MR Unsafe Devices in Zones III and IV

Under special, specific circumstances, external devices or objects demonstrated to be ferromagnetic and MR Unsafe may still be brought into Zone III if they are deemed by the MR technologist to be necessary and appropriate for patient care. However, they should only be brought into Zone III if they under the *direct* supervision of specifically designated MR technologist who is thoroughly familiar with the device, its function, and the reason supporting its entry into Zone III.

The safe use of MR Unsafe devices while in Zone III is the responsibility of the specifically named MR technologist. Furthermore, such devices must be appropriately, physically secured or restricted at all times they are in Zone III to ensure that they are not placed too close to the magnet and accidentally become exposed to the static magnetic field or gradients that might result in them becoming dangerous projectiles or no longer accurately functional.

MR Unsafe devices or objects are prohibited in Zone IV.

> Because MR safety is the responsibility of the MR technologist, if an unforeseen ferrous object is discovered the scanner room, the technologist is responsible for securing the area as needed (i.e., requiring all individuals to clear the room and prohibiting re-entry) and determining how to safely remove the object from Zone IV.

IMPLANTED MEDICAL DEVICES AND OTHER POTENTIAL CONTRAINDICATIONS FOR MR

The concern for any implanted medical device is how it may be affected by the three fundamental variants of magnetic fields necessary to generate images:

- the strong static magnetic field (B_o),
- radiofrequency (RF) magnetic fields (B_1), and
- time varying magnetic field gradients (dB/dt).

Accordingly, issues to consider include potential magnetic field interactions, heating, induced currents, and artifacts.

The decision "to scan or not to scan" is the responsibility of the MR Radiologist and is ultimately based upon whether the risks of the potential consequences of the device interactions with the various magnetic fields are outweighed by the benefits of the exam. Both active and passive implantable medical devices can contain ferromagnetic and/or metallic components that may render the device incompatible with MR and therefore contraindicated by the implant manufacturer. In addition, these devices may cause artifacts that negatively impact image quality. Fortunately, there is a significant number of implantable medical devices that are either MR Safe or MR Conditional.

If an MR Radiologist does not authorize the exam for a particular patient:

- For inpatients, the MR technologist or operations assistant (as directed by the technologist) should make a note in the Progress Notes and notify the patient's nurse that the scan could not be performed.
- For outpatients, the MR technologist or operations assistant (as directed by the technologist) should notify the referring physician that the scan could not be performed.

MR technologists must seek MR safety information directly from the implant manufacturer. They should also refer to the website MRIsafety.com (at www.mrisafety.com) for questions related to MR safety and for additional information regarding various classifications of implants and even specific models. THE LIST (http://mrisafety.com/Thelist_search.asp) is especially useful for researching the MR safety status of such devices. Furthermore, TRA recommends that each MR facility make available in each Control Room a current copy of *Reference Manual for Magnetic Resonance Safety, Implants, and Devices* (Shellock 2017).

The MR technologist is responsible for confirming that any implanted device within an individual who enters Zone III or IV is MR Safe or MR Conditional.

For MR Conditional implants, the MR technologist is responsible for confirming that ***all*** of the implant manufacturer's stated conditions for safe, effective use are met. Accordingly, the technologist must contact the manufacturer to obtain the latest safety information to ensure patient safety relative to the particular MR system.

The MR technologist is responsible for verifying and documenting the MR safety status of any implanted device using information (such as package inserts) from the manufacturer or the aforementioned references. He/she should evaluate each device individually, using the most current information available at the time of the assessment. Documentation must establish that the device is MR Safe or MR Conditional. For all MR Conditional implants, the MR technologist must confirm that *all* of the manufacturer's stated safe conditions are met for that particular MR system where the patient will undergo his/her exam.

If the MR safety status of a particular device is unknown and cannot be confirmed, the MR technologist must assume the device is MR Unsafe.

All movement into and out of the magnet should be deliberate and slow. Move the patient SLOWLY in and out of the magnet. Do not allow him/her to sit up quickly after being removed from the magnet.

Obtaining an Order for MR Safety Screening Radiographs

- At acute care facilities and provider-based outpatient imaging centers (including Novant Health Imaging Kernersville and Novant Health Imaging Maplewood), the MR technologist or operations assistant (as directed by the technologist) should contact any radiologist and obtain a verbal order for the MR safety screening radiographs (if such x-rays are needed).
  - The technologist or operations assistant should document the verbal order in the patient's electronic medical record (e.g., "V/O Do head, chest, abdomen screening x-rays for MR per Dr. Smith").
- At independent diagnostic testing facilities (IDTFs) or free-standing imaging centers (including Novant Health Imaging Piedmont and Novant Health Imaging Triad), the MR technologist or operations assistant (as directed by the technologist) must contact the referring physician for the order for MR safety screening radiographs (if such x-rays are needed).

Active Implantable Medical Devices

With active implants, functionality is dependent upon an energy source such as electrical, mechanical, or pneumatic power. Examples include pacemakers, defibrillators, neurostimulators, drug pumps, CNS shunt valves, and cochlear implants.

Some of these devices contain an integral power source whereas others derive their necessary power through close coupling between an implanted coil and an external coil that forms part of the completed system. Active implants contain parts that may suffer damage during exposure to MR – the implant as a whole may be attracted by the static magnetic field or the sensing/stimulation lead electrodes may inappropriately sense electrical energy induced either by the magnetic or RF fields and alter therapy. A potential may exist for tissue damage from induced current especially RF, where high current density flows through very small surface electrodes. Larger metallic components may also suffer temperature increase. Lastly, the devices may cause significant artifacts that degrade image quality.

The GE MR system at Novant Health Imaging Piedmont (185 Kimel Park Drive, Suite 100, Winston-Salem, NC) includes an RF transmit/receive head coil. This system may be used to image safely those patients needing an exam of the head region yet who have an implanted device outside of the field of view (such as a neurostimulator or bladder stimulator).

To confirm lead placement and to confirm that the leads are appropriately connected to a power source or pulse generator, the MR technologist or operations assistant (as directed by the technologist) should obtain a medical order for the following radiographs for the purpose of MR safety screening:

- Two views of the chest.

Cochlear Implants

Although newer cochlear implants may be MR Conditional, they usually have ferromagnetic components and are activated by electronic and/or magnetic mechanisms. Consequently, an MR exam may be contraindicated due to the possibility of patient injury and/or alteration /damage to the function of the device by the static magnetic field. Additionally, the implant's internal magnet will cause substantial artifacts if the device is left in place during the MR exam.

Drug Infusion Pumps

Infusion pumps can be powered by an internal power source via an internal battery, through a mechanical clockwork mechanism, or powered by gas pressure through an internal pressure reservoir system. Programmable implantable infusion pumps usually contain ferromagnetic components and a magnetic switch. Other implanted infusion pumps are not directly programmable but have a constant flow rate and also contain ferromagnetic components. Because of these components, the pumps are contraindicated for MR procedures.

