MRI Information for
Medtronic Spinal and Biologics Devices

Not for distribution in the US or its territories.
Table of Contents

MRI Information for Medtronic Spinal and Biologics Implants ................................................. 4

MR Safe ............................................................................................................................................ 5
  MASTERGRAFT™ Granules and Mini-Granules (Oral Maxillofacial) ........................................... 5
  MASTERGRAFT™ Granules and Mini-Granules (Orthopaedic) .................................................. 6
  MASTERGRAFT™ Matrix .............................................................................................................. 7
  MASTERGRAFT™ Putty (Oral Maxillofacial) .............................................................................. 8
  MASTERGRAFT™ Putty (Orthopaedic) ....................................................................................... 9
  MASTERGRAFT™ Strip .............................................................................................................. 10
  KYPHON™ ActivOs™ Bone Cement with Hydroxyapatite ..................................................... 11
  KyphOs™ FS Bone Substitute .................................................................................................. 12
  KYPHON™ HV-R™ Bone Cement ........................................................................................... 13
  KYPHON™ Xpede™ Bone Cement ......................................................................................... 14

MR Conditional .......................................................................................................................... 15
  ATLANTIS™ Anterior Cervical Plate System ............................................................................ 15
  BRYAN® Cervical Disc ........................................................................................................... 17
  CD HORIZON™ Spinal System ............................................................................................... 19
    - CD HORIZON™ ANTAORES™ DUAL ROD SYSTEM ......................................................... 19
    - CD HORIZON™ ECLIPSE .................................................................................................. 19
    - CD HORIZON™ FENESTRATED SCREW SPINAL SYSTEM .............................................. 19
    - CD HORIZON™ LEGACY™ 3.5MM, 4.5MM, 5.5MM, 6.5MM ......................................... 19
    - CD HORIZON™ LEGACY™ ANTERIOR DUAL ROD SYSTEM ....................................... 19
    - CD HORIZON™ LEGACY™ CORTICAL BONE SCREW .................................................. 19
    - CD HORIZON™ LEGACY™ ILIAC SPINAL SYSTEM ..................................................... 19
    - CD HORIZON™ LEGACY™ PEEK ROD SYSTEM ........................................................... 19
    - CD HORIZON™ LONGITUDE™ SPINAL SYSTEM .......................................................... 19
    - CD HORIZON™ M10 ......................................................................................................... 19
    - CD HORIZON™ M8 ......................................................................................................... 19
    - CD HORIZON™ MRC ....................................................................................................... 19
    - CD HORIZON™ PERC PEEK SYSTEM ......................................................................... 19
    - CD HORIZON™ SEXTANT SPINAL SYSTEM ................................................................ 19
    - CD HORIZON™ SOLERA™ ............................................................................................. 19
    - CD HORIZON™ SOLERA™ FENESTRATED SCREW SPINAL SYSTEM ............................ 19
    - CD HORIZON™ X10 CROSSLINK™ SYSTEM ................................................................ 19
  COLORADO 2™ Spinal System .................................................................................................... 21
  COLORADO 2™ FX Spinal System ............................................................................................ 22
  LIBERTY™ Posterior Spinal System ......................................................................................... 23
  TSRH™ Spinal System ............................................................................................................... 24
MRI Information for Medtronic Spinal and Biologics Implants

Metallic objects may pose problems for the use of Magnetic Resonance Imaging (MRI) due to displacement forces and torque, excessive implant heating, and image artifacts. The specific devices listed in this document have all been classified as MR-Safe or MR-Conditional in accordance with American Society for Testing Materials International, F2503, Standard Practice for “Marking Medical Device and Other Items for Safety in the Magnetic Resonance Environment” and with the applicable portions of ISO 14630 which indicates that test methods in ASTM F2052 Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment, ASTM 2119 Test Method for Evaluation of MR Image Artifacts from Passive Implants, ASTM F2182 Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging, and ASTM F2213 Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment can be used to evaluate the safety of an implant in the MRI environment. ISO 14630 also utilizes the safety terms and symbols given in ASTM F2503 Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment.

All devices labeled as MR-Safe contain no metal and may undergo an MRI scan with no conditions, unless another implanted device is present.

All devices labeled as MR-Conditional pose no known MRI-related hazards or additional risks to patients scanned under the specific MR-scan parameters provided in this booklet.

Medtronic Spinal and Biologics implants deemed to be “worst case” in terms of size, materials, and metallic volumes were tested directly for MRI-related issues. Testing was conducted using a 1.5 Tesla and/or 3 Tesla MRI systems utilizing the MRI ASTM standards ASTM F2052, ASTM F2119, ASTM F2182, and ASTM F2213. For devices that were evaluated, but were not tested directly, engineering rationales were completed to compare these devices to a “worst case” Medtronic product and to adopt the worst case MRI parameters. These devices are identified and are provided as such in this booklet. Based on this approach, several devices may use the same MRI parameters, as specifically indicated in this booklet.
MASTERGRAFT™ Granules and Mini-Granules (Oral Maxillofacial)

The MASTERGRAFT™ Granules and Mini-Granules may be used alone or in combination with autograft to provide bone void filler that is resorbed/remodeled and is replaced by host bone during the healing process. MASTERGRAFT™ Granules and Mini-Granules are packed into bony voids or gaps to fill and/or augment dental oral/maxillofacial bony tissue. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone.

Procedures specific to MASTERGRAFT™ Granules include:

- Filling of dental extraction sockets
- Filling of cystic defects
- Oral/maxillofacial augmentation or reconstruction.

Procedures specific to MASTERGRAFT™ Mini Granules include:

- Filling of periodontal defects
- Sinus lifts
- Alveolar ridge augmentation
- Filling of dental extraction sockets
- Filling of cystic defects
- Oral/maxillofacial augmentation or reconstruction.

MASTERGRAFT™ Granules may be used with or without internal fixation, and may be mixed with autograft as a bone graft extender. MASTERGRAFT™ Granules and Mini-Granules are manufactured from biphasic calcium phosphate ceramic.

The aforementioned materials used to manufacture MASTERGRAFT™ Granules and Mini-Granules are non-metallic, non-conducting material. As such, there are no concerns with the performance of MASTERGRAFT™ Granules in an MRI environment and this device can justifiably be labeled as MR-Safe per ASTM F2503.

Review the MRI labeling for the devices used in conjunction with the MASTERGRAFT™ Granules or Mini-Granules before performing an MRI scan on the patient. In the event the patient has devices other than the Medtronic MASTERGRAFT™ Granules or Mini-Granules device, contact the specific device manufacturer. The presence of other implants or the health state of the patient may necessitate a reduction of the MRI parameters.
MASTERGRAFT™ Granules and Mini-Granules (Orthopaedic)

The MASTERGRAFT™ Granules and Mini-Granules may be used alone or in combination with autograft to provide bone void filler that is resorbed/remodeled and is replaced by host bone during the healing process. MASTERGRAFT™ Granules and Mini-Granules are packed into bony voids or gaps to fill and/or augment dental oral/maxillofacial bony tissue. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone.

MASTERGRAFT™ Granules and Mini-Granules are manufactured from biphasic calcium phosphate ceramic. The aforementioned materials used to manufacture MASTERGRAFT™ Granules and Mini-Granules are non-metallic, non-conducting material. As such, there are no concerns with the performance of MASTERGRAFT™ Granules in an MRI environment and this device can justifiably be labeled as MR-Safe per ASTM F2503.

Review the MRI labeling for the devices used in conjunction with the MASTERGRAFT™ Granules or Mini-Granules before performing an MRI scan on the patient. In the event the patient has devices other than the Medtronic MASTERGRAFT™Granules or Mini-Granules device, contact the specific device manufacturer. The presence of other implants or the health state of the patient may necessitate a reduction of the MRI parameters.
MASTERGRAFT™ Matrix

The MASTERGRAFT™ Matrix is to be combined with autogenous bone marrow and is indicated for bony voids or gaps not intrinsic to the stability of the bony structure. MASTERGRAFT™ Matrix is to be gently packed into bony voids or gaps of the skeletal system (i.e. the posterolateral spine, pelvis, ilium, and/or extremities). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The device resorbs and is replaced with bone during the healing process.

MASTERGRAFT™ Matrix is manufactured from a combination of medical grade purified collagen of bovine origin and biphasic calcium phosphate ceramic.

The aforementioned materials used to manufacture MASTERGRAFT™ Matrix are non-metallic, non-conducting material. As such, there are no concerns with the performance of MASTERGRAFT™ Matrix in an MRI environment and this device can justifiably be labeled as MR-Safe per ASTM F2503.

Review the MRI labeling for the devices used in conjunction with the MASTERGRAFT™ Matrix before performing an MRI scan on the patient. In the event the patient has devices other than the Medtronic MASTERGRAFT™ Matrix device, contact the specific device manufacturer. The presence of other implants or the health state of the patient may necessitate a reduction of the MRI parameters.
MASTERGRAFT™ Putty (Oral Maxillofacial)

The MASTERGRAFT™ Putty is combined with either sterile water and/or autograft to provide a bone void filler that is resorbed/remodeled and is replaced by host bone during the healing process. MASTERGRAFT™ Putty is packed into bony voids or gaps to fill and/or augment dental oral/maxillofacial bony tissue. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone.

Procedures include:
- Filling of periodontal defects
- Filling of dental extraction sockets
- Filling of cystic defects
- Sinus lifts
- Alveolar ridge augmentation
- Oral/maxillofacial augmentation or reconstruction.

MASTERGRAFT™ Putty may be used with or without internal fixation, and may be mixed with autograft as a bone graft extender. MASTERGRAFT™ Putty is manufactured from a combination of medical grade purified collagen of bovine origin and biphasic calcium phosphate ceramic.

The aforementioned materials used to manufacture MASTERGRAFT™ Putty are non-metallic, non-conducting material. As such, there are no concerns with the performance of MASTERGRAFT™ Putty in an MRI environment and this device can justifiably be labeled as MR-Safe per ASTM F2503.

Review the MRI labeling for the devices used in conjunction with the MASTERGRAFT™ Putty before performing an MRI scan on the patient. In the event the patient has devices other than the Medtronic MASTERGRAFT™ Putty device, contact the specific device manufacturer. The presence of other implants or the health state of the patient may necessitate a reduction of the MRI parameters.
MASTERGRAFT™ Putty (Orthopaedic)

The MASTERGRAFT™ Putty combined with either autogenous bone marrow, and/or sterile water, and/or autograft is indicated as a bone void filler for bony voids or gaps not intrinsic to the stability of the bony structure. Additionally, MASTERGRAFT™ with autograft as a bone graft extender. MASTERGRAFT™ Putty devices are to be gently packed into bony voids or gaps of the skeletal system (e.g. the posterolateral spine, pelvis, ilium, and/or extremities). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. Both devices resorb and are replaced with bone during the healing process.

MASTERGRAFT™ Putty is manufactured from a combination of medical grade purified collagen of bovine origin and biphasic calcium phosphate ceramic.

The aforementioned materials used to manufacture MASTERGRAFT™ Putty are non-metallic, non-conducting material. As such, there are no concerns with the performance of MASTERGRAFT™ Putty in an MRI environment and this device can justifiably be labeled as MR-Safe per ASTM F2503.

Review the MRI labeling for the devices used in conjunction with the MASTERGRAFT™ Putty before performing an MRI scan on the patient. In the event the patient has devices other than the Medtronic MASTERGRAFT™ Putty device, contact the specific device manufacturer. The presence of other implants or the health state of the patient may necessitate a reduction of the MRI parameters.
MASTERGRAFT™ Strip

The MASTERGRAFT™ Strip is to be combined with autogenous bone marrow and is indicated for bony voids or gaps not intrinsic to the stability of the bony structure and can be used as a bone graft extender. The device is to be gently packed into bony voids or gaps of the skeletal system (i.e. the posterolateral spine, pelvis, ilium, and/or extremities). These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The device resorbs and is replaced with bone during the healing process. MASTERGRAFT™ Strip is manufactured from a combination of medical grade purified collagen of bovine origin and biphasic calcium phosphate ceramic.

The aforementioned materials used to manufacture MASTERGRAFT™ Strip are non-metallic, non-conducting material. As such, there are no concerns with the performance of MASTERGRAFT™ Strip in an MRI environment and this device can justifiably be labeled as MR-Safe per ASTM F2503.

Review the MRI labeling for the devices used in conjunction with the MASTERGRAFT™ Strip before performing an MRI scan on the patient. In the event the patient has devices other than the Medtronic MASTERGRAFT™ Strip device, contact the specific device manufacturer. The presence of other implants or the health state of the patient may necessitate a reduction of the MRI parameters.
KYPHON™ ActivOs™ Bone Cement with Hydroxyapatite

KYPHON™ ActivOs™ Bone Cement with Hydroxyapatite is indicated for use as a fixation material in vertebral compression fractures undergoing balloon kyphoplasty treatment.

