Radiology

MR Labeling Information for Implants and Devices:
Explanation of Terminology[1]

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The magnetic resonance (MR) environment may pose risks or problems to patients with certain implants and other medical devices primarily due to factors that include electromagnetic field interactions, MR imaging–related heating, and the creation of artifacts (1–5). In addition, for electrically activated implants and other medical devices, there are concerns that the MR system may affect the operation of the medical device and/or induce currents in the device (1–3,5). With the growing use of MR imaging in the 1990s, the U.S. Food and Drug Administration (FDA) recognized the need for standardized tests to address MR safety issues for implants and other medical devices (4,6). Thus, over the years, testing methods have been developed by various organizations, including the American Society for Testing and Materials (ASTM) International (formerly the American Society for Testing and Materials), with an ongoing commitment to ensure patient safety in the MR environment (7–10).

The FDA is responsible for reviewing the MR terminology and labeling that manufacturers provide for their devices. The MR terminology, as it pertains to performing MR examinations in patients with implants and other medical devices, has continued to evolve to keep pace with advances in MR technology (4,6,11). Unfortunately, members of the MR imaging community frequently do not understand the terms that are used and are often confused by the conditions that are specified in "MR conditional" labeling. This lack of understanding may result in patients with implants being exposed to potentially hazardous MR imaging conditions or in inappropriately preventing them from undergoing needed MR examinations. Importantly, there is now new labeling terminology, which is associated with expanded labeling information. Therefore, the goal of this editorial is to present background information about the terms used for MR labeling of implants and other medical devices, to define the current terms, and to illustrate the use of the new labeling by providing a sample label with a detailed explanation of how the terminology is used.

Prior Terminology

In 1997, the FDA Center for Devices and Radiological Health (CDRH) first proposed terms to be used to label MR information for medical devices, which were presented in the draft document, "A Primer on Medical Device Interactions with Magnetic Resonance Imaging Systems" (6). These terms were defined as follows:

MR safe: This term indicates that the device, when used in the MR environment, has been demonstrated to present no additional risk to the patient but may affect the quality of the diagnostic information.

MR compatible: This term indicates that the device, when used in the MR environment, is MR safe and has been demonstrated to neither significantly affect the quality of the diagnostic information nor have its operations affected by the MR device.

This document further stated, "The use of the terms, 'MR compatible' and 'MR safe' without specification of the MR environment in which the device was tested should be avoided since interpretation of these claims may vary and are difficult to substantiate rigorously. Statements such as 'intended for use in the MR environment' or similar claims along with appropriate qualifying information are preferred (ie, test conditions should be specifically stated)" (6). Here, the term "MR environment" encompasses the static, gradient (time-varying), and radiofrequency (RF) electromagnetic fields that may affect an implant or device.

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With this terminology, testing of an implant or device for "MR safety" involved in vitro assessments of static magnetic field interactions, MR-related heating, and, in some cases, induced electrical currents (ie, from gradient magnetic fields), while "MR compatibility" testing required all of these assessments, as well as characterization of artifacts. In addition, it may have been necessary to evaluate the effect of various MR imaging conditions on the functional or operational aspects of an implant or device (2–4,6–10).

Revised Terminology

In time, it became apparent that the terms "MR safe" and "MR compatible" were confusing and were often used interchangeably or incorrectly (2–4,11,12). In particular, the terms were sometimes used without including the list of conditions for which the device had been demonstrated to be safe, in some cases inappropriately giving the impression that the device is safe or compatible in all MR environments. Therefore, in an effort to develop more appropriate terminology and, more importantly, because the misuse of these terms could result in serious accidents for patients and others in the MR environment, the MR Task Group of ASTM International Committee F04 on Medical and Surgical Materials and Devices developed standard ASTM F2503, which includes a new set of MR labeling terms with associated icons (4). The new terms defined in ASTM F2503 (released in August 2005) and currently recognized by the FDA are as follows (11,13):

MR safe: An item that poses no known hazards in all MR imaging environments. With this terminology, MR safe items are nonconducting, nonmetallic, and 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 MR environment with specified conditions of use. Field conditions that define the MR environment include static magnetic field strength, spatial gradient, time rate of change of the magnetic field (dB/dt), RF fields, and specific absorption rate (SAR). Additional conditions, including specific configurations of the item (eg, 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 MR environment. In particular, testing for items that may be placed in the MR 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, 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 MR environments. MR unsafe items include magnetic items such as a pair of ferromagnetic scissors.

