

MRI Safety Update 2008: Part 2, Screening Patients for MRI

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OBJECTIVE. This article is the second part of a two-part series on MRI safety. In this article, part 2, the topic of screening patients for MRI procedures is addressed.

CONCLUSION. To prevent incidents and accidents associated with MRI, it is necessary to regularly revisit the safety topics that directly impact patient management especially with respect to the subjects that are “new,” those that should be reassessed because of recent changes, topics that deserve emphasis because of controversy or confusion, and information that should be considered in light of new findings.

In consideration of the constant evolution of issues related to MRI safety and the need to update and revise existing guidelines and policies and procedures, there is an ongoing challenge to be aware of the latest developments associated with this topic. Notably, comprehensive reviews and textbooks have been written on the subject of MRI safety and there are Websites with content that is updated on a regular basis [1–15]. Therefore, the reader is referred to those important resources. The goal of this article is to provide an MRI safety update that covers selected topics including those that are “new” (e.g., MRI contrast agents and nephrogenic systemic fibrosis [NSF]), subjects that should be reassessed because of recent changes (e.g., screening patients and individuals), topics that deserve emphasis because of controversy or confusion (e.g., certain policies and procedures), and information that should be considered in light of new findings (e.g., MRI test results for implants and devices, including items evaluated at 3 T).

Screening Patients for MRI Procedures and Individuals for the MRI Environment

The implementation of appropriate policies and procedures to screen a patient for an MRI examination or an individual before permitting entry into the MRI environment (i.e., the MR system room) is a vital aspect of a facility's MRI safety program that, when conducted properly, prevents problems,

accidents, and injuries. Therefore, although this topic has been covered in great detail [1, 2, 7–9, 11–17], it needs to be revisited because of the previously described concerns related to the use of MRI contrast agents and NSF as well as other matters that must be considered.

A health care worker specially trained in MRI safety must perform the MRI screening activities whether it involves a patient or another individual. This worker is someone who has undergone training and education to fully understand the potential hazards and issues associated with the MRI environment and MRI procedures and who is aware of the latest information on the screening forms for patients and individuals.

Screening requires the use of written forms [1, 2, 7–9, 11–17]. Two different screening forms, one for patients and one for other individuals, that provide questions to identify potential problems relative to an MRI procedure or the MRI environment have been developed [1, 12, 14, 17]. Screening forms with the latest information are shown in Figure 1, including screening forms for patients in English (Figs. 1A and 1B) and Spanish (Figs. 1C and 1D) and a screening form for nonpatient individuals (Fig. 1E). The form intended for patients includes questions to address NSF risks [12, 14]. All forms may be downloaded for use at www.MRIsafety.com

Typically, screening forms were created with patients in mind and, therefore, ask certain questions that are inappropriate for individuals who may simply need to enter and work in the MRI environment. Therefore, a

MAGNETIC RESONANCE (MR) ENVIRONMENT SCREENING FORM FOR INDIVIDUALS*

The MR system has a very strong magnetic field that may be hazardous to individuals entering the MR environment or MR system room if they have certain metallic, electronic, magnetic, or mechanical implants, devices, or objects. Therefore, all individuals are required to fill out this form BEFORE entering the MR environment or MR system room. Be advised, the MR system magnet is ALWAYS on.

*NOTE: If you are a patient preparing to undergo an MR examination, you are required to fill out a different form.

Date / / Name Last Name First Name Middle Initial Age

Address Telephone (home) () -

City Telephone (work) () -

State Zip Code

1. Have you had prior surgery or an operation (e.g., arthroscopy, endoscopy, etc.) of any kind? No Yes
If yes, please indicate date and type of surgery: Date / / Type of surgery

2. Have you had an injury to the eye involving a metallic object (e.g., metallic slivers, foreign body)? No Yes
If yes, please describe:

3. Have you ever been injured by a metallic object or foreign body (e.g., BB, bullet, shrapnel, etc.)? No Yes
If yes, please describe:

4. Are you pregnant or suspect that you are pregnant? No Yes

WARNING: Certain implants, devices, or objects may be hazardous to you in the MR environment or MR system room. Do not enter the MR environment or MR system room if you have any question or concern regarding an implant, device, or object.

