Medtronic
SOFAMOR DANEK

CD HORIZON ENGAGE™ 6.35

Spinal System Surgical Technique

as described by:

Sigurd H. Berven, MD
Assistant Professor in Residence
Orthopaedic Surgery
University of California, San Francisco
San Francisco, California

Bernard A. Rawlins, MD
Associate Professor of Clinical
Orthopaedic Surgery
Weill Cornell Medical School and
The Hospital for Special Surgery
New York, New York

Thoracic Pedicle Screw Technique
described by:

Lawrence G. Lenke, MD
The Jerome J. Gilden Professor of
Orthopedic Surgery
Co-chief Adult/Pediatric Spine
Washington University
School of Spine

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

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Preface

The CD HORIZON ENGAGE™ 6.35 Spinal System can be used for degenerative, deformity, and tumor/trauma indications. It enables the surgeon to optimize implant choices with options that include bolts (posted screws), slotted connectors, multi axial screws, fixed angle screws, and hooks. The System is uniquely versatile because it allows engagement of the rod with a variety of connection options. This versatility empowers the surgeon to choose the ideal correction and to respond capably to the challenges of curve rigidity, osteoporosis, and prior surgery. For illustrating the use of the CD HORIZON ENGAGE™ 6.35 Spinal System instrumentation, this technique will focus on the correction of a T3 to L3 right thoracic, left lumbar scoliotic curve.

The technique is divided into four sections:

- Bolt (Posted Screw) Placement
- Thoracic Pedicle Screw Placement
- Hook Placement
- Deformity Correction

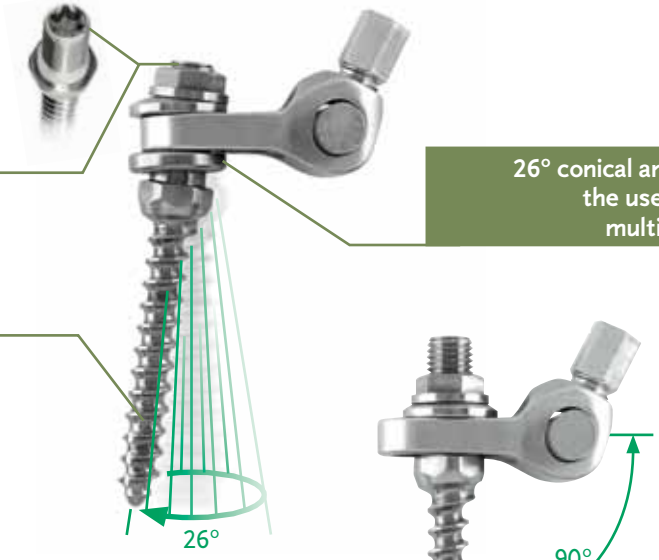
Implant Features and Benefits

Pedicle Bolts

Internal TORX 25 driving mechanism provides a strong instrument-to-implant interface for driving into dense sclerotic bone

26° conical angulation with the use of a drop-on multi-axial washer

Available in six diameter sizes to accommodate varying patient anatomy



Post height of the Short-post Bolts eliminates post cutting step and leaves the TORX 25 intact for ease of revision

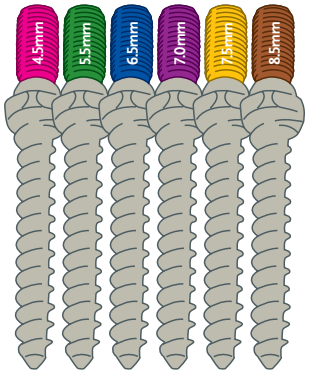
Fixed 90/90 right angle connection

6.35mm diameter post minimizes post bending or breaking when performing vertebral manipulation

Long-post Bolt option provides reduction capabilities

9mm diameter hex provides an alternative interface for driving the bolt or for holding the bolt while removing the multi-axial nut during revision surgeries

Self-tapping bone screw minimizes operative time



- Titanium posts are color-coded by screw diameter for easier identification and match the CD HORIZON® LEGACY™ System color-coding

Implant Features and Benefits (continued)

Connectors

- Multiple connector options provide a range of adjustability and versatility
- Oval-shaped rod channel eases placement of connectors onto contoured rods
- Low profile of connector, plus a medialized rod, provides optimal area for bone graft placement

Connector	Size	Medial/Lateral Offset	Design Feature
Slotted	Extra Small Small Medium Large	6.0mm to 8.0mm 8.0mm to 13.0mm 8.0mm to 17.0mm 13.5mm to 21.0mm	Medial/lateral adjustability provides ease of construct assembly and reduction of coronal plane rod bending requirements; reduces stress at the bone/screw interface
Angled, Left and Right	Small Medium	8.0mm to 13.0mm 8.0mm to 17.0mm	15° of fixed sagittal angulation to overcome L5 to S1 connection difficulties; provides smaller offset than the Sagittal Spinner
Sagittal Spinner	Medium Large	13.0mm to 18.0mm 13.0mm to 22.0mm	Rotates in the sagittal plane for adjustment to the sagittal contouring of the rod; overcomes L5-S1 connection difficulties
Coronal Spinner	Medium	9.5mm to 14.5mm	Rotates in the coronal plane to allow facet preservation or connection to a short rod
Coronal Spinner, Offset	Medium	9.5mm to 14.5mm	Offset design allows rod channel to line up with other connectors; also rotates in the coronal plane to allow facet preservation or connection to a short rod

Multi Axial Nut

- Used for either a 90/90, right-angle connection or a multi axial connection
- Eliminates multiple components by staking the washer to the nut

Set Screws

- Two for the system; however, both use a 6.35mm break-off hex to minimize instrumentation requirements

Stackable Multi Axial Washers

- Provides 26° of conical angulation
- Stackable for dorsal height adjustment
- Can be used with any slotted connector

Implant Features and Benefits (continued)

Open and Closed Hooks

- Open hooks utilize G4 Reverse Angle Thread Technology to simplify top-loading Set Screw introduction and to virtually eliminate cross-threading
- Closed-hook, oval-shaped rod channel eases placement onto contoured rods

Hook Type	Placement	Blade Direction	Throat Sizes Available	Design Feature
Pedicle Hook, Open or Closed	Articular Process	↑	6.5mm, 8.0mm	Bifid blade grasps thoracic pedicle for increased stability
Wide Blade Hook, Open or Closed	Lamina	↕	5.0mm, 6.5mm, 8.0mm, 9.5mm, 11.0mm	Wider blade width distributes forces evenly over a wider area of bone
	Transverse Process	↕		
Narrow Blade Hook, Open or Closed	Lamina	↕	5.0mm, 6.5mm, 8.0mm, 9.5mm, 11.0mm	Narrower blade width minimizes metal volume in the spinal canal
	Transverse Process	↕		
Offset Hook, Open	Lamina	↕	6.5mm	Used to medialize or lateralize the rod in supralaminar or infralaminar position; Back up a pedicle screw at the same level
	Transverse Process	↕		

Rod-to-Rod Connectors

- Two-Set-Screw design provides a smaller alternative to domino connectors
- Allows connectors to be stacked between implants for a stronger connection overall
- Open-to-Closed connector enables placement onto a construct without removing existing hardware
- At least two connectors are required when connecting to another rod. Space the connectors apart for increased strength.

Multi Axial and Fixed Angle Screws

- Utilizes the "gold standard" CD HORIZON® LEGACY™ System 6.35mm screws
- Screws feature G4 Reverse Angle Thread Technology to ease top-loading Set Screw introduction and virtually eliminate cross-threading
- Multi Axial Screws are available in eight diameters for optimal patient anatomy matching
- Fixed Angle Screws are available in six diameters for optimal patient anatomy matching

Instruments

Quick Connect Handles

Quick Connect Ratcheting Handle
9339082

Quick Connect Universal Handle
9960106

Pedicle Preparation

In-Line Round Awl
9960105

Lumbar Ball Handle Probe
9960110

Tap
8683750 (3.75mm)
8684500 (4.5mm)
836-015 (5.5mm)
836-016 (6.5mm)
836-018 (7.5mm)

Thoracic Ball Handle Probe
7480112

Sounding/Feeler Probe
8572102

Dual-Ended Feeler Probe
7480100

Bolt Insertion

Primary Bolt Driver
9960107

Auxiliary Bolt Driver
9960108

Instruments

Screw Insertion

Multi Axial Screwdriver, Short
7486109

Self-Retaining Screwdriver
7480114

Fixed Angle Screwdriver, US
7486280

Multi Axial Screw Head Positioner
9960335

Hook Preparation

Laminar Elevator
9960220

Transverse Process Elevator
7480222

Pedicle Elevator
7480225

Hook Placement

Lateral Hook Holder
9960212

Straight Hook Holder
9960216

Curved Hook Holder
9960217

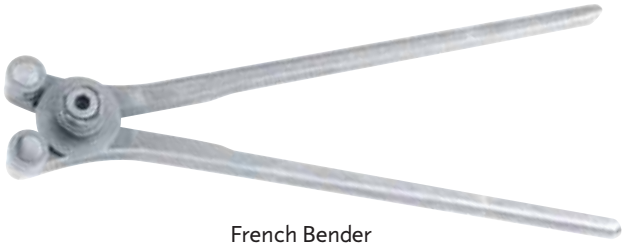
Hook Pusher
9966231

Instruments

Rod Contouring

Rod Template
808-575

Plate/Rod Bender, Left
(Flat Bender)
9960265

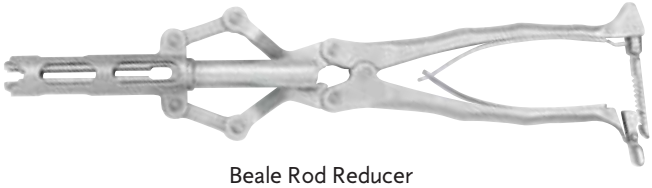


French Bender
808-530

Plate/Rod Bender, Right
(Flat Bender)
9960266

Rod Reduction

6.35mm Rod Pusher
7486235



Beale Rod Reducer
7486134

Forceps Rocker
9960142

Instruments

Nut Placement and Final Tightening

Nut Driver
9960111

Torque Limiting Nut Driver
9960112

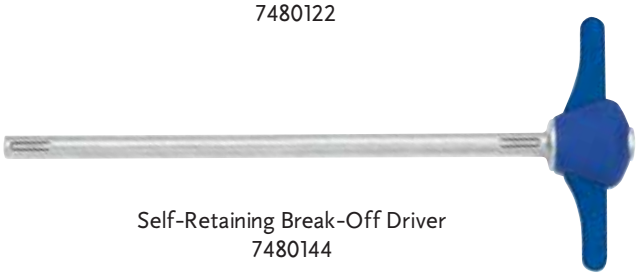
Bolt Counter Torque
9960130

Speed Wrench
9960131

Angled Wrench
9960109

Set Screw Placement and Final Tightening

Plug Starter, Dual End
7480122



Self-Retaining Break-Off Driver
7480144

Provisional Driver
7480131

Instruments

Set Screw Placement and Final Tightening (continued)

Connector Counter Torque
9960113

T27 Obturator (Open Set Screw Insert)
7480154

Screw/Hook Counter Torque
7486150

Closed Set Screw Insert (T25)
9960135

Long-Post Bolt Cutters

Tube, Outer, Bolt Cutter
9960201

Tube, Inner, Bolt Cutter
9960202

Handle, Bottom, Bolt Cutter
9960203

Handle, Top, Bolt Cutter
9960204

Bolt Cutter Obturator
8369043

Instruments

Correction

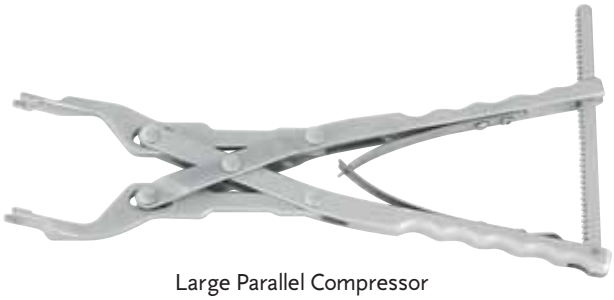
Hex Rod Rotation Wrench
7486285

In Situ Benders
7486255 Left
7486260 Right

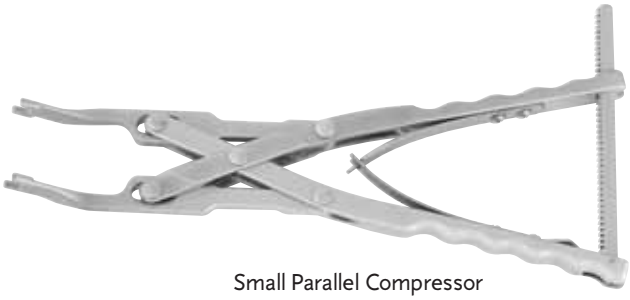
Coronal Plane Benders
7486265L Left
7486270R Right

Rod Gripper
9960176

Compression and Distraction

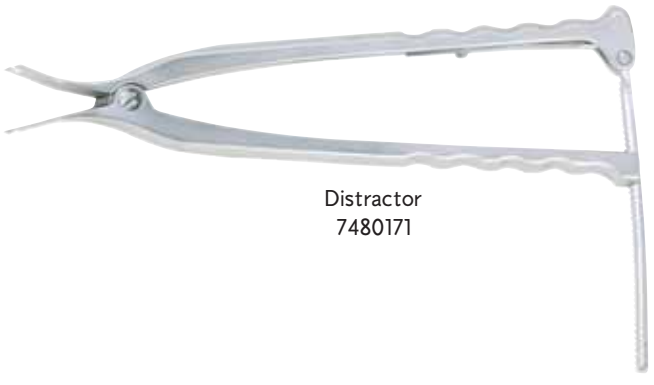


Large Parallel Compressor
7480166



Small Parallel Compressor
7480165

Palm Distractor
9960133



Distractor
7480171

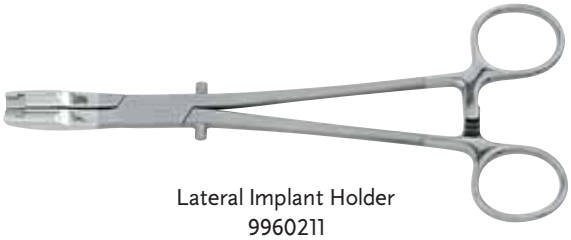
Instruments

Optional Instrumentation (Not included in the set configuration)

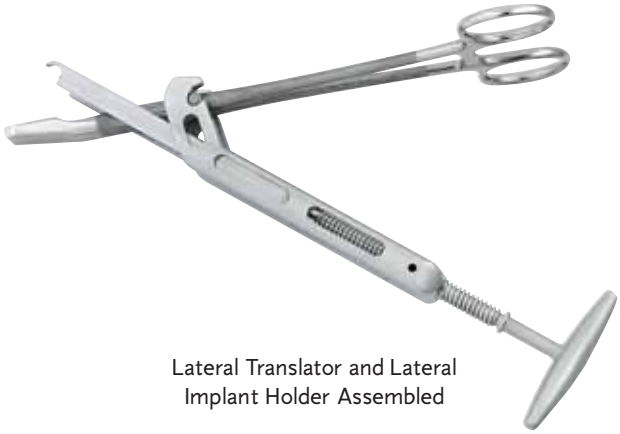
TLIF Distractor
9960136

Vice Grips, Angled
9960321

Lateral Translator
9960210



Lateral Implant Holder
9960211



Lateral Translator and Lateral
Implant Holder Assembled

Preoperative Planning

Preoperatively, any spinal surgery should be studied and a scheme of the construct defined. The Illustrations shown are two typical CD HORIZON ENGAGE™ 6.35 Spinal System constructs for a right thoracic, left lumbar curve. These schemes, which are strictly for illustrative purposes, are examples of how these types of scoliosis can be corrected.

Figure 1 shows a right thoracic, left lumbar curve instrumented with hooks, bolts, and slotted connectors from T3 to L3. This case can also be treated using thoracic pedicle screws instead of hooks and wire (Figure 2).

