Magnetic Properties of Medtronic ENT Otology Implant Devices

July 2009

RE: Magnetic Properties of Medtronic ENT Otology Implant Devices

To whom it may concern:

The effects of Magnetic Resonance Imaging (MRI) scans on Medtronic ENT otology implants are addressed below. Included in the scope of this letter are all otology implants, including both ossicular (middle ear) prostheses and ventilation tubes that are composed of one or more of the following available materials:

Stainless steel (Austenitic grade, ASTM F138)

Titanium or titanium alloy (ASTM F67 and F136)

Platinum

Porous polyethylene polymer or polyethylene with stainless steel wire

Fluoroplastic polymer or fluoroplastic with stainless steel wire

Hydroxylapatite and hydroxylapatite composite with silicone elastomer

Generally, MRI scans are contraindicated for patients with certain metallic and metal-containing devices, such as selected aneurysm clips, select cochlear implants (i.e., Medtronic ENT Audiant, etc.), or neurostimulator TENS units. However, studies conducted on otology devices manufactured from the above materials, by Medtronic ENT as well as other otology device manufacturers, support the lack of significant hazard for patients with middle ear implants undergoing MRI scans.

In an attempt to provide guidance to the user on material MR compatibility, the following criteria are used to determine the level of material/MR compatibility.

- Magnetically induced displacement force and torque
- Radio frequency heating
- Image artifacts

The biomaterials utilized in Medtronic ossicular implants include Polycel®, Hydroxylapatite (H/A), H/A-coated Polycel, platinum, titanium, stainless steel, fluoroplastic and Flex H/A. Due to the variety of materials used in otologic implants and the variety of MR conditions to which they may be exposed, it is difficult to provide a concrete statement that would cover all materials and conditions. In reviewing the Medtronic and available published literature regarding MR compatibility, the following conclusions can be made.

MRI Compatibility of Medtronic Otologic Prostheses

Material	MR Safe	MR Unsafe	MR Conditional	Comments
Polycel	X			Based on scientific rationale[1]
Hydroxylapatite	X			Based on scientific rationale[1]
H/A-Polycel	X			Based on scientific rationale[1]
Platinum			X[2]	Based on test data[3,4,5]
Titanium			X[6]	Based on test data[3,4,5]
Stainless steel			X[7]	Based on test data[3,4,5]
Fluoroplastic	X			Based on scientific rationale[1]
Flex H/A	X			Based on scientific rationale[1]

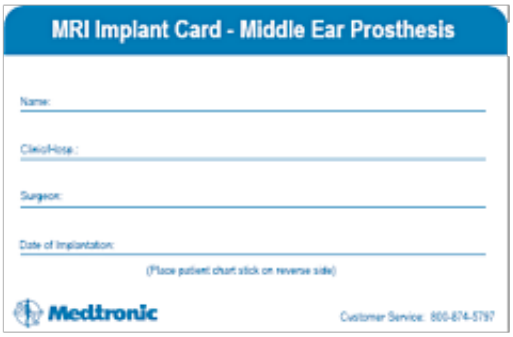
1. Material is non-conducting or a nonmagnetic item and poses no known hazards in all MR environments.
2. Testing has shown that platinum is suitable when tested in a 1.5 and 4.7 Tesla environment.
3. Williams MD, Antonelli PJ, Williams LS, Moorhead JE. Middle Ear Prosthesis Displacement in High-Strength Magnetic Fields. Otol Neurotol. 2001 Mar; 22(2):158-61.
4. Kwok P, Waldeck A, Strutz J. How Do Metallic Middle Ear Implants Behave in the MRI? Laryngorhinootologie, 2003 Jan;82(1):13-8.
5. Fritsch HT, Mosier KM. MRI Compatibility Issues in Otology Curr Opin Otolaryngol Head Neck Surg 15:335-340.
6. Testing has shown that titanium is suitable when tested in a 4.7 Tesla environment.
7. All stainless steel shows some degree of magnetism ex vivo, but not clinically significant in vivo.

Based on the available data, Medtronic ENT ossicular prostheses can be categorized as follows:

MR Safe: Polycel, H/A, H/A-Polycel, Flex H/A, and fluoroplastic

MR Conditional: Platinum, titanium, and stainless steel are safe in magnetic fields 3.0 Tesla or less.

In 2009, Medtronic otologic implants will be packaged with an MRI card that may be given to the patient.


MRI Implant Card - Middle Ear Prosthesis

Name:

Clinic/Hosp.:

Surgeon:

Date of Implantation:

(Place patient chart stick on reverse side)

Medtronic

Customer Service: 800-874-5797


Please provide this card to MRI facility

Based on available data, Medtronic Ear Implants of the following materials are categorized as follows:

MR Safe: Polycel, HA, HA-Polycel, Flex HA and Fluoroplastic

MR Conditional: Platinum, Titanium and Stainless Steel are safe in magnetic fields 3.0 Tesla or less

See below for specific information on this patient's implant:

place prosthesis chart stick here: OR enter implant information below:

Lot # :

REF # :

Description :

Material :

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Sincerely,

Medtronic ENT Regulatory Affairs

Rev.7/09

Additional articles that may be of interest:

1 **Effects of Magnetic Resonance Imaging Fields on Stapedectomy Prostheses**
Edward L. Applebaum, M.D., Galdino E. Valvassori, M.D., Archives of Otolaryngology, Volume 111, pages 820-821, December 1985.

2 **Interaction between Magnetic Fields and Metallic Ossicular Prostheses**
David W. White, M.D., American Journal of Otolaryngology, Volume 8, Number 2, pages 90-92, March 1987.

3 **Imaging of Ossicular Prostheses**
Barry E. Hirsch M.D., et al., Journal of Otolaryngology – Head and Neck Surgery, Volume 111, Number 4, pages 494-496, October, 1994.

4 **Magnetic Resonance Imaging of Stapes Prostheses**
Mark J. Syms, M.D., Gregory W. Petermann, M.D., American Journal of Otology, Volume 21, pages 494-498, July, 2000.

5 **Magnetic Prosthesis Displacement in High Strength Magnetic Fields**
Michelle D. Williams, M.D., Patrick Antonelli, M.D., et al., presented at the American Otological Society Annual Meeting, May 12-13, 2000 [pending publication].

6 **The Effect of Nuclear Magnetic Resonance Imaging on Metallic Middle Ear Prostheses**
Mattucci KF, Setzen M, Hyman R, Chaturvedi G., Otolaryngology Head Neck Surg, 94: 441-3, 1986.

7 **Middle Ear Prosthesis: Significance of Magnetic Resonance Imaging**
Leon JA, Gabriele OF, Magnetic Resonance Imaging, 5: 405-6, 1987.

8 **Metallic Otologic Implants: in vitro Assessment of Ferromagnetism at 1.5T**
Shellock FG, Schatz CJ, American Journal of Neuroradiology, 12: 279-281, 1991.

9 **Further Studies on the Effects of Magnetic Imaging on Middle Ear Implants**
Applebaum EL, Valvassori GE, Ann Otol Rhinol Laryngol, 99: 801-4, 1990.

10 **The Interactions Between Metal Stapes Prostheses and High-Intensity Magnetic Fields During Magnetic Resonance Tomography**
Garaventa G, Satrango L, Vellucci F, Pagano M, Pallestrini EA, Acta Otorhinolaryngol Ital, 11: 455-63, 1991. [Italian]

11 **MRI Compatibility Issues in Otology**
Michael H. Fritsch and Kristine M. Mosier, Current Opinions in Otolaryngol Head Neck Surgery, 15:335-340, 2007.