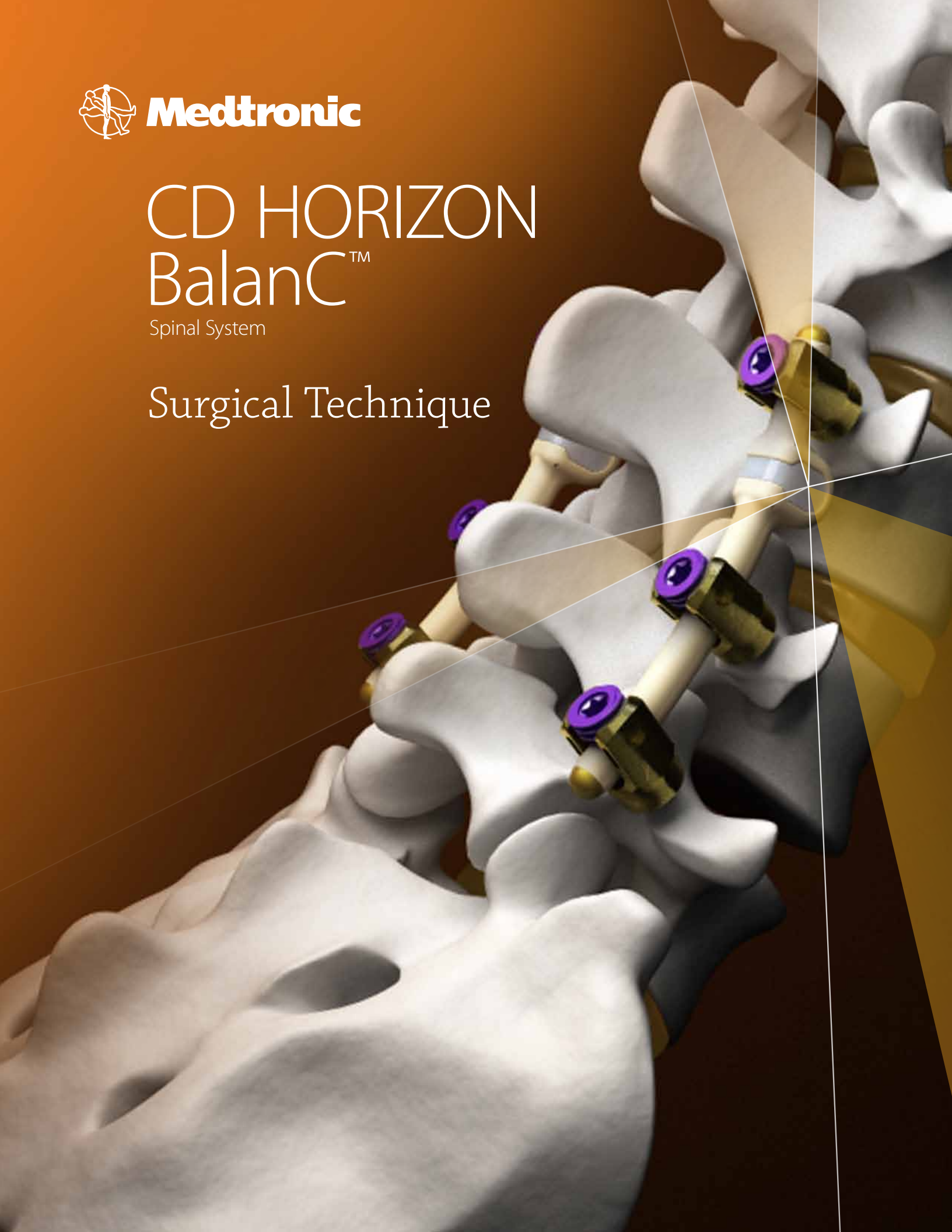
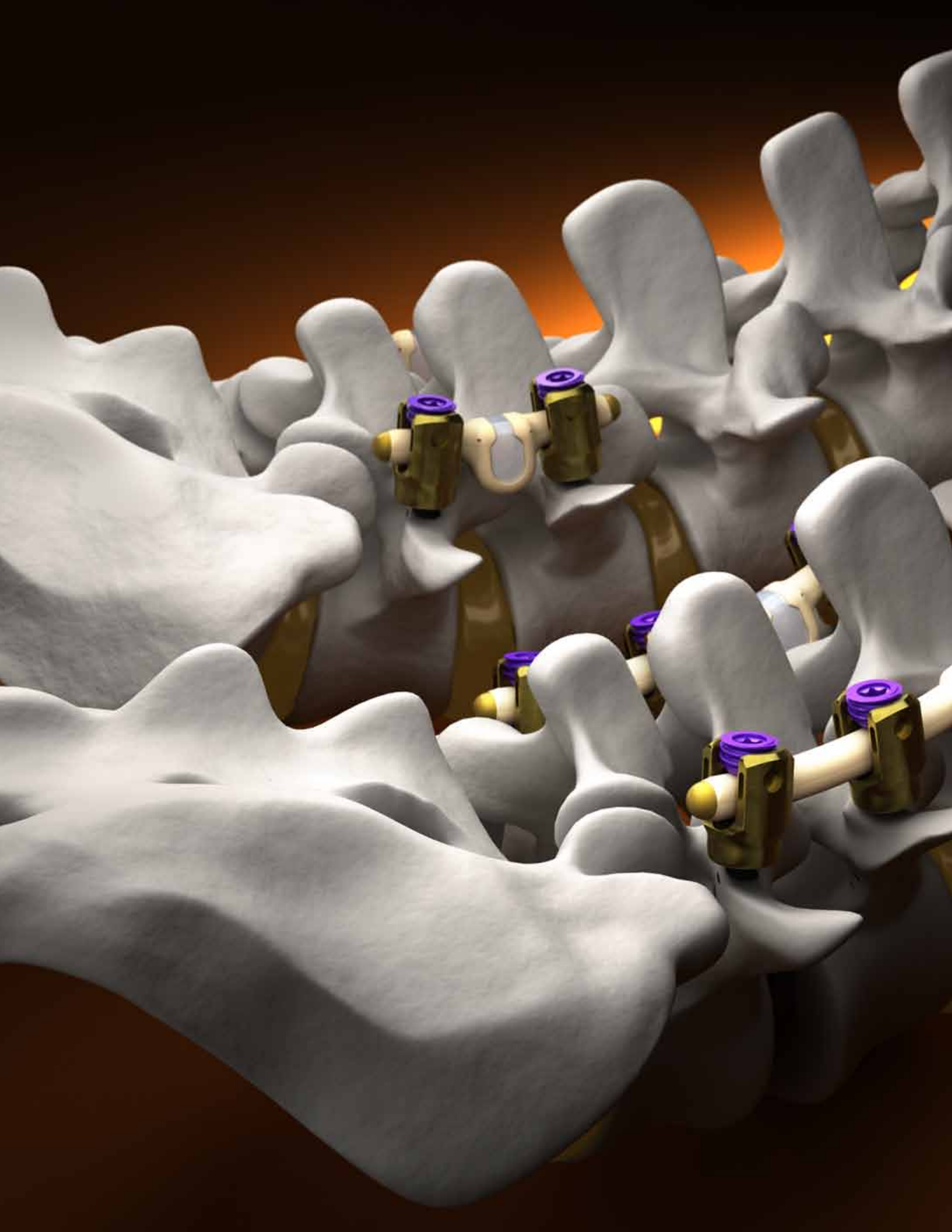
Medtronic

