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To: Whom it may concern

From: Gyrus ENT L.L.C., a subsidiary of Gyrus ACMI, Inc. (Formerly Smith & Nephew, Inc., ENT Division) -
Regulatory Affairs / Quality Assurance

MRI Information for Gyrus ENT Otology Implants and Devices

MR imaging is considered contraindicated for patients with metallic implant because of risks associated with movement or dislodgment for ferromagnetic implants and MRI-related heating for metallic implants that are a certain length or that form a closed conducting loop. With the exception of several production lots of a particular type of middle ear implant (see Table One) manufactured and distributed in late 1987 and early 1988, materials used by Gyrus ENT, LLC in the manufacture of middle ear implant devices are generally considered acceptable for patients undergoing MRI procedures (see below).

Table One

Specific Lots of S&N, Inc. (Richards) McGee Platinum/Stainless Steel Pistons Contraindicated for MRI

This series of McGee Platinum/Stainless Steel pistons were manufactured using ferromagnetic stainless steel in late 1987 and early 1988. The affected production lots of these pistons, given in Table 1 below, were recalled by Smith & Nephew, Inc. in 1989. Importantly, MRI is contraindicated for anyone having received a McGee Platinum/Stainless Steel piston from these lots.

S&N Catalog No.	Lot Nos.
14-0330	1W91100, 4U09690
14-0331	4U09700
14-0332	1W91110, 4U58540, 4U86300
14-0333	4U09710, 1W91120
14-0334	4U09720, 1W34390, 2WR4073
14-0335	1W34400, 4U09730

S&N Catalog No.	Lot Nos.
14-0336	3U18350, 3U50470, 4UR2889
14-0337	3U18370, 4UR2889
14-0338	3U18390, 4U02900, 4UR1453
14-0339	3U18400, 3U50480
14-0340	3U18410, 3U50500
14-0341	3U41200, 4UR2889

Based on the MRI testing conducted on product samples representative of the Gyrus ENT otologic implant line of products by Shellock R & D Services, Inc., Dr. Frank Shellock, a patient with one of the following products (otologic implants) will not experience an additional hazard or risk relative to the use of an MR system operating with a static magnetic field of **3-Tesla or less** (*Please review the explanation of the previous and current labeling terms applied to implants and devices, to follow.):

Table Two

MR-Conditional* Otologic Implants

Gyrus, ENT Catalog No.	Name	Material	Piston Diameter	Functional Length
7014-5934	Smart Piston	Fluoroplastic/ Nitinol	0.8 mm	4.75 mm
14-0150	McGee Piston	Stainless Steel	0.8 mm	5.5 mm
			Wire Diameter	Overall Length
14-0194	HouseWire Loop	Stainless Steel	0.13	6.5 mm
14-0725	TantalumWire Loop	Tantalum	0.13	5 mm
			Well Diameter	Functional Length
7014-2167	Richard's Bucket Handle	Titanium	1 mm	5 mm

Other studies have supported the above findings including those listed below.¹⁻⁶

1. Fritsch MH, Gutt JJ, and Naumann IC. Magnetic Properties of Middle Ear and Stapes Implants in a 9.4-T Magnetic Resonance Field. *Otology & Neurotology* 2006; 27: 1064-1069.

2. Applebaum EL, Valvassori GE. Effects of magnetic resonance imaging fields on stapedectomy prostheses. *Archives of Otolaryngology* 1985; 111:820-821.
3. Hirsch BE, Weissman JL, Curtin HD, and Kamerer DB. Imaging of ossicular prostheses. *Otolaryngology – Head and Neck Surgery* 1994; 111:494-496.
4. Rodriquez P. MRI indication for the referring surgeon. <http://www.gcnet.com/maven/aurora/mri/precautions.html>.
5. Shellock FG. MR imaging of metallic implants and materials: A compilation of the literature. *AJR* 1988; 141:811-814.
6. White DW. Interaction between magnetic fields and metallic ossicular prosthesis. *American Journal of Otolaryngology* 1987; 8(2):90-92.

Implants and Device: Labeling for MRI and an Explanation of Terminology

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Previous MRI Labeling Terminology

The terminology applied to implants and devices relative to the MRI environment has evolved over the years. In 1997, the Food and Drug Administration, Center for Devices and Radiological Health, proposed definitions for the terms “MR Safe” and “MR Compatible” (1). These terms were defined as follows:

MR Safe -the device, when used in the MRI environment, has been demonstrated to present no additional risk to the patient or other individual, but may affect the quality of the diagnostic information. The MRI conditions in which the device was tested should be specified in conjunction with the term MR safe since a device which is safe under one set of conditions may not be found to be so under more extreme MRI conditions.

