CD Horizon®
Spinal System Surgical Technique

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Introduction

The CD HORIZON® Spinal System represents a further development of the Cotrel-Dubousset Instrumentation designed by Dr. Yves Cotrel and based on the three-dimensional surgical correction techniques developed by Professor Jean Dubousset. Additionally, the CD HORIZON Spinal System expands on earlier concepts by providing the surgeon with various technique options, including rod rotation, translation, segmental correction, in-situ rod contouring or combinations of these methods.

The basic objective of the original Cotrel-Dubousset system also applies to the CD HORIZON Spinal System. That is, to restore as completely as possible the balance of the spine in all three anatomical planes. Therefore, simultaneous visualization of the deformity in the three planes is essential for operative correction. Comprehensive preoperative radiographic studies should be utilized to determine the “strategic vertebrae” in order to mobilize them and then, by segmental actions obtain deformity correction compatible with three-dimensional spinal balance.

It is beyond the scope of this presentation to address the basic principles of three-dimensional instrumentation and correction. Rather, this manual is presented only as a technique guide for utilization of the CD HORIZON Spinal System implants and instruments. It is recommended that the inexperienced surgeon attend organized scientific meetings and learn from other surgeons with greater experience the concepts, principles, and techniques of three-dimensional surgical correction of the spine.

NOTE: Illustrations have been simplified for clarity. The case presented is for illustrative purposes only.
Design criteria

The CD HORIZON® Spinal System design criteria were based on a decade’s worth of worldwide surgical experience with Cotrel-Dubousset Instrumentation. The characteristics of the system are numerous and several are listed below:

- Efficient instruments
- Top loading, top tightening implants
- Low profile, anatomically designed implants
- Adaptable to various surgical techniques
- Allows for decreased inventory requirements
- Revisability

The range of CD HORIZON Spinal System implants and instruments are on the following pages.
CD HORIZON® SPINAL SYSTEM IMPLANTS

- Pedicle Hook
- Wide Blade Hook
- Angled Blade Hook
- Left Offset Hook
- Narrow Blade Hook
- Right Offset Hook
- Narrow Blade Ramped Hook
- Standard Blade Ramped Hook
- Right Angled Hook
- Extended Body Hook
- Large Pedicle Hook
- Large Groove Hook
- Extended Body, Large Groove Hook
- Left Angled Hook
- Large Pedicle, Small Groove Hook
- Narrow Blade, Small Groove Hook

LOW PROFILE CROSSLINK®

- CROSSLINK Offset Plate
- 5.5mm x 40mm Bone Screw
- 6.5mm x 40mm Bone Screw
- 7.5mm x 40mm Bone Screw
- Break-off Set Screw
- Domino Connector
- Axial Connector
- Hex End Rod
Instruments

CD HORIZON® SPINAL SYSTEM INSTRUMENTS

- Final Plug Driver
- Provisional Plug Driver
- T20 / T25 Shaft
- Modular Handle for T20 / T25 Shaft
- In-situ Benders
- Hook Pusher
- Rod Pusher
- French Bender
- Counter Torque
- Dual Purpose Hook Pusher
- Dual Purpose Implant Holder

Surgical Technique
CD HORIZON® SPINAL SYSTEM INSTRUMENTS (continued)
SURGICAL TECHNIQUE

CD HORIZON® SPINAL SYSTEM

LOW PROFILE CROSSLINK® SYSTEM INSTRUMENTS

Corkscrew

Plug/Introducer

Plug/Set Screw Starter

Rod Reducer with Rod Reducer Lever Arm

Rocker

Plate Benders

Plate Template

Plate Holder
Patient Position

The patient is placed in the prone position following induction of anesthesia, intubation and placement of monitors. Care should be taken in positioning to avoid pressure areas and compromise of the abdomen (Fig. 1). The patient is then prepped and draped in the usual manner.
Incision and Exposure

The skin and subcutaneous tissue are incised longer than the planned fusion. Once bleeding is controlled, the exposure is deepened through the fascial level and dissection is carried out laterally to the transverse processes (Fig. 2).

Fig. 2
**Hook Placement**

As previously noted in this manual, the CD HORIZON® Spinal System offers a number of anatomic top loading hooks of different shapes and sizes. However, any CD HORIZON hook may be treated as a closed hook simply by placing the break-off set screw into the hook prior to insertion of the rod. The surgeon must choose the appropriate hook based on the individual patient’s anatomy, deformity type, method of correction, and direction of force application in order to provide proper purchase on the vertebrae.

