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Guidelines for MRI Clearance of Patients with Metallic SUBJECT: **Implants of Uncertain Identity**

PURPOSE:

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To establish a systematic approach for safely performing MRI exams of patients with metallic implants of uncertain identity. In all MRI facilities, a recurring challenge occurs whereby MRI safety screening procedures identify a patient with an implanted metallic object of uncertain/unknown identity. Despite the best attempts of the MRI safety team, there are many situations where accurate identification of the implant cannot be determined.

PROCEDURE:

Standard procedure and published guidelines (e.g., ACR MRI Safety Guidelines) recommend that the identity of the object be ascertained to determine whether the patient can enter the MRI environment and be scanned safely. However, it is also widely appreciated and noted in the ACR guidelines that in many circumstances the risk of injury to the patient is very low and outweighed by the diagnostic information that would be provided by the MRI exam. Therefore, it is acceptable, under local guidelines, to perform the MRI study despite incomplete information regarding the exact nature of the metallic implant. Unfortunately, there are understandable inconsistencies in the algorithm determining which patients can safely undergo MRI procedures and which patients should not. For this reason, there is an unmet need to provide a standardized approach to ensure that important safety principles are followed, while balancing the need to obtain important diagnostic information essential for guiding treatment of the patient.

POLICY:

Iowa Radiology has reviewed and approved the following principles for scanning patients with metallic implants of uncertain identity:

- 1. All attempts should be made to obtain written documentation to identify specific implants. The procedures outlined in this document and subsequent addenda should never replace good faith attempts to identify an implanted device.
- 2. If the identity of the metallic implant is determined, but there are no published MRI safety recommendations, the guidelines suggested by this memo can be used.
- 3. Iowa Radiology will follow published MRI safety guidelines as closely as possible. These guidelines recognize that the need to obtain diagnostic information may outweigh the potential risk of injury in some circumstances. The committee also understands that it is standard of care at many institutions to scan some patients with implanted devices of unknown origin in appropriate situations. A standardized approach is advocated to mitigate uncertainty associated with this approach.
- 4. Informed consent is neither required nor recommended for this approach, since, by definition, implants discussed in this document are of unknown identity and, therefore, the specific risk of injury is unknown.

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- 5. A successful prior MRI exam is not sufficient to "clear" any metallic implant whose identity is known or unknown. This principle applies broadly to MRI safety practices.
- 6. Consideration should be given to limiting scanning to 1.5T in these patients.

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- 7. If questions regarding the safe scanning of a patient remain following the screening process, a radiologist should be consulted.
- 8. The use of radiography or CT to identify the nature and location of metallic implants (e.g., location of shrapnel in patients with known gunshot wounds) may be appropriate. This is already performed routinely in patients identified at risk for ocular metal foreign bodies. The use of radiography in unconscious patients with no known medical history may also be appropriate. Thorough documentation of findings from radiographs obtained for the purpose of metallic implant detection or characterization should be made to avoid unnecessary repeat radiographs for future MRI exams (unless new metallic implants are placed).
- 9. Consideration for alternative diagnostic methods should be made, depending on the nature of the clinical question, availability of alternative diagnostic methods and the potential risk from the metallic implant.
- 10. Individuals accompanying a patient (e.g., a parent) may not enter Zone 4 (scanner room) if they have a metallic implant of unknown identity, unless this is addressed specifically by one of the general classes of implant (below).
- 11. Scanning of patients with metallic implants of unknown identity should not be performed in research subjects, unless explicitly permitted under an IRB approved protocol.
- 12. In general, no waiting period is necessary for patients who have recently undergone procedure/implant placement prior to their MRI. Notable exceptions include recent pacemaker lead placement (please see "Pacemaker Guidelines").
- 13. It is also recognized that patients are often aware that they have a general class of metallic implant (e.g., shrapnel, coronary stent, etc.), but have no information on the specific make or model. Even when medical records can be obtained, they often do not contain the necessary information. However, knowledge of the general class of implant can help guide whether to scan the patient, even when the specific make, model or other relevant information is not available. Based on the general safety profile of these classes of implants, general approaches to MRI scanning will be developed by Iowa Radiology radiologists for approval.
- 14. The following represent classes of implants that the committee has determined *cannot* be scanned safely unless the identity of the implant is determined and documentation regarding the safe use of MRI with those implants is obtained:
 - a. All non-cardiac stimulator and pump devices (including ventriculostomy pumps) that contain electronics and/or electronic leads, as well as abandoned leads, will not be permitted for any MRI scanning, unless the specific device can be identified and there are guidelines and procedures available from the manufacturer for safe MRI scanning.
 - b. Patients with neurovascular aneurysm clips of uncertain identity will not be scanned.
- 15. Recently-developed guidelines for cardiac pacemakers and ICD devices include consideration for pacemakers of unknown identity. Please see those guidelines.

