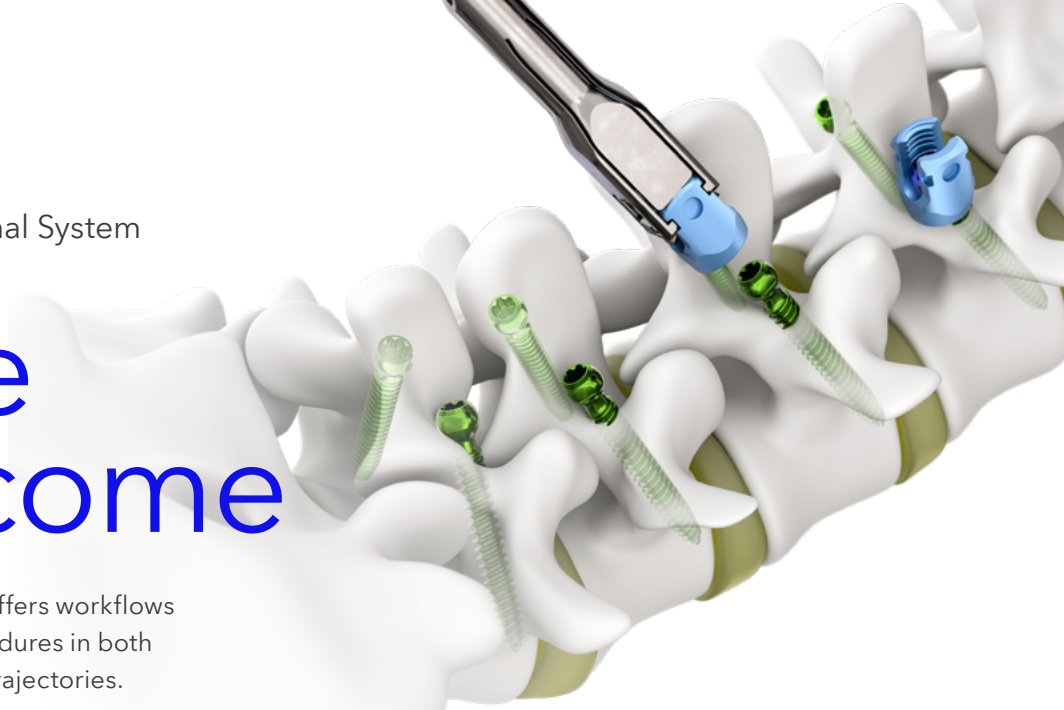
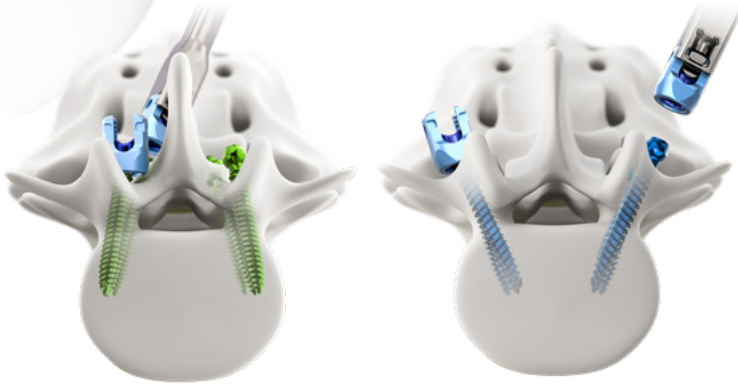
Medtronic

CD Horizon™ ModuLeX™ 5.5 Spinal System

Visualize the outcome



Fully enabled procedural solution that offers workflows for fluoro, navigation, and robotic procedures in both cortical bone screw and pedicle screw trajectories.



