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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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, 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)**

![Superior Facet Rule Diagram](image)

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

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

![Cephalo-Caudal Starting Points Diagram](image)

Color Reference Chart
- **Unsafe**
- **Safe**

Color Coding:
- **T9, T8, T7**  
- **T10, T6**  
- **T11, T5, T4**  
- **T12, T3, T2, T1**
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>
<thead>
<tr>
<th>Level</th>
<th>Cephalad-Caudal Starting Point</th>
<th>Medial-Lateral Starting Point</th>
</tr>
</thead>
<tbody>
<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>
</tr>
</tbody>
</table>
Fixed Angle Screwdrivers (7480280)
Tube Derotators (7480290)
Ratcheting Handles (9339082)
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 1a and 1b). 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 periapical convex screws (Figure 2). 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 3).
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 4a and 4b). Typically, four periapical vertebrae are utilized.
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 5). 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 6). 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 7). Then the rod is captured at both ends but only locked into the caudal screws.
Starting caudad and then moving cephalad, the apical segments on the concave rod are then sequentially captured with the Forceps Rocker (Figure 8a), twisted to perform an apical derotation maneuver (Figure 8b), and then provisionally tightened with a Set Screw to hold the screw in this derotated position on the rod (Figure 8c). The corresponding convex periapical screws are continually being derotated to accomplish the BAVD technique.
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 9). 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.
COMPRESSION/DISTRACTION

In situ rod contouring for coronal translation correction may be performed at this point after removing the convex apical Screwdrivers (Figure 10). 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 11). 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 12). 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 optimize the upper lowest instrumented vertebrae alignment (Figure 13). 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 14).
Following thorough decortication (Figure 15) and bone graft placement (Figure 16), 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 17). 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 18a and 18b). Typically, this will be performed at three to five apical segments.
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 19a and 19b).
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 40-50º, depending on the preoperative kyphosis magnitude and stiffness (Figure 20).
ROD PLACEMENT

Engage the rods bilaterally by turning them 180° and capturing at least three levels beginning at T3 and working towards L2 (Figure 21a and 21b). 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 22a and 22b). 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 23 and 24).
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 25a and 25b). 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 26), 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 27a and 27b).
CD HORIZON® X10 CROSSLINK™ PLATE PLACEMENT

CD HORIZON® X10 CROSSLINK™ Plates are placed at approximately T5-T6 and T11-T12 to increase stability (Figure 28a and 28b).
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 to construct bony fusions 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 TOSYI™ rods, hooks, screws, plates, CROSSLINK™ staples, connectors, vastus and washer; IDOLUS™ hooks, hooks, connectors, and washers; LIBERTY™ rods and screws; DYNALOK™ PLIPS™ and DYNALOK™ CLASSIC™ both along with rod/bolt connectors; and Sofamor Danek Multi-keel rods and screws. Please note that certain components are specifically designed to work with the CD HORIZON Spinal System only, such as 45° and 65° L.5mm rods or ø6.35mm rods, while other components can connect to both ø5.5mm and ø6.35mm rods. Care should be taken to select the correct components 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 rod 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 PEAK OPTIMA-LT. 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 Medtronic Catalog for further information on warranties and limitations of liability.

Never use stainless steel and titanium implant components in the same construct.

Medical grade titanium, titanium alloy and medical grade cobalt-chromium-molybdenum alloy may be used together. Never use stainless steel and titanium implant components in the same construct.

The CD HORIZON Spinal System also includes anterior staples made of Shape Memory Alloy (NiTi – NiT). Shape Memory Alloy is compatible with titanium, titanium alloy and cobalt-chromium-molybdenum alloy implants. Do not use with stainless steel.

PEAK OPTIMA-LT implants may be used with stainless steel, titanium or cobalt-chromium-molybdenum alloy implants. CD HORIZON PEAK 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 system 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 re-used under any circumstances.

INDICATIONS:
The CD HORIZON Spinal System is intended for posterior, non-cervical fusion for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis and/or lordosis); tumor; pseudarthrosis; and/or failed previous fusion.

When used in a percutaneous, non-cervical, posterior approach with the SEXTANT™ instrumentation, the CD HORIZON spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis and/or lordosis); tumor; pseudarthrosis; and/or failed previous fusion. Additionally, when used as a pedicle screw system, certain components are specifically designed and/or intended for use as a pedicle screw system. The CD HORIZON Spinal System instrumentation contains 3.5mm, 4.5 mm, 5.5mm and/or 6.35mm rods and associated implants, which are intended to be used with device specific instruments.

MEDTRONIC SOFAMOR DANEK CD HORIZON® Spinal System instrumentation contains 3.5mm, 4.5 mm, 5.5mm and/or 6.35mm rods and associated implants, which are intended to be used with device specific instruments.

