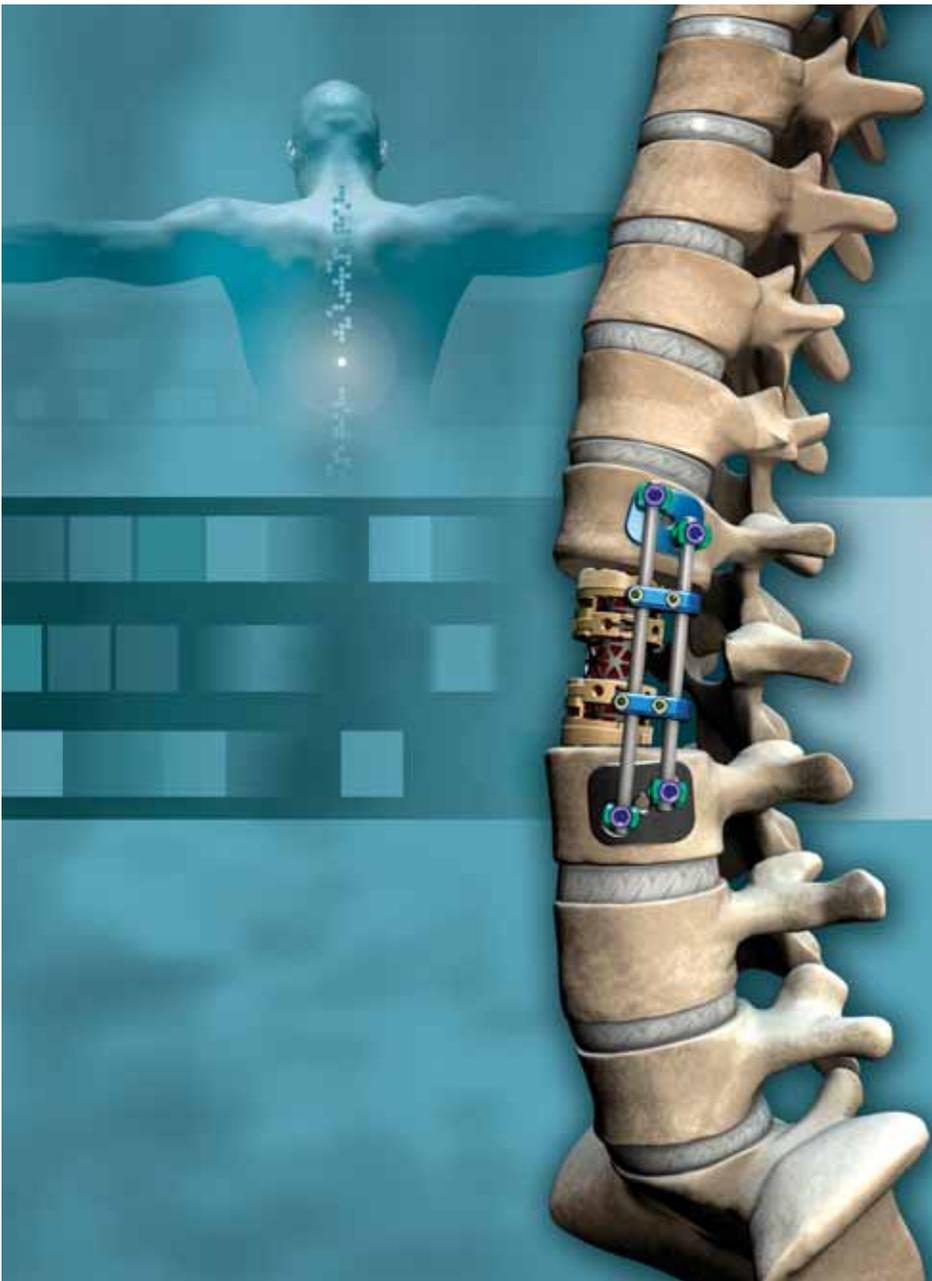


CD HORIZON[®] LEGACY[™]

Anterior Spinal System Tumor/Trauma Surgical Technique



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Features and Benefits

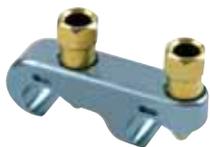
All CD HORIZON® LEGACY™ Anterior Spinal System implants are manufactured using 6Al4V or CP Grade II Titanium. Basic implants consist of vertebral body staples, fixed screws, CROSSLINK® Plates and 5.5mm diameter rods.



Vertebral Body Staples – This design offers contour in two planes to provide exceptional fit and a lower overall profile. The under surface is shaped to fit the sagittal curvature of the vertebral body and the concavity between the superior and inferior end plates of each instrumented vertebra. The upper surface has a smooth finish 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 postoperatively. The contoured staples are offered in four sizes to ensure a better fit for patients of various sizes. Each staple is clearly marked with the size, caudal or rostral orientation and color-coded; blue (rostral) or dark gray (caudal). The staples have longer prongs and serrations that provide greater stability than the previous version and are contoured to fit.



CD HORIZON® LEGACY™ Anterior System Fixed Screws – The top-loading, top-tightening design facilitates a simplified construct assembly, compatible with a 5.5mm diameter rod. Open 5.5mm and 6.5mm diameter screws are available to accommodate various instrumented levels. Additionally, a 7.5mm diameter screw can be used as a “rescue screw” in the medium and large vertebral body staple. The screw design and blunt tip offers a precautionary feature, bicortical purchase.



CD HORIZON® LEGACY™ Anterior Spinal System CROSSLINK® Plate – This cross connector utilizes the tested CD HORIZON® X10 CROSSLINK® Plate design. The design allows the one-piece implant to be easily applied to the dual rod construct for a top-loading approach. The CROSSLINK® Plates are offered in 1mm increments, from 13mm to 19mm. The ease of use and top-tightening features make this an excellent benefit to the system.

Case 1



Hook Compressor
94632



Rod Gripper
7480175



Caliper
9339095



Parallel Compressor, Small
7480165



In Situ Benders
7480255, Left
7480260, Right



Parallel Compressor, Large
7480166



Parallel Capturing Distractor
6480172



Parallel Distractor
7480170



Multi-Level Hook Compressor (optional)
808-503



Parallel Post Style Distractor
6480173

Instrument Set (Continued)

Case 2



Fixed Angle Screw Positioner
6481010



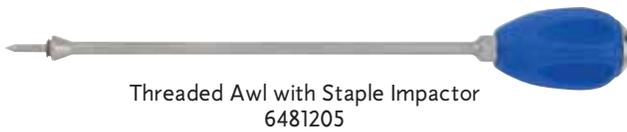
13mm/14mm Crosslink Measuring Tool
8691013



Depth Gauge
870-501



15mm/16mm Crosslink Measuring Tool
8691014



Threaded Awl with Staple Impactor
6481205



17mm/18mm Crosslink Measuring Tool
8691015



Staple Impactor
6481005



19mm Crosslink Measuring Tool
8691016



Counter Torque
6480150



Universal Quick Connect Ratcheting Handle
9960106



Quick Connect Ratcheting Handle
9339082

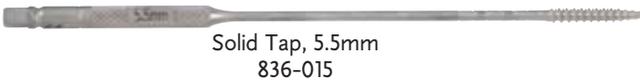


Fixed Angle Screwdriver
6480282

Case 2 (Continued)