Associated icons: In addition to the terms "MR safe," "MR conditional," and "MR unsafe," the ASTM International MR marking standard introduced corresponding icons, consistent with international standards for colors and shapes of safety signs (13). These icons are intended for use on items that may be brought into or near the MR environment, as well as in product labeling for implants and other medical devices. The icons may be reproduced in color or in black and white; however, the use of color is encouraged because of the added visibility (13).

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. Of importance, for MR conditional items, the item's labeling must include the parameters and results used for testing that are sufficient to characterize the behavior of the item in the MR environment (13) (Fig 1).

Further details and a comprehensive discussion of the labeling applied to passive implants are presented in the recent FDA document, "Guidance for Industry and FDA Staff: Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment" (11).

Figure 1

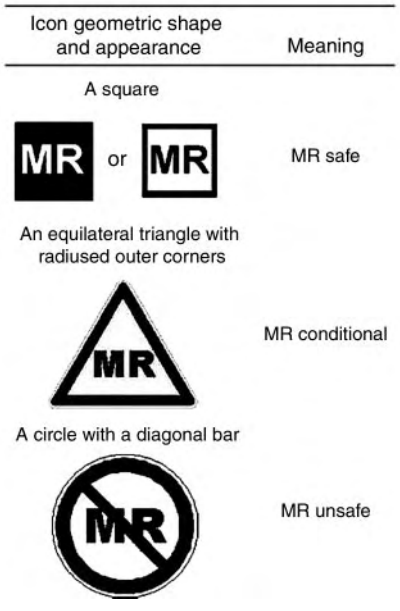

Figure 1: Icons used for MR labeling of implants and devices. Each icon corresponds to a specific term: MR safe, MR conditional, and MR unsafe. These icons are intended to be used on items that may be brought into or near the MR environment, as well as in product (eg, implants and devices) labeling.

Use of Terminology: Reasons for Confusion

Because of the variety of MR systems and MR conditions in clinical use today (eg, ranging from 0.2 to 9.4 T), the current terminology is intended to help elucidate labeling matters for medical devices and other items that may be used in the MR environment to ensure the safe use of MR technology. However, it should be noted that this updated termi-

nology has not been applied retrospectively to the many implants and devices that previously received FDA-approved labeling using the terms "MR safe" or "MR compatible" (in general, this applies to those objects tested prior to the release of the ASTM International standard for labeling, August 2005).

Therefore, this important point must be understood to avoid undue confusion regarding the matter of the labeling that has been applied to previously tested implants (ie, labeled as MR safe or MR compatible) versus those that have recently undergone MR testing (ie, now labeled as MR conditional) (2,3).

The labeling for medical devices that were *appropriately* labeled by using the historical definitions for MR safe or MR compatible, including the list of conditions for which the device has been determined to be safe or compatible, is still accurate. Indeed, part of the confusion that exists on this matter is due to the coexistence of the newer terminology with the prior labeling terminology.

To eliminate this ongoing confusion, in 2005 the FDA recognized the new set of terms in ASTM F2503 and asks that manufacturers use them for all new products. When manufacturers make a submission to the FDA for an existing device, the FDA requests that the manufacturers of these previously approved devices update their labeling to use the new MR terminology. Labeling information for implants and other medical devices has been compiled and is available in published and online formats (2,14). Specific testing and labeling for active implants (eg, those involving electronics) is currently being developed by an International Standards Organization–International Electrotechnical Commission joint working group.

Figure 2

MRI Information

Non-clinical testing has demonstrated the Example Implant is MR Conditional. It can be scanned safely under the following conditions:

-Static magnetic field of 3-Tesla.

-Spatial gradient field of 720-Gauss/cm or less.

-Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2-W/kg for 15-minutes of scanning.

-In non-clinical testing, the Example Implant produced a temperature rise of less than 2.0°C at a maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2- W/kg for 15 minutes of MR scanning in a (static magnetic field strength _____) (model _____) (MR system manufacturer _____) (software version _____) MR scanner.

Image Artifact

MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of the device. Therefore, it may be necessary to optimize MR imaging parameters for the presence of this implant.

