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

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

As described by:

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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
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)**

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

**CEPHALO–CAUDAL STARTING POINTS (B)**
## 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).

<table>
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<th>Level</th>
<th>Cephalad-Caudal Starting Point</th>
<th>Medial-Lateral Starting Point</th>
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<tr>
<td>T1</td>
<td>Midpoint TP</td>
<td>Junction: TP-Lamina</td>
</tr>
<tr>
<td>T2</td>
<td>Midpoint TP</td>
<td>Junction: TP-Lamina</td>
</tr>
<tr>
<td>T3</td>
<td>Midpoint TP</td>
<td>Junction: TP-Lamina</td>
</tr>
<tr>
<td>T4</td>
<td>Junction: Proximal Third-Midpoint TP</td>
<td>Junction: TP-Lamina</td>
</tr>
<tr>
<td>T5</td>
<td>Proximal Third TP</td>
<td>Junction: TP-Lamina</td>
</tr>
<tr>
<td>T6</td>
<td>Junction: Proximal Edge-Proximal Third TP</td>
<td>Junction: TP-Lamina-Facet</td>
</tr>
<tr>
<td>T7</td>
<td>Proximal TP</td>
<td>Midpoint Facet</td>
</tr>
<tr>
<td>T8</td>
<td>Proximal TP</td>
<td>Midpoint Facet</td>
</tr>
<tr>
<td>T9</td>
<td>Proximal TP</td>
<td>Midpoint Facet</td>
</tr>
<tr>
<td>T10</td>
<td>Junction: Proximal Edge-Proximal Third TP</td>
<td>Junction: TP-Lamina-Facet</td>
</tr>
<tr>
<td>T11</td>
<td>Proximal Third TP</td>
<td>Just medial to lateral pars</td>
</tr>
<tr>
<td>T12</td>
<td>Midpoint TP</td>
<td>At the level of lateral pars</td>
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INDEPENDENT DEROTION 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 Bridge Nut
7480398

Derotator Inline Handle
7480397

Derotator Interlink
7480395
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).
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.
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.
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 caudal 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.
BONE–TO–SCREW INTERFACE ASSESSMENT

Once the screws are in position, attach a Fixed Angle Screwdriver to the implant heads of the periaxial 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).
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.
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
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.
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.

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

“It is highly recommended that the Set Screw not be broken off or finally tightened under compression.”
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.
DECORTICATION AND BONE GRAFT PLACEMENT

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

The CD HORIZON\textsuperscript{®} 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\textsuperscript{®} X10 CROSSLINK™ MULTI-SPAN\textsuperscript{®} Plate is necessary, place the 7/32\textsuperscript{°} 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.
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:

- Early or late loosening of any of the components.
- Disassembly, bending, and/or breakage of any of the components.
- Foreign body (allergic) reaction to implants, debris, corrosion products (from crevice, fretting, and/or general corrosion), including metastasizing, metallic debris, and/or bone dust.
- Pressure on the spine 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 instrumentation.
- Post-operative change in spinal curvature, loss of correction, height, and/or reduction.
- Infection.
- Dural tear, pseudoneurinome, fistula, persistent CSF leakage, meningeal tears.
- 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 of or continuation of pain, numbness, neurapraxia, sensory loss, tingling sensation, and/or visual defects.
- Cauda equina syndrome, neuropathy, neurologic deficits (transient or permanent), paraplegia, paraparesis, reflex irritations, irritative syndromes.
- Urinary retention or loss of bladder control or other types of urological system compromise.
- Sacral nerve injury, resulting in muscle weakness and/or incontinence.
- 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. Retrograde graft.
- Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery.
- 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 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, spondylolisthesis, 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 one or more of its components can be expected to pull out, bend or fracture as a result of exposure to everyday 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 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 spinal surgical techniques, good judgment, 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 poor neurovascular access are also poor candidates for spine fusion.

PHYSICIAN NOTE:

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

CAUTION: Federal law (USA) restricts these devices to sale by or on the order of a physician. Other proscriptive, intraproscriptive, 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 instruments are subject to repeated sharpening, 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 stress on the implant, such stress may cause metal fatigue and consequent breakage, bending or loosening of the device during the healing process is complete, which may result in further injury or the need to remove the device permanently.