Please indicate if you have any of the following:

Yes No Aneurysm clip(s)

Yes No Cardiac pacemaker

Yes No Implanted cardioverter defibrillator (ICD)

Yes No Electronic implant or device

Yes No Magnetically-activated implant or device

Yes No Neurostimulation system

Yes No Spinal cord stimulator

Yes No Cochlear implant or implanted hearing aid

Yes No Insulin or infusion pump

Yes No Implanted drug infusion device

Yes No Any type of prosthesis or implant

Yes No Artificial or prosthetic limb

Yes No Any metallic fragment or foreign body

Yes No Any external or internal metallic object

Yes No Hearing aid
(Remove before entering the MR system room)

Yes No Other implant

IMPORTANT INSTRUCTIONS

Remove all metallic objects before entering the MR environment or MR system room including hearing aids, beeper, cell phone, keys, eyeglasses, hair pins, barrettes, jewelry (including body piercing jewelry), watch, safety pins, paperclips, money clip, credit cards, bank cards, magnetic strip cards, coins, pens, pocket knife, nail clipper, steel-toed boots/shoes, and tools. Loose metallic objects are especially prohibited in the MR system room and MR environment.

Please consult the MRI Technologist or Radiologist if you have any question or concern BEFORE you enter the MR system room.

I attest that the above information is correct to the best of my knowledge. I have read and understand the entire contents of this form and have had the opportunity to ask questions regarding the information on this form.

Signature of Person Completing Form: Signature Date / /

Form Information Reviewed By: First name Signature

MRI Technologist Radiologist Other

E

Fig. 1 (continued)—Forms with latest information used for screening patients before undergoing MRI procedures and for screening nonpatient individuals before entering MRI environment (e.g., MRI technologist, physician, relative, visitor, allied health professional, maintenance worker, custodial worker, fire fighter, security officer). Forms may be downloaded for use at www.MRIsafety.com.
E, Form used to screen individuals prior to entry into MRI environment.

specified conditions of use. The safety of “MR conditional” items must be verified with the specific scanner and MR environment in which they will be used.

Importantly, this statement refers to terminology that has only been used for labeling of implants and devices since approximately August 2005 [12, 14, 24, 25] and fails to recognize that these terms have not been applied retrospectively by the U.S. Food and Drug Administration (FDA) [12, 14].

The terminology applied to implants and devices relative to the MRI environment has evolved over the years. In 1997, the Center for Devices and Radiological Health proposed definitions for the terms “MR safe” and “MR compatible” as follows [27]:

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.

To implement this terminology, “MR safety” testing of an implant or object involved assessments of magnetic field interactions, heating, and, in some cases, induced electrical currents, whereas “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 [12, 14].

Thus, over the years, manufacturers generally used the terms “MR safe” and “MR compatible” when labeling medical implants and devices. However, in time it became apparent that these terms were confusing and were often used interchangeably or incorrectly [28]. 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 [24, 25]. The new terms—MR safe, MR conditional, and MR unsafe—are defined in an ASTM International document [25] as discussed below.

MR safe—An item that poses no known hazards in all MRI environments. Using the new terminology, “MR safe” items include nonconducting, nonmetallic, nonmagnetic 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, time-varying magnetic field (dB/dt), radiofrequency (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 and voltages, electromagnetic

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

In addition to the new terms, ASTM International introduced corresponding icons consistent with international standards for colors and shapes of safety signs [24, 25]. The icons are intended for use on items that may be brought into or near the MRI environment as well as in product labeling. The icons may be reproduced in color or in black and white; however, the use of color is encouraged because of the added visibility.

The MR safe icon consists of the letters “MR” in green in a white square with a green border or the letters “MR” in white within a green square. The MR conditional icon consists of the letters “MR” in black inside a yellow triangle with a black border. The MR unsafe icon consists of the letters “MR” in black on a white field inside a red circle with a diagonal red band. For MR conditional items, the item labeling must include results of testing sufficient to characterize the behavior of the item in the MRI environment.

The new terminology is intended to help clarify matters related to biomedical implants and devices to ensure the safe use of MRI technology. Importantly, as previously indicated, this new terminology has not been applied retrospectively to implants and devices that previously received FDA-approved labeling using the terms “MR safe” or “MR compatible.” Accordingly, this should be understood to avoid undue confusion regarding the matter of labeling for “older” versus “newer” implants. To date, relatively few implants have the term “MR conditional” applied in comparison with those labeled using the previous labeling scheme, MR safe and MR compatible [12, 14].

