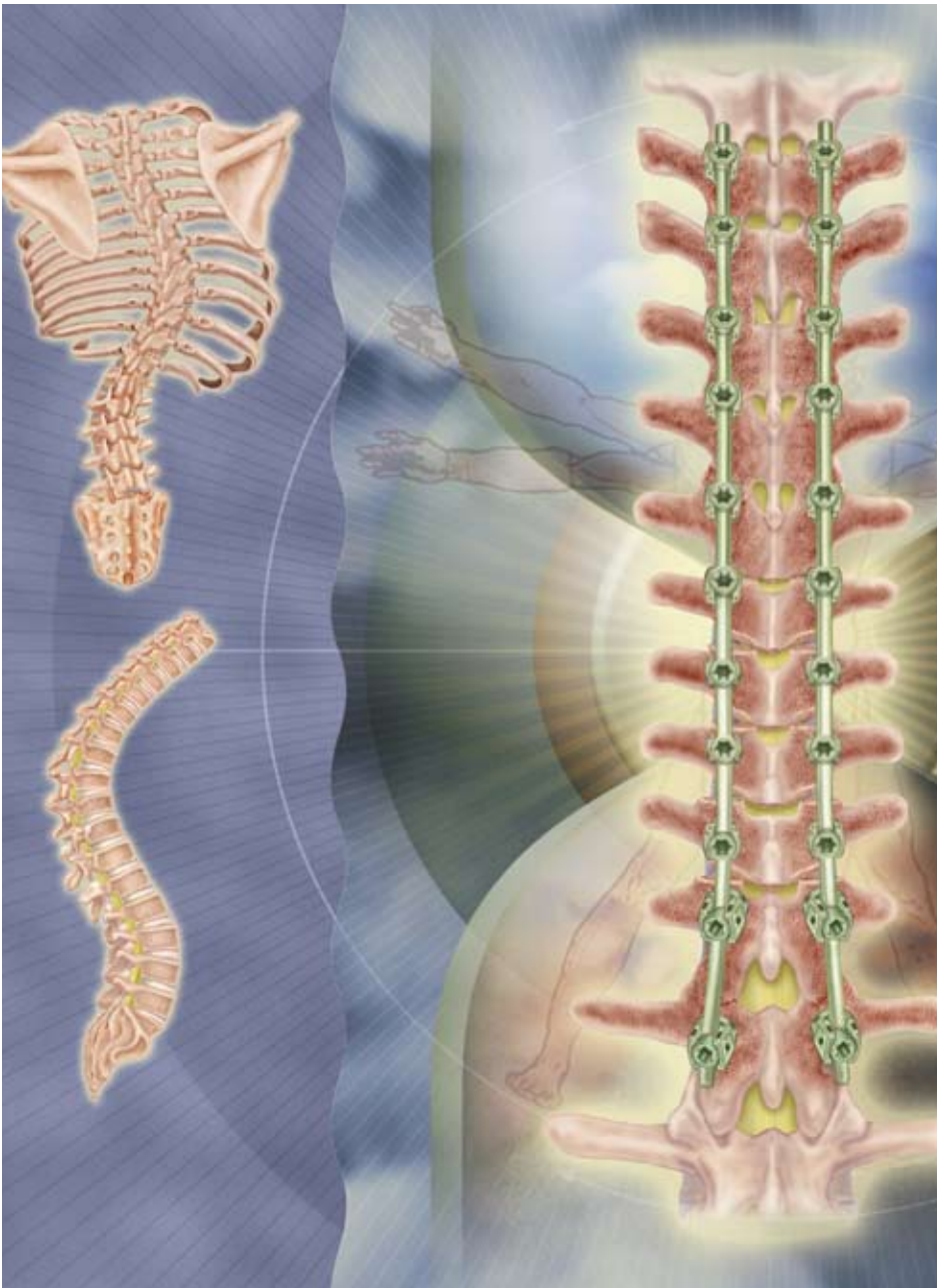


CD HORIZON® LEGACY™ Spinal System

With Vertebral Column Manipulation (VCM) Instrument Set
Advanced Deformity Correction Surgical Technique



Thoracic Idiopathic Scoliosis Correction
Utilizing Bilateral Apical Vertebral
Derotation (BAVD)

Scheuermann's Kyphosis Correction
Utilizing Pedicle Screws and Apical
Smith-Petersen Osteotomies (SPO)

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PREFACE

Dear Colleagues:

Scoliosis is known to be a complex three-dimensional deformity to the spine with resultant adverse effects on the rib cage and chest organs. Ever since Drs. Yves Cotrel and Jean Dubousset introduced their revolutionary surgical approach to scoliosis using the CD® System of segmental fixation, surgeons have attempted to maximize operative correction in all three planes of the deformity: coronal, sagittal, and axial. The most elusive part of the deformity to correct has been axial plane rotational malalignment, which has challenged surgeons for several decades.

Two recent advances to help us achieve optimal three-dimensional correction have included (1) proliferation of the safe and efficacious use of thoracic and lumbar pedicle screw fixation in scoliotic vertebrae, with (2) instruments attached to the periapical screws to derotate them. What once seemed impossible has now become commonplace—placing pedicle screws into the individual vertebrae involved in the scoliotic deformity thereby obtaining strong three-column purchase of these vertebral segments. This has subsequently offered us the opportunity to actually derotate the apical vertebrae with its resultant favorable effects on the rib cage and thoracic and lumbar prominences.

This surgical technique guide highlights a simple, yet effective method of Bilateral Apical Vertebral Derotation (BAVD) using the CD HORIZON® LEGACY™ Spinal System and its Vertebral Column Manipulation Set module, which can be applied to almost any scoliotic deformity where segmental CD HORIZON® LEGACY™ Spinal System pedicle screw purchase has been performed. In addition, a second technique for correction of a thoracic hyper-kyphotic deformity is presented. Utilizing bilateral segmental pedicle screws and apical Smith-Petersen Osteotomies (SPO), almost any thoracic and thoracolumbar kyphotic deformity can be corrected without the need for a preliminary anterior release procedure. I hope these techniques will aid in your quest for obtaining safe and optimal three-dimensional correction of your patients with idiopathic scoliosis as well as varying kyphotic spinal deformities.

Sincerely,



Lawrence G. Lenke, MD

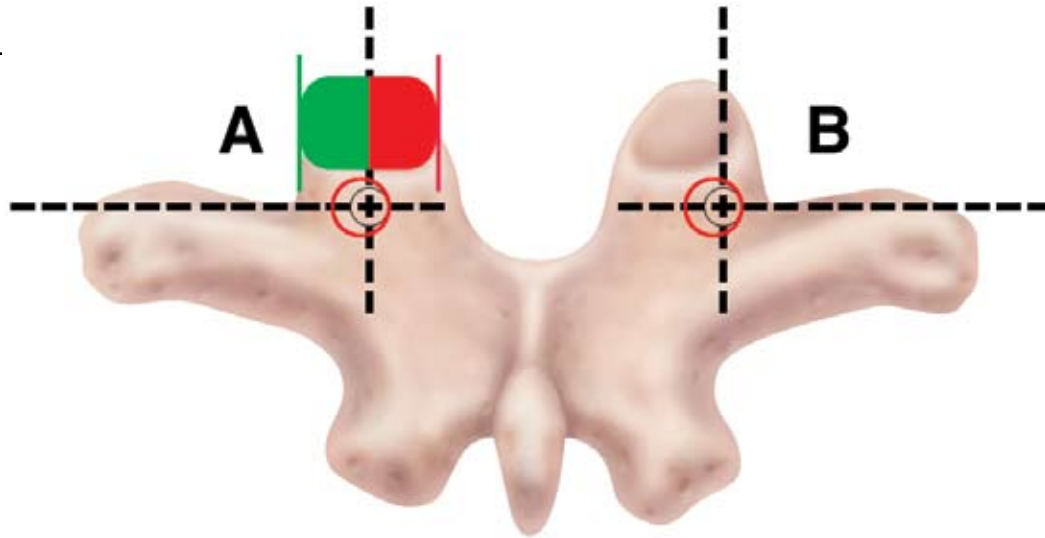
PEDICLE SCREW STARTING POINTS FOR THE STRAIGHT-FORWARD TRAJECTORY

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

SUPERIOR FACET RULE (A)

Color Reference Chart

	Unsafe
	Safe

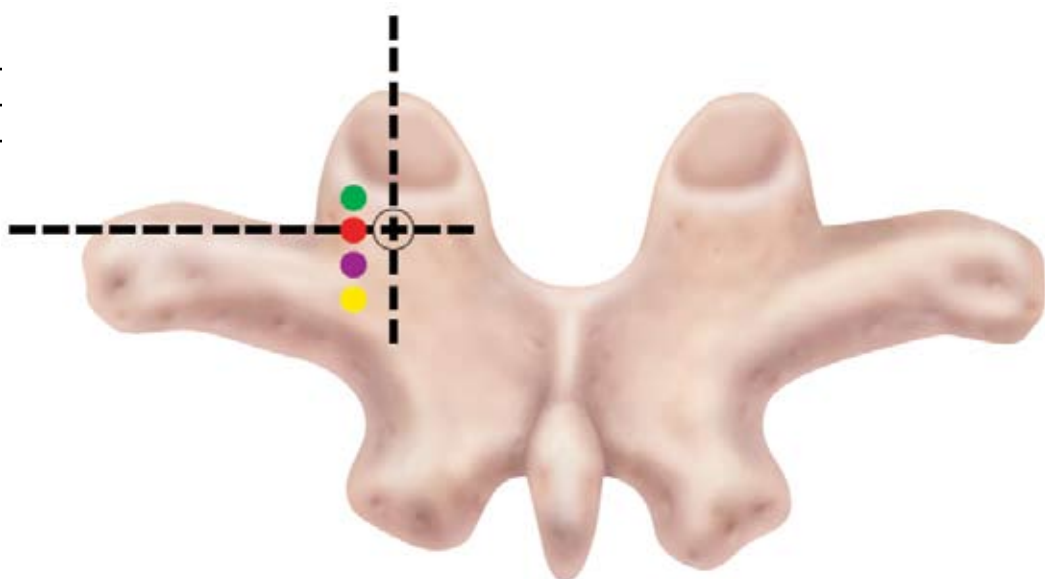


NOTE: Do not start medial to the midpoint of the superior facet.