Figure 2: Example of MR labeling information for a medical implant or device.

Figure 3

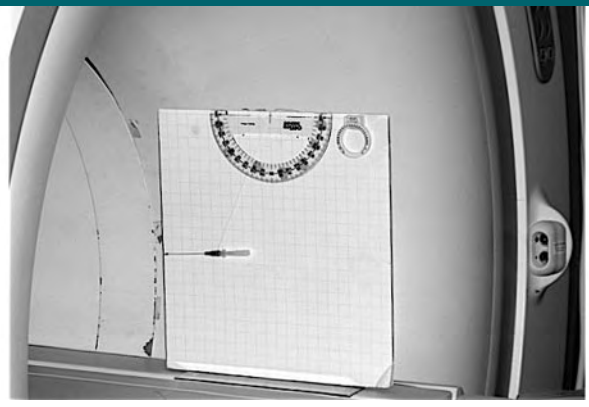

Figure 3: Example of the position of the highest spatial magnetic gradient (720 G/cm for the 3-T MR system used for testing in this case) used for the deflection angle measurement performed for an intravenous catheter. This point was inside and near the inner part of the bore of the MR system. Note the deflection angle of 24°.

MR Conditional Labeling Information: Explanation of the Content

In addition to the frequent problems associated with understanding the MR labeling, the actual content of the label is often misunderstood with respect to the conditions indicated for a given implant that is labeled as MR conditional. Therefore, the following is an example of MR conditional labeling for an implant, called "Example Implant," along with an explanation of the content, provided for each aspect of the label (1–4,11,13) (Fig 2).

MR Imaging Information

Nonclinical testing has demonstrated that the Example Implant *is MR conditional. It can be imaged safely under the following conditions:*

Static magnetic field of 3 Tesla.

This is the static magnetic field for which the implant had acceptable test results, generally the highest static magnetic field used for testing the implant. In some cases the labeling will state, "static magnetic field of 3 Tesla or less"

or "static magnetic field of 3 Tesla, only" or "static magnetic field of 1.5 Tesla or 3 Tesla." Therefore, carefully reading and implementing this portion of the labeling information for the implant is advised in order to avoid possible injuries to patients.

Spatial gradient field of 720 Gauss/cm or less.

This is a frequently misinterpreted parameter because the user sees the term "gradient field" and presumes that it refers to the time-varying or gradient fields used during MR imaging. However, the term "spatial gradient field" for medical device labeling relates to the rate at which the static magnetic field strength changes over space per unit length (thus, indicated as dB/dx or, in this case, as 720 G/cm for this example). Notably, the point of the highest spatial magnetic gradient is the position where translational attraction (ie, determined with the deflection angle method) is typically assessed for an implant or device, according to ASTM F2052-06e1. For example, Figure 3 shows the deflection angle measured for an intravenous catheter at the point of the highest spatial magnetic gradient (720 G/cm for the 3-T MR system used in this case). The MR system manufacturer is able to provide spatial gradient magnetic field information for a particular MR system, or it may determined by using a Gaussmeter.

Maximum MR system reported whole body averaged specific absorption rate (SAR) of 2 W/kg for 15 minutes of scanning.

Confusion commonly exists with respect to this stated parameter insofar as the term "scanning" is presumed to apply to the entire MR imaging procedure when, in fact, it applies to only each particular pulse sequence that is used and, of course, multiple sequences are used when performing the MR imaging examination. Therefore, to adequately safeguard the patient, the whole-body averaged SAR for each scan sequence must be maintained at or below 2 W/kg for each scan sequence.

In nonclinical testing, the Example Implant *produced a temperature rise of less than 2.0°C at a maximum MR system reported whole body averaged specific absorption rate (SAR) of* 2 *W/kg for* 15 *minutes of MR scanning in a (static magnetic field strength ____) (model ____) (MR system manufacturer ____) (software version ____) MR scanner.*

The labeling for the implant has additional information with respect to the temperature rise that is associated with certain MR parameters, which is based on the findings obtained in the MR-related heating test. Therefore, as seen in this example, the expected "worst case" temperature rise is 2.0°C or less during MR imaging performed at a whole-body averaged SAR of 2 W/kg for 15 minutes, using a particular MR system type (ie, with the make, model, and software of the imager indicated). The MR system reported whole-body averaged SAR of 2 W/kg is the level specified in the ASTM F2182-02a and is the level commonly reported in device labeling, although higher or lower SAR levels may also be indicated. (It should be noted that, in this labeling section, certain labels for implants and other medical devices may state that this information applies to the use of a particular type of transmit RF coil that should be used, such as a transmit body or transmit head RF coil.)

