



Medtronic

SOFAMOR DANEK

CD HORIZON® ANTARES®

Spinal System Surgical Technique

as described by:

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SURGICAL TECHNIQUE
Table of Contents



Preface	2
Implants	3
Instruments	4
Surgical Technique Introduction	6
Surgical Technique Steps	7
Catalog Listing	17



SURGICAL TECHNIQUE

Preface

Dear Colleague:

Anterior internal fixation of the thoracic and thoracolumbar spine is a growing trend in spinal surgery. In the thoracic and thoracolumbar spine, anterior fixation is indicated for burst fractures with significant canal compromise, vertebral body tumors requiring corpectomy and other indications requiring anterior stabilization. Primary advantages of anterior internal fixation include the ability to provide complete canal clearance and decompression of bony fragments and/or total resection of a tumor. Additionally, anterior thoracic and thoracolumbar (ATL) surgery allows for fusion of a minimal number of motion segments, thus allowing for more normal spine mechanics.

The specific goal in the development of the CD HORIZON ANTARES Spinal System was to design a rod-based system primarily for the management of thoracic, thoracolumbar, and lumbar burst fractures and tumors that permits anterior load sharing, allows for distraction to perform reduction and compression of the bone graft, is CT/MRI compatible, and easy to implant. The CD HORIZON ANTARES Spinal System consists of unique vertebral body staples, **CROSSLINK®** Plates, and anterior instruments used in conjunction with a variety of CD HORIZON M8 Spinal System screws and rods to create a highly-versatile anterior fixation system.

Specific design criteria met in the development of the CD HORIZON ANTARES Spinal System are:

- titanium construction which is compatible with current CT and MRI scanning technology
- among the lowest profile of available implant systems
- superior fit with anatomical structures
- top-loading and top-tightening system
- improved anterior instruments
- construct rigidity equal to or greater than other anterior spine fixation devices
- use of color-coding to assist the surgical staff with the construct implantation

Through extensive testing, design modifications, and continuous review, the design goals have been met and exceeded. The CD HORIZON ANTARES Spinal System incorporates a truly revolutionary design that allows for maximum surgical simplicity and intra-operative flexibility.

Sincerely,

A handwritten signature in black ink, appearing to read "David G. Schwartz".

David G. Schwartz, M.D.

A handwritten signature in black ink, appearing to read "Stephen L. Ondra".

Stephen L. Ondra, M.D.

SURGICAL TECHNIQUE

Implants

ANTARES
CD HORIZON[®] Spinal System

All CD HORIZON ANTARES Spinal System implants are manufactured using 6Al4V or CP Grade II Titanium. Basic implants consist of vertebral body staples, fixed screws, CROSSLINK[®] Plates, and 5.5mm diameter rods.



Vertebral Body Staples – This unique design offers contour in two planes to provide exceptional fit and a lower overall profile. The ventral surface is shaped to fit not only the sagittal curvature of the vertebral body but the concavity between the superior and inferior endplates of each instrumented vertebra. The dorsal surface has a smooth surface to minimize irritation to vascular structures and soft tissues. Additionally, the dual spikes are contained within the interior of the plate as a safety feature. The offset spikes provide excellent stability during implantation and system rigidity post-operatively. Staples are offered in three sizes to insure precise fit for diverse patient populations. Each staple is clearly marked with the size and caudal or rostral orientation. The color-coded blue (rostral) or dark gray (caudal) surface treatment to each staple identifies the caudal or rostral orientation.



CD HORIZON M8 Fixed Screws – The top-loading, top-tightening design facilitates a simplified construct assembly. Open 5.5mm and 6.5mm diameter screws are used and offer a better fit at all instrumented levels. Additionally, 7.5mm diameter screws may be used as a “rescue screw” in the medium and large vertebral body staple.



CD HORIZON ANTARES CROSSLINK Plates – This unique cross connector is a modification of the tested Low Profile CROSSLINK design. The design allows the one-piece implant to be easily applied to the dual rod construct for a top-loading approach. CROSSLINK Plates are offered in 1mm increments from 11mm to 19mm.



SURGICAL TECHNIQUE

Instruments

Staple Impactor



Awl



CROSSLINK®
Plate Holder



Plate/Rod Holder



Awl Guide



Guide Shaft



M8 Fixed Angle Screwdriver



CROSSLINK® Plate Template



Size availability from
11mm to 19mm.

Rod Rotation Wrench



Angled Awl



Awl



SURGICAL TECHNIQUE
Instruments



Rocker



French Bender



Hex Driver



Fixed Egg Handle



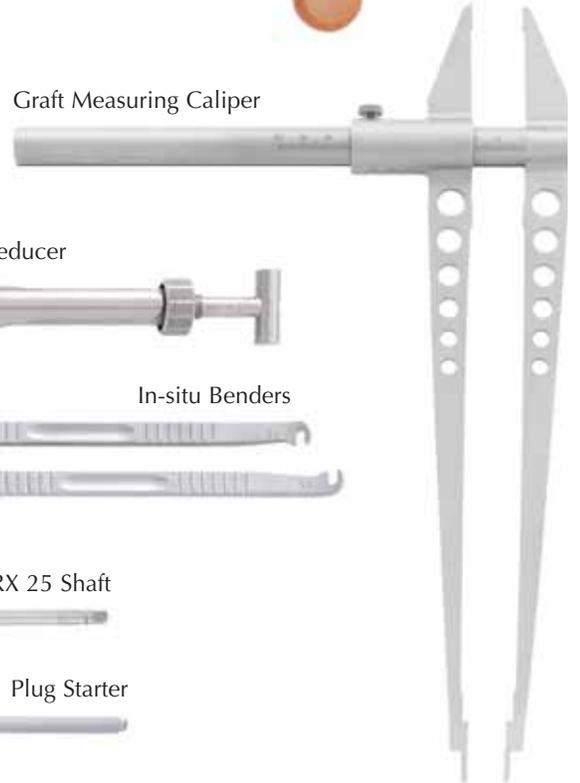
Counter Torque



Fixed Handle



Graft Measuring Caliper



Rod Reducer



5.5mm Solid Tap



6.5mm Solid Tap



In-situ Benders



TORX 25 Shaft



Plug Starter



5mm Tapered Hex Shaft



Patient Positioning, Surgical Exposure, and Corpectomy

When treating thoracic and thoracolumbar fractures or tumors with anterior instrumentation, the approach is usually from the patient's left side, but if indications warrant, the operation can be accomplished from the patient's right side. The preoperative axial MRI or CT should be checked to ensure the aorta is midline. Occasionally a left deviation of the aorta will necessitate a right-sided approach.