Set screw

- Reverse square set screw

New rod size

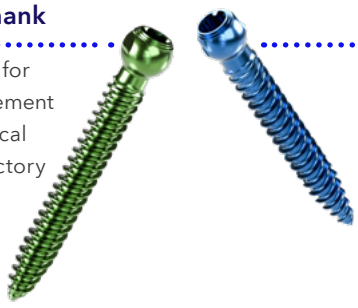
- Titanium rod
- 5.5mm dia. × 25mm L

Tulip

- 12.7 dia. ×16.25 H
- Compatible with full 5.5mm rod options
- One size fits all

Cortical shank

- Optimized for screw placement in the cortical bone trajectory



ATS shank

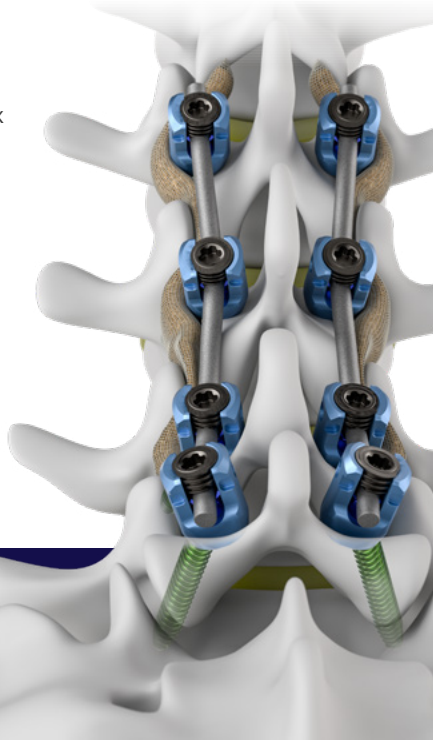
- Awl Tip Screw (ATS) with fully threaded dual lead
- Features similar to a self-drilling and self-tapping screw

ModuLeX™ 5.5 screw technology

Adaptable to both open or minimally invasive mini-open approaches to treat degenerative procedures.

Magnifuse™ bone graft

- Most osteoinductive among leading brands of demineralized bone matrix based on internal pre-clinical models*[1,2]
- Offers containment and prevents graft migration
- Fiber technology



* Animal studies are not indicative of human clinical outcomes.

1. Histological scoring table based on images from Edwards, JT et al. Clin Orthop Relat Res. 1998;357:219-228.
2. Data on File from Medtronic internal testing (11/2016):Grafton™ DBM products, Magnifuse™ Bone Graft, Xpanse™ Bone Insert, Mastergraft™ Matrix ongoing final product testing (2006-2014); Accell Connexus®, three manufacturing lots tested on 2005; Accell Evo3,® three manufacturing lots tested on 2010/2014; DBX® Strip, three manufacturing lots tested on 2010; DBX® Mix, two manufacturing lots tested on 2010; Allomatrix® DBM, five manufacturing lots tested on 1999/2005; Puros® one manufacturing lot tested on 2010.

Procedural efficiency you can see | **Modular solutions** designed for operative flexibility | **Strength** in the connection

