

## 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*

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**Abstract**—Advances in magnetic resonance (MR) imaging over the past 2 decades have led to MR becoming an increasingly attractive imaging modality. With the growing number of patients treated with permanent implanted or temporary cardiovascular devices, it is becoming ever more important to clarify safety issues in regard to the performance of MR examinations in patients with these devices. Extensive, although not complete, *ex vivo*, animal, and clinical data are available from which to generate recommendations regarding the safe performance of MR examination in patients with cardiovascular devices, as well as to ascertain caveats and contraindications regarding MR examination for such patients. Safe MR imaging involves a careful initial patient screening, accurate determination of the permanent implanted or temporary cardiovascular device and its properties, a thoughtful analysis of the risks and benefits of performing the examination at that time, and, when indicated, appropriate physician management and supervision. This scientific statement is intended to summarize and clarify issues regarding the safety of MR imaging in patients with cardiovascular devices. (*Circulation*. 2007;116:2878-2891.)

**Key Words:** AHA Scientific Statement ■ magnetic resonance imaging ■ cardiovascular devices

Advances in magnetic resonance (MR) imaging and MR angiography over the last 2 decades have led to MR becoming an increasingly attractive imaging modality. MR imaging provides excellent spatial resolution and multiplanar 3-dimensional analysis, while not exposing patients to ionizing radiation, the risks of invasive procedures, or potentially nephrotoxic iodinated contrast agents. MR imaging has thus developed into a broadly applied diagnostic tool for patients with cardiovascular and other disease states, and the number of patients undergoing scanning each year is increasing. At the same time, an increasing number of patients are being

treated with permanently or temporarily implanted cardiovascular devices.

There remains confusion and controversy regarding which patients with cardiovascular devices can safely undergo MR examination. This has led to the unsafe examination of patients with certain devices and to the misinformed and inappropriate refusal to refer or scan patients with other devices, thus depriving the patient and treating physician of clinically useful information. Furthermore, many of the reported cases of MR-related injuries and most of the few fatalities that have occurred have been the result of failure to

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follow established safety guidelines or the use of outdated information related to the safety aspects of biomedical implants and devices. Accordingly, this scientific statement is intended to summarize and clarify issues regarding the safety of MR imaging in patients with cardiovascular devices.

It is beyond the scope of this document to provide guidelines for every cardiovascular device. Furthermore, most devices have been tested under very specific circumstances (eg, magnetic field strength, radiofrequency [RF] energy levels, and type of RF transmission coils). Additionally, devices may undergo manufacturing modification, particularly with regard to metallic composition, while retaining the same basic name, and new devices will be introduced into the market constantly. Therefore, for specific guidelines for specific devices, particularly when there is doubt as to the safety of scanning a patient with a given device, the reader is encouraged to refer to a more detailed source of safety information, such as dedicated Web sites,<sup>1,2</sup> reference manuals,<sup>3</sup> or, when available, the manufacturer's product information. Broader information on MR examinations is available at several well-recognized expert Web sites<sup>4-7</sup> and in published and online documents.<sup>8-17</sup>

### General Safety Considerations

Risks associated with MR imaging generally arise from 3 distinct mechanisms related to MR imaging: (1) the static main magnetic field; (2) RF energy; and (3) gradient magnetic fields. There are several potential risks associated with MR scanning of specific cardiovascular devices that result from these processes.<sup>3,9-12,14,16-21</sup> Most of these risks can be understood by consideration of the areas discussed below.

#### Static Magnetic Fields

Most currently used clinical MR scanners are 1.5 to 3 tesla (T), which corresponds to  $\approx 30\,000$  to  $60\,000$  times the strength of the Earth's magnetic field. The greatest risk from the main magnetic field is attraction of a ferromagnetic object into the scanner. For the purposes of this statement, the term "ferromagnetic" is used to denote a substance that experiences an attractive force in the presence of a magnetic field. As a result of ferromagnetic interactions, a device may be moved, rotated, dislodged, or accelerated toward the magnet. Thus, a ferromagnetic object might be accelerated toward the magnet at dangerously high velocities and/or with dangerously high forces, creating a "projectile effect" that could lead to significant patient injury or damage to the MR system. Device function may also be altered or negated as a result of interactions with the strong static magnetic fields. Most, but importantly not all, currently implanted cardiovascular devices are either nonferromagnetic or weakly ferromagnetic. The higher the static magnetic field of the MR system, the greater the resultant ferromagnetic forces on weakly or overtly ferromagnetic materials. Thus, findings from *ex vivo* studies at fields of 1.5 T or lower may not necessarily apply to imaging of devices at higher field strengths (eg, 3 T and higher), which produce significantly greater forces. For devices in which the ferromagnetism of the device is a significant safety concern, consideration should be given to performing the study at the lowest field strength available to reduce whatever ferromagnetic risk might

be present. Finally, all healthcare professionals are reminded that currently used MR scanners are typically superconducting and thus are always "on."

#### RF Energy

During MR imaging, RF energy is "pulsed" into the body to generate the MR image. The body will absorb some of the RF power and therefore will heat up (usually less than  $1^\circ\text{C}$ ) directly owing to ohmic heating. The dosimetric term used to characterize RF energy is the specific absorption rate (SAR, measured in watts per kilogram). SAR increases with the square of the field strength.<sup>22</sup> Certain metallic devices (such as leads) can act as an "antenna" and concentrate this RF energy, which leads to excessive local heating, especially at the tip of these devices. An example of such an interaction is the heating (and subsequent melting at the skin entry site) of a Swan-Ganz (pulmonary artery) thermodilution catheter.<sup>23</sup> These concerns are most relevant for electrically conductive implants such as wires or leads, particularly when such wires or leads form large loops. Fractured leads may pose a particularly high risk of thermal injury. Concentration of RF energy is frequency dependent and therefore changes for a given device in a different field strength. The multiparametric nature of this risk results in the seemingly paradoxical situation of being able to identify implants/wires that test as being safe at a given field strength/frequency yet are unsafe at a higher or lower one. RF energies used in the MR imaging process can also induce electrical currents in wires and leads, which could possibly induce arrhythmias.