It is important to ensure the patient is positioned in a true lateral position and that the position is maintained throughout the procedure (Figure 1).

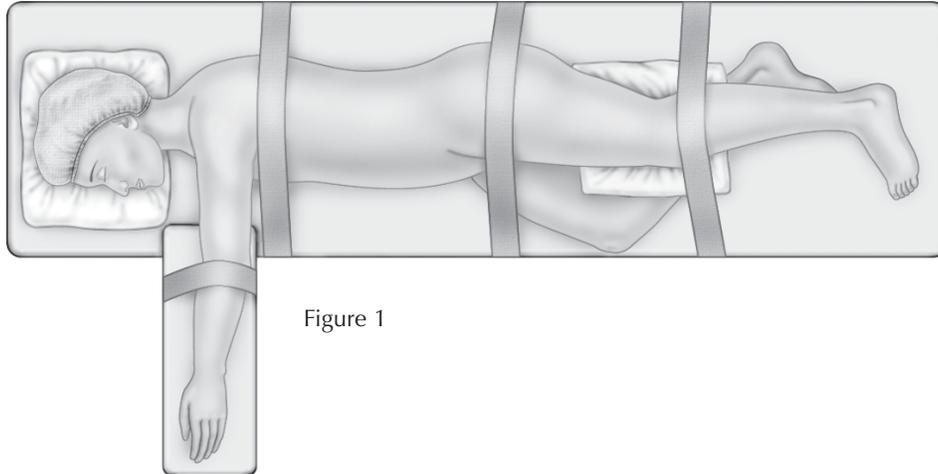


Figure 1

Measuring the Coronal Diameter of the Vertebral Body

Using a depth gauge, measure the coronal diameter of the vertebral body above and below the corpectomy (Figure 2). This distance is used to determine the length of the screws to be used. This may also be done using the graduated scale on the preoperative MRI/CT films (Figure 3).

Preoperative Planning of the Screw Length

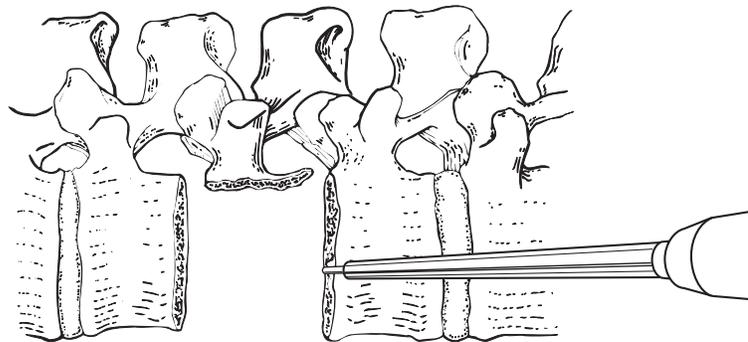


Figure 2

The screw length can also be determined by measuring the vertebral body width on a preoperative CT scan or MRI scan. Use the scale provided on the scan to accommodate magnification.

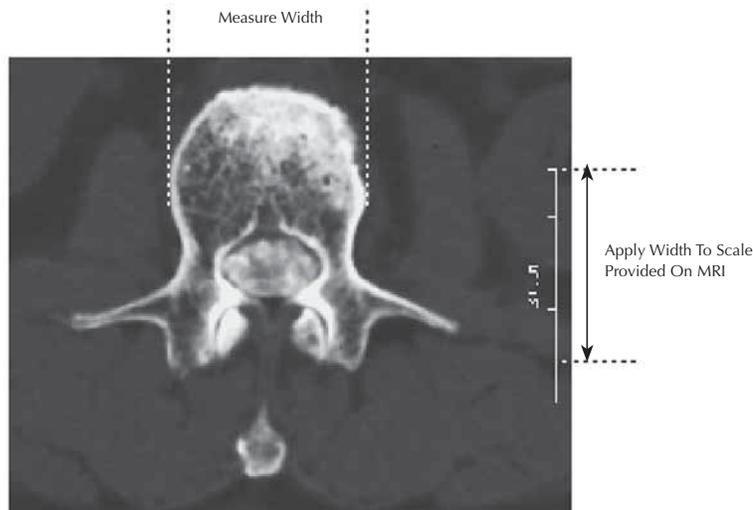


Figure 3

STEP 2

SURGICAL TECHNIQUE

Placement of the Vertebral Body Staples

The appropriate-sized staple is selected and placed on the Staple Impactor (Figure 4). Staples are available in three sizes (21, 23, and 25mm) with either a caudal (gray) or rostral (blue) orientation. The largest staple that will fit within the confines of the vertebral body should be used.



Figure 4

The staple attaches to the Staple Impactor by threading the Impactor Shaft through the center hole in the staple until snug. The staple is then impacted into position and the Impactor unthreaded from the center retaining hole (Figure 5). Pilot holes are then made using the provided free-hand Awl (Figure 6). Generally, the posterior screw is directed 10° anteriorly and the anterior screw is directed 0° to the sagittal plane. When correctly placed, the staples will insure that the anterior rod will be longer than the posterior rod.

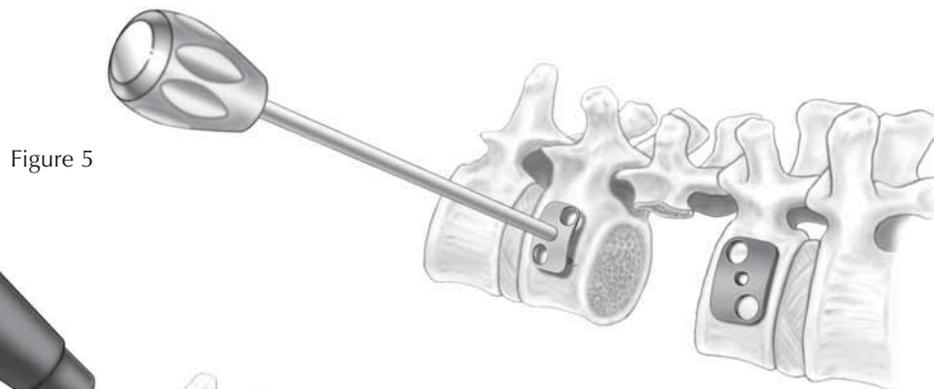


Figure 5



Figure 6

Placement of the Vertebral Body Staples (cont.)

