CD HORIZON® Spinal System
M8 Multi Axial Screw Surgical Technique

as described by:
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Since first used by Dr. Paul Harrington in the late 1960’s, pedicle screws have gone through multiple phases and changes. For several indications, pedicle screws are currently viewed as a needed addition for spinal fusion due to the immediate fixation they provide.

The Medtronic CD HORIZON® M8 Multi Axial Screw System is designed to facilitate the placement of pedicle screws through versatility and ease of use. The multi axial capability provides 28° of freedom in any direction for a total of 56. This multi axial capability allows for easier rod placement and reduction, even when the screws are not perfectly aligned with one another. In addition, the ease of applying compression and distraction enhance the ability to place interbody fusion material.

Other essential features of the M8 Multi Axial Screw System include a buttress thread design, a single locking mechanism and top loading implants. The M8 is a 5.5mm rod system and can be combined with fixed angle screws and hooks, which share the same closure mechanism.
The Multi Axial Screw System is available in stainless steel and titanium.
Instrument Set

- Provisional Plug Driver
- Pedicle Probe
- Solid Tap
- Tapered Hex Shaft
- TORX 25 Shaft
- Plug/DDT Starter
- Straight Probe
- Curved Probe
- Hex Rod Rotation Wrench
- Multi Axial Screwdriver
- Universal Handle
- Ratcheting Handle
- Rod Reducer
- Rod Reducer II
- Power Grip
- Curved Compressor
- Curved Distractor
- Awl
- Counter Torque
Instruments that may be used with Low Profile CROSSLINK® System

- Rod Pusher
- Cork Screw
- Rod Holder
- Straight Implant Holder
- Curved Implant Holder
- Rocker
- French Bender
- In situ Benders
- Plate Benders
- Plate Template
- Plate Holder
- Hex Head Screwdriver
With the pedicles prepared and the proper screw lengths determined, the Multi Axial Screws are inserted from L4 to S1, bilaterally, using the Multi Axial Screwdriver (8680052) (Fig. 1a). The hex end of the screwdriver is fully engaged into the screw head. The instrument sleeve is then threaded into the screw head (Fig. 1b). The combination of the hex head and the threaded sleeve provide a stable insertion instrument for driving the Multi Axial Screw.

When fully inserted, the screws should extend 50-80% into the vertebral body and be parallel to the superior endplate (for sacral fixation, especially when bone is osteopenic, bicortical purchase may be utilized).

Once the screw is inserted, the instrument sleeve is unscrewed and disengaged from the screw.
When necessary, decompression laminectomies are performed to address any stenosis in the central canal, lateral recess and neural foramina. After decompression, Multi Axial Screws can be used to accomplish both anatomic reduction and rigid fixation.

After the insertion of the Multi Axial Screws and prior to inserting the rods, the lordotic alignment of the lumbar spine should be verified via intraoperative lateral X-ray or C-arm. Maintenance of lordosis over the instrumented levels is very important. Prior to rod insertion, extend the hips by adjusting the table to increase lordosis.

Due to differences in pedicle angles, as measured from the sagittal midline, screw position may be misaligned from a posterior view (Fig. 2). Traditional fixation methods required precise bending of the rods to compensate for this; however, the Multi Axial Screw may be angled up to 28° medial and lateral to facilitate placement of the rod (Fig. 3).
STEP 3

The rod is placed into the top loading screws beginning from either the cephalad or caudad direction (Fig. 4). The rod is best inserted using a rod gripper (85603).

**Provisional Implant Closure**

With the rod laying in the bottom of the screw head, the break off set screws (hereafter referred to as the “plugs”) may be seated into the top of the implant holder using the plug starter (84692E) (Fig. 5 and 5a). To limit the possibility of cross-threading the plug, the plug starter is turned counter clockwise until a “click” is heard. If necessary, the rod may be pushed into the implant using a rod pusher (C6201) or rod reducer II (858-989).
When the rod is not fully seated into the head of the screw, the rocker (815-500) is preferred for reduction (Fig. 6a). The screw head is grasped from either side by the instrument with the rocker cam above the rod. The rocker is then rotated backward levering the rod into the screw head. The plug starter is then used to insert the plug (Fig. 6b).
If compression or distraction is needed, it is carried out at this time. Care should be taken with all plugs to ensure that the feet of either the compressor (94632) or distractor/spreader (94633) are placed securely against the implant body and not against the plug (Fig. 7). Failure to do this may result in slippage of the implant or premature breaking of the plug.