MR Compatible -a device shall be considered "MR compatible" if it is MR safe and the device, when used in the MRI environment, has been demonstrated to neither significantly affect the quality of the diagnostic information nor have its operations affected by the MR system. The MRI conditions in which the device was tested should be specified in conjunction with the term MR safe since a device which is safe under one set of conditions may not be found to be so under more extreme MR conditions. Using this terminology, MRI testing of an implant or object involved assessments of magnetic field interactions, heating, and, in some cases, induced electrical currents while MR compatibility testing required all of these as well as characterization of artifacts. In addition, it may have been necessary to evaluate the impact of various MRI conditions on the functional or operational aspects of an implant or device (2).

“New” Terminology

Over the years, manufacturers generally used the terms “MR safe” and “MR compatible” to label medical devices. However, in time it became apparent that these terms were confusing and were often used interchangeably or incorrectly (3). Therefore, in an effort to clarify the terminology and, more importantly, because the misuse of these terms could result in serious accidents for patients and other individuals, the MR task group of the American Society for Testing and Materials (ASTM) International developed a new set of terms with associated icons (4). The new terms, MR Safe, MR Conditional, and MR Unsafe are defined by the ASTM document, as follows:

MR Safe - an item that poses no known hazards in all MRI environments. Using the new terminology, “MR safe” items include non-conducting, non-metallic, non-magnetic items such as a plastic Petri dish. An item may be determined to be MR Safe by providing a scientifically based rationale rather than test data.

MR Conditional - an item that has been demonstrated to pose no known hazards in a specified MRI environment with specified conditions of use. Field conditions that define the MRI environment include static magnetic field strength, spatial gradient, dB/dt (time varying magnetic fields), radio frequency (RF) fields, and specific absorption rate (SAR). Additional conditions, including specific configurations of the item (e.g., the routing of leads used for a neurostimulation system), may be required.

For MR Conditional items, the item labeling includes results of testing sufficient to characterize the behavior of the item in the MRI environment. In particular, testing for items that may be placed in the MRI environment should address magnetically induced displacement force and torque, and RF heating. Other possible safety issues include but are not limited to, thermal injury, induced currents/voltages, electromagnetic compatibility, neurostimulation, acoustic noise, interaction among devices, and the safe functioning of the item and the safe operation of the MR system. Any parameter that affects the safety of the item should be listed and any condition that is known to produce an unsafe condition must be described.

MR Unsafe - an item that is known to pose hazards in all MRI environments. MR Unsafe items include magnetic items such as a pair of ferromagnetic scissors.

Use of Terminology

The new terminology is intended help elucidate matters related to biomedical implants and devices in order to ensure the safe use of MRI technology. Importantly, it should be noted that this new terminology has not being applied *retrospectively* to implants and devices that previously received Food and Drug (FDA) approved labeling using the terms “MR safe” or “MR compatible” (i.e., in general, this applies to those objects tested prior to August, 2005).

Accordingly, this should be understood in order to avoid undue confusion regarding the matter of labeling for “older” vs. “newer” implants. To date, relatively few implants have the term “MR conditional” applied in comparison to those labeled using the previous labeling scheme, “MR safe” and “MR compatible” (i.e., of the more than 1,800 implants tested for MRI issues, to date) (5).

REFERENCES

- (1) United States Food and Drug Administration, Center for Devices and Radiological Health, A Primer on Medical Device Interactions with Magnetic Resonance Imaging Systems. <http://www.fda.gov/cdrh/ode/primerf6.html>, 1997.
- (2) Shellock FG. Reference Manual for Magnetic Resonance Safety Implants and Device: 2007 Edition. Biomedical Research Publishing Group, Los Angeles, CA, 2007.
- (3) Shellock FG, Crues JV. Commentary: MR safety and the American College of Radiology White Paper. American Journal of Roentgenology 2002;178:1349-1352.
- (4) American Society for Testing and Materials (ASTM) International, Designation: F2503-05. Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment. ASTM International, West Conshohocken, PA, 2005.
- (5) www.MRIsafety.com; The List