Option:

As an option, the surgeon may elect to use the provided Awl Guides. These guides attach to the Guide Shaft (Figure 7) and allow for the staple to be retained. Choose the appropriate Awl Guide for the selected staple. The staple is positioned and impacted in the usual manner (Figure 8). With the Awl Guide attached to the staple, the awl will create a trajectory for the posterior screw that is 10° anterior (Figure 9). Using the guide for the anterior position will create a pilot hole 0° posterior (Figure 10). After creating both pilot holes, the Awl Guide/Staple Impactor assembly is detached from the staple by unthreading the Guide Shaft from the center retaining hole.



Figure 7



Figure 8

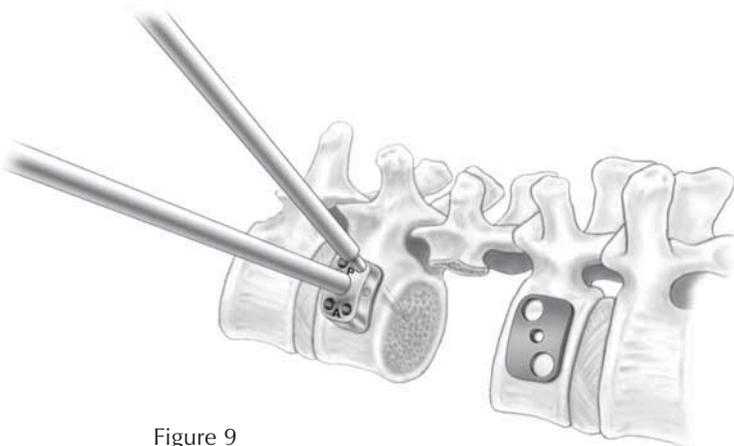


Figure 9

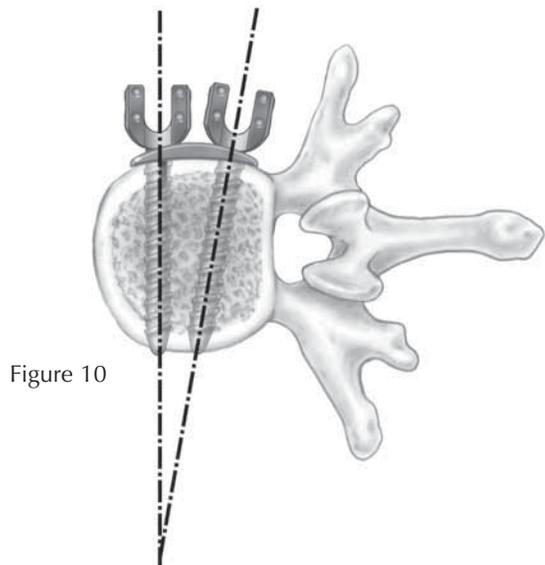


Figure 10

STEP 3

SURGICAL TECHNIQUE

Screw Placement

The CD HORIZON® M8 Fixed Screws are then driven until the head of the screw makes contact with the staple (Figure 11). Care should be taken to ensure that the screw openings are aligned from segment to segment allowing for rod introduction (Figure 12). Each screw should extend approximately two millimeters beyond the far cortex to ensure bicortical fixation.