#### Gradient Magnetic Fields

Time-varying magnetic fields called gradients (dB/dt, measured in teslas per second) are used to encode for various aspects of the image acquisition. Although the gradients are much weaker than the main magnetic field, the gradients are repeatedly and rapidly turned on and off. The rapidly changing magnetic fields from the gradients can induce electrical currents in electrically conductive devices and may directly excite peripheral nerves. Although current-generation scanners operate at levels that will not directly excite cardiomyocytes, the gradients can induce currents within electrically conductive wires and leads that could cause arrhythmias.

In addition to the above considerations, several other issues merit mention. The location of the device relative to the anatomy to be studied is also an important consideration in assessing the risk-benefit ratio of the study. An understanding of the risks involved in such study requires an expert understanding of the physics involved in MR scanning. For example, some MR imaging studies of the brain may theoretically produce maximal dB/dt values over a cardiac pulse generator and leads implanted in the upper thorax. Therefore, particularly in cases in which there is a relative contraindication to device examination and the examination location is distinct from the device location, consultation with a person with expertise in MR physics and MR safety is recommended.

The very flow of electrically conductive blood in the presence of powerful static magnetic fields produces very small voltages that may produce electrocardiographic aberrations, including elevation of the ST segment, T-wave abnor-

**Table 1. Older and Newer Terminology Used for Labeling Implanted Devices**

Older terminology	
MR safe	The device, when used in the MR 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 MR conditions in which the device was tested should be specified in conjunction with the term "MR safe," because a device that is safe under 1 set of conditions may not be found to be so under more extreme MR imaging conditions.
MR compatible	A device shall be considered "MR compatible" if it is MR safe and the device, when used in the MR environment, has been demonstrated to neither significantly affect the quality of the diagnostic information nor have its operations affected by the MR system. The MR imaging conditions in which the device was tested should be specified in conjunction with the term "MR compatible," because a device that is safe under 1 set of conditions may not be found to be so under more extreme MR conditions.
Newer terminology	
MR safe	An item that poses no known hazards in any MR environment. Using the new terminology, "MR safe" items include nonconducting, nonmetallic, nonmagnetic items, such as a plastic Petri dish.
MR conditional	An item that has been demonstrated to pose no known hazards in a specified MR imaging environment with specified conditions of use. Conditions that define the MR environment include static magnetic field strength, spatial magnetic gradient, dB/dt (time-varying magnetic fields), RF fields, and SAR. Additional conditions, including specific configurations of the item (eg, the routing of leads used for a neurostimulation system), 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.

malities, and even the appearance of arrhythmias. The stronger the static magnetic field, the greater the magnitude of these observed perturbations. This phenomenon may complicate monitoring of the heart rhythm during scanning, lead to inappropriate inhibition of pacemaker function, or create arrhythmia artifacts on event loop recorders.

Most important to the issue of patient safety during MR examination is the "do no harm" approach. If there is a question as to the safety of the MR study, unless circumstances dictate otherwise and the benefits of the examination are believed to outweigh the possible risks, the examination should be deferred until it can be verified that study of the patient is safe. If it cannot be discerned that the patient can safely undergo MR examination, alternative imaging modalities should be used whenever possible.

### Patient Screening

Given the risks associated with MR imaging of certain cardiovascular (as well as other) implants and devices, thorough and effective screening procedures for patients who are to undergo MR examinations are essential.<sup>3,17,24</sup> Indeed, most MR examination adverse events are believed to be due to deficiencies in screening methods.<sup>3</sup> Therefore, all patients should undergo a thorough screening procedure for cardiovascular and other implants and devices, including an interview with a healthcare worker specifically trained in MR safety and completion of a standardized screening form, which should then be thoroughly reviewed by the MR technologist or physician. MR screening forms are available for download at several Web sites.<sup>1,4,7</sup> Whenever possible and practical, particularly if there is doubt regarding patient reliability, any implanted devices should be identified via wallet-sized cards the patient may have been given and/or procedure notes. If the specific identity of a device cannot be confirmed, but it is believed for clinical reasons that the scan should be performed at that time, consideration should be given to performing the study at the lowest field strength available to reduce whatever ferromagnetic risk might be present. Inpatients should be examined for the presence of

temporary devices (eg, pulmonary artery catheters or temporary pacing leads). If, during scanning, a metallic object is identified that the patient has not reported having implanted, the study should be stopped and the patient further questioned until the metallic object is identified. MR technologists should be well trained on MR safety issues, because they may often represent the "last line of defense."

### Safety Terminology for Implants and Devices

Terminology applied to implants and devices relative to the MR environment has evolved over the years. In 1997, the Food and Drug Administration (FDA), Center for Devices and Radiological Health, proposed definitions for the terms "MR safe" and "MR compatible" (Table 1).<sup>25</sup> With this terminology, MR testing of an implant or object for MR safety involved assessments of magnetic field interactions, heating, and, in some cases, induced electrical currents, whereas MR compatibility testing required all of these plus characterization of artifacts. In addition, it may have been necessary to evaluate the functional or operational aspects of an implant or device relative to specific MR imaging conditions. Over time, however, it became apparent that these terms were often applied incorrectly or used interchangeably.<sup>26</sup> Therefore, to clarify the terminology and, more importantly, because the misuse of these terms could result in serious accidents for patients and others, the American Society for Testing and Materials International developed a new set of terms: "MR safe," "MR conditional," and "MR unsafe" (Table 1).<sup>27</sup> Notably, the US FDA is not mandating retesting (and relabeling) of implants and devices that have already received approved labeling with the older terminology. Therefore, the reader should be aware that there may be confusion with regard to the labeling of certain biomedical implants.

The labeling approved by the FDA using the latest American Society for Testing and Materials International designation is given for each device type discussed that has been labeled with this newer terminology. In addition, a more general discussion of safety issues is also provided that uses the expertise of the writing group to synthesize the FDA labeling using the American Society for Testing and Materi-

als terminology with the latest experimental and clinical data, as well as expert consensus opinion, to give guidance to as broad a target audience as possible for issues regarding MR safety and cardiovascular devices.

### MR Imaging After Device Implantation

In general, if a device is a nonferromagnetic “passive” implant (ie, there is no electronically or magnetically activated component) made from a nonferromagnetic material (eg, titanium, titanium alloy, or nitinol), and if there are no concerns associated with MR-related heating, the patient with the device may undergo MR imaging immediately after implantation. The issue of when patients who have been treated with weakly ferromagnetic devices may undergo MR examination has not been established definitively for every device and thus remains controversial. For weakly ferromagnetic devices, it is theoretically possible that the forces present during an MR examination could move or dislodge such a device. On the other hand, some devices, such as many intravascular coils and stents that are firmly implanted into the vessel wall or adjacent tissues during the implantation process, may be further passively or actively anchored to the vessel wall or adjacent tissues and are subject to constant hemodynamically generated forces from the beating of the heart and resultant blood flow that are often much greater than the forces associated with the MR examination. However, it is generally believed that the tissue healing process that occurs over the weeks after implantation may in some cases provide an additional degree of device anchoring, and thus, it has been advocated by some to wait  $\approx 6$  weeks before MR imaging of certain devices.

For some weakly ferromagnetic devices, there are currently sufficient data and consensus that it can be recommended that patients with such devices can undergo MR examination any time after scanning. For weakly ferromagnetic devices for which there are not currently enough data and consensus to make the recommendation that scanning can be performed safely any time after implantation, the writing group recommends that the physician weigh the risks and benefits of scanning patients with such devices on a case-by-case basis and adopt the following approach: For cases that occur in the days to weeks after device implantation in which there is a clear potential clinical benefit of scanning the patient at that time (eg, acute back pain and lower-extremity weakness after trauma), the benefits of the MR examination will likely outweigh any risks of the examination, and MR examination should generally be performed. For patients in whom it makes little difference whether the scan is performed at a given time or weeks later (eg, those with chronic back pain), it may be prudent to defer MR examination until  $\approx 6$  weeks after such device implantation.

## Coronary Artery and Peripheral Vascular Stents

### Background Data

Most coronary artery and peripheral vascular stents are composed of either 316L stainless steel or nitinol. Less commonly, stents may be composed of or contain variable

amounts of platinum, cobalt alloy, gold, tantalum, MP35N, or other materials.<sup>3</sup> Most coronary and peripheral vascular stents exhibit nonferromagnetic or weakly ferromagnetic characteristics. Most of the stents currently used for carotid procedures are made of nitinol and are nonferromagnetic or only weakly ferromagnetic. Implantation of the stent against the vessel wall provides for immediate anchoring of the stent. It is generally believed that additional anchoring of the stent into the vessel wall occurs over  $\approx 6$  to 8 weeks primarily due to tissue ingrowth. Although this latter phenomenon may have led to recommendations that MR scanning be deferred for 6 to 8 weeks in patients treated with nonferromagnetic coronary stents, there are no good clinical data or rationale to support this recommended delay.

In 1 study, ex vivo testing at 1.5 T on 19 different coronary stents revealed 2 to be nonferromagnetic and the remaining 17 to be at worst “minimally” ferromagnetic.<sup>28</sup> Other ex vivo studies of various coronary stents also led to the conclusions that MR examination with those stents tested would be safe.<sup>29–32</sup> Studies of peripherally implanted stents yielded generally similar results, with the exception of a stainless steel Zenith/Cook iliac stent (Cook), which at 3 T was found to have ferromagnetic properties.<sup>3,33,34</sup> Studies conducted thus far have not suggested any increased risk of stent subacute or late thrombosis after MR examination.<sup>32,35–38</sup>

More recently, ex vivo study has been conducted on several of the more commonly used coronary drug-eluting stents, including 2005 to 2006 versions of the Cypher (Johnson & Johnson/Cordis), Taxus Express (Boston Scientific), Taxus Liberte (Boston Scientific), and Endeavor (Medtronic) stents.<sup>3,39–41</sup> These ex vivo studies demonstrated a lack of ferromagnetic interactions at 3 T that would pose a risk for stent migration. Therefore, for those drug-eluting stents tested, it is believed that MR examination may be performed immediately after implantation. In those studies that evaluated stent heating, only minimal to modest heating ( $<1^{\circ}\text{C}$  for a single stent and  $<2^{\circ}\text{C}$  for 2 long, overlapping stents) was evident. The effect of the MR examination on heating of the drug or polymer coating used in drug-eluting stents is unknown, although heating of the stent (and possible resultant effects on the drug/polymer coating) might be somewhat mitigated by flowing blood. A recent retrospective review of patients with myocardial infarction who underwent MR examination within 2 weeks (median 3 days) of stent implantation detected no increased incidence of clinical adverse events at 30-day and 6-month follow-up compared with those who had undergone stent implantation at more distant time points. Thirty-nine percent of the stents implanted in the study group were drug-eluting stents, and no adverse cardiovascular events occurred in patients treated with drug-eluting stents.<sup>42</sup>

### Labeling/Recommendations

Most coronary and peripheral vascular stents that have been tested have been labeled as “MR safe”; the remainder have been labeled as “MR conditional.”<sup>1</sup> Tested coronary artery stents (including tested drug-eluting coronary stents) that are nonferromagnetic (all currently used coronary stents) can be safely scanned at 3 T or less any time after implantation. MR



examination at  $\leq 3$  T in patients with peripheral stents that are nonferromagnetic can be performed immediately after implantation. The timing of MR examination at  $\leq 3$  T in patients with peripheral stents that are weakly ferromagnetic should be determined on a case-by-case basis. For cases in which there is a clear potential clinical benefit of scanning in the days to weeks after implantation, the benefits of the MR examination will likely outweigh the risks of the examination, and MR examination should generally be performed. In patients with chronic conditions in which it makes little difference whether the scan is performed at a given time or weeks later, it may be prudent to defer MR examination until  $\approx 6$  weeks after device implantation.

The reader should be aware that local artifact remains an issue for many stents. The degree of in-stent stenosis cannot be assessed reliably in the case of coronary stents or peripheral stents, although patency of the peripheral stent can usually be inferred from a complete assessment of the MR examination.

## Aortic Stent Grafts

### Background Data

The majority of endovascular aortic stent grafts, but not all, are made from nonferromagnetic or weakly ferromagnetic materials. An *ex vivo* study of stent grafts at 3.0 T found that most exhibited nonferromagnetic or weakly ferromagnetic properties, with the exception of several EndoFit stent grafts and extenders (Endomed Inc).<sup>43</sup> Thus far, there have been several published studies of MR examinations in patients with aortic stent grafts that have not noted any adverse clinical events related to the MR examinations.<sup>44,45</sup> The MR characteristics of the Zenith AAA endovascular graft (Cook) have been evaluated through bench testing in MR systems with static fields of  $\leq 1.5$  T, and this stent graft was found to exhibit significant deflection and torque of the stainless steel metallic component of the endovascular graft and therefore did not meet standard "MR safe" bench test criteria.<sup>46</sup>

A practical consideration in MR examinations of endovascular stents relates to the potential magnetic susceptibility effects (artifacts) induced by the metallic components of the stent grafts. Most stent grafts create minimal artifacts, which allows for diagnostic visualization of the endostent lumen and for evidence of endostent leak. However, 3 stent grafts (Zenith AAA endovascular graft [Cook], Endologix AAA stent [Endologix], and Lifepath AAA stent [Edwards Lifesciences Corp]) have been reported to show severe susceptibility artifact that makes evaluation of the endostent lumen or surrounding tissues problematic.<sup>47</sup>

### Labeling/Recommendations

Most aortic stent grafts that have been tested have been labeled as "MR safe"; the Zenith AAA endovascular graft stent has been labeled as "MR unsafe."<sup>1,3</sup> Patients with stent grafts made from nonferromagnetic materials may be scanned immediately after implantation at 3 T or less. The timing of MR examination at 3 T or less in patients with aortic stent grafts that are weakly ferromagnetic should be weighed on a case-by-case basis. For cases in which there is a clear potential clinical benefit of scanning in the days to weeks after implantation, the benefits of the MR examination will

likely outweigh the risks of the examination, and MR examination should generally be performed. In patients with chronic conditions in which it makes little difference whether the scan is performed at a given time or weeks later, it may be prudent to defer MR examination until  $\approx 6$  weeks after device implantation.

The approved manufacturer's labeling for the Zenith AAA endovascular graft states in part, "Adverse events have not been reported clinically in patients who have undergone MRI. However, sufficient data are not available to demonstrate MRI safety and there may be potential risks (eg, device migration, vessel damage) that could be associated with force applied to the metallic components of the Zenith AAA Endovascular Graft. Therefore, a careful assessment of these potential risks and the potential benefits to the patient should be completed before use of MR imaging."<sup>46</sup> The writing group agrees with this approach.

Although patients with the Endologix AAA or Lifepath AAA stents may undergo MR imaging, because of the artifacts created by these stents, MR examination is not recommended as the modality of choice for examinations specifically targeted toward evaluation of the stent grafts.

## Prosthetic Heart Valves, Annuloplasty Rings, and Sternal Suture Wires

### Background Data

Prosthetic heart valves and annuloplasty rings are made from a variety of materials. Bioprosthetic heart valves are composed primarily of nonmetallic materials (usually porcine tissue or bovine pericardium) but may contain small amounts of metal (used for scaffolding rings), depending on whether or not they are "stentless" or have other design features. Mechanical heart valves are composed of a variety of metals, including titanium alloy, MP35N, pyrolytic carbon, Elgiloy, chromium cobalt alloy, nitinol, 316L stainless steel, and 316LVM stainless steel.<sup>3,43,48-50</sup> Some annuloplasty rings contain no metal, whereas others may be composed in part of titanium, chromium cobalt, and other metallic materials.<sup>3,51</sup> Sternal wires are most commonly composed of stainless steel or similar alloys.

Many heart valve prostheses and annuloplasty rings have been evaluated to determine whether they are acceptable for patients undergoing MR examinations with scanners operating at 1.5 T or less.<sup>3,43,48,49,51</sup> Of these, several displayed measurable yet relatively minor magnetic field interactions in relation to the static magnetic fields of the MR systems used for testing. The forces exerted on these valves and rings are less than the forces exerted by gravity and considerably less than those exerted by the beating heart and resultant pulsatile blood flow ( $\approx 7.2$  N).<sup>52</sup> A recent study using tissue samples excised during heart valve replacement surgery demonstrated that the forces required to pull a suture through a valve annulus tissue were significantly greater than magnetically induced forces at  $< 4.7$  T.<sup>53</sup> Accordingly, patients with degenerative valvular diseases are unlikely to be at risk for valve dehiscence (loosening or unseating of the valve from its sewed-in position in the heart) during exposure to static magnetic fields up to 4.7 T.

MR-related heating of prosthetic heart valves and annuloplasty rings has been assessed with *ex vivo* techniques. These studies indicated that temperature increases are relatively minor, with studies reporting heating ranging from 0°C to 0.8°C.<sup>48,49,51,54,55</sup> As with vascular stents, any heating is likely to be somewhat dissipated by flowing blood. Although there is a theoretical possibility of an electromagnetic interaction with a heart valve that contains metal in the disk or leaflet that could inhibit opening and closing of the mechanical heart valve prosthesis (referred to as the Lenz effect), this has never been demonstrated experimentally or reported clinically.<sup>56</sup> Those valves and rings that have undergone testing thus far at 3 T have not demonstrated clinically significant magnetic field interaction or MR-related heating and thus have been found to be safe for clinical MR examinations.<sup>3,43</sup>

Numerous clinical studies have demonstrated the safety of performing MR examinations in patients with prosthetic heart valves.<sup>55,57,58</sup> Of note, 28 patients recently underwent apparently uneventful cardiac MR imaging after percutaneous pulmonary valve implantation.<sup>59</sup> As of this writing, we are unaware of any case of a patient incident or injury related to the presence of a heart valve prosthesis or annuloplasty ring in association with an MR examination.

### Labeling/Recommendations

The majority of prosthetic heart valves and annuloplasty rings that have been tested have been labeled as “MR safe”; the remainder of heart valves and rings that have been tested have been labeled as “MR conditional.”<sup>1</sup> On the basis of the above studies and findings, the presence of a prosthetic heart valve or annuloplasty ring that has been formally evaluated for MR safety should not be considered a contraindication to an MR examination at 3 T or less (and possibly even 4.7 T in some cases) any time after implantation. MR examination of patients with sternal wires is generally considered to be safe.

## Cardiac Closure and Occluder Devices

### Background Data

Cardiac closure and left atrial appendage occluder devices are typically made from metals that include nitinol, titanium, titanium alloy, MP35N, 316L stainless steel, and 304V stainless steel. In addition, nonmetallic fabrics and other materials are often used for these devices.<sup>1,3,60–62</sup> In tests for magnetic field interactions conducted at 1.5 T, devices made from 304V stainless steel displayed weakly ferromagnetic qualities, whereas those made from nitinol, titanium, titanium alloy, and MP35N were nonferromagnetic.<sup>3,60,61</sup>

Several closure devices have been evaluated at 3 T. For those tested, studies demonstrated acceptable deflection angles, torque, and MR-related heating with regard to the intended *in vivo* uses of these specific devices.<sup>3,62</sup> To date, at least 1 left atrial appendage occlusion device, the Watchman left atrial appendage device (Atritech, Inc), has been tested at 3 T. Findings indicated that patients with this device can be safely scanned at 3 T (Frank Shellock, unpublished data, 2006).

### Labeling/Recommendations

The majority of cardiac closure and occluder devices that have been tested have been labeled as “MR safe”; several that

have been tested are labeled as “MR conditional.”<sup>1</sup> Patients with nonferromagnetic cardiac closure and occluder devices may undergo MR procedures at any time after implantation. The timing of MR examination at 3 T or less in patients with cardiac closure or occluder devices that are weakly ferromagnetic should be weighed on a case-by-case basis. For cases for which there is a clear potential clinical benefit of scanning in the days to weeks after implantation, the benefits of the MR examination will likely outweigh the risks of the examination, and MR examination should generally be performed. In patients with chronic conditions in which it makes little difference whether the scan is performed at a given time or weeks later, it may be prudent to defer MR examination until ≈6 weeks after device implantation.

## Inferior Vena Cava Filters

### Background Data

Many inferior vena cava (IVC) filters are made of nonferromagnetic materials, whereas some others are composed of weakly ferromagnetic materials.<sup>3</sup> Devices such as IVC filters are attached with hooks. As is typical for healing processes throughout the body, it is generally believed that IVC filters become incorporated securely into the vessel wall, primarily due to tissue ingrowth, within ≈4 to 6 weeks after implantation. Therefore, it is unlikely that such implants would become moved or dislodged as a result of exposure to static magnetic fields of MR systems operating at up to 1.5 T.

Studies of MR examination of both animals and humans with implanted IVC filters have thus far not reported complications or symptomatic filter displacement.<sup>63–68</sup> Several animal studies have even used “real-time” MR for the placement of IVC filters.<sup>69,70</sup>

### Labeling/Recommendations

Most IVC filters that have been tested have been labeled as “MR safe”; the remainder of IVC filters that have been tested are classified as “MR conditional.”<sup>1</sup> Patients who have been treated with nonferromagnetic IVC filters can undergo MR examination any time after filter implantation. In patients who have been treated with a weakly ferromagnetic IVC filter (Gianturco bird nest IVC filter [Cook], stainless steel Greenfield vena cava filter [Boston Scientific]), it is advised that the patient wait at least 6 weeks before undergoing an MR examination (because these older devices initially may not be anchored as firmly in place as other devices discussed in the present report), unless there is a strong clinical indication to perform the MR examination sooner after implantation, and as long as there is no reason to suspect that the device is not positioned properly or that it is not firmly in place. Most studies of IVC filters have generally been conducted at 1.5 T or less, although many IVC filters have now been evaluated at 3 T and deemed acceptable for MR examination.<sup>1,3</sup>

## Embolization Coils

### Background Data

The earliest embolization coils were stainless steel; more recently developed coils are often made from platinum or

other alloys. Commonly used embolization coils are either nonferromagnetic or weakly ferromagnetic.

Because of the shape of certain coils, the theoretical potential of coil heating during an MR examination exists. An *ex vivo* study of the Guglielmi detachable coil (Boston Scientific) found that there were no magnetic field interactions and that the temperature increase was minimal during extreme MR imaging conditions.<sup>71</sup> Subsequently, >100 patients with Guglielmi detachable coils have reportedly undergone MR imaging without incident.<sup>72</sup> Other embolization coils made from nitinol, platinum, or platinum and iridium with similar configurations have been evaluated and found to be safe for patients undergoing MR procedures performed in studies at 3 T or less.<sup>3,18,72–75</sup> To date, there have been no reports of adverse events associated with MR examinations conducted on patients with platinum coils implanted in the neurovasculature.

Coils composed of stainless steel may create local artifact, which limits the usefulness of the MR examination if the coil is in the region of interest. Platinum coils, in contrast, create less local artifact, and some (but not necessarily all) do not significantly affect the quality of diagnostic information.<sup>3,18,72–75</sup>

### Labeling/Recommendations

Most embolization coils that have been tested have been labeled as “MR safe”; the remainder that have been tested have been labeled as “MR conditional.”<sup>1</sup> Patients who have been treated with nonferromagnetic embolization coils can undergo MR examination any time after coil implantation. The timing of MR examination at 3 T or less in patients with embolization coils that are weakly ferromagnetic should be weighed on a case-by-case basis. For cases in which there is a clear potential clinical benefit of scanning in the days to weeks after implantation, the benefits of the MR examination will likely outweigh the risks of the examination, and MR examination should generally be performed. In patients with chronic conditions in which it makes little difference whether the scan is performed at a given time or weeks later, it may be prudent to defer MR examination until  $\approx$ 6 weeks after device implantation. Patients with tested coils<sup>1,3</sup> may undergo MR examination at up to 3 T, according to the conditions under which they were tested.

### Loop Recorder (Event Monitor)

#### Background Data

The 9526 Reveal Plus insertable loop recorder (ILR; Medtronic) is a single-use, subcutaneously implanted programmable device that contains 2 surface electrodes used to continuously record the patient’s electrocardiogram. The Reveal Plus ILR contains no lead wires; however, the electromagnetic fields produced during MR imaging may adversely affect the data stored by the Reveal Plus ILR.

*Ex vivo* evaluation of the Reveal Plus ILR did not suggest significant risk of device movement or dislodgment.<sup>76</sup> Clinical MR study of 10 patients with these loop recorders demonstrated no subjective symptoms experienced by patients, no adverse clinical events, and no damage to the devices, although rhythm monitoring was not performed

during these examinations. Of note, interrogation of the devices after MR revealed tachyarrhythmias and bradyarrhythmias recorded during the examinations that were believed to be artifacts.<sup>77</sup>

### Labeling/Recommendations

The Reveal Plus ILR has been labeled as “MR conditional.”<sup>1</sup> Patients with a Reveal Plus ILR can undergo MR examination any time after implantation, provided there is no reason to believe the device is not well implanted. Because of the theoretical risk of electromagnetic fields adversely affecting data stored by the device, all stored data should be downloaded before scanning. Because this device contains ferromagnetic components, the strong magnetic fields associated with the MR system can create sufficient magnetic field interactions for the Reveal Plus ILR such that the patient may feel slight movement of this device.<sup>76</sup> Although this does not represent a safety hazard, the patient should be informed of this possibility to avoid undue concern.

## Hemodynamic Monitoring and Temporary Pacing Devices

### Background Data

Cardiovascular catheters, such as pulmonary artery hemodynamic monitoring/thermodilution catheters (including the Swan-Ganz catheter [Edwards Lifesciences]), and temporary transvenous cardiac pacing devices generally contain no ferromagnetic components but may incorporate nonferromagnetic, electrically conductive materials.<sup>3,78,79</sup> The MR examination may induce sufficient voltages and currents in electrically conductive material so as to result in thermal injuries and burns to adjacent tissue (including myocardial tissue).<sup>80,81</sup> Although the theoretical risk exists that MR examination in patients with retained temporary epicardial leads, which consist of electrically conductive material, could lead to cardiac excitation or thermal injury, such retained leads are typically relatively short in length, usually do not form large loops, and are generally not believed to pose a significant risk during MR scanning.

Hartnell et al<sup>79</sup> reported on 51 patients with retained temporary epicardial pacing wires who underwent clinical MR examinations. Of those patients examined with electrocardiographic monitoring, no arrhythmias were noted, and for all patients, no symptoms suggestive of arrhythmia or other cardiac dysfunction were noted (although the anatomic region examined and the energies used in the examinations were not specifically described).<sup>79</sup> To date, there is no report of complications related to the MR scanning of a patient with retained epicardial leads.

There is 1 report in the literature of a Swan-Ganz thermodilution catheter that “melted” at the skin entry site in a patient undergoing MR examination.<sup>23</sup> It was postulated that the RF fields transmitted by the MR system caused heating of the copper wires within the catheter.

One *ex vivo* study of temporary transvenous pacing leads reported temperature increases of up to 63.1°C.<sup>82</sup> Preliminary results of a recent study confirmed that even unconnected temporary transvenous pacing (as well as permanent pacing) leads can undergo high temperature increases at 1.5 T.<sup>83</sup> In a



chronic-pacemaker animal model undergoing MR examination at 1.5 T, temperature increases of up to 20°C were measured, although pathological and histological examination did not demonstrate heat-induced damage of the myocardium.<sup>84</sup> The MR imaging conditions that generated such elevated lead temperatures included use of the body RF coil to transmit RF energy over the area of the lead (eg, an MR examination of the chest/thorax).

To the best of our knowledge, there are no studies assessing the safety of temporary pacemakers (lead and external pulse generator). Unlike permanent devices, temporary pacemakers use unfixed leads that are more prone to movement, longer leads that may be more prone to induction of lead currents, and a less sophisticated pulse generator, which makes them likely more susceptible to electromagnetic interference.

### Labeling/Recommendations

Those few catheters that contain conducting wires and those few temporary transvenous pacing wires that have been tested have been labeled as “MR unsafe.”<sup>91</sup> Patients with pulmonary artery hemodynamic monitoring/thermodilution catheters (such as the Swan-Ganz catheter) and similar catheters that have conductive wires or similar components should not undergo MR examinations because of the possible associated risks, unless *in vivo* testing provides labeling information or instructions for use that permit examinations to be performed safely. Patients with nonferromagnetic pulmonary artery catheters that contain no electrically conductive pathways in the catheter may undergo MR examination; however, it must be emphasized that such conditions must be verified before such patients undergo MR examination. Patients with retained temporary epicardial pacing wires are believed to be able to safely undergo MR procedures, and patients do not need to be routinely screened for the presence of such wires before scanning. Because of the possible risks involved with temporary-pacemaker external pulse generators, such generators should not be introduced into the MR environment. Although temporary transvenous lead heating might be minimized or avoided by scanning anatomic regions above (eg, head/brain) or below (eg, lower extremities) cardiac pacing leads, scanning of patients with temporary transvenous pacing leads (without the generator) is not recommended. Furthermore, because the harsh electromagnetic environment associated with the MR system can alter the operation of an external pulse generator or damage it, it may not be possible to reliably pace the patient during the MR examination, which makes the issue of scanning a patient with a temporary transvenous lead irrelevant in most cases.

## Permanent Cardiac Pacemakers and Implantable Cardioverter Defibrillators

### Background Data

Due to the wide prevalence of cardiovascular diseases, a significant proportion of patients who would ideally be referred for MR examinations will have permanent cardiac pacemakers or implantable cardioverter defibrillators (ICDs). It has been estimated that a patient with a pacemaker or implanted defibrillator has a 50% to 75% likelihood of having

a clinical indication for MR imaging over the lifetime of their device.<sup>85</sup> These devices contain metal with variable ferromagnetic qualities, as well as complex electrical systems, and additionally consist of 1 or several leads implanted into the myocardium. The potential for movement of the device, programming changes, asynchronous pacing, activation of tachyarrhythmia therapies, inhibition of pacing output, and induced lead currents that could lead to heating and cardiac stimulation has led to concerns regarding the performance of MR examinations in patients with permanent pacemakers and ICDs.<sup>10,15,76,86–91</sup> These factors might lead to clinical sequelae that include changes in pacing/defibrillation thresholds, pacemaker ICD dysfunction or damage (including battery depletion), arrhythmia, or death. Deaths associated with MR examination of patients with pacemakers/ICDs have been reported.<sup>91–95</sup> As best as can be determined, all of these deaths occurred in the setting of MR examinations that were not supervised or monitored by a physician. Because of these factors, it was not possible to determine the precise mechanism of death as it relates to the MR examination and the presence of a pacemaker/ICD in most cases,<sup>93–95</sup> although in 1 recent report, ventricular fibrillation was believed to have been the cause of death in at least 3 patients.<sup>91</sup>

There have been small to modestly sized prospective human trials in recent years at 0.5- to 2.0-T field strength that have reported on the relative safety of MR examination in the setting of pacemakers. Only 1 study has placed no anatomic limitations on MR procedures used for the patients studied. Martin and colleagues<sup>93</sup> reported on a series of 54 patients who underwent a total of 62 MR examinations using a 1.5-T MR system. Pacemakers were examined before and after MR imaging. Pacemaker-dependent patients were excluded from the study, and heart rhythm was monitored during the examination. Pacing threshold changes were noted in 40 of 107 leads, of which 10 were judged to be significant, 2 of which required a change in programmed output. No episodes of pacing above the upper rate limit or arrhythmias were noted.<sup>93</sup> A small series of patients with ICDs who were undergoing neurological MR examination found that none of the 8 patients scanned experienced significant adverse clinical events; in 1 patient, a change in programming was noted.<sup>96</sup> One study involving *ex vivo* device testing and *in vivo* animal testing found that ICDs manufactured after 2000 may be more resistant to changes in function during MR examination.<sup>97</sup> Several other small series have reported on the results of MR scanning in patients with pacemakers or ICDs,<sup>98–103</sup> and it is believed that at least several hundred patients with these devices have undergone examination.<sup>104,105</sup> Recent studies of patients with pacemakers or ICDs have confirmed the findings of these earlier studies, and these study investigators, among others, have proposed strategies and protocols for safe pacemaker/ICD scanning.<sup>106,107</sup> No deaths have been reported in studies in which patients were deliberately scanned and properly monitored, although cases of changes in pacing threshold, programming changes, need for device reprogramming, and possibly battery depletion have been noted. In addition, incidents in which pacemaker or ICD dysfunction has occurred in patients who have undergone MR examination at some time are listed on the



FDA Web site, although possible causative associations usually cannot be established with confidence.<sup>92</sup>

Writing on behalf of the FDA, Faris and Shein<sup>90</sup> have both acknowledged and pointed out the shortcomings of research thus far on studies of MR imaging of patients with pacemakers and ICDs. They go on to state that “while FDA recognizes that there are pacemaker and ICD patients for whom, on a case-by-case basis, the diagnostic benefit from MR imaging outweighs the presumed risks, we believe that those risks have not yet been characterized and mitigated sufficiently to justify the routine use of MR examination in those populations.” Faris and Shein recently reiterated their position in an updated editorial.<sup>108</sup>

### Labeling/Recommendations

The present writing group believes that despite the above discussion of patients with pacemakers or ICDs who have been scanned safely, the following must be noted: (1) these studies were conducted at institutions with expertise in MR imaging and electrophysiology; (2) the number of patients who experienced adverse events that have gone unreported is unknown; (3) considerable controversy exists over safety issues regarding MR scanning of patients with pacemakers and ICDs; and (4) the presence of a pacemaker or ICD should still be considered a strong relative contraindication to routine MR examination, which is therefore discouraged. Patients who have a pacemaker or ICD should not undergo an MR study if an alternative diagnostic test is available, and MR imaging should only be considered in cases in which the potential benefit to the patient clearly outweighs the risks to the patient. Risks to the patient are likely increased in centers without highly experienced personnel in both function and programming of the device and operations/pulse sequences of the MR scanner. Thus, scanning should only be performed at extremely experienced centers with expertise in MR imaging and electrophysiology. If such scanning is performed, the risks of MR scanning should be discussed specifically and clearly with the patient, and the written informed consent should specifically list risks, including (1) pacemaker/ICD dysfunction, (2) pacemaker/ICD damage, (3) arrhythmia, and (4) death. Any institution at which MR scanning of pacemakers/ICDs is performed should have some formal program of quality control to track adverse events. The patient’s heart rhythm and vital signs should be monitored throughout the MR examination. A physician with pacemaker/ICD expertise should be in attendance during scanning, and a “crash cart,” including a defibrillator, must be available throughout the procedure to address any adverse events. A person with expertise in MR physics and safety should be involved with the scan to optimally plan the scan to minimize risk. The pacemaker/ICD should be interrogated before and after the procedure.

Specific comments regarding such scanning of non-pacemaker-dependent patients, pacemaker-dependent patients, and patients with ICDs are given below and in Table 2, based in part on previous recommendations<sup>1,3,91,93,96,109</sup> and on the general consensus of the present writing group. Recommendations regarding the scanning of patients with

**Table 2. Recommendations for the Performance of MR Examinations in Patients With Pacemakers or ICDs**

#### General recommendations:

MR examination of non-pacemaker-dependent patients is discouraged and should only be considered in cases in which there is a strong clinical indication and in which the benefits clearly outweigh the risks

MR examination of pacemaker-dependent patients should not be performed unless there are highly compelling circumstances and when the benefits clearly outweigh the risks

MR examination of patients with ICDs should not be performed unless there are highly compelling circumstances and when the benefits clearly outweigh the risks

Scanning should only be performed at extremely experienced centers with expertise in MR imaging and electrophysiology.

Establish and document the risk-benefit ratio for the patient.

Obtain written and verbal informed consent. Written informed consent should specifically list risks, including (1) pacemaker/ICD dysfunction, (2) pacemaker/ICD damage, (3) arrhythmia, and (4) death.

A physician with ACLS and pacemaker/ICD expertise should decide whether it is necessary to reprogram the pacemaker/ICD before the MR examination and should be in attendance for the entire study.