**Pedicle Hook**

The pedicle hook may be applied from T1 through T10. The hook shoe direction is always cephalad and is in the infralaminar position. The facet capsule is divided, and a portion of the inferior facet process may be removed to facilitate insertion of the hook (Fig. 3). The pedicle finder is used to localize the pedicle (Fig 4). Once the pedicle has been clearly identified, the hook may be inserted either with an implant holder or with the dual purpose instrument. The appropriate hook pusher should be utilized to facilitate placement of the hook.
Supralaminar Position

The direction of this hook is always caudal. A small laminotomy and division of the ligamentum flavum is carried out on the superior lamina. The laminar elevator may be used to dissect the ligamentum flavum from the lamina. The amount of bone removed from the lamina may vary depending on the size of the hook to be utilized. The inferior edge of the lamina above may also be removed to permit easier placement of this hook. An implant holder is used to insert the hook. If necessary a small lamina spreader may be used to enlarge the opening while inserting the hook.

Infrafaminar Position

This hook is always inserted in the cephalad direction and is generally used at T10 or below. Again, a small laminotomy with division of the ligamentum flavum is performed. The laminar elevator may be used to facilitate hook placement. The implant holder with hook pusher can be utilized to promote hook insertion.
Transverse Process Position

This generally is a wide blade hook and is usually used in a claw construct. It may be placed in a cephalad or caudal direction. Generally the hook is placed in the caudal direction. The transverse process elevator is used to start placement of this hook by dissecting the soft tissues from the superior aspect of the transverse process. The hook is held by an implant holder during insertion.

**NOTE:** All hooks should be continuously checked during the insertion process to ensure that they remain in the correct position. Facet fusion may be performed in a standard manner following implantation of the hooks (Fig. 5).
**Rod Contouring**

The appropriate size rod is measured and cut to the correct length outside the operative field. To achieve the correct sagittal plane contour, the rod is bent in small incremental steps using a french bender (Fig. 6). At this point, bone graft harvesting and decortication may take place. The low profile of the CD HORIZON® spinal implants make decortication possible even after the construct is assembled.
Rod Insertion

The rod is then entered into the top loading implants beginning from either the cephalad or caudad directions (Fig. 7). The break-off set screw (hereafter referred to as the “plug”) is inserted into the implant either with the free hand method using the plug starter or with a plug introducer instrument. The rod is best inserted using the appropriate rod holder.
Provisional Implant Closure

Method 1

If the rod is laying in the bottom of the implant groove, the plug may be seated into the top of the implant using the free hand technique with the plug starter (Fig. 8). The plug starter is turned counterclockwise until an audible “click” occurs to limit the possibility of cross-threading. The rod may also be pushed into the implant with a rod pusher. However, the implant should be controlled during this process. The lateral implant holder is especially effective in maintaining implant control while pushing the rod into the bottom of the implant (Fig. 9). The plug starter can be used to place the plug into the implant when using either the lateral implant holder or the curved implant holder.
**Method 2**

An alternative method of reducing the rod into the implant when only a slight height difference exists between the rod and implant is to use the rocker instrument. This instrument allows the rod to be seated into the bottom of the implant (Fig. 10a). The implant is grasped from the sides with the rocker cam above the rod. The rocker is rotated backward thereby levering the rod into the implant groove (Fig. 10b). The plug starter is then used to attach the plug.
Method 3

The plug introducer instrument can be used when additional force is needed to seat the rod into the implant. This instrument is placed over the rod with its “flanges” parallel to the rod. The tines of the plug introducer are positioned over the rod and the implant (Fig. 11a). The sleeve of the plug introducer is then turned clockwise to secure the implant to the instrument (Fig. 11b). Visually inspect to ensure that the plug introducer is securely attached to the implant.

