rod, the set screws will be inserted with either the Plug Starter or the Provisional Driver. The G4 Technology Reverse-Angle Thread Form, patented by Medtronic Sofamor Danek USA, Inc., simplifies the set screw insertion process.

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 the Forceps tips facing the same direction as the hook blade (**Figure 18**). This angle will avoid dislodgment of the hook. Lever the Forceps Rocker backwards over the rod to seat the rod into the saddle of the implant. The levering action allows the rod to be fully seated in the saddle of the implant. The Dual Ended Plug Starter is then used to place the set screw (**Figure 19**).

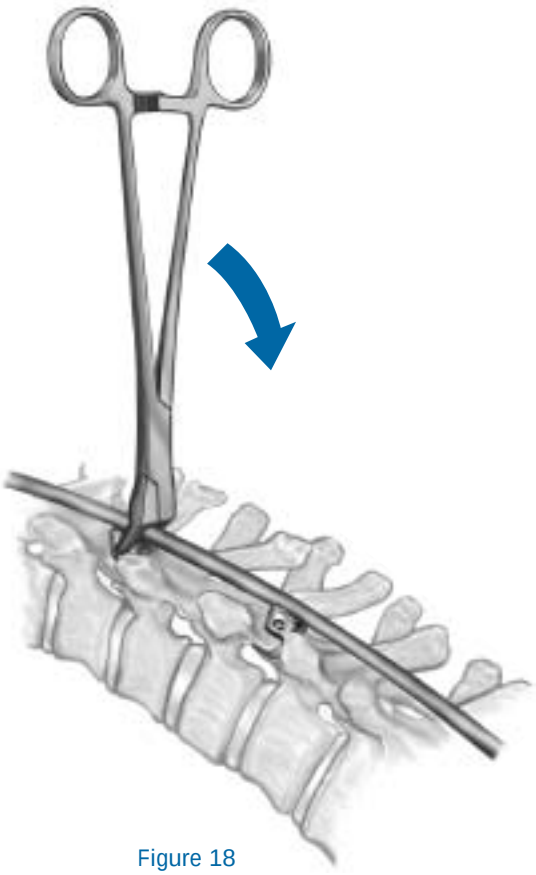


Figure 18

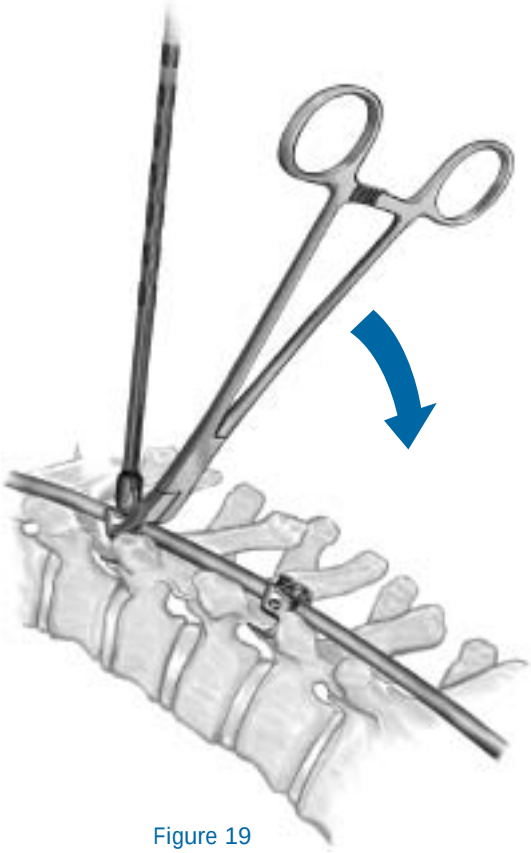


Figure 19

Rod Reduction (cont.)

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 reducer is placed over the implant with the ratchet portion parallel to the rod. The reducer is then slowly closed by squeezing the handles together, allowing the attached sleeve to slide down and seat the rod into the saddle of the implant (**Figure 20**). A set screw is then placed through the set screw tube of the reducer using the Provisional Driver (**Figure 21**).

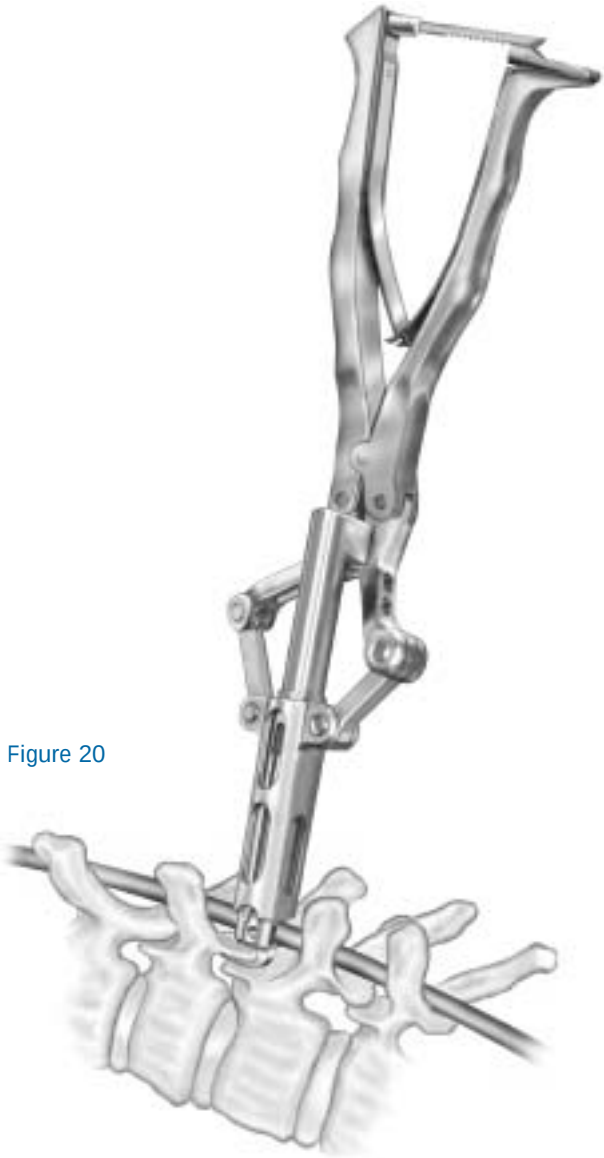


Figure 20

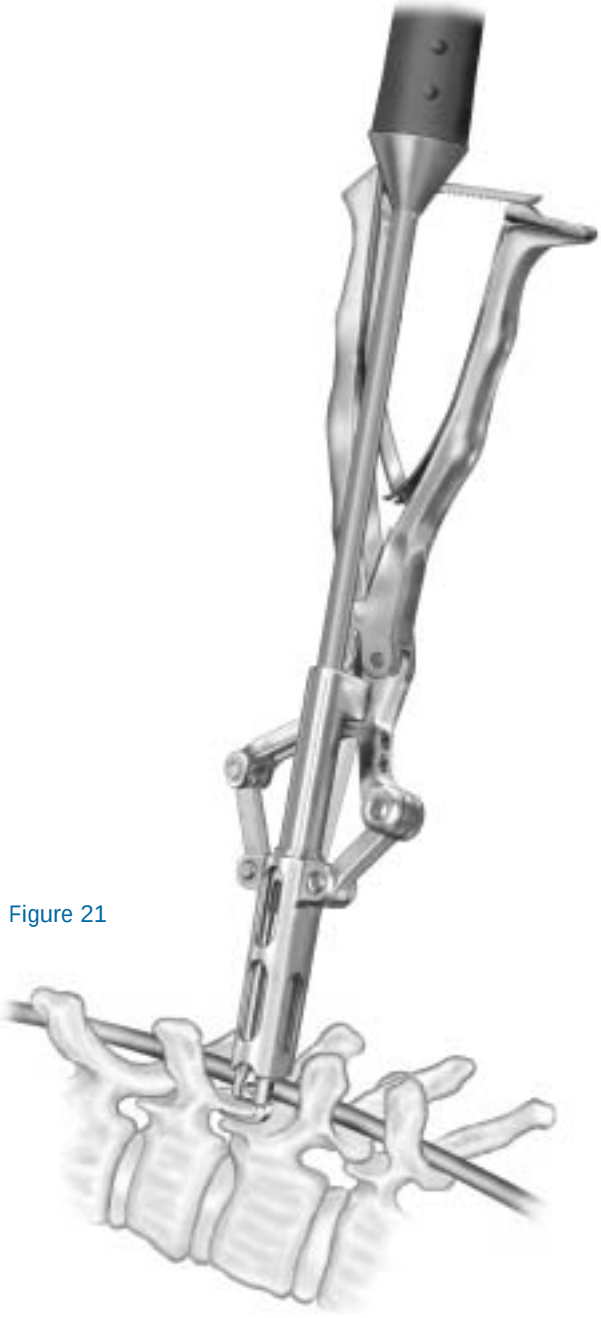


Figure 21

Rod Reduction (cont.)

Lateral Translator

If the rod lies medial or lateral to the implant, the Translator provides translational capabilities. Attach the tines of the Translator Implant Holder to the side of the implant (**Figure 22**). To assemble the Translator Rod Pusher with the Translator Implant Holder, insert the coupling sleeve axles of the Translator in the Implant Holder guide by pulling up on the spring-loaded tube (**Figure 23**).

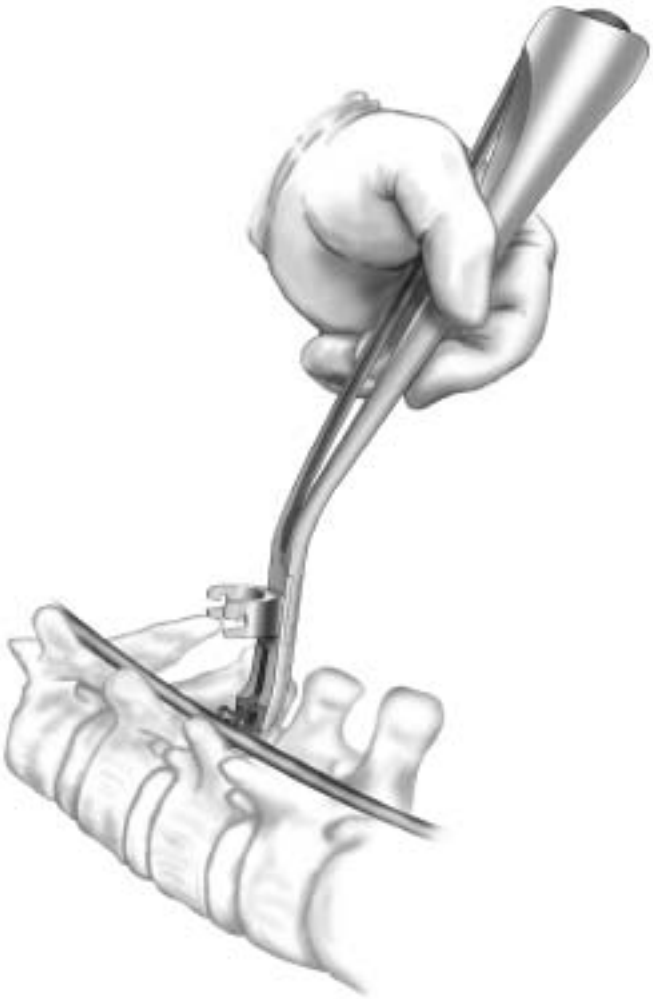


Figure 22

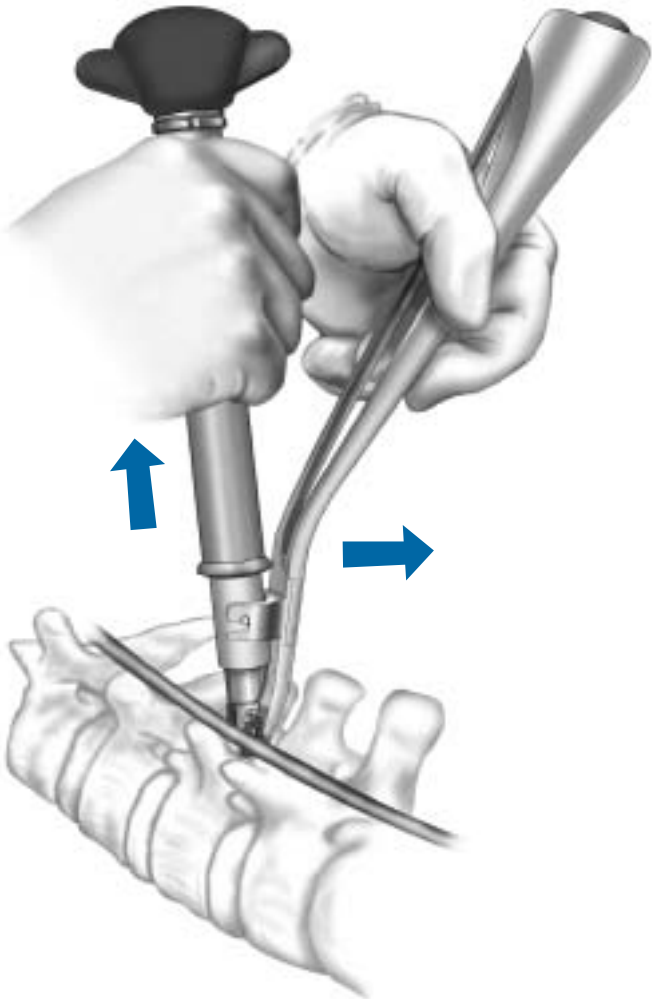


Figure 23

Rod Reduction (cont.)