CD HORIZON BalanC™

Spinal System

Surgical Technique





CD HORIZON BalanC™

Spinal System

Surgical Technique

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.

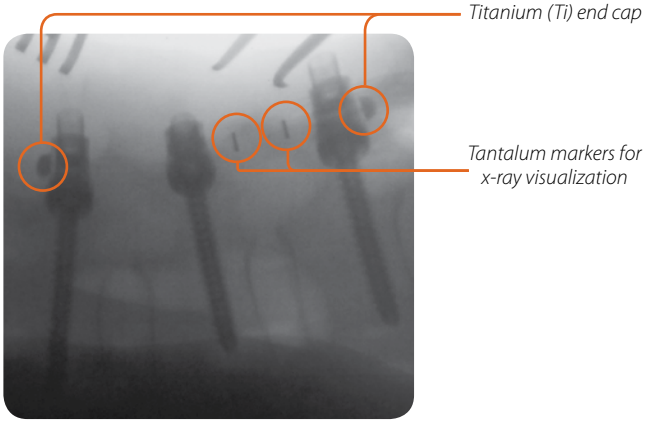
Multi-level Rod

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

Single-level Rod

CD HORIZON BalanC™ Rod Features

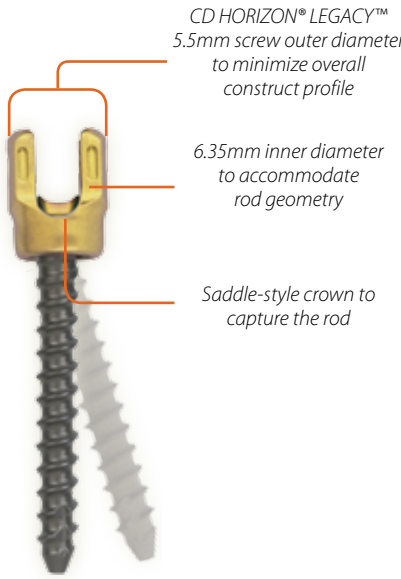
- Oval cross section
- Pre-cut/pre-bent rod options
- Titanium (Ti) end cap
- Tantalum markers for x-ray visualization



[1]ASTM F1798

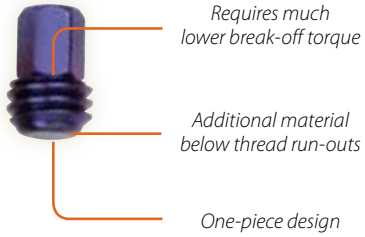
CD HORIZON® LEGACY™ PEEK Rod Multi-Axial Screw

Mechanical testing demonstrates that the CD HORIZON® LEGACY™ PEEK Rod multi-axial screws are designed to provide secure locking capabilities[1] 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[1] 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

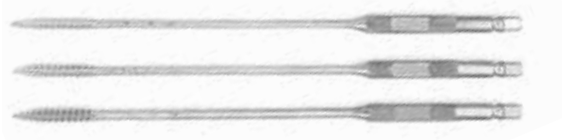
Dual Ended Feeler Probe
7480100

Sounding/Feeler Probe
8572102

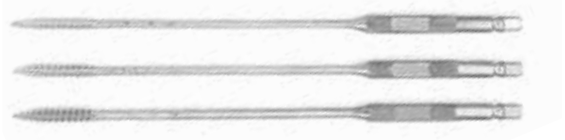
Straight Lumbar Probe
803-290

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 *continued*

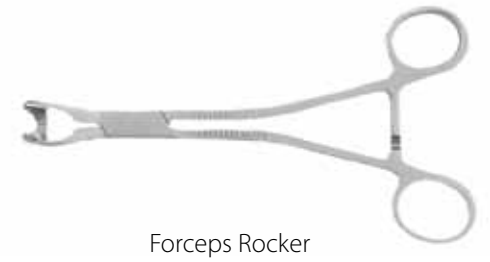
Set Screw Insertion

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 *continued*

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

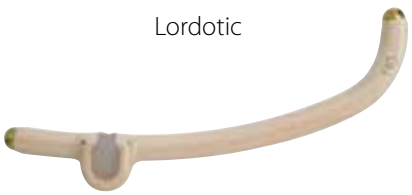
Multi-level Straight
Non-expandable Template
79901060/79901090

CD Horizon BalanC™ Rod Options

Standard

Lordotic

Straight



Extra Lordotic

CD HORIZON BalanC™

Spinal System

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:

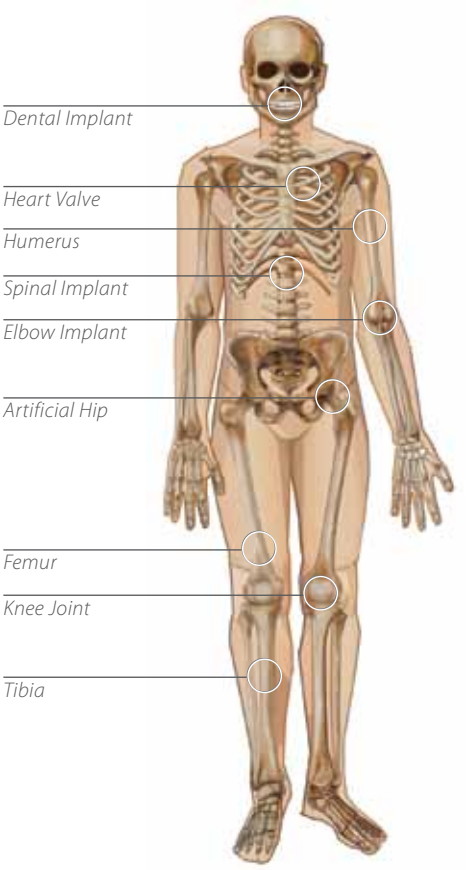
- Spinal implants
- Heart valves/stents
- Artificial joints
- Dental implants

