MRI Information for
Medtronic Spinal and Biologics Devices

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MRI Information for Medtronic Spinal 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. Medtronic Spinal and Biologics implants that were deemed to be “worst case” in terms of materials and metallic volumes were evaluated for MRI-related issues. Testing was conducted using either a 1.5 Tesla and/or 3-Tesla MR system. The specific implants listed in this document have all been classified as MR-Conditional in accordance with American Society for Testing Materials International, F2503-05, Standard Practice for “Marking Medical Device and Other Items for Safety in the Magnetic Resonance Environment.”

All devices labeled as MR-Conditional pose no known MRI-related hazards or additional risks to patients under these specific testing conditions.

MRI assessment summaries for tested Medtronic Spinal and Biologics implants are provided in this document where details about static magnetic fields, implant heating, and artifact information can be found.

For information about specific products, please contact Medtronic.
Cervical Disc

PRESTIGE® ST Cervical Disc

DESCRIPTION

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 F-138) 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.
Non-clinical testing demonstrated that 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 min 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) MR system:

*Highest temperature change* +1.8 °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 MR 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 that 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**
MR 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>4,989 mm²</td>
<td>2,950 mm²</td>
<td>9,596 mm²</td>
<td>13,770 mm²</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 MR imaging parameters to compensate for the presence of this device may be necessary.
Cervical Disc

PRESTIGE® LP Cervical Disc

DESCRIPTION

The PRESTIGE® LP Cervical Disc consists of two articulating components which are available in various sizes.

The device is made of titanium alloy/titanium carbide composite.
Non-clinical testing demonstrated that the PRESTIGE® LP Cervical Disc System 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 PRESTIGE® LP Cervical Disc System implant produced the following temperature rise during MRI performed for 15 min 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).

MR system:

*Highest temperature change* +1.6 °C

Therefore, the MRI-related heating experiments for the PRESTIGE® LP Cervical Disc System implant at 3-Tesla using a transmit/receive RF body coil at an MR 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 that 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 lower than 3-Tesla/128-MHz has not been evaluated.

**Artifact Information**
MR 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 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>1,401 mm²</td>
<td>1,093 mm²</td>
<td>2,101 mm²</td>
<td>2,422 mm²</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 MR imaging parameters to compensate for the presence of this device may be necessary.*
Cervical Interbody Fusion

PEEK PREVAIL® Cervical Interbody Device

DESCRIPTION

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 is manufactured from PEEK Optima LT1® and 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.

![Image of PEEK PREVAIL Cervical Interbody Device](image-url)
PEEK PREVAIL® Cervical Interbody Device

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 (Magnetic Resonance Imaging) performed for 15 minutes of scanning (i.e., per pulse sequence) in 1.5 Tesla/64 MHz MR 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) MR systems:

| MR system reported, whole body average SAR | 1.5 Tesla | 3 Tesla |
| Calorometry Measured values, whole body averaged SAR | 2.9 W/kg | 2.9 W/kg |
| Highest temperature change | 2.1 W/kg | 2.7 W/kg |
| | 1.5 °C | 1.9 °C |

Artifact Information
MR 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 MR 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 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 +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 MR technologist) that 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, please 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.
Lumber Disc

MAVERICK Total Disc Replacement System

DESCRIPTION

The MAVERICK Total Disc Replacement System consists of two cobalt-chromium molybdenum alloy articulating components. The two components each have one polished articulating side and one roughened, hydroxypatite-coated bone-contacting side. The male (inferior) component and female (superior) component are available in three footprints to meet the anatomical needs of the patients (i.e., Small, Medium, and Large). Both endplates may be pre-angled either 3° or 6°. The male component is available in only one height, but the female (superior) component is offered in several heights. Different size (female and male) components can be used in combination with each other. Therefore, the surgeon is able to interchange components to build a wide configuration of constructs.

The MAVERICK implant components are fabricated from medical grade cobalt-chromium-molybdenum alloys described by ASTM F-1537.
MAVERICK Total Disc Replacement System

MRI Information

Non-clinical testing demonstrated that the MAVERICK Disc Replacement 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 MAVERICK Disc Replacement System produced the following temperature rise during MRI performed for 15 min 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) MR 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 body coil at an MR 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 that 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 for a static magnetic field less than 3-Tesla has not been evaluated.

Artifact Information
MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of the MAVERICK Replacement 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>9,799 mm²</td>
<td>6,933 mm²</td>
<td>13,513 mm²</td>
<td>12,799 mm²</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 MR imaging parameters to compensate for the presence of this device may be necessary.
Lumbar Interbody

LT-CAGE® Device

DESCRIPTION

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 mm to 18 mm at the narrow end of the taper, 17 to 22 mm at the wide end of the taper, and in lengths ranging from 20 mm 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, with the trade name of PEEK-OPTIMA® LT1. This device is known as the LT-CAGE® PEEK Lumbar Tapered Fusion Device.
Non-clinical testing demonstrated that 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 min 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) MR 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 MR 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 that 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**
MR 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>1,437 mm²</td>
<td>990 mm²</td>
<td>2,347 mm²</td>
<td>4,253 mm²</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 MR imaging parameters to compensate for the presence of this device may be necessary.
Lumber Interbody

SOVEREIGN® Spinal System

DESCRIPTION

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 Optima® (polyetheretherketone) and contains tantalum radiopaque markers. The screws used with this device are manufactured from titanium alloy.
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-min of scanning (i.e., per pulse sequence) in 1.5-Tesla/64-MHz MR 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) MR systems:

<table>
<thead>
<tr>
<th></th>
<th>1.5-Tesla</th>
<th>3-Tesla</th>
</tr>
</thead>
<tbody>
<tr>
<td>MR system reported, whole body averaged SAR</td>
<td>2.9-W/kg</td>
<td>2.9-W/kg</td>
</tr>
<tr>
<td>Calorimetry 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>+1.8°C</td>
<td>+1.7°C</td>
</tr>
</tbody>
</table>

**Artifact Information**

MR 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:
<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>1,540-mm²</td>
<td>1,397-mm²</td>
<td>3,595-mm²</td>
<td>3,782-mm²</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 MR 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 20-mm 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 Magnetic Resonance Imaging (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 and 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 +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 MR technologist) that 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, please 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.
Lumbar Fusion Plate

PYRAMID® Anterior Lumbar Plate

DESCRIPTION

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.
Non-clinical testing demonstrated that 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 min 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) MR 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 MR 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 that 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**
MR 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>3,249 mm²</td>
<td>2,585 mm²</td>
<td>5,905 mm²</td>
<td>4,899 mm²</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 MR imaging parameters to compensate for the presence of this device may be necessary.
Lumbar Fusion Plate

SMA Staples

PURPOSE

The Medtronic Sofamor Danek SPINAL STAPLE System is intended to be an implant system used for treatment of thoracic and/or lumbar scoliosis and other deformities of the spine (i.e., kyphosis and/or lordosis).

DESCRIPTION

All of the implants are made of Shape Memory Alloy (Nitinol - NiTi). Shape Memory Alloy (SMA) is compatible with titanium implants only. Do not use with stainless steel. Never use stainless steel and titanium implant components in the same construct.

To achieve best results, do not use any of the Medtronic Sofamor Danek SPINAL STAPLE System implants with or without graft with implants from any other system or manufacturer unless specifically allowed to do so in this, or another Medtronic Sofamor Danek document. As with all orthopedic implants, none of the Medtronic Sofamor Danek SPINAL STAPLE System implants should ever be reused under any circumstances.
Non-clinical testing demonstrated that the SMA Staple 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 produced the following temperature rise during MRI performed for 15 min 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) MR system:

*Highest temperature change* +1.6 °C

Therefore, the MRI-related heating experiments for the SMA Staple at 3-Tesla using a transmit/receive RF body coil at an MR 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 that 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**
MR 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. 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>1,460 mm²</td>
<td>1,016 mm²</td>
<td>2,482 mm²</td>
<td>1,919 mm²</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 MR imaging parameters to compensate for the presence of this device may be necessary.
Untested Implants (Rationales)

Not all Medtronic Spinal and Biologics devices were evaluated for MRI-related issues. The implants and/or systems that were deemed to be “worst case” in terms of materials and metallic volumes were evaluated for MRI-related issues. For devices not evaluated, engineering rationales were completed to compare these devices to a previously evaluated Medtronic product. The following table indicates what the worst-case system is for the devices that were not evaluated for MRI-related issues, but have an engineering rationale to adopt the results of the Worst Case System.

<table>
<thead>
<tr>
<th>Spinal System</th>
<th>Worst Case Spinal System</th>
</tr>
</thead>
<tbody>
<tr>
<td>TELAMON® PEEK System</td>
<td>SOVEREIGN® Spinal System</td>
</tr>
<tr>
<td>CRESENT® PEEK Spinal System</td>
<td></td>
</tr>
<tr>
<td>CAPSTONE CONTROL™ Spinal System</td>
<td></td>
</tr>
<tr>
<td>ANATOMIC PEEK Cervical Fusion System</td>
<td></td>
</tr>
<tr>
<td>CORNERSTONE® PSR Spacer</td>
<td></td>
</tr>
<tr>
<td>CLYDESDALE™ PEEK Spacer</td>
<td></td>
</tr>
<tr>
<td>PERIMETER® System</td>
<td>X-STOP® Spinal System</td>
</tr>
<tr>
<td>PERIMETER®-C System</td>
<td></td>
</tr>
<tr>
<td>INTREPID System</td>
<td>LT CAGE® Lumbar Cage</td>
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<tr>
<td>CD HORIZON SPIRE™ Stabilization System</td>
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<tr>
<td>TELAMON® Titanium Spacer</td>
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<tr>
<td>AFFINITY® Cage System</td>
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<tr>
<td>INTER FIX™ RP Fusion System</td>
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</table>
Please 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>
<tbody>
<tr>
<td>Medtronic, Inc.</td>
<td>800 933 2635 (In U.S.A)</td>
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<tr>
<td>1800 Pyramid Place</td>
<td>901 396 3133 (Outside U.S.A)</td>
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<td>Earl Bakkenstraat</td>
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<tr>
<td>6422 PJ Heerlen</td>
<td></td>
</tr>
<tr>
<td>The Netherlands</td>
<td></td>
</tr>
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