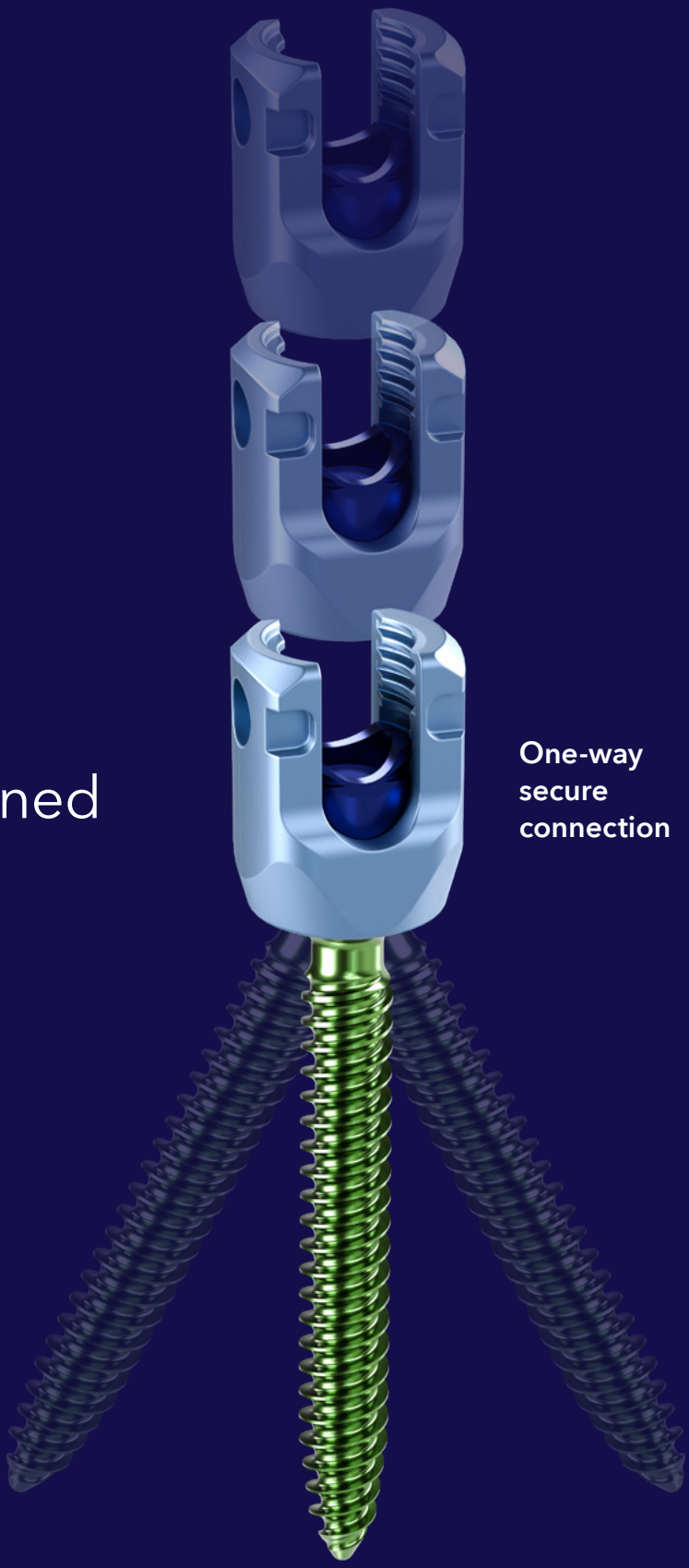
Strength in the connection

- Patented locking mechanism for secure modular shank and head connection
- "One-way" connection provides confidence in connection assembly and construct stability
- Provides comparable strength and stability compared to CD Horizon™ Legacy™ spinal system[1]

1 Based on internal testing per ASTM 1798

Modular solutions designed for operative flexibility

- One size modular tulip
- Compatible with the full CD Horizon™ 5.5mm rod options
- Up to 54° (cone) of angulation between the head and shank assembly with cortical screw, *in-situ*
- Up to 50° (cone) of angulation between the head and shank assembly with ATS Screw, *in-situ*

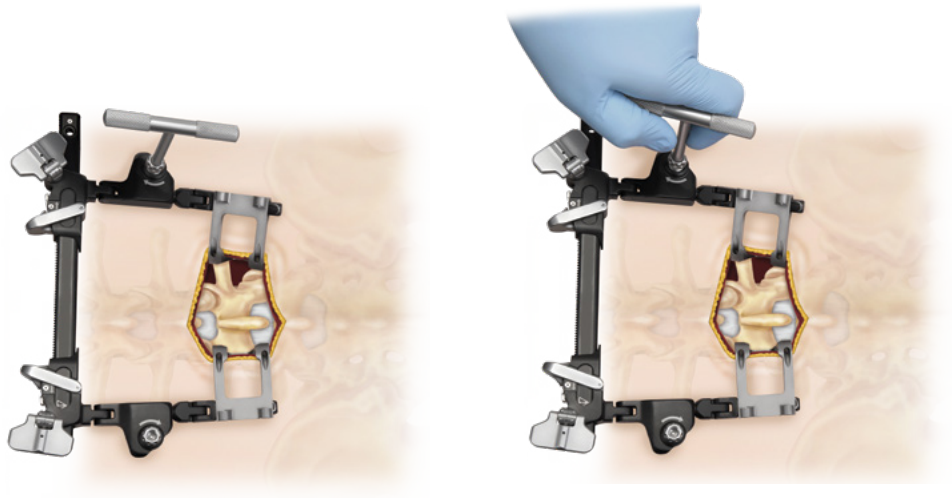


One-way secure connection

Versatile instruments for efficiency, improved visibility, and better access of the surgical site