Solid Tap, 4.5mm
836-014



Solid Tap, 5.5mm
836-015



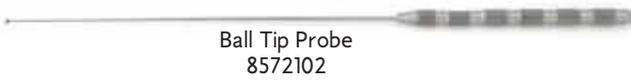
Solid Tap, 6.5mm
836-016



T25 Driver, Quick Connect
7484147



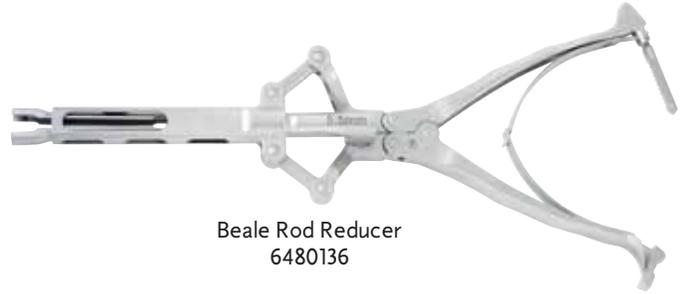
Set Screw Starter
7480122



Ball Tip Probe
8572102



Quick Connect Awl
6481000



Beale Rod Reducer
6480136



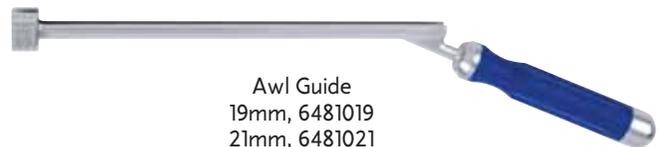
Crosslink Holder
6481011



Provisional Driver
7480130



French Bender
7480162



Awl Guide
19mm, 6481019
21mm, 6481021
23mm, 6481023
25mm, 6481025

Instrument Set (Continued)

Case 3



7/32" Breakoff Driver
6480144



Obturator
7484154



or
7/32" Plug Starter (for Crosslinks)
6480122



3.0mm Hex Driver
8110530



5.5mm Forcep Rocker
7480142



Coronal Plane Bender
7480265, Left
7480270, Right



6.35mm Hex Breakoff Driver
7480144

When treating thoracic and thoracolumbar fractures or tumors with anterior instrumentation, the approach is usually from the patient's left side, particularly below the diaphragm. If indications warrant, the operation can be accomplished from the patient's right side. The preoperative axial MRI or CT scan should be reviewed to ensure the aorta is midline. A left deviation of the aorta may require a right-sided approach above the diaphragm.

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).

The appropriate intervertebral discs and vertebral body are removed from the desired fusion area, using a variety of general surgical instruments.

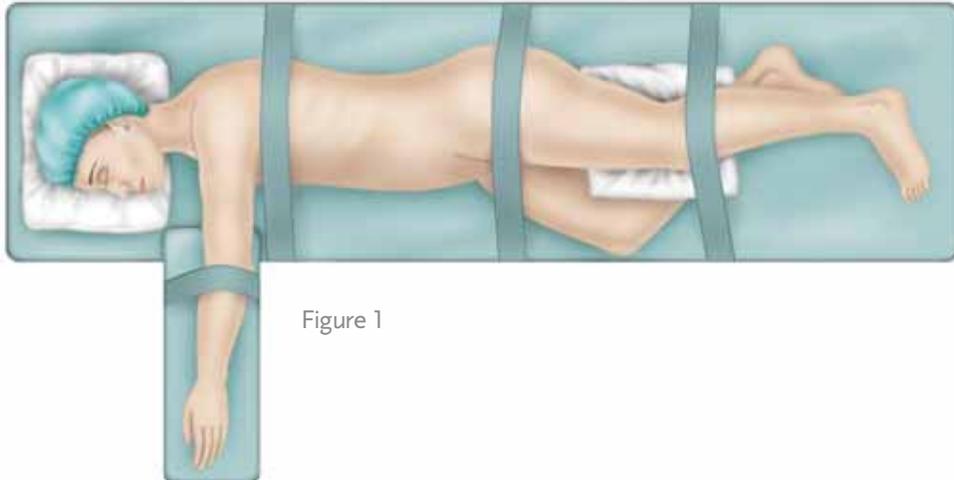


Figure 1

Measuring the Coronal Diameter of the Vertebral Body

Using the 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 implanted. This may also be done using the graduated scale on the preoperative MRI/CT films (Figure 3). If unable to measure preoperatively, the intraoperative option of determining screw length and trajectory with the Awl and Tap can be used.

Preoperative Planning of the Screw Length

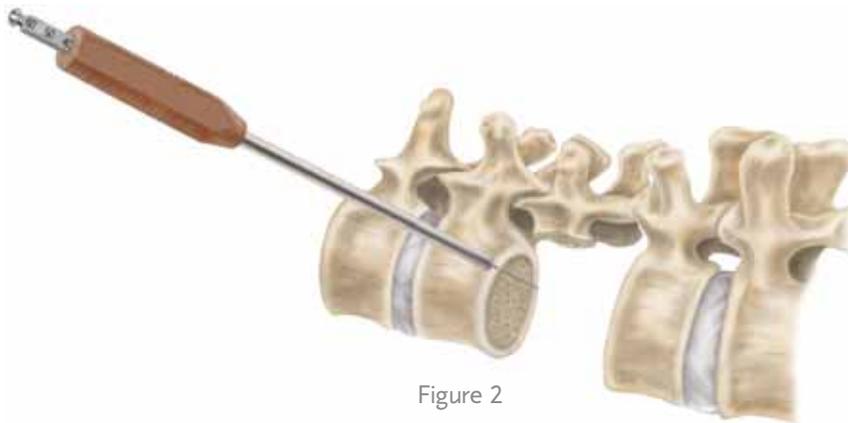


Figure 2

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.

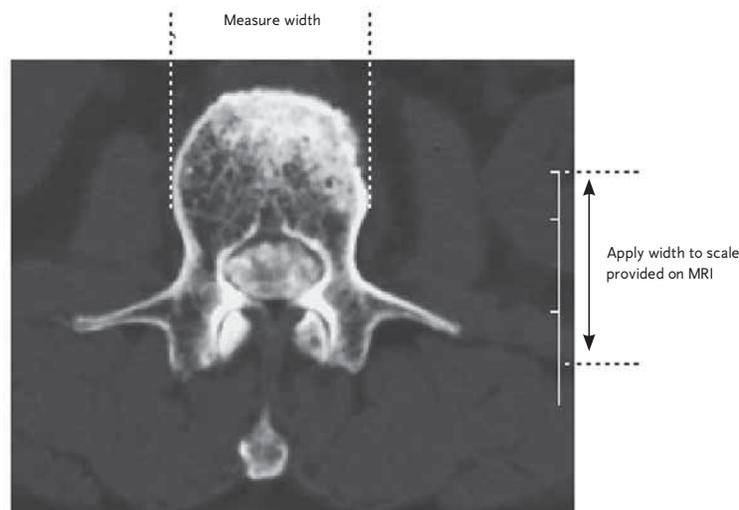


Figure 3

Placement of the Vertebral Body Staples

The appropriately-sized staple is selected and placed on the Staple Impactor (Figure 4). Staples are available in four sizes with both a caudal (dark gray) and rostral (blue) orientation. The largest staple that will fit within the confines of the vertebral body should be used. Intraoperative fluoroscopy can be used to assist in ideal staple positioning.