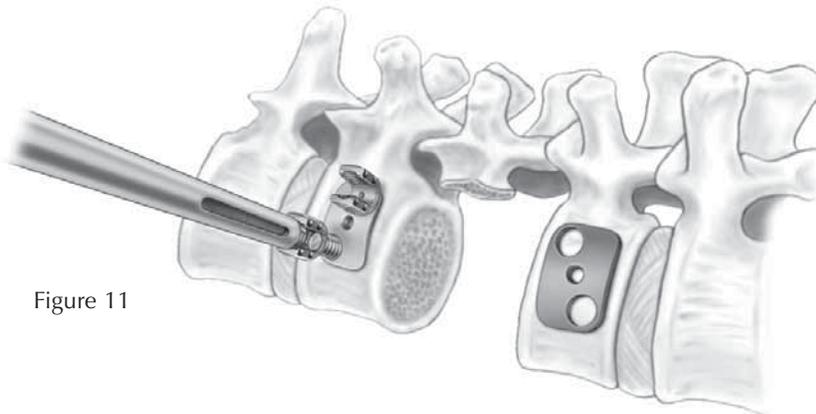


Figure 11

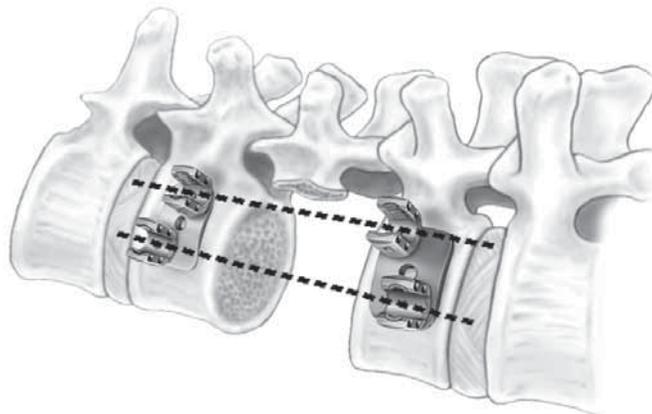
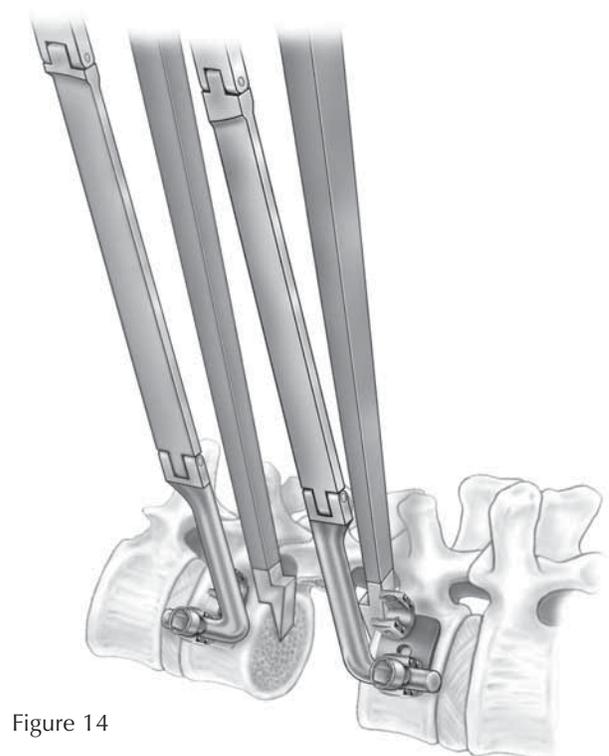
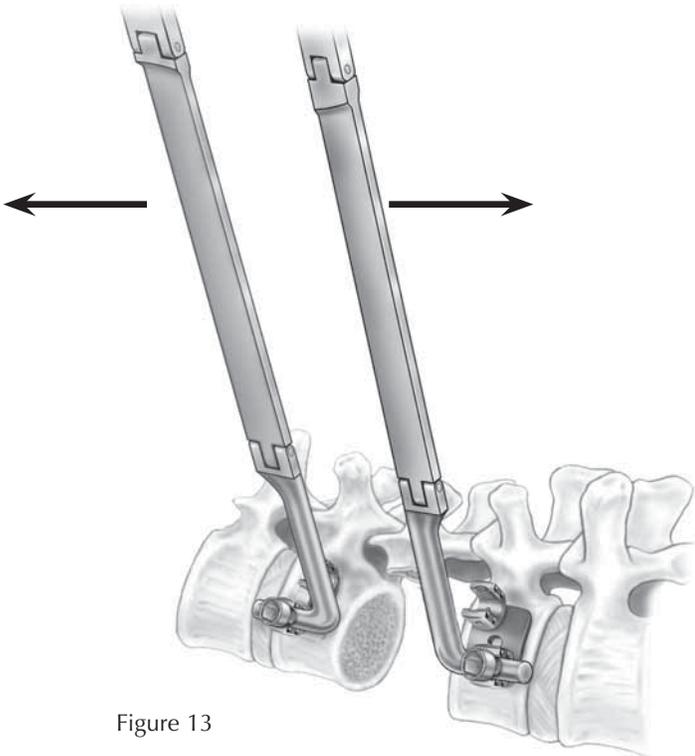


Figure 12

SURGICAL TECHNIQUE
Fracture Reduction

STEP 4

A vertebral body spreader or the provided distractor may be used against the heads of the rostral and caudal screws. Insert the arms of the distractor into the screw heads. Insert a CD HORIZON® M8 Set Screw over each arm of the distractor using the Tapered Hex Shaft. Each set screw should be provisionally tightened. A distractive force is placed against the heads until the desired reduction is achieved. Once reduction has been achieved, the Graft Measuring Caliper may be used to determine the required graft length.



STEP 5

SURGICAL TECHNIQUE

Implanting the Bone Graft

After careful selection, measurement, and placement of the graft into the corpectomy site, distraction is released (Figure 15). Depress the ratchet lever on the distractor until the graft comes in full contact with the superior and inferior endplates. Remove the set screws and the distractor from the surgical site.

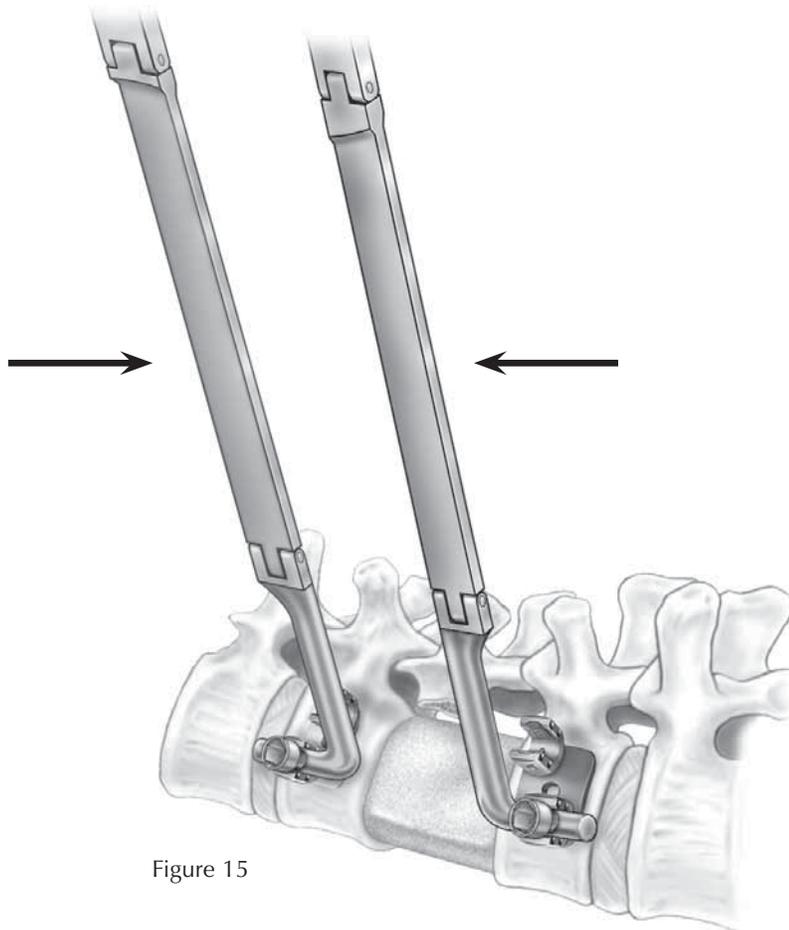


Figure 15

SURGICAL TECHNIQUE
Placing the Spinal Rods

STEP 6

Measure the required rod length using the Graft Measuring Caliper or using the 20" Rod Template. Measure for the posterior rod first. Select a pre-cut rod or cut a rod to length and place in the posterior screws (Figure 16). Set screws are applied and "finger tightened". This process is repeated for the anterior rod. Once the proper alignment is achieved, tighten either the rostral or caudal set screw provisionally.