Retractor

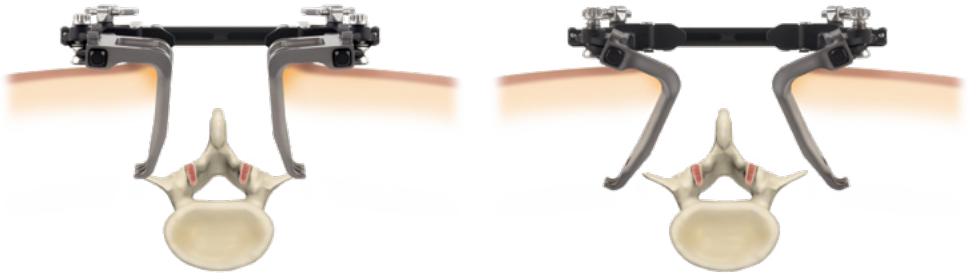
Provides midline tissue and muscle retraction with the ability to obtain a TLIF trajectory for interbody prep work and placement.



Toe out

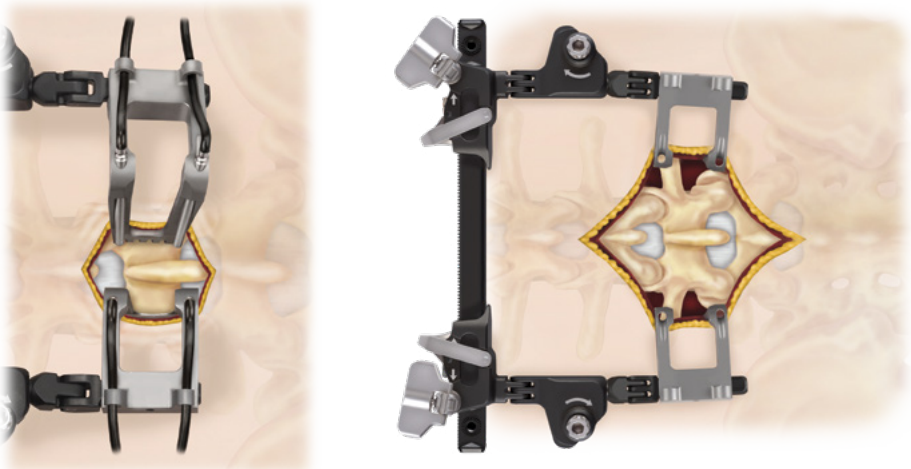
Facilitate distal retraction without additional incision.

Allows for sufficient access and increased visibility of the disc space with minimal incision.



Compatible with Scintillant bent tip or Quadrant bent tip lightsource for illumination of surgical site.

Bed frame attachment using METRx™ or Thompson Surgical flex arm.



Retractor

Hand-held retractor

Teeth
Features "arc" cut-out at distal end for facet clearance

Minimizes radiographic obstruction and enables hand-drop maneuver

- 25mm lateral offset

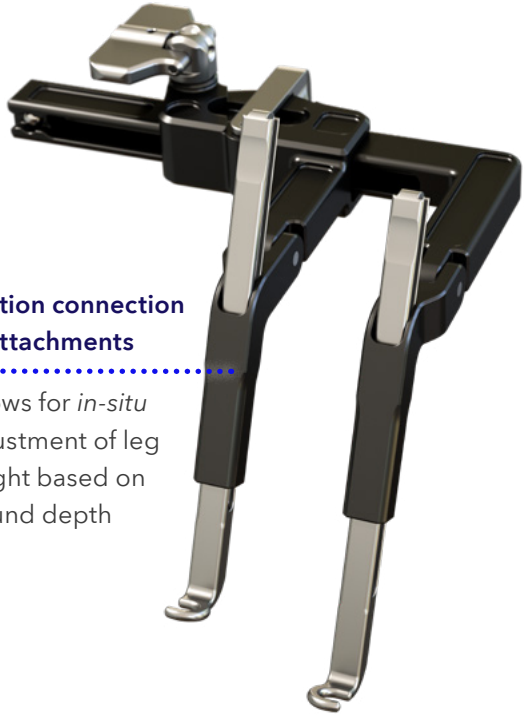
Allows for medial/lateral and cephalad/caudal instrument angulation