Figure 4



The staple attaches to the Staple Impactor by threading the Impactor Shaft into the center hole in the staple until snug. The staple is then impacted into position (Figure 5). Pilot holes are made using the provided Threaded Awl, and the Impactor is unthreaded from the center retaining hole (Figure 6). Generally, the screws are directed at a 10° convergent angle. When correctly placed, the staples will ensure that the anterior rod will be longer than the posterior rod.

Figure 5

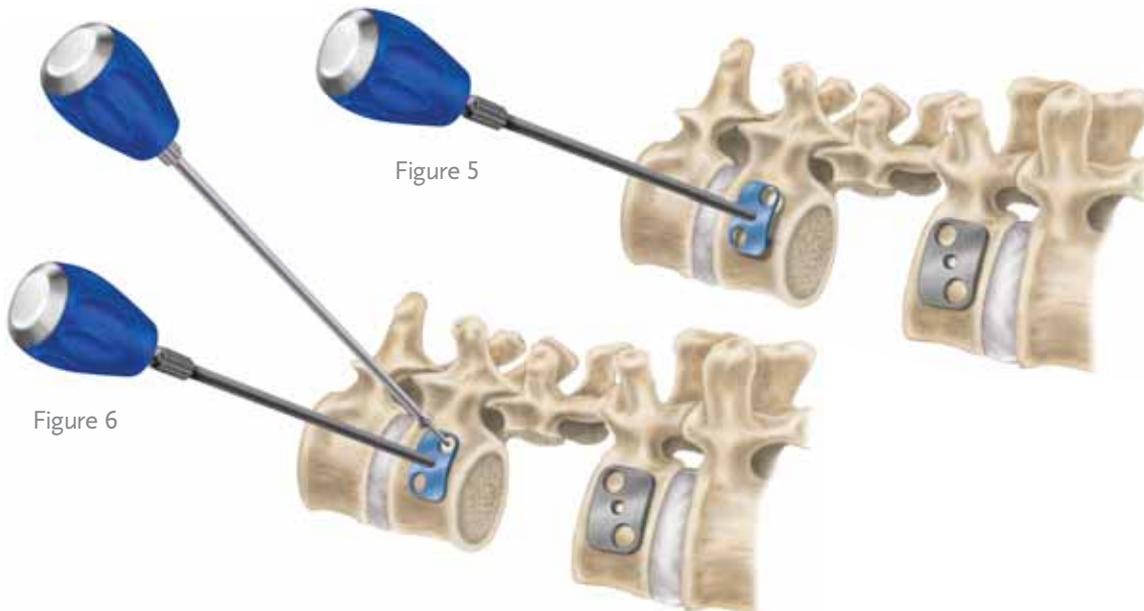


Figure 6

Awl Guide Option

As an option, the surgeon may elect to use the provided Awl Guides. After the staple is impacted into the vertebral body, the Awl Guide connects under the Staple Impactor (Figure 7). The thumb wheel on the Staple Impactor may be turned to temporarily lock the two instruments together (Figure 8). Using these instruments, the awl will create a 10° convergent trajectory for both the anterior and posterior screws (Figures 9 and 10). After both pilot holes are created, the thumb wheel may be released and the Staple Impactor unthreaded from the center of the staple.



Figure 7



Figure 8

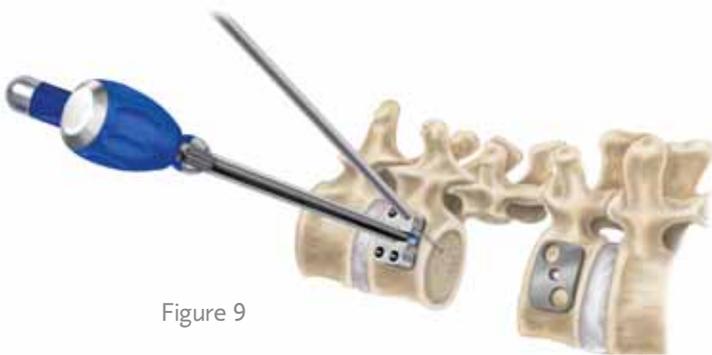


Figure 9

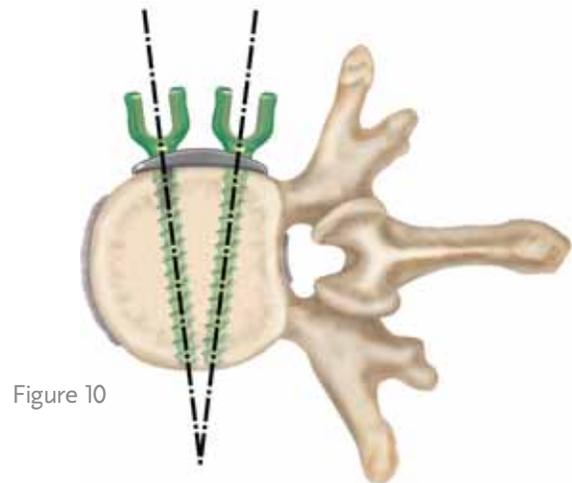


Figure 10

Screw holes may be tapped so that the CD HORIZON® LEGACY™ Anterior Spinal System Fixed Angle Screws can be inserted 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 contact the far cortex to ensure bicortical fixation.

