


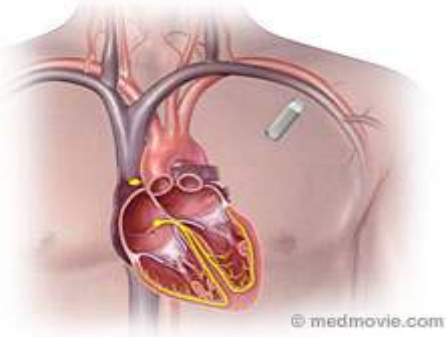

MRI IMPLANT TABLE EDITED MARCH 2013

Device	1.5 T C	3.0T C	Comments and Guidelines
Aneurysm Clip	Yes C*	Yes C*	<ul style="list-style-type: none"> • Aneurysm clips made from ferromagnetic materials are contraindicated for MR procedure, since excessive magnetically induced forces may displace these clips, causing serious injury or death. • By comparison aneurysm clips classified as non-ferromagnetic (eg. Titanium alloy) have been tested and shown to be safe for patients undergoing MR procedures at 1.5T or lower. • All aneurysm clips must be checked and documented for MRI compatibility. • Every aneurysm clip placed here at UCSF since 1985, is safe at both 1.5T and 3T. (Sugita T2 aneurysm Clip, Yasargil Phynox aneurysm clip (FE), Yasargil Titanium aneurysm clip (FT)) • Aneurysm clips placed at an outside hospital, must have written documentation stating the make, model, and date of insertion. This information must be reviewed and confirmed for MRI compatibility before the patient is allowed in the scan room. • Due to the increased artifacts generated by the 3 Tesla, the 1.5Tesla should be the scanner of choice, unless specific high resolution imaging is needed and has been approved by the radiologist.  <p data-bbox="562 1214 1354 1279"> http://www.mrisafety.com/safety_article.asp?subject=146 http://www.radiology.ucsf.edu/patient-care/patient-safety/mri </p>
			C*=Conditional, see comments

MRI IMPLANT TABLE EDITED MARCH 2013

Device	1.5 T C	3.0T C	Comments and Guidelines
Breast Tissue Expander	No	No	<ul style="list-style-type: none"> • Adjustable breast tissue expanders and mammary implants are utilized for breast reconstruction following mastectomy, for the correction of breast and chest-wall deformities and underdevelopment, for tissue defect procedures, and for cosmetic augmentation. These devices are typically equipped with either an integral injection site or a remote injection dome • it is recommended that a patient with a breast tissue expander that has a metallic component be identified prior to MRI so that the radiologist is aware of the potential problems related to the generation of artifacts as well as a possible injury. • There are various breast tissue expanders that have magnetic ports to allow for a more accurate detection of the injection site. These devices are substantially attracted to the static magnetic fields of MR systems and, therefore, may be uncomfortable, injurious, or contraindicated for patients undergoing MR procedures. • Expanders which are unsafe for MRI include the following expanders: Contour Profile Tissue Expander McGhan Medical Breast Tissue Expander Magna-Site Tissue Expander <div data-bbox="661 935 1108 1222" style="text-align: center;"> </div> <p data-bbox="569 1256 1339 1287">http://www.mrisafety.com/safety_article.asp?subject=16</p>

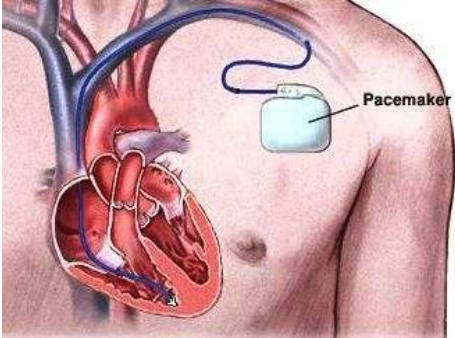
MRI IMPLANT TABLE EDITED MARCH 2013

<p>Cardiac Loop Recorder</p>	<p>Yes C*</p>	<p>Yes C*</p>	<p>Reveal Plus (Model # 9526) Insert able Loop Recorder (ILR) Magnetic and Radio Frequency (RF) fields produced by MRI may adversely affect the data being stored by the Reveal Plus Insert able Loop Recorder (ILR). Since the ILR contains ferromagnetic components, the strong magnetic field of the MRI system may apply a mechanical force on the ILR. The patient may be able to feel this magnetic force on the ILR. While this does not represent a safety hazard, the patient should be made aware of this possibility to avoid undue patient concern.</p>   <p>Reveal DX (Model # 9528) and Reveal XT (Model # 9529) Insert able Cardiac Monitor Non-clinical testing demonstrates that Reveal DX and Reveal XT devices are safe for use in the MRI environment when used according to these instructions. The Reveal DX and Reveal XT can be safely scanned in patients under the following conditions:</p>
------------------------------	-------------------	-------------------	--