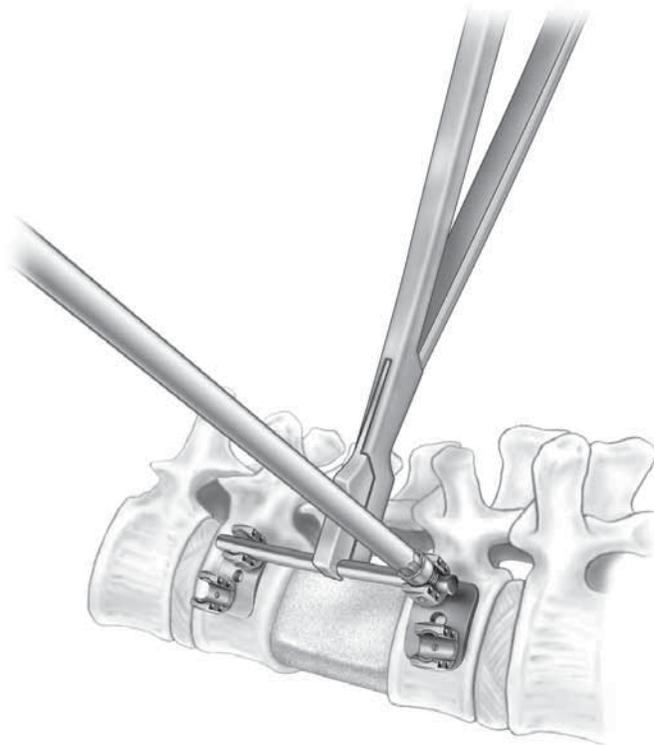


Figure 16

STEP 7

FINAL TIGHTENING Final Tightening

The compressor is placed on the outside of the Vice Grip and the unsecured screw (Figure 17). A compressive force is applied to the construct to lock the anterior graft in place. Tighten the remaining posterior set screw. Repeat this procedure for the anterior rod. Once the final position is confirmed, the set screws are broken off (Figure 18).

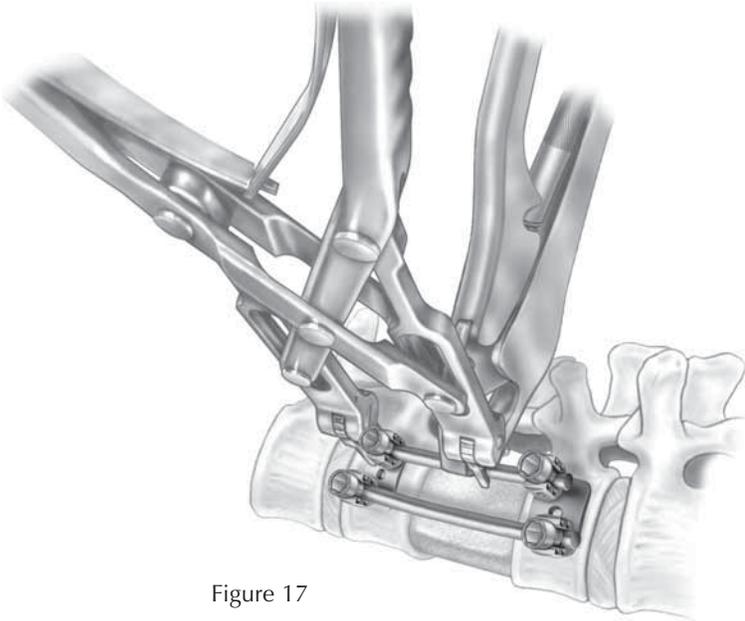


Figure 17



Figure 18

SURGICAL TECHNIQUE
Placing the **CROSSLINK®** Plates

STEP 8

The CROSSLINK Plates are added to the construct to provide torsional stability. Two CROSSLINK Plates are recommended for each construct. Use the CROSSLINK Plate Measuring Tools to determine the required implant size (Figure 19). Plates are offered in one-millimeter increments from 11mm to 19mm to provide exceptional fit. Grasp the selected CROSSLINK Plate with the CROSSLINK Holder and place on the spinal rods (Figure 20).

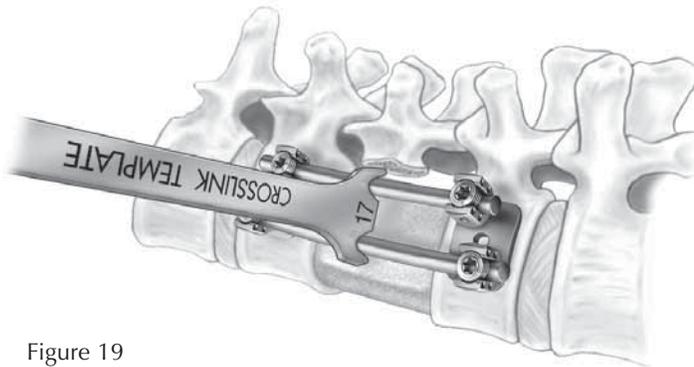


Figure 19

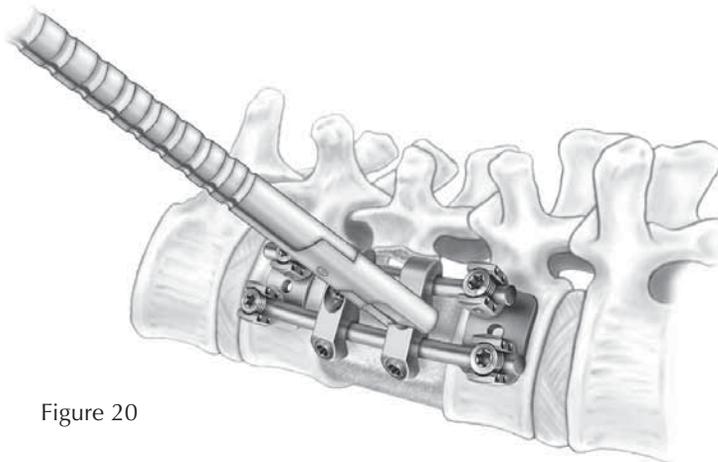


Figure 20

STEP 8

SURGICAL TECHNIQUE

Placing the **CROSSLINK®** Plates *(cont.)*

CROSSLINK Plate Set Screws may be oriented either anteriorly or posteriorly (Figure 21). Orientation will depend on the surgical exposure. Construct rigidity is identical regardless of the plate orientation. If two CROSSLINK® Plates will be used, place the first in the rostral 1/3 of the construct and the second in the caudal 1/3 of the construct (Figure 22).