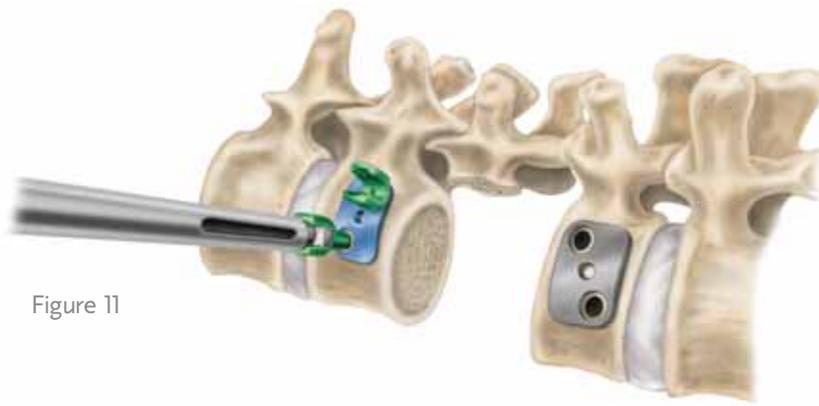


Figure 11

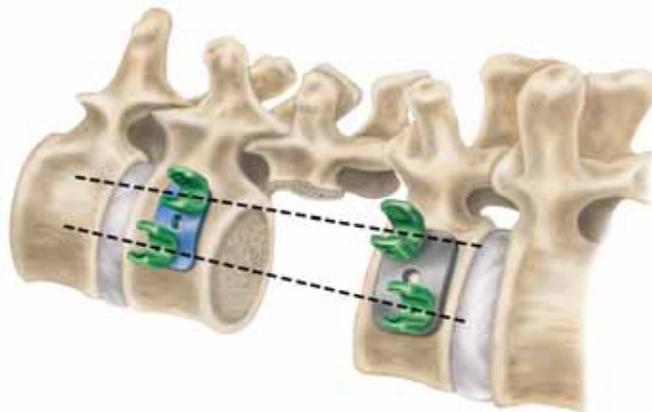
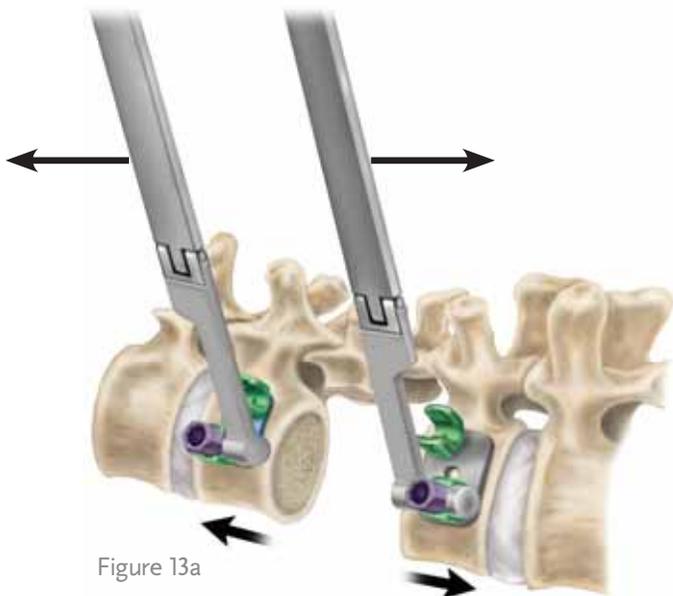


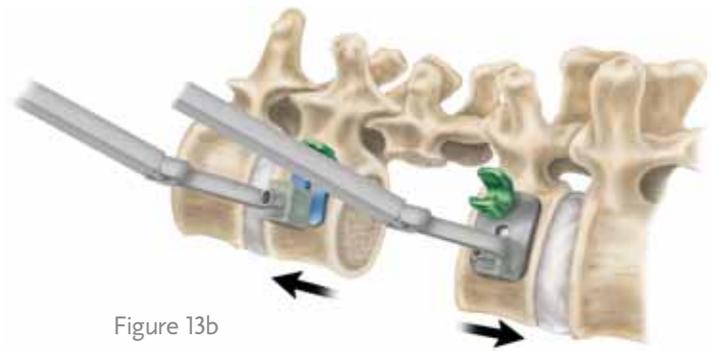
Figure 12

Distraction

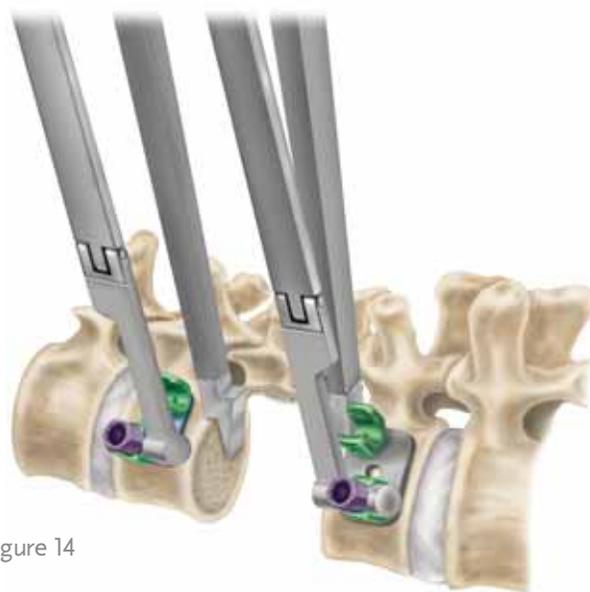
A vertebral body spreader or the provided Distractor may be used against the heads of the rostral and caudal screws. Insert the arms of the Distractor into the screw heads. If using a Parallel Post Style Distractor, insert a CD HORIZON® LEGACY™ Anterior Spinal System Set Screw over each arm of the Distractor using the Set Screw Starter. Each Set Screw should be provisionally tightened. A distractive force is placed against the heads until the desired distraction is achieved (Figure 13a). Please note that if the Parallel Capturing Distractor is used, Set Screws are not needed during distraction (Figure 13b). Once distraction has been achieved, the Graft Measuring Caliper may be used to determine the required graft length (Figure 14).



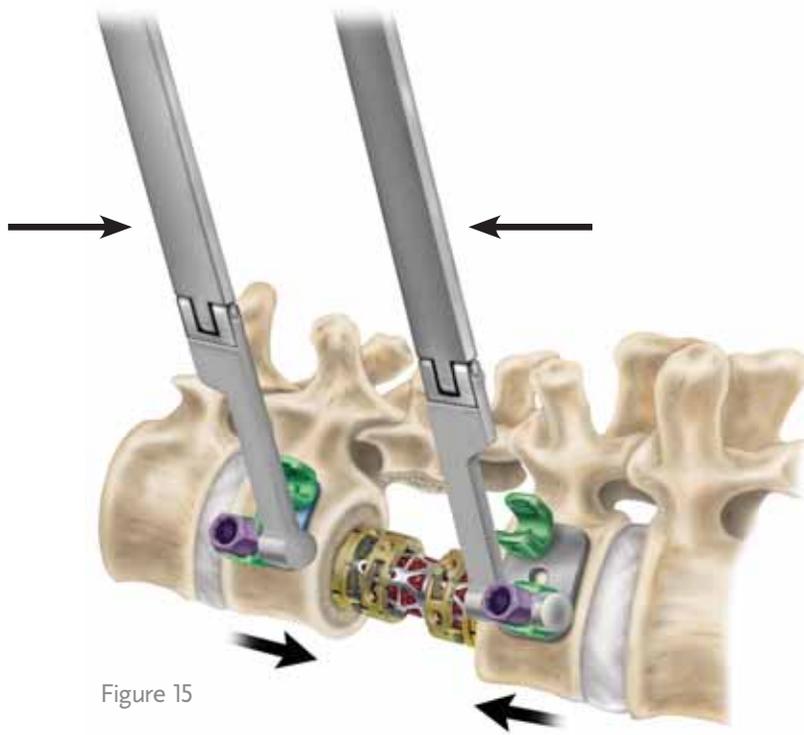
Parallel Post Style Distractor



Parallel Capturing Distractor



After careful selection, measurement, and placement of the corpectomy device and graft into the corpectomy site, distraction is released (Figure 15). Depress the ratchet lever on the Distractor until the corpectomy device comes in full contact with the superior and inferior end plates. Remove the Set Screws and the Parallel Post Style Distractor from the surgical site.



Rod Placement

Measure the required rod length using the Graft Measuring Caliper or the 20" Rod Template. The posterior rod is measured first. Cut the 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 Screws provisionally.