DEVICE FIXATION:

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

**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 operator 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 ensure that the implant surfaces are not scratched or nicked. Some such motions 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 ridline 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 reinserted 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 over tighten or use a screw/bolt that is too long or too large. Over-tightening, using an incorrectly sized screw/bolt, or accidentally advancing the guide wire during tap or screw/rod 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 vertebra 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 wherever 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 fine-tuning 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 muscle activity. The risk of bending, loosening, or breakage of a temporary internal fixation device postoperatively may be increased if the patient is active, or if the patient is debilitated or dehydrated. 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 bending motions and any type of sport participation. The patient should be advised not to smoke tobacco or alcoholic products, or to consume alcohol or non-steroidal anti-inflammatory medications such as aspirin during the bone graft healing process.
3. The patient should be advised of their liability 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 mechanical fatigue, these stresses can cause the eventual bending, loosening, or breakage of the device(s). It is important that immobilization of the spinal surgical site be maintained until firm bony union is established and confirmed by roentgenographic examination. If a state of non-union persists or if the components loosen, bend, and/or break, the device(s) should be revised and/or removed immediately before serious injury occurs. The patient must be adequately warned of these hazards and closely supervised to ensure union prior to 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 fusion is solid, 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 positioning, possibly resulting in injury; (3) Risk of additional injury from postoperative trauma; (4) Bending, loosening, and breakage, which can result in implant 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, 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 orthopaedic implants, the CD HORIZON® Spinal System components should never be used 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 prior to sterilization and insertion into a sterile surgical field (if applicable). Inspection of the return of the product to Medtronic Sofamor Danek. Cleaning and decontamination of instruments can be performed with aldehyde-free solvents at higher temperatures. Cleaning and decontamination must include the use of neutral cleansers followed by a deionized water rinse. Note: Certain cleaning solutions such as those containing formalin, glutaraldehyde, methanol 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 improper proper 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 processes below:

<table>
<thead>
<tr>
<th>METHOD</th>
<th>CYCLE</th>
<th>TEMPERATURE</th>
<th>EXPOSURE TIME</th>
</tr>
</thead>
<tbody>
<tr>
<td>Steam</td>
<td>Pre-Vacuum</td>
<td>270°F (132°C)</td>
<td>4 Minutes</td>
</tr>
<tr>
<td>Steam</td>
<td>Gravity</td>
<td>259°F (127°C)</td>
<td>60 Minutes</td>
</tr>
<tr>
<td>Steam*</td>
<td>Pre-Vacuum*</td>
<td>273°F (134°C)</td>
<td>10 Minutes*</td>
</tr>
<tr>
<td>Steam*</td>
<td>Gravity*</td>
<td>273°F (134°C)</td>
<td>10 Minutes*</td>
</tr>
</tbody>
</table>

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 the following parameters: as a minimum to prevent the potential risk of transmission of Crohn's disease, exposure 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 disinfection 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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**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 acrylic 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 sterilized.

**Intended Use:** This 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.

**Possible Adverse Effects:**
- Breakage, slippage, misfit, or mishandling of the instruments, such as sharp edges, may cause injury to the patient or 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 operating 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.

**NOTE:** Due to 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 require sterilization according to these parameters so as to minimize the potential risk of transmission ofCreutzfeldt-Jakob disease, especially of surgical instruments that could come into contact with the central nervous system.

**Implied warranties of merchantability and fitness for a particular purpose or use are specifically excluded. See the MSD catalog for further information and limitations of liability.

**DO NOT IMPLANT THE INSTRUMENTS:**
- Do not use this instrument for any action for which it was not intended such as hammering, prying, or lifting.
- Instruments should be treated as any precision instrument and should be carefully placed on trays, cleaned after each use, and stored in a dry environment.

**OPERATIVE USE:**
- Unless labeled for single use, this instrument may be re-used. Additional back-up instruments should be available in case of an unexpected need.

**CLEANING AND DECONTAMINATION:**
- Unless just removed from an unopened Medtronic Sofamor Danek package, all instruments must be disinfected (if applicable) and cleaned using neutral cleaners before sterilization and introduction into a sterile surgical field (if applicable) return of the product to the Medtronic Sofamor Danek. Cleaning and disinfesting of instruments can be performed with aldehyde-free solutions at higher temperatures. Cleaning and decontamination must include the use of neutral cleaners followed by a disinfectant wipe.

**Stereotaxic System:**
- Implantable systems are supplied as either sterile or non-sterile. Sterile implants 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.

**Packaging:** Packages for 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.

**Removal:** Remove all packaging material prior to sterilization. Only sterile instruments and implants should be used in surgery. Always immediately re-sterilize all instruments used in surgery. Instruments should be thoroughly cleansed 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.

**STEREILIZATION:**
- 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 instruments 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:

*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.*

**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*

**Usa For Us Audiences Only**

**CAUTION: FEDERAL (U.S.) LAW restricts this device 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 fluid accumulation.
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 fracts, 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 dissatisfactory of multi-component instruments occurring during surgery.

**Additional Precautions:**
1. Excessive forces when using bending or fixation instruments can be dangerous especially where bone fragility is encountered during the operation.
2. Any form of distraction 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 surgeons require the use of instruments which incorporate a measuring function. Ensure that these are not worn, that any exposed edges are clearly visible.
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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For more information go to www.myspinetools.com

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