As described by:
J. Kenneth Burkus, MD
Hughston Orthopaedic Hospital
Columbus, Georgia

Randall F. Dryer, MD
Central Texas Spine Institute
Austin, Texas

Richard A. Hynes, MD
The B.A.C.K Center
Melbourne, Florida

ZEPHIR® System incorporates technology developed by Gary K. Michelson, MD.
# PEEK PREVAIL™ Cervical Interbody Device

## Surgical Technique

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Instrument Set</td>
<td>2</td>
</tr>
<tr>
<td>Patient Positioning and Approach</td>
<td>3</td>
</tr>
<tr>
<td>Discectomy</td>
<td>4</td>
</tr>
<tr>
<td>Anterior Vertebral Body Preparation</td>
<td>5</td>
</tr>
<tr>
<td>Trialing and End-plate Preparation</td>
<td>6</td>
</tr>
<tr>
<td>Implant Placement</td>
<td>7</td>
</tr>
<tr>
<td>ZEPHIR® Anterior Cervical Screw Placement</td>
<td>9</td>
</tr>
<tr>
<td>Revision Tool</td>
<td>11</td>
</tr>
<tr>
<td>Explantation</td>
<td>12</td>
</tr>
<tr>
<td>Product Ordering Information</td>
<td>13</td>
</tr>
<tr>
<td>Important Product Information</td>
<td>14</td>
</tr>
</tbody>
</table>
Instrument Set

- Mallet: 6472061
- Awl: 6650165
- Threaded Inserter Outer: 1220777
- Threaded Inserter Shaft: 1220222
- Trasp: 5mm, 5220564; 6mm, 5220664; 7mm, 5220764; 8mm, 5220864; 9mm, 5220964
- Quad Drive Screwdriver: 1204444
- Flexdriver: 1209999
- Universal Handle: 6650250
- Revision Tool: 1201111
- Quad Driver Sleeve: 1206666
Patient Positioning and Approach

The patient is placed in the supine position with the head in slight extension. The mandible is tilted out of the surgical field. The posterior cervical spine is supported to establish and maintain normal lordosis. The surgeon selects a right- or left-sided approach to the cervical spine (Figure 1).

A transverse or oblique skin incision is made. A muscle-splitting approach is made to the spine through an avascular dissection plane. The strap muscles, trachea and esophagus are retracted medially, and the carotid sheath is retracted laterally. Hand-held retractors are used to provide initial exposure of the anterior vertebral column and the adjacent longus coli muscles (Figure 2). After the anterior longitudinal ligament, disc spaces and central portions of the vertebral bodies have been exposed, the longus coli muscles are subperiosteally elevated, and self-retaining retractor blades are securely positioned beneath them.

A slotted blade may be used if an anterior osteophyte prevents proper positioning. Longitudinal self-retaining retractors are then placed to provide visualization (Figure 3). A vertebral body distractor may also be used. The distraction pins are positioned midline in the vertebral bodies adjacent to the disc (Figure 4). The distractor is placed over the pins, and gentle distraction is applied.
Discectomy

Pituitaries, curettes, and thin-footed Kerrison rongeurs may be used to remove the disc material and cartilage to expose the posterior longitudinal ligament. A high-speed drill with a burr (match tip/round) may be used for removal of the posterior disc and osteophytes to achieve neural decompression (Figures 5a and 5b). The posterior longitudinal ligament and osteophytes are then carefully removed.
Anterior Vertebral Body Preparation

Once the discectomy is complete, a high-speed drill with a burr is used to carefully shape the inferior lip of the superior vertebral body and the superior lip of the inferior vertebral body to match the flanges found on both the trial and implant. This chamfer must be cut at an angle to allow each screw to be inserted at an angle into the vertebral bodies (Figure 6). It is important that the chamfer match the angle of the flange to ensure proper screw placement.
Trialing and End-plate Preparation

Once the decompression and anterior vertebral body preparation are completed, a PEEK PREVAIL™ Cervical Interbody Device size is determined by selecting the Trasp that provides the most satisfactory fit in the prepared disc space. The Trasp is a dual-purpose instrument with a Trial on one end and a Rasp on the other.

