CD HORIZON® SEXTANT™
Rod Insertion System Surgical Technique

as described by:
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Memphis, Tennessee
Dear Colleagues:

Although it can be highly effective, lumbar pedicle fixation has some well-known drawbacks. One of these, which has been termed “fusion disease,” is a result of the significant spinal exposure and paraspinous muscle stripping necessary to place traditional spinal hardware.

The CD HORIZON SEXTANT Rod Insertion System was designed to minimize the approach-related morbidity of traditional lumbar pedicle fixation. The instrumentation uses CD HORIZON® M8 Multi Axial Screw implants and pre-contoured rods that are inserted percutaneously. This is made possible by the use of a geometrically constrained inserter that passes the rod directly into the screw heads through a small stab wound.

Bone grafting techniques will vary depending on the indication. I will typically place the bone graft anteriorly through laparoscopic portals. If decompression is required, I will perform a minimally invasive posterior interbody technique through METRx™ System tubes. When faced with revision surgery, I may choose a minimally invasive posterolateral graft. The SEXTANT Rod Insertion Instrumentation works well regardless of the grafting technique chosen.

I hope you find the CD HORIZON SEXTANT Rod Insertion System an effective tool in your practice. I have personally found that my patients benefit from the reduced morbidity in both short and long terms. For the right indications, this fixation method has become my technique of choice.

Sincerely,

Kevin T. Foley, M.D.
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INSTRUMENTS

Rod Inserter Assembly (8675300)

Screw Extender A

Screw Extender B

Rod Inserter

Lock Screw Retaining Sleeve

Quick Connect Ratcheting T-Handle (836-009)

Quick Connect Modular Handle (836-010)

Quick Connect Ratcheting Handle (836-011)

Rod Template (8670096)

9.4mm METRx™ System Dilator (9560421)

5.3mm METRx™ System Dilator (9560420)

Large Dilator (8675422)

Taps (4.5, 5.5, 6.5mm, and Self-Drilling)

Rod Trocar Tip (8670030)
INSTRUMENTS AND IMPLANTS

Quick Connect Trocar (8670000)

Quick Connect Pedicle Probe (8670003)

Trocar/Probe Sleeve (8670007)

Disposable Guidewire, Sharp (8670002)

M8 Multi Axial Screwdriver (8670020)

Extender Reattachment Driver (8670021)

Final Plug Driver Shaft (8670090)

Disposable Guidewire, Blunt (8670001)

Combination Plug Driver (8670040)

Compressor Handle (8670095)

ONE-TIME USE INSTRUMENTS

PAK Needle
Available with one Bevel and one Trocar tip (8670009); with two Beveled Tips (8670010); or with two Trocar Tips (8670015)

IMPLANTS

Cannulated M8 Multi Axial Set Screw (8670855)

5.5mm Pre-Bent Titanium Rod (Available in lengths from 30 to 90mm)

Cannulated M8 Multi Axial Screw
(Available in 5.5, 6.5, and 7.5mm diameter with lengths from 35 to 55mm.)
Preliminary

Preoperative Planning and Set Up

Preoperative planning can be useful in determining the proper starting point and screw trajectory. An axial view demonstrates the distance lateral to the pedicle initially taken through the skin (Figure 1). The starting point is rarely directly over the pedicle.

When using the CD HORIZON SEXTANT Rod Insertion System the patient should be positioned prone, lying flat on the table. Either a radiolucent frame or chest rolls may be used, but a knee to chest position should be avoided. Verify that adequate fluoroscopic images of the pedicles can be obtained in both an AP and lateral view before proceeding (Figure 2). Some tables have pedestals that make it difficult to get a true AP view of the pedicles, especially at the S1 level. While adjustments in patient positioning can be made, tables that limit good AP fluoro should generally be avoided. A longer prep area is also necessary because the rod inserter can have an entry point relatively far away from the levels being instrumented.

“I prefer to use chest rolls instead of a frame, as they are completely radiolucent.”