KYPHON™ ActivOs™ Bone Cement with Hydroxyapatite includes a sterile powder and a sterile liquid component that when mixed form the product. The nominal composition of KYPHON™ as follows:

- **POWDER** (22.5 g of sterile powder in a packet)
  - Methylmethacrylate-styrene-copolymer 38%
  - Bariumsulfate 10%
  - Dibenzoyl peroxide 2%
  - Hydroxyapatite 50%

- **LIQUID** (9.0 g of sterile liquid in a vial)
  - Methylmethacrylate (monomer) 99.45%
  - N,N-dimethyl-p-toluidine 0.6%
  - Hydroquinone monomethylether 60ppm

† The actual weight percentages of the individual components will vary within accepted ranges.

The aforementioned materials used to manufacture KYPHON™ ActivOs™ Bone Cement with Hydroxyapatite are non-metallic, non-conducting materials. As such, there are no concerns with the performance of KYPHON™ ActivOs™ Bone Cement with Hydroxyapatite in an MRI environment, and this device can be justifiably labeled as MR-Safe per ASTM F2503.

Review the MRI labeling for the devices used in conjunction with the KYPHON™ ActivOs™ Bone Cement with Hydroxyapatite before performing an MRI scan on the patient. In the event the patient has devices other than the KYPHON™ ActivOs™ Bone Cement with Hydroxyapatite device, contact the specific device manufacturer. The presence of other implants or the health state of the patient may necessitate a reduction of the MRI parameters.
KyphOs™ FS Bone Substitute

KyphOs™ FS Bone Substitute is a cancellous bone substitute for use during balloon kyphoplasty treatment of type A1.1, A1.2, or A3.1<sup>1</sup> vertebral body fractures.


KyphOs™ FS Bone Substitute is a sterile, osteoconductive bone substitute material based on inorganic calcium phosphate salts. The powder component consists of calcium and phosphate salts and the starter solution consists of an aqueous phosphate solution. KyphOs™ FS Bone Substitute contains no materials of human or animal origin. The composition of KyphOs™ FS is as follows:

<table>
<thead>
<tr>
<th>POWDER COMPOSITION&lt;sup&gt;†&lt;/sup&gt; (% w/w)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Ca₃(PO₄)₂</td>
<td>77.4</td>
</tr>
<tr>
<td>Mg₃(PO₄)₂</td>
<td>14.3</td>
</tr>
<tr>
<td>MgHPO₄ + 3H₂O</td>
<td>4.7</td>
</tr>
<tr>
<td>SrCO₃</td>
<td>3.6</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>LIQUID COMPOSITION&lt;sup&gt;†&lt;/sup&gt; (% w/v)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Diammonium hydrogen phosphate solution (NH₄)₂HPO₄</td>
<td>46.23</td>
</tr>
</tbody>
</table>

<sup>†</sup>The actual weight percentages of the individual components will vary within accepted ranges.

The aforementioned materials used to manufacture KyphOs™ FS Bone Substitute are non-metallic, non-conducting material. As such, there are no concerns with the performance of KyphOs™ FS Bone Substitute in an MRI environment and this device can justifiably be labeled as MR-Safe per ASTM F2503.

Review the MRI labeling for the devices used in conjunction with the KyphOs™ FS Bone Substitute before performing an MRI scan on the patient. In the event the patient has devices other than the Medtronic KyphOs™ FS Bone Substitute device, contact the specific device manufacturer. The presence of other implants or the health state of the patient may necessitate a reduction of the MRI parameters.
KYPHON™ HV-R™ Bone Cement

KYPHON™ HV-R™ Bone Cement is indicated for the treatment of pathological fractures of the vertebral body due to osteoporosis, cancer, or benign lesions using a kyphoplasty or vertebroplasty procedure. Cancer includes multiple myeloma and metastatic lesions, including those arising from breast or lung cancer, or lymphoma. Benign lesions include hemangioma and giant cell tumor.

KYPHON™ HV-R™ Bone Cement is provided as a two component system. The powder component consists of a PMMA copolymer (polymethylmethacrylate/ methyl-methacrylate-styrene copolymer) with barium sulfate as a radiopacifier and benzoyl peroxide as an initiator. The liquid component consists of methylmethacrylate monomer, with the addition of hydroquinone as a stabilizer and N,N-dimethyl-p-toluidine as a promoter. The powder and liquid components are mixed prior to use. The nominal composition of KYPHON™ HV-R™ is as follows:

<table>
<thead>
<tr>
<th>Composition of KYPHON™ HV-R™ Bone Cement†</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>POWDER</strong></td>
</tr>
<tr>
<td>Methylmethacrylate-styrene-copolymer</td>
</tr>
<tr>
<td>Barium sulfate</td>
</tr>
<tr>
<td>Benzoil peroxide</td>
</tr>
<tr>
<td><strong>LIQUID</strong></td>
</tr>
<tr>
<td>Methylmethacrylate (monomer)</td>
</tr>
<tr>
<td>N, N-dimethyl-p-toluidine</td>
</tr>
<tr>
<td>Hydroquinone</td>
</tr>
</tbody>
</table>

† The actual weight percentages of the individual components will vary within accepted ranges.

The aforementioned materials used to manufacture KYPHON™ HV-R™ Bone Cement are non-metallic, non-conducting material. As such, there are no concerns with the performance of KYPHON™ HV-R™ Bone Cement in an MRI environment and this device can justifiably be labeled as MR-Safe per ASTM F2503.

Review the MRI labeling for the devices used in conjunction with the KYPHON™ HV-R™ Bone Cement before performing an MRI scan on the patient. In the event the patient has devices other than the Medtronic KYPHON™ HV-R™ Bone Cement device, contact the specific device manufacturer. The presence of other implants or the health state of the patient may necessitate a reduction of the MRI parameters.
KYPHON™ Xpede™ Bone Cement

KYPHON™ Xpede™ Bone Cement is indicated for the treatment of pathological fractures of the vertebral body due to osteoporosis, cancer, or benign lesions using a cementoplasty (i.e. kyphoplasty or vertebroplasty) procedure. Cancer includes multiple myeloma and metastatic lesions, including those arising from breast or lung cancer, or lymphoma. Benign lesions include hemangioma and giant cell tumor. Pathologic fracture may include a symptomatic vertebral body microfracture (as documented by appropriate imaging and/or presence of a lytic lesion) without obvious loss of vertebral body height.

Kypthon™ Xpede™ Bone Cement is provided as a two component system. The powder component consists of a PMMA copolymer (polymethylmethacrylate/methyl-methacrylate-styrene copolymer) with barium sulfate as a radiopacifier and benzoyl peroxide as an initiator. The liquid component consists of methylmethacrylate monomer, with the addition of hydroquinone as a stabilizer and N,N-dimethyl-p-toluidine as a promoter. The powder and liquid components are mixed prior to use. The nominal composition of KYPHON™ Xpede™ is as follows:

<table>
<thead>
<tr>
<th>Component</th>
<th>Composition</th>
</tr>
</thead>
<tbody>
<tr>
<td>POWDER</td>
<td>20 grams of sterile powder in a packet</td>
</tr>
<tr>
<td>Methylmethacrylate-styrene copolymer</td>
<td>69.1% w/w</td>
</tr>
<tr>
<td>Barium sulfate</td>
<td>30.0% w/w</td>
</tr>
<tr>
<td>Benzoyl peroxide</td>
<td>0.9% w/w</td>
</tr>
<tr>
<td>LIQUID</td>
<td>9.0 grams of sterile liquid in a vial</td>
</tr>
<tr>
<td>Methylmethacrylate (monomer)</td>
<td>99.5% w/w</td>
</tr>
<tr>
<td>N,N-Dimethyl-p-toluidine</td>
<td>0.5% w/w</td>
</tr>
<tr>
<td>Hydroquinone</td>
<td>75 ppm</td>
</tr>
</tbody>
</table>

† The actual weight percentages of the individual components will vary within accepted ranges.

The aforementioned materials used to manufacture Kyphon™ Xpede™ Bone Cement are non-metallic, non-conducting material. As such, there are no concerns with the performance of Kyphon™ Xpede™ Bone Cement in an MRI environment and this device can justifiably be labeled as MR-Safe per ASTM F2503.

Review the MRI labeling for the devices used in conjunction with the Kyphon™ Xpede™ Bone Cement before performing an MRI scan on the patient. In the event the patient has devices other than the Medtronic Kyphon™ Xpede™ Bone Cement device, contact the specific device manufacturer. The presence of other implants or the health state of the patient may necessitate a reduction of the MRI parameters.
MR Conditional

ATLANTIS™ Anterior Cervical Plate System

The ATLANTIS™ Anterior Cervical Plate System components are temporary implants intended for anterior interbody screw fixation of the cervical spine during the development of a cervical spinal fusion.

The ATLANTIS™ Anterior Cervical Plate System consists of a variety of shapes and sizes of bone plates (setscrews and washers are pre-assembled to the plates), screws, and associated instruments.

The ATLANTIS™ Anterior Cervical Plate System implant components are made from titanium alloy, with certain plates having sub components manufactured from shape memory alloys (Nitinol-NiTi).

Bench top testing of the worst case within the ATLANTIS™ Anterior Cervical Plate System resulted in classifying the system MR-Conditional in a 1.5 Tesla and 3.0 Tesla MRI systems.

The MRI test results for the ATLANTIS™ Anterior Cervical Plate System, which outlines the MRI scanning conditions and settings to be used is on page 16. In the event the patient has devices other than the ATLANTIS™ Anterior Cervical Plate System device, contact the specific device manufacturer. The presence of other implants or the health state of the patient may necessitate a reduction of the MRI parameters.
MRI COMPLIABILITY TESTING RESULTS

<table>
<thead>
<tr>
<th>Classification</th>
<th>Settings</th>
<th>Max Heating</th>
<th>Artifacts</th>
</tr>
</thead>
<tbody>
<tr>
<td>MR-Conditional</td>
<td>1.5 Tesla, 64 MHz</td>
<td>≤ 5.9°C</td>
<td>See below.</td>
</tr>
<tr>
<td></td>
<td>3.0 Tesla, 128 MHz</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

MRI INFORMATION

Non-clinical testing has demonstrated the ATLANTIS™ Anterior Cervical Plate System is MR-Conditional. A patient with this device can be safely scanned in an MRI system meeting the following conditions:

**Static Magnetic Field**
- Static magnetic field of 1.5 Tesla or 3 Tesla.
- Maximum spatial field gradient of 3000 Gauss/cm or less.
- Maximum MRI system reported, whole body averaged specific absorption rate (SAR) of 2.0W/kg or less (Normal Operating Mode).

**MRI-Related Heating**
Under the scan conditions defined above, the worst case construct within the ATLANTIS™ Anterior Cervical Plate System produced a temperature increase of 5.9°C above the background after 15 minutes of continuous scanning in non-clinical testing per ASTM F2182.

**Artifact Information**
MRI image quality may be compromised if the area of interest is in the same area or relatively close to the position of the ATLANTIS™ Anterior Cervical Plate System. The artifact size information is as follows:

<table>
<thead>
<tr>
<th>Pulse Sequence</th>
<th>T1-SE</th>
<th>T1-SE</th>
<th>GRE</th>
<th>GRE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Signal Void Size</td>
<td>3,408mm²</td>
<td>734mm²</td>
<td>4,466mm²</td>
<td>1,573mm²</td>
</tr>
<tr>
<td>Imaging Plane</td>
<td>Parallel</td>
<td>Perpendicular</td>
<td>Parallel</td>
<td>Perpendicular</td>
</tr>
</tbody>
</table>

Therefore, optimization of MRI imaging parameters to compensate for the presence of this device may be necessary.
The BRYAN™ Cervical Disc is a cervical intervertebral disc prosthesis designed to permit motion similar to the normal cervical functional spinal unit. The prosthesis is intended to treat stable cervical degenerative disc disease without fusion, thereby providing the patient with the capability for motion at the treated level.

The BRYAN™ Cervical Disc consists of a polyurethane nucleus designed to fit between two titanium alloy surfaces (shells).

The BRYAN™ Cervical Disc is indicated for use in skeletally mature patients undergoing primary surgery for treatment of mechanically stable, degenerative disc disease of the cervical spine at any one level or two adjacent levels between C3 and C7, as demonstrated by signs and/ or symptoms of radiculopathy and/ or myelopathy associated with spondylotic foraminal or canal stenosis and/or disc herniations.

The MRI test results for the BRYAN™ Cervical Disc, which outlines the MRI scanning conditions and settings to be used is on page 18. In the event the patient has devices other than the BRYAN™ Cervical Disc device, contact the specific device manufacturer. The presence of other implants or the health state of the patient may necessitate a reduction of the MRI parameters.
MRI INFORMATION
Non-clinical testing demonstrated that the BRYAN™ Cervical Disc is MR-Conditional. It can be scanned safely under the following conditions:

**Static Magnetic Field**
- Static magnetic field of 1.5 Tesla and 3.0 Tesla.
- Highest Spatial gradient magnetic field of 720 Gauss/cm
- Maximum whole body average specific absorption rate (SAR) of 2.0 W/kg or less under Normal Operating Mode only, for 15 minutes of scanning (per pulse sequence).

In non-clinical testing, the BRYAN™ Cervical Disc produced a maximum temperature rise of 1.7°C at a maximum whole body averaged SAR of 2.1 W/kg, as assessed by calorimetry for 15 minutes of MRI scanning (per pulse sequence) in a 1.5-Tesla MRI system (1.5-Tesla/64-MHz, Magnetom, Siemens Medical Solutions, Malvern, PA. Software Numaris/4, Version Syngo MRI 2002B DHHS). Additionally, the BRYAN™ Cervical Disc System produced a maximum temperature rise of 2.0°C at a maximum whole body averaged SAR of 2.7 W/kg, as assessed by calorimetry for 15 minutes of MRI scanning (per pulse sequence) in a 3-Tesla MRI system (3-Tesla/128-MHz, Excite, G3.0-052B, General Electric Healthcare, Milwaukee, WI).

**Artifact Information**
MRI image quality may be compromised if the area of interest is in the same area or relatively close to the position of the BRYAN™ Cervical Disc. The artifact size information is as follows:

<table>
<thead>
<tr>
<th>Pulse Sequence</th>
<th>T1-SE</th>
<th>T1-SE</th>
<th>GRE</th>
<th>GRE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Signal Void Size</td>
<td>582mm²</td>
<td>557mm²</td>
<td>1,350mm²</td>
<td>1,287mm²</td>
</tr>
<tr>
<td>Imaging Plane</td>
<td>Parallel</td>
<td>Perpendicular</td>
<td>Parallel</td>
<td>Perpendicular</td>
</tr>
</tbody>
</table>

The image artifact extends approximately 25 mm from the device, when scanned in non-clinical testing using a gradient echo sequence in a 3 Tesla MRI system (Excite, HDx, Software 14X.M5, General Electric Healthcare, Milwaukee, WI) using a transmit/receive RF body coil.
CD HORIZON™ Spinal System

The following systems are classified under the CD Horizon™ Spinal System:

- CD HORIZON™ ANTARES™ Dual Rod System
- CD HORIZON™ ECLIPSE
- CD HORIZON™ Fenestrated Screw Spinal System
- CD HORIZON™ LEGACY™ 3.5mm, 4.5mm, 5.5mm, 6.5mm
- CD HORIZON™ LEGACY™ Anterior Dual Rod System
- CD HORIZON™ LEGACY™ Cortical Bone Screw
- CD HORIZON™ LEGACY™ Iliac Spinal System
- CD HORIZON™ LEGACY™ PEEK Rod System
- CD HORIZON™ LONGITUDE™ Spinal System
- CD HORIZON™ M10
- CD HORIZON™ M8
- CD HORIZON™ MRC
- CD HORIZON™ PERC PEEK SYSTEM
- CD HORIZON™ SEXTANT Spinal System
- CD HORIZON™ SOLERA™
- CD HORIZON™ SOLERA™ Fenestrated Screw Spinal System
- CD HORIZON™ X10 CROSSLINK™ System

The CD HORIZON™ Spinal System is intended to help provide immobilization and stabilization of spinal segments as an adjunct to fusion of the thoracic, lumbar, and/or sacral spine. The CD HORIZON™ Spinal System consists of a variety of shapes and sizes of rods, hooks, screws, CROSSLINK™ Plates, staples, and connecting components, as well as implant components from other Medtronic spinal systems, which can be rigidly locked into a variety of configurations, with each construct being tailor-made for the individual case.

The CD HORIZON™ Spinal System implant components are fabricated from medical grade stainless steel, medical grade titanium, titanium alloy, medical grade cobalt-chromium-molybdenum alloy, or medical grade PEEKOPTIMA-LT1. Certain CD HORIZON™ Spinal System components may be coated with hydroxyapatite.

Bench top testing of the worst case system, the CD HORIZON™ ENGAGE™ Spinal System implant made of stainless steel and CD HORIZON™ LEGACY™ 3.5mm Spinal System made of titanium alloy resulted in classifying the system MR-Conditional in a 1.5 Tesla and 3.0 Tesla MRI system.

The MRI test results for the CD HORIZON™ Spinal System outlining the MRI scanning conditions and settings to be used are indicated on page 20. In the event the patient has devices other than the CD HORIZON™ Spinal System device, contact the specific device manufacturer. The presence of other implants or the health state of the patient may necessitate a reduction of the MRI parameters.
MRI COMPATIBILITY TESTING RESULTS

<table>
<thead>
<tr>
<th>Classification</th>
<th>Settings</th>
<th>Max Heating</th>
<th>Artifacts</th>
</tr>
</thead>
<tbody>
<tr>
<td>MRI Conditional</td>
<td>1.5 Tesla, 64 MHz</td>
<td>≤ 9.6°C</td>
<td>Not Tested</td>
</tr>
<tr>
<td></td>
<td>3.0 Tesla, 128 MHz</td>
<td>≤ 6.7°C</td>
<td>See below.</td>
</tr>
</tbody>
</table>

MRI INFORMATION

Non-clinical testing demonstrated the CD HORIZON™ Spinal System is MR-Conditional. A patient with this device can be safely scanned immediately after device placement under the following conditions:

**Static Magnetic Field**
- Static magnetic field of 1.5 Tesla or 3 Tesla only.
- Highest spatial gradient magnetic field of 720 Gauss/cm.
- Maximum whole body averaged specific absorption rate (SAR) of 2.0 W/kg or less under normal operating mode only, for 15 minutes of scanning (per pulse sequence).

**MRI-Related Heating**
In non-clinical testing, the worst case construct with in the CD HORIZON™ Spinal System produced a maximum temperature rise of 9.6°C at an MRI system reported wholebody averaged SAR of 2.0 W/kg in a 1.5 Tesla MRI system. Additionally, the worst case construct within the CD HORIZON™ Spinal System produced a maximum temperature rise of 6.7°C at an MRI system reported whole body averaged SAR of 2.0 W/kg in a 3 Tesla (GE Signa HDx) MRI system.

**Artifact Information**
MRI image quality may be compromised if the area of interest is in the same area or relatively close to the position of the CD HORIZON™ Spinal System. The artifact size information is as follows:

<table>
<thead>
<tr>
<th>Pulse Sequence</th>
<th>T1-SE</th>
<th>T1-SE</th>
<th>GRE</th>
<th>GRE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Signal Void Size</td>
<td>83,199mm²</td>
<td>16,576mm²</td>
<td>100,378mm²</td>
<td>22,762mm²</td>
</tr>
<tr>
<td>Imaging Plane</td>
<td>Parallel</td>
<td>Perpendicular</td>
<td>Parallel</td>
<td>Perpendicular</td>
</tr>
</tbody>
</table>

The image artifact extends approximately 75mm from the device when scanned in non-clinical testing using a gradient echo sequence in a 3 Tesla MRI system (Excite, HDx, Software 14X.M5, General Electric Healthcare, Milwaukee, WI) using a transmit/receive RF body coil. Therefore, optimization of MRI imaging parameters to compensate for the presence of this device may be necessary.
COLORADO 2™ Spinal System

The COLORADO 2™ Spinal System is intended to help provide immobilization and stabilization of spinal segments as an adjunct to fusion of the thoracic, lumbar, and/or sacral spine. The COLORADO 2™ Spinal System consists of a variety of shapes and sizes of rods, hooks, screws, cross connectors, and connecting components. COLORADO 2™ implant components can be rigidly locked into a variety of configurations, with each construct being tailor-made for the individual case.

The COLORADO 2™ Spinal System implant components are fabricated from medical grade stainless steel. Alternatively, the entire system may be made out of medical grade titanium or titanium alloy.

The COLORADO 2™ Spinal System was not directly tested; the CD HORIZON™ Spinal System was selected to represent that system due to similarity of materials and a configuration at least as challenging to MRI imaging as the COLORADO 2™ Spinal System.

Bench top testing of the worst case system, the CD HORIZON™ Spinal System resulted in classifying the system MR-Conditional in a 1.5 Tesla and 3.0 Tesla MRI system.

The COLORADO 2™ Spinal System can be scanned under the same conditions as the CD HORIZON™ Spinal System (see page 20). In the event the patient has devices other than the COLORADO 2™ Spinal System, contact the specific device manufacturer. The presence of other implants or the health state of the patient may necessitate a reduction of the MRI parameters.
COLORADO 2™ FX Spinal System

The COLORADO 2™ FX Spinal System is intended to help provide immobilization and stabilization of spinal segments as an adjunct to fusion of thoracic, lumbar, and/or sacral spine. The COLORADO 2™ FX Spinal System consists of a variety of shapes and sizes of rods, hooks, screws, cross connectors, and connecting components. COLORADO 2™ FX implant components can be rigidly locked into a variety of configurations, with each construct being tailor-made for the individual case.

The COLORADO 2™ FX Spinal System implant components are fabricated from medical grade titanium alloy.

The COLORADO 2™ FX Spinal System was not directly tested; the CD HORIZON™ Spinal System was selected to represent that system due to similarity of materials and a configuration at least as challenging to MRI imaging as the COLORADO 2™ FX Spinal System.

Bench top testing of the worst case system, the CD HORIZON™ Spinal System resulted in classifying the system MR-Conditional in a 1.5 Tesla and 3.0 Tesla MRI system.

The COLORADO 2™ FX Spinal System can be scanned under the same conditions as the CD HORIZON™ Spinal System (see page 20). In the event the patient has devices other than the COLORADO 2™ FX Spinal System, contact the specific device manufacturer. The presence of other implants or the health state of the patient may necessitate a reduction of the MRI parameters.
LIBERTY™ Posterior Spinal System

The LIBERTY™ Posterior Spinal System is a temporary implant used for the correction and stabilization of the spine. The system is also intended to assist temporary stabilization and augment the development of a solid spinal fusion. These implants are intended to be removed after the development of a solid fusion mass.

The LIBERTY™ Posterior Spinal System consists of a variety of shapes and sizes of rods, hooks, screws, cross connectors, and connecting components.

The LIBERTY™ Posterior Spinal System implant components can be rigidly locked into a variety of configurations, with each construct being tailor-made for the individual case.

The LIBERTY™ Posterior Spinal System implant components are fabricated from medical grade stainless steel described by such standards as ASTM F138, Grade 2, or its ISO equivalent.

The LIBERTY™ Posterior Spinal System was not directly tested; the CD HORIZON™ Spinal System was selected to represent that system due to similarity of materials and a configuration at least as challenging to MRI imaging as the LIBERTY™ Posterior Spinal System.

Bench top testing of the worst case system, the CD HORIZON™ Spinal System resulted in classifying the system MR-Conditional in 1.5 Tesla and 3.0 Tesla MRI systems.

The LIBERTY™ Posterior Spinal System can be scanned under the same conditions as the CD HORIZON™ Spinal System (see page 20). In the event the patient has devices other than the LIBERTY™ Posterior Spinal System, contact the specific device manufacturer. The presence of other implants or the health state of the patient may necessitate a reduction of the MRI parameters.
TSRH™ Spinal System

The TSRH™ Spinal System consists of a variety of shapes and sizes of rods, hooks, screws, cross connectors, staples, plates, and connecting components, as well as implant components from other Medtronic spinal systems, which can be rigidly locked into a variety of configurations, with each construct being tailor-made for the individual case.

The TSRH™ Spinal System implant components are fabricated from medical grade stainless steel, medical grade titanium or titanium alloy, and/or medical grade cobalt-chromium-molybdenum alloy. Certain TSRH™ Spinal System components may be coated with hydroxyapatite.

The TSRH™ Spinal System was not directly tested; the CD HORIZON™ Spinal System was selected to represent that system due to similarity of materials and a configuration at least as challenging to MRI imaging as the TSRH™ Spinal System.

Bench top testing of the worst case system, the CD HORIZON™ Spinal System resulted in classifying the system MR-Conditional in a 1.5 Tesla and 3.0 Tesla MRI systems.

The TSRH™ Spinal System can be scanned under the same conditions as the CD HORIZON™ Spinal System implant (see page 20). In the event the patient has devices other than the TSRH™ Spinal System, contact the specific device manufacturer. The presence of other implants or the health state of the patient may necessitate a reduction of the MRI parameters.
The UCSS™ Screw Set consists of screws designed to compress bone grafts. Both cortical and cancellous screw threads are available. The screws are fabricated from medical grade stainless steel, or titanium alloy. The UCSS™ Screw Set was not directly tested; the CD HORIZON™ Spinal System was selected to represent that system due to similarity of materials and a configuration at least as challenging to MRI imaging as the UCSS™ Screw Set.

Bench top testing of the worst case system, the CD HORIZON™ Spinal System resulted in classifying the system MR-Conditional in 1.5 Tesla and 3.0 Tesla MRI systems.

The UCSS™ Screw Set can be scanned under the same conditions as the CD HORIZON™ Spinal System (see page 20). In the event the patient has devices other than the UCSS™ Screw Set, contact the specific device manufacturer. The presence of other implants or the health state of the patient may necessitate a reduction of the MRI parameters.
DYNAMIC COMPRESSION Shape Memory Alloy (SMA) Staple System

The SMA Staple System is intended to help achieve compression in fixation of bones in the hand, foot, tibia, and ankle.

The SMA Staple System is made of Shape Memory Alloy (Nitinol-NiTi) as described by ASTM F2063. Shape Memory Alloy is compatible with titanium implants only.

Bench top testing of the SMA Staple System made of Nitinol resulted in classifying the system MR-Conditional in a 3.0 Tesla MRI system.

The MRI test results for the SMA Staple System made of nitinol, which outlines the MRI scanning conditions and settings to be used are listed below. In the event the patient has devices other than the Medtronic device, contact the specific device manufacturer. The presence of other implants or the health state of the patient may necessitate a reduction of the MRI parameters.
MRI COMPATIBILITY TESTING RESULTS

<table>
<thead>
<tr>
<th>Classification</th>
<th>Settings</th>
<th>Max Heating</th>
<th>Artifacts</th>
</tr>
</thead>
<tbody>
<tr>
<td>MRI Conditional</td>
<td>3.0 Tesla, 128 MHz</td>
<td>(\leq 1.6^\circ\text{C})</td>
<td>See below.</td>
</tr>
</tbody>
</table>

MRI INFORMATION

Non-clinical testing demonstrated the SMA Staple System is MR Conditional. A patient with this device can be scanned safely immediately after placement under the following conditions:

**Static Magnetic Field**
- Static magnetic field of 3 Tesla or less.
- Maximum spatial gradient magnetic field of 720 Gauss/cm or less.

**MRI-Related Heating**

In non-clinical testing, the SMA Staple System produced the following temperature rise during MRI performed for 15 minutes of scanning (i.e. per pulse sequence) in the 3 Tesla (3 Tesla/128 MHz, Excite, HDx, Software 14X.M5, General Electric Healthcare, Milwaukee, WI) MRI system:
- Highest temperature change +1.6°C.

Therefore, the MRI-related heating experiments for the SMA Staple System at 3 Tesla using a transmit/receive RF body coil at an MRI system reported wholebody averaged SAR of 2.9 W/kg (i.e. associated with a calorimetry measured whole body averaged value of 2.7W/kg) indicated the greatest amount of heating that occurred in association with these specific conditions was equal to or less than +1.6°C. An MRI heating test for a static magnetic field less than 3 Tesla has not been evaluated.

**Artifact Information**

MRI image quality may be compromised if the area of interest is in the same area or relatively close to the position of the SMA Staple System. The artifact size information is as follows:

<table>
<thead>
<tr>
<th>Pulse Sequence</th>
<th>T1-SE</th>
<th>T1-SE</th>
<th>GRE</th>
<th>GRE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Signal Void Size</td>
<td>1,460mm²</td>
<td>1,016mm²</td>
<td>2,482mm²</td>
<td>1,919mm²</td>
</tr>
<tr>
<td>Imaging Plane</td>
<td>Parallel</td>
<td>Perpendicular</td>
<td>Parallel</td>
<td>Perpendicular</td>
</tr>
</tbody>
</table>

Therefore, optimization of MRI imaging parameters to compensate for the presence of this device may be necessary.
LT-CAGE™ Device

The LT-CAGE™ Lumbar Tapered Fusion Device and the LT-CAGE™ PEEK Lumbar Tapered Fusion Device consist of hollow, perforated, machined cylinders with opposing flats. The cages have a tapered design with an angle of 8.8° and are available in diameters ranging from 14 to 18mm at the narrow end of the taper, 17 to 22mm at the wide end of the taper, and in lengths ranging from 20 to 26mm. There are two holes on each of the two flat sides. On each of the two rounded aspects, there is a single rounded slot. The implants have a helical screw thread on the outer surface. One end of the device is closed. The other end is open to be filled with bone graft and is used to engage the drive instrument for insertion of the device.

The LT-CAGE™ Lumbar Tapered Fusion Device implant is made from implant grade titanium alloy (Ti-6Al-4V) described by such standards as ASTM F136 or its ISO equivalent. Alternatively, the tapered device can be made from Polyetheretherketone. This device is known as the LT-CAGE™ PEEK Lumbar Tapered Fusion Device.
**MRI COMPATIBILITY TESTING RESULTS**

<table>
<thead>
<tr>
<th>MRI Summary Table</th>
</tr>
</thead>
<tbody>
<tr>
<td>Classification</td>
</tr>
<tr>
<td>MR Conditional</td>
</tr>
</tbody>
</table>

**MRI INFORMATION**

Non-clinical testing demonstrated the LT CAGE™ Lumbar Tapered Fusion Device Implant is MR-Conditional. A patient with this device can be scanned safely immediately after placement under the following conditions:

**Static Magnetic Field**
- Static magnetic field of 3 Tesla or less
- Maximum spatial gradient magnetic field of 720 Gauss/cm or less

**MRI-Related Heating**

In non-clinical testing, the LT-CAGE™ Lumbar Tapered Fusion Device implant produced the following temperature rise during MRI performed for 15 minutes of scanning (i.e. per pulse sequence) in the 3 Tesla (3 Tesla/128 MHz, Excite, HDx, Software 14X.M5, General Electric Healthcare, Milwaukee, WI) MRI system:

- Highest temperature change +1.6°C

Therefore, the MRI-related heating experiments for the LT-CAGE™ Lumbar Tapered Fusion Device implant at 3 Tesla using a transmit/receive RF body coil at an MRI system reported whole body averaged SAR of 2.9 W/kg (i.e. associated with a calorimetry measured whole body averaged value of 2.7 W/kg) indicated the greatest amount of heating that occurred in association with these specific conditions was equal to or less than +1.6°C. An MRI heating test for a static magnetic field less than 3 Tesla has not been evaluated.

**Artifact Information**

MRI image quality may be compromised if the area of interest is in the same area or relatively close to the position of the LT-CAGE™ Lumbar Tapered Fusion Device Implant. The artifact size information is as follows:

<table>
<thead>
<tr>
<th>Pulse Sequence</th>
<th>T1-SE</th>
<th>T1-SE</th>
<th>GRE</th>
<th>GRE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Signal Void Size</td>
<td>1,437mm²</td>
<td>990mm²</td>
<td>2,347mm²</td>
<td>4,253mm²</td>
</tr>
<tr>
<td>Imaging Plane</td>
<td>Parallel</td>
<td>Perpendicular</td>
<td>Parallel</td>
<td>Perpendicular</td>
</tr>
</tbody>
</table>

Therefore, optimization of MRI imaging parameters to compensate for the presence of this device may be necessary.
The AFFINITY™ Anterior Cervical Cage System consists of a hollow, threaded, tapered metal device which inserts into the intervertebral disc space. The AFFINITY™ implants are available in diameters ranging from 6 to 12mm and in lengths ranging from 12 to 14mm.

The AFFINITY™ Anterior Cervical Cage System implants are made from implant grade titanium alloy (Ti-6Al-4V) described by ASTM F136 or its ISO equivalent.

The AFFINITY™ Anterior Cervical Cage System was not directly tested; the LT-CAGE™ Lumbar Tapered Fusion Device implant was selected to represent that system due to similarity of materials and a configuration at least as challenging to MRI imaging as the AFFINITY™ Anterior Cervical Cage System.

Bench top testing of the worst case system, the LT-CAGE™ Lumbar Tapered Fusion Device Implant made of titanium alloy resulted in classifying the system MR-Conditional in a 3.0 Tesla MRI system.

The AFFINITY™ Anterior Cervical Cage System can be scanned under the same conditions as the LT-CAGE™ Lumbar Tapered Fusion Device Implant (see page 29). In the event the patient has devices other than the AFFINITY™ Anterior Cervical Cage System, contact the specific device manufacturer. The presence of other implants or the health state of the patient may necessitate a reduction of the MRI parameters.
INTER FIX™ Threaded Fusion Device and INTER FIX™ RP Threaded Fusion Device

The INTER FIX™ Threaded Fusion Device consists of a hollow, perforated, metallic cylinder and endcap. The INTER FIX™ RP Threaded Fusion Device consists of a hollow, perforated, metallic cylinder with a single, large, outer radiused groove along the entire longitudinal axis that extends into the inside diameter of the device. Both ends of the INTER FIX™ RP implant are closed. The INTER FIX™ and INTER FIX™ RP implants are available in diameters ranging from 12 to 24mm and in lengths ranging from 20 to 29mm. The endcaps of the INTER FIX™ implants are sized according to the diameter of the cylinders and are applied to the open end of the cylinders after they are filled with autogenous bone graft.

The INTER FIX™ and the INTER FIX™ RP implants are made from implant grade titanium alloy (Ti-6Al-4V) conforming to ASTM F136.

The INTER FIX™ Threaded Fusion Device and the INTER FIX™ RP Threaded Fusion Device were not directly tested; the LT-CAGE™ Lumbar Tapered Fusion Device implant was selected to represent that system due to similarity of materials and a configuration at least as challenging to MRI imaging as the INTER FIX™ and INTER FIX™ RP implants.

Bench top testing of the worst case system, the LT-CAGE™ Lumbar Tapered Fusion Device Implant made of titanium alloy resulted in classifying the system MR-Conditional in a 3.0 Tesla MRI system.

The INTER FIX™ Threaded Fusion Device and INTER FIX™ RP Threaded Fusion Device can be scanned under the same conditions as the LT-CAGE™ Lumbar Tapered Fusion Device Implant (see page 29). In the event the patient has devices other than the INTER FIX™ Threaded Fusion Device and INTER FIX™ RP Threaded Fusion Device, contact the specific device manufacturer. The presence of other implants or the health state of the patient may necessitate a reduction of the MRI parameters.
MAVERICK™ Disc Replacement System

The MAVERICK™ Disc Replacement System is a spinal arthroplasty system intended to replace a damaged lumbar intervertebral disc. The MAVERICK™ Disc Replacement System is a permanent implant intended to maintain motion at the affected level. The MAVERICK™ Disc Replacement System consists of two cobalt-chrome-molybdenum alloy articulating components. The two components each have one polished articulating side and one roughened, hydroxyapatite-coated bone-contacting side.

The MAVERICK™ Disc Replacement System implant components are fabricated from medical grade cobalt-chromium-molybdenum alloy described by ASTM F1537.

Bench top testing of the MAVERICK™ Disc Replacement System implant made of cobalt-chromium-molybdenum alloy resulted in classifying the system MR-Conditional in a 3.0 Tesla MRI system.

The MRI test results for the MAVERICK™ Disc Replacement System made of cobalt-chromium-molybdenum alloy, which outlines the MRI scanning conditions and settings to be used is on the following page. In the event the patient has devices other than the MAVERICK™ Disc Replacement System device, contact the specific device manufacturer. The presence of other implants or the health state of the patient may necessitate a reduction of the MRI parameters.
MRI COMPATIBILITY TESTING RESULTS

<table>
<thead>
<tr>
<th>MRI Summary Table</th>
</tr>
</thead>
<tbody>
<tr>
<td>Classification</td>
</tr>
<tr>
<td>MRI Conditional</td>
</tr>
</tbody>
</table>

MRI INFORMATION

Non-clinical testing demonstrated the MAVERICK™ Disc Replacement System is MRI Conditional. A patient with this device can be scanned safely immediately after placement under the following conditions:

Static Magnetic Field
- Static magnetic field of 3 Tesla or less.
- Maximum spatial gradient magnetic field of 720 Gauss/cm or less.

MRI-Related Heating
In non-clinical testing, the MAVERICK™ Disc Replacement System produced the following temperature rise during MRI performed for 15 minutes of scanning (i.e. per pulse sequence) in the 3 Tesla (3 Tesla/128 MHz, Excite, HDx, Software 14X.M5, General Electric Healthcare, Milwaukee, WI) MRI system:
- Highest temperature change +1.8°C

Therefore, the MRI-related heating experiments for the MAVERICK™ Disc Replacement System at 3 Tesla using a transmit/receive RF bodycoil at an MRI system reported whole body averaged SAR of 2.9 W/kg (i.e. associated with a calorimetry measured whole body averaged value of 2.7 W/kg) indicated the greatest amount of heating that occurred in association with these specific conditions was equal to or less than +1.8°C. An MRI heating test lower than 3 Tesla/128 MHz has not been evaluated.

Artifact Information
MRI image quality may be compromised if the area of interest is in the same area or relatively close to the position of the MAVERICK™ Disc Replacement System. The artifact size information is as follows:

<table>
<thead>
<tr>
<th>Pulse Sequence</th>
<th>T1-SE Signal Void Size</th>
<th>T1-SE Imaging Plane</th>
<th>GRE Signal Void Size</th>
<th>GRE Imaging Plane</th>
</tr>
</thead>
<tbody>
<tr>
<td>Parallel</td>
<td>9,799mm²</td>
<td>6,933mm²</td>
<td>13,513mm²</td>
<td>12,799mm²</td>
</tr>
<tr>
<td>Perpendicular</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Therefore, optimization of MRI imaging parameters to compensate for the presence of this device may be necessary.
SATELLITE™ Spinal System

The SATELLITE™ Spinal System is a spherical implant designed to hold bone parts in alignment while they heal in order to promote interbody fusion. The SATELLITE™ Spinal System is intended to be inserted between the vertebral bodies into the disc space from L3 to S1 to help provide stabilization and to help promote intervertebral body fusion. This internal fixation device is intended for, and designed solely for holding bone parts in alignment while they heal. The SATELLITE™ Spinal System is intended to be used with bone graft.