The spring-loaded design of the Translator Rod Pusher allows translation of the rod until it is over the head of the implant (**Figure 24**).

With the rod over the implant, turn the T-handle at the top of the Translator Rod Pusher clockwise until the rod is fully seated into the saddle of the implant (**Figure 25**). Using the Provisional Driver, slide a set screw down the center of the Translator Rod Pusher and tighten.

When the rod lies far lateral to the implant, in-situ bending of the rod can be carried out to bring the rod closer to the implant and allow use of the Translator.

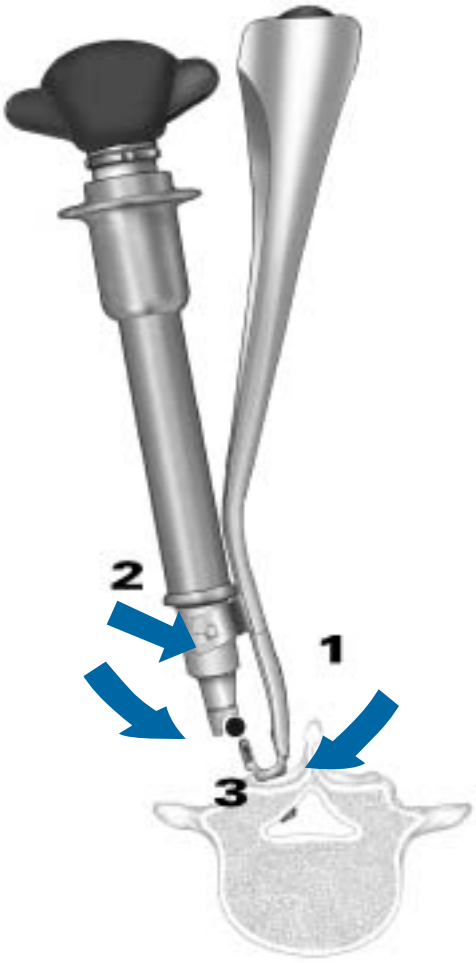


Figure 24

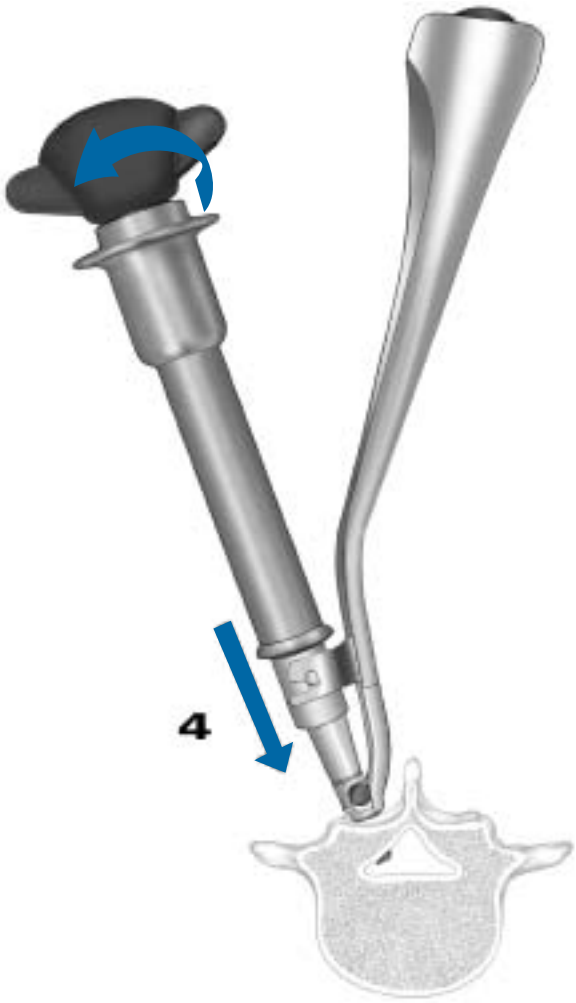


Figure 25

Deformity Correction

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

Rod Rotation

Once the contoured rod and all of the set screws have been placed, the rod is ready to be rotated into its final position. The rotation must be done slowly in order to prevent rapid neurologic changes and/or injury to the spinal cord. The rotation is done using two Rod Grippers (**Figure 26**). It is important to monitor the interval hooks, which tend to back out during rod rotation. Several methods are proposed: use of the C-Shaped Rod Pusher, the placement of C-rings on the rod prior to rotation, placement of the Rod Gripper on the rod just below the hook to buttress it, or the use of a hook stabilizer instrument, which is available upon special ordering request.

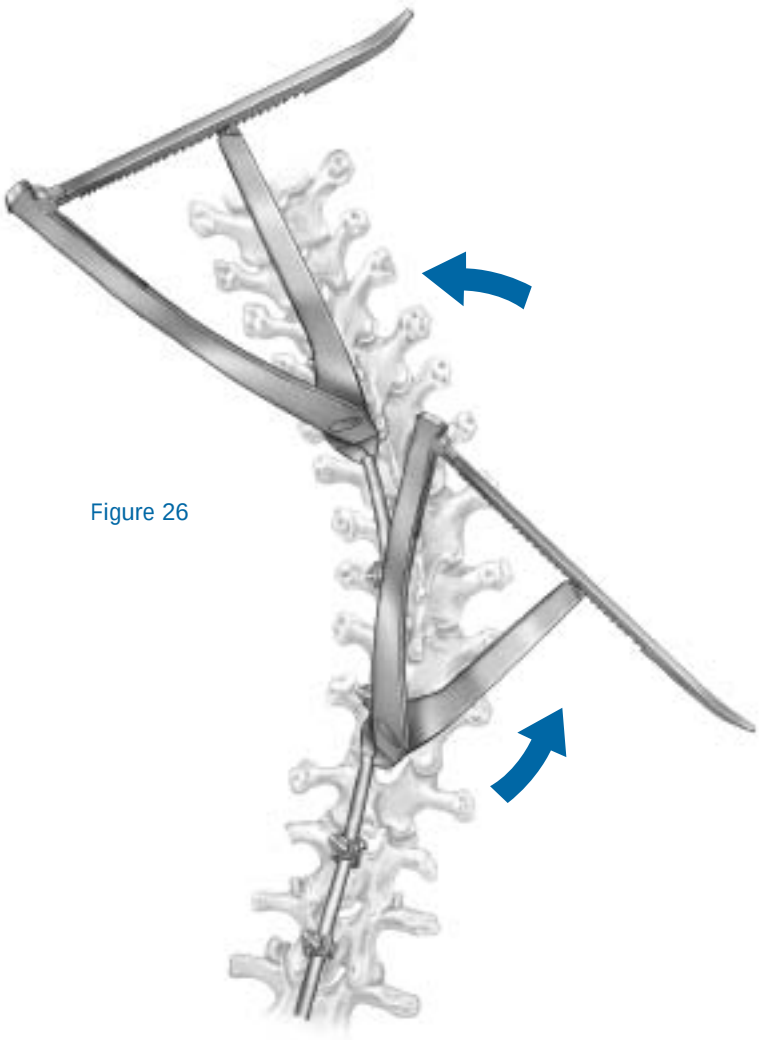


Figure 26

Deformity Correction (cont.)

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

In-Situ Bending

In-Situ Benders may be used for correction and final adjustment of the rod in the sagittal and/or coronal plane. The rod is bent in small incremental steps using the two bender tips positioned near each other on the rod (**Figure 27**).

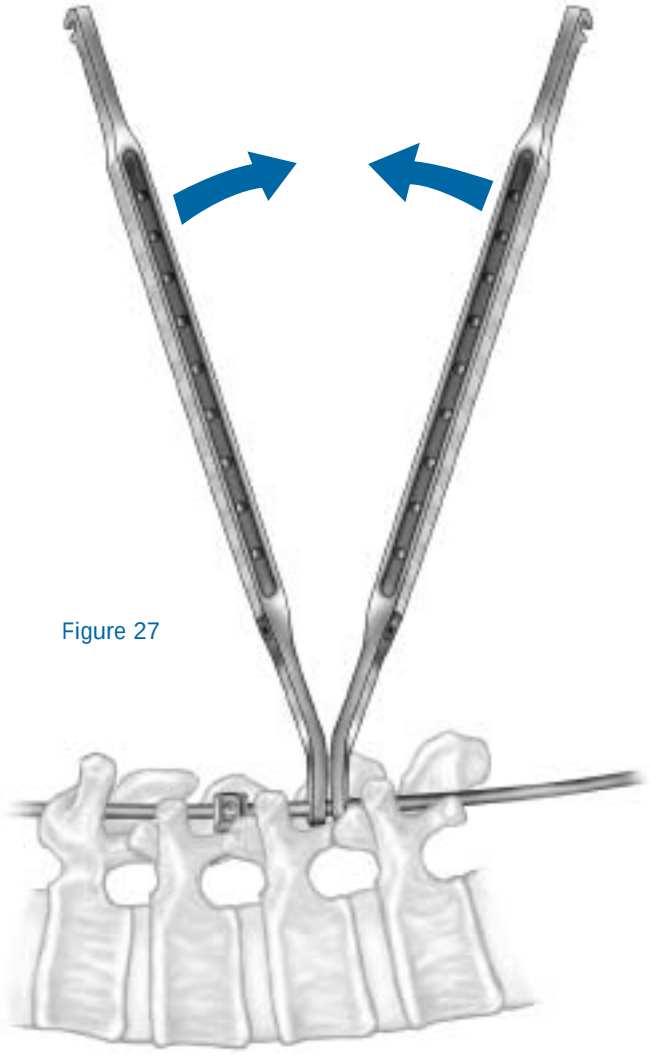


Figure 27

Compression/Distraction

Once the rod is secured in the implants, distraction and/or compression are performed to place the hooks in their final position. The Parallel Compressor, Distractor, Provisional Driver, and Rod Gripper are used to carry out these maneuvers. It is recommended to use the Rod Gripper as a stop for distraction maneuvers rather than the implant (**Figure 28**), with the exception of the inverted claw. Compression maneuvers are most often carried out directly on two hooks (**Figure 29**). Care should be taken to ensure that the foot of either instrument is placed against the implant body and not against the set screw. After these maneuvers are complete, the set screw is tightened with the Provisional Driver.

