



## Magnetic Resonance Imaging (MRI) Information for Grace Medical Tympanostomy Tubes

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October 1, 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 Tympanostomy Tube 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 Tympanostomy Tube 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 tympanostomy tubes 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 tympanostomy tubes 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 4,000-Gauss/cm(40-T/m) or less.
- MR system reported, whole-body-averaged specific absorption rate (SAR) of 2  $\delta$ W/kg for 15 minutes of scanning (i.e., per pulse sequence) in the Normal Operating Mode.

### **MRI-Related Heating**

Under controlled testing conditions a temperature rise equal to or less than +1.6 °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.

Should you have any questions regarding a tympanostomy tube, or if a tube is not in one of the tables below, please contact Grace Medical at 1-866-472-2363.



**Table 1. MR Safe**

<b>Device Family</b>	<b>Family Product Number(s)</b>	<b>Device Material(s)</b>
Tympanostomy Tubes	510-XXX, 520-XXX, 525-XXX, 530-XXX	Fluoroplastic, Silicone, Polyethylene

(XXX = 000 through 999, i.e. Product number 510-XXX means all products ranging from 510-000 through 510-999)

**Table 2. MR Conditional**

<b>Device Family</b>	<b>Family Product Number(s)</b>	<b>Device Material(s)</b>
Tympanostomy Tubes	500-XXX, 500-XXXM, 500-XXXM1, 525-XXXW	Titanium, Fluoroplastic with Stainless Steel Wire

(XXX = 000 through 999, i.e. Product number 500-XXX means all products ranging from 500-000 through 500-999)