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Abbreviations:
DBS = deep brain stimulation
FDA = Food and Drug Administration
RF = radiofrequency
SAR = specific absorption rate

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[2] ** . Multiple body systems

MR Procedures: Biologic Effects, Safety, and Patient Care[1]

The technology used for magnetic resonance (MR) procedures has evolved continuously during the past 20 years, yielding MR systems with stronger static magnetic fields, faster and stronger gradient magnetic fields, and more powerful radiofrequency transmission coils. Most reported cases of MR-related injuries and the few fatalities that have occurred have apparently been the result of failure to follow safety guidelines or of use of inappropriate or outdated information related to the safety aspects of biomedical implants and devices. To prevent accidents in the MR environment, therefore, it is necessary to revise information on biologic effects and safety according to changes that have occurred in MR technology and with regard to current guidelines for biomedical implants and devices. This review provides an overview of and update on MR biologic effects, discusses new or controversial MR safety topics and issues, presents evidence-based guidelines to ensure safety for patients and staff, and describes safety information for various implants and devices that have recently undergone evaluation.

Magnetic resonance (MR) procedures have been utilized in the clinical setting for approximately 20 years. During this time the technology has evolved continuously, yielding MR systems with stronger static magnetic fields, faster and stronger gradient magnetic fields, and more powerful radiofrequency (RF) transmission coils. Short-term exposures to the electromagnetic fields used for MR procedures at the levels currently recommended by the U.S. Food and Drug Administration (FDA) and with adherence to proper safety guidelines have yielded relatively few serious injuries for the more than 150 million MR examinations performed to date, with the exception of several second- and third-degree burns that have occurred (1–4).

Many of the MR-related injuries and the few fatalities that have occurred were the apparent result of failure to follow safety guidelines or of the use of inappropriate or outdated information related to the safety aspects of biomedical implants and devices (1–7). The preservation of a safe MR environment requires constant attention to the care of patients and individuals with metallic implants and devices, because the variety and complexity of these objects constantly changes (5–7). Therefore, to guard against accidents in the MR environment, it is necessary to revise information on biologic effects and safety according to changes that have occurred in MR technology and with regard to the use of current guidelines for biomedical implants and devices (1,2,5–17).

In consideration of the above, this review will *(a)* provide an overview of and update on MR biologic effects, *(b)* discuss new or controversial MR safety topics and issues, *(c)* present evidence-based guidelines to ensure safety for patients and staff members, and *(d)* describe MR safety information for various implants and devices that have recently undergone evaluation.

While a comprehensive discussion of MR biologic effects, safety, and patient care is not within the scope of this review, these topics have been addressed in recently published review articles (8–12,16,17) and textbooks (5–7). In addition, there are at least two Web sites devoted to MR safety that are updated with content on a frequent basis (18,19).

BIOLOGIC EFFECTS OF STATIC MAGNETIC FIELDS

The introduction of MR technology as a clinical imaging modality in the early 1980s is responsible for a substantial increase in human exposure to strong static magnetic fields

ESSENTIALS

- *Most reported cases of MR-related injuries and the few fatalities that have occurred have apparently been the result of failure to follow safety guidelines or of use of inappropriate or outdated information related to the safety aspects of biomedical implants and devices.*
- *To prevent accidents and injuries in the MR environment, it is necessary to revise information on biologic effects and safety according to changes that have occurred in MR technology and with regard to use of current guidelines for biomedical implants and devices.*
- *The preservation of a safe MR environment requires constant attention to the care of patients and individuals with metallic implants and devices, because the variety and complexity of these objects constantly changes.*

(1,9,16). Most MR systems in use today operate with magnetic fields ranging from 0.2 to 3.0 T. In the research setting, an exceptionally powerful MR system operating at 8.0 T is located at Ohio State University (Columbus). According to the latest guidelines from the FDA, clinical MR systems that use a static magnetic field up to 8.0 T are considered a "nonsignificant risk" for patients. The exposure of research subjects to fields stronger than 8.0 T requires approval of the research protocol by an institutional review board and the informed consent of the subjects.

Schenck (1,9) conducted comprehensive reviews of biologic effects associated with exposure to static magnetic fields. With regard to short-term exposures (eg, limited exposures or those associated with the clinical use of MR systems), the available information for effects of static magnetic fields on biologic tissues is extensive (1,9,20–38). Investigations include studies on alterations in cell growth and morphology, cell reproduction and teratogenicity, DNA structure and gene expression, pre- and postnatal reproduction and development, blood-brain barrier permeability, nerve activity, cognitive function and behavior, cardiovascular dynamics, hematologic indexes, temperature regulation, circadian rhythms, immune responsiveness, and other biologic processes (20–38). In the majority of these studies, the authors concluded that exposures to static magnetic fields produce no substantial harmful biologic effects. Although there have been some reports of potentially injurious effects of static magnetic fields on isolated cells or organisms, none of these effects have been verified or firmly established as a scientific fact (1,9). The relatively few documented injuries that have occurred in association with MR system magnets were attributed to the inadvertent presence or introduction of ferromagnetic objects (eg, oxygen tanks, aneurysm clips) into the MR environment (1,5–7,9).

With regard to the effects of long-term exposure to static magnetic fields, there are interactions between tissues and static magnetic fields that could theoretically lead to pathologic changes in human subjects (1,9,16). However, quantitative analysis of these mechanisms indicates that they are below the threshold of importance with respect to long-term adverse biologic effects (1,9,16).

At present, the pertinent literature does not contain carefully controlled studies that demonstrate the absolute safety of chronic exposure to powerful magnetic fields. With the increased clinical use of interventional MR procedures, there is a critical need for such investigations. However, it may be virtually impossible to demonstrate "absolute safety," given the various difficulties in conducting such a study. In addition, although there is no evidence for a cumulative effect of magnetic field exposures on health, further studies of the exposed populations (eg, MR health care workers, patients who undergo repeated studies) will be helpful in establishing rational guidelines for occupational and patient exposures to static magnetic fields (1,9,16).

BIOLOGIC EFFECTS OF GRADIENT MAGNETIC FIELDS

During MR procedures, gradient magnetic fields may stimulate nerves or muscles by inducing electric fields in patients. This topic has been thoroughly reviewed by Schaefer et al (8), Nyenhuis et al (39), and Bourland et al (40). The potential for interactions between gradient magnetic fields and biologic tissue is dependent on a variety of factors, including the fundamental field frequency, the maximum flux density, the average flux density, the presence of harmonic frequencies, the waveform characteristics of the signal, the polarity of the signal, the distribution of current in the body, the electric properties, and the sensitivity of the particular cell membrane (8,39–48).

Several investigations have been conducted to characterize MR system–related gradient magnetic field–induced stimulation in human subjects (41–48). At sufficient exposure levels, peripheral nerve stimulation is perceptible as a "tingling" or "tapping" sensation. At gradient magnetic field exposure levels of 50%–100% above perception thresholds, patients may become uncomfortable or experience pain (8). At extremely high levels, cardiac stimulation is of concern. However, the induction of cardiac stimulation requires exceedingly strong and/or rapid gradient magnetic fields—more than an order of magnitude greater than those used in commercially available MR systems (8,39,40). Fortunately, current safety standards for gradient magnetic fields associated with present-day MR systems appear to provide adequate protection from potential hazards or injuries in patients (2,8,16,39).

Of interest, results of studies performed in human subjects indicate that anatomic sites of peripheral nerve stimulation vary depending on the activation of a specific gradient (ie, x, y, or z gradient) (8). Stimulation sites for x gradients included the bridge of the nose, the left side of the thorax, the iliac crest, the left thigh, the buttocks, and the lower back. Stimulation sites for y gradients included the scapula, the upper arms, the shoulder, the right side of the thorax, the iliac crest, the hip, the hands, and the upper back. Stimulation sites for z gradients included the scapula, the thorax, the xyphoid, the abdomen, the iliac crest, and the upper and lower back (8). Typically, peripheral nerve stimulation sites were at bony prominences. According to Schaefer et al (8), because bone is less conductive than the surrounding tissue it may increase current densities in narrow regions of tissue between bone and skin, resulting in lower nerve stimulation thresholds than expected.

ACOUSTIC NOISE

Various forms of acoustic noise are produced in association with the operation of an MR system (49). The primary source of acoustic noise, however, is the gradient magnetic field activated during the MR procedure. This noise occurs during rapid alterations of current within the gradient coils that, in the presence of the powerful static magnetic field of the MR

system, produce substantial (lorentzian) forces. Acoustic noise, manifested as loud tapping, knocking, or chirping sounds, is generated when these forces cause motion or vibration of the gradient coils as they impact their mountings.

Problems associated with acoustic noise for patients and health care workers include simple annoyance, difficulties in verbal communication, heightened anxiety, temporary hearing loss, and, potentially, permanent hearing impairment (49–61). Acoustic noise may pose a particular hazard to specific patient groups who are at increased risk. Patients with psychiatric disorders, the elderly, and pediatric patients may be confused or experience heightened anxiety (49,51). Sedated patients may experience discomfort due to high noise levels. Certain drugs are known to increase hearing sensitivity (52). Neonates with immature anatomic development may have an increased reaction to acoustic noise, as has been reported by Philbin et al (53).

Characteristics of MR-related Acoustic Noise

Variations in MR-related acoustic noise occur with alterations in the gradient output (rise time or amplitude) associated with different MR parameters (49,54–64). Noise levels, pitch, and frequency characteristics are predominantly increased when section thickness, field of view, repetition time, and echo time are decreased. The physical features of the MR system, especially the presence or absence of special sound insulation, and the material and construction of gradient coils and support structures also affect the transmission of acoustic noise and its perception by the patient.

The patient's presence and the patient's size also affect the level of acoustic noise. An increase in acoustic noise has been reported with a patient or volunteer present in the bore of the MR system (63); this may be due to pressure doubling (ie, an increase in sound pressure) close to an object, as sound waves reflect and undergo in-phase enhancement. Noise characteristics also have a spatial dependence. For example, noise levels have been found to vary by as much as 10 dB as a function of patient position along the magnet bore (63).

MR-related acoustic noise levels have been measured during a variety of pulse sequences for MR systems with static magnetic field strengths ranging from 0.2 to 4.7 T (54–56,61–64). Recent studies performed with MR parameters that included "worst-case" pulse sequences showed that, not surprisingly, fast gradient-echo, fast spin-echo, and echo-planar pulse sequences produced the greatest acoustic noise levels (49,55,56).

MR-related Acoustic Noise and Permissible Limits

The FDA indicates that MR-related acoustic noise levels must be below the level of concern established by pertinent federal regulatory or other recognized standards-setting organizations (2). If the acoustic noise is not below this level, the sponsor (ie, the manufacturer of the MR system) must recommend steps to reduce or alleviate the noise perceived by the patient. A single upper limit of 140 dB is applied to peak acoustic noise (2). However, the instructions for use of MR systems must advise the MR system operator to provide hearing protection to patients for operation above an acoustic noise level of 99 dB (2).

In general, acoustic noise levels recorded by various researchers in association with conventional or routine MR procedures have been below the maximum limit permissible by the U.S. Occupational Safety and Health Administration (2). Notably, when one considers that the duration of exposure is one of the more important physical factors that determine the effect of noise on hearing, then acoustic noise levels associated with MR procedures do not tend to be problematic because of the relative short periods of exposure (65,66).

Prevention of Acoustic Noise Problems

Various techniques have been described to attenuate noise and, thus, prevent problems or hazards associated with exposure to MR-related acoustic noise (49,64). The simplest and least expensive means is to use disposable earplugs or commercially available noise-abatement headphones (49). Earplugs, when properly used, can decrease noise by 10–30 dB, which usually affords adequate protection for MR environments with relatively loud MR systems. Regardless of the technique used, facilities operating with MR systems that generate substantial acoustic noise should require all patients undergoing an examination to wear a protective hearing device. Exposure of staff members, health care workers, and other individuals (eg, relatives, visitors) to loud MR systems is also of concern (49,56). Therefore, these individuals should likewise be required to use an appropriate means of hearing protection if they remain in the room during the operation of these units (49).

BIOLOGIC EFFECTS OF RF FIELDS

The majority of the RF power transmitted for MR imaging or spectroscopy (eg, carbon decoupling, fast spin-echo pulse sequences, magnetization transfer contrast pulse sequences) is transformed into heat within the patient's tissues as a result of resistive losses (11,67). Not surprisingly, the primary biologic effects associated with exposure to RF radiation are related to the thermogenic qualities of this electromagnetic field (11,67–77).

Prior to 1985, there were no published reports concerning thermal or other physiologic responses of human subjects exposed to RF radiation during MR procedures. Since then, many investigations have been conducted to characterize the thermal effects of MR procedure–related heating (68–74,78). This topic has been reviewed by Schaefer (67,76) and Shellock (11).

MR Procedures and Specific Absorption Rate of RF Radiation

Thermoregulatory and other physiologic changes that a human subject exhibits in response to exposure to RF radiation are dependent on the amount of energy that is absorbed. The dosimetric term used to describe the absorption of RF radiation is the specific absorption rate (SAR) (11,67,76,79). The SAR is the mass normalized rate at which RF power is coupled to biologic tissue and is typically expressed in watts per kilogram. The relative amount of RF radiation that an individual encounters during an MR procedure is usually characterized with respect to the whole-body averaged and peak SAR levels (ie, the SAR averaged in 1 g of tissue).

Measurements or estimates of SAR are not trivial, particularly in human subjects. There are several methods of determining this parameter for the purpose of RF energy dosimetry in association with MR procedures (67,76,79,80). The SAR that is produced during an MR procedure is a complex function of numerous variables, including the frequency (ie, determined by the strength of the static magnetic field of the MR system), the repetition time, the type of RF coil used, the volume of tissue contained within the coil, the configuration of the ana-

tomic region exposed, and the orientation of the body to the field vectors, as well as other factors (11,67,76,79,80).

Thermophysiologic Responses to MR Procedure–related Heating

Thermophysiologic responses to MR procedure–related heating depend on multiple physiologic, physical, and environmental factors (11,67,76,77). These include the duration of exposure, the rate at which energy is deposited, the status of the patient's thermoregulatory system, the presence of an underlying health condition, and the ambient conditions within the MR system.

With regard to the thermoregulatory system, when subjected to a thermal challenge the human body loses heat by means of convection, conduction, radiation, and evaporation. Each of these mechanisms is responsible to a varying degree for heat dissipation as the body attempts to maintain thermal homeostasis (11,67,77,79). If the thermoregulatory effectors are not capable of totally dissipating the heat load, then there is an accumulation, or storage, of heat along with an elevation in local and/or overall tissue temperatures (11,76,77).

Various underlying health conditions may affect an individual's ability to tolerate a thermal challenge, including cardiovascular disease, hypertension, diabetes, fever, old age, and obesity (81–85). In addition, medications such as diuretics, β-blockers, calcium blockers, amphetamines, muscle relaxants, and sedatives can also greatly alter thermoregulatory responses to a heat load. In fact, certain medications have a synergistic effect with respect to tissue heating if the heating is specifically caused by exposure to RF radiation (86).

The environmental conditions that exist in and around the MR system will also affect the tissue temperature changes associated with RF-induced heating. During an MR procedure, the amount of tissue heating that occurs and the concomitant exposure to RF energy that is tolerable are dependent on environmental factors that include ambient temperature, relative humidity, and airflow.

MR Procedure–related Heating and Human Subjects

To our knowledge, the first study of human thermal response to RF radiation–induced heating during an MR procedure was conducted by Schaefer et al (87). Temperature changes and other physiologic parameters were assessed in volunteer subjects exposed to relatively high, whole-body, averaged SARs (approximately 4.0 W/kg). The data indicated that there were no excessive temperature elevations or other deleterious physiologic consequences related to these exposures to RF radiation (87).

Several studies were subsequently conducted with volunteer subjects and patients undergoing clinical MR procedures with the intent of obtaining information that would be applicable to patient populations typically encountered in the MR setting (68–75). These investigations demonstrated that changes in body temperature were relatively minor (ie, $<0.6°C$). While there was a tendency for statistically significant increases in skin temperatures to occur, these were of no serious physiologic consequence.

Of interest, various studies reported a poor correlation between body or skin temperature changes versus whole-body averaged SARs during clinical MR procedures (69,73). These findings are not surprising considering the range of thermophysiologic responses possible to a given SAR that are dependent on the individual's thermoregulatory system and the presence of one or more underlying condition(s) that can alter or impair the ability to dissipate heat.

An extensive investigation was conducted in volunteer subjects exposed to a 1.5-T 64-MHz MR procedure with a whole-body averaged SAR of 6.0 W/kg (75), which, to our knowledge, is the highest level of RF energy to which human subjects have ever been exposed with an MR system. This excessive amount of RF radiation was achieved by using nonclinical MR imaging parameters (75). Tympanic membrane temperature, six different skin temperatures, heart rate, blood pressure, oxygen saturation, and skin blood flow were monitored (75). The findings indicated that an MR procedure performed at a whole-body averaged SAR of 6.0 W/kg can be physiologically tolerated by an individual with normal thermoregulatory function (75).

MR Procedure–related Heating and Very High Field Strength MR Systems

There are over 200 MR systems operating with a static magnetic field strength of 3 T, several operating at 4 T, a few operating at 7 T, one operating at 8 T (74), and at least one MR unit that operates at a field strength higher than 8 T is in the final stage of installation (likely completed by the time this article is published). For a given application, these very high field strength systems are capable of generating RF power depositions that greatly exceed those associated with a 1.5-T MR system. Of note, with the doubling of field strength (eg, 1.5 vs 3.0 T), the RF power deposition increases four times for a given MR imaging pulse sequence. Therefore, investigations are needed for characterization of thermal responses in human subjects to determine potential thermogenic hazards associated with the use of these powerful MR devices. To date, however, with the exception of work conducted at 8 T by Kangarlu et al (74), there has been virtually no investigation of MR procedure–related heating with regard to very high field strength MR systems.

MR SAFETY AND PATIENT CARE

Screening Patients for MR Procedures and Individuals for the MR Environment

The establishment of thorough and effective screening procedures for patients and other individuals is one of the most critical components of a program to guard the safety of all those preparing to undergo MR procedures or to enter the MR environment (5,13,15–17,89). An important aspect of protecting individuals from MR system–related accidents and injuries involves an understanding of the risks associated with the various implants, devices, accessories, and other objects that may cause problems in this setting (5,13,15–17). This requires obtaining information and documentation about these objects in order to provide the safest MR setting possible. In addition, because MR-related incidents have been due to deficiencies in screening methods and/or a lack of proper control of access to the MR environment (especially with regard to preventing personal items and other potentially problematic objects from entering the MR room) (3,4), it is crucial to set up procedures and guidelines to prevent such incidents from occurring. Various guidelines and recommendations have been developed to facilitate the screening process (15,17,88,89).

Screening patients for MR.—Certain aspects of screening patients for MR procedures may take place during the scheduling process. This must be conducted by a health care worker who is specially trained in MR safety (17,88,89). That is, this individual should be *(a)* trained to

understand the potential hazards and issues associated with the MR environment and MR procedures and *(b)* familiar with the information contained on screening forms for patients and individuals. During this time, it may be ascertained if the patient has any implant that may be contraindicated for the MR procedure (eg, ferromagnetic aneurysm clip, pacemaker) or if there is any condition that requires careful consideration (eg, patient is pregnant or has a disability). Preliminary screening helps to prevent scheduling of patients who may be inappropriate candidates for MR examinations.

At the facility, it is advisable for every patient to undergo comprehensive screening in preparation for the MR examination. Comprehensive patient screening involves the use of a printed form to document the screening procedure, a review of the information on the screening form, and an oral interview to verify the information and allow discussion of any question or concern that the patient may have (15,88,89). A health care worker trained in MR safety must conduct this aspect of patient screening. Various forms have been developed for screening patients in preparation for MR procedures (5,15,17–19,88,89). An example of a recently developed form for this use is shown in Figure 1 (18,19).

With the use of any type of written questionnaire, limitations exist related to incomplete or incorrect answers provided by the patient (18,19,88,89). For example, there may be difficulties associated with patients who are impaired with respect to their vision, language fluency, or level of literacy. Therefore, an appropriate accompanying family member or other individual (eg, referring physician) should be involved in the screening process to verify any information that may affect patient safety. Versions of this form should also be available in other languages, as needed (ie, specific to the demographics of the population served by the MR facility) (17,88).

In the event that the patient is comatose or unable to communicate, the form should be completed by the most qualified individual (eg, physician, family member) with knowledge of the patient's medical history and present condition. If the screening information is inadequate, it is advisable to look for surgical scars on the patient and/or to obtain conventional radiographs of the skull and/or chest to search for implants that may be particularly hazardous in the MR environment (eg, aneurysm clip, cardiac pacemaker).

After completion of the screening form used for patients, a health care worker trained in MR safety must review the contents of the form. Next, an oral interview should be conducted by the MR safety–trained health care worker to verify the information on the form and to allow discussion of any question or concern that the patient may have before undergoing the MR procedure. This allows for clarification or confirmation of the answers to the questions posed to the patient so that there is no miscommunication regarding important MR safety issues. In addition, because the patient may not be fully aware of the medical terminology used for a particular implant or device, it is imperative that this particular information on the form be discussed during the oral interview.

It should be noted that having undergone a previous MR procedure without incident does not guarantee a safe subsequent MR examination. Various factors (eg, static magnetic field strength of the MR system, orientation of the patient, orientation of a metallic implant or object) can substantially change the scenario (17,88,89). Therefore, a comprehensive screening procedure must be conducted each time a patient prepares to undergo an MR procedure. This is not an inconsequential matter, because a surgical intervention or accident involving a metallic foreign body may have occurred that could affect the safety of the patient entering the MR environment.

Screening individuals for the MR environment.—Similar to the procedure conducted for screening patients, all other individuals (eg, MR technologists, patient's family members, visitors, allied health professionals, maintenance workers, custodial workers, firefighters, security officers) should undergo screening by using appropriate guidelines before being allowed into the MR environment (17–19). This involves the use of a printed form to document the screening procedure, a review of the information on the form, and an oral interview to verify the information and allow discussion of any question or concern that the individual may have before entry to the MR environment is permitted.

In general, MR screening forms were developed with patients in mind and, therefore, contain many questions that are inappropriate or confusing to other individuals who may need to enter the MR environment. Therefore, a screening form was recently created for individuals who need to enter the MR environment and/or MR system room (Fig 2) (18,19). To prevent problems that may occur in individuals who respond to the MR facility during emergencies, a procedure should be in place to screen these individuals well in advance of their entry to the MR environment.

Metallic Orbital Foreign Bodies and Screening

The single case report in 1986 by Kelly et al (90) about a patient who sustained an ocular injury from a retained metallic foreign body has led to controversy regarding the procedure required to screen individuals prior to their entry to the MR environment (91–93). To date, this incident is the only serious eye-related injury that has occurred in association with the MR setting, according to recent review of the peer-reviewed literature and review of data files from the Manufacturer and User Facility Device Experience Database (MAUDE; available at *www.fda.gov/cdrh/maude.html*) and the Medical Device Report (available at *www.fda.gov/CDRH/mdrfile.html*), both from the FDA Center for Devices and Radiological Health.

In the past, any individual or patient suspected of having an orbital foreign body typically underwent screening with conventional radiography of the orbits to determine whether a metallic object was present. Thus, screening radiographs of the orbits were obtained routinely not only in individuals who had a history of injury from a foreign body but also in those who simply had a history of exposure to metallic objects, such as welders, grinders, metal workers, sculptors, and others. Obviously, conventional radiographs of the orbits may have been obtained unnecessarily in many individuals because of this policy.

Seidenwurm et al (93) presented research and a new set of guidelines for radiographic screening of individuals suspected of having metallic foreign bodies. Their investigation addressed the cost-effectiveness of the use of a clinical versus a radiographic technique to screen individuals for orbital foreign bodies before an MR procedure (93). The costs of screening were determined on the basis of published data, disability rating guides, and results of a practice survey. A sensitivity analysis was performed for each variable. For their analysis, the benefit of screening was prevention of immediate, permanent, nonameliorable, or unilateral blindness. Seidenwurm et al (93) implemented the following policy: "If a patient reports injury from an ocular foreign body that was subsequently removed by a doctor or

MAGNETIC RESONANCE (MR) PROCEDURE SCREENING FORM FOR PATIENTS

Date _____/_____/_____ Patient Number _____

Name _____ Age _____ Height _____ Weight _____
Last name First name Middle Initial

Date of Birth _____/_____/_____ Male ❒ Female ❒ Body Part to be Examined _____
month day year

Address _____ Telephone (home) (_____) _____-_____

City _____ Telephone (work) (_____) _____-_____

State _____ Zip Code _____

Reason for MRI and/or Symptoms _____

Referring Physician _____ Telephone (_____) _____-_____

1. Have you had prior surgery or an operation (e.g., arthroscopy, endoscopy, etc.) of any kind? ❒ No ❒ Yes
   If yes, please indicate the date and type of surgery:
   Date _____/_____/_____ Type of surgery _____
   Date _____/_____/_____ Type of surgery _____
2. Have you had a prior diagnostic imaging study or examination (MRI, CT, Ultrasound, X-ray, etc.)? ❒ No ❒ Yes
   If yes, please list:

	Body part	Date	Facility
MRI		____/____/____	
CT/CAT Scan		____/____/____	
X-Ray		____/____/____	
Ultrasound		____/____/____	
Nuclear Medicine		____/____/____	
Other_____		____/____/____	

3. Have you experienced any problem related to a previous MRI examination or MR procedure? ❒ No ❒ Yes
   If yes, please describe: _____
4. Have you had an injury to the eye involving a metallic object or fragment (e.g., metallic slivers, shavings, foreign body, etc.)? ❒ No ❒ Yes
   If yes, please describe: _____
5. Have you ever been injured by a metallic object or foreign body (e.g., BB, bullet, shrapnel, etc.)? ❒ No ❒ Yes
   If yes, please describe: _____
6. Are you currently taking or have you recently taken any medication or drug? ❒ No ❒ Yes
   If yes, please list: _____
7. Are you allergic to any medication? ❒ No ❒ Yes
   If yes, please list: _____
8. Do you have a history of asthma, allergic reaction, respiratory disease, or reaction to a contrast medium or dye used for an MRI, CT, or X-ray examination? ❒ No ❒ Yes
9. Do you have anemia or any disease(s) that affects your blood, a history of renal (kidney) disease, or seizures? ❒ No ❒ Yes
   If yes, please describe: _____

For female patients:

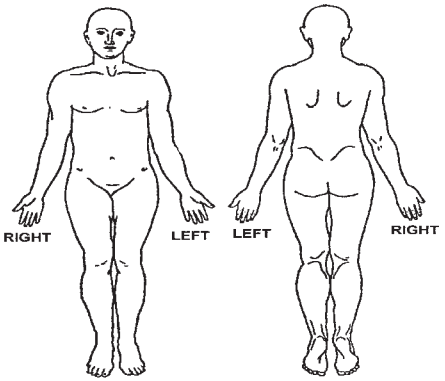
10. Date of last menstrual period:_____/_____/_____ Post menopausal? ❒ No ❒ Yes
11. Are you pregnant or experiencing a late menstrual period? ❒ No ❒ Yes
12. Are you taking oral contraceptives or receiving hormonal treatment? ❒ No ❒ Yes
13. Are you taking any type of fertility medication or having fertility treatments? ❒ No ❒ Yes
    If yes, please describe: _____
14. Are you currently breastfeeding? ❒ No ❒ Yes

WARNING: Certain implants, devices, or objects may be hazardous to you and/or may interfere with the MR procedure (i.e., MRI, MR angiography, functional MRI, MR spectroscopy). **Do not enter** the MR system room or MR environment if you have any question or concern regarding an implant, device, or object. Consult the MRI Technologist or Radiologist BEFORE entering the MR system room. **The MR system magnet is ALWAYS on.**

Please indicate if you have any of the following:

❒ Yes ❒ No Aneurysm clip(s)
❒ Yes ❒ No Cardiac pacemaker
❒ Yes ❒ No Implanted cardioverter defibrillator (ICD)
❒ Yes ❒ No Electronic implant or device
❒ Yes ❒ No Magnetically-activated implant or device
❒ Yes ❒ No Neurostimulation system
❒ Yes ❒ No Spinal cord stimulator
❒ Yes ❒ No Internal electrodes or wires
❒ Yes ❒ No Bone growth/bone fusion stimulator
❒ Yes ❒ No Cochlear, otologic, or other ear implant
❒ Yes ❒ No Insulin or other infusion pump
❒ Yes ❒ No Implanted drug infusion device
❒ Yes ❒ No Any type of prosthesis (eye, penile, etc.)
❒ Yes ❒ No Heart valve prosthesis
❒ Yes ❒ No Eyelid spring or wire
❒ Yes ❒ No Artificial or prosthetic limb
❒ Yes ❒ No Metallic stent, filter, or coil
❒ Yes ❒ No Shunt (spinal or intraventricular)
❒ Yes ❒ No Vascular access port and/or catheter
❒ Yes ❒ No Radiation seeds or implants
❒ Yes ❒ No Swan-Ganz or thermodilution catheter
❒ Yes ❒ No Medication patch (Nicotine, Nitroglycerine)
❒ Yes ❒ No Any metallic fragment or foreign body
❒ Yes ❒ No Wire mesh implant
❒ Yes ❒ No Tissue expander (e.g., breast)
❒ Yes ❒ No Surgical staples, clips, or metallic sutures
❒ Yes ❒ No Joint replacement (hip, knee, etc.)
❒ Yes ❒ No Bone/joint pin, screw, nail, wire, plate, etc.
❒ Yes ❒ No IUD, diaphragm, or pessary
❒ Yes ❒ No Dentures or partial plates
❒ Yes ❒ No Tattoo or permanent makeup
❒ Yes ❒ No Body piercing jewelry
❒ Yes ❒ No Hearing aid *(Remove before entering MR system room)*
❒ Yes ❒ No Other implant _____
❒ Yes ❒ No Breathing problem or motion disorder
❒ Yes ❒ No Claustrophobia

Please mark on the figure(s) below the location of any implant or metal inside of or on your body.



IMPORTANT INSTRUCTIONS

Before entering the MR environment or MR system room, you must remove all metallic objects including hearing aids, dentures, partial plates, keys, beeper, cell phone, eyeglasses, hair pins, barrettes, jewelry, body piercing jewelry, watch, safety pins, paperclips, money clip, credit cards, bank cards, magnetic strip cards, coins, pens, pocket knife, nail clipper, tools, clothing with metal fasteners, & clothing with metallic threads.

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

NOTE: You may be advised or required to wear earplugs or other hearing protection during the MR procedure to prevent possible problems or hazards related to acoustic noise.

I attest that the above information is correct to the best of my knowledge. I read and understand the contents of this form and had the opportunity to ask questions regarding the information on this form and regarding the MR procedure that I am about to undergo.

Signature of Person Completing Form: _____ Date _____/_____/_____
Signature

Form Completed By: Patient Relative Nurse _____ _____
Print name Relationship to patient

Form Information Reviewed By: _____ _____
Print name Signature

❒ MRI Technologist ❒ Nurse ❒ Radiologist ❒ Other_____

Figure 1. Example of an MR procedure screening form for patients. (Reprinted, with permission, from the Institute for Magnetic Resonance Safety, Education, and Research.)

MAGNETIC RESONANCE (MR) ENVIRONMENT SCREENING FORM FOR INDIVIDUALS*

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

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

Date ____/____/____ (month day year) Name _____ (Last Name First Name Middle Initial) Age _____

Address _____ Telephone (home) (____) ____-____

City _____ Telephone (work) (____) ____-____

State _____ Zip Code _____

1. Have you had prior surgery or an operation (e.g., arthroscopy, endoscopy, etc.) of any kind? ❒ No ❒ Yes
   If yes, please indicate date and type of surgery: Date ____/____/____ Type of surgery_____
2. Have you had an injury to the eye involving a metallic object (e.g., metallic slivers, foreign body)? ❒ No ❒ Yes
   If yes, please describe: _____
3. Have you ever been injured by a metallic object or foreign body (e.g., BB, bullet, shrapnel, etc.)? ❒ No ❒ Yes
   If yes, please describe: _____
4. Are you pregnant or suspect that you are pregnant? ❒ No ❒ Yes

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

Please indicate if you have any of the following:

❒ Yes ❒ No Aneurysm clip(s)
❒ Yes ❒ No Cardiac pacemaker
❒ Yes ❒ No Implanted cardioverter defibrillator (ICD)
❒ Yes ❒ No Electronic implant or device
❒ Yes ❒ No Magnetically-activated implant or device
❒ Yes ❒ No Neurostimulation system
❒ Yes ❒ No Spinal cord stimulator
❒ Yes ❒ No Cochlear implant or implanted hearing aid
❒ Yes ❒ No Insulin or infusion pump
❒ Yes ❒ No Implanted drug infusion device
❒ Yes ❒ No Any type of prosthesis or implant
❒ Yes ❒ No Artificial or prosthetic limb
❒ Yes ❒ No Any metallic fragment or foreign body
❒ Yes ❒ No Any external or internal metallic object
❒ Yes ❒ No Hearing aid *(Remove before entering the MR system room)*
❒ Yes ❒ No Other implant_____

IMPORTANT INSTRUCTIONS

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

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

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

Signature of Person Completing Form: _____ (Signature) Date ____/____/____

Form Information Reviewed By: _____ (Print name) _____ (Signature)

❒ MRI Technologist ❒ Radiologist ❒ Other _____

Figure 2. Example of a screening form for individuals who must enter an MR environment. (Reprinted, with permission, from the Institute for Magnetic Resonance Safety, Education, and Research.)

that resulted in negative findings on any examination, we perform MR imaging. . . Those persons with a history of injury and no subsequent negative eye examination are screened radiographically." The findings of their study indicated that the use of clinical screening before radiography increased the cost-effectiveness of foreign body screening by an order of magnitude (ie, assuming base-case ocular foreign body removal rates). Of note is that Seidenwurm et al have performed approximately 100 000 MR procedures using this protocol without incident.

Thus, an occupational history of exposure to metallic fragments, by itself, is not sufficient to mandate radiographic orbital screening (92,93). Therefore, current practice guidelines for foreign body screening should be altered in consideration of this information and because radiographic screening before MR procedures on the basis of occupational exposure alone is not clinically necessary, nor is it cost-effective (92,93).

Updated guidelines for orbital foreign body screening.—The procedure to follow with regard to a patient suspected of having an orbital foreign body involves a clinical screening protocol that entails asking the patient if he or she has had an ocular injury (93). If an ocular injury from a metallic object was sustained, the patient is asked if a medical examination was conducted at the time of the injury and if he or she was informed by the doctor that the object was completely removed (93). If *(a)* there was no injury, *(b)* the individual was informed that the ophthalmologic examination results were normal, or *(c)* the foreign body was removed at the time of the injury, the patient then proceeds to MR imaging. On the basis of the results of the clinical screening protocol, the patient should be screened with conventional radiography if an ocular injury related to a metallic object was sustained and the patient was not informed that the postinjury eye examination result was normal (93). In this case, the MR examination is postponed and the patient is scheduled for screening radiography.

Excessive Heating and Burns Associated with MR Procedures

The use of RF coils, physiologic monitors, electronically activated devices, and external accessories or objects made from conductive materials has caused excessive heating that resulted in burn injuries to patients undergoing MR procedures (3–6,94–101). Heating of implants and similar devices may also occur in association with MR procedures, but this tends to be problematic primarily for objects made from conductive materials that have an elongated shape, such as electrodes, leads, guidewires, and certain types of catheters (eg, catheters with thermistors or other conducting components) (102–108).

More than 30 incidents of excessive heating have been reported in patients undergoing MR procedures in the United States that were unrelated to equipment problems or the presence of conductive external or internal implants or materials (3,4,109). These incidents include first-, second-, and third-degree burns experienced by patients. In many of these cases, the reports pertaining to these incidents indicated that the limbs or other body parts of the patients were in direct contact with body RF coils or other RF transmit coils of the MR systems or that there were skin-to-skin contact points suspected to be responsible for these injuries (3,4,109).

In consideration of these injuries, guidelines have been developed to prevent excessive heating and burns related to MR

procedures (Appendix A) (19). The adoption of these guidelines will help to ensure that patient safety is maintained, especially as more conductive materials and electronically activated devices are used in association with MR procedures.

Tattoos and Permanent Cosmetics

Traditional (ie, decorative) and cosmetic tattoo procedures have been performed for thousands of years. Cosmetic tattooing or "permanent cosmetics" are used to reshape, recolor, recreate, or modify eye shadow, eyeliner, eyebrows, lips, beauty marks, and cheek blush. In addition, permanent cosmetics are used to hide scars and for other aesthetic applications (110,111).

There is considerable controversy regarding the MR safety aspects of tattoos and permanent cosmetics (112–121). Problems related to MR procedures and tattoos and permanent cosmetics are associated with the use of iron oxide or other metal-based pigments. Because a small number of patients with permanent cosmetics who underwent MR procedures (fewer than 10 documented cases) experienced transient skin irritation, cutaneous swelling, or heating sensations (3,4), many radiologists have refused to perform MR procedures in individuals with permanent cosmetics (Shellock FG, unpublished observations, 2002). Obviously, this undue concern for possible adverse events prevents patients with permanent cosmetics from having access to a potentially important diagnostic imaging modality (115).

In a study conducted by Tope and Shellock (115), the frequency and severity of adverse events associated with MR imaging were determined in a population of subjects with permanent cosmetics. A questionnaire was distributed to clients of cosmetic tattoo technicians. One hundred thirty-five (13.1%) study subjects underwent MR imaging after having permanent cosmetics applied. Of these, only two (1.5%) experienced problems associated with MR imaging: One subject reported a sensation of "slight tingling" and the other subject reported a sensation of "burning," both transient in nature (115). On the basis of these findings, as well as of other available information (3,4), it is apparent that MR procedures may be performed in patients with permanent cosmetics without any serious soft-tissue reactions or adverse events. Therefore, the presence of permanent cosmetics should not prevent patients from undergoing MR procedures.

Of interest, decorative tattoos tend to cause worse problems (including first- and second-degree burns) in patients undergoing MR procedures than do cosmetic tattoos. For example, Kreidstein et al (119) reported that a patient experienced a sudden burning pain at the site of a decorative tattoo during MR imaging of the lumbar spine at 1.5 T. Surprisingly, in order to permit completion of the MR examination, an excision of the tattooed skin was performed (119). The authors of this report stated, "Theoretically, the application of a pressure dressing of the tattoo may prevent any tissue distortion due to ferromagnetic pull" (119). However, this simple and relatively benign procedure was not attempted in this patient. The authors also indicated that "in some cases, removal of the tattoo may be the most practical means of allowing MRI" (119). Kanal and Shellock (120) commented on this report in a letter to the editor, suggesting that the response to this situation was "rather aggressive." Clearly, the trauma, expense, and morbidity associated with excision of a tattoo far exceed those that may be associated with MR-related tattoo interactions.

Because of the relatively remote possibility of an incident occurring in a patient with permanent cosmetics or a tattoo and due to the relatively minor short-term complication or adverse event that may develop (ie, transient cutaneous redness and swelling) (3,4,115), the patient should be permitted to undergo an MR procedure. Any problem regarding performance of an MR procedure in a patient with permanent cosmetics or a tattoo should not prevent the examination, because the diagnostic information that is provided by this modality may be crucial for the care of the patient. For patients in whom MR-related heating may occur, it is advisable to apply an ice pack or cold compress to the site of the tattoo or permanent cosmetics as a precautionary measure, since this a relatively innocuous procedure that adds little risk, time delay, or expense to the MR examination and could reduce the possibility of thermal injury (although, to date, there are no empiric data to support this).

Information on this topic has also been provided to patients by the FDA Center for Food Safety and Applied Nutrition, Office of Cosmetics and Colors fact sheet (116), as follows: "The risks of avoiding an MRI when your doctor has recommended one are likely to be much greater than the risks of complications from an interaction between the MRI and tattoo or permanent makeup. Instead of avoiding an MRI, individuals who have tattoos or permanent makeup should inform the radiologist or technician of this fact in order to take appropriate precautions, avoid complications, and assure the best results."

Pregnant Patients and MR Procedures

MR procedures have been used to evaluate obstetric, placental, and fetal abnormalities in pregnant patients for more than 18 years (122–125). Initially, there were substantial technical problems with the use of MR imaging, due primarily to the presence of image degradation caused by fetal motion. However, several technologic improvements, including the development of high-performance gradient systems and rapid pulse sequences, provided advances that were especially useful for imaging pregnant patients. Thus, high-quality MR studies for obstetric and fetal applications may now be accomplished routinely in the clinical setting (125).

Diagnostic imaging is often required during pregnancy (122). Thus, it is not uncommon to consider the use of an MR procedure in a pregnant patient. Safety issues exist that are related to possible adverse biologic effects associated with exposure to the static magnetic, gradient magnetic, and RF electromagnetic fields used for MR procedures (5,13,122). As such, many laboratory and clinical research investigations have been conducted to determine the effects of the use of unenhanced MR procedures during pregnancy (29,34–36,126,127). The overall findings from these studies indicate that there is no substantial evidence of injury or harm to the fetus; however, additional research on this topic is warranted.

Guidelines for MR in pregnant patients.—In 1991, the Safety Committee of the Society for Magnetic Resonance Imaging issued a document entitled "Policies, Guidelines, and Recommendations for MR Imaging Safety and Patient Management" (13), which stated that "MR imaging may be used in pregnant women if other nonionizing forms of diagnostic imaging are inadequate or if the examination provides important information that would otherwise require exposure to ionizing radiation (eg, fluoroscopy, computed tomography). Pregnant patients should be informed that, to date, there has been no indication that the use of clinical MR imaging during pregnancy has produced deleterious effects." These guidelines have been subsequently adopted by the American College of Radiology and are consid-

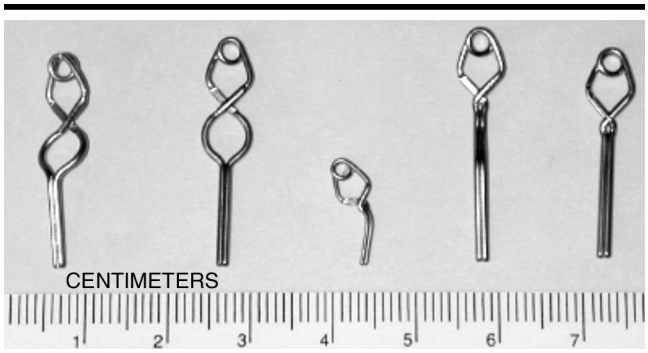


Figure 3. Examples of aneurysm clips with a variety of shapes and sizes (different versions of Spetzler Titanium Aneurysm Clips; Healthcare Corporation, V. Mueller Neuro/Spine, San Carlos, Calif). Aneurysm clips may be made from various materials, including ferromagnetic and nonmagnetic metals.

ered to be the standard of care with respect to the use of MR procedures in pregnant patients.

Accordingly, in cases where the referring physician and attending radiologist can defend that the findings of the MR procedure have the potential to affect the care of the mother or fetus (eg, to address important clinical problems or help identify potential complications, anomalies, or complex fetal disorders), the MR procedure may be performed with oral and written informed consent, regardless of the trimester (13,122).

MR PROCEDURES AND IMPLANTS AND DEVICES

The MR environment may be unsafe for individuals with certain biomedical implants or devices, owing primarily to movement or dislodgment of objects made from ferromagnetic materials (3–7,103,128–143). As previously stated, while excessive heating and the induction of electric currents may also present risks to patients with implants or devices, these problems are typically associated with implants that have elongated configurations and/or are electronically activated (eg, neurostimulation systems, cardiac pacemakers) (94,101–103).

To date, more than 1200 objects have been tested for MR safety, with over 200 evaluated at 3 T or higher (5–7,18,128–142). This information is available to MR health care professionals and others as published reports, compiled lists, and, in its entirety, online at *www.MRIsafety.com*. The topic of MR safety for implants and devices was recently reviewed by Shellock (5,103). As such, the intent for the material presented in the current review is to provide information for implants and devices for which there may be controversy or confusion, with an update on objects tested at 3 T or higher.

Evaluation of Implants and Devices for Safety in the MR Environment

The evaluation of an implant or device with regard to the MR environment is not a trivial matter. The proper assessment of an object typically entails characterization of magnetic field interactions (translational attraction and torque), MR-related heating, induced electric currents, and artifacts. A thorough evaluation of the effects of the MR environment on the functional and operational aspects of certain implants and devices may also be necessary. It is important to note that an object demonstrated to be safe according to one set of MR conditions may be unsafe under more "extreme" conditions (eg, stronger static magnetic field, greater level of RF power deposition, faster gradient field, different RF transmission coil). Accordingly, the specific test conditions for a given implant or device must be known before one makes a decision regarding whether a particular object is safe for an individual in the MR environment.

Magnetic field–related issues.—Magnetic field–related translational attraction and torque are known to present hazards to individuals with certain implants or devices (5–7). Currently, MR systems used in clinical and research settings operate with a static magnetic field that ranges from 0.2 to 8.0 T. Most previous ex vivo tests performed to assess objects for MR safety used units with a static magnetic field of 1.5 T or lower (5,103). Accordingly, this could present problems, insofar as it is possible that an object that displayed "weakly" ferromagnetic qualities in association with a 1.5-T MR system may exhibit substantial magnetic field interactions with an MR system operating at a stronger static magnetic field strength (5,103,128–131). Therefore, investigations have been conducted and are ongoing in which 3- and 8-T MR systems are being used to determine MR safety regarding implants and devices relative to these powerful units (128–131). This is especially crucial because most facilities with a 3-T MR imager currently do not perform MR procedures in patients with metallic objects because of the lack of safety information.

Long-bore versus short-bore MR systems.—Different magnet configurations exist for commercially available 1.5- and 3.0-T MR systems. These include conventional "long-bore" and "short-bore" systems used for whole-body (1.5- and 3.0-T MR systems) and head-only (3.0-T MR systems) clinical applications. In recent reports, it has been indicated that short-bore MR systems have significantly higher spatial gradients than do long-bore MR systems, especially for MR systems operating at 3 T (129,130). This can affect MR safety for a given metallic implant or device (129,130). Therefore, this is an additional factor that must be taken into consideration when evaluating objects for safety in the MR environment.

Aneurysm clips.—The presence of an intracranial aneurysm clip (Fig 3) in a patient referred for an MR procedure or in an individual who needs to enter the MR environment represents a situation that requires careful consideration because of the associated risks (5–7,103,137–152). Aneurysm clips made from ferromagnetic materials are contraindicated for MR procedures because excessive magnetically induced forces may displace these clips, causing serious injury or death. By comparison, aneurysm clips classified as nonferromagnetic or weakly ferromagnetic (eg, made from Elgiloy, Phynox, titanium alloy, or commercially pure titanium) have been tested and shown to be safe for patients undergoing MR procedures at 1.5 T or lower (5–7,137–152). In 1998, Shellock and Kanal (146) provided guidelines based on the relevant peer-reviewed literature for the care of a patient with an aneurysm clip (Appendix B).

Various studies have been performed to support imaging in patients with nonferromagnetic aneurysm clips (Fig 4). For example, Pride et al (145) reported findings from several patients with nonferromagnetic aneurysm clips who were imaged at 1.5 T. There was no objective

adverse outcome for these patients, which confirmed that MR procedures can be performed safely in patients with nonferromagnetic clips. Brothers et al (138) also demonstrated MR safety at 1.5 T for patients with nonferromagnetic aneurysm clips. Their report was particularly important, because MR imaging was found to be better than computed tomography for postoperative assessment of patients with aneurysms, especially with regard to the ability to show small zones of ischemia (138).

To our knowledge, only one ferromagnetic aneurysm clip–related fatality has been reported in the peer-reviewed literature (143). This incident was the result of erroneous information pertaining to the type of aneurysm clip that was present in the patient—the clip was believed to be a nonferromagnetic Yasargil aneurysm clip (Aesculap, South San Francisco, Calif) but turned out to be a ferromagnetic Vari-Angle clip (Codman & Shurtleff, Raynham, Mass) (143).

Aneurysm clips tested at 3 and 8 T.—Various aneurysm clips have been tested for magnetic field interactions in association with 3- and 8-T MR systems (128–130). Findings indicated that the clips either exhibited a lack of magnetic field interactions or relatively weak magnetic field–related translational attraction and torque at 3 T. Accordingly, some aneurysm clips are considered to be entirely safe for patients undergoing procedures with MR systems operating at 3 T, while others require further characterization of magnetic field–induced torque (128,129).

An early investigation to determine magnetic field interactions for medical implants at 8 T involved an assessment of aneurysm clips (131). Aneurysm clips representative of those made from nonferromagnetic or weakly ferromagnetic materials used for temporary or permanent treatment of aneurysms or arteriovenous malformations were selected for that study. Test results showed that MR safety at 8 T for the aneurysm clips was dependent not only on the material but also on the dimensions, model, shape, size, and blade length of a given clip.

Heart valve prostheses and annuloplasty rings.—Numerous heart valve prostheses and annuloplasty rings have undergone testing for MR safety (5–7,128,153–158). Of these, the majority showed measurable but relatively minor translational attraction and/or torque in association with exposure to the MR systems used for testing. Since the magnetic field–related forces exerted on heart valves and annuloplasty rings are deemed minimal compared with the force exerted by the beating heart (ie, approximately 7.2 N) (153,154), an MR procedure is considered to be safe for a patient with any of the heart valve prostheses or annuloplasty rings that have undergone testing to date (5–7,128,153–158). This includes the Starr-Edwards model Pre-6000 heart valve prosthesis, which had previously been suggested to be potentially hazardous for a patient in the MR environment.

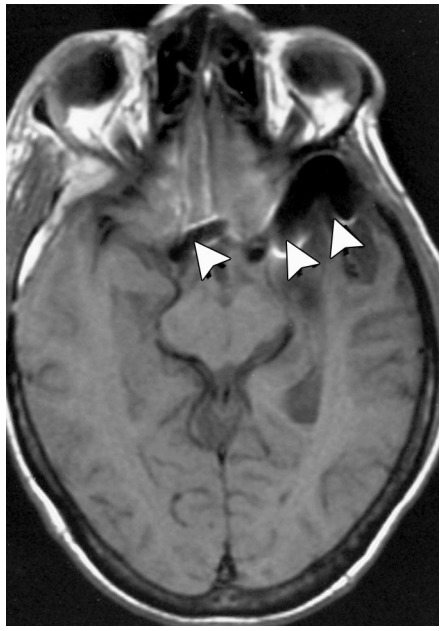
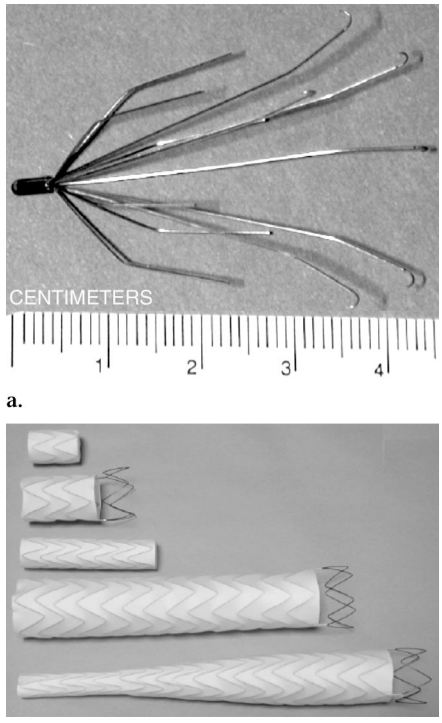


Figure 4. Transverse T1-weighted spin-echo MR image (repetition time, 500 msec; echo time, 20 msec) of the brain obtained at 1.5 T in a patient with nonferromagnetic aneurysm clips. Note the presence of relatively small signal void artifacts (arrowheads) associated with these implants.

Heart valve prostheses and annuloplasty rings tested at 3 T.—Many heart valve prostheses and annuloplasty rings have now been evaluated for MR safety by using 3-T units (128). Findings indicate that one annuloplasty ring (Carpentier-Edwards Physio Annuloplasty Ring, Mitral model 4450; Edwards Lifesciences, Irvine, Calif) showed relatively minor magnetic field interactions. Therefore, similar to heart valve prostheses and annuloplasty rings tested at 1.5 T, because the actual attractive forces exerted on these implants are deemed minimal compared to the force exerted by the beating heart, MR procedures at 3 T are not considered to be hazardous for individuals with these implants (5,128).

Additional heart valves and annuloplasty rings from the Medtronic Heart Valve Division (Minneapolis, Minn) have undergone MR safety testing at 3 T. These implants were tested for magnetic field interactions and artifacts by using a shielded 3-T MR system. According to information provided by Medtronic (Bayer KM, personal communication, 2002), these specific implants are safe for patients undergoing procedures with MR systems operating up to 3 T.



a.

b.

Figure 5. Examples of **(a)** an intravascular filter (Recovery Nitinol Filter; Bard Peripheral Vascular, Tempe, Ariz) and **(b)** stents (Endomed, Phoenix, Ariz) that have undergone MR safety testing.

Coils, filters, and stents.—There are many different types of coils, filters, and stents that are used for a variety of applications (Fig 5). These implants are commonly made from metallic materials such as platinum, titanium, stainless steel, Phynox, Elgiloy, and nitinol, which are mostly nonmagnetic or weakly ferromagnetic at 1.5 T or lower (5,159–169). Heating and induced currents have been evaluated for a wide variety of shapes and sizes of these implants, and there do not appear to be any safety issues for these devices. For those coils, filters, and stents found to have no magnetic field interactions, an MR procedure may be performed immediately after placement (5–7,159,160). However, for those implants made from weakly ferromagnetic materials, it is typically recommended to wait 6–8 weeks to

allow tissue ingrowth to help retain the implant in place (5–7,159,160). If there is any possibility that a coil, filter, or stent is not positioned properly or is not firmly in place, the patient should not be allowed into the MR environment.

It should be noted that because coils, filters, and stents are being developed on an ongoing basis, general MR safety guidelines cannot be provided for these implants. Therefore, it is necessary to obtain documentation that clearly identifies the device, material, and manufacturer in order to avoid hazardous situations in the MR environment. The results of a study by Taal et al (169) support the fact that not all stents are safe for patients undergoing MR procedures. They reported that "an appreciable attraction force and torque" was found for two types of Gianturco stents. In consideration of these results, Taal et al advised that "specific information on the type of stent is necessary before a magnetic resonance imaging examination is planned."

MR safety at 3 T and coils and stents.—Several different coils and stents have been evaluated at 3 T (103,161). Of the implants tested, two displayed magnetic field interactions that exceeded levels that might present risks to patients (103). However, similar to other coils and stents, tissue ingrowth may be sufficient to prevent these implants from posing a substantial risk to a patient or individual in the 3-T MR environment. Thus, this MR safety issue warrants further study.

Essure device.—The Essure device (Conceptus, San Carlos, Calif) is an implant developed for permanent female contraception (170). It is composed of 316L stainless steel, platinum, iridium, nickel-titanium alloy, silver solder, and polyethylene terephthalate fibers. The Essure device is a dynamically expanding microcoil that is placed in the proximal section of the fallopian tube by using a nonincisional technique. Subsequently, the Essure device elicits a benign tissue response resulting in tissue in-growth that anchors it and occludes the fallopian tube, resulting in permanent contraception.

An MR safety assessment of this implant involved testing for magnetic field interactions at 1.5 T, heating, induced electric currents, and artifacts (170). The findings indicated that it is safe for a patient with the Essure device to undergo an MR procedure with an MR system operating at 1.5 T or lower.

Essure device and testing at 3 T.—The Essure device was recently evaluated for MR safety at 3 T and was found to be safe for patients undergoing MR procedures operating at this field strength (128).

TheraSeed radioactive seed implant.—The TheraSeed radioactive seed implant (Theragenics, Buford, Ga) is used to deliver low-level radiation from palladium 103 to the prostate gland to treat cancer. This relatively small implant is composed of a titanium tube with two graphite pellets and a lead marker inside. Treatment may involve placement of 80–120 seeds. MR testing for magnetic field interactions, heating, induced currents, and artifacts revealed that the TheraSeed implant is safe for patients undergoing MR procedures at 1.5 T or lower.

Cardiac pacemakers.—Cardiac pacemakers are the most common electronically activated implants found in patients referred for MR procedures. Unfortunately, the presence of a pacemaker is considered to be a strict contraindication for the MR environment (5–7,169–171). Potential adverse interactions between pacemakers and MR procedures include movement of the pulse generator or leads, electrode heating, induction of ventricular fibrillation, rapid pacing, reed switch malfunction (or normal reed switch function in the presence of a powerful magnetic field), asynchronous pacing, inhibition of pacing output, alteration of programming with possible damage to pacemaker circuitry, and other problems (5–7,171–190). Some of these issues are theoretic, while others have been studied in vitro, in laboratory animals, and in human subjects.

More than 10 deaths have been attributed to MR procedures performed in patients with a cardiac pacemaker (3,4,189, 190). These fatalities were poorly characterized, since there was no electrocardiographic monitoring during the examinations. Furthermore, for each case, the mode of death (ie, mechanism responsible for the adverse cardiac pacemaker–MR procedure interaction) was not reported, and it was unknown whether these patients were pacemaker dependent (3,4,189,190). Of importance, there have been no deaths associated with physician-supervised imaging (189,190). In a recent letter to the editor addressing the controversy that exists with regard to imaging patients with cardiac pacemakers, Gimbel (190) pointed out that pacemaker-related deaths occurred in patients "'inadvertently' placed in the MRI environment without the attending physician conducting the MRI knowing that the patient being scanned had a pacemaker. Thus, none of the easily implemented techniques that might have allowed a harmless scan to proceed were implemented."

To date, more than 200 patients with a cardiac pacemaker have undergone MR procedures safely, either inadvertently or during purposeful monitored attempts to perform much-needed examinations (179,180,184,187–191). Thus, there is growing evidence that MR examinations may be performed in certain patients by following highly specific procedures and MR conditions. Accordingly, restrictions for conducting MR procedures in patients with cardiac pacemakers may be modified in the near future. Until then, it is advisable to continue to restrict all patients with cardiac pacemakers from the MR environment.

Investigations in human subjects with cardiac pacemakers have suggested various strategies for safe MR procedures. These strategies include imaging only non–pacemaker-dependent patients, programming the pacemaker device to an "off" or asynchronous mode, programming to a bipolar lead configuration, limiting the RF energy, and performing MR examinations only if the pulse generator is positioned outside of the bore of the MR system (179,180,184,185,187,188).

In a recent study by Martin et al (191), however, results of MR performed at 1.5 T indicate that these strategies may not be necessary for non–pacemaker-dependent patients at 1.5-T MR imaging. In their investigation, in order to examine risk in the broadest possible population, no restrictions were placed on the anatomy imaged, the type of pulse sequence and imaging parameters used for MR imaging, or the type of pacemaker present in the patient. Pacemaker-dependent patients were excluded to eliminate problems if pacing was inhibited during imaging. Of importance, absolute requirements for performing MR procedures in these non–pacemaker-dependent patients included the attendance of a cardiologist with pacemaker expertise, the presence of resuscitation equipment in proximity to the MR system room, and the presence of a physician certified in advanced cardiac life support who could respond to any untoward consequence. As such, it is important to recognize that imaging these non–pacemaker-dependent patients was not a trivial matter and required continuous monitoring and the means to rapidly intervene in the event of an emergency (191).

Findings from the study by Martin et al (191) showed that 1.5-T MR procedures did not cause substantial problems or difficulties. Furthermore, the results of this

investigation emphasized that it was not necessary to inhibit the pacing pulse, to reprogram the pulse generator, or to change MR parameters to achieve safety, as was done in prior studies in patients with cardiac pacemakers. However, given the infinite possibilities of pacing systems and cardiac and lead geometry, as well as variable RF and gradient magnetic fields, absolute safety with regard to pacemaker and MR interactions cannot be assured under all operational conditions. Nevertheless, on the basis of information in the peer-reviewed literature it appears that with appropriate patient selection, as well as continuous monitoring and preparedness for resuscitation efforts, performance of MR procedures in patients with an implanted cardiac pacemaker but who are not pacemaker dependent may be achieved with reasonable safety, even at static magnetic field strengths of 1.5 T.

In the past, the presence of any electronically activated implant was considered a strict contraindication for an individual in the MR environment. Over the years, however, various studies have been performed to define safety criteria for electronic devices (104,106–108). Therefore, if highly specific guidelines are followed, MR procedures may be conducted safely in patients with various electronically activated implants, including neurostimulation systems, cochlear implants, and programmable drug infusion pumps (5–7,104,106–108). In fact, some of these electronically activated devices have received approval from the FDA for "MR safe" labeling claims.

In consideration of the findings for conducting safe MR procedures in patients with electronically activated devices that have been published in the peer-reviewed literature, it is hoped that cardiac pacemaker manufacturers will be encouraged to proactively support and/or conduct investigations directed toward identifying safety criteria for their respective devices. This will ultimately have a substantial effect on patient care and the overall health care of patients with pacemakers who may require MR procedures.

Neurostimulation system for deep brain stimulation.—Because of the increased interest in the use of deep brain stimulation (DBS) of the thalamus, globus pallidus, and subthalamic nucleus for treatment of medically refractory movement disorders and other types of neurologic conditions, the number of patients receiving implantable pulse generators and DBS electrodes is rapidly growing (106,107,192–194). The use of MR imaging in patients with neurostimulation systems is frequently desired for surgical planning, as well as for the ongoing management of underlying conditions (106,107,192–195). In addition, MR imaging may be needed in various clinical scenarios, including verification of lead position, evaluation of patients with poor or worsening outcome, and examination of patients with other pathologic abnormalities unrelated to DBS neurostimulation, such as stroke, tumor, or hemorrhage (107).

As with all electronically activated devices in the MR environment, it is generally recommended that patients with a neurostimulation system should not undergo MR imaging because of the potential for serious consequences, including movement of the leads or implantable pulse generator, excessive MR imaging–related heating, induced electric currents, and functional disruption of the operational aspects of the device (5–7). Thus, before performing MR in a patient with a DBS system, it is essential to collect in vitro experimental data to define MR conditions that may permit imaging to be performed safely (106,107).

From an MR safety point of view, the greatest concern for electronically activated or electrically conductive implants in the brain is excessive MR imaging–related heating, which can cause irreversible tissue damage (106,107). Results from studies conducted to date (106,107) and a recent report (195) revealed that there is a realistic potential for injury due to excessive MR imaging–related heating of neurostimulation systems used for DBS.

Recently, investigators have evaluated MR-related heating for the only neurostimulation system (Activa Tremor Control System; Medtronic) approved by the FDA for use in chronic DBS (106,107). This neurostimulation system is a fully implantable multiprogrammable device designed to deliver electric stimulation to the thalamus or other brain structures. The basic implantable system is composed of the neurostimulator (or implantable pulse generator), the DBS lead, and an extension that connects the lead to the implantable pulse generator. This neurostimulation system delivers high-frequency electric stimulation to a multiple-contact electrode placed in the ventral intermediate nucleus of the thalamus or another anatomic site.

In their studies on neurostimulation systems, Rezai et al (106) and Finelli et al (107) indicated that MR safety for neurostimulation systems is highly dependent on a number of critical factors. To simulate a worst-case clinical application of DBS, these investigations evaluated bilateral DBS applications, such that two neurostimulators, two extensions, and two leads were assessed during in vitro experiments. Different configurations were evaluated for the bilateral neurostimulation systems to characterize worst-case and clinically relevant positioning scenarios (106,107). MR imaging procedures were performed on a gel-filled phantom designed to approximate the head and upper torso of a human subject. Temperature changes were studied in association with MR examinations conducted at 1.5 T and 64 MHz at various levels of RF energy by using the transmit-receive RF body coil and transmit-receive RF head coil. The findings from these studies indicated that substantial heating occurs under certain conditions, while other conditions produced relatively minor physiologically inconsequential temperature increases. Furthermore, factors that strongly influenced local temperature increases at the electrode tip included the positioning of the neurostimulation system (especially the electrode), the type of RF coil used, and the SAR used for the MR procedure.

According to the study by Rezai et al (106), MR-related heating does not appear to present a major safety concern for patients with the bilateral neurostimulation systems that underwent testing, as long as highly specific guidelines pertaining to the positioning of these neurostimulation devices and to the parameters used for MR imaging are carefully adhered to. Finelli et al (107) reported that MR imaging sequences commonly used for clinical procedures can be performed safely with the use of a transmit-receive RF head coil at 1.5 T in patients with a bilateral DBS system.

It should be noted that most present-day high-field-strength MR systems are used with a body coil to transmit RF and a receive-only head coil. Therefore, additional studies are required to characterize the effect of the use of this transmit-receive RF coil combination with regard to MR imaging–related heating of neurostimulation systems used for DBS.

It is important to note that the exact safety recommendations for the particular neurostimulation system, with regard to the pulse generator, leads, electrodes, operational conditions for the device, positioning of these components, and MR system conditions, must be carefully followed for MR imaging (106,107,195). As highlighted by two recent serious accidents (195), the failure to follow safety recommendations strictly may result in

serious temporary or permanent injury to the patient, including the possibility of transient dystonia, paralysis, coma, or even death.

Gastric electric stimulation.—Gastric electric stimulation, performed by using a specialized neurostimulation device (Enterra Therapy Gastric Electrical Stimulation System; Medtronic), is indicated for treatment of patients with chronic intractable nausea and vomiting secondary to gastroparesis of diabetic or idiopathic origin. Gastric electric stimulation uses mild electric pulses to stimulate the stomach to help control symptoms associated with gastroparesis.

The gastric electric stimulation device is composed of a neurostimulator, an implantable intramuscular lead, and an external programming system. Currently, the use of MR procedures in patients with this device is contraindicated owing to possible hazards related to dislodgment or heating of the neurostimulator and/or the leads used for stimulation. In addition, the voltage induced through the lead and neurostimulator may cause uncomfortable "jolting" or "shocking" levels of stimulation (5).

Postoperative MR Procedures

Because confusion exists regarding the issue of performing an MR procedure during the postoperative period in a patient with a metallic implant or device, guidelines have been developed pertaining to this MR safety topic (19). Study results have supported that, if a metallic object is a passive implant (ie, there is no electronically or magnetically activated component associated with the operation of the object) and it is made from a nonferromagnetic material (eg, titanium, titanium alloy, nitinol), the patient with the object may undergo an MR procedure at 1.5 T or lower immediately after implantation (5–7,135,145,149,159). In fact, there are several reports that describe placement of vascular stents and other implants with MR-guided procedures that include the use of high-field-strength (1.5-T) MR systems (164,167,168). In addition, a patient or individual with a nonferromagnetic passive implant would be allowed to enter the MR environment associated with a 1.5-T or lower-strength MR system immediately after implantation of such an object. Currently, there are few data to provide guidelines for MR environments with imagers operating at 3 T or higher.

For an implant or device that exhibits weakly magnetic qualities, it is typically necessary to wait for 6–8 weeks after implantation before performing an MR procedure or allowing the individual to enter the MR environment (5–7,156,160). For example, certain intravascular and intracavitary coils, stents, filters, and cardiac occluders designated as weakly ferromagnetic become firmly incorporated into tissue 6–8 weeks after placement. In these cases, retentive forces, or counterforces, provided by tissue ingrowth, scarring, or granulation essentially serve to prevent these objects from presenting hazards to individuals in the MR environment. Those implants or devices that may be weakly magnetic but that are rigidly fixed in the body, such as a bone screw, may be studied immediately in the postoperative period (19). Typically, specific information pertaining to the recommended postoperative waiting period may be found in the labeling or product insert for a weakly magnetic implant or device.

If there is any concern regarding the integrity of the tissue with respect to its ability to retain the implant or object in place or if the implant cannot be properly identified, the individual in such cases should not be exposed to the MR environment. Specific information pertaining to the recommended postoperative waiting period may be found in the labeling or product insert for a weakly magnetic implant or device.

CONCLUSIONS

With the continued advances in MR technology and the development of more sophisticated implants and devices, there is an increased potential for hazardous situations to occur in the MR environment. Therefore, to prevent incidents and accidents, it is necessary to be aware of the latest information pertaining to MR biologic effects, to use current evidence-based guidelines to ensure safety for patients and staff members, and to follow proper recommendations pertaining to biomedical implants and devices.

APPENDIX A

The following guidelines, reprinted, with permission, from the Institute for Magnetic Resonance Safety, Education, and Research (19), pertain to the prevention of excessive heating and burns in association with MR procedures.

1. Prepare the patient for the MR procedure by ensuring that there are no unnecessary metallic objects contacting the patient's skin (eg, metallic drug delivery patches, jewelry, necklaces, bracelets, key chains, etc).

2. Prepare the patient for the MR procedure by using insulation material (ie, appropriate padding) to prevent skin-to-skin contact points and the formation of "closed-loops" from touching body parts.

3. Insulating material (minimum recommended thickness, 1-cm) should be placed between the patient's skin and transmit RF coil that is used for the MR procedure (alternatively, the RF coil itself should be padded). For example, position the patient so that there is no direct contact between the patient's skin and the body RF coil of the MR system. This may be accomplished by having the patient place his/her arms over his/her head or by using elbow pads or foam padding between the patient's tissue and the body RF coil of the MR system. This is especially important for those MR examinations that use the body coil or other large RF coils for transmission of RF energy.

4. Use only electrically conductive devices, equipment, accessories (eg, ECG leads, electrodes, etc), and materials that have been thoroughly tested and determined to be safe and compatible for MR procedures.

5. Carefully follow specific MR safety criteria and recommendations for implants made from electrically conductive materials (eg, bone fusion stimulators, neurostimulation systems, etc).

6. Before using electrical equipment, check the integrity of the insulation and/or housing of all components including surface RF coils, monitoring leads, cables, and wires. Preventive maintenance should be practiced routinely for such equipment.

7. Remove all non-essential electrically conductive materials from the MR system (ie, unused surface RF coils, ECG leads, cables, wires, etc).

8. Keep electrically conductive materials that must remain in the MR system from directly contacting the patient by placing thermal and/or electrical insulation between the conductive material and the patient.

9. Keep electrically conductive materials that must remain within the body RF coil or other transmit RF coil of the MR system from forming conductive loops. Note: The patient's tissue is conductive and, therefore, may be involved in the formation of a conductive loop, which can be circular, U-shaped, or S-shaped.

10. Position electrically conductive materials to prevent "cross points." For example, a cross point is the point where a cable crosses another cable, where a cable loops across itself, or where a cable touches either the patient or sides of the transmit RF coil more than once. Even the close proximity of conductive materials with each other should be avoided because some cables and RF coils can capacitively couple (without any contact or crossover) when placed close together.

11. Position electrically conductive materials to exit down the center of the MR system (ie, not along the side of the MR system or close to the body RF coil or other transmit RF coil).

12. Do not position electrically conductive materials across an external metallic prosthesis (eg, external fixation device, cervical fixation device, etc) or similar device that is in direct contact with the patient.

13. Allow only properly trained individuals to operate devices (eg, monitoring equipment) in the MR environment.

14. Follow all manufacturer instructions for the proper operation and maintenance of physiologic monitoring or other similar electronic equipment intended for use during MR procedures.

15. Electrical devices that do not appear to be operating properly during the MR procedure should be removed from the patient immediately.

16. Closely monitor the patient during the MR procedure. If the patient reports sensations of heating or other unusual sensation, discontinue the MR procedure immediately and perform a thorough assessment of the situation.

17. RF surface coil decoupling failures can cause localized RF power deposition levels to reach excessive levels. The MR system operator will recognize such a failure as a set of concentric semicircles in the tissue on the associated MR image or as an unusual amount of image nonuniformity related to the position of the RF coil.

APPENDIX B

The following guidelines, adapted from a report by Shellock and Kanal (146), pertain to the care of a patient with an aneurysm clip referred for an MR procedure.

1. Specific information (ie, manufacturer, type or model, material, and lot and serial numbers) about the aneurysm clip must be known so that only patients with nonferromagnetic or weakly ferromagnetic clips are allowed into the MR environment. This information is provided in the labeling of the aneurysm clip by the manufacturer. The implanting surgeon is responsible for properly communicating this information in the patient's records.

2. An aneurysm clip that is in its original package and is made from Phynox, Elgiloy, MP35N, titanium alloy, commercially pure titanium, or other material known to be nonferromagnetic or weakly ferromagnetic does not need to be evaluated for ferromagnetism; as such, these are considered to be safe for MR procedures performed at 1.5 T or lower.

3. The radiologist and implanting surgeon are responsible for *(a)* evaluating the information pertaining to the aneurysm clip, *(b)* verifying its accuracy, *(c)* obtaining written documentation, and *(d)* deciding to perform the MR procedure after considering the risk-versus-benefit aspects for a given patient.

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