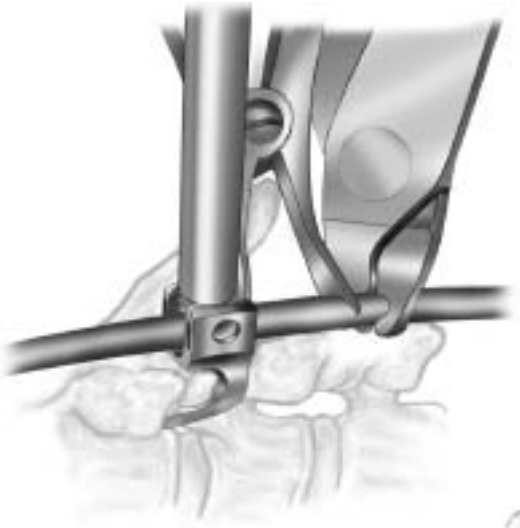


Figure 28

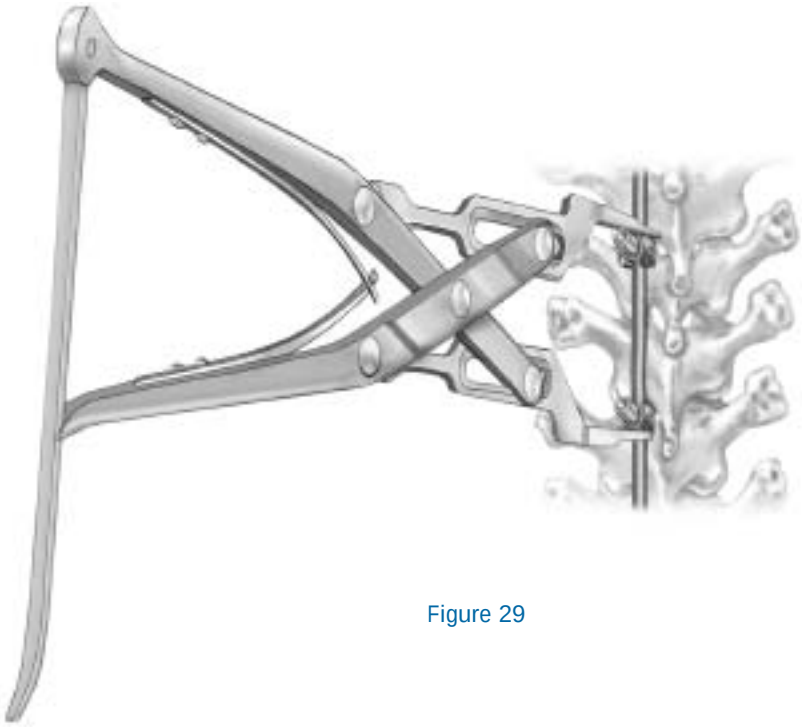


Figure 29

Stabilization/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 (shown on page 17), 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 30**). Once the rod is secured to the implants, distraction and/or compression are performed to place the hooks in their final position. Refer to Step 9 to ensure the appropriate steps are followed.

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

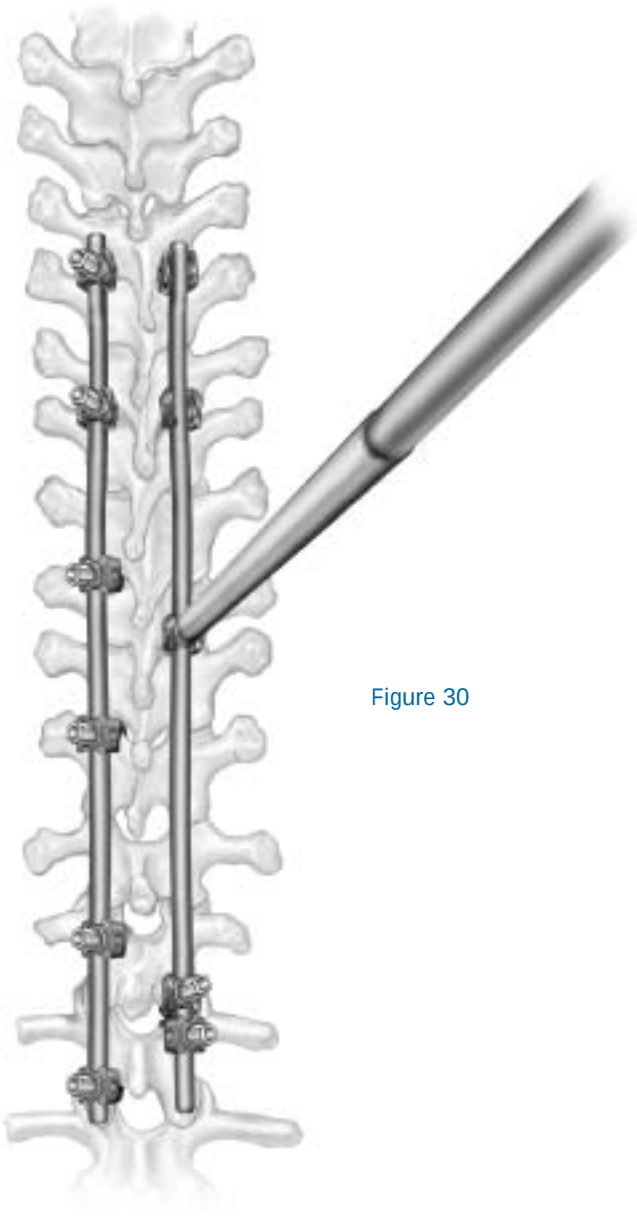


Figure 30

Final Tightening

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

Set Screw Break-Off

The Counter Torque instrument is placed over the implant and the rod (**Figure 31**). The Break-Off Driver is then placed through the cannulated Counter Torque. The Self-Retaining Break-Off Driver provides adequate leverage for breaking the set screw heads (between 9 and 11 Nm). 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 32**). The broken-off part of the set screw is captured in the cannulated portion of the Self-Retaining Break-Off Driver. Following final tightening, the sheared-off portions of the set screws accumulated in the driver are removed using the T27 Obturator shaft (**Figure 33**).

Non Break-Off Set Screws

The CD HORIZON LEGACY 5.5 Spinal System offers the possibility of using Non Break-Off Set Screws. The final tightening maneuver is equivalent to that performed on the Break-Off Set Screws using the Counter Torque to avoid torquing of the construct. A torque wrench screwdriver is used to tighten the Non Break-Off Set Screws and to ensure a consistent torque between 9 and 11 Nm.

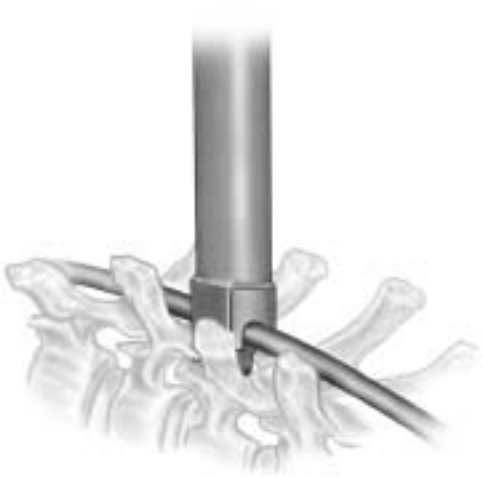


Figure 31

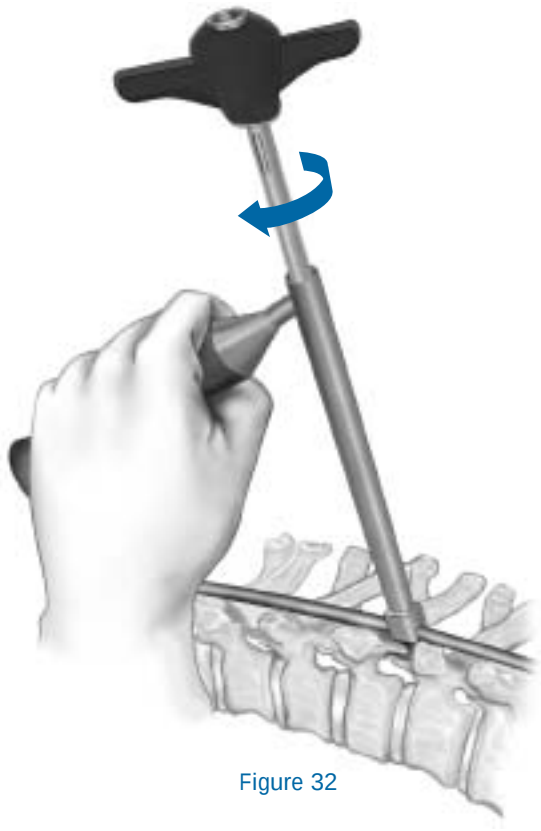


Figure 32

Figure 33

Transverse Link Placement/Closure

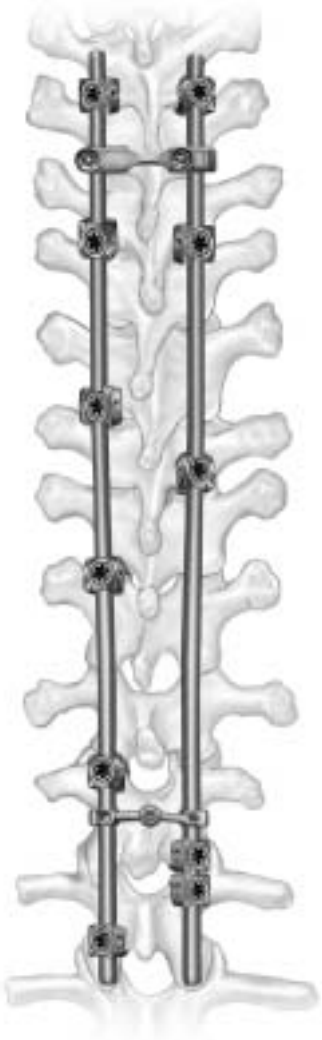
Once final tightening of the set screws is completed, it is mandatory that transverse links be placed to provide rotational stability to the construct. A framed construct resists rotational forces. Ideally, the transverse links should be placed close to the construct extremities. Three transverse link systems are available: the DLT System (EU), the Low Profile CROSSLINK® Plate, and the X10 CROSSLINK® Plate.

The DLT System is available for compression and distraction, due to its free hook. It is placed on the rod with the help of the DLT Holder, and the hooks are then pushed either by the Compressor or the Spreader, depending on the chosen model.

The X10 CROSSLINK Plate is low profile and ideal for use in the thoracic region (**Figure 34**). When using the X10 CROSSLINK Plate, please refer to the surgical technique.

Following transverse link placement, wound closure is performed in the customary manner.

Figure 34



Pedicle Screw Correction Technique

Dear Colleagues:

Thoracic and lumbar pedicle screws offer a benefit over hooks or sublaminar wires in several ways: Three-column fixation allows better pull-out strength and greater control in the sagittal, coronal, and rotational planes due to increased stability to axial, bending, and rotational forces. Additionally, fewer motion segments may need to be arthrodesed, which should lessen or obviate the need for postoperative bracing. Other benefits include the ability to provide secure fixation following a laminectomy, when the posterior elements are otherwise incompetent, and the ability to treat three-column injuries with adequate stability. Furthermore, any correction technique is possible when using pedicle screws as anchors.

Overall, in spinal deformity, pedicle screw fixation has shown greater three-dimensional correction, decreased rates of postoperative curve progression, and potentially higher fusion rates.

Sincerely,

Lawrence G. Lenke, M.D.

Thoracic Facetectomy/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 (**Figure 35**).

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 in **Figure 36** can be used as a guide for starting points and screw trajectory.