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- 16. The following classes of implants have been reviewed and guidelines regarding specific safety recommendations have been addressed in the Appendix (see attached):
 - Non-coronary vascular and biliary metallic stents, endostents, IVC filters and non-neuro embolization coils.
 - Coronary artery stents.
 - Cardiac valves.
 - GI Clips

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- Neuro-embolization coils.
- Shrapnel, non-medical metallic foreign bodies, etc.
- Unresponsive patients with inadequate medical records needed to confirm the absence of metallic implants.
- Penile Implants
- Intra-uterine devices (IUDs).
- Orthopedic hardware, including recent surgery.
- Unknown Scleral Buckles
- History of Orbital Trauma
- Metallic piercings, tattoos and other metallic cosmetic materials / devices
- Skin Staples and Drug Delivery Patches
- Vascular Access Ports
- Maximum Spatial Gradient
- Waiting Period Following Surgery per Dr Frank Shellock (founder of MRISafety.com)
- 17. A subgroup of radiologists with expertise in clinical areas relevant to these implants will meet, review the literature and make standardized recommendations that will form an addendum to this document. Furthermore, as new types or classes of devices arise or become more clinically relevant, additional groups of metallic implants may be appended to this document.

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MRI Guidelines for Technologists/Providers for Unknown/Unverified Implants

How to use the guidelines: The following document is part of an on-going effort by Iowa Radiology to establish guidelines regarding the appropriateness of MRI scanning of implants that either do not have specific manufacturer recommendations regarding their MRI compatibility OR cannot be specifically identified/verified due to unavailability of relevant information in the patient's chart.

• For MRI Technologists:

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- This document has been reviewed by Iowa Radiology physicians and is specifically designed for the MRI Technologists to use during the MRI screening process.
- <u>Unless otherwise specified</u>, the MRI Technologists may use this document to review unknown/unverified implants at their own discretion WITHOUT a radiologist's input.
 - Certain unknown/unverified implants WILL require Radiologist input and will be **color-coded (red).**
 - If there are specific questions regarding an item that does not appear on this list, or if

clarification of a guideline is needed, then the MRI technologist should contact a radiologist.
 If the implant can be verified specifically by manufacturer make/model, then any specific recommendations made by the manufacturer or on MRISafety.com generally supersede any of the recommendations in this document.

• As always, **common sense is paramount**, and if there is any doubt, please discuss with a Radiologist.

For Radiologists:

• If the unknown/unverified implant is not on this list, then the case should be reviewed and scanned at the discretion of the Radiologist after considerations such as the necessity of MRI that may necessitate discussion with the ordering provider, alternative imaging methods, and risk/benefits for performing the MRI.

• For Ordering Providers:

• Patient Safety and Screening is of the MRI staff's utmost concern.

• This document is not comprehensive but reflects the best and on-going efforts by Iowa Radiology to establish general safety guidelines after soliciting advice from multiple national and international MRI safety experts.

• If the patient's implants cannot be verified, then the Radiologist may contact you, as the ordering provider, to discuss necessity of MRI or alternative imaging methods.

• Please provide as much history as possible, particularly if there is specific history that will focus the imaging exam by the Radiologist (ie. if patient is aware of a specific foreign body/implant)

Assessing Unresponsive Patients with Insufficient Clinical History to Exclude Metallic Implants a. Radiologist Discretion is Required.

a. Only a radiologist can clear <u>an unresponsive</u> patient for MRI (no other services can clear patient for MRI without Radiologist input).

b. All unresponsive patients must be screened.

c. Assessment for foreign implant positioning near any critical anatomical structures should be performed by the covering Radiologist.