History of Silicone Material

» Extensive uses in medical applications

» Has been used in:

- Small joint implants
- Spinal implants
- Cranial valves and catheters



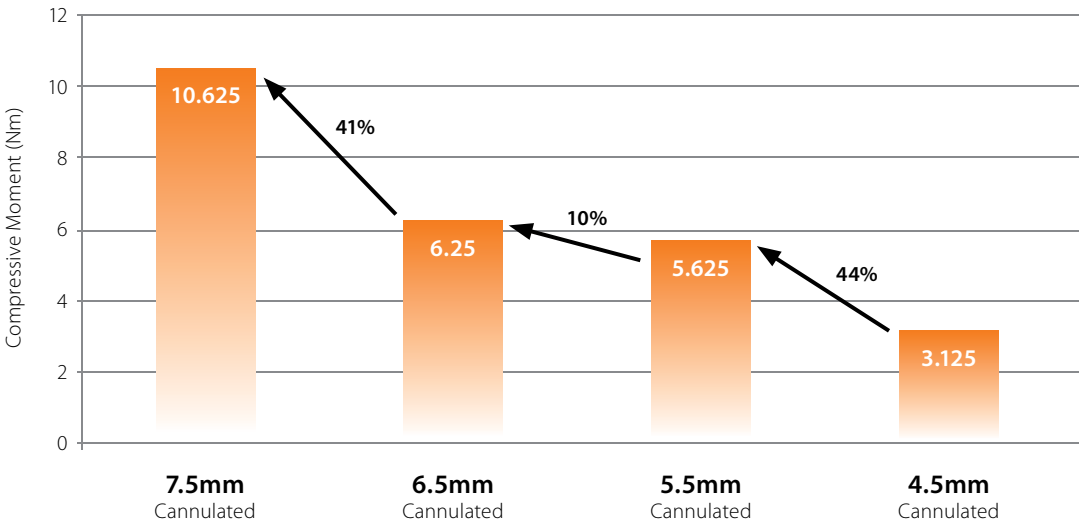
Biocompatibility of PEEK and Silicone Material

» 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)

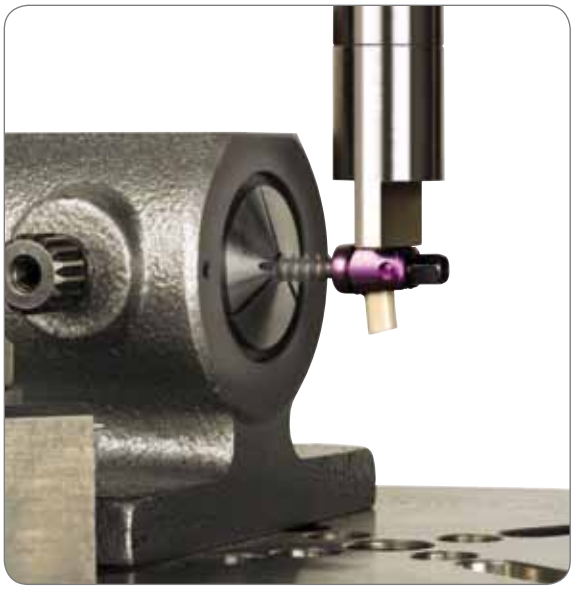
Material Characteristics: PEEK and Silicone *continued*

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.

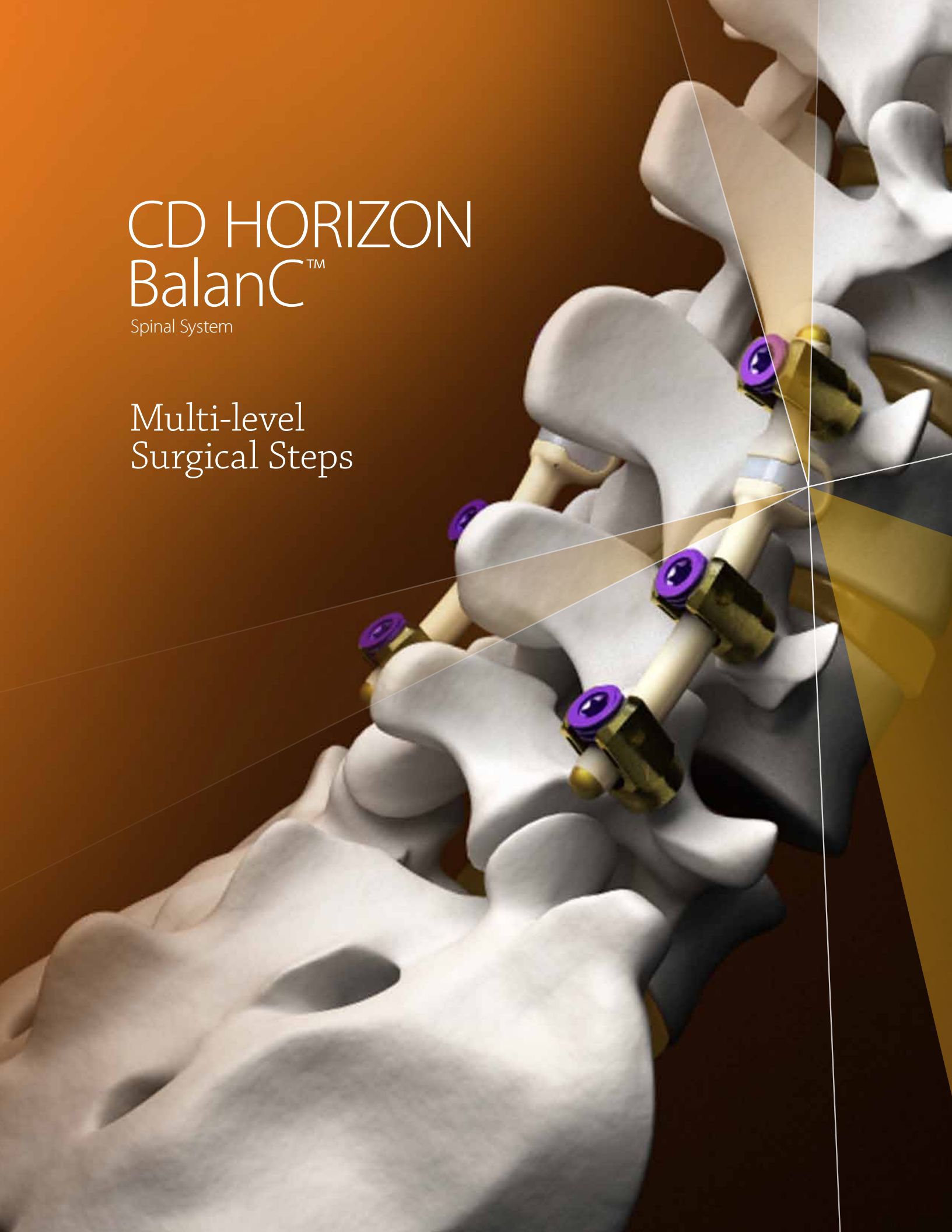


*ASTM F2193

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.