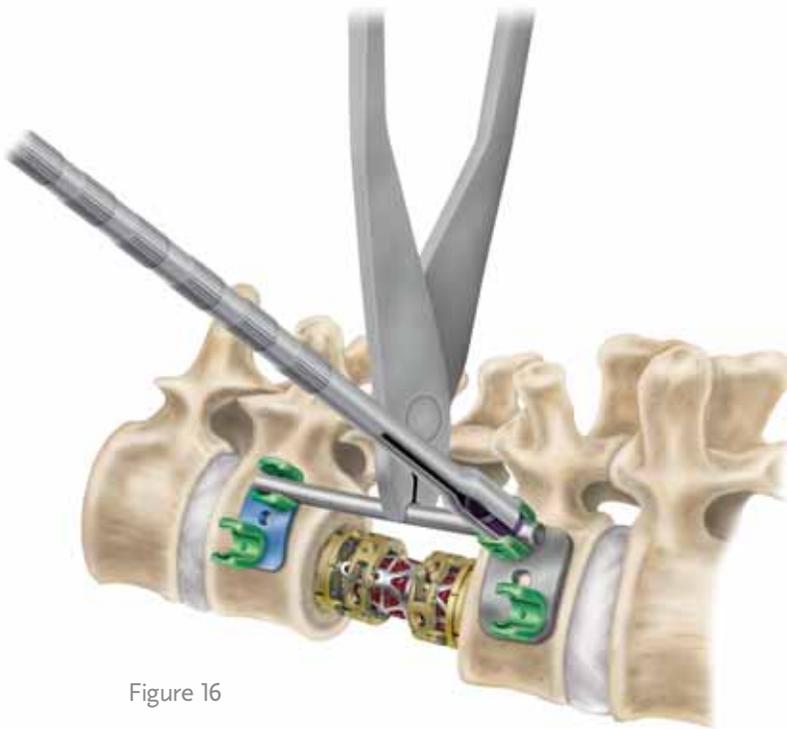


Figure 16

The Compressor is placed on the outside of the unsecured screws (Figure 17). A compressive force is applied to the construct to lock the corpectomy device in place. Provisionally 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 using the Counter Torque and the Hex Breakoff Driver (Figure 18).

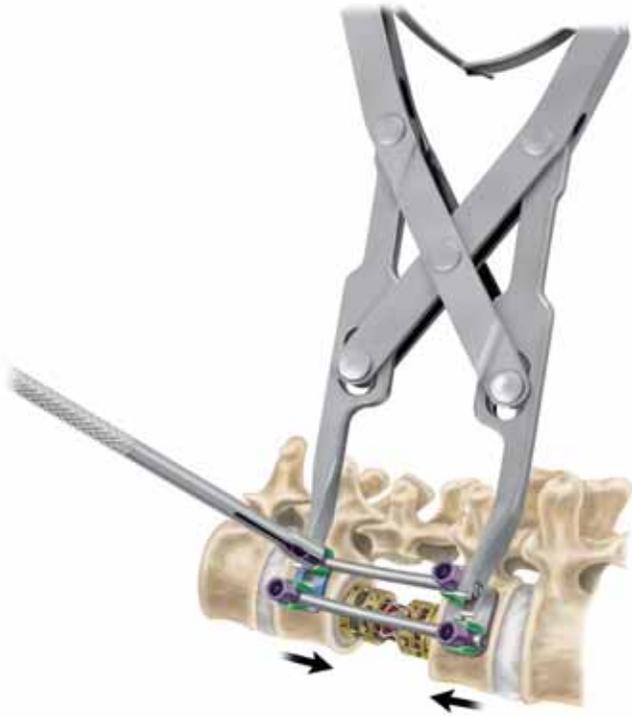


Figure 17



Figure 18

Placing the CROSSLINK® Plates

The CROSSLINK® Plates are added to the construct to provide torsional stability. Two CROSSLINK® Plates are recommended for each construct. Use the Crosslink Measuring Tools to determine the required implant size (Figure 19). Plates are offered in one-millimeter increments from 13mm to 19mm to provide a precise fit. Grasp the selected CROSSLINK® Plate with the Crosslink Holder and place on the rods (Figure 20).

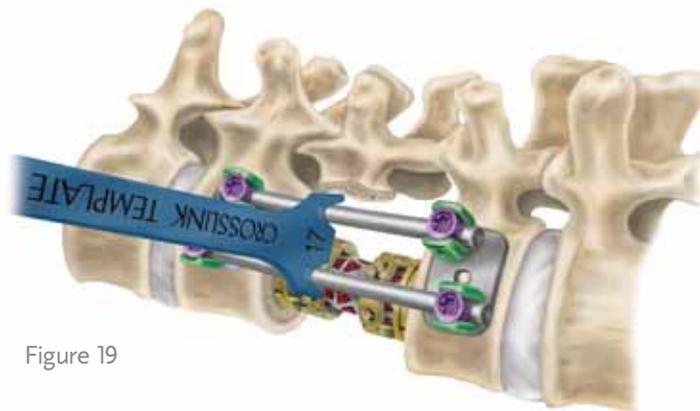


Figure 19

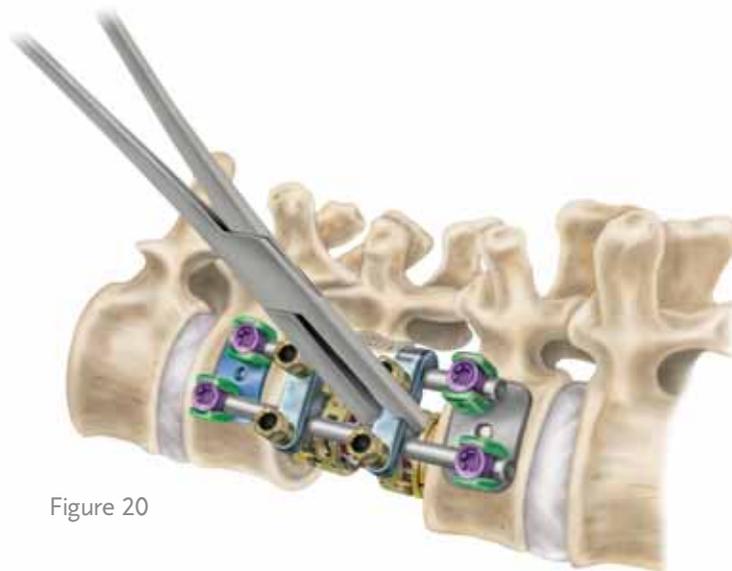


Figure 20

CROSSLINK® Plate Set Screws may be oriented facing 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). Use the 7/32" Breakoff Driver for final tightening of the CROSSLINK® Plate Set Screws.



Figure 21

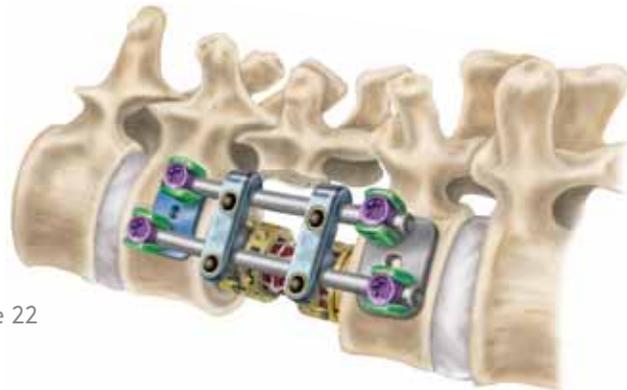


Figure 22

Explanation

If removal of the construct is necessary, the 3.0mm Hex Driver may be used to remove the CROSSLINK® Plate Set Screws. Place the tip of the 3.0mm Hex Head shaft (Removal Driver) into the CROSSLINK® Plate Set Screw and confirm that the 3.0mm tip is completely inserted so that the tip does not strip the hex. Turn the 3.0mm Hex Driver counterclockwise to loosen the CROSSLINK® Plate Set Screw from the rod. Next, the T25 Driver will remove the remaining Set Screws. Finally, the fixed angle screws, staples and rods are removed using the same instruments used for insertion.

Product Ordering Information

IMPLANTS

PART #	DESCRIPTION
6541019	Rostral Staple, 19mm
6541021	Rostral Staple, 21mm
6541023	Rostral Staple, 23mm
6541025	Rostral Staple, 25mm
6541119	Caudal Staple, 19mm
6541121	Caudal Staple, 21mm
6541123	Caudal Staple, 23mm
6541125	Caudal Staple, 25mm
6541213	Single Staple, 13mm
6541215	Single Staple, 15mm
6541217	Single Staple, 17mm

6543520	Fixed Angle Screw, 5.5mm × 20mm
6543525	Fixed Angle Screw, 5.5mm × 25mm
6543530	Fixed Angle Screw, 5.5mm × 30mm
6543535	Fixed Angle Screw, 5.5mm × 35mm
6543540	Fixed Angle Screw, 5.5mm × 40mm
6543545	Fixed Angle Screw, 5.5mm × 45mm
6543550	Fixed Angle Screw, 5.5mm × 50mm
6543620	Fixed Angle Screw, 6.5mm × 20mm
6543625	Fixed Angle Screw, 6.5mm × 25mm
6543630	Fixed Angle Screw, 6.5mm × 30mm
6543635	Fixed Angle Screw, 6.5mm × 35mm
6543640	Fixed Angle Screw, 6.5mm × 40mm
6543645	Fixed Angle Screw, 6.5mm × 45mm
6543650	Fixed Angle Screw, 6.5mm × 50mm
6543655	Fixed Angle Screw, 6.5mm × 55mm
6543660	Fixed Angle Screw, 6.5mm × 60mm

7440020	Breakoff Set Screw, Titanium
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PART #	DESCRIPTION
8110713	CROSSLINK® Plate, 13mm
8110714	CROSSLINK® Plate, 14mm
8110715	CROSSLINK® Plate, 15mm
8110716	CROSSLINK® Plate, 16mm
8110717	CROSSLINK® Plate, 17mm
8110718	CROSSLINK® Plate, 18mm
8110719	CROSSLINK® Plate, 19mm

8699050	5.5mm × 50mm Rod
8699055	5.5mm × 55mm Rod
8699060	5.5mm × 60mm Rod
8699065	5.5mm × 65mm Rod
8699070	5.5mm × 70mm Rod
8699075	5.5mm × 75mm Rod
8699080	5.5mm × 80mm Rod
8699085	5.5mm × 85mm Rod
8699090	5.5mm × 90mm Rod
8699095	5.5mm × 95mm Rod
8699100	5.5mm × 100mm Rod

869-022	5.5mm CP4 Lined Rod (500mm Length)
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Product Ordering Information (Continued)

INSTRUMENT SET

PART #	DESCRIPTION
94632	Hook Compressor
6480172	Parallel Capturing Distractor
6480173	Parallel Post Style Distractor
7480165	Parallel Compressor, Small
7480166	Parallel Compressor, Large
7480170	Parallel Distractor
7480255	In Situ Bender, Left
7480260	In Situ Bender, Right
9339095	Caliper
808-503	Multi-Level Hook Compressor (optional)
836-014	Solid Tap, 4.5mm
836-015	Solid Tap, 5.5mm
836-016	Solid Tap, 6.5mm
870-501	Depth Gauge
8572102	Ball Tip Probe

6480122	7/32" Plug Starter
6480144	7/32" Breakoff Driver
7480265	Coronal Plane Bender, Left
7480270	Coronal Plane Bender, Right
7484154	Obturator
7480142	5.5mm Forcep Rocker
7480144	6.35mm Hex Breakoff Driver

808-575	20" Rod Template
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PART #	DESCRIPTION
6480136	Beale Rod Reducer
6480150	Counter Torque
6480282	Fixed Angle Screwdriver
6481000	Quick Connect Awl
6481005	Staple Impactor
6481010	Fixed Angle Screw Positioner
6481011	CROSSLINK® Plate Holder
6481019	Awl Guide, 19mm
6481021	Awl Guide, 21mm
6481023	Awl Guide, 23mm
6481025	Awl Guide, 25mm
6481205	Threaded Awl with Staple Impactor
7480122	Set Screw Starter
7480162	French Bender
7480175	Rod Gripper
7484147	T25 Driver, Quick Connect
8691013	Crosslink Measuring Tool 13mm/14mm
8691014	Crosslink Measuring Tool 15mm/16mm
8691015	Crosslink Measuring Tool 17mm/18mm
8691016	Crosslink Measuring Tool 19mm
7480130	Provisional Driver
9339082	Quick Connect Ratcheting Handle
9960106	Universal Quick Connect Ratcheting Handle

Important Product Information

General Instruments

PURPOSE

This instrument is intended for use in surgical procedures.

DESCRIPTION

Unless otherwise stated, instruments are made out of a variety of materials commonly used in orthopedic and neurological procedures including stainless steel and acetyl copolymer materials which meet available national or international standards specifications. Some instruments are made out of aluminum, and some with handles made of resin bonded composites, and while these can be steam autoclaved, certain cleaning fluids must not be employed. None of the instruments should be implanted.

INTENDED USE

This instrument is a precision device which may incorporate a measuring function and has uses as described on the label.

Unless labeled for single use, this instrument may be re-used.

If there is any doubt or uncertainty concerning the proper use of this instrument, please contact MEDTRONIC SOFAMOR DANEK Customer Service for instructions. Any available surgical techniques will be provided at no charge.

WARNINGS

The methods of use of instruments are to be determined by the user's experience and training in surgical procedures.

Do not use this instrument for any action for which it was not intended such as hammering, prying, or lifting.

This instrument should be treated as any precision instrument and should be carefully placed on trays, cleaned after each use, and stored in a dry environment.

To avoid injury, the instrument should be carefully examined prior to use for functionality or damage. A damaged instrument should not be used. Additional back-up instruments should be available in case of an unexpected need.

MEDTRONIC SOFAMOR DANEK does not and cannot warrant the use of this instrument nor any of the component parts upon which repairs have been made or attempted except as performed by MEDTRONIC SOFAMOR DANEK or an authorized MEDTRONIC SOFAMOR DANEK repair representative.

Implied warranties of merchantability and fitness for a particular purpose or use are specifically excluded. See the MEDTRONIC SOFAMOR DANEK catalog for further information about warranties and limitations of liability.

DO NOT IMPLANT THE INSTRUMENTS.

POSSIBLE ADVERSE EFFECTS

Breakage, slippage, misuse, or mishandling of instruments, such as on sharp edges, may cause injury to the patient or operative personnel.

Improper maintenance, handling, or poor cleaning procedures can render the instrument unsuitable for its intended purpose or even dangerous to the patient or surgical staff.

Proper patient selection and operative care are critical to the success of the device and avoidance of injury during surgery. Read and follow all other product information supplied by the manufacturer of the implants or the instruments.

Special precautions are needed during pediatric use. Care should be taken when using instruments in pediatric patients, since these patients can be more susceptible to the stresses involved in their use.