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- d. Recommended radiographic series for unresponsive patients includes radiographs of:
 - i. Minimum: Head/Neck (including orbits), entire torso (chest, abdomen/pelvis)
 - ii. Additional radiographs of proximal extremities (shoulders/humerus and hips/femurs) can also be considered.
 - iii. A Head CT can be substituted instead of Orbit radiographs.

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Appendix: MRI Guidelines for Technologists/Nurses/Providers for Unknown/Unverified Implants (continued)

Passive Vascular Implants/Coils/Stents/Filters (Continue below for more specific guidelines)

All patients with passive (no electronic components) vascular devices (e.g. coils, amplatz vascular occlude devices, arterial or venous stents, and IVC/SVC filters) that are within a blood vessel such as coils, amplatz vascular occlude devices, arterial or venous stents, and IVC filters implanted in the USA can be imaged at 1.5 or 3T immediately after implantation. For brain aneurysm clips and cardiac devices (e.g. pacemakers and defibrillators) please refer to separate policy in MRI Safety Manual.

Many older or discontinued devices have not undergone testing at 3T. Although it is preferred that patients with such an untested device undergo MRI at 1.5T, if a scan at 1.5T is not feasible or a 3T exam is preferred for legitimate clinical reasons, the patient may undergo MRI at 3T, however, 1.5T is preferred utilizing normal mode.

Minimum SAR for diagnostic clinical images will be used. The technologist has flexibility to edit scanner parameters.

Stent grafts are excluded and reviewed on a case by case basis.

Reference:

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https://medicine.yale.edu/diagnosticradiology/patientcare/policies/mri_safety_manual_november2022_284424_284_11023_v26.pdf (pg. 47)

 $https://medicine.uiowa.edu/radiology/sites/medicine.uiowa.edu.radiology/files/wysiwyg_uploads/mri-scanning-pts-with-stents-coils-heart-valves.pdf$

Coronary Artery Stents

- a. Coronary artery stents will remain part of the patient's screening process:
 - a. If the stents are known, then please follow manufacturer's recommendations.
 - b. If the stents are unknown, then coronary artery stents are okay to scan with several guidelines to consider:

a. Recommended Scanner Strength: 1.5T is preferred for unverified cardiac stents, and 3T should ONLY be used if the protocol requires 3T or if there is no 1.5T MRI scanner physically available at the site for use.

b. Recommended Operating Mode: Normal Mode

Reference: http://www.ismrm.org/smrt/safety_page/2017.Shellock.Coronary.Stent.MRI.Guidelines.pdf

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Cardiac Valves (including TAVR)

- a. Please follow manufacturer recommendations for known valves_
- b. All unknown cardiac valves are okay to be scanned, if the following guidelines are followed:

 a. Starr-Edwards caged-ball prosthesis valve (was only placed in 1960 to 1964) can only be scanned on 1.5T. A chest radiograph can be used to confirm its presence if patient had a cardiac valve placed during those years.

b. Recommended Scanner Strength: 1.5T is preferred for unverified cardiac valves, and 3T should ONLY be used if the protocol requires 3T or if there is no 1.5T MRI scanner physically available at the site for use.

c. Recommended Operating Mode: Normal Mode

Reference

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http://www.ismrm.org/smrt/safety_page/2016.Shellock.Heart.Valves.Annuloplasty.Rings.MRI.Guidelines.pdf

Biliary Endostents

a. All unverified biliary endostents are okay to scan with the following guidelines:

a. Recommended Scanner Strength: 1.5T is preferred for unverified biliary endostents, and 3T should ONLY be used if the protocol requires 3T or if there is no 1.5T MRI scanner physically available at the site for use.

b. Recommended Operating Mode: Normal Mode

IVC Filters

a. If IVC filters are completely unknown and cannot be identified, then it is okay to scan on IVC filters, but only (strictly) at $1.5T_{-}$

- b. If a 1.5T magnet is unavailable, then all IVC filters can be scanned on 3T EXCEPT:
 - a. Greenfield and Bird's Nest Filter: Should only be scanned on 1.5T
 - i. If a 3T scanner is the only option available at the site, an abdominal radiograph should be performed and evaluation for the characteristic configuration of Greenfield or Bird's Nest should be performed by the Radiologist. If a Greenfield or Bird's Nest IVC filter is present, the patient should be rescheduled for imaging at a site with a 1.5T scanner.
 - b. Recommended Scanner Strength: See above for guidelines.
 - c. Recommended Operating Mode: Normal Mode