Fig. 11a
Fig. 11b
**Rod Insertion (continued)**

**Method 3 (continued)**

Either one or two corkscrew devices are attached to the flanges of the plug introducer and the rod is driven into the top loading implant (Fig. 11c). To verify that the rod is fully seated in the implant, inspect visually or place the provisional plug driver into the cannulation of the plug introducer. Check to see that the uppermost etching mark on the shaft of the plug driver is completely inside the cannulation of the plug introducer. If the etching mark is not completely inside the introducer then the corkscrews must be turned further to fully seat the rod (Fig. 11d). Once the etching mark is confirmed to be entirely inside the introducer (Fig. 11e), then the driver can be removed.
The plug implant is then placed into the cannulation of the introducer and secured with the provisional plug driver (Fig. 12). The plug driver instrument is again placed in the cannulation of the introducer and matched to the hex drive of the plug. The provisional plug driver is turned counterclockwise until an audible “click” and a palpable slight dropping of the instrument is noted. This ensures that the thread of the plug is lined up with the thread of the implant and limits the possibility of cross-threading (Fig. 13).

An alternative method is to seat the plug on the plug starter instrument and then insert the instrument (with plug) into the cannulation of the plug introducer. Again, the plug starter is turned counterclockwise until the “click” is noted. The plug is then seated in the implant. The provisional plug driver is used to temporarily lock the rod to the implant. Enough force can be generated by the pear-shaped handle of the provisional plug driver to maintain secure closure of the implant without breaking off the head of the plug. The provisional plug driver may be used to loosen and tighten the implant closure for all compression/distraction or rotation maneuvers.
Method 4

Occasionally the rod lies medial or lateral to the implant channel and controlled translation would be helpful. The rod reducer instrument and the accompanying lever arm may be used in these situations. The tines of the rod reducer are attached to a side of the hook in a manner similar to that of the lateral implant holder. By holding the coupling sleeve and stabilizing bar, position the tines of the instrument over the side of the implant body with the open side facing the rod. Once the tines are in position, hold the rod reducer steady with the stabilizing bar and slide the coupling sleeve downward until the implant is properly engaged (Fig. 14a). With the implant contained, turn the threaded knob at least one full clockwise revolution; now the implant may be manipulated by the rod reducer. For translation of a laterally positioned rod, attach the lever arm to the coupling sleeve axles. Turn the threaded knob while manipulating the lever arm with a sweeping motion to capture the rod (Fig. 14b).
Manually translate the rod until it is above the channel of the implant (Fig. 14c).

Turn the threaded knob in a clockwise manner until the rod is captured in the implant channel. The lever arm may now be removed. Continue tightening the threaded knob until complete rod reduction is achieved. The provisional plug driver may be used to confirm the rod position in the implant channel (Fig. 14d).

Use the plug starter to introduce the plug into the implant channel (Fig. 14e). Turn the plug starter counterclockwise until an audible “click” is noted. The provisional plug driver is used to temporarily lock the rod within the implant.

**NOTE:** If the rod is directly above the hook or screw channel, the rod reducer may be used without the lever arm.
**STEP 6**

**Force Application / Rod Rotation**

Force application is achieved by the curved compressor or curved spreader instruments. Care should be taken to ensure that the feet of either instrument are placed against the implant body and not against the plug (Fig. 15). Failure to do this may result in slippage of the implant or premature breaking of the plug. The provisional plug driver may be used to maintain temporary locking and security of the rod/implant construct. Temporary fixation of the implant may be done numerous times without damage to either the plug or implant threads. If the plug has been tightened in a cross-threaded position, it should be removed and replaced.

As necessary, the rod may be rotated with the power grip and/or hex rotation wrench instruments. C-ring instruments may be placed to maintain hook position while allowing rotation of the rod. Hooks should be checked for alignment following rotation maneuvers and the necessary forces should be applied to resecure the implants if needed.
Bone Grafting and Crosslink® PLATING

Decortication and bone grafting can now take place. Low Profile CROSSLINK® Plates may also be added at this time.

After tightening the plugs, the appropriate size Low Profile CROSSLINK Plate or CROSSLINK Multi-Span® Plate is determined with the measuring template (Fig. 16). Rods may be spread or compressed as necessary.

With use of the plate holder (810-510), the appropriate Low Profile CROSSLINK Plate or Multi-Span Plate is selected and pressed down onto the rods (Fig. 17).

Plate benders should be used to contour the Low Profile CROSSLINK Plates or the Multi-Span Plates. When bending the Low Profile CROSSLINK and Multi-Span Plates, do not exceed 20° in any single plane.