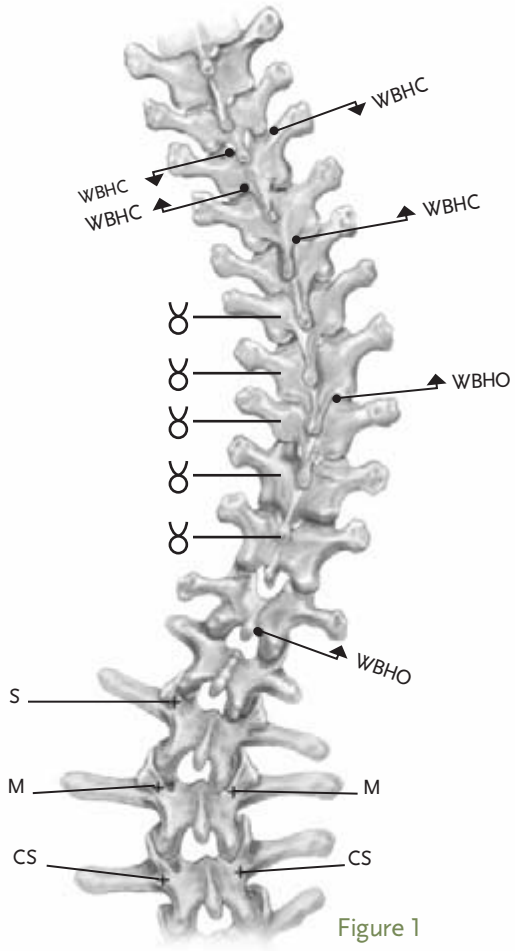


Figure 1

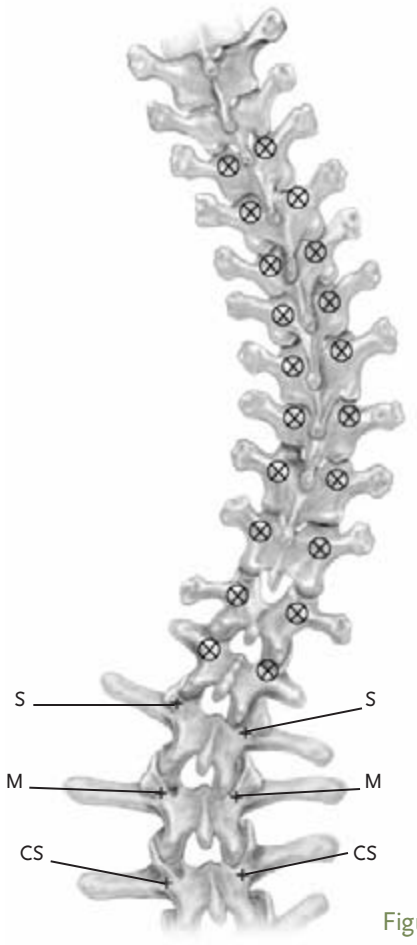


Figure 2

Implant Legend		
= Up-going Hook	= Wire	**XS** = Extra Small Connector
= Down-going Hook	**NBHC** = Narrow Blade Hook, Closed	**S** = Small Connector
+ = Pedicle Bolt	**OH** = Offset Hook	**M** = Medium Connector
NBHO = Narrow Blade Hook, Open	**PHC** = Pedicle Hook, Closed	**L** = Large Connector
WBHO = Wide Blade Hook, Open	⊗ = Pedicle Screw	**SS** = Sagittal Spinner
PHO = Pedicle Hook, Open	**WBHC** = Wide Blade Hook, Closed	**CS** = Coronal Spinner

Pedicle Preparation

Identify the appropriate anatomical landmarks for creating the entry points of the pilot holes for bolt insertion (Figure 3). Pilot holes are then created with a sharp awl or high-speed burr, depending on the surgeon's preference (Figure 4). A pedicle "blush" may be visualized at this time suggesting entrance into the cancellous bone of the pedicle.

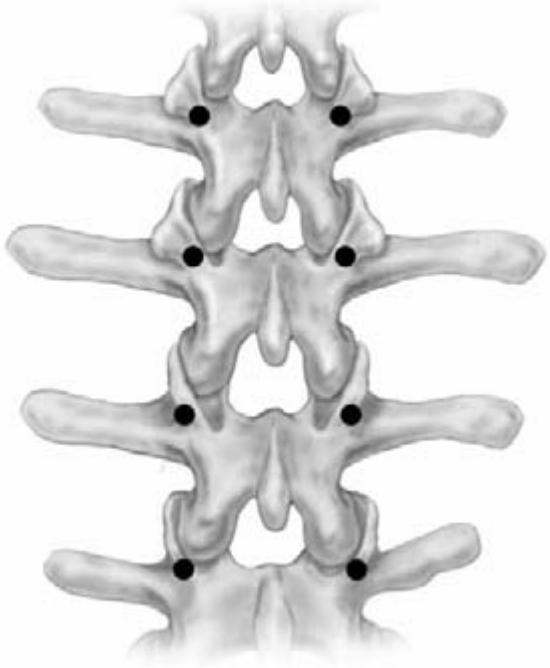


Figure 3

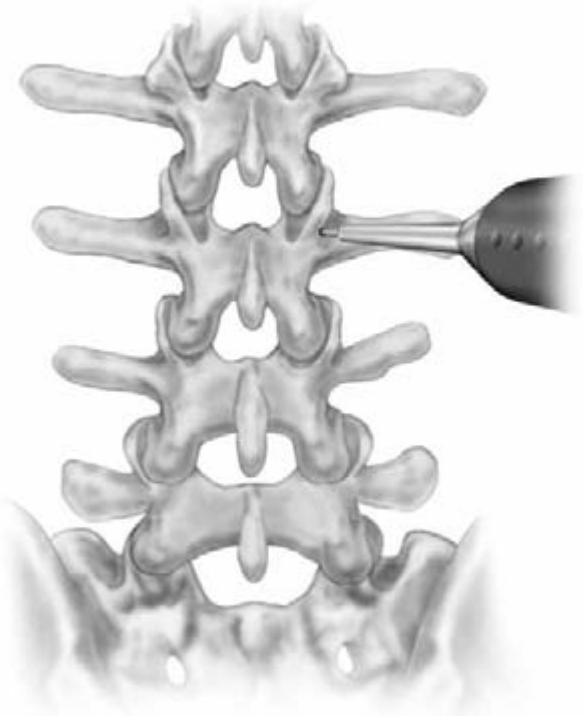


Figure 4

Pedicle Preparation (continued)

The Lumbar or Thoracic Ball Handle Probe is then used to probe the pedicle. Initially, the tip should be pointed laterally to avoid perforation of the medial cortex (Figure 5). Grip the side of the handle to avoid applying too much ventral pressure. Insert the tip of the probe approximately 20mm to 25mm (Figure 6), and then remove the probe and reposition it so the tip is directed medially.

Figure 5

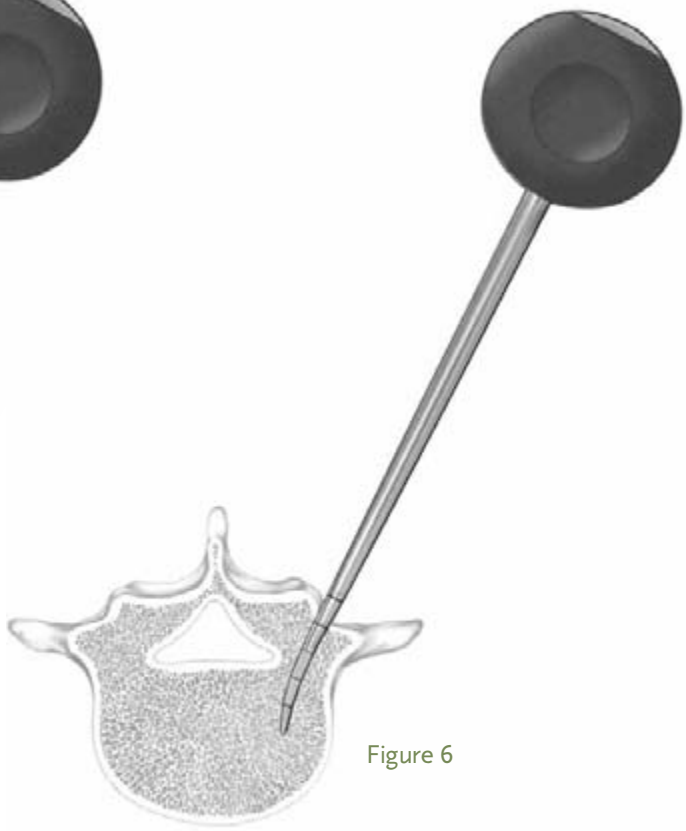


Figure 6

Pedicle Preparation (continued)

Carefully place the probe into the base of the hole and use the instrument markings to advance the probe to the desired depth (Figure 7). Finally, rotate the probe 180 degrees to ensure adequate room for the bolt.

Check to ensure that only blood is coming out of the pedicle and that the bleeding is not excessive. Using a Feeler Probe, palpitate for any perforations in the pedicle walls. Check to the base (floor) of the hole to confirm five distinct bony borders: a floor and four walls (medial, lateral, superior, and inferior) (Figure 8).

Figure 7

Figure 8

Pedicle Preparation (continued)

The CD HORIZON ENGAGE™ System Pedicle Bolts have a self-tapping flute to obviate the tapping step. The bolts may be inserted immediately following the preparation and probing of the pedicle. However, in cases of dense, sclerotic, or osteoporotic bone, tapping is recommended. The instrument set contains taps in sizes of 3.75mm, 4.5mm, 5.5mm, 6.5mm, and 7.5mm that allow tapping to size or undertapping for enhanced bolt purchase.The selected diameter tap is advanced into the vertebral body through the pedicle (Figure 9) then removed. Finally, the Feeler Probe is used again to palpate for perforations in the pedicle walls (Figure 10).

Figure 9

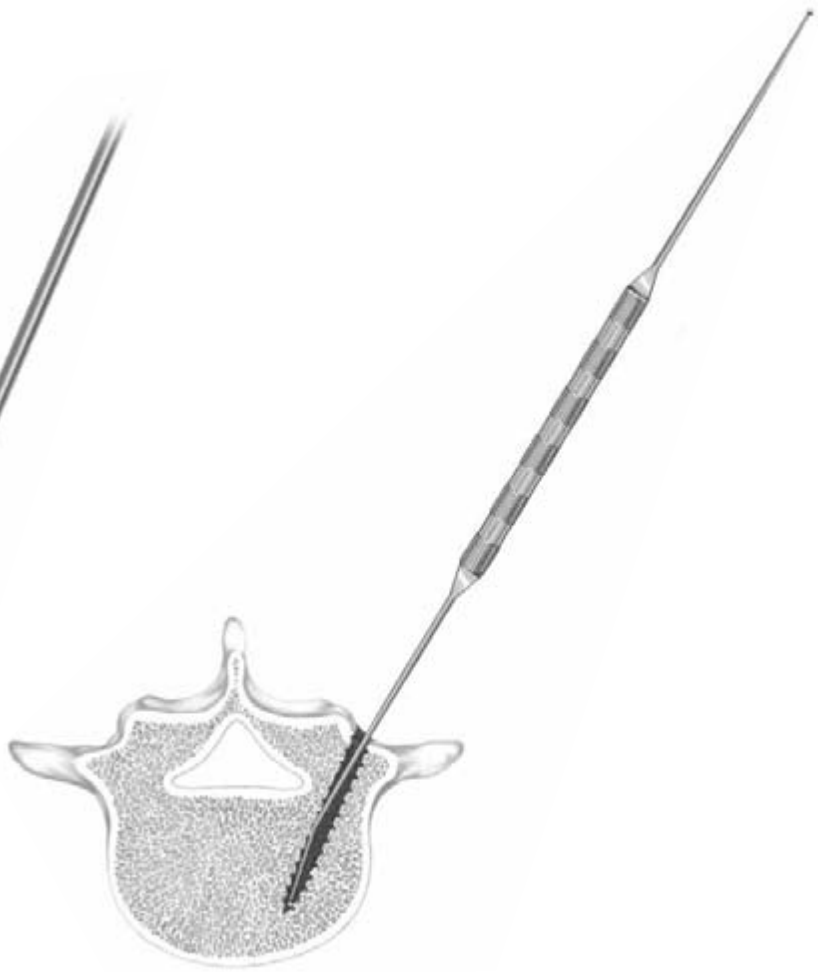


Figure 10

Bolt Placement

Once the appropriate bolt diameter and length has been determined by intraoperative observation and preoperative measurement, insert the selected bolt into the Primary Bolt Driver (Figure 11 and 12). The bolt might have to be rotated slightly to ensure proper seating onto the T25. The combination of the T25 and self-retaining sleeve provide a stable insertion instrument for placing the bolts.

Figure 11

Figure 12

Bolt Placement (continued)

If a Multi Axial Washer will be used in the construct, it may be pre-loaded onto the bolt for placement in conjunction with the bolt (Figure 13). Alternatively, the Auxiliary Bolt Driver may be used by fully seating the female hex over the bolt head (Figure 14a and 14b).

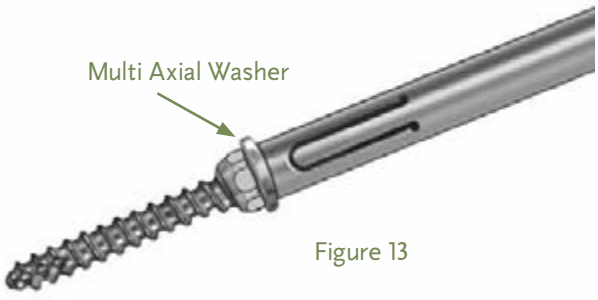


Figure 13

Figure 14a

Figure 14b

Bolt Placement (continued)

Slowly insert the bolt into the lumbar pedicle (Figure 15). For sacral fixation, especially when the bone is osteopenic, bicortical purchase may be utilized. Upon placement of all of the bolts, positioning may be checked radiographically to verify proper placement.

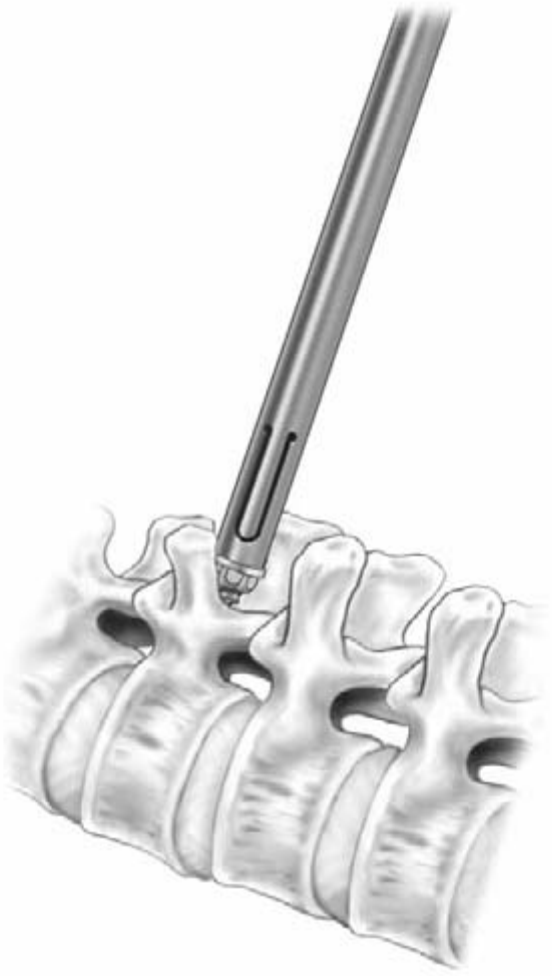


Figure 15

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 16).

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.