The SATELLITE™ Spinal System implant is fabricated from cobalt chrome. Alternatively, the device may be manufactured from PEEK- polyetheretherketone with tantalum markers.

The SATELLITE™ Spinal System (cobalt chrome, PEEK with tantalum markers) was not directly tested; the MAVERICK™ Disc Replacement System was selected to represent that system due to similarity of materials and a configuration at least as challenging to MRI imaging as the SATELLITE™ Spinal System.

Bench top testing of the worst case system, the MAVERICK™ Disc Replacement System implant made of cobalt-chromium-molybdenum alloy resulted in classifying the system MR-Conditional in a 3.0 Tesla MRI system.

The SATELLITE™ Spinal System can be scanned under the same conditions as the MAVERICK™ Disc Replacement System (see page 33). In the event the patient has devices other than the SATELLITE™ Spinal System, contact the specific device manufacturer. The presence of other implants or the health state of the patient may necessitate a reduction of the MRI parameters.
The PEEK PREVAIL™ Cervical Interbody Device is an intervertebral body fusion device with internal screw fixation. The screws protrude through the interbody portion of the device and stabilize the vertebral body while preventing expulsion of the implant. The implant is “I-Beam” shaped with a 2 screw midline configuration. This device is intended to be radiolucent and the interior space of the product is to be used with autograft.

The PEEK PREVAIL™ Cervical Interbody device implant contains tantalum radiopaque markers and a Nitinol screw locking mechanism. The screws used with this device (ZEPHIR™ Anterior Cervical Screws) are manufactured from Titanium Alloy.
MRI INFORMATION
The PEEK PREVAIL™ Cervical Interbody Device was determined to be MR-Conditional based on non-clinical testing and comparison to previously evaluated Medtronic products. A patient with this device can be safely scanned immediately after device placement under the following conditions.

Static Magnetic Field
- Static magnetic field of 1.5 Tesla and 3 Tesla.
- Maximum spatial gradient magnetic field of 3000 Gauss/cm or less
- Maximum whole body average specific absorption rate (SAR) of 2.0 W/kg or less under Normal Operating Mode, for 15 minutes of scanning per pulse sequence.

MRI-Related Heating
In non-clinical testing, a worst case interbody device representative of the PEEK PREVAIL™ Cervical Interbody Device produced the following temperature rises during an MRI performed for 15 minutes of scanning (i.e. per pulse sequence) in 1.5 Tesla/64 MHz MRI system (Magnetom, Siemens Medical Solutions, Malvern, PA. Software Numaris/4, Version Syngo MR 2002B DHHS Active-shielded, horizontal field scanner) and 3 Tesla/128 MHz (Excite, HDx, Software 14X.M5, General Electric Healthcare, Milwaukee, WI. Active-shielded, horizontal field scanner) MRI systems:

<table>
<thead>
<tr>
<th>MRI system reported, whole body average SAR</th>
<th>1.5 Tesla</th>
<th>3 Tesla</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calormetry Measured values, whole body averaged SAR</td>
<td>2.1 W/kg</td>
<td>2.7 W/kg</td>
</tr>
<tr>
<td>Highest temperature change</td>
<td>1.5 °C</td>
<td>1.9 °C</td>
</tr>
</tbody>
</table>

Artifact Information
MRI image quality may be compromised if the area of interest is in the same area or relatively close to the position of the PEEK PREVAIL™ Cervical Interbody Device. Therefore, optimization of MRI imaging parameters to compensate for the presence of this device may be necessary.

MRI Patient Counseling Information
Physicians should communicate with the patient the following information about MRI with respect to the PEEK PREVAIL™ Cervical Interbody Device:

- PEEK PREVAIL™ Cervical Interbody Device performance has been established for MRI systems at field strengths of 1.5 Tesla and 3.0 Tesla.
- During an MRI, the patient may notice a warming sensation around the implant or feel a tingling sensation. If the warming or tingling sensation is uncomfortable, the patient should communicate this to the MRI technologist, the MRI should be stopped, and the settings adjusted to reduce or eliminate the sensation. The highest temperature change observed in non-clinical testing was +1.9°C (associated with specific conditions previously listed). Additionally, the metal in the implant may cause the MRI image to be distorted in the area around the implant. The MRI can be adjusted to minimize the image distortion.

Physicians should instruct patients to:
- Inform any healthcare personnel (e.g. doctor or MRI technologist) an implanted interbody device exists prior to receiving an MRI.
- The patient’s doctor will recommend whether or not an MRI is appropriate.

If PEEK PREVAIL™ Cervical Interbody Device is used in connection with any device which is not MR Conditional, be advised this combination has not been tested in the MRI environment and, therefore, higher heating and possible injury to the patient may occur.
The PRESTIGE™ LP Cervical Disc is a two-piece articulating device that is inserted into the intervertebral disc space as a single unit at a single cervical level using an anterior approach. The device is manufactured from a titanium ceramic composite (Ti-6Al-4V with 10% TiC) and consists of two metal plates which function via a ball and trough mechanism. The superior component of the implant contains the ball portion of the mechanism, and the inferior component contains the trough portion. These two features engage to create an interface designed to allow for motion after implantation. Each component is affixed to the adjacent vertebral body by two rail geometries incorporating anti-migration teeth which are press fit into two pre-drilled holes in the vertebral bone. The portion of the flat surface between the rails and contacting the vertebral endplate contains commercially pure titanium (CP Ti) plasma thermal sprayed coating designed to permit bony on-growth for additional device incorporation. The remaining portion of the flat surface is titanium ceramic roughened to enhance fixation.
MRI INFORMATION
Non-clinical testing demonstrated that the PRESTIGE™ LP Cervical Disc is MR Conditional. A patient with this device can be scanned safely immediately after placement under the following conditions:

Static Magnetic Field
- Static magnetic field of 3.0-Tesla
- Maximum spatial gradient magnetic field of 3000-Gauss/cm or less
- Whole body average specific absorption rate (SAR) of 2.9 –W/kg and peak SAR level of 6.0-W/kg

MRI-Related Heating
In non-clinical testing, the PRESTIGE™ LP Cervical Disc produced the following temperature rise during MRI performed for 15-min in the 3.0-Tesla (3.0-Tesla/128-MHz, Excite, HDx, Software 14X.M5, General Electric Healthcare, Milwaukee, WI) MRI system:

Highest temperature change +1.6°C.

Therefore, the MRI-related heating experiments for the PRESTIGE™ LP Cervical Disc at 3.0-Tesla using a transmit/receive RF body coil at an MRI system reported whole body averaged SAR of 2.9 -W/kg (i.e. associated with a calorimetry measured whole body averaged value of 2.7-W/kg) indicated the greatest amount of heating that occurred in association with these specific conditions was equal to or less than +1.6°C. MRI-Heating test for static magnetic field less than 3-Tesla has not been evaluated.

Artifact Information
MRI image quality may be compromised if the area of interest is in the same area or relatively close to the position of the PRESTIGE™ LP Cervical Disc System Implant. The artifact size information for a 3-Tesla MRI system is as follows

<table>
<thead>
<tr>
<th>Pulse Sequence</th>
<th>T1-SE</th>
<th>T1-SE</th>
<th>GRE</th>
<th>GRE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Signal Void Size</td>
<td>1,401mm²</td>
<td>1,093mm²</td>
<td>2,101mm²</td>
<td>2,422mm²</td>
</tr>
<tr>
<td>Imaging Plane</td>
<td>Parallel</td>
<td>Perpendicular</td>
<td>Parallel</td>
<td>Perpendicular</td>
</tr>
</tbody>
</table>

Therefore, optimization of MRI imaging parameters to compensate for the presence of this device may be necessary. The maximum artifact size (as seen on the gradient echo pulse sequence) extends approximately 15mm relative to the size and shape of the PRESTIGE™ LP Cervical Disc implant.
The PRESTIGE™ Cervical Disc is a two-piece articulating metal-on-metal device that is inserted into the intervertebral disc space at a single cervical level using an anterior approach. The device is manufactured from wrought type 316 stainless steel (ASTM F138) and consists of two metal plates which function via a ball and trough mechanism. The superior component of the implant contains the ball portion of the mechanism, and the inferior component incorporates the trough portion. The flat portion of each component, which contacts the vertebral endplate, is roughened through a grit blasting process.

Each component is affixed to the vertebral body by two bone screws through an anterior fang. The bone screws are held in place by a lock screw mechanism. In the implanted disc, the bone screws are divergent in the cephalic/caudal direction and convergent in the medial/lateral direction.
**MRI COMPATIBILITY TESTING RESULTS**

<table>
<thead>
<tr>
<th>Classification</th>
<th>Settings</th>
<th>Max Heating</th>
<th>Artifacts</th>
</tr>
</thead>
<tbody>
<tr>
<td>MR Conditional</td>
<td>3.0 Tesla, 128 MHz</td>
<td>( \leq 1.8^\circ \text{C} )</td>
<td>See below.</td>
</tr>
</tbody>
</table>

**MRI INFORMATION**

Non-clinical testing demonstrated the PRESTIGE™ ST Cervical Disc System is MR Conditional. A patient with this device can be scanned safely immediately after placement under the following conditions:

**Static Magnetic Field**
- Static magnetic field of 3 Tesla or less.
- Maximum spatial gradient magnetic field of 720 Gauss/cm or less.

**MRI-Related Heating**

In non-clinical testing, the PRESTIGE™ ST Cervical Disc System produced the following temperature rise during MRI performed for 15 minutes of scanning (i.e. per pulse sequence) in the 3 Tesla (3 Tesla/128 MHz, Excite, HDx, Software 14X.M5, General Electric Healthcare, Milwaukee, WI) MRI system:
- Highest temperature change \(+1.8^\circ \text{C}\)

Therefore, the MRI-related heating experiments for the PRESTIGE™ ST Cervical Disc System at 3 Tesla using a transmit/receive RF body coil at an MRI system reported whole body averaged SAR of 2.9 W/kg (i.e. associated with a calorimetry measured whole body averaged value of 2.7 W/kg) indicated the greatest amount of heating that occurred in association with these specific conditions was equal to or less than \(+1.8^\circ \text{C}\). An MRI heating test lower than 3 Tesla/128 MHz has not been evaluated.

**Artifact Information**

MRI image quality may be compromised if the area of interest is in the same area or relatively close to the position of the PRESTIGE™ ST Cervical Disc System. The artifact size information is as follows:

<table>
<thead>
<tr>
<th>Pulse Sequence</th>
<th>T1-SE</th>
<th>T1-SE</th>
<th>GRE</th>
<th>GRE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Signal Void Size</td>
<td>4,989mm²</td>
<td>2,950mm²</td>
<td>9,596mm²</td>
<td>13,770mm²</td>
</tr>
<tr>
<td>Imaging Plane</td>
<td>Parallel</td>
<td>Perpendicular</td>
<td>Parallel</td>
<td>Perpendicular</td>
</tr>
</tbody>
</table>

Therefore, optimization of MRI imaging parameters to compensate for the presence of this device may be necessary.
PYRAMID™ +4 Anterior Lumbar Plate

The PYRAMID™ +4 ANTERIOR LUMBAR PLATE System is a supplemental fixation device consisting of a variety of shapes and sizes of plates, and screws, as well as ancillary products and instrument sets. The PYRAMID™ +4 ANTERIOR LUMBAR PLATE System components can be locked into a variety of configurations, with each construct being tailor-made for the individual case.

As with all orthopedic and neurosurgical implants, none of the PYRAMID™ +4 ANTERIOR LUMBAR PLATE Fixation System components should ever be reused under any circumstances.

PYRAMID™ +4 ANTERIOR LUMBAR PLATE System implant components are made of titanium alloy. Stainless steel and titanium implant components must not be used together in a construct.
MRI COMPATIBILITY TESTING RESULTS

<table>
<thead>
<tr>
<th>Classification</th>
<th>Settings</th>
<th>Max Heating</th>
<th>Artifacts</th>
</tr>
</thead>
<tbody>
<tr>
<td>MR Conditional</td>
<td>3.0 Tesla, 128 MHz</td>
<td>≤1.9°C</td>
<td>See below.</td>
</tr>
</tbody>
</table>

MRI INFORMATION

Non-clinical testing demonstrated the PYRAMID™ Anterior Lumbar Plate and screws is MR Conditional. A patient with this device can be scanned safely immediately after placement under the following conditions:

Static Magnetic Field
- Static magnetic field of 3 Tesla or less
- Maximum spatial gradient magnetic field of 720 Gauss/cm or less

MRI-Related Heating

In non-clinical testing, the PYRAMID™ Anterior Lumbar Plate and screws produced the following temperature rise during MRI performed for 15 minutes of scanning (i.e. per pulse sequence) in the 3 Tesla (3 Tesla/128 MHz, Excite, HDx, Software 14X.M5, General Electric Healthcare, Milwaukee, WI) MRI system:
- Highest temperature change +1.9°C

Therefore, the MRI-related heating experiments for the PYRAMID™ Anterior Lumbar Plate and screws at 3 Tesla using a transmit/receive RF body coil at an MRI system reported whole body averaged SAR of 2.9 W/kg (i.e. associated with a calorimetry measured whole body averaged value of 2.7 W/kg) indicated the greatest amount of heating that occurred in association with these specific conditions was equal to or less than +1.9°C. An MRI heating test for a static magnetic field less than 3 Tesla has not been evaluated.