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.

Figure 1

Figure 2

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 anteriorposterior (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.

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.

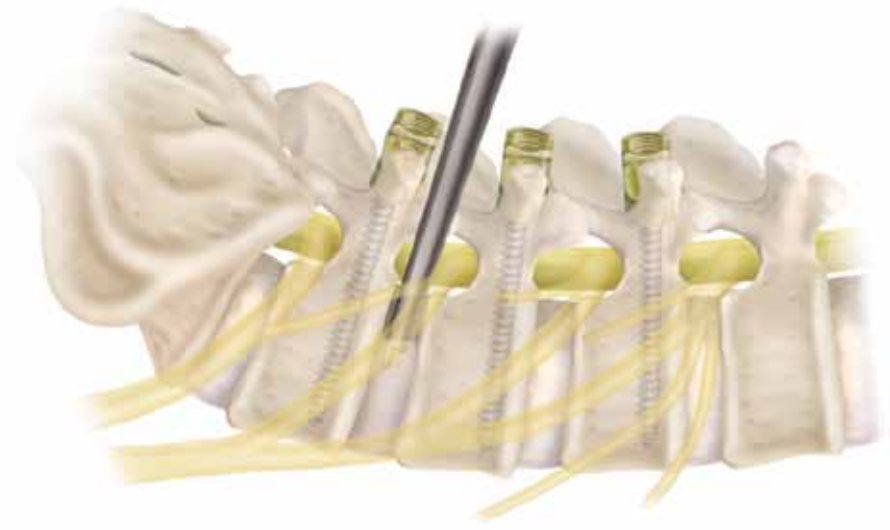


Figure 3

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.

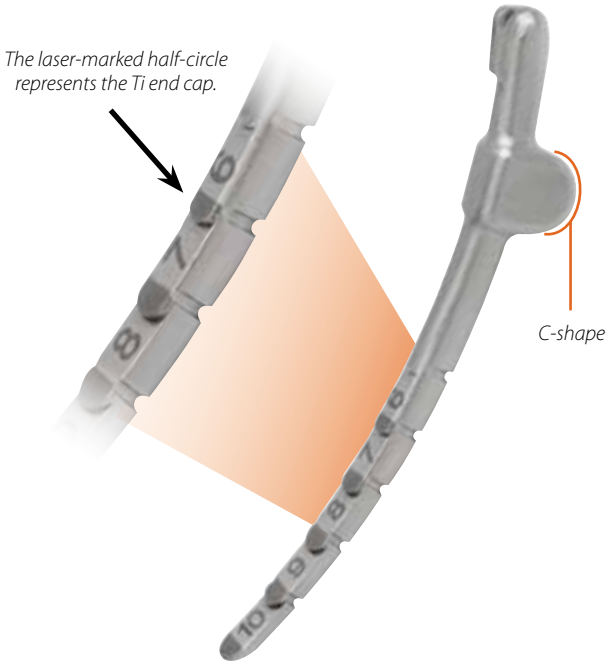


Figure 4

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.

Single-level
Expandable Templates

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.

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.

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.

Figure 5

Important

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.

Figure 6

Figure 7

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

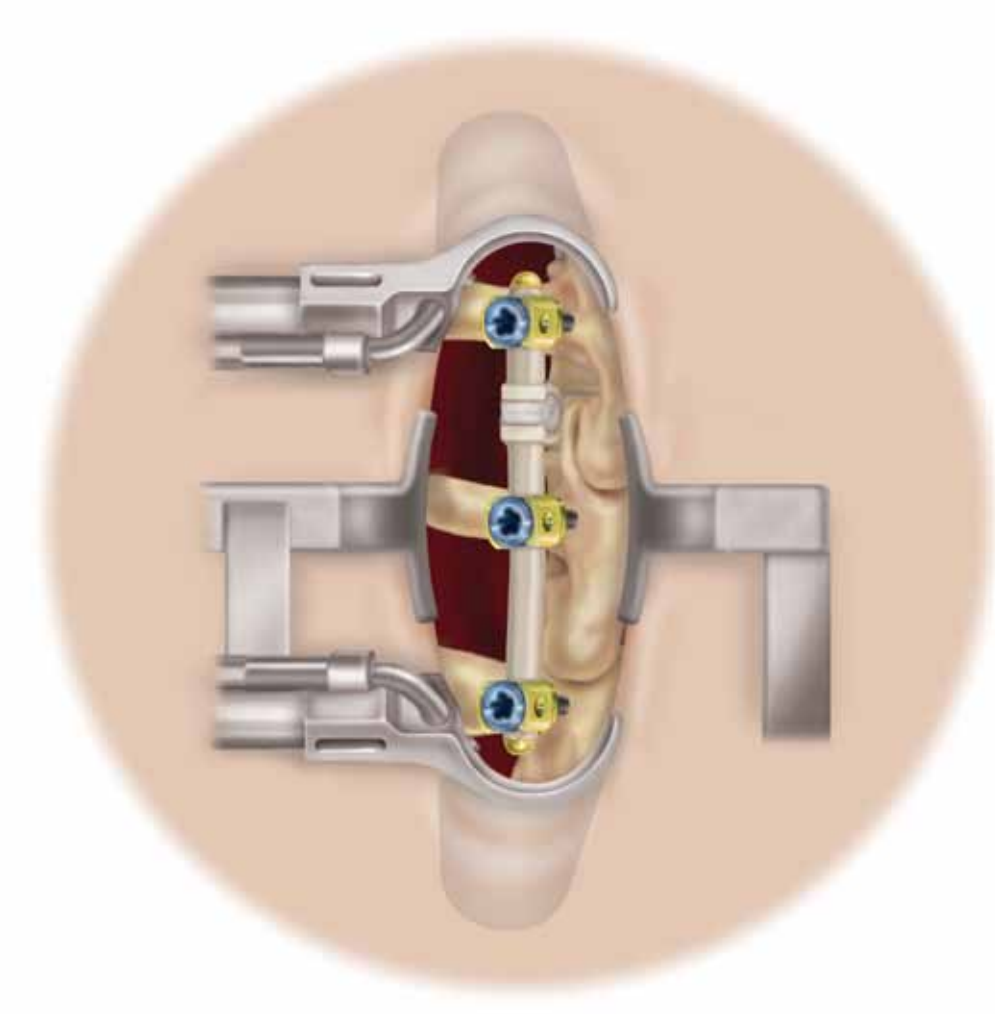
When all implants are securely in place, final tightening and break-off of the set screw heads are done. Insert the final self-retaining break-off driver into the cannulated portion of the PEEK counter torque, which should be positioned over the implant and rod **(Figure 8)**. The T-handle on the driver 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.