– Kevin Foley, M.D.
STEP 2

PRELIMINARY

POSITIONING OF SKIN INCISIONS

A 22-gauge spinal needle can be used to verify the appropriate location of the skin incisions. The needle is positioned on the skin directly over the pedicle on an AP image. The needle is then moved laterally 1 to 2 cm and inserted through the skin to the intersection of the facet and transverse process (Figure 3). Both AP and lateral images confirm that the appropriate starting place has been determined (Figures 4A and 4B).
CONSIDERING PEDICLE ANATOMY

Consider the pedicle as roughly a cylindrical structure. The ideal starting point is at the intersection of the facet and the transverse process (the lateral edge of the cylinder). As the pedicle is navigated, the trajectory should be aimed toward the medial wall, but not approach it too closely (Figure 5).

“*I prefer placing the heads of the screws lateral to the facet for a number of reasons. This position helps avoid the superior facet, aids in lowering the profile, and helps follow the natural inclination of the pedicles.*”

– Kevin Foley, M.D.
CONSIDERING NAVIGATION OPTIONS–
FLUORONAV™ VIRTUAL FLUOROSCOPY SYSTEM

The FluoroNav System can also provide assistance with pedicle navigation. The SEXTANT instrumentation is designed to work interchangeably with the FluoroNav System making integration a very simple proposition. An additional module containing all of the necessary attachments is required for utilizing the FluoroNav System (Figure 6).

The primary benefit of using the FluoroNav System is that a green virtual extension of the instruments will demonstrate the safety of any proposed pedicle trajectory (Figure 7). The proper trajectory can be determined prior to navigating the pedicle. Another important benefit relates to the ability to see multiple views simultaneously without the increase of radiation exposure.

“The red line represents the position of the probe at the entry to the pedicle. The green line is a virtual extension along the probe’s trajectory. The trajectory can be adjusted until it is ideal prior to navigating the pedicle.”

— Kevin Foley, M.D.
Needle Insertion

A PAK Needle is used to gain access to the pedicle. After placing the PAK Needle at the intersection of the facet and the transverse process, the needle may be advanced partially through the pedicle (Figure 8). An AP image should show the needle tip at the lateral margin of the pedicle initially (Figures 9A and 9B). As the needle advances towards the base of the pedicle, on the lateral image, it should approach the pedicle center on the AP image (Figures 9C and 9D).

“I generally place both needles before moving on to the next step. I find that my visualization of the second pedicle is accomplished more easily when done before the initial screw is inserted.”

– Kevin Foley, M.D.
Guidewire Insertion
The inner stylet of the needle is removed to allow the guidewire to be inserted into the pedicle (Figures 10 and 11). Be extremely careful with regards to the position of the guidewire. Unintentional advancement of the wire can potentially be very dangerous. Once the guidewire is inserted, the needle may be removed.

“The guidewire is not meant to be used as a dissecting tool. Rather, it serves as a 'switching stick' so that you are able to easily re-find the pedicle.”

— Kevin Foley, M.D.
Awl Insertion

The Quick Connect Trocar (Awl) may also be used to gain access to the pedicle. First insert the Trocar through the Trocar/Probe Sleeve. After placing the Trocar at the intersection of the facet and the transverse process, the Trocar/Probe Sleeve may be docked onto the pedicle and the Trocar advanced partially through the pedicle. Remove the Trocar while maintaining the Trocar/Probe Sleeve in place (Figure 12). If further dissection is desired, the Quick Connect Pedicle Probe may be inserted into the pedicle through the Trocar/Probe Sleeve and advanced. After removing the Probe, insert the Guidewire Centering Sleeve into the Trocar/Probe Sleeve (Figure 13). Insert the Guidewire into the pedicle through the sleeves, then remove both sleeves.
The fascia and muscle must be dilated to allow for screw placement. Three dilators are used to gently make a path of the appropriate dimension (Figures 14 and 15). The first two dilators are removed, leaving the third dilator to serve as a tissue protection sleeve during the tapping step.

Figure 14

Figure 15
The pedicle is prepared by placing the tap over the guidewire and through the third dilation sleeve (Figure 16). In dense bone, where the screw may be difficult to advance, ensure that the pedicle is fully prepared by using a tap the same size as the inserted screw to avoid possible screwdriver damage. Fluoroscopy should be used to verify the position of the guidewire and the tap during this step (Figure 17). Screw length can be determined by using the calibration markings on the shaft of the tap. After tapping, remove the dilator but leave the guidewire in place.
Before a screw can be inserted into the pedicle, the screw extenders must be assembled to the Multi Axial Screws. First, a set screw is placed in the set screw retaining sleeve by pushing the smooth cap of the set screw into the distal end of the sleeve (Figure 18). Make certain the threads are not inside the sleeve (Figure 19).