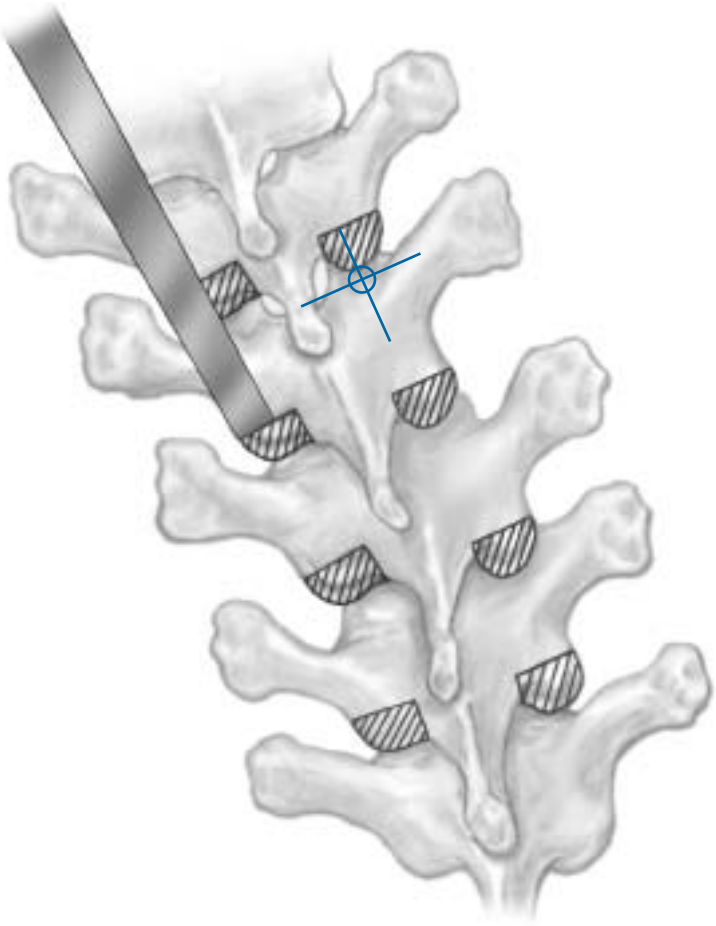
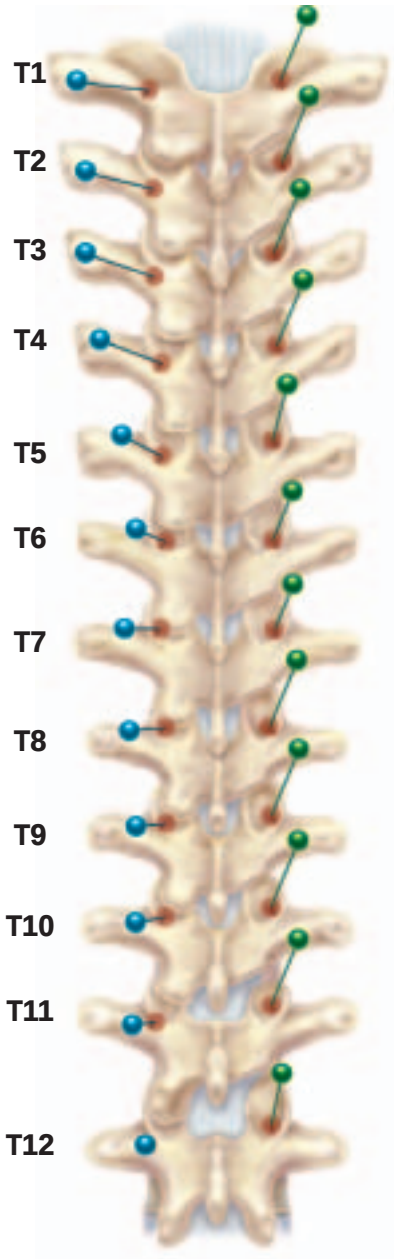


Figure 35

Thoracic Pedicle 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).

Tear Here



Level	Cephalad-Caudad Starting Point	Medial-Lateral Starting Point
T1	Midpoint 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

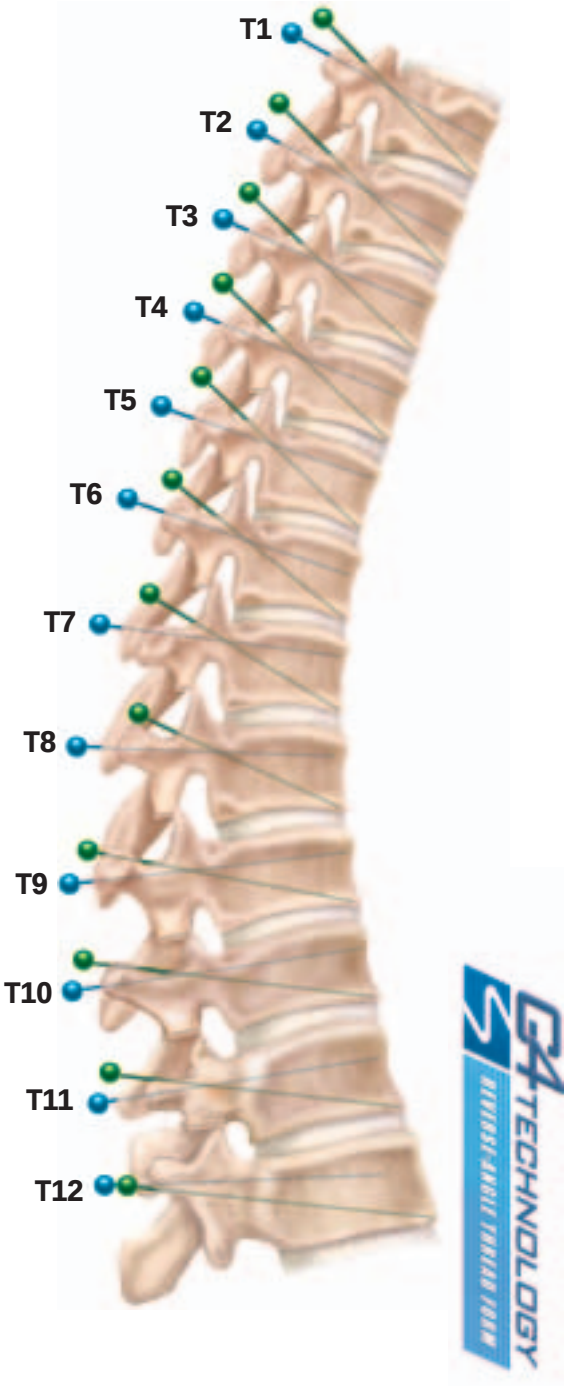


Figure 36

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 Ball Handle 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 37**).

Figure 37

Pedicle Preparation (cont.)

Grip the side of the handle to avoid applying too much ventral pressure. Insert the tip approximately 20mm to 25mm (**Figure 38**), 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 39**). Rotate the probe 180° to ensure adequate room for the screw.

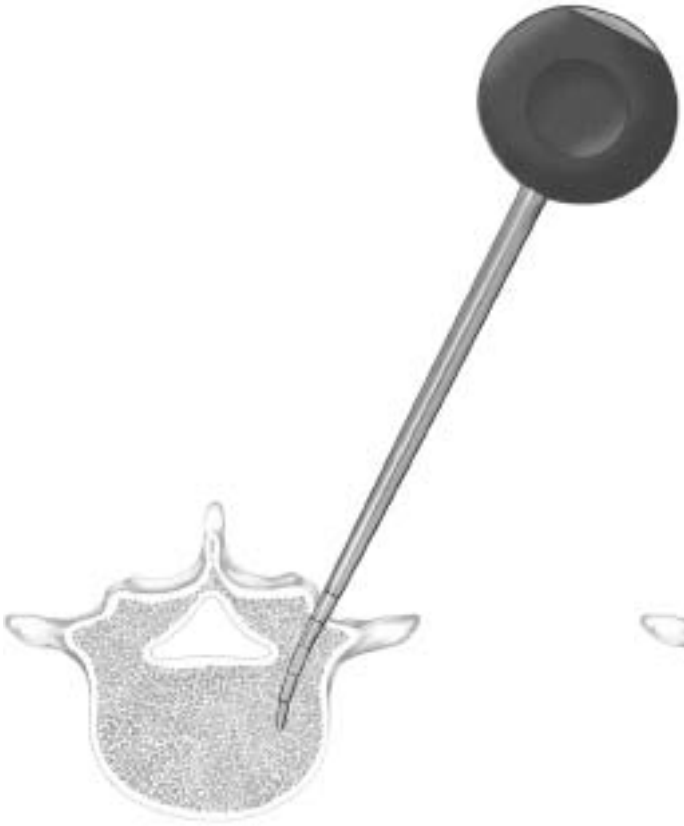


Figure 38

Figure 39

Pedicle Preparation (cont.)

Check to ensure that only blood is coming out of the pedicle and that the bleeding is not excessive. Using a flexible ball tipped probe, advance a Sounding/Feeler Probe to the base (floor) of the hole to confirm five distinct bony borders: a floor and four walls (medial, lateral, superior, and inferior) (**Figure 40**). Give special care to the first 10 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 41**). 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 42**). Select the appropriate screw diameter and length by both preoperative measurement and intraoperative observation.

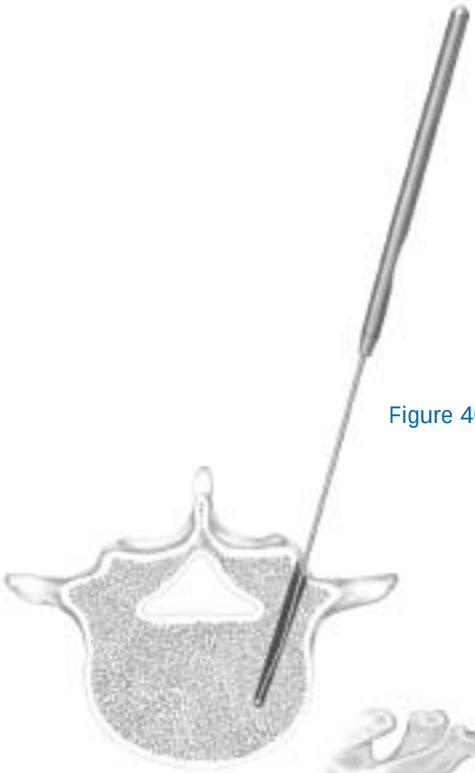


Figure 40

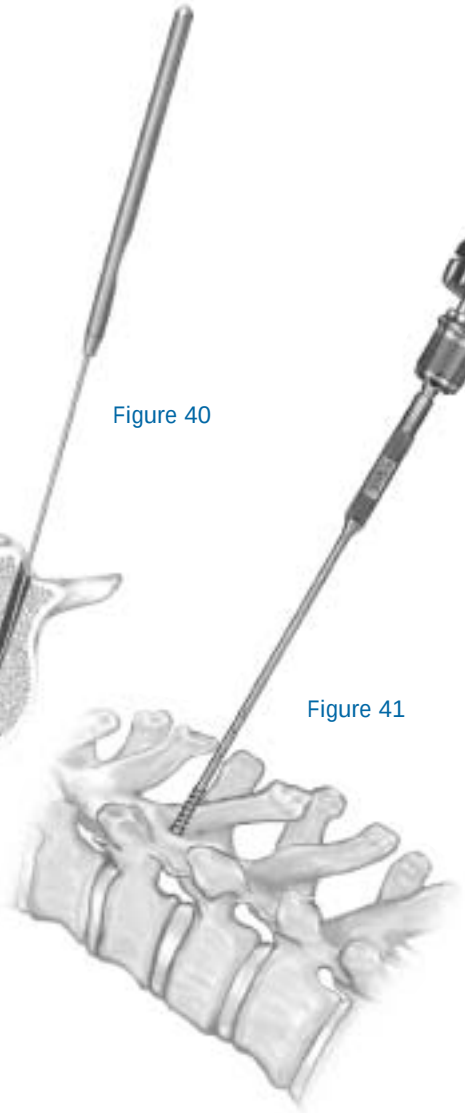


Figure 41

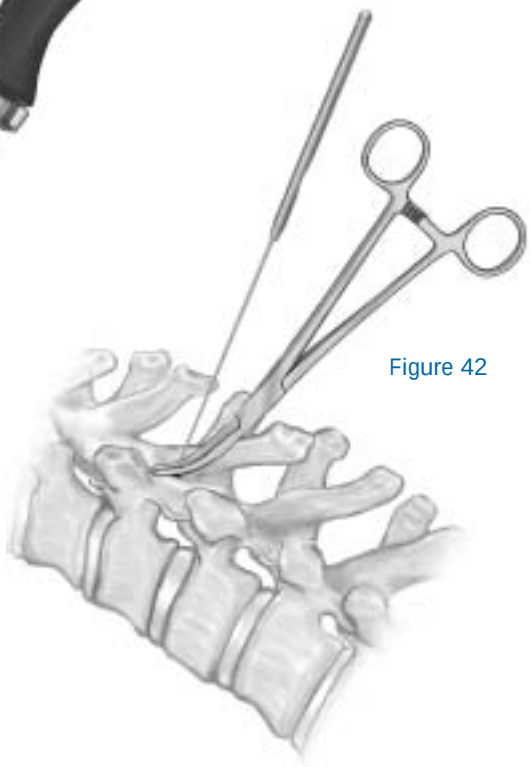


Figure 42

Screw Placement

Thread a screw onto either the Fixed Angle or Multi Axial Screwdriver and slowly advance the screw down the pedicle to ensure proper tracking while allowing for viscoelastic expansion (**Figures 43a and 43b**). Screws should be placed at every segment on the correction side and every third or fourth level on the supportive side. Insert at least two screws at the proximal and distal end of the supportive side. For some pathologies, such as kyphosis and congenital scolioisis, more screws are placed for greater construct rigidity. Screws should be checked radiographically at this time to ensure instraosseous screw placement.