The set screws are advanced using the screwdriver to a torque of approximately 60 in-lbs., alternating tightening from side to side to ensure uniform closure (if using a CROSSLINK Multi-Span Plate, the midline screw is tightened after the set screws are secured). Two screwdrivers may be used simultaneously to advance the set screws for uniform closure.

NOTE: The Low Profile CROSSLINK Plates are part of the TSRH® Spinal System, the 6.35mm Stainless Steel and Titanium and 5.5mm Stainless Steel Low Profile CROSSLINK Multi-Span Plates are part of the CD HORIZON® Spinal System and the 5.5mm Titanium Low Profile CROSSLINK Multi-Span Plates are part of the Medtronic Sofamor Danek Multi Axial Screw System.
Bone Grafting and Crosslink® PLATING (continued)

If it is necessary to contour the Low Profile CROSSLINK® Multi-Span® Plate, follow these steps:

- Shorten the telescopic mechanism slightly less than the span between the rods and provisionally tighten the midline set screw.

- Bend the plate as required using the plate benders. However, do not exceed 20° in any single plane.

- Loosen the midline set screw and apply the CROSSLINK Plate as stated above.
Final Tightening AND CLOSURE

When all implants are securely seated in place, final tightening and break off of the head of the plug is done. The counter torque device is placed over the implant and rod (Fig. 18a) while the final plug driver is inserted through the cannulation of the counter torque. The T-handle provides adequate leverage for the break off of the plug head between 11-14N-m. The handle of the counter torque device should be held to prevent torquing of the construct while the plug is secured and broken (Fig. 18b). If necessary, the internal plug may be removed using the modular T-25 Shaft and Handle (Fig. 19). Once a plug has been removed, it should be discarded and replaced with a new one.

Wound closure is then performed in the customary manner.
The CD HORIZON® Spinal System is indicated to provide implantation 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 configuration 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 TS™ rods, hooks, screws, plates, CROSSLINK® connectors, spacers, washers, CD® hooks, components and SCLEX™ bar and connectors; LIBERTY™ rods and screws; DYNALOCK® PLUS®/Ribs. Please note that certain components are specifically designed to connect to 4.5mm, 6.5mm, or 6.85mm rod, while other components can connect to both 5.5mm rods and 6.35 mm rods. Care should be taken so that the correct components are used in the spinal system.

CD HORIZON® Spinal System components are fabricated from medical grade stainless steel described in Appendix A, and are intended for use in 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 (pseudarthrosis). The CD HORIZON® Spinal System implant components are fabricated from medical grade stainless steel, and are intended to be used for one or more of the following purposes: (a) having severe spondylolisthesis with objective evidence of neurologic impairment, (b) fracture, (c) dislocation, (d) scoliosis, (e) kyphosis, (f) spinal tumor, and/or (g) failed previous fusion (pseudarthrosis). When used as a posterior spine thoracic/lumbar system, the CD HORIZON® CANNULATED M8 MULTI-AXIAL SPINAL SYSTEM is 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 (pseudarthrosis).

INDICATIONS: IMPORTANT INFORMATION ON THE CD HORIZON® Spinal System

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POTENTIAL ADVERSE EVENTS All of the possible adverse events associated with spinal fusion surgery without instrumentation are possible. With instrumentation, a listing of potential adverse events includes, but is not limited to: 1. Early or late loosening of any or all of the components. 2. Signs of local inflammation. 3. Foreign body (allergic) reaction to implants, debris, corrosion products (from crevice, fretting, and/or general corrosion), including metallosis, staining, tumor formation, and/or autoimmune disease. 4. Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, fibrosis, necrosis, and/or pain. Burial. Tissue or nerve damage caused by improper positioning and placement of implants or instruments. 5. Post-operative change in spinal curvature, loss of correction, height, and/or reduction. 6. Infection. 7. Dural tears, pseudomeningocele, fistula, persistent CSF leaks, meningitis. 8. Loss of neurological function (e.g., sensory and/or motor), including paralysis (complete or incomplete), dyesthesis, hyperesthesia, anesthesia, paraparesis, appearance of radiculopathy, and/or the development or continuation of pain, numbness, hyperesthesia, pain, sensory loss, tingling sensation, and/or visual deficits.

