MRI Safety Policies

YNHH Fitkin MRI
789 Howard Ave, New Haven CT 06510
203 688 5656

Smilow MRI
20 York Street, New Haven CT 06510
203 200 5146

Smilow MR Breast Center
20 York Street, New Haven CT 06510
203 200 5253

Smilow MR OR
20 York Street, New Haven CT 06510
203 200 6655

YNHH Pediatric MRI
20 York Street, New Haven CT 06510
203 200 2646

Shoreline MRI
111 Goose Lane, Guilford CT 06437
203 453 7181

ST Raphael Campus MRI
1450 Chapel Street, New Haven CT 06511
203 789 4120

North Haven MRI
6 Devine Street North Haven, CT 06473
203 287 6969

Park Ave MRI
5520 Park ave Trumbull, CT 06611
203 666 3562

Milford Campus of Bridgeport Hospital
300 Seaside Ave, Milford CT 06460
203-301-1543

YALE-NEW HAVEN HOSPITAL DEPT. OF DIAGNOSTIC RADIOLOGY POLICY AND PROCEDURE MANUAL MRI Safety Manual	Reviewed/Updated 9/2024		Policy No.
	SUBJECT: INDEX		

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GENERAL SAFETY INFORMATION

MRI SCREENING

MRI PREGNANCY RELATED ISSUES

MRI CONTRAST RELATED ISSUES

MRI SCHEDULING RELATED AND OTHER POLICIES

NURSING RELATED AND OTHER POLICIES

Acronyms

0.5 mT 5 Gauss Line

ACR American College of Radiology

AED Automated Emergency Defibrillator

ASTM American Society for Testing and Materials

ARRT American Registry of Radiologic Technologists

CPR Cardiopulmonary Resuscitation

DB Decibel

FDA Food and Drug Administration

GBCA Gadolinium based contrast agent

MR Magnetic Resonance

MRI Magnetic Resonance Imaging

RF Radio Frequency

RMS Root Mean Square

SAR Specific Absorption Rate

SMS staples/superficial metallic sutures

SOP Standard Operating Procedure

TVMF Time Varying Magnetic Fields

T Tesla

W/kg Watt/kilogram

YALE-NEW HAVEN HOSPITAL DEPT. OF DIAGNOSTIC RADIOLOGY POLICY AND PROCEDURE MANUAL MRI Safety Manual	Reviewed Date 2021	Last Revision 2020	Policy No.
	SUBJECT: INTRODUCTION		

Magnetic Resonance Imaging is an ever changing, evolving technology. There are potential risks in the MR environment, not only for the patient but also for the accompanying family members, attending health care professionals and others who find themselves only occasionally or rarely in the magnetic fields of MR scanners, such as security, housekeeping personnel, firefighters, police, etc. This manual has been developed to help guide the MR staff regarding these issues.

The policies written in this manual are guidelines to follow as a standard of care throughout the Yale New Haven Health system MRI departments. It is at the discretion of the supervising radiology attending to divert from any policy in an emergency situation. Please refer to page 101 “Exceptions of MR safety policies” for further detail.

It is the intent of the Yale New Haven Hospital safety manual to:

- Protect and educate all patients, direct and ancillary personal about the possible risks, associated with the MR Suite including but not limited to static, time-varying magnetic fields and RF pulses.
- To be in compliance with the most up to date MR safety information provided by the Joint Commission and the ACR
- Prove helpful as the field of MRI continues to evolve and mature, providing MR services that are among the most powerful, yet safest, of all diagnostic procedures to be developed in the history of modern medicine.

1.All clinical and research MR sites, irrespective of magnet format or field strength, including installations for diagnostic, research, interventional, and/or surgical applications, should maintain MR safety policies

2. These policies and procedures will be regularly reviewed by the MR Safety Officer and the Medical Director to account for the significant changes in the MR center environment. This will take into account ACR, Joint Commission and international standards.

3. The responsibility for implementation and maintenance of these policies and procedures belong to the Medical Director of the YNHH MRI Centers.

4. Annually, all MR personnel will review safety within the MR environment

5. Provide all non-MR staff, patients and their families with appropriate materials (e.g., guidelines, brochure, and poster) that explain the potential for accidents and adverse events in the MRI environment.

6. Provide Access to all updated safety policies to all MR staff online and/or an updated hard copy in every MR area.

7. MR safety incidents or "near incidents" that occur in the MRI center are to be reported to the Manager of the center, the MR safety officer, and the Medical Director in a timely manner, an Event Report (RL solutions) should be documented by the technologist via the intranet and to the FDA Maude website if any equipment was involved www.fda.gov/medwatch.

The MR task group of the American Society for Testing and Materials (ASTM) International has developed a set of MR safety terms. This terminology is NOT being applied retrospectively to implants and devices that previously received FDA approved labeling using the terms "MR safe" or "MR compatible". This applies to those objects tested prior to December 2005.

Particularly with regard to nonclinical and incidental equipment, current products marketed with ill-defined terminology such as ‘‘nonmagnetic’’, or the outdated classifications described above (‘‘MR compatible’’), should NOT be presumed to conform to a particular current ASTM classification.

To go along with the new terminology, the ASTM introduced corresponding icons consistent with international standards for colors and shapes of safety signs. They are intended for use on items that may be brought into or near the MRI environment as well as in product labeling.

- MR SAFE - is an item that poses no known hazards in all MRI environments. Using the new terminology, "MR Safe" items include non-conducting, non-metallic, non-magnetic items such as a plastic Petri dish. The "MR Safe" icon consists of the of the letters "MR" in green in a white square with a green border - or - the letters "MR" in white in a green square.

- MR CONDITIONAL - is an item that has been demonstrated to pose no known hazards in a specified MR environment as long as specified conditions of use are met. The "MR Conditional" icon consists of the letter "MR" in black inside a yellow triangle with a black border. The item labeling must include the results of testing and the specific conditions of use sufficient to characterize the behavior of the item in the MRI environment.

- MR UNSAFE - is an item that is known to pose hazards in all MRI environments. MR Unsafe items include magnetic items such as a pair of ferromagnetic scissors. The "MR Unsafe" icon consists of the letters "MR" in black in a white field inside a red circle with a diagonal red band.

- Safety in MRI Not Evaluated- For devices that have historically not provided any information about MRI safety

NEW ASTM Approved Labeling, no other Labeling is acceptable

The ACR established the 4 zone concept as defined in the ACR Guidance Document for Safe MR Practices: 2007. The four zone concept provides for progressive restrictions in access to the MRI scanner. All MRI Suites are marked with Zone signs

• **Zone I**: General public freely accessible to the public. This area is typically outside the MR environment.

• **Zone II**: Limited Access: This is the Zone located between the public uncontrolled Zone 1 and the strictly controlled Zone 3. This area has limited access - available to patients, family members and hospital personnel who have been safety trained or safety screened by Level 2 MR personnel. It is in Zone II that the answers to MR screening questions, patient histories, medical insurance questions, etc. are typically obtained.

• **Zone III**: The MR scanner (Zone 4) itself is located adjacent to this space. Zone III can be defined as regions from which potentially hazardous energies (related to the MR imaging process) may be accessed. Zone III regions should be physically restricted from general public access by, for example, key locks, passkey locking systems, or any other reliable, physically restricting method. Only MR personnel shall be provided free access, such as the access keys or passkeys, to Zone III. Patients, family members, or hospital staff that has undergone safety screening or safety training will be allowed access to this area only when accompanied by appropriate MR personnel.

• **Zone IV**: Is the room housing the MR scanner itself. Zone IV should also be demarcated and clearly marked as being potentially hazardous due to the presence of very strong magnetic fields. Zone IV, by definition, will always be located within Zone III as it is the MR magnet and its associated magnetic field which generates the existence of Zone III. Only patients and family members, or hospital staff accompanied by Level 2 MR personnel who have undergone safety screening or safety training will be admitted to this Zone.

Non-MR Personnel should be accompanied by, or under the immediate supervision of and visual contact with, one specifically identified MR person for the entirety of their duration within Zone III and a level 2 MR person in Zone IV restricted regions.

SITE ACCESS RESTRICTIONS:

MRI Center, Fitkin Basement

The MRI outpatient center is located at 789 Howard Avenue. Stretcher/wheelchair bound patients will be transferred to MR safe equipment in the prep hold area located adjacent to MR 5 and MR 1. The amount of additional hospital staff for any procedural MRI's will be restricted to 3 people per service; this will help alleviate overcrowding and potential safety incidents.

Smilow (Level 2), MRI Suite

The Smilow MRI Suite is located at 20 Park Street, second floor of the Smilow Cancer Hospital. Stretcher and wheelchair bound patients will be transferred to MR safe equipment in the prep hold area. The amount of additional hospital staff for any procedural MRI's will be restricted to 3 people per service; this will help alleviate overcrowding and potential safety incidents in the suite

Smilow (Level 1) Breast Center MRI Suite

The Breast Center MRI Suite is located at 20 Park Street; first floor of the Smilow Cancer Hospital is divided into four zones. All stretcher bound patients will attempt to be scheduled on the second floor MRI suite. Wheelchair bound patients will be transferred to MR safe equipment in the changing area.

North Haven, MRI Suite

The North Haven MRI suite located at 6 Devine Street in North Haven is divided into four zones. Stretcher and wheel chair bound patients will be transferred to MR safe equipment in the transfer area.

Pediatric Suite West Pavilion:

The Pediatric MRI Suite is located on the second floor of the YNHH Children's Hospital. Due to limited space in the suite, stretcher bound patients will be transferred to MR safe stretchers in the MRI intake room. The amount of additional hospital staff for procedural

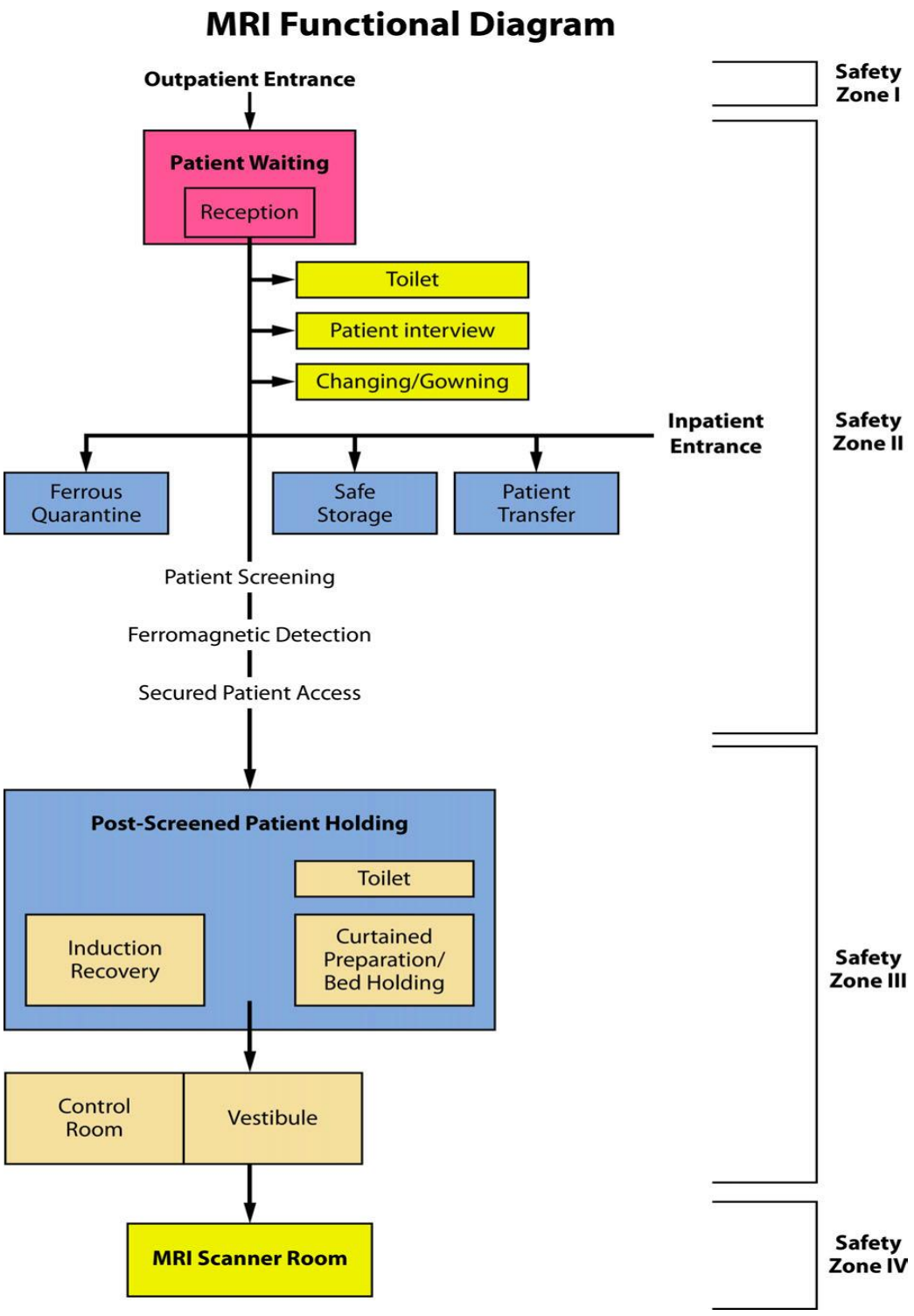
MRI will be restricted to 3 people per service; this will help alleviate overcrowding and potential safety incidents. For the safety of patients, families and staff, the detachable table at this location must be used.

Shoreline Medical Center Guildford, CT MRI Suite

The YNHH Temple Street MRI suite located at 111 Goose Lane Guilford CT. The amount of additional hospital staff for procedural MRI will be restricted to 3 people per service; this will help alleviate overcrowding and potential safety incidents. The detachable table will be used to transfer wheelchair or stretcher patients from MR safe area to MR scan room.

St Raphael, MRI Center

The St Raphael's Campus MRI center located 1450 Chapel Street New Haven CT. Due to limited space in the suite, stretcher bound and wheel chair patients will be transferred to MR safe equipment in the nursing area. The amount of additional hospital staff for procedural MRI will be restricted to 3 people per service; this will help alleviate overcrowding and potential safety incidents.


MRI Functional Diagram
Outpatient Entrance
Patient Waiting
Reception
Toilet
Patient interview
Changing/Gowning
Inpatient Entrance
Ferrous Quarantine
Safe Storage
Patient Transfer
Patient Screening
Ferromagnetic Detection
Secured Patient Access
Post-Screened Patient Holding
Toilet
Induction Recovery
Curtained Preparation/ Bed Holding
Control Room
Vestibule
MRI Scanner Room
Safety Zone I
Safety Zone II
Safety Zone III
Safety Zone IV

The time varying magnetic fields in MRI produce auditory, induced voltage and thermal issues that we should be aware of.

Induced Voltage Considerations:

Implanted wires pose a possibility of creating a current along the wire inside the MRI

- Patients with implanted wires in anatomically and/or functionally sensitive area should be considered at a higher risk. The decision to perform imaging and/or limit the rate of magnetic field change and strength of the magnetic field should be reviewed by the radiologist supervising the case.

Thermal Considerations:

SAR-Specific Absorption Rate is defined as the RF power absorbed per unit of mass of an object. It is measured in watts per kilogram (w/kg). The SAR describes the potential for heating of the patient's tissues due to application of the RF necessary to produce the MR signal. Technologists will monitor SAR levels introduced to the patient, and will stay within appropriate levels. Electric currents can be created during MR imaging which could cause burns to the patient.

- All electrical connections such as surface coil leads, monitoring devices, etc., must be physically checked by the scanning technologist before beginning the scan to ensure the integrity of the thermal and electrical insulation.
- All unnecessary or unused electrically conductive materials external to the patient should be completely removed from the MR system before scanning starts.
- For electrically conductive material, wires, leads, implants, etc., that are required to remain in the bore of the magnet with the patient during imaging, pads, etc. should be placed between the patient and the electrically conductive material during imaging to keep the electrical conductor from directly contacting the patient. Pads can also be placed between the conductive material and the wall of the magnet if the body coil is being used, no loops should be created.
- Care is needed to ensure that the patients' tissues do not directly come into contact with the inner bore if the scanner during the imaging process. Pads should be placed between the patient and the magnet walls. It is also important to ensure that the patients' own tissues do not form large conductive loops. Therefore, care should be taken to ensure that the patients' arms and legs not be positioned in such a way as to form a loop within the bore of the magnet.
- There have been rare reports of thermal injuries/burns associated with clothing that contained electrically conductive materials, such as metallic threads and silver impregnated clothing. As such, all patients remove their own clothing and instead change into provided gowns.

- All unconscious/unresponsive patients should have attached leads insulated from their skin during scanning.
- It is important to follow established product MR Conditional labeling and safety guidelines carefully and precisely, applying them to and only to the static magnetic field strengths at which they had been tested. MR scanning at either stronger and/or weaker magnetic field strengths than those tested may result in significant heating where none had been observed at the tested field strength(s).
- The patient should immediately report any burning/or discomfort to the MR technologist, the scan should be stopped and the situation accessed. A RL solution should be documented by the technologist via the Intranet and to the FDA Maude website if any equipment was involved www.fda.gov/medwatch

Auditory Considerations:

Patients **ALWAYS** need to have hearing protection as well as their family members who accompany them into the scan room. Please review our Ear plug policy below.

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	SUBJECT: EAR PLUGS DURING AN MRI EXAM		

MRI Imaging with Ear Plugs:

The noise generated by scanning may reach a level in the scan room and in the bore of the magnet that can result in temporary (and occasionally) permanent hearing loss. Properly inserted earplugs will limit the level of the noise that reach the inner ear.
Any patient who undergoes an MRI, as well as anyone in Zone 4 during a scan, MUST wear earplugs.*

The earplugs will be inserted by the MRI staff. The earplugs are Latex Free and have an acceptable NNR rating.
In pediatric patients, and patients with unusual shaped ear canals, the earplugs may not fit properly to limit the noise level. In these instances, MRI staff will use another form of hearing protection such as headphones or ear muffs that will hold the earplugs in place and further dampen the noise level.

If a patient has their own custom ear plugs, designed for their ear canals it is acceptable to use after they have been wanded for metal. MR staff need to check they are inserted.

*A patient who is deaf in one or both ears, does not need to use hearing protection in the affected ear canal. Please document in EPIC

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	SUBJECT: FIREFIGHTERS, POLICE AND SECURITY CONSIDERATIONS		

A.) All MR sites should arrange to prospectively educate their local fire marshals, police and security personnel about the potential hazards of responding to emergencies in the MR suite.

B.) It should be stressed that even in the presence of a fire or other emergency the magnetic field may be present and fully operational. Free access to Zone IV by firefighters and other non-MRI personnel with air tanks, axes, crowbars, guns, etc. can prove to be catastrophic or even lethal. Helium is not flammable and does not pose a fire hazard directly; however, the liquid oxygen that can result from the super cooled air might well increase the fire hazard in this area. If there are appropriately trained MRI personnel available during the emergency who are able to keep the emergency responders from the magnet room and the five gauss line, then quenching the magnet should not be a requirement. As part of the Zone III and IV restrictions, all MR sites must have clearly marked, readily accessible MR Conditional or MR Safe fire extinguishing equipment physically stored within Zone III or IV.

C.) If the fire or emergency is in the magnet room, and the emergency response personnel and their equipment must enter the room, a decision to quench the magnet should be made to protect the health and lives of the emergency responders. Should a quench be performed, appropriately designated MRI personnel still need to ensure that

all non MRI personnel continue to be restricted from the magnet room until the designated MRI personnel have verified that the static field is either no longer detectable or at least sufficiently attenuated so as to no longer present a potential hazard **(see Cryogen related policy**)

In the event of a fire at any YNHH MRI suites and please follow the following procedure:

R.A.C.E. RESPONSE PROTOCOL:

R.A.C.E. Stands for RESCUE, ALARM, CONFINE AND EXTINGUISH.

- RESCUE: Injured visitors, employees or staff must rapidly be rescued from the immediate area of the fire/smoke origin.
- ALARM: At the sight of flames or smoke, immediately activate a Fire Alarm Pull Station.
- CONFINE: Fire, Smoke and Toxic combustion products must be confined to the area of fire origin as much as possible. Close the door to the room of fire origin as soon as any rescue is accomplished.
- EXTINGUISH: If at all possible, staff should make one attempt to extinguish the fire with a hand-held fire extinguisher. They are to be used only after Rescue, Alarm and Confine have been completed. A fire extinguisher is not a replacement for activating the fire alarm system. Any fire that a fire extinguisher has been used on is to be reported to the Governing Police Department and/or Fire Marshal.

To Use a fire Extinguisher, use the PASS Protocol

P.A.S.S. FIRE EXTINGUISHER PROTOCOL:

P.A.S.S.: method is used for the proper operation of a hand held fire extinguisher.

- **P.A.S.S.:** Stands for *Pull, Aim, Squeeze, Sweep.*
- ***PULL:*** Pull the safety ring/pin at the top of the fire extinguisher.
- **AIM:** Aim the discharge nozzle at the base of the fire.
- **SQUEEZE:** Squeeze the handle of the fire extinguisher together to discharge the agent.
- **SWEEP:** Sweep the agent side to side at the base of the fire.

- Whenever using a fire extinguisher, the following is to be remembered.
- Maintain a clear exit
- Keep your back to that clear exit.
- If at any time you feel as if you are in danger evacuate the area and close the door behind you.

YNHH MRI CENTERS GENERAL EVACUATION PLAN

IN CASE FIRE OR SMOKE

1. Stay calm.
2. Always sound the building fire alarm immediately. If the alarm fails to operate, warn other occupants by knocking on doors and shouting warnings.
3. Call your centers Emergency number. (Temple ST 911, YNHH 155, St. Raphael's 155, Guilford 911, North Haven 911, Yale University Office of the Fire Marshal @ (203) 4329923) from a safely located telephone. Give as much information as possible to the dispatcher. Do not assume that someone else has already notified them. They will immediately notify the Fire Department and

dispatch officers to the scene. Do not hang up until told to do so by the dispatcher.

4. Before opening the door, feel it with the back of your hand. If it is not hot skip to STEP 5. If it is hot, do the following

- Seal cracks around the door with towels, tape, bed clothing or similar items to keep out the smoke. Shout for help. Call your centers Emergency number. (Temple ST 911, YNHH 155, St. Raphael's 155, Guilford 911, North Haven 911 Yale University Office of the Fire Marshal 203-432-9923) and tell them that you are unable to get out of your room. They will be in contact with officers at the fire. Remain calm until firefighters reach you from the hallway or window. Their first duty upon arriving at a fire is to search for persons trapped in the burning building.

5. If you are able to leave your room, do so immediately and:

- Take your key with you in case you are forced to return. Close all doors behind you as you exit. This will lessen the spread of smoke and damage.
- Go to the nearest exit or stairway. Do not use an elevator.
- If smoke, heat or fire blocks your exit, go to an alternate exit.
- If all exits from a floor are blocked go back to your room and follow the procedures described above in step 4

6. If smoke is present, keep low to the floor. Take short breaths to avoid inhaling any more smoke than necessary.
7. Leave the building immediately. When the Police and/or Firefighters arrive, direct them to the fire.

Non-essential staff should follow exit signs and or the directions of Police and Firefighters. Do not re-enter the building for any reason until the Fire Department has declared it safe.

FIRE ALARM ACTIVATION PROCEDURE

In the event of a fire alarm activation alarm or other emergency, visitors, employees and non-essential staff are to evacuate the building using the nearest stairway or exit. Essential staff and patients undergoing procedures should be aware of their surroundings and be vigilant in checking for smoke or fire. An immediate evacuation order may be issued by Governing Fire, Security, Police Department, or a representative from the Fire Marshal's Office. If an evacuation order is issued, it must be followed immediately.

Elevators are not to be used during a fire alarm or smoke/fire condition. During a fire alarm evacuation, non-essential staff should assist ambulatory patients in evacuating the building by following the exit signs which lead to the building exits. Once outside, everyone should move away from the exit discharge doors of the building and to avoid congregating close to the building where they may hamper emergency operations. Do not block the exits or fire department access to the building.

The onsite administrator or business manager of each department will be responsible for the management of the evacuation process. They are to have a list of all employees in their department with them and are to advise the fire department of any employee that is missing. If the onsite administrator or business manager is not available, they are to have designated someone who is to manage the evacuation process for their department or group.

Any disabled individual who cannot evacuate using the outside means of egress are to be moved to the other side of the smoke barrier doors and wait for the fire department to remove them safely from the building. The buddy system is to be used for these employees. YNHH staff is to notify the fire department when they reach the street that there may be disabled individuals still in the building and where they are located.

The fire alarm system is not to be silenced or reset without the permission of the fire department.

Occupants are not to reenter the building until the "All Clear" is given by the fire department.

MRI EMERGENCY PROCEDURES

- When a call has been placed for a fire or police emergency in the MRI Center, MR technologists at all scanners should immediately stop scanning and remove patients from the scanner room.
- The MR safety officer should be called and informed of the emergent situation so that they can be on site prior to the arrival of emergency personnel.
- The MR safety officer and a designated MR staff member should monitor the scanner room doors to prevent free access by emergency personnel. (NOTE: Even in the event of a fire or other emergency the magnetic fields are likely to be present and fully operational.)
- In the case of a fire that is not in the scanner room, quenching the magnet should not become necessary.
- If the fire is in a location that fire fighters and their equipment (oxygen, canisters, crowbars, axes, defibrillators, ETC.) need to enter the scanner room, a decision to quench the magnet may become necessary to protect the health and lives of the emergency personnel.
- If a quench is performed the MR safety officer and MR technologists need to ensure that all emergency personnel are restricted from the scanner room until the static magnetic field is no longer present.

FIRE PREVENTION PLAN:

Accumulations of flammable or combustible waste material are not to be left in the building. Computer rooms are not to be used for storage. All combustible waste materials are to be removed each day. Smoking is not allowed anywhere in the building. Corridors and stairs are not to be used for storage or equipment areas since they become an obstruction during an emergency. Storage and equipment can cause a fire if it is energized equipment, or contribute fuel to a fire, which will fill the corridor with smoke and toxic fumes. The building has a fire alarm system with consists of smoke detectors and pull stations and a fire sprinkler system. The building has also been provided with emergency lighting and exit signs to locate the exit stairwells. Hand held fire extinguishers have been provided throughout the building.

Questions regarding Yale University building be directed to the Yale University Office of the Fire Marshal @ (203) 4329923

In the event of a system quench it is imperative that all personnel/patients be evacuated from the MR scan room as quickly and as safely feasible.

- Stop all scanning and open the scan room door immediately. If the door to the scan room is closed the pressure may build up making it impossible to open the door. In this event, it may become necessary to break the glass window to allow the gasses to escape and the pressure to lessen so that the scan room door may be opened.
- The access to the scan room should be immediately restricted to all individuals until the arrival of the MR equipment service personnel.
- Do not rely upon the oxygen sensors in the room to warn of low oxygen levels in the room. This technology is now considered by industry experts not to be sufficiently reliable to allow for continued operations during situations of power outage, etc.
- It is especially important to ensure that all police and fire response personnel are restricted from entering the MR scan room with their equipment (axes, air tanks, guns, etc.) until it can be confirmed that the magnetic field has been successfully dissipated, as there may still be considerable static magnetic field present despite a quench or partial quench of the magnet.
- MR Safety Officer and MR Medical Director need to be informed immediately

- In a Quench or Emergency Situation

- **What**:
- RF Lindgren Door Release
- **Where**:
- Located on the inside and outside of every MRI door
- **Why**:
- The purpose of this door is to break the RF seal if needed.
- **When**: In a quench situation, the pressure in the room could change and you might need to break the seal to get in or out of the room.

- **How**: Press the red button and the seal become disengaged, twist it and the seal will reengage

- **What**:
- Emergency Hatch
- **Where**:
- All MRI rooms with doors that open IN have emergency hatches
- **Why**:
- To balance the pressure in a room with an open in door
- **When**:
- During a quench Situation if you are in the room the pressure in the room might be too great to pull the door open, hence the emergency hatch

MRI Personnel Screening:

All MR personnel are to undergo an MR Screening process as part of their employment interview to ensure their own safety in the MR environment. At this time, it is the employees' responsibility to fully disclose any trauma, procedure or surgery that they have experienced or undergone in which ferromagnetic objects or devices may have become introduced within them or on them. This will permit an appropriate screening to be performed upon the employee to determine the safety of introducing them to the MR environment.

Personnel Definitions:

Non-MR Personnel

Patients, visitors or facility staff who do not meet the criteria of level 1 or level 2 MR personnel will be referred to as non-MR personnel. Specifically, non-MR personnel will be the terminology used to refer to any individual or group who has not within the previous 12 months undergone the designated formal training in MR safety issues defined by the MR safety director of that installation.

Level 1 MR Personnel

Individuals who have passed minimal safety educational efforts to ensure their own safety as they work within Zone III and IV will be referred to as level 1 MR personnel (e.g., MRI department office staff and patient aides.) Level 1 MR personnel are not permitted to directly admit, or be designated responsible for, non-MR personnel in Zone IV.

Level 2 MR Personnel

Individuals who have been more extensively trained and educated in the broader aspects of MR safety issues, including, issues related to the potential for thermal loading or burns and direct neuromuscular excitation from rapidly changing gradients, will be referred to as level 2 MR personnel (e.g., MRI technologists, radiologists, radiology department nursing staff.)

MRI Personnel and Non MRI Personnel:

All individuals working in Zones III and/or IV of the MR environment should be documented to have completed the MR safety program consisting of at least one MR safety lecture a year approved by the medical director. These educational efforts should be documented and reviewed annually.

Personnel MR Training:

All employees must be safety trained before entering the suite. Specific training will be up to the medical director and continually accessed to meet department needs. At many YNHH facilities training includes filling out an employee MRI screening

sheet, watching a designated MR safety video and speaking with a level 2 MR employee.

Family Members and Non MR Personnel:

All family members and companions entering Zones III and/or Zone IV will be required to complete an MRI safety form. Any positive responses and possible contraindications to these areas will be discussed with the MR technologist. If the technologist cannot resolve the issues the radiologist will be consulted.

In addition to the screening form, pregnant family members who want to go into zone IV will also be given information about pregnancy and MRI. It is their choice to stay in the room during the MRI.

All non-MR Personnel and family members who are going into Zone IV - the scanner room - will remove all metal objects and personal belongings, and will be wanded by a ferrous metal detector in Zone II before given permission to enter Zone III and Zone IV..

Device/Object Screening:

- MRI staff members should pay particular attention to the stretchers and beds of inpatient and remove all oxygen tanks and any other potential hazards.
- All portable metallic or partially metallic devices that are on or external to the patient (e.g., oxygen cylinders) are to be positively identified in writing as non-ferromagnetic and either MR safe or MR compatible prior to admitting them into Zone III.

- As part of the Zone III site restriction and equipment testing and clearing responsibilities, all sites should have ready access to a strong handheld magnet (1000-Gauss) and/or a handheld ferromagnetic detection device. This will enable the site to test external, and even some superficial internal devices or implants for the presence of grossly detectable ferromagnetic attractive forces.
- If external devices/objects are demonstrated to be ferromagnetic and non-MR safe/conditional, they may still, under specific circumstances, be brought into Zone IV if deemed by MR personnel to be necessary and appropriate for the care of the patient (ex. arterial line, catheter bag with clip). These devices/objects must be appropriately secured at all times. The safe utilization of these devices is the responsibility of MR personnel to ensure that they do not inadvertently become introduced too close to the MRI scanner and become a hazardous projectile or no longer accurately function.
- Never assume MR safety information about any device if it's not clearly documented in writing and following ASTM testing standards. If a device's MR safety status is unknown, it should not be permitted in the magnet field.
- A prior MR examination with an implanted device at any given static magnetic field strength (stronger or weaker) is not in and of itself sufficient evidence, and will not be relied upon to determine the MR safety

- Outpatients will be checked in by the receptionist at the front desk of the MRI department. Two Patient identification markers will be used. (Example Full Name, DOB, Address). They will be given a wrist band and be handed a safety sheet to fill out (if not done beforehand). Anyone accompanying the patient will also fill out a safety sheet.
- The MR personnel (level 1 or 2) will review the safety sheet to ensure that there are no positive responses. Any positive responses will be discussed between the patient and a level 2 staff member to confirm that the patient has understood the safety form and understands any risks that are involved with the MRI procedure.
- If the patient is getting contrast two additional steps should be taken before scheduling the patient. The patients eGFR and pregnancy status (if applicable) should be known.
- The patient will be instructed to remove any metal objects and secure their belongings in the lockers. All patients will be requested to change into hospital attire.
- After the patient has changed, the patient and any accompanying companions or facility staff members will be wanded with a ferromagnetic detector have a final

check, or full stop for patient and exam verification, metallic objects and any contraindications to the MRI procedure with Level 2 MR staff.

- Having safely undergone a prior MR examination with an implanted device at any given static magnetic field strength (stronger or weaker) is not in and of itself sufficient evidence, and will not be relied upon to determine the MR safety/compatibility for that device

YALE-NEW HAVEN HOSPITAL DEPT. OF DIAGNOSTIC RADIOLOGY POLICY AND PROCEDURE MANUAL MRI Safety Manual	Reviewed Date 2021	Last Revision 2021	Policy No.
	SUBJECT: MRI SCREENING INPATIENTS		

MRI Screening Process for all Inpatients

- Inpatient safety needs to be reviewed every time a patient has an MRI. They will be screened utilizing the inpatient screening form located in Epic. The form will be filled out on the floor with the patient. The patient needs to be alert and oriented x3 to be able to fill out their own screening sheet. If the patient is unable to complete the form (i.e. due to altered mental status) a nurse, physician, and/or family member may complete the form on the patient's behalf. (Unresponsive patients with no family members please see page 37)
- If the patient is getting contrast two additional steps should be taken before scheduling the patient. The patients eGFR and pregnancy status (if applicable) should be known
- Inpatients will have their safety form reviewed for any contraindications to the MR procedure by the MR personnel before an appointment will be scheduled. Inpatients will not be scheduled without a complete and signed safety form.
- After these steps the patient will be scheduled.