Next, the sleeve is placed into the screw extender (Figure 20). Initially the two buttons on the extender must be depressed, but they should be released after the sleeve is partially inserted. As the sleeve slides down, an audible “click” will be heard, confirming the sleeve is in the correct, most upward position (Figure 21). NOTE: The proper position of the sleeve is very important as it will allow for the rod to engage the saddle of the Multi Axial Screw.
A CD HORIZON® Cannulated M8 Multi Axial Screw is placed in the distal end of the extender (Figure 22) and the combination plug driver is used to advance the set screw (Figure 23). The inner sleeve prevents the set screw from traveling too far into the saddle of the M8 screw. Before implantation, check to make sure the set screw is in the appropriate position by visual inspection and by manually passing a rod between the screw head and the set screw.
The screwdriver is placed into the screw assembly from the top. The tip of the screwdriver passes through the set screw and into the head of the Multi Axial Screw (Figure 24). Since the screwdriver passes through the set screw, care should be taken during screwdriver insertion and removal. This will ensure the position of the set screw is not changed by the screwdriver (Figure 25).
The entire screw extender assembly is inserted over the guidewire and into the pedicle. If the screw is difficult to advance, remove the assembly while leaving the guidewire in place, and ensure the pedicle is fully prepared by using a tap the same size as the inserted screw. This will avoid possible screwdriver damage. After driving the screw assembly into the pedicle, remove the guidewire to prevent it from being advanced. Be certain that the screw assembly is not inserted too far. If the multi axial head of the M8 screw is driven too forcefully against bone, it will lose its multi axial capabilities making it difficult to connect the assemblies during subsequent steps (Figures 26 and 27).
The process is repeated for the second screw on the same side (Figure 28). After inserting both, the screw assemblies should be at approximately the same height outside of the patient. Both assemblies should move freely following insertion.

“Pay close attention to where the heads of the screws end up. Their position determines rod trajectory in both a sagittal and coronal plane. Also keep in mind that changing the position of the heads, by either ‘wanding’ the extenders or altering screw height, will help avoid things like facets, and the iliac crest.”

– Kevin Foley, M.D.
Rotate the extenders so the two flat sides are facing each other (Figure 29). The male and female parts are then mated together and rotated so there is no gap between the two extenders. Once the extenders are connected and the flat surfaces are completely flush, the rod inserter can be attached.

“Pay particular attention to how the extenders line up. Look between them and make sure the flat sides are perfectly matched. If they are not, twist the two extenders until they are. Extenders that are not connected correctly will cause the rod to miss one or more of the screw heads.”

– Kevin Foley, M.D.
The rod inserter is attached to the two screw assemblies by lining up the pegs of the inserter and the grooves of the assemblies (Figure 30). The thumb screw on the side of the inserter is tightened to attach the device securely. A rod trocar tip must then be placed into the tip of the rod inserter by backing out, and then pushing down the thumb screw on top of the inserter (Figure 31). After the trocar is in place, tighten the thumb screw to securely fasten the tip.
The rod trocar is used to help make a path through the fascia and muscle down to the saddle of the first screw (Figure 32). A small skin incision is required, then the trocar is advanced through the muscle until it hits the first screw saddle as confirmed on lateral fluoroscopy.

Figure 32
The appropriate rod length may be determined by placing the rod templates into the two screw extenders (Figure 33). If the template is beyond the line of a particular rod length, the next size rod must be used. After determining rod size, the templates are removed before rod insertion. In the figure below, 60mm is the appropriate size rod.

Figure 33
Replace the rod trocar with the appropriate sized rod as determined by the rod template. Trocar removal is accomplished by reversing the steps for attachment. Pass the rod through the screw heads so the tapered tip of the rod is completely through the distal screw as verified by lateral fluoroscopy (Figures 34 and 35).

“You should never apply excessive force (such as a mallet) to the inserter when passing the rod. If the rod does not easily pass through both screws, reassess the situation.”