Figure 8

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

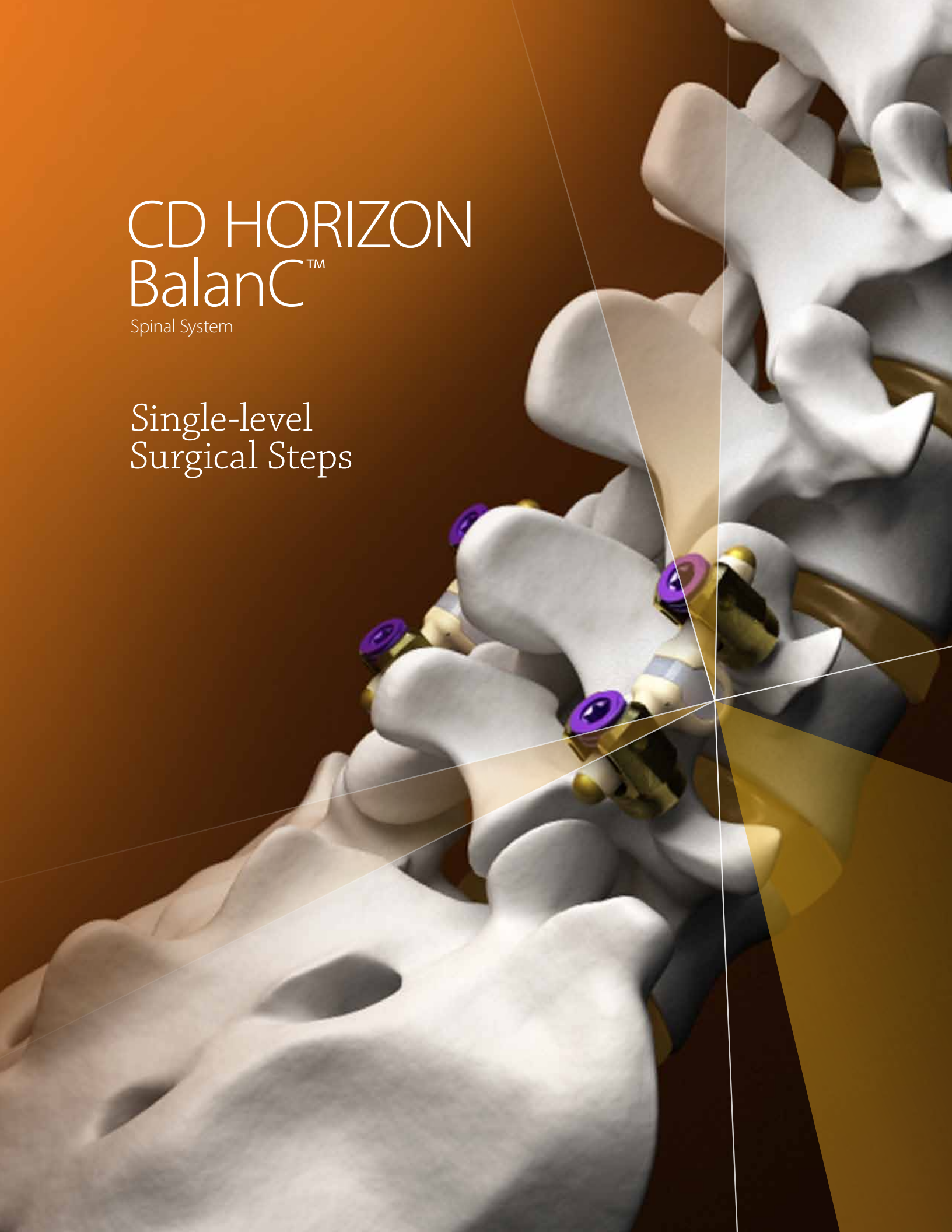


As an alternative to standard open midline approaches, many surgeons are choosing a less invasive option. The new CD HORIZON BalanC™ Spinal System utilizing the MAST QUADRANT™ Retractor System features a familiar dilation technique that allows for access, fusion, and fixation in one approach.

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.

Figure 9

Figure 10

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 anteriorposterior (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.

Information

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 acheive 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.

Single-level standard curvature template.

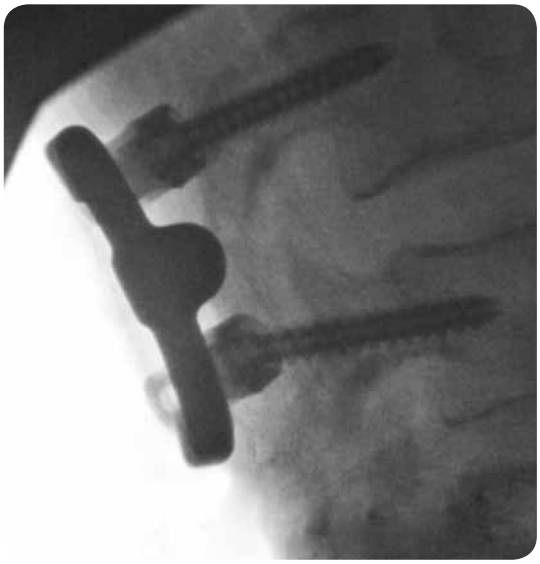
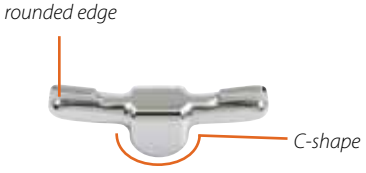


Figure 11



Single-level
Non-expandable 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

