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From: OSTA, Gyrus ACMI, an Olympus company
(Formerly Gyrus ENT LLC, and Smith & Nephew, Inc., ENT Division)

MRI INFORMATION FOR GYRUS ACMI OTOLOGY IMPLANT 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 ACMI 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 with a 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

MRI Information
All current Gyrus ACMI MR Conditional implants are packaged with an MRI Patient Card (*please review the explanation of the previous and current labelling terms applied to implants and devices, to follow.):

MR-Safe*
Devices that are made from non-metallic materials (i.e. Implants and Ventilation Tubes made from HA, Plasti-pore, Silicone, Fluoroplastic) are inherently non-conducting and non-magnetic and pose no known hazards in all MR environments and therefore are considered MR Safe.

MR-Conditional*
Devices that have 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.

The **MRI Conditional Information** for Gyrus ACMI implants (excluding the Lots listed in Table One above) is, as follows:

Non-clinical testing of representative worst case samples has demonstrated that patients with these specific Gyrus ACMI otologic implants can undergo MRI safely, immediately after implantation under the following conditions:

- Static magnetic field of 3-Tesla or less
- Maximum spatial gradient field of 720-Gauss/cm or less.
- MR system reported, whole-body-averaged specific absorption rate (SAR) of 2 –W/kg for 15 minutes of scanning (i.e., per pulse sequence).

The following tables summarize the Gyrus ACMI implants, based on worst case representative sample testing (data on file), available literature reviewed as referenced below 1-7, and a review of the materials used in their construction as allowed by ASTM F2503[8].

Table 2: MR Safe (Materials include: Hydroxylapatite (HA), Fluoroplastic, Plasti-pore, Hapex)

Device Family	Family Product Number(s)	Device Family	Family Product Number(s)
Grote Canal, HA Reconstruction Blocks, Attic Defect	1408XX, 709217XX	Applebaum Incus Replacement	1409XX
Vocom	1430XX, 70143019	Austin Mod TORP	140063
HA Granules	911101	Black Oval	1408XX, 1409XX
Jahn Tube	1409XX		

Table 3: MR Conditional (Materials include: Nitinol, Stainless Steel, Titanium, Tantalum, Platinum)

Device Family	Family Product Number(s)	Device Family	Family Product Number(s)
CAP / TORP / PORP	140063, 1408XX, 701458XX, 701405XX, 140057, 70143XXX, 70145XXX, 1400XX, 140XXX, 70140XXX, 70141XXX	House Type	1401XX
Micron, Micron II	70142XXX, 70141XXX	Kartush Incus	1408XX, 70145XXX
Smart Pistons	70142XXX, 70143XXX, 70145XXX	Ribbon loops	1407XX
Pistons (various)	141XXX, 140XXX, 70140XXX, 1400XX, 70145XXX, 1407XX	Sheehy-type incus	1404XX
Bucket Handles, Cups, Classic			701458XX, 701409XX, 140XXX
Goldenberg			140721, 140722
Grate, Grote			

(XX = 00 through 99) (XXX = 000 through 999)

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.qcnet.com/maven/aurora/mri/precatuions.html.
5. Shellock FG. MR imaging of metallic implants and materials: A compilation of the literature. AJR 1988; 141:811-814.
6. Shellock FG. Implants and Device: Labeling for MRI and an explanation of Terminology. MRIsafety.com
7. White DW. Interaction between magnetic fields and metallic ossicular prosthesis. American Journal of Otolaryngology 1987; 8(2):90-92.
8. ASTM F2503-08: American Society for Testing and Materials (ASTM), Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment. ASTM International.