- 15°-37° medial/lateral
- 5°-22° cephalad/caudal

Hand-drop blade
Titanium Alloy

Solid blade
Carbon Fiber

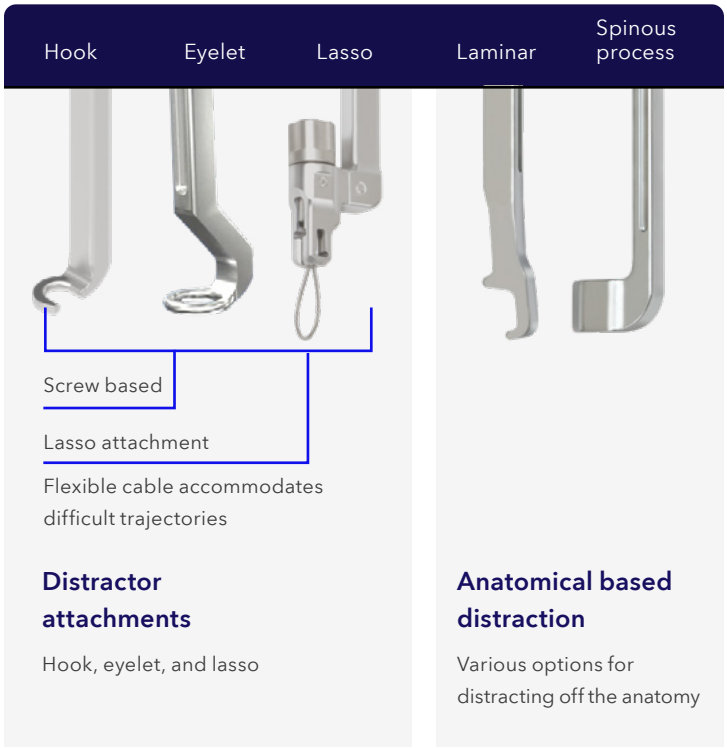
Distractor



Friction connection of attachments

Allows for *in-situ* adjustment of leg height based on wound depth

Adaptable access instruments with a variety of attachment options to fit patient anatomy and/or surgeon preference