- The patient will be put into the transport system. The inpatient transporter will transport the patient to the designated Zone II area, where staff will inform the technologists of the patient arrival
- Inpatients including emergency room patients should be prepared for their MRI exam before they leave their floor: all personal belongings (including clothing) should remain at bedside and not travel with patients to the MR procedure area.
- In Zone 2 in the MRI facility, MR unsafe medical equipment will be replaced with MR Conditional equipment.
- If the patient is on oxygen they will be put on walled oxygen.
- Before entering Zone III the patient will be wanded with a ferromagnetic detector and have a final check, or full stop for patient identification, exam verification and all safety concerns with level 2 MR staff
- For mechanically ventilated patient please follow that specific process.
- Any accompanying companions or facility staff members will also be wanded and safety screened by MR staff for any ferromagnetic objects or safety concerns
- Having safely undergone a prior MR examination with an implanted device at any given static magnetic field strength (stronger or weaker) is not in and of itself sufficient evidence, and will not be relied upon to determine the MR safety/compatibility for that device

YALE-NEW HAVEN HOSPITAL DEPT. OF DIAGNOSTIC RADIOLOGY POLICY AND PROCEDURE MANUAL MRI Safety Manual	Reviewed Date 2024	Last Revision 2024	Policy No.
	SUBJECT: Unresponsive Patients in MRI		

I. Policy

Screening of patients for whom an MR examination is deemed necessary but who are unconscious, unresponsive, not alert and oriented x 3 or for other reasons unable to provide their own reliable histories regarding prior surgery, presence of “active” implants or exposure to metallic foreign objects, and for whom such histories cannot be reliably obtained from others:

All patients who meet these criteria will be asked to undergo a single view chest and abdomen (including the pelvis) radiograph and skull radiograph to exclude potentially dangerous metallic foreign objects/devices (if these areas have not already been images with CT or x-ray during this hospital admission).

In addition, the patient should be physically examined by an ordering health care professional for evidence of scars that could indicate prior surgery, gunshot wounds or other trauma of their extremities. If this is detected, a radiograph (if recently obtained imaging of such areas is not already available during hospital admission) should be obtained of the region of interest.
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Final determination of whether or not to scan any given patient will be made by the supervising radiologist.

II. Procedure

If a patient is unconscious, unresponsive or for other reasons unable to provide their own reliable histories, the responsible health care professional or supervising radiologist will order single view radiographs of the chest, abdomen (including pelvis) and skull, if these areas have not already been imaged with CT or x-ray during hospital admission. A verbal order for these images to MRI technologist from the radiologist is also acceptable (similar to foreign body orbit process). The service reading the potential MRI should interpret and dictate the plain-film radiographs obtained for MRI screening.

The ordering health care provider will examine the patient for any additional areas of scars, gunshot wounds, or deformities that might indicate an implant or foreign body.

This examination will be documented in Epic (progress notes) before the patient will be scheduled for their MRI exam. If any areas of concern are found, they can be imaged with a radiograph of the region if imaging not already performed during hospital stay.

All imaging will be reviewed by a radiologist. If the x-rays show any unexpected foreign bodies or active implants, an **attending radiologist** must clear the patient and determine that we are okay to proceed with the scan.

Approval to image can be communicated verbally to the MR technologist (including by a radiology trainee (resident/fellow) after they have spoken to their attending) **or** documented in epic (in study protocol **or** study notes) with the name of the attending that has approved to scan.

After the patient has been cleared by the radiologist, the standard inpatient process will continue. If there any question the MR safety officer or medical director of MRI can be consulted.

YALE-NEW HAVEN HOSPITAL DEPT. OF DIAGNOSTIC RADIOLOGY POLICY AND PROCEDURE MANUAL MRI Safety Manual	Reviewed Date 2020	Last Revision 2020	Policy No.
	SUBJECT: OXYGEN CYLINDERS		

- No oxygen cylinders of **any kind** will be allowed in Zone IV - the scan room
- When the patient enters Zone IV - the scan room - the patient will be hooked up to wall mounted oxygen
- Under no circumstances will standard ferromagnetic oxygen tanks be brought into Zones III or Zone IV.
- MRI conditional oxygen cylinders are allowed in Zone III with strict supervision on a case by case basis. **NEVER** Zone IV
- Hospital staff transporting inpatients with standard ferrous oxygen cylinders will exchange the O2 from tank to wall O2. All ferromagnetic oxygen cylinders will be stored in a holder. While the patient waits for their exam or waits to be transported back to their room the wall mounted oxygen will be used
- MRI conditional oxygen cylinders are silver with a light green top.

The "Oxytote" oxygen cylinders are not MRI safe. They indeed have ferromagnetic components. They are to be treated as any other ferrous oxygen cylinder and will be exchanged for our traditional aluminum cylinders as outlined above.

YALE-NEW HAVEN HOSPITAL DEPT. OF DIAGNOSTIC RADIOLOGY POLICY AND PROCEDURE MANUAL MRI Safety Manual	Reviewed Date 2020	Last Revision 2020	Policy No.
	SUBJECT: Penile Implants		

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.

YNHH all penile implants implanted after 1997 are considered MR Conditional on our 1.5 and 3T systems.

YALE-NEW HAVEN HOSPITAL DEPT. OF DIAGNOSTIC RADIOLOGY POLICY AND PROCEDURE MANUAL MRI Safety Manual	Reviewed Date 2024	Last Revision 2024	Policy No.
	SUBJECT: Foreign Body in Orbits		

Policy

"All patients with a history of orbital trauma by a potential ferromagnetic foreign body for which they sought medical attention or for which there is otherwise high clinical suspicion for globe penetration by a ferromagnetic body are to have their orbits evaluated either by a single orbit radiograph with additional views as necessary or by a radiologist's review and assessment of prior thin-section CT (obtained since the suspected traumatic event), if available. Evaluation of a prior MR examination's susceptibility artifact of the region of the orbits may provide an experienced physician with important information on the ferromagnetic nature of the foreign body, but MR images alone are insufficient to clear orbits."-ACR white paper 2024

Procedure

At YNHH a patient will have orbital x-rays for foreign body if the following criteria are met:

- They have sought out medical attention in the past for a foreign body in the orbit.
- No available CT or MRI for a radiologist to verify they are cleared.

If a patient arrives for an MRI and needs orbital x-rays, it is appropriate for the technologist to take a verbal or written order from the radiology attending physician.

There is no need to obtain an order from the patient's referring physician, inpatient or outpatient.

Radiologist Responsibility

A radiologist from the service (i.e. Neuro, MSK, Body, Peds) that will interpret the ordered MRI examination will determine whether there are any contraindications for the MRI. This service will interpret and dictate the plain-film radiographs obtained for MRI screening.

Ordering & Scheduling Foreign Body X-ray of Orbits:

- From the Technologist Worklist: From tech worklist select the patient, right click and select Order Entry
- Change Order Mode to cosign required **OR** per protocol:no cosign required
- Under New Order select XR EYE Foreign Body as the exam
- Enter a Reason example "per radiologist, MRI clearance"
- Click the Provider Button Change the Ordering DR to Radiology Referring MED Physician
- Click Sign Order
- Schedule as appropriate

YALE-NEW HAVEN HOSPITAL DEPT. OF DIAGNOSTIC RADIOLOGY POLICY AND PROCEDURE MANUAL MRI Safety Manual	Reviewed Date 2021	Last Revision 2021	Policy No.
	SUBJECT: Plain Film X-rays for MRI Clearance		

If a patient has an MRI ordered and the radiologist requires further imaging to safely perform the MRI, it is appropriate for the technologist to take a verbal or written order from the radiology attending physician.

There is no need to obtain an order from the patient's referring physician, inpatient or outpatient.

Radiologist Responsibility

A radiologist from the service (i.e. Neuro, MSK, Body, Peds) that will interpret the ordered MRI examination will determine whether there are any contraindications for the MRI. This service will interpret and dictate the plain-film radiographs obtained for MRI screening.

Ordering & Scheduling Foreign Body X-rays for MRI Studies:

Please use Order entry in Epic.

- From the Technologist Worklist: From tech worklist select the patient, right click and select Order Entry
- Change Order Mode to cosign required **OR** per protocol: no cosign required
- Under New Order select the appropriate exam.
- Enter a Reason example "per radiologist, MRI clearance"
- Click the Provider Button Change the Ordering DR to Radiology Referring MED Physician
- Click Sign Order
- Schedule as appropriate

YALE-NEW HAVEN HOSPITAL DEPT. OF DIAGNOSTIC RADIOLOGY POLICY AND PROCEDURE MANUAL MRI Safety Manual	Creation Date 3/2022	Last Revision 2/2023	Policy No.
	SUBJECT: CARDIAC IMPLANTATIONS: VALVES, STENTS, ABANDONED CARDIAC LEADS, NON-FUNCTIONAL PACEMAKERS		

CARDIAC VALVES

All cardiac valves are considered immediately safe to scan on a 1.5T and 3T.

CORONARY ARTERY STENTS

All coronary stents are considered immediately safe to scan on a 1.5T and 3T.

ABANDONED LEADS: INTRACARDIAC OR PERMANENT EPICARDIAL WITH NO ATTACHED Pacer/ICD

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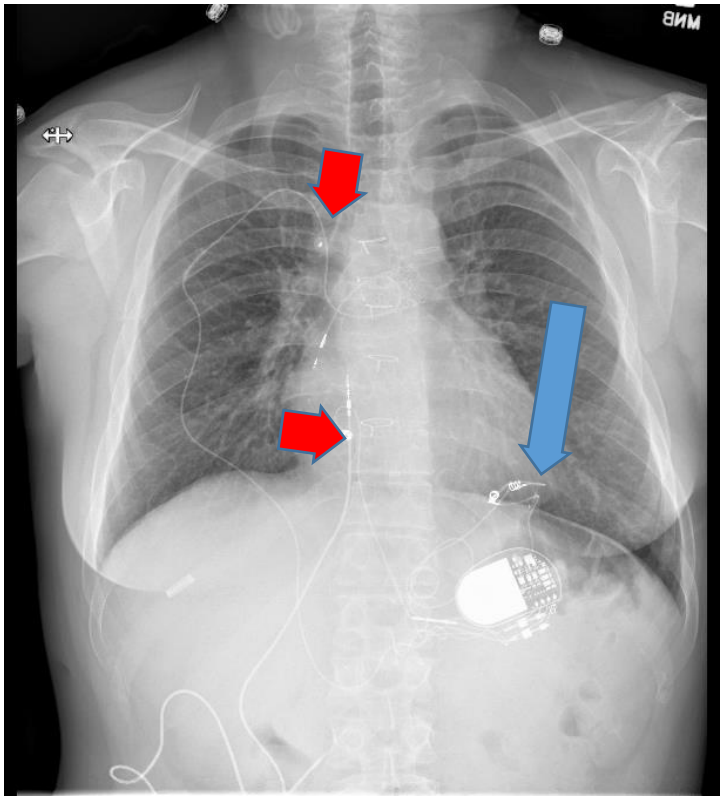
PROCESS

1. Radiologist approves scan using same process as pacemakers to confirm medical necessity.
2. Radiologist obtains informed consent. This is an off-label scan.
   MR scan where the **intracardiac/permanent epicardial leads** are in the RF field is higher risk due to potential of heating and conduction compared to those where RF field does not cover leads. Regardless of RF proximity, a standard procedural consent form explaining risk and benefits of the MRI will need to be signed by a radiologist from supervising service and patient and/or their legal surrogate per normal hospital policy. Consent form may be waived if deemed a medical emergency with ordering attending clinician and attending radiologist agreeing on medically necessity and emergent need for MRI with documentation of that in EPIC or radiologists' protocol. Risks include lead heating, tissue damage, and arrhythmia induction. Consent form should be scanned into EPIC.
3. EP team does NOT need to be present (as no device to interrogate). Case should be booked in monitored slot with Radiology nursing. MRI should be performed using non-conditional pacer protocol (1.5T only, low SAR, limit sequences as much as possible.
4. If it is unclear if there are abandoned leads a recent chest x-ray should be reviewed or a new chest x-ray ordered if needed (see image below).
5. These exams can be performed over weekend or overnight if medically acuity justifies it. In this setting a Radiology RN needs to be available to monitor the patient and a radiologist should obtain consent. If Radiology RN not available, another nurse must accompany the patient who can monitor the patient for any arrhythmia development etc.

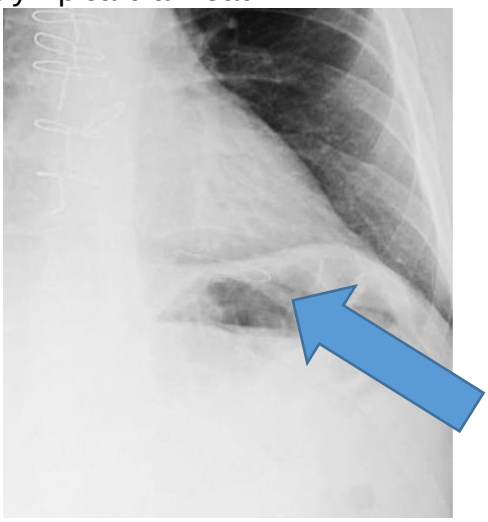


Example- abandoned intracardiac leads (red arrow) and permanent epicardial leads (blue arrow)- Permanent epicardial leads look like regular pacer wire, with pins or coils at end. There are often placed in congenital heart disease cases by CT surgery, or patients with poor vascular access where intracardiac lead not possible.

ABANDONED LEADS: TEMPORARY EPICARDIAL (No pacer device)

Abandoned **temporary epicardial leads** are considered safe to scan on 1.5 and 3T. These are small leads usually with no coils or pins at end that are often placed during cardiac surgery that can be pulled out fully or left in place and clipped at skin surface.

Example of a Temporary Epicardial Lead



ABANDONED LEADS WITH AN INTACT FUNCTIONAL PACEMAKER/ICD DEVICE

Follow standard MR pacemaker process. EP service needs to be present for these exams and will handle informed consent.

NON-FUNCTIONAL INTACT PACEMAKER/ICD WITH OR WITHOUT ABANDONED LEADS:

Current limited data on safety of MRI with a non-functional intact device does suggest MRI can be performed safely when done in monitored environment using imaging protocols that follow MR non-conditional functioning pacemakers/ICDs[1].

PROCESS

1. Radiologist approves scan using same process as pacemakers to confirm medical necessity.
2. EP service will need to confirm that pacer/ICD battery is dead and device not functional. If there is no electrical function, EP does NOT need to attend the scan. Case should be booked in monitored slot with Radiology nursing. MRI should be performed using non-conditional pacer protocol (1.5T only, low SAR, limit sequences as much as possible). If device still has any ability to function, EP team member should attend scan to interrogate device following standard MRI pacemaker process.
3. If EP not involved, radiologist obtains informed consent. This is an off-label scan. For a MR scan where patient just has non-functional intact ICD/pacer device with no other abandoned leads, risks are low and similar to scanning functional non-conditional ICD/pacer device. If patient also has abandoned intracardiac/permanent epicardial leads**,** scans with leads in RF field is higher risk due to potential of heating and conduction compared to those where RF field does not cover leads. Regardless of RF proximity, a standard procedural consent form explaining risk and benefits of the MRI will need to be signed by a radiologist from supervising service and patient and/or their legal surrogate per normal hospital policy. Consent form may be waived if deemed a medical emergency with ordering attending clinician and attending radiologist agreeing on medically necessity and emergent need for MRI with documentation of that in EPIC or radiologists' protocol. Risks include lead heating, tissue damage, and arrhythmia induction. Consent form should be scanned into EPIC.
4. Typically these exams should only be done during normal business hours (M to F 8am to 5pm) as EP team needs to confirm device is not-functional and document that in medical record.

REFERENCES

1. Padmanabhan et al. Safety of magnetic resonance imaging in patients with legacy pacemakers and defibrillators and abandoned leads. Heart Rhythm; V15, 2 2018. 228-233

2. Greenhill MJ, Rangan P, Su W, Weiss JP, Zawaneh M, Unzek S, Tamarappoo B, Indik J, Tung R, Morris MF. MRI in Patients with Cardiovascular Implantable Electronic Devices and Fractured or Abandoned Leads. Radiol Cardiothorac Imaging. 2024 Jun;6(3):e230303. doi: 10.1148/ryct.230303. Erratum in: Radiol Cardiothorac Imaging. 2024 Aug;6(4):e249004. doi: 10.1148/ryct.249004. PMID: 38869431; PMCID: PMC11211945.

YALE-NEW HAVEN HOSPITAL DEPT. OF DIAGNOSTIC RADIOLOGY POLICY AND PROCEDURE MANUAL MRI Safety Manual	Reviewed Date 2020	Last Revision 2019	Policy No.
	SUBJECT: PACEMAKER PROCESS		

Performing Cardiac Pacemaker/Defibrillator Studies- Radiologist Guide

Workflow/Process- Multiple departments involved

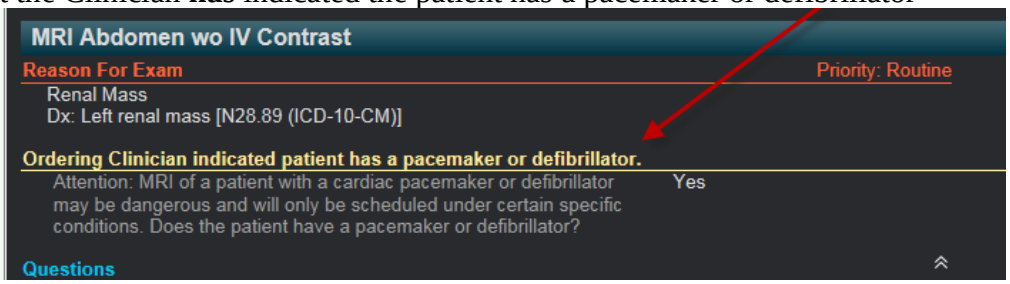
1. Radiologist Approves the Case based on indication and necessity of obtaining MRI (see steps below)
2. EP approves, (A) device and (B) patient's clinical status being fit more MRI
3. Patient scheduled with 3 resources (1) 1.5T MRI machine, (2) Radiology Nursing and (3) EP team.

What is the Radiologists responsibility?

The initial step of imaging any patient with a pacemaker is assessing the appropriateness of the request and need for the MRI. This responsibility lies on a radiologist from the section supervising the case.

How do you know if there is an MRI request for a patient with a pacemaker?

Study that the Clinician **has** indicated the patient has a pacemaker or defibrillator



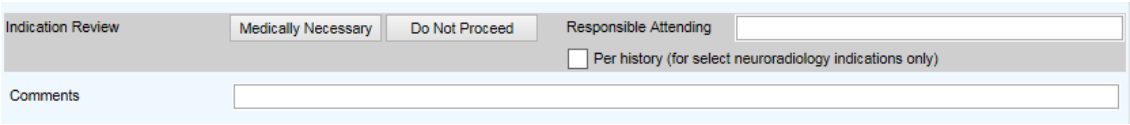
How does the radiologist disapprove or approve and protocol a case?

- Responsible Attending: An attending radiologist must review indication for all pacemaker requests and have their name entered in the **Responsible Attending** field; except for select neuroradiology studies per protocol below defined with neuroradiology division. For those specific studies, click the checkbox next to Per history (for select neuroradiology indications only). **NOTE- a resident/fellow can still protocol all these cases, they just need to list**

attending who approved the case. If attending protocols, please list your own name in the space.

- If radiologist agrees with the Indication for the MRI order, click **Medically Necessary** and **protocol** exam as you normally would. **NOTE- our job is to assess if the MRI is needed. The EP team assess the pacemaker system and determines MR Conditional or Non MR Conditional status and if they can be scanned off-label when needed. For some studies they will re-consult the radiologist to discuss.**

- If radiologist disagrees with the order the radiologist should indicate **Do Not Proceed** and **write comments** on agreement/discussion that occurred with ordering provider in comments section. Alternatively, the radiologist can indicate **Do Not Proceed** and **write comments** on reasoning and a radiology scheduling assistant (CSA) will communicate this to ordering provider on behalf of the radiologist. When requested by the ordering provider, they will notify radiologist to discuss case further with the ordering provider.



MRI pacemaker - Neuroradiology exempt indications list

This list is:
-Stroke cases
-Multiple Sclerosis (MS) evaluation
-Malignancy staging/work-up/gamma knife planning
-R/o cord compression
-R/o Osteo/discitis
-Any cases ordered by Orthopedics/Neurology/neurosurgery (since they have usually given thought into whether MRI is truly needed or not). This includes out-patient providers from these specialties.

All other cases handled by the neuroradiology division need to follow standard process detailed above.

YSC Life/Limb-Threatening (STAT) MRI in Patients with an Implanted Cardiac Device (ICD) policy for ED or In-patients

Objective: Order to begin time of under two hours during normal weekday business hours or by 10am following business day.

Work-flow for ordering health care professional

Health care provider orders highest priority MRI (Life/Limb Threatening -Within 2 hours) and notes presence of pacer/ICD.

MRI scans of patients with implanted cardiac devices can only be performed M-F (excluding holidays) between 8am-5pm

- Call the Smilow MRI tech at **(203-200-5144)** to inform them of this order.
- EP team will need chest-x-ray within 48 hours prior to MRI. If none is available, order stat portable chest x-ray with indication "evaluate implanted cardiac device prior to MRI".
- **Do not request EP consult.** Radiology department will contact relevant EP team for this study.
- Nurse or provider must fill out MRI safety sheet ASAP.

Work-flow following placement of order of Life/limb threatening (true Stat) MRI

- When exam is ordered, scheduler contacts radiologist.
- Radiologist approves MRI following routine pacemaker approval process. Radiologist will discuss with clinical team and technologist as needed
- Radiologist protocols exam.
    - If technologist or scheduler observes that a life-threatening/STAT MRI order for a pacemaker patient exists with no protocol, they will immediately call responsible radiology service during normal business hours or first thing in AM if ordered after hours to get approval and protocol
- Once exam is approved and protocoled by radiologist, scheduler immediately contacts EP team (**203-506-3493**) and notifies them of Life-Threatening MRI exam to initiate emergent EP approval process
- EP team informs MRI scheduler when they will be available to assess patient and approve/reject MRI exam.
- When expected time for EP clearance is known, scheduler communicates this information to ordering health care professional.
    - Scheduler also informs health care team that patient's nurse (not MRI or transport team) will be responsible for patient transport to MRI when called.
    - Provider may be required to stay for MRI for select exams (eg. hyperacute stroke)

SRC MRI workflow for ED and in-patients with an Implanted Cardiac Devices (ICD/pacers)

Objective: Timely performance of MR scans for ED or in-patients at the SRC campus. **MRI pacemaker scans can only be performed 8-5 Monday to Friday currently. No after hour scans are possible at any YNHHS site.**

Workflow

- Exam is ordered by clinical team.
- Radiologist protocols and approves exam.
    - Radiologist should review indication, clinical history and exam priority. For truly Life/Limb orders, radiologist should agree on exam acuity (and that it takes priority over other high acuity scans). If there is any disagreement an attending-to-attending discussion should occur so case can be properly triaged.
    - If technologist or scheduler observes that a life-threatening/STAT MRI order for a pacemaker patient exists with no protocol, they will immediately call responsible radiology service during normal business hours (or first thing in AM if ordered after hours) to get approval and protocol.
- Scheduler contacts EP team leader(s) at (**203-506-9135 or 203-688-5367) between 7am-6pm Monday to Friday** and notifies them of any MRI exams and if the case is a Life/Limb-Threatening MRI exam to initiate emergent EP approval process.

- Scheduler reviews chest xray column for xray within the last year time.
    - If no chest xray completed within YNHHS or viewable in PACS in last one year, scheduler contacts ordering team and tells them to order single view CXR.

- EP team initially informs MRI scheduler:

    - When they will be available to assess patient and expect to complete their clearance

- Scheduler communicates to ordering health care provider:
    - When expected time for EP clearance is known
    - For life/limb threatening exams scheduler will inform health care team that patient's nurse or other team member (not MRI staff or transport staff) will be responsible for patient transport to MRI when patient is called.

The clinical team provider/RN does NOT need to stay with patient for every case. Provider or RN is required to stay in MRI suite for code strokes (until stroke confirmed negative). If patient is clinically unstable it is also advisable for RN or provider to stay in MR suite during the scan.. Radiology RN will also assist.

- If the order is for an in-patient or ED patient after hours the lead radiology MRI tech or MRI scheduler should let clinical team know what steps they can take to expediate work up when EP arrives the following AM. Please use script below.

***"Please ensure there is a chest x-ray within one year available and initiate a device interrogation. This will expediate work up for EP team when they arrive in the AM**". If assistance is needed, clinical team can call device vendor.*

- EP team will review the device. There are three types of device combinations each requiring varying resources:

    - **Intact MR Conditional devices with no abandoned leads:** These are FDA approved scans.
        - All conditional devices can be worked up and monitored by approved EP or Radiology RN .
        - MRI techs may review the device to see if patient can be scanned at 1.5 vs 3T to help find quickest slot available.
        - All Medtronic conditional devices should be discussed with Radiology RNs to see if this is a device they can program and monitor <u>without</u> EP RN. If yes, can schedule accordingly without any EP RN resource.

    - **Traditional Non conditional ("MR unsafe") devices (AKA "Hopkins A"):** These are off label scans.
        - Scan can be supervised by EP RN or EP APRN. EP APP will review and discuss the scan with patient
    - **ANY (conditional or non-conditional) device with permanent epicardial and/or abandoned intravascular leads (AKA "Hopkins B")**
        - **Off-label** scan that needs supervision by EP APRN. EP APP will review and discuss scan with patient. These patients are currently enrolled in a clinical registry.

EP team will let radiology scheduler know which team needs to get involved after device review and EP approval occurs.

Scheduling life/limb threatening pacer MRI at SRC

- For any life/limb threatening scan EP team will try and have a resource available to complete scan within a few hours at the SRC campus. If this is not possible EP will need to communicate they are not able to complete scan at SRC campus in timely fashion and when they can accommodate patient emergently at York Street campus
    - Clinical team will need to decide if they want to fully transfer patient or just arrange for transport to York Street and back to SRC after scan complete.

Scheduling Routine/Urgent ED or inpatient pacemaker MRI exams at SRC:

If case cannot be handled by Radiology RN, EP team will need to communicate when they will have relevant team members available on that campus to complete case. If the clinical team cannot wait that long they will need to consider transfer to York Street campus.

- Currently Wednesday is the only day at SRC campus with EP RN staff scheduled.
- York street campus currently scans pacer cases Wednesday and Friday.
- If EP team will not be able to get a team member to SRC campus within 24-36 hours to complete scan then
    - Radiology lead tech/supervisor and EP manager will jointly review case and determine when patient could be accommodated at York Street campus.
    - Radiology team member will inform clinical team of expected time frame case could be completed at SRC campus vs York Street Campus so clinical team can make decision on if patient transfer will be needed.
        - A transfer should not be done until a slot is assigned to the patient to get scan done at York Street campus

YALE-NEW HAVEN HOSPITAL DEPT. OF DIAGNOSTIC RADIOLOGY POLICY AND PROCEDURE MANUAL MRI Safety Manual	Reviewed Date 2021	Last Revision 9/2019	Policy No.
	SUBJECT: PASSIVE VASCULAR IMPLANTS COILS, STENTS, FILTERS –CARDIAC STENTS SEE PAGE 43		

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.

Minimum SAR for diagnostic clinical images will be used. The technologist has flexibility to edit scanner parameters. If needed, image quality can be reviewed with radiologist to ensure diagnostic quality.

- In the event that it is unclear whether a patient does or does not have an aneurysm clip in place, plain films should be obtained.

- If the patient is identified to have an aneurysm clip, the type of aneurysm clip must be documented. All documentation must be in writing**; phone or verbal histories are not permitted.**

- Having safely undergone a prior MR examination with an aneurysm clip at any given static magnetic field strength is not in and of itself sufficient evidence, and will not be relied upon to determine the MR safety/compatibility of that aneurysm clip.

- All Aneurysm clips surgically placed here at YNHH Main Campus after and including 1986 are MR Conditional and can be scanned on a 3T. (Sugita aneurysm Clip, Yasargil Phynox aneurysm clip (FE), Yasargil Titanium aneurysm clip (FT)).

- Other aneurysm clips may be acceptable on a 3T as long as guidelines are met. To image an aneurysm clip on 3T, specific information (i.e., manufacturer, type or model, and material) about the aneurysm clip must be known and documented. The technologist will check the implant against Dr. Shellocks, “The List” located at www.mrisafety.com for confirmation, or the company’s site if ASTM guidelines for testing have been followed.

- If the type of aneurysm clip cannot be identified and documented the MRI will not be done unless approved by a radiologist.

- If the artifact is great, moving the patient to a 1.5 might be considered if possible

The lead of a stimulator may heat and cause injury during an MRI scan using the body coil. This may occur even when a part of the body remote from the head or neck is scanned. Magnetic and RF fields produced by MRI may change the pulse generator settings or activate the device. Always identify the device and follow its specific instructions.

LIVA NOVA (formally CYBERONICS) VAGAL NERVE STIMULATOR

- The vagal nerve stimulator must be turned off by qualified personnel prior to starting the exam. The patient should have it turned back on after the exam.
- MRI areas and parameters are restricted based on VNS model and implant location.

https://vnstherapy.com/healthcare-professionals/mri

SCHEDULING LIVA NOVA (CYBERONICS) VNS

- Before the procedure starts, identify the make/model and confirm it is eligible for the exam ordered. Contact the adult or pediatric epilepsy fellow. The **C**ontinuous **A**uditory and **V**isual **E**KG Department (C.A.V.E 688 3269) can provide current adult or pediatric epilepsy fellow pager numbers.
- **PLEASE CONTACT AS EARLY AS POSSIBLE TO CONFIRM AVAILABILITY**

BRAIN STIMULATORS (Continued)

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SCHEDULING MEDTRONIC DBS

- http://manuals.medtronic.com/manuals/main/en_US/manual/therapy?therapy=DBS+for+Epilepsy
- A qualified person should be made aware of the time and location of the scan to coordinate the turning on/off of the Medtronic DBS. DBS Rep 405 659 1643

SCHEDULING ST Jude/Abbott DBS

- https://manuals.sjm.com/Search-Form?re=North-America&cc=US&ln=EN&ct=professional&qry=infinity&ipp=10

PLEASE CONTACT AS EARLY AS POSSIBLE TO CONFIRM AVAILABILITY

NEUROPACE RNS therapy

- The RNS therapy system by Neuropace can be imaged based on model number
- RNS System Programming Manual (neuropace.com)
- Contact the adult or pediatric epilepsy fellow. The **C**ontinuous **A**uditory and **V**isual **E**KG Department (C.A.V.E 688 3269) can provide current adult or pediatric epilepsy fellow pager numbers.
- **PLEASE CONTACT AS EARLY AS POSSIBLE TO CONFIRM AVAILABILITY**

All active devices should be researched and the manufacturer's current recommendations should always be followed. Medtronic's Resource: **1- 800 505 INFO**

MEDTRONIC Technical Support 8007070933

Medtronic Bladder Stimulator:

http://manuals.medtronic.com/manuals/main/en_US/manual/therapy?therapy=SNM+for+Bowel+Control Medtronic MRI-Patient Information **1-800-510-6735**

Medtronic Intrathecal Pump

http://manuals.medtronic.com/manuals/main/en_US/manual/index

8637 Medtronic Synchomed II intrathecal pump allowed on a 1.5T and 3T needs to be checked by a device programmer after the MRI ***Flowsheet Appendix H****

Outpatients:

See if patient can set up their own appointment with the Physician who manages their pump. If not-call reps listed below based on the drug in pump.

Inpatients:

Baclofen-Call Kevin (860)-480-5380

Any other medication- Call Melanie (203)-464-5887

Medtronic Spinal Cord Stimulators

Intellis 97715 RestoreSensor 97714

RestoreUltra 97712 PrimeAdvanced 97702 RestoreAdvanced 97713

SCS Melanie (203)-464-5887 melanie.s.grippe@medtronic.com

Skyler-Medtronic local rep 540-220-7679

http://manuals.medtronic.com/manuals/mri/en_US/home

Abbott (Saint Jude Medical) Resources

Prodigy MR Protégé MRI Proclaim Elite

- https://www.sjm.com/en/professionals/resources-and-reimbursement/technical-resources/mri-ready-resources/resources-for-radiology-professionals
- https://manuals.sjm.com/
- https://mri.merlin.net/ #18007277846 toll free number

Boston Scientific Resources

Precision Montage Precision Spectra

- http://www.bostonscientific.com/manuals/manuals/landing-page/US-english.html

Chris Schroder 8607984529

Nevro Resources

Senza

Impendence check valid for 7 days (email correspondence Hausner-Reynolds 2/15/19)

- https://www.nevro.com/English/Physicians/manuals/default.aspx

Nevro Rep-Beverly 203-388-5434

ZIMMER Biomet

1 (800) 447-3625 (guidance document appendix E)

YALE-NEW HAVEN HOSPITAL DEPT. OF DIAGNOSTIC RADIOLOGY POLICY AND PROCEDURE MANUAL MRI Safety Manual	Reviewed Date 2020	Last Revision 2018	Policy No.
	SUBJECT: Orthodontic Dental Devices		

Orthodontic Appliances Policy

Most dental braces/orthodontic hardware is non-ferromagnetic, but some exhibit measurable deflection in a strong magnetic field, and others include magnetic components.

