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

February 23, 2024

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 ï 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.

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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 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.

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Table 1. MR Safe

Device Family	Family Product Number(s)	Device Material(s)
Stapes Prostheses-Pistons	400-XXX, 401-XXX, 402-XXX, 403-XXX, 406-XXX, 408-XXX, 436-XXX	Fluoroplastic
Partial and Total Prostheses	1XX, 190-XXX, 749-XXX	HA
Partial and Total Prostheses	209, 210, 259, 260, 270, 271, 272, 273, 293, 293A	HA, Silicone

(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

Device Family	Family Product Number(s)	Device Material(s)
ALTO Partial and Total Prostheses	6XX, 612-001L, 612-002R	Titanium, HA, Silicone
ALTO Concise	650-075, 655-075	Titanium, Silicone
K-Helix Prostheses	756-XXX, 757-XXX	Titanium
Strasnick Prostheses	220-XXX, 270-XXX	Titanium, Silicone
Precise and other Ossicular Prostheses	280, 280M, 602-XXX, 652-XXX, 700-XXX, 705-XXX, 706-XXX, 707-XXX, 708-XXX, 709-XXX, 720-XXX, 750-XXX, 751-XXX, 752-XXX, 753-XXX, 765-XXX, 770-XXX	Titanium, HA, Silicone, Nitinol
Stapes Prostheses-Piston	409-XXX, 410-XXX, 412-XXX, 413-XXX, 415-XXX, 417-XXX, 418-XXX, 419-XXX, 440-XXX, 442-XXX, 443-XXX, 452-XXX, 453-XXX, 454-XXX, 456-XXX, 460-XXX, 461-XXX, 462-XXX, 463-XXX, 465-XXX, 466-XXX, 467-XXX, 468-XXX, 469-XXX, 470-XXX, 471-XXX, 472-XXX, 473-XXX	Titanium, Platinum, Stainless Steel, Nitinol, Fluoroplastic
Stapes Prostheses-Buckets	420-XXX, 421-XXX, 422-XXX, 423-XXX, 424-XXX, 425-XXX, 426-XXX, 427-XXX, 428-XXX, 430-XXX, 431-XXX, 432-XXX	Titanium, Nitinol
Partial and Total Prostheses	200 through 208, 250 through 258, 220-800	Titanium, HA, Silicone
Foot Plate Shoes	636-XXX, 638-XXX	Titanium
ISJ and SRP	755, 758-XXX	Nitinol, Fluoroplastic

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