Exposure of these devices to the MR environment may result in medication dosing inaccuracies, including over-infusion or under-infusion or untended bolus. Exposure may also result in mechanical problems with the pump, such as motor stalling and the pump not restarting after MR.

Intrathecal Medication Pumps

An intrathecal pump or a "pain pump" delivers prescribed amounts of pain medication through a catheter directly to the fluid around the spinal cord, the intrathecal space. When delivered in small doses, the side effects often experienced with larger oral doses of the same medications may be minimized. These pumps can lessen the pain associated with failed back surgery, cancer, or nerve pain. They can also reduce spasticity, or muscle rigidity, caused by cerebral palsy, multiple sclerosis, stroke, brain injury, or spinal cord injury.

While patients with pain pumps may undergo MR exams, the magnetic field will temporarily stop the rotor of the pump motor and suspend drug infusion

for the duration of MR exposure. Even though the pump should then resume normal operation when removed from the MR magnetic field, there is potential for a delay in the return of proper drug infusion and the logging of motor stall events after the MR scan. For these reasons, trained personnel must verify the pump performance after the exam.

Patients Managed by Comprehensive Pain Specialists *(Baclofen Pumps Only)*

While the Clinic no longer places Baclofen pumps, the practice does continue to service those existing pumps that its physicians (currently Drs. David O'Toole and Thomas Meloy) have placed.

Comprehensive Pain Specialists (160 Kimel Forest Drive, Suite 100, Winston-Salem, NC) is open Monday through Friday from 7:30am until 4:00pm. A nurse is available (during routine hours or on call) to check the Baclofen pumps (only for the patients of the aforementioned physicians) at (336) 714-6400.

Patients Managed by Other Pain Management Clinics

If the patient with a medication pump is not a patient of the Advanced Pain Management Clinic, he/she must contact the physician who placed the device before the MR scan to confirm that the physician can interrogate the device after the scan. Then, after the MR exam is completed, the patient must go to the physician to get it checked to confirm that it is functioning properly**.**

Cardiac Implantable Electronic Devices (CIEDs)

A CEID device is an implanted cardiac pacing device such as a pacemaker (PM), an implantable cardioverter defibrillator (ICD), or a cardiac resynchronization therapy defibrillator (CRT-D). The platform for these devices includes a pulse generator, leads, and electrodes (Figure 11). Because of the complex electronic and ferromagnetic components, the CEID functionality can be severely disrupted in the MR environment, thus causing direct harm to the patient. Concerns include:

- Device movement
- Unexpected programming changes (e.g. resetting to default parameters)
- Inhibition of device output
- Inappropriate sensing of fast transients and elevated cardiac rates
- Transient asynchronous pacing
- Device reed switch malfunction
- Rapid cardiac pacing

- Induction of ventricular fibrillation
- Local thermogenic cardiac tissue destruction

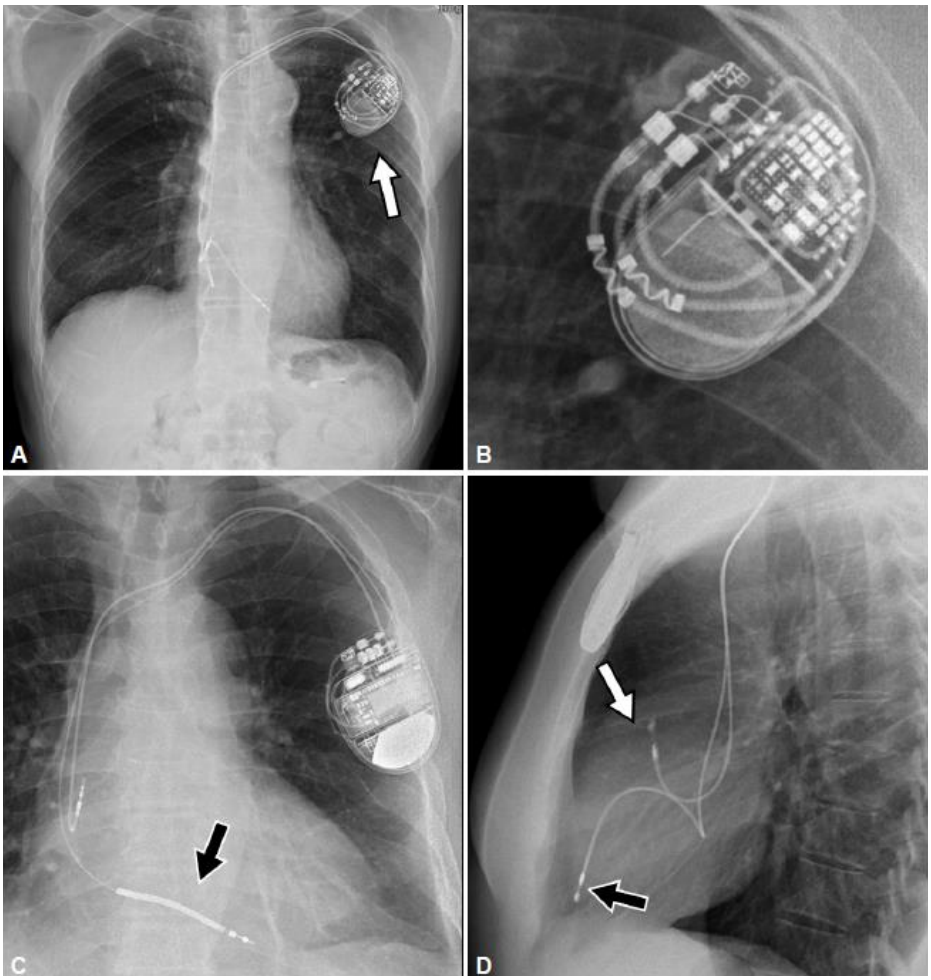

Figure 11. Components of cardiac pacemaker (PM) and implantable cardioverter defibrillator (ICD). (A) Frontal chest x-ray show pulse generator (white arrow) and right heart chamber PM leads. (B) X-ray shows PM pulse generator, including battery. (C) ICD includes pulse generator, leads, and right ventricular shock coil that appears as thick black band (black arrow). (D) Lateral chest x-ray shows right ventricular lead (black arrow) and right atrial lead (white arrow) of PM. (From Hwang 2017)

Furthermore, RF heating risks may exist for patients who have retained epicardial or pericardial pacing wires, even if the pulse generator has been removed.

In addition to causing direct harm to the patient in the MR environment, the metallic and other electrically conductive components might cause artifacts that significantly degrade the diagnostic value of the images, particularly if the CIED is implanted close to the area of interest, like in cardiac or breast imaging. While research concludes most modern pacemaker systems show only little effect on cardiac MR images (at least when implanted in the right pectoral region) especially ICD systems will often cause larger imaging artifacts or even total signal void in cardiac images mainly due to the larger battery (Nordbeck 2015). This effect can even be experienced in MR Conditional devices and should already be taken into account before the patient is admitted to the MR rather than referred for an alternative diagnostic technique.