CEPHALO-CAUDAL STARTING POINTS (B)

Color Reference Chart

	T9, T8, T7
	T10, T6
	T11, T5, T4
	T12, T3, T2, T1

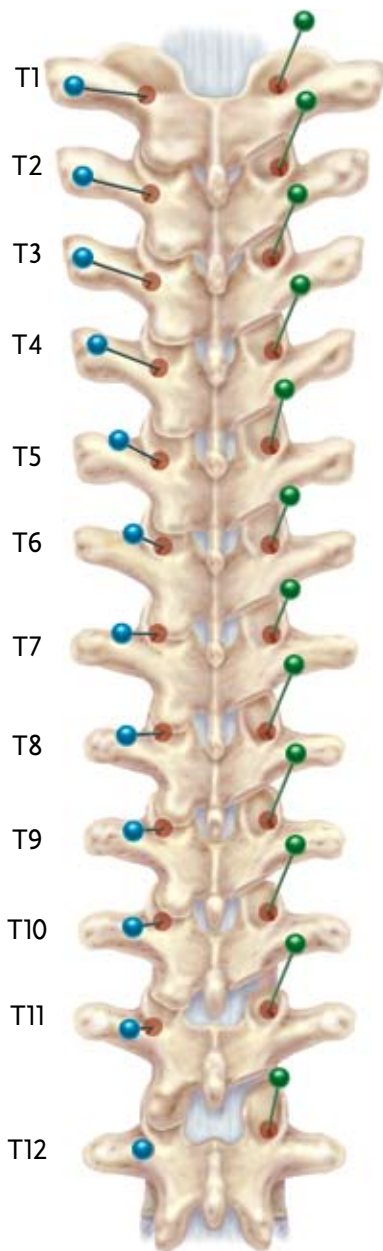


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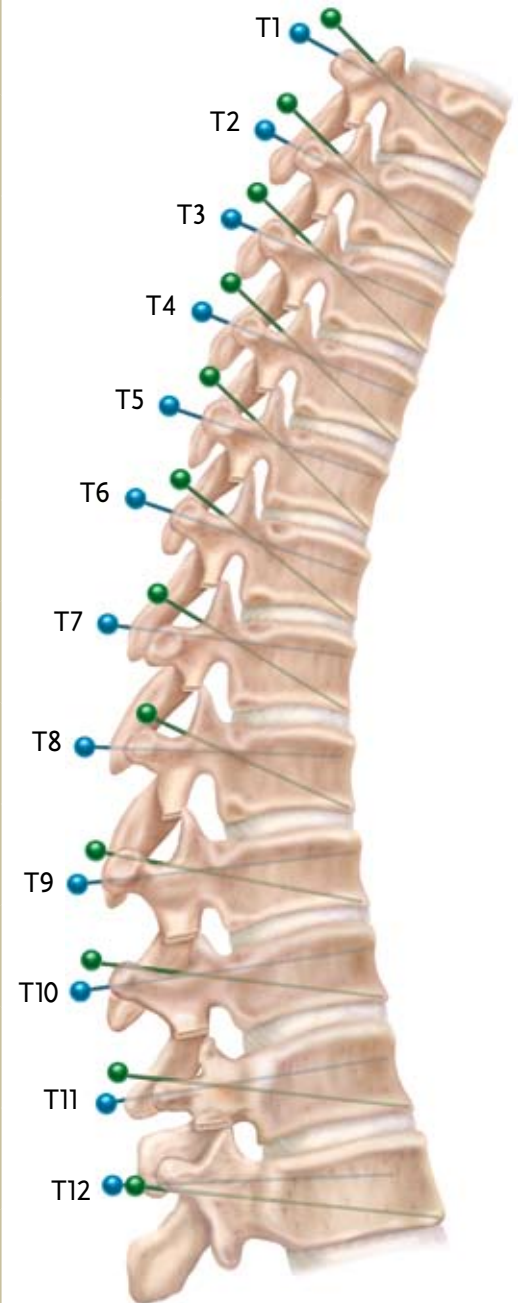
PEDICLE SCREW STARTING POINTS FOR THE STRAIGHT-FORWARD TRAJECTORY

THORACIC PEDICLE (TP) 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



INDEPENDENT DEROTATION INSTRUMENTS



Fixed Angle Screwdrivers
7484282 (4.5mm)
7480280 (5.5mm)
7486280 (6.35mm)



Tube Derotators
7484290 (4.5mm)
7480290 (5.5mm)
7486290 (6.35mm)



Ratcheting Handles
9339082

VERTEBRAL COLUMN MANIPULATION (VCM) INSTRUMENTS



Derotator Implant Holder
7480391 (5.5mm)
7486391 (6.35mm)



Derotator Bridge, Small
7480392



Derotator Bridge, Medium
7480393



Derotator Bridge, Large
7480394



Derotator Bridge Handle
7480396



Derotator Inline Handle
7480397



Derotator Bridge Nut
7480398



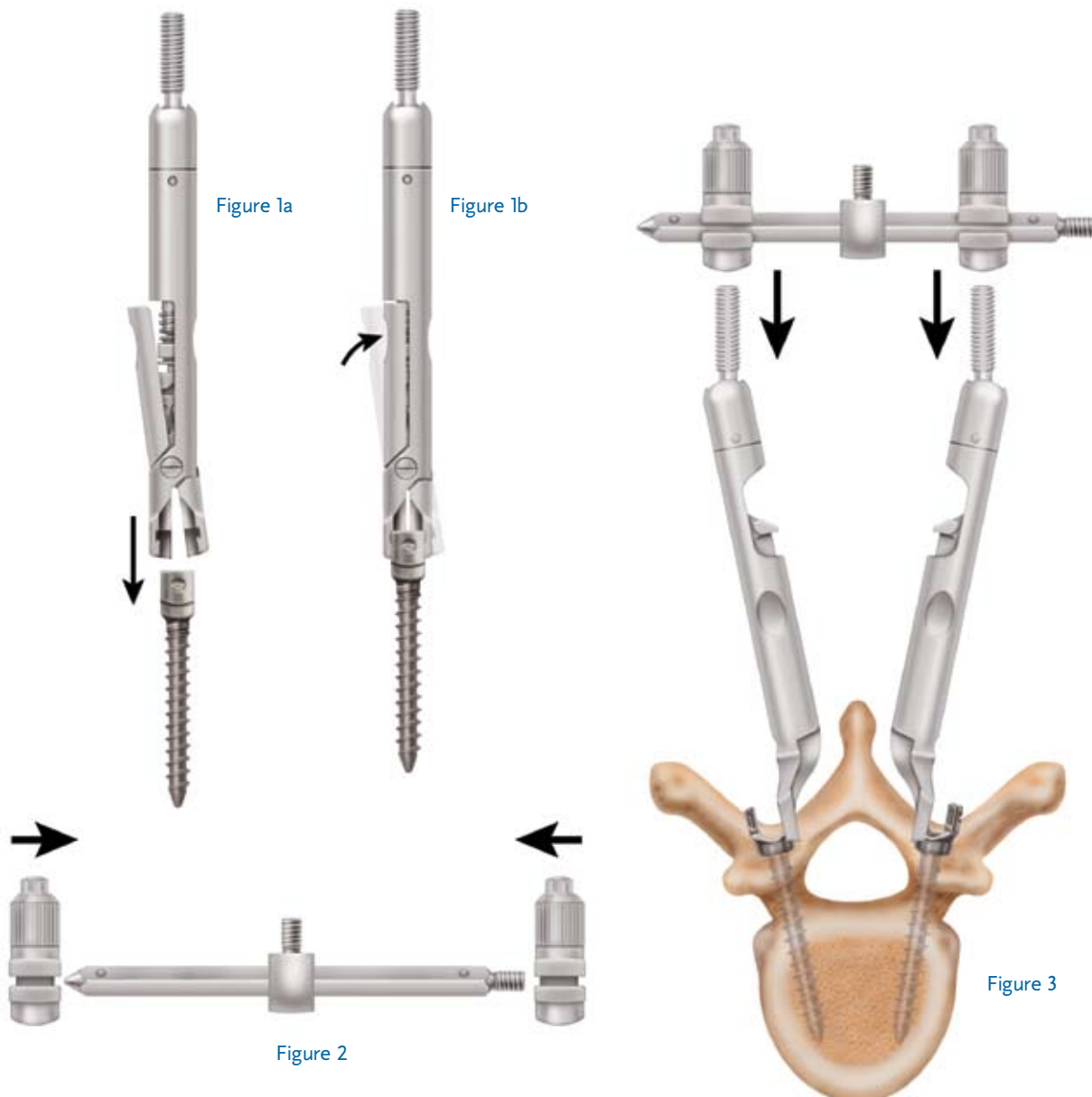
Derotator Interlink
7480395

VERTEBRAL COLUMN MANIPULATION (VCM) ASSEMBLY

VERTEBRAL COLUMN MANIPULATION (VCM) ASSEMBLY

The VCM assembly can be utilized on either Multi Axial or Fixed Angle Screws. Once the assembly is triangulated, the Multi Axial Screws will mimic the control of a Fixed Angle Screw to allow vertebral body manipulation. Attach the Implant Holder to the implant via the slots on the head of the Multi Axial or Fixed Angle Screw. If Fixed Angle Screws are used, attachment to the medial side of the implant is preferred. Lock the Implant Holder to the screw head by squeezing the open lever on the tube (Figure 1a and Figure 1b). Repeat this step on the contralateral side.

Choose a Derotator Bridge that spans the distance between the Implant Holders and then slide Derotator Bridge Nuts onto each end (Figure 2). The threaded middle portion of the Derotator Bridge should be facing up. Finger tighten the Bridge Nuts and then place the assembly onto the Implant Holders. (Figure 3).



VERTEBRAL COLUMN MANIPULATION (VCM) ASSEMBLY (CONT.)

VERTEBRAL COLUMN MANIPULATION (VCM) ASSEMBLY (CONT.)

Once positioned onto the Implant Holders, securely tighten the Bridge Nuts using either the blue Bridge Handle or a Break Off Hex Driver (7480144) (**Figure 4**).

Once the Derotator Bridge Nuts are secure, the Bridge Handles can be attached at either end of the Derotator Bridge, on the threaded middle portion of the Derotator Bridge, or both (**Figure 5**). Repeat the attachment process at each level to be manipulated.



Figure 4

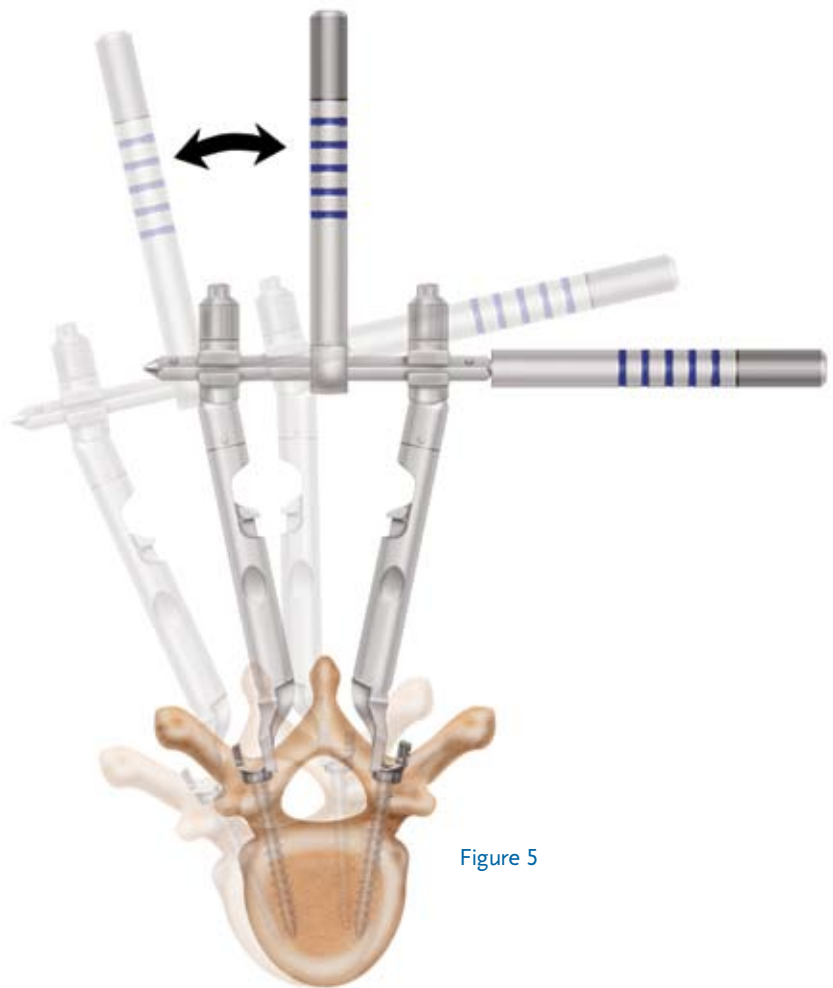


Figure 5

VERTEBRAL COLUMN MANIPULATION (VCM) ASSEMBLY (CONT.)

VERTEBRAL COLUMN MANIPULATION (VCM) ASSEMBLY (CONT.)

The Bridge Derotation instruments can link multiple levels using the Derotator Interlinks. Ensure the Interlink Nuts are fully loosened and slide the Interlink over the Bridge Handles at two adjacent levels and tighten the Interlink Nuts. (**Figures 6a and 6b**).

The instrumentation is easily removed by pushing the release button located on the shaft of each holder. Complete disassembly can be performed on the back table.

To continue the BAVD technique turn to page 13.



THORACIC BILATERAL APICAL VERTEBRAL DEROTATION (BAVD) SURGICAL TECHNIQUE

SCREW PLACEMENT

Perform a thorough exposure of the posterior elements to be included in the instrumentation and fusion. The appropriate diameter and length pedicle screws are placed at strategic positions for the deformity. For a typical right thoracic idiopathic scoliosis, this would entail a screw at every level for the left-sided correcting rod. On the contralateral, stabilizing rod side a minimum of two screws should be placed at the cephalad and caudad ends with four convex periapical screws (**Figure 7a and 7b**). Although both fixed and multi axial pedicle screws may be utilized, I prefer fixed angled screws at the apex to maximize derotational applied forces and multi axial screws at the ends of the construct. I also prefer to utilize stainless steel implants, however for illustrative purposes CD HORIZON® LEGACY™ 5.5mm titanium implants are shown in this technique.

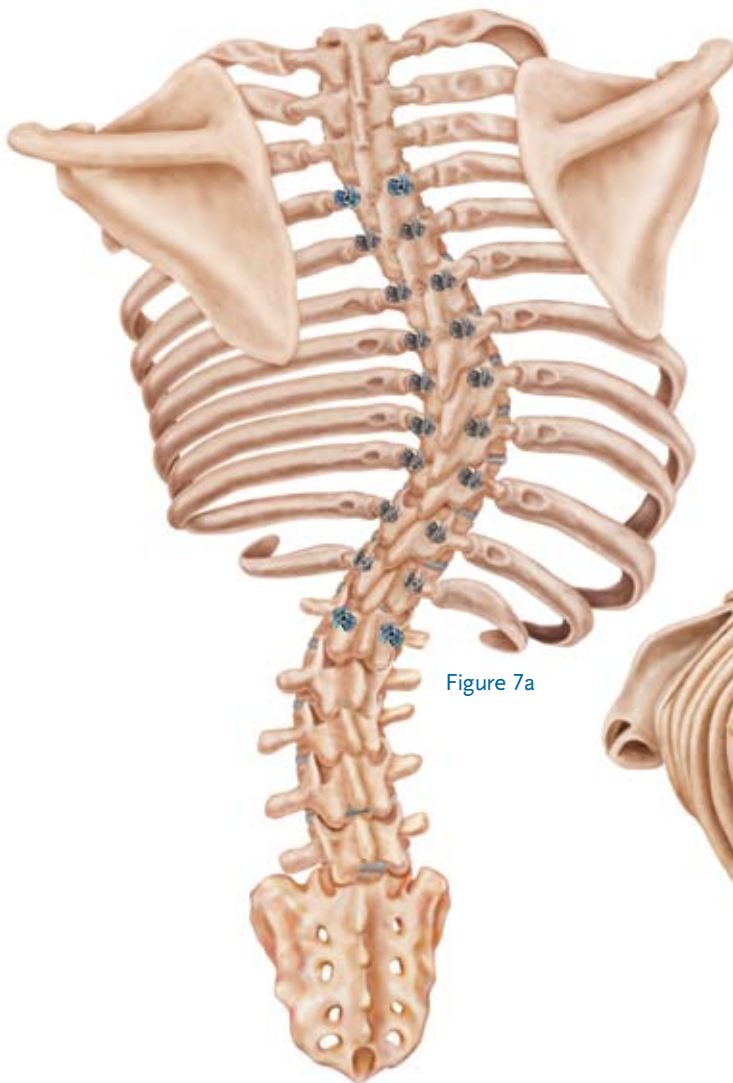


Figure 7a

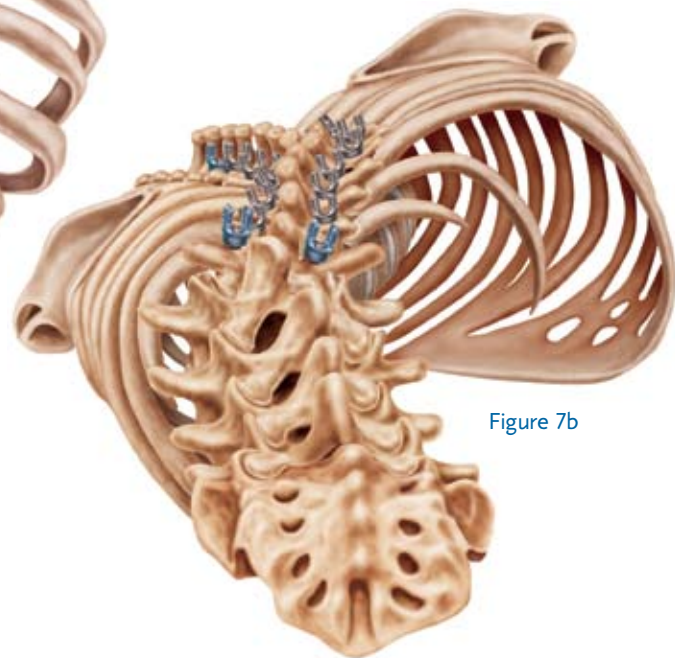


Figure 7b

BONE-TO-SCREW INTERFACE ASSESSMENT

Once the screws are in position, attach a Fixed Angle Screwdriver to the implant heads of the periapical convex screws (**Figure 8**). Move the screwdriver medially and laterally to assess the individual bone/screw interface grip of these screws, and thus the corresponding ability to directly derotate the apical region of the scoliosis while maintaining a firm grip on the handles (**Figure 9**).



Figure 8



Figure 9

THORACIC BAVD SURGICAL TECHNIQUE (CONT.)

DEROTATION ASSESSMENT

Next, a periapical derotational test is performed by placing convex Fixed Angle Screwdrivers on each of the right-sided convex apical screws, and the Tube Derotators on the corresponding apical concave Fixed Angle Screws (**Figure 10a and 10b**). Typically, four periapical vertebrae are utilized.



Figure 10a



Figure 10b

DEROTATION ASSESSMENT (CONT.)

With ventral and medially-directed spinal implant forces, a periapical derotational maneuver is assessed to quantify the degree of safe and effective derotational corrective forces to be applied (**Figure 11**). It is important to initiate the BAVD technique with the convex Screwdrivers and closely follow with the concave Tube Derotators.

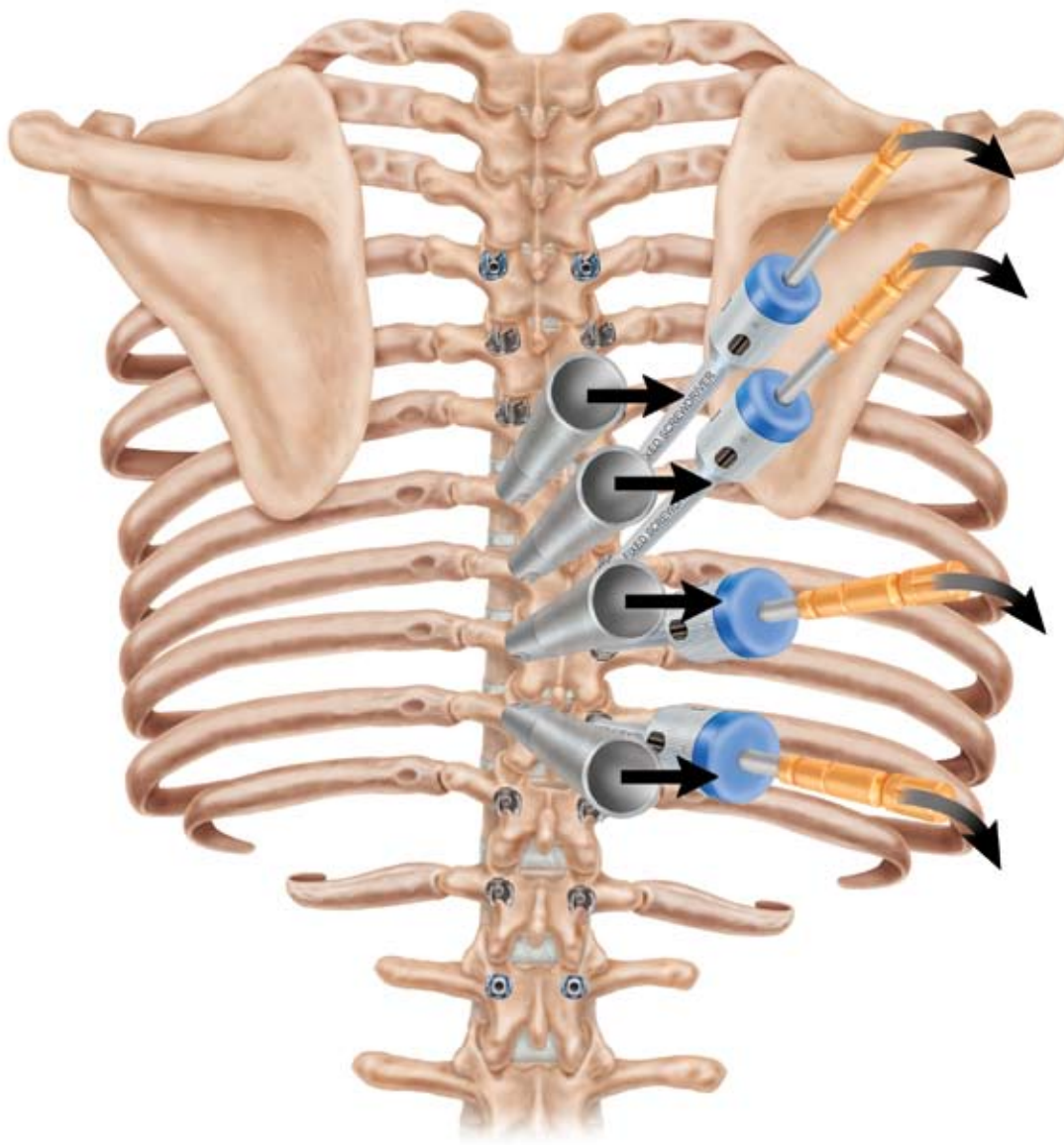


Figure 11

THORACIC BAVD SURGICAL TECHNIQUE (CONT.)

ROD PLACEMENT

Next, the correction rod should be contoured in the sagittal plane only. With the right-sided convex Fixed Angle Screwdrivers holding the spine in this derotated position, the 180° rotated rod is captured proximally in the cephalad three screws with loosely applied Set Screws (**Figure 12**). The rod should then be rotated 180° into its correct sagittal position, cantilevered and captured into the distal one or two screws, which are provisionally tightened with Set Screws (**Figure 13**). Then the rod is captured at both ends but only locked into the caudal screws. With VCM instrumentation the rod channel remains open for placement of the correcting rod.



Figure 12

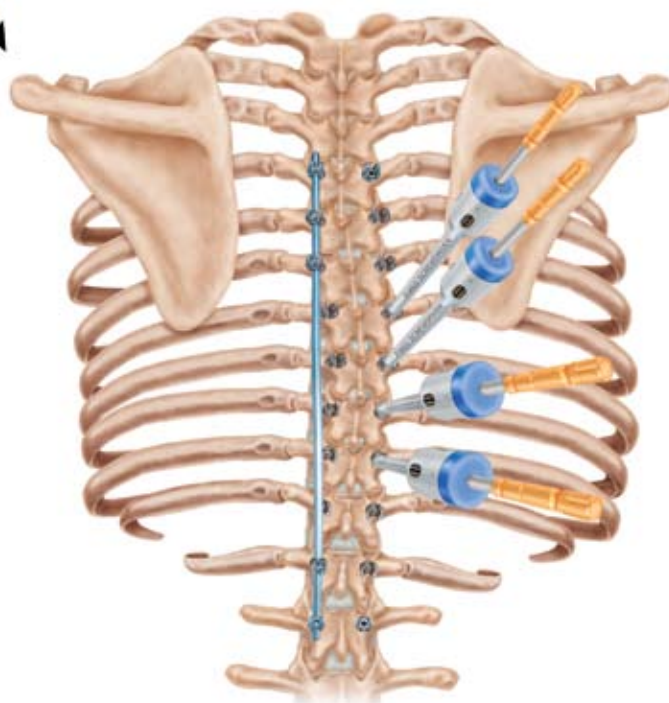


Figure 13

ROD PLACEMENT (CONT.)

Starting caudad and then moving cephalad, the apical segments on the concave rod are then sequentially captured with the Forceps Rocker (**Figure 14a**), twisted to perform an apical derotation maneuver (**Figure 14b**), and then provisionally tightened with a Set Screw to hold the screw in this derotated position on the rod (**Figure 14c**). The corresponding convex periapical screws are continually being derotated to accomplish the BAVD technique.

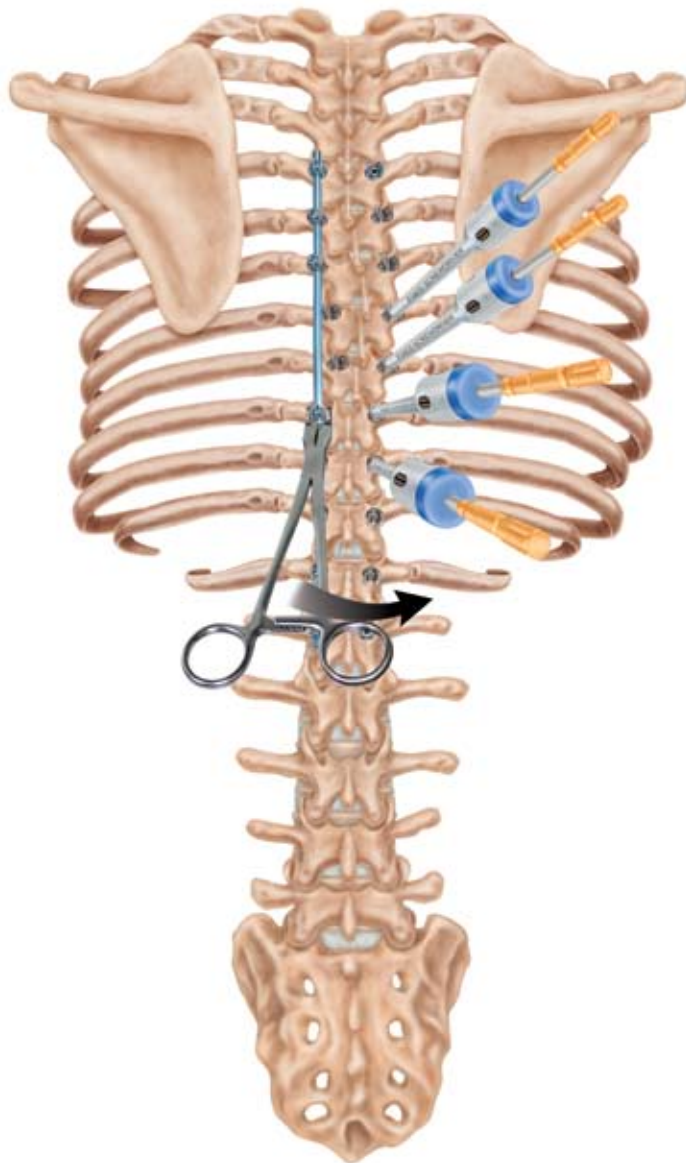


Figure 14a



Figure 14b



Figure 14c

THORACIC BAVD SURGICAL TECHNIQUE (CONT.)

ROD PLACEMENT (CONT.)

Sequential tightening from the caudad end of the construct through the periapical levels is performed until the entire apex has been derotated and captured with Set Screws (**Figure 15**). The cephalad levels are still loose at this point of the correction procedure. Do not perform final break off tightening on the Set Screws during this step.

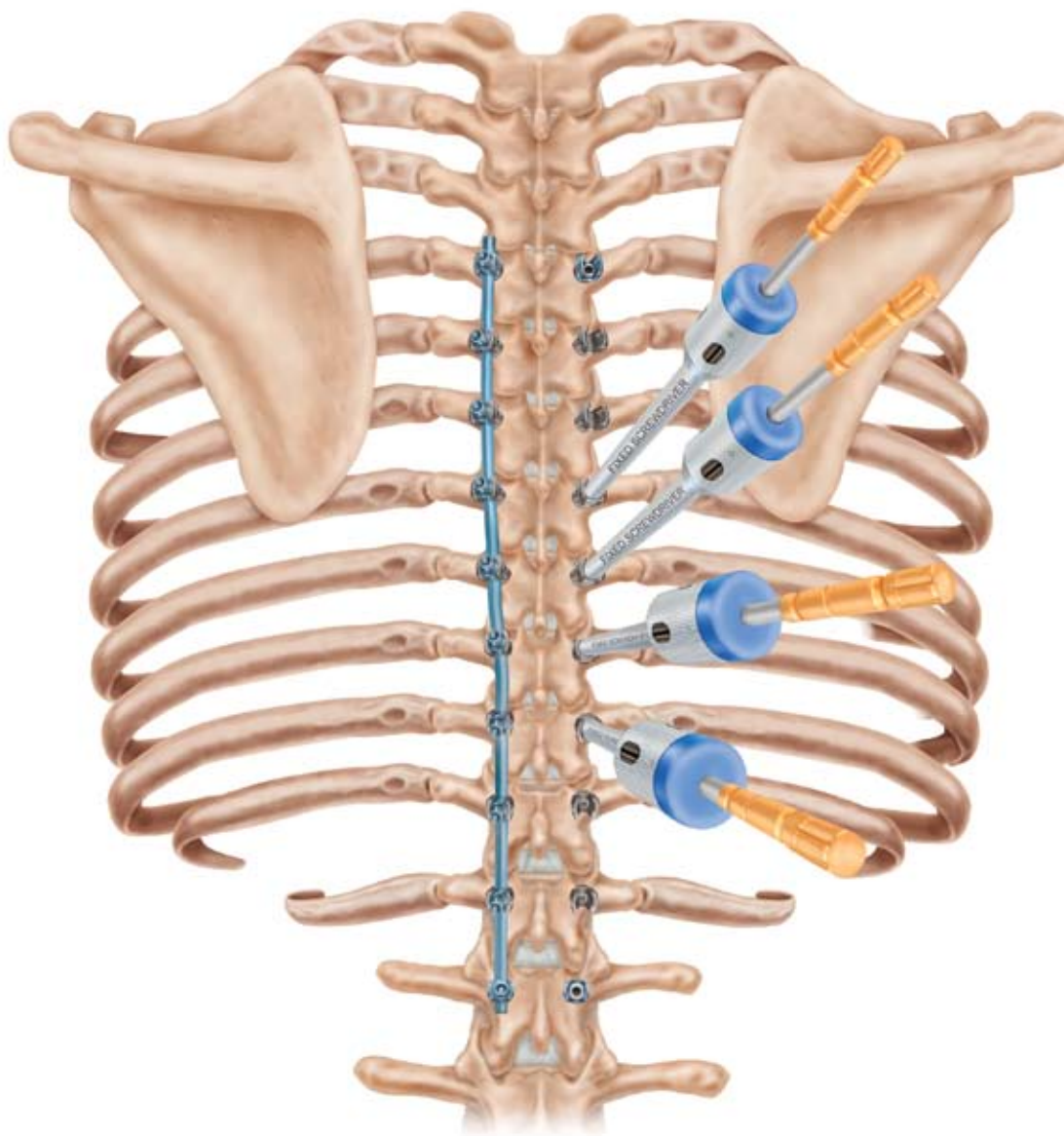


Figure 15

COMPRESSION/DISTRACTION

In situ rod contouring for coronal translation correction may be performed at this point after removing the convex apical Screwdrivers or VCM instrumentation (**Figure 16**). Compression and/or distraction forces may also be applied to the individual screws on the concave side with typically mild screw compression forces applied to the top two or three screws (**Figure 17**). It is preferred that compression be released just prior to the Set Screws being broken off or finally 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.

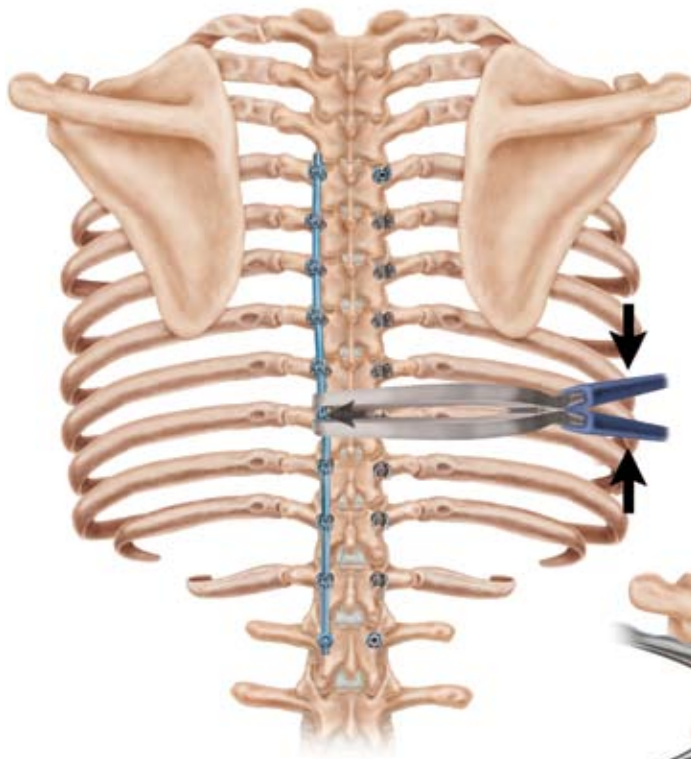


Figure 16



Figure 17

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

THORACIC BAVD SURGICAL TECHNIQUE (CONT.)

FINAL DEROTATION AND STABILIZING ROD PLACEMENT

A second BAVD maneuver is then performed around the rod. All the Set Screws are provisionally tightened at the cephalad and caudad ends. Fixed Angle Screwdrivers are applied to the four periapical convex screws, and the Tube Derotators are placed on the corresponding periapical concave Fixed Angle Screws. The Set Screws are then loosened over these four apical concave levels, and the spine and chest wall are derotated around the rod at each of the four periapical levels from cephalad to caudad. The corrected position is maintained by provisionally tightening with Set Screws (**Figure 18**). This second derotation maneuver around the rod further locks the spine into a derotated position at the apex.

The right-sided stabilizing rod is then contoured to the corrected spinal alignment and engaged from cephalad to caudad, captured at each level with Set Screws. Appropriate compression and/or distraction forces may then be applied to those screws as well as to facilitate the upper lowest instrumented vertebrae alignment (**Figure 19**). It is preferred that compression be released just prior to the Set Screws being broken off or finally 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.

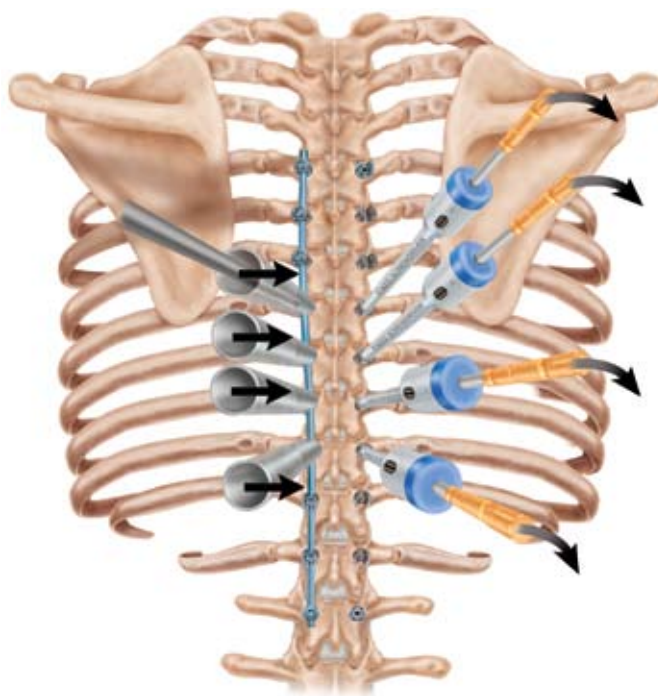


Figure 18

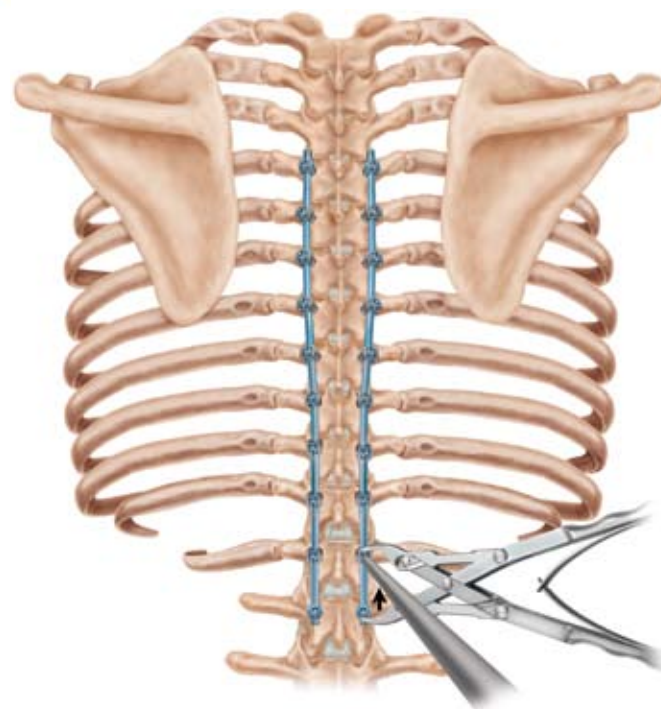


Figure 19

SET SCREW BREAK OFF

Appropriate intraoperative coronal and lateral based radiographs are performed to assess the correction of the spinal deformity. Minor adjustments in the horizontalization of the upper and lower instrumented vertebrae may then be performed as required. Ensure that the rod is fully reduced and parallel in the base of the screw head. Set Screw heads are then sheared off thereby locking the screws to the rod (**Figure 20**).

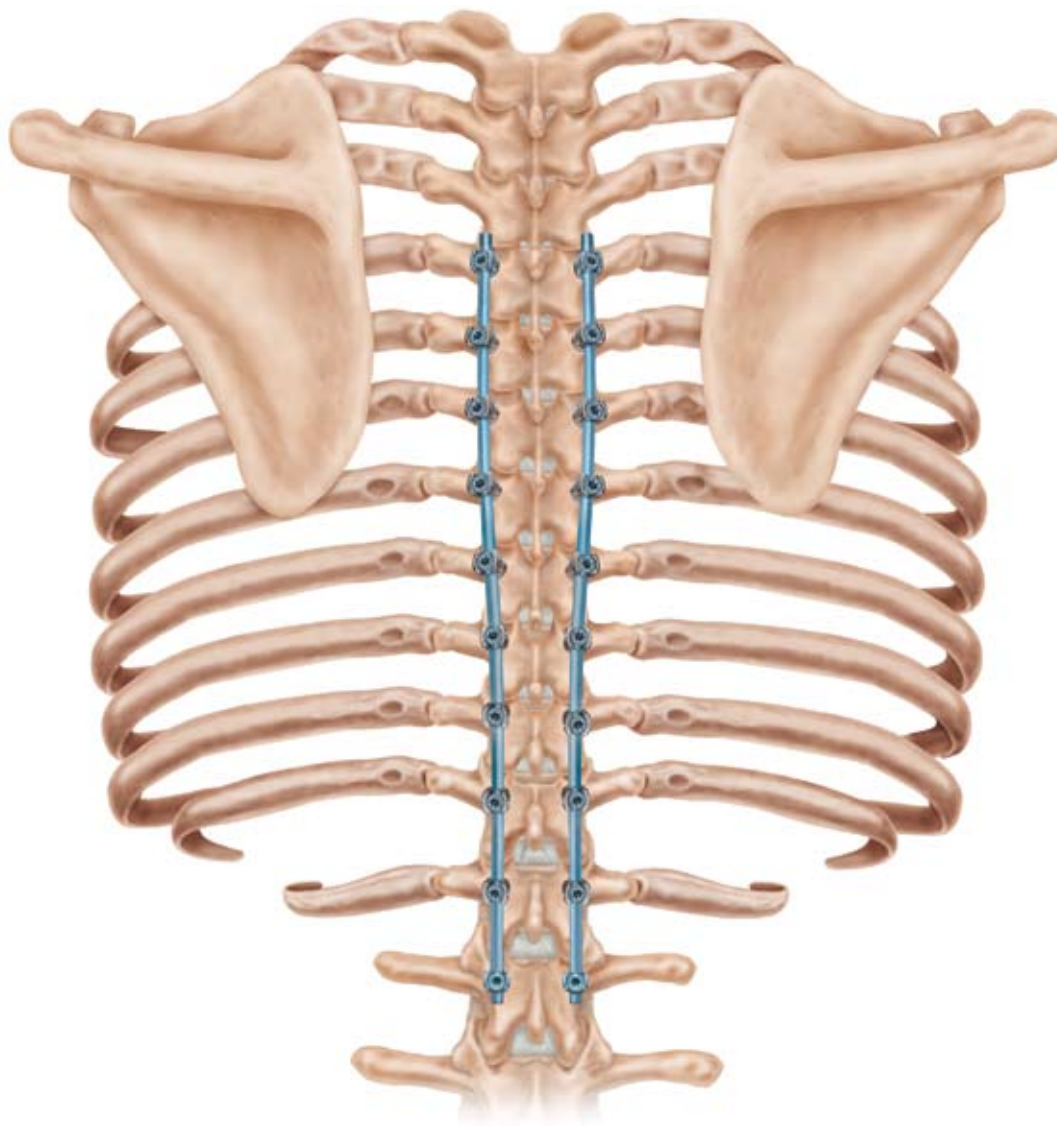


Figure 20

THORACIC BAVD SURGICAL TECHNIQUE (CONT.)

CD HORIZON® X10 CROSSLINK™ PLATE PLACEMENT

Following thorough decortication (**Figure 21**) and bone graft placement (**Figure 22**), the proximal and distal ends of the construct are measured for CD HORIZON® X10 CROSSLINK™ Plates. Refer to the CD HORIZON® X10 CROSSLINK™ Plate Surgical Technique for a detailed placement guide. The CD HORIZON® X10 CROSSLINK™ Plates are designed to make the construct rectangular and rigid and to resist the tendency of the construct to rotate (**Figure 23**). The final construct should be assessed for stability and rigidity, and then wound closure is performed.



Figure 21

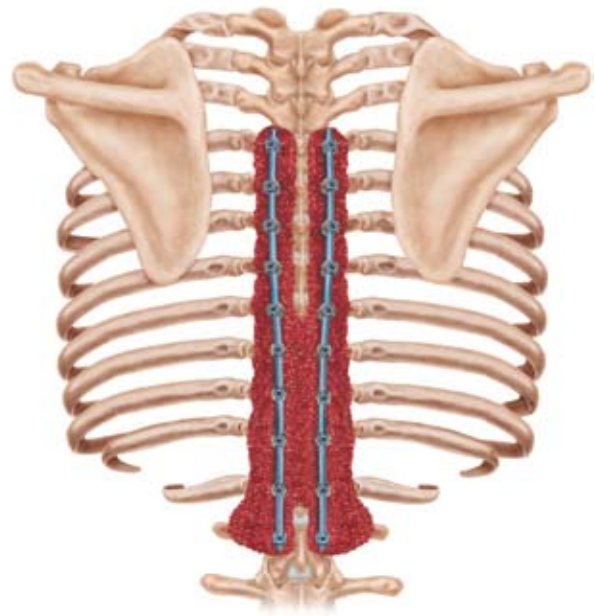


Figure 22

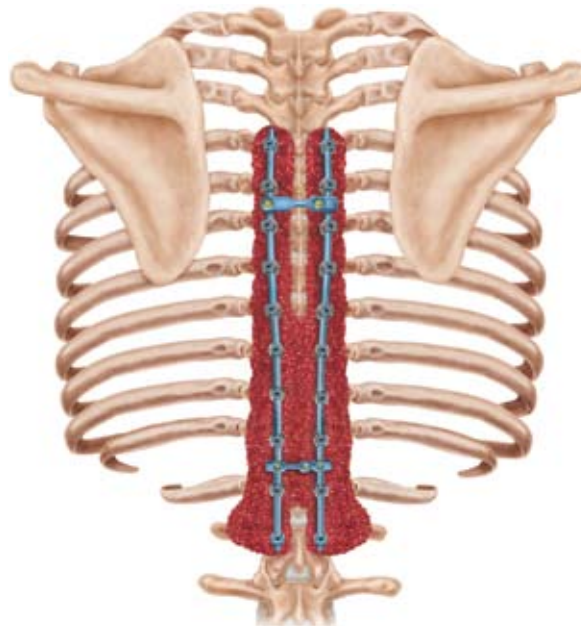


Figure 23

SCHEUERMANN'S KYPHOSIS CORRECTION SURGICAL TECHNIQUE

OSTEOTOMY

Clean the facet joints and perform a posterior column Smith-Petersen Osteotomy (SPO) by removing the inferior part of the spinous process and ligamentum flavum along with the facet joints bilaterally (Figure 24a and 24b). Typically, this will be performed at three to five apical segments.



Figure 24a



Figure 24b

SCHEUERMANN'S KYPHOSIS CORRECTION SURGICAL TECHNIQUE (CONT.)

SCREW PLACEMENT

Place CD HORIZON® LEGACY™ System Multi Axial Screw bilaterally from T3 to T12. Place CD HORIZON® LEGACY™ System Reduction Multi Axial Screws bilaterally in L1 and L2 (**Figure 25a and 25b**).

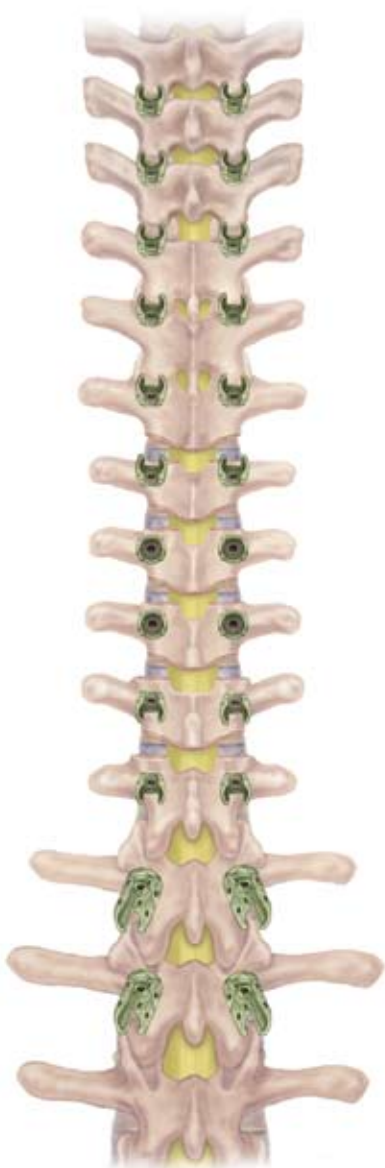


Figure 25a



Figure 25b

SCHEUERMANN'S KYPHOSIS CORRECTION SURGICAL TECHNIQUE (CONT.)

ROD CONTOURING

Measure for the appropriate rod length and then contour the rods with a rod bender to the final expected sagittal plane alignment of around 40 – 50°, depending on the preoperative kyphosis magnitude and stiffness (**Figure 26**).

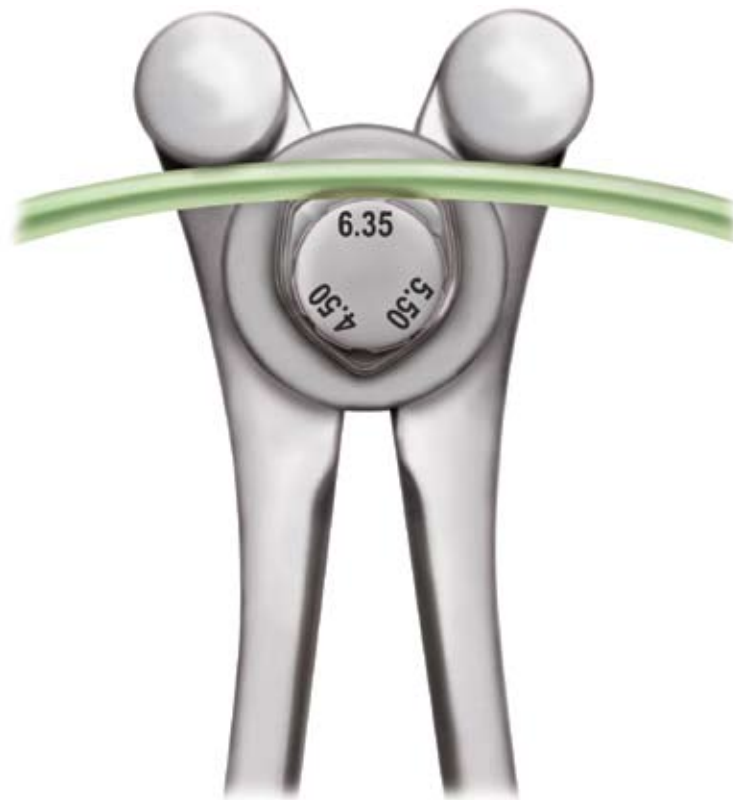


Figure 26

SCHEUERMANN'S KYPHOSIS CORRECTION SURGICAL TECHNIQUE (CONT.)

ROD PLACEMENT

Engage the rods bilaterally by turning them 180° and capturing at least three levels beginning at T3 and working towards L2 (**Figure 27a and 27b**). Then rotate both rods 180° to position them in the appropriate sagittal contour. Capture the rod at each level by provisionally tightening the Set Screws.

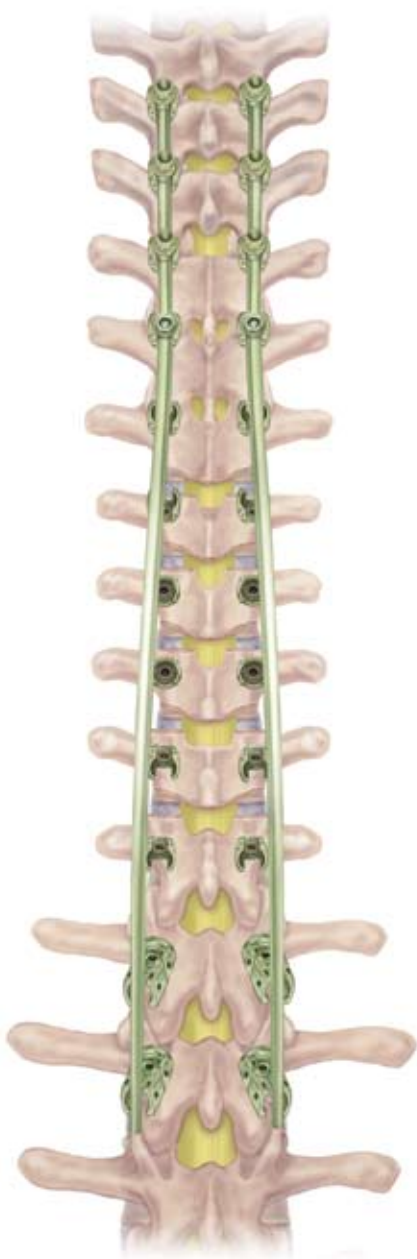


Figure 27a

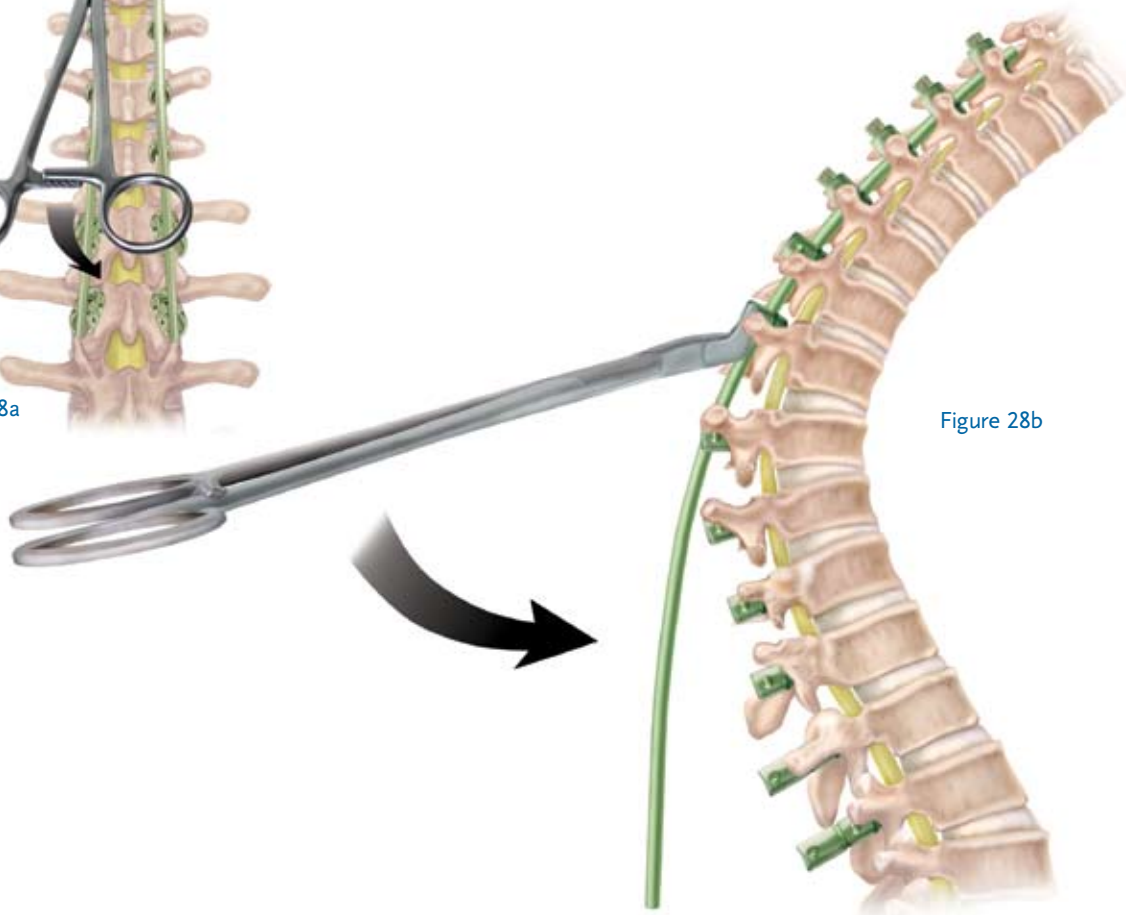


Figure 27b

SCHEUERMANN'S KYPHOSIS CORRECTION SURGICAL TECHNIQUE (CONT.)

ROD REDUCTION

Begin working side-by-side from the proximal to distal end using the rocker to reduce the rods bilaterally (Figure 28a and 28b). The Extended Rocker can be used to reduce the rod into the Reduction Screw heads.



SCHEUERMANN'S KYPHOSIS CORRECTION SURGICAL TECHNIQUE (CONT.)

ROD REDUCTION (CONT.)

As the rod reduction process progresses, the reduction screw Set Screws can be advanced to assist the rod reduction (Figure 29 and 30).



Figure 29



Figure 30

SCHEUERMANN'S KYPHOSIS CORRECTION SURGICAL TECHNIQUE (CONT.)

COMPRESSION

After the rods are all reduced, begin bilateral compression at T10 – T11 to close the posterior column of the osteotomy and then work up the spine towards T3 (**Figure 31a and 31b**). Caudal compression of thoracic pedicle screws appears to be a stronger corrective force than cephalad compression. It is preferred that compression be released just prior to the Set Screws being broken off or finally 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.

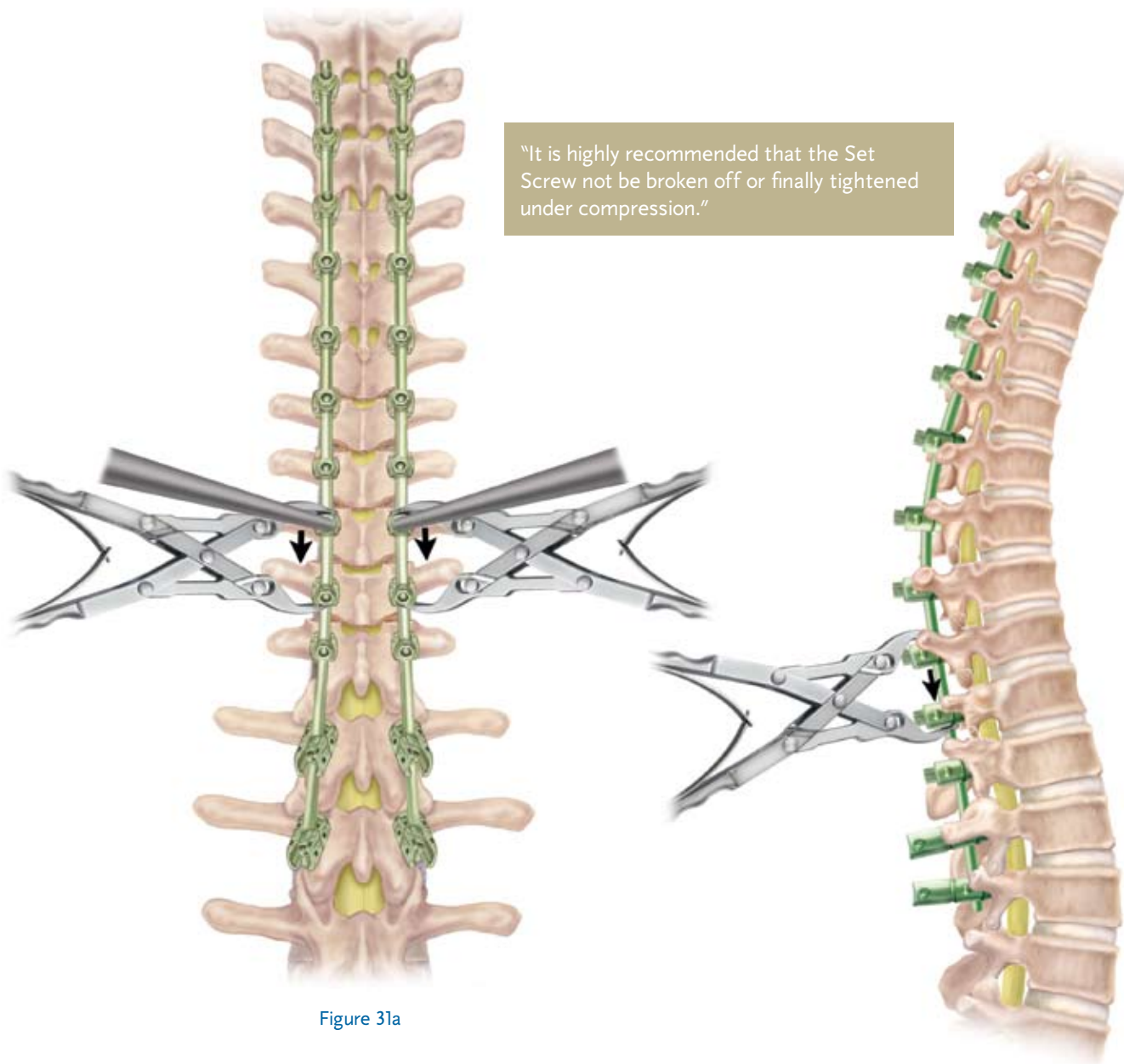


Figure 31a

Figure 31b

SCHEUERMANN'S KYPHOSIS CORRECTION SURGICAL TECHNIQUE (CONT.)

REDUCTION SCREW BREAK OFF

Once the rod is completely reduced and all the Set Screws fully advanced and provisionally tightened, the Set Screws in the standard Multi Axial Screws may be broken off. Ensure that the rod is fully reduced and parallel in the base of the screw head.

To break off the extended portion of the reduction Multi Axial Screws, slide the tab breaker over each extended tab of the implant head and apply pressure to the tab breaker away from the rod.

The Ring Counter Torque should be maintained over the implant head during this step. After this is completed, the reduction Set Screw may be broken off using the final Set Screw Driver with the standard counter torque in place.

If the soft tissue prevents the lateral tab from being broken off laterally, first break off the medial tab medially (**Figure 32**), then break off the Set Screw using the Ring Counter Torque, then break off the lateral tab medially.

If the tabs do not bend and break off easily, ensure that the Set Screw is fully advanced. If the Set Screw is not fully advanced, its threads will offer resistance and prevent the tabs from being broken off.



Figure 32

SCHEUERMANN'S KYPHOSIS CORRECTION SURGICAL TECHNIQUE (CONT.)

DECORTICATION AND BONE GRAFT PLACEMENT

The spine is decorticated using a burr and bone graft is added (**Figure 33a and 33b**).

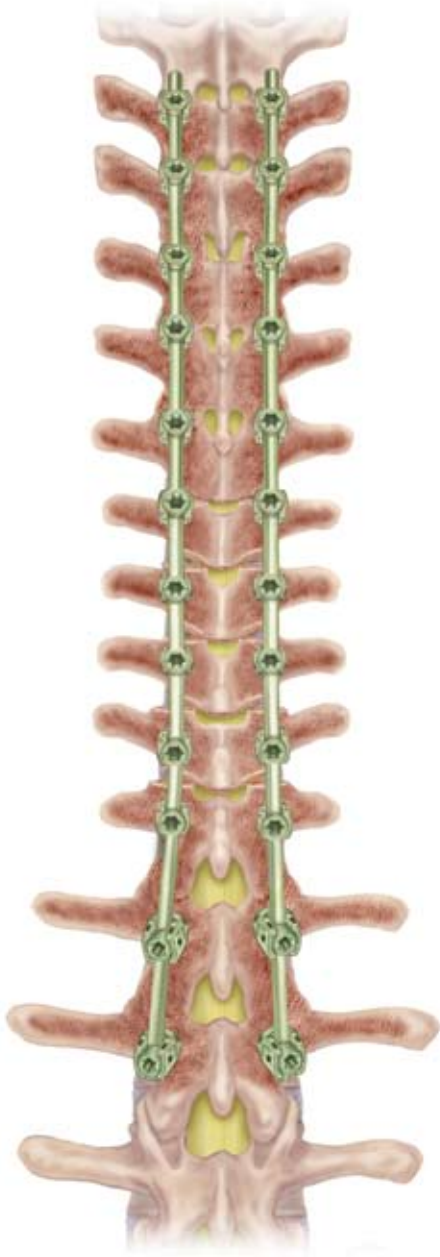


Figure 33a

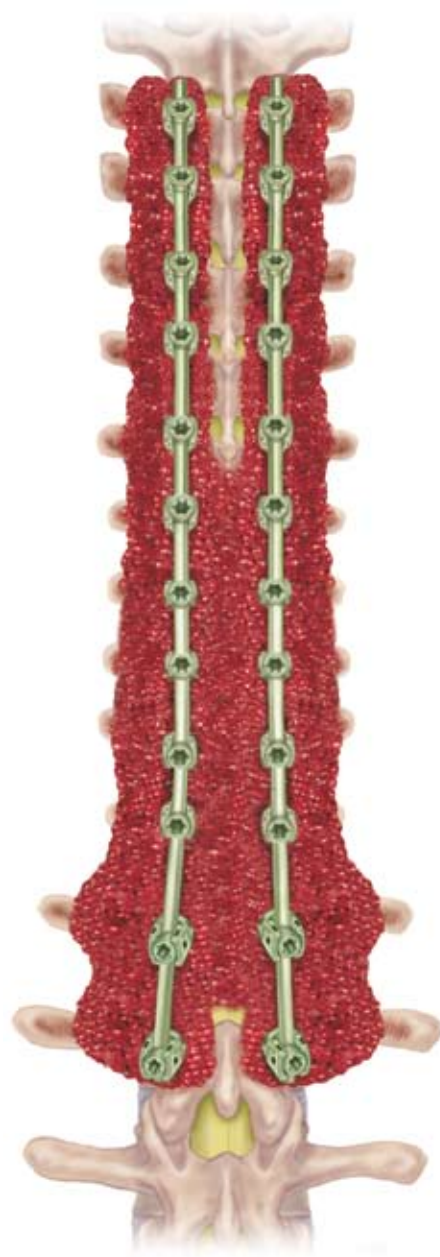


Figure 33b

SCHEUERMANN'S KYPHOSIS CORRECTION SURGICAL TECHNIQUE (CONT.)

CD HORIZON® X10 CROSSLINK™ PLATE PLACEMENT

CD HORIZON® X10 CROSSLINK™ Plates are placed at approximately T5 – T6 and T11 – T12 to increase stability (Figure 34a and 34b).

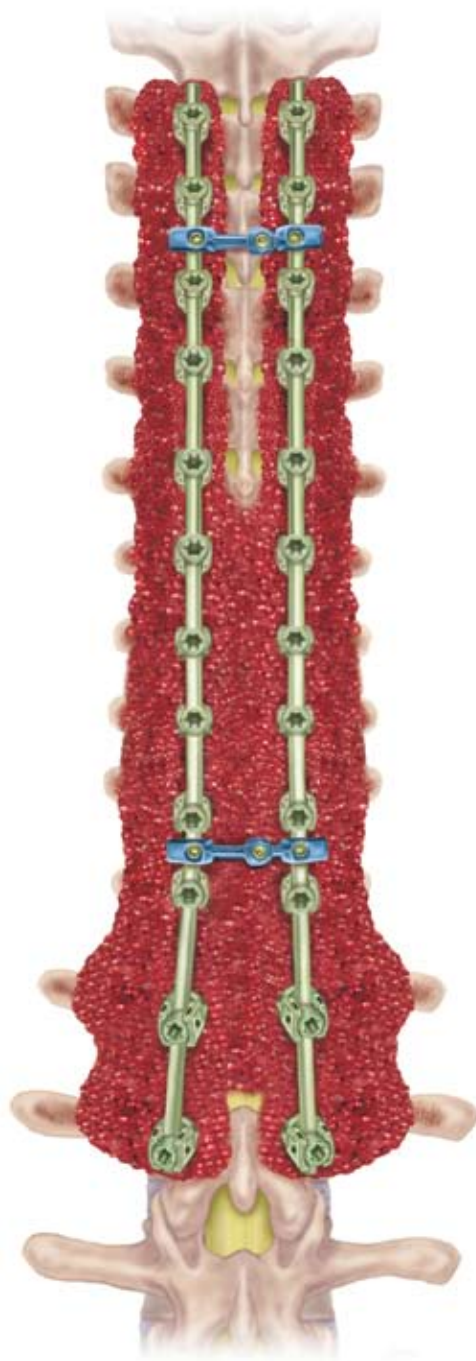


Figure 34a



Figure 34b

IMPLANT EXPLANTATION

The CD HORIZON® LEGACY™ Set Screws (plugs) may be removed using the T27 Obturator and the Self-Retaining Break-Off Driver. The T27 Obturator is inserted into the working end of the Self-Retaining Break-Off Driver, so that the knurled portion of the T27 Obturator is flush with the driver. Insert the obturator tip through the Counter Torque, which should be seated on the screw, and into the plug, turning counter-clockwise until the plug has been removed. The pedicle screws may be removed using either the Multi Axial Screwdriver or the Self-Retaining Screwdriver in connection with the Ratcheting Handle. First, attach the Ratcheting Handle to the modular end of the driver. Next, fully engage the hex end of the screwdriver into the screw head, then, if utilizing the Multi Axial Screwdriver, thread the instrument sleeve into the screw head. Turn counter-clockwise until the pedicle screws have been removed.

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

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 washer, GDL™ 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 ø3.5mm, ø4.5mm, ø5.5mm rods or ø6.35mm rods, while other components can connect to both ø5mm rods and ø6.35mm rods. Care should be taken so that the correct components are used in the spinal construct.

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

The CD HORIZON® Spinal System implant components are fabricated from medical grade stainless steel, medical grade titanium, titanium alloy, medical grade cobalt-chromium-molybdenum alloy, or medical grade PEEK OPTIMA-LT1. Certain CD HORIZON® Spinal System components may be coated with hydroxyapatite. No warranties, express, or implied, are made. Implied warranties of merchantability and fitness for a particular purpose or use are specifically excluded. See the 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 (NiTiNi – NITI). Shape Memory Alloy is compatible with titanium, titanium alloy and cobalt-chromium-molybdenum alloy. Do not use with stainless steel.

PEEK OPTIMA-LT1 implants may be used with stainless steel, titanium or cobalt-chromium-molybdenum alloy implants. CD HORIZON® PEEK Rods are not to be used with CROSSLINK® Plates.

To achieve best results, do not use any of the CD HORIZON® Spinal System implant components with components from any other system or manufacturer unless specifically allowed to do so in this or another Medtronic 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) pseudoarthrosis, (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.

The CD HORIZON® LEGACY 3.5mm rod and associated components, when used as a pedicle screw fixation system of the non-cervical posterior spine in skeletally mature patients, are indicated for one or more of the following: (1) degenerative spondylolisthesis with objective evidence of neurologic impairment, (2) fracture, (3) dislocation, (4) scoliosis, (5) kyphosis, (6) spinal tumor, and/or (7) failed previous fusion (pseudoarthrosis).

In addition, when used as a pedicle screw fixation system, the CD HORIZON® LEGACY 3.5mm rod and associated components, are indicated for skeletally mature patients: (a) having severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar-first sacral (L5-S1) vertebral joint; (b) who are receiving fusions using autogenous bone graft only; (c) who are having the device fixed or attached to the lumbar and sacral spine (L3 and below); and (d) who are having the device removed after the development of a solid fusion mass.

When used as a pedicle screw system in skeletally mature patients, the CD HORIZON® Spinal System PEEK rods and associated components are intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion in the treatment of the following acute and chronic instabilities of the thoracic, lumbar and sacral spine: (1) degenerative spondylolisthesis with objective evidence of neurologic impairment, (2) kyphosis, and/or (3) failed previous fusion. Additionally, when used as a pedicle screw device, the CD HORIZON® Spinal System PEEK rod constructs are indicated for use in patients who: (1) are receiving fusion with autogenous graft only, (2) who are having the device attached to the lumbar or sacral spine, and/or (3) who are having the device removed after the development of a solid fusion mass.

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

CONTRAINDICATIONS:

Contraindications include, but are not limited to:

- Active infectious process or significant risk of infection (immunocompromise).
- Signs of local inflammation.
- Fever or leukocytosis.
- Morbid obesity.
- Pregnancy.
- Mental illness.
- Grossly distorted anatomy caused by congenital abnormalities.
- Any other medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the presence of congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count.
- Rapid joint disease, bone absorption, osteopenia, osteomalacia and/or osteoporosis.
- Suspected or documented metal allergy or intolerance.
- Any case not needing a bone graft and fusion.
- Any case where the implant components selected for use would be too large or too small to achieve a successful result.
- Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
- Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
- Any patient unwilling to follow postoperative instructions.
- 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.
- Disassembly, bending, and/or breakage of any or all of the components.
- Foreign body (allergic) reaction to implants, debris, corrosion products (from crevice, fretting, and/or general corrosion), including metallosis, staining, tumor formation, and/or autoimmune disease.
- Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, fibrosis, neurosis, and/or pain. Bursitis. Tissue or nerve damage caused by improper positioning and placement of implants or instruments.
- Post-operative change in spinal curvature, loss of correction, height, and/or reduction.
- Infection.
- Dural tears, pseudomeningocele, fistula, persistent CSF leakage, meningitis.
- Loss of neurological function (e.g., sensory and/or motor), including paralysis (complete or incomplete), dysesthesias, hyperesthesia, anesthesia, paresthesia, appearance of radiculopathy, and/or the development or continuation of pain, numbness, neuroma, spasms, sensory loss, tingling sensation, and/or visual deficits.
- Cauda equina syndrome, neuropathy, neurological deficits (transient or permanent), paraplegia, paraparesis, reflex deficits, irritation, arachnoiditis, and/or muscle loss.
- Urinary retention or loss of bladder control or other types of urological system compromise.
- Scar formation possibly causing neurological compromise or compression around nerves and/or pain.
- Fracture, microfracture, resorption, damage, or penetration of any spinal bone (including the sacrum, pedicles, and/or vertebral body) and/or bone graft or bone graft harvest site at, above, and/or below the level of surgery. Retropulsed graft.
- Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery.
- Non-union (or pseudoarthrosis). Delayed union. Mal-union.
- Cessation of any potential growth of the operated portion of the spine.
- Loss of or increase in spinal mobility or function.
- Inability to perform the activities of daily living.
- Bone loss or decrease in bone density, possibly caused by stresses shielding.
- Graft donor site complications including pain, fracture, or wound healing problems.
- Ileus, gastritis, bowel obstruction or loss of bowel control or other types of gastrointestinal system compromise.
- Hemorrhage, hematoma, occlusion, seroma, edema, hypertension, embolism, stroke, excessive bleeding, phlebitis, wound necrosis, wound dehiscence, damage to blood vessels, or other types of cardiovascular system compromise.
- Reproductive system compromise, including sterility, loss of consortium, and sexual dysfunction.
- Development of respiratory problems, e.g. pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.
- Change in mental status.
- Death.

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

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 (pseudoarthrosis). 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 not good 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.

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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 3.5mm, 4.5 mm, 5.5mm and/or 6.35mm rods and implants, which are intended to be used with device specific instruments.

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

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

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

IMPORTANT INFORMATION ON THE CD HORIZON® SPINAL SYSTEM

PREOPERATIVE:

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

INTRAOPERATIVE:

1. Extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological functions.
2. Breakage, slippage, or misuse of instruments or implant components may cause injury to the patient or operative personnel.
3. The rods should not be repeatedly or excessively bent. The rods should not be reverse bent in the same location. Use great care to insure that the implant surfaces are not scratched or notched, since such actions may reduce the functional strength of the construct. If the rods are cut to length, they should be cut in such a way as to create a flat, non-sharp surface perpendicular to the midline of the rod. Cut the rods outside the operative field. Whenever possible, use pre-cut rods of the length needed.
4. Utilize an imaging system to facilitate surgery.
5. To insert a screw properly, a guide wire should first be used, followed by a sharp tap. Caution: Be careful that the guide-wire, if used, is not inserted too deep, becomes bent, and/or breaks. Ensure that the guide-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.

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. 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)	60 Minutes
Steam*	Pre-Vacuum*	273° F (134° C)*	20 Minutes*
Steam*	Gravity*	273° F (134° C)*	20 Minutes*

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

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.

FOR FURTHER INFORMATION:

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IMPORTANT INFORMATION FOR MEDTRONIC SOFAMOR DANEK INSTRUMENTS

PURPOSE:

This instrument is intended for use in surgical procedures.

DESCRIPTION:

Unless otherwise stated, instruments are made out of a variety of materials commonly used in orthopedic and neurological procedures including stainless steel and acetyl copolymer materials which meet available national or international standards specifications. Some instruments are made out of aluminum, and some with handles made of resin bonded composites, and while these can be steam autoclaved, certain cleaning fluids must not be employed. None of the instruments should be implanted.

Intended Use:

This instrument is a precision device which may incorporate a measuring function and has uses as described on the label.

Unless labeled for single use, this instrument may be re-used.

If there is any doubt or uncertainty concerning the proper use of this instrument, please contact MEDTRONIC SOFAMOR DANEK Customer Service for instructions. Any available surgical techniques will be provided at no charge.

WARNINGS:

The methods of use of instruments are to be determined by the user's experience and training in surgical procedures.

Do not use this instrument for any action for which it was not intended such as hammering, prying, or lifting.

This instrument should be treated as any precision instrument and should be carefully placed on trays, cleaned after each use, and stored in a dry environment.

To avoid injury, the instrument should be carefully examined prior to use for functionality or damage. A damaged instrument should not be used. Additional back-up instruments should be available in case of an unexpected need.

MEDTRONIC SOFAMOR DANEK does not and cannot warrant the use of this instrument nor any of the component parts upon which repairs have been made or attempted except as performed by MEDTRONIC SOFAMOR DANEK or an authorized MEDTRONIC SOFAMOR DANEK repair representative.

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.

DO NOT IMPLANT THE INSTRUMENTS.**POSSIBLE ADVERSE EFFECTS:**

Breakage, slippage, misuse, or mishandling of instruments, such as on sharp edges, may cause injury to the patient or operative personnel.

Improper maintenance, handling, or poor cleaning procedures can render the instrument unsuitable for its intended purpose, or even dangerous to the patient or surgical staff.

Proper patient selection and operative care are critical to the success of the device and avoidance of injury during surgery. Read and follow all other product information supplied by the manufacturer of the implants or the instruments.

Special precautions are needed during pediatric use. Care should be taken when using instruments in pediatric patients, since these patients can be more susceptible to the stresses involved in their use.

There are particular risks involved in the use of instruments used for bending and cutting rods. The use of these types of instruments can cause injury to the patient by virtue of the extremely high forces which are involved. Do not cut rods in situ. In addition, any breakage of an instrument or the implant in this situation could be extremely hazardous. The physical characteristics required for many instruments does not permit them to be manufactured from implantable materials, and if any broken fragments of instruments remain in the body of a patient, they could cause allergic or infectious consequences.

Over-bending, notching, striking and scratching of the implants with any instrument should be avoided to reduce the risk of breakage. Under no circumstances should rods or plates be sharply or reverse bent, since this would reduce the fatigue life of the rod and increase the risk of breakage. When the configuration of the bone cannot be fitted with an available device and contouring of the device is absolutely necessary, contouring should be performed only with proper bending equipment, and should be performed gradually and with great care to avoid notching or scratching the device.

Extreme care should be taken to ensure that this instrument remains in good working order. Any surgical techniques applicable for use of this system should be carefully followed. During the procedure, successful utilization of this instrument is extremely important. Unless labeled for single use, this instrument may be reused. This instrument should not be bent or damaged in any way. Misuse of this instrument, causing corrosion, "freezing-up", scratching, loosening, bending and/or fracture of any or all sections of the instrument may inhibit or prevent proper function.

It is important that the surgeon exercise extreme caution when working in close proximity to vital organs, nerves or vessels, and that the forces applied while correcting the position of the instrumentation is not excessive, such that it might cause injury to the patient.

Excessive force applied by instruments to implants can dislodge devices, particularly hooks.

Never expose instruments to temperatures in excess of 134° C that may considerably modify the physical characteristics of the instruments.

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

This device should be used only by physicians familiar with the device, its intended use, any additional instrumentation and any available surgical techniques.

For the best results MEDTRONIC SOFAMOR DANEK implants should only be implanted with MEDTRONIC SOFAMOR DANEK instruments.

Other complications to the patient and/or hospital staff may include, but are not limited to:

1. Nerve damage, paralysis, pain, or damage to soft tissue, visceral organs or joints.
2. Breakage of the device, which could make necessary removal difficult or sometimes impossible, with possible consequences of late infection and migration. Breakage could cause injury to the patient or hospital staff.
3. Infection, if instruments are not properly cleaned and sterilized.
4. Pain, discomfort, or abnormal sensations resulting from the presence of the device.
5. Nerve damage due to surgical trauma.
6. Dural leak in cases of excessive load application.
7. Impingement of close vessels, nerves and organs by slippage or misplacement of the instrument.
8. Damage due to spontaneous release of clamping devices or spring mechanisms of certain instruments.
9. Cutting of skin or gloves of operating staff.
10. Bony fracture, in cases of deformed spine or weak bone.
11. Tissue damage to the patient, physical injury to operating staff and/or increased operating time that may result from the disassembly of multi-component instruments occurring during surgery.

OTHER PRECAUTIONS:

1. Excessive forces when using bending or fixation instruments can be dangerous especially where bone friability is encountered during the operation.
2. Any form of distortion or excessive wear on instruments may cause a malfunction likely to lead to serious patient injury.
3. Regularly review the operational state of all instruments and if necessary make use of repair and replacement services.

DEVICE FIXATION:

Some surgeries require the use of instruments which incorporate a measuring function. Ensure that these are not worn, that any surface engravings are clearly visible.

Where there is a need for a specified tightening torque, this may normally be achieved with torque setting instruments supplied by MEDTRONIC SOFAMOR DANEK, the pointer on these instruments must indicate ZERO before use. If not, return for recalibration.

With small instruments, excess force, beyond the design strength of the instrument, can be caused even by simple manual overloading. Do not exceed recommended parameters.

To determine the screw diameter with the screw gauge, start with the smallest test hole.

PACKAGING:

MEDTRONIC SOFAMOR DANEK instruments may be supplied as either sterile or non-sterile. Sterile instruments will be clearly labeled as such on the package label. The sterility of instruments supplied sterile can only be assured if the packaging is intact.

Packages for both sterile and non-sterile components should be intact upon receipt. All sets should be carefully checked for completeness and all components should be carefully checked for signs of damage, prior to use. Damaged packages or products should not be used and should be returned to MEDTRONIC SOFAMOR DANEK.

Remove all packaging material prior to sterilization. Only sterile implants and instruments should be used in surgery. Always immediately re-sterilize all instruments used in surgery. Instruments should be thoroughly cleaned prior to re-sterilization. This process must be performed before handling, or before returning product to MEDTRONIC SOFAMOR DANEK.

EXAMINATION:

Instruments must always be examined by the user prior to use in surgery.

Examination should be thorough, and in particular, should take into account a visual and functional inspection of the working surfaces, pivots, racks, spring or torsional operation, cleanliness of location holes or cannulations, and the presence of any cracks, bending, bruising or distortion, and that all components of the instrument are complete.

Never use instruments with obvious signs of excessive wear, damage, or that are incomplete or otherwise unfunctional.

CLEANING AND DECONTAMINATION:

Unless just removed from an unopened Medtronic Sofamor Danek package, all instruments 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 the set of process parameters below:

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

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

It is important to note that a sterilization wrap, package or sterilization container system should be used to enclose the case or tray in order to maintain sterility.

Although the treatment of the instrument, materials used, and details of sterilization have an important effect, for all practical purposes, there is no limit to the number of times instruments can be re-sterilized.

OPERATIVE USE:

The physician should take precautions against putting undue stress on the spinal area with instruments. Any surgical technique instruction manual should be carefully followed. If an instrument breaks in surgery and pieces go into the patient, these pieces should be removed prior to closure and should not be implanted.

REMOVAL OF IMPLANTS:

For the best results, the same type of MEDTRONIC SOFAMOR DANEK instruments as used for implantation should be used for implant removal purposes. Various sizes of screwdrivers are available to adapt to the removal drive sizes in auto break fixation screws.

It should be noted that where excessive bone or fibrous growth has occurred from the first surgery, there may be added stress on the removal instruments and the implants. Both instrument and implant may be prone to possible breakage. In this case it is necessary to first remove the bone and/or tissue from around the implants.

FURTHER INFORMATION:

In case of complaint, or for supplementary information, please contact MEDTRONIC SOFAMOR DANEK.

PRODUCT COMPLAINT:

Any Health Care Professionals (e.g., customer users of MEDTRONIC SOFAMOR DANEK instruments), who have any complaint or who have experienced dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify the distributor, MEDTRONIC SOFAMOR DANEK. Further, if any instrument "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 or MEDTRONIC SOFAMOR DANEK 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 or MEDTRONIC SOFAMOR DANEK should be notified as soon as possible 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, and the nature of the complaint.

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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.

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

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