Information for New or Controversial Implants and Devices

Although a summary of the MRI test data that are available for the more than 1,800 implants and devices is not within the scope of this article, a selection of items evaluated in

the MRI environment is presented to illustrate new or controversial findings for these objects, with an emphasis on electronically activated implants as well as 3-T information.

ActiPatch

The ActiPatch (BioElectronics) is a medical drug-free device that delivers pulsed electromagnetic frequency therapies to accelerate healing of soft-tissue injuries. The ActiPatch has an embedded battery-operated microchip that delivers continuous pulsed therapy to reduce pain and swelling.

The ActiPatch must be removed before a patient undergoes an MRI procedure to prevent possible damage to this device and the potential risk of excessive heating.

Body-Piercing Jewelry

Ritual or decorative body piercing is popular as a form of self-expression. Different types of materials are used to make body-piercing jewelry including ferromagnetic and nonferromagnetic metals as well as non-metallic materials [12, 14, 29–31]. The presence of body-piercing jewelry made from ferromagnetic material presents potential problems for a patient referred for an MRI examination or an individual in the MRI environment. Risks include uncomfortable sensations from movement or displacement that may be mild to moderate depending on the site of the body piercing and the ferromagnetic qualities of the jewelry (e.g., mass, degree of magnetic susceptibility). In extreme cases, serious injuries may occur. In addition, for body-piercing jewelry made from electrically conducting material forming certain lengths or closed loops of a certain diameter, there is the possibility of MRI-related heating that could cause excessive temperature increases and burns [12, 14].

Because of safety issues, metallic body-piercing jewelry should be removed before entering the MRI environment. However, patients or individuals with body piercing are frequently reluctant to remove their jewelry. Therefore, if it is not possible to remove metallic body-piercing jewelry, the patient or individual should be informed regarding the potential risks. In addition, if the body-piercing jewelry is made from ferromagnetic material, some means of stabilization (e.g., application of adhesive tape or bandage) should be used to prevent movement or displacement. To prevent MRI-related heating of body-piercing jewelry made from conductive materials (e.g., the pierced body part

will be in the area of the transmit RF coil), gauze, tape, or other similar material should be used to wrap the jewelry in such a manner as to insulate it (i.e., prevent contact) as much as possible from the underlying skin [12, 14]. The patient should be instructed to immediately inform the MR system operator if any heating or other unusual sensation is felt in association with the body-piercing jewelry. If this occurs, scanning should be stopped immediately and steps should be taken to prevent possible patient injury.

Foley Catheter with Temperature Sensor

MRI safety instructions—The MRI safety instructions [14] for the Bardex Latex-Free Temperature-Sensing 400-Series Foley Catheter (C.R. Bard, Inc.) include the following warning:

This product should never be connected to the temperature monitor or connected to a cable during an MRI procedure. Failure to follow this guideline may result in serious injury to the patient. Refer to “Instructions for Use.” It is important to closely follow these specific conditions that have been determined to permit the examination to be conducted safely. Any deviation may result in a serious injury to the patient.

Nonclinical testing showed that these Foley catheters with temperature sensors are MR conditional. A patient with one of these devices can be scanned safely immediately after placement under the following conditions:

- static magnetic field of 3 T or less with regard to magnetic field interactions,
- spatial gradient magnetic field of 720 G/cm or less with regard to magnetic field interactions, and
- maximum MR system–reported whole-body-averaged SAR of 3.5 W/kg at 1.5 T or 3 W/kg at 3 T for 15 minutes of scanning.

Importantly, the MRI procedure should be performed using an MR system operating at a static magnetic field strength of 1.5 or 3 T only. The safe use of an MR system operating at a lower or higher field strength for a patient with a Foley catheter with temperature sensor has not been determined.

Special instructions—The position of the wire of the Foley catheter with temperature sensor has an important effect on the amount of heating that may develop during an MRI procedure. Accordingly, the Foley catheter with temperature sensor must be positioned

in a straight configuration down the center of the patient table (i.e., down the center of the MR system without any loop) to prevent possible excessive heating associated with an MRI procedure.