The following conditions and/or strategies may reduce CIED artifact(s) in cardiac MR (Hwang 2016):

- Long distance (> 6 cm) between the CIED pulse generator and heart
- Right chest CIED pulse generator
- Long-axis plane of MR scan rather than short-axis plane
- Short-axis plane of MR scan at the basal left ventricle
- Frequency scout prior to SSFP
- Adjusting the center offset frequency to transfer artifact using SSFP sequence
- Spoiled GRE sequence rather than SSFP

If a CEID is not labeled as MR Conditional, it must be considered MR Unsafe.

For patients with CIEDs, to confirm lead placement and to confirm that the leads are appropriately connected to the pulse generator, the MR technologist or operations assistant (as directed by the technologist) should obtain a medical order for the following radiographs for the purpose of MR safety screening:

- Two views of the chest.

Comprehensive research over the last decade has led to the development of MR Conditional CIEDs (Figure 12). With such devices, MR imaging is possible – but device manufacturers have strict guidelines that must be followed and there can be no other indications that would prevent safe scanning. Main device-specific considerations particularly refer to the field strength of the scanner (mostly 1.5 T), the permitted scan zone (no thoracic exclusion zone), and sequence specific SAR (<2.0 W/kg). Today, there are MR Conditional PMs, ICD, and CRT-Ds – and even 3.0-Tesla MR is possible with several of these devices.

RF and gradient fields may interfere with their operation. Malfunction of the device could potentially cause pain or discomfort to the patient or damage the nerve fibers at the site of the implanted electrodes. Additional concerns include the potential for heating of the neurostimulator, its leads, lead electrodes, and subsequent thermal injury to surrounding tissue.

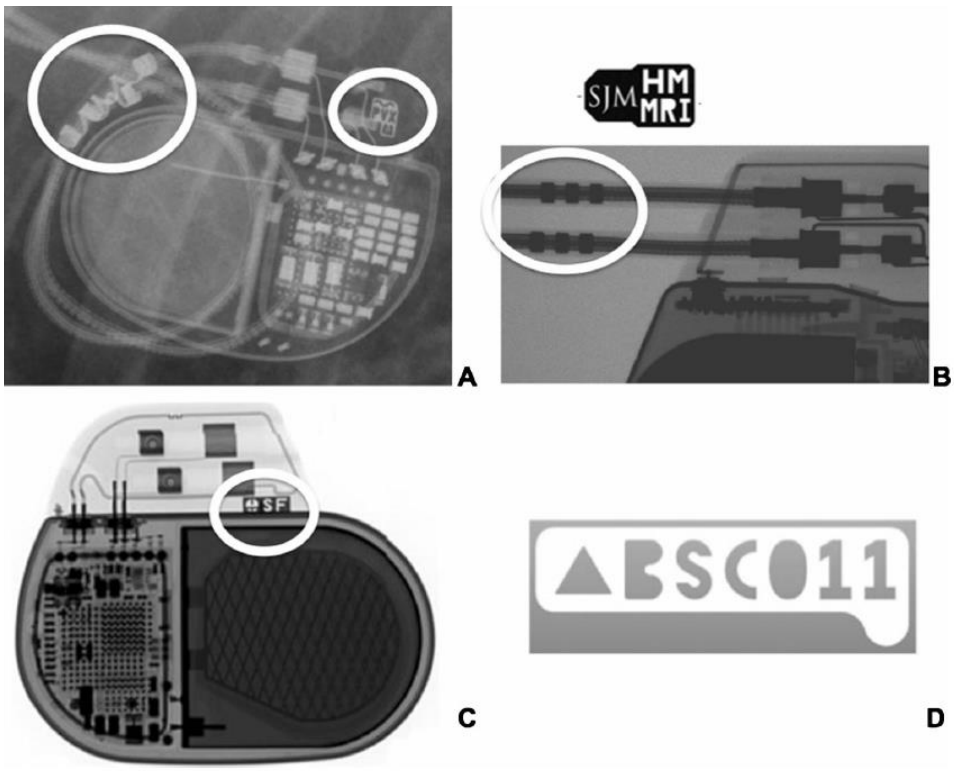

Figure 12. Vendor-specific markers on MR Conditional pacing systems identifiable on routine chest x-rays. (A) Medtronic. (B) St. Jude Medical. (C) Biotronik. (D) Boston Scientific. (From van der Graaf 2014)

RF heating risks may exist for patients who have retained epicardial or pericardial pacing wires, *even if the pulse generator has been removed*. See Figure 13 for a demonstration of "antenna effect" focal heating.

For pacemaker patients undergoing MR exams (Fowler 2017):

- Call the device manufacturer with patient name and birthday to verify the pulse generator and the leads are MR Safe or MR Conditional. Both the generator AND the leads must be from same manufacturer.
- Obtain a statement from the cardiologist stating that the device can be placed into MR Mode.
- Page the manufacturer representative to coordinate the MR scan time.
- An ACLS-certified RN, PA, or NP must monitor the patient.
- When the device is switched to MR mode, the patient must be placed immediately on SPO_2, EKG, and BP monitors.
- Ask the representative if the device is in Continuous Pacing Mode (usually 60 bpm) or other mode.
- When scanning the patient, use low SAR mode, preferably on AV2 as this scanner has a lower gradient slew rate/rise time.
- When nearing the end of the exam (i.e., 10 minutes left), page the manufacturer representative so the device can be returned to Normal Operating Mode as soon as possible.

Note: *The most recent information from Medtronic (May 2017) no longer requires that the patient must be able to communicate with the staff during the MR exam.*

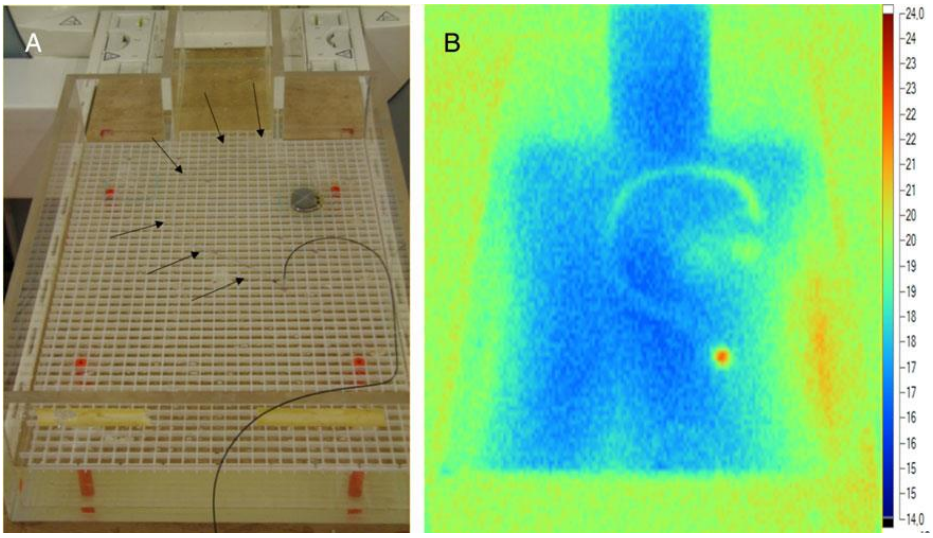

Figure 13. Visualization of RF-induced heating of pacemaker from "antenna effect." (A) Experimental setup emulating left thoracic implantation of conventional one-chamber pacemaker system in a gel-filled torso phantom. Arrows indicate pacemaker lead. Black temperature probe attached to tip of pacemaker lead. (B) Heat map assessed by infrared camera after 2 min of TSE sequence indicates temperature increase at lead tip. (From Nordbeck 2015.)

