FDA INSIGHTS

MR Safety of Cardiovascular Implants

New standards are being developed to ensure patient safety during procedures involving magnetic resonance imaging.

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The views and opinions presented in this article are those of the author and do not necessarily reflect those of the US FDA, the US Department of Health and Human Services, or the Public Health Service.

Each year, hundreds of thousands of patients receive new implants, many of which are cardiovascular devices. Simultaneously, the scope and complexity of interventional MR procedures continue to expand, with cardiovascular specialists at the vanguard of the development of new techniques. In particular, increasing requirements for high-resolution dynamic imaging of the cardiovascular system are helping to drive the development of faster MR scanners with ever-increasing resolution and more extreme MR environments. New interventional procedures require a complete array of patient monitors and support systems, anesthesia devices, and surgical tools that are safe and function correctly in the MR environment. As a result, the issue of the safety of implants in the MR environment is of paramount importance to the medical community and to the millions of patients who receive MR scans each year.

SAFETY ISSUES

An MR scanner has a large static magnetic field that is always present. During imaging, pulsed radiofrequency (RF) fields and gradient magnetic fields (dB/dt) are applied. MR accidents are a result of adverse interactions between these electromagnetic fields and implants or other medical devices. The principal safety issues for medical devices in the MR environment are magnetically induced displacement force and torque, RF heating, gradient-induced nerve stimulation, acoustic noise, image artifact and, for electrically active devices, electromagnetic compatibility and electromagnetic interference. Although severe accidents are not common, there have been a number of deaths and serious injuries caused by the interactions of devices with the MR environment.

STATIC FIELD EFFECTS

The most common MR systems, 1.5-T scanners, have static fields that are orders of magnitude larger than the Earth's approximately 0.6 10^{-5}-T magnetic field. The static magnetic field acts on devices to produce two types of forces. A magnetically induced torque is produced, which tries to align

ICON GEOMETRIC SHAPE AND APPEARANCE	MEANING
A square 	MR Safe
An equilateral triangle with radiused outer corners 	MR Conditional
A circle with a diagonal bar 	MR Unsafe

Figure 1. MR safety icons. (Extracted with permission from F2503-05 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment, copyright ASTM International. A copy of the complete standard may be purchased from ASTM at www.astm.org.)

the device with the magnetic field as a compass needle is aligned with the Earth's magnetic field. The spatial gradient in the magnetic field produces the magnetically induced projectile force familiar to anyone who has picked up a paper clip with a small magnet. Unfortunately, both of these static field effects have been responsible for the deaths of patients. A 5-year-old boy died after being struck in the head during an MRI scan by a magnetic oxygen cylinder that was brought into the room and pulled into the magnet. An elderly woman with an intracranial aneurysm clip died after the MR scanner's static field moved the clip, tearing an adjacent artery and producing a hemorrhage.

RF HEATING

RF heating of the body during an MR scan is produced by currents induced by the RF excitation pulses applied during scanning. IEC 60601-2-33 defines acceptable levels of RF heating during clinical scanning. The potential for RF-induced heating is greatly increased by the presence of metallic implants or other medical devices, particularly long, thin objects like leads for neurostimulators or pacemakers. Extreme care must be taken if a decision is made to scan a patient with an electrically active implant. In 2003, a patient with an implanted neurostimulator underwent an MR scan that produced a thermal lesion around the intracerebral electrode contacts that left the patient comatose and with a severe permanent disability.

TIME RATE OF CHANGE OF MAGNETIC FIELD

The principal effects produced by the pulsed gradient fields are peripheral nerve stimulation and cardiac stimulation. The thresholds for painful nerve stimulation are less than those for cardiac stimulation, so the painful nerve stimulation threshold serves as a safety threshold for dB/dt. Current FDA guidance follows the recommendations in IEC 60601-2-33 and limits the dB/dt to levels that prevent cardiac stimulation in any operating mode and minimize the occurrence of intolerable peripheral nerve stimulation in the patient in any operating mode.

STANDARDS DEVELOPMENT AND TERMINOLOGY

In the late 1990s, the FDA Center for Devices & Radiological Health (CDRH) initiated the development of standards for the MR safety of implants and other medical devices through ASTM International (formerly the American Society for Testing and Materials). To date, five standards addressing MR safety of medical devices have been published. All have been recognized by the FDA. Four test methods address the principal safety concerns and image artifacts: ASTM F2052 and F2213, for measurement of magnetically induced displacement force and torque, respectively; F2182 on measurement of RF-induced heating; and F2119 on evaluation of MR image artifacts. ASTM F2503, Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment, was published in August 2005. It contains new terminology and icons defining the safety of objects in the MR environment. The new terms, *MR Safe, MR Conditional,* and *MR Unsafe* are defined as follows.

MR Safe. *An item that poses no known hazards in all MR environments.* MR Safe items include nonconducting, 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 specified MR environment include field strength, spatial gradient, dB/dt, RF fields, and specific absorption rate. Additional conditions, including specific configurations of the item, may be required.*

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.

In addition to the terms, the standard introduces corresponding icons, consistent with international standards for colors and shapes of safety signs. The icons, shown in Figure 1, are intended to be used on items that may be brought into or near the MR 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.

For MR Conditional items, ASTM F2503 requires the item labeling to include results of testing sufficient to characterize the behavior of the item in the MR environment. In particular, the testing 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.

The ASTM MR test methods are being revised to replace the former terms *MR Safe* and *MR Compatible* with the new terms *MR Safe, MR Conditional,* and *MR Unsafe*. The historical definitions for MR Safe and MR Compatible required the conditions under which the device had been shown to be safe or compatible to always be listed with the term. Although the historical definition of MR Safe has sometimes been used appropriately, the MR safety community determined that the term is also misused by citing it alone, with-

out the required list of conditions for which the device has been determined to be safe. Therefore, representatives from across the MR community, including the clinical community, MR system manufacturers, accessory device manufacturers, and government agencies concluded that the risk of serious injury or death caused by the misuse of the historical definition was great enough to support the development of the terminology in ASTM F2503. The new terminology and icons will serve to reduce the possibility of MR-related injuries involving implants and other medical devices.

The FDA is in the processing of drafting MR safety labeling for implants and other medical devices using the new terminology. The implant labeling will be similar to that given in the Guidance for Non-Clinical Tests and Recommended Labeling for Intravascular Stents and Associated Delivery Systems (http://www.fda.gov/cdrh/ode/guidance/1545.html), but will include the new MR Conditional term. The wording has not been finalized, but will be provided in a future issue of *Endovascular Today*.

CONCLUSIONS

The number of MR scans and interventional MR procedures will continue to increase as will the number of patients with both passive and electrically active implants. At the same time, the ASTM standards effort will continue to expand the existing standards to fully address the issues facing electrically active devices in the MR environment. The new MR safety terminology and icons should have a great impact on ensuring the safety of patients and medical personnel in the MR environment. However, the entire medical community must be aware of potential hazards affecting MR safety and must remain vigilant to ensure that MR accidents do not occur.

A number of organizations are working to increase MR safety and to educate the medical community, patients and the medical device industry through publications, courses, Web sites, and standards development activities. These groups include the FDA, the American College of Radiology, ASTM International, the Radiological Society of North America, International Society for Magnetic Resonance in Medicine, International Electrotechnical Commission, International Committee on Non-Ionizing Radiation Protection, the National Electrical Manufacturers Association MR Technical Committee, and ECRI (formerly the Emergency Care Research Institute). Each one of these organizations can provide additional information about MR safety. ■

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