Figure 43a

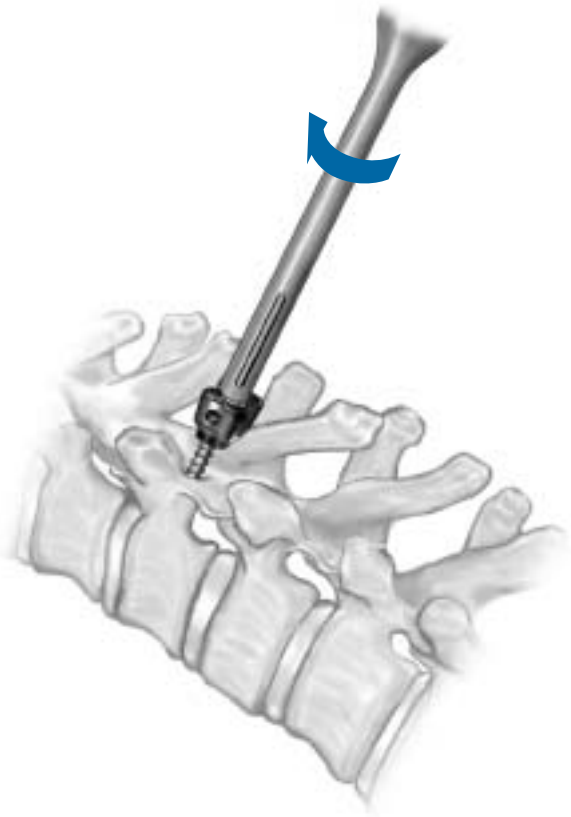


Figure 43b

Rod Contouring/Placement

Once correct screw placement has been verified radiographically, measure and contour rods in the sagittal and coronal planes. The rods have an orientation line that serves as a reference point during contouring. Clamping the rod with Rod Grippers at both ends helps prevent the rod from rotating during contouring (**Figure 44**).

Figure 44

Rod Reduction

For non-hyperkyphotic deformities, place the rod on the concavity first. The contoured rod is placed into the previously placed screws. There are several methods and instruments that can facilitate fully seating the rod into the saddle of the implant. NOTE: Care should be taken with any of the following reduction methods. Improper instrument use may loosen implants or damage the residual facets and other bony anatomy.

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 (**Figure 45**) and then lever backwards over the rod. The levering action allows the rod to be fully seated into the saddle of the implant. The Dual Ended Plug Starter is then used to introduce the set screw (**Figure 46**).

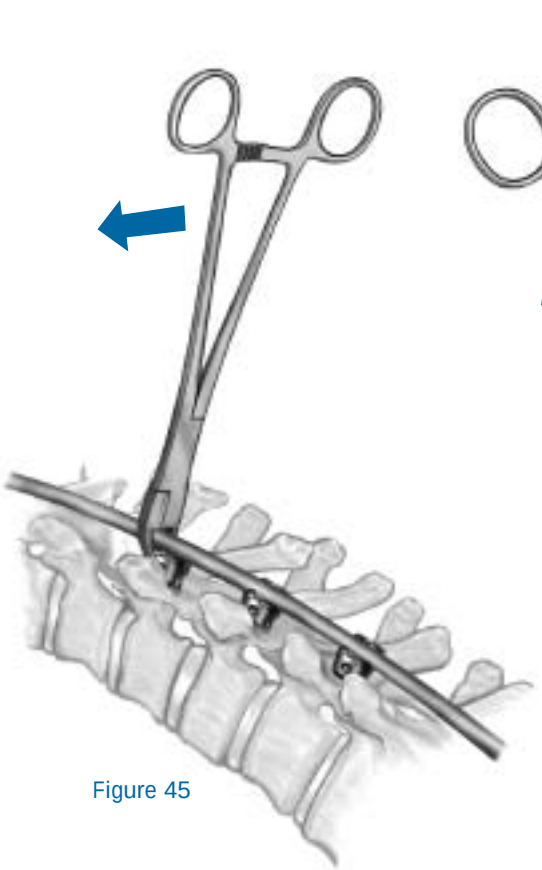


Figure 45

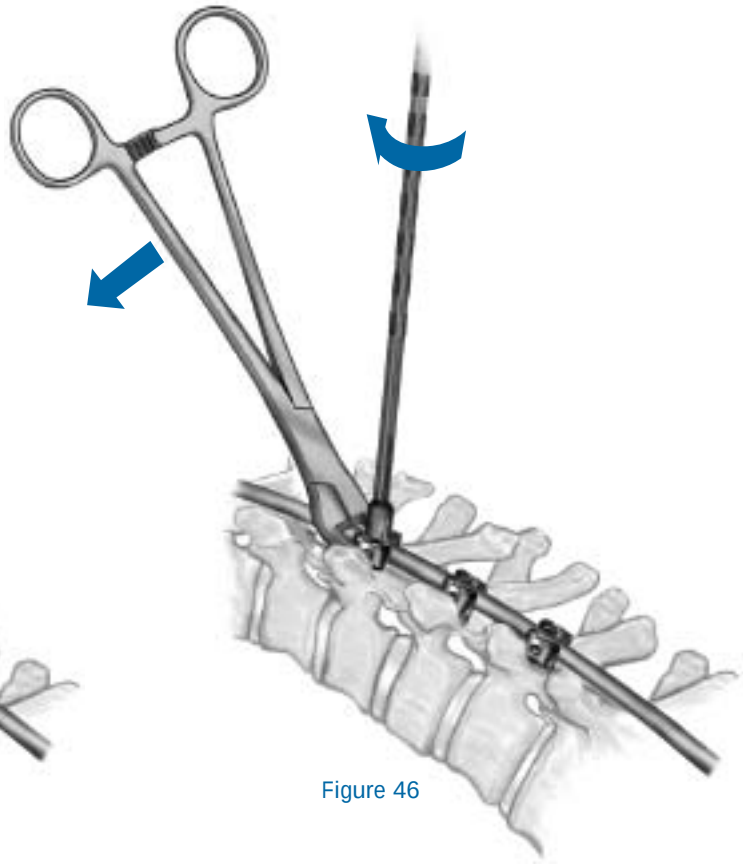


Figure 46

Rod Reduction (cont.)

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 reducer is placed over the implant with the ratchet portion parallel to the rod (**Figure 47**). The reducer is then slowly closed, allowing the attached sleeve to slide down and seat the rod into the implant saddle. A set screw is then placed through the plug tube with the Dual Ended Plug Starter and provisionally tightened with the Provisional Driver (**Figure 48**).

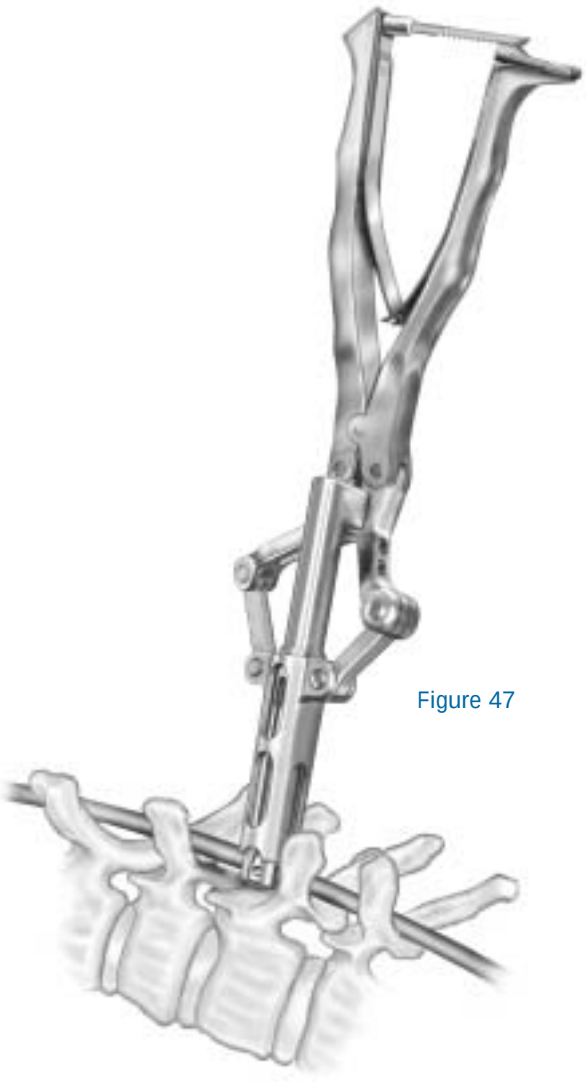


Figure 47

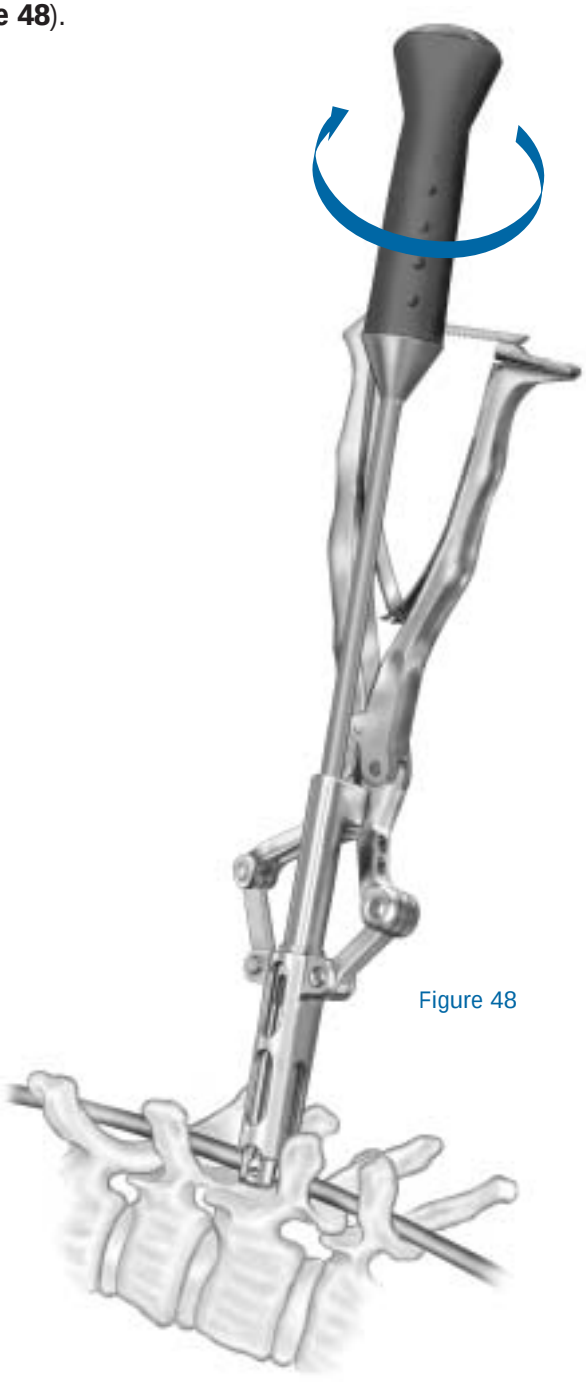


Figure 48

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. 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 (**Figure 49**). Tighten the apical set screws and perform the appropriate compression or distraction (**Figure 50**). Watch the screw/bone interface with all correction maneuvers.

