NON CIED IMPLANTS & FOREIGN BODIES

PURPOSE

- To ensure patients with active and passive implants are appropriately evaluated and safely undergo MR imaging.
- To decrease the incidence of patients being inappropriately denied MR imaging due to the presence of implants.

DEFINITIONS

- MR safe implants/materials are those that are composed of nonmetallic, nonmagnetic and nonconductive components that post no known hazards in any MR imaging environment.
- MR conditional implants are those that have been demonstrated to pose no known hazards when imaged under specified conditions including static magnetic field strength, spatial gradient, time rate of change of the magnetic field, RF fields and specific absorption rate (SAR).
- MR unsafe implants are those that are known to pose hazards in all MR environments.
- MR nonconditional implants are those that have not received a designation of MR safe, MR conditional or MR unsafe or those implants in which any component is nonconditional.
- Passive implants are those that do not have electronic components (surgical clips, vascular stents, cardiac valves, orthopedic fixation hardware, etc).
- Active implants are those that have electronic components (pacemakers, defibrillators, cardiac event recorders, deep brain / spinal / peripheral nerve stimulators, cochlear implants, etc).

MR SAFE IMPLANTS

- MR safe implants are those that are composed of nonmetallic, nonconductive and nonmagnetic components that post no known hazards in any MR imaging environment. Plastic implants are an example of MR safe implants.
- The following implants are regarded as MR safe at 1.5 Tesla and 3.0 Tesla either due to being composed on nonmetallic or non-ferromagnetic metallic components or having ferromagnetic components of sufficiently low mass as to pose a limited safety risk:
  - Cardiac – coronary artery stents, CABG surgical clips, bovine/porcine cardiac valves, TAVR valves,
    temporary epicardial pacer leads (both intact and abandoned)
  - Vascular – Metallic stents, PTFE grafts, arteriovenous (AV) fistulas, IVC filters, venous access devices (peripheral IVs, PICCs, midlines, TICCs, triple lumen catheters, Permacaths, Quintons and chest ports)

- Genitourinary – Foley and suprapubic catheters, bladder slings, intrauterine implants (IUDs), vaginal pessaries, urethral bulking agents, percutaneous nephrostomy catheters, ureteral stents
- Orthopedic – Joint replacements, rods/plates/screws used to fixate fractures
- Neurologic – spinal hardware (excluding Harrington rods), Ommaya reservoirs
- Surgical Materials – Surgical clips within the neck, chest, abdomen, pelvis or extremities, mesh material used for hernia repair, percutaneous drainage catheters
- Oncologic – Prostate radiation seeds, radiation fiducial markers in the prostate or other organs
- Miscellaneous – acrylic/glass eye replacements

- Use **Normal** scan mode with all these implants.
- These implants do not need device approval Foreign Body / Implant / Device form (MI-0651) completed; however the MR technologist should verify the accuracy of the patient's history sheet.
- The implants listed above do not require a waiting period following placement before they can undergo MR imaging (i.e. they can be scanned immediately after placement if needed).

MR CONDITIONAL PASSIVE IMPLANTS

- MR conditional implants are those implants that do not contain electronic components and are not automatically regarded as MR safe (see list of MR safe implants above).
- The MR technologist must research the implant and complete the Foreign Body / Implant / Device form (MI-0651). The supervising radiologist will then review the form and supporting documentation and determine whether to proceed with the MR examination.
- Passive implants that have been previously researched and had a device form signed by a radiologist do not a new device form completed if no changes to the implant have occurred since the last MR exam and as long as the implant's conditions can be met on a particular MR scanner.
- Sedated, intubated, altered and unconscious patients with MR conditional implants can undergo MR imaging if implant conditions can be met due to the low risk of patient injury.
- Codman Hakim programmable VP shunts do not need a device form completed; however the MR technologist is responsible for ensuring the implant's conditions can be met on a particular MR scanner.

MR CONDITIONAL ACTIVE IMPLANTS

- Active implants are those that have electronic components (pacemakers, defibrillators, cardiac event recorders, deep brain / spinal / peripheral nerve stimulators, pain pumps, bladder stimulators, cochlear implants, etc).
- Scheduling notifies the MR department that an outpatient with active implant is requesting a MR exam.

- Scheduling sends the clinician's order and a copy of patient's implant card to the MR department at the intended imaging site.
- The MR technologist determines if the implant's conditions can be met on the intended MR scanner.
- Once all requirements have been met and all necessary approvals obtained, the patient may be scheduled for the MR exam.
- Once the patient is scheduled, the MR department notifies the appropriate implant manufacturer to schedule their personnel to be available for the patient's appointment (if applicable).
- The MR department will schedule the appropriate hospital personnel (radiology nurse) to monitor the patient as needed.
- A MR technologist must complete a Foreign Body / Implant / Device form or Cardiac Implanted Electronic Device MR Approval form (MI-0651 or MI-0664) and have the supervising radiologist sign the form before the patient can be scanned.
- The device form must be completed prior to each MR exam performed on a new day if the implant has a lead(s) that could have fractured since the prior MR exam (unless otherwise specified in individual device sections).
- Sedated, intubated, altered and unconscious patients with MR conditional implants can undergo MR imaging if implant conditions can be met due to the low risk of patient injury.