The provisional plug driver (84687E) may be used to maintain temporary locking and security of the rod/implant construct. Usually, temporary fixation of the implant may be performed numerous times without damage to either the plug or implant threads. However, if the plug has been cross-threaded, it must be replaced.

At this point, compression or distraction may be performed. In either maneuver, the plug on one side of the motion segment should be provisionally tightened, with the other plug loose in the implant. Compression or distraction will occur against the provisionally tightened implant. Once satisfactory compression or distraction has been achieved, final tightening may be performed. Distraction is seldom indicated other than while performing a PLIF because of the increased risk of implant breakage, pseudoarthrosis and creating segmental kyphosis.

If it is determined there is inadequate anterior column support, supplemental means to reinforce the anterior column (PLIF) may be performed prior to final tightening of the plugs. When a PLIF is performed, compression should be applied to the posterior rod/screw construct to assure rigid fixation.
When all implants are securely in place, final tightening and break off of the plug head is done. The appropriate size counter torque device (858-990) is placed over the implant and rod (Fig. 8a) while the tapered hex shaft (815-516) and quick connect handle (836-010) are inserted through the cannulation of the counter torque. The T-handle provides adequate leverage for the break-off of the plug head (between 10-12 N-m for M8). The handle of the counter torque device should be held firmly to prevent torquing of the construct while the plug is secured and sheared off (Fig. 8b).

If desired, the security of the screw/rod interface may be checked after the plug heads have been sheared off by placing a distractor between the screws and applying moderate distraction. If motion is present, the plug is either cross-threaded or the rod may not be fully seated in the saddle of the screw. If the plug is cross-threaded, it must be replaced with a new one. If the rod is not fully seated, place the appropriate size counter torque over the head of the screw. The TORX 25 is then used to further tighten the plug until the rod is fully seated in the saddle of the screw.

If necessary, the plug may be removed after final tightening using the TORX 25 shaft (815-518) and quick connect handle (836-010) (Fig. 9). Once a plug has been removed, it should be discarded and replaced with a new one.

NOTE: The appropriate size counter torque device MUST be used during final tightening.
Decortication and bone grafting can now take place. Low Profile CROSSLINK® Plates may also be added at this time.

Following the final tightening of the screws and rods, the appropriate size Low Profile CROSSLINK® Plate or CROSSLINK® MULTI-SPAN® Plate is determined with the measuring template (Fig. 10). Rods may be spread or compressed as necessary.

With use of the plate holder (810-510), the appropriate Low Profile CROSSLINK® Plate or CROSSLINK® MULTI-SPAN® Plate is selected and pressed down onto the rods (Fig. 11).

Plate benders (810-525) should be used to contour the Low Profile CROSSLINK® Plates or the CROSSLINK® MULTI-SPAN® Plates. When bending the Low Profile CROSSLINK® and CROSSLINK® MULTI-SPAN® Plates, do not exceed 20° in any single plane.

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

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

- Shorten the telescopic mechanism slightly less than the span between the rods and provisionally tighten the midline set screw.
- Bend the plate as required using the plate benders. However, do not exceed 20° in any single plane.
- Loosen the midline set screw and apply the CROSSLINK® Plate as stated above.

Wound closure is then performed in the customary manner.
Patients must be warned to avoid physical activities that would place excessive stress upon the implant or bone graft, which could delay or prevent healing. However, regular graduated mild to moderate activity is beneficial to bone formation, particularly when the vertebrae have been adequately stabilized internally. Patients should be instructed in the proper methods of getting in and out of bed, from a sitting position, etc.

Please see the package insert at the end of this brochure for other Warnings, Precautions and Possible Adverse Events about the CD HORIZON® Spinal System.