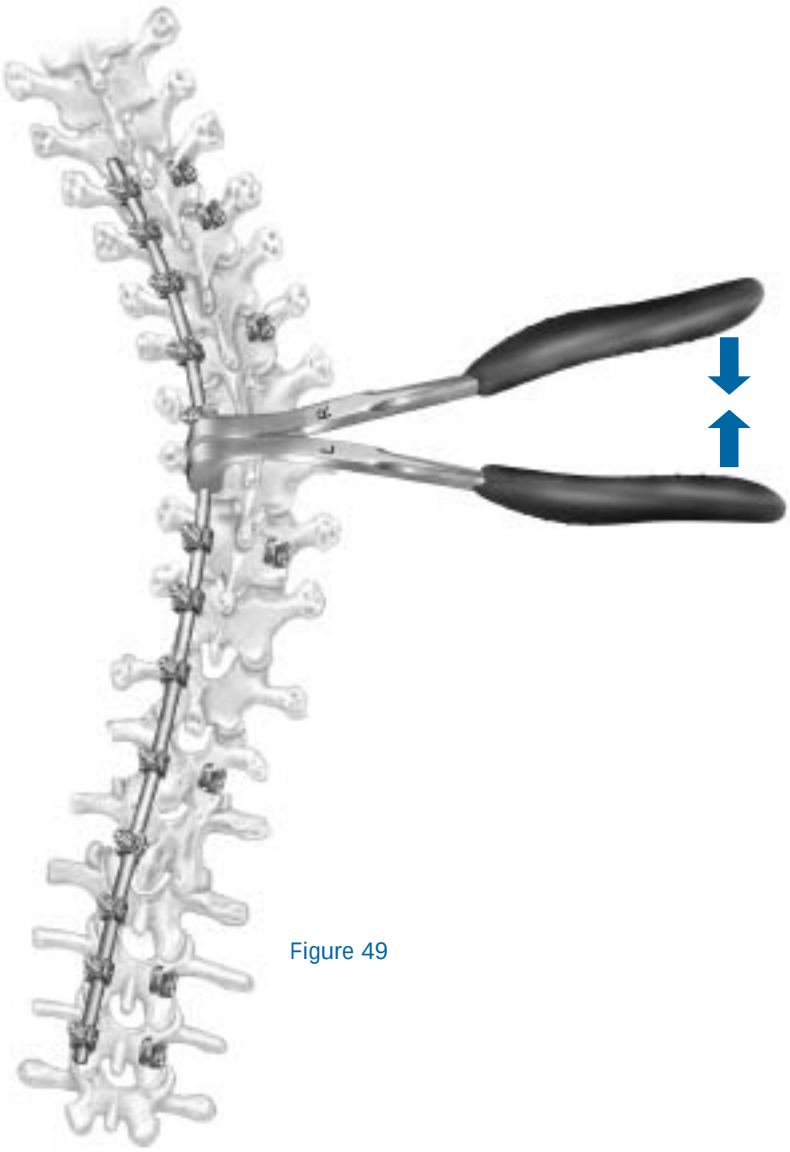


Figure 49

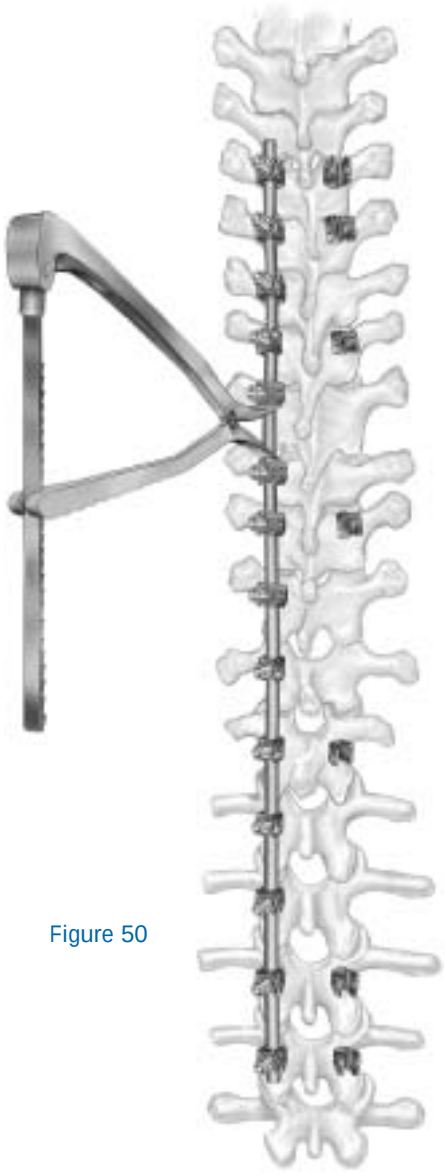


Figure 50

Deformity Correction (cont.)

Placing the Stabilizing Rod

Following placement of the second rod and set screws (**Figure 51**), convex compressive forces are placed on the segments using the Parallel Compressor to horizontalize the lowest instrumented vertebra and mildly compress the convexity of the deformity (**Figure 52**). NMEP and/or SSEP monitoring are performed to detect slow progressions of neurologic deficits.

Fixation is verified with A/P and lateral x-rays to confirm spinal correction and alignment.

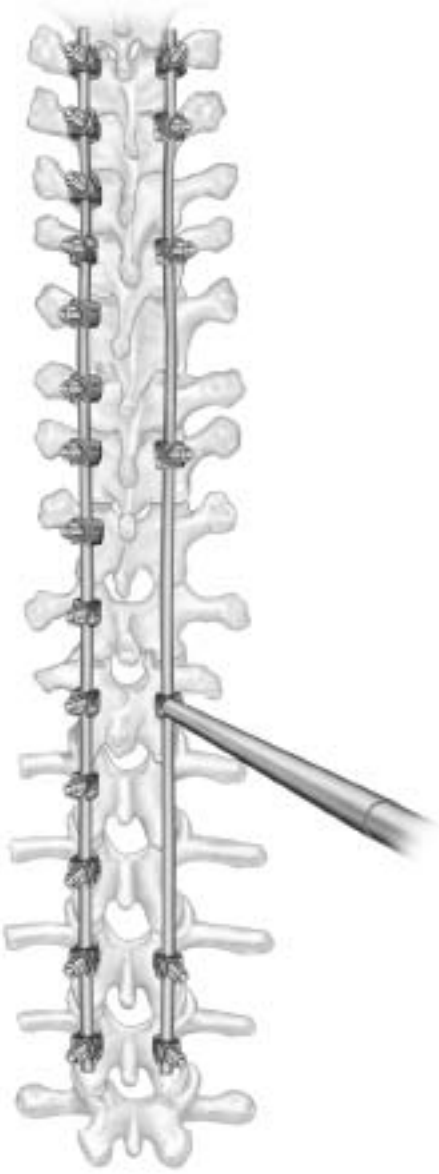


Figure 51

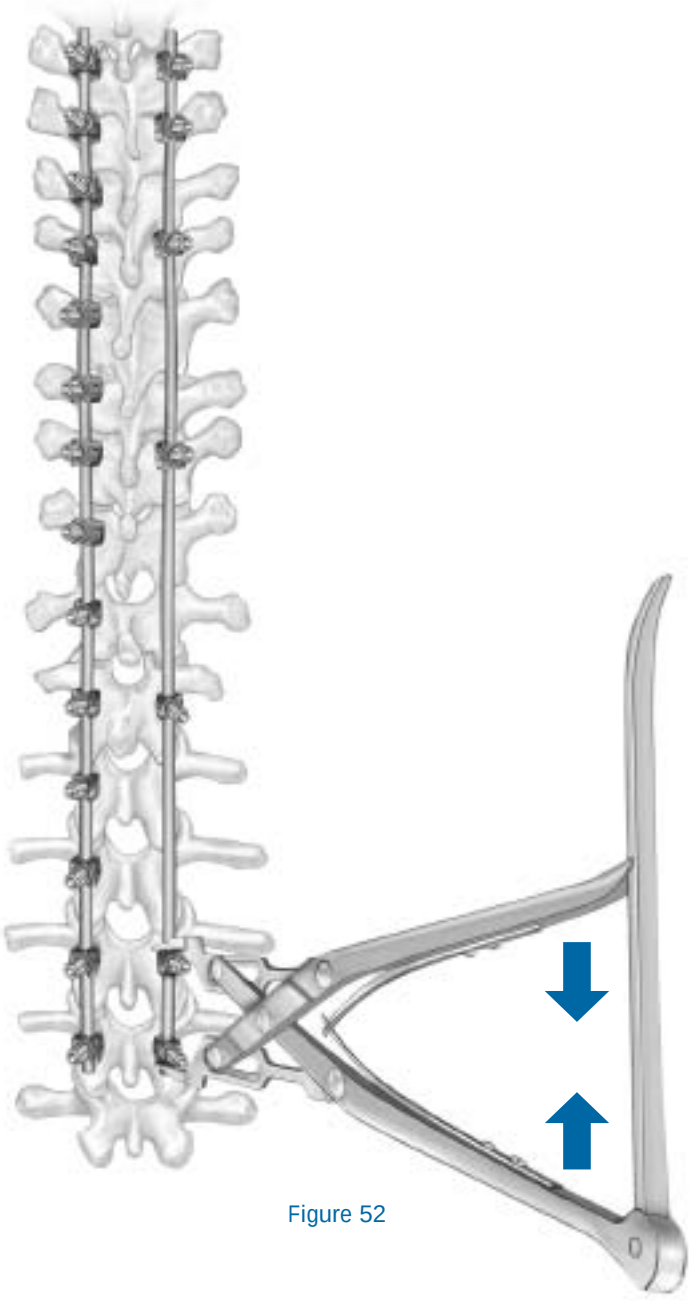


Figure 52

Final Tightening/Decortication/X10 CROSSLINK® Plate Placement

Using the Counter Torque and the Self-Retaining Break-Off Driver, the set screws are sheared off, which locks the rods into place (**Figure 53**).

The posterior elements are decorticated with a burr and the bone graft is placed. The X10 CROSSLINK Plates should be placed at the proximal and distal ends of the construct (**Figure 54**). Refer to the X10 CROSSLINK Plate Surgical Technique for placement steps.

NOTE: Implant Explantation

For removal of the set screw once it is broken off, a TORX 27 shaft must be used exclusively. The TORX 27 shaft is inserted into the cannulated Break-Off Driver and, once the TORX 27 tip is correctly inserted into the set screw, the driver is used for set screw removal.

The TORX 27 print on CD HORIZON LEGACY 5.5mm Spinal System implants is larger than on the standard CD HORIZON Spinal System implants, allowing easier removal.