Non-Neuroembolization Coils

- **a.** All coils placed within a blood vessel, implanted in the USA can be imaged at 1.5 or 3T
 - a. See Neuroembolization coils for guidelines on brain aneurysm coils



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GI Clips

- **a.** Pre-MRI safety screening in patients who may have had hemostasis clips placed during endoscopy or colonoscopy remains necessary. The concern is that torqueing of a ferromagnetic hemostasis clip in a strong magnetic field could lead to bleeding or injury at the site of biopsy / polypectomy.
 - **a. Resolution Clip**. Initially, this clip was considered MR unsafe but it is now considered MR conditional.
 - b. Olympus. There are several models of Olympus GI clips. Two of these models, "Quick-Clip 2" (HX-201LR-135 and HX-201UR-135) are considered MRI unsafe and are contraindications to MRI.
 - i. According to the package insert for the Olympus clips, it has been shown that Olympus clips are retained for an average of 9.4 days, but possibly longer. According to Shellock et al AJR 2008, 191:1-10, for a patient with a contraindicated Olympus clip, that "before MRI, the physician should confirm that there are no residual clips in the gastrointestinal tract". This can be done via abdominal radiograph or repeat endoscopy / colonoscopy to inspect the same area where the clip was originally placed.
- **b.** Therefore, screening for patients with possible GI clips continues to be necessary. The length of time needed to screen is unknown, but it is highly unlikely that indefinite screening is necessary since all clips should eventually pass. Since the timing of this passage is unknown, we consider 6 weeks to be a reasonable time during which a patient with a possible Olympus clip should be screened.
- **c.** If the patient has undergone an endoscopy or colonoscopy within the past 6 weeks, it should be determined whether a clip was placed, and if so, which type of clip. If the type of clip is known (and is not an Olympus clip) then the patient can proceed to scanning. In the situation where
 - **a.** it is unknown whether a clip was placed,
 - **b.** a clip was placed but the type of clip is unknown, or
 - **c.** an Olympus clip was placed, then the MRI should be delayed until 6 weeks after clip placement, if possible. If this delay impacts clinical care, then an abdominal radiograph (preferred) or repeat endoscopy can be obtained to determine whether a hemostasis clip is still present. If no clips are present then the patient can proceed safely to MRI.

For a more detailed reference please see:

https://radiology.wisc.edu/wp-content/uploads/2017/10/Memo-GI-Clips-9-25-13-final.pdf

Neuroembolization Coils

- a.All platinum coils are okay to scan
- b. Adhesives/glue (onyx) are okay to scan
- c. Stent-Assisted Coiling, "Pipeline Stents" are okay to scan.
- d. Recommended Scanner Strength: Okay up to 3T
- e. Recommended Operating Mode: Normal mode

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<u>General Guidelines about Shrapnel (Ballistic Implants) and Non-Medical Metallic Foreign Bodies, etc</u> a. Radiologist Discretion is Required.

- a. Shrapnel should be assessed to determine if it is located near a 'critical anatomical location'
- b. Cases with shrapnel should be reviewed on a case-by-case basis by an attending radiologist
- c. If there is a question of possible shrapnel and no relevant imaging is available, then radiographs should be used to assess relevant anatomy prior to MRI.

d. If the shrapnel is superficial, then a hand magnet can be used to assess if the shrapnel is ferromagnetic:

- i. If the shrapnel IS ferromagnetic, the scan should not proceed without discussion with the attending Radiologist.
- ii. If the shrapnel IS NOT ferromagnetic, then the patient can proceed with the scan.

All patients with shrapnel should be warned about the potential for heating/movement of these objects and this discussion should be documented in technologist/nursing notes.

iv. If the patient is unresponsive, then please see above protocol regarding assessing unresponsive patients. A discussion between Radiologist and provider regarding necessity of imaging and alternative imaging modalities prior to MRI.