Artifact Information

MRI image quality may be compromised if the area of interest is in the same area or relatively close to the position of the PYRAMID™ Anterior Lumbar Plate and screws. The artifact size information is as follows:

<table>
<thead>
<tr>
<th>Pulse sequence</th>
<th>T1-SE</th>
<th>T1-SE</th>
<th>GRE</th>
<th>GRE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Signal Void Size</td>
<td>3,249mm²</td>
<td>2,585mm²</td>
<td>5,905mm²</td>
<td>4,899mm²</td>
</tr>
<tr>
<td>Imaging Plane</td>
<td>parallel</td>
<td>perpendicular</td>
<td>parallel</td>
<td>perpendicular</td>
</tr>
</tbody>
</table>

Therefore, optimization of MRI imaging parameters to compensate for the presence of this device may be necessary.
The SOVEREIGN™ Spinal System is an intervertebral body fusion device with internal screw fixation. The screws protrude through the interbody portion of the device and stabilize the vertebral body while preventing expulsion of the implant. The implant is lens-shaped with three holes for placement of titanium screws. If the physician chooses to use screws with the implant, the accompanying cover plate must be used. This device is intended to be radiolucent and the interior space of the product is to be used with bone graft.

The SOVEREIGN™ Spinal System interbody device is manufactured from PEEK (polyetheretherketone) and contains tantalum radiopaque markers. The screws used with this device are manufactured from titanium alloy.
MRI INFORMATION

In non-clinical testing the SOVEREIGN™ Spinal System was determined to be MR-Conditional. A patient with this device can be scanned safely immediately after placement under the following conditions:

Static Magnetic Field
- Static magnetic field of 1.5 Tesla and 3 Tesla.
- Maximum spatial gradient magnetic field of 3000 Gauss/cm or less
- Maximum whole body average specific absorption rate (SAR) of 2.0 W/kg or less under Normal Operating Mode, for 15 minutes of scanning per pulse sequence.

MRI-Related Heating
In non-clinical testing, the SOVEREIGN™ Spinal System produced the following temperature rises during MRI performed for 15 minutes of scanning (i.e. per pulse sequence) in 1.5 Tesla/64 MHz MRI system (Magnetom, Siemens Medical Solutions, Malvern, PA. Software Numaris/4, Version Syngo MR 2002B DHHS Active-shielded, horizontal field scanner) and 3 Tesla/128 MHz (Excite, HDx, Software 14X.M5, General Electric Healthcare, Milwaukee, WI) MRI systems:

| MRI system reported, whole body averaged SAR | 1.5 Tesla | 3 Tesla |
| Calorimetry measured values, whole body averaged SAR | 2.1 W/kg | 2.7 W/kg |
| Highest temperature change | +1.8°C | +1.7°C |

Artifact Information
MRI image quality may be compromised if the area of interest is in the same area or relatively close to the position of the SOVEREIGN™ Spinal System. The artifact size information is as follows:

| Pulse Sequence | T1-SE | T1-SE | GRE | GRE |
| Signal Void Size | 1,540mm² | 1,397mm² | 3,595mm² | 3,782mm² |
| Imaging Plane | Parallel | Perpendicular | Parallel | Perpendicular |

Therefore, optimization of MRI imaging parameters to compensate for the presence of this device may be necessary. The maximum artifact size (i.e. as seen on the gradient echo pulse sequence) extends approximately 20mm relative to the size and shape of the SOVEREIGN™ Spinal System.

MRI Patient Counseling Information
Physicians should communicate with the patient the following information about MRI with respect to the SOVEREIGN™ Spinal System:
- SOVEREIGN™ Spinal System performance has been established for MRI systems at field strengths of 1.5 Tesla and 3.0 Tesla.
- During an MRI, the patient may notice a warming sensation around the implant or feel a tingling sensation. If the warming or tingling sensation is uncomfortable the patient should communicate this to the MRI technologist, the MRI should be stopped, and the settings adjusted to reduce or eliminate the sensation. The highest temperature change observed in non-clinical testing was +1.8°C (associated with specific conditions listed above).
- Additionally, the metal in the implant may cause the MRI image to be distorted in the area around the implant. The MRI can be adjusted to minimize the image distortion.

Physicians should instruct patients to:
• Inform any healthcare personnel (e.g. doctor or MRI technologist) they have an implanted interbody device prior to receiving and MRI.
• The patient’s doctor will recommend whether or not an MRI is appropriate.

If SOVEREIGN™ Spinal System is used in connection with any device which is not MR Conditional, be advised this combination has not been tested in the MRI environment and, therefore, higher heating and possible injury to the patient may occur.
ANATOMIC PEEK Cervical Fusion System

The ANATOMIC PEEK Cervical Fusion System device is intended for stabilization use and to promote bone fusion during the normal healing process following surgical correction of disorders of the spine. The product should be implanted only by a physician who is thoroughly knowledgeable in the implant’s material and surgical aspects and who has been instructed as to its mechanical and material applications and limitations. This device is manufactured from medical grade polyetheretherketone (PEEK) with tantalum markers and is provided sterile.

The ANATOMIC PEEK Cervical Fusion System device consists of PEEK cages of various widths and heights, which can be inserted between two cervical vertebral bodies to give support and correction during cervical interbody fusion surgeries. The hollow geometry of the implants allows them to be packed with autogenous bone graft in cervical interbody fusion procedures. When used in the cervical spine, the ANATOMIC PEEK devices are used individually with supplemental fixation and autograft bonegraft.

The ANATOMIC PEEK Cervical Fusion System was not directly tested; the SOVEREIGN™ Spinal System was selected to represent that system due to similarity of materials and a configuration at least as challenging to MRI imaging as the ANATOMIC PEEK Cervical Fusion System.

The ANATOMIC PEEK Cervical Fusion System can be scanned under the same conditions as the SOVEREIGN™ Spinal System (see page 44). In the event the patient has devices other than ANATOMIC PEEK Cervical Fusion System, contact the specific device manufacturer. The presence of other implants or the health state of the patient may necessitate a reduction of the MRI parameters.
The CAPSTONE CONTROL™ Spinal System consists of cages of various widths and heights, which can be inserted between two lumbar or lumbosacral vertebral bodies to give support and correction during lumbar interbody fusion surgeries. The hollow geometry of the implants allows them to be packed with autogenous bone graft.

The CAPSTONE CONTROL™ Spinal System is made from polyetheretherketone (PEEK). The device contains radiographic markers manufactured from tantalum.

The CAPSTONE CONTROL™ Spinal System was not directly tested; the SOVEREIGN™ Spinal System was selected to represent that system due to similarity of materials and a configuration at least as challenging to MRI imaging as the CAPSTONE CONTROL™ Spinal System.

Bench top testing of the worst case system, the SOVEREIGN™ Spinal System made of PEEK, titanium alloy, and tantalum resulted in classifying the system MR-Conditional in 1.5 and 3.0 Tesla MRI systems.

The CAPSTONE CONTROL™ Spinal System can be scanned under the same conditions as the SOVEREIGN™ Spinal System (see page 44). In the event the patient has devices other than the CAPSTONE CONTROL™ Spinal System, contact the specific device manufacturer. The presence of other implants or the health state of the patient may necessitate a reduction of the MRI parameters.
CAPSTONE CONTROL PTC™ Spinal System

The CAPSTONE CONTROL PTC™ Spinal System consists of cages of various widths and heights, which can be inserted between two lumbar or lumbosacral vertebral bodies to give support and correction during lumbar interbody fusion surgeries. The hollow geometry of the implants allows them to be packed with autogenous bone graft.

The CAPSTONE CONTROL PTC™ Spinal System is made from polyetheretherketone (PEEK). The device contains radiographic markers manufactured from tantalum.

The CAPSTONE CONTROL PTC™ Spinal System was not directly tested; the SOVEREIGN™ Spinal System was selected to represent that system due to similarity of materials and a configuration at least as challenging to MRI imaging as the CAPSTONE CONTROL PTC™ Spinal System.

Bench top testing of the worst-case system, the SOVEREIGN™ Spinal System made of PEEK, titanium alloy, and tantalum resulted in classifying the system MR-Conditional in 1.5 and 3.0 Tesla MRI systems.

The CAPSTONE CONTROL PTC™ Spinal System can be scanned under the same conditions as the SOVEREIGN™ Spinal System (see page 44). In the event the patient has devices other than the CAPSTONE CONTROL PTC™ Spinal System, contact the specific device manufacturer. The presence of other implants or the health state of the patient may necessitate a reduction of the MRI parameters.
The CAPSTONE™ L Spinal System consists of cages of various widths and heights, which can be inserted between two lumbar or lumbosacral vertebral bodies to give support and correction during lumbar interbody fusion surgeries. The hollow geometry of the implants allows them to be packed with autogenous bonegraft.

The CAPSTONE™ L Spinal System is made from polyetheretherketone (PEEK). The device contains radiographic markers manufactured from tantalum.

The CAPSTONE™ L Spinal System was not directly tested; the SOVEREIGN™ Spinal System was selected to represent that system due to similarity of materials and a configuration at least as challenging to MRI imaging as the CAPSTONE™ L Spinal System.

The CAPSTONE™ L Spinal System can be scanned under the same conditions as the SOVEREIGN™ Spinal System (see page 44). In the event the patient has devices other than the CAPSTONE™ L Spinal System, contact the specific device manufacturer. The presence of other implants or the health state of the patient may necessitate a reduction of the MRI parameters.
CAPSTONE™ Spinal System (PEEK)

The CAPSTONE™ Spinal System (PEEK) consists of cages of various widths and heights, which can be inserted between two lumbar or lumbosacral vertebral bodies to give support and correction during lumbar interbody fusion surgeries. The hollow geometry of the implants allows them to be packed with autogenous bone graft.

The CAPSTONE™ Spinal System (PEEK) is made from polyetheretherketone (PEEK). The device contains radiographic markers manufactured from tantalum.

The CAPSTONE™ Spinal System (PEEK) was not directly tested; the SOVEREIGN™ Spinal System was selected to represent that system due to similarity of materials and a configuration at least as challenging to MRI imaging as the CAPSTONE™ Spinal System (PEEK) implants.

Bench top testing of the worst case system, the SOVEREIGN™ Spinal System made of PEEK, titanium alloy, and tantalum resulted in classifying the system MR-Conditional in 1.5 and 3.0 Tesla MRI systems.

The CAPSTONE™ Spinal System (PEEK) can be scanned under the same conditions as the SOVEREIGN™ Spinal System (see page 44). In the event the patient has devices other than the CAPSTONE™ Spinal System (PEEK), contact the specific device manufacturer. The presence of other implants or the health state of the patient may necessitate a reduction of the MRI parameters.
The CLYDESDALE™ Spinal System PEEK interbody fusion devices are intended for stabilization use and to promote bone fusion during the normal healing process following surgical correction of disorders of the spine. The product should be implanted only by a physician who is thoroughly knowledgeable in the implant’s material and surgical aspects and who has been instructed as to its mechanical and material applications and limitations.

The CLYDESDALE™ Spinal System consists of PEEK cages of various widths and heights, which include Tantalum markers. These devices can be inserted between two lumbar or lumbosacral vertebral bodies to give support and correction during lumbar interbody fusion surgeries. The hollow geometry of the implants allows them to be packed with autogenous bone graft.

The CLYDESDALE™ Spinal System was not directly tested; the SOVEREIGN™ Spinal System was selected to represent that system due to similarity of materials and a configuration at least as challenging to MRI imaging as the CLYDESDALE™ Spinal System.

The CLYDESDALE™ Spinal System can be scanned under the same conditions as the SOVEREIGN™ Spinal System (see page 44). In the event the patient has devices other than CLYDESDALE™ Spinal System, contact the specific device manufacturer. The presence of other implants or the health state of the patient may necessitate a reduction of the MRI parameters.
CORNERSTONE™ PSR Spinal System

The CORNERSTONE™ PSR Spinal System device is intended for stabilization use and to promote bone fusion during the normal healing process following surgical correction of disorders of the spine. The product should be implanted only by a physician who is thoroughly knowledgeable in the implant’s material and surgical aspects and who has been instructed as to its mechanical and material applications and limitations. This device is manufactured from medical grade polyetheretherketone (PEEK) with tantalum or titanium alloy wire markers and is provided sterile.

