

SPINAL CORD & NERVE STIMULATORS

GENERAL POLICIES & PROCEDURES

- Spinal cord and nerve stimulators are examples of MR conditional active implants.
- The MRI technologist must research the 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 MRI.
- A stimulator that has been researched and approved within the past **3 months** does not need a new form MI-0651 completed provided:
 - There have been no changes to the stimulator since the last MRI.
 - The stimulator's conditions can be met on the MRI scanner to be used.
- If approved by the supervising radiologist, altered, unconscious, sedated and intubated patients with a stimulator can undergo MRI provided the stimulator's conditions can be met.

SPINAL CORD STIMULATORS

- Pre scan radiographs are not required provided the stimulator's programmer does not return a fault during device interrogation/programming and the stimulator's conditions do not require pre scan radiographs.
- Some models of spinal cord stimulators require radiography confirmation that the leads terminate in the posterior aspect of the osseous spinal canal.

VAGAL NERVE STIMULATORS (VNS)

- All VNS patients are required to have lateral radiographs of the cervical and thoracic spine performed within **3 months** prior to the MRI to verify that the stimulator 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.
- An appropriate healthcare professional with access to a VNS Therapy programming system must prepare the VNS implant before the patient enters the MRI scanner 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 stimulator settings in case of a reset.
 - Perform System Diagnostics to ensure proper operation of the stimulator.
 - 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 stimulator interrogation to verify programming was successful.
- The patient will be properly positioned for the MRI according to manufacturer guidelines.

- **The body transmit coil must never be used when imaging a patient.** This can result in temperature increases of up to 30° Celsius (86° 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/required.
- 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 MRI of patients with VNSs include:
 - Heating effects from RF energy around the generator pack and especially the leads.
 - Non-significant levels of current induced through the stimulator leads by the time-varying gradient magnetic fields.
 - Inadvertent stimulator reset which erases historical information stored on the stimulator (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.
 - stimulator malfunction or damage.
- After the exam is completed, the patient will be moved to Zone 3, and an appropriate healthcare professional will place the VNS back to its original setting.