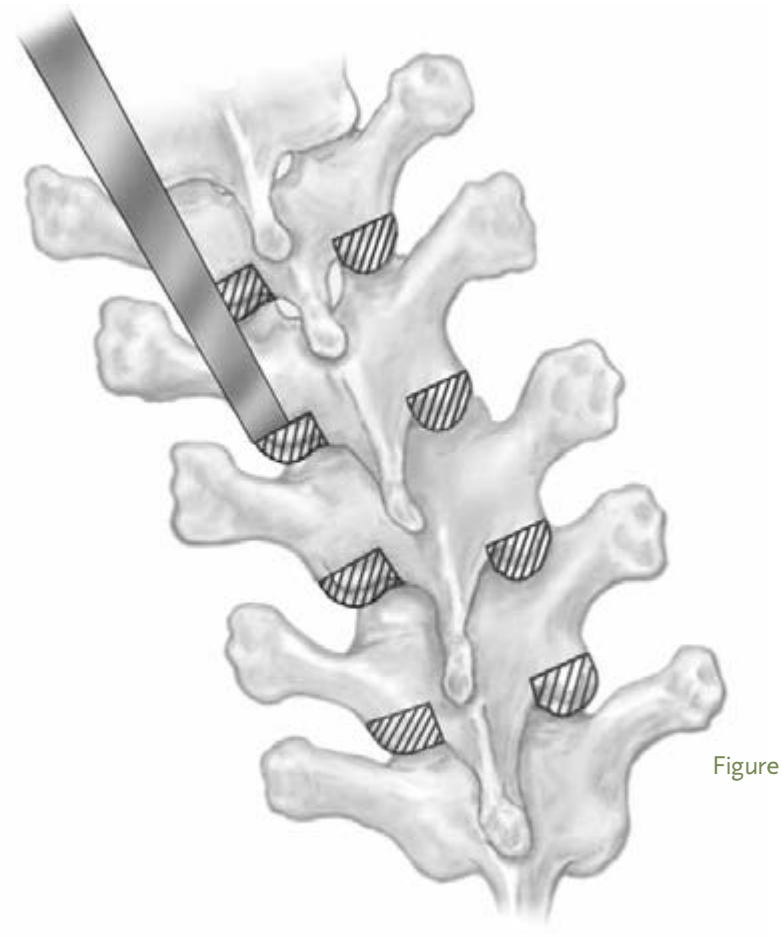
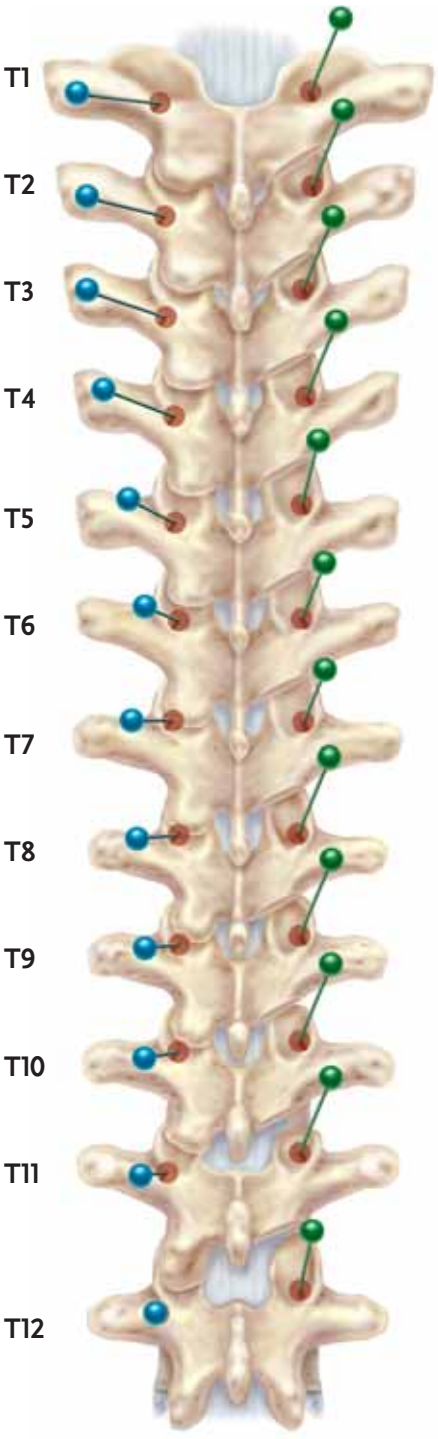


Figure 16

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).



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

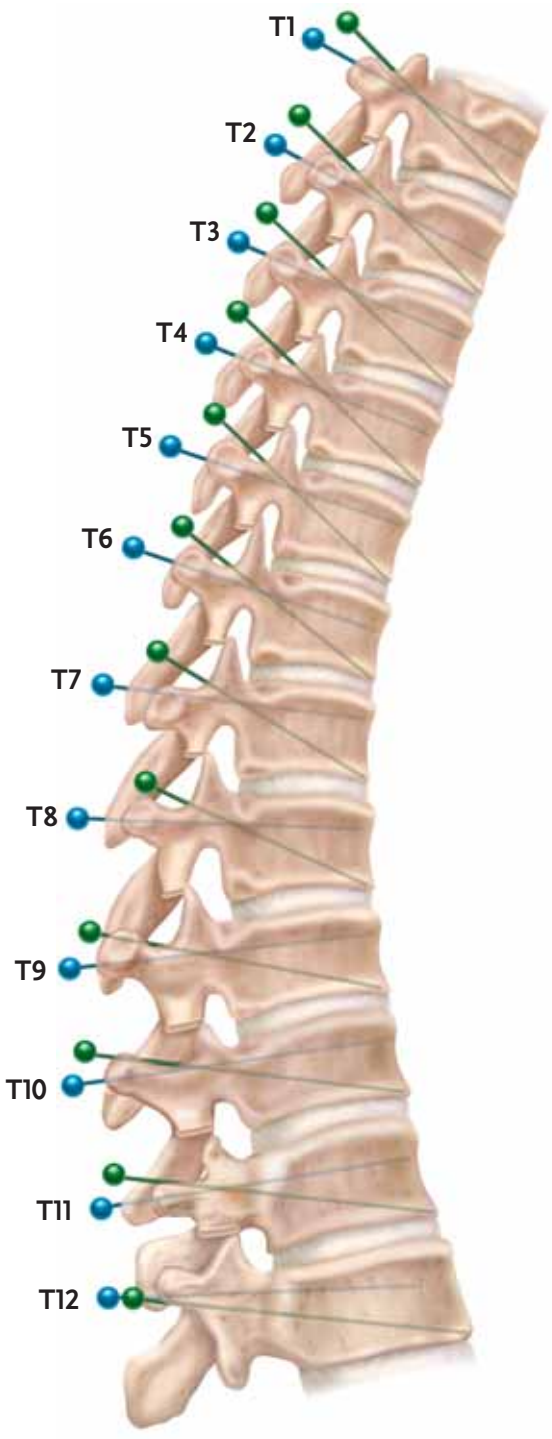


Figure 17

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 18).

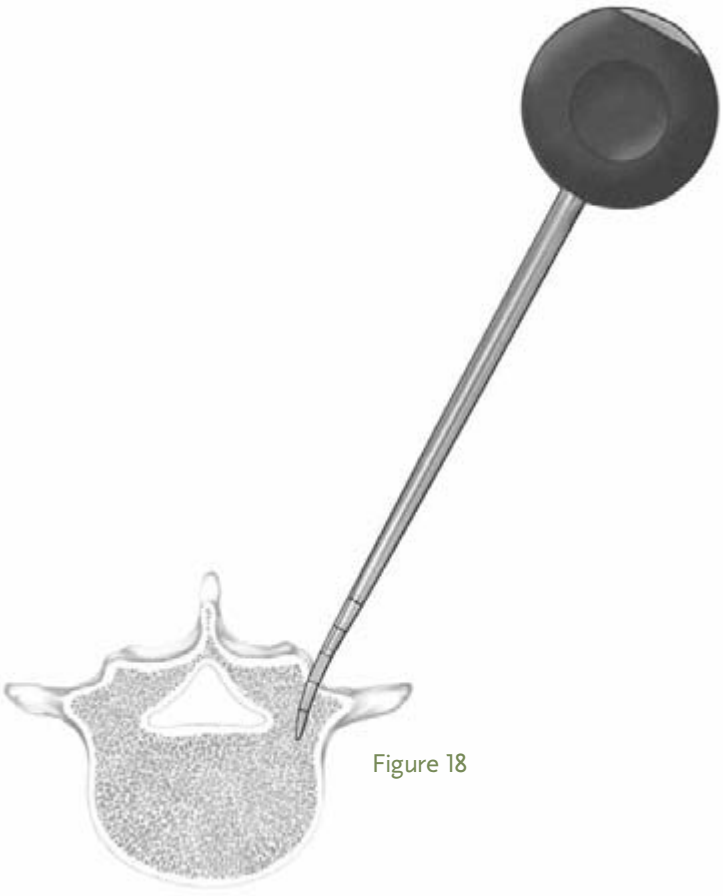


Figure 18

Pedicle Preparation (continued)

Grip the side of the handle to avoid applying too much ventral pressure. Insert the tip approximately 20mm to 25mm (Figure 19), and then remove the probe to reorient it so 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 20). Rotate the probe 180° to ensure adequate room for the screw.

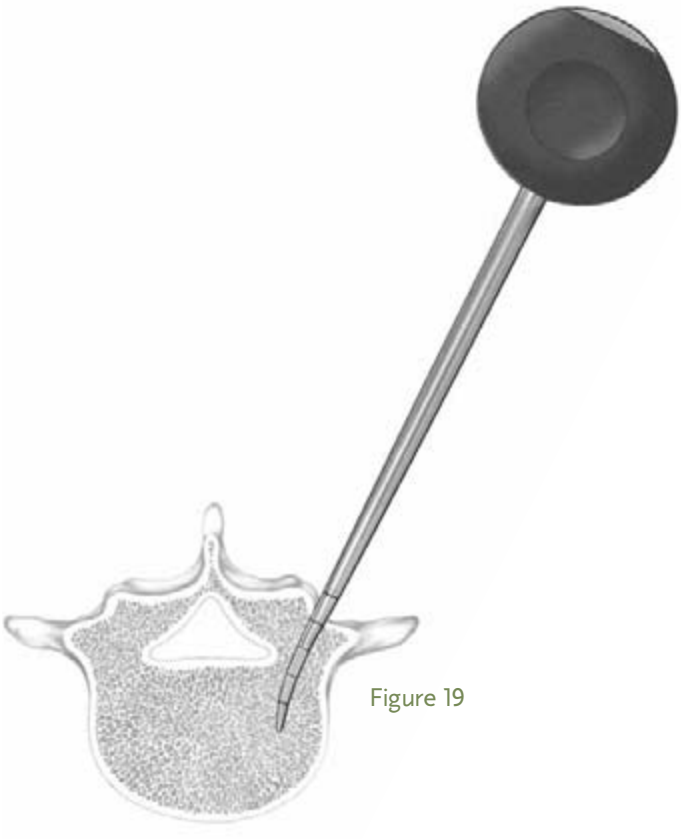


Figure 19

Figure 20

Pedicle Preparation (continued)

Check to ensure that only blood is coming out of the pedicle and that the bleeding is not excessive. Advance a flexible ball tipped 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 21). 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 22). Palpate the tapped pedicle tract with a flexible Sounding/Feeler Probe. Clamp a hemostat to the exposed Sounding/Feeler Probe and measure the depth of the hole (Figure 23). Select the appropriate screw diameter and length by both preoperative measurement and intraoperative observation.

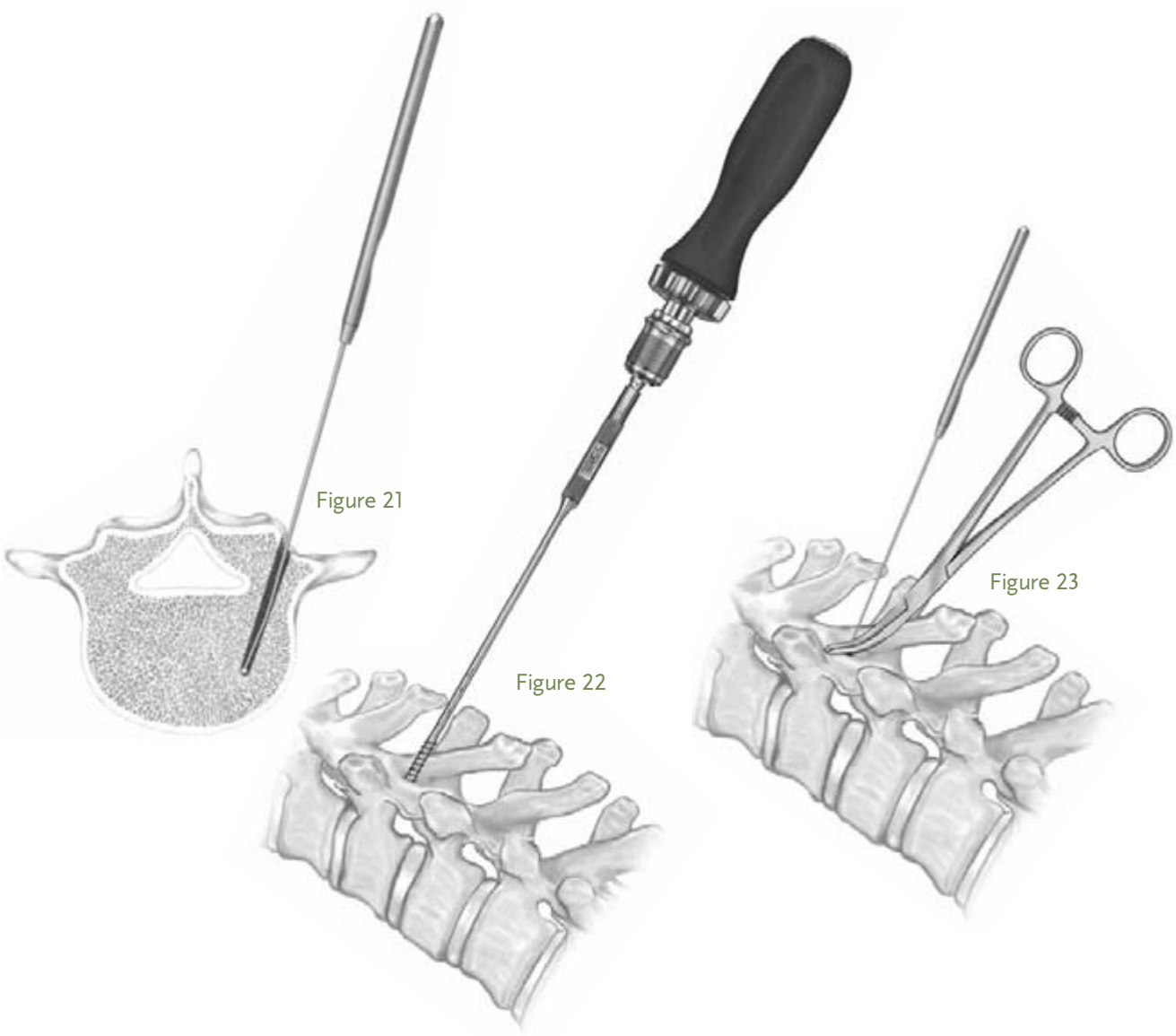


Figure 21

Figure 22

Figure 23

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 24 and 25). 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 24

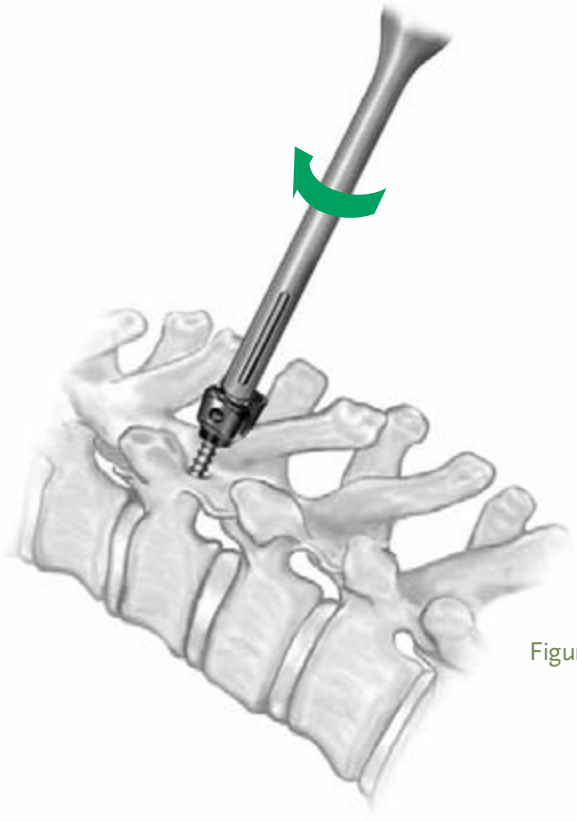


Figure 25

Hook Options/Placement

The CD HORIZON ENGAGE™ 6.35mm Spinal System offers open and closed hooks with a wide blade, narrow blade, and pedicle blade design with a variety of sizes available. See page 5 for additional hook implant options. The wide blade and narrow blade hooks may be placed at the infralaminar, supralaminar, infratransverse, or supratransverse process. However, the pedicle hooks are for pedicle placement only. The appropriate hook is chosen based on the patient's anatomy, deformity degree and type, method of correction and the 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. When placing Open Hooks, use the Straight, Curved, or Lateral Hook Holders. When placing Closed Hooks, use the Straight or Curved Hook Holders. The Hook Pusher may be used with either the Open or Closed Hooks to assist with seating the hook (Figure 26).