See History of Orbital Trauma for guidelines regarding clearing the orbits for possible metallic foreign bodies

General Guidelines/Considerations:

- a. Mixed Shrapnel: Could potentially be ferromagnetic
- b. Military Shrapnel: Should be assumed to be ferromagnetic
- c. Domestic Shrapnel: Could be lead-based.
- c. Recommended Scanner Strength: 1.5T ONLY
- d. Recommended Operating Mode: Normal Mode

Penile Implants

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- a. There are 2 penile Implants that are considered unsafe for MRI. They are the Omniphase by Dacomed, which was discontinued and replaced with the Duraphase by Dacomed. The Duraphase model was discontinued in 1995.
- b. All penile implants implanted after 1997 are considered MR Conditional on our 1.5 and 3T systems.

Reference: page 40 Yale MRI safety manual:

https://medicine.yale.edu/diagnosticradiology/patientcare/policies/mri_safety_manual_november2022_284424_284_11023_v26.pdf

Intrauterine Devices (IUDs)

a. All IUDS placed in the USA are be okay to scanned on 1.5T.

b. Please note that IUDs placed outside of the USA may be contain copper/ferromagnetic material (older IUDs placed several decades ago) and may not be removable.

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- c. For staff with IUDs (Radiology staff, clinical providers, ancillary staff):
 - a. IF the IUD has been placed in USA, then the staff is cleared for Zone 4.
 - b. If IUD has been placed in a foreign country, then every attempt to verify the IUD should be performed. If the IUD cannot be verified, please follow recommendations outlined for patients below.
- d. For patients with IUDs:

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a. If the IUD was placed in USA and make/model cannot be verified, then the patient is still okay to scan on 1.5T.

- b. If the IUD was placed in foreign country and make/model cannot be verified:
 - i Radiologist Discretion is Required.

A. Scan should not be performed until discussion with ordering providers about risks/benefits for patient regarding the use of MRI. The discussion should be documented and consideration for other imaging modalities should be performed.

- c. Recommended Scanner Strength: See above for guidelines
- d. Recommended Operating Mode: Normal Mode

Orthopedic Devices

a. Internal Fixation Devices

a. All implanted orthopedic/maxillofacial hardware that is anchored into bone, beneath the skin is OKAY to scan, regardless of surgery date.

- b. No waiting period to scan.
- c. Recommended Scanner Strength: 1.5T and 3T okay
- d. Recommended Operating Mode: Any
- a. <u>External Fixation Devices (MRI ordered for patient with external fixation device in place)</u>

a. MRI technologist/nurse should confirm with ordering team (or team that has placed the device, such as Orthopedics/Trauma) that there is medical necessity to scan the area of interest and that external fixation device must remain in place during the scan.

b. If the need for a scan has been confirmed, then consultation with an attending radiologist should be performed to confirm a protocol that will answer the clinical question with the shortest possible scan/sequences to limit power deposition.

c. If the manufacturer's specifications state that an external fixation device is not definitively MR-compatible/conditional, then the patient should not undergo MRI. Given the limited literature available on MRI in the presence of external fixation devices, if the device is considered MR conditional, then the scan can proceed so long as the following guidelines are followed:

- i. All unknown external fixation components should be first cleared with a hand magnet.
 - 1. If a component demonstrates strong attraction to the hand-magnet, the MRI scan should not proceed.
- ii. If external fixation device is NOT part of the anatomy being scanned (defined as the fixation device will be 30 cm away from the bore of the magnet), then the device is considered okay to scan on 1.5T in normal mode.
- iii. If external fixation device involves part of the anatomy that needs to be scanned or needs to enter the bore of the magnet (fixation device is at the bore entrance or 30 cm inside the bore of the magnet), please adhere to the protocol below:



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1. Patients cannot be sedated and/or have impaired consciousness.

2. A discussion regarding the possibility of heating of the external fixation components should occur between the patient and the technologist/nurse and should be documented in the tech/nursing notes. The patient should be instructed to immediately alert the MRI technologist if any heating/discomfort occurs.

3. If a patient experiences heating/discomfort, then the scan should be immediately stopped, and an attending radiologist should be consulted to discuss the adequacy of the images obtained and next appropriate steps.

d. Recommended Scanner Strength: 1.5T ONLY

e. Recommended Operating Mode: Normal Mode

Unknown Scleral Buckle

- a. Item that is used to repair a retinal tear, typically not metal (silicone, rubber, plastic)
- b. Conditional Rare, old scleral buckles may be ferromagnetic, though majority are not (<u>www.mrisafety.com</u>)
- c. If unknown, then obtain a radiograph to assess for metal/ferromagnetic component. If none is seen, then OK to scan.