Final end-plate preparation is carried out with the Rasp. The Rasp creates a mortise for the PEEK PREVAIL™ Cervical Interbody Device. The Rasp will decorticate the end plates with minimal bone removal. Additionally, the Rasp will help ensure adequate end-plate preparation (Figure 7).

Confirm the implant size and height by reinserting the Trial head after using the Rasp head (Figure 8). Once the appropriate height is identified, choose the corresponding PEEK PREVAIL™ Cervical Interbody Device.

Helpful Hint

While the Trial is inserted, use fluoroscopy to ensure there are no visible gaps between the flange and bone.
Implant Placement

Select the appropriately sized implant that corresponds to the final Trasp used in the end-plate preparation step. Pack the implant with autograft and attach it to the Threaded Inserter (Figures 9a and 9b).
Implant Placement continued

The device should be oriented with the flanged surface positioned anteriorly (Figures 10a and 10b). It is important to ensure the implant is seated in the disc space as close to midline as possible (Figures 11a and 11b). This midline placement will facilitate proper insertion of the screws.
ZEPHIR® Anterior Cervical Screw Placement

Select the Self-Drilling Screw length that is most appropriate for the patient’s anatomy. Using a “stab-and-grab” Quad Drive Screwdriver, pick up the appropriate screw with the quad drive portion of the screwdriver shaft in the screw head (Figure 12). Before placing the screws, release the cephalad/caudal distraction. Insert each screw and stop right before it passes the Nitinol locking wire to ensure the implant remains centered. The screw should be inserted at a angle, perpendicular to the chamfered lip (Figure 13a). The Flexdriver can be used for screw insertion to accommodate a patient’s anatomy if needed (Figure 13b).

Prior to insertion of the screws, using the Awl is recommended to establish the trajectory and ensure proper placement of the screws.
With the screw in place, just above the Nitinol wire, tighten the screw to engage the locking mechanism (Figures 14a and 14b). Once the screw head passes the Nitinol wire, do not drive the screw further into the vertebral body. Only a quarter to a half turn is recommended. This will prevent the screws from stripping.

As the screw is inserted, the Nitinol locking wire will deflect and allow the screw to continue until fully inserted. When the screw head is seated, the Nitinol locking wire will retract over the head of the screw to prevent the screw from backing out. Repeat the screw insertion step to secure the final construct (Figure 15).

**Important**

Once the screw head passes the Nitinol wire, do not drive the screw further into the vertebral body. Only a quarter to a half turn is recommended.
Revision Tool

Removal of the screws from the PEEK PREVAIL™ Cervical Interbody Device can be accomplished using the Revision Tool. The "stab-and-grab" end of the Revision Tool is inserted into the head of the screw and rotated counterclockwise. The Revision Tool must be held flush against the head of the screw for it to work properly (Figure 16). Begin with the flat surface side of the Revision Tool oriented toward the Nitinol wire. As the Revision Tool is rotated, it will deflect the wire from the head of the screw and will allow the screw to be removed from the implant (Figures 17a and 17b). Once the head of the screw is past the Nitinol locking wire the screw can be removed with the Revision Tool or a standard screwdriver (Figure 18).
Explantation

Removal of the implant can be accomplished by using a high-speed burr to resect the implant. The implant can be removed by exposing the anterior surface of the implant and creating a clear plane around the implant by removing surrounding bone with a high-speed burr or osteotomes. Once the screws have been removed, the Threaded Inserter can be reattached to the implant, still intact, and removed with an in-line slap hammer.
## Product Ordering Information

### Implant Measurements

<table>
<thead>
<tr>
<th>Part Number</th>
<th>Posterior Height</th>
<th>Anterior Height</th>
<th>Inner Volume</th>
</tr>
</thead>
<tbody>
<tr>
<td>4210564</td>
<td>5mm</td>
<td>6mm</td>
<td>0.4cc</td>
</tr>
<tr>
<td>4210664</td>
<td>6mm</td>
<td>7mm</td>
<td>0.5cc</td>
</tr>
<tr>
<td>4210764</td>
<td>7mm</td>
<td>8mm</td>
<td>0.6cc</td>
</tr>
<tr>
<td>4210864</td>
<td>8mm</td>
<td>9mm</td>
<td>0.7cc</td>
</tr>
<tr>
<td>4210964</td>
<td>9mm</td>
<td>10mm</td>
<td>0.8cc</td>
</tr>
</tbody>
</table>