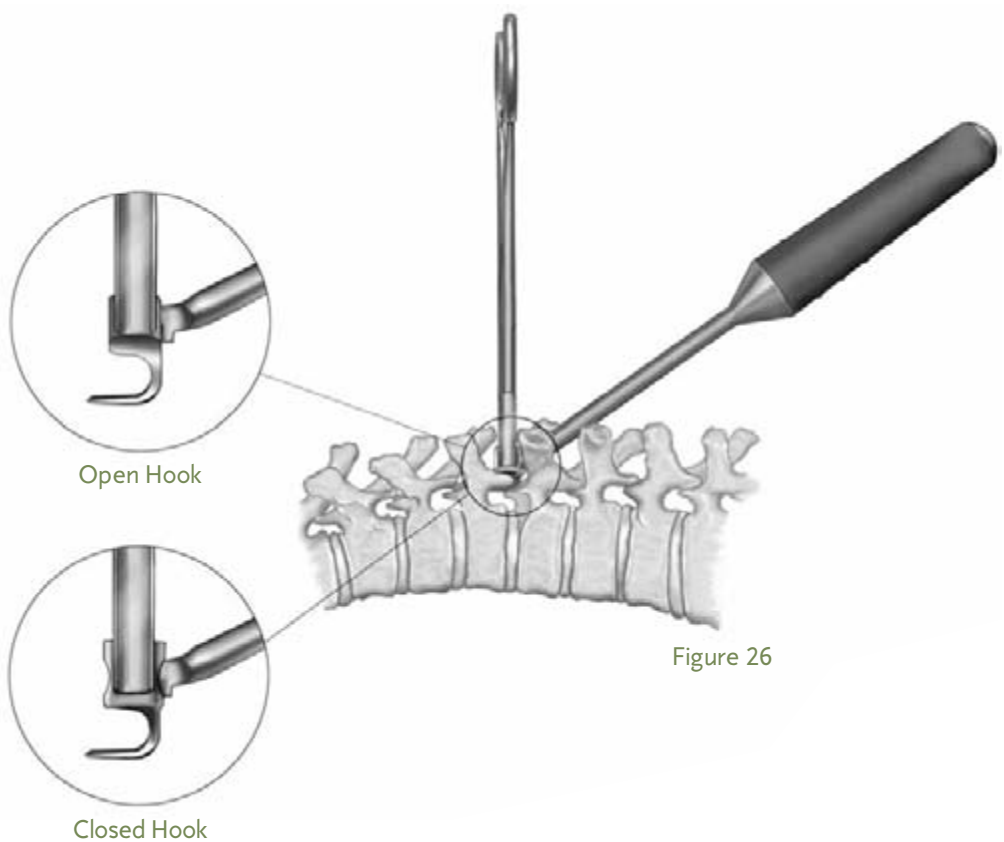


Figure 26

Pedicle Hook Placement

The facet capsule is first divided, and a portion of the inferior facet process may be removed to facilitate hook insertion (Figure 27). Once the pedicle has been identified clearly with the help of the Pedicle Elevator (Figure 28), the hook may be inserted in a cephalad (up-going) direction.

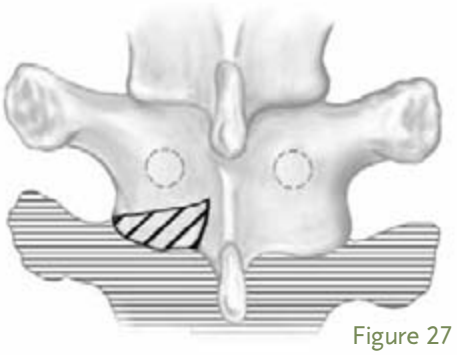


Figure 27

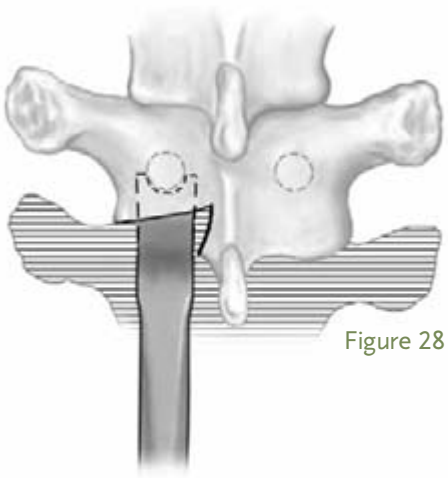
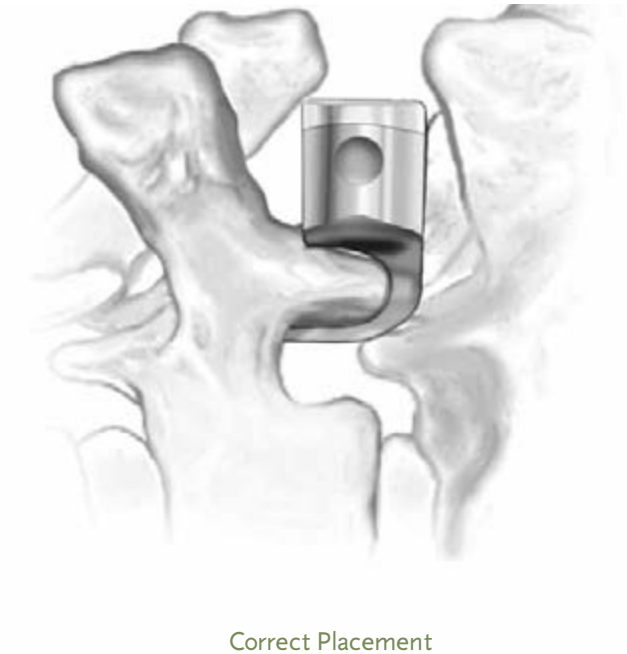


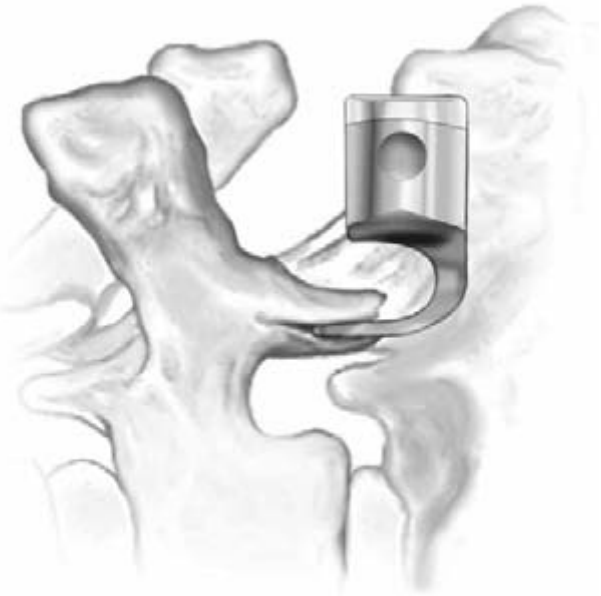
Figure 28

Pedicle Hook Placement (continued)

If needed, a mallet may be used to impact the Hook Pusher to help seat the hook. Ensure the Pedicle Hook is placed into the joint cavity and is not splitting the inferior articular process (Figure 29a and 29b).



Correct Placement
Figure 29a



Incorrect Placement
Figure 29b

Supralaminar Hook Placement

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 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 chosen. The upper edge of the lamina below may then be resected to ease the placement of this hook. The Laminar Elevator can be used to check the space between laminar and peridural structures (Figure 30). A Narrow or Wide Blade Hook is then inserted in a caudal (down-going) direction (Figure 31).

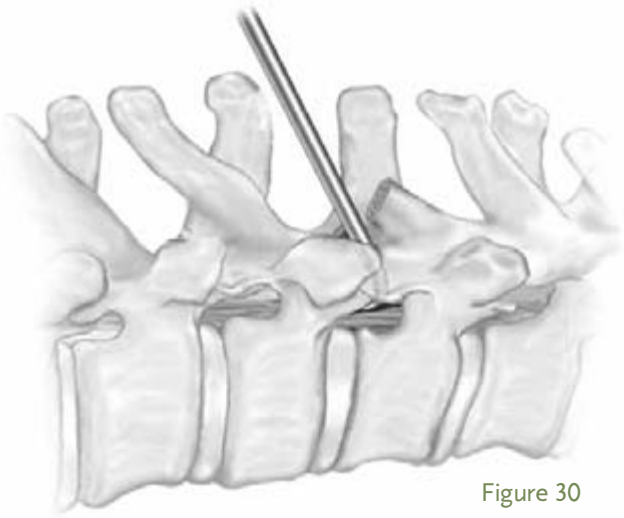


Figure 30

Figure 31

Infralaminar Hook Placement

This hook is always inserted in the cephalad direction (up-going). When using 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 (Figure 32). A Narrow or Wide Blade Hook is then inserted in a cephalad (up-going) direction (Figure 33).

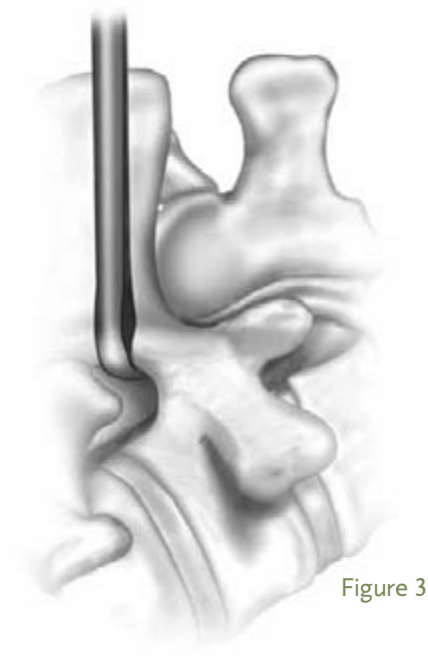


Figure 32

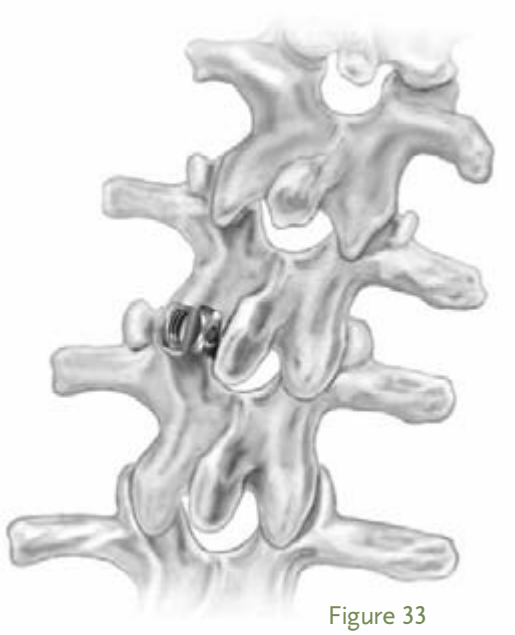


Figure 33

Transverse Process Hook Placement

This is generally a Wide Blade Hook and is typically used in a pedicle/transverse claw construct as a caudal (down-going) hook (Figure 34). 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.

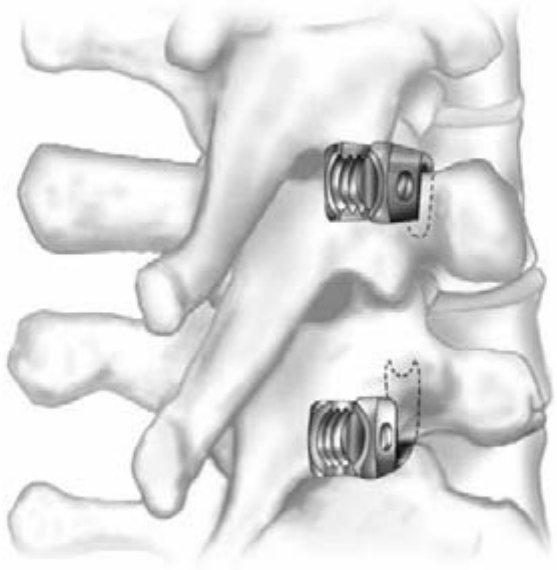


Figure 34

Construct Overview

The versatility of implants offered in the CD HORIZON ENGAGE™ 6.35 System enables the surgeon to perform their preferred technique for deformity correction. As seen in the figures below, the same right thoracic, left lumbar can be instrumented using a bolt, connector, thoracic pedicle screw technique (Figure 35a) or using a bolt, connector, hook, and wire technique (Figure 35b). For the purposes of illustrating the use of the CD HORIZON ENGAGE™ 6.35 Spinal System instrumentation in the correction of a right thoracic, left lumbar curve, the constructs below will be used.

Note: The CD HORIZON ENGAGE™ 6.35 Spinal System does not include wire or cable, but wire and cable are available in the MSD Wire and ATLAS® Cable Systems.

Figure 35a

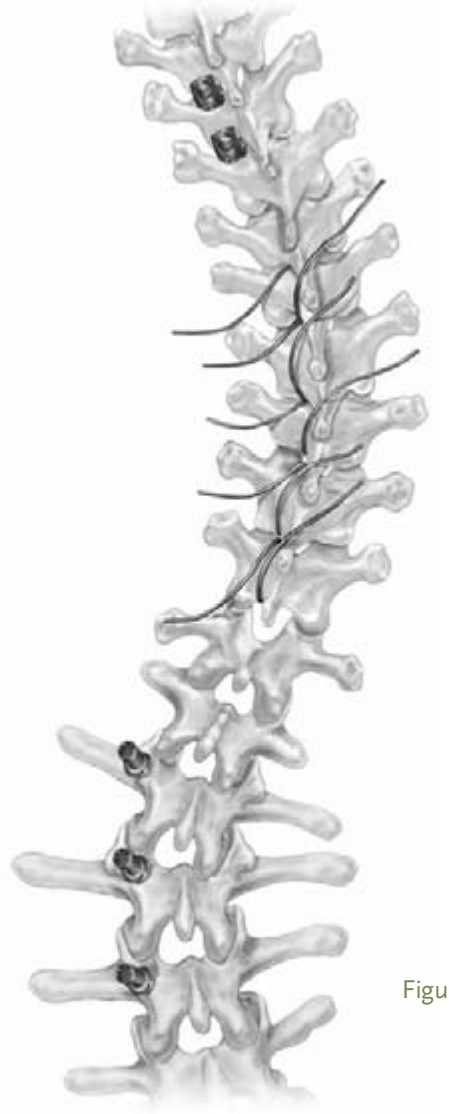


Figure 35b

Rod Contouring

A rod template may be used to assist in determining the length and contour of the rod prior to rod bending. The rod is contoured to the expected sagittal contour of the spine using the French Bender (Figure 36) or the Plate/Rod Bender (Figure 37).

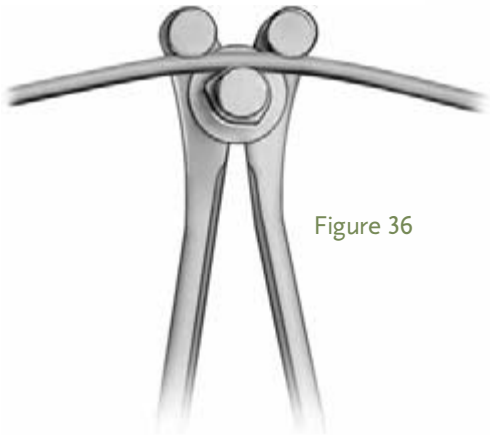


Figure 36

Figure 37

Rod/Slotted Connector Placement

The Slotted Connector allows versatility when engaging the screw to the rod. In rigid lumbar deformities, a top-loading implant is limited in its ability to capture the rod where as the Bolt and Slotted Connector facilitates this connection, eliminates coronal plane bending requirements, and reduces the stress at the bone/screw interface.

The rod is placed into the proximal hooks or screws first. If it is determined that Multi Axial Washers are required, the washers can be placed over the bolt post. The Multi Axial Washers give the slotted connector 26° of conical angulation around the pedicle bolt (Figure 38a). If Multi Axial Washers are not used, the Slotted Connector will have a 90/90, or fixed right angle, connection to the bolt (Figure 38b). The Slotted Connectors are then placed onto the rod and rotated over the bolt posts (Figure 39). The Slotted Connectors provide an effective way to easily connect to the rod in a rigid lumbar deformity.

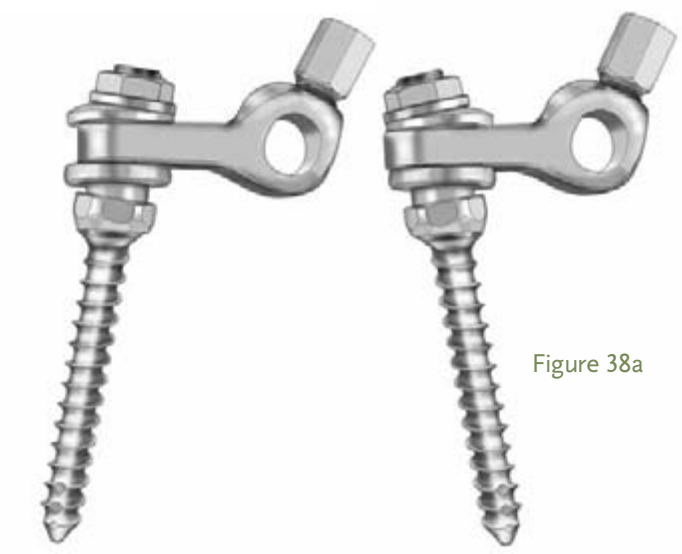


Figure 38a

Figure 38b

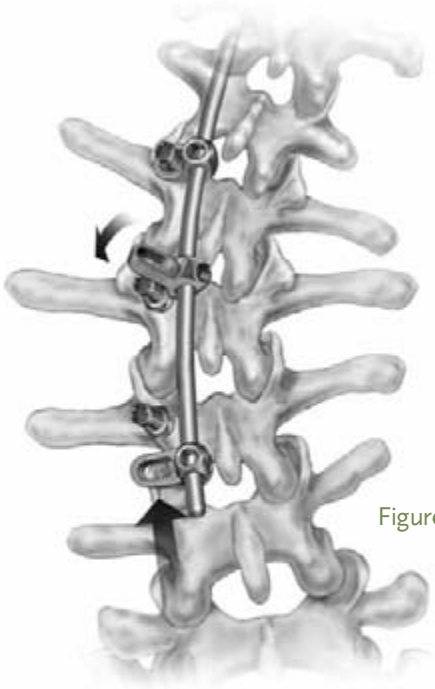


Figure 39

Multi Axial Nut Placement

The Slotted Connectors are loosely secured to the bolt with the Multi Axial Nuts using the Speed Wrench (Figure 40) or the Torque Limiting Nut Driver in combination with the Bolt Counter Torque (Figure 41). The Multi Axial Nut is the only fixation nut in the system and is used for both multi-axial and 90/90 connections.