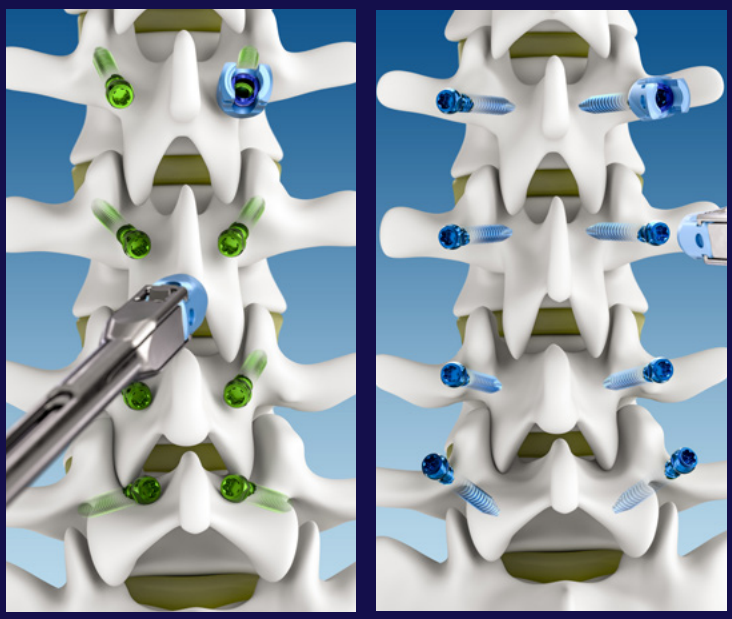
Distractor attachments

Hook, eyelet, and lasso

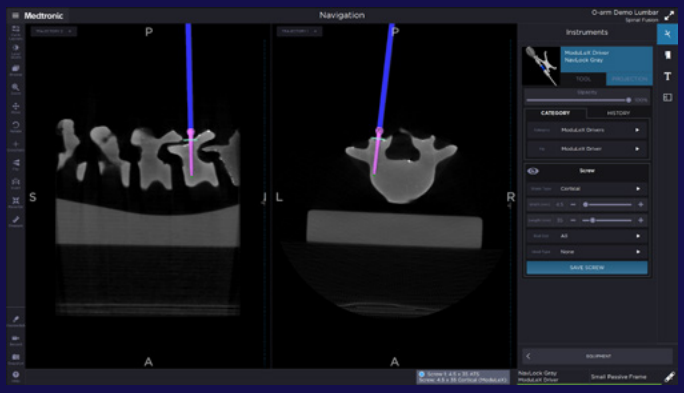
Anatomical based distraction

Various options for distracting off the anatomy

Procedural efficiency you can see



Greater visualization of patient anatomy with modular screw assembly (*in-situ*) compared to fully assembled screw.



ModuLeX™ screw technology offers an efficient navigation workflow by allowing placement of the screw shank at the beginning of the procedure to minimize the effects of shifts in anatomy during decompression.

Mazor™ X robotic guidance system and StealthStation™ navigation system for navigation and robotic-assisted guidance.

Important product information on the CD Horizon™ spinal system

Indications

The CD Horizon™ spinal system with or without Sextant™ instrumentation is intended for posterior, non-cervical fixation as an adjunct to fusion for the following indications: degenerative disc disease (DDD - defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e. fracture or dislocation), spinal stenosis, curvatures (i.e. scoliosis, kyphosis, or lordosis), tumor, pseudarthrosis, and/or failed previous fusion.

Except for hooks, when used as an anterolateral thoracic/lumbar system, the CD Horizon™ spinal system titanium, cobalt chrome, and stainless steel implants may also be used for the same indications as an adjunct to fusion.

With the exception of DDD, CD Horizon™ Legacy™ 3.5mm rods and associated components may be used for indications in skeletally mature patients as an adjunct to fusion. The 3.5mm rods may be used for the specific pediatric indications noted.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, CD Horizon™ spinal system titanium, cobalt chrome, and stainless steel implants are indicated as an adjunct to fusion to treat progressive spinal deformities (i.e. scoliosis, kyphosis, or lordosis) including idiopathic scoliosis, neuromuscular scoliosis, and congenital scoliosis. Additionally, the CD Horizon™ spinal system is intended to treat pediatric patients diagnosed with the following conditions: spondylolisthesis/spondylolysis, fracture caused by tumor and/or trauma, pseudarthrosis, and/or failed previous fusion. These devices are to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

The CD Horizon™ PEEK rods are intended to provide posterior supplemental fixation when used with an interbody fusion cage for patients diagnosed with DDD. These DDD patients may also have up to grade 1 spondylolisthesis or retrolisthesis at the involved level. This device is intended for 1-2 level use in the lumbosacral spine (L2 – S1) in skeletally mature patients. Devices are intended for use with an interbody fusion cage at the instrumented level and is not intended for stand-alone use.

The CD Horizon™ Spire™ plate is a posterior, single-level, non-pedicle supplemental fixation device intended for use in the non-cervical spine (T1-S1) as an adjunct to fusion in skeletally mature patients. It is intended for plate fixation/attachment to spinous processes for the purpose of achieving supplemental fixation in the following conditions: DDD, spondylolisthesis, trauma, and/or tumor.

To achieve additional levels of fixation, 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 Vertex™ indications.

Contraindications

Contraindications include:

- Active infectious process or significant risk of infection (immunocompromise).
- Signs of local inflammation.
- Fever or leukocytosis.
- Morbid obesity.
- Pregnancy.
- Mental illness.

POTENTIAL ADVERSE EVENTS

All adverse events associated with spinal fusion surgery without instrumentation are possible. With instrumentation, a listing of potential adverse events includes:

- Early or late loosening of components.
- Disassembly, bending, or breakage of components.
- Foreign body (allergic) reaction to implants, debris, corrosion products (from crevice, fretting, or general corrosion) including metallosis, staining, tumor formation, or autoimmune disease.
- Pressure on skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, fibrosis, necrosis, or pain.