### Implant Set Configuration

**Set Type 2096**

<table>
<thead>
<tr>
<th>Part Number</th>
<th>Description</th>
<th>Qty.</th>
</tr>
</thead>
<tbody>
<tr>
<td>4210564</td>
<td>5mm × 16mm × 14mm</td>
<td>2</td>
</tr>
<tr>
<td>4210664</td>
<td>6mm × 16mm × 14mm</td>
<td>2</td>
</tr>
<tr>
<td>4210764</td>
<td>7mm × 16mm × 14mm</td>
<td>2</td>
</tr>
<tr>
<td>4210864</td>
<td>8mm × 16mm × 14mm</td>
<td>1</td>
</tr>
<tr>
<td>4210964</td>
<td>9mm × 16mm × 14mm</td>
<td>1</td>
</tr>
<tr>
<td>11000000</td>
<td>Implant Case</td>
<td>1</td>
</tr>
</tbody>
</table>

### Instrument Set Configuration

**Set Type 2125**

<table>
<thead>
<tr>
<th>Part Number</th>
<th>Description</th>
<th>Qty.</th>
</tr>
</thead>
<tbody>
<tr>
<td>5220564</td>
<td>5mm Trasp, 16mm × 14mm</td>
<td>1</td>
</tr>
<tr>
<td>5220664</td>
<td>6mm Trasp, 16mm × 14mm</td>
<td>1</td>
</tr>
<tr>
<td>5220764</td>
<td>7mm Trasp, 16mm × 14mm</td>
<td>1</td>
</tr>
<tr>
<td>5220864</td>
<td>8mm Trasp, 16mm × 14mm</td>
<td>1</td>
</tr>
<tr>
<td>5220964</td>
<td>9mm Trasp, 16mm × 14mm</td>
<td>1</td>
</tr>
<tr>
<td>1220777</td>
<td>Threaded Inserter Outer</td>
<td>1</td>
</tr>
<tr>
<td>1220222</td>
<td>Threaded Inserter Shaft</td>
<td>2</td>
</tr>
<tr>
<td>1209999</td>
<td>Flexdriver</td>
<td>1</td>
</tr>
<tr>
<td>1206666</td>
<td>Quad Driver Sleeve</td>
<td>2</td>
</tr>
<tr>
<td>1204444</td>
<td>Quad Drive Screwdriver</td>
<td>2</td>
</tr>
<tr>
<td>6650250</td>
<td>Universal Handle</td>
<td>2</td>
</tr>
<tr>
<td>8792811</td>
<td>3.5mm Self-Drilling ZEPHIR® System Screw, 11mm Length</td>
<td>6</td>
</tr>
<tr>
<td>8792813</td>
<td>3.5mm Self-Drilling ZEPHIR® System Screw, 13mm Length</td>
<td>6</td>
</tr>
<tr>
<td>8792815</td>
<td>3.5mm Self-Drilling ZEPHIR® System Screw, 15mm Length</td>
<td>6</td>
</tr>
<tr>
<td>8792911</td>
<td>4.0mm ZEPHIR® System Rescue Screw, 11mm Length</td>
<td>3</td>
</tr>
<tr>
<td>8792913</td>
<td>4.0mm ZEPHIR® System Rescue Screw, 13mm Length</td>
<td>3</td>
</tr>
<tr>
<td>8792915</td>
<td>4.0mm ZEPHIR® System Rescue Screw, 15mm Length</td>
<td>3</td>
</tr>
<tr>
<td>8797033</td>
<td>ZEPHIR® System Screw Caddy</td>
<td>1</td>
</tr>
<tr>
<td>1201111</td>
<td>Revision Tool</td>
<td>1</td>
</tr>
<tr>
<td>6650165</td>
<td>Awl</td>
<td>1</td>
</tr>
<tr>
<td>6472061</td>
<td>Mallet</td>
<td>1</td>
</tr>
<tr>
<td>1207777</td>
<td>Upper Tray</td>
<td>1</td>
</tr>
<tr>
<td>1850079</td>
<td>Instrument Lid</td>
<td>1</td>
</tr>
<tr>
<td>1850076</td>
<td>Instrument Base</td>
<td>1</td>
</tr>
</tbody>
</table>
Important Product Information

PURPOSE
The PEEK PREVAIL™ Cervical Interbody Device is indicated for anterior cervical interbody fusion procedures in skeletally mature patients with cervical disc disease at one level from the C2-C3 disc to the C7-T1 disc. This system is intended for single-level use only in the cervical and thoracic anterior spine.

DESCRIPTION
The PEEK PREVAIL™ Cervical Interbody Device is an intervertebral body fusion device with internal screw fixation. The screws protrude through the interbody portion of the device and stabilize the vertebral body while preventing expulsion of the implant. The implant is “T”-shaped with a 2 screw configuration. This device is intended to be radiculodisectomy and the anterior intervertebral portion of the body to be used with autograft.

The PEEK PREVAIL™ Cervical Interbody device implant is manufactured from PEEK OPTIMA™ carbon/carbon tantalum radiopaque markers and a fluted screw/locking mechanism. The screws used with this device (ZEPHIR™ Anterior Cervical Screws) are manufactured from Titanium Alloy.

Implanted Warranty of Mechatribility and Feasibility for a particular purpose or use are specifically included. See the Medtronic Catalog or prior list for further information about warranties and limitations of liability.

INDICATIONS
The PEEK PREVAIL™ Cervical Interbody Device is indicated for anterior cervical interbody fusion procedures in skeletally mature patients with cervical disc disease at one level from the C2-C3 disc to the C7-T1 disc. Cervical disc disease is defined as intratable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. The PEEK PREVAIL™ Cervical Interbody Device must be used with internal screw fixation provided by ZEPHIR™ Anterior Cervical Screws. The PEEK PREVAIL™ Cervical Interbody Device implants are to be used with autograft and implanted via an open, anterior approach.

This device is to be used in patients who have had six or more of non-operative treatment.

CONTRAINDICATIONS
The PEEK PREVAIL™ Cervical Interbody device is not intended for posterior surgical implantation.

Contraindications include, but are not limited to:
1. Any case needing to mix metals from different components.
2. Any case not described in the indications.
3. Any medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors or congenital abnormalities, elevation of sedentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count.
4. Any patient having inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition.
5. Any patient unwilling to co-operate with postoperative instructions.
6. Fever or local infection.
7. Infection local to the operative site.
8. Mental illness.
10. Rapid postoperative, bone absorption, osteopenia, and/or osteoporosis. Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction and/or the amount of mechanical fixation.
11. Signs of local inflammation.
12. Suspected or documented metal allergy or intolerance.

These devices must not be used for pediatric cases, nor where the patient still has general skeletal growth.

Contraindication of this device are consistent with those of other spinal systems.

POTENTIAL ADVERSE EVENTS
All of the possible adverse events or complications associated with spinal fusion surgery without instrumentation are expected to be used.

Contraindications in all of the possible adverse events or complications include, but is not limited to:
1. Bone los or decrease in bone density, possibly caused by stress shielding.
2. Guaquilae syndrome, neupathy, neurogenic deficits (transient or permanent), paraesthesia, paraplegia, reflex defects, anechodochial, and/or muscle loss.
3. Cessation of any potential growth of the operated portion of the spine. Loss of spinal mobility or function. Inability to perform the activities of daily living.
4. Change in mental status.
5. Death.
6. Development of respiratory problems, e.g., pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.
7. Asymmetry, bending, and/or breakage of any of all of the components.
8. Dental leaks, pseudomucous, fistula, persistent CSF leakage, malignity.
9. Early or late loosening of the components. Implant migration.
10. Foreign body (calcium) reaction to the implants, debris, Foreign products, including metalloids, staining, tumor formation and/or autoimmune disease.
11. Fracture, metal, reaction, permeation, and/or separation of any spinal bone of the autofautograft or, in the bone-graft harvest site at, above, and/or below the level of surgery.
13. Graft donor site complications including pain, fracture, infection, or wound healing problems.
14. Hemorrhage, hematoma, occlusion, venous, arterial, embolus, stroke, excessive bleeding, phlebitis, damage to blood vessels, or cardiovascular system compromise. Wound necrosis or wound dehiscence.
15. Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery.
17. Loss of neurological function, including paralysis (complete or incomplete), dysesthesia, hyperesthesia, anesthesia, paresthesia, and/or development or continuation of pain, numbness, tingling sensation, sensory loss and/or paresis.
19. Postoperative change in spinal curvature, loss of correction, height, and/or reduction.
20. Sore formation possibly causing neurological compromise around nerves and/or pain.
21. Subsidence of the device into vertebral body(s).

22. Tissue or nerve damage, irritation, and/or pain caused by improper positioning and placement of implants or instrumentation.

NOTE: Additional surgery may be necessary to correct some of these anticipated adverse events.

WATERMARKS
A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery where other patient conditions may compromise the result. The PEEK PREVAIL™ Cervical Interbody Device must be used with the ZEPHIR™ Anterior Cervical Screws to augment stability. Use of this product without autograft may not be successful. This implant can withstand body loads without the support of bone. In this event, bending, loosening, disassembly and/or breakage of the device is likely to eventually occur.

Preoperative and operating procedures, including knowledge of surgical techniques, proper selection and placement of the implant and good judgment are important considerations in the success of surgery. Never more an internal fusion device under any circumstance. Even when a removed device appears undamaged, it may have small defects in internal stress patterns that may lead to early breakage. Damage of the thread will reduce the stability of the instrumentation.

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.

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

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

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. Plastic polymer implants are subject to repeated stressors in use, and their strength is limited by the need to adapt the design to the size and shape of human bone. Unless great care is taken in patient selection, proper placement of the implant, and postoperative management to maximize stress on the implant, such stressors may cause material 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.

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 damaged. Implants and instruments should be protected during storage especially from aqueous environments.
4. Further information on the system will be made available on request.
5. Since mechanical parts are involved, the surgeon should be familiar with the various components before using the equipment and should personally assemble the device to verify that all parts and necessary instruments are present before the surgery begins.
6. The type of construct to be assembled for the case should be determined prior to beginning the surgery. An adequate inventory of implant kits should be available at the time of surgery, including sizes larger and smaller than those expected to be used.
7. Unless sterile packaged, all parts should be cleaned and sterilized before use. Additional sterile components should be available in case of an unexpected need.

INTRAOPERATIVE
1. The instructions in any available applicable surgical technique manual should be carefully followed.
2. At all times, extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological function.
3. Breakage, leakage, or misuse of instruments or implant components may cause injury to the patient or operative personnel.
4. To assure proper fusion below and around the location of the instrumentation, autograft should be used. Autograft must be placed in the area to be fused and the graft material must extend from the upper to the lower vertebrae being fused. When using the PEEK PREVAIL™ Cervical interbody device, autograft should be used.
5. Bone cement should not be used since 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.

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. When partial weight bearing is recommended or required prior to firm bony union, the patient must be warned that bending, loading or breakage of the device are complications which can occur as a result of excessive 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, demented or otherwise unable to use crutches or other weight supporting devices. The patient should be warned to avoid falls or sudden jolts in spinal position.
2. To avoid the maximum chances for a successful surgical result; the patient or device should not be exposed to mechanical situations 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 or consume alcohol during the bone healing process.
3. The patient should be advised of their inability to bend at the point of spinal fusion and taught to compensate for this.

PACKAGING
Packaging for each of the components should be intact upon receipt. If a laser 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 decontaminating 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

The contents of the implant package for the PEEK PREVAIL™ Cervical Interbody Device are provided sterile via gamma irradiation. The ZEPHIR® Anterior Cervical Screws and general instruments used with the PEEK PREVAIL™ Cervical Interbody Device are provided non-sterile.

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 one of the sets of process parameters below:

<table>
<thead>
<tr>
<th>METHOD</th>
<th>CYCLE</th>
<th>TEMPERATURE (°F)</th>
<th>EXPOSURE TIME</th>
</tr>
</thead>
<tbody>
<tr>
<td>Steam</td>
<td>Pre-Vacuum</td>
<td>270°F (132°C)</td>
<td>60 Minutes</td>
</tr>
<tr>
<td>Steam*</td>
<td>Pre-Vacuum*</td>
<td>273°F (134°C)*</td>
<td>20 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., temperature, 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 material prior to sterilization. Only sterile implants and instruments should be used in surgery. No implant should be re-used once it comes into contact with human tissue or body fluid. Always immediately clean and re-sterilize instruments that have been used in surgery. This process must be performed before handling or (if applicable) returning to Medtronic.

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 or 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.

FURTHER INFORMATION

Recommended directions for use of this system (surgical operative techniques) are available at no charge upon request. If further information is needed or required, please contact Medtronic.

Medtronic B.V.
Earl Bakkenstraat 10
6229 EZ Heerlen
The Netherlands
Tel: +31 45 566 80 00
Fax: +31 45 566 80 50

Medtronic Sofamor Danek USA, Inc.
1800 Pyramid Place
Memphis, TN 38132
Telephone 800 933 2635 (In U.S.A.)
901 396 3133 (Outside of U.S.A.)
Fax 901 396 0356

Please contact Customer Service or your Sales Representative for the most up-to-date package insert.

©2009 MEDTRONIC SOFAMOR DANEK USA, Inc. All rights reserved.
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 acrylic 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 been 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 Customer Service for instructions. Any available surgical techniques will be provided on request.

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 slicing. 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. In an ideal 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 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 or an authorized Medtronic repair representative. Implanted warranties of merchantability and fitness for a particular purpose are specifically excluded. See the Medtronic catalog for further information about warranties and limitations of liability. DO NOT INFLAT THE INSTRUMENTS.

POSSIBLE ADVERSE EFFECTS:
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 rod or plate shrapnel or bone shaves, 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 with proper bending equipment, and should be performed gradually and with great care to avoid notching or scratching the device.

Cleaning and Decontamination:
Medtronic instruments may be supplied as either 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. Unless labeled for single use, this instrument may be re-used. Instruments 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. All packaging material prior to sterilization. Only sterile implants and instruments should be in use. 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.

EXAMINATION:
Instruments must always be examined by the use 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, pivot, axle, 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.

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

Stereotaxic instruments such as for implantation, removal, template, 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:
Medtronic instruments may be supplied as either 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. Unless labeled for single use, this instrument may be re-used. Instruments 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. All packaging material prior to sterilization. Only sterile implants and instruments should be in use. 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.

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

For the best results, the same type of Medtronic instruments as used for implantation should be used for implant removal purposes. Various sizes of screwdrivers are available to adapt to the removal drive size 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 implant. 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 implant.

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

Surgical Technique

For the best results, the same type of Medtronic instruments as used for implantation should be used for implant removal purposes. Various sizes of screwdrivers are available to adapt to the removal drive size 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 implant. 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 implant.

FURTHER INFORMATION:
In case of complaint, or for supplementary information, please contact Medtronic.

PRODUCT COMPLAINT:
All Health Care Professionals (e.g., customer users of Medtronic 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. Further, any instrument ‘‘malfunction”, i.e., it 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 should be notified immediately. If any Medtronic product ever ‘‘malfunctions” and may have contributed or caused to the death or serious injury of a patient, the distributor or Medtronic should be notified as soon as possible by telephone, fax or written correspondence. When filling a complaint, please provide the component(s) name and number, lot number(s), your name and address, and the nature of the complaint.

USE FOR US Audiences Only

Medtronic B.V.

1000 Pyramid Place
Memphis, TN 38132

Telephone: 800 876 3133 (In U.S.A.)
901 396 3133 (Outside of U.S.A.)
Fax: 901 396 0316

Please contact Customer Service or your Sales Representative for the most up-to-date package insert.

©2009 MEDTRONIC SAPIER DANEK USA, Inc. All rights reserved.
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 important medical information.