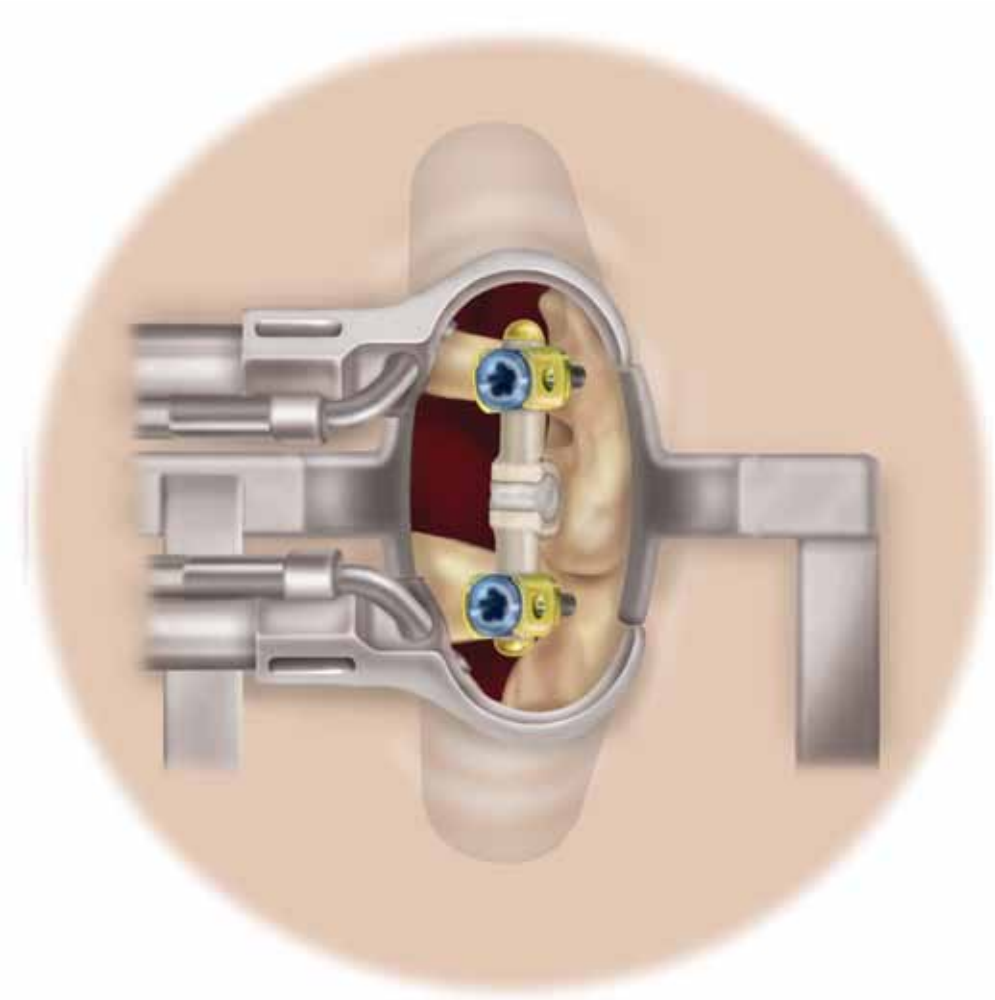
When all implants are securely in place, final tightening and break-off of the set screw heads are done. Insert the final self-retaining break-off driver into the cannulated portion of the PEEK counter torque, which should be positioned over the implant and rod **(Figure 12)**. The T-handle on the driver 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.

Figure 12

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

Part Number	Description
79810040	Rod, 6.0 x 6.9, 40 mm, Standard
79810045	Rod, 6.0 x 6.9, 45 mm, Standard
79810050	Rod, 6.0 x 6.9, 50 mm, Standard
79810060	Rod, 6.0 x 6.9, 60 mm, Standard
79810070	Rod, 6.0 x 6.9, 70 mm, Standard
79810080	Rod, 6.0 x 6.9, 80 mm, Standard
79810090	Rod, 6.0 x 6.9, 90 mm, Standard
79810100	Rod, 6.0 x 6.9, 100 mm, Standard
79810110	Rod, 6.0 x 6.9, 110 mm, Standard
79810120	Rod, 6.0 x 6.9, 120 mm, Standard
79810130	Rod, 6.0 x 6.9, 130 mm, Standard
79820060	Rod, 6.0 x 6.9, 60 mm, Straight
79820070	Rod, 6.0 x 6.9, 70 mm, Straight
79820080	Rod, 6.0 x 6.9, 80 mm, Straight
79820090	Rod, 6.0 x 6.9, 90 mm, Straight
79820100	Rod, 6.0 x 6.9, 100 mm, Straight
79820110	Rod, 6.0 x 6.9,110 mm, Straight
79820120	Rod, 6.0 x 6.9, 120 mm, Straight
79820130	Rod, 6.0 x 6.9, 130 mm, Straight
79830060	Rod, 6.0 x 6.9, 60 mm, Lordotic
79830070	Rod, 6.0 x 6.9, 70 mm, Lordotic
79830080	Rod, 6.0 x 6.9, 80 mm, Lordotic
79830090	Rod, 6.0 x 6.9, 90 mm, Lordotic
79830100	Rod, 6.0 x 6.9, 100 mm, Lordotic
79830110	Rod, 6.0 x 6.9, 110 mm, Lordotic
79830120	Rod, 6.0 x 6.9, 120 mm, Lordotic
79830130	Rod, 6.0 x 6.9, 130 mm, Lordotic
79840060	Rod, 6.0 x 6.9, 60 mm, Extra Lordotic
79840070	Rod, 6.0 x 6.9, 70 mm, Extra Lordotic
79840080	Rod, 6.0 x 6.9, 80 mm, Extra Lordotic
79840090	Rod, 6.0 x 6.9, 90 mm, Extra Lordotic
79840100	Rod, 6.0 x 6.9, 100 mm, Extra Lordotic
79840110	Rod, 6.0 x 6.9, 110 mm, Extra Lordotic
79840120	Rod, 6.0 x 6.9, 120 mm, Extra Lordotic
79840130	Rod, 6.0 x 6.9, 130 mm, Extra Lordotic

Instruments/Templates

Part Number	Description
79900040	Rod Template, 40 mm, Standard
79900045	Rod Template, 45 - 60 mm, Standard
79900060	Rod Template, 60 - 90 mm, Standard
79900090	Rod Template, 90 - 130 mm, Standard
79903060	Rod Template, Expandable, 60 - 80 mm, Lordotic
79903090	Rod Template, Expandable, 90 - 130 mm, Lordotic
79901060	Rod Template, 60 - 90mm, Straight
79901090	Rod Template, 90 - 130 mm, Straight
79902060	Rod Template, Expandable, 60 - 80mm, Extra Lordotic
79902090	Rod Template, Expandable, 90 - 130 mm, Extra Lordotic
79960011	Rod Holder, Forcep
7756188	2.5 mm Hex Right-Angle Screwdriver

Cases/Trays

Part Number	Description
7991016	Instrument Set Label
7991015	Instrument Tray
1850076	Outer Case
1850079	Case Lid
79800000	BalanC Implant Suitcase 1
79800001	BalanC Implant Suitcase 2 - Multi Level Rod Module

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

Important Information on the CD HORIZON BalanC™ Spinal System

PURPOSE
The CD HORIZON BalanC™ Spinal System is intended to help provide stabilization and/or immobilization of spinal segments of the lumbar and/or sacral 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® PEEK Rod Spinal System. Refer to the CD HORIZON® Spinal System package insert for information regarding those implants. Care should be taken so 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. Implied warranties of merchantability and fitness for a particular purpose or use are specifically excluded. 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 Medtronic document. As with all orthopedic and neurosurgical implants, none of the CD HORIZON BalanC™ Spinal System components should ever be reused under any circumstances.

INDICATIONS
Any C-shaped portion of a CD HORIZON BalanC™ rod is indicated for maximum one level use from L1 to S1 in the following spinal pathologies:

- Spinal stenosis;
- Spondylolisthesis (non-isthmic) up to Grade 1;
- 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 up to Grade 2;
- Degenerative disc disease.

A single-level C-shaped CD HORIZON BalanC™ rod, or any C-shaped section of a CD HORIZON BalanC™ rod, is intended to be used in conjunction with bone screws and set screws contained with the CD HORIZON® PEEK Rod Spinal System as posterior instrumentation, with bone graft or bone substitute as an adjunct to fusion, or without bone graft as stabilization where 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® PEEK Rod Spinal System for posterior fixation as an adjunct to fusion at one, two, or three levels (interbody grafting suggested).

CONTRAINDICATIONS
Contraindications include, but are not limited to:

- Active infectious process or significant risk of infection (immunocompromise).
- Signs of local inflammation at or around the target surgical site.
- Fever or leukocytosis.
- Morbid obesity.
- Pregnancy.
- Spondylolysis 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, elevation of sedimentation rate unexplained 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 any of the device materials.
- Any case where the implant components selected for use would 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 utilization would interfere with anatomical structures or expected physiological performance.
- Any patient unwilling or unable to follow postoperative instructions.
- Unilateral 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.

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

- Early or late loosening of any or all of the components.
- Disassembly, bending, and/or breakage of any or all of the components.
- Foreign body (allergic) reaction to implants, debris, corrosion products (from crevice, fretting, and/or general corrosion) including metallosis, staining, tumor formation, and/or autoimmune disease.
- Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, fibrosis, necrosis, and/or pain.
- Bursitis and tissue or nerve damage caused by improper positioning and placement of implants or instruments.
- Post-operative change in spinal curvature, loss of correction, height, and/or reduction.
- Infection.
- Dural tears, pseudomeningocele, fistula, persistent CSF leakage, and meningitis.
- Loss of neurological function (e.g., sensory and/or motor), including paralysis (complete or incomplete), dysesthesias, hyperesthesia, anesthesia, paresthesia, appearance of radiculopathy, and/or the development or continuation of pain, numbness, neuroma, spasms, sensory loss, tingling sensation, and/or visual deficits.
- Cauda equina syndrome, neuropathy, neurological deficits (transient or permanent), paraplegia, paraparesis, reflex deficits, irritation, arachnoiditis, and/or muscle loss.
- Urinary retention, loss of bladder control, or other types of urological system compromise.
- Scar formation possibly causing neurological compromise or compression around nerves and/or pain.
- Fracture, microfracture, resorption, damage, or penetration of any spinal bone (including the sacrum, pedicles, and/or vertebral body) and/or bone graft or bone graft harvest site at, above, and/or below the level of surgery.
- Retropulsed graft.
- Herniated nucleus pulposus, disc disruption or degeneration at, above, or below the level of surgery.
- Non-union (or pseudarthrosis), delayed union, and mal-union.
- Loss of or increase in spinal mobility or function.
- Inability to perform the activities of daily living.
- Bone loss or decrease in bone density, possibly caused by stresses shielding.
- Graft donor site complications including pain, fracture, or wound healing problems.
- Ileus, gastritis, bowel obstruction, loss of bowel control, or other types of gastrointestinal system compromise.
- Hemorrhage, hematoma, occlusion, seroma, edema, hypertension, embolism, stroke, excessive bleeding, phlebitis, wound necrosis, wound dehiscence, damage to blood vessels, or other types of cardiovascular system compromise.
- Reproductive system compromise including sterility, loss of consortium, and sexual dysfunction.
- Development of respiratory problems (e.g. pulmonary embolism, atelectasis, bronchitis, pneumonia, etc.).
- Change in mental status.
- Death.

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

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 results. 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 adjunct to fusion can withstand body loads without the support of bone. In this event, bending, loosening, disassembly, 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 where achieving fusion is not the purpose of the intervention, care must be taken to ensure that the patient has sufficient load bearing capacity at the target segment. Patients with compromised (pathological or iatrogenic) load bearing capacity (stability) at the target segment may be poor candidates for non-fusion surgery at this level.

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

This device was designed for single patient use only. Do not reuse, reprocess, or resterilize this product. Reuse, reprocessing, or resterilizsation may compromise the structural integrity of the device and/or create a risk of contamination of the device which could result in patient injury, illness, or death.

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 size and shape of human bones. Unless great care is taken in patient selection, proper placement of the implant, and postoperative management to minimize stresses on the implant, such stresses may cause device fatigue and consequent breakage, bending, or loosening of the device, which may result in further injury or the need to remove the device prematurely.

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

- Patient conditions and/or pre dispositions such as those addressed in the aforementioned contraindications should be avoided.
- Care should be used in the handling and storage of the implant components. The implants should not be scratched or otherwise damaged. Implants and instruments should be protected during storage, especially from corrosive environments.
- An adequate inventory of implants should be available at the time of surgery, normally a quantity in excess of what is expected to be used.
- Since mechanical parts are involved, the surgeon should be familiar with the various components before using the equipment and should personally assemble the devices to verify that all parts and necessary instruments are present before the surgery begins. The CD HORIZON BalanC™ Spinal System components (described in the DESCRIPTION section) are not to be combined with the components from another manufacturer.
- All components and instruments should be cleaned and sterilized before use. Additional sterile components should be available in case of an unexpected need.