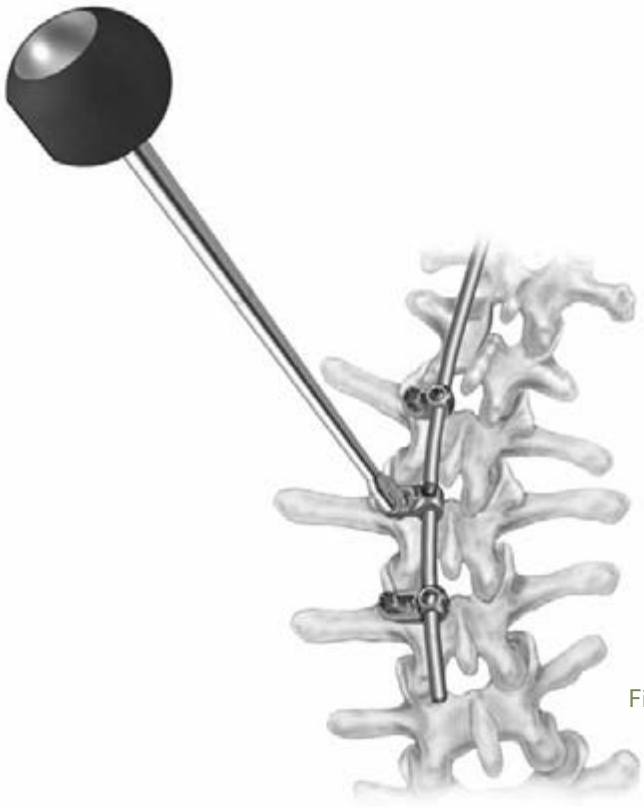


Figure 40

Figure 41

Set Screw Placement

The set screws are also placed and loosely secured at this time using either the Dual Ended Set Screw Starter (Figure 42a) or the Provisional Set Screw Driver (Figure 42b). However, based on preference, the set screws may be pre-loaded into the slotted connectors and closed hooks prior to placement.

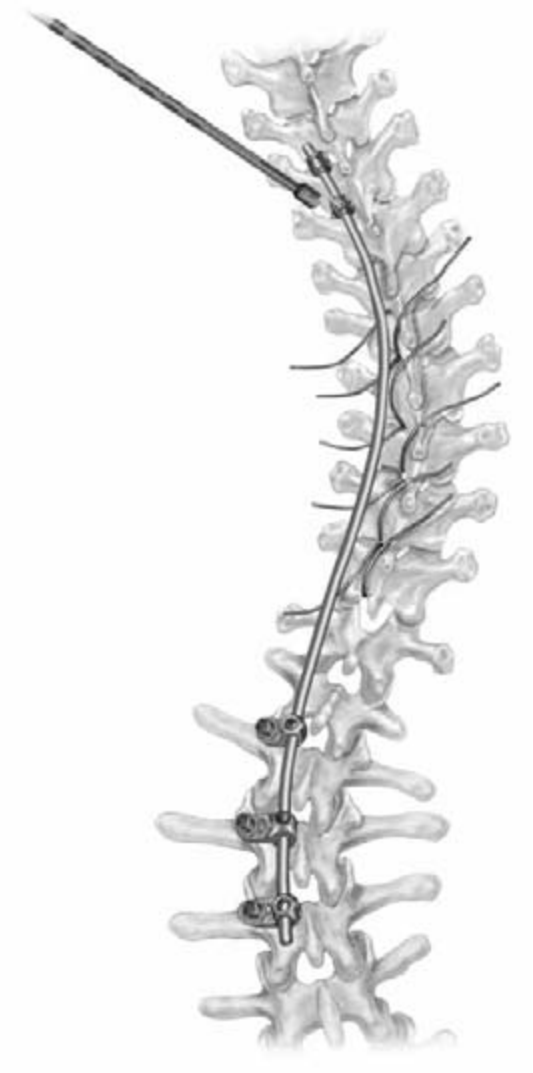


Figure 42a

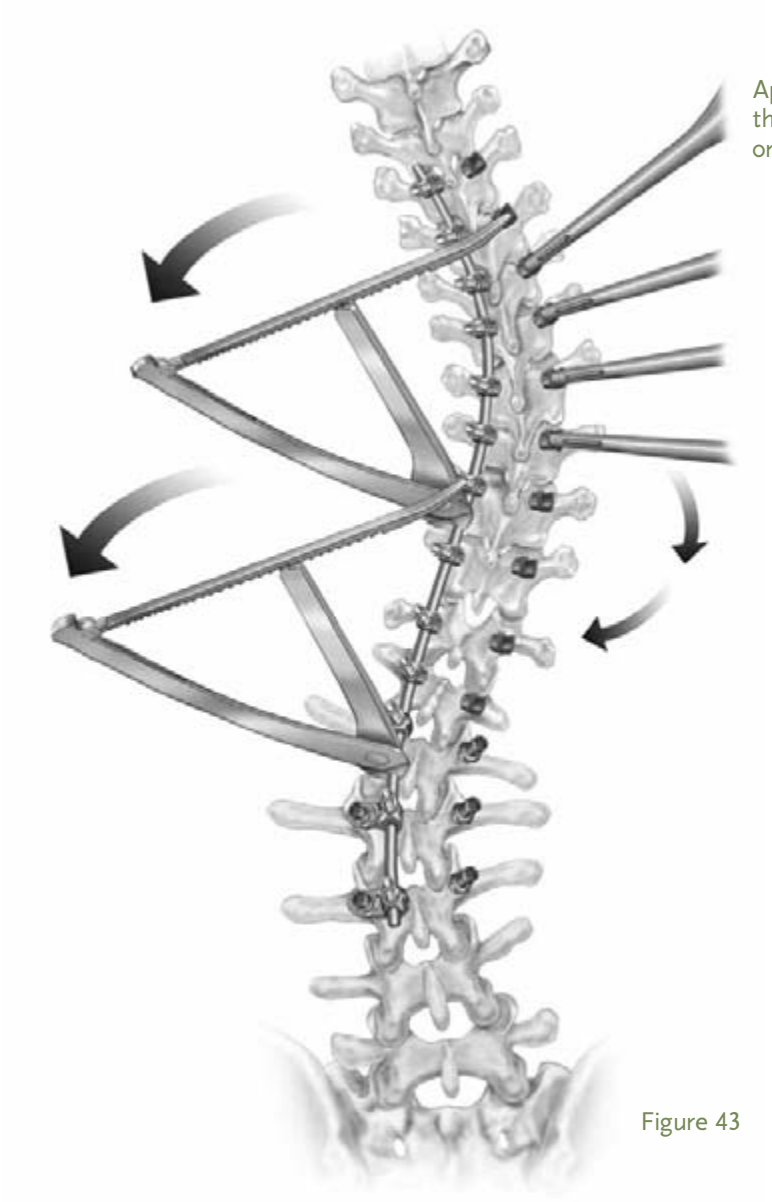
Figure 42b

Rod Rotation and Correction

Once all of the slotted connectors on the correction rod have been placed and all Multi-Axial Nuts and Set Screws have been loosely secured (Figure 43), the deformity is corrected.

In the setting of an all-screw construct, deformity correction is accomplished with simultaneous forces at the apical curve convexity and concavity. Specifically apical derotation at the convex thoracic curve enables the concave screws on other connectors to engage the rod in a corrected position. Subsequent rod rotation and segmental compression/distraction can significantly enhance curve correction in the axial, coronal and sagittal planes.

NOTE: Apical Derotation Instruments are available by ordering the Apical Derotation Instrument Set for the CD HORIZON® LEGACY™ System.



Apply downward and then medial pressure on the screwdrivers.

Figure 43

Rod Rotation and Correction (continued)

If a pedicle screw, connector, hook, and wire construct is used, the proximal hooks are held in place with a Compressor and the rod is rotated using a Rod Gripper partially correcting the lumbar spine (Figure 44). The Hex Rod Rotation Wrench may also be used to assist with rod rotation. While the rod is held in place, the Set Screws in the proximal hooks are then tightened to help prevent the rod from rotating and losing the correction.

The wires or cables placed prior to rod placement are then sequentially tightened to correct the thoracic spine. The rod must continue to be held in sagittal plane alignment by an assistant during this step. This provides a counter force to the correction of the deformity by the wires/cables and prevents the rod from rotating back toward the spine and compromising the deformity correction. When the desired correction is obtained, the Set Screws and then the Multi Axial Nuts are provisionally tightened to hold the correction (Figure 45). If additional rotational correction of the vertebral body about the rod is required, it can be obtained by gently manipulating the pedicle bolts, and thereby the vertebral body, into the desired position and then provisionally tightening the Set Screw and Multi Axial Nut to lock the correction in place.

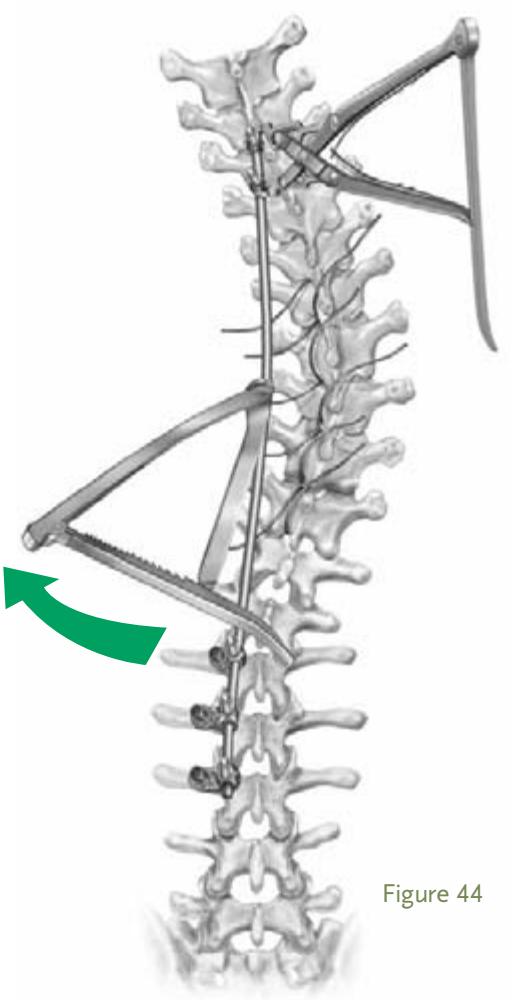


Figure 44

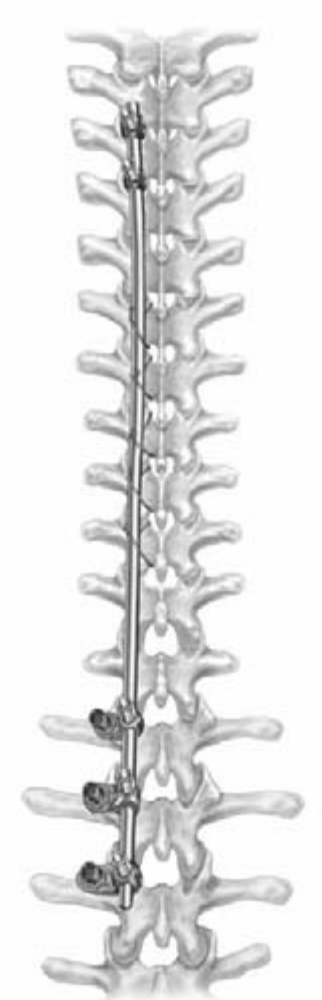


Figure 45

In situ Bending

In situ Benders or coronal plane benders may be used for additional 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 46a and 46b).

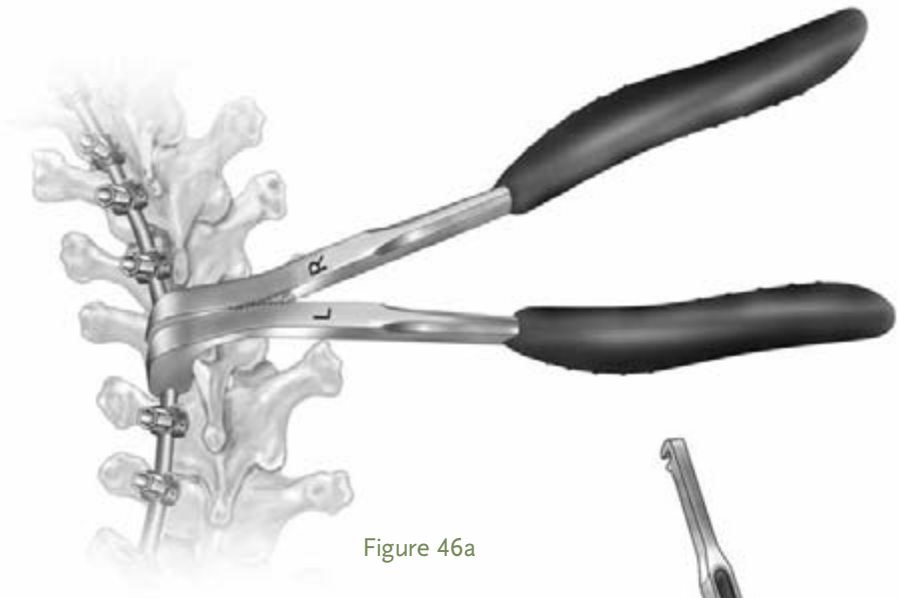


Figure 46a

Figure 46b

Stabilizing Rod Placement

With the desired correction achieved the stabilizing rod is placed and provisionally locked with the Multi Axial Nuts and Set Screws (Figure 47).

Compression and/or distraction may be applied to the distal vertebra along the rod through the rod connector to correct angulation of the last vertebral level fused as dictated by the deformity.

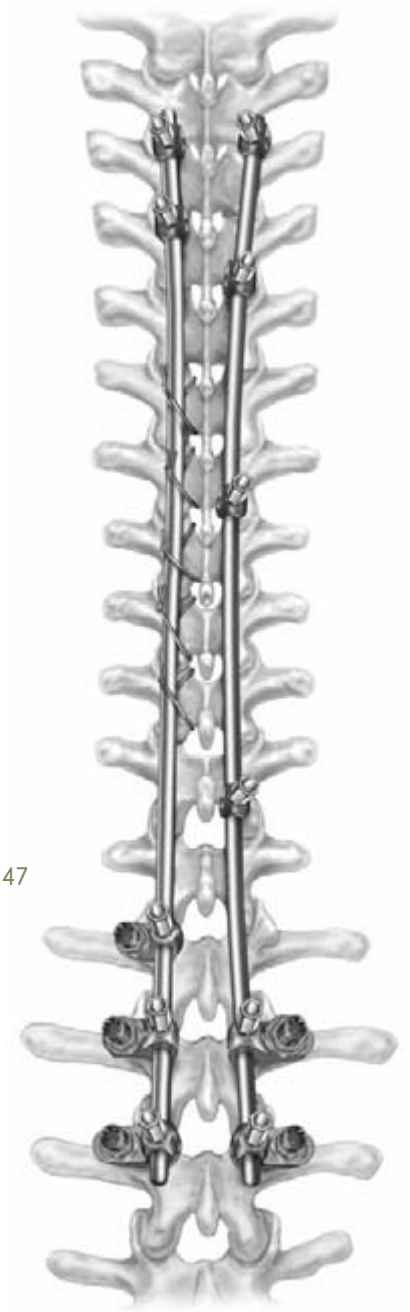


Figure 47

Rod Reduction

If rod reduction is required for the open hooks or screws, there are three instruments that are included in the instrument set and can be used to assist with this. They are the Forceps Rocker, the Beale Rod Reducer, and a standard Rod Pusher.

Forceps Rocker

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 48a). This angle will avoid dislodging the hook. Lever the Forceps Rocker backward 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 48b).