History of Orbital Trauma:

- a. Clinical Screening Protocol
 - a. Every patient is to be asked if they have had an ocular injury. If the patient has sustained an ocular injury, ask whether they had a medical examination at the time of the injury and whether they were told by the examining doctor, "It's all out."
 - If they did not have an injury, if they were told their ophthalmologic examination was normal, and/or if the foreign body was removed entirely at the time of the injury, then they can proceed to MR imaging.
 - If they did have an injury and have not had a clear eye exam, or the foreign body was not able to be removed, proceed with the Radiographic Screening Protocol below.
- b. Radiographic Screening Protocol
 - a. Based on the results of the clinical screening protocol, patients must be screened radiographically if they sustained an ocular injury related to a metallic foreign object and they were told that the eye examination revealed that the foreign body was not removed.
 - b. In the event that the removal of the entire metallic foreign body cannot be verified or if there is insufficient information to confirm that there is no metallic foreign body present, screening radiography should be used prior to MRI.

Reference: http://www.mrisafety.com/SafetyInformation_view.php?editid1=293

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General Guidelines on Tattoos:

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Patients should be advised of the following:_

a. Shellock et al.¹³ investigated burning or heating associated with tattoos used for permanent cosmetics, but determined that the actual risk of any incident occurring was fairly remote and should not negate an MRI if needed. They suggested that a cold compress may be applied to minimize any risk to the patient and that the risk is far greater to the patient in the long term if a clinically important MRI procedure was cancelled. The FDA agrees that adverse tattoo incidents appear to be rare and have no long-lasting effects.⁴³

Per 2020 ACR Safety Manual page 35-36:

Patients with tattoos within the RF transmit volume. For patients with extensive, dark, or loop- shaped tattoos or tattooed eyeliner, to decrease the potential for RF heating of the tattooed tissue, it is recommended that cold compresses or ice packs be placed on the tattooed areas and kept in place throughout the MR process if these tattoos are within the volume in which the body coil is being used for RF transmission. This approach is especially appropriate if fast/turbo spin-echo or other high-RF-duty-cycle) MR sequences are anticipated in the study. If another coil is being used for RF transmission, a decision must be made if high RF-transmitted power is to be anticipated by the study protocol design. If so, then the above precautions should be followed. **Parenthetically, although not an RF thermal concern, patients with tattoos that had been placed within 48 hours prior to the pending MR examination should be advised of the potential for smearing or smudging of the edges of the freshly placed tattoo.**

Certain tattoos have ferromagnetic inks, and are okay to scan, but the patient should be warned about potential risks, such as heating and smearing.

- a. This also applies to 'permanent make-up' type of tattoos (eyebrows, etc).
- b. If the patient is undergoing sedation, they should be made aware of the risks prior to MRI.
- c. Radiologist Discretion is required if the patient is unconscious.
- d. If the patient is unconscious, then the covering radiologist and medical provider should have a discussion regarding medical necessity and risk/benefits about doing the MRI
 - i. Cold compresses can be considered for use at site of tattoos (please see Shellock guidelines)

e. Recommended Scanner Strength: 1.5T is preferred for NEW tattoos (placed < 6 weeks prior to scan), and 3T should ONLY be used if the protocol requires 3T or if there is no 1.5T MRI scanner physically available at the site for use. For older tattoos, ANY scanner strength is appropriate.

f. Recommended Operating Mode: Normal Mode<u>for new tattoos</u> (ANY operating mode for <u>older tattoos</u>).

General Guidelines Body Piercings (including microdermal implants/surface anchors)

a. If possible, all piercings or jewelry SHOULD be removed by the technologist/patient.b. If the jewelry is removable, but patient refuses to remove jewelry, then the MRI should not be performed.



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c. If the jewelry absolutely CANNOT be removed:

a. The technologist should scan with the jewelry with a hand magnet to assess ferromagnetic properties.