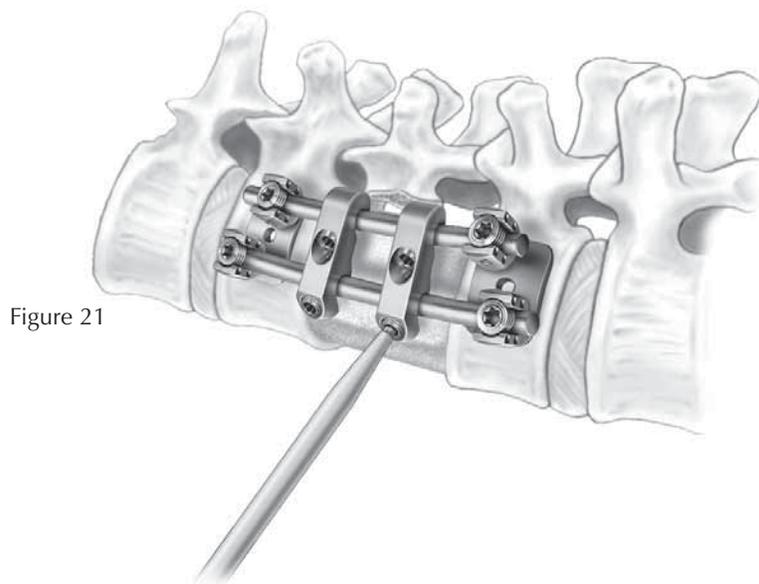


Figure 21

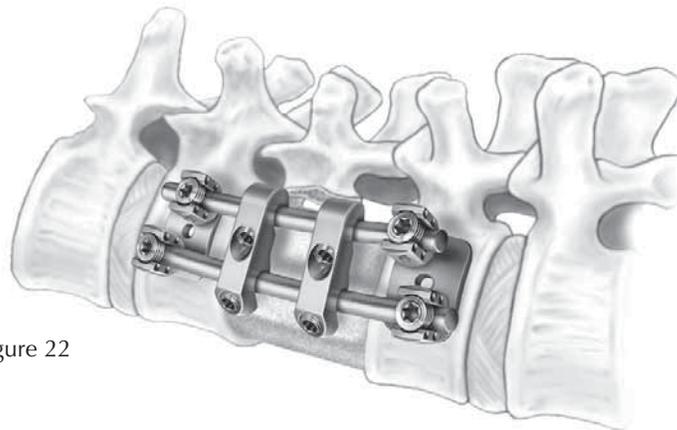


Figure 22



CATALOG NUMBER	DESCRIPTION	CATALOG NUMBER	DESCRIPTION
8698500	Small Staple, Caudal, Ti	8110617	Dual Rod CROSSLINK®, 17mm, Ti
8698501	Small Staple, Rostral, Ti	8110618	Dual Rod CROSSLINK®, 18mm, Ti
8698502	Medium Staple, Caudal, Ti	8110619	Dual Rod CROSSLINK®, 19mm, Ti
8698503	Medium Staple, Rostral, Ti	822-355	Graft Measuring Caliper
8698504	Large Staple, Caudal, Ti	94633	Spreader
8698505	Large Staple, Rostral, Ti	8691017	Anterior Rack and Pinion Distractor
8590855	M8 Set Screws	84692E	Plug Driver
855-012	5.5 Titanium Rod, CP	84799LH	Left In-situ Bender
808-575	20" Rod Template	84799RH	Right In-situ Bender
8691118	ANTARES Screw Gauge	808-530	French Bender
859-525	M8 5.5 x 25mm Fixed Angle Screw, Ti	808-555	Power Grip
859-530	M8 5.5 x 30mm Fixed Angle Screw, Ti	836-015	QC 5.5mm Solid Tap
859-535	M8 5.5 x 35mm Fixed Angle Screw, Ti	836-016	QC 6.5mm Solid Tap
859-540	M8 5.5 x 40mm Fixed Angle Screw, Ti	815-500	Rocker
859-545	M8 5.5 x 45mm Fixed Angle Screw, Ti	820-555	5.5mm Rod Holder
859-550	M8 5.5 x 50mm Fixed Angle Screw, Ti	836-010	QC Universal Handle
859-555	M8 5.5 x 55mm Fixed Angle Screw, Ti	836-012	QC Fixed Egg Handle
859-630	M8 6.5 x 30mm Fixed Angle Screw, Ti	836-013	QC Fixed Handle
859-635	M8 6.5 x 35mm Fixed Angle Screw, Ti	858-989	M8 Rod Reducer II
859-640	M8 6.5 x 40mm Fixed Angle Screw, Ti	858-990	M8 Counter Torque
859-645	M8 6.5 x 45mm Fixed Angle Screw, Ti	8691000	Awl
859-650	M8 6.5 x 50mm Fixed Angle Screw, Ti	8691001	Awl Guide, Small
859-655	M8 6.5 x 55mm Fixed Angle Screw, Ti	8691002	Awl Guide, Medium
8698050	5.5mm Rod, L=50mm, Ti	8691003	Awl Guide, Large
8698055	5.5mm Rod, L=55mm, Ti	8691004	Guide Shaft
8698060	5.5mm Rod, L=60mm, Ti	8691005	Staple Impactor
8698065	5.5mm Rod, L=65mm, Ti	815-507	Awl
8698070	5.5mm Rod, L=70mm, Ti	815-516	Tapered Hex Shaft
8698075	5.5mm Rod, L=75mm, Ti	815-518	TORX 25 Shaft
8698080	5.5mm Rod, L=80mm, Ti	8691008	M8 Fixed Angle Screwdriver
8698085	5.5mm Rod, L=85mm, Ti	8691009	Angled Awl
8698090	5.5mm Rod, L=90mm, Ti	8691010	Rod Rotation Wrench - Anterior
8698095	5.5mm Rod, L=95mm, Ti	8691011	CROSSLINK® Holder
8698100	5.5mm Rod, L=100mm, Ti	8691012	CROSSLINK® Measuring Tool, 11-12mm
8110611	Dual Rod CROSSLINK®, 11mm, Ti	8691013	CROSSLINK® Measuring Tool, 13-14mm
8110612	Dual Rod CROSSLINK®, 12mm, Ti	8691014	CROSSLINK® Measuring Tool, 15-16mm
8110613	Dual Rod CROSSLINK®, 13mm, Ti	8691015	CROSSLINK® Measuring Tool, 17-18mm
8110614	Dual Rod CROSSLINK®, 14mm, Ti	8691016	CROSSLINK® Measuring Tool, 19mm
8110615	Dual Rod CROSSLINK®, 15mm, Ti	8691018	Compressor
8110616	Dual Rod CROSSLINK®, 16mm, Ti	803-900	3.5mm Hex-Head Screwdriver