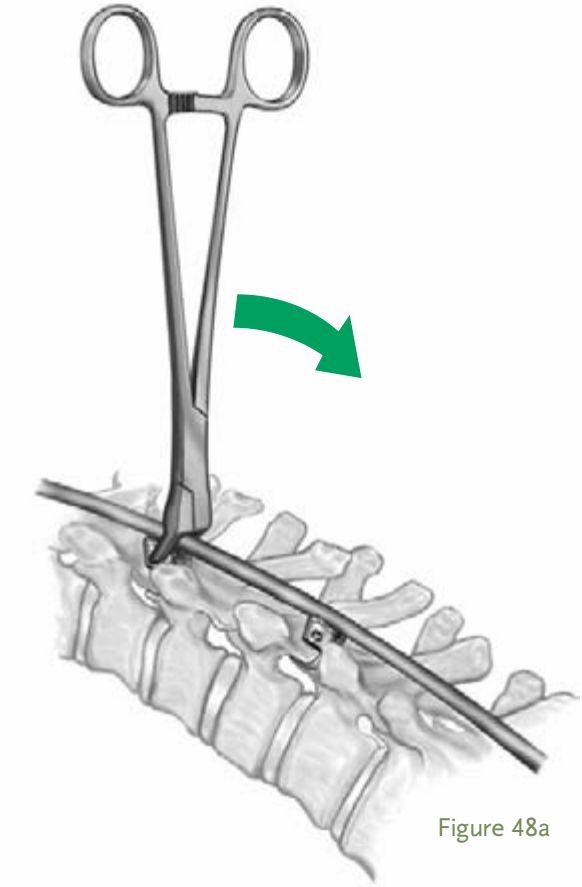


Figure 48a

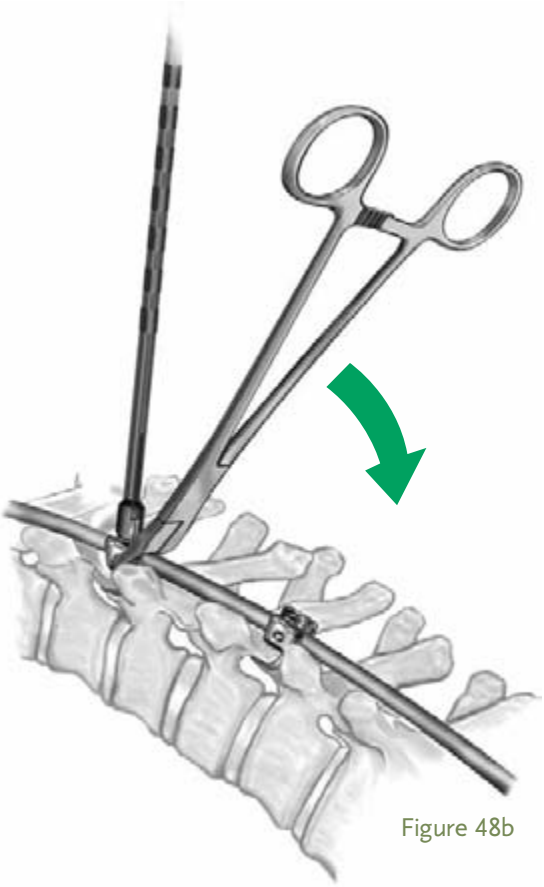


Figure 48b

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 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 49). A Set Screw is then placed through the set screw tube of the reducer using the Provisional Driver (Figure 50).

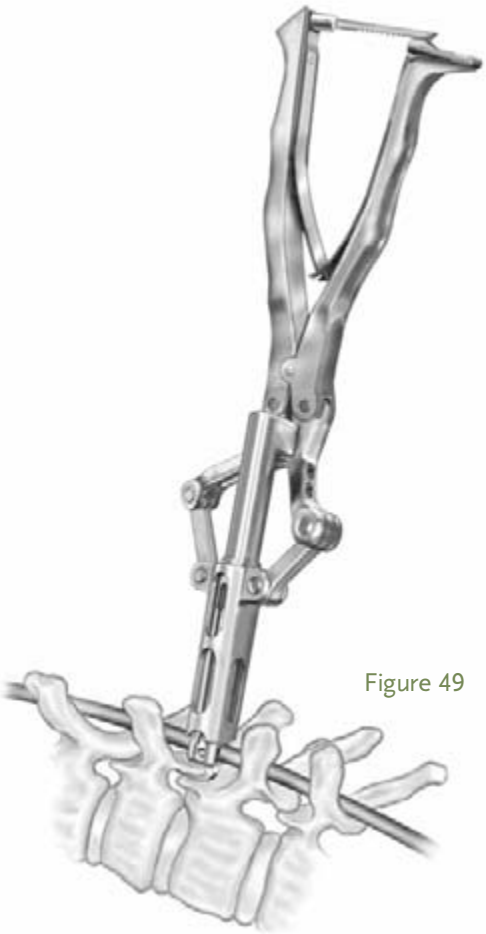


Figure 49

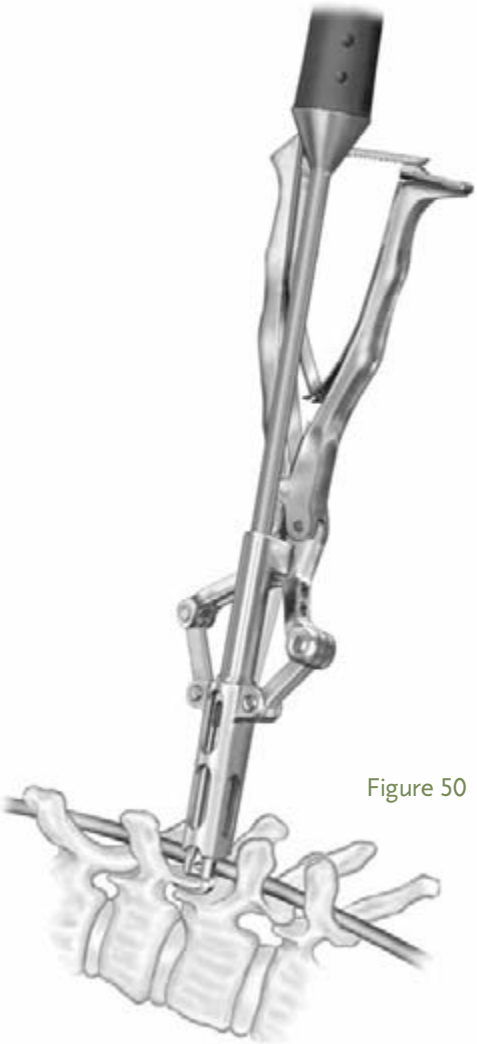


Figure 50

Compression/Distraction

Once the stabilizing rod is secure, distraction and/or compression are performed to place the hooks in their final position or to gain added correction. The Parallel Compressors, Distractors, 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 51), with the exception of the inverted claw. Compression maneuvers are most often carried out directly on two hooks (Figure 52). Care should be taken to ensure 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 using the Provisional Driver. It is preferred that compression be released just prior to the Set Screws being broken off or final tightened. This technique will help ensure that the implant head and rod are normalized to one another and thus allow for the rod to be fully seated in the implant head during the final tightening step.

"It is highly recommended that the Set Screws not be broken off or final tightened under compression."

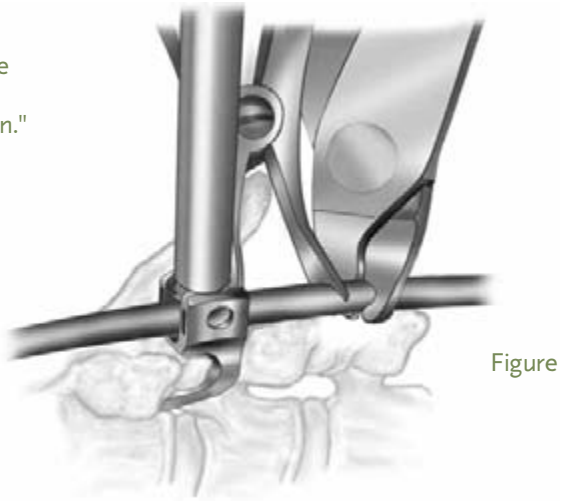


Figure 51

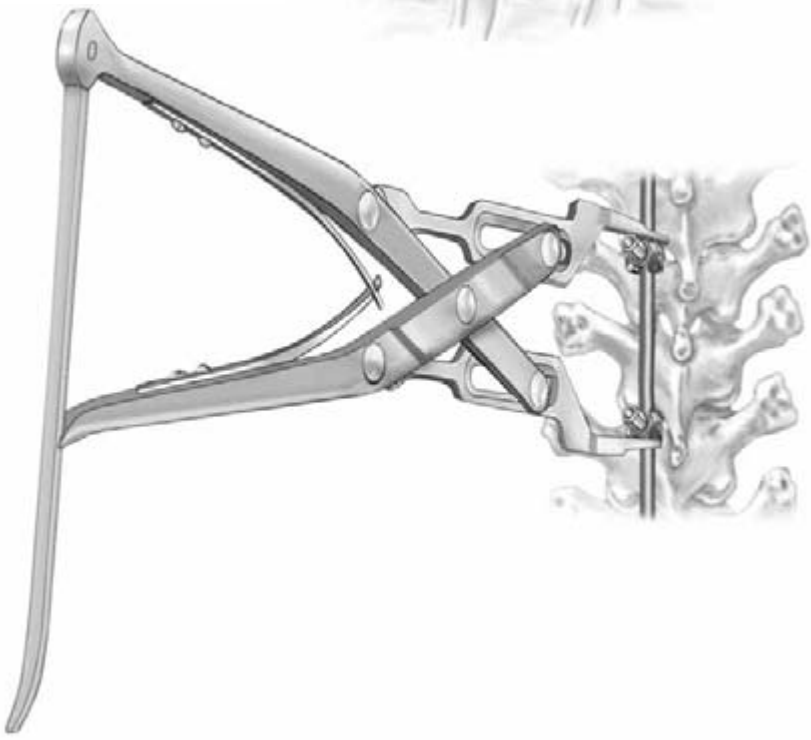


Figure 52

Set Screw Final Tightening

Once fixation is verified radiographically to confirm spinal correction and alignment, final tightening and/or break-off of the Set Screw heads is performed. The appropriate Counter Torque is placed over the implant and the rod (Figure 53). The Self Retaining Break-Off Driver is then placed through the cannulated Counter Torque and seated onto the Set Screw. The handle of the Counter Torque should be held firmly and the Break-Off Driver turned clockwise to shear off the set screw head (Figure 54). The part of the Set Screw that is broken off is then captured in the cannulated portion of the Self-Retaining Break-Off Driver. Following final tightening, the broken-off portions of the Set Screws accumulated in the driver are removed using the T27 Obturator shaft (Figure 55).

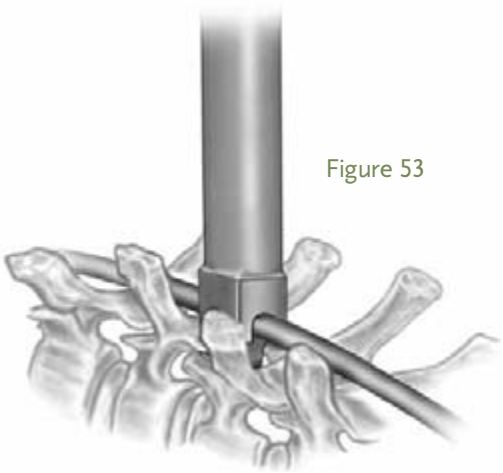


Figure 53

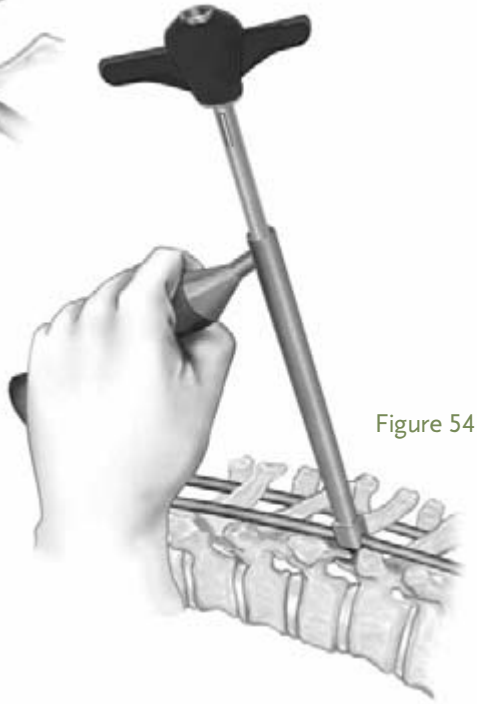


Figure 54

Figure 55

Multi Axial Nut Final Tightening

Once all set screws have been broken off, the final tightening is performed on the Multi Axial Nuts. The Bolt Counter Torque is placed through the cannulated Torque Limiting Nut Driver and then seated into the top of the bolt (Figure 56). The handle of the Bolt Counter Torque should be firmly held and the Torque Limiting Nut Driver turned clockwise. The handle on the Torque Limiting Nut Driver will then snap between 10 to 12 Nm, indicating the Multi Axial Nut is tightened to the appropriate torque. For those surgeons who prefer to tighten the nut by feel, a T-Handled Nut Driver is also provided with the instruments.

Figure 56

Long-post Bolt Cutting

If Long-post Bolts are used in the construct, a Bolt Cutter is provided to cut the posts once final tightening has been performed. The Bolt Cutter must be assembled. First place the Inner Cutter Tube into the Outer Cutter Tube and rotate 180° (Figure 57). You will feel the Inner Cutter Tube snap into place and the green dots on each tube will line up signifying the cutting assembly is in the open position (Figure 58).

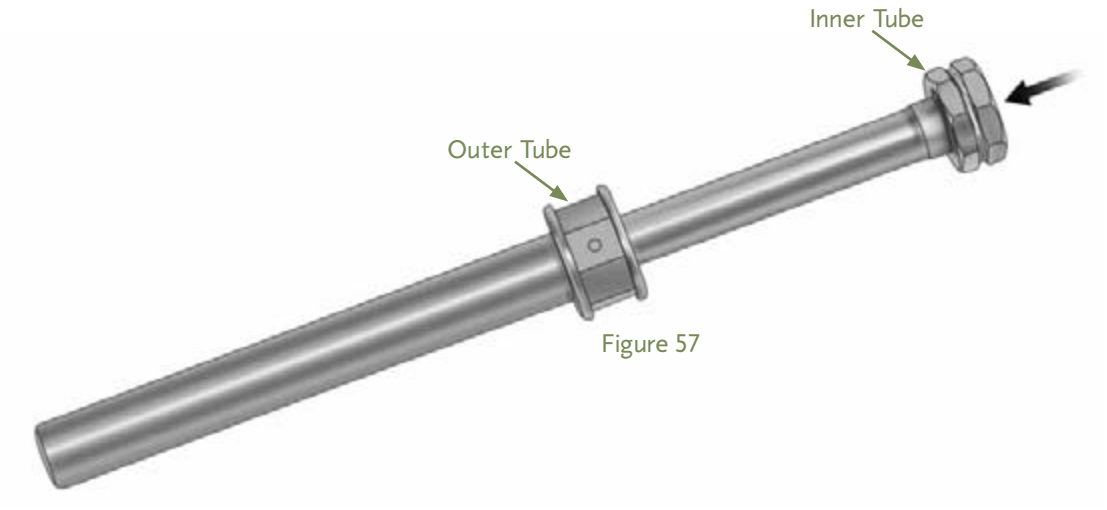


Figure 57

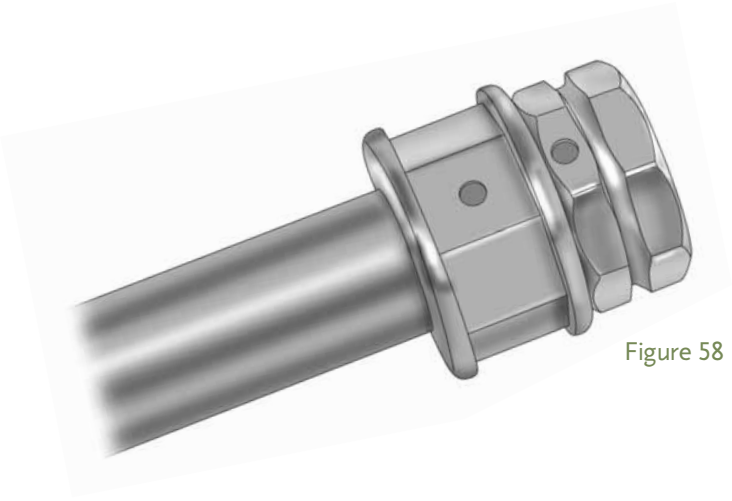


Figure 58

Long-post Bolt Cutting (continued)

Slide the cutting assembly over the post to be cut and then attach the Closed Handle onto the top of the assembly (Figure 59). Next, attach the Open Handle below the Closed Handle at roughly a 90° angle (Figure 60). Once both handles are attached, lever them together to cut the post (Figure 61). If the cut portion of the post becomes stuck in the cutter assembly, use the Obturator to push it out (Figure 62).