- i. If the jewelry IS ferromagnetic as determined by the technologist/nurse, then scan cannot proceed and a discussion with the medical provider should occur.
- ii. If jewelry IS NOT ferromagnetic, then please follow the following guidelines:
 - 1. Jewelry could be affixed with tape/adhesive, etc. to prevent movement.
 - 2. Technologist should discuss potentials risks with patients. (ex. thermal heating)
 - and document that this discussion took place in the technologist/nursing notes.

d. Recommended Scanner Strength: 1.5T is preferred for unverified/irremovable jewelry, and 3T should ONLY be used if the protocol requires 3T or if there is no 1.5T MRI scanner physically available at the site for use.

e. Recommended Operating Mode: Normal Mode

Skin Staples and Drug Delivery Patches

Per 2020 ACR Safety Manual page 35:

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Skin staples or multiple implants in proximity to each other. Although, in general, thermal risks associated with individual small dermal implants and/or piercings are quite small, dermal implants that are in close proximity or directly contact one another may increase the risk of thermal injury if the items are in the volume associated with RF energy power deposition. An example of this might include skin staples and superficial metallic sutures (SMSs). Patients requested to undergo MR studies in whom there are skin staples or SMSs may be permitted to undergo the MR examination if the skin staples or SMSs are not ferromagnetic and are not in or near the anatomic volume undergoing direct RF power deposition. If the nonferromagnetic skin staples or SMSs are within the volume to be RF-irradiated for the requested MR study, several precautions are recommended.

- 1. Warn the patient and make sure that they are especially aware of the possibility that they may experience warmth or even burning along the skin staple or SMS distribution. As is good practice for all MR studies, the patient should be instructed to report immediately if they experience warmth or burning sensations during the study (and not, for example, wait until the "end of the knocking noise").
- 2. Place a cold compress or ice pack along the skin staples or SMSs if this can be safely clinically accomplished during the MRI examination. This will help to serve as a heat sink for any focal power deposition that may occur, thus decreasing the likelihood of a clinically significant thermal injury or burn to adjacent tissue.

Drug-delivery patches and pads. Some drug-delivery patches contain metallic components. Scanning the region of the metallic foil may result in thermal injury or alteration in drug-delivery rate by heating, if the patch is

within the volume of RF irradiation.^{oo} Because removal or repositioning can result in altering of the patient dose, consultation with the patient's prescribing physician would be indicated in assessing how to best manage the patient. If the metallic foil of the patch delivery system is positioned on the patient so that it is in the volume of excitation of the transmitting RF coil, the case should be specifically reviewed with the Level 2 MR Physician overseeing safe execution of the study. Alternative options may include placing a cold compress or ice pack directly on the patch. This solution may still substantially alter the rate of delivery or absorption of the medication by the patient (and be less comfortable for the patient, as well). This ramification should therefore

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not be treated lightly, and a decision to proceed in this manner should be made by a knowledgeable radiologist attending the patient and with the concurrence of the referring physician as well.

If the patch for a prescription medication is removed, it should only be removed on the specific order of a physician caring for that particular patient.

Vascular Access Ports

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In the clinical magnetic resonance imaging (MRI) setting, it is often necessary to manage patients with vascular access ports (1-6).

MRI labeling information exists for many vascular access ports. By following the pertinent MRI labeling information (i.e., presented in the *Instructions for Use*, Patient Identification Card, etc.), patients with vascular access ports have safely undergone MRI examinations, including those performed at 1.5- and 3-Tesla (1-6). Notably, there has never been an adverse event reported in association with performing MRI in patients with these particular implants.

Unfortunately, the standard policy that MRI labeling information is required before allowing the use of MRI in patients with vascular access ports limits access to this important diagnostic imaging modality for those patients for which labeling information is unavailable. However, in consideration of the relevant peer-reviewed literature and other related information (1-6), it is acceptable and safe to perform MRI examinations in patients with vascular access ports by following specific guidelines developed by taking into consideration the primary safety concerns (i.e., magnetic field interactions and MRI- related heating) for these implants.

Notably, by adhering to these admittedly conservative MRI conditions, patients with vascular access ports can benefit from the diagnostic imaging information provided by one of the most important noninvasive imaging modalities.

Guidelines. The following guidelines apply to using MRI in patients with vascular access ports:

(1) Patients with all commercially available vascular access ports 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 vascular access ports can undergo MRI immediately after placement of these implants.