Neurostimulation (Neuromodulation) Systems

Neurostimulators are used to control pain, functional electronic stimulation or limb movement through the stimulation of muscles and nerves, deep brain stimulation in the treatment of involuntary movement (such as in Parkinson's Disease), neurostimulation for bladder/bowel control as continence devices, and vagus nerve stimulation for the control of epilepsy seizures.

These devices may either contain an integral power source or derive their power through coupling to an external part of the device. They may be implanted in the abdomen, the upper chest, or within or adjacent to limbs, with leads and electrodes running subcutaneously to the target site such as the spinal cord or the appropriate nerve or muscle requiring stimulation.

As described by Shellock ("Neurostimulation...," 2017), variables that impact MR-related heating include (but are not limited to):

- The specific type of neuromodulation system
- The electrical characteristics of the specific neuromodulation system
- The field strength and RF wavelength of the MR system
- The type of transmit RF coil (i.e. transmit head versus transmit body RF coil)
- The amount of RF energy delivered (i.e., the RF power level, SAR)
- The technique used to calculate or estimate SAR used by the MR system
- The patient's anatomy undergoing MR imaging
- The landmark position or body part undergoing MR relative to the transmit RF coil
- The orientation and configuration of the implantable pulse generator (IPG), extension (e.g., the cable connecting the pulse generator (PG) to the implanted lead), and the lead relative to the source of RF energy (i.e. the transmit RF coil).

Patients with implanted or retained wires in anatomically or functionally sensitive areas (e.g., myocardium or epicardium, implanted electrodes in the brain) should be considered at higher risk, especially from faster MR sequences, such as echo planar imaging (that may be used in such sequences as diffusion-weighted imaging, functional imaging, perfusion weighted imaging, MR angiographic imaging, etc.). The decision to limit the dB/dt (rate of magnetic field change) and maximum strength of the magnetic field of the gradient subsystems during imaging of such patients should be reviewed by an MR radiologist supervising the case or patient. (Kanal 2013)

Cerebrospinal Fluid (CSF) Shunt Valves and Accessories

CSF shunts are used for the treatment of hydrocephalus. They are positioned to enable the CSF to be drained from the cerebral ventricles or subarachnoid spaces into another absorption site (e.g., the right atrium of the heart or the peritoneal cavity) through a system of small catheters. A valve is inserted into the pathway of catheters keeps the CSF from flowing away from the brain and moderates the pressure or flow rate. Some valves are fixed pressure (i.e., monopressure) and others have adjustable or programmable settings. The drainage system enables the excess CSF with the brain to be evacuated, thereby reducing pressure within the cranium.

There are many different types of CSF shunt valves and associated accessories. For shunt valves that utilize magnetic components, highly specific safety guidelines must be followed in order to perform MR procedures safely in patients with these devices. For example, the magnetic field may change the pressure setting of programmable hydrocephalus shunts, resulting in over- or under-drainage of patient's CNS fluid. MR-related heating may also occur.

Passive Implantable Medical Devices

Passive implants require no power source for their function. Examples include orthopedic implants, clips, coils, stents, heart valves, and tissue expanders.

Orthopedic Implants, Materials, and Devices

Made from nonferromagnetic materials, most orthopedic implants and devices are MR Safe or MR Conditional. However, due to the length of the implant or the formation of a conductive loop, MR-related heating may be a problem for some orthopedic implants, especially cervical fixation devices and internal or external fixation systems ("Orthopedic Implants…," 2017). In addition, large metallic implants may significantly reduce image quality if near the imaging volume.

Graf (2006) reported torque on metal implants due to the induction of eddy currents from movement. While weak in fringe fields (especially for small parts), torque forces were considerable for larger implants (such as fixation devices) and increased with static field strength, steeper spatial gradients (dB/dx), and more rapid movement in the scanner. Furthermore, gradient switching was shown to produce fast alternating torque. Significant vibrations at off-center positions of the metal parts may explain why patients with an extended metallic implant sometimes report feeling sensations during MR exams.

Aneurysm Clips

The following information on aneurysm clips is taken from MRIsafety.com (at http://www.mrisafety.com/SafetyInfov.asp?SafetyInfoID=229).

Certain types of intracranial aneurysm clips (e.g., those made from martensitic stainless steels such as 17-7PH or 405 stainless steel) are contraindicated for MR procedures because excessive, magnetically induced forces can displace these implants and cause serious injury or death. In contrast, aneurysm clips classified as nonferromagnetic or weakly ferromagnetic (e.g., those made from Phynox, Elgiloy, austentitic stainless steels, titanium alloy, or commercially pure titanium) are acceptable for patients undergoing MR procedures ("Aneurysm Clips," 2017).

Many aneurysm clips have been tested for magnetic field interactions in association with 3-Tesla MR systems. If findings for specific implants indicated that they either exhibited no magnetic field interactions or relatively minor or weak magnetic field interactions, they are considered acceptable for patients undergoing MR procedures using MR systems operating at 3-Tesla or less.

There has never been a report of an injury to a patient or individual in the MR environment related to the presence of an aneurysm clip made from a nonmagnetic or weakly magnetic material. In fact, there have been cases in which patients with ferromagnetic aneurysm clips (based on the extent of the artifact seen during MR imaging or other information) have undergone MR procedures without sustaining injuries.

To date, only one ferromagnetic aneurysm clip-related fatality has been reported in peer-reviewed literature. According to this report, the patient became symptomatic at a distance of approximately 1.2-meters from the bore of the MR system, suggesting that translational attraction of the aneurysm clip was likely responsible for dislodgment of this implant.

This incident was the result of erroneous information pertaining to the type of aneurysm clip that was present in the patient – the clip was thought to be a nonmagnetic Yasargil aneurysm clip (Aesculap Inc.) and turned out to be a magnetic Vari-Angle clip (Codman & Shurtleff).

If a patient has a history of cerebral aneurysm surgery, the neurosurgeon is responsible for providing documentation regarding the device. This written documentation should be in the form of a chart insert or an operative note signed by the surgeon.

If a chart insert or operative note is not available, the neurosurgeon may provide documentation that includes the patient's name and date of birth, the clip manufacturer, type, and model number. This information ***must not be*** accepted verbally from the neurosurgeon's office staff –written documentation signed by the neurosurgeon is required for our records.