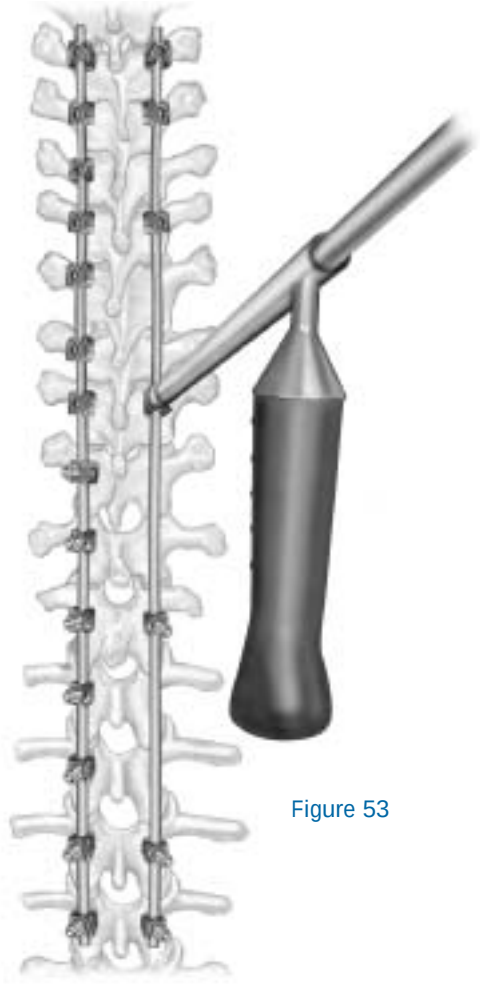


Figure 53

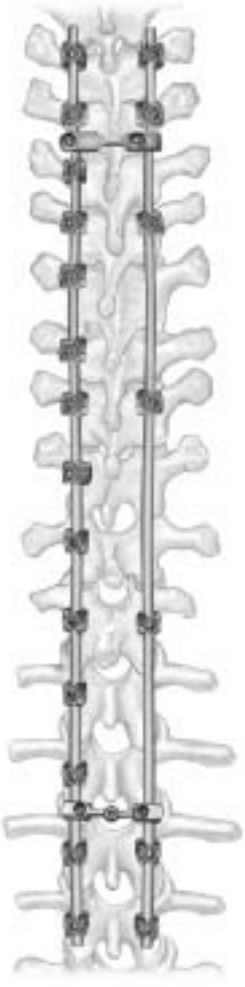
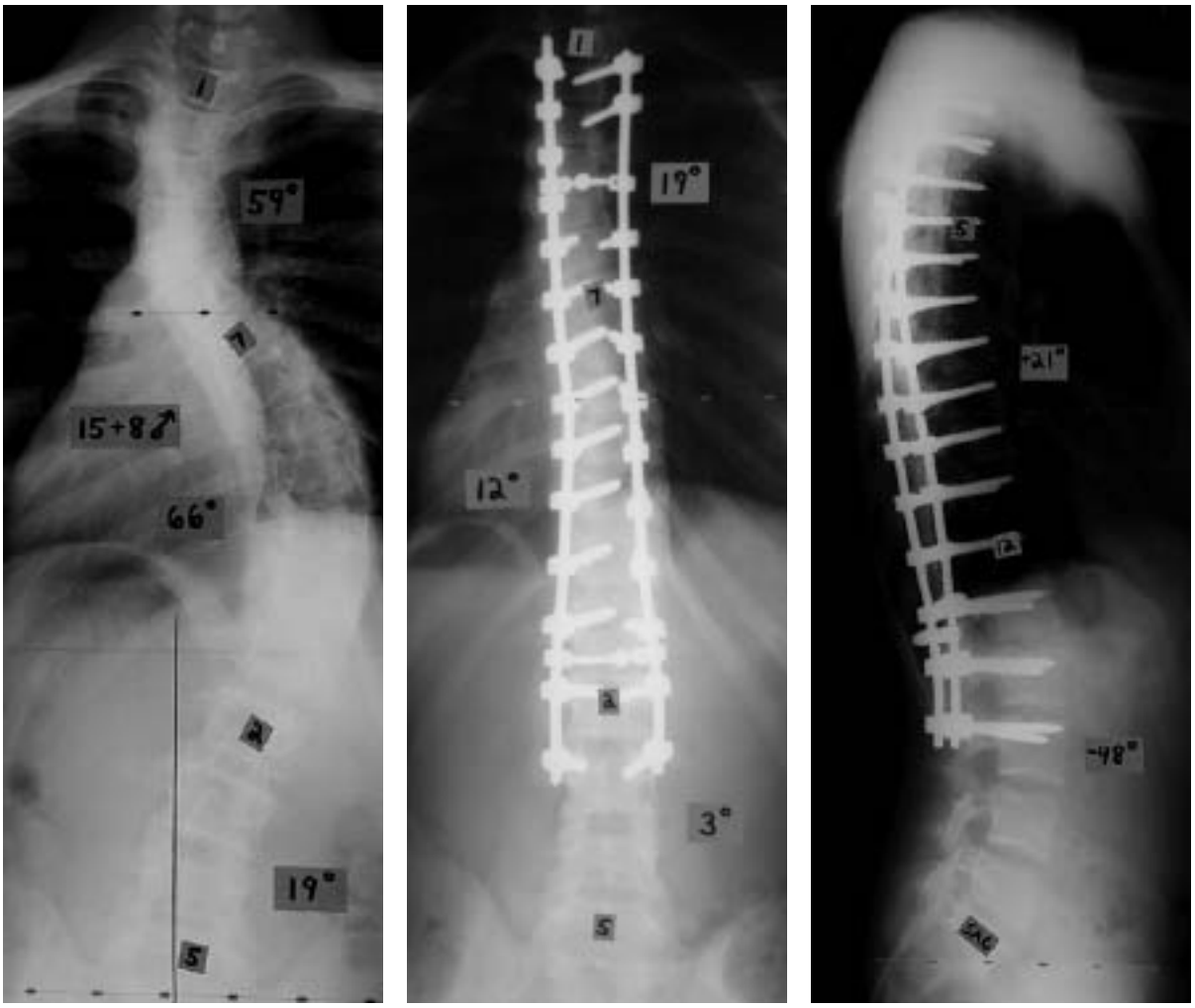


Figure 54

Case Presentation



Case Description: Lenke 2AN, AIS

System Used: CD HORIZON LEGACY 5.5 Spinal System with X10 CROSSLINK® Plates

Correction Maneuvers Used:

- Segmental cantilever
- Proximal thoracic compression
- In-situ translation
- Direct apical derotation (mid-thoracic)
- Selective compression and distraction to horizontalize, centralize, and neutralize the lowest instrumented vertebra

Product Ordering Information

HOOKS		
Catalog Number		**Description**
Titanium	**Stainless Steel**	
7541102	7561102	Pedicle Hook, Small
7541103	7561103	Pedicle Hook, Medium
7541104	7561104	Pedicle Hook, Large
7541112	7561112	Wide Blade Hook, Small
7541113	7561113	Wide Blade Hook, Medium
7541114	7561114	Wide Blade Hook, Large
7541122	7561122	Narrow Blade Hook, Small
7541123	7561123	Narrow Blade Hook, Medium
7541124	7561124	Narrow Blade Hook, Large
7541133	7561133	Ramped Thoracic, Wide Blade, Medium
7541142	7561142	Ramped Thoracic, Narrow Blade, Small
7541143	7561143	Ramped Thoracic, Narrow Blade, Medium
7541153	7561153	Lumbar Supralaminar, Medium
7541162	7561162	Lumbar Angled Blade, Small
7541163	7561163	Lumbar Angled Blade, Medium
7541172	7561172	Extended Body, Small
7541173	7561173	Extended Body Hook, Medium
7541174	7561174	Extended Body Hook, Large
7541188	7561188	Upper Thoracic Hook, Left
7541189	7561189	Upper Thoracic Hook, Right
7541198	7561198	Offset Hook, Right
7541199	7561199	Offset Hook, Left
7541203	7561203	Pedicle, Medium, with Lip
7541213	7561213	Wide Blade, Medium, with Lip
7541223	7561223	Narrow Blade, Medium, with Lip
RODS		
869-021	868-021	5.5mm Hex End 20" Rod
SET SCREWS		
7540000	7560000	5.5mm Break-Off Set Screw

Product Ordering Information

FIXED ANGLE SCREWS					
Catalog Number		Description	Catalog Number		Description
Titanium	Stainless Steel		Titanium	Stainless Steel	
7543425	7563425	4.5mm X 25mm	7542630	7562630	6.0mm X 30mm
7543430	7563430	4.5mm X 30mm	7542635	7562635	6.0mm X 35mm
7543435	7563435	4.5mm X 35mm	7542640	7562640	6.0mm X 40mm
7543440	7563440	4.5mm X 40mm	7542645	7562645	6.0mm X 45mm
7543445	7563445	4.5mm X 45mm	7542650	7562650	6.0mm X 50mm
7543450	7563450	4.5mm X 50mm	7543630	7563630	6.5mm X 30mm
7542525	7562525	5.0mm X 25mm	7543635	7563635	6.5mm X 35mm
7542530	7562530	5.0mm X 30mm	7543640	7563640	6.5mm X 40mm
7542535	7562535	5.0mm X 35mm	7543645	7563645	6.5mm X 45mm
7542540	7562540	5.0mm X 40mm	7543650	7563650	6.5mm X 50mm
7542545	7562545	5.0mm X 45mm	7543655	7563655	6.5mm X 55mm
7542550	7562550	5.0mm X 50mm	7543730	7563730	7.5mm X 30mm
7543525	7563525	5.5mm X 25mm	7543735	7563735	7.5mm X 35mm
7543530	7563530	5.5mm X 30mm	7543740	7563740	7.5mm X 40mm
7543535	7563535	5.5mm X 35mm	7543745	7563745	7.5mm X 45mm
7543540	7563540	5.5mm X 40mm	7543750	7563750	7.5mm X 50mm
7543545	7563545	5.5mm X 45mm	7543755	7563755	7.5mm X 55mm
7543550	7563550	5.5mm X 50mm	7543760	7563760	7.5mm X 60mm
7543555	7563555	5.5mm X 55mm			

Product Ordering Information

MULTI AXIAL SCREWS					
Catalog Number		Description	Catalog Number		Description
Titanium	Stainless Steel		Titanium	Stainless Steel	
7544020	7564020	4.0mm X 20mm	7545535	7565535	5.5mm X 35mm
7544025	7564025	4.0mm X 25mm	7545540	7565540	5.5mm X 40mm
7544030	7564030	4.0mm X 30mm	7545545	7565545	5.5mm X 45mm
7544035	7564035	4.0mm X 35mm	7545550	7565550	5.5mm X 50mm
7544040	7564040	4.0mm X 40mm	7545555	7565555	5.5mm X 55mm
7544045	7564045	4.0mm X 45mm	7546525	7566525	6.5mm X 25mm
7544520	7564520	4.5mm X 20mm	7546530	7566530	6.5mm X 30mm
7544525	7564525	4.5mm X 25mm	7546535	7566535	6.5mm X 35mm
7544530	7564530	4.5mm X 30mm	7546540	7566540	6.5mm X 40mm
7544535	7564535	4.5mm X 35mm	7546545	7566545	6.5mm X 45mm
7544540	7564540	4.5mm X 40mm	7546550	7566550	6.5mm X 50mm
7544545	7564545	4.5mm X 45mm	7546555	7566555	6.5mm X 55mm
7545025	7565025	5.0mm X 25mm	7546560	7566560	6.5mm X 60mm
7545030	7565030	5.0mm X 30mm	7547525	7567525	7.5mm X 25mm
7545035	7565035	5.0mm X 35mm	7547530	7567530	7.5mm X 30mm
7545040	7565040	5.0mm X 40mm	7547535	7567535	7.5mm X 35mm
7545045	7565045	5.0mm X 45mm	7547540	7567540	7.5mm X 40mm
7545050	7565050	5.0mm X 50mm	7547545	7567545	7.5mm X 45mm
7545525	7565525	5.5mm X 25mm	7547555	7567555	7.5mm X 55mm
7545530	7565530	5.5mm X 30mm	7547560	7567560	7.5mm X 60mm

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 SOFAMOR DANEK spinal systems, which can be rigidly locked into a variety of configurations, with each construct being tailor-made for the individual case.

Certain implant components from other MEDTRONIC SOFAMOR DANEK spinal systems can be used with the CD HORIZON® Spinal System. These components include TSRH® rods, hooks, screws, plates, CROSSLINK® plates, connectors, staples and washers, GDLH® rods, hooks, connectors and CROSSLINK® bar and connectors; LIBERTY® rods and screws; DYNALOK PLUS™ bolts. Please note that certain components are specifically designed to connect to ø 4.5mm, ø 5.5mm, or ø 6.35mm rods, while other components can connect to both ø 5.5mm rods and ø 6.35mm rods. Care should be taken so that the correct components are used in the spinal construct.

