# CAPSTONE® PEEK Spinal System

## Surgical Technique

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Implant and Instrument Set Features</td>
<td>2</td>
</tr>
<tr>
<td>Instrument Set</td>
<td>3</td>
</tr>
<tr>
<td>X-ray Marker Location</td>
<td>4</td>
</tr>
<tr>
<td>Implant Sizing</td>
<td>5</td>
</tr>
<tr>
<td>TLIF: Open and MAST™ Techniques</td>
<td></td>
</tr>
<tr>
<td>Laminotomy and Facetectomy</td>
<td>7</td>
</tr>
<tr>
<td>Disc Space Preparation</td>
<td>8</td>
</tr>
<tr>
<td>Distraction</td>
<td>9</td>
</tr>
<tr>
<td>End-plate Preparation</td>
<td>10</td>
</tr>
<tr>
<td>Trial Insertion</td>
<td>11</td>
</tr>
<tr>
<td>CAPSTONE® PEEK Interbody Spacer Insertion</td>
<td>12</td>
</tr>
<tr>
<td>Final Placement</td>
<td>13</td>
</tr>
<tr>
<td>Navigation and Neuromonitoring Options</td>
<td>14</td>
</tr>
<tr>
<td>Additional Fixation Options</td>
<td>15</td>
</tr>
<tr>
<td>Explantation</td>
<td>15</td>
</tr>
<tr>
<td>PLIF: Open and MAST™ Techniques</td>
<td></td>
</tr>
<tr>
<td>Laminotomy and Facetectomy</td>
<td>17</td>
</tr>
<tr>
<td>Disc Space Preparation</td>
<td>18</td>
</tr>
<tr>
<td>Distraction</td>
<td>19</td>
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<td>22</td>
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<td>23</td>
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<td>Navigation and Neuromonitoring Options</td>
<td>24</td>
</tr>
<tr>
<td>Additional Fixation Options</td>
<td>25</td>
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<td>25</td>
</tr>
<tr>
<td>Product Ordering Information</td>
<td>26</td>
</tr>
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<td>Important Product Information</td>
<td>27</td>
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</table>
Implant and Instrument Set Features

Implant Set Features

» Self-distracting, bulleted tip
» Convex-shaped Implants are designed to fit patient anatomy and to allow more accurate sizing
» Teeth on the surface reduce likelihood of expulsion

Instrument Set Features

» Posterior Lumbar Interbody Fusion (PLIF) or Transforaminal Lumbar Interbody Fusion (TLIF) procedural solutions combining CAPSTONE® Instrument Set, Posterior Microscope Instrument (PMI) Set, SCISSOR JACK™ Distractor, METRx® System, CD HORIZON® Sextant® II Rod Insertion System, PYRAMETRIX® Advance Instrument Set or the CD HORIZON® ENGAGE™ Spinal System
» Distractor/Trials are designed with bullet-tip shape for self-distraction and ease of insertion
» Convex-shaped Trials are designed to fit patient anatomy and to allow more accurate sizing
» Compatible with open, mini-open, or MAST™ technique approaches
Instrument Set

Distractor/Trial
2980822

Distractor/Trial
2981032

Threaded Inserter
2980001

Slap Hammer
9074002
X-ray Marker Location

Below are diagrams demonstrating the location of the x-ray markers as the view is rotated from a lateral to a straight AP view.


## Implant Sizing

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Width = 10mm
TLIF: Open and MAST™ Techniques
Laminotomy and Facetectomy

A facetectomy is performed on the ipsilateral side. Using an osteotome or drill, remove the ascending and descending articular processes.

Additional bony removal may be carried out using a Kerrison rongeur or drill.

A 1cm-square annulotomy is made with a scalpel in Kambin’s triangle. The disc is removed using a pituitary rongeur and curettes.

The main goal of this step is to remove extruded fragments, decompress neural elements and provide entry into the disc space for distraction, with minimal or no nerve root retraction. If there is significant disc space collapse, a complete discectomy may not be possible until disc space distraction is complete.
Disc Space Preparation

Open TLIF Technique

Remove disc using the Rotate Cutter. The instruments are blunt tipped and side cutting for safety.

