as described by:

Kevin T. Foley, M.D.
Baptist Hospital
Memphis, Tennessee

James D. Schwender, M.D.
Abbott Northwestern Hospital
Minneapolis, Minnesota

David P. Rouben, M.D.
Jewish Hospital Health Service
Louisville, Kentucky
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THE NEWEST INNOVATION IN UNILATERAL INTERBODY INSTRUMENTATION

- Designed for both an open and MAST TLIF approach.
- Smaller tip geometries for easier access and ability to more precisely prepare the disc space.
- Bayoneted instruments allow for better visualization for both minimal access or open surgical technique.
- Includes impacted or expanding distraction options for minimal access approach.
- Rubberized handles for increased comfort and tactile feel.
- Color coding by surgical step for easy identification of instruments.
**INSTRUMENT SET TECHNIQUE**

**Bony Exposure**
- Straight Osteotome
  - 9198120 – 1/4"
  - 9198125 – 1/2"
- Angled Osteotome
  - 9198130 – 1/4"
  - 9198135 – 1/2"

**Disc Removal & Endplate Preparation**
- Angled Ring Curette
  - 9198220 – Straight Hood
  - 9198221 – Angled Hood
  - 9198222 – Bent Hood
- Angled Cup Curette
  - 9198210 – Straight
  - 9198211 – Left
  - 9198212 – Right
- Box Chisel
  - 9198108 – 8mm
  - 9198110 – 10mm
  - 9198112 – 12mm
  - 9198114 – 14mm
- Rasp
  - 9198240
- Rotating Cutter
  - 9198270 – Straight
  - 9198271 – Curved

**Distractors**
- Impacted Distractor
  - 9198305 – 5mm
  - 9198306 – 6mm
  - 9198307 – 7mm
  - 9198308 – 8mm
  - 9198309 – 9mm
  - 9198310 – 10mm
  - 9198311 – 11mm
  - 9198312 – 12mm

**Graft Impactors**
- Straight Tamp
  - 9198260
- 9198251 – Angled Impactor
  - 9198250 – Straight Impactor

Incorporates technology developed by Gary K. Michelson, M.D.
Localize Anatomy

Identify and mark the midline. Approach marks should be made approximately 4.5 to 5.0cm on each side from the midline. Measurements may vary depending on patient body habitus.

Place a 22 gauge spinal needle at lateral mark on the side of the pathology. A spinal needle should be inserted and directed at the center of the facet inline with the disc space to insure proper trajectory.
Soft Tissue Dilation

Dilate the soft tissues to either a 22 or 26mm diameter using the METRx™ System. Insert the corresponding Radiance™ Illumination System.

View of Facet through METRx Tube

Fluoroscopy Showing Tube Placement
A facetectomy is performed on the ipsi-lateral side. Using an Osteotome or drill, remove the ascending and descending articular processes.

The facetectomy allows for improved visualization of the disc space and decompression of the neural elements.
Additional bony removal may be carried out for decompression at this time using a Kerrison Rongeur or drill. Use caution not to violate pedicle walls.
A 1cm square annulotomy is made with a scalpel in Kambin’s Triangle. Disc removal is initiated using a Pituitary Rongeur.

View through METRx™ Tube of disc space
Disc Removal Cont’d

Continue disc removal using either the Straight or Curved Rotating Cutters. The Rotating Cutters are blunt tipped and side cutting to improve safety.

A T-handle or a handheld power drill may be used for more efficient removal of disc.
Contra-lateral Instrumentation

Insert CD HORIZON® Cannulated M8 Multi-Axial Screws using the CD HORIZON® SEXTANT™ Rod Insertion System on the contra-lateral side to provide provisional distraction during disc space prep.

The METRx™ System may be used to identify pedicle landmarks prior to insertion of the screws, as well as provide access to perform a decompression and bone grafting for fusion.
Anatomical Restoration of Disc Space Height

Re-establish the disc space height by using either the Impacted Distractor or the Expanding Distractor.

Incorporates technology developed by Gary K. Michelson, M.D.
Endplate Preparation

Using various Curettes and Scrapers, remove the cartilaginous material from the disc space and the endplates.

Straight Curette
Endplate Preparation Cont’d

Specially designed angled instruments allow disc resection and endplate preparation on the contra-lateral side.

Continue preparation of the bony endplates using Curettes, Scrapers, and Rasp.

Cup Curette

Straight Ring Curette

Angled Serrated Curette

Rasp
Choose the appropriate size construct based on the use of the trial sizers.
Apply compression to the contra-lateral screws. Break off set screws to maintain compression on the interbody construct.
Insert Screw on the Ipsilateral Side

Ipsilateral instrumentation may be placed under direct visualization through the METRx™ Tube, or by removing the tube and using fluoro guidance. In either case, place guidewires into pedicles to allow utilization of the CD HORIZON® Sextant™ instrumentation for screw and rod placement.
METRx™ X-Tube Option

Open Technique Option
**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 (i.e., scoliosis, kyphosis and/or lordosis);
- Tumor; pseudarthrosis; and/or failed previous fusion.