Important product information on the Magnifuse™ family

Indications

- Magnifuse™ bone graft is intended for use as a bone graft substitute in bony voids or gaps of the skeletal system (i.e. spine, pelvis and extremities) not intrinsic to stability of bony structure. Voids or gaps may be surgically created defects or defects created by traumatic injury to bone.
- Magnifuse™ bone graft may be used in a manner comparable to autogenous bone or allograft bone. Magnifuse™ bone graft may be mixed with fluid such as bone marrow aspirate, blood, sterile water, or sterile saline to adjust consistency and handling of bone graft material. Magnifuse™ bone graft is resorbed/remodeled and replaced by host bone during the healing process.

Contraindications

- Presence of infection at the transplantation site.
- Treatment of spinal insufficiency fractures.

Caution

- This product may contain trace amounts of antibiotics (gentamicin), surfactant, and other processing solutions used in processing bone tissue as well as mesh. Caution should be exercised if the patient is allergic to antibiotics or chemicals.

Precautions

- Extensive donor blood serum testing, medical and social history screening procedures, and tissue microbiological testing were used in the qualification of tissue donors. Despite viral inactivation and extensive tissue donor selection and qualification processes used in providing this tissue graft, transmission of infectious disease through use of tissue graft is still possible.
- Bacterial infection at the graft site may also occur. Adverse outcomes potentially attributable to Magnifuse™ bone graft must be reported promptly to Medtronic.
- Adequate fixation should be used to stabilize the implant site during bone formation and healing in bony voids or gaps of the skeletal system.

Important product information on the Mazor™ robotic guidance platform

Indications

The Mazor X™ system is indicated for precise positioning of surgical instruments or spinal implants during general spinal surgery. It may be used in either open or minimally invasive or percutaneous procedures.

Mazor X™ system 3-D imaging capabilities provide a processing and conversion of 2-D fluoroscopic projections from standard C-Arms into volumetric 3-D image. It is intended to be used whenever the clinician and/or patient benefits from generated 3-D imaging of high contrast objects.

The Mazor X™ navigation tracks the position of instruments, during spinal surgery, in relation to the surgical anatomy and identifies this position on diagnostic or intraoperative images of a patient.

Please see the package insert for the complete list of indications, contraindications, warnings, precautions, and other important medical information. An electronic version of the package insert may be found at www.medtronic.com/manuals.

Important product information on the O-arm™ imaging system

Indications

The O-arm™ O2 imaging system is a mobile x-ray system designed for 2D fluoroscopic and 3D imaging for adult and pediatric patients weighing 60 lbs or greater and having an abdominal thickness greater than 16cm, and is intended to be used where a physician benefits from 2D and 3D information of anatomic structures and objects with high x-ray attenuation such as bony anatomy and metallic objects. The O-arm™ O2 imaging system is compatible with certain image guided surgery systems.

Please see the package insert for the complete list of indications, contraindications, warnings, precautions, and other important medical information. An electronic version of the package insert may be found at www.medtronic.com/manuals.

Important product information on the Stealthstation™ S8 system

Indications

The StealthStation™ S8 system is intended as an aid for precisely locating anatomical structures in either open or percutaneous surgical procedures. The StealthStation™ system is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the skull, a long bone, or vertebra, can be identified relative to a CT or MR- based model, fluoroscopy images, or digitized landmarks of the anatomy.

Please see the package insert for the complete list of indications, contraindications, warnings, precautions, and other important medical information. An electronic version of the package insert may be found at www.medtronic.com/manuals.

Medtronic
Spinal and Biologics Business
Worldwide Headquarters

2600 Sofamor Danek Drive
Memphis, TN 38132

Medtronic
Sofamor Danek USA, Inc.
1800 Pyramid Place
Memphis, TN 38132
(901) 396-3133
(800) 876-3133

Customer Service:
(800) 933-2635

medtronic.com

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Note: Manuals can be viewed using a current version of any major internet browser. For best results, use Adobe Acrobat® Reader with the browser.

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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.

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