(3) The MRI examination should be performed using the following parameters:

- 1.5-Tesla or 3-Tesla, only
- Whole body averaged specific absorption rate (SAR) of 2-W/kg (i.e., operating in the Normal Operating Mode for the MR system)
- Maximum imaging time, 15 minutes per pulse sequence (multiple pulse sequences per patient are allowed)

Important Note: Any deviation from the above MRI conditions requires prior approval by a radiologist or the supervising physician.

Important Note: These guidelines must be reviewed on an annual basis to confirm that no new vascular access port has become available that substantially deviates from the above MRI conditions or that is labeled, MR Unsafe (7).

Reference: http://www.ismrm.org/smrt/safety_page/2019.Shellock.VAP.MRI.Guidelines.pdf



-adapted from University of Wisconsin, Univ of Iowa, Yale and MRISafety.com

*updated January, 2023;

Maximum Spatial Gradient

- maximum spatial gradient occurs within the bore wall at the entrance to the bore and decreases moving towards the center where most implants will be located and is often not reflective of what the implant will experience.

Per ACR Safety Manual page 30:

MR scanner vendors also provide maximum SFG values for model-specific systems. However, applying those SFG values to day-to-day decisions can be confusing. The maximum SFG values quoted by the manufacturer for a given MR system may be located behind the shroud or cover of the scanner, in a region not directly accessible to the patient. Because an implant or device within a patient may not be exposed to this region of maximum SFG associated with that particular MR scanner (depending on its position in the patient and the patient's positioning on the MR scanner table), the **model-specific maximum SFG values are unlikely to represent the actual SFG value that will be experienced by a device/implant/foreign body as the patient undergoes an MR examination in that scanner.**

Waiting Period Following Surgery per Dr Frank Shellock (founder of MRISafety.com)

(Guidelines for the Management of the Post-Operative Patient Referred for a Magnetic Resonance Procedure)

There is often confusion regarding the issue of performing a magnetic resonance (MR) procedure during the post-operative period in a patient with a metallic implant or device. Studies have supported that, if the metallic object is a "passive implant" (i.e. there is no electronically- or magnetically-activated component associated with the operation of the device) and it is made from nonferromagnetic material, the patient may undergo an MR procedure immediately after implantation using an MR system operating at 1.5-Tesla or less (or, the field strength that was used to test the device, including 3-Tesla). In fact, there are several reports that describe placement of vascular stents, coils, filters, and other implants using MR-guided procedures that include the use of high-field-strength (1.5- and 3-Tesla) MR systems. Additionally, a patient or individual with a nonferromagnetic, passive implant is allowed to enter the MR environment associated with a scanner operating at 1.5-Tesla (or, the field strength that was used to test the device, including 3-Tesla) or less immediately after implant is allowed to enter the MR environment associated with a scanner operating at 1.5-Tesla (or, the field strength that was used to test the device, including 3-Tesla) or less immediately after its implantation.

For an implant or device that exhibits magnetic qualities, it may be necessary to wait a period of six weeks after implantation before performing an MR procedure or allowing the individual or patient to enter the MR environment. For example, certain intravascular and intracavitary coils, stents, and filters designated as magnetic become firmly incorporated into tissue a minimum of six weeks following placement. In these cases, retentive or counter-forces provided by tissue ingrowth, scarring, granulation, or other mechanisms serve to prevent these objects from presenting risks or hazards to patients or individuals in the MR environment with regard to movement or dislodgement.

However, patients with implants or devices that are "weakly magnetic" but rigidly fixed in the body (e.g., bone screws, other orthopedic implants, or other devices) may be studied immediately after implantation. Specific information pertaining to the recommended post-operative waiting period may be found in the labeling or product insert for an implant or device.

-adapted from University of Wisconsin, Univ of Iowa, Yale and MRISafety.com

*updated January, 2023;

Of course, the information above pertains to magnetic field interactions and further consideration must be given to MRI-related heating for the implant or device under consideration.

Special Note: 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 the implant cannot be properly identified, the patient or individual should not be exposed to the MR environment.

*The document, Guidelines for the Management of the Post-Operative Patient Referred for a Magnetic Resonance Procedure, was developed by the Institute for Magnetic Resonance Safety, Education, and Research (<u>www.IMRSER.org</u>) and published with permission. Reviewed and updated 2018.

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