CD HORIZON BalanC™
Spiral System
Surgical Technique

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CD HORIZON BalanC™ Spinal System Overview

The CD HORIZON BalanC™ Spinal System is compatible with the CD HORIZON® LEGACY™ PEEK Rod Spinal System. The CD HORIZON BalanC™ rod is made of silicone and polyetheretherketone (PEEK) in its dynamic portion, while the fusion portion is entirely made of PEEK. The dynamic portion is designed to maintain motion, creating a transitional zone between the fused and mobile segments.

When used in a single-level procedure, the CD HORIZON BalanC™ Spinal System rod provides stabilization without fusion.

CD HORIZON® LEGACY™ PEEK Rod Multi-Axial Screw

Mechanical testing demonstrates that the CD HORIZON® LEGACY™ PEEK Rod multi-axial screws are designed to provide secure locking capabilities in conjunction with the PEEK material, while maintaining the characteristics of the CD HORIZON® LEGACY™ Spinal System screw design. Mechanical test results are not indicative of clinical outcomes.

CD HORIZON® LEGACY™ PEEK Rod Set Screw

The CD HORIZON® LEGACY™ PEEK Rod set screw is designed with G4 reverse angle thread technology. This technology provides locking capabilities and resistance to screw back-out. These features, in conjunction with the PEEK material, allow for a much lower breakoff torque while maintaining the necessary grip strength. The torque required for locking the PEEK rod into the multi-axial screw has decreased compared to a titanium rod to accommodate the PEEK material. Although a lower torque is used, the locking mechanism helps maintain the necessary rod-to-screw interface strength required for the longevity of the product. Mechanical test results are not indicative of clinical outcomes.
CD HORIZON® LEGACY™ PEEK Rod Instrument Set to be used with the CD HORIZON BalanC™ Spinal System

Pedicle Preparation

- In-Line Round Awl
  7480104
- Dual Ended Feeler Probe
  7480100
- Sounding/Feeler Probe
  8572102
- Straight Lumbar Probe
  803-290
- Lumbar Ball Handle Probe
  7480110
- Quick Connect Ratcheting Handle
  9339082
- Self Drilling Tap
  8670055 (5.5mm)
  8670065 (6.5mm)
  8670075 (7.5mm)
- Tap
  836-015 (5.5mm)
  836-016 (6.5mm)
  836-018 (7.5mm)

Screw Insertion

- Final Self-Retaining Screwdriver
  7480114
- Multi-Axial Screwdriver
  7221007
- Cannulated Attachment Driver
  7221005
CD HORIZON® LEGACY™ PEEK Rod Instrument Set to be used with the CD HORIZON BalanC™ Spinal System

**Set Screw Insertion**

Dual Ended Plug Starter
7480122

Long Provisional Driver
7480130

**Rod Reduction**

MAST™ Beale Rod Reducer
7480136

Forceps Rocker
7480142
CD HORIZON® LEGACY™ PEEK Rod Instrument Set to be used with the CD HORIZON BalanC™ Spinal System

Compression and Distraction

- MAST™ PEEK Distractor
  7221000
- MAST™ PEEK Compressor
  7221001

Final Tightening

- Final Self-Retaining Break-Off Driver
  7480144
- PEEK Counter Torque
  7221002
- T27 Obturator
  7480154
- Tapered Hex Driver
  7480114
CD HORIZON BalanC™ Spinal System

Instruments/Templates

Rod Holder
79960011

Single-level Non-expandable Template
79900040

Multi-level Lordotic Expandable Template
79902060/79903060/79903090

Multi-level Standard Curvature Non-expandable Template
79900045/79900060/79900090

Hex Driver for Disassembly/Assembly of Expandable Templates
7756188

Multi-level Straight Non-expandable Template
79901060/79901090

CD Horizon BalanC™ Rod Options

Standard

Lordotic

Straight

Extra Lordotic
Material Characteristics and Screw Performance
Material Characteristics: PEEK and Silicone

Biocompatibility

**History of PEEK Material**

» More than 20 years of medical applications
» Has been used in:
  - Spinal implants
  - Heart valves/stents
  - Artificial joints
  - Dental implants

**History of Silicone Material**

» Extensive uses in medical applications
» Has been used in:
  - Small joint implants
  - Spinal implants
  - Cranial valves and catheters

**Biocompatibility of PEEK and Silicone Material**

» Internal testing demonstrates that these materials meet all biological requirements:
  - Cytotoxicity (influence on cell growth)
  - Sensitization (assess possible contact hazards)
  - Genotoxicity (alteration of DNA or genes)
  - Implantation (biological response to implantation)
  - Chronic toxicity (evaluation of chronic toxicity)
  - Carcinogenicity (determination of cancer risk)
Material Characteristics: PEEK and Silicone continued

Fatigue Testing for Cannulated Multi-Axial Screws (MAS) for PEEK Rod

Mechanical testing is not indicative of clinical results.