MAST™ TLIF Technique
Distraction

Open TLIF Technique

The disc space is sequentially distracted with a Distractor/Trial or the SCISSOR JACK™ Distractor until adequate disc space height is obtained and adequate foraminal size is restored.

If the SCISSOR JACK™ Distractor is used, insert the distractor with the curved sides touching the end plates and expand the distractor until the desired height is obtained.

Insert supplemental screw and rod fixation on the contralateral side to maintain distraction during disc space preparation and provisionally tighten the construct.

MAST™ TLIF Technique
End-plate Preparation

Open TLIF Technique

Specifically designed angled instruments allow disc resection and end-plate preparation.

MAST™ TLIF Technique
Trial Insertion

Open TLIF Technique

Insert the Distractor/Trial until the desired disc space height is established. Use AP and lateral fluoroscopy to confirm proper placement and trajectory.

AP View

MAST™ TLIF Technique
CAPSTONE® PEEK Interbody Spacer Insertion

Open TLIF Technique

The appropriately sized CAPSTONE® PEEK Interbody Spacer is chosen during the trialing step and is firmly attached to the Inserter.

Before inserting the interbody spacer, place autograft anteriorly and contralaterally, or in the interbody spacer central cavity.

Gently impact the CAPSTONE® PEEK Interbody Spacer until it is 3mm to 4mm below the posterior margin of the annulus.

Care should be taken to ensure the interbody spacer is aligned properly.

MAST™ TLIF Technique
Final Placement

Open TLIF Technique

After the CAPSTONE® PEEK Interbody Spacer is placed, the contralateral screw-rod construct is compressed to preload the interspace and restore lordosis. The extradural space and foramina are probed to ensure adequate decompression of the neural elements.

To facilitate satisfactory immobilization of the grafted interspace, segmental fixation is applied ipsilaterally using the standard technique.
Navigation and Neuromonitoring Options

**Navigation Option**

The FluoroNav® MAST™ Spinal Procedural Solution can provide assistance with pedicle navigation. An additional module containing all of the necessary attachments is required for using the FLUORONAV® MAST™ Spinal Procedural Solution.

**Neuromonitoring Option**

For neuromonitoring, a NIM PAK Needle or Pedicle Probe may be used to access the pedicle. Triggered EMG monitoring can be performed during advancement of the needle into the pedicle to ensure proper placement.
Additional Fixation Options and Explanations

The CD HORIZON® LEGACY™ System Set Screws (plugs) may be removed using the T27 Obturator and the Self-Retaining Breakoff Driver. The T27 Obturator is inserted into the working end of the Self-Retaining Breakoff Driver so that the knurled portion of the T27 Obturator is flush with the driver. Insert the T27 Obturator tip through the Counter Torque, which should be seated on the screw, and into the plug, turning counterclockwise until the plug has been removed. The pedicle screws may be removed using either the multi-axial Screwdriver or the Self-Retaining Screwdriver in connection with the Ratcheting Handle. First, attach the Ratcheting Handle to the modular end of the driver. Next, fully engage the hex end of the Screwdriver into the screw head, then, if using the multi-axial screwdriver, thread the instrument sleeve into the screw head. Turn counterclockwise until the pedicle screws have been removed.

If removal of a CD HORIZON® X10 CROSSLINK® MULTI-SPAN® Plate is necessary, place the 7/₃₂” torque-limiting set screwdriver over the midline nut and turn counterclockwise to loosen. Place the 3.0mm Hex Head Shaft Removal Driver into a standard Medtronic Quick Connect Handle. Place the tip of the 3.0mm Internal Hex Screwdriver into the set screw and confirm that the 3.0mm tip is completely inserted and seated in the set screw so that the tip does not strip the hex. Turn the screwdriver counter-clockwise to loosen the set screw from the rod.

The CAPSTONE® PEEK Interbody Spacer may be removed by using the Threaded Inserter. Attach the Threaded Inserter to the interbody spacer and remove the spacer from the disc space. If greater force is needed, place the Slap Plate in the space between the impaction cap and the thumbwheel on the Inserter. Gently impact the slap plate to remove the implant.

Distraction and bone removal may also be required before the interbody spacer can be removed with the Threaded Inserter.

*Refer to the package insert for the fixation used.
PLIF: Open and MAST™ Techniques
**Laminotomy and Facetectomy**

A conventional discectomy is performed by incising the annulus with a 15-scalpel blade lateral to the dural sac.