The CORNERSTONE™ PSR Spinal System consists of cages of various widths and heights, which can be inserted between two cervical vertebral bodies to give support and correction during cervical interbody fusion surgeries. The hollow geometry of the implants allows them to be packed with autogenous bone graft in cervical fusion procedures. The CORNERSTONE™ PSR Spinal System device is to be used with supplemental instrumentation and is to be implanted via an open, anterior approach.

The CORNERSTONE™ PSR Spinal System was not directly tested; the SOVEREIGN™ Spinal System was selected to represent that system due to similarity of materials and a configuration at least as challenging to MRI imaging as the CORNERSTONE™ PSR Spinal System.

The CORNERSTONE™ PSR Spinal System can be scanned under the same conditions as the SOVEREIGN™ Spinal System (see page 44). In the event the patient has devices other than the CORNERSTONE™ PSR Spinal System, contact the specific device manufacturer. The presence of other implants or the health state of the patient may necessitate a reduction of the MRI parameters.
CRESCE...TM PEEK Spinal System

The CRESCENT™ PEEK Spinal System fusion device is intended for stabilization use and to promote bone fusion during the normal healing process following surgical correction of disorders of the spine. The product should be implanted only by a physician who is thoroughly knowledgeable in the implant’s material and surgical aspects and who has been instructed as to its mechanical and material applications and limitations.

The CRESCENT™ PEEK Spinal System consists of PEEK cages of various widths and heights, which can be inserted between two lumbar or lumbosacral vertebral bodies to give support and correction during lumbar interbody fusion surgeries. The hollow geometry of the implants allows them to be packed with autogenous bone graft.

The CRESCENT™ PEEK Spinal System was not directly tested; the SOVEREIGN™ Spinal System was selected to represent that system due to similarity of materials and a configuration at least as challenging to MRI imaging as the CRESCENT™ PEEK Spinal System.

The CRESCENT™ PEEK Spinal System can be scanned under the same conditions as the SOVEREIGN™ Spinal System (see page 44). In the event the patient has devices other than the CRESCENT™ PEEK Spinal System, contact the specific device manufacturer. The presence of other implants or the health state of the patient may necessitate a reduction of the MRI parameters.
The ELEVATE™ Spinal System is an expandable PEEK, Tantalum, and Titanium alloy interbody device consisting of various lengths and starting heights, which can be inserted between two lumbar or lumbosacral vertebral bodies to give support and correction during lumbar interbody fusion surgeries.

The ELEVATE™ Spinal System expands for adjustable lordosis and height to match patient anatomy. The hollow geometry of the implants allows them to be packed with autogenous bone graft. The implants may be implanted via a posterior or transforaminal approach and the procedure may be open or minimally invasive.

The ELEVATE™ Spinal System can be implanted unilaterally and bilaterally.

The ELEVATE™ Spinal System is intended to be inserted with ELEVATE™ Spinal System reusable instruments.

The ELEVATE™ Spinal System implants are for single use only.

The ELEVATE™ Spinal System was not directly tested; the SOVEREIGN™ Spinal System was selected to represent that system due to similarity of materials and a configuration at least as challenging to MRI imaging as the ELEVATE™ Spinal System.

The ELEVATE™ Spinal System can be scanned under the same conditions as the SOVEREIGN™ Spinal System (see page 44). In the event the patient has devices other than the CAPSTONE™ L Spinal System, contact the specific device manufacturer. The presence of other implants or the health state of the patient may necessitate a reduction of the MRI parameters.
The HOURGLASS™ Vertebral Body Spacer is intended for vertebral body replacement to aid in the surgical correction and stabilization of the spine. This system is indicated for single-level use only in the thoracic and lumbar anterior spine.

The HOURGLASS™ Vertebral Body Spacer consists of PEEK-polyetheretherketone implants of various lengths. The HOURGLASS™ Vertebral Body Spacer implant components are made of medical grade PEEK-polyetheretherketone and Tantalum markers.

The HOURGLASS™ Vertebral Body Spacer must be used with additional anterior and/or posterior spinal instrumentation to augment stability. Do not use implant components from any other manufacturer with HOURGLASS™ Vertebral Body Spacer components. They must not be used together in a construct. As with all orthopedic implants, in no case may the implants be re-used.

The HOURGLASS™ Vertebral Body Spacer was not directly tested; the SOVEREIGN™ Spinal System was selected to represent that system due to similarity of materials and a configuration at least as challenging to MRI imaging as the HOURGLASS™ Vertebral Body Spacer implants.

Bench top testing of the worst case system, the SOVEREIGN™ Spinal System made of PEEK, titanium alloy, and tantalum resulted in classifying the system MR-Conditional in 1.5 and 3.0 Tesla MRI systems.

The HOURGLASS™ Vertebral Body Spacer can be scanned under the same conditions as the SOVEREIGN™ Spinal System (see page 44). In the event the patient has devices other than the HOURGLASS™ Vertebral Body Spacer, contact the specific device manufacturer. The presence of other implants or the health state of the patient may necessitate a reduction of the MRI parameters.
The PERIMETER™-C Spinal System consists of spacers of various widths and heights, which can be inserted between two cervical vertebral bodies to give support and correction during cervical interbody fusion procedures. Additionally, this implant has six degrees of lordosis and the superior and inferior surfaces of the implant are designed with teeth which interact with the surface of the vertebral endplates to aid in resisting expulsion. The hollow geometry of the implants allows them to be packed with autogenous bonegraft and is to be used with supplemental fixation in all procedures.

The PERIMETER™-C Spinal System is made from polyetheretherketone (PEEK) with tantalum wire markers and is provided sterile.

The PERIMETER™-C Spinal System was not directly tested; the SOVEREIGN™ Spinal System was selected to represent that system due to similarity of materials and a configuration at least as challenging to MRI imaging as the PERIMETER™-C Spinal System.

The PERIMETER™-C Spinal System can be scanned under the same conditions as the SOVEREIGN™ Spinal System (see page 44). In the event the patient has devices other than the PERIMETER™-C Spinal System, contact the specific device manufacturer. The presence of other implants or the health state of the patient may necessitate a reduction of the MRI parameters.
PERIMETER™ Interbody Fusion Device (PEEK)

The PERIMETER™ Interbody Fusion device consists of cages of various widths and heights which can be inserted between two lumbar or lumbosacral vertebral bodies to give support and correction during lumbar interbody fusion surgeries. The hollow geometry of the implants allows them to be packed with autogenous bone graft. The PERIMETER™ Interbody device is to be used with supplemental instrumentation. The PERIMETER™ Interbody Fusion device is offered in a variety of sizes ranging from 8 to 20mm in height, 21 to 28mm in length, and between 19 and 38mm in width. An array of lordosis options are provided for this device spanning from 4 to 15° of angulation. The PEEK polyetheretherketone device is designed with teeth across both the superior and inferior surfaces to allow the implant to grip the superior and inferior endplates, thus providing expulsion resistance.

The PERIMETER™ Interbody Fusion device (PEEK) is made from polyetheretherketone. The device contains radiographic markers manufactured from titanium alloy or tantalum.

The PERIMETER™ Interbody Fusion device (PEEK) was not directly tested; the SOVEREIGN™ Spinal System was selected to represent that system due to similarity of materials and a configuration at least as challenging to MRI imaging as the PERIMETER™ Interbody Fusion device (PEEK).

The PERIMETER™ Interbody Fusion device can be scanned under the same conditions as the SOVEREIGN™ Spinal System (see page 44). In the event the patient has devices other than the PERIMETER™ Interbody Fusion device, contact the specific device manufacturer. The presence of other implants or the health state of the patient may necessitate a reduction of the MRI parameters.
TELAMON™ PEEK Spinal System

The TELAMON™ PEEK Spinal System fusion device is intended for stabilization use and to promote bone fusion during the normal healing process following surgical correction of disorders of the spine. The product should be implanted only by a physician who is thoroughly knowledgeable in the implant’s material and surgical aspects and who has been instructed as to its mechanical and material applications and limitations.

The TELAMON™ PEEK Spinal System consists of PEEK cages of various widths and heights, which can be inserted between two lumbar or lumbosacral vertebral bodies to give support and correction during lumbar interbody fusion surgeries. The hollow geometry of the implants allows them to be packed with autogenous bone graft or bone substitute materials.

The TELAMON™ PEEK Spinal System was not directly tested; the SOVEREIGN™ Spinal System was selected to represent that system due to similarity of materials and a configuration at least as challenging to MRI imaging as the TELAMON™ PEEK Spinal System.

The TELAMON™ PEEK Spinal System can be scanned under the same conditions as the SOVEREIGN™ Spinal System (see page 44). In the event the patient has devices other than TELAMON™ PEEK Spinal System, contact the specific device manufacturer. The presence of other implants or the health state of the patient may necessitate a reduction of the MRI parameters.
T2 XVBR™ Spinal System

T2 XVBR™ Spinal System is an adjustable vertebral body replacement implant intended for use in the thoracolumbar spine to replace a collapsed, damaged, or unstable vertebral body due to tumor or trauma. The T2 XVBR™ Spinal System is offered in a variety of centerpiece diameters and modular End Caps.

The End Caps can be used to add Kyphosis/Lordosis to the construct enabling the construct to be customized to each patient’s anatomy.

As with all orthopedic and neurosurgical implants, none of the T2 XVBR™ Spinal System components should ever be reused under any circumstances.

The T2 XVBR™ Spinal System is manufactured from three materials. The primary material is Titanium Alloy; the device also includes small amounts for Cobalt Chrome and Nitinol.
MRI INFORMATION
In non-clinical testing the T2 XVBR™ Spinal System was determined to be MR Conditional. A patient with this device can be scanned safely, immediately after placement under the following conditions:

Static Magnetic Field
- Static magnetic field of 1.5 Tesla and 3 Tesla.
- Maximum spatial gradient magnetic field of 3000 Gauss/cm or less
- Maximum whole body average specific absorption rate (SAR) of 2.0 W/kg or less under Normal Operating Mode, for 15 minutes of scanning per pulse sequence.
- No local RF transmit coils shall be placed over the device.

MRI-Related Heating
Based on measurements of RF heating according to ASTM F2182, the T2 XVBR™ Spinal System produced a maximum temperature of 7.74°C above the background for a whole body SAR of 2 W/kg in a 1.5-Tesla/64-MHz and 3.0-Tesla/128-MHz MRI Systems for a 15-min of scanning (i.e. per pulse sequence).

Artifact Information
MRI image quality may be compromised if the area of interest is in the same area or relatively close to the position of the T2 XVBR™ Spinal System. The artifact size information is as follows:

<table>
<thead>
<tr>
<th>Pulse sequence</th>
<th>T1-SE</th>
<th>T1-SE</th>
<th>GRE</th>
<th>GRE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Signal Void Size</td>
<td>5,073mm²</td>
<td>1,879mm²</td>
<td>8,916mm²</td>
<td>4,928mm²</td>
</tr>
<tr>
<td>Imaging Plane</td>
<td>parallel</td>
<td>perpendicular</td>
<td>parallel</td>
<td>perpendicular</td>
</tr>
</tbody>
</table>

The image artifact extends approximately 20mm from the device when scanned in non-clinical testing using the gradient echo pulse sequence in a 3 Tesla MRI system (Excite, HDx, Software 14X.M5, General Electric Healthcare, Milwaukee, WI) with a transmit/receive RF body coil. Therefore, optimization of MRI imaging parameters to compensate for the presence of this device may be necessary.

The presence of other implants or the health state of the patient may require a modification of the MRI conditions.

If T2 XVBR™ Spinal System is used in connection with any device which is not MR Conditional, be advised this combination has not been tested in the MRI environment and, therefore, higher heating and possible injury to the patient may occur.
The T2 ALTITUDE™ Expandable Corpectomy System is intended for vertebral body replacement to aid in the surgical correction and stabilization of the spine for tumor and trauma pathologies. This system is indicated for single and two-level use only in the thoracic and lumbar anterior spine.

The T2 ALTITUDE™ Expandable Corpectomy System is a distractible system. This device is inserted between two vertebral bodies in the thoracic and lumbar spine and is expanded to aid in the surgical correction and stabilization of the spine. The device may be implanted through a lateral or posterior approach using a minimally invasive technique or implanted through a lateral, posterior, or anterior approach through a traditional open technique. The device is not intended to be used as a stand alone implant.

The T2 ALTITUDE™ Expandable Corpectomy System is made of titanium alloy, cobalt chrome, and nitinol.

The T2 ALTITUDE™ Expandable Corpectomy System was not directly tested; the T2 XVBR™ Spinal System was selected to represent that system due to similarity of materials and a configuration at least as challenging to MRI imaging as the T2 ALTITUDE™ Expandable Corpectomy System.

The T2 ALTITUDE™ Expandable Corpectomy System can be scanned under the same conditions as the T2 XVBR™ Spinal System (see page 60). In the event the patient has devices other than the T2 ALTITUDE™ Expandable Corpectomy System, contact the specific device manufacturer. The presence of other implants or the health state of the patient may necessitate a reduction of the MRI parameters.
The VERTEX™ Reconstruction System is intended to help provide immobilization and stabilization of spinal segments as an adjunct to fusion of the, cranio-cervical, cervical, and/or upper thoracic spine (Occiput-T3).