Additional MRI safety instructions—Additional safety instructions include the following:

- (1) The Foley catheter with temperature sensor should not be connected to the temperature-monitoring equipment during the MRI procedure.
- (2) If the Foley catheter with temperature sensor has a removable catheter connector cable, it should be disconnected before the MRI procedure.
- (3) Remove all electrically conductive material from the bore of the MR system that is not required for the procedure (e.g., unused surface coils, cables).
- (4) Keep electrically conductive material that must remain in the bore of the MR system from directly contacting the patient by placing thermal and electrical insulation (including air) between the conductive material and the patient.
- (5) Position the Foley catheter with temperature sensor in a straight configuration down the center of the patient table to prevent cross points and conductive coils or loops.
- (6) The wire and connector of the Foley catheter with temperature sensor should not be in contact with the patient during the MRI procedure; position the device accordingly.
- (7) MRI should be performed using an MR system with static magnetic strength of 1.5 or 3 T only.
- (8) At 1.5 T, the MR system whole-body-averaged SAR should not exceed 3.5 W/kg for 15 minutes of scanning.
- (9) At 3 T, the MR system reported whole-body-averaged SAR should not exceed 3 W/kg for 15 minutes of scanning.

Glaucoma Drainage Implants (Shunt Tubes)

A glaucoma drainage implant or device, also known as a shunt tube, is implanted to maintain an artificial drainage pathway to control intraocular pressure for patients with glaucoma [12, 14, 32–37]. Intraocular pressure is lowered when aqueous humor flows from inside the eye through the tube into the space between the plate that rests on the scleral surface and surrounding fibrous capsule. The implantation of a glaucoma drainage device is used to treat glaucoma

that is refractory to medical and standard surgical therapy. These cases are usually in patients in whom standard drainage procedures have failed or in patients who have a poor prognosis including failed trabeculectomy, buphthalmos and juvenile glaucoma, neovascular glaucoma and glaucoma secondary to uveitis, traumatic glaucoma, cataract with glaucoma, and high-risk cases of primary glaucoma.

Importantly, for certain glaucoma drainage implants, radiographic findings may suggest the diagnosis of an orbital foreign body if the ophthalmic history is unknown, as reported by Ceballos and Parrish [32]. In that case report, a patient was denied an MRI examination for fear of dislodging an apparent “metallic foreign body.” In fact, the patient had a Baerveldt glaucoma drainage implant that was mistakenly identified as an orbital metallic object based on its radiographic characteristics (i.e., due to the presence of barium-impregnated silicone).

At least one glaucoma drainage implant, the EXPRESS miniature glaucoma shunt (Optonol Ltd.), is made from 316L stainless steel. However, many other glaucoma drainage implants are made from nonmetallic materials and are safe for patients undergoing MRI procedures. Commonly used devices that do not contain metal include the following:

- Baerveldt glaucoma drainage implant (Pharmacia Co.),
- Krupin-Denver eye valve to disk implant (E. Benson Hood Laboratories),
- Ahmed glaucoma valve (New World Medical),
- Molteno drainage device (Molteno Ophthalmic Ltd.), and
- Joseph valve (Valve Implants Limited).

Hemostatic (Ligating) Vascular Clips

In general, it was previously believed that because virtually all hemostatic (also called ligating) vascular clips and similar devices (including “endoclips” deployed through endoscopes) are made from nonferromagnetic materials such as tantalum, titanium, and certain forms of stainless steel, patients with these implants are not at risk for injury in association with MRI procedures [11, 12, 14, 38]. Furthermore, patients with nonferromagnetic versions of these implants may undergo MRI examinations procedures immediately after they are placed. To date, for the hemostatic clips that have undergone MRI testing, there has been no patient injury or other problem related to MRI.

However, several new hemostatic clips in use today present potential problems for patients referred for MRI procedures. Patients with these clips require special attention to ensure the safe use of MRI. In some cases, MRI is deemed unsafe. In others, a waiting period is necessary and radiographs must be obtained and inspected to determine whether the clips are present before performing MRI. Specific MRI-related labeling statements for the hemostatic clips that require further attention during the MRI screening procedure are as follows:

Resolution Clip—The Resolution Clip (Boston Scientific) is indicated for placement in the gastrointestinal tract for endoscopic marking or hemostasis. Currently, the Resolution Clip is labeled, as follows [39]: “Do not perform MRI procedures on patients who have had clips placed within their gastrointestinal tract, as this could be harmful to patients.”

Long Clip HX-600-090L—The Long Clip HX-600-090L (Olympus Medical Systems) is indicated for placement within the gastrointestinal tract for endoscopic marking, hemostasis, or closure of gastrointestinal tract luminal perforations within 20 mm as a supplementary method. Currently, the Long Clip HX-600-090L is labeled as follows: “Do not perform MRI procedures on patients who have clips placed within their gastrointestinal tracts. This could be harmful to the patient.”