Effects of Long-Term and Multiple Exposures to the MR System

There are patients with implanted aneurysm clips previously tested and designated as MR Safe or MR Conditional who have undergone repeated exposures to strong magnetic fields during follow-up MR examinations. Long-term or multiple exposures to the strong magnetic fields in MR have been suggested to grossly magnetize aneurysm clips, even if they are made from nonferromagnetic or weakly ferromagnetic materials, presenting a substantial hazard to an individual in the MR environment. However, according to MRISafety.com ("Aneurysm Clips," 2017), a study of aneurysm clips made from Elgiloy, Phynox, titanium alloy, commercially pure titanium, and austenitic stainless steel concluded that long-term or multiple exposures to 1.5-Tesla MR systems should not result in significant changes in their magnetic properties.

Artifacts Associated with Aneurysm Clips

MR imaging and MR angiography are frequently used to evaluate the brain or cerebral vasculature of patients with aneurysm clips. Yet an additional problem associated with aneurysm clips is the artifacts they produce.

The size of the signal voids are related to the type of material (i.e., magnetic susceptibility) used to make a particular clip. Clearly, an aneurysm clip that causes a relatively large artifact is less desirable because it can impact the diagnostic capabilities of the MR procedure if the area of interest is in the immediate location of where the aneurysm clip was implanted. Fortunately, aneurysm clips exist that are made from materials (i.e., commercially pure titanium and titanium alloy) that create minimal artifacts.

Burtscher (1998) conducted artifact research to determine the extent to which titanium aneurysm clips could improve the quality of MR imaging compared to stainless steel aneurysm clips and to assess whether the associated artifacts could be reduced by controlling MR imaging parameters. His work concluded that the use of titanium aneurysm clips reduced MR artifacts by approximately 60% compared to stainless steel aneurysm clips. Additionally, using spin echo pulse sequences with high bandwidths further reduced MR imaging artifacts or, if necessary, gradient echo pulse sequences with a low echo times (TE).

Guidelines for Aneurysm Clips and MR Procedures

In consideration of the knowledge pertaining to aneurysm clips, the following guidelines are recommended with regard to performing an MR procedure in a patient with an aneurysm clip or before allowing an individual with an aneurysm clip into the MR environment:

1) Specific information (i.e., manufacturer, type or model, and material) about the aneurysm clip must be known, especially with respect to the material used to make the aneurysm clip, so that only patients or individuals with nonferromagnetic or weakly ferromagnetic clips are allowed into the MR environment. The manufacturer provides this information in the labeling of the aneurysm clip. The implanting surgeon is responsible for properly recording and communicating this information in the patient's or individual's records.
2) An aneurysm clip that is in its original package and 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. Aneurysm clips made from nonferromagnetic or weakly ferromagnetic materials in original packages do not require testing of ferromagnetism because the manufacturers ensure the pertinent MR safety or conditional aspects of these clips and, therefore, are responsible for the accuracy of the labeling.
3) If the aneurysm clip is not in its original package and/or properly labeled, it should undergo testing for magnetic field interactions following appropriate testing procedures to determine if it is safe or unsafe for the MR environment.
4) The MR Radiologist and implanting surgeon are responsible for evaluating the information pertaining to the aneurysm clip, verifying its accuracy, obtaining written documentation, and deciding to perform the MR procedure after considering the risk versus benefit aspects for a given patient.
5) Consideration must be given to the static magnetic field strength that is to be used for the MR procedure and the strength of the static magnetic field that was used to test magnetic field interactions for the aneurysm clip in question.

Coils, Filters, Stents, and Grafts

A wide variety of coils, stents, filters and vascular grafts have been evaluated for MR safety. Implants made of nonferromagnetic materials are acceptable for patients relative to the use of the particular field strength used for the *ex vivo* testing. Notably, **it is not necessary to wait after surgery to perform an MR procedure in a patient with a passive metallic implant that is made from a *nonmagnetic* material** ("Coils, Filters,...," 2017).

Although most coils, stents, filters and vascular grafts are made from nonferromagnetic materials, some have demonstrated magnetic field interactions.

Patients who have undergone recently placement of an IVC filter must wait ***at least*** one month before receiving an MR exam.

If an MR exam is requested by the referring physician less than one month after filter placement, the MR technologist must contact ***an MR Radiologist*** to authorize the MR procedure.

Fortunately, the devices that exhibited positive magnetic field interactions typically become incorporated securely in tissue within *six weeks* after implantation due to ingrowth and other mechanisms. Therefore, for most of these devices that have been tested, it is unlikely that these implants would become moved or dislodged as a result of exposure to MR systems operating at 1.5-Tesla or less.

To date, there has been no reported case of excessive heating in association with MR and these types of implants ("Coils, Filters,...," 2017). However, MR-related heating may be of concern for certain configurations or shapes for coils, stents, filters, and vascular grafts.

Taal (1997) demonstrated that not all stents are safe for patients undergoing MR procedures. This study reported that "an appreciable attraction force and torque" was found for the Gianturco stent (William Cook Europe) and the modified Gianturco stent by Song (Sooho Meditech Company). Both of these are self-expandable esophageal stents and are made of stainless steel. Based upon these results, the investigators advised, "…specific information on the type of stent is necessary before a magnetic resonance imaging examination is planned."

Vascular grafts frequently have clips or fasteners applied that may present problems for MR due to the associated imaging artifacts. Weishaupt (2000) evaluated the artifact size on three-dimensional MR angiograms as well as the MR issues for 18 different commercially available hemostatic and ligating clips. The artifact size was dependent on clip size, clip orientation, echo time, and degree of k-space coverage. At 1.5-Telsa, there was no substantial magnetic field interaction or heating measured for the implants.

Different coils, stents, filters and vascular grafts have been evaluated at 3-Tesla. Of these implants, two displayed magnetic field interactions that exceeded the ASTM International guideline for safety (i.e. the deflection angles were greater than 45°). However, similar to other comparable implants, tissue ingrowth and other mechanisms are sufficient to prevent them from posing a substantial risk to a patient or individual in the 3-Tesla MR environment.

Bare Metal and Drug Eluting Coronary Artery Stents

Patients with coronary artery disease are often treated by percutaneous transluminal coronary angioplasty (PTCA). Re-narrowing at the angioplasty site, or restenosis, occurs in as many as 50% of patients following PTCA. Therefore, after coronary artery intervention, either a bare metal or drug eluting stent may be placed in an effort to prevent restenosis.

MR safety information has been obtained for many bare metal and drug eluting coronary artery stents, which have been reported to be acceptable for patients undergoing MR procedures at 3-Tesla or less (i.e. based on assessments of magnetic field interactions and MR-related heating). Notably, for these coronary artery stents, patients may undergo MR procedures immediately after placement ("Coils, Filters,...," 2017 and "Coronary Artery Stents…," 2017).

1. Patients with all commercially available coronary artery stents (including drug-eluting and non-drug eluting or bare metal versions) can be scanned at 1.5-Tesla/64-MHz or 3-T/128-MHz, regardless of the value of the spatial gradient magnetic field
2. Patients with all commercially available coronary artery stents can undergo MR immediately after placement of these implants.
3. The MR exam must be performed using the following parameters:
   - 1.5-Tesla or 3-Tesla, only
   - Whole body averaged specific absorption rate (SAR) of 2-W/kg, operating in the Normal Operating Mode for the MR system
   - Maximum imaging time, 15 minutes per pulse sequence (multiple sequences per patient are allowed)

Heart Valves and Annulosplasty Rings

Under testing conditions, the measured attraction of heart valves and annulosplasty rings to the static magnetic field is minimal compared to the force exerted by the beating heart (Kanal 2017).