**Explantation**

The plugs (set screws) may be removed using the TORX 25 shaft (815-518) and quick-connect handle (836-010), turning counterclockwise until the plug has been removed. The pedicle screws may be removed using the Multi Axial Screwdriver (8680052). Fully engage the hex end of the screwdriver into the screw head, then thread the instrument sleeve into the screw head. Turn counterclockwise until the pedicle screws have been removed.
# Product Ordering Information

## M8 Multi Axial Screws

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## M8 Cases and Instruments

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## Additional Products

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### Low Profile CROSSLINK® Plate

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#### Cases and Instruments

| 125-166         | 125-166               | Modular Tray with Brackets | 1       |
| 115-166P        | 105-166P              | Modular Tray Lid Plate | 1       |
| 115-157         | 105-157               | Mini Module Container (Set Screws) | 1       |
| 115-150P        | 105-150P              | Tray Plate | 1       |
| 105-109         | 105-109               | Generic Lid | 1       |
| 125-128         | 125-128               | Implant Module Lid - CROSSLINK® Plates | 1       |
| 115-129         | 105-129               | Upper Implant Module | 1       |
| 115-130         | 105-130               | Lower Implant Module | 1       |
| 810-501         | 810-501               | Low Profile CROSSLINK® Plate Template | 1       |
| 810-510         | 810-510               | Low Profile CROSSLINK® Plate Holder | 2       |
| 810-525         | 810-525               | Low Profile CROSSLINK® Plate Benders | 2       |
| 803-900         | 803-900               | Hex Head Screwdriver | 1       |
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 configuration being made for the individual patient.

Certain implant components from other Medtronic Sofamor Danek spinal systems can be used with the CD Horizon® Spinal System. These components include TSFH® rods, hooks, screws, plates, CROSSLINK® plates, connectors, stapes and washers, GDLH™ rods, hooks, connectors and CROSSLINK® and connectors and CROSSLINK® CLASSIC bolts along with rod/bolt connectors; and Sofamor Danek Multi-Axial rods and screws. Please note that certain components are specifically designed to connect to ø5.5mm, ø4.5mm rods and ø3.5mm rods. When used as a pedicle screw system for patients with severe spondylolisthesis, dislocation, scoliosis, kyphosis, spinal tumor, and/or failed previous fusion (pseudarthrosis), care should be taken so that the correct components are used in the surgical 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, alloy, medical grade cobalt-chromium-molybdenum alloy, or medical grade PEK 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 MSD 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, alloy and/or medical grade cobalt-chromium-molybdenum alloy may be used together with 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, alloy and cobalt-chromium-molybdenum alloy. Do not use stainless steel.

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

To achieve best results, do not use any of the CD Horizon® Spinal System implant components with components from any other system or 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:
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; spondylolisthesis; 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® Spinal System components are intended for use in posterior fusion surgical procedures in skeletally mature patients only. The devices are not intended for use in anterior cervical discectomy and fusion, lateral lumbar interbody fusion, and pedicle splitting.

For hooks, when used as an anterior thoracic/lumbar system, the CD Horizon® system components such as ECLIPSE® components 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; spondylolisthesis; kyphosis; and/or lordosis; tumor; pseudarthrosis; and/or failed previous fusion.

The CD Horizon® Spinal System is intended for anterior, 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; spondylolisthesis; kyphosis; and/or lordosis; tumor; pseudarthrosis; and/or failed previous fusion.

For rods and associated components intended to be used as a pedicle screw system, the CD Horizon® Spinal System could include 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; spondylolisthesis; kyphosis; and/or lordosis; tumor; pseudarthrosis; and/or failed previous fusion.

In addition, when used as a pedicle screw fixation system, the CD Horizon® Spinal System can be used to provide immobilization and stabilization of spinal segments as an adjunct to fusion in the following acute and chronic instabilities of the thoracic, lumbar and sacral spine; degenerative spondylolisthesis; objective evidence of neurologic impairment, (2) kyphosis, and/or (3) failed previous fusion. Additionally, when used as a pedicle screw device, the CD Horizon® Spinal System PEAK rod constructs are intended for use in patients who: (1) are receiving fusion with autogenous bone graft only; (2) who are having the device attached to the lumbar and sacral spine; and/or (3) who 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. Contraindications include, but are not limited to:
   a. Active infectious process or significant risk of infection (immunocompromise).
   b. Significant risk of infection (immunocompromise).
   c. Any case not needing a bone graft and fusion.
   d. Any case where the implant components selected for use would be too large or too small to achieve a successful result.
   e. Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
   f. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
   g. Any patient unwilling to follow postoperative instructions.
   h. 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, causing skin irritation, pressure sores, and/or increased risk of infection.
5. Tissue or nerve damage caused by improper positioning and placement of implants or instruments.
6. Post-operative change in spinal curvature, loss of correction, height, and/or reduction.
7. Infection.
8. Dural tears, pseudomeningocele, fistula, persistent CSF leakage, meningitis.
9. Loss of neurological function (e.g., sensory and/or motor), including paralysis (complete or incomplete), dysesthesia, hypesthesia, anesthesia, paresthesia, appearance of radiculopathy, and/or the development or continuation of pain, numbness, neurona, spasms, sensory loss, tingling sensation, and/or visual deficits.
10. Cauda equina syndrome, neuropathy, neurologiacal defects (transient or permanent), paraplegia, paraparesis, reflex deficits, irritation, arachnoiditis, and/or muscle loss.
11. Urinary retention or loss of bladder control or other types of urological system compromise.
12. Sacral formation possibly causing neurological compromise or compression around nerves and/or pain.
13. Fracture, microfracture, resorption, damage, or penetration of any spinal bone (including the sacrum, pedicles, and a vertebral body) and/or the graft or bone graft harvest site at, above, and/or below the level of surgery.
14. Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery.
16. Cessation of any potential growth of the operated portion of the spine.
17. Loss of or increase in spinal mobility or function.
18. Inability to perform the activities of daily living.
19. Bone loss or decrease in bone density, possibly caused by stresses shielding.
20. Graft donor site complications including pain, fracture, or wound healing problems.
21. Ileus, gastriitis, bowel obstruction or loss of bowel control or other types of gastrointestinal system compromise.
22. Reproductive system compromise, including sterility, loss of consortual, 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, spondylolisthesis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis). The safety and effectiveness of use of this product with or 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.
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 crater-like fatigue and consequent breakage, bending or loosening of the device before the healing process is complete, which may result in further injury or the need to remove the device prematurely.

Device Fixation:

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

MEDTRONIC SOFAMOR DANEK CD HORIZON Spinal System instrumentation contains 3.5mm, 4.5mm, 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 9 Nm. (70 to 80 head part should not remain in the patient.

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

PREOPERATIVE:

1. Only patients that meet the criteria described in the indications should be selected.

2. Patient conditions and/or pre-dispositions such as those addressed in the aforementioned contraindica-

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 must be protected during stor-

4. An adequate inventory of implants should be available at the time of surgery, normally a quantity in ex-

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 com-

6. All components and instruments should be cleaned and sterilized before use. Additional sterile

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 pa-

3. The rods should not be repeatedly or excessively bent. The rods should not be reverse bent in the same

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 care-

6. Caution: Do not overlap or use a screw/bolt that is either too long or too large. Overlapping, using an

7. Bone graft must be placed in the area to be fused and graft material must extend from the upper to

8. To assure maximum stability, two or more CROSSLINK® plates or DTT Transverse Links on two bi-

9. Before closing the soft tissues, provisionally tighten (finger tighten) all of the nuts or screws, espe-

10. To allow the maximum chances for a successful surgical result, the patient or devices should not be

POSTOPERATIVE:

1. Detailed instructions on the use and limitations of the device should be given to the patient. If partial

2. To allow the maximum chances for a successful surgical result, the patient or devices should not be

3. The patient should be advised of their inability to bend or rotate at the point of spinal fusion and

4. Failure to immobilize a delayed or non-union of bone will result in excessive and repeated stresses on the

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. 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 to transfer or support forces developed during normal activities. If the device is not

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PRODUCT COMPLAINTS:

Any Health Care Professional (e.g., customer or user of this system of products), who has any com-

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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 judgement 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.