The screw diameter should always be chosen considering the anatomy of the patient. To ensure maximum fatigue resistance, the largest possible screw diameter for the patient should be used.
CD HORIZON
BalanC™
Spinal System

Multi-level
Surgical Steps
Approach and Screw Placement

With the pedicles prepared and the proper screw lengths determined, fully insert the hex end of the multi-axial screwdriver into the screw head (Figure 1). Next, thread the screwdriver sleeve into the screw head (Figure 2). The combination of the hex head and the threaded sleeve provides a stable insertion instrument for inserting the multi-axial screws bilaterally. Once a screw is inserted, the instrument sleeve is unscrewed and the screwdriver is disengaged from the screw.

The screw diameter should always be chosen considering the anatomy of the patient. To ensure maximum fatigue resistance, the largest possible diameter for the patient should be used.

The multi-axial screwdriver (7221007) is specific to the CD HORIZON® LEGACY™ PEEK Rod System Instrument Set and is not interchangeable with the multi-axial screwdriver from the CD HORIZON® LEGACY™ 5.5mm System Instrument Set.
Screw Placement continued

Intraoperative anterior-posterior (AP) and lateral radiographs are taken to evaluate the position of the screws in two planes. When fully inserted, the screws should be parallel to the superior end plate.

![Image]

Information

According to computational analysis, it is recommended that the screws surrounding the dynamic portion are placed into the pedicle as deep as possible without compromising the multi-axial capability of the screw head to achieve maximum potential for motion.

Computational analysis is not indicative of clinical results.

Discectomy and End Plate Preparation

For the fusion level(s), a conventional discectomy is performed unilaterally or bilaterally as indicated (Figure 3). Soft fragments from the intradiscal space or extruded fragments are removed in a conventional fashion. The main goal of this step is to remove extruded fragments, to decompress neural elements and to provide entry to the disc space for distraction with minimal or no nerve root retraction. Thorough endplate preparation with removal or the cartilagenous endplates should be accomplished prior to insertion of the interbody construct. The disc space is sequentially distracted until the original disc space height is obtained and the normal foraminal opening is restored.

The dynamic portion of the device is intended to be used as dynamic stabilization without fusion, therefore complete disc removal should not be performed.

![Image]

Important

Disc preparation should be performed at the fusion level(s) only.
Using the Multi-level Non-expandable Templates

Non-expandable templates are provided for single-level constructs as well as multi-level constructs for standard and straight rod curvatures. The rod holder that is provided in the CD HORIZON BalanC™ Instrument Set is used to deliver the template into the screw heads.

After placing the multi-axial screws, position the template such that the C-shape falls evenly between the two most cranial screw heads. Adjust the position of the template as necessary to ensure the rounded end, which simulates the titanium end cap, extends cephalically beyond the head.

Determine the correct implant length by reading the markings on the template. If the laser-marked half-circle area is inside the screw head, the next longer size rod should be chosen (Figure 4).

If preferred, the template can be used in conjunction with a fluoroscope to determine the correct implant length. Position the template as described above. Utilizing a lateral fluoroscopic image, count the number of grooves that are visible caudally from the most inferior screw. For each visible groove, subtract 10mm from the maximum length on the template to determine the correct implant length.

A lateral image can be taken to ensure a proper selection of the rod curvature. If the rod template is not seated correctly inside the head of all screws, a more appropriate rod curvature should be chosen or slight adjustments of the height of the multi-axial screw(s) can be performed.
Using the Expandable Templates

After placing the multi-axial screws, position the template such that the C-shape falls evenly between the two most superior screw heads. Adjust the position of the template as necessary to ensure the rounded end, which simulates the titanium end cap, extends cephalically beyond the head.

Check the fit of the inferior end of the template. The rounded end of the template should extend beyond the head of the most caudal multi-axial screw.