There are particular risks involved in the use of instruments used for bending and cutting rods. The use of these types of instruments can cause injury to the patient by virtue of the extremely high forces which are involved. Do not cut rods in situ. In addition, any breakage of an instrument or the implant in this situation could be extremely hazardous. The physical characteristics required for many instruments does not permit them to be manufactured from implantable materials, and if any broken fragments of instruments remain in the body of a patient, they could cause allergic or infectious consequences.

OVER-BENDING, NOTCHING, STRIKING AND SCRATCHING OF THE IMPLANTS WITH ANY INSTRUMENT SHOULD BE AVOIDED TO REDUCE THE RISK OF BREAKAGE.

Under no circumstances should rods or plates be sharply or reverse bent, since this would reduce the fatigue life of the rod and increase the risk of breakage. When the configuration of the bone cannot be fitted with an available device and contouring of the device is absolutely necessary, contouring should be performed only with proper bending equipment, and should be performed gradually and with great care to avoid notching or scratching the device.

Extreme care should be taken to ensure that this instrument remains in good working order. Any surgical techniques applicable for use of this system should be carefully followed. During the procedure, successful utilization of this instrument is extremely important. Unless labeled for single use, this instrument may be reused. This instrument should not be bent or damaged in any way. Misuse of this instrument, causing corrosion, "freezing-up", scratching, loosening, bending and/or fracture of any or all sections of the instrument may inhibit or prevent proper function.

It is important that the surgeon exercise extreme caution when working in close proximity to vital organs, nerves or vessels, and that the forces applied while correcting the position of the instrumentation is not excessive, such that it might cause injury to the patient.

Excessive force applied by instruments to implants can dislodge devices, particularly hooks.

Never expose instruments to temperatures in excess of 134° C that may considerably modify the physical characteristics of the instruments.

USA For US Audiences Only

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

This device should be used only by physicians familiar with the device, its intended use, an additional instrumentation and any available surgical techniques.

For the best results MEDTRONIC SOFAMOR DANEK implants should only be implanted with MEDTRONIC SOFAMOR DANEK instruments.

Other complications to the patient and/or hospital staff may include, but are not limited to:

1. Nerve damage, paralysis, pain, or damage to soft tissue, visceral organs or joints.
2. Breakage of the device, which could make necessary removal difficult or sometimes impossible, with possible consequences of late infection and migration. Breakage could cause injury to the patient or hospital staff.
3. Infection, if instruments are not properly cleaned and sterilized.
4. Pain, discomfort, or abnormal sensations resulting from the presence of the device.
5. Nerve damage due to surgical trauma.
6. Dural leak in cases of excessive load application.
7. Impingement of close vessels, nerves and organs by slippage or misplacement of the instrument.
8. Damage due to spontaneous release of clamping devices or spring mechanisms of certain instruments.
9. Cutting of skin or gloves of operating staff.
10. Bony fracture, in cases of deformed spine or weak bone.
11. Tissue damage to the patient, physical injury to operating staff and/or increased operating time that may result from the disassembly of multi-component instruments occurring during surgery.

OTHER PRECAUTIONS

1. Excessive forces when using bending or fixation instruments can be dangerous especially where bone friability is encountered during the operation.
2. Any form of distortion or excessive wear on instruments may cause a malfunction likely to lead to serious patient injury.
3. Regularly review the operational state of all instruments and if necessary make use of repair and replacement services.

DEVICE FIXATION

Some surgeries require the use of instruments which incorporate a measuring function. Ensure that these are not worn, that any surface engravings are clearly visible.

Where there is a need for a specified tightening torque, which may normally be achieved with torque setting instruments supplied by MEDTRONIC SOFAMOR DANEK; the pointer on these instruments must indicate ZERO before use. If not, return for recalibration.

With small instruments, excess force, beyond the design strength of the instrument, can be caused even by simple manual overloading. Do not exceed recommended parameters.

To determine the screw diameter with the screw gauge, start with the smallest test hole.

PACKAGING

MEDTRONIC SOFAMOR DANEK instruments may be supplied as sterile or non-sterile. Sterile instruments will be clearly labeled as such on the package label. The sterility of instruments supplied sterile can only be assured if the packaging is intact.

Packages for both sterile and non-sterile components should be intact upon receipt. All sets should be carefully checked for completeness and all components should be carefully checked for signs of damage, prior to use. Damaged packages or products should not be used and should be returned to MEDTRONIC SOFAMOR DANEK.

Remove all packaging material prior to sterilization. Only sterile implants and instruments should be used in surgery. Always immediately re-sterilize all instruments used in surgery. Instruments should be thoroughly cleaned prior to re-sterilization. This process must be performed before handling, or before returning product to MEDTRONIC SOFAMOR DANEK.

EXAMINATION

Instruments must always be examined by the user prior to use in surgery.

Examination should be thorough, and in particular, should take into account a visual and functional inspection of the working surfaces, pivots, racks, spring or torsional operation, cleanliness of location holes or cannulations, and the presence of any cracks, bending, bruising or distortion, and that all components of the instrument are complete.

Never use instruments with obvious signs of excessive wear, damage, or that are incomplete or otherwise unfunctional.

CLEANING AND DECONTAMINATION

Unless just removed from an unopened MEDTRONIC SOFAMOR DANEK package, all instruments 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. Unless specified elsewhere, these products are recommended to be steam sterilized by the hospital using the set of process parameters below:

METHOD	CYCLE	TEMPERATURE	EXPOSURE TIME
Steam	Pre-Vacuum	270°F (132°C)	4 Minutes
Steam	Gravity	250°F (121°C)	60 Minutes
Steam*	Pre-Vacuum*	273°F (134°C)*	20 Minutes*
Steam*	Gravity*	273°F (134°C)*	20 Minutes*

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.

It is important to note that a sterilization wrap, package or sterilization container system should be used to enclose the case or tray in order to maintain sterility.

Although the treatment of the instrument, materials used, and details of sterilization have an important effect, for all practical purposes, there is no limit to the number of times instruments can be re-sterilized.

OPERATIVE USE

The physician should take precautions against putting undue stress on the spinal area with instruments. Any surgical technique instruction manual should be carefully followed. If an instrument breaks in surgery and pieces go into the patient, these pieces should be removed prior to closure and should not be implanted.

Important Product Information (Continued)

REMOVAL OF IMPLANTS

For the best results, the same type of MEDTRONIC SOFAMOR DANEK instruments as used for implantation should be used for implant removal purposes. Various sizes of screwdrivers are available to adapt to the removal drive sizes in auto break fixation screws.

It should be noted that where excessive bone or fibrous growth has occurred from the first surgery, there may be added stress on the removal instruments and the implants. Both instrument and implant may be prone to possible breakage. In this case it is necessary to first remove the bone and/or tissue from around the implants.

PRODUCT COMPLAINT

Any Health Care Professionals (e.g., customer users of MEDTRONIC SOFAMOR DANEK instruments), who have any complaint or who have experienced dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify the distributor, MEDTRONIC SOFAMOR DANEK. Further, if any instrument "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 or MEDTRONIC SOFAMOR DANEK 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 or MEDTRONIC SOFAMOR DANEK should be notified as soon as possible by telephone, FAX or written correspondence. When filing a complaint, please provide the component(s) name and number, lot number(s), your name and address, and the nature of the complaint.

FURTHER INFORMATION

In case of complaint, or for supplementary information, please contact MEDTRONIC SOFAMOR DANEK.