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/or sacral spine secondary to degenerative spondylolisthesis, ankylosing spondylitis, rheumatoid arthritis, and/or mechanical instability of the lumbar spine caused by the radicular, radiculopathy, spondylitis, neurologic deficit, sciatica, back pain, radiculitis, and/or mechanical dysfunction of the lumbar spine.

CONTRAINDICATIONS: Contraindications include, but are not limited to:

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

PROPROCUTIVE:
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 contraindica-
tions 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 internal screws and screw/bolts as well as 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 thelettes section) are not to be combined with the components from another manufacturer. Different metal types should never be used together.
6. All components and instruments should be cleaned and sterilized before use. Additional sterile compo-
nents 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 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 rod outside the operative field. Whenever possible, use pre-cut rods of the length needed.
4. Whenever possible or necessary, an imaging system should be utilized to facilitate surgery.
5. To insert a screw properly, a guide wire should first be used, followed by a sharp tap.
6. Caution: Do not overtap or use a screw/bolt that is either too long or too large. Overtapping or using an incorrectly sized screw/bolt may cause the device to damage, hemorhage, 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 OCLUSOL® plates or DTT Transverse Links on two bilateral-
dy placed, continuous rods, should be used whenever possible.
9. Bone cement should not be used because the safety and effectiveness of bone cement has not been determined for spinal uses, and this material will make removal of the components difficult or impossible.
10. The heat generated from the curing process may also cause neurological damage and bone necrosis.
11. Before closing the soft tissues, all of the nuts or screws should be tightened firmly. Recheck the tight-
ness 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.

POSTPROCAPATIVE:
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 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 sud-
den 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 use nicotine products, or to consume alcohol or anti-stressors or anti-inflammatory medica-
tions 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

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 DECONTOAMINATE:
All instruments and implants must first be cleaned using established hospital methods before sterilization and introduction into a sterile surgical field. Additionally, all instruments and implants that have been previ-
ously taken into a sterile surgical field must be decontaminated and cleaned using established hospital methods before sterilization and introduction into a sterile surgical field. Cleaning and decontamination can include the use of neutral cleaners followed by a deionized water rinse. Note: certain cleaning solutions such as those containing caustic soda, formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used. Also, certain instruments may require dismantling before cleaning.

STERILIZATION:
Unless marked sterile and clearly labeled as such, the CD HORIZON® Spinal System components, as well as those implants from other MEDTRONIC SOFAMOR DANEK spinal systems specifically indicated for use with the CD HORIZON® Spinal System, described in this insert are provided non-sterile and must be steril-
ized prior to use. These products are recommended to be steam sterilized by the hospital using one of the three sets of process parameters below:

NOTE: The following note applies to the process parameter identified with the ** below:

For use of this product and instruments outside the United States, some non-U.S. Health Care Authorities rec-
ommend 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.

METHOD CYCLE TEMPERATURE EXPOSURE TIME
Steam Gravity 250° F (121° C) 30 Minutes
** Steam Gravity 273° F (135° C) 18 Minutes
Steam Pre-Vacuum 270° F (132° C) 4 Minutes

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

PRODUCT COMPLAINTS:
Any Health Care Professional (e.g. customer or user of this system of products), who has any complaint or which has experienced any desired reaction in the product quality, identity, durability, reliability, safety, effec-
tiveness and/or performance, should notify the distributor or MEDTRONIC SOFAMOR DANEK. Further, if any of the implanted CD HORIZON® Spinal System component(s) ever “malfunctions”, (i.e. does not meet any of its performance specifications or otherwise does not perform as intended), or is suspected of doing so, the distributor should be notified immediately. If any MEDTRONIC SOFAMOR DANEK product ever “malfunctions” and may have caused or contributed to the death or serious injury of a patient, the distributor should be noti-
ied immediately by telephone, fax or written correspondence. Upon filing a complaint please provide the component(s) name, part number, lot number(s), your name and address, the nature of the complaint, and notification of whether a written report for the distributor is requested.

FURTHER INFORMATION:
In case of complaint, or for supplementary information, or further directions for use of this system, please see the address page on this information sheet.

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For product availability, labeling limitations, and/or more information on any Medtronic Sofamor Danek products, contact your MEDTRONIC SOFAMOR DANEK USA Sales Associate, or call MEDTRONIC SOFAMOR DANEK USA Customer Service toll free: 800-933-2635.

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See package insert for labeling limitations.