COCHLEAR IMPLANTS

- The MR Technologist must research the cochlear implant and complete the Foreign Body / Implant / Device form (MI-0651). The supervising radiologist will then review the form and supporting documentation and determine whether to proceed with the MR exam.

SPINAL CORD STIMULATORS

- The MR Technologist must research the spinal cord stimulator and complete the Foreign Body / Implant / Device form (MI-0651). The supervising radiologist will then review the form and supporting documentation and determine whether to proceed with the MR exam.
- Imaging must meet manufacturer guidelines.
- Pre scan radiographs are not required as long as the device programmer confirms that the stimulator leads are intact.

VAGAL NERVE STIMULATORS (VNS)

- The only FDA-approved VNSs in the US are manufactured by Cyberonics (now LivaNova) and all models are MR conditional at 1.5T and 3T under the specific conditions:
  - Static magnetic fields of 1.5T or 3T only.
  - Spatial gradient field of ≤ 720 Gauss/cm.

  - Normal operating only mode.
  - Use of only local transmit/receive coils.
  - Maximum head-specific SAR of ≤ 3.2 W/kg over 15 mins.
- Potential risks of MR imaging of patients with VNSs include:
  - Heating effects from RF energy around the implant pack and especially the leads.
  - Non-significant levels of current induced through the implant leads by the time-varying gradient magnetic fields.
  - Inadvertent implant reset which erases historical information stored on the implant (serial number).
  - Inadvertent *Magnet Mode activation* (i.e. brief magnet application and removal, which initiates a stimulation) from magnetic fields.
  - Delivery of AutoStim may occur if the feature is programmed on and a rapid increase in heart rate occurs (for 106 model only).
  - Image distortion and artifacts.
  - Magnetic field interactions.
  - Implant malfunction or damage.
- <u>The body transmit coil must never be used when imaging a patient.</u> This can result in temperature increases of up to 30 degrees Celsius (86 degrees Fahrenheit) along the leads within the carotid sheath. Surgical removal of the VNS Therapy System is required if imaging using a transmit RF body coil is needed.
- The MR technologist must research the VNS and complete the Foreign Body / Implant / Device form (MI-0651). The supervising radiologist will then review the form and supporting documentation and determine whether to proceed with the MR exam.
- An appropriate healthcare professional with access to a VNS Therapy programming system must prepare the VNS implant before the patient enters an MR system room.
- Steps in preparing the VNS system:
  - Perform an interrogation and complete the manufacture's VNS interrogation form (see page 7 of VNS manual). This information is used to restore the implant settings in case of a reset.
  - Perform System Diagnostics to ensure proper operation of the implant.
  - Reprogram the Output Current (OC) parameter settings for Normal Mode (Output Current 0 mA), Magnet Mode (Magnet Current 0 mA) and AutoStim Mode (AutoStim current 0 mA and tachycardia detection off for Model 106).
  - Perform an Implant Interrogation to verify programming was successful.
  - Verify that placement of the VNS Therapy System is located between C7-T8. All VNS patients are required to have lateral radiographs of the cervical and thoracic spine performed within <u>3 months</u> prior to the MR exam date to verify that the implant leads terminate between the C7 and T8 vertebra.
- See pages 10 and 11 (images 84 and 85) of the Cyberonics VNS Manual for discussion of imaging in cases of abandoned, broken or transected leads.

- The patient will be properly positioned for the MR exam according to manufacturer guidelines.
- After the exam is completed, the patient will be moved to Zone 3, and an appropriate healthcare professional will be available to place the VNS back to its original setting.

EVALUATION OF A METALLIC FOREIGN BODY OF UNKNOWN COMPOSITION

- Each case will be assessed via a risk-benefit analysis.
- MR imaging should only be approved if no other imaging modality can provide the needed clinical information.
- It is the responsibility of the supervising radiologist to assess the foreign body for magnetically induced force and torque, current induction and RF heating in regard to proximity to vital anatomic structures.
- The MR technologist must fill out the Foreign Body / Implant / Device form (MI-0651) and have the supervising radiologist sign the form prior to proceeding with the exam.

ASSESSMENT OF AN UNCONSCIOUS/ALTERED PATIENT

- Each case will be assessed via a risk-benefit analysis.
- MR imaging should only be approved if no other imaging modality can provide the needed clinical information.
- In the event a patient is unable to provide accurate medical history and he/she does not have family available to provide that history, the patient will have radiographs of the head, chest, abdomen and pelvis to assess for the presence of any metallic foreign bodies.
- If any metallic foreign body is present, it is the responsibility of the supervising radiologist to assess the foreign body for magnetically induced force and torque, current induction and RF heating in regard to proximity to vital anatomic structures.
- The MR technologist must fill out the Foreign Body / Implant / Device form (MI-0651) and have the supervising radiologist sign the form prior to proceeding with the exam.