Managing Patients With Unlabeled Passive Implants on MR Systems Operating Below 1.5 T

Frank G. Shellock, PhD, FACR, FISMRM,[1*] Matthew S. Rosen, PhD,[2] Andrew Webb, PhD,[3] W. Taylor Kimberly, MD, PhD,[4] Sunder Rajan, PhD,[5] Aleksandar N. Nacev, PhD,[6] and John V. Crues, MD[7]

The standard of care for managing a patient with an implant is to identify the item and to assess the relative safety of scanning the patient. Because the 1.5 T MR system is the most prevalent scanner in the world and 3 T is the highest field strength in widespread use, implants typically have "MR Conditional" (i.e., an item with demonstrated safety in the MR environment within defined conditions) labeling at 1.5 and/or 3 T only. This presents challenges for a facility that has a scanner operating at a field strength below 1.5 T when encountering a patient with an implant, because scanning the patient is considered "off-label." In this case, the supervising physician is responsible for deciding whether to scan the patient based on the risks associated with the implant and the benefit of magnetic resonance imaging (MRI). For a passive implant, the MRI safety-related concerns are static magnetic field interactions (i.e., force and torque) and radiofrequency (RF) field-induced heating. The worldwide utilization of scanners operating below 1.5 T combined with the increasing incidence of patients with implants that need MRI creates circumstances that include patients potentially being subjected to unsafe imaging conditions or being denied access to MRI because physicians often lack the knowledge to perform an assessment of risk vs. benefit. Thus, physicians must have a complete understanding of the MRI-related safety issues that impact passive implants when managing patients with these products on scanners operating below 1.5 T. This monograph provides an overview of the various clinical MR systems operating below 1.5 T and discusses the MRI-related factors that influence safety for passive implants. Suggestions are provided for the management of patients with passive implants labeled MR Conditional at 1.5 and/or 3 T, referred to scanners operating below 1.5 T. The purpose of this information is to empower supervising physicians with the essential knowledge to perform MRI exams confidently and safely in patients with passive implants.
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Magnetic resonance imaging (MRI) has been utilized in the clinical setting for approximately four decades. Despite the well-known hazards, this imaging modality has an exemplary safety profile, if appropriate safety guidelines and policies are carefully followed.[1–5] The predominant factor responsible for preventing MRI-related injuries and fatalities is the screening procedure that is conducted prior to allowing the patient to undergo MRI, which primarily involves determining the presence of metallic implants.[1–7] It is well known that MRI may be contraindicated for a patient with a metallic implant because of issues that can result in serious injury or death. These include movement or dislodgment of a magnetic implant or device, excessive MRI-related heating associated with power deposition from the radiofrequency (RF) fields, RF fields and time-varying magnetic fields inducing currents that may result in unintentional stimulation or

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*Address reprint requests to: F.G.S., 7751 Veragua Dr., Playa Del Rey, CA 90293, USA. E-mail: frank.shellock@mrisafety.com

From the [1]Keck School of Medicine, University of Southern California, Los Angeles, California, USA; [2]Department of Radiology, A. A. Martinos Center for Biomedical Imaging, Massachusetts General Hospital, Boston, Massachusetts, USA; [3]Department of Radiology, Leiden University Medical Center, Leiden, Netherlands; [4]Division of Neurocritical Care, Department of Neurology, Massachusetts General Hospital, Boston, Massachusetts, USA; [5]Warrenton, Virginia, USA; [6]Promaxo, Oakland, California, USA; and [7]ProNet Imaging Medical Group and RadNet Management, Los Angeles, California, USA

other electrical issues in active implants, changes in the operational aspects of the device, damage to the function of the device, the difficulty in interpreting MR images due to signal loss and/or distortion, and the misinterpretation of an imaging artifact as an abnormality.[1,2,5,8] Accordingly, screening forms used by MRI facilities have an extensive list of medical products that include passive implants (i.e., an implant that does not have electronics or a power source), such as aneurysm clips, heart valve prostheses, and stents and the more complex, active implants (i.e., an implant that functions with a source of electrical energy and/or a power source), such as cardiac pacemakers and neuromodulation systems.[1–7]

The standard of care for managing a patient with an implant is to identify the item during the screening procedure and to assess the relative safety of scanning the patient.[1–7] This is readily accomplished by referring to the labeling approved by the United States Food and Drug Administration (FDA) that is in the product's *Instructions for Use* (IFU) or product manual. Because the 1.5 T MR system is the most prevalent scanner in the world and 3 T is the highest field strength in widespread use, implant manufacturers have confined their testing and labeling to 1.5 and/or 3 T scanners, only.[5,8–11] Accordingly, implants typically have "MR Conditional" (i.e., an item with demonstrated safety in the MR environment within defined conditions) labeling at 1.5 or 3 T only.[5,8,9] This presents challenges for a facility that has a scanner operating at a field strength below 1.5 T when encountering a patient with an implant, because scanning the patient is considered "off-label."[10,11] However, the absence of labeling does not necessarily imply that the implant poses a risk to the patient in association with MRI.

In this situation, as a matter of the practice of medicine, the supervising physician (which is usually a radiologist, although other physicians may be responsible as the decision makers including neurologists, neurosurgeons, intensivists, cardiologists, and orthopedic surgeons) is responsible for deciding whether to scan the patient based on consideration of the potential risks associated with the implant and the benefit of the diagnostic information afforded by MRI.[4,10,11] For a passive implant, contemplation of the MRI safety-related aspects that impact the device is relatively straightforward, since the main concerns are static magnetic field interactions (i.e., force and torque) and RF field-induced heating.[1–5,8,12–16] For active implants, because of the complicated nature of these devices, the supervising physician must deliberate on a multitude of issues that include the ones for passive implants as well as possible unintended stimulation caused by the gradient magnetic fields and/or RF fields, gradient magnetic field-induced vibration, and malfunction of the active implant due to one or more the electromagnetic fields applied during MRI.[8,12–18]

Substantial improvements in hardware and software have resulted in a resurgence in MR systems operating below 1.5 T. An array of different scanner geometries, field strengths, and different use-cases are found in this realm including an open-architecture, vertical (transverse) field 1.2 T scanner and the lower field strength (generally defined as MR systems operating in the range of 0.25 to 1.0 T) MR systems that have horizontal (longitudinal) or vertical (transverse) field magnets.[10,11,19–22] Also operating below 1.5 T are scanners with unique features or designed for specialized applications such as a very-low-field (0.064 T), point-of-care MR system,[23,24] dedicated extremity scanners,[25,26] an upright MR system,[27] a neonatal scanner,[28] an MRI-guided, radiotherapy system,[29] and a single-sided, interventional MR scanner.[30,31]

The growing worldwide utilization of these MR systems combined with the increasing incidence of patients with metallic implants that need MRI creates undesirable circumstances that include patients potentially being subjected to unsafe imaging conditions or being denied access to MRI because physicians often lack the knowledge to conduct a proper assessment of risk vs. benefit.[8,10,11,16] This latter scenario often occurs because facilities with scanners operating below 1.5 T have a policy to only scan patients with implants that have labeling that pertains to their specific MR systems, primarily because there is an assumption that performing MRI in these cases may be prohibited or unsafe. Thus, it is vital for the supervising physician to have a complete understanding of the MRI-related safety issues that impact passive implants so that a competent decision can be made when imaging patients with these medical products on scanners operating below 1.5 T.[8,10,11,16]

In consideration of the above challenges, this monograph will provide an overview of the various clinical MR systems operating below 1.5 T and, because passive implants are the most prevalent medical products used in patients, the MRI-related factors that influence safety for these items will be discussed. In addition, suggestions will be provided for the management of patients with passive implants on scanners operating below 1.5 T. The purpose of presenting this information is to empower supervising physicians with the essential knowledge to perform MRI exams confidently and safely in patients with passive implants.

MR Systems Operating Below 1.5 T

More than 35 different clinical MR systems operate at static magnetic field strengths below 1.5 T (Table 1). The following information is presented on a selection of MR systems that have distinctive characteristics to illustrate the wide range of scanner types.

0.064 T, Swoop Portable MR Imaging System (Hyperfine, www.hyperfine.io)

The Swoop Portable MR Imaging System (Fig. 1a) uses a biplanar 0.064 T permanent magnet for dedicated, head-only

TABLE 1. Examples of Clinical MR Systems Operating Below 1.5 T

Scanner	Field Strength (T)	Company
Swoop Portable MR Imaging System	0.064	Hyperfine, www.hyperfine.io
Promaxo MRI System	0.065	Promaxo, www.promaxo.com
Concerto	0.2	Siemens Healthineers, www.siemens-healthineers.com
C-Scan	0.2	Esaote, www.esaote.com
E-Scan	0.2	Esaote, www.esaote.com
OPENMARK II MRI System	0.2	Anke, www.anke.com
Opera	0.2	Esaote, www.esaote.com
Profile I, II, III	0.2	GE Healthcare, www.gehealthcare.com
Viva	0.2	Siemens Healthineers, www.siemens-healthineers.com
Panorama	0.23	Philips, www.philips.com
Superstar	0.23	Neusoft Medical Systems, www.neusoftmedical.com
G-Scan Brio	0.25	Esaote, www.esaote.com
Magspin Extremity MRI	0.25	JaingSu Magspin, www.magnspin.com
S-Scan MRI System	0.25	Esaote, www.esaote.com
AIRIS Vento, AIRIS Vento Plus	0.3	Fujifilm, www.fujifilm.com
Marcom 0.5 T	0.3	SternMed, www.sternmed.de
OPENMARK III	0.3	Anke, www.anke.com
O-Scan	0.31	Esaote, www.esaote.com
Magnetom C!	0.35	Siemens Healthineers, www.siemens-healthineers.com
MRIdian LINAC MR System	0.35	ViewRay, www.viewray.com
Ovation HD	0.35	GE Healthcare, www.gehealthcare.com
Polar 35	0.35	Basda Medical, www.basdamri.com
Magnifico	0.4	Esaote, www.esaote.com
APERTO Lucent, APERTO Lucent Plus	0.4	Fujifilm, www.fujifilm.com
OPENMARK 4000 MRI System	0.4	Anke, www.anke.com
MROpen	0.5	ASG Superconductors, www.asgsuperconductors.com
OPENMARK 5000	0.5	Anke, www.anke.com
Polar 50	0.5	Basda Medical, www.basdamri.com
Marcom 0.5 T	0.5	SternMed, www.sternmed.de
Synaptive	0.5	Synaptive, www.synaptive.com
Supernova OS5	0.5	Kampao Medical, www.kampo.cn
Magnetom Free.Max	0.55	Siemens Healthineers, www.siemens-healthineers.com
Upright Multi-Position MR	0.6	Fonar, www.fonar.com
BSTAR-070	0.7	Basda Medical, www.basdamri.com
Altair	0.7	Fujifilm, www.fujifilm.com
Embrace Neonatal MRI System	1.0	Aspect Imaging, www.aspectimaging.com

TABLE 1. Continued

Scanner	Field Strength (T)	Company
Magnetom Harmony	1.0	Siemens Healthineers, www.siemens-healthineers.com
Magnetom Impact Expert	1.0	Siemens Healthineers, www.siemens-healthineers.com
Panorama HFO	1.0	Philips, www.philips.com
OASIS, OASIS Velocity	1.2	Fujifilm, www.fujifilm.com

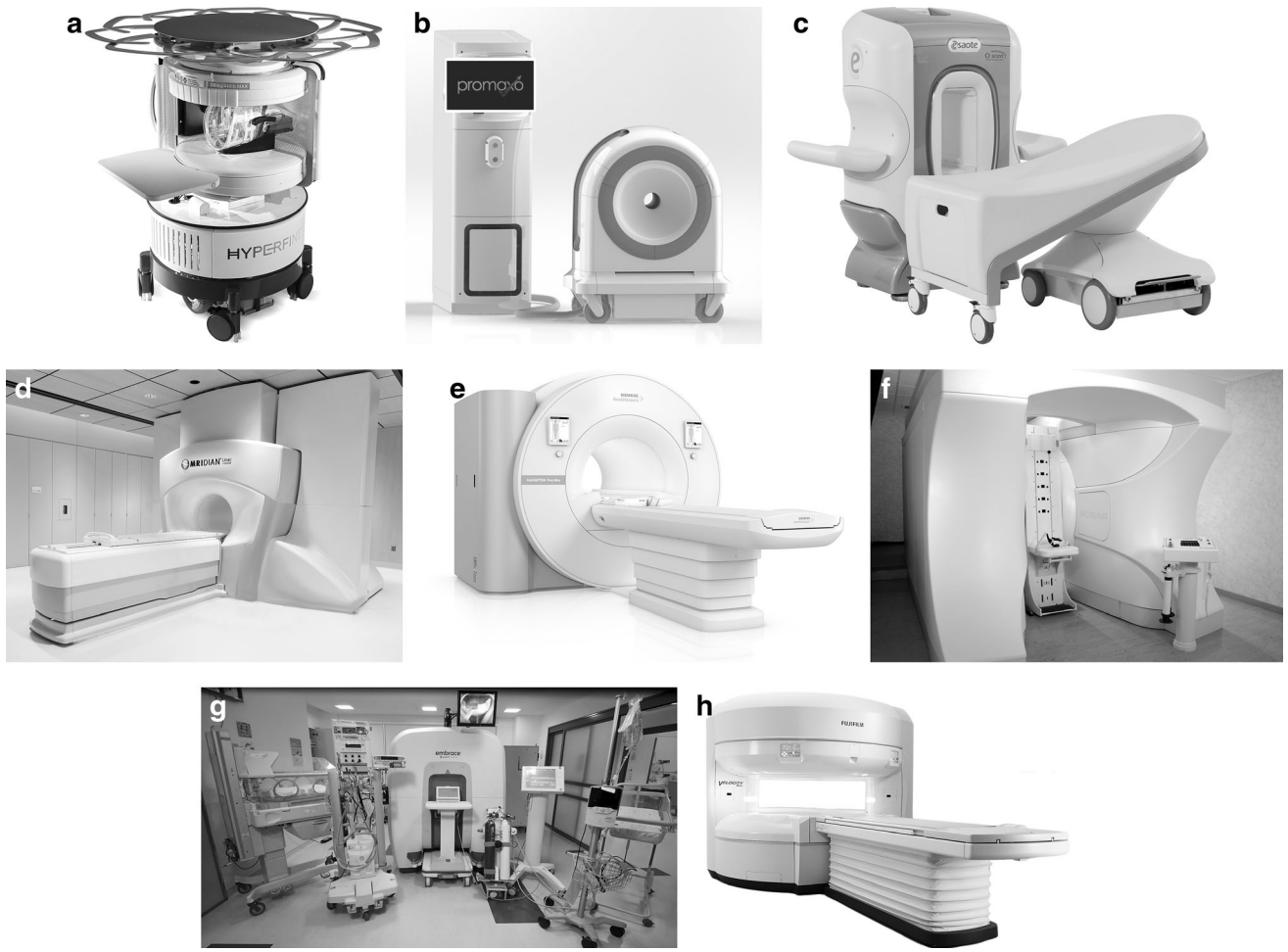

FIGURE 1: Examples of unique MR systems operating below 1.5 T. (a) 0.064 T, Swoop Portable MR Imaging System (Hyperfine, www.hyperfine.io); (b) 0.065 T, Promaxo MRI System (Promaxo, www.promaxo.com); (c) 0.31 T, O-scan Esaote Dedicated MRI (Esaote SpA, www.esaote.com); (d) 0.35 T, MRIdian LINAC MR System (ViewRay, www.viewray.com; (e) 0.55 T, Magnetom Free. Max (Siemens Healthineers, www.siemens-healthineers.com); (f) 0.6 T Upright Multi-Position MR (Fonar, www.fonar.com); (g) 1.0 T, Embrace Neonatal MRI System (Aspect Imaging, www.aspectimaging.com); (h) 1.2 T, OASIS Velocity (Fujifilm, www.fujifilm.com).

imaging. The use of the very-low-field permanent magnet reduces the power consumption of the scanner, which can operate using a standard, 110 V electrical outlet. This MR system does not have magnetic or RF shielding but, instead, employs dynamic electromagnetic interference for cancellation of ambient electromagnetic noise. The Swoop Portable MR Imaging System is mounted on motorized wheels, which permits transportation to the patient's bedside. MR imaging has been performed in non-standard settings, including the intensive care unit, emergency department, mobile van, and in lower resource environments.

0.065 T, Promaxo MRI System (Promaxo, www.promaxo.com)

The Promaxo MRI System (Fig. 1b) has a single-sided, 0.065 T magnetic field that is specially configured to permit urologists

to perform MRI-guided, interventional procedures of the prostate, particularly when co-registered with images containing Prostate Imaging Reporting & Data System (PI-RADS) lesions. Due to the unique form factor and advanced electromagnetic noise compensating techniques, the Promaxo MRI System is being utilized in ambulatory surgical centers, stand-alone urology offices, and hospital-associated urology centers.

0.31 T, O-scan Esaote Dedicated MRI (Esaote SpA, www.esaote.com)

The O-scan Esaote Dedicated MRI (Fig. 1c) uses a 0.31 T permanent magnet for extremity-only exams, including MR imaging of the patient's knee, elbow, wrist, hand, foot, ankle, forearm, and calf. Because of its compact design, well-contained magnetic fringe field, and localized RF shielding, this MRI system can be installed in a single room (eg, orthopedic surgeon's office) to provide point-of-care MRI.

0.35 T, MRIdian LINAC MR System (ViewRay, www.viewray.com)

The MRI-guided linear accelerator (MRI-LINAC) system (Fig. 1d) uses MRI combined with radiotherapy to treat various forms of cancer, with specific advantages for soft-tissue tumors.[29] The delivery of radiation is fully integrated with MRI, such that the system delivers radiation while monitoring the target area, permitting individualized, day-to-day, treatment planning that results in improved outcomes.[29]

0.55 T, Magnetom Free.Max (Siemens Healthineers, www.siemens-healthineers.com)

The Free.Max MR system (Fig. 1e) has an architecture similar to conventional, horizontal bore 1.5 and 3 T clinical scanners. This is the first MR system with an 80-cm diameter bore, which is currently the largest available bore size, permitting scanning of morbidly obese patients.

0.6 T Upright MRI (Fonar, www.fonar.com)

The Upright MRI (Fig. 1f) has a 0.6 T static magnetic field that is transverse to the patient. The patient bed of this MR system moves with three degrees of freedom between the planar surfaces of its dipole electromagnet. The field orientation and open architecture of this scanner permit static and dynamic imaging of the patient in prone, supine, and decubitus positions, as well as with the patient in different postures, including recumbent, sitting, standing, upright flexion, upright extension, rotation, and lateral bending.

1.0 T, Embrace Point-of-Care Neonatal MRI System (Aspect Imaging, www.aspectimaging.com)

The Embrace Point-of-Care Neonatal MRI System (Fig. 1g) is specially designed to image neonatal patients. It uses a 1-T permanent, self-shielded magnet and it does not require RF shielding, permitting it to be installed in a neonatal intensive care unit (NICU), and allowing the use of standard patient support equipment (eg, incubator, ventilator, physiological monitoring systems, etc.). This scanner has a thermally controlled patient capsule that incorporates acoustic dampening, which reduces the maximum in-bore acoustic noise to 83 dB.

1.2 T, OASIS Velocity (Fujifilm, www.fujifilm.com)

At the upper end of the spectrum of scanners operating below 1.5 T is the transverse magnetic field, 1.2 T Oasis Velocity (Fig. 1h). The open-sided configuration of this MR system accommodates patients with a large body habitus and has the advantage of being able to position the patient's anatomy of interest in the middle of the bore, which permits the optimal use of certain pulse sequences, such as fat- or water-suppression techniques. Because of the accessibility to the patient, this scanner may be effectively used for interventional or MRI-guided procedures, such as breast biopsies.

MRI-Related Issues for Passive Implants

Magnetic Field Interactions

TRANSLATIONAL ATTRACTION AND TORQUE. Magnetic field interactions associated with MRI, translational attraction and/or torque may cause movement or dislodgment of a magnetic implant, resulting in an uncomfortable sensation for the patient, an injury, or fatality.[1–5,8,9] Therefore, both translational attraction and torque are important to assess for metallic implants before allowing patients to undergo MRI.[1,2,5,9,12,13,18,19,32]

The effect of translational attraction acting on a magnetic (recognizing that there are varying types of "magnetism" that include ferromagnetic, diamagnetic, and paramagnetic materials) implant is responsible for a displacement hazard that may occur in the immediate area of the MR system.[1,3,8,10,12,13] That is, as the patient is moved into a conventional scanner, crossing through the spatial gradient magnetic field (i.e., the intensity of the static magnetic field that changes in relation to the distance from the MR system), until reaching the opening of the bore, where the magnitude of the spatial gradient magnetic fields is typically at a maximal level.[5,8,16,33]

The effect of torque (i.e., rotational alignment of the implant with the direction of the static magnetic field) acting on a magnetic implant is maximum in the center of the MR system, where the magnetic field is homogenous.[5,8,12,13,16,18] Torque, which is proportional to the strength of the static magnetic field, will greatly influence implants that have elongated shapes, while implants with spherical configurations will be unaffected.[12,13] Accordingly, both translational attraction and torque combine on a magnetic implant, as the patient moves into the MR system's bore and then into the center of the scanner.[1,3,8,10,12]

Various factors influence the risk of performing MRI on a patient with a magnetic implant including the strength of the static magnetic field, the value of the spatial gradient magnetic field (further discussed below), the magnetic susceptibility of the material used to make the implant, the mass of the implant, the geometry of the implant, the location and orientation of the implant, *in situ*, and the presence of counterforces that retain or anchor the implant in place (e.g., sutures, screws, encapsulation by fibrous tissue, tissue ingrowth, and others).[1,2,5,8] In virtually every instance, once a medical product is implanted, counterforces contribute to a margin of safety with respect to force-related issues.[1,2,5,8] Consequently, sufficient counterforces can exist to retain even a magnetic implant in a patient when the item is utilized according to its intended indication. There are many examples of passive and active implants made from magnetic materials or that incorporate magnets for functional purposes with MR Conditional labeling claims approved by the FDA because the counterforces were taken into consideration, including a magnetically activated orthopedic implant, magnetically activated esophageal sphincters, programmable cerebrospinal fluid (CSF) shunt valves, and cochlear implants.[1,2,5,8]

SPATIAL GRADIENT MAGNETIC FIELD: IMPLICATIONS FOR PASSIVE IMPLANTS. In the early days of MRI, a labeled implant only had information for the static magnetic field that was used for the evaluation of translational attraction, utilizing the deflection angle method.[5] This technique involves attaching the implant by a lightweight string to an inverted protractor, allowing it to move freely in space (obviously, this test scenario is a poor surrogate for the tissue-related forces acting on an implant; however, it does include a margin of safety). The test apparatus is then positioned at the point of the highest "patient-accessible" spatial gradient magnetic field (i.e., since this is the worst-case position of greatest attractive force that the patient with the implant will pass through when entering the bore of the scanner for an MRI exam) and the angle of deflection is measured.[5,33] Thus, the spatial gradient magnetic field value indicated in the labeling for the implant is where the measurement of force was measured for the implant and not a value that, if it was exceeded, would pose a risk to the patient with respect to force acting on the implant.

With the introduction of short-bore MR systems that inherently had higher spatial gradient magnetic fields compared with long-bore scanners, it was deemed necessary to report the value of the spatial gradient magnetic field used for the deflection angle measurement when labeling an implant. The addition of this metric was believed to be important because studies indicated that deflection angles recorded for implants were significantly higher using short-bore vs. long-bore MR systems.[34,35] Therefore, in addition to the limit for the strength of the static magnetic field, present-day MR Conditional labeling claims for implants approved by the FDA indicate a maximum value for the spatial gradient magnetic field, reported in gauss/cm or T/m.[8,32,33]

As indicated above, what is often unappreciated by MRI healthcare professionals is that the spatial gradient magnetic field value assigned to an implant is not an absolute safety threshold, whereby, if the value associated with the MRI exam is higher than the value indicated in the labeling, the implant would pose a hazard to the patient with respect to translational attraction. This is especially the case when one considers the previously mentioned counterforces that serve to effectively maintain the implant within the patient. And, being aware that, implants made from ferrous materials that inherently exhibited high spatial gradient magnetic field values during testing were nevertheless approved to be labeled MR Conditional by the FDA. Thus, it should be realized that, if a spatial gradient magnetic field value is exceeded for an implant, there is no risk of injury relative to magnetic field-related force, if the level for the specific static magnetic field is followed for a passive, implant labeled MR Conditional.

This latter aspect of the spatial gradient magnetic field has particular relevance for a patient with a passive implant undergoing MRI on a 1.2-T transverse field scanner, which has a maximum spatial gradient magnetic field higher (approximately, 2400 gauss/cm) than those associated with 1.5 and 3 T, longitudinal field MR systems. Despite this higher value, counterforces acting on the implant are expected to prevent harm to the patient.

MR SYSTEMS OPERATING BELOW 1.5 T. Over the years, several investigations assessed magnetic field interactions for passive implants using scanners operating below 1.5 T,[36–38] beginning with the seminal work by New et al[36] in 1983 and the more recent study that was the first to use a very low field (<100 mT) MR system, by van Speybroeck et al.[22] The findings indicated that implants made of low magnetic susceptibility materials (i.e., similar to all passive implants with MR Conditional labeling at 1.5 and/or 3 T) would not pose a risk to patients undergoing MRI exams on the scanners utilized in these studies.[22,36,37]

MR systems with lower static magnetic fields inherently produce lower translational attraction and torque and, as such, create reduced magnetic field interactions for metallic implants.[8,10,19–22,36,37] While certain head-only, extremity-only, and whole-body scanners operating below 1.5 T have transverse magnetic fields with concomitant directional alterations for translational attraction and torque, the orientation of the magnetic field is of no importance for passive implants labeled MR Conditional at 1.5 or 3 T. Notably, there has been no report of a magnetic field-related injury to a patient

with a passive implant labeled MR Conditional at 1.5 and/or 3 T.

MAGNETIC FIELD-RELATED, OPERATIONAL DISTURBANCE OF A PASSIVE IMPLANT. If a passive implant has a magnetic component (eg, magnetically activated orthopedic implant, magnetically activated esophageal sphincters, or programmable CSF shunt valves), it is possible for the powerful static magnetic field of the scanner to disrupt the operation of the device.[5,8,9] Therefore, as part of the testing performed to evaluate safety, this aspect of the implant is assessed using ex vivo testing techniques.[5,8,9] For a magnetically activated, passive implant that is labeled MR Conditional at 1.5 and/or 3 T, as long as all conditions are followed, performing an MRI exam at a lower field strength will not result in an unintended change in function of the device, regardless of the direction of the static magnetic field.

For example, programmable CSF shunt valves utilize an external programmer that interfaces with the device to change the opening pressure (i.e., the valve setting) to regulate the outflow of CSF. The MR Conditional labeling for this type of passive implant indicates that the valve setting must be determined by a suitable healthcare professional (eg, neurologist, neurosurgeon, or registered nurse) before the MRI exam, and then rechecked and reset, as needed, after MRI to ensure patient safety.[5,8,9] Therefore, scanning patients on MR systems operating below 1.5 T should follow a similar procedure.

RF Field-Induced Implant Heating

RF fields associated with MRI generate electrical currents in conductors, such as metallic implants, that can produce tissue heating primarily due to resistive losses.[8,12–14] A metallic implant has high conductivity and, therefore, low resistance to electrical currents, which results in a minimal amount of implant heating. However, the tissue immediately surrounding the implant can heat excessively during MRI due to dissipation of electric fields.[8,12–14]

The primary variables that impact RF field-induced heating of an implant include: the type of implant (i.e., aneurysm clip, total hip prosthesis, vascular stent, etc.), the electrical characteristic of the material used to make the implant, the transmitted RF wavelength (eg, 64 MHz at 1.5 T; 128 MHz at 3 T, etc.), the length of the implant, the type of transmit RF coil used for MRI, the amount of RF energy delivered during MRI (i.e., based on the whole-body averaged [WBA], specific absorption rate [SAR]), the location of the implant relative to the transmitted RF energy, and the orientation of the RF energy to the implant.[8,12–14,38–42]

One consideration of RF field-related heating that may not be intuitive is that, for a given implant, heating can be different depending on the frequency of the RF wavelength in tissues and the length of the implant.[8,12–14] Accordingly, *less* RF field-induced heating may occur at 128 MHz (3 T) vs. 64 MHz (1.5 T) if the implant's length is longer than the resonant length at 128 MHz, but near the resonant length at 64 MHz.[12–14] This phenomenon has been reported for passive implants, such as sternal closure systems and orthopedic implants.[8,14,39–41]

Another less obvious feature of implant heating during MRI is that the orientation of the RF field, namely the electric field (E-field), relative to an implant also results in different heating.[38,42,43] A recent computational modeling study by Fujimoto et al[38] involving passive implants (generical hip and knee implants) examined the SAR distribution related to using a birdcage RF coil associated with a conventional, longitudinal static magnetic field, 1.5 T scanner compared to using a planar-pair RF coil, used by a transverse static magnetic field, 1.2-T MR system. The findings of the computational modeling demonstrated that the planar-pair system exhibited a substantially lower risk of RF-induced heating of the hip and knee implants compared with the birdcage system.[38] This finding was similar to those reported for deep brain stimulation leads.[43] Consequently, the RF coils used by transverse field scanners tend to heat implants less than the RF coils used by longitudinal field MR systems in the investigated cases,[38,43] which has important implications for patients when considering the risks related to unlabeled implants.

With further respect to RF field-induced heating of metallic implants, the "antenna effect" (i.e., when the E-field couples with elongated, conductive implants and amplifies the deposition of RF energy in the tissue) should also be considered.[8,12–14,16] A worst-case length for an implant is such that, the lower the RF frequency, the longer that the implant needs to be to exhibit an excessive temperature rise. For example, for a simple, linear metallic implant showing a resonant effect in tissue like muscle, the approximate lengths would be 12–15 cm at 128 MHz (3 T), 25–30 cm at 64 MHz, 41 cm at 42 MHz (1 T), 75 cm at 23 MHz (0.55 T), and 640 cm at 2.7 MHz (0.064 T) (the latter two values do not exist for medical implants).[10]

MR SYSTEMS OPERATING BELOW 1.5 T/64 MHZ. MR systems transmitting RF fields below 64 MHz (i.e., 1.5 T) generate appreciably lower SAR values than higher field strength scanners.[12–14,19] This factor combined with the critical dimensions of RF field-induced heating contributes to overall, lower temperature profiles for passive implants. Importantly, in our research that involved consideration of the peer-reviewed literature and a review of the manufacturer user and facility device experience (MAUDE) database, we found no report of a thermal injury associated with an MRI exam performed in a patient with a passive implant labeled MR Conditional at 1.5 or 3 T.

Suggestions for Managing Patients with Unlabeled Passive Implants on MR Systems Operating Below 1.5 T

Taking into account the potential safety issues, it is acceptable for MRI facilities to develop a general written policy to effectively manage patients with passive implants labeled MR Conditional at 1.5 and/or 3 T referred for MRI exams on scanners operating below 1.5 T. This policy should include the following essential elements:

1. The policy should be established by the supervising physician who is ultimately responsible for patient safety. This individual should have a complete understanding about the MRI-related issues that can impact a passive implant.
2. In consideration of the effects of force, torque (keeping in mind the effect of counterforces), and RF field-induced heating, patients with all passive implants that have been labeled MR Conditional at 1.5 and/or 3 T can be safely scanned on MR systems operating below 1.5 T, regardless of the direction of the static magnetic field (i.e., longitudinal or transverse) and without concern for the level of the spatial gradient magnetic field.
3. To ensure patient safety with respect to the RF field, a margin of safety can be provided when the passive implant is located within the area of the transmitted RF energy by operating the scanner in the Normal Operating Mode, which defaults the WBA SAR to 2 W/kg. If a passive implant has MR Conditional labeling indicating a WBA SAR value lower than 2 W/kg, that value should be followed.
4. For MR Conditional, passive implants that have functional components such as programmable CSF shunt valves, magnetically activated orthopedic implants, or other similar devices, it is necessary to follow the specific conditions indicated in the MRI labeling.

Possible Limitations

The information in this monograph specifically focused on MRI-related safety issues for passive implants, specifically labeled MR Conditional at 1.5 and/or 3 T. For other unlabeled passive implants, in addition to force, torque, and RF field-induced heating, other factors such as Lenz effect-related force and time-varying, gradient magnetic field-related heating, may theoretically pose risks to patients scanned on MR systems operating below 1.5 T. Therefore, for unlabeled passive implants, supervising physicians should also take these factors into consideration when making decisions to ensure patient safety.

Regarding Lenz effect-related force, this occurs with electrically conductive materials that develop eddy currents in the presence of strong static magnetic fields, such as those associated with MR systems.[8] One scenario to be aware of involves a patient with a relatively large, nonferrous metallic device, like an external fixation system. Rapid motion of the patient (eg, as the patient enters the scanner's bore) can result in force that acts on the device, opposing the motion. This force may be detected by the patient as a pulling or tugging sensation, which may cause the MRI technologist to erroneously believe that the device has ferrous components, and possibly cancel the MRI examination. Slowly moving a patient with a large metallic implant into and out of the bore of the scanner is essential to mitigate Lenz effect-related force that might be induced, decreasing the likelihood of a misunderstanding, or unnecessary exam cancellation.[8]

Gradient magnetic fields may create measurable heating of certain passive implants.[14] The impact of the gradient magnetic fields is primarily determined by the surface area and thickness of the implant, the electrical conductivity of the metal, the rate of change of the gradient magnetic fields, and the relative orientation of the implant to the gradient magnetic fields.[14] Thus, gradient magnetic field-induced heating has been reported to be potentially substantial for patients with sizeable or "bulky" passive implants such as large cranial plates and acetabular cups.[14] However, to our knowledge, there has been no report of an injury to a patient that has been attributed to gradient magnetic field-induced heating of a passive implant. Furthermore, passive implants are not required to undergo an evaluation of gradient-induced heating for the purpose of MR Conditional labeling.[32]

Conclusion

Patients with passive implants that do not have labeling for scanners operating below 1.5 T are often prevented from undergoing MRI exams on those scanners. With the vital knowledge of the MRI-related issues that include magnetic field interactions (force and torque) and RF field-induced heating, the supervising physician can implement a written policy to safely scan patients with passive implants labeled MR Conditional at 1.5 and 3 T. A similar strategy may be applied when performing MRI in study subjects on scanners operating below 1.5 T in a research setting.[19–21]

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