Important Information on the CD HORIZON® Spinal System

PURPOSE:

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

DESCRIPTION:

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

Certain implant components from other MEDTRONIC SOFAMOR DANEK spinal systems can be used with the CD HORIZON® Spinal System. These components include TSRH® rods, hooks, screws, plates, CROSSLINK® plates, connectors, staples and washers, GDLH® rods, hooks, connectors and CROSSLINK® bar and connectors; LIBERTY® rods and screws; DYNALOK PLUS™ bolts. Please note that certain components are specifically designed to connect to \varnothing 4.5mm, \varnothing 5.5mm, or \varnothing 6.35mm rods, while other components can connect to both \varnothing 5.5mm rods and \varnothing 6.35mm rods. Care should be taken so that the correct components are used in the spinal construct.

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

The CD HORIZON® Spinal System implant components are fabricated from medical grade stainless steel described by such standards as ASTM F138 or ISO 5832-1 or ISO 5832-9. Alternatively, the entire system may be made out of medical grade titanium or titanium alloy described by such standards as ASTM F67 or ASTM F136 or ISO 5832-3 or 5832-2. 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 neurosurgical 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® Spinal System is intended for posterior, non-cervical fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis and/or lordosis); tumor; pseudarthrosis; and/or failed previous fusion.

When used in a percutaneous, non-cervical, posterior approach with the SEXTANT™ instrumentation, the CD HORIZON® cannulated screws are intended for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis and/or lordosis); tumor; pseudoarthrosis; and/or failed previous fusion.

Except for hooks, when used as an anterolateral thoracic/lumbar system, CD HORIZON® components such as ECLIPSE® components are intended for the following indications: (1) degenerative disc disease (as defined by back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), (2) spinal stenosis, (3) spondylolisthesis, (4) spinal deformities (i.e., scoliosis, kyphosis, and/or lordosis), (5) fracture, (6) pseudarthrosis, (7) tumor resection, and/or (8) failed previous fusion.

The CD HORIZON® SPINOUS PROCESS Plate is a posterior, non-pedicle supplemental fixation device, intended for use in the non-cervical spine (T1 – S1). It is intended for plate fixation/attachment to spinous process for the purpose of achieving supplemental fusion in the following conditions: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); and/or tumor.

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

CONTRAINDICATIONS:

Contraindications include, but are not limited to:

1. Active infectious process or significant risk of infection (immunocompromised).
2. Signs of local inflammation.
3. Fever or leukocytosis.
4. Morbid obesity.
5. Pregnancy.
6. Mental illness.
7. Grossly distorted anatomy caused by congenital abnormalities.
8. Any other medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the presence of congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count.
9. Rapid joint disease, bone absorption, osteopenia, osteomalacia and/or osteoporosis. Osteoporosis or osteopenia is 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.
17. Any case not described in the indications.

POTENTIAL ADVERSE EVENTS

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

1. Early or late loosening of any or all of the components.
2. Disassembly, bending, and/or breakage of any or all of the components.
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. Bursitis. 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 leakage, meningitis.
8. Loss of neurological function (e.g., sensory and/or motor), including paralysis (complete or incomplete), dysesthesias, hyperesthesia, anesthesia, paresthesia, appearance of radiculopathy, and/or the development or continuation of pain, numbness, neuroma, spasms, sensory loss, tingling sensation, and/or visual deficits.
9. Cauda equina syndrome, neuropathy, neurological deficits (transient or permanent), paraplegia, paraparesis, reflex deficits, irritation, arachnoiditis, and/or muscle loss.
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, resorption, damage, or penetration of any spinal bone (including the sacrum, pedicles, and/or vertebral body) and/or bone graft or bone graft harvest site at, above, and/or below the level of surgery. Retropulsed graft.
13. Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery.
14. Non-union (or pseudarthrosis). Delayed union. Mal-union.
15. Cessation of any potential growth of the operated portion of the spine.
16. Loss of or increase 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 stresses shielding.
19. Graft donor site complications including pain, fracture, or wound healing problems.
20. Ileus, gastritis, bowel obstruction or loss of bowel control or other types of gastrointestinal system compromise.
21. Hemorrhage, hematoma, occlusion, seroma, edema, hypertension, embolism, stroke, excessive bleeding, phlebitis, wound necrosis, wound dehiscence, damage to blood vessels, or other types of cardiovascular system compromise.
22. Reproductive system compromise, including sterility, loss of consortium, and sexual dysfunction.
23. Development of respiratory problems, e.g. pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.
24. Change in mental status.
25. Death.

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

WARNING AND PRECAUTIONS:

WARNING: The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis). The safety and effectiveness of this device for any other conditions are unknown.