Patients may experience vibrations. Loosening is possible if the dental implant is not firmly bonded or ligated.

Artifacts from metal components may interfere with assessment of certain parts of the brain or cervical spine, especially at 3T.

MRI PROCESS

Prior to appointment

During the pre-appointment call, the MRI tech aid[1] will alert patients with orthodontic appliances that they may feel slight vibrations during MRI. The patient will be advised that they are not required to remove fixed appliances (including wires) prior to any spine/chest/abdominal/pelvic/extremity MRI. However, any components that are easily detachable should be removed before the exam, and loose components should be tightened or secured prior to the exam.

Patients undergoing MRI of the brain should be informed that their MRI images will be monitored for significant MRI artifact, which may necessitate a repeat exam following removal of orthodontic appliance. Outpatients who require general anesthesia (intubation) to undergo MRI are required to have orthodontic appliances removed prior to exam. Patients who are intubated for other reasons (e.g. from the ED) do not require hardware removal.
Patients undergoing MRI with conscious/moderate sedation do not require orthodontic hardware removal.

Immediately prior to exam

Confirm with patient that their orthodontic appliance is not loose, does not employ

magnets, and is not otherwise MRI conditional or unsafe.

During MRI

If there is interfering artifact, the images should be reviewed by the supervising radiologist to ensure the scan is diagnostic. If necessary, sequences may be repeated after swap of phase and frequency encoding directions to move artifact away from area of interest and/or moving patient to a 1.5 Tesla scanner, if available.

If the radiologist determines that the artifact is serious enough to request removing the wires from the braces, the patient will reschedule after removal.

In truly emergent (hospitalized or ED patients) cases where the scan must be repeated for patient care, the referring service (not MRI or radiologist) should contact pediatric or adult dentistry services via page operator to assist with hardware removal prior to attempting re-scan.

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[1] Recommended script for tech aid for a patient that has orthodontic hardware/braces that is undergoing a brain MRI:

"Almost all dental appliances such as braces decrease the MRI scan quality, but the test is usually still diagnostic. We do not recommend that you have them removed unless you need general anesthesia to complete the MRI, but if they make it difficult for the radiologist to evaluate certain parts of the brain, we may ask that you return for a repeat MRI after having them removed. Any parts that are easily detachable should be removed before the exam, and any that are loose should be tightened or secured prior to the exam."

Recommended script for tech aid for a patient that has orthodontic appliance that is undergoing MRI of any body part besides MRI brain:

"Your braces/dental hardware, including wires, should not affect the quality of your MRI and do not need to be removed, but you may feel some vibration or mild tugging during the test. Any parts that are easily detachable should be removed before the exam, and any that are loose should be tightened or secured prior to the exam."

YALE-NEW HAVEN HOSPITAL DEPT. OF DIAGNOSTIC RADIOLOGY POLICY AND PROCEDURE MANUAL MRI Safety Manual	Reviewed Date 2021	Last Revision 2018	Policy No.
	SUBJECT: Trans-Dermal Medication Patches and Wound Dressings		

Wound Dressings and Trans-Dermal Medication Patches
There are thousands of medical dressings and trans-dermal medication patches that are available and have never been tested for MRI safety. Some wound dressings may contain silver, and some Trans dermal medication patches have a metallic backing. Even clear medication patches could contain metallic particles that are invisible to the naked eye.
Exposing these dressings or patches to excessive (RF) can increase their temperature. Increased temperature of metallic particles could cause burns to the patient. Also an increase temperature of a trans dermal patch could in theory alter the dosage given by the transdermal patch.

Transdermal Medication Patches
Transdermal Medication patches like (fentanyl patches) contain prescribed medication. It is out of a technologist's scope of practice to manage these medication patches. ANY patch located in the Radio Frequency (RF) field needs to be removed as we can not reliably determine if a patch has a metal backing. If a patch is known to have metal backing, it needs to be removed before the MRI even if not location in the RF field.

Outpatients:
Outpatients will remove their own transdermal drug delivery patches that need to be removed per guidelines above. After the exam the patient will be given the original patch back and should contact their prescribing physician for a replacement if needed.

Inpatients
Any medication patches that need to be removed should be removed by the floor RN before the patient is sent for. DI nursing will remove any inpatient medication patches per standard hospital protocol.

Wound Dressings that do not contain metallic components or medication
Wounds dressings that don't contain silver or any medication have no MRI restrictions.
Wounds Dressings that possibly contain metallic components or medication
Wound dressings that contain or possibly contain silver /medication are evaluated on an individual basis before having an MRI by the MRI team and the Radiologist
Some of the questions to consider are:
Is the dressing in the RF field? Can the exam be shortened? Is it urgent?
Will the chemical makeup of the dressing degrade image quality?

OLYMPUS

Your Vision, Our Future

Date: September 3, 2014 Document Number: DN0007169
To: Whom it may concern Revision: AB
From: OSTA, Gyrus ACMI, an Olympus company. (Formerly Gyrus ENT LLC, and Smith & Nephew, Inc., ENT Division)

MRI Information for Gyrus ACMI Otology Implant Devices

MR imaging is considered contraindicated for patients with metallic implant because of risks associated with movement or dislodgment for ferromagnetic implants and MRI-related heating for metallic implants that are a certain length or that form a closed conducting loop. With the exception of several production lots of a particular type of middle ear implant (see Table One) manufactured and distributed in late 1987 and early 1988, materials used by Gyrus ACMI in the manufacture of middle ear implant devices are generally considered acceptable for patients undergoing MRI procedures (see below).

Table One

Specific Lots of S&N, Inc. (Richards) McGee Platinum/Stainless Steel Pistons Contraindicated for MRI

This series of McGee Platinum/Stainless Steel pistons were manufactured with a ferromagnetic stainless steel in late 1987 and early 1988. The affected production lots of these pistons, given in Table 1 below, were recalled by Smith & Nephew, Inc. in 1989. Importantly, MRI is contraindicated for anyone having received a McGee Platinum/Stainless Steel piston from these lots.

S&N Catalog No.	Lot Nos.
14-0330	1W91100, 4U09690
14-0331	4U09700
14-0332	1W91110, 4U58540, 4U86300
14-0333	4U09710, 1W91120
14-0334	4U09720, 1W34390, 2WR4073
14-0335	1W34400, 4U09730

S&N Catalog No.	Lot Nos.
14-0336	3U18350, 3U50470, 4UR2889
14-0337	3U18370, 4UR2889
14-0338	3U18390, 4U02900, 4UR1453
14-0339	3U18400, 3U50480
14-0340	3U18410, 3U50500
14-0341	3U41200, 4UR2889

MRI Information

All current Gyrus ACMI MR Conditional implants are packaged with an MRI Patient Card.
(*Please review the explanation of the previous and current labeling terms applied to implants and devices, to follow.):

MR-Safe*
Devices that are made from non-metallic materials (i.e. Implants and Ventilation Tubes made from HA, Plasti-pore, Silicone, Fluoroplastic) are inherently non-conducting and non-magnetic and pose no known hazards in all MR environments and therefore are considered MR Safe.

MR-Conditional*
Devices that have been demonstrated to pose no known hazards in a specified MRI environment with specified conditions of use. Field conditions that define the MRI environment include static magnetic field strength, spatial gradient, dB/dt (time varying magnetic fields), radio frequency (RF) fields, and specific absorption rate (SAR). Additional conditions, including specific configurations of the item (e.g., the routing of leads used for a neurostimulation system), may be required.

OLYMPUS SURGICAL TECHNOLOGIES AMERICA
Gyrus ACMI ▪ 2925 Appling Road ▪ Bartlett, TN 38133 ▪ USA
901.373.0200 ▪ *Fax:* 901.373.0220 ▪ www.olympus-osta.com

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Your Vision, Our Future

The **MRI Conditional Information** for Gyrus ACMI implants (excluding the Lots listed in Table One above) is, as follows:
Non-clinical testing of representative worst case samples has demonstrated that patients with these specific Gyrus ACMI otologic implants can undergo MRI safely, immediately after implantation under the following conditions:

- Static magnetic field of 3-Tesla or less
- Maximum spatial gradient field of 720-Gauss/cm or less.
- MR system reported, whole-body-averaged specific absorption rate (SAR) of 2 –W/kg for 15 minutes of scanning (i.e., per pulse sequence).

The following tables summarize the Gyrus ACMI implants, based on worst case representative sample testing (data on file), available literature reviewed as referenced below [1-7], and a review of the materials used in their construction as allowed by ASTM F2503[8].

Table 2: MR Safe (Materials include: Hydroxylapatite (HA), Fluoroplastic, Plasti-pore, Hapex)

Device Family	Family Product Number(s)	Device Family	Family Product Number(s)
Grote Canal, HA Reconstruction Blocks, Attic Defect	1408XX, 709217XX	Applebaum Incus Replacement	1409XX
Vocom	1430XX, 70143019	Austin Mod TORP	140063
HA Granules	911101	Black Oval	1408XX, 1409XX
Jahn Tube	1409XX		

Table 3: MR Conditional (Materials include: Nitinol, Stainless Steel, Titanium, Tantalum, Platinum),

Device Family	Family Product Numbers(s)	Device Family	Family Product Numbers(s)
CAP / TORP / PORP	140063, 1408XX, 701458XX, 701405XX, 140057, 70143XXX, 70145XXX, 1400XX, 140XXX, 70140XXX, 70141XXX	House Type	1401XX
Micron, Micron II	70142XXX, 70141XXX	Kartush Incus	1408XX, 70145XXX
Smart Pistons	70142XXX, 70143XXX, 70145XXX	Ribbon loops	1407XX
Pistons (various)	141XXX, 140XXX, 70140XXX, 1400XX, 70145XXX, 1407XX	Sheehy-type incus	1404XX
Bucket Handles, Cups, Classic	70142XXX, 142XXX, 1404XX, 1406XX, 70921XXX	Wehrs Incus	701458XX, 701409XX, 140XXX
Goldenberg	1409XX, 701459XX,	Wire loop	140721, 140722
Grate, Grote	1408XX, 70140990		

(XX = 00 through 99) (XXX = 000 through 999)

1. Fritsch MH, Gutt JJ, and Naumann IC. Magnetic Properties of Middle Ear and Stapes Implants in a 9.4-T Magnetic Resonance Field. Otology & Neurotology 2006; 27: 1064-1069.
2. Applebaum EL, Valvassori GE. Effects of magnetic resonance imaging fields on stapedectomy prostheses. *Archives of Otolaryngology* 1985; 111:820-821.
3. Hirsch BE, Weissman JL, Curtin HD, and Kamerer DB. Imaging of ossicular prostheses. *Otolaryngology – Head and Neck Surgery* 1994; 111:494-496.
4. Rodriquez P. MRI indication for the referring surgeon. http://www.gcnet.com/maven/aurora/mri/precatuions.html.
5. Shellock FG. MR imaging of metallic implants and materials: A compilation of the literature. *AJR* 1988; 141:811-814.
6. Shellock FG. Implants and Device: Labeling for MRI and an explanation of Terminology. MRIsafety.com
7. White DW. Interaction between magnetic fields and metallic ossicular prosthesis. *American Journal of Otolaryngology* 1987; 8(2):90-92.
8. ASTM F2503-08: American Society for Testing and Materials (ASTM), Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment. ASTM International

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An attending radiologist (or trainee in consultation with attending radiologists) should weigh the risks versus benefits of the MRI. If a resident or fellow protocols the case, they need to include the name of the attending radiologist who made the decision in the protocol.

If the patient states they have been shot and states that no bullets/fragments remain, no further investigation of the area is recommended. If the patient is unsure if bullets/fragments are remaining, the issue should be brought to the radiologist's attention. In those cases, further imaging with x-rays or review of any prior imaging of the area of interest will likely be needed to get a better sense of bullet location and bullet shape.

Traditionally, risks from retained metallic foreign objects (bullets and shrapnel) in the body have been (1) heating from RF exposure, and (2) movement (translation and rotation), which may injure adjacent structures. Studies have shown that temperature changes occurring with small metal object, such as bullets, is minimal[1]. Thus, in practice, the major safety issue is movement. This risk only pertains to bullets/fragments that contain ferromagnetic componets[1]. In each case, the supervising radiologist must weigh the potential benefits of the MRI exam versus the potential risks. Below are some considerations to help guide the decision:
Size: The less mass the object has the less likely it is to shift position.
Shape: Objects with jagged edges or sharp points have higher risk to injure an adjacent structure
Composition: Bullets with steel or stainless steel cores (such as armor piercing bullets and some shotgun bullets) have the highest risk of movement. Non-steel containing bullets are unlikely to be ferromagnetic and will not move in the MRI magnetic field[1,2]. If the bullet has broken up within the body and created a trail, the composition is likely nonferrous[2]. If the composition of the bullet is not known, you should presume it may be ferromagnetic.

If the shooting was military related, it could be an armor piercing bullet which may be ferrous but may also fragment. In that setting, presume it is ferrous and higher risk.

If patient has been shot multiple times in same region it will be difficult to know if all bullets/fragments are non-ferrous. In this setting assume it is ferrous/higher risk.

Location: If it is not located adjacent to a vital neural, vascular, or soft tissue anatomic structure, movement of the object is unlikely to result in harm, regardless of the composition. For example, a small metallic foreign body in the subcutaneous tissues or bone poses minimal risk to the patient. A bullet embedded fully within the bone and away from neurovascular structures/spinal canal it should have very little risk.

Length of time the object has been lodged: The longer an object is inside the body, the more likely it has been secured by scar tissues, and less likely it is to shift positions.

What should we do if radiologist deems there is potential risk of injury (eg. near vessel or nerve), but MRI is needed for patient care?
In this situation, the risk versus benefit should be discussed with the ordering health care professional. If he/she deems the MRI necessary and the radiologist agrees, this should be documented in Epic and written informed consent should be obtained from the patient. The MR should be performed at 1.5T. Patient should be slowly placed into and removed from scanner.

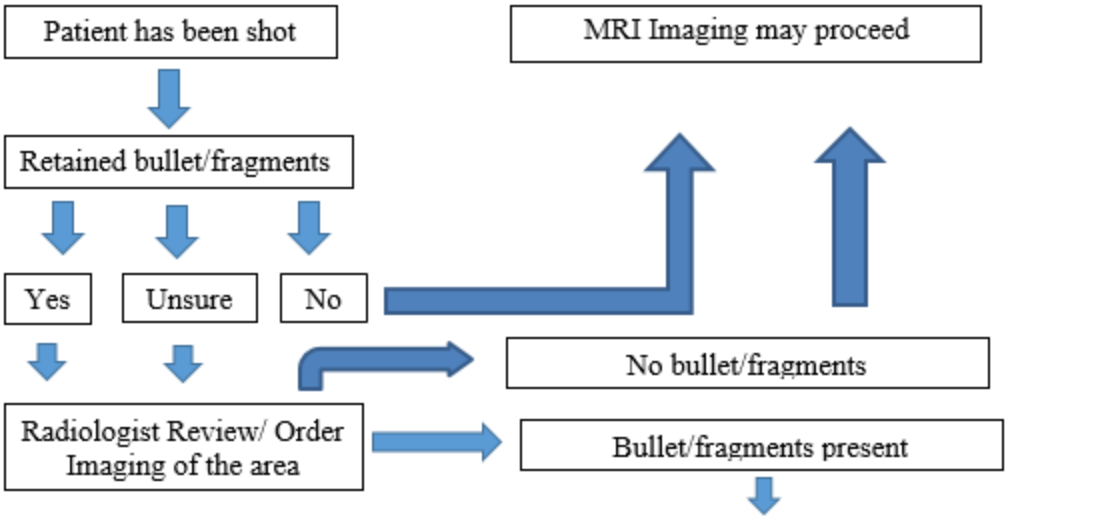
Here is an example of risk versus benefit workflow;
A patient has multiple fragments under the skin in his hand for 10+ years and a MRI of the brain was ordered for stroke

- Size- Minimal risk
- Shape- Minimal risk
- Composition- Unlikely you will know what composition is. Modern BBs are usually made from steel and plated with zinc or copper. They have the potential for movement in the magnetic field. Other BBs (especially older ones) are made of lead and will remain in place.
- Location- Minimal risk for any harm if bullet has some movement
- Length of time: +10 years

Decision= Scan, minimal risk. No informed consent needed.

[1]http://www.imrser.org/pdf/2013.thespine.bullets.pdf

[2]https://www.ajronline.org/doi/full/10.2214/AJR.20.23648



Technologist to ask are all fragments from same injury/episode[1]
Technologist to ask is the injury military related (armor piercing bullet) [1]

https://www.ajronline.org/doi/full/10.2214/AJR.20.23648

Lower Risk

If the bullet is fragmented, it is likely composed of nonferrous metal.

If the bullet/fragment has smooth or rounded edges, movement unlikely to damage surrounding tissue.

If the shooting occurred > 1 yr ago, it has higher chance of being stabilized by scar tissue.

Higher Risk

If the bullet is intact, it is more likely composed of ferrous metal.

If the bullet has jagged/sharp edges, movement is more likely to damage surrounding.

If the shooting is recent, it is less likely to be secured by scar tissue.

If Radiologist determines low risk of injury, decision should be documented in Epic by that radiologist or his designee (which may be MRI tech).

If Radiologist determines higher risk of injury but MRI clinically necessary without alternate test than discuss with ordering physician, obtain written informed consent, and image on a 1.5T scanner.

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YALE-NEW HAVEN HOSPITAL DEPT. OF DIAGNOSTIC RADIOLOGY POLICY AND PROCEDURE MANUAL MRI Safety Manual	Reviewed Date 2022	Last Revision 2-2022	Policy No.
	SUBJECT: External Fixators		

De Puy Synthes has updated their labeling on all standard external fixators to the ASTM 2005 guidelines of MR Safe, MR Conditional and MR Unsafe. This labeling is retroactive so all fixators currently on the market that were labeled MR Safe should now be considered MR Conditional. Stryker/Hoffman also has some external fixator devices with MR conditional labeling at 1.5T (with some approval at 3T) as well. Per discussion with vendor the Hoffman 2 MR conditional set has MR conditional FDA approval for scanning the ex-fix within or outside of bore, while the Hoffman 3 MR conditional set only has MR conditional approval for scanning outside of the bore.

Many other manufacturers don't provide any formal guidance on MR safety of their fixators, so safety of these devices is often unclear.

To date there has been no reported incident involving MRI and external fixators (even when scanned off-label) when basic safety principles are followed. The main risks are movement of ferromagnetic parts or RF (or gradient) induced heating or currents. Because there is substantial variability in ex-fix parts and construct it is impossible to test every configuration across multiple MRI sequences.

Guidance is provided below.

If device is labeled as MR conditional
Scan at 1.5T when possible. Some manufacturers only apply MR Conditional status when the fixator is **outside of the MRI bore (see discussion above)**. The MR tech should investigate which device was used and if the MRI for the patient will meet scanning parameters applied to MR conditional status. If device is MR conditional and falls within approved scanning parameters then no further approval process is needed.

If the device needs to enter the bore (but has MR conditional status only applied when it remains outside the bore) then following steps should be taken.

- All external parts of the external fixator are tested with a bar magnet to ensure no ferromagnetic components.
- Keep SAR as low as possible in Normal Operating Mode.
- Protocol should be tailored to the minimum amount of sequences required.

- Radiologist should document in protocol or chart that review was performed (with caring orthopedic team when needed) and that exam is needed for patient care. This is to confirm benefit outweighs theoretical risk of heating/nerve stimulation and possible device movement since device being scanned "off-label".

If device has no MR safe or MR conditional labeling
Clinical benefit must outweigh theoretical risks. Always scan at 1.5T.

The technologist can image the patient with the fixator (within or outside the bore) if the following conditions are met.

- All external parts of the external fixator are tested with a bar magnet to ensure no ferromagnetic components.
- Keep SAR as low as possible in Normal Operating Mode.
- Protocol should be tailored to the minimum amount of sequences required.
- Radiologist should document in protocol or chart that review was performed (with caring orthopedic team when needed) and that exam is needed for patient care. This is to confirm benefit outweighs risks of heating/nerve stimulation and possible device movement since device being scanned "off-label" and no MR safety status exists.

<u>References</u>
Hayden et al. Magnetic Resonance Imaging of Trauma Patients Treated With Contemporary External Fixation Devices: A Multicenter Case Series. J Orthop Trauma. 2017 Nov;31(11):e375-e380.

Scott et al. External Fixation Devices Within the Magnetic Resonance Imaging Bore: A Safety and Radiologic Analysis, Journal of Orthopaedic Trauma: January 2021 - Volume 35 - Issue 1 - p e25-e30

Gillig et al. Safety and Complications Associated With MRI-Conditional External Fixators in Patients With Tibial Plateau Fractures: A Case Series, Journal of Orthopaedic Trauma: October 2018 - Volume 32 - Issue 10 - p 521-525

Perry KJ, Massey PA, Simoncini A, Barton RS. MRI Safety of external fixation devices: a review of the literature. Curr Orthop Pract 2018; 29:302-307.

http://www.mrisafety.com/SafetyInformation_view.php?editid1=268

YALE-NEW HAVEN HOSPITAL DEPT. OF DIAGNOSTIC RADIOLOGY POLICY AND PROCEDURE MANUAL MRI Safety Manual	Reviewed Date 2024	Last Revision 8-2024	Policy No.
	SUBJECT: Breast Tissue Expanders		

Breast tissue expanders are temporary implants that may contain a magnetic port. Depending on the make and model of the expander, there can be safety concerns for MRI.

When an implant is identified as "unsafe" or the model type is unknown:

The radiologist and ordering provider can do a risk versus benefit assessment to determine whether or not an MRI should be performed.

Risks include the movement of the magnetic port of the implant, potential MRI related heating, polarity reversal of the magnet, and artifacts in the immediate area of the port If the benefits of the MRI outweigh the possible risks from the expanders, the following guidelines should be followed:

- Radiologist must provide written and verbal informed consent to the patient explaining the risks
- Preferably scan on 1.5T at all times, except for selective 3T indications after risk vs. benefit analysis of the clinical situation
- Stabilize the tissue expander by wrapping the patient with coban
- Scan patient prone if possible to minimize or prevent movement
- Monitor patient visually and verbally throughout exam. If the patient reports any unusual sensation or discomfort-abort immediately

Models below are considered MRI Conditional
MENTOR® SPECTRUM® Post-Operatively-Adjustable Saline Breast Implant
MENTOR® BECKER™ Expander/Breast Implant
MENTOR® BECKER™ Smooth Tissue Expanders

Models below are considered MRI unsafe
All CONTOUR PROFILE® Breast Tissue Expanders /CPX™ Tissue Expanders (codes 354-6XXX, 354-7xxx, 354-8 xx, 354, 9xx)

References https://doi.org/10.1097/PRS.0000000000009614

COCHLEAR IMPLANT WORKFLOW

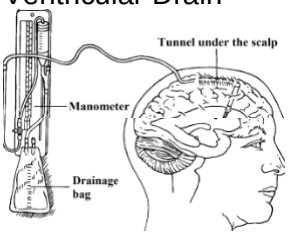
1. A patient with a cochlear implant falls into the queue (MD should have marked "yes" to the implant question on the order)
2. Collect all implant information:
    a. Make/Model
    b. Whether or not there is a magnet implanted under the skin
    c. Whether or not a wrap kit is needed, and coordinate with ENT if necessary
3. Review the type of scan ordered and where the ROI is – Are we scanning the head/neck area?
4. If **No**:
    a. Proceed with the scan following the implant guidelines
5. If **Yes:**
    a. Review any prior imaging with the implant to see artifact extension
    b. If the ROI is near the cochlear implant or if there is a chance that the artifact may interfere with the imaging of the ROI, confirm with a radiologist about where to schedule the exam (especially for protocols requesting 3T only and cases involving bilateral implants)
    c. If the patient is receiving anesthesia/sedation (adult or pediatric) and we are scanning the head/neck, confirm with the radiologist if they want to proceed on a 1.5T knowing that the images may still be degraded, or if they want to speak with the ordering provider to discuss alternative imaging or removing the magnet under the skin prior to the scan.

Device	1.5	3.0	**Comments, Guidelines **
Cochlear Implants 	Some models yes	Some models yes	Some types of cochlear implants employ an internal magnet used in conjunction with an external magnet to align and retain a radio frequency transmitter coil. Other types of cochlear implants are electronically activated. Follow manufacturers FDA approved guidelines. For these devices. +1 877 279 5411.- Cochlear USA surgical hotline 6am-6pm

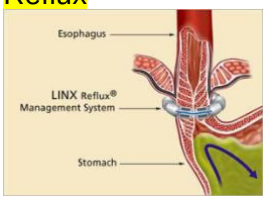
MISCELLANEOUS IMPLANTS

Device	1.5	3.0	**Comments, Guidelines **
Bivona Trach	yes*	yes*	If you are imaging Brain, C-spine, T-spine or Chest Area these should be replaced with a Shiley or non-metallic trach due to the artifact they produce. In necessary situations these areas can be imaged, but the radiologist and ordering physician should be aware that the artifact will affect the spinal cord and extend up into the midbrain. Sequences that will be effected most are DWI SWI t2*, or any gradient weighted images."

Device	1.5	3.0	**Comments Guidelines**
Cardiac Loop Recorder Implantable Cardiac Monitor ST Jude 3500	Yes	Yes	Read company guidelines

Device	1.5	3.0	Comments, Guidelines
External Ventricular Drain 	Yes	Yes	An external ventricular drain (EVD) is a device used in neurosurgery that relieves raised intracranial pressure and monitors CSF fluid levels. Both are safe to use on either the 1.5 or 3.0T. This device does not cause artifacts.

Device	1.5	3.0	**Comments Guidelines**
Intra osseous Vas acces	NO	NO	Should be removed before MRI. EZ-10 is a brand used by paramedics in the field sometimes if rapid access is necessary

Device	1.5	3.0	Comments, Guidelines
Linux Reflux 	Some models yes	No	Patients who have the newer LINX device implanted June 2015 and later can undergo a 1.5T MRI. These patients should have a blue implant card.

Device	1.5	3.0	Comments, Guidelines
Magnimplant Magnatract Sternum	No	No	Magnimplant" and "Magnatract"in a combined system to correct for pectus excavatum or sunken chest Deformity, in pediatric patients.

Device	1.5	3.0	**Comments Guidelines**
Paraguard	Yes	Yes	ALL copper IUD, Paraguards can be imaged on 1.5,3T

Device	1.5	3.0	Comments, Guidelines
Braun Perifix Epidural Catheter 	Yes	Yes	This Catheter is used in epidural procedures. It is made of polyamide nylon and tungsten powder. It does contain a Springwound wire made of stainless steel, which may cause an artifact. It has been tested for use on 1.5 and 3 Tesla magnets. All Perfix catheters, gauges and length and tip configurations are considered safe at these strengths.

Device	1.5	3.0	**Comments Guidelines**
Reveal XT 9529 DX	Yes	Yes	6 week waiting period, Its best practice to send the data collected on the device before the MRI. If an appointment was never set up it is not

9528			necessary to delay care. The technologist should continue with the MRI. For more information, contact **(800) 742-0884 ask for the representative in the area** Check the most up to date Specific MRI instructions on the site below or call 800 505 INFO http://manuals.medtronic.com/manuals/main/us/en_US/home

Device	1.5	3.0	**Comments Guidelines**
Reveal LINQ	Yes	Yes	**NO waiting period,** Its best practice to send the data collected on the device before the MRI. Patients are able do this themselves if they have the *MyCareLink Patient Monitor*. If the patient doesn't have it, there is no need to delay care. The technologist should continue with the MRI. For more information, contact **(800) 742-0884 ask for the representative in the area** Check the most up to date Specific MRI instructions on the site below or call 800 505 INFO http://manuals.medtronic.com/manuals/main/us/en_US/home

Device	1.5	3.0	**Comments Guidelines**
Scleral Buckle	AFTER WANDING	AFTER WANDING	Tantalum Clips used in scleral buckle surgery are acceptable on 1.5 and 3T Please Wand the orbital area with the ferromagnetic wand**.**

Device	1.5	3.0	**Comments Guidelines**
Swanz-Ganz Catheters	Some models yes	Some models yes	Some brands are safe for 1.5 and 3T Check the manufacturers FDA approved guidelines Ex. Edwards Life Sciences model numbers Pedi catheter 040F4, 040HF4, 015F4, 015HF4 flow directed catheter 111F7, 114F7, 115F7, 123F6 are SAFE on 1.5 and 3T

Device	1.5	3.0	**Comments Guidelines**
Temperature Foley Catheters	Some models yes	Some models yes	Some brands are conditional for 1.5 and 3T Check the updated manufacturers FDA approved guidelines Ex. All Bard Temp Foleys are OK on 1.5 and 3T. They should be ran straight down the center of the table-no loops/wires and must be disconnected from any temp monitoring devices

Device	1.5	3.0	**Comments Guidelines**
X-stop Vertebrae implant	Yes	Yes	May cause increased artifact

Miscellaneous Objects MR Conditional or MR Safe on 1.5 and 3T

Burr hole reservoir

Vicrly

Raney Clip

Pexy Clip

Neuro Hemo Clip

Weck Clip

Neuro Ligating Clip

Surgi Clip

Resolution Clip

Gastro Duodeno or Jejuno tube procedures

TIPPS Procedures

Retention disc

Retention ring

Screw Implant

Plate Implant

Ommaya Reservoir

Watchman

Surgicel

Surgiflo

DuraGen

Duraguard

Durepair

Burr hole cover

Prolene

PICC placement

Quinton

Hickman

Skin Staples

Catheters

Rickmans Reservoir

Zenith AAA Endovascular Graft

Testicular Implants

YALE-NEW HAVEN HOSPITAL DEPT. OF DIAGNOSTIC RADIOLOGY POLICY AND PROCEDURE MANUAL MRI Safety Manual	Reviewed Date 2021	Last Revision 2020	Policy No.
	SUBJECT: PREGNANT MRI HEALTHCARE PROVIDERS AND PREGNANT PATIENTS		

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a.) Pregnant Health Care Employees:

All pregnant health care practitioners are permitted to work in and around the MR environment throughout all stages of their pregnancy. Although permitted to work in and around the MR environment, pregnant healthcare practitioners are requested not to remain within the MR scanner room during actual data acquisition.

b.) Pregnant Patients 1.5 and 3T

Pregnant patients may undergo MR scans at any stage of their pregnancy if the referring physician and the supervising radiologist determine that the risk-benefit ratio to the patient warrants that the study be performed.

1.) Pregnant patients may be allowed to have an MRI exam on a 3 Tesla magnet, if the area being imaged is a brain or extremity. Pelvis, abdomen or spine exams should be performed at 1.5 when imaging at 3T is unlikely to provide additional diagnostic value.
2.) The technologist is required to give the patient an information sheet about MRI and pregnancy. This should be documented.
3.) Fetal MRI can be performed on a 1.5 or 3T.
4.) Intravenous gadolinium-based contrast agents should generally NOT be administered for MRI to pregnant patients. Exceptions may be made at the radiologist discretion, but the reason for the exception must be documented by the radiologist in the EMR.

c.) Possible Pregnant Patients and NON Contrast

Patients will not be given a urine hCG test unless they are going to receive a gadolinium-based contrast agent for the MRI exam. In the event the patient is scheduled for a non-contrast exam and is unsure of pregnancy, the department will assume the patient is pregnant and follow the guidelines above for pregnant patients.

d.) Pregnant Companions

The companion will be given an information sheet on MRI and pregnancy. It is their choice to stay in the room during imaging. (Repeated occupational exposure to TVMF is not an issue).

e.) Pre procedure Pregnancy Testing

For Pre procedure Pregnancy Testing please follow the:

PATIENT RADIATION PROTECTION & SAFETY (INCLUDING PREGNANCY) policy located in GENERAL DEPARTMENT GUIDELINES on SharePoint under Radiology.

Review of the literature shows no evidence to suggest that oral ingestion by an infant of the tiny amount of gadolinium contrast medium excreted into breast milk would cause toxic effects [8]. We believe, therefore, that the available data suggest that it is safe for the mother and infant to continue breast-feeding after receiving such an agent.

If the mother remains concerned about any potential ill effects, she should be given the opportunity to make an informed decision as to whether to continue or temporarily abstain from breast-feeding after receiving a gadolinium contrast medium. If the mother so desires, she may abstain from breast-feeding for 24 hours with active expression and discarding of breast milk from both breasts during that period. In anticipation of this, she may wish to use a breast pump to obtain milk before the contrast study to feed the infant during the 24-hour period following the examination.

References

1. Kubik-Huch RA, Gottstein-Aalame NM, Frenzel T, et al. Gadopentetate dimeglumine excretion into human breast milk during lactation. *Radiology* 2000; 216:555-558.

2.. Rofsky NM, Weinreb JC, Litt AW. Quantitative analysis of gadopentetate dimeglumine excreted in breast milk. *J Magn Reson Imaging 1993*; 3:131-132.

3. Schmiedl U, Maravilla KR, Gerlach R, Dowling CA. Excretion of gadopentetate dimeglumine in human breast milk. *AJR Am J Roentgenol* 1990; 154:1305-1306.