– Kevin Foley, M.D.
SURGICAL TECHNIQUE

FINAL TIGHTENING

After verifying with AP, lateral, and oblique views that the rod is seated in the heads of both screws, the set screws can be tightened. NOTE: Before attempting to tighten the set screws, the lock screw retaining sleeves must be lowered! Press the buttons on the screw extenders and push the inner sleeves down. This step allows the set screws to engage the rod.

The compressor handles may be used for provisional tightening (Figure 36). With both handles in place, the construct can be compressed, held and provisionally tightened. Final tightening is achieved with the final plug driver by tightening until the set screw heads shear off (Figure 37). The sheared-off portion of the set screws will be retained inside the retaining sleeves.

“The set screws should firmly tighten after 1 1/4 rotations. If they do not, then the rod is not seated properly with the screw saddle.”

– Kevin Foley, M.D.
The rod inserter must be detached from the rod by again reversing the steps of attachment. After the inserter is disconnected from the rod, the entire rod inserter assembly may now be pulled out of the patient (Figure 38). The final construct can then be viewed with AP and lateral fluoroscopy (Figures 39A and 39B).
STEP 18  SURGICAL TECHNIQUE  CLOSURE

The entire process is repeated for the contra-lateral side. Closure is accomplished with a few interrupted stitches in the fascia, a subcuticular skin suture, and Steri Strips™ (Figure 40).

NOTE: Implant Explantation

The CD HORIZON® M8 Cannulated Multi Axial Screw set screws and rods may be removed by applying the combination plug driver from the SEXTANT instrumentation set to the set screw and turning counter-clockwise until the set screw is removed. The M8 Cannulated Multi Axial Pedicle Screws may be removed by applying the M8 Multi Axial screwdriver or extender reattachment driver from the SEXTANT instrumentation set to the screw and turning counter-clockwise until the screw is removed from the pedicle.

Figure 40

Post-Op Lateral View  Post-Op AP View
# PRODUCT INFORMATION

## CANNULATED M8 MULTI AXIAL TITANIUM SCREWS AND SET SCREWS

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(PAK Needle Sold Separately)

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Important Information on the CD HORIZON™ Spinal System

PURPOSE:
The CD HORIZON™ Spinal System is intended to help provide immobilization and stabilization of spinal segments as an adjunct to fusion of the thoracic, lumbar, and/or sacral spine.

DESCRIPTION:
The CD HORIZON™ Spinal System consists of a variety of shapes and sizes of rods, hooks, screws, OPOSLINK® Plates, staples and connecting components, as well as implant components from other MEDTRONIC SOFAMOR DANEK spinal systems, which can be rigidly locked into a variety of configurations, with each construct being tailor-made for the individual case.

Certain implant components from other MEDTRONIC SOFAMOR DANEK spinal systems can be used with the CD HORIZON™ Spinal System. These components include TSF® rods, hooks, screws, plates, OPOSLINK® plates, connectors, staples and washers, GDUR® rods, hooks, connectors and OPOSLINK® bar and connectors; LEBERT® rod and connectors; DYNALOK® and DYNALOK® PLUS connectors; and DYNALOK® hooks. Please note that certain components are specifically designed to connect to 4.5mm, 6.5mm, or 6.35mm rods, while other components can connect to both 6.5mm and 6.35mm rods. Care should be taken so that the correct components are used in the spinal construct.

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

The CD HORIZON™ Spinal System implant components are fabricated from medical grade stainless steel described by such standards as ASTM F138 or ASTM F582 or ASTM F582-2. MEDTRONIC SOFAMOR DANEK expressly warrants that these devices are fabricated from one of the foregoing material specifications. No other warranties, express or implied, are made. Implied warranties of merchantability and fitness for a particular purpose or use are specifically excluded. See the MSD Catalog for further information about warranties and limitations of liability. Never use stainless steel and titanium implant components in the same construct.

The CD HORIZON™ Spinal System also includes anterior staples made of Shape Memory Alloy (Nitinol – NiTi). Shape Memory Alloy is compatible with titanium implants only. Do not use with stainless steel.

To achieve best results, do not use any of the CD HORIZON™ Spinal System implant components with components from any other system or manufacturer unless specifically allowed to do so in this or another MEDTRONIC SOFAMOR DANEK document. As with all orthopaedic and neurological implants, none of the CD HORIZON™ Spinal System components should ever be reused under any circumstances.