When the expandable short lordotic template is being used and the template is not expanded, if the rounded edge is inside the screw head, the next longer size rod should be chosen. If a length adjustment is necessary, lift the template from the screw heads. Adjustments should not be made in situ. Lengthen or shorten the insert of the template to the next detent position as needed.

As before, reposition the template in the multi-axial screw heads and check the length.

When an appropriate length has been established, the largest number visible on the stem of the insert represents the implant length (in 10s of mm).

A lateral image can be taken to ensure a proper selection of the rod curvature. If the rod template is not seated correctly inside the head of all screws, a more appropriate rod curvature should be chosen or slight adjustment(s) of the height of the multi-axial screw(s) can be performed.
Rod Placement

Use the template to select the appropriate size rod. The CD HORIZON BalanC™ Spinal System rods are sterile packed. The rod is implanted using the rod holder and should be positioned to match the rod template.

Compression and Distraction

If either compression or distraction is needed, it should be performed at this stage.

» Provisionally tighten the set screws above and below the dynamic portion.

» Provisionally tighten the set screws of the fusion portion of the CD HORIZON BalanC™ Spinal System rod and perform compression or distraction maneuvers as needed.

» Compression or distraction may only be performed on the outermost screws to ensure a stress point or notch does not occur between two screws. Compression or distraction will occur against the provisionally tightened implant (Figure 5). The long provisional driver may be used to temporarily lock and secure the rod and implant construct.

» Once satisfactory compression or distraction has been achieved, final tightening may be performed. It is preferred that compression be released prior to set screws break-off. This technique will help ensure that the implant head and the rod are normalized to one another.

Information

According to computational analysis, by placing the dynamic portion of the rod parallel to the A/P plane, maximum potential for motion may be achieved.

Computational analysis is not indicative of clinical outcomes.

For multi-level constructs, particular care should be taken on the order of set screw placement. Always position and tighten the set screws above and below the dynamic portion of the rod first.
Rod Reduction

The MAST™ Beale rod reducer is the preferred method for reduction when the rod is lying even to the top of the implant head. To use the MAST™ Beale rod reducer, position the reducer so that the handles are perpendicular to the rod and grasp the screw head from above (Figure 6). Slowly compress the reducer handles, allowing the sleeve to slide down and seat the rod. The dual ended plug starter or long provisional driver is then inserted through the reducer to insert the set screw into the head of the pedicle screw (Figure 7).

NOTE: Care should be taken with any rod reduction maneuver. Improper instrument use may dislodge the implants or damage the bony or neurologic anatomy.

Information

The MAST™ Beale rod reducer (7480136) should be used with the CD HORIZON® LEGACY™ PEEK Rod System Instrument Set instead of the MAST™ Beale rod reducer from the CD HORIZON® LEGACY™ 5.5mm System Instrument Set.

Important

For the dynamic portion of the rod, it is important that a rod is chosen that is fully seated into the heads of the multi-axial screws of the dynamic portion of CD HORIZON BalanC™ Spinal System rod. It is not recommended that rod reduction is performed around the dynamic portion of the rod.

For the fusion portion of the rod, if the rod is not fully seated into the bottom of the screw head of the fusion portion of the rod, the MAST™ Beale rod reducer can be used to fully seat the rod into the head of the set screw.
Final Tightening

When all implants are securely in place, final tightening and break-off of the set screw heads are done. Insert the final self-retaining break-off driver into the cannulated portion of the PEEK counter torque, which should be positioned over the implant and rod (Figure 8). The T-handle on the driver provides adequate leverage for the break-off of the set screw head. The handle of the PEEK counter torque device should be held firmly to prevent torquing of the construct while the set screw is secured and sheared off. The final construct should be assessed for stability and rigidity, and then wound closure is performed.

Explantation

The CD HORIZON® LEGACY™ PEEK Rod set screws may be removed using the T27 Obturator and the self-retaining break-off driver. The T27 Obturator is inserted into the working end of the self-retaining break-off driver, so that the bottom portion of the T27 Obturator is flush with the driver. Insert the obturator tip through the PEEK counter torque, which should be seated on the screw, and into the set screw, turning counterclockwise until the set screw 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 utilizing the multi-axial screwdriver, thread the instrument sleeve into the screw head. Turn counterclockwise until the pedicle screws have been removed.
CD HORIZON BalanC™ Spinal System Utilizing Minimally Invasive Instrumentation