**Contraindications:**

2. Loss of neurological function (e.g., sensory and/or motor), including paralysis (complete or partial).
3. Loss of neurological function (e.g., sensory and/or motor), including paralysis (complete or partial).
4. Traumatic or traumatic spinal injury.
5. Severe intraspinal abscess.
6. Spinal cord or nerve root compression.
7. Vertebral fracture or subluxation.
8. Spinal instability.
10. Suspected or documented metal allergy.
11. Any case where the implant components selected for use would be too large or too small to provide adequate fixation.
12. Any case where the implant components selected for use would be too large or too small to provide adequate fixation.
13. Any case where the implant components selected for use would be too large or too small to provide adequate fixation.
14. Any case where the implant components selected for use would be too large or too small to provide adequate fixation.
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:

- Early or late loosening of any or all of the components.
- Disassembly, bending, and/or breakage of any or all of the components.
- Foreign body (allergic) reaction to implants, corrosion products (from crevice, fretting, and/or general corrosion), including metallosis, staining, tumor formation, and/or autoimmune disease.
- Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant, possibly causing skin necrosis, infection, fibrosis, necrosis, and/or pain.
- Bursitis, Tissue or nerve damage caused by improper positioning and placement of implants or instruments.
- Post-operative change in spinal curvature, loss of correction, height, and/or reduction.
- Infection.
- Dural tears, pseudomeningocele, fistula, persistent CSF leakage, meningitis.
- Loss of neurological function (e.g., sensory and/or motor), including paralysis (complete or incomplete), dysesthesia, hypothermia, anesthesia, areflexia, appearance of radiculopathy, and/or the development or continuation of pain, numbness, neuroma, spasms, sensory loss, tingling sensation, and/or visual deficits.
- Cauda equina syndrome, neuropathy, neurological deficits (transient or permanent), paraesthesia, sensory deficits, itching, anaesthesia, and/or muscle weakness.
- Loss of fixation or loss of intervertebral or changes in pathological abnormal pathology.
- Scar formation possibly causing neurological compression or compression around nerves due to pain.
- 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. Repetitive graft.
- Herniated nucleus pulposus, disc disruption or degeneration at above, at, or below the level of surgery.
- Non-union (or pseudarthrosis). Delayed union. Mal-union.
- Cessation of any potential growth of the operated portion of the spine.
- Loss of or increase in spinal mobility or function.
- Inability to perform the activities of daily living.
- Bone loss or decrease in bone density, possibly caused by stress shielding.
- Graft donor site complications including pain, fracture, or wound healing problems.
- Illus, gastritis, bowel obstruction or loss of bowel control or other types of gastrointestinal system compromise.
- Hemorrhage, hematoma, occlusion, sepsis, edema, hyperesthesia, embolism, stroke, excessive bleeding, phlebitis, wound necrosis, and/or ulceration, damage to blood vessels, or other types of cardiovascular system compromise.
- Reproductive system compromise, including sterility, loss of consortium, and sexual dysfunction.
- Development of respiratory problems, e.g. pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.
- Change in mental status.
- 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 those spinal conditions with significant risk factors requiring spinal 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, disc herniation, kyphosis, scoliosis, kyphosis, and/or lordosis.

**PRECAUTION:** The implantation of pedicle screw spinal systems should be performed only by experienced spinal surgeons with specific training in the use of pedicle screw spinal instruments. This is 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. Failure to properly select and comprehend 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. This is because the wear that occurs at the bone-implant interface is the major factor in 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™ 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. 

PREOPERATIVE:

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

2. Preoperative 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 from damage and stored away 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 and should prepare the desired instruments before the operation 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 operating personnel.

3. The rods should not be repeatedly or excessively bent. The rods should not be reversed 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 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. Do not overlap or use a screw that is either too long or too large. Overlapping 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 vertebral body 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 consent form.

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) is complicated which may result in 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 jobs 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 limited 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, to avoid consuming alcohol or non-steroidal 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 position.

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 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 intramedullary 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 osteogenicis. 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 looser 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 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/or implant 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 alkaline-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 removed from 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 sterile field. Unless specified otherwise, all implants are recommended to be steam sterilized by the hospital using one of the three sets of process parameters below:

<table>
<thead>
<tr>
<th>METHOD</th>
<th>CYCLE</th>
<th>TEMPERATURE</th>
<th>EXPOSURE TIME</th>
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<tr>
<td>Steam</td>
<td>Pre-Vacuum</td>
<td>270°F (132°C)</td>
<td>4 Minutes</td>
</tr>
<tr>
<td>Steam</td>
<td>Gravity</td>
<td>290°F (143°C)</td>
<td>30 Minutes</td>
</tr>
<tr>
<td>Steam*</td>
<td>Gravity*</td>
<td>273°F (134°C)</td>
<td>20 Minutes*</td>
</tr>
</tbody>
</table>

Note: Because of the many variables involved in sterilization, each medical facility should calibrate and verify the sterilization process (e.g. temperatures, times) used for their equipment.

For outside the United States, some non-U.S. Health Care Authorities recommend sterilization according to these parameters so as to minimize the 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, 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 malfunction(s) (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 the implant or component ever malfunction(s) and have caused 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, your name and address, the nature of the complaint, and notification of whether a written report for the distributor is requested.

FURTHER INFORMATION:

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

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