There has been no report of a patient incident or injury related to the presence of these devices. However, not all heart valve prostheses have been evaluated and at least one prototype exists that has magnetic components ("Heart Valves…," 2017). Accordingly, the MR technologist should refer to the manufacturer for MR safety guidance.

Hemostatic Clips, Other Clips, Fasteners, and Staples

According to MRIsafety.com (Hemostatic Clips…," 2017), various hemostatic vascular clips, other types of clips, fasteners, and staples made from nonferromagnetic materials such as tantalum, commercially pure titanium, and nonferromagnetic forms of stainless steel have been evaluated and are not attracted by static magnetic fields of MR systems operating at 3-Telsa or less. In addition, some forms of ligating, hemostatic, or other types of clips are made from biodegradable material. Therefore, patients that have implants made from nonmagnetic or "weakly" magnetic materials are not at risk for injury during MR procedures. More importantly, for devices that have been tested to date, there has been no report of an injury to a patient with a hemostatic vascular clip, other type of clip, fastener, or staple in the MR environment. **Patients with *nonferromagnetic* versions of these implants may undergo MR exams immediately after they are placed.**

MR personnel must screen each patient for endoscopic clips. For those patients who have undergone upper endoscopy or colonoscopy within 30 days of the MR exam, the MR technologist or operations assistant (as directed by the technologist) should obtain a medical order for the following x-rays for the purpose of MR safety screening:

- Supine abdominal images include entire abdomen and pelvis from diaphragm to rectum.

Specific MR-related labeling statements for certain *endoscopic* hemostatic clips require further attention during the pre-MR screening procedure. These include ("Hemostatic Clips…," 2017):

- Long Clip, HX-600-090L (Olympus Medical Systems Corporation)
- QuickClip2, HX-201LR-135 & HX-201UR-135 (Olympus Medical Systems Corporation)
- QuickClip2 Long, HX-201LR-135L & HX-201UR-135L (Olympus Medical Systems Corporation)
- TriClip Endoscopic Clipping Device (Wilson-Cook Medical, Inc.)

Olympus Endoscopic Clips

While GI clips are designed to eventually pass through the body, Olympus endoscopic clips have been shown to remain in the patient an average of 9.4 days. Retention, however, is based on a variety of factors and may result in a longer retention period.

Because Olympus clip fixing devices are radiopaque, they are identifiable on x-rays. Therefore, all patients who have undergone upper endoscopy and colonoscopy within 30 days of the MR procedure should be screened for retained residual clips via radiographic imaging. An MR Radiologist must review the x-ray and specifically authorize the MR procedure.

TriClip Endoscopic Clipping Device

A study by Gill (2009) involved exposing excised tissue to a 1.5-Tesla MR system. Because the TriClip demonstrated "detachment from gastric tissue," it should be considered MR Unsafe.

Ocular Implants, Lens Implants, and Devices

Various ocular implants, lens implants, and devices have undergone MR testing. Their potential risks range from patient discomfort to implant movement or dislodgement causing tissue damage and possible loss of vision. They may also produce problematic imaging artifacts.

While many lens implants pose no MR hazard because they are not made from metallic or conducting material, several have demonstrated positive magnetic field interactions in association with 1.5-Telsa MR systems. These include the Fatio eyelid spring, the Unitek round wire eyelid spring, the retinal tack made from martensitic (i.e., ferromagnetic) stainless steel, and the Troutman magnetic ocular implant ("Ocular...," 2017).

A patient with a Fatio eyelid spring or Unitek round wire eyelid spring may experience discomfort but would probably not be injured as a result of exposure to an MR system. In fact, patients have undergone MR exams with eyelid wires after having a protective plastic covering placed around the globe along with a firmly applied eye patch as a precaution.

The retinal tack made from martensitic stainless steel and Troutman magnetic ocular implant may injure a patient undergoing an MR procedure, although no such case has ever been reported ("Ocular...," 2017).

To rule out a retinal tack or scleral buckle, the MR technologist or operations assistant (as directed by the technologist) should obtain a medical order for the following radiographs for the purpose of MR safety screening:

- Two identical Water's views (same projection, not tilted) of the orbits.

Table 3. MR imaging compatibility of implanted devices used by ophthalmologists (Reiter 2015).

Implanted Device	MR Compatibility
EX-PRESS glaucoma filtration device	Safe up to 3 T
Glaucoma drainage devices	All types are safe
Artificial intraocular lens	All types are safe
Scleral buckling element	All tantalum clips are safe
Orbital implants after enucleation	All types are safe[a]
Gold- and platinum-weighted eyelid implants	Safe up to 3 T
Punctal plugs	All types are safe

[b] Except older magnetic orbital implants that were used in the 1940s-1950s.

Intraocular lenses (IOLs)

van Rijn (2012) tested in a 7-Tesla scanner a set of 23 intraocular lenses (IOLs) that ranged with regard to the presence of dyes and metals and geometric shapes. The IOLs were positioned in a phantom gel and scanned using a three-dimensional gradient echo (GRE) sequence. Images were visually inspected to determine the spatial extent of any signal voids. Fiber-optic temperature probes were utilized to measure the RF heating using a GRE sequence with powers 10 time higher than clinical settings.

Results showed no significant displacement of any of the tested IOLs. However, a significant magnetic susceptibility artifact was caused by the small platinum component of the Work Platinum Clip IOL. (None of the other 22 IOLs caused measurable artifacts.) Measurements of RF-induced heating in the IOLs showed no significant temperature rise (<0.25°C).

One study (van Rijn 2012) of a set of 23 intraocular lenses (IOLs) in a 7-Tesla scanner indicated that MR scanning did not induce movement or RF heating of any of the cataract lens replacements. However, one IOL (the Worst Platinum Clip) caused a significant imaging artifact.

Contact Lenses

Tokue (2013) reported that circle contact lenses (also known as color contact lenses and big eye contact lenses) used for cosmetic purposes usually contain iron oxide and other metals that yield susceptibility artifacts. (Figure 14).

Although prescription, non-tinted contact lenses may be worn by the patient during MR exams, tinted contacts should be removed for any exam that results in RF exposure to the eyes.

Figure 14. A 28 year old female wearing circle contact lenses. (From Tokue 2013)

Otologic Implants

Passive otologic implants consist of ventilation (or "vent") tubes and those devices used in tympanoplasty (i.e., surgery to reconstruct the tympanic membrane or eardrum) and stapedioplasty (i.e., surgery to address hearing loss usually caused by otosclerosis that includes stapedotomy and stapedectomy).