Note: Post Cutter may be used only on Long-post Bolts.

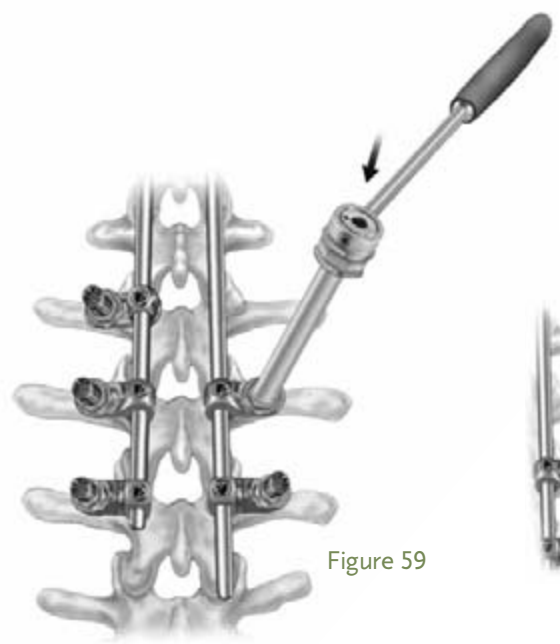


Figure 59

Figure 60

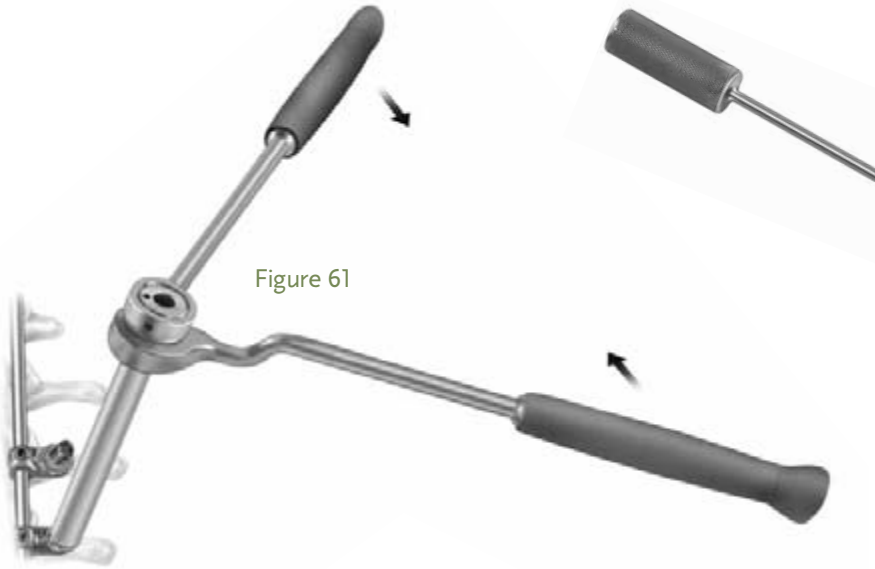


Figure 61

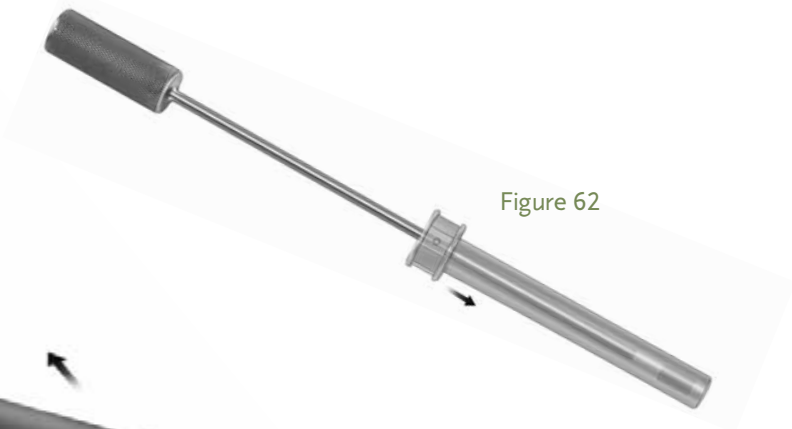


Figure 62

CROSSLINK® Plate Placement

It is recommended that a CROSSLINK® Plate be used to significantly increase the torsional stability of a construct. Ideally, a CROSSLINK® Plate should be placed on each end of the construct. Two systems are available for use with the CD HORIZON ENGAGE™ 6.35 Spinal System: the X10 CROSSLINK™ Plate (Figure 63) and the Low Profile CROSSLINK® Plate.

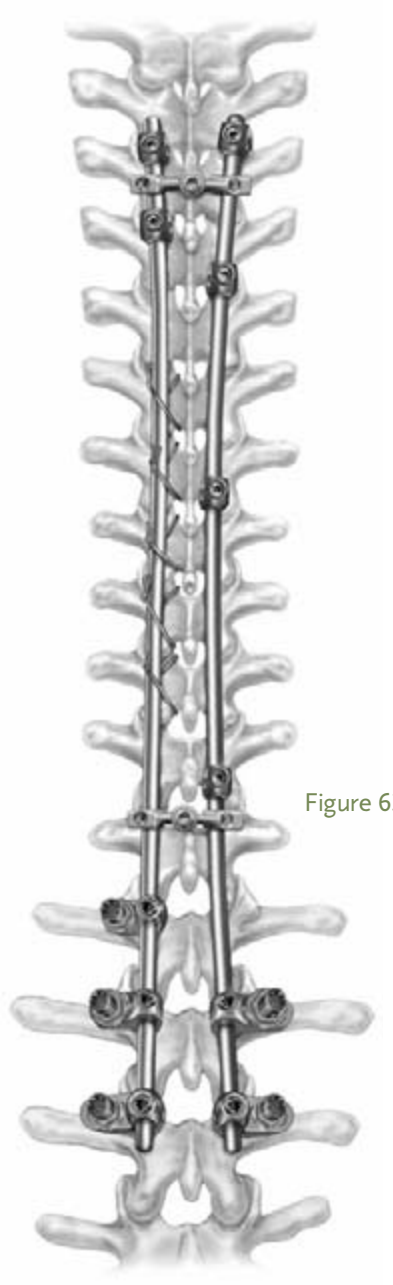


Figure 63

Rod-to-Rod Connector Placement

Rod-to-Rod Connectors are provided in the system to allow surgeons to connect to an existing construct during a revision procedure. They can also be used to connect two rods when using three, four, or multiple rod techniques for complex surgeries. The Connectors provide the ability for modular connection, adding to an existing construct, or providing iliac fixation to a construct. Connectors should be utilized in tandem when connecting two rods together, with a minimum of two per side (Figure 64). The Rod-to-Rod Connectors should also be spaced apart, between levels, to increase the overall strength of the construct and avoid the possibility of a pivot point between the two connected rods.

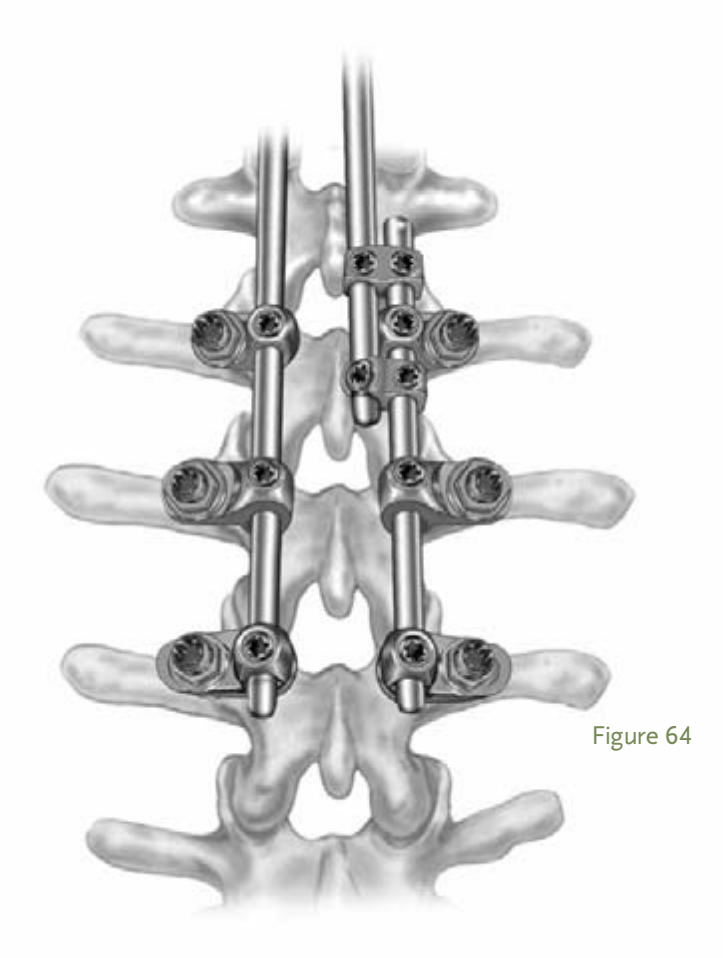


Figure 64

Product Ordering Information–Implants

Short-post Bolts					
Catalog Number		Description	Catalog Number		Description
Stainless	Titanium		Stainless	Titanium	
99614525	99414525	4.5mm X 25mm	99617030	99417030	7.0mm X 30mm
99614530	99414530	4.5mm X 30mm	99617035	99417035	7.0mm X 35mm
99614535	99414535	4.5mm X 35mm	99617040	99417040	7.0mm X 40mm
99614540	99414540	4.5mm X 40mm	99617045	99417045	7.0mm X 45mm
99614545	99414545	4.5mm X 45mm	99617050	99417050	7.0mm X 50mm
99614550	99414550	4.5mm X 50mm	99617055	99417055	7.0mm X 55mm
99615525	99415525	5.5mm X 25mm	99617060	99417060	7.0mm X 60mm
99615530	99415530	5.5mm X 30mm	99617530	99417530	7.5mm X 30mm
99615535	99415535	5.5mm X 35mm	99617535	99417535	7.5mm X 35mm
99615540	99415540	5.5mm X 40mm	99617540	99417540	7.5mm X 40mm
99615545	99415545	5.5mm X 45mm	99617545	99417545	7.5mm X 45mm
99615550	99415550	5.5mm X 50mm	99617550	99417550	7.5mm X 50mm
99615555	99415555	5.5mm X 55mm	99617555	99417555	7.5mm X 55mm
99616525	99416525	6.5mm X 25mm	99617560	99417560	7.5mm X 60mm
99616530	99416530	6.5mm X 30mm	99617565	99417565	7.5mm X 65mm
99616535	99416535	6.5mm X 35mm	99617570	99417570	7.5mm X 70mm
99616540	99416540	6.5mm X 40mm	99618535	99418535	8.5mm X 35mm
99616545	99416545	6.5mm X 45mm	99618530	99418530	8.5mm X 30mm
99616550	99416550	6.5mm X 50mm	99618540	99418540	8.5mm X 40mm
99616555	99416555	6.5mm X 55mm	99618545	99418545	8.5mm X 45mm
99616560	99416560	6.5mm X 60mm	99618550	99418550	8.5mm X 50mm
99616565	99416565	6.5mm X 65mm	99618555	99418555	8.5mm X 55mm
			99618560	99418560	8.5mm X 60mm
			99618565	99418565	8.5mm X 65mm
			99618570	99418570	8.5mm X 70mm

Product Ordering Information–Implants

Long-post Bolts					
Catalog Number		Description	Catalog Number		Description
Stainless	Titanium		Stainless	Titanium	
99624525	99424525	4.5mm X 25mm	99627030	99427030	7.0mm X 30mm
99624530	99424530	4.5mm X 30mm	99627035	99427035	7.0mm X 35mm
99624535	99424535	4.5mm X 35mm	99627040	99427040	7.0mm X 40mm
99624540	99424540	4.5mm X 40mm	99627045	99427045	7.0mm X 45mm
99624545	99424545	4.5mm X 45mm	99627050	99427050	7.0mm X 50mm
99624550	99424550	4.5mm X 50mm	99627055	99427055	7.0mm X 55mm
99625525	99425525	5.5mm X 25mm	99627060	99427060	7.0mm X 60mm
99625530	99425530	5.5mm X 30mm	99627530	99427530	7.5mm X 30mm
99625535	99425535	5.5mm X 35mm	99627535	99427535	7.5mm X 35mm
99625540	99425540	5.5mm X 40mm	99627540	99427540	7.5mm X 40mm
99625545	99425545	5.5mm X 45mm	99627545	99427545	7.5mm X 45mm
99625550	99425550	5.5mm X 50mm	99627550	99427550	7.5mm X 50mm
99625555	99425555	5.5mm X 55mm	99627555	99427555	7.5mm X 55mm
99626525	99426525	6.5mm X 25mm	99627560	99427560	7.5mm X 60mm
99626530	99426530	6.5mm X 30mm	99627565	99427565	7.5mm X 65mm
99626535	99426535	6.5mm X 35mm	99627570	99427570	7.5mm X 70mm
99626540	99426540	6.5mm X 40mm	99628530	99428530	8.5mm X 30mm
99626545	99426545	6.5mm X 45mm	99628535	99428535	8.5mm X 35mm
99626550	99426550	6.5mm X 50mm	99628540	99428540	8.5mm X 40mm
99626555	99426555	6.5mm X 55mm	99628545	99428545	8.5mm X 45mm
99626560	99426560	6.5mm X 60mm	99628550	99428550	8.5mm X 50mm
99626565	99426565	6.5mm X 65mm	99628555	994 28555	8.5mm X 55mm
			99628560	99428560	8.5mm X 60mm
			99628565	99428565	8.5mm X 65mm
			99628570	99428570	8.5mm X 70mm

Slotted Connectors		
Catalog Number		Description
Stainless	Titanium	
99653200	99453200	Rod Bolt Connector, Extra Small
99653201	99453201	Rod Bolt Connector, Small
99653202	99453202	Rod Bolt Connector, Medium
99653203	99453203	Rod Bolt Connector, Large
99653205	99453205	Rod Bolt Connector, Right Angled, Small
99653206	99453206	Rod Bolt Connector, Right Angled, Medium
99653207	99453207	Rod Bolt Connector, Left Angled, Small
99653208	99453208	Rod Bolt Connector, Left Angled, Medium
99653301	99453301	Coronal Spinner Connector, Medium
99653302	99453302	Coronal Spinner Connector, Offset, Medium
99653305	99453305	Sagittal Spinner Connector, Medium
99653306	99453306	Sagittal Spinner Connector, Large

Product Ordering Information–Implants

Closed Hooks		
Catalog Number		Description
Stainless	Titanium	
99671165	99471165	Closed Pedicle Hook, Small
99671180	99471180	Closed Pedicle Hook, Medium
99671250	99471250	Closed Hook, Narrow Blade, Extra Small Groove
99671265	99471265	Closed Hook, Narrow Blade, Small Groove
99671280	99471280	Closed Hook, Narrow Blade, Medium Groove
99671295	99471295	Closed Hook, Narrow Blade, Large Groove
99671212	99471212	Closed Hook, Narrow Blade, Extra Large Groove
99671350	99471350	Closed Hook, Wide Blade, Extra Small Groove
99671365	99471365	Closed Hook, Wide Blade, Small Groove
99671380	99471380	Closed Hook, Wide Blade, Medium Groove
99671395	99471395	Closed Hook, Wide Blade, Large Groove
99671312	99471312	Closed Hook, Wide Blade, Extra Large Groove

Open Hooks		
Catalog Number		Description
Stainless	Titanium	
99672165	99472165	Open Hook, Pedicle, Small
99672180	99472180	Open Hook, Pedicle, Medium
99672250	99472250	Open Hook, Narrow Blade, Extra Small Groove
99672265	99472265	Open Hook, Narrow Blade, Small Groove
99672280	99472280	Open Hook, Narrow Blade, Medium Groove
99672295	99472295	Open Hook, Narrow Blade, Large Groove
99672212	99472212	Open Hook, Narrow Blade, Extra Large Groove
99672350	99472350	Open Hook, Wide Blade, Extra Small Groove
99672365	99472365	Open Hook, Wide Blade, Small Groove
99672380	99472380	Open Hook, Wide Blade, Medium Groove
99672395	99472395	Open Hook, Wide Blade, Large Groove
99672312	99472312	Open Hook, Wide Blade, Extra Large Groove
7661198	7641198	Open Offset Hook, Right
7661199	7641199	Open Offset Hook, Left

Product Ordering Information–Implants

Multi Axial Screws					
Catalog Number		Description	Catalog Number		Description
Stainless	Titanium		Stainless	Titanium	
76644520	76444520	4.0mm X 20mm	76646525	76446525	6.5mm X 25mm
76644525	76444525	4.0mm X 25mm	76646530	76446530	6.5mm X 30mm
76644530	76444530	4.0mm X 30mm	76646535	76446535	6.5mm X 35mm
76644535	76444535	4.0mm X 35mm	76646540	76446540	6.5mm X 40mm
76644540	76444540	4.0mm X 40mm	76646545	76446545	6.5mm X 45mm
76644545	76444545	4.0mm X 45mm	76646550	76446550	6.5mm X 50mm
76644550	76444550	4.0mm X 50mm	76646555	76446555	6.5mm X 55mm
76644520	76444520	4.5mm X 20mm	76646560	76446560	6.5mm X 60mm
76644525	76444525	4.5mm X 25mm	76646565	76446565	6.5mm X 65mm
76644530	76444530	4.5mm X 30mm	76646570	76446570	6.5mm X 70mm
76644535	76444535	4.5mm X 35mm	76646575	76446575	6.5mm X 75mm
76644540	76444540	4.5mm X 40mm	76647525	76447525	7.5mm X 25mm
76644545	76444545	4.5mm X 45mm	76647530	76447530	7.5mm X 30mm
76644550	76444550	4.5mm X 50mm	76647535	76447535	7.5mm X 35mm
76645020	76445020	5.0mm X 20mm	76647540	76447540	7.5mm X 40mm
76645025	76445025	5.0mm X 25mm	76647545	76447545	7.5mm X 45mm
76645030	76445030	5.0mm X 30mm	76647550	76447550	7.5mm X 50mm
76645035	76445035	5.0mm X 35mm	76647555	76447555	7.5mm X 55mm
76645040	76445040	5.0mm X 40mm	76647560	76447560	7.5mm X 60mm
76645045	76445045	5.0mm X 45mm	76647565	76447565	7.5mm X 65mm
76645050	76445050	5.0mm X 50mm	76647570	76447570	7.5mm X 70mm
76645520	76445520	5.5mm X 20mm	76647575	76447575	7.5mm X 75mm
76645525	76445525	5.5mm X 25mm	76648525	76448525	8.5mm X 25mm
76645530	76445530	5.5mm X 30mm	76648530	76448530	8.5mm X 30mm
76645535	76445535	5.5mm X 35mm	76648535	76448535	8.5mm X 35mm
76645540	76445540	5.5mm X 40mm	76648540	76448540	8.5mm X 40mm
76645545	76445545	5.5mm X 45mm	76648545	76448545	8.5mm X 45mm
76645550	76445550	5.5mm X 50mm	76648550	76448550	8.5mm X 50mm
76645555	76445555	5.5mm X 55mm	76648555	76448555	8.5mm X 55mm
76645560	76445560	5.5mm X 60mm	76648560	76448560	8.5mm X 60mm
76646025	76446025	6.0mm X 25mm	76648565	76448565	8.5mm X 65mm
76646030	76446030	6.0mm X 30mm	76648570	76448570	8.5mm X 70mm
76646035	76446035	6.0mm X 35mm	76648575	76448575	8.5mm X 75mm
76646040	76446040	6.0mm X 40mm			
76646045	76446045	6.0mm X 45mm			
76646050	76446050	6.0mm X 50mm			
76646055	76446055	6.0mm X 55mm			
76646060	76446060	6.0mm X 60mm			
76646065	76446065	6.0mm X 65mm			
76646070	76446070	6.0mm X 70mm			
76646075	76446075	6.0mm X 75mm			

Product Ordering Information–Implants

Fixed Angle Screws					
Catalog Number		Description	Catalog Number		Description
Stainless	Titanium		Stainless	Titanium	
7662420	7642420	4.0mm X 20mm	7662625	7642625	6.0mm X 25mm
7662425	7642425	4.0mm X 25mm	7662630	7642630	6.0mm X 30mm
7662430	7642430	4.0mm X 30mm	7662635	7642635	6.0mm X 35mm
7662435	7642435	4.0mm X 35mm	7662640	7642640	6.0mm X 40mm
7662440	7642440	4.0mm X 40mm	7662645	7642645	6.0mm X 45mm
7662445	7642445	4.0mm X 45mm	7662650	7642650	6.0mm X 50mm
7662450	7642450	4.0mm X 50mm	7662655	7642655	6.0mm X 55mm
7662455	7642455	4.0mm X 55mm	7662660	7642660	6.0mm X 60mm
7663420	7643420	4.5mm X 20mm	7663625	7643625	6.5mm X 25mm
7663425	7643425	4.5mm X 25mm	7663630	7643630	6.5mm X 30mm
7663430	7643430	4.5mm X 30mm	7663635	7643635	6.5mm X 35mm
7663435	7643435	4.5mm X 35mm	7663640	7643640	6.5mm X 40mm
7663440	7643440	4.5mm X 40mm	7663645	7643645	6.5mm X 45mm
7663445	7643445	4.5mm X 45mm	7663650	7643650	6.5mm X 50mm
7663450	7643450	4.5mm X 50mm	7663655	7643655	6.5mm X 55mm
7663455	7643455	4.5mm X 55mm	7663660	7643660	6.5mm X 60mm
7662520	7642520	5.0mm X 20mm	7663665	7643665	6.5mm X 65mm
7662525	7642525	5.0mm X 25mm	7663670	7643670	6.5mm X 70mm
7662530	7642530	5.0mm X 30mm	7663725	7643725	7.5mm X 25mm
7662535	7642535	5.0mm X 35mm	7663730	7643730	7.5mm X 30mm
7662540	7642540	5.0mm X 40mm	7663735	7643735	7.5mm X 35mm
7662545	7642545	5.0mm X 45mm	7663740	7643740	7.5mm X 40mm
7662550	7642550	5.0mm X 50mm	7663745	7643745	7.5mm X 45mm
7662555	7642555	5.0mm X 55mm	7663750	7643750	7.5mm X 50mm
7663525	7643525	5.5mm X 25mm	7663755	7643755	7.5mm X 55mm
7663530	7643530	5.5mm X 30mm	7663760	7643760	7.5mm X 60mm
7663535	7643535	5.5mm X 35mm	7663765	7643765	7.5mm X 65mm
7663540	7643540	5.5mm X 40mm			
7663545	7643545	5.5mm X 45mm			
7663550	7643550	5.5mm X 50mm			
7663555	7643555	5.5mm X 55mm			
7663560	7643560	5.5mm X 60mm			

Set Screws/Nuts/Washers		
Catalog Number		Description
Stainless	Titanium	
99653115	99453115	Closed Implant Set Screw, Break Off
7660000	7645000	Open Implant Set Screw, Break Off
99653105	99453105	Multi Axial Nut
99653110	99453110	Multi Axial Washer
Rods		
808-088	969-022	6.35mm Rod
Rod-to-Rod Connectors		
99653501	99453501	6.35mm Closed/Closed Connector
99653502	99453502	6.35mm Open/Closed Connector

Product Ordering Information–Instruments

Quick Connect Handles	
Catalog Number	Description
9339082	Quick Connect Ratcheting Handle
9960106	Quick Connect Universal Handle

Pedicle Preparation	
9960105	Awl
9960110	Straight Lumbar Ball Handle Probe
7480112	Thoracic Ball Handle Probe
8683750	3.75mm Tap
8684500	4.5mm Tap
836-015	5.5mm Tap
836-016	6.5mm Tap
836-018	7.5mm Tap
8572102	Sounding/Feeler Probe, 2mm
7480100	Dual Ended Feeler Probe

Bolt Placement	
9960107	Primary Bolt Driver
9960108	Auxiliary Bolt Driver

Screw Placement	
7486109	Short Multi Axial Screwdriver
7480114	Screwdriver, Noncaptive
7486280	Fixed Angle Screwdriver, US
7486150	Counter Torque
9960335	Multi Axial Screw Head Positioner

Hook Preparation	
9960220	Laminar Elevator
7480222	Transverse Process Elevator
7480225	Pedicle Elevator

Hook Placement	
9960212	Lateral Hook Holder
9960216	Straight Hook Holder
9960217	Curved Hook Holder
9966231	Hook Pusher

Rod Contouring	
808-575	20″ Rod Template
808-530	French Bender
9960265	Plate/Rod Bender, Left
9960266	Plate/Rod Bender, Right

Rod Reduction	
7486134	Beale Rod Reducer, Short
9960142	Forceps Style Rocker
7486235	6.35mm Rod Pusher

Correction	
Catalog Number	Description
7486285	Hex Rod Rotation Wrench
9960176	Rod Gripper
7486255	6.35mm Left In Situ Bender
7486260	6.35mm Right In Situ Bender
7486265	Coronal Plane Bender, Left
7486270	Coronal Plane Bender, Right

Compression and Distraction	
7480166	Large Parallel Compressor
7480165	Small Parallel Compressor
9960133	Palm Distractor
7480171	Distractor

Nut Placement and Final Tightening	
9960111	Nut Driver
9960112	Torque Limiting Nut Driver
9960109	Angled Wrench
9960130	Bolt Counter Torque
9960131	Speed Wrench

Set Screw/Nut Placement	
7480122	Plug Starter, Dual End
7480144	Self Retaining Set Screw Driver
7480131	Provisional Driver, Short
7486150	Screw/Hook Counter Torque
9960113	Connector Counter Torque

Removal	
7480154	T27 Obturator
9960135	Closed Set Screw Insert

Long-post Bolt Cutters	
9960201	Tube, Outer, 6.35mm Bolt Cutter
9960202	Tube, Inner, 6.35mm Bolt Cutter
9960203	Handle, Bottom, 6.35mm Bolt Cutter
9960204	Handle, Top, 6.35mm Bolt Cutter
8369043	Obturator

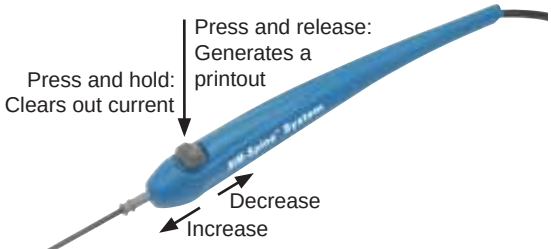
Optional Instrumentation	
9960136	TLIF Distractor
9960321	Vice Grips, Angled
9960210	Lateral Translator
9960211	Lateral Implant Holder

NIM-SPINE™ System Product Ordering Information

The NIM-SPINE™ System is a powerful, multi-modality neural integrity monitor that includes both the technical capabilities demanded by monitoring professionals, and the ease-of-use features necessary to allow surgeons to directly monitor the patient's nerve root and spinal cord function.

The NIM-SPINE™ System Pedicle Probe can be used to gain access to the pedicle. EMG monitoring can be performed during advancement of the probe into the pedicle to ensure proper placement. Further evaluation can be performed after screw placement by utilizing the NIM-SPINE™ System Stim-Controlled Ball Tip Probe to stimulate the screw. Free-running EMG will monitor any nerve root irritation during this procedure.

	Item	Description
Disposables	9450015	23cm Ball Tip Probe
	9450051	2.3mm Ball Tip Probe
	9450020	Pedicle Needle
	9450057	Stim-Controlled Ball Tip Probe
	9450059	Straight Pedicle Probe
	9450019	Thoracic Pedicle Probe
	9450047	Lumbar Pedicle Probe



NIM-SPINE™ System Stim-Controlled Ball Tip Probe

NIM-SPINE™ System Touch Screen Monitor

NIM-SPINE™ System Pedicle Probe

Important Information on the CD HORIZON ENGAGE™ 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 washer, GDLH™ rods, hooks, connectors and CROSSLINK® bar and connectors; LIBERTY" rods and screws; DYNALOK® PLUS and DYNALOK CLASSIC® bolts along with rod/bolt connectors; and Sofamor Danek Multi-Axial rods and screws. Please note that certain components are specifically designed to connect to f4.5mm, f5.5mm rods or f6.35mm rods, while other components can connect to both f5.5mm rods and f6.35mm rods. Care should be taken so that the correct components are used in the spinal construct.

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

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

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:

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 SEXTANT™ instrumentation, the CD HORIZON 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 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 (immuno-compromise).
2. Signs of local inflammation.
3. Fever or leukocytosis.
4. Morbid obesity.
5. Pregnancy.
6. Mental illness.
7. Grossly distorted anatomy caused by congenital abnormalities.
8. Any other medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the presence of congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count.
9. Rapid joint disease, bone absorption, osteopenia, osteomalacia and/or osteoporosis.
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 patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
14. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
15. Any patient unwilling to follow postoperative instructions.
16. 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:

Early or late loosening of any or all of the components.

1. Disassembly, bending, and/or breakage of any or all of the components.
2. 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.
3. 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.
4. Post-operative change in spinal curvature, loss of correction, height, and/or reduction.
5. Infection.
6. Dural tears, pseudomeningocele, fistula, persistent CSF leakage, meningitis.
7. 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.
8. Cauda equina syndrome, neuropathy, neurological deficits (transient or permanent), paraplegia, paraparesis, reflex deficits, irritation, arachnoiditis, and/or muscle loss.
9. Urinary retention or loss of bladder control or other types of urological system compromise.
10. Scar formation possibly causing neurological compromise or compression around nerves and/or pain.
11. 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.
12. Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery.
13. Non-union (or pseudarthrosis). Delayed union. Mal-union.
14. Cessation of any potential growth of the operated portion of the spine.
15. Loss of or increase in spinal mobility or function.
16. Inability to perform the activities of daily living.
17. Bone loss or decrease in bone density, possibly caused by stresses shielding.
18. Graft donor site complications including pain, fracture, or wound healing problems.
19. Ileus, gastritis, bowel obstruction or loss of bowel control or other types of gastrointestinal system compromise.
20. Hemorrhage, hematoma, occlusion, seroma, edema, hypertension, embolism, stroke, excessive bleeding, phlebitis, wound necrosis, wound dehiscence, damage to blood vessels, or other types of cardiovascular system compromise.
21. Reproductive system compromise, including sterility, loss of consortium, and sexual dysfunction.
22. Development of respiratory problems, e.g., pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.
23. Change in mental status.
24. Death.

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

WARNING:

The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis). The safety and effectiveness of this device for any other conditions are unknown. The implants are not prostheses.

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

PRECAUTION:

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

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

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

Important Information on the CD HORIZON ENGAGE™ Spinal System (continued)

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

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

Implant Selection:

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

Device Fixation:

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

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

INTRAOPERATIVE:

1. Extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological functions.
2. Breakage, slippage, or misuse of instruments or implant components may cause injury to the patient or operative personnel.
3. The rods should not be repeatedly or excessively bent. The rods should not be reverse bent in the same location. Use great care to insure that the implant surfaces are not scratched or notched, since such actions may reduce the functional strength of the construct. If the rods are cut to length, they should be cut in such a way as to create a flat, non-sharp surface perpendicular to the midline of the rod. Cut the rods outside the operative field. Whenever possible, use pre-cut rods of the length needed.
4. Utilize an imaging system to facilitate surgery.
5. To insert a screw properly, a guide wire should first be used, followed by a sharp tap. Caution: Be careful that the guide-wire, if used, is not inserted too deep, becomes bent, and/or breaks. Ensure that the guide-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.
6. Caution: Do not overtap or use a screw/bolt that is either too long or too large. Overtapping, using an incorrectly sized screw/bolt, or accidentally advancing the guidewire during tap or screw/bolt insertion, may cause nerve damage, hemorrhage, or the other possible adverse events listed elsewhere in this package insert. If screws/bolts are being inserted into spinal pedicles, use as large a screw/bolt diameter as will fit into each pedicle.
7. Bone graft must be placed in the area to be fused and graft material must extend from the upper to the lower vertebrae being fused.
8. To assure maximum stability, two or more CROSSLINK® plates or DTT Transverse Links on two bilaterally placed, continuous rods, should be used whenever possible.
9. 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.

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.

1. 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.
2. 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.
3. 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.
4. 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 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. Unless specified elsewhere, 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.

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 Sofamor Danek. 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 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 and number, lot number(s), your name and address, the nature of the complaint and notification of whether a written report from the distributor is requested.

FURTHER INFORMATION: If further directions for use of this system are needed, please check with Medtronic Sofamor Danek Customer Service.

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

SOFAMOR S.N.C**
13, rue de la Perdrix
93290 TREMBLAY
FRANCE
Tele: (33) 3.21.89.50.00
or (33) 1.49.38.80.00
Fax: (33) 3.21.89.50.09
**authorized EC representative

Notes

listen. respond. deliver.

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

MEDTRONIC SOFAMOR DANEK USA, INC.
Spinal Division
Worldwide Headquarters
1800 Pyramid Place
Memphis, TN 38132
(901) 396-3133
(800) 876-3133
Customer Service: (800) 933-2635

www.sofamordanek.com
For more information go to www.myspinetools.com

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