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Contact Customer Service or your Sales Representative for the most up-to-date version of the package insert.

Important Product Information

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 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 spinal systems can be used with the CD HORIZON® Spinal System. These components include TSRH® rods, hooks, screws, plates, CROSSLINK® plates, connectors, staples and washer, GDLH® rods, hooks, connectors and CROSSLINK® bar and connectors; LIBERTY® rods and screws; DYNALOK® PLUS and DYNALOK CLASSIC® bolts along with rod/bolt connectors; and Medtronic Multi-Axial rods and screws. Please note that certain components are specifically designed to connect to 3.5mm, 4.5mm, 5.5mm rods or 6.35mm rods, while other components can connect to both 5.5mm rods and 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, medical grade titanium, titanium alloy, medical grade cobalt-chromium-molybdenum alloy, or medical grade PEEK OPTIMA®-LT1. Certain CD HORIZON® Spinal System components may be coated with hydroxyapatite. No warranties express, or implied, are made. Implied warranties of merchantability and fitness for a particular purpose or use are specifically excluded. See the Medtronic catalog for further information about warranties and limitations of liability.

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

Medical grade titanium, titanium alloy and/or medical grade cobalt-chromium-molybdenum alloy may be used together. Never use titanium, titanium alloy and/or medical grade cobalt-chromium-molybdenum alloy with stainless steel 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, titanium alloy and cobalt-chromium-molybdenum alloy. Do not use with stainless steel.

The CD HORIZON® AGILE™ Dynamic Stabilization device is comprised of four components and are comprised by a combination of materials. The proximal and distal rod components are manufactured from commercially pure titanium. The cable is fabricated from a 7x7 filament yarn made from titanium alloy, with a cylinder rotary-swaged to the end, made from the same material. The spacer portion of the device is manufactured from Polycarbonate-Urethane.

PEEK OPTIMA-LT1 implants may be used with stainless steel, titanium or cobalt-chromium-molybdenum alloy implants. **CD HORIZON® PEEK Rods are not to be used with CROSSLINK® Plates.**

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

INDICATIONS:

The CD HORIZON® Spinal System with or without SEXTANT® instrumentation 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.

Except for hooks, when used as an anterolateral thoracic/lumbar system, the CD HORIZON® Spinal System may also be used for the same indications.

With the exception of degenerative disc disease, the CD HORIZON® LEGACY™ 3.5mm rods and the CD HORIZON® Spinal System PEEK rods and associated components may be used for the aforementioned indications in skeletally mature patients.

The CD HORIZON® SPIRE™ 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 processes for the purpose of achieving supplemental fusion in the following conditions: degenerative disc disease (as previously defined); spondylolisthesis, trauma; and/or tumor.

When used as a pedicle screw fixation system in skeletally mature patients, the CD HORIZON® AGILE™ Dynamic Stabilization device is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion in the treatment of the degenerative spondylolisthesis with objective evidence of neurologic impairment and/or failed previous fusion in the thoracic, lumbar and/or sacral spine. Additionally, when used as a pedicle screw fixation system, the CD HORIZON® AGILE™ Dynamic Stabilization device is indicated for use in patients who are receiving fusions with autogenous graft only; who are having the device fixed or attached to the lumbar or sacral spine; and/or are having the device removed after the development of a solid fusion mass.

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 (immunocompromise).
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. Suspected or documented metal allergy or intolerance.
10. Any case not needing a bone graft and fusion.
11. Any case where the implant components selected for use would be too large or too small to achieve a successful result.
12. Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
13. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.

14. Any patient unwilling to follow postoperative instructions.

15. Any case not described in the indications.

NOTA BENE: Although not absolute contraindications, conditions to be considered as potential factors for not using this device include:

1. Severe bone resorption.

2. Osteomalacia.

3. Severe osteoporosis.

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, neurosis, 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:

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. The implants are not prostheses. In the absence of fusion, the instrumentation and/or one or more of its components can be expected to pull out, bend or fracture as a result of exposure to every day mechanical stresses.

PRECAUTION:

The implantation of pedicle screw spinal systems should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient. A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where many extenuating circumstances may compromise the results. This device system is not intended to be the sole means of spinal support. Use of this product without a bone graft or in cases that develop into a non-union will not be successful. No spinal implant can withstand body loads without the support of bone. In this event, bending, 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.

USA For US Audiences Only

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.

Important Product Information (Continued)

DEVICE FIXATION:

In cases where a percutaneous posterior approach is used refer to the CD HORIZON® SEXTANT® surgical technique. Medtronic CD HORIZON® Spinal System instrumentation contains 3.5mm, 4.5 mm, 5.5mm and/or 6.35mm rods and implants, which are intended to be used with device specific instruments. For self breaking plugs, always hold the assembly with the Counter Torque device. Tighten and break-off the head of the plug to leave the assembly at optimum fixation security. After the upper part of the self breaking plug has been sheared off, further re-tightening is not necessary and not recommended. The head part should not remain in the patient. **AFTER THE UPPER PART OF THE SELF BREAKING PLUG HAS BEEN SHEARED OFF, RE-ADJUSTMENT IS NOT POSSIBLE UNLESS THE PLUG IS REMOVED AND REPLACED WITH A NEW ONE.**

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

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

When using the CD HORIZON® AGILE™ Dynamic Stabilization device, refer to the surgical technique for the appropriate directions for use.

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.
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. Utilize an imaging system to facilitate surgery.
5. To insert a screw properly, a guide wire should first be used, followed by a sharp tap. Caution: Be careful that the guide-wire, if used, is not inserted too deep, becomes bent, and/or breaks. Ensure that the guide-wire does not advance during tapping or screw insertion. Remove the guide-wire and make sure it is intact. Failure to do so may cause the guide wire or part of it to advance through the bone and into a location that may cause damage to underlying structures.
6. **Caution:** Do not overlap or use a screw/bolt that is either too long or too large. Overtapping, using an incorrectly sized screw/bolt, or accidentally advancing the guidewire during tap or screw/bolt insertion, may cause nerve damage, hemorrhage, or 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 CROSSLINK® plates or DTT Transverse Links on two bilaterally placed, continuous rods, should be used whenever possible.
9. Before closing the soft tissues, provisionally tighten (finger tighten) all of the nuts or screws, especially screws or nuts that have a breakoff 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.

CLEANING AND DECONTAMINATION:

Unless just removed from an unopened Medtronic 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. 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.

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

PRODUCT COMPLAINTS:

Any Health Care Professional (e.g., customer or user of this system of products), who has any complaints or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify the distributor, Medtronic. Further, if any of the implanted spinal system component(s) ever "malfunctions," (i.e., does not meet any of its performance specifications or otherwise does not perform as intended), or is suspected of doing so, the distributor should be notified immediately. If any Medtronic product ever "malfunctions" and may have caused or contributed to the death or serious injury of a patient, the distributor should be notified immediately by telephone, FAX or written correspondence. When filing a complaint, please provide the component(s) name and number, lot number(s), your name and address, the nature of the complaint and notification of whether a written report from the distributor is requested.



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listen. respond. deliver.

The surgical technique shown is for illustrative purposes only. The technique(s) actually employed in each case will always depend upon the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient.

Please see the package insert for the complete list of indications, warnings, precautions, and other medical information.

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