A person with expertise in MR physics and safety should be involved with the scan to optimally plan the scan to minimize risk, and consideration should be given to using scanning parameters (eg, lowest RF power levels, weakest/slowest necessary gradient magnetic fields) that are believed to minimize study risk.

#### Prescanning steps outside the MR environment:

For non-pacemaker-dependent patients, pretest pacemaker functions

For pacemaker-dependent patients, pretest pacemaker functions and reprogram to asynchronous mode

For patients with ICDs, pretest ICD functions and disable therapy and detection for tachycardia/bradycardia modes

The patient’s heart rhythm and vital signs should be monitored throughout the MR procedure.

Appropriate personnel and a “crash cart,” including defibrillator, must be available throughout the procedure to address an adverse event.

Maintain visual and voice contact with the patient throughout the procedure.

Instruct the patient to alert the MR system operator to any unusual sensations or problems.

#### After the examination:

For non-pacemaker-dependent patients, a physician with electrophysiological expertise should interrogate the pacemaker and reprogram as needed

For pacemaker-dependent patients, a physician with electrophysiological expertise should interrogate the pacemaker function and reprogram the pacemaker

For patients with ICDs, a physician with electrophysiological expertise should perform postscan device reprogramming and defibrillation threshold testing

ACLS indicates advanced cardiovascular life support.

permanent pacemakers and ICDs can be expected to evolve over time as more studies become available.

Those pacemakers that have been tested have been labeled as “MR unsafe.”<sup>1</sup> At present, MR examination of non-pacemaker-dependent patients is discouraged and should only be considered in cases in which there is a strong clinical indication, in which the benefits clearly outweigh the risks, and then according to the criteria listed in the text and Table

2. There are few current data on the performance of MR examination of pacemaker-dependent patients, and MR examination of pacemaker-dependent patients should not be performed unless there are highly compelling circumstances in which the benefits clearly outweigh the risks and then according to the criteria listed in the text and Table 2. MR examination of patients with ICDs should not be performed unless there are highly compelling circumstances in which the benefits clearly outweigh the risks and then according to the criteria listed in the text and Table 2. Although 1 study discussed above found that ICDs manufactured after 2000 may be more resistant to changes in function during MR examination, this finding should not be taken as a “green light” to routinely scan patients with such ICDs. Fractured leads may pose a particularly high risk of thermal injury, and MR examination should not be performed in patients with pacemakers or ICDs with known lead fractures. The writing committee emphasizes that efforts by industry to manufacture pacemakers and ICDs that are specifically designed to be acceptable for patients undergoing MR procedures should be intensified, an approach preferable to the current “ad hoc” methods described above.

### **Retained Transvenous Pacemaker and Defibrillator Leads**

#### **Background Data**

Retained transvenous pacemaker and defibrillator leads (leads left in the body after explantation of the permanent pacemaker or ICD generator) pose significant theoretical risks, including heating and cardiac excitation. Retained fractured leads may pose a particularly high risk of thermal injury.

#### **Labeling/Recommendations**

To the best of our knowledge, no clinical studies have specifically addressed the risks of retained transvenous pacemaker or ICD leads. It is the consensus of the writing group that patients with retained transvenous pacemakers or ICD leads be approached similarly to those with pacemakers or ICDs, as outlined above. MR examination of patients with retained transvenous leads is discouraged, and MR examination should only be considered in centers with expertise in MR and electrophysiology, and only in cases in which there is a strong clinical indication. MR examination should not be performed in patients with known retained transvenous leads that have fractures.

### **Hemodynamic Support Devices**

#### **Background Data and Labeling/Recommendations**

Hemodynamic support devices, including intra-aortic balloon pumps, right ventricular assist devices, and left ventricular

assist devices, are complex devices with variable degrees of ferromagnetic materials, moving parts, and electrical components. Although formal evaluation of these devices in regard to MR safety has not been conducted, it is believed that these devices should be considered absolute contraindications to MR examination, particularly given that most hemodynamic support systems involve equipment likely to be affected by the electromagnetic fields used during MR imaging.

### **Summary and Conclusions**

Advances in MR imaging over the last 2 decades have led to MR becoming an increasingly attractive imaging modality, one that provides excellent spatial resolution and multiplanar 3-dimensional analysis while not exposing patients to the risks associated with computerized tomography and invasive procedures. MR will increasingly be used in the population as a whole and in many cases may be the best imaging modality available for the increasing number of patients with permanently implanted and temporary cardiovascular devices. Extensive, although not complete, *ex vivo*, animal, and clinical data are available from which to generate recommendations regarding the safe performance of MR examination in patients with cardiovascular devices, as well as to ascertain caveats and contraindications regarding MR examination for patients with certain cardiovascular devices. Safe MR imaging involves a careful initial patient screening, accurate determination of the cardiovascular (and other) device and its properties, a thoughtful analysis of the risks and benefits of performing the examination at that time, and, when indicated, appropriate physician supervision.

The recommendations in the present statement are meant to serve as a guide for physicians, MR technologists, nurses, and other healthcare professionals. The reader is reminded that discussions of device safety are based on research through mid-2006 and are based only on devices that are commercially available as of this writing; recommendations in this statement will not necessarily apply to devices developed in the future. When doubt remains as to the safety of performing an MR examination, the reader is urged to consult a more detailed source of information, such as dedicated Web sites, reference manuals, or, especially, the manufacturer’s product information when available. Because of the increasing use of MR examinations, as well as the increasing number of cardiovascular devices implanted in patients, efforts by industry, working in collaboration with academia, to manufacture devices, including pacemakers and ICDs, that are specifically designed to be safe for MR examination should be continued and intensified.

## Disclosures

## Writing Group Disclosures

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This table represents the relationships of writing group members that may be perceived as actual or reasonably perceived conflicts of interest as reported on the Disclosure Questionnaire, which all members of the writing group are required to complete and submit. A relationship is considered to be "significant" if (1) the person receives \$10 000 or more during any 12-month period, or 5% or more of the person's gross income; or (2) the person owns 5% or more of the voting stock or share of the entity, or owns \$10 000 or more of the fair market value of the entity. A relationship is considered to be "modest" if it is less than "significant" under the preceding definition.

\*Modest.

†Significant.

## Reviewer Disclosures

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