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

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

Preoperative and operating procedures, including knowledge of surgical techniques, good reduction, and proper selection and placement of the implants are important considerations in the successful utilization of the system by the surgeon. Further, the proper selection and compliance of the patient will greatly affect the results. Patients who smoke have been shown to have an increased incidence of non-unions. These patients should be advised of this fact and warned of this consequence. Obese, malnourished, and/or alcohol abuse patients are also poor candidates for spine fusion. Patients with poor muscle and bone quality and/or nerve paralysis are also poor candidates for spine fusion.

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

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

Other preoperative, intraoperative, and postoperative warnings and precautions are as follows:

Implant Selection:

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

Device Fixation:

In cases where a percutaneous posterior approach is used refer to the CD HORIZON® SEXTANT™ System surgical technique.

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

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

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

PREOPERATIVE:

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 cleaned and sterilized before use. Additional sterile components should be available in case of an unexpected need.

INTRAOPERATIVE:

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

Caution: Be careful that the guidewire, if used, is not inserted too deep, becomes bent, and/or breaks. Ensure that the guidewire does not advance during tapping or screw insertion. Remove the guidewire and make sure it is intact. Failure to do so may cause the guidewire or part of it to advance through the bone and into a location that may cause damage to underlying structures. Do not overtap or use a screw that is either too long or too large. Overtapping or using an incorrectly sized screw may cause nerve damage, hemorrhage, or the 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 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. 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. Recheck the tightness of all nuts or screws after finishing to make sure that none loosened during the tightening of the other nuts or screws. Failure to do so may cause loosening of the other components.

POSTOPERATIVE:

The physician's postoperative directions and warnings to the patient, and the corresponding patient compliance, are extremely important.

1. Detailed instructions on the use and limitations of the device should be given to the patient. If partial weight-bearing is recommended or required prior to firm bony union, the patient must be warned that bending, loosening and/or breakage of the device(s) are complications which may occur as a result of excessive or early weight-bearing or muscular activity. The risk of bending, loosening, or breakage of a temporary internal fixation device during postoperative rehabilitation may be increased if the patient is active, or if the patient is debilitated or demented. The patient should be warned to avoid falls or sudden jolts in spinal position.
2. To allow the maximum chances for a successful surgical result, the patient or devices should not be exposed to mechanical vibrations or shock that may loosen the device construct. The patient should be warned of this possibility and instructed to limit and restrict physical activities, especially lifting and twisting motions and any type of sport participation. The patient should be advised not to smoke tobacco or utilize nicotine products, or to consume alcohol or non-steroidals or anti-inflammatory medications such as aspirin during the bone graft healing process.
3. The patient should be advised of their inability to bend or rotate at the point of spinal fusion and taught to compensate for this permanent physical restriction in body motion.
4. Failure to immobilize a delayed or non-union of bone will result in excessive and repeated stresses on the implant. By the mechanism of fatigue, these stresses can cause the eventual bending, loosening, or breakage of the device(s). It is important that immobilization of the spinal surgical site be maintained until firm bony union is established and confirmed by roentgenographic examination. If a state of non-union persists or if the components loosen, bend, and/or break, the device(s) should be revised and/or removed immediately before serious injury occurs. The patient must be adequately warned of these hazards and closely supervised to insure cooperation until bony union is confirmed.
5. As a precaution, before patients with implants receive any subsequent surgery (such as dental procedures), prophylactic antibiotics may be considered, especially for high-risk patients.
6. The CD HORIZON® Spinal System implants are temporary internal fixation devices. Internal fixation devices are designed to stabilize the operative site during the normal healing process. After the spine is fused, these devices serve no functional purpose and may be removed. While the final decision on implant removal is, of course, up to the surgeon and patient, in most patients, removal is indicated because the implants are not intended to transfer or support forces developed during normal activities. If the device is not removed following completion of its intended use, one or more of the following complications may occur: (1) Corrosion, with localized tissue reaction or pain; (2) Migration of implant position, possibly resulting in injury; (3) Risk of additional injury from postoperative trauma; (4) Bending, loosening and breakage, which could make removal impractical or difficult; (5) Pain, discomfort, or abnormal sensations due to the presence of the device; (6) Possible increased risk of infection; (7) Bone loss

due to stress shielding; and (8) Potential unknown and/or unexpected long term effects such as carcinogenesis. Implant removal should be followed by adequate postoperative management to avoid fracture, re-fracture, or other complications.

7. Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopedic implants, the CD HORIZON® Spinal System components should never be reused under any circumstances.

PACKAGING:

Packages for each of the components should be intact upon receipt. If a loaner or consignment system is used, all sets should be carefully checked for completeness and all components including instruments should be carefully checked to ensure that there is no damage prior to use. Damaged packages or products should not be used, and should be returned to MEDTRONIC SOFAMOR DANEK.

CLEANING AND DECONTAMINATION:

Unless just removed from an unopened Medtronic Sofamor Danek package, all instruments and implants must be disassembled (if applicable) and cleaned using neutral cleaners before sterilization and introduction into a sterile surgical field or (if applicable) return of the product to Medtronic Sofamor Danek. Cleaning and disinfecting of instruments can be performed with aldehyde-free solvents at higher temperatures. Cleaning and decontamination must include the use of neutral cleaners followed by a deionized water rinse.

Note: certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used. Also, many instruments require disassembly before cleaning.

All products should be treated with care. Improper use or handling may lead to damage and/or possible improper functioning of the device.

STERILIZATION:

Unless marked sterile and clearly labeled as such in an unopened sterile package provided by the company, all implants and instruments used in surgery must be sterilized by the hospital prior to use. Remove all packaging materials prior to sterilization. Only sterile products should be placed in the operative field. These products are recommended to be steam sterilized by the hospital using one of the three sets of process parameters below:

METHOD	CYCLE	TEMPERATURE	EXPOSURE TIME
Steam	Pre-Vacuum	270° F (132° C)	4 Minutes
Steam	Gravity	250° F (121° C)	30 Minutes
Steam*	Gravity*	273° F (134° C)*	20 Minutes*

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

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, identity, durability, reliability, safety, effectiveness 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 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

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 or 901-396-3133

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SURGICAL TECHNIQUE

Notes

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



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