This is done bilaterally and soft fragments are then removed from the intradiscal space or extruded fragments are then removed with disc rongeurs in a conventional fashion.

The main goal of this step is to remove extruded fragments, decompress neural elements and provide entry to the disc space for distraction with minimal or no nerve root retraction. If there is significant disc space collapse, a complete discectomy may not be possible until disc space distraction is accomplished.
Disc Space Preparation

Open PLIF Technique

With the Distractor/Trial secured in the disc space, remove the disc using the Rotate Cutters and/or Shavers. The instruments are blunt tipped and side cutting for safety.
Distraction

Open PLIF Technique

The disc space is sequentially distracted with the Distractor/Trial or the SCISSOR JACK™ Distractor until the original disc space height is obtained and the normal foraminal opening is restored.

If the SCISSOR JACK™ Distractor is used, insert the distractors with the curved sides touching the end plates and expand the distractors until the desired height is obtained.

Note

When two SCISSOR JACK™ Expandable Distractors are used in this approach, position the horizontal bars perpendicular to the disc space to ensure they do not interfere with one another.

MAST™ PLIF Technique
The remaining soft tissue or cartilaginous end plate is removed with vigorous scraping or curettage. Scrape medially under the midline and gradually work laterally in a sweeping motion until both caudal and cephalad end plates are cleared of soft tissue. The removal of the soft tissue from the end plate surface allows for graft incorporation.
**Trial Inserter**

Insert the trials until the desired disc space height is established. A Slap Hammer can be used for trial removal.

**Open PLIF Technique**

**MAST™ PLIF Technique**
CAPSTONE® PEEK Interbody Spacer Insertion

Open PLIF Technique

The appropriately sized CAPSTONE® PEEK Interbody Spacer is chosen during the trialing step and is firmly attached to the Inserter.

Before inserting the interbody spacer, place autograft anteriorly.

Gently impact the CAPSTONE® PEEK Interbody Spacer until it is 3mm to 4mm below the posterior margin of the annulus.

Care should be taken to ensure the interbody spacer is aligned properly.

MAST™ PLIF Technique
Final Placement

Open PLIF Technique

After the CAPSTONE® PEEK Interbody Spacer is placed, the extradural space and foramina are probed to ensure adequate decompression of the neural elements.

To facilitate satisfactory immobilization of the grafted interspace, segmental fixation is applied using the standard technique.

MAST™ PLIF Technique
Navigation and Neuromonitoring Options

Navigation Option
The FLUORONAV® MAST™ Spinal Procedural Solution can provide assistance with pedicle navigation. An additional module containing all of the necessary attachments is required for using the FluoroNav® MAST™ Spinal Procedural Solution.

Navigation Option
For neuromonitoring, a NIM PAK Needle or Pedicle Probe may be used to access the pedicle. Triggered EMG monitoring can be performed during advancement of the needle into the pedicle to ensure proper placement.
Additional Fixation Options and Explanations

The CD HORIZON® LEGACY™ System Set Screws (plugs) may be removed using the T27 Obturator and the Self-Retaining Breakoff Driver. The T27 Obturator is inserted into the working end of the Self-Retaining Breakoff Driver so that the knurled portion of the T27 Obturator is flush with the driver. Insert the T27 Obturator tip through the Counter Torque, which should be seated on the screw, and into the plug, turning counterclockwise until the plug has been removed. The pedicle screws may be removed using either the multi-axial Screwdriver or the Self-Retaining Screwdriver in connection with the Ratcheting Handle. First, attach the Ratcheting Handle to the modular end of the driver. Next, fully engage the hex end of the Screwdriver into the screw head, then, if using the multi-axial screwdriver, thread the instrument sleeve into the screw head. Turn counterclockwise until the pedicle screws have been removed.

If removal of an CD HORIZON® X10 CROSSLINK® MULTI-SPAN® Plate is necessary, place the 7/₃₂"" Torque-Limiting Set Screwdriver over the midline nut and turn counterclockwise to loosen. Place the 3.0mm Hex Head Shaft Removal Driver into a standard Medtronic Quick Connect Handle. Place the tip of the 3.0mm Internal Hex Screwdriver into the set screw and confirm that the 3.0mm tip is completely inserted and seated in the set screw so that the tip does not strip the hex. Turn the screwdriver counter-clockwise to loosen the set screw from the rod.

The CAPSTONE® PEEK Interbody Spacer may be removed by using the Threaded Inserter. Attach the Threaded Inserter to the interbody spacer and remove the spacer from the disc space. If greater force is needed, place the Slap Plate in the space between the impaction cap and the thumbwheel on the Inserter. Gently impact the slap plate to remove the implant.

Distraction and bone removal may also be required before the interbody spacer can be removed with the Threaded Inserter.

*Refer to the package insert for the fixation used.*
## Product Ordering Information

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CD HORIZON® Spinal System

PURPOSE
The CD HORIZON® Spinal System is intended to help provide immobilization and stabilization of spinal segments as an adjacent 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 TSPR® Rods, Screws, Plates, CROSSLINK® Plates, Connectors, CROSSLINK® Rods, Hooks, Connectors and Washer, 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 spine construct.

CD HORIZON® Holes are intended for posterior use only. CD HORIZON® and CD HORIZON® ECLIPS® Connectors and associated screws are intended for anterior use only. However, for patients of smaller stature, CD HORIZON® 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-LT. 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 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 Nitinol – (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 7% flaxament 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-LT® 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® instruments are intended for posterior, 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); spondylothesis; trauma (i.e., fracture or dislocation); spinal stenosis; lordosis; tumor; pseudarthrosis; and/or failed previous fusion.

CD HORIZON® DRAG™ Plates are posterior, non-pedicle supplemental fixation device intended for use in the non-cervical spine (T1-S1). It is intended for use as a plate fixation/attachment to spinous processes for the purpose of achieving supplemental fusion in the following conditions: degenerative disc disease (as previously defined); spondylothesis; 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 adjacent to fusion in the treatment of the degenerative spondylothesis 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 to either the lumbar or sacral spine; and/or are having the device removed after the development of a solid fusion mass.

CD HORIZON® Spinal System Rods and associated components may be used for the following indications of use:

1. Scoliosis.
2. Kyphosis.
3. Spondylolisthesis.
4. Degenerative disc disease.
5. Cervical, thoracic, and/or lumbar instability.
6. Infection.
7. Partial spondylolysis.
8. Painful spondylolisthesis.
10. Degenerative disc disease.

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 infection.
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 unrelated by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential.
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 physiologic performance.
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 Effects
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. Burns. 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, pseudomeningocoele, fistula, persistent CSF leakage, menin gitis.
8. Loss of neurological function (e.g., sensory and/or motor), including paralysis (complete or incom‐ plete), dysesthesia, hyperesthesia, paresthesia, hypotension, appearance of symptoms, and/or paralysis, and/or the development or continuation of pain, numbness, neuroma, spasm, sensory loss, tingling sensation, and/or psychological 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. Deep vein thrombosis possibly causing neurovascular compromise or compression around nerves and/or pain.
12. Fracture, microfracture, resorption, damage, or penetration of any spinal bone (including the sacrum, pedicle, 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.
15. Cessation of any potential growth of the operated portion of the spine.
16. Loss or occurrence 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, ecchymosis, ecchymosis, edema, hypertensive, 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.

Warnings
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 spondylothesis 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 everyday 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 result. 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 deviate from a non-union will not be successful. No spinal implant can withstand body loads without the support of bone. In this event, bending, 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 success of the surgery. 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 also smokers are also poor candidates for spine fusion. Patients with poor bone and muscle quality and/or vascular and neurologic problems are also poor candidates for spine fusion.

Physician Note
Although the physician is the learned intermediary between the company and the patient, patients and their family and/or personal support system should be made aware of the important medical information given in this document should be conveyed to the patient.
IMPLANT SELECTION

The selection of the proper size, shape and design of the implant for each patient is crucial to the success of the surgery. The 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, placement of this implant postoperative management to minimize stresses on the implant, such stresses may cause metal fatigue and consequent breakage, bending or loosening of the device. Therefore, 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. The device consists of two sections, the lower vertebrae being fused. In cases where a percutaneous posterior approach is used refer to the CD HORIZON® Spinal System components (described in the DESCRIPTION section) are not to be combined with the components from another manufacturer.

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2. Breakage of the device, which could make necessary removal difficult or sometimes impossible, with other complications to the patient and/or hospital staff may include, but are not limited to:

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

3. Regularly review the operational state of all instruments and if necessary make use of repair and replacement services.

4. Damage due to spontaneous release of clamping devices or spring mechanisms of certain instruments.

5. Cutting of skin or gloves of operating staff.

6. Dural leaks 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 could 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 frailty 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 surgeons require the use of instruments which incorporate a measuring function. Ensure that these are not worn, that any surface engravings are clearly visible.

PACKAGING

MEDITRONIC 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 MEDITRONIC SOFAMOR DANEK.

CLEANING AND DECONTAMINATION

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

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 one of the sets of process parameters below:

```plaintext
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.

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.
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.

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

PRODUCT COMPLAINTS
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.

FOR FURTHER INFORMATION:
Medtronic B.V.
Earl Bakkenstraat 10
6422 P.J Heerlen
The Netherlands
Tel: +31 45 566 80 00

Medtronic Sofamor Danek USA, Inc.
1800 Pyramid Place
Memphis, TN 38132
Telephone 800 876 3133 (In U.S.A.)
901 396 3133 (Outside of U.S.A.)
FAX 901 396 0356

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Contact Customer Service or your Sales Representative for the most up-to-date version of the package insert.
The CAPSTONE® Spinal System consists of PEEK cages of various widths and heights, which can be inserted between two lumbar or lumbosacral vertebral bodies to give support and correction during lumbar interbody fusion surgeries. The hollow geometry of the implants allows them to be packed with autogenous bone graft. No warrants, express or implied, are made. Implied warranties of merchantability and fitness for a particular purpose or use are specifically excluded. See the MDT Catalog or price list for further information about warranties and limitations of liability.

INDICATIONS
The CAPSTONE® Spinal System is indicated for use with autogenous bone graft in patients with degenerative disc disease (DDD) at one or two levels from L2 to S1. These DDD patients may also have up to Grade I Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. These implants may be implanted via an open or a minimally invasive posterior approach. Alternatively, these implants may also be implant ed via an anterior and/or transforminal approach. These implants are to be used with autogenous bone graft. These devices are intended to be used with supplemental fixation instrumentation, which has been cleared by the FDA for use in the lumbar spine.

CONTRAINDICATIONS
This device is not intended for cervical spine use. Contraindications include, but are not limited to:

- Infection, local to the operative site
- Signs of local inflammation
- Fever or leukocytosis
- Morbid obesity
- Pregnancy
- Mental illness
- Any other condition which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors or congenital abnormalities, fracture local to the operative site, or elevation of segmentation rate unexplainable by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count.
- Suspected or documented allergy or intolerance to composite materials.
- Any case not needing a fusion
- Any case not described in the indications
- Any patient unwilling to cooperate with postoperative instructions
- Patients with a known hereditary or acquired bone fragility or calcification problem should not be considered for this type of surgery.
- These devices must not be used for pediatric cases, nor where the patient still has general skeletal growth.
- Spondylolisthesis unable to be reduced to Grade 1.
- Any case where the implant components selected for use would be too large or too small to achieve a successful result.
- Any case that requires the mixing of metals from two different components or systems.
- Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
- Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.
- Prior fusion at the level to be treated.

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

- Severe bone resorption
- Osteomalacia
- Severe osteoporosis

POSSIBLE ADVERSE EVENTS
Adverse effects may occur when the device is used either with or without associated instrumentation. The potential risk of adverse effects as a result of movement and non-stabilization may increase in cases where associated complementary support is not employed. Potential adverse events include but are not limited to:

1. Implant migration
2. Breakage of the device(s)
3. Foreign body reaction to the implants including possible tumor formation, auto immune disease, and/or scarring
4. Pressure on the surrounding tissues or organs.
5. Loss of proper spinal curvature, correction, height, and/or reduction.
6. Infection
7. Bone fracture or stress shielding at, above, or below the level of surgery
8. Non-union (or pseudoarthrosis)
9. Loss of neurological function, appearance of radiculopathy, dural tears, and/or development of pain. Neurovascular compromise including paralysis temporary or permanent retrograde ejaculation in males, or other types of serious injury. Cerebral spinal fluid leakage
10. Haemorrhage of blood vessels and/or hematomas
11. Discitis, arachnoiditis, and/or other types of inflammation
12. Deep venous thrombosis, thrombophlebitis, and/or pulmonary embolus
13. Bone graft donor site complications
15. Early or late loosening or movement of the device(s)
16. Urinary retention or loss of bladder control or other types of urological system compromise.
17. Scar formation possibly causing neurological compromise or compression around nerves and/or pain.
18. 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: Retrophused graft.
19. Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery.
20. Loss of or increase in spinal mobility or function.
21. Reproductive system compromise, including sterility, loss of consortium, and sexual dysfunction.
22. Development of respiratory problems, e.g. pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.
23. Change in mental status.
24. Cessation of any potential growth of the operated portion of the spine.
25. Death.

WARNINGS AND PRECAUTIONS
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 results. Use of this product without bone graft of in cases that do not develop a union will not be successful.

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

Patients with previous spinal surgery at the levels to be treated may have different clinical outcomes compared to those with a previous surgery.

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.

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. Surgical implants are subject to repeated stresses in use, and their strength is limited by the need to adapt the design to the human anatomy. Unless great care is taken in patient selection, placement of the implant, and postoperative management to minimize stresses on the implant, such stresses may cause material fatigue and consequent breakage or loosening of the device before the fusion process is complete, which may result in further injury or the need to remove the device prematurely.

DEVICE FIXATION

Installation and positional adjustment of implants must only be done with special ancillary instruments and equipment supplied and designated by MEDTRONIC. In the interests of patient safety, it is therefore recommended that MEDTRONIC implants are not used with devices from any other source.

Never, under any circumstances, reuse a CAPSTONE® Spinal System device. Even when a removed device appears undamaged, it may have small defects or internal stress patterns that may lead to early breakage.

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 taken in the handling and storage of the device(s). They should not be scratched or damaged. Devices should be protected during storage especially from corrosive environments.
4. Further information about this system will be provided upon request.
5. The surgeon should be familiar with the various devices before use and should personally verify that all devices are present before the surgery begins.
6. The size of device for the case should be determined prior to beginning the surgery. An adequate inventory of implant sizes should be available at the time of surgery, including sizes larger and smaller than those expected to be used.
7. Unless supplied sterile, all devices should be cleaned and sterilized before use. Additional sterile components should be available in case of any unexpected need.

INTRAOPERATIVE

1. The instructions in any available CAPSTONE® Spinal System 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 functions.
3. Breakage, slippage, or misuse of instruments or implants may cause injury to the patient or operating personnel.
4. To assure proper fusion below and around the location of the fusion, autogenous bone graft must be used.
5. When used via a posterior approach, supplemental posterior instrumentation is recommended. Posterior supplemental fixation is limited to Medtronic Sofamor Danek posterior instrumentation systems.
6. Bone cement should not be used, because this material may make removal of these components difficult or impossible. The heat generated from the curing process may damage or deform the PEK devices.

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. The patient must be warned that loosening, and/or breakage of the device(s) are complications which may occur as result of early or excessive weight-bearing, muscular activity or sudden jolts or shock to the spine.

2. The patient should be advised not to smoke or consume excess alcohol, during period of the bone fusion process.

3. The patient should be advised of the inability to bend at the point of spinal fusion and taught to compensate for this permanent physical restriction in body motion.

4. It is important that immobilization of union is established and confirmed by roentgenographic examination. If a non-union develops or if the components loosen, migrate, and/or break, the devices should be revised and/or removed immediately before serious injury occurs.

5. CAPSTONE® Spinal System implants are interbody devices and are intended to stabilize the operative area during the fusion process.

6. Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible.

PACKAGING

Devices are supplied in a sterile form. Packages for each of the components should be intact upon receipt. Once the seal on the package has been broken, the product should not be re-sterilized. 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 disinfesting 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

Devices are supplied in a sterile form. Once the seal on the package has been broken, the product should not be re-sterilized. When supplemental fixation is used, refer to the package insert of the supplemental instrumentation for sterilization information.

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.

Covered by one or more of U.S. Pat. Nos. 5,772,661; 5,860,973 and other pending patent applications.
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.

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