As an alternative to standard open midline approaches, many surgeons are choosing a less invasive option. The new CD HORIZON BalanC™ Spinal System utilizing the MAST QUADRANT™ Retractor System features a familiar dilation technique that allows for access, fusion, and fixation in one approach.
CD HORIZON
BalanC™
Spinal System

Single-level
Surgical Steps
Approach and Screw Placement

With the pedicles prepared and the proper screw lengths determined, fully insert the hex end of the multi-axial screwdriver into the screw head (Figure 9). Next, thread the screwdriver sleeve into the screw head (Figure 10). The combination of the hex head and the threaded sleeve provides a stable insertion instrument for inserting the multi-axial screws bilaterally. Once a screw is inserted, the instrument sleeve is unscrewed and the screwdriver is disengaged from the screw.

Important

The screw diameter should always be chosen considering the anatomy of the patient. To ensure maximum fatigue resistance, the largest possible diameter for the patient should be used.

Information

The multi-axial screwdriver (7221007) is specific to the CD HORIZON® LEGACY™ PEEK Rod System Instrument Set and is not interchangeable with the multi-axial screwdriver from the CD HORIZON® LEGACY™ 5.5mm System Instrument Set.
Screw Placement continued

Intraoperative anterior-posterior (AP) and lateral radiographs are taken to evaluate the position of the screws in two planes. When fully inserted, the screws should be parallel to the superior end plate.

According to computational analysis, it is recommended that the screw is placed into the pedicle as deep as possible without compromising the multi-axial capability of the screw head to achieve maximum potential for motion.

Computation analysis is not indicative of clinical results.

Using the Single level Non-expandable Rod Template

The CD HORIZON BalanC™ Instrument Set contains two single-level standard curvature templates used to determine the appropriate rod length. The measurement of the shortest template is 40-45mm, and the longest is 45-55mm. The rod holder that is provided in the CD HORIZON BalanC™ Instrument Set is used to deliver the template into the screw heads.

After placing the multi-axial screws, position the template such that the C-shape falls evenly between the two most superior screw heads (Figure 11). Adjust the position of the template as necessary to ensure the rounded edge, which simulates the titanium end cap, extends cephalically beyond the head of the screw.

Determine the correct implant length by reading the markings on the template.
Rod Placement

Use the template to select the appropriate size rod. The CD HORIZON BalanC™ rods are sterile packed. The rod is implanted using the rod holder and should be positioned to match the rod template.

⚠️ Important

Compression/distraction as well as rod reduction should not be performed in a single-level application.

Final Tightening

When all implants are securely in place, final tightening and break-off of the set screw heads are done. Insert the final self-retaining break-off driver into the cannulated portion of the PEEK counter torque, which should be positioned over the implant and rod (Figure 12). The T-handle on the driver provides adequate leverage for the break-off of the set screw head. The handle of the PEEK Counter Torque device should be held firmly to prevent torquing of the construct while the set screw is secured and sheared off. The final construct should be assessed for stability and rigidity, and then wound closure is performed.

Explantation

The CD HORIZON® LEGACY™ PEEK Rod set screws may be removed using the T27 Obturator and the self-retaining break-off driver. The T27 Obturator is inserted into the working end of the self-retaining break-off driver, so that the bottom portion of the T27 Obturator is flush with the driver. Insert the obturator tip through the PEEK counter torque, which should be seated on the screw, and into the set screw, turning counterclockwise until the set screw 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 utilizing the multi-axial screwdriver, thread the instrument sleeve into the screw head. Turn counterclockwise until the pedicle screws have been removed.
CD HORIZON BalanC™ Spinal System
Utilizing Minimally Invasive Instrumentation

As an alternative to standard open midline approaches, many surgeons are choosing a less invasive option. The new CD HORIZON BalanC™ Spinal System utilizing the MAST QUADRANT™ Retractor System features a familiar dilation technique that allows for access, fusion, and fixation in one approach.
# Product Ordering Information

## Implants

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The CD HORIZON BalanC™ Spinal System is used in conjunction with the CD HORIZON® LEGACY™ PEEK Rod Spinal System. In addition to ordering the CD HORIZON BalanC™ Spinal System one of the below options has to be selected based on the choice of using cannulated or non-cannulated multi-axial screws.

**CD HORIZON® PEEK Cannulated Multi-Axial Screw Ordering Guide:**
- CD HORIZON® PEEK Multi-Axial Screws and Screw Preparation Module
- CD HORIZON® PEEK Instrument Set

**CD HORIZON® PEEK Non-Cannulated Multi-Axial Screw Module Ordering Guide:**
- CD HORIZON® PEEK Multi-Axial Screws and Screw Preparation Module
- CD HORIZON® PEEK Instrument Set
- CD HORIZON® PEEK Rod Non-Cannulated Multi-Axial Screw Set
CD HORIZON BalanC™ Spinal System

PURPOSE
The CD HORIZON BalanC™ Spinal System is intended to help provide stabilization and/or realignment of spinal segments of the lumbar and/or thoracic spine.

DESCRIPTION
The CD HORIZON BalanC™ Spinal System consists of a variety of curvatures and sizes of PEEK rods with silicone bumpers that are specifically designed to be used with bone screws and set screws contained with the CD HORIZON® PEAK Rod Spinal System. Refer to the CD HORIZON® Spinal System package insert for information regarding those implants. Care should be taken to ensure that the correct components are used in the spinal construct.

The CD HORIZON BalanC™ Spinal System implant components are fabricated from medical grade PEEK and silicone elastomer. No warranties expressed or implied, are made. Implanted materials are inert and fit for their specific purpose or use as specifically included. See the MDT Catalog for further information about warranties and limitations of liability.

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

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

INDICATIONS
Any C-shaped portion of a CD HORIZON BalanC™ rod is indicated for maximum three level use from L1 to L5 in the following spinal pathologies:

- Degenerative disc disease.
- Early stage degenerative disc disease.
- Any non-C-shaped portion of a CD HORIZON BalanC™ rod is indicated for maximum three level use sub-adjacent to a C-shaped portion of a CD HORIZON BalanC™ rod in the following spinal pathologies:
  - Spinal stenosis.
  - Spondylolisthesis (non-athletic) up to Grade 1.
  - Degenerative disc disease.

CONTRAINDICATIONS
Contraindications include, but are not limited to:

- Active infection or sign of risk for infection (immunosuppressed).
- Signs of local inflammation at or around the target spinal site.
- Fever or leukocytosis.
- Medullary bone.
- Pregnancy.
- Previous surgery, if any, at the treated level(s).
- Any case where more than one third of the facet joint must be resected at a level treated with a C shaped portion of a rod.
- Scoliosis greater than 10 degrees.
- Grossly distorted anatomy caused by congenital abnormalities.
- Any other medical or surgical condition which would preclude the potential benefit of spinal implant surgery such as the presence of congenital abnormalities, revision of instrumentation site unseparable from other disease, elevation of white blood count (WBC), or a marked left shift in the WBC differential count.
- Spondylolisthesis or documented or anticipated discitis or infection to any of the device materials.
- Any case where the implant components selected for use will be too large or too small to achieve a successful result.
- Any patient having inadequate tissue coverage over the operative site or inadequate bone stock or quality.
- Any patient in which implant localization would interfere with anatomic structures or expected physiological performance.
- Any patient unwilling or unable to follow postoperative instructions.
- Unstored application of the CD HORIZON BalanC™ Spinal System.
- 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:

- Severe bone resorption.
- Osteomalacia.
- Severe osteoporosis.

POSSIBLE ADVERSE EVENTS
All of the possible adverse events associated with spinal surgery without instrumentation are possible. With instrumentation, a history of potential adverse events includes, but is not limited to:

- Early or late loosening of any of the components.
- Disc herniation, and/or breakage of any of all of the components.
- Foreign body (allergic) reaction to implants, debris, corrosion products (from crevice, fretting, and/or general corrosion).
- Breakage, slippage, or misuse of instruments or implant components may cause injury to the patient or operative personnel.
- Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, fibrosis, necrosis, and/or pain.
- Bursts or 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.
- Loss of neurological function (e.g., sensory and/or motor), including paralysis (complete or incomplete), paraplegia, paraparesis, reflex deficits, intussus, arachnoiditis, and/or muscle loss.
- Urethral retention, loss of bladder control, or other types of urological system compromise.
- Scare formation possibly causing neurological compromiser or compression around nerves and/or pain.
- Fracture, microfracture, reabsorption, damage, or penetration of any bone (including the sacrum, pelvis, and/or vertebral body) and/or bone graft or bone graft material, set screw, and/or bone畿 submerged set screw.
- Reproductive system compromise including sterility, loss of contraceptive, and sexual dysfunction.
- Development of inflammatory problems (e.g., pulmonary embolism, anaphylaxis, bronchitis, pneumonia, etc.).
- Change in mental status.
- Death.

Note: Additional surgery may be necessary to correct some of these potential adverse events.

PRECAUTION
The implantation of pelvic screw spinal systems should be performed only by experienced spinal surgeons with specific training in the use of this pelvic 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 spine surgery where many underlying circumstances may compromise the result. This device system is not intended to be the sole means of spinal support at levels where fusion is intended. No spinal implant that is intended to be an adjacent fusion to withstand body loads without the support of bone. In this event, bending, bowing, dislocation, and/or breakage of the device(s) may eventually occur.

In cases where the C-shaped portion of a rod is being used (without bone graft) as stabilization when achieving fusion is not the purpose of the intervention. Any remaining portion of a CD HORIZON® BalanC™ rod is intended to be used in conjunction with bone screws and set screws contained with the CD HORIZON® PEAK Rod Spinal System posterior instrumentation, with bone graft or bone substitute as an adjunct to fusion, or without bone graft as stabilization when achieving fusion is not the purpose of the intervention. Any remaining portion of a CD HORIZON® BalanC™ rod is intended to be used in conjunction with bone screws and set screws contained with the CD HORIZON® PEAK Rod Spinal System for posterior fixation in an adjacent fusion at one, two, or three levels (intervertebral grafting suggested).
STERILIZATION

All products should be treated with care. Improper use or handling may lead to damage and/or possible improper functioning of the device.

STERILIZATION AND DECONTAMINATION

Unless just removed from an unopened sterile MEDTRONIC package, all instruments and implants must be unpackaged, disassembled (if applicable), and cleaned before sterilization. Introduction into a sterile surgical field, or any return of the product to MEDTRONIC. Remove all packaging materials prior to sterilization. DECONTAMINATION instructions and associated disassembly instructions (if applicable) can be found at http://www.mediqon.com.

Note: Certain cleaning solutions such as those containing formalin, glutaraldehyde, benzalkonium chloride, and/or alkaline cleaners may damage some devices, particularly instruments, these solutions should not be used unless instructed by the Instrument Care, Cleaning and Sterilization Quick Reference Guide part number 0381424. Also, many instruments require disassembly before cleaning.

Sterilization according to the above parameters so as to minimize the potential risk of transmission of cell-borne and/or bacterial disease, especially of surgical instruments that could come into contact with the central nervous system.

PRODUCT COMPLAINTS

Any health care professional (e.g., customer or user of this system of products) who has any complaints or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness, and/or performance should notify the distributor, Medtronic. Further, if any of the implanted spinal system component(s) “malfunction” (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 by telephone, FAX, or written communication. 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 or not a written report from the distributor is requested.

FURTHER INFORMATION

Contact customer service or your sales representative for the most up-to-date version of the package insert.

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Contact customer service or your sales representative for no charge upon request. If further information is needed or required, please contact MEDTRONIC.

Important Information on the CD HORIZON BalanC™ Spinal System continued

> Caution: Do not overtight or use a screw/bolt that is either too long or too large. Overstressing, using an incorrectly sized screw/bolt, or accidentally advancing the guidewire during tap or screw/bolt insertion may cause nerve damage, hematomas, or other possible adverse events. Make eliminated from this package insert. If screw/bolts are being inserted into spin ppedicles, use a large screw/bolt diameter as will fit into each pedicle.

> Bone graft must be placed in the area to be fused and graft material must extend from the upper to the lower vertebral being fused.

> Avoid excessive reduction of a C-shaped section of a rod. Improper positioning of the C-shaped section of a rod may result in excessive reduction of the rod in the multi-axis screw head which may result in separation of the silicon bumper from the rod.

> Before closing the soft tissues, provisionally tighten (finger tighten) all of the nuts or screw, especially screws or nuts that have a break-of-hexagon. Since 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 of the intended set is undone.

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

Failure to immobilize or bone loss due to stress shielding; and (8) Potential unknown and/or unexpected long term effects which

important that immobilization of the spinal surgical site be maintained until firm bony union is established and confirmed by

inflammatory medications such as aspirin during the bone graft healing process.

The physician’s postoperative directions and warnings to the patient and the corresponding patient compliance are extremely

Detailed instructions on the use and limitations of the device should be given to the patient. If partial weight-bearing is

Recommended directions for use of this system (surgical operative techniques) are available at no charge upon request. If further

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Notes
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.