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

The CD HORIZON® Spinal System implant components are fabricated from medical grade stainless steel described by such standards as ASTM F138 or ISO 5832-1 or ISO 5832-9. Alternatively, the entire system may be made out of medical grade titanium or titanium alloy described by such standards as ASTM F67 or ASTM F136 or ISO 5832-3 or 5832-2. MEDTRONIC SOFAMOR DANEK expressly warrants that these devices are fabricated from one of the foregoing material specifications. No other warranties, express or implied, are made. Implied warranties of merchantability and fitness for a particular purpose or use are specifically excluded. See the MEDTRONIC SOFAMOR DANEK Catalog for further information about warranties and limitations of liability. **Never use stainless steel and titanium implant components 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 implants only. **Do not use with stainless steel.**

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 SOFAMOR DANEK document. As with all orthopaedic and neurosurgical implants, none of the CD HORIZON® Spinal System components should ever be reused under any circumstances.

INDICATIONS, CONTRAINDICATIONS AND POSSIBLE ADVERSE EVENTS:

INDICATIONS:

The CD HORIZON® Spinal System is intended for posterior, non-cervical fixation 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.

When used in a percutaneous, non-cervical, posterior approach with the CD HORIZON® SEXTANT™ instrumentation, the CD HORIZON® cannulated screws are intended 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; pseudoarthrosis; and/or failed previous fusion.

Except for hooks, when used as an anterolateral thoracic/lumbar system, CD HORIZON® components such as ECLIPSE® components are intended for the following indications: (1) degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), (2) spinal stenosis, (3) spondylolisthesis, (4) spinal deformities (i.e., scoliosis, kyphosis, and/or lordosis), (5) fracture, (6) pseudarthrosis, (7) tumor resection, and/or (8) failed previous fusion.

The CD HORIZON® SPINOUS PROCESS Plate is a posterior, non-pedicle supplemental fixation device, intended for use in the non-cervical spine (T1 – S1). It is intended for plate fixation/attachment to spinous process for the purpose of achieving supplemental fusion in the following conditions: 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); 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:

1. Active infectious process or significant risk of infection (immunocompromise).
2. Signs of local inflammation.
3. Fever or leukocytosis.
4. Morbid obesity.
5. Pregnancy.
6. Mental illness.
7. Grossly distorted anatomy caused by congenital abnormalities.
8. Any other medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the presence of congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count.
9. Rapid joint disease, bone absorption, osteopenia, osteomalacia and/or osteoporosis. Osteoporosis or osteopenia is a relative contraindication since this condition may limit the degree of obtainable correction, stabilization, and/or the amount of mechanical fixation.
10. Suspected or documented metal allergy or intolerance.
11. Any case not needing a bone graft and fusion.
12. Any case where the implant components selected for use would be too large or too small to achieve a successful result.
13. Any case that requires the mixing of metals from two different components or systems.
14. Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
15. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
16. Any patient unwilling to follow postoperative instructions.
17. Any case not described in the indications.

POTENTIAL ADVERSE EVENTS:

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

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

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

WARNING AND PRECAUTIONS:

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.

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

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

Preoperative and operating procedures, including knowledge of surgical techniques, good reduction, and proper selection and placement of the implants are important considerations in the successful utilization of the system by the surgeon. Further, the proper selection and compliance of the patient will greatly affect the results. Patients who smoke have been shown to have an increased incidence of non-unions. These patients should be advised of this fact and warned of this consequence. Obese, malnourished, and/or alcohol abuse patients are also poor candidates for spine fusion. Patients with poor muscle and bone quality and/or nerve paralysis are also poor candidates for spine fusion.

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

CAUTION: Federal law (USA) restricts these devices to sale by or on the order of a physician.

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

Implant Selection:

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

Device Fixation:

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

Important Information on the CD HORIZON® Spinal System

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

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

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

PREOPERATIVE:

1. Only patients that meet the criteria described in the indications should be selected.
2. Patient conditions and/or predispositions such as those addressed in the aforementioned contraindications should be avoided.
3. Care should be used in the handling and storage of the implant components. The implants should not be scratched or otherwise damaged. Implants and instruments should be protected during storage, especially from corrosive environments.
4. An adequate inventory of implants should be available at the time of surgery, normally a quantity in excess of what is expected to be used.
5. Since mechanical parts are involved, the surgeon should be familiar with the various components before using the equipment and should personally assemble the devices to verify that all parts and necessary instruments are present before the surgery begins. The CD HORIZON® Spinal System components (described in the DESCRIPTION section) are not to be combined with the components from another manufacturer. Different metal types should never be used together.
6. All components and instruments should be cleaned and sterilized before use. Additional sterile components should be available in case of an unexpected need.

INTRAOPERATIVE:

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

POSTOPERATIVE:

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

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

PACKAGING:

Packages for each of the components should be intact upon receipt. If a loaner or consignment system is used, all sets should be carefully checked for completeness and all components including instruments should be carefully checked to ensure that there is no damage prior to use. Damaged packages or products should not be used, and should be returned to MEDTRONIC SOFAMOR DANEK.

CLEANING AND DECONTAMINATION:

Unless just removed from an unopened Medtronic Sofamor Danek 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 Sofamor Danek. Cleaning and disinfecting of instruments can be performed with aldehyde-free solvents at higher temperatures. Cleaning and decontamination must include the use of neutral cleaners followed by a deionized water rinse.

Note: certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used. Also, many instruments require disassembly before cleaning.

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

STERILIZATION:

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

METHOD	CYCLE	TEMPERATURE	EXPOSURE TIME
Steam	Pre-Vacuum	270° F (132° C)	4 Minutes
Steam	Gravity	250° F (121° C)	30 Minutes
Steam*	Gravity*	273° F (134° C)*	20 Minutes*

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

Remove all packaging materials prior to sterilization. Use only sterile products in the operative field.

PRODUCT COMPLAINTS:

Any Health Care Professional (e.g. customer or user of this system of products), who has any complaint or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify the distributor or MEDTRONIC SOFAMOR DANEK. Further, if any of the implanted CD HORIZON® 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 SOFAMOR DANEK 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, part number, lot number(s), your name and address, the nature of the complaint, and notification of whether a written report for the distributor is requested.

FURTHER INFORMATION:

In case of complaint, or for supplementary information, or further directions for use of this system, please see the address listed below.

IN THE USA

Customer Service Division
MEDTRONIC SOFAMOR DANEK USA, INC.
1800 Pyramid Place
Memphis, Tennessee 38132 USA
Telephone: 800-876-3133
or 901-396-3133

IN EUROPE

Tele: (33) 3.21.89.50.00
or (33) 1.49.38.80.00
Fax: (33) 3.21.89.50.09

MEDTRONIC SOFAMOR DANEK International**
13, rue de la Pedtrix
93290 TREMBLAY EN FRANCE
FRANCE

**authorized EC representative

©2004 MEDTRONIC SOFAMOR DANEK USA, INC. All rights reserved.

Notes

MEDTRONIC SOFAMOR DANEK EUROPEAN SPINE CENTER

ZAC Paris Nord II – 13, rue de la Perdrix
BP50302
95940 ROISSY CDG Cedex – FRANCE Tel: +33 1 49 38 80 00 Fax: +33 1 49 38 80 01

SOFAMOR SNC
RCS Bobigny B617 320 486 – NAF 331B

MEDTRONIC ÖSTERREICH GmbH
Millenium Tower - Handelskai 94 – 96
1200 VIENNA – AUSTRIA
Tel: +43 1 240 44 130 Fax: +43 1 240 44 330

MEDTRONIC BELGIUM
Boechoutlaan 55
1853 STROMBEEK-BEVER – BELGIUM
Tel: +32 2 456 09 00 Fax: +32 2 460 26 67

MEDTRONIC B.V.
Trg Drazena Petrovica 3/V
10 000 ZAGREB – CROATIA
Tel: +385 1 48 81 120 Fax: +385 1 48 44 060

MEDTRONIC CZECHIA s.r.o.
Sokolovska 77 – 79
186 PRAGUE 8 - CZECH REPUBLIC
Tel: +49 211 52 93 000 Fax: +49 211 52 93 302

MEDTRONIC-VACARE A/S
Birkeroed Kongevej 150B
3460 BIRKEROED-DENMARK
Tel: +45 45 82 33 66 Fax: +45 45 82 33 65

MEDTRONIC FINLAND LTD.
Sahaajankatu 24
P.O. Box 230
00811 HELSINKI – FINLAND
Tel: +35 8 97 55 25 011 Fax: +35 8 97 75 52 50 18

MEDTRONIC FRANCE SAS
112, avenue du Général Leclerc
92514 BOULOGNE BILLANCOURT CEDEX – FRANCE
Tel: +33 1 55 38 17 00 Fax: +33 1 55 38 18 00

MEDTRONIC GmbH
Emanuel-Leutze-Str. 20
40547 DUSSELDORF – GERMANY
Tel: +49 211 52 93 000 Fax: +49 211 52 93 302

MEDTRONIC HELLAS S.A.
5, Ag Varvaras Str
GR15231 HALANDRI, ATHENS – GREECE
Tel: +30 1 06779099 Fax: +30 1 06779399

MEDTRONIC HUNGARIA Kft.
Alkotas Point
Alkotas U. 50
H-1123 BUDAPEST – HUNGARY
Tel: +36 1 889 0600 Fax: +36 1 889 0699

MEDTRONIC ISRAEL
World Trade Center
41, Hameyasdim St.
40500 EVEN YEHUDA – ISRAEL
Tel: +972 9 891 22 23 Fax: +972 9 891 93 20

MEDTRONIC ITALIA S.p.A.
Piazza Indro Montanelli, 30
20099 SESTO SAN GIOVANNI (MI) – ITALY
Tel: +39 02 241371 Fax: +39 02 24138 223

MEDTRONIC MEDITERRANEAN S.A.L
Regional Development Center (RDC)
St. Charles City Center 6th Floor
Omar Daouk Street - P.O. Box 13.6572
2020-0908 BEIRUT-LEBANON
Tel: +961 1 370670 Fax: +961 1 369655

MEDTRONIC NETHERLANDS
Earl Bakkenstraat 10
6422 PJ HEERLEN - THE NETHERLANDS
Tel: +31 45 566 83 62 Fax: +31 45 566 83 63

MEDTRONIC VINGMED AS
Fjordvn. 1. P.O. Box 366
1323 HOEVIK – NORWAY
Tel: +47 67580680 Fax: +47 67101212

MEDTRONIC POLAND Sp. Z.o.o.
U1. Ostrobramska 101
04-041 WARSZAWA – POLAND
Tel: +48 22 465 69 00 Fax: +48 22 465 69 17

MEDTRONIC PORTUGAL
Rua Torras da Fonseca Torre - E-8-A/B
1600-209 LISBOA – PORTUGAL
Tel: +35 12 17 24 51 00 Fax: +35 12 17 24 51 99

MEDTRONIC SOUTH AFRICA
1 Eastgate Lane, Bedfordview
JOHANNESBURG 2047 – REPUBLIC OF SOUTH AFRICA
Tel: +27 11 677 4800 Fax: +27 11 616 1104

MEDTRONIC IBERICA S.A.
C/Calendula, 93 - Edificio «Medtronic G»
El soto de la Moralega - Alcobendas
28109 ALCOBENDAS (MADRID) - SPAIN
Tel: +34 916 250 500 Fax: +34 916 250 580

MEDTRONIC SWEDEN AB
Box 265
17725 JARFALLA – SWEDEN
Tel: +46 8 52 22 00 00 Fax: +46 8 52 22 00 50

MEDTRONIC SCHWEIZ AG
MEDTRONIC EUROPE
Route du Molliau, 31 - Case Postale
CH1131 TOLOCHENAZ – SWITZERLAND
Tel: +41 21 803 8000 Fax : +41 21 803 8099

MEDTRONIC LTD
Suite one - Sherbourne House - Croxley Business Center
WD1 8YE WATFORD - UNITED KINGDOM
Tel: +44 192 321 22 13 Fax: +44 192 324 10 04

REF EULEGDEFST04 – ©2004 MEDTRONIC SOFAMOR DANEK 03/2004 – All Rights Reserved.

Medtronic
SOFAMOR DANEK

CE 0123