In addition to the McGee stapedectomy piston prosthesis, there are several other **MR Unsafe otologic implants**, including the following ("Otologic implants," 2017):

- Tuebingen Type Ventilation Tubes with Wire, Gold-Platinum, Stainless steel
- Tuebingen Type Ventilation Tubes with Wire, Gilded Silver, Stainless Steel
- Tuebingen Type Ventilation Tubes with Wire, Pure Titanium, Stainless Steel
- Minimal Type Ventilation Tube, Gold-coated, Stainless Steel

The McGee stapedectomy piston prosthesis, made from platinum and chromium-nickel alloy stainless steel, is ferromagnetic and has been recalled by the manufacturer. ***Patients who received this device have been issued warnings to avoid MR procedures.*** (See MRISafety.com for the specific item and lot numbers of the recalled McGee implants that are considered to be a contraindication for MR procedures.)

Many otologic implants have been evaluated for magnetic field interactions at 3-Tesla. (See THE LIST (http://mrisafety.com/Thelist_search.asp.) Considering the relatively small size of these devices, MR-related heating is not a concern at 3-Telsa and all those tested are considered to be acceptable for patients based on findings for translational attraction, torque, and according to the intended uses of the specified devices ("Otologic implants," 2017).

Penile Implants

There are number of penile implants available on the market. Under testing conditions, some have exhibited either no magnetic field interactions or relatively minor or weak magnetic field interactions whereas some have demonstrated substantial ferromagnetic qualities when exposed to a 1.5-Telsa MR system. Fortunately, for the latter, it is unlikely that a penile implant would injure severely a patient undergoing an MR exam. However, for certain implants, MR is inadvisable due to patient discomfort.

Intrauterine Devices (IUDs) and Other Contraceptive Devices

IUDs are typically made from combination of nonmetallic (i.e., plastic) and metallic materials. While copper is commonly the metal component, stainless steel and other metals may be used.

Several copper IUDs have been tested and are safe for patients in MR systems operating at 3-Telsa or less. However, an artifact may be seen for the metallic components. (The extent of the artifact is small due to the magnetic susceptibility of copper.) Note that none of the stainless steel IUDs have been tested to determine whether they are acceptable for patients undergoing MR procedures ("Intrauterine Contraceptive…", 2017).

Mirena Intrauterine System (IUS)

The Mirena IUS is a hormone-releasing device that contains levonorgestrel to prevent pregnancy. This T-shaped device is made entirely from nonmetallic materials that include polyethylene, barium sulfate (i.e. which makes it radiopaque), and silicone. Accordingly, the Mirena is safe for patients undergoing MR procedures using MR systems operating at all static magnetic field strengths.

Implanon Implant

The Implanon implant (Etonogestrel) is a single-rod, nonmetallic, subdermal device that offers women up to three years of contraceptive protection. This implant is acceptable for patients undergoing MR procedures at all static magnetic field strengths – it is MR Safe.

Diaphragms

Contraceptive diaphragms may have a metallic ring that maintains it in position during use and may cause significant image artifacts. However, there is no danger of heating under conditions currently recommended by the FDA. Furthermore, MR examinations have been performed in patients without complaints or adverse sensations related to movement.

Although the presence of a diaphragm is no a contraindication for a patient undergoing an MR examination using an MR system operating at 3-Tesla or less, it is best to remove a contraceptive diaphragm prior to an MR procedure ("Diaphragms…," 2018).

Breast Tissue Expanders and Implants

Breast tissue expanders and mammary implants include injection sites that are used for saline placement to expand the prosthesis during surgery. This injection port may contain stainless steel to guard against piercing the port by the needle used to fill the implant. But it may also be a magnetic port to allow for more accurate detection of the injection site.

While the stainless steel port may not pose a serious hazard to a patient undergoing an MR exam, a magnetic port will produce relatively large artifacts on MR images that are problematic to assessment of breast tissue pathology. Furthermore, the magnetic port is substantially attracted to the static magnetic field of an MR system and, therefore, may be uncomfortable, injurious, or contraindicated for patients undergoing MR procedures.

One particular tissue expander, the MAGNA-SITE (McGhan Medical/INAMED Aesthetics; Allergan, Inc.) is MR Unsafe. Its Product Information document states *"Diagnostic testing with Magnetic Resonance Imaging (MRI) is contraindicated in patients with MAGNA-SITE expanders in place. The MRI equipment could cause movement of the MAGNA-SITE breast tissue expander, and result in not only patient discomfort, but also expander displacement, requiring revision surgery. In addition, the MAGNA-SITE magnet could interfere with MRI detection capabilities."*

Transdermal Patches

Medication Patches

While the transdermal market is dominated by hormone replacement therapy (HRT) patches, patches are also used for delivery of testosterone, nicotine, nitroglycerine, analgesics, and cold and sinus remedies. Because some drug patches contain metallic foil, scanning them may result in thermal injury or burn to the patient. In addition, exposure of a fentanyl patch to a heat source may result in increased absorption of the drug, resulting in overdosing of the opioid (MedlinePlus 2017). Consequently, **all transdermal medication**

patches located within the field of view that will be exposed to RF radiation (i.e., the transmit RF coil) during the MR procedure must be removed from the patient before entering the MR environment.

If the body part with the medication patch is not within the transmit RF coil during the exam, there is no risk of heating to the patient. For example, if the patient is wearing a medication patch on his/her torso and is scheduled to undergo an MR exam of the brain using a transmit/receive coil, the patch may remain on during the exam.

Before any MR procedure, each patient must be screened to determine if the patient has a transdermal patch. If the patch is located in the field of view that will be exposed to RF radiation (i.e., the transmit RF coil) during the MR procedure, it must be removed prior to the exam.

For Inpatients

- An MR technologist or operations assistant must contact the patient's nurse to inform him/her of the scheduled MR procedure.
- The patient's nurse must confirm whether the patient is wearing a transdermal patch.
- If the patient is wearing a transdermal patch that is contraindicated for the scheduled MR exam, the nurse should contact the physician for instructions regarding medical coverage during the procedure and for patch replacement orders. Before the patient leaves the floor for the MR Department, the nurse must remove and dispose of the patch per hospital policy.
- The MR technologist must screen the patient in Zone II for the presence of transdermal patches. If the patient arrives in the MR Department and the patch has not been removed, the floor nurse will be required to come to the department to remove the patch.
- Upon completion of the MR procedure and the patient's return to his/her room, the patient's nurse will apply a replacement patch as ordered by the patient's physician.

For Outpatients

- The MR technologist must screen each patient in Zone II for the presence of any transdermal patch.
- If the patient is wearing a patch located within the field of view that will be exposed to the RF radiation during the MR procedure, the patch must be removed prior to the exam.
  - If the patch delivers an over-the-counter (OTC) product, the technologist must have the patient remove the patch and discard it. (The patch should not be re-used.)
  - If the patch delivers prescription medication, the physician responsible for prescribing the patch should be contacted to determine if the patch may be removed temporarily during the MR procedure. After the MR exam, a new patch should be applied following the directions of the prescribing physician.