INDICATIONS, CONTRAINDICATIONS AND POSSIBLE ADVERSE EVENTS:

INDICATIONS:
The CD HORIZON™ System is intended for the following indications:

- When used as a pedicle screw fixation system of the cervical or posterior spine in skeletally mature patients, the CD HORIZON™ 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) spondylolisthesis, (5) kyphosis, (6) spinal tumor, and/or (7) failed previous fusion (pseudarthrosis).

- When used as a pedicle screw fixation system, the CD HORIZON™ Spinal System is indicated for skeletally mature patients (a) having severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar-sacral joint (L5-S1) vertical joint; (b) who are receiving fusions using autogenous bone graft only; (c) who are having the device fixed or attached to the lumbar and sacral spine (L3 and below); and (d) who are having the device removed after the development of a solid fusion mass.

- When used as a posterior, non-cervical, non-pedicle screw fixation system, the CD HORIZON™ Spinal System is intended for the following indications:
  - Degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies),
  - Spinal stenosis,
  - Spondylolisthesis,
  - Spinal deformities (i.e., scoliosis, kyphosis, and/or lordosis),
  - Fracture,
  - Pseudarthrosis,
  - Spondylolysis,
  - Spondylolisthesis,
  - Spinal deformities (i.e., scoliosis, kyphosis, and/or lordosis),
  - Fracture,
  - Pseudarthrosis,
  - Spondylolysis,
  - Spondylolisthesis,
  - Spinal deformities (i.e., scoliosis, kyphosis, and/or lordosis),
  - Fracture,
  - Pseudarthrosis,
  - Spondylolysis,
  - Spondylolisthesis,
  - Spinal deformities (i.e., scoliosis, kyphosis, and/or lordosis),
  - Fracture,
  - Pseudarthrosis,
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  - Fracture,
CAUTION: FEDERAL LAW (USA) RESTRICTS THESE DEVICES TO SALE BY OR ON THE ORDER OF A PHYSICIAN. Other preoperative, intraoperative, and postoperative warnings and precautions are as follows:

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

**DEVICE FIXATION:**
In cases where a percutaneous posterior approach is used refer to the CD HORIZON proper placement of the implant, and postoperative management to minimize stresses on the implant, such stresses may cause metal fatigue and consequent breakage, bending or loosening of the device before the healing process is complete, which may result in further injury or the need to remove the device prematurely.

**PRODIRECTIONS:**
1. Only patients that meet the criteria described in the indications should be selected.
2. Patient conditions and/or predispositions 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. Different metal types should never be used together.
6. All components and instruments should be cleansed and sterilized before use. Additional sterile components should be available in case of an unexpected need.

**INTRAOPERATIVE:**
1. Extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological functions.
2. Breakage, slippage, or misuse of instruments or implant components may cause injury to the patient or operative personnel.
3. The rods should not be repeatedly or excessively bent. The rods should not be reverse bent in the same location. Use great care to 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. 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. Caution: Be careful that the Guide-wire, if used, is not inserted too deep, becomes bent, and/or breaks. Ensure that the Guide-wire does not advance during tapping or screw insertion. Remove the Guide-wire and make sure that the screw is intact. Failure to do so may cause the guide wire or part of it to advance in the patient selection, and into a location that may cause damage to underlying structures. Do not over tap or use a screw that is either too long or too large. Over tapping or using an incorrectly sized screw may cause nerve damage, hemorrhage, or other possible adverse events listed elsewhere in this package insert.
6. 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.
7. To assure maximum stability, two or more CROSSLINK® plates or DTT Transverse Links on two bilaterally placed, continuous rods, should be used whenever possible.
8. Bone contamination and/or bone loss will not be removed, nor will bone cement be used. The surgeon must measure 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. The heat generated from the curing process may also cause neurologic damage and bone necrosis.
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. Redtighten the tightness of all screws or nuts after finishing to make sure that none loosened during the tightening of the other nuts or screws. Failure to do so may cause loosening of the other components.