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

1. Early or late loking of any or all of the components.
2. Disassembly, bending, and/or breakage of any of the components.
3. Foreign body (allergic) reaction to implants, debits, corrosion products (from crevice, fretting, and/or general corrosion), includ-
ing metal particulates. (See Table 1 for detailed list of components.)
4. Pressure on the side from component parts in patients with lymphatic tissue coverage over the implant possibly causing skin penetration, irritation, fibrosis, neurosensory, and/or pain. Blister. Tissue or nerve damage caused by improper positioning and place-
ment of implants or instrumentation.
5. Post-operative change in spinal curvature, loss of correction, height, and/or reduction.
6. Infection.
7. Dural tears, pseudoaneurysms, fistula, persistent CSF leakage, meninges.
8. Loss of neurologic function (e.g., sensory and/or motor), including paralysis (complete or incomplete), dysesthesia, hypo-
aesthesia, radiculopathy, appearance of radiopacity, and/or the development or continuation of pain, numbness,
numbness, pain, spasm, loss of function, sensation, and/or visual deficits.
9. Cauda equina syndrome, neuropathy, neurological deficits (transient or permanent), paraplegia, paraparesis, reflex deficits, irrita-
tion of nerve roots, and/or urinary incontinence.
10. Urinary retention or loss of bladder control or other types of urological system compromise.
11. Scar formation possibly causing neurological compromise or compression around nerves and/or pain.
12. Fracture, microfracture, resolution, damage, or penetration of any spinal bone (including the sacrum, pedicles, and/or vertebral body), and/or bone graft or bone graft harvest site at, above, and/or below the level of surgery. Retropulsed graft.
13. Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery.
15. Cessation of any potential growth of the operated portion of the spine.
16. Loss or gain in spinal mobility or function.
17. Inability to perform the activities of daily living.
18. Bone loss or decrease in bone density, possibly caused by stress shielding.
19. Graft donor site complications including pain, fracture, or wound healing problems.
20. Re, gus, dsters, bowel obstruction or loss of bowel control or other types of gastrointestinal system compromise.
21. Hernomhage, hematoma, oclusion, seroma, edema, hypertension, embolism, stroke, excess bleeding, phlebitis, phlebitis, wound necrosis, wound delamination, diease to blood vessels, or other types of cardiovascular system compromise.
22. Reproductive system compromise, including sterility, loss of continence, and sexual dysfunction.
23. Change in mental status.
24. Death.

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

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

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

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

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

Preoperative and operating procedures, including knowledge of surgical techniques, good judgment, and proper selection and place-
ment 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 paralyses 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.

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For US Audiences Only

CAUTION: Federal law (U.S.) 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 suture anchors are subject to repeated strain, 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 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 OTT Transverse Links, the MIS plug should be tightened to between 8 and 9 ft-lbs (70 to 80 inch lbs).

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

**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 function.
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 ensure that the implant surfaces are not scratched or notched, since such actions may reduce the functional strength of the construct. If the rods are cut to length, they should be cut in such a way as to create a flat, non-sharp surface perpendicular to the midline of the rod. Cut the rods outside the operative field. Wherever 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 sure 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 ovate or use a screw/bolt that is either too long or too large. Overtapping, using an incorrectly sized screw/bolt, or accidentally ovating the guide 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 vertebral end-plate.
8. To assure maximum stability, two or more CROSSLINK® plates or OTT 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 or removal 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 removal 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 chance 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 utilize nicotine products, or to consume alcohol or non-steroidal 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 loss due to stress shielding; and (8) Potential unknown and/or unexpected long term effects such as carcinogenesis. Implant 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 tissue decubitus 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 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.
4. Any revision surgery should be treated in such a manner that reuse in another surgical procedure is not possible.
5. As a precaution, before patients with implants receive any subsequent surgery (such as dental procedures), prophylactic antibiotics should be administered.
6. 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 or removal 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.
7. 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.
8. 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. Wherever possible, use pre-cut rods of the length needed.
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.

**STEROIDIZATION:**
Unless marked sterile and sterile labeled as such in an unopened sterile package provided by the company, all implants and instru-
ments 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.

<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 (134° C)</td>
<td>4 Minutes</td>
</tr>
<tr>
<td>Steam</td>
<td>Gravity</td>
<td>270° F (134° C)</td>
<td>20 Minutes</td>
</tr>
<tr>
<td>Steam*</td>
<td>Pre-Vacuum*</td>
<td>273° F (134° C)</td>
<td>20 Minutes*</td>
</tr>
<tr>
<td>Steam*</td>
<td>Gravity*</td>
<td>273° F (134° C)</td>
<td>20 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 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, serial number, 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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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.