The VERTEX™ Reconstruction System is a posterior system, which consists of a variety of shapes and sizes of plates, rods, hooks, screws, multi-axial screws, and connecting components, which can be rigidly locked to the rod in a variety of configurations, with each construct being tailor-made for the individual case. Titanium ATLAS™ cable may be used with this system at the surgeon's discretion.

The VERTEX™ Reconstruction System is fabricated from medical grade titanium, medical grade titanium alloy, and medical grade cobalt chromium. Medical grade titanium, medical grade titanium alloy, and/or medical grade cobalt chromium may be used together. Never use titanium, titanium alloy, and/or cobalt chromium with stainless steel in the same construct. The VERTEX™ Reconstruction System includes a retaining ring for the multi-axial screw made of Shape Memory Alloy (Nitinol – NiTi). Shape Memory Alloy is compatible with titanium, titanium alloy, and cobalt chromium implants only. The posted screw connectors and some multi-axial screws contain elastomeric stakes made of silicone adhesive commonly used in implantable medical devices. Do not use with stainless steel.
MRI INFORMATION
Non-clinical testing has demonstrated that the VERTEX™ Reconstruction System is MR-Conditional. The non-clinical testing was performed evaluating the VERTEX™ Reconstruction System in conjunction with and without the ATLAS™ Cable system. A patient with this device can be safely scanned in an MRI system meeting the following conditions:

Static Magnetic Field
- Static magnetic field of 1.5 Tesla or 3 Tesla.
- Maximum spatial gradient magnetic field of 3000 gauss/cm (30 T/m)
- Maximum MRI system reported, whole body averaged specific absorption rate (SAR) of <2W/kg (Normal Operating Mode), for a continuous 6 minutes of scanning per pulse sequence within a quadrature whole-body radiofrequency transmit coil.

MRI-Related Heating
Under the scan conditions defined above, the VERTEX™ Reconstruction System is expected to produce a maximum temperature rise of less than 6.8°C after 6 minutes of continuous scanning.

Artifact Information
In non-clinical testing, the image artifact caused by the device extends 25mm from the VERTEX™ Reconstruction System when imaged with a gradient echo pulse sequence in a 3.0 T MRI system.

The presence of other implants or the health state of the patient may require a modification of the MRI conditions.

MRI Patient Counseling Information
Physicians should communicate with the patient the following information about MRI with respect to the VERTEX™ Reconstruction System:
- VERTEX™ Reconstruction System performance has been established for MRI systems at field strengths of 1.5 Tesla and 3.0 Tesla.
- During an MRI, the patient may notice a warming sensation around the implant or feel a tingling sensation. If the warming or tingling sensation is uncomfortable, the patient should communicate this to the MRI technologist, the MRI should be stopped, and the settings adjusted to reduce or eliminate the sensation. The highest temperature change observed in non-clinical testing was +6.8°C (associated with specific conditions listed above).
- Additionally, the metal in the implant may cause the MRI image to be distorted in the area around the implant. The MRI can be adjusted to minimize the image distortion.

Physicians should instruct patients to:
- Inform any healthcare personnel (e.g. doctor or MRI technologist) they have an implanted posterior cervical-thoracic fusion device prior to receiving an MRI.
- The patient’s doctor will recommend whether or not an MRI is appropriate.

The VERTEX™ Reconstruction System in conjunction with and without the ATLAS™ Cable system was tested in the MRI environment.

If the VERTEX™ Reconstruction System is used in connection with any other device which is not MR Conditional, be advised this combination has not been tested in the MRI environment and, therefore, higher heating and possible injury to the patient may occur.
X-STOP™ Interspinous Spacer Spinal Stabilization System

The X-STOP™ Interspinous Spacer System (“X-STOP™ Spacer”) is a titanium implant that fits between the spinous processes of the lumbar spine. It is made from Ti-6Al-4V Eli titanium alloy (ISO 5832-3) and consists of two components: a spacer assembly and a wing assembly.

The X-STOP™ PEEK Interspinous Spacer System (“X-STOP™ PEEK Spacer”) is manufactured from PEEK-polyetheretherketone polymer and Ti-6Al 4V Eli titanium alloy. The X-STOP™ PEEK Spacer fits between the spinous processes of the lumbar spine and is comprised of two components, a wing assembly and a spacer assembly.

The MRI test results for the X-STOP™ Interspinous Spacer Spinal Stabilization System, which outlines the MRI scanning conditions and settings to be used, are listed on the following page. In the event the patient has devices other than X-Stop™ Interspinous Spacer Spinal Stabilization System, contact the specific device manufacturer. The presence of other implants or the health state of the patient may necessitate a reduction of the MRI parameters.
**MRI INFORMATION**

The X-STOP™ Interspinous Spacer was determined to be MR-Conditional. Non-clinical testing demonstrated the X-STOP™ Interspinous Spacer Implant is MR Conditional. A patient with this device can be scanned safely immediately after placement under the following conditions:

**Static Magnetic Field**
- Static magnetic field of 3 Tesla
- Maximum spatial gradient magnetic field of 720 Gauss/cm or less
- Normal operating mode with a maximum whole body averaged absorption rate (SAR) of 2.0W/kg for 15 minutes of scanning

**MRI-Related Heating**

In non-clinical testing, the X-STOP™ Interspinous Spacer produced the following temperature rise during MRI performed for 15 minutes of scanning (i.e. per pulse sequence) in the 3 Tesla (3 Tesla/128 MHz, Excite, HDx, Software 14X.M5, General Electric Healthcare, Milwaukee, WI) MRI system:

- Highest temperature change +1.7°C

Therefore, the MRI-related heating experiments for the X-STOP™ Interspinous Spacer at 3 Tesla using a transmit/receive RF body coil at an MRI system reported whole body averaged SAR of 2.9 W/kg (i.e. associated with a calorimetry measured whole body averaged value of 2.7 W/kg) indicated the greatest amount of heating that occurred in association with these specific conditions was equal to or less than +1.7°C. An MRI heating test for a static magnetic field less than 3 Tesla has not been evaluated.

**Artifact Information**

MRI image quality may be compromised if the area of interest is in the same area or relatively close to the position of the X-STOP™ Interspinous Spacer. The artifact size Information is, as follows:

<table>
<thead>
<tr>
<th>Pulse Sequence</th>
<th>T1-SE</th>
<th>T1-SE</th>
<th>GRE</th>
<th>GRE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Signal Void Size</td>
<td>2,058mm²</td>
<td>1,210mm²</td>
<td>3,929mm²</td>
<td>3,830mm²</td>
</tr>
<tr>
<td>Imaging Plane</td>
<td>Parallel</td>
<td>Perpendicular</td>
<td>Parallel</td>
<td>Perpendicular</td>
</tr>
</tbody>
</table>

Therefore, optimization of MRI imaging parameters to compensate for the presence of this device may be necessary.
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 fusion in the following conditions: degenerative disc disease (as previously defined), spondylolisthesis, trauma, or tumor.

The CD HORIZON™ SPIRE™ Plate implants are made from implant grade titanium alloy (Ti-6Al-4V).

The CD HORIZON™ SPIRE™ Plate was not directly tested; the X-STOP™ Interspinous Spacer was selected to represent that system due to similarity of materials and a configuration at least as challenging to MRI imaging as the CD HORIZON™ SPIRE™ Plate implants.

Bench top testing of the worst case system, the X-STOP™ Interspinous Spacer made of titanium alloy resulted in classifying the system MR-Conditional in a 3.0 Tesla MRI system.

The CD HORIZON™ SPIRE™ Plate can be scanned under the same conditions as the X-STOP™ Interspinous Spacer (see page 65). In the event the patient has devices implanted other than the CD HORIZON™ SPIRE™ Plate, contact the specific device manufacturer. The presence of other implants or the health state of the patient may necessitate a reduction of the MRI parameters.
INFINITY™ OCT System

The INFINITY™ OCT System is a posterior occipitocervical-upper thoracic system, which consists of a variety of shapes and sizes of plates, rods, hooks, set screws, multi-axial screws, and connecting components, which can be rigidly locked to the rod in a variety of configurations, with each construct being tailor-made for the individual case.

The INFINITY™ OCT System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the occipitocervical junction, the cervical spine (C1 to C7), and the thoracic spine from T1-T3:

• Traumatic spinal fractures and/or traumatic dislocations.
• Instability or deformity.
• Failed previous fusions (e.g. pseudarthrosis).
• Tumors involving the cervical spine.
• Degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability.

The INFINITY™ OCT System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

MRI INFORMATION

The INFINITY™ OCT System was determined to be MR Conditional based on non-clinical testing and engineering rationales. A patient with this device can be safely scanned immediately after device placement under
the following conditions:

- Static magnetic field of 1.5 Tesla or 3.0 Tesla.
- Maximum spatial gradient magnetic field of 3000 gauss/cm (30 T/m)
- Maximum MR system reported whole body averaged specific absorption rate (SAR) of <2W/kg (Normal Operating Mode) for a continuous 6 minutes of scanning per pulse sequence within a quadrature whole-body radiofrequency transmit coil.

Under the scan conditions defined, a worst case posterior occipitocervical-upper thoracic system representative of the INFINITY™ OCT System produced a maximum temperature rise of less than 6.8°C after 6 minutes of continuous scanning.

MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of the INFINITY™ OCT System. The image artifact extends approximately 25mm from the device when imaged with a gradient echo pulse sequence in a 3.0 T MRI system.

The presence of other implants or the health state of the patient may require a modification of the MR conditions.

**MRI Patient Counseling Information**

Physicians should communicate with the patient the following information about MRI with respect to the INFINITY™ OCT System:

- INFINITY™ OCT System performance has been established for MRI systems at field strengths of 1.5 Tesla and 3.0 Tesla.
- During an MRI, the patient may notice a warming sensation around the implant or feel a tingling sensation. If the warming or tingling sensation is uncomfortable, the patient should communicate this to the MR technologist, the MRI should be stopped, and the settings adjusted to reduce or eliminate the sensation. The highest temperature change observed in non-clinical testing was 6.8°C (associated with specific conditions previously listed).
- Additionally, the metal in the implant may cause the MRI image to be distorted in the area around the implant. The MRI can be adjusted to minimize the image distortion.

Physicians should instruct patients to:

- Inform any healthcare personnel (e.g. doctor or MR technologist) they have an implanted posterior cervical-thoracic fusion device prior to receiving an MRI.
- The patient’s doctor will recommend whether or not an MRI is appropriate.

If the INFINITY™ OCT System is used in connection with any other device which is not MR Conditional, be advised this combination has not been evaluated in the MR environment and, therefore, higher heating and possible injury to the patient may occur.
ARTiC-L™ and ARTiC-XL™ 3D Ti Spinal Systems

The ARTiC-L™ 3D Ti Spinal System with TiONIC™ Technology and ARTiC-XL™ 3D Ti Spinal System with TiONIC™ Technology consist of Additively Manufactured (AM) titanium spacers of various widths, lengths, heights and lordotic angles and reusable instruments used for implantation and extraction of the subject implant. The subject implant assembly consists of three components: an implant body (-01 component), pivot pin (-02 component), and dowel pin (-03 component) as shown below. The implant body (-01 component) will be Additively Manufactured (AM) using a powder bed fusion system developed by Electro Optical Systems (EOS), which creates a non-porous and fully solidified titanium implant body. The subject implants do not consist of applied coatings and are singular fused bodies. The implant final assembly is achieved by a combination of AM and post processing, which includes machining.

MRI INFORMATION

In non-clinical testing, the ARTiC-L™ 3D Ti Spinal System and ARTiC-XL™ 3D Ti Spinal System was determined to be MR Conditional. A patient with this device can be safely scanned immediately after device placement under the following conditions:

**Static Magnetic Field**
- Static magnetic field of 1.5 Tesla and 3-Tesla.
- Maximum spatial gradient magnetic field of 3000-Gauss/cm (30 T/m) or less
- Maximum whole body average specific absorption rate (SAR) of 2.0 -W/kg under Normal operating mode for 15 minutes of scanning per pulse sequence.
MRI-Related Heating
Under the scan conditions defined above, the ARTiC-L™ and ARTiC-XL™ 3D Ti Spinal System is expected to produce a maximum temperature rise of less than 5.0°C after 15 minutes of continuous scanning.

Artifact Information
In non-clinical testing, the image artifact caused by the device extends approximately 13mm for a spin echo sequence and 23 mm for a gradient echo sequence in a 3-Tesla MR system. Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary.

If ARTiC-L™ 3D Ti Spinal System and ARTiC-XL™ 3D Ti Spinal System is used in connection with any device which is not MR Conditional, be advised that this combination has not been tested in the MR environment and, therefore, higher heating and possible injury to the patient may occur.

The presence of other implants or the health state of the patient may require a modification of the MR conditions.
See device-specific package insert for a complete listing of indications, contraindications, warnings, and precautions.

**CUSTOMER SERVICE INFORMATION**

<table>
<thead>
<tr>
<th>ADDRESS</th>
<th>TELEPHONE</th>
</tr>
</thead>
</table>
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