Other Therapy Delivery Patches

The ActiPatch (BioElectronics) is a medical, drug-free device that delivers pulsed electromagnetic frequency therapies to accelerate healing of soft tissue injuries ("Transdermal Medication…," 2017). The ActiPatch has an embedded battery-operated microchip that delivers continuous pulsed therapy to reduce pain and swelling. Accordingly, the patch must be removed prior to performing an MR procedure to prevent possible damage to the device and the potential risk of excessive heating.

Because the BioElectronics ActiPatch healing patch contains a battery-operated microchip, it must be removed for any MR exam to prevent damage to the device and the risk of potential heating.

Tattoos

MR exams of patients with tattoos, including permanent eye makeup, using iron oxide-based pigments have shown artifacts around those regions as well as local edema (Kangarlu 2014).

When imaging patients with extensive or dark tattoos in the area of the body subject to RF exposure, the MR technologist must decrease the potential for RF heating of the tattooed tissue. As a precautionary measure, a cold compress or ice pack wrapped in a dry towel should be placed on the tattooed area and kept in place during the entire MR exam (Kanal 2013). This is especially appropriate for FSE (or other high RF duty cycle) sequences.

If the patient's tattoos are within the volume of the RF transmit coil, the MR technologist should place a cold compress or an ice pack wrapped in a dry towel on the tattooed area. This heat sink should remain in place for the duration of the exam.

During screening, MR personnel should ask the patient if he/she has had any permanent coloring applied to any part of the body. This is includes not only decorative designs of conventional tattoos, but eyeliner, lip liner, and lip coloring. Patients who have received their tattoo within 48 hours prior to the MR exam should be advised by MR personnel of the potential for smearing or smudging of the edges of the freshly placed tattoo.

Makeup

Imaging artifacts associated with the presence of iron oxide or other types of metal in pigments have been reported for certain types of eye makeup. Accordingly, the patient should remove excessive eye make-up (including mascara, eye liner, and eye shadow) prior to undergoing an MR exam of that will require RF exposure to the eyelids.

Patients should remove eye excessive makeup (including eye liner, mascara, and eye shadow) prior an MR exam that will require RF exposure to the eyelids.

Metallic Foreign Bodies

Penetrating Foreign Body in Eye

If the patient has a history of an eye injury with any type of metallic object, the patient must be screened with orbital radiographic images to assess the presence of metallic foreign body. A radiologist must review the x-rays and authorize the MR procedure. The MR technologist must document on the MRI Patient Screening Form the name of the radiologist who approved the exam.

If the patient has a history of an eye injury with any type of metallic object, the MR technologist or operations assistant (as directed by the technologist) should obtain a medical order for the following radiographs for the purpose of MR safety screening:

- Two identical Water's views (same projection, not tilted) of the orbits.

Any radiologist may review the radiographs and clear the orbits for metal.

Pellets, Bullets, and Shrapnel

The majority of pellets and bullets tested in the MR environment have been found to be composed of nonferromagnetic materials. However, they are often contaminated with ferromagnetic metals. Testing has indicated that ferromagnetic ammunition tends to be manufactured in foreign countries and/or used for military applications. Shrapnel typically contains steel and therefore present a potential hazard for MR imaging. Both steel containing and non-steel containing bullets did not significantly heat, even under extreme MR conditions at 3-T (Dedini 2013). Notably, in an effort to reduce lead poisoning in "puddling" type ducks, the federal government requires many states in the eastern US to use steel shotgun pellets rather than lead.

Because pellets, bullets, and shrapnel are frequently contaminated with or made of ferromagnetic materials, the risk versus benefit of performing an MR procedure should be carefully considered on a case-by-case basis by the MR Radiologist. Consideration must be given to a metallic object that is located near or in a vital anatomic structure with the assumption that the object is likely ferromagnetic and can potentially move. Furthermore, the artifacts can be substantial at the immediate position of the metal object(s).

Body Piercing

Even if body piercing is made from nonferromagnetic materials, it may cause artifacts or may be subject to RF-related heating if it is near the imaging volume. As a precautionary measure, the patient should remove all body piercings prior to the MR exam.

Indwelling Catheters

Depending upon the type and manufacturer, indwelling catheters may contain ferromagnetic material or metal. Accordingly, the MR technologist prior to imaging the patient must confirm the MR safety label of the device.

Certain Foley catheters have sensors to measure the temperature of the urine in the bladder and are MR Conditional.

Dental Implants, Devices, and Materials

Most dental implants, devices, and materials made from ferromagnetic materials (with the exception of dental implants that incorporate magnetically-activated components) tend to be held in place with sufficient counter-forces to prevent them from causing problems related to movement or dislodgment in association with MR systems operating 3-Tesla or less. In addition, for the dental devices that have undergone evaluation, MR-related heating does not appear to pose problems.

Dental devices with magnetically-activated components present potential problems during MR exams. The issues include possible demagnetization of the magnetic components and substantial image artifacts produced by the magnetic components.

Skin Staples and Superficial Metallic Sutures

Patients with skin staples or superficial metallic structures (SMS) may undergo an MR exam provided the devices are not ferromagnetic and are not in the anatomic volume of RF power deposition for the study to be performed.

If the devices are within the volume to be RF-irradiated, the MR technologist should:

- Warn the patient and make sure that he/she is especially aware of the possibility of experiencing warmth or even burning along the skin staple or SMS distribution. Instruct the patient to report **immediately** this warming or burning sensation and not to wait until the “end of the knocking noise.”

- Place a cold compress or ice pack wrapped in a dry cloth along the skin staples or SMS if it can be safely clinically accomplished during the MR exam. (This will serve as a heat sink for any power deposition that may occur, thus decreasing the likelihood of a clinically significant thermal injury or burn to the adjacent tissue.)

Assistive Technology

Assistive technology includes assistive, adaptive, and rehabilitative devices for individuals with disabilities.

Mobility Tools

Orthoses and prosthetic limbs must be removed from the patient prior to the MR exam.

Hearing Tools

Hearing aids must be removed from the patient prior to the MR exam.

Vision Tools

Devices for visual impairment include eSight electronic eyeglasses (eSight Corporation) and Brainport V100 oral electronic vision aids (Wicab, Inc.). Both of these devices must be removed prior to the MR exam.

Another device for visual impairment is the Argus II Retinal Prosthesis System (Second Sight Medical Products, Inc.) used in patients with severe to profound retinitis pigmentosa. Also known as the Bionic Eye or Retinal Implant, it provides electrical stimulation of the retina to induce visual perception in blind individuals.

The Argus II system includes a retinal implant, a miniature video camera housed in the patient's glasses, and a small computer or video processing unit (VPU) worn by the patient. The Argus II retinal implant is MR Conditional so MR imaging of these patients is possible, but only on a 1.5-Tesla or 3.0-Tesla system and only if all other manufacturer specified conditions are met. However, the patient's glasses and the VPU must be removed before the patient enters the MR environment.

SCANNING PATIENTS CONTRAINDICATED FOR MR

Although there is a significant number of implantable medical devices that are either MR Safe or MR Conditional, MR technologists may be faced with the following scenarios that require significant effort to provide safe patient care: