Magnetic Resonance Imaging (MRI) Information for Grace Medical Otologic Implants

June 12, 2017

Dear Medical Professional:

MRI may be contraindicated or can pose risks for patients that have certain metallic implants primarily due to substantial magnetic field interactions or excessive MRI-related heating. Therefore, caution is advised when using MRI procedures in patients with metallic implants and devices.

The Otologic device families listed in Table 1 below are considered MR Safe according to the American Society for Testing and Materials (ASTM) International, Designation: F2503-13 since these items are made from non-metallic and non-conducting materials.

The Otologic device families listed in Table 2 below are considered MR Conditional according to the American Society for Testing and Materials (ASTM) International, Designation: F2503-13 and based on MRI tests conducted on selected implants that represented worst case with regard to materials and mass.

The MRI Information is, as follows:

**Imaging at 3 Tesla or Less**
Non-clinical testing has demonstrated that patients with these specific Grace Medical ossicular implants can undergo MRI safely, immediately after implantation under the following conditions:

- Static magnetic field of 3-Tesla or less
- Maximum spatial gradient magnetic field of 20,000-Gauss/cm or less.
- MR system reported, whole-body-averaged specific absorption rate (SAR) of 4 \( \text{W/kg} \) for 15 minutes of scanning (i.e., per pulse sequence).

**MRI-Related Heating**
Under controlled testing conditions a temperature rise equal to or less than +1.7 °C occurred.

**Artifact Information:**
MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the device. Therefore, optimization of imaging parameters may be necessary.
Imaging at 7 Tesla or Less
Non-clinical testing has demonstrated that patients with these specific Grace Medical ossicular implants can undergo MRI safely, immediately after implantation under the following conditions:

- Static magnetic field of 7-Tesla or less
- Maximum spatial gradient magnetic field of 2,000-Gauss/cm or less.
- MR system reported, whole-body-averaged specific absorption rate (SAR) of 4 ï¿½ W/kg for 15 minutes of scanning (i.e., per pulse sequence).

MRI-Related Heating
Under controlled testing conditions a temperature rise equal to or less than +0.3 °C occurred.

Artifact Information:
MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the device. Therefore, optimization of imaging parameters may be necessary.

All ossicular implants that are considered MR Conditional have been packaged with an MRI Patient Card. Should you have any questions regarding a specific implant, or if an implant is not in one of the tables below, please contact Grace Medical at 1-866-472-2363.
Table 1. MR Safe

<table>
<thead>
<tr>
<th>Device Family</th>
<th>Family Product Number(s)</th>
<th>Device Material(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stapes Prostheses-Pistons</td>
<td>401-XXX, 402-XXX, 403-XXX, 404-XXX, 405-XXX, 406-XXX, 408-XXX, 436-XXX</td>
<td>Fluoroplastic</td>
</tr>
<tr>
<td>Partial and Total Prostheses</td>
<td>1XX, 190-XXX, 749-XXX</td>
<td>HA</td>
</tr>
<tr>
<td>Partial and Total Prostheses</td>
<td>200 through 273, 293, 293A</td>
<td>HA, Silicone</td>
</tr>
</tbody>
</table>

(XX = 00 through 99) (XXX = 000 through 999, i.e. Product number 190-XXX means all products ranging from 190-000 through 190-999)

Table 2. MR Conditional

<table>
<thead>
<tr>
<th>Device Family</th>
<th>Family Product Number(s)</th>
<th>Device Material(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALTO Partial and Total Prostheses</td>
<td>6XX, 612-001L, 612-002R</td>
<td>Titanium, HA, Silicone</td>
</tr>
<tr>
<td>K-Helix Prostheses</td>
<td>756-XXX, 757-XXX</td>
<td>Titanium</td>
</tr>
<tr>
<td>Strasnick Prostheses</td>
<td>220-XXX, 270-XXX</td>
<td>Titanium, Silicone</td>
</tr>
<tr>
<td>Foot Plate Shoes</td>
<td>636-XXX, 638-XXX</td>
<td>Titanium</td>
</tr>
<tr>
<td>ISJ and SRP</td>
<td>755, 758-XXX</td>
<td>Nitinol, Fluoroplastic</td>
</tr>
</tbody>
</table>

(XX = 00 through 99) (XXX = 000 through 999, i.e. Product number 190-XXX means all products ranging from 190-000 through 190-999)