**POSTOPERATIVE:**
The physician's postoperative directions and warnings to the patient, and the corresponding patient compliance, are extremely important.
1. Detailed instructions on the use and limitations of the device should be given to the patient. If partial weight-bearing is recommended or required prior to firm bony union, the patient must be warned that bending, loosening and/or breakage of the device(s) are complications which may occur as a result of excessive or early weight bearing or muscular activity. The risk of bending, loosening, or breakage of a temporary internal fixation device during postoperative rehabilitation may be increased if the patient is active, or if the patient is debilitated or demented. The patient should be warned to avoid falls or sudden jolts in spinal position.
2. To allow the maximum chances for a successful surgical result, the patient or devices should not be exposed to mechanical vibrations or shock that may loosen the device construct. The patient should be warned of this possibility, including the risk of sports participation, especially lifting and heating 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 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 noninvasive examination. If a state of non-union persists or if the components loosen, bend, and/or break, the device(s) should be removed and/or removed immediately before serious injury occurs. The patient must be adequately warned of these hazards and closely supervised to insure cooperation until bony union is confirmed.
5. As appreciation, 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 components are temporary internal fixation devices. Internal fixation devices are designed to stabilize the operative site during the normal healing process. After the spine is fused, these devices serve no functional purpose and may be removed. While the final decision on implant removal is, of course, up to the surgeon and patient, in most patients, removal is indicated because the implants are not intended to transfer or support forces developed during normal activities. If the device is not removed following completion of its intended use, one or more of the following complications may occur: (1) Corrosion, with localized tissue reaction or pain; (2) Migration of implant position, possibly resulting in injury; (3) Risk of additional injury from postoperative trauma; (4) Bending, loosening and breakage, which could make removal impractical or difficult; (5) Pain, discomfort, or abnormal sensations due to the presence of the device; (6) Possible increased risk of infection; (7) Bone loss due to stress shielding; and (8) Potential unknown and/or unexpected long term effects such as carcinogenesis. Implant removal should be followed by adequate postoperative management to avoid fracture, re-fracture, or other complications.
7. Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopedic implants, the CD HORIZON Spinal System components should never be reused under any circumstances.

**PRODUCTS:**
Packages for each of the components should be intact upon receipt. If a loosening or contamination 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 Medtronics Sofamor Danek package, all implants and implants used in surgery must be disassembled (if applicable) and cleaned using neutral cleaners before sterilization and introduction into a sterile surgical field or of any applicable return of the products to the MEDTRONIC SOFAMOR DANEK. Cleaning and decontamination of implants can be performed with aldehydes or other aldehydes; however, this process may damage some devices, instruments and/or instruments, these solutions should not be used. Also, many medical devices require disassembly before cleaning.

All products should be treated with care. Improper use or handling may lead to damage and/or possible impairment or 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. For a STERILITY ASSURANCE LEVEL, 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 TIME</th>
<th>TEMPERATURE</th>
<th>EXPOSURE TIME</th>
</tr>
</thead>
<tbody>
<tr>
<td>Steam Pre-Vacuum</td>
<td>270°F (132°C)</td>
<td>4 Minutes</td>
<td></td>
</tr>
<tr>
<td>Steam</td>
<td>250°F (121°C)</td>
<td>30 Minutes</td>
<td></td>
</tr>
<tr>
<td>Steam+</td>
<td>273°F (134°C)*</td>
<td>20 Minutes*</td>
<td></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 risk of transmission of Creutzfeldt-Jacob diseases, especially of surgical instruments that could come into contact with the central nervous system.

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 who has experienced any dissatisfaction in the product quality, durability, reliability, safety, effectiveness and/or performance, should notify the distributor or MEDTRONIC SOFAMOR DANEK. Further, any if any of the implantable 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 notified immediately by telephone, fax or written correspondence. When 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 below.

**IN THE USA**

Customer Service Division
Medtronic Sofamor Danek
1800 Pyramid Place
Memphis, Tennessee 38132 USA
Telephone: 901-876-3133 or 901-876-3135
Fax: 901-876-3136
Medtronic Sofamor Danek International* 13, rue de la Redette
92290 TREMBLAY EN FRANCE FRANCE
*authorized EC representative
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The METRx System allows surgeons to treat herniated discs using a revolutionary technique that drastically reduces scarring and provides for a rapid return to normal activity.

The CD HORIZON SEXTANT System has opened new realms of opportunity in minimally invasive pedicle screw fixation, that provide greater options for physicians and patients than ever before.

The CD HORIZON ECLIPSE System is an exciting innovation in scoliosis management that allows for expedited patient rehabilitation as well as a greatly improved cosmetic result.