4. Weinmann HJ, Brasch RC, Press WR, Wesbey GE. Characteristics of gadolinium-DTPA complex: a potential NMR contrast agent.

YALE-NEW HAVEN HOSPITAL DEPT. OF DIAGNOSTIC RADIOLOGY POLICY AND PROCEDURE MANUAL MRI Safety Manual	Reviewed Date 2021	Last Revision 2018	Policy No.
	SUBJECT: IV AND ORAL CONTRAST AGENTS		

IV Contrast Agents

No patient is to be administered MR contrast agents without orders from a licensed physician. Intravenous injection-qualified MR technologists may start and attend to peripheral intravenous lines if they have undergone the requisite training.

Injections may be performed through an appropriately sized IV line, which may be removed after the exam. The IV line will remain in place during the examination should IV drug therapy be required. This will apply to all patients.

For a patient with a history of contrast reactions please follow the premedication policy. if a patient experiences a contrast reaction the technologist should immediately contact the radiologist and nurse so that appropriate action may be taken. An incident report (R/L solution) is to be filled out via the intranet under Event Reporting. The FDA and the manufacturer of the contrast should also be contacted.

Oral Contrast

Please note for exams the patient may be asked to drink Breeza oral contrast. There are no significant contraindications for this agent and the agent can be given safely in patients with reported Sulfa Allergies.

YALE-NEW HAVEN HOSPITAL DEPT. OF DIAGNOSTIC RADIOLOGY POLICY AND PROCEDURE MANUAL MRI Safety Manual	Reviewed Date 2021	Last Revision 2018	Policy No.
	SUBJECT: Gadolinium and eGFR Screening		

The ACR has categorized GBCA agents into groups of risk factors related to Nephrogenic System Fibrosis (NSF). Dotarem, Gadavist, Prohance, Multihance Elucirem/Vueway and Eovist are Group II. Group I (highest risk) and Group III agents are not currently available/on formulary at YNHH. YNHH patient contrast screening policies have been tailored to the agents and the potential risk of adverse effect related to low eGFR values and risk of NSF when given standard weight based dosing. For a complete list of contrast agent groups and any additional info please visit the ACR website and read the current ACR Manual on Contrast Media https://www.acr.org/Quality-Safety/Resources/Contrast-Manual.

OUTPATIENTS

Contrast from Group II (such as Dotarem, Multihance, Elucirem/Vueway and Eovist)

Outpatients receiving a GBCA from group II do not need to be screened for eGFR.

EGFR only required for higher than weight based dosing. If valid eGFR is < 30 ml/min/1.73m^2 double dose GBCA will be administered only if all of the following conditions are met;

-Documented approval by the supervising radiologist by assigning/signing an appropriate protocol

-Informed consent obtained by supervising radiologist (or his/her designated resident/fellow) and signed by the patient. (Note: Informed consent and reason for exam should be documented in the report)

INPATIENTS

All inpatient requests for contrast-enhanced MRI exams require the ordering health professional to answer a series of ordering screen questions designed to identify patients who might be at risk for NSF. Risk factors include deteriorating renal function.

Contrast from Group II (such as Dotarem, Multihance, Elucirem/Vueway and Eovist)

Inpatients receiving a GBCA from group II do not need to be screened for eGFR.

EGFR only required higher than weight based dosing. If valid eGFR is < 30 ml/min/1.73m^2 double dose GBCA will be administered only if all of the following conditions are met;

-Documented approval by the supervising radiologist by assigning and signing an appropriate protocol

-Informed consent obtained by supervising radiologist (or his/her designated resident/fellow) and signed by the patient. (Note: Informed consent and reason for exam should be documented in the report)

TABLE 1. ACR Manual Classification of Gadolinium-Based Agents Relative to Nephrogenic Systemic Fibrosis

Group I: Agents associated with the greatest number of NSF cases:
• Gadodiamide (Omniscan® – GE Healthcare)
• Gadopentetate dimeglumine (Magnevist® – Bayer HealthCare Pharmaceuticals)
• Gadoversetamide (OptiMARK® – Guerbet)
Group II: Agents associated with few, if any, unconfounded cases of NSF:
• Gadobenate dimeglumine (MultiHance® – Bracco Diagnostics)
• Gadobutrol (Gadavist® – Bayer HealthCare Pharmaceuticals; Gadovist in many countries)
• Gadoteric acid (Dotarem® – Guerbet, Clariscan – GE Healthcare)
• Gadoteridol (ProHance® – Bracco Diagnostics)
• Gadopiclenol* (Elucirem® – Guerbet, Vueway® – Bracco Diagnostics)
• Gadoxetate disodium (Eovist – Bayer HealthCare Pharmaceuticals; Primovist in many countries)
Group III: Agents for which data remains limited regarding NSF risk, but for which few, if any unconfounded cases of NSF have been reported:
• No agents currently in this category (as of April 2024)

Patients on Dialysis or with Acute Kidney Injury (AKI)

If the patient is on dialysis or has known AKI, laboratory testing and calculation of eGFR is not useful or necessary (i.e., eGFR is not accurate in this setting).

Contrast from Group II

- Patients who are on dialysis or with AKI and receiving GBCA from group II do not need informed consent given that current data has not shown any unconfounded cases of NSF with these agents.
- Patients on dialysis should be scheduled for dialysis **as close as possible** following conclusion of the MRI exam. Hemodialysis is preferred over peritoneal dialysis whenever possible due presumed higher efficiency infiltration of GBCAs.

Off Label Usage

Radiologists commonly use contrast media for a clinical purpose not contained in the FDA labeling and thus commonly use contrast media off-label. Physicians have latitude in using gadolinium chelates off label as guided by clinical indication. This also includes pediatric usage in patients under the age of 2.

Non-standard Contrast Dosing (ie- double dosing or multiple doses of contrast in 24 hours)

1. Higher than standard weight based dosing

This is occasionally needed for some group II agents is with some MR angiography, brain MRI, and cardiac MRI applications. In this setting, the Group II agent should be treated like a group III agent (where there is potential for NSF in at risk populations) as there is limited data on utilization of GBCA's with non-standard dosing in this population. The rules of double dosing agents as detailed above would apply in this setting.

2. Receiving more than one GBCA dose in 24 hours.

Occasionally patients need more than one dose of GBCA within a 24-hour period. Two or more doses of GBCA within 24 hours should be avoided when feasible to allow for proper renal elimination. However, if a study needs to be performed requiring a second dose of contrast based on clinical necessity or scheduling it can be performed without radiologist approval as long as the patients eGFR is >30 and they are not in AKI. The NSF risk of more than one (standard) dose of an ACR classified group II agents in patients is likely negligible in patients who have eGFR > 30.

If eGFR is < 30 (and patient is not on dialysis), then all non-stat or non-urgent studies should be delayed for 24 hours to allow for adequate renal clearance. If on dialysis, dialysis should be performed as soon as possible after the MRI.

There is no contraindication to undergoing an urgent or stat contrast enhanced MRI for a patient who has already been administered one dose of GBCA within a 24-hour period if clinically needed.

Exceptions regarding Contrast Usage in Patients

Exceptions to the above policies may be made at the discretion of the supervising radiologist, such as in the rare instance of an acute, life-threatening condition, and after consultation with the referring health care professional if consent cannot be obtained from the patient or surrogate when needed. However, the rationale for the exception must be documented by the supervising radiologist.

Documentation of Contrast Usage

1. MRI technologists will record the specific GBCA and the dose administered to each patient by annotating the MRI exam and documenting dose in EPIC.
2. The radiologist reporting the exam will include the specific GBCA and dose in their report for every contrast-enhanced MRI procedure

Gad Quick Reference Sheet

Who Needs eGFR testing?

Outpatients

- Patient getting higher than standard dose (ie. Double dosing) of group II/III agent (Cardiac, Gamma Mets exams this is standard)

eGFR Labs must be less than 6 weeks old and eGFR greater than 30
If eGFR less than 30 Radiologist needs to consent.

Inpatients:

- Patient getting higher than standard dose (ie. Double dosing) of group II/III agent (Cardiac, Gamma Mets exams this is standard)

If eGFR is less than 30 Radiologist needs to consent.

What do we do with prior Gadolinium "allergic-like" event?

If a patient has had a prior reaction to a gadolinium agent but is approved to have a repeat scan with gadolinium (see pretreatment policy in contrast manual) effort should be made to determine which contrast agent the reaction occurred with. If unknown, Dotarem can be used. If with Dotarem, then Multihance should be used.

https://medicine.yale.edu/diagnosticradiology/patientcare/policies/premedication/ Premedication Policy

Who needs a Hcg urine test?

All females getting contrast who have started menses or are between ages 10-55

Adults (age 18+) can sign a waiver, peds (age 10-17) cannot sign waiver

YALE-NEW HAVEN HOSPITAL DEPT. OF DIAGNOSTIC RADIOLOGY POLICY AND PROCEDURE MANUAL MRI Safety Manual	Reviewed Date 2021	Last Revision 2020	Policy No.
	SUBJECT: Gadolinium Dosing Information		

I. Purpose

To standardize dosing of gadolinium-based contrast agents (GBCAs) in adult and pediatric patients to allow radiology technicians to administer GBCA when ordered by a provider. This protocol will be reviewed annually by the Yale New Haven Health System (YNHHS) Formulary Integration Radiology Subcommittee, local site Pharmacy and Therapeutics Committees and YNHHS Formulary Integration Committee.

II. Background

Gadolinium-based contrast agents (GBCAs) are intravenous drugs used in diagnostic imaging procedures to enhance the quality of magnetic resonance imaging (MRI) or magnetic resonance angiography (MRA).

III. Patient Population

Adult and pediatric patients undergoing MRI procedures.

IV. Procedure

Provider shall order MRI procedure. Radiologist receiving procedure order will protocol the MRI. Once the procedure is protocoled by the Radiologist, the radiology technician will follow the Dosing Protocol outlined in the table below. All dosing will be in mL/kg.

Adult Gadolinium Dosing Chart

WEIGHT (KG)	DOTAREM	EOVIST	MULTIHANCE	ELUCIREM	PROHANCE
2	0.4	0.2	0.4	0.2	0.4
5	1	0.5	1	0.5	1
10	2	1	2	1	2
20	4	2	4	2	4
30	6	3	6	3	6
40	8	4	8	4	8
50	10	5	10	5	10
60	12	6	12	6	12
70	14	7	14	7	14
80	16	8	16	8	16
90	18	9	18	9	18
100	20	10	20	10	20
110	22	11	22	11	22
120	24	12	24	12	24
130	26	13	26	16	26
140	28	14	28	14	28
150	30	15	30	15	30
160	32	16	32	16	32
170	34	17	34	17	34
180	36	18	36	18	36

REFERENCES:

1.Dotarem® (gadoterate meglumine) [prescribing information]. Bloomington, IN: Guerbet LLC; July 2016
American College of Radiology Committee on Drugs and Contrast Media. Manual on Contrast

<4kg **0.5 ml**
4-9kg **1ml**

KG	mL
10-12.4	2
12.5-17.4	3
17.5-22.4	4
22.5-27.4	5
27.5-32.4	6
32.5-37.4	7
37.5-42.4	8
42.5-47.4	9
47.5-57.4	10
57.5-67.4	12
67.5-77.4	14
77.5-87.4	16
87.5-97.4	18
97.5-107.4	20
107.5-117.4	22
117.5-127.4	24
127.5-137.4	26
137.5-147.4	28
147.5-157	30

Pediatrics > 2-year-old, Adolescents and Adults

Patients age 2 years and older undergoing MRI procedures will be administered gadolinium-based contrast (Dotarem®) according to the above dosing chart. Dotarem® dosing for patients weighing greater than 157 kg will be discussed with Attending Radiologist. Gadolinium contrast is administered at a rate of 1-2 mL/second, and line is flushed with normal saline after administration.

Pediatrics < 2-year-old

Pediatric patients under the age of 2 years requiring gadolinium contrast:

Weight 4 kg - 10 kg: 0.025mM/kg of gadolinium containing contrast (Dotarem®) will be administered.
1cc of dotarem 4kg-9kg discussed via email with JP 8/8/17 9am

Weight < 4 kg:
0.5cc of dotarem
For any pediatric patient weighing less than 4 kg. (10 lbs.), approval must be obtained by Attending Radiologist. **Radiologist protocol counts as approval discussed with JP via email 8/8/17 9am**

YALE-NEW HAVEN HOSPITAL DEPT. OF DIAGNOSTIC RADIOLOGY POLICY AND PROCEDURE MANUAL MRI Safety Manual	Reviewed Date 2021	Last Revision 2020	Policy No.
	SUBJECT: MRI Premedication Policy/ Physician Contrast Coverage		

https://medicine.yale.edu/diagnosticradiology/patientcare/policies/premedication/ Click for full policy and allergic like definitions

For Planned Administration of Contrast Agents:		
Previous reaction to allergens (eg shellfish, peanuts, medications, etc):		
Mild	**Moderate**	**Severe**
None	None	None
Previous reaction to **same** class of contrast agent going to be given:		
Mild	**Moderate**	**Severe**
None	Pre-medicate and use different agent	Do not give contrast*
Previous reaction to a **different class** of Contrast agent than type to be given:		
Mild	**Moderate**	**Severe**
None	None	None

Allergic Like Reaction Definitions[1]:		
Mild	**Moderate**	**Severe**
Limited urticaria[2] / pruritis[2]	Diffuse urticaria / pruritis	Diffuse edema, or facial edema with dyspnea
Nasal congestion	Diffuse erythema, stable vital signs	Diffuse erythema with hypotension
Cutaneous Edema	Facial edema without dyspnea	Laryngeal edema with stridor and/or hypoxia
Sneezing / conjunctivitis / rhinorrhea	Throat tightness or hoarseness without dyspnea	Wheezing / bronchospasm, significant hypoxia
Limited "itchy"/"scratchy" throat	Wheezing / bronchospasm, mild or no hypoxia	Anaphylactic shock (hypotension + tachycardia)

https://medicine.yale.edu/diagnosticradiology/patientcare/policies/premedication/

Pre-Medication Regimen

Adult Out-patients:

- 50mg prednisone PO 13, 7 and 1 hour before the injection.
- 10mg cetirizine (Zyrtec®) PO within 1 hour of the injection.
  - *Note: Zyrtec preferred for less drowsy option. 50mg diphenhydramine (Benadryl®) IV/PO within 1 hour of the injectionis acceptable alternative.*

Adult ED and In-Patients:

- 40mg methylprednisolone IV 4 hours before injection.
  - Alternative: 200mg hydrocortisone IV 4 hours before injection.
- 50mg diphenhydramine (Benadryl®) IV within 1 hour of the injection OR 10mg cetirizine (Zyrtec®) PO within 1 hour of the injection.

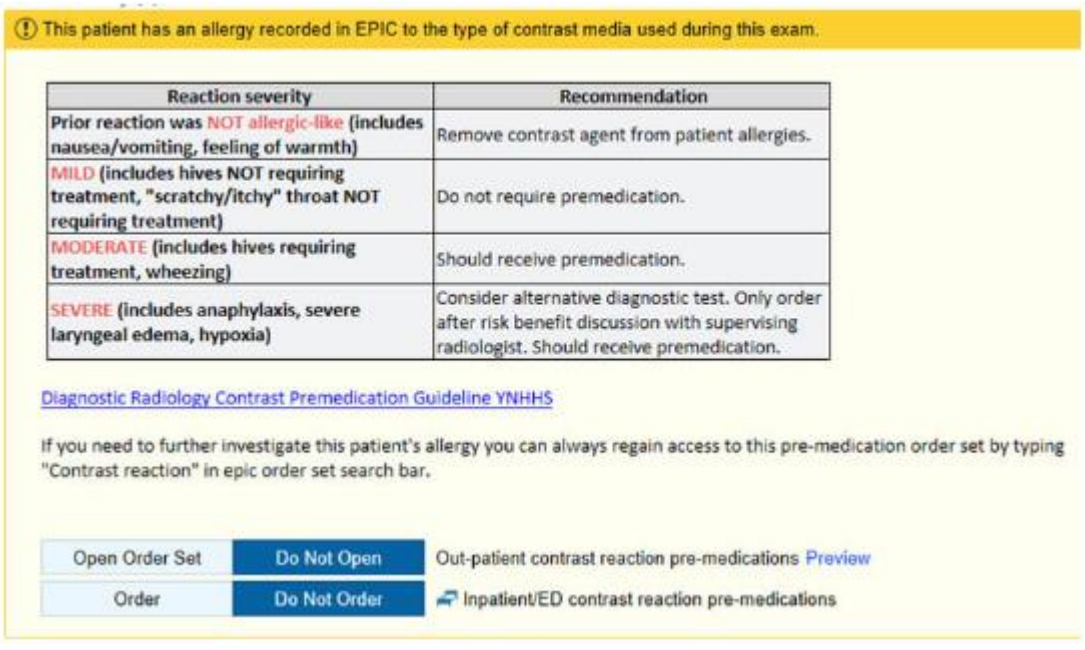
Pediatric Out-patients (For patients less than 50kg):

- Prednisolone 0.7mg/kg (not to exceed 50mg) PO 13, 7 and 1 hour before the injection OR Prednisone 0.7mg/kg (not to exceed 50mg) PO 13, 7 and 1 hour before the injection.
- Antihistamine:
  - Patient >6 months of age: cetirizine (Zyrtec®) PO within 1 hour of the injection (age-based dosing: see prescribing information).
    - Note: Zyrtec preferred for less drowsy option. Diphenhydramine (Benadryl®) 1mg/kg PO (not to exceed 50mg) is acceptable alternative.
  - Patient <6 months of age: Diphenhydramine (Benadryl®) 1mg/kg PO (not to exceed 50mg) within 1 hour of the injection.

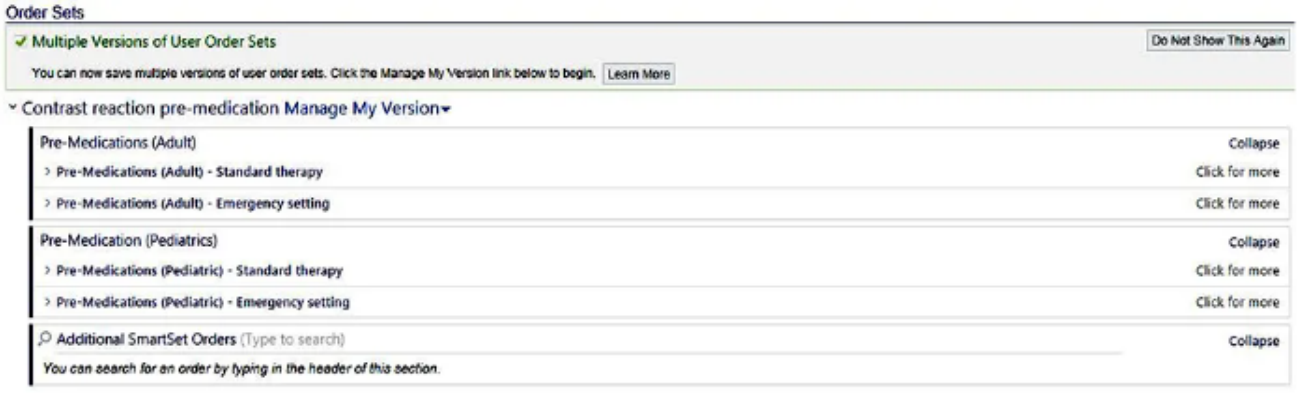
Pediatric ED and In-Patients:

- Methylprednisolone 1mg/kg (not to exceed 40mg) IV 4 hours before injection.
  - Alternative: Hydrocortisone 1mg/kg (not to exceed 200mg) IV 4 hours before injection.
- Diphenhydramine (Benadryl®) 1mg/kg IV (not to exceed 50mg) within 1 hour of the injection OR age-based dosing of cetirizine (Zyrtec®) PO within 1 hour of the injection.

Premedication order set is linked to EPIC order entry if contrast study ordered in patient with relevant contrast allergy documented in EPIC Allergies (screen shot below)



Premedication order set is linked to EPIC order entry if contrast study ordered in patient with relevant contrast allergy documented in EPIC Allergies



Contrast Reaction or urgent adverse patient event coverage (non-urgent situations such as contrast extravasation, mild contrast side effects (nausea/vomiting), and falls will be handled by the supervising service during normal business hours)

MONDAY - FRIDAY

	Patient Location	Day Shift (8am-5pm)	Evenings and night (5pm-8am)
MR	Fitkin (Open 7am to 11pm)	If neuro case, neuro (Fitkin) Otherwise, body MR (Fitkin)	ED YNHH
	Smilow 2 (Open 24/7)	If neuro case, neuro (Smilow) Otherwise, body CT (Smilow)	Neuro (Smilow) until 11pm. ED YNHH 11pm-7am
	Smilow 1 (Tue-7am to 7pm, M/W/Thu-7am-430pm, F-7am-3pm)	Breast	Closed now. When open ED YNHH
	Pedi (Open 7am to 7pm)	Pediatrics	ED YNHH
	Saint Raphael's (Open 24/7)	Neuro SRC, Body SRC, Chest SRC, MSK SRC	ED SRC

SATURDAY - SUNDAY

	Patient Location	Day Shift (8am-5pm)	Afternoon & Nights (5pm-8am)
MR	Smilow 2 (Open 24/7)	If neuro case, neuro (Smilow) Otherwise, body CT (Smilow)	Neuro (Smilow) until 11pm. ED YNHH 11pm-7am
	Smilow 1 (7am to 12pm Sat only)	*If neuro case, neuro (Smilow) otherwise Body Smilow*	ED
	Fitkin (7:00am to 4pm Sat and Sun)	If neuro case, neuro MR (Smilow) Otherwise, body CT (Smilow)	ED YNHH
	Pedi	Pediatrics-until noon. ED after.	ED YNHH

NEURO SMILOW-200-3181	PEDIATRICS-688-6184	
NEURO FITKIN- 688-8905	CARDIAC SP- 688-3570	ED SRC-789-3929/789-6097
BREAST-200-5229		MSK SRC- 789-3704
	BODY MR FITKIN-688-3171	BODY SRC-789-6092/3
ED YNHH-688-6180	BODY CT SMILOW-200-5734	NEURO SRC- 789-4126

YALE-NEW HAVEN HOSPITAL DEPT. OF DIAGNOSTIC RADIOLOGY POLICY AND PROCEDURE MANUAL MRI Safety Manual	Reviewed Date 2021	Last Revision 2018	Policy No.
	SUBJECT: MRI EMERGENCY DEPARTMENT and STAT REQUESTED EXAMS		

ED patients requiring an MRI will receive priority over most inpatient orders. If there are no available openings on the schedule, the Radiologist will look at the clinical needs of the inpatients scheduled and decide which patient to reschedule to accommodate the most emergent case.

There are multiple levels of "Stat" Ordered exams: *Life-Threatening* and *Urgent:*

A Stat patient that is considered *Life Threatening* will be scheduled within 30 minutes of receipt of the order and the completed safety form. Scanning should begin within 2 hours.

A Stat patient that is considered *Urgent* will be scheduled within 30 minutes of receipt of the order and the completed safety form. Scanning should begin within 6 hours.

To schedule an ED MRI two important steps must be done before the patient will be given a scheduled time:

1. The order must be placed in EPIC

2. The inpatient screening process must be followed with completion of the MRI safety form.

The next available time slot will be given to the ED requested patient and a call will be placed to the ED to alert them of the time. Patient transportation appointment will be scheduled in advance of scan time

Yale Diagnostic Radiology
In-house MRI Requests:

October, 2012

- This document sets out the procedures/expectations for MRI requests
- MRI is available 24/7 although there are **limited sub-specialized radiologists and technologists available after hours.**
- Whilst radiologists and technologists are available after hours, it is important that the requests they respond to are appropriate and clinically indicated.
- MRI requests have therefore recently been divided into 4 categories as follows:

Category	Definition	Start time*
Life threatening	**Imminent loss of life, limb or function**	**<2hrs**
Urgent	**Delay in diagnosis could lead to inferior outcome**	**<6hrs****
Routine		**<24hrs**
Time Dependent	**Specific timing necessity e.g. sedation, following a procedure etc.**	**As stipulated by requestor**

***time from receipt of satisfactorily completed safety sheet.**
**** urgent requests received after 11:00 pm may be scheduled at 6:30 am.**

- **Life threatening MRI requests will be started within 2 hours of the safety sheet being received 24/7**
- **In collaboration with the orthopedic, neurology, general and neurosurgery departments, the following definition of life threatening indications have been agreed:**

1) Mass Lesion with acute CNS deterioration

CT (or inadequate outside MRI) evidence of a mass lesion with significant neurologic deterioration over 24 hours where the condition is clinically expected to require either

- Further anatomic information (including additional MR sequences) in order to provide safe treatment

or

- Stereotaxy as a necessary part of providing safe operative care (CT-based stereotaxy being inadequate).

2) Acute Spinal Cord Injury or Deterioration

A rapid acute cord compression protocol (see page 81) has been developed for abbreviated MRI exam in patients with suspected cord compression presenting to the ED. Acute injury or deterioration of spinal cord function including weakness and or sacral dysfunction due to a suspected mass lesion, discitis, osteomyelitis, cauda equina syndrome, or epidural abscess.

- Acute deterioration must have occurred over a short enough time such that rapid treatment is likely to result in restoration of function.

- **A likely diagnosis of radiculopathy, sensory loss-only or fixed severe deficits of >48hrs duration is NOT deemed life threatening.**

3) Unstable Spine Correction

For planning an unstable spine correction, particularly when an occult soft tissue component may compress neural elements upon deformity correction.

- Neurologic exam may be intact. e.g. bilateral jumped facets to rule out disc herniation.

4) Stroke, if:

1) Diagnosis is uncertain.

2) Time of onset is unclear.
(MR perfusion/diffusion in attempt to define ischemic penumbra prior to intravenous lytics/catheter based intervention)

3) Patient has a contrast allergy and needs angiography.

4) Patient is of pediatric age group.

5) Acute Aortic Dissection, if there is a contraindication to iodinated contrast.

6) Acute Appendicitis in Pregnancy, if the general surgery attending consult deems the patient's condition to be life-threatening.

Yale New Haven Hospital

Stat MRI procedure for Acute Stroke Evaluation

Selected acute stroke patients will undergo a stat MRI procedure to further assess cerebral ischemia and possible candidacy for thrombolysis or neuro-intervention. Indications include:

1. Patients with a suspected stroke syndrome (NIHSS $\geq$ 10)
2. Patients who present with an uncertain time of symptom onset
3. Patients with an uncertain diagnosis
4. Pediatric patients
5. Patients being considered for CTA but with a known contrast dye allergy

1. The acute stroke team (resident/NP/attending) will enter the order (MRI - brain w/o contrast), **It is the responsibility of the referring clinician to complete the on-line MRI safety sheet.** If the patient is not alert and orientated, follow the unresponsive MRI clearance protocol for guidance located on page 37 of this manual.
2. The acute stroke team (resident/NP/attending) will then contact the neuroradiology fellow on-call at 203-200-3181 to alert him/her of the acute stroke patient and MRI order.
3. Once the case is protocoled the MRI team communicates with the patient's and ensures the stroke/ED team is transporting the patient to the MRI scanner.
4. In MRI, the team will stay with the patient unless the patient is found not to have an acute stroke and there are no hemodynamic or respiratory concerns, in which case the patient could be transported back to their location by standard transport.

    - Life Threatening Stroke Protocol includes: Ax DWI, Ax FLAIR and Ax SWI sequences.
    - Ax EPI perfusion will be added if the patient has separate IV access for gadolinium and specific request is made.

Approved by Stroke Center and Dept. of Radiology: 4.10; 12.10; 05.11; 12.12; 03.13;

YALE-NEW HAVEN HOSPITAL DEPT. OF DIAGNOSTIC RADIOLOGY POLICY AND PROCEDURE MANUAL MRI Safety Manual	Reviewed Date 2021	Last Revision 2020	Policy No.
	SUBJECT: SRC ON CALL PROCESS and OVERNIGHT PROCESS		

Process for overnight MR Cases:

1. The clinician places the order in EPIC, MR staff, Nurse or Clinician obtains and completes the MRI safety sheet via Encounters in EPIC.
2. The patient must be escorted to the MR Suite by an MD, PA, or RN, for patients that require monitoring.

Calling in the MRI tech for a case at SRC when a technologist is no longer in house.
Technologist on call contact info should NEVER be given to a non-radiologist. Only a radiologist can initiate calling in the on-call MRI technologist.

1. Verify:

   (a) This is a truly urgent case that needs to be imaged off hours
   (b) Ask the ordering physician/team to fill out the MRI safety sheet
   (c) Protocol the case and call the on-call technologist to let them know you approved and protocoled the case.
   (d) For life threatening cases (such as acute cord compression or stroke) the technologist will come to the hospital once notified of the case. For non-life threatening cases the on call technologist will wait until the safety sheet is completed and cleared before heading to the hospital.
2. Coverage and contact numbers for SRC is detailed below.

SRC is staffed 24 hours Monday to Thursday. On Friday, Saturday, and Sunday there is some in house and on call coverage as listed below-

Sunday 10PM – Friday 11PM (Tech in house)
Saturday and Sunday 7am – 3:30pm (Tech in house)
Techs call be called at SRC 203-680-7330

All other times follow on-call details below. Only call in the tech if it is truly an urgent/emergent scan that cannot wait until the next day. Techs will not come in unless called by radiologist who is protocoling the study.

Fridays 11pm – Saturdays 7am

Call On-call Tech at 203-640-1947. Don't call Smilow tech unless you need help reaching on call tech

*Saturdays 3:30pm – Sundays 7am * then again * Sunday 330pm until 10pm*

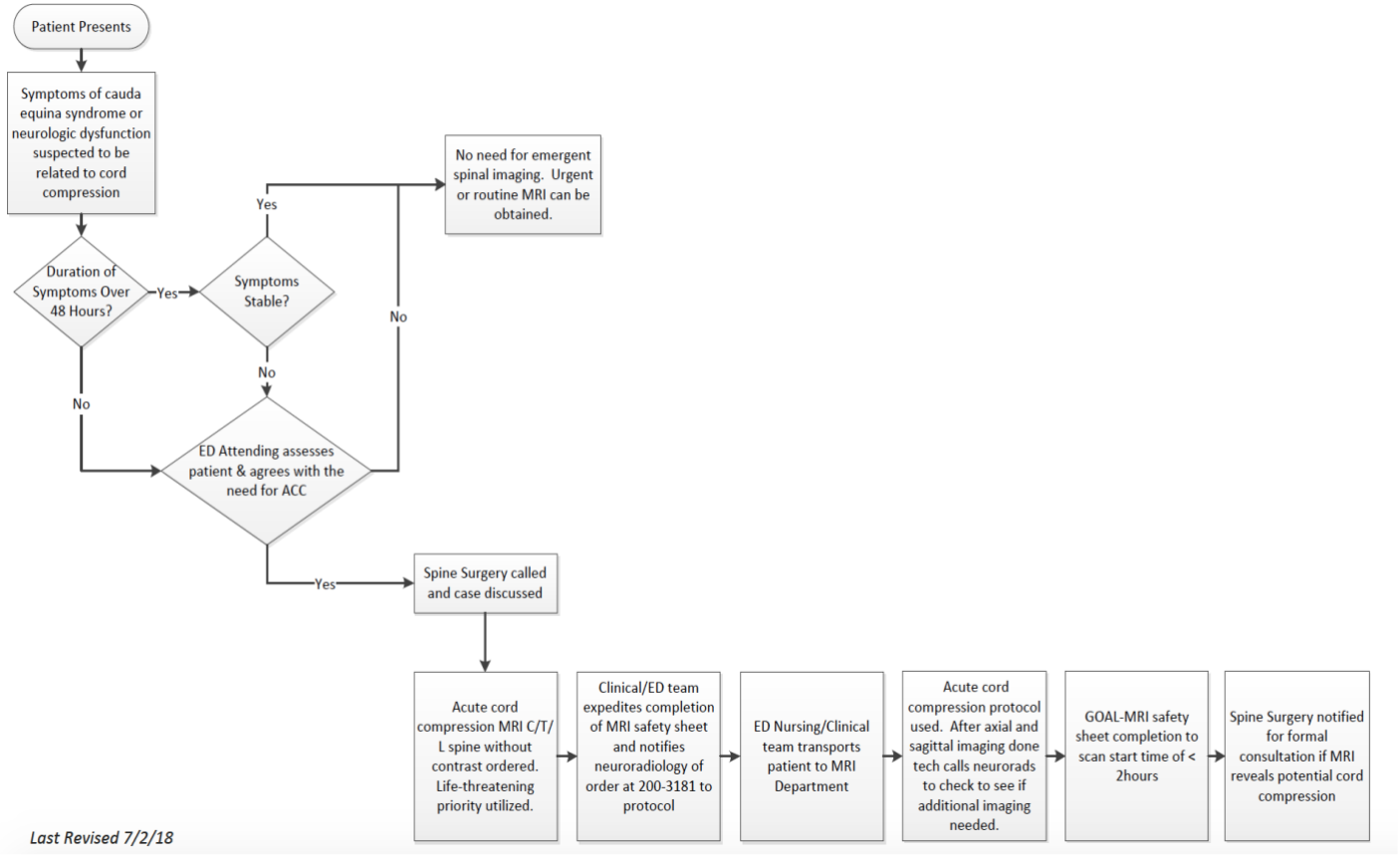
Call On-call Tech at 203-640-1947. Don't call Smilow tech unless you need help reaching on call tech

YALE-NEW HAVEN HOSPITAL DEPT. OF DIAGNOSTIC RADIOLOGY POLICY AND PROCEDURE MANUAL MRI Safety Manual	Reviewed Date 2020	Last Revision 2018	Policy No.
	SUBJECT: Acute Cord Compression		

Acute Cord Compression MRI Protocol

The acute cord compression protocol has been designed to allow for rapid imaging of high risk patients presenting with new or worsening symptoms, of under 48 hours duration, suspected to have acute cord compression or cauda equina syndrome. The protocol was developed by Radiology in conjunction with MRI Operations, Spine Surgery and Emergency Medicine, to rapidly diagnose or exclude cord compression. Other neurologic conditions that can potentially mimic cord compression symptoms will not be well assessed by this rapid protocol, and the patient may need to come back for repeat imaging in those cases.

Acute Cord Compression (ACC) Protocol



Continued Next Page…
Steps for neuroradiology once notified of potential case:

1. Neuro-rads called by ED to protocol and discuss case:
    - If case is at **York Street**, alert Smilow MR tech
    - If case is at **SRC**, and tech in house, alert tech
        - If after-hours at **SRC** (this will usually be the neuro attending overnight M-F, and occasionally fellow on weekend), call tech to come in after you approve case (you do not need to wait for safety sheet completion before calling tech). See SRC after-hour coverage on page 84
2. Techs monitor for safety sheet completion and interface with ED staff to transport patient to magnet once safety sheet cleared and MRI ready to accept patient.
3. The provider and/or RN **DO NOT** need to stay and monitor the patient unless they feel it is necessary because the patient clinical status mandates it.
4. Tech calls neuro-rad to check case after axial and sag sequences done. Contrast and additional sequences can be obtained as discretion of neuroradiologist.
5. Goal:
    - MRI safety sheet complete to MRI start of <2 hours
    - MRI complete to prelim <1 hour

YALE-NEW HAVEN HOSPITAL DEPT. OF DIAGNOSTIC RADIOLOGY POLICY AND PROCEDURE MANUAL MRI Safety Manual	Reviewed Date 2021	Last Revision 2018	Policy No.
	SUBJECT Magnet Room Cleaning		

Cleaning of the MRI suite to include the table, pads, coils, and the inside of the magnet bore is performed by the MRI staff to prevent the transmission of infections. Routine cleaning personnel are not allowed to enter the MRI suite because of the dangerous magnetic field strength that can cause potential catastrophic events harming personnel and the MRI system.

1. Gloves must always be worn when handling contaminated equipment and working with a cleaning disinfectant.
2. Cleaning of the table and pads is performed before and after each patient exam with a hospital approved disinfectant and all cleaning equipment must be MRI safe.
3. Periodic inspection of pads for fraying and tearing is done each month and replaced as necessary.
4. Patient contact inside the magnet bore of the MR unit can transmit infection so cleaning requires an MRI staff member to travel on the table inside the bore to sanitize and disinfect the tunnel walls.
5. MRI magnet room cleaning schedule is available in your area

YALE-NEW HAVEN HOSPITAL DEPT. OF DIAGNOSTIC RADIOLOGY POLICY AND PROCEDURE MANUAL MRI Safety Manual	Reviewed Date 2021	Last Revision 2018	Policy No.
	SUBJECT: LATEX ALLERGIES IN MRI		

If a patient has a latex allergy it should be documented in the patient's chart. Latex allergic patient's sensitivity may vary from a reaction only triggered by actual contact with a latex product to a severe reaction from airborne particles.

The MRI suites at YNHH Main Campus are latex free, except for the Medrad endo-rectal coil. (All Invivo Products, O2 Tubing, suction catheters, gloves, Siemens Call ball are latex free)

For more information, please see the Clinical Practice Manual Latex Precautions and Latex Allergies

YALE-NEW HAVEN HOSPITAL DEPT. OF DIAGNOSTIC RADIOLOGY POLICY AND PROCEDURE MANUAL MRI Safety Manual	Reviewed Date 2020	Last Revision 2018	Policy No.
	SUBJECT: PATIENT MONITORING		

MONITORING BY NURSING STAFF: CRITICAL CARE PATIENTS

This policy conforms fundamentally with the policy developed jointly by the Society of Critical Care Medicine and the American Association of Critical Care Nurses. Patients must be transported with the same level of monitoring required on the sending unit.

It is the responsibility of the health care team on the sending unit to assess the stability of the patient and assure personnel required for safe transportation.

- All ICU patients are to be transported to diagnostic procedures with a minimum of a RN and transporter
- All patients requiring cardiac monitoring are to be transported with a minimum of a RN and transporter
- Patients receiving blood or blood products must be accompanied by an RN
- Patients requiring restraints must be accompanied by an RN or PCA
- Any unstable patient who requires or is at risk for requiring acute intervention beyond the scope of nursing practice must be accompanied by an MD/LIP
- Non critical care personnel may provide transport for ICU patients deemed appropriate to travel without an RN or MD support. These patients must be transported without cardiac monitoring and a MD/LIP order is required indicating the patient may travel without cardiorespiratory monitoring

MONITORING BY MRI STAFF FOR THERMAL INJURY

Monitoring of patients is necessary in the MR scanner. The potential for thermal injury from possibly excessive radio frequency power deposition exists. Sedated, anesthetized and/or unconscious patients may not be able to express symptoms of such injury. Patients who require EKG monitoring and who are unconscious, sedated and/or anesthetized should be examined before scanning and after repositioning to ensure that MR safe EKG leads and any other electrically conductive material is not in contact with the patient or coiled so as to induce a current. For more on thermal injuries please refer to page 17.

The location of the Code Carts should be known by all MRI staff members. These will be checked daily by assigned MR staff for expired medications and functioning equipment.

1. It should be stressed that the magnetic field is **Always ON.** As in any emergency; it is the responsibility of appropriately trained and knowledgeable MRI personnel to ensure the safety of all non MRI personnel as well as that of patients and family.
2. In the event of a code:

YNHH Main Campus:

- Outpatients call 155 for outpatients, and say: Adult medical emergency for an adult, Pediatric medical emergency for a pediatric.
- Inpatients, 155
- North Haven Devine St call 911
- St Raphael Medical Campus call 155
- Shoreline Medical Center call 911
- Park Avenue/Trumbull. Call 911 and page overhead for help.

Give the appropriate location:

3. The patient will be removed from the scan room (zone 4) immediately and the scan room door closed and locked. MR staff members/nursing will transfer patient to nearest recovery area, get the code cart and start basic life support until the code

team arrives. Full resuscitative measures should not be undertaken in the scanner room (Zone 4).

4. Other MRI personnel can offer assistance; such as direct the code team to the right location
5. A radiologist should be notified that a code has been called if possible.
6. While the code is in progress it is imperative that all scanner doors be closed and monitored by MRI personnel to prevent any accidental entry which could result in injury.
7. When the code team arrives they are responsible for the patient. MRI personnel will maintain the safety of all staff in the magnetic environment.
8. After the code it is the responsibility of the MRI staff to call the pharmacy so that the code cart can be restocked as soon as possible.

Workflow for removing sedated and routine MRI Patients from zone 4

Continued on the Next Page

Workflow for Emergency in MRI Suite – Removing patient from scanner to recovery bay.
Algorithm for Sedation or Anesthesia Case

Steps in Workflow

A recovery bay will be open to receive a patient in all sedation and anesthesia cases across all sites in case of emergency. Portable monitor can be used when available. **Step in Process**	**Description**	**Team Member**
In Scanner		
Decision made that patient in distress and needs to be moved from scanner for care	The patient may or may not be coding but needs to be removed from scanner for appropriate assessment and management.	MD (Anesthesia or Sedation)
Make decision to call a code	This decision will be made by MD provider. Provider should call out clearly and ask Tech to Call the code team using closed loop communication.	MD (Anesthesia or Sedation)
Call Code Team by dialing 155	Tech will call the code team and announce campus and location	Technologist or Tech Aid Tech Aid
Stand by door to MRI suite to allow access for Code Team	The door to MRI suite can only be accessed by MRI staff. An individual must stand by the door to the suite to allow Code Team to access	
Prepare to move patient out of scanner	Prepare patient to be moved by disconnecting monitoring lines and pumps.	RN or Technologist
Disconnect wall 02 source		
It was determined that it is a safety risk to try to keep the oxygen attached to the flow meter while moving patient. Self-inflating bags will function without oxygen source and can be reconnected once in recovery bay.		MD (Anesthesia or Sedation)
Undock MRI Table or transfer patient to stretcher		Technologist/ MR Nurse (1)

Move MRI Table from Scanner to Recovery Bay Lock MRI Zone 4 door	In a coordinated effort, available team members will move the table and patient. MD will ventilate from head of bed. RN and Tech will help guide table from MRI scanner, into available Recovery Bay. Close access to MRI magnet ASAP.	MD Technologist Sedation RN and/or MR RN (1) Technologist or tech aid

In Recovery

MD and RN staff will initiate recovery/resuscitation. Code cart can be retrieved if needed in preparation of code team arrival.	As soon as RN is notified that patient is emergently moving out of scanner, RN will create room for MRI table by moving stretcher out of the way.	MR RN (1 and 2) MD Any other available MRI staff

Other Steps Not Yet Assigned or Included in Workflow

Liaise with Parent / Family Member	If family is present during induction, Child Life will be assigned to liaise with parent.	Child Life Specialist

Role Clarity

Team Member	Role
MD Provider	Make decision to move patient out of scanner Make decision to call a code. *Call-out to Tech using closed loop communication.* Disconnect Self-Inflating BVM from 02 source Move MRI Table from Scanner to Recovery Bay with others staff Lead Code / Assign Roles
Sedation RN	Prepare to move patient out of scanner Disconnect monitors and support devices Move MRI Table from Scanner to Recovery Bay with other staff
MR RN (1)	Prepare to move patient out of scanner Disconnect monitors and support devices Help undock MRI Table Move MRI Table from Scanner to Recovery Bay with other staff

Workflow for Emergency in MRI Suite – Removing patient from scanner to recovery bay.
Algorithm for routine MRI scan

Steps in Workflow

Note: A decision was made to place the portable monitor on the MRI table fort all cases where available **Step in Process**	**Description**	**Team Member**
In Scanner		
Patient in Distress. Assess patient to determine if responsive	Patient notifies technologist or technologist noted patient in distress	Technologist and tech aid
Call code if needed.	Call 155 and specify location. The patient may or may not be coding but needs to be removed from scanner for appropriate assessment and management.	Technologist or tech aid Technologist or tech aid
Transfer to stretcher or undock table and remove patient from scanner.		
Notify nursing.	IF CODE NOT CALLED Nursing is available 24-7 and should be called first to assess patient	Technologist or other MRI staff member
Nurse assesses patient	Vital signs and basic exam should be performed by nursing. Nurses to assess stability of patient	Diagnostic Radiology RN Diagnostic Radiology RN
Determine if Radiologist or other medical assistance needed.		

Remodulin (Treprostinil) Pumps

Remodulin/Treprostinil is a continuous therapy that cannot be switched to the MR Conditional Iradimed Pumps. The pumps used are a specific type called a Legacy CAAD. These patients need to come down with a RN from the floor. The pump is kept outside the room and the extension tubing is ran through the waveguide hole in the MR room.

Special Instructions

Remind the RN coming down to: (1) bring down enough extension tubing to run the pump outside the room (2)bring down enough medication to prime all the extensions and last the entire exam

Patients Receiving Blood

When blood or any type of blood product is being administered IV there is always a risk of reaction to the product, these patients should always come down with a nurse. If an MRI is ordered with contrast and a reaction happens it may be difficult to distinguish which agent caused a potential allergy?

Instructions

Non-contrast MRI–can come anytime, bloods needs to be monitored with a floor RN
MRI using contrast- (routine priority) should wait for blood to be finished. This can occur immediately after the product is done with no time delay.

MRI using contrast- (urgent or life threatening priority) should not be delayed and can be scanned while blood product is still infusing. The benefit of the scan is felt to outweigh any risk of confusion with an allergic reaction in this setting.

As always, any pump or pole being used with the blood product must be MR-conditional if brought into zone 4.

Artic Sun Protocol

Artic Sun is a therapy to regulate the bodies' temperature. It consists of gel pads that have temperature regulated water flowing through them. The pads are all over the patient's body and the water is regulated from a machine.

Special Instructions

The machine is disconnected and left on the floor the pads can stay on the patient's body during an MRI scan. MRI staff should verify there are no defibrillator pads under the artic sun pads.

YALE-NEW HAVEN HOSPITAL DEPT. OF DIAGNOSTIC RADIOLOGY POLICY AND PROCEDURE MANUAL MRI Safety Manual	Reviewed Date 2021	Last Revision 2018	Policy No.
	SUBJECT: FERROUS OBJECT IN MR SCAN ROOM		

In the event of a ferrous object in the MR scan room, an evaluation of the situation must be done immediately.

If the object is inside the patient or in the imaging field:

1. Stop the scan and speak with the patient. If the object is identified, and can be removed safely (i.e. a bobby pin) do so with caution.

2. If the object is unidentified or is unsafe for the MRI (i.e. undocumented aneurysm clip) **SLOWLY** move the patient out of the magnet and slide them on to a stretcher. The patient should not sit up, and all movements should be slow until outside of the MRI room.

If the object is pinning a patient or staff member:

1a. If the person is unconscious, bleeding profusely, at risk of losing a limb or extremity, or in severe pain, you must manually quench the magnet to bring down the field in order to release the object and the person.

1b. If the person is responsive and able to tell you they feel OK, you may be able to leave them in the position until a service engineer can respond and ramp the magnet down slowly to avoid a full quench. If you choose the latter, and the person then loses consciousness, or their condition worsens, immediately quench the magnet manually.

2. Once the person is released, get them out of the room and obtain medical help, code procedure pg 91. The MRI manager, safety officer and medical director should be informed immediately. The event should be reported on RL solutions via the intranet and the www.fda.gov/medwatch website.

If the object is solitary and not creating a life threatening situation;

A service engineer can ramp the magnet down slowly to avoid a quench
Contrast Adverse Reaction Contact Info

www.fda.gov/medwatch (800 FDA 1088)

YALE-NEW HAVEN HOSPITAL DEPT. OF DIAGNOSTIC RADIOLOGY POLICY AND PROCEDURE MANUAL MRI Safety Manual	Reviewed Date 2020	Last Revision 2018	Policy No.
	SUBJECT: MRI Safety Officer Responsibilities		

Purpose: To outline the role and responsibilities required of the MRI safety officer in

Definitions: Responsibilities of the MR Safety Officer include, ensuring that MR safe practice guidelines are established, implemented and enforced according to ACR Accreditation Requirements and MR Safe Practice 2013 at all sites.

MR Safety Officer

- Coordinates with the development, implementation of the MRI Safety policies and procedures in compliance with the ACR MRI requirements and MRI Safe Practice 2013.

- Liaison as a consultant to the MR team regarding safety contraindications to ensure the MR unit is safe for patients, visitors, members of the public and staff.
- Coordinates with the MR medical director on revisions of MR safety policies and provides training

- Develop, implement and enforce policies and procedures consistent with ACR's Position Statement on Quality Control and Improvement, Safety, Infection control and Patient Education.

- Responsible for and submission of all materials, including clinical and phantom images, as appropriate, quality control data and such other information as required by the ACR MRI Accreditation Program.

- Responsible for reporting any MR safety incidents or "near misses" that occur in the MRI environment to the Manager, Medical Director and to the FDA via the Maude database.

- Provides Level 1 personnel training for ancillary departments to ensure all visitors are compliant with the MR Safety Manual

- Active Participant in YNHH System MRI Safety Committee

YALE-NEW HAVEN HOSPITAL DEPT. OF DIAGNOSTIC RADIOLOGY POLICY AND PROCEDURE MANUAL	Reviewed Date 2020	Last Revision 2018	Policy No.
MRI Safety Manual	SUBJECT: MRI Medical Director Responsibilities		

Purpose: To outline the role and responsibilities required of the medical director in

Definitions: MR medical director whose responsibilities will include ensuring that MR safe practice guidelines are established and maintained as current and appropriate for the site.

MR Director

- Responsible for the development and implementation of MR Safety policies and procedures in compliance with the most recent ACR White Paper on Magnetic Resonance (MR) Safety.

- Ensures that a physician is present and immediately available when contrast is administered to patients.

- Develop, implement and enforce policies and procedures consistent with ACR's Position Statement on Quality Control and Improvement, Safety, Infection control, Patient and Staff Education.

- Be responsible for assuring compliance with the recommendations of the medical physicist.

- Be responsible for the oversight and submission of all materials, including clinical and phantom images, as appropriate, quality control data and such other information as required by the MRI Accreditation Program.

- Be responsible for notifying the ACR within 15 days of any changes in imaging equipment (units) or changes in the use of equipment that could affect clinical or phantom images.

- Takes a lead role in YNHH System MRI Safety Committee

- Provides personnel training for ancillary departments to ensure all staff are compliant with the MRI Safety Manual

YALE-NEW HAVEN HOSPITAL DEPT. OF DIAGNOSTIC RADIOLOGY POLICY AND PROCEDURE MANUAL MRI Safety Manual	Reviewed Date 2021	Last Revision 2018	Policy No.
	SUBJECT: Wanding		

Due to the presence of a powerful magnetic field, the MRI environment can be dangerous for patients and staff. Precautions must be taken to assure that ferromagnetic materials/devices do not get close enough to the MRI scanner to pose a danger.

Any loose metallic objects or devices will be placed in a locker or some designated secure space in Zone I or II.

Interrogation with a ferromagnetic detector is an important part of the screening process for all individuals entering the MRI environment.

All non- MR personnel, patients, visitors, ancillary facility members and anyone else MR staff deem necessary, need to be evaluated by thorough “wanding” with ferromagnetic detector in Zone II before given permission to enter Zone III or Zone IV. This group includes but is not limited to nurses and PCA staff accompanying patients, environmental services, cardiology and anesthesia staff".

Employees who regularly work in MR do not need to be wanded. This group includes, but is not limited, to Radiologists, MR nursing, MR technologists and MR technical assistants.

All MR staff members can wand visitors, companions and facility staff

members after appropriate training.

Access to the MRI suite will be denied to any person who is not in compliance

YALE-NEW HAVEN HOSPITAL DEPT. OF DIAGNOSTIC RADIOLOGY POLICY AND PROCEDURE MANUAL MRI Safety Manual	Reviewed Date 2020	Last Revision 11/2018	Policy No.
	SUBJECT: Exemptions of MR Safety Policies		

MRI safety policies are based on FDA standards, manufacturer's recommendations, current research and experience, they exist to create a safe standard of care and have been approved by the YNHH MRI Safety Committee**.** Exceptions to these policies may be made at the discretion of the supervising radiologist, such as in the rare instance of an acute, life-threatening condition, and after consultation with the referring health care professional. Potential exemptions include, but are not limited to, scanning a patient with a metallic foreign body of unknown composition, unknown active or passive implant, or waiving informed consent for a scan that would typically need it. Any exemptions should be taken seriously and the rationale for the exception must be documented by the supervising **ATTENDING** RADIOLOGIST in EPIC via the comments section for the exam protocol or via a written clinical note in the patients' medical record EPIC. A non-radiologist clinician cannot override any MRI safety policy unless there is co-documentation by the attending radiologist as noted above. MRI technologists will not scan any patient in these cases until documentation in completed by the supervising attending radiologist.

Some programmable shunts have pressure settings that may need to be known pre-MRI and verified post-MRI. Identify the shunt and its FDA approved process before imaging.

Programmable Shunts that need to be checked

An outpatient with a programmable shunt THAT NEEDS TO BE CHECKED must have an appointment set up before scanning. Not all programmable shunts need to be checked. The shunt settings should be checked within 24 hours by the patient's "shunt manager" (i.e. clinician, device rep).

For all pediatric patients with strata shunts-please contact pedi Neurosurgery at 475-227-6034 or 203-988-9477 to have shunt checked.

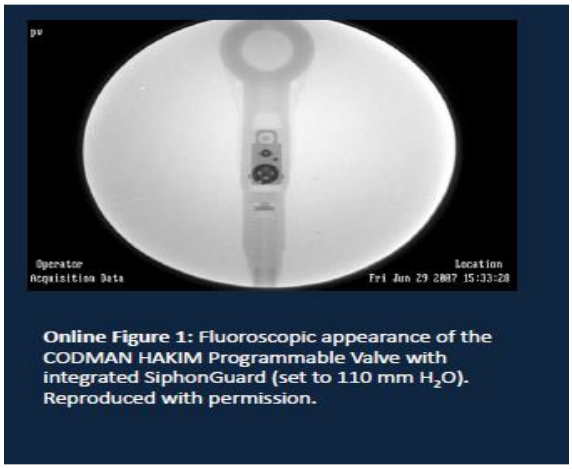
An inpatient with a programmable shunt that needs to be checked must have a Neurosurgery consult before scanning. (i.e. Neurosurgery needs to be comfortable checking the shunt post MRI before we can image) PLEASE CONTACT NEUROSURGERY AS EARLY AS POSSIBLE TO COORDINATE (203 412 1030).

If the type of shunt is unknown, or we have incomplete records, gather as much information as possible and ask a Neuroradiologist (203 200 3181) to (1) confirm whether the shunt is programmable or non-programmable using shunt X-rays and (2) document in EPIC notes. Neurosurgery consult is available to the Neuroradiologist as back-up. If both Neuroradiology and Neurosurgery are unable to confirm the type of shunt, the patient will be rescheduled.

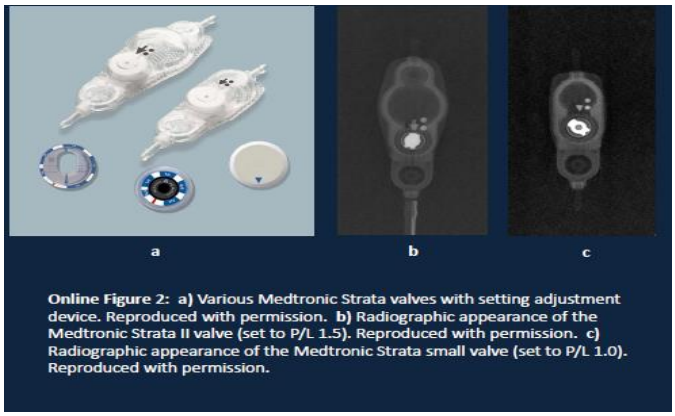
Common Shunts- Refer to MRI safety or manufacturer guidelines

- ProGAV Shunts- Aesculap, ***do not need to be checked***
- Delta Shunts- Medtronic, ***do not need to be checked***
- Codman Certas Plus, ***do not need to be checked***
- Strata Shunts- Medtronic, need to be checked
- Codman Hakim, need to be checked Codman Rep –Rob Dupris 9176780926

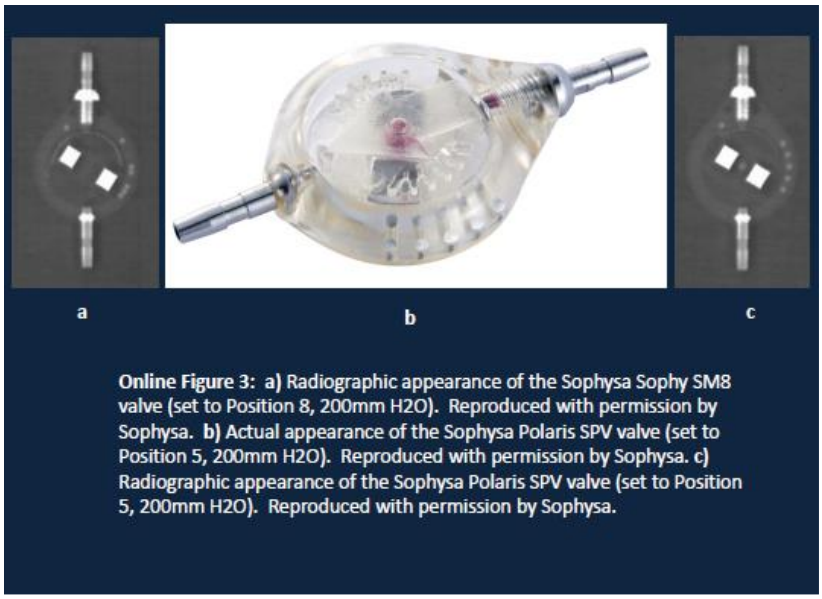
Below are some examples of programmable shunt appearance via X-ray/Fluoro



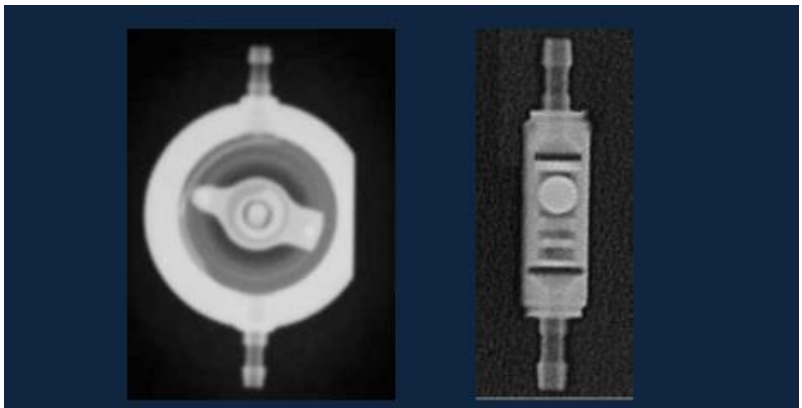
Online Figure 1: Fluoroscopic appearance of the CODMAN HAKIM Programmable Valve with integrated SiphonGuard (set to 110 mm H_2O). Reproduced with permission.



Online Figure 2: **a)** Various Medtronic Strata valves with setting adjustment device. Reproduced with permission. **b)** Radiographic appearance of the Medtronic Strata II valve (set to P/L 1.5). Reproduced with permission. **c)** Radiographic appearance of the Medtronic Strata small valve (set to P/L 1.0). Reproduced with permission.

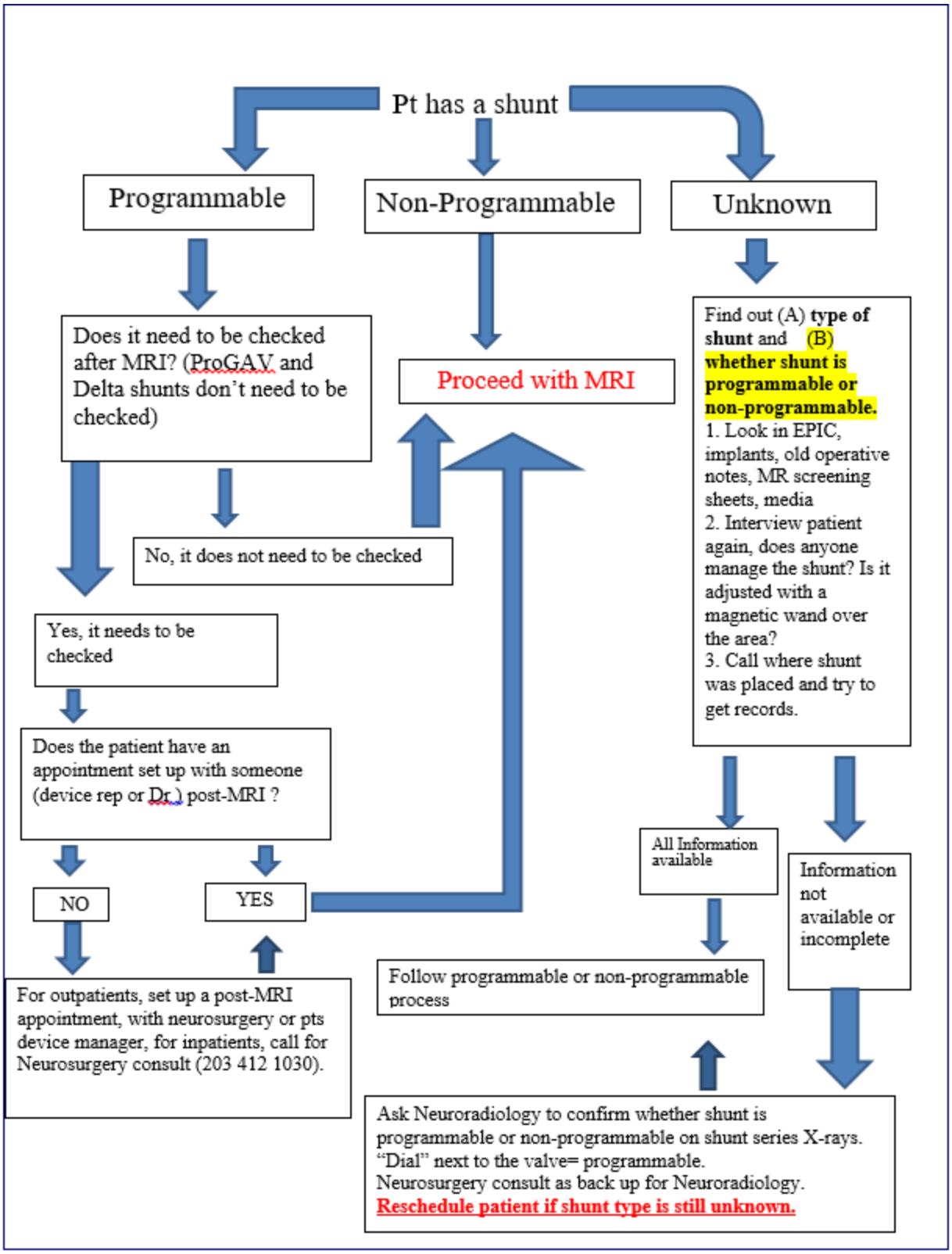


Online Figure 3: **a)** Radiographic appearance of the Sophysa Sophy SM8 valve (set to Position 8, 200mm H2O). Reproduced with permission by Sophysa. **b)** Actual appearance of the Sophysa Polaris SPV valve (set to Position 5, 200mm H2O). Reproduced with permission by Sophysa. **c)** Radiographic appearance of the Sophysa Polaris SPV valve (set to Position 5, 200mm H2O). Reproduced with permission by Sophysa.



Online Figure 4: **a)** Radiographic appearance of adjustable unit, Aesculap Miethke proGAV Programmable Shunt System (set to 0 cm H_2O). Reproduced with permission by Aesculap, Inc. **b)** Radiographic appearance of gravitational unit, Aesculap Miethke proGAVÒ Programmable Shunt System (25 cm H_2O unit). Reproduced with permission.

http://www.ajnr.org/content/ajnr/31/7/1343.full.pdf


Pt has a shunt
Programmable
Non-Programmable
Unknown
Does it need to be checked after MRI? (ProGAV and Delta shunts don't need to be checked)
Proceed with MRI
Find out (A) type of shunt and (B) whether shunt is programmable or non-programmable.
1. Look in EPIC, implants, old operative notes, MR screening sheets, media
2. Interview patient again, does anyone manage the shunt? Is it adjusted with a magnetic wand over the area?
3. Call where shunt was placed and try to get records.
No, it does not need to be checked
Yes, it needs to be checked
Does the patient have an appointment set up with someone (device rep or Dr.) post-MRI ?
All Information available
Information not available or incomplete
NO
YES
For outpatients, set up a post-MRI appointment, with neurosurgery or pts device manager, for inpatients, call for Neurosurgery consult (203 412 1030).
Follow programmable or non-programmable process
Ask Neuroradiology to confirm whether shunt is programmable or non-programmable on shunt series X-rays.
"Dial" next to the valve= programmable.
Neurosurgery consult as back up for Neuroradiology.
Reschedule patient if shunt type is still unknown.

YALE-NEW HAVEN HOSPITAL DEPT. OF DIAGNOSTIC RADIOLOGY POLICY AND PROCEDURE MANUAL MRI Safety Manual	Reviewed Date 2021	Last Revision 2019	Policy No.
	SUBJECT: POST GRID		

Intracranial Electrodes and MRI (Post Grid Protocol)

The root cause of epileptic seizures can be difficult to find. A routine EEG using electrodes on the scalp surface may not locate the origin of a patient's seizures. In these cases, neurosurgeons may need to do more direct monitoring using intracranial electrodes such as subdural grid, strips and/or depth electrodes. The electrodes are placed in the operative room, and the patient undergoes post-operative imaging (MR/CT). They are continuously monitored for a length of time (typically less than 14 days) before the removal of the electrodes.

Some companies' (e.g. Ad-Tech) electrodes do not provide ASTM MRI labelling, but they have an excellent MR safety record with decades of clinical use and research testing. YNHH follows tailored guidelines that have been created based on our years of clinical experience, and published data on this topic.

Our MR guidelines are:

1.5T
Transmit/Receive Head Coil
The protruding leads need to be aligned straight and separated as much as the patients dressing allow.
The sequences performed will be kept to what is clinically necessary.
Head Imaging Only

Davis L. M., Spencer D. D., Spencer S. S., Bronen R. A. (1999). MR imaging of implanted depth and subdural electrodes: is it safe? Epilepsy Res. 35, 95–98. 10.1016/S0920-1211(99)00007-8

Carmichael, D. W., Thornton, J. S., Rodionov, R. , Thornton, R. , McEvoy, A. , Allen, P. J. and Lemieux, L. (2008), Safety of localizing epilepsy monitoring intracranial electroencephalograph electrodes using MRI: Radiofrequency-induced heating. J. Magn. Reson. Imaging, 28: 1233-1244. doi:10.1002/jmri.21583

1- See guidance in composition section

Claustrophobia is defined as extreme or irrational fear of confined places. Many MRI patients feel a varying degree of claustrophobia and/or emotional distress. Having an MRI can have a stressful effect on a patient, in fact a patient might not know they suffer from claustrophobia until their first MRI experience.

Some techniques to combat claustrophobia and/or emotional distress are:

Before the MR exam:

- Prepare and educate the patient about their MR procedure (e.g., MR machine dimensions, noise and potential vibrations, table movements throughout the exam, coil positions and shapes, intercom system, constant presence of the MRI technologist).
- Allow an appropriately screened companion to remain with the patient during the MR examination.
- Position the patient feet first (if exam appropriate)

During the MR exam:

- Maintain verbal, visual, and/or physical contact with the patient during the MR procedure.
- Audio distractions: appropriate stereo system to provide music to the patient.
- Visual distractions: video monitor or goggles, mirrors or prism glasses to redirect the patient's line of sight, a blindfold so that the patient is not aware of the surroundings.
- Comforting environment: bright lights inside of the MR system, fan inside of the MR system.
- Use a sedative or other similar medication.
- Perform the scan as rapidly as possible and do the most important sequences first.

YALE-NEW HAVEN HOSPITAL DEPT. OF DIAGNOSTIC RADIOLOGY POLICY AND PROCEDURE MANUAL MRI Safety Manual	Reviewed Date 2021	Last Revision 2019	Policy No.
	SUBJECT: Tattoos Jewelry Body Piercings and Hair Extensions		

Below is our policy for Tattoos, Jewelry, Body Piercings and Hair Extensions

Tattoos:
Tattoo ink can contain products such as iron oxide that have potential to react with the RF field creating e-fields and in turn burns. Although this is highly unlikely, safety measures should still be put in place.

Before the Exam:

- Tattoos should be discussed with the patient.

During the Exam:

- Maintain verbal, and visual contact with the patient during the MR procedure.
- If the patient is uncomfortable at any point during the exam stop.

Jewelry/Dermal piercings and Magnetic Eyelashes
Before the MR Exam:

- All jewelry that can be removed, should be removed particularly pieces that are in the area of RF exposure.
- If the jewelry can't be removed easily, position it away from the skin as much as possible.
- Prepare and educate the patient about their MR procedure and potential vibrations felt around the jewelry from the magnet (even nonferrous metal can potentially vibrate during gradient excitation.)
- A tester magnet or a ferromagnetic wand can be used to determine if it is ferromagnetic.
- If it is ferromagnetic, a wrap such as coban or tape can be placed around the item to help prevent it from dislodging.

During the Exam:

- Maintain verbal, and visual contact with the patient during the MR procedure.
- If the patient is uncomfortable at any point during the exam stop.

Hair Extensions:
Occasionally the seams of the hairpiece extension include small amounts of metal that may produce an artifact. Others are semi-permanent and attached with hairpins.

Hairpins are typically elongated in shape, very small and highly ferrous. Not only can these pins become projectiles, they can get stuck in the small crevasses of a mechanical MR table, essentially putting the table out of service or creating an artifact that appears on all images until removed.

Before the MR exam:

- ALL hairpins need to be removed before proceeding with the MRI.
- Ask the patient to remove all hair pieces. Scan the patients head with a ferromagnetic detector to confirm no hair pins are present.

YALE-NEW HAVEN HOSPITAL DEPT. OF DIAGNOSTIC RADIOLOGY POLICY AND PROCEDURE MANUAL MRI Safety Manual	Reviewed Date 2023	Last Revision 2023	Policy No.
	SUBJECT: Self-Medicating Anxiolytics Outpatients		

Self-Medicating Outpatient MRI Exams

Claustrophobia and anxiety are everyday experiences during an MRI. Occasionally an outpatient may request an anxiolytic medication from their ordering provider. This medication is not prescribed, controlled, or taken while under the care of hospital staff. The patient should follow all instructions from the ordering prescriber and pharmacist.
YNHHS requests that all medicated outpatients have a ride home in place before the imaging appointment. Outpatients will be reminded of this during a pre-appointment notification, and the appointment may be rescheduled to a time when a mode of transport is available.
If a patient has arrived medicated and plans on operating heavy machinery (driving) and did not follow the guidance of procuring a ride before the appointment. The patient can wait in the facility until a ride is procured.
If the patient chooses not to wait for a ride and plans to drive, security should be notified, and all reasonable efforts should be made to prevent the patient from leaving the Hospital.
The technologist involved in the case writes a note in the Electronic Medical Record summarizing the events and the discussions with the patient regarding the risks of discharge.

General Scripting Example:
Sir or Madam, You have taken medication and should not drive yourself at this time. Please wait in the facility until a way for you to get home is set up. Safety is our top priority. Is there anyone we can call for you? Can we assist you in setting up an Uber or a rideshare? (if possible)
General Documentation example:
Patient X arrived at the facility and appeared to be under the influence. The patient was asked, and it was discovered they had taken an anxiolytic for the pain to “get through” the MRI. After speaking with them, it was discovered the patient didn’t have a ride set up. The patient refused to wait in the facility, call a friend or family member or connect with a ride-sharing service. The patient left, and security called.

Appendix A

YNHH Position on Static Field Gradients

In 2019 the ACR Committee of MR Safety addressed the confusion around the Static Field Gradient, and ASTM MR Conditional labeling.

When a device or implant receives MR Conditional labeling, one of the values assigned is the static field gradient (SFG), i.e. the magnetic field change over distance. Interpretations of this value has caused confusion.
Example of MR Conditional label: (Static Gradient Field of 720g/cm or less)

Vendors provide SFG maps for each magnet. Many of the maps show SFG values higher than a specific device label. For example, you could have an implant that has a SFG rating of 720 g/cm or less and the maximum SFG on your MRI magnet is 1100g/cm.

When reviewing SFG maps for determining safety of scanning an MR conditional implant, two things should be addressed for the magnet being used and the implant in question;

(1) Clinically accessible area
(2) Patient accessible area

Clinically Accessible Area:
The highest SFG areas are not clinically accessible. They are located behind the magnet housing (the plastic bore cover). Additional high SFG regions in front of the plastic covering are in an area utilized by staff not by patients.

Patient Accessible Area:
Patient accessible areas are rarely higher than the standard ASTM labeling[2]. In some instances, there is a high SFG at the very periphery of the bore.

2

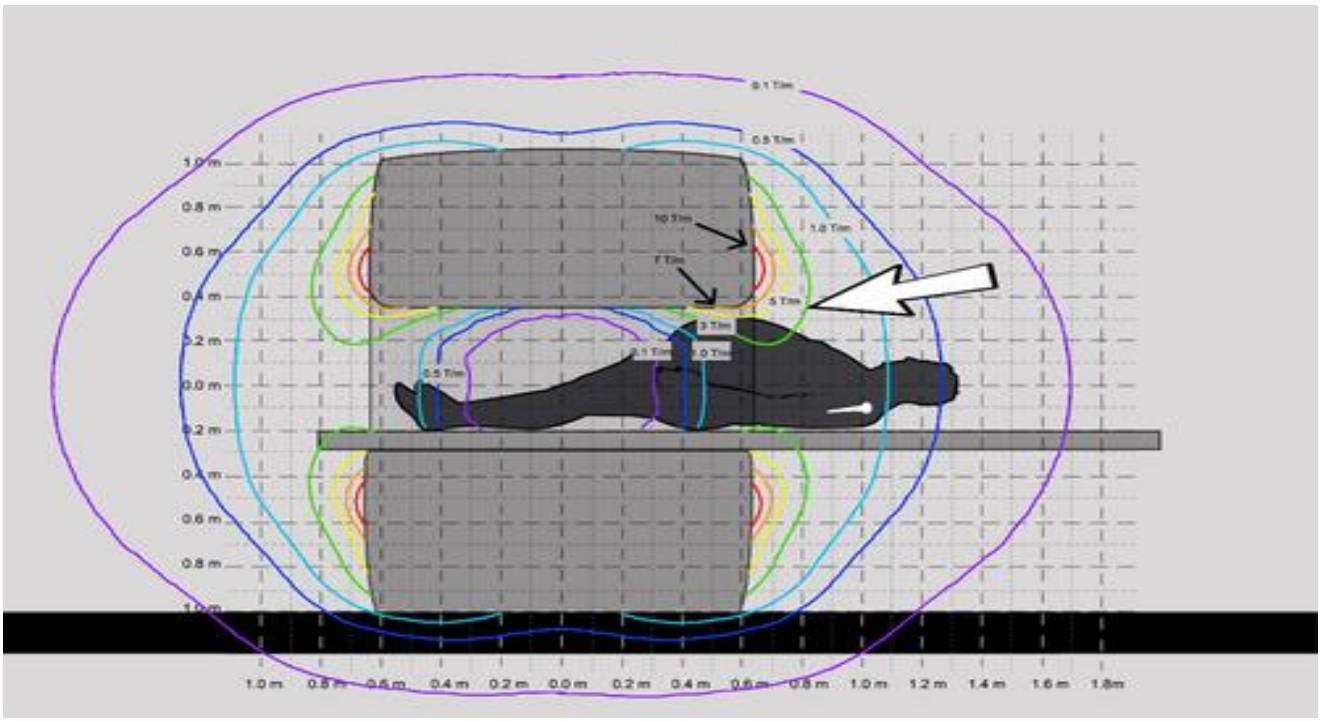


Figure 1 shows a patient in position for a knee MRI. The Orange line identifies 7T/m (700g/cm) SFG.

Conclusion:

We recognize that some MRI Magnets might have SFG ratings higher than what an implant or device is labelled to. We strive to keep all patients, as close to the table/gantry midline, as possible. This will keep the implant exposed to the lowest SFG necessary during the majority of the MRI exam.

References:

ACR guidance document on MR safe practices: Updates and critical information 2019
First published: 29 July 2019
https://doi.org/10.1002/jmri.26880

Regarding the Value Reported for the Term "Spatial Gradient Magnetic Field" and How This Information Is Applied to Labeling of Medical Implants and Devices
Frank G. Shellock, Emanuel Kanal, and Tobias B. Gilk
American Journal of Roentgenology 2011 196:1, 142-145

Appendix B

Multi Hance (Bracco)

- 1-800-257-5181

Dotarem and Elucirem (Guebert)

- Fill out contrast reaction form

Eovist (Bayer)

- 1-888-84bayer.

Appendix C

MRI Safety Websites

http://www.mrisafety.com
Includes "the List" updated yearly list of MR tested devices

http://www.imrser.org
MR Safety Papers, guidelines and information

http://cmemeded.com/mrisafety
MR Safety Courses

http://www.acr.org/Quality-Safety/Radiology-Safety/MR-Safety
ACR website section on MRI Safety

http://enterprise.astm.org

ASTM standards for testing

Appendix D

- https://medicine.yale.edu/diagnosticradiology/patientcare/policies/premedication/

  Premedication Policy link

  http://translation.ynhh.org/SitePages/Home.aspx

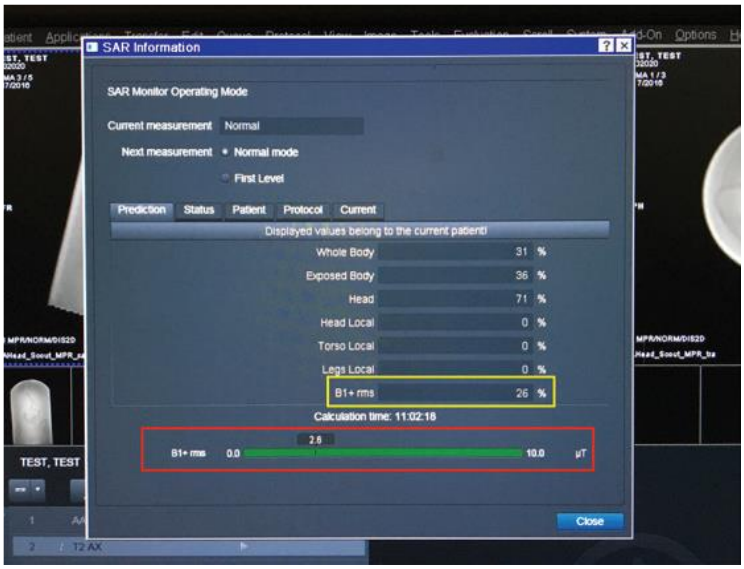
  Translated documents link

Appendix E

Lowering SAR and B1rms Values

Increase	Decrease	Use	Use Sparingly or Avoid
TR	Flip Angle	Parallel Imaging	FS Sequence
Concatenations	Slices	Low Sar Mode if available	STIR Sequence
Slice Thickness	Phase Resolution	Gradient Echo sequences	Extra SAT bands
Averages	Flip Angle		Spin Echo/FSE sequences

How to check SAR and B1RMS on Siemens



Set up your sequence with a Pause
During the Pause click on the SAR button and go to the Prediction Tab
Click on the Line you're interested in B1rms or whole body SAR (e.g. highlighted above in yellow)
Look at the read out (the green line highlighted above in RED)
B1RMS number is displayed,
*SAR value may be displayed in w/lb multiply by 2.2 to convert to w/kg

Appendix F

SpF Implant Devices, Active/Obsolete/MRI Guidance Chart Preliminary Rev. X1 12/3/2012 H.S.

					MRI Section (The effects of MRI procedures using MR systems and conditions above these levels have not been determined.)					
Model	**STATUS**	**Reference # (Located on Box End Label)**	**Model Name (Located on Box End Label)**	**Cathode Type**	**MR Static Magnetic Field**	**Maximum Spatial Gradient (Gauss/cm)**	**Maximum Whole Body Averaged Specific Absorption Rate (SAR) (W/kg)**	**Maximum Gradient Magnetic Fields**	**MRI Artifact Summary**	
SpF PLUS-Mini (60µA) #0177	ACTIVE	REF 10-1398M	SpF® - PLUS 60/M	MESH	1.5 Tesla or Less.	250	1.1 W/kg for 25 Minutes of Imaging.	20 Tesla/Second or Less.	Table 2	
		REF 10-1398W	SpF® - PLUS 60/W	WAVE						
SpF XL IIb (Mini 40) (40µA) #0153		REF 10-1335M	SpF® - XL IIb 2/DM	MESH		450			Table 1	
		REF 10-1335W	SpF® - XL IIb 2/DW	WAVE						
SpF PLUS-Mini (60µA) #0177	OBSOLETE	REF 10-1397M	SpF® - PLUS 2/FM	MESH	1.5 Tesla or Less	250	1.1 W/kg for 25 Minutes of Imaging.	20 Tesla/Second or Less.	Table 2	
		REF 10-1397W	SpF® - PLUS 2/FW	WAVE						
		REF 10-1399M	SpF® - PLUS-L 2/FM	MESH	N/A	N/A	N/A	N/A	N/A	
		REF 10-1399W	SpF® - PLUS-L 2/FW	WAVE						
		REF 10-1400M	SpF® - PLUS-L 2/DM	MESH						
		REF 10-1400W	SpF® - PLUS-L 2/DW	WAVE						
SpF XL IIb (Mini 40)	OBSOLETE	REF 10-1336M	SpF® - XL IIb 2/FM	MESH	1.5 Tesla or Less.	450	1.1 W/kg for 25 Minutes of Imaging.	20 Tesla/Second or Less.	Table 1	
		REF 10-1336W	SpF® - XL IIb 2/FW	WAVE						

(40µA) #0153		REF 10-1396W	SpF® - XL 4/CW	WAVE	N/A	N/A	N/A	N/A	N/A	
		REF 10-1345M	SpF® - XL IIb-L 2/DM	MESH						
		REF 10-1345W	SpF® - XL IIb-L 2/DW	WAVE						
		REF 10-1346M	SpF® - XL IIb-L 2/FM	MESH						
		REF 10-1346W	SpF® - XL IIb-L 2/FW	WAVE						
SpF XL IIb (40µA)	OBSOLETE	REF 10-1385M	SpF® - XL IIb 2/DM	MESH	1.5 Tesla or Less.	450	1.1 W/kg for 25 Minutes of Imaging.	20 Tesla/Second or Less.	Table 3	
		REF 10-1385W	SpF® - XL IIb 2/DW	WAVE						
		REF 10-1386W	SpF® - XL IIb 2/FW	WAVE						
SpF XL II (40µA)	OBSOLETE	REF 10-1375W	SpF® - XL II 2/DW	WAVE	N/A	N/A	N/A	N/A	N/A	
EBI® SpF® - PLUS (60µA) #05	OBSOLETE	REF 10-1389M	SpF® - PLUS 2/DM	MESH	N/A	N/A	N/A	N/A	N/A	
		REF 10-1389W	SpF® - PLUS 2/DW	WAVE						
		REF 10-1391M	SpF® - PLUS 2/FM	MESH						
		REF 10-1391W	SpF® - PLUS 2/FW	WAVE						
					MRI Section (The effects of MRI procedures using MR systems and conditions above these levels have not been determined.)					
Model	**STATUS**	**Reference # (Located on Box End Label)**	**Model Name (Located on Box End Label)**	**Cathode Type**	**MR Static Magnetic Field**	**Maximum Spatial Gradient (Gauss/cm)**	**Maximum Whole Body Averaged Specific Absorption Rate (SAR) (W/kg)**	**Maximum Gradient Magnetic Fields**	**MRI Artifact Summary**	
EBI® SpF® - XL (40µA)	OBSOLETE	REF 10-1370WI	SpF® - XL 4/CW	WAVE	N/A	N/A	N/A	N/A	N/A	
		REF 10-1370W	SpF® - XL 4/CW							
SpF-2T	OBSOLETE	REF 10-1362	SpF® - 2T/D	STRAIGHT		450	1.1 W/kg for 25		Table 3	

(20µA)		REF 10-1332	SpF® - 2T/C		1.5 Tesla or Less.		Minutes of Imaging.	20 Tesla/Second or Less.		
		REF 10-1382W	SpF® - 2T/FW	WAVE		450				
		REF 10-1362W	SpF® - 2T/DW							
		REF 10-1392W	SpF® - 2T/GW							
		REF 10-1332W	SpF® - 2T/CW							
		REF 10-1363W	SpF® - 2T/DLW	WAVE	N/A	N/A	N/A	N/A	N/A	
		REF 10-1393W	SpF® - 2T/GLW							
SpF-4T (20µA)	OBSOLETE	REF 10-1334	SpF® - 4T/C	STRAIGHT	N/A	N/A	N/A	N/A	N/A	
SpF-2, Bullet Shape, (20µA)	OBSOLETE	REF 10-1304	SpF® - 2/C							
SpF-4, Bullet Shape Original BGS (20µA)	OBSOLETE	REF 10-1302	SpF® - 4/F							
		N/A, (6/22/1991)	SpF® - 4							

Appendix G

Passive Vascular Implant Background

How do implants get tested?

For a passive implant to acquire a MR Conditional rating, a series of ASTM tests have to be performed. Two of those tests will be discussed below.

The F2052-15 test measures the deflection angle of an implant to see if gravitational forces or the B0 forces are more influential on the device. The test does not take into account any designed or naturally occurring counterforces once a device is implanted in the human body. Thousands of passive vascular devices mentioned above (coils, stents, and filters) have been tested and brought to market in the USA have passed this test at 1.5 and 3 Tesla. There are some devices that were brought to market before ASTM standards were created, and others before 3T scanners were in use. Based on additional testing or clinical research, most have had their labeling changed to include 3T. The YNHHS MRI Safety Committee feels the risk of harm is very low from MRI for a patient from any passive vascular device.

The F2182-11a test assesses the relationship between RF induced heating and the implant. This is the current standard, but is not very precise and likely is over-conservative as it does not take into account the cooling effects of blood perfusion, which is known to have a major impact on heat reduction of passive vascular devices. The **periphery** of the RF transmission field is where maximum heating occurs. During testing, devices are placed in the area where heating would be maximized to show

worst case scenarios (usually the edges of the phantom), and the results may not reflect the situations in patients when passive vascular devices are not on the periphery, but more centered in the body/ field and therefore exposed to lower RF transmission energies.

How can we predict heating risk?

The standard method to predict heating in a passive implant is to monitor SAR (specific absorption rate) values. SAR is estimated by adding up all the RF pulses in a sequence, dividing by TR and then taking that number and dividing by the patient's weight (watts of power/kg). Burns are thought to be created within an area of the body with high resistance to "electron traffic". RF is introduced into the body and then dissipated by normal thermoregulatory systems. If there is an area where it cannot dissipate heat efficiently, an e-field is created ("energy pile-up"), and this is thought to produce a burn. However, the relationship between RF and e-field creation is not precise. While RF is a component of the SAR calculation, using SAR to predict burns caused by e-fields is indirect and difficult to foresee.

It is also important to note SAR levels received in the clinical setting are not accurate. Different manufacturers calculate SAR with different methods and exponents, and the SAR levels can even vary between software levels on the same MRI scanner. SAR reported at the clinical work station has been shown to be many times higher than actual values. The limitations of SAR values in clinical MRI are widely known in the MR community. A newer value called B1rms, which is not patient dependent, is being used

for active implant testing. This value is more accurate, but it's not the standard ASTM test for passive implant testing.

In clinical MRI there are two SAR settings "normal mode" and "first level". The large majority of passive vascular devices have a SAR value that can be satisfied by one of these two modes. There are a handful of devices that have a ASTM labeling with a SAR rating lower than the normal operating mode setting of 2w/kg. Given limitations of testing and SAR estimates, our policy is to always keep the SAR values as low as possible for diagnostic clinical images

Reference

MR Safety Officer Training Course

MR Safety Facebook Group- multiple discussions

Dr Donald Mcrobbie SAR B1rms calculation https://drdonaldmcrobbie.com/2018/03/20/sar-and-b1rms-what-are-they/

Coils:

Updated stainless steel embolization coil guidelines Cook medical.
https://www.cookmedical.com/support/general-product-information/

Slesnick, T.C., Schreier, J., Soriano, B.D. et al. Pediatr Cardiol (2016) 37: 62. https://doi.org/10.1007/s00246-015-1240-3

Standards:

ASTM F2182-11a Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging, ASTM International, West Conshohocken, PA, 2011, https://doi.org/10.1520/F2182-11A

ASTM F2052-15 Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment, ASTM International, West Conshohocken, PA, 2015, https://doi.org/10.1520/F2052-15

Woods, T. O. (2007), Standards for medical devices in MRI: Present and future. J. Magn. Reson. Imaging, 26: 1186-1189. doi:10.1002/jmri.21140

SAR:

Baker KB, Tkach JA, Nyenhuis JA, et al. Evaluation of specific absorption rate as a dosimeter of MRI-related implant heating. J Magn Reson Imaging 2004;20:315–320.

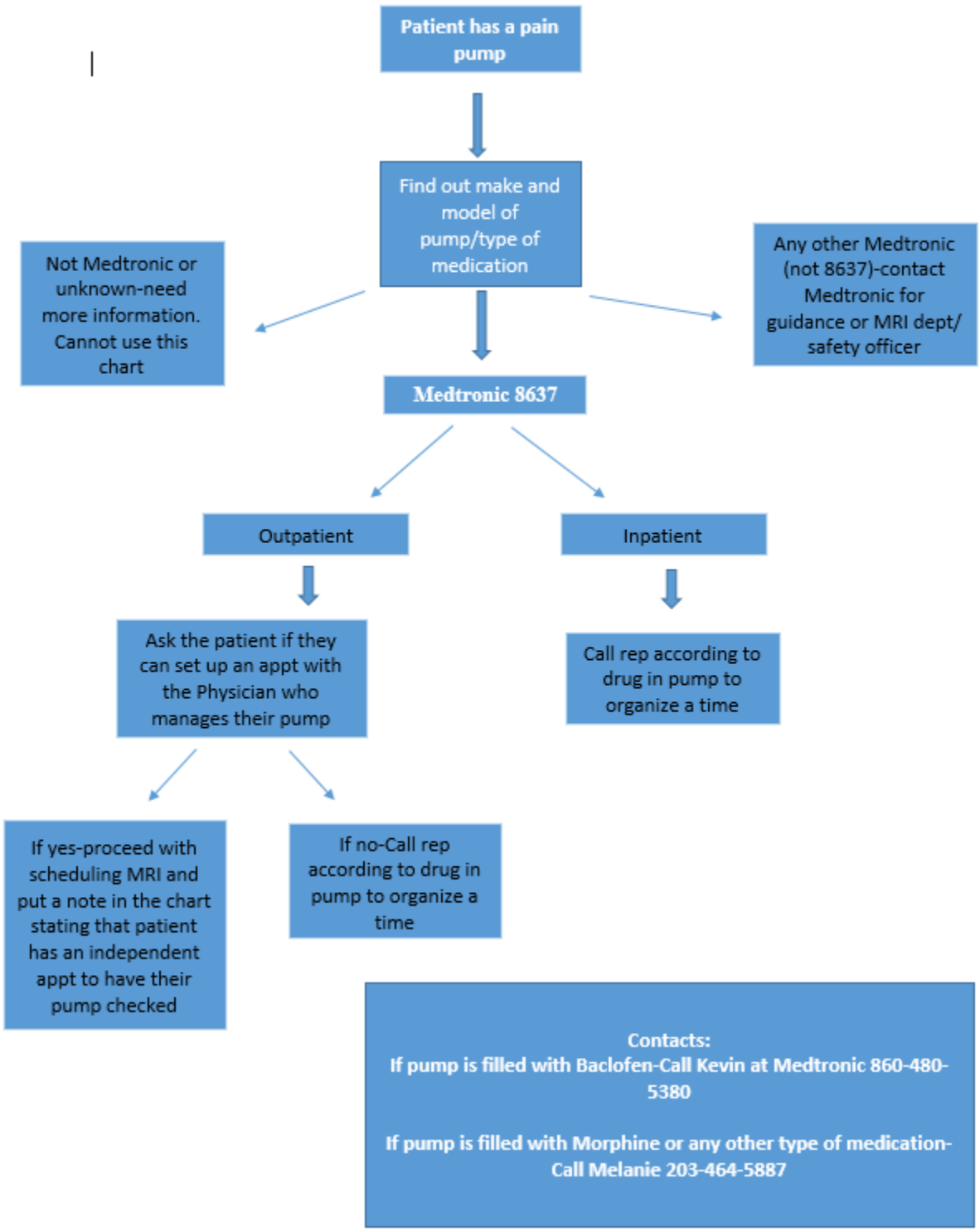
B1+RMS, The root-mean-square value of the MRI Effective Component of the RF Magnetic (B1) Field http://www.mrisafety.com/SafetyInfov.asp?SafetyInfoID=362

Stents:

Coils, Filters, Stents, and Grafts http://www.mrisafety.com/SafetyInfov.asp?SafetyInfoID=171Hiramoto JS, et al. The effect of magnetic resonance imaging on stainless-steel Z-stent-based abdominal aortic prosthesis. J Vasc Surg 2007;45:472-474

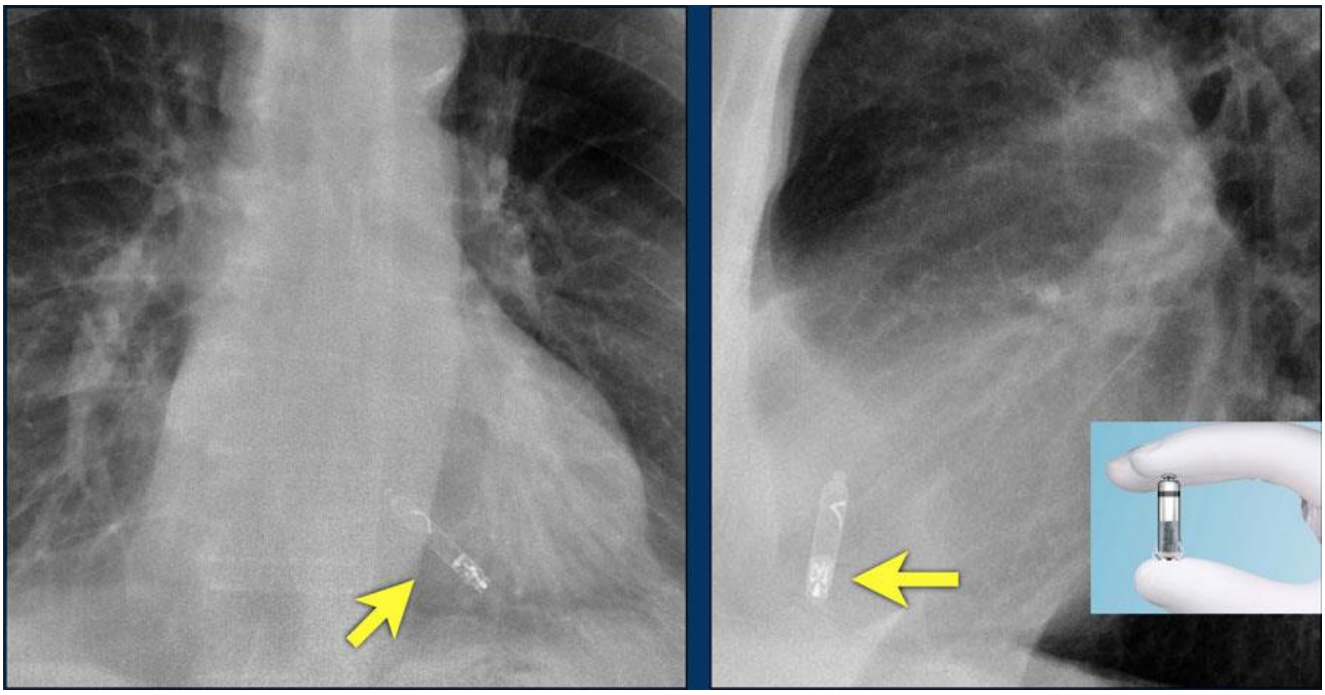
T. Resch, M. Malina, B. Lindblad, J. Malina, J. Brunkwall, K. Ivancev**The impact of stent design on proximal stent-graft fixation in the abdominal aorta: an experimental study** Eur J Vasc Endovasc Surg, 20 (2000), pp. 190-195

Appendix H

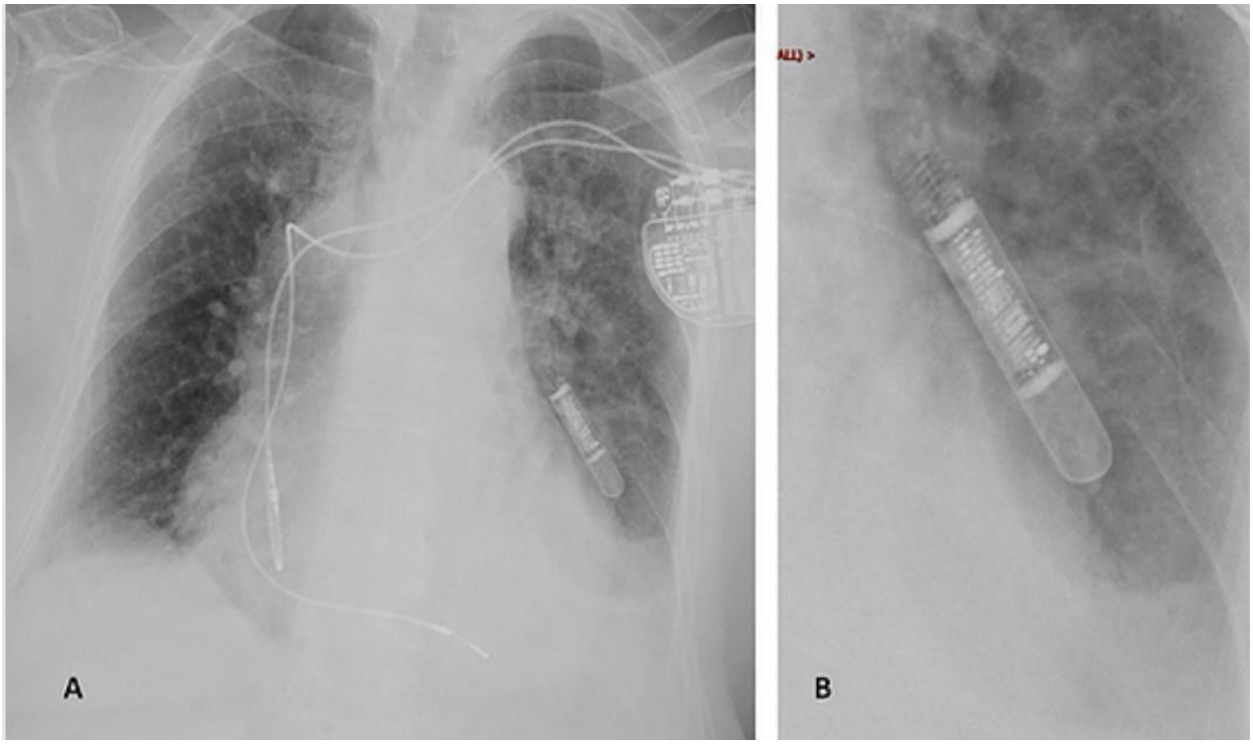

Patient has a pain pump
Find out make and model of pump/type of medication
Not Medtronic or unknown-need more information. Cannot use this chart
Any other Medtronic (not 8637)-contact Medtronic for guidance or MRI dept/ safety officer
Medtronic 8637
Outpatient
Inpatient
Ask the patient if they can set up an appt with the Physician who manages their pump
Call rep according to drug in pump to organize a time
If yes-proceed with scheduling MRI and put a note in the chart stating that patient has an independent appt to have their pump checked
If no-Call rep according to drug in pump to organize a time
Contacts:
If pump is filled with Baclofen-Call Kevin at Medtronic 860-480-5380
If pump is filled with Morphine or any other type of medication-Call Melanie 203-464-5887

Appendix I

Medtronic Micra – wireless pacemaker

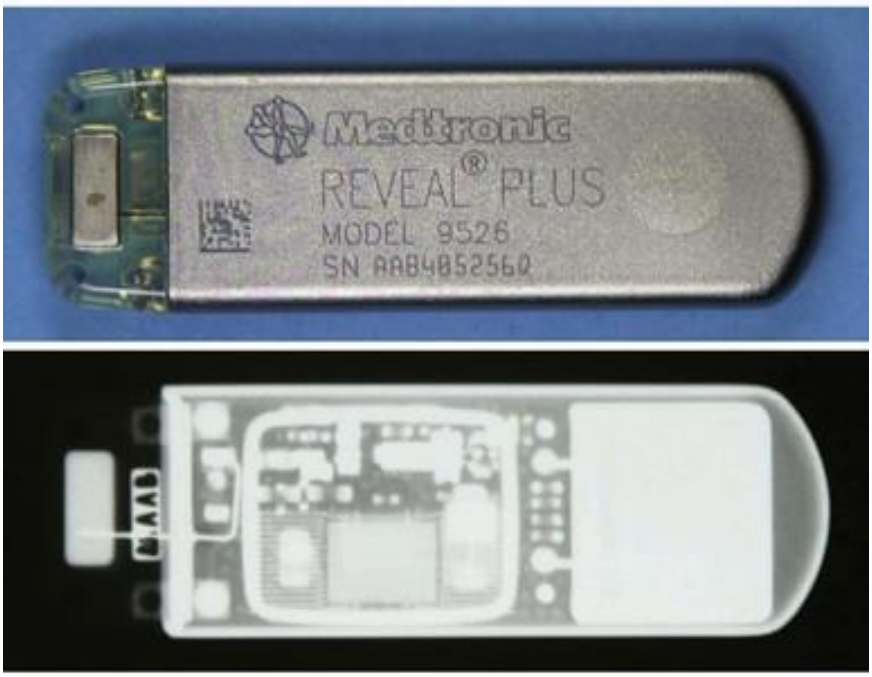


Medtronic Reveal Linq –Loop Recorder



Miscellaneous- Loop Recorders

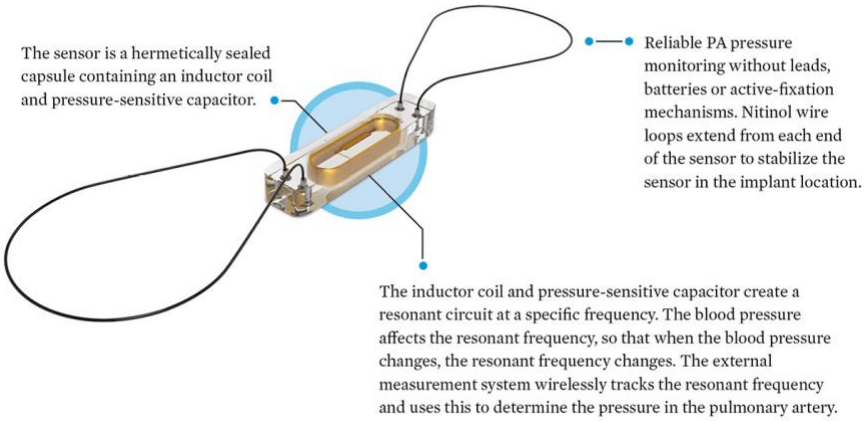
MEDTRONIC REVEAL XL

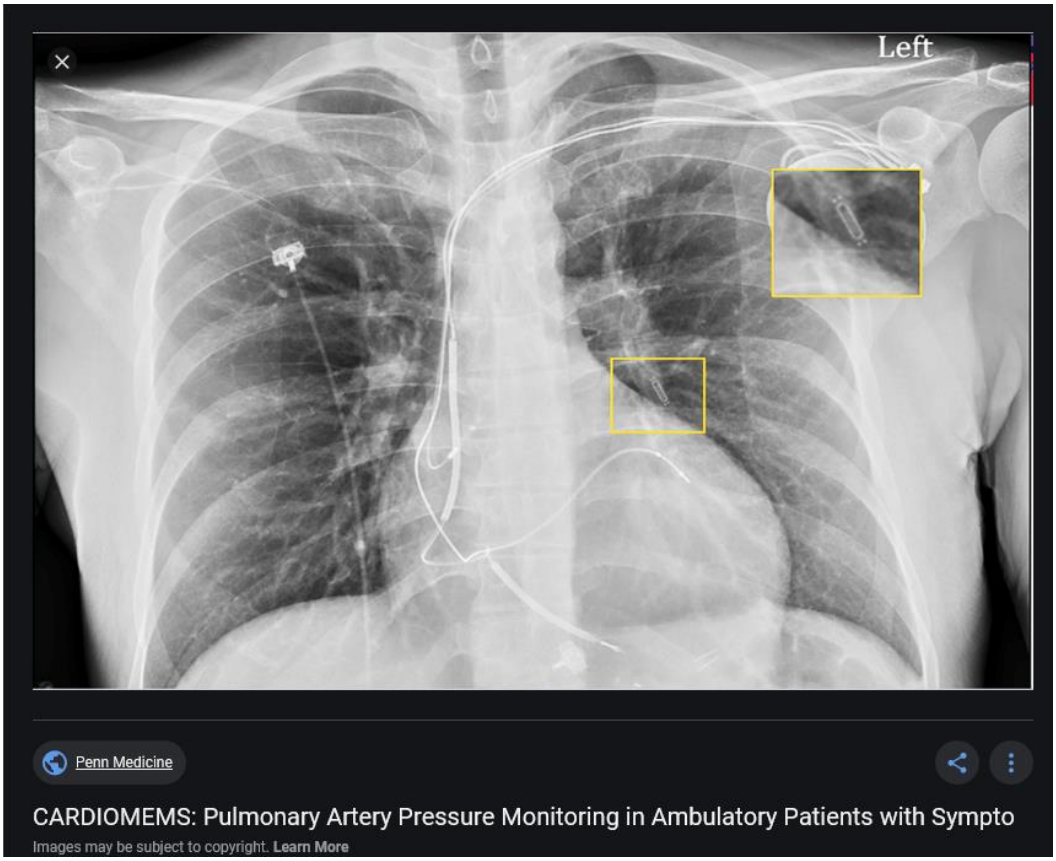


ST. JUDE MEDICAL SJM CONFIRM

Miscellaneous- CardioMEMS

Measures pulmonary artery pressure. Not sure if you guys have come across it? It's implanted in the pulmonary artery and looks similar to the leadless pacemaker and loop recorder.


The sensor is a hermetically sealed capsule containing an inductor coil and pressure-sensitive capacitor.
Reliable PA pressure monitoring without leads, batteries or active-fixation mechanisms. Nitinol wire loops extend from each end of the sensor to stabilize the sensor in the implant location.
The inductor coil and pressure-sensitive capacitor create a resonant circuit at a specific frequency. The blood pressure affects the resonant frequency, so that when the blood pressure changes, the resonant frequency changes. The external measurement system wirelessly tracks the resonant frequency and uses this to determine the pressure in the pulmonary artery.


Left
Penn Medicine
CARDIOMEMS: Pulmonary Artery Pressure Monitoring in Ambulatory Patients with Sympto
Images may be subject to copyright. Learn More

Appendix J

2/14/19 MRI Process for the Mechanically Ventilated Adult Patient

- RT transports patient on cross vent to MRI holding area (Zone 1), transfers to wall oxygen and sets up cross vent on stand
- RT removes all metal (phones, pagers, badge, hair pins, etc) and is wanded prior to entering MRI Zone 3
- RT takes Servo-I ventilator to MRI scan room to gaussed area.
    - Tethers vent to wall
    - Hooks up medical gases
    - Locks wheels
    - Enters ventilator settings
    - Attaches ETCO2
    - Attaches NIF adapter and green tubing to auxiliary alarm outside scanner room
- While RT is setting up Servo-I ventilator, ICU nurse, MRI nurse and MRI tech are prepping patient (vital signs, IV pumps, etc)
- RT returns to holding area and patient is transported on cross vent to Zone 2B
- Nurse and patient are wanded to enter Zone 3
- Patient is transported into Zone 3 on cross-vent to doorway of Zone 4
- For “head first” entry into scanner room, cross vent and stand will remain at the foot of the stretcher minimizing risk of pull into scanner room
- For “feet first” entry into scanner room, cross vent and stand will remain at the head of the stretcher minimizing risk of pull into the scanner room
- RT takes Servo-I ventilator out of stand-by mode and circuit tubing is bought outside of scanner room and patient is transitioned to Servo-I ventilator.
- **Time out is performed to confirm that patient is now being ventilated on the Servo-I ventilator.**
- Patient is bought into scanner room, RT maintains airways as the patient is transferred onto scanner table and into the scanner.
- RT turns on auxiliary alarm and confirms positive pressure
- RT attaches ambu bag to wall oxygen in scanner room
- Team performs a verbal final check that patient is on ventilator, vital signs are stable and auxiliary alarm is in place
- Cross vent stand with oxygen tank are returned to MRI prep hold

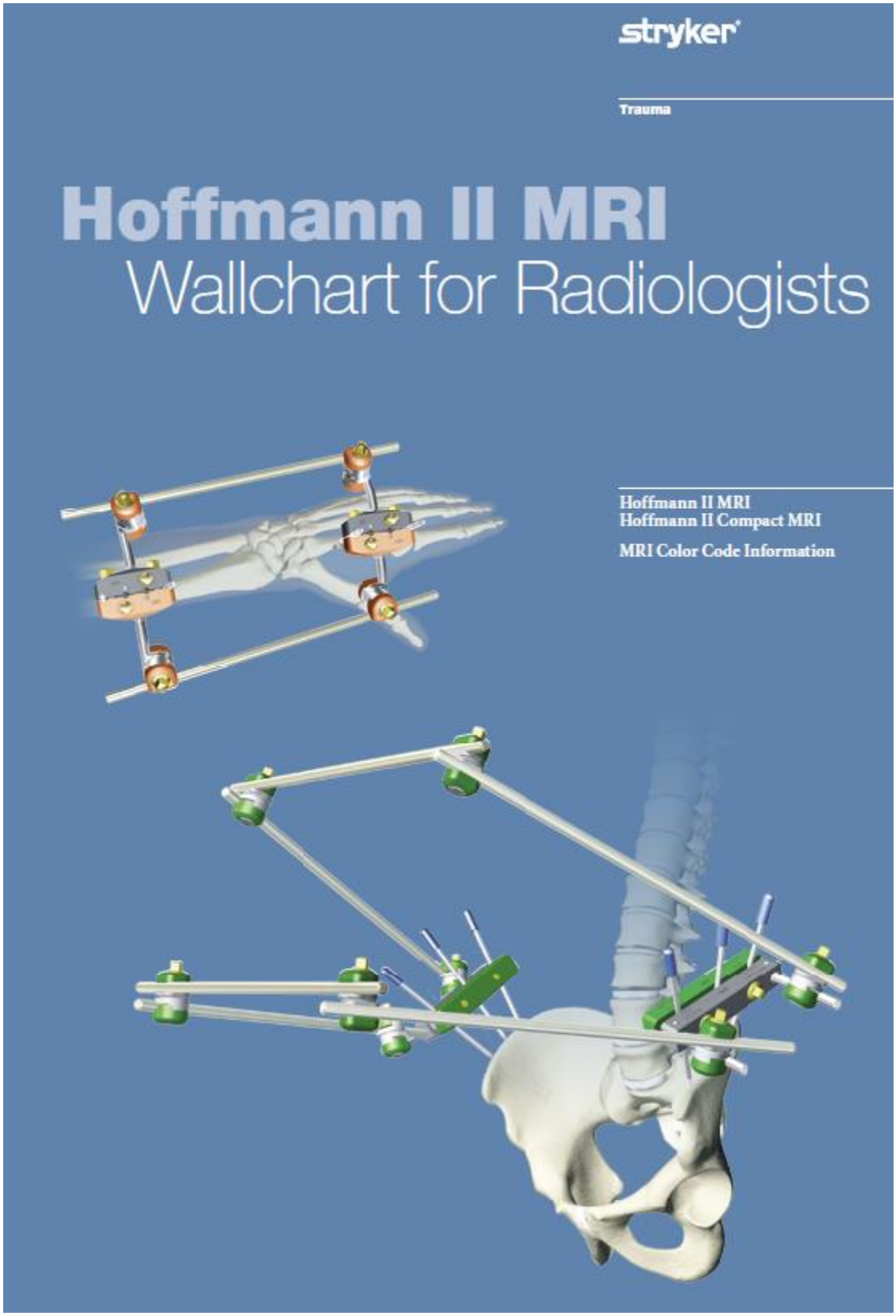
End of Scan

- Cross vent stand with oxygen tank are returned to Zone 3 outside of scanner room
- Patient is removed from scanner and bought out of Zone 4 to Zone 3 with RT maintaining airway

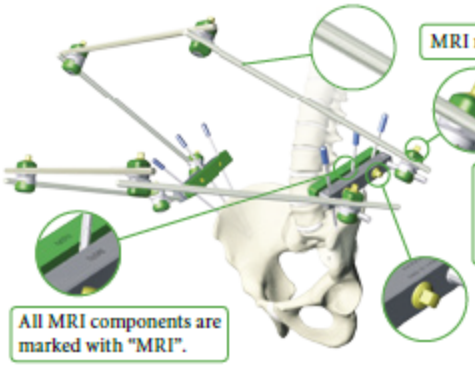
- RT transitions the patient from the Servo-I to the cross vent.
- **Time out is performed to confirm that patient is now being ventilated on the cross vent.**
- The patient is returned to holding area and cross vent is attached to wall oxygen.
- RT returns to MRI scanner to remove Servo-I vent, cleaned, set up, tested and returned to Zone 3
- Patient is transported back to ICU

Stand for cross vent and tank with oximeter. Stored prep-hold area (Zone 1)

Appendix K


stryker
Trauma
Hoffmann II MRI
Wallchart for Radiologists
Hoffmann II MRI
Hoffmann II Compact MRI
MRI Color Code Information

Technical Details - Hoffmann® II MRI

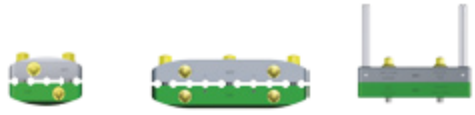


The Hoffmann® II MRI System is designed for MRI use up to 3.0 Tesla. To ensure patient safety during MRI procedures and to distinguish the system from the standard Non-MRI Hoffmann® II System, the Hoffmann® II MRI is color-coded in GREEN.

Hoffmann® II MRI

The MRI components have been tested according to ASTM Standards F2052, F2182, and F2213.

The color coding scheme illustrated below must be followed to ensure correct MRI usage.

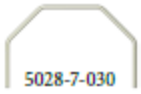


4921-2-020 4921-2-060 4921-2-080

4921-1-010 4921-1-020 4921-1-030

MRI posts have a GOLD tip.

4921-2-140



5028-7-030

5028-8-XXX

These Straight and Curved Rods are designed for MRI use. They are color coded in YELLOW.

4921-1-100

4921-0-000

4921-0-015

The Hoffmann® II MRI System can only be guaranteed for MRI use when using Stryker's Apex® Pins to build a frame.

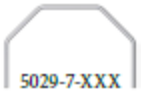
Standard Hoffmann® II (Non MRI Safe)

These products are ferromagnetic and/or conductive; therefore, they are not MRI Safe.

4920-2-020 4920-2-060 4920-2-080

4920-1-010 4920-1-020 4920-1-030

4920-2-140



5029-7-XXX

5029-8-XXX

These standard rods come in aluminium, carbon and stainless steel. Do not mix them with the MRI System since they are **not** MRI Safe.

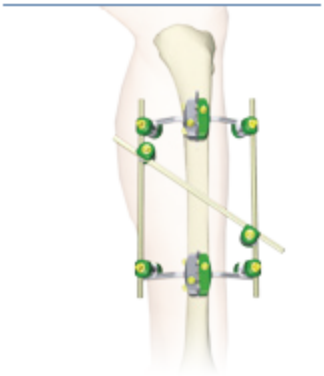
4920-1-100

4920-0-000

4920-0-015

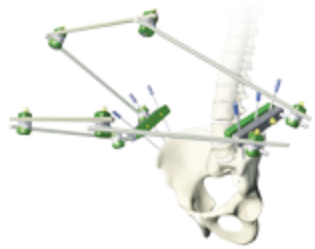
It has been shown by specific MRI tests that the Hoffmann® II MRI External Fixation System may be used for patients undergoing MRI procedures using up to 3.0 Tesla MR systems if certain specific conditions are followed.

Two commonly used frames have been tested for MRI use at 1.5 and 3.0 Tesla. The results are as follows:



1.5 Tesla MR System
∇B_{max}: 31.4mT/cm
ΔT_{max}: 2.65°C at 2.0W/kg at a whole body average SAR for MR imaging time of 6 minutes

3.0 Tesla MR System
∇B_{max}: 70 mT/cm
ΔT_{max}: 2.34°C at 0.5W/kg at a whole body average SAR for MR imaging time of 6 minutes



1.5 Tesla MR System
∇B_{max}: 31.4mT/cm
ΔT_{max}: 1.70°C at 2.0W/kg at a whole body average SAR for MR imaging time of 6 minutes

3.0 Tesla MR System
∇B_{max}: 70 mT/cm
ΔT_{max}: 2.56°C at 0.5W/kg at a whole body average SAR for MR imaging time of 6 minutes

In this testing, each of the frames shown above produced a temperature rise not greater than 3°C for a maximum MR imaging time of 6 minutes. Tests have been performed using MR systems from different suppliers. Please note that the Specific Absorption Rate (SAR) may be reported differently, e.g. as whole body averaged SAR **or** as partial SAR by the software depending on the MR system used.

Note:
These tests have been performed in areas where the greatest temperature increase is expected with commonly used frames.[1] Due to the versatility of the system, an unlimited number of frames can be built which makes it impossible to test each and every construct.

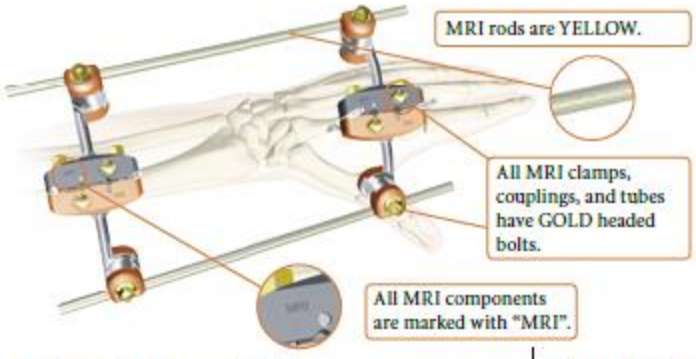
Based on the test results, the Hoffmann® II MRI may be used in MRI procedures under the specified conditions. There are factors that can influence these results like the number of pins used in the clamps and the number of open and closed loops in the frame. Therefore, it is recommended that each frame be evaluated by a radiologist or MR scientist before the MRI procedure to ensure patient safety. Since different frame configurations and frame sizes might lead to higher temperature increases, Stryker recommends for patient's safety to minimize SAR settings as much as possible.

None of the components should move or migrate in the 1.5 or 3.0-Tesla MRI environments.
Non-clinical testing has not been performed to rule out the possibility of component movement or migration at static magnetic field strengths higher than 3.0 Tesla or maximum spatial gradients higher than 70.0 mT/cm.

MR image quality may be compromised if the area of interest is in the exact same area as or relatively close to the position of the frame or its individual components

[1] Test Data on File at Stryker Trauma AG

Technical Details - Hoffmann® II Compact™ MRI



The Hoffmann® II Compact™ MRI is also designed for MRI use up to 3.0 Tesla. To ensure patient safety during MRI procedures and to distinguish the system from the standard Non-MRI Hoffmann® II Compact™ System, the Hoffmann® II Compact™ MRI is color-coded in ORANGE.

Hoffmann® II Compact™ MRI

The MRI components have been tested according to ASTM Standards F2052, F2182, and F2213.

The color coding scheme illustrated below must be followed to ensure correct MRI usage.

4941-2-020 4941-2-200

4941-1-058 4941-1-010 4941-1-020

MRI posts have a GOLD tip.

4941-2-140

5048-5-XXX

MRI rods are YELLOW.

4941-1-100 4941-0-015

The Hoffmann® II Compact™ MRI can only be guaranteed for MRI use when using Apex® Pins to build a frame.

Standard Hoffmann® II Compact™ (Non MRI Safe)

MRI

These products are ferromagnetic and/or conductive; therefore, they are not MRI Safe.

4940-2-020 4940-2-200

4940-1-058 4940-1-010 4940-1-020

4940-2-140

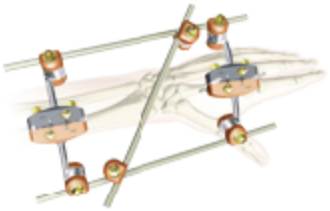
5049-5-XXX

These standard rods come in carbon and stainless steel. Do not mix them with the MRI System since they are **not** MRI Safe.

4940-1-100 4920-0-015

It has been shown by specific MRI tests that the Hoffmann® II Compact™ MRI External Fixation System may be used for patients undergoing MRI procedures using up to 3.0 Tesla MR systems if certain specific conditions are followed.

Two standard wrist frames have been tested at 1.5 and 3.0 Tesla. The results are as follows:



3.0 Tesla MR System
∇B_{max}: 70 mT/cm
ΔT_{max}: 1.55°C at 0.5W/kg at a whole body average SAR for MR imaging time of 6 minutes

3.0 Tesla MR System
∇B_{max}: 70 mT/cm
ΔT_{max}: 1.96°C at 0.5W/kg at a whole body average SAR for MR imaging time of 6 minutes

In this testing, each of the frames shown above produced a temperature rise of less than 3°C for a maximum MR imaging time of 6 minutes. Tests have been performed using MR systems from different suppliers. Please note that the monitored Specific Absorption Rate (SAR) refers to the whole body averaged SAR **or** to the partial SAR depending on the software that is used.

Note:
These tests have been performed in areas where the greatest temperature increase is expected with commonly used frames.[1] **Due to the versatility of the system, an unlimited number of frames can be built which makes it impossible to test each and every construct.**

Based on the test results, the Hoffmann® II Compact™ MRI may be used in MRI procedures under the specified conditions. There are factors that can influence these results like the number of pins used in the clamps and the number of open and closed loops in the frame. Therefore, it is recommended that each frame be evaluated by a radiologist or MR scientist before the MRI procedure to ensure patient safety. Since different frame configurations and frame sizes might lead to higher temperature increases, Stryker recommends for patient's safety to minimize SAR settings as much as possible.

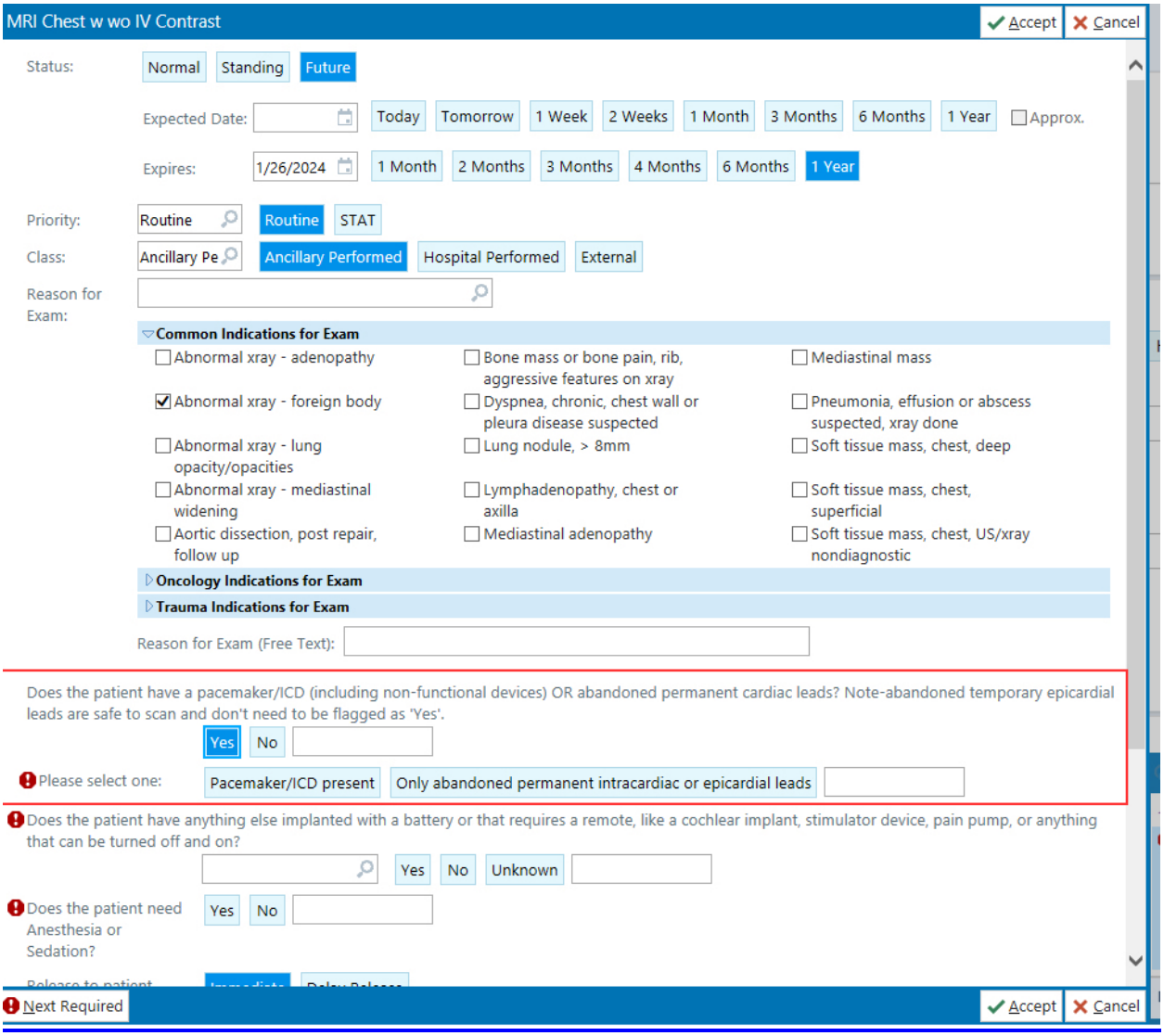
None of the components should move or migrate in the 1.5 or 3.0-Tesla MRI environments.
Non-clinical testing has not been performed to rule out the possibility of component movement or migration at static magnetic field strengths higher than 3.0 Tesla or maximum spatial gradients higher than 70.0 mT/cm.

MR image quality may be compromised if the area of interest is in the exact same area as or relatively close to the position of the frame or its individual components

[1] Test Data on File at Stryker Trauma AG

Appendix L

New order screen for MRI-
Pacemaker question has been revised so we can pro-actively identify patients with abandoned intracardiac or permanent epicardial leads. A new question about electric devices has also been added.



Radiologist Workflow
Non-functioning Pacemaker

1. Confirm that the exam is medically necessary during protocol process like a regular pacer/ICD case.
2. If EP team does not end up doing formal assessment of device (ie- it is already documented to be non-functional), then Radiologist will need to consent patient on the day of exam with pre-populated consent form located in the technologist area. If EP team needs to see patient to evaluate device they will go over risks/benefits and document consent in Epic. Radiologist does not need to consent in this setting.

Retained intracardiac leads or permanent epicardial leads (temporary epicardial leads are safe to scan)

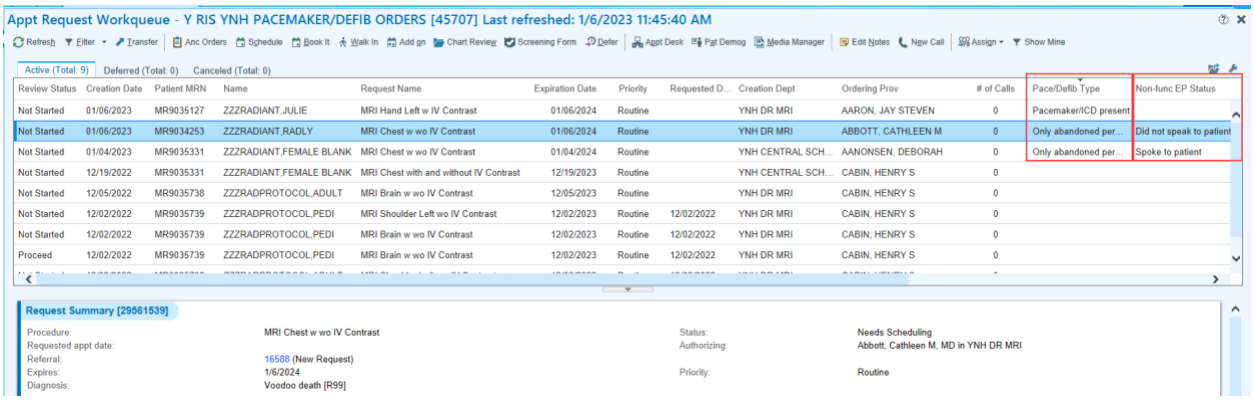
1. Confirm that the exam is medically necessary during protocol process like a regular pacer/ICD case. It does not matter if the lead was from a conditional MR device, all are treated the same.
2. Radiologist will consent patient on the day of the exam with pre-populated consent form located in the technologist area. EP team will NOT be involved in these cases as there is no device to program.

Detailed Non-functioning Pacemaker Workflow

- MRI order is placed
- Order question "Does the patient have a pacemaker/ICD (functional or non-functional) OR abandoned permanent cardiac leads?" is answered **"Yes"**
    - Option 1 is selected for **"Pacemaker/ICD present"** (see image above)
- Order appears in pacemaker queue
- Radiologist protocols case and deems it medically necessary
- EP confirms that the device is dead by either reviewing the chart or confirming through device interrogation. EP will select 1 of 2 options in their epic work-que
    - EP spoke with patient → no additional consent is needed by radiology. EP will document consent in EP note.
    - EP did not speak to patient → standard consent form will need to be signed by patient and supervising radiologist
- CSA schedules patient in a pacemaker slot with nursing
- If consent is needed by radiology-technologist will contact radiologist from the service when the patient arrives
- Radiologist will consent patient with pre-populated consent form located in the technologist area (attached)
- Technologist will perform scan on a 1.5T using the lowest possible SAR with nursing to monitor patient

Detailed Abandoned Intra-Cardiac or Permanent Epicardial Leads Workflow

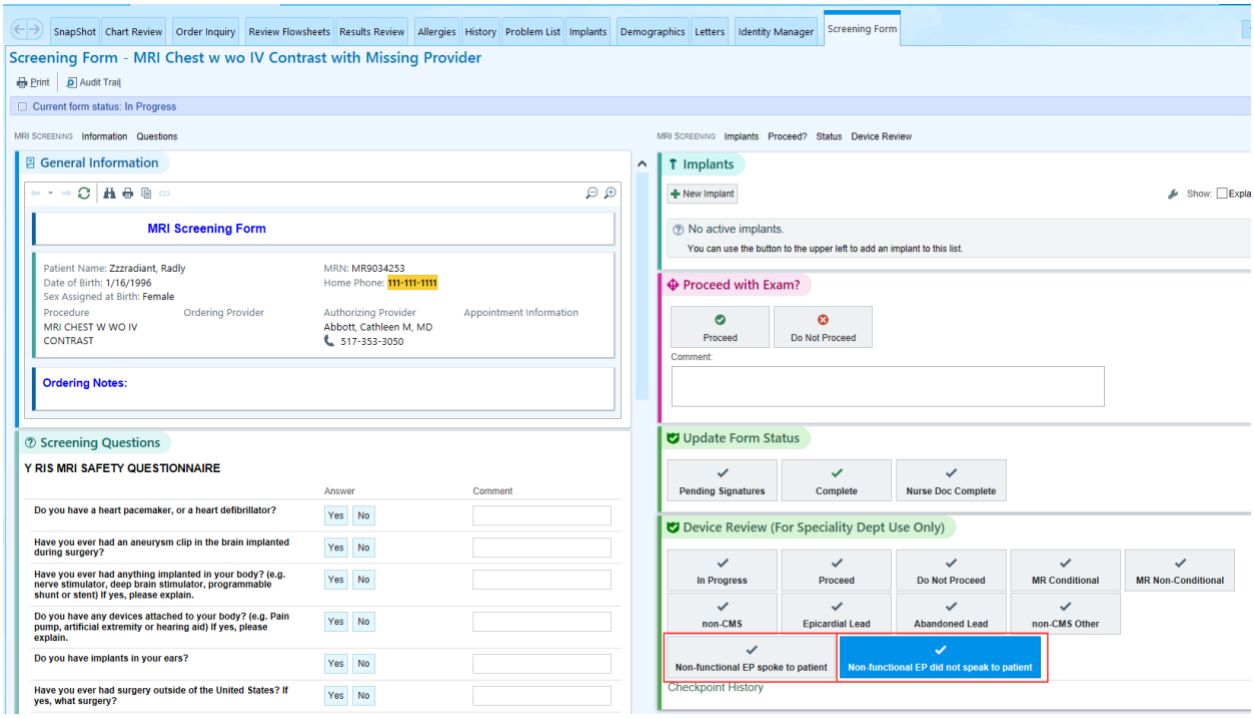
- MRI order is placed
- Order question "Does the patient have a pacemaker/ICD (functional or non-functional) OR abandoned permanent cardiac leads?" is answered **"Yes"**
    - Option number 2 is selected for **"Only abandoned permanent intracardiac or epicardial leads (i.e no pacemaker/ICD device present)** (see image above)
- Order appears in pacemaker queue with the retained lead identified in the column
- CSA informs MRSO of patient
- Radiologist protocols exam and deems it medically necessary
- MRSO obtains all necessary information and confirms retained leads through chest xray review (with Radiologist if needed). MRSO will click the proceed button signaling the patient is ready to schedule
- CSA schedules patient in a monitored slot with nursing (1.5T)
- Technologist will contact radiologist on the service when the patient arrives
- Radiologist will consent patient with pre-populated consent form
- Technologist will perform exam on a 1.5T using the lowest possible SAR with nursing to monitor



EP Team Workflow

Non-functioning Pacemaker

1. Confirm that pacemaker is non-functioning
    a. If EP assesses the patient to confirm non-functional device they will document risk/benefit discussion in Epic note and press the "EP spoke to patient" button
    b. If this is confirmed by chart review but EP team does not assess patient they will press the "EP did not speak to patient" button. Radiologist will need to get consent in these cases.



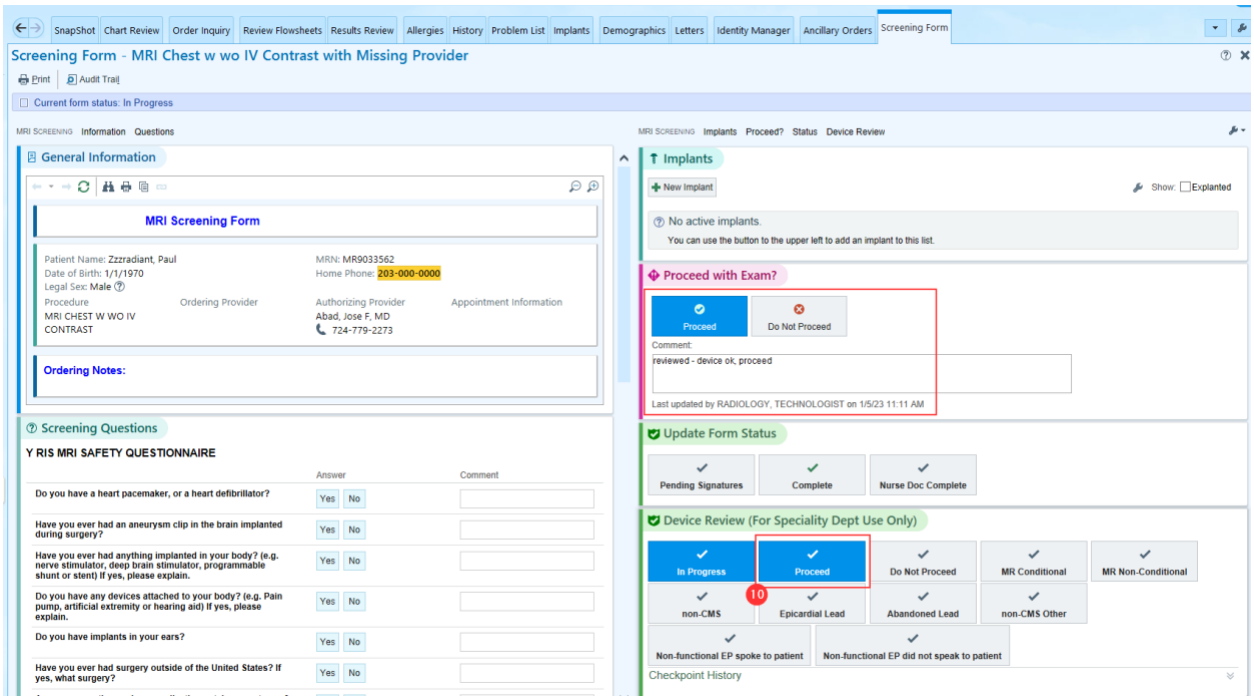
CSA Workflow

Non-functioning Pacemaker- EP team does NOT have to present during scan

1. If EP hit the **"Spoke to patient"** symbol-and all check marks from MRSO and radiologist are completed-ok to proceed with standard pacemaker scheduling in a RN only slot. No additional consent form is needed.
2. If EP hit the **"Did not speak to patient"** symbol-we have to do informed consent.
    a. Once all check marks from MRSO and radiologist are completed-ok to proceed with standard pacemaker scheduling process in a RN monitored slot
    b. Inform MRSO of appointment day/time. On the day of scan informed consent will take place.

Retained Leads- EP team does NOT have to be present during exam

1. Retained lead will be visible in Epic report
2. Inform MRSO of patient
3. Once MRSO clears patient-ok to schedule on a 1.5T in an RN monitored slot (MRSO will click proceed-green check will appear)



Technologist Individual Workflow

Non-functioning Pacemaker

1. If EP spoke with patient and note present in Epic documented risk/benefit of MRI with patient then no additional consent is needed by Radiologist
2. If EP did not assess patient (no note in Epic documented risks/benefits of MRI) - Radiologist will need to come consent patient using the pre-populated consent form.
3. Contact rad from supervising service when patient arrives. These cases should only be done in RN monitored slot during normal business hours.
4. Perform scan on 1.5T-lowest SAR possible. Nursing to monitor

Retained/Abandoned Leads- For retained intravascular leads or **permanent** Epicardial leads (these look very different from temporary epicardial wires which are safe to scan)

1. Call radiologist from the service to come consent the patient using the pre-populated consent form. This form will be located in Fitkin by MR1 and can also be accessed on SharePoint
2. Perform scan on 1.5T-lowest possible SAR with nursing to monitor.

Pre-populated consent form

Delivery Network/Location

NAME:

BIRTH DATE:

MRN:

DOS:

(If handwritten, patient name, MRN, birth date, and DOS)

YALE NEW HAVEN HEALTH

Consent for Operation or Special Procedure

This form is available in multiple languages. Please use an interpreter and the appropriate consent form for patients who do not speak English.

SECTION A:

1. After discussing other options, including no treatment, with the responsible practitioner or his/her delegated representative, I give *(insert name of person performing procedure)* _____ permission to perform the following operation, procedure(s) or treatment *(list name or description of operation(s), procedure(s) and/or treatment(s) - indicate applicable level, side, or site)*:

   MRI EXAM WITH KNOWN RETAINED EPICARDIAL AND /OR INTRACARIAC LEADS OR NON-FUNCTIONAL DEVICE

   I understand that this procedure is for purposes of diagnosis and/or treatment for *(describe reasons for procedure)*:

2. I give permission to my responsible practitioner to do whatever may be necessary if there is a complication or unforeseen condition during my procedure.
3. My responsible practitioner has explained to me in a way that I understand: (a) the nature and purpose of the procedure(s); (b) the potential benefits and risks and possible side effects of the procedure(s) both during it and during recuperation, including bleeding, infection, accidental injury of other body parts, failure to permanently improve my condition or death, as well as the potential risks and benefits of the medications that may be administered to me as part of the procedure; and (c) the alternative(s) to the procedure(s) and their potential risks and benefits, including the option of not having the procedure. I understand that other complications may occur, including but not limited to:

   Lead movement, heating or electric current generation that could injure my heart, cause arrhythmia, or result in death

   ☐ **(Contents of discussion including risks, benefits and alternatives are documented in an office or hospital chart note)**
4. I understand the purpose and potential benefits of the procedure in relation to my goals. My responsible practitioner has explained to me what results to expect, and the chances of achieving them. I understand that no promises or guarantees have been made or can be made about the results of the procedure(s).
5. I agree to have anesthesia as necessary to perform the procedure(s). I understand that if an anesthesiologist is to be involved he/she will speak to me about the risks of anesthesia in more detail and I may be asked to sign a separate anesthesia or sedation consent form.
6. I give permission to the hospital and/or its departments to examine and keep tissue, blood, body parts, or fluids removed from my body during the procedure(s) to aid in diagnosis and treatment, after which they may be used for scientific research or teaching by appropriate persons. If these things are used for science or teaching, my identity will not be disclosed. I will no longer own or have any rights to these things regardless of how they may be used.
7. If the procedure listed above involves the implantation/transplantation of tissue from a human or animal source, my responsible practitioner has described to me the risks and benefits of, and alternatives to, receiving this product.
8. I understand that some of the system hospitals are teaching hospitals. Doctors or other health practitioners who are members of the care team and are in training may help my practitioner with the procedure. I understand that these trainees are supervised by qualified staff and the responsible practitioner will be present at all important times during the procedure. I also understand that associate(s), surgical assistants and/or other non-physicians or trainees may assist my responsible practitioner or perform parts of the procedure under the responsible practitioner's supervision, as permitted by law and hospital policy. This includes compliance with the overlapping surgery policy which ensures that the attending surgeon will be present for the critical and key portions of my case and that an alternate attending physician will be designated should the need arise. If others who are not hospital staff will be present in the operating room, the responsible practitioner has spoken with me about this. I understand that a representative of an equipment vendor or a visitor may be present in the procedure area and that if that occurs, any visitor or vendor will comply with any applicable policy regarding observers in the Operating Room or other procedural area.
9. I give permission to the hospital and the above-named practitioner to photograph and/or visually record or display the procedure(s) for medical, scientific, or educational purposes. I understand that I will not be identified to those not involved in my care unless a separate consent is signed.
10. I understand that my responsible practitioner may deem it necessary for me to have a blood transfusion during or after the procedure(s).I understand what a blood transfusion is, the procedures used, the benefits of receiving a transfusion and the risks involved. The benefits include better oxygen delivery to all parts of my body (for red blood cells) and treating or decreasing the risks of bleeding (for platelets and plasma products). The risks include: fever, chills, and allergic reactions which are generally mild and transient; on rare occasions major transfusion reactions occur such as rapid breakdown of blood cells and acute lung or kidney injury; and rarely bacterial, viral or other infections such as hepatitis B, hepatitis C, human immunodeficiency virus (HIV) and other pathogens. I understand these risks exist, although screening and testing of blood donors and their blood is performed to minimize these risks. My questions regarding alternatives have been addressed by the responsible practitioner in relation to my specific circumstances.

[1] In cases of refusal of blood by a parent or guardian of a minor in a situation in which transfusion may be anticipated, contact Legal and Risk Services immediately, as in most cases court intervention will be sought

F8203

F8203_English (Rev. 10/19)
Available in multiple languages

Appendix M

B. Braun Medical Inc.
Medical Affairs
3773 Corporate Parkway, suite 300
Center Valley, PA 18034
Telephone: 1(800)-854-6851

25 October 2023

Ms. Samantha Carter
Yale-New Haven Hospital
20 York Street
New Haven CT 06510

Subject: The composition of the Perifix® FX and Contiplex® FX Springwound catheter and the MRI compatibility of the catheters.

Dear Ms. Carter:

This letter is in response to your inquiry regarding the composition of the Perifix® FX and Contiplex® FX Springwound catheters, and the MRI conditionality of the Perifix FX and of the Contiplex FX Springwound catheters. B. Braun Medical Inc. has received 510(K) clearance from the FDA for the Perifix FX and the Contiplex FX Springwound catheters. The labeling, which includes the product Instructions for Use (IFU), is currently being updated to reflect this approval. The design, size offerings, and item numbers are identical to the current offerings for the Perifix FX and Contiplex FX Springwound catheters.

The PERIFIX FX Springwound Catheters is comprised of a flexible spring wire core enclosed within a soft copolymer jacket.

The CONTIPLEX FX Springwound Continuous Nerve Block Catheters is comprised of a flexible spring wire core enclosed within a soft copolymer jacket.

The tables on the next page of this letter provide MRI safety information specific to each catheter. The catheters have not been tested outside of theses specific MR conditions and therefore, we cannot comment on any use outside the parameters listed on the tables. If the springwound catheters will be used in an MR environment, B. Braun recommends that they are used within the conditions provided in this letter. Failure to follow these conditions may result in injury.

This information will provide you with relevant data to assist you in decision making about the utilization of these products. B. Braun does not endorse the use of its products, or any other products, in any manner other than as described in the approved prescribing information. Please refer to the indication for use for full prescribing information. Further, this information is not intended to provide specialist advice or instructions regarding the products and services sold by B. Braun. This information is provided independently of any sale of product and is not intended to constitute product performance information, and no express or implied warranty of any kind is made with respect to the product, underlying data or the information contained herein. This information is not intended to be reproduced without prior written permission of B. Braun.

If further technical assistance is needed, please feel free to contact B. Braun Medical Affairs at (800) 854-6851.

Sincerely,
Marie-Claude Gutekunst

Marie-Claude Gutekunst MSN RN BCMAS
Medical Affairs- Medical Information

MRI Safety Information

MR Conditional The PERIFIX FX *Springwound* Catheter is MR Conditional. For all MR Examinations: A patient implanted with the PERIFIX FX Springwound Epidural Catheter may be safely scanned at 1.5T or 3.0T under the following conditions. Failure to follow these conditions may result in injury.

Parameter	Condition/Information
Device Configuration	Closed-Tip Multi-Port or Open-Tip Uniport Not Filled or Filled with Any Liquid or Any Drug
Static Magnetic Field Strength (B0)	1.5T and 3.0T
Maximum Spatial Field Gradient	20 T/m (2000 Gauss/cm) 1.5T 17 T/m (1700 Gauss/cm) 3.0T*
RF Excitation	Any
RF Transmit Coil Type	Any
Operating Mode	Normal Operating Mode
RF Conditions	Whole-Body Averaged SAR ≤ 2 W/kg
Scan Duration	2 W/kg whole-body averaged SAR for 60 minutes of continuous RF (a sequence or back to back series/scan without breaks).
Scan Regions	Any landmark is acceptable.
Image Artifact	The presence of the PERIFIX FX *Springwound* Epidural Catheter may produce an image artifact. Some manipulation of scan parameters may be needed to compensate for the artifact.
Additional Instructions	Ensure proper and secure fixation of the PERIFIX FX *Springwound* Nerve Block Catheter to the patient using an appropriately applied dressing. Failure to ensure the secure fixation of the PERIFIX FX *Springwound* Nerve Block Catheter to the patient's skin can result in a displacement of the catheter. * For patient landmarks that will place the catheter inserted region inside the MRI bore, and for patients positioned prone or on their side, the edge of the body at the catheter location must be at least 10 cm inside from the wall of the magnet bore.

MRI WARNINGS:

NO LOCAL RF TRANSMIT COIL MUST BE PLACED OVER THE PERIFIX FX SPRINGWOUND EPIDURAL CATHETER. PLACING A LOCAL RF TRANSMIT COIL OVER THE PERIFIX FX SPRINGWOUND EPIDURAL CATHETER CAN RESULT IN SERIOUS AND PERMANENT INJURY INCLUDING COMA, PARALYSIS, OR DEATH.

DISCONTINUE THE MRI IMMEDIATELY IF THE PATIENT BECOMES UNRESPONSIVE TO QUESTIONS OR EXPERIENCES ANY HEATING, PAIN, SHOCKING SENSATIONS, UNCOMFORTABLE STIMULATION, OR UNUSUAL SENSATIONS.

MR SCANS MUST BE CONDUCTED USING THE STATED MRI EQUIPMENT AND SCAN CONDITIONS. FAILURE TO FOLLOW ALL WARNINGS AND GUIDELINES RELATED TO MRI CAN RESULT IN SERIOUS AND PERMANENT INJURY, INCLUDING COMA, PARALYSIS, OR DEATH.

ENSURE PROPER AND SECURE FIXATION OF THE PERIFIX FX SPRINGWOUND EPIDURAL CATHETER TO THE PATIENT'S BACK. FAILURE TO ENSURE THE SECURE FIXATION OF THE PERIFIX FX SPRINGWOUND EPIDURAL CATHETER TO THE PATIENT'S SKIN CAN RESULT IN A DISLOCATION OF THE CATHETER.

AFTER MRI CHECK FOR CATHETER DISLOCATION. CHECK THE CORRECT PLACEMENT OF THE PERIFIX FX SPRINGWOUND EPIDURAL CATHETER AFTER THE MRI. FAILURE TO ENSURE CORRECT PLACEMENT OF THE CATHETER AFTER THE MRI CAN RESULT IN INCORRECT OPERATION OF THE PERIFIX FX SPRINGWOUND EPIDURAL CATHETER AND INCORRECT PATIENT TREATMENT.

Parameter	Condition/Information
Device Configuration	Closed-Tip Multi-Port or Open-Tip Uniport Not Filled or Filled with Any Liquid or Any Drug
Static Magnetic Field Strength (B0)	1.5T and 3.0T
Maximum Spatial Field Gradient	20 T/m (2000 Gauss/cm) 1.5T 17 T/m (1700 Gauss/cm) 3.0T*
RF Excitation	Any
RF Transmit Coil Type	Any
Operating Mode	Normal Operating Mode
RF Conditions	Whole-Body Averaged SAR ≤ 2 W/kg
Scan Duration	2 W/kg whole-body averaged SAR for 60 minutes of continuous RF (a sequence or back to back series/scan without breaks).
Scan Regions	Any landmark is acceptable.
Image Artifact	The presence of the CONTIPLEX FX *Springwound* Continuous Nerve Block Catheter may produce an image artifact. Some manipulation of scan parameters may be needed to compensate for the artifact.
Additional Instructions	Ensure proper and secure fixation of the CONTIPLEX FX *Springwound* Nerve Block Catheter to the patient using an appropriately applied dressing. Failure to ensure the secure fixation of the CONTIPLEX FX *Springwound* Nerve Block Catheter to the patient's skin can result in a displacement of the catheter. * For patient landmarks that will place the catheter inserted region inside the MRI bore, and for patients positioned prone or on their side, the edge of the body at the catheter location must be at least 10 cm inside from the wall of the magnet bore.

MRI WARNINGS:

NO LOCAL RF TRANSMIT COIL MUST BE PLACED OVER THE CONTIPLEX FX SPRINGWOUND CONTINUOUS NERVE BLOCK CATHETER. PLACING A LOCAL RF TRANSMIT COIL OVER THE CONTIPLEX FX SPRINGWOUND CONTINUOUS NERVE BLOCK CATHETER CAN RESULT IN SERIOUS AND PERMANENT INJURY INCLUDING COMA, PARALYSIS, OR DEATH.

DISCONTINUE THE MRI IMMEDIATELY IF THE PATIENT BECOMES UNRESPONSIVE TO QUESTIONS OR EXPERIENCES ANY HEATING, PAIN, SHOCKING SENSATIONS, UNCOMFORTABLE STIMULATION, OR UNUSUAL SENSATIONS.

MR SCANS MUST BE CONDUCTED USING THE STATED MRI EQUIPMENT AND SCAN CONDITIONS. FAILURE TO FOLLOW ALL WARNINGS AND GUIDELINES RELATED TO MRI CAN RESULT IN SERIOUS AND PERMANENT INJURY, INCLUDING COMA, PARALYSIS, OR DEATH.

ENSURE PROPER AND SECURE FIXATION OF THE CONTIPLEX FX SPRINGWOUND CONTINUOUS NERVE BLOCK CATHETER TO THE PATIENT'S BACK. FAILURE TO ENSURE THE SECURE FIXATION OF THE CONTIPLEX FX SPRINGWOUND CONTINUOUS NERVE BLOCK CATHETER TO THE PATIENT'S SKIN CAN RESULT IN A DISLOCATION OF THE CATHETER.

AFTER MRI CHECK FOR CATHETER DISLOCATION. CHECK THE CORRECT PLACEMENT OF THE CONTIPLEX FX SPRINGWOUND CONTINUOUS NERVE BLOCK CATHETER AFTER THE MRI. FAILURE TO ENSURE CORRECT PLACEMENT OF THE CATHETER AFTER THE MRI CAN RESULT IN INCORRECT OPERATION OF THE CONTIPLEX FX SPRINGWOUND CONTINUOUS NERVE BLOCK CATHETER AND INCORRECT PATIENT TREATMENT.

Appendix N

Bridgeport Hospital – Main Campus
MRI Compatibility: Medline Foley Catheters

Dear Bridgeport Hospital,

Medline silicone and silicone temperature-sensing Foley catheters are MRI-conditional and can be used with MRI technology in an acceptable MRI environment. These guidelines are to be followed for both Medline single-pull Foley catheters and those found within the Medline-branded convenience trays.

Medline-branded Foley catheters were assessed per ASTM F2503-13, *Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment*. The performance data supports that the subject device can be labeled "MR Conditional."

Additional instructions and requirements are included in the provided MRI Information Notice.

- For Medline Foley catheter trays that contain a urine meter with metal clamp, appropriate MR-safe sandbags must be placed over the clamp prior to imaging.
- For Medline silicone temperature-sensing Foley catheters, the catheter and probe must be positioned in a straight configuration down the center of the patient table without any loops. Remove any hospital cables or monitoring equipment prior to the MRI procedure.

Importantly, the MRI procedure should be performed using an MR system operating at 1.5-Tesla or 3-Tesla ONLY (no other MR system field strength/frequency, higher or lower, should be used). The safe use of an MR system operating at lower or higher field strength for a patient with Medline's 100% Silicone 400 Series Temperature Sensing Foley Catheter has not been determined.

Please note: The "400 series" mentioned in the MRI Information Notice is in reference to the series of thermistor probe used. This information is applicable to all Medline silicone temperature-sensing Foley catheters.

If you have any additional questions, please feel free to contact Medline Urology.

Sincerely,

Jack Dzvonik
Quality Engineer Associate – Urology
Medline Industries, LP
jdzvonik@medline.com

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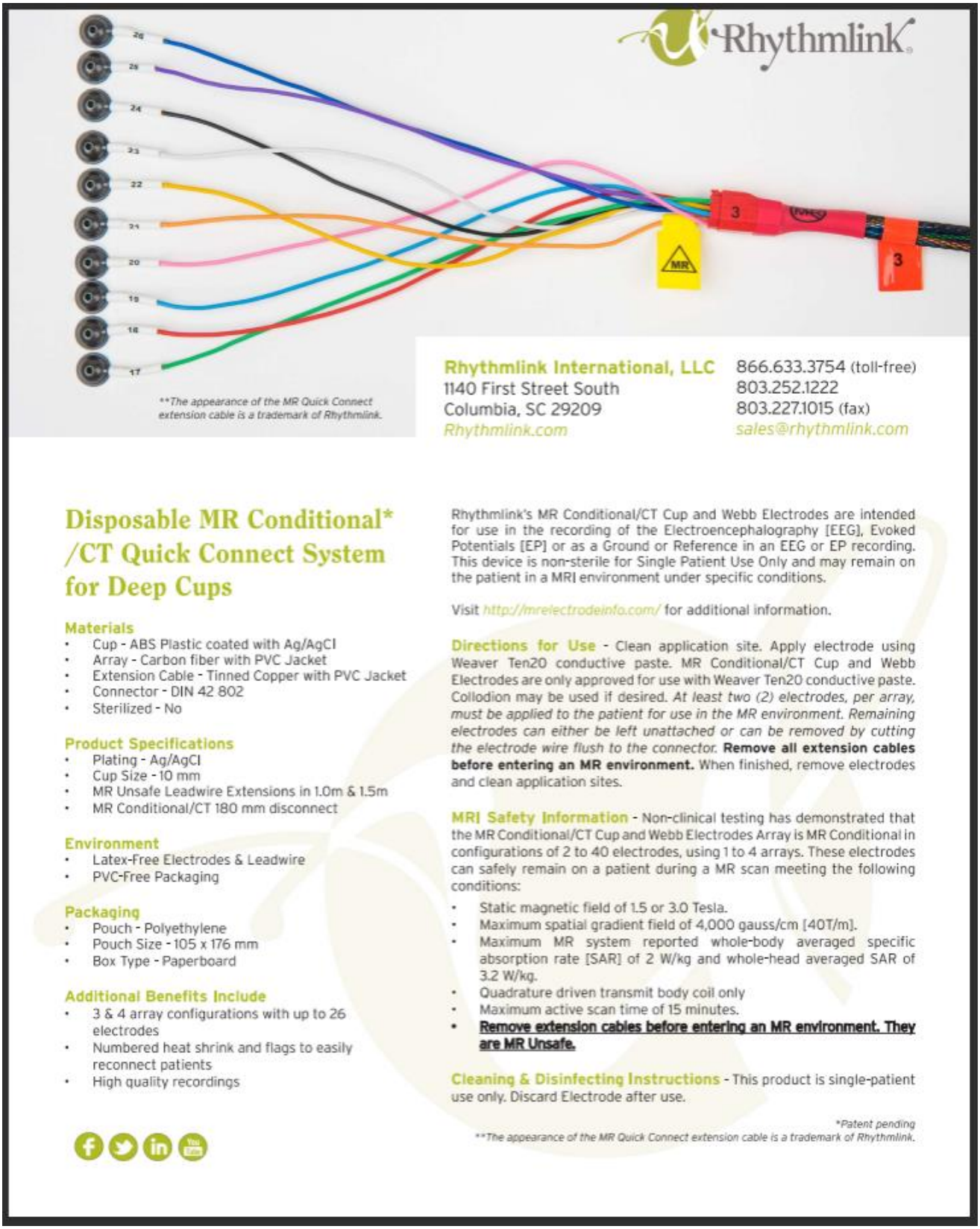
Appendix O



Rhythmlink

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***The appearance of the MR Quick Connect extension cable is a trademark of Rhythmlink.*

Disposable MR Conditional* /CT Quick Connect System for Deep Cups

Materials
- Cup - ABS Plastic coated with Ag/AgCl
- Array - Carbon fiber with PVC Jacket
- Extension Cable - Tinned Copper with PVC Jacket
- Connector - DIN 42 802
- Sterilized - No

Product Specifications
- Plating - Ag/AgCl
- Cup Size - 10 mm
- MR Unsafe Leadwire Extensions in 1.0m & 1.5m
- MR Conditional/CT 180 mm disconnect

Environment
- Latex-Free Electrodes & Leadwire
- PVC-Free Packaging

Packaging
- Pouch - Polyethylene
- Pouch Size - 105 x 176 mm
- Box Type - Paperboard

Additional Benefits Include
- 3 & 4 array configurations with up to 26 electrodes
- Numbered heat shrink and flags to easily reconnect patients
- High quality recordings

Rhythmlink's MR Conditional/CT Cup and Webb Electrodes are intended for use in the recording of the Electroencephalography [EEG], Evoked Potentials [EP] or as a Ground or Reference in an EEG or EP recording. This device is non-sterile for Single Patient Use Only and may remain on the patient in a MRI environment under specific conditions.

Visit *http://mrelectrodeinfo.com/* for additional information.

Directions for Use - Clean application site. Apply electrode using Weaver Ten20 conductive paste. MR Conditional/CT Cup and Webb Electrodes are only approved for use with Weaver Ten20 conductive paste. Collodion may be used if desired. *At least two (2) electrodes, per array, must be applied to the patient for use in the MR environment. Remaining electrodes can either be left unattached or can be removed by cutting the electrode wire flush to the connector.* **Remove all extension cables before entering an MR environment.** When finished, remove electrodes and clean application sites.

MRI Safety Information - Non-clinical testing has demonstrated that the MR Conditional/CT Cup and Webb Electrodes Array is MR Conditional in configurations of 2 to 40 electrodes, using 1 to 4 arrays. These electrodes can safely remain on a patient during a MR scan meeting the following conditions:
- Static magnetic field of 1.5 or 3.0 Tesla.
- Maximum spatial gradient field of 4,000 gauss/cm [40T/m].
- Maximum MR system reported whole-body averaged specific absorption rate [SAR] of 2 W/kg and whole-head averaged SAR of 3.2 W/kg.
- Quadrature driven transmit body coil only
- Maximum active scan time of 15 minutes.
- **Remove extension cables before entering an MR environment. They are MR Unsafe.**

Cleaning & Disinfecting Instructions - This product is single-patient use only. Discard Electrode after use.

**Patent pending*
***The appearance of the MR Quick Connect extension cable is a trademark of Rhythmlink.*

Rhythmlink

English

MR Conditional*/CT Cup and Webb** Electrodes

Disposable EEG Cup/Webb Quick Connect System™

Intended Use

The MR Conditional/CT Cup and Webb Electrodes are intended for use in the recording of the Electroencephalography (EEG), Evoked Potentials (EP) or as a Ground or Reference in an EEG or EP recording. This device is non-sterile for Single Patient Use Only and may remain on the patient in a MRI environment under specific conditions.

Caution

Federal (USA) law restricts this device to sale by or on the order of a physician and it should only be used in compliance with accepted industry standards. Rhythmlink International, LLC is not responsible for injury, infection or other damage resulting from the use or misuse of this product.

MR Conditional/CT Cup and Webb Electrodes are for professional use only and should only be used in compliance with accepted industry standards. The included extension cables (Fig. 1) are MR Unsafe. Remove all extension cables before entering a MR environment.

Instructions for Use

Clean application site. Apply electrode using Weaver Ten20 conductive paste. MR Conditional/CT Cup and Webb Electrodes are only approved for use with Weaver Ten20 conductive paste. Collodion may be used if desired. *At least two (2) electrodes, per array, must be applied to the patient for use in the MR environment. Remaining electrodes can either be left unattached or can be removed by cutting the electrode wire flush to the connector.* Remove all extension cables before entering an MR environment. When finished, remove electrodes and clean application sites.

MRI Safety Information

Non-clinical testing has demonstrated that the MR Conditional/CT Cup and Webb Electrodes Array (Fig. 2) is MR Conditional in configurations of 2 to 40 electrodes, using 1 to 4 arrays. These electrodes can safely remain on a patient during a MR scan meeting the following conditions:

- Static magnetic field of 1.5 or 3.0 Tesla
- Maximum spatial field gradient of 4,000 gauss/cm (40T/m)
- Maximum MR system reported whole-body averaged specific absorption rate (SAR) of 2 W/kg and whole-head averaged SAR of 3.2 W/kg
- Quadrature driven transmit body coil only
- Maximum active scan time of 15 minutes

Under the scan conditions defined above, the MR Conditional/CT Cup and Webb Electrodes are expected to produce a maximum temperature rise of 4°C or less after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends less than 2.5 mm from the MR Conditional/CT Cup and Webb Electrodes when imaged with a gradient echo pulse sequence and a 3.0 Tesla MRI system.

The MR Conditional/CT Cup and Webb Electrodes have not been tested in simultaneous combination with other devices.

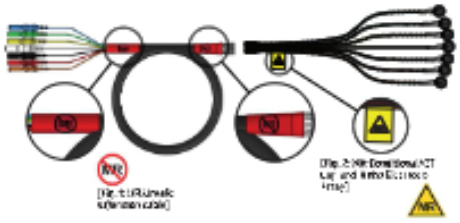
Artifact Information

MR image quality may be compromised if the area of interest is in the same area or relatively close to the position of the device. Therefore, it may be necessary to optimize MR imaging parameters for the presence of this device.

MR image artifacts can affect the device surrounding on each side from the device surface as follows:

Worst-case artifacts of:	Spin Echo	Gradient Echo
Test object length	1.46 mm	2.11 mm
Test object diameter	2.22 mm	2.46 mm

The included extension cables are MR Unsafe. Remove all extension cables before entering an MR environment.



[Fig. 1: MR Unsafe extension cable]

[Fig. 2: MR Conditional/CT Cup and Webb Electrodes Array]

Avoid prolonged or repeated exposure to substances containing acetone or ethyl acetate. These solvents can damage the electrode and may lead to premature product failure.

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Rhythmlink.com

FOR SINGLE USE ONLY

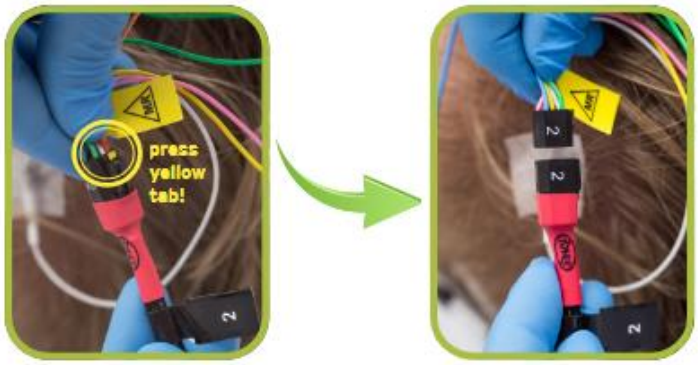
Rx Only

*PATENT PENDING
**Patent NO. D 844738

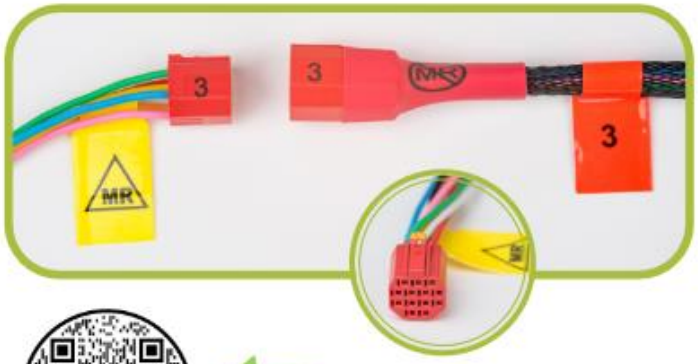
L27001 rev005

HOW TO USE RHYTHMLINK'S QUICK CONNECT SYSTEM™

When a patient is referred to MRI simply disconnect by **pressing down gently on the yellow tab** and pull apart.



When the patient returns from the radiology suite, use the number labeling to reconnect. Matching number to number line up the connectors and insert the tab. You will hear a click which indicates the connector is locked in place.



SCAN THE QR CODE TO SEE OUR APPLICATION VIDEO!

or visit the link below to view video:
www.rhythmlink.com/QC

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