INTRAOPERATIVE

- Extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological functions.
- Breakage, slippage, or misuse of instruments or implant components may cause injury to the patient or operative personnel.
- Use great care to ensure that the implant surfaces are not scratched or notched since such actions may reduce the functional strength of the construct. If the rods are cut to length, they should be cut in such a way as to create a flat, non-sharp surface perpendicular to the midline of the rod. Cut the rods outside the operative field. Whenever possible, use pre-cut rods of the length needed. If a section of rod containing a radiographic marker is cut from the rod, it will no longer be possible to visualize that end of the rod under radiographic examination.
- Use great care when choosing the rod/C-shape to ensure selection of the most appropriate length and curvature of the rod/C-shape for the patient.
- Utilize an imaging system to facilitate surgery.
- Caution: Be careful that a guide-wire, if used, is not inserted too deep, becomes bent, and/or breaks. Ensure that the guide-wire does not advance during tapping or screw insertion. Remove the guide-wire and make sure it is intact. Failure to do so may cause the guide wire or part of it to advance through the bone and into a location that may cause damage to underlying structures.

Important Information on the CD HORIZON BalanC™ Spinal System *continued*

- **Caution:** Do not overtap or use a screw/bolt that is either too long or too large. Overtapping, using an incorrectly sized screw/bolt, or accidentally advancing the guidewire during tap or screw/bolt insertion may cause nerve damage, hemorrhage, or the other possible adverse events listed elsewhere in this package insert. If screws/bolts are being inserted into spinal pedicles, use as large a 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 vertebrae being fused.
- Avoid excessive reduction of a C-shaped section of a rod. Improper positioning of the C-shaped section of a rod may require excessive reduction of the rod in order to seat the rod in the multi-axial screw heads which may result in separation of the silicone bumper from the rod.
- Before closing the soft tissues, provisionally tighten (finger tighten) all of the nuts or screws, especially screws or nuts that have a break-off feature. Once this is completed, go back and firmly tighten all of the screws and nuts. Recheck the tightness of all nuts or screws after finishing to make sure that none loosened during the tightening of the other nuts or screws. Failure to do so may cause loosening of the other components.

POSTOPERATIVE

The physician's postoperative directions and warnings to the patient and the corresponding patient compliance are extremely important.

- Detailed instructions on the use and limitations of the device should be given to the patient. If partial weight-bearing is recommended or required prior to firm bony union, the patient must be warned that bending, loosening, and/or breakage of the device(s) are complications which may occur as a result of excessive or early weight-bearing or muscular activity. The risk of bending, loosening, or breakage of the CD HORIZON BalanC™ during postoperative rehabilitation may be increased if the patient is active, or if the patient is debilitated or demented. The patient should be warned to avoid falls or sudden jolts in spinal position.
- To allow the maximum chances for a successful surgical result, the patient or devices should not be exposed to mechanical vibrations or shock that may loosen the device construct. The patient should be warned of this possibility and instructed to limit and restrict physical activities, especially lifting and twisting motions and any type of sport participation. The patient should be advised not to smoke tobacco or utilize nicotine products, or to consume alcohol or non-steroidals or anti-inflammatory medications such as aspirin during the bone graft healing process.
- The patient should be advised of their inability to bend or rotate at the point of spinal fusion and taught to compensate for this permanent physical restriction in body motion.
- Failure to immobilize a delayed or non-union of bone will result in excessive and repeated stresses on the implant. By the mechanism of fatigue, these stresses can cause the eventual bending, loosening, or breakage of the device(s). It is important that immobilization of the spinal surgical site be maintained until firm bony union is established and confirmed by roentgenographic examination. If a state of non-union persists or if the components loosen, bend, and/or break, the device(s) should be revised and/or removed immediately before serious injury occurs. The patient must be adequately warned of these hazards and closely supervised to ensure cooperation until bony union is confirmed.
- As a precaution, before patients with implants receive any subsequent surgery (such as dental procedures), prophylactic antibiotics may be considered, especially for high-risk patients.
- When used as an adjunct to fusion, the CD HORIZON BalanC™ Spinal System implants are temporary internal fixation devices. Internal fixation devices are designed to stabilize the operative site during the normal healing process, and after the spine is fused these devices serve no functional purpose. In some procedures, these implants may be removed after a period of time. If the device is not removed following completion of its intended use, one or more of the following complications may occur: (1) Corrosion with localized tissue reaction or pain; (2) Migration of implant position, possibly resulting in injury; (3) Risk of additional injury from postoperative trauma; (4) Bending, loosening, and breakage which could make removal impractical or difficult; (5) Pain, discomfort, or abnormal sensations due to the presence of the device; (6) Possible increased risk of infection; (7) Bone loss due to stress shielding; and (8) Potential unknown and/or unexpected long term effects such as carcinogenesis. Implant removal should be followed by adequate postoperative management to avoid fracture, re-fracture, or other complications.
- Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopedic implants, the CD HORIZON BalanC™ Spinal System components should never be reused under any circumstances.

PACKAGING

Packages for each of the components should be intact upon receipt. 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 sterile MEDTRONIC package, all instruments and implants must be unpackaged, disassembled (if applicable), and cleaned before sterilization, introduction into a sterile surgical field, or if applicable, return of the product to MEDTRONIC. Remove all packaging materials prior to disassembly (if applicable) and cleaning. Cleaning instructions and associated disassembly instructions (if applicable) can be found at http://manuals.medtronic.com.

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 unless instructed by the Instrument Care, Cleaning and Sterilization Quick Reference Guide part number 0381424. Also, many instruments require disassembly before cleaning.

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

STERILIZATION

Unless 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:

METHOD	CYCLE	TEMPERATURE	EXPOSURE TIME	DRY TIME
Steam	Pre-Vacuum	270°F (132°C)	4 Minutes	30 Minutes
Steam	Gravity	250°F (121°C)	60 Minutes	30 Minutes
Steam*	Pre-Vacuum*	273°F (134°C)*	20 Minutes*	30 Minutes
Steam*	Gravity*	273°F (134°C)*	20 Minutes*	30 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. Not all of the sterilization parameters are considered to be standard cycles according to the Food and Drug Administration (FDA). In the United States, use only sterilizer accessories that have been cleared by the FDA for the selected sterilization cycle parameters (time and temperature). Users should only use sterilizer accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared for use in their markets. *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.

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) 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 or not 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.

EC REP

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

Notes

Notes

www.medtronic.com

www.medtronic.eu

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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.

Medtronic