Additional information—Olympus endoscopic clips have been shown to remain in the patient an average of 9.4 days, but retention is based on a variety of factors and may result in a longer retention period. Before MRI, the physician should confirm that there are no residual clips in the gastrointestinal tract. The following techniques may be used for confirmation:

- (1) View the lesion under radiologic imaging. Olympus clip-fixing devices are radiopaque. Using radiography, the physician can determine if any residual clips are in the gastrointestinal tract. If no clips are evident under radiologic imaging, MRI may be performed.
- (2) Endoscopically examine the lesion. If no clips remain at the lesion, MRI may be performed.

QuickClip2, HX-201LR-135, and HX-201UR-135—The QuickClip2, HX-201LR-135, and HX-201UR-135 (Olympus Medical Systems) are indicated for placement within the gastrointestinal tract for endoscopic mark-

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ing, hemostasis, or closure of gastrointestinal tract luminal perforations within 20 mm as a supplementary method. Currently, the QuickClip2 (HX-201LR-135 and HX-201UR-135) is labeled as follows: “Do not perform MRI procedures on patients who have clips placed within their gastrointestinal tracts. This could be harmful to the patient.”

Additional information—Olympus endoscopic clips have been shown to remain in the patient an average of 9.4 days, but retention is based on a variety of factors and may result in a longer retention period. Before MRI, the physician should confirm that there are no residual clips in the gastrointestinal tract. The following techniques may be used for confirmation:

- (1) View the lesion under radiologic imaging. Olympus clip-fixing devices are radiopaque. Using radiography, the physician can determine whether any residual clips are in the gastrointestinal tract. If no clips are evident under radiologic imaging, MRI may be performed.
- (2) Endoscopically examine the lesion. If no clips remain at the lesion, MRI may be performed.

QuickClip2 Long, HX-201LR-135L, and HX-201UR-135L—The QuickClip2 Long, HX-201LR-135L, and HX-201UR-135L (Olympus Medical Systems) are indicated for placement within the gastrointestinal tract for endoscopic marking, hemostasis, or closure of gastrointestinal tract luminal perforations within 20 mm as a supplementary method. Currently, the QuickClip2 Long (HX-201LR-135L and HX-201UR-135L) is labeled as follows: “Do not perform MRI procedures on patients who have clips placed within their gastrointestinal tracts. This could be harmful to the patient.”

Additional information—Olympus endoscopic clips have been shown to remain in the patient an average of 9.4 days, but retention is based on a variety of factors and may result in a longer retention period. Before MRI, the physician should confirm that there are no residual clips in the gastrointestinal tract. The following techniques may be used for confirmation:

- (1) View the lesion under radiologic imaging. Olympus clip-fixing devices are radiopaque. Using radiography, the physician can determine whether any residual clips are in the gastrointestinal tract. If no clips are evident

under radiologic imaging, MRI may be performed.

- (2) Endoscopically examine the lesion. If no clips remain at the lesion, MRI may be performed.

PillCam (M2A) Capsule Endoscopy Device

The PillCam (M2A) Capsule Endoscopy Device (Given Imaging) is an ingestible device for use in the gastrointestinal tract. Peristalsis moves the PillCam (M2A) Capsule smoothly and painlessly throughout the gastrointestinal tract, transmitting color video images as it passes. The procedure allows patients to continue daily activities during the endoscopic examination. The PillCam (M2A) Capsule Endoscopy Device has been used to diagnose diseases of the small intestine including Crohn’s disease, celiac disease and other malabsorption disorders, benign and malignant tumors of the small intestine, vascular disorders, and medication-related small-bowel injuries.

MRI safety information—Undergoing MRI while the capsule is inside the patient’s body may result in serious damage to his or her intestinal tract or abdominal cavity. If the patient did not positively verify the excretion of the PillCam (M2A) Capsule Device, he or she should contact the physician for evaluation and possible abdominal radiography before undergoing an MRI examination [12, 14].

Sleuth Implantable ECG-Monitoring System

The Sleuth Implantable ECG-Monitoring System (Sleuth IMD model 2010, Transoma Medical) is an implantable, patient-activated and automatically activated monitoring system that records subcutaneous ECG and is indicated for patients with clinical syndromes or at increased risk of cardiac arrhythmias and patients who experience transient symptoms that may suggest a cardiac arrhythmia [12, 14].