Image Artifact

MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of the device. Therefore, it may be necessary to optimize MR imaging parameters for the presence of this implant.

This is a common statement for many implants and devices. Since the size of the artifact for an implant or device may affect the diagnostic use of MR imaging, information is typically provided in the label that characterizes the size and shape of the artifacts associated with certain pulse sequences (eg, T1-weighted spin echo and gradient echo), according to ASTM F2119-07 or an equivalent method. For devices with a lumen (eg, stent), the labeling may indicate whether the lumen is obscured by the size of the artifact.

The FDA also recommends that the patient register the conditions under which their MR conditional implant can be imaged safely with the MedicAlert Foundation or another equivalent organization (11).

This editorial presents current FDA recommendations for MR safety terminology and labeling for implants and other medical devices and provides an explanation of how this information may be applied. Notably, the specific content of the MR labeling may take other forms (especially for electrically active implants and devices) as the format continues to be refined by the FDA in an ongoing effort to properly communicate this information to ensure patient safety.

References

1. Shellock FG, Crues JV. MR procedures: biologic effects, safety, and patient care. Radiology 2004;232(3):635–652.
2. Shellock FG. Reference manual for magnetic resonance safety implants and device: 2009 edition. Los Angeles, Calif: Biomedical Research Publishing Group, 2009.
3. Shellock FG, Spinazzi A. MRI safety update 2008. II. Screening patients for MRI. AJR Am J Roentgenol 2008;191(4):1140–1149.
4. Woods TO. Standards for medical devices in MRI: present and future. J Magn Reson Imaging 2007;26(5):1186–1189.
5. Levine GN, Gomes AS, Arai AE, et al. Safety of magnetic resonance imaging in patients with cardiovascular devices: an American Heart Association scientific statement from the Committee on Diagnostic and Interventional Cardiac Catheterization, Council on Clinical Cardiology, and the Council on Cardiovascular Radiology and Intervention, endorsed by the American College of Cardiology Foundation, the North American Society for Cardiac Imaging, and the Society for Cardiovascular Magnetic Resonance. Circulation 2007;116(24):2878–2891.
6. A primer on medical device interactions with magnetic resonance imaging systems. U.S. Food and Drug Administration, Center for Devices and Radiological Health Web site. http://www.fda.gov/cdrh/ode/primerf6.html. Published 1997.
7. American Society for Testing and Materials International. Designation: ASTM F2052-06e1, standard test method for measurement of magnetically induced displacement force on medical devices in the magnetic res-

onance environment. West Conshohocken, Pa: American Society for Testing and Materials International, 2006.

8. American Society for Testing and Materials International. Designation: ASTM F2213-06, standard test method for measurement of magnetically induced torque on medical devices in the magnetic resonance environment. West Conshohocken, Pa: American Society for Testing and Materials International, 2006.

9. American Society for Testing and Materials International. Designation: ASTM F2119-07, standard test method for evaluation of MR image artifacts from passive implants. West Conshohocken, Pa: American Society for Testing and Materials International, 2007.

10. American Society for Testing and Materials International. Designation: ASTM F2182-02a, standard test method for measurement of radio frequency induced heating near passive implants during magnetic resonance imaging. West Conshohocken, Pa: American Society for Testing and Materials International, 2002.

11. Guidance for industry and FDA staff: establishing safety and compatibility of passive implants in the magnetic resonance (MR) environment. U.S. Food and Drug Administration Web site. http://www.fda.gov/cdrh/osel/guidance/1685.html. Published August 21, 2008.

12. Shellock FG, Crues JV 3rd. MR safety and the American College of Radiology White Paper. AJR Am J Roentgenol 2002;178(6):1349–1352.

13. American Society for Testing and Materials International. Designation: F2503-08, standard practice for marking medical devices and other items for safety in the magnetic resonance environment. West Conshohocken, Pa: American Society for Testing and Materials International, 2005.

14. MRISafety Web site. *http://www.mrisafety.com/*. Accessed June 2009.