MRI information—This device is MR conditional at 1.5-T MRI. The monitoring system does not need to be adjusted during MR scanning. However, MR scanning may cause electromagnetic interference that may cause the system to record ECG events. MR scanning may also interfere with the quality of the ECG signal. Therefore, ECG data acquired during MRI may be inaccurate or unusable.

The Sleuth IMD model 2010 was determined to be MR conditional based on information provided in the following document published by the 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, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, Pennsylvania, 2005 [25].

Nonclinical testing has shown that the Sleuth IMD is MR conditional. It can be scanned safely under the following conditions:

- static magnetic field of 1.5 T,
- spatial gradient magnetic field of 250 G/cm, and
- maximum MR system-reported whole-body-averaged specific absorption rate (SAR) of 3.5 W/kg for 15 minutes of scanning.

In nonclinical testing in a phantom, the device produced a temperature rise of 1.3°C or less at a maximum whole-body-averaged SAR of 3.5 W/kg for 15 minutes of MR scanning in a 1.5-T MR system (Magnetom, Siemens Medical Solutions; software Numaris/4, Version Syngo MR 2002B DHHS active-shielded, horizontal field scanner, Siemens).

Instructions for use—The maximum whole-body-averaged SAR reported was measured by the MR system. MR image quality may be compromised if the area of interest is in the same area or is relatively close to the position of the Sleuth IMD. Table 1 provides maximum signal voids (artifact size) for the standard imaging pulse sequences at 1.5 T per ASTM F2119.

The effect of performing MRI procedures using higher static magnetic field or higher levels of RF energy on a patient with the Sleuth IMD has not been determined. MRI health care professionals are advised to contact Transoma Medical to ensure that the latest safety information is obtained and is carefully followed to ensure patient safety relative to the use of an MR procedure.

Note that magnetic forces may act on the housing of the implanted Sleuth IMD and result in a tugging sensation that patients may feel. This force does not pose a safety hazard, but to mitigate patient alarm, patients should be made aware of the possibility of such a sensation.

VeriChip Microtransponder

The VeriChip Microtransponder (VeriChip Corporation) is a miniaturized, implant-

TABLE I: Maximum Signal Voids (Artifact Size) for the Standard Imaging Pulse Sequences at 1.5 T per American Society for Testing and Materials International (F2119)

Signal Void (cm ²)	Pulse Sequence	Imaging Plane
115	T1-weighted spin echo	Parallel
68	T1-weighted spin echo	Perpendicular
162	Gradient echo	Parallel
280	Gradient echo	Perpendicular

Note—Data apply to the Sleuth implantable ECG-monitoring system (Sleuth IMD model 2010, Transoma Medical).

able RF identification device. The microtransponder is a passive device that contains an electronic circuit that is activated externally by a low-power electromagnetic field emitted by a battery-powered scanner. The microtransponder is implanted subcutaneously. With regard to MRI procedures, the labeling for this device states: “Patients with the VeriChip Microtransponder may safely undergo MRI diagnostics, in up to 7-T cylindrical systems” [12, 14].

Instructions for patients undergoing MRI—

- The patient should be monitored continuously throughout the MRI procedure using visual and audio means (e.g., intercom system).
- Instruct the patient to alert the MR system operator of any unusual sensations or problems so that, if necessary, the MR system operator can immediately terminate the procedure.
- Provide the patient with a means to alert the MR system operator of any unusual sensations or problems.
- Do not perform MRI if the patient is sedated, anesthetized, confused, or otherwise unable to communicate with the MR system operator.

Insulin Pumps

The MRI information pertains to the following insulin pumps from Animas Corporation, a Johnson & Johnson Company:

- Animas 2020 Insulin Pump,
- IR Animas 1200,
- IR 1000 Insulin Pump,
- IR 1100 Insulin Pump, and
- IR 1200 Insulin Pump.

Each insulin pump indicated should not be exposed to very strong electromagnetic fields, such as those from MRI units, RF welders, or magnets used to pick up automobiles. Very strong magnetic fields, such as that associated with MRI, can “magnetize” the portion of the insulin pump’s motor that regulates in-

sulin delivery and, thus, damage this device.

For the patient: If you plan to undergo an MRI, remove the insulin pump beforehand and keep it outside of the MR system room during the procedure. If the pump is accidentally allowed into the MR system room, disconnect the pump immediately and contact Animas Pump Support for important instructions.

For the health care professional: Do not bring the insulin pump into the MR system at any time. If the pump is accidentally allowed into the MR system room, disconnect the pump immediately and contact Animas Pump Support for important instructions.

*Cozmo Pump: an infusion pump—*According to the User Manual for the Cozmo Pump (Deltec), which is a device used to administer insulin, the following is stated regarding MRI:

Caution: Avoid strong electromagnetic fields, like those present with Magnetic Resonance Imaging (MRI) and direct x-ray, as they can affect how the pump works. If you cannot avoid them, you must take the pump off.

*MiniMed 2007 Implantable Insulin Pump System—*The MiniMed 2007 Implantable Insulin Pump System (Medtronic) is designed to withstand common electrostatic and electromagnetic interference but must be removed before an MR procedure. Any magnetic field exceeding 600 G will interfere with the proper functioning of the pump for as long as the pump remains in that field. Fields higher than that, such as those emitted by an MR system, may cause irreparable damage to the pump.

By comparison, infusion sets (MMT-11X, MMT-31X, MMT-32X, MMT-37X, MMT-39X; Medtronic) used with this device contain no metallic components and are safe to be used and can remain attached to the patient during an MR procedure. The only exceptions are Polyfin infusion sets. Polyfin infusion sets (MMT-106 and MMT-107,

MMT-16X, MMT-30X, MMT-36X; Medtronic) have a surgical steel needle that remains in the subcutaneous tissue. These infusion sets should be removed before any MR procedure.

Codman Hakim Programmable Valve

The Codman Hakim Programmable Valve (Codman, a Johnson & Johnson Company) offers the ability to optimize the opening pressure of a CSF shunt system before and after implantation. This feature is considered to be an important one because the condition of the patient with the shunt will often change over the course of treatment. The use of a programmable CSF shunt valve allows the surgeon to noninvasively change the opening pressure, negating the need for revision surgery to alter the valve pressure. Furthermore, the programmability of the valve may allow the development of specialized treatment regimes.

The opening pressure of the Codman Hakim Programmable Valve is changed through the use of an externally applied magnetic field. The spring in the ball-and-spring mechanism of the valve sits atop a rotating spiral cam that contains a stepper motor. Applying a specific magnetic field to the stepper motor will cause the cam to turn slightly, increasing or decreasing the tension on the spring and ball, thus changing the opening pressure of the valve.

With regard to MRI, the product insert for the Codman Hakim Programmable Valve states:

*MRI information—*The Codman Hakim Programmable Valve is considered MR Conditional according to ASTM F 2503. The valve demonstrates no known hazards when an MRI is performed under the following conditions:

- MRI can be performed at any time after implantation
- Use an MR system with a static magnetic field of 3 T or less
- Use an MR system with a spatial gradient of 720 gauss/cm or less
- Limit the exposure to RF energy to a whole-body-averaged specific absorption rate (SAR) of 3 W/kg for 15 minutes
- Verify the valve setting after the MRI procedure (see Programming the Valve, product insert information provided with the valve)

In non-clinical testing, the valve produced a temperature rise of 0.4 degrees C at a max-

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imum whole-body-averaged specific absorption rate (SAR) of 3.0 W/kg for 15 minutes of MR scanning in a 3-T Excite, General Electric MR scanner.

MR image quality may be compromised if the area of interest is relatively close to the device. Distortion may be seen at the boundaries of the artifact. Therefore, optimization of the MR imaging parameters may be necessary. The following chart provides a comparison between the signal void and imaging pulse sequence at 3-Tesla:

Signal Void Size	Pulse Sequence	Scan Orientation Relative to Implant
1590 mm ²	T1-SE	long axis view
1022 mm ²	T1-SE	short axis view
2439 mm ²	GRE	long axis view
2404 mm ²	GRE	short axis view

Summary

To prevent incidents and accidents, it is vital to be cognizant of basic information as well as the latest findings that impact the use of MRI to ensure safety for patients, staff members, and others. Having this knowledge is particularly important because of the evolutionary advancements in MRI technology and the increased potential for hazardous situations to occur in this environment.

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FOR YOUR INFORMATION

The reader's attention is directed to the commentary on this article, which appears on the following pages.

FOR YOUR INFORMATION

The reader's attention is directed to part I accompanying this article, titled "MRI Safety Update 2008: Part I, MRI Contrast Agents and Nephrogenic Systemic Fibrosis," which begins on page xxx.