MRI IMPLANT TABLE EDITED MARCH 2013

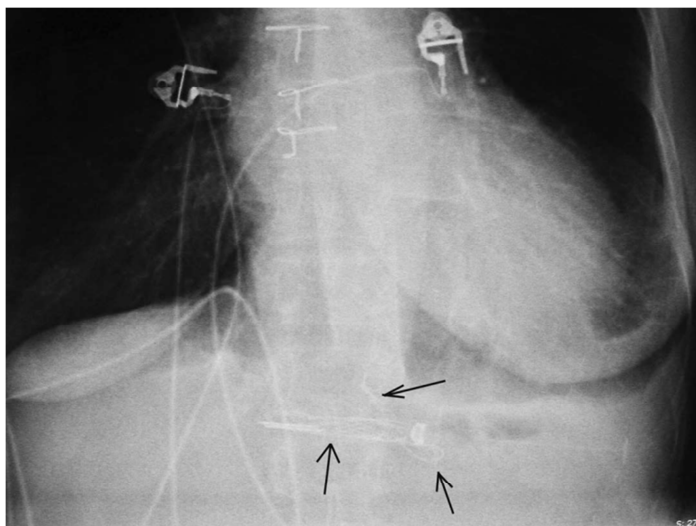
		<p>MRI Equipment Requirements</p> <ul style="list-style-type: none">• The MRI equipment must be a closed bore, cylindrical magnet with a static magnetic field of 1.5 Tesla (T) or 3.0 T.• MRI equipment must be used in normal operating mode (based on standards defined in IEC 60601-2-33). Refer to Reveal DX or Reveal XT Clinician Manual for additional information.• If local or surface coils are needed, please refer to the Reveal DX or Reveal XT Clinician Manual for additional information. <p>MRI Procedural Requirements</p> <ul style="list-style-type: none">• Verify that the Reveal DX or the Reveal XT is at least 6 weeks post-implant. This waiting period allows sufficient time for implant pocket and wound healing and minimizes the effects of device “tugging” caused by the magnetic fields.• Verify that the Reveal DX or Reveal XT implant location is in the subcutaneous tissue of the chest region.• Uninterrupted duration of active scanning (when RF and gradients are on) over the chest during MRI must not exceed 30 minutes. A waiting period of at least 10 minutes is required if additional chest scans are necessary.• Check that additional implantable devices are not present, including abandoned pacing leads.• Medtronic has not tested interactions with all other implanted devices or abandoned pacing leads.• The MRI procedure may overwrite the recorded data in the Reveal DX or the Reveal XT. Print or save the data stored in the Reveal DX or Reveal XT to diskette before the MRI.
--	--	--

MRI IMPLANT TABLE EDITED MARCH 2013

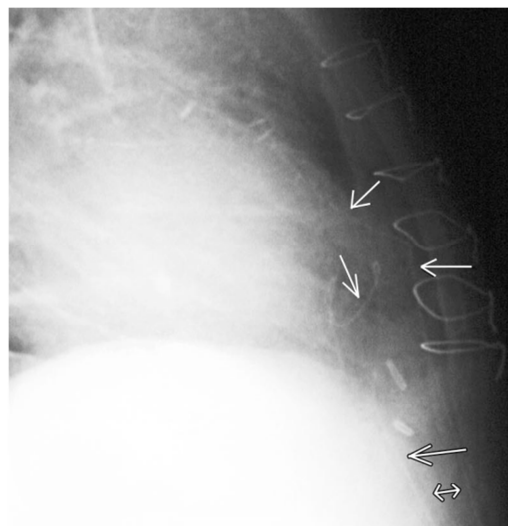
			<ul style="list-style-type: none"> The Patient Assistant and the Medtronic CareLink Model 2090 Programmer are not MRI safe and should not be brought into MRI controlled room (magnet room). Continued below..... <p>Post-MRI operation</p> <ul style="list-style-type: none"> Check the programmed parameters of the Reveal DX or the Reveal XT after the MRI procedure. Print or save the data collected during the MRI procedure to diskette because the MRI procedure may temporarily affect the Reveal DX or the Reveal XT's event detection and recording. The date and time of the MRI procedure should be recorded under the Patient icon in the notes section for future reference. Note: The Cardiac Compass trend data cannot be cleared and might show irregularities at the time of the MRI operation. <p>www.mrisafety.com/safety_info.asp</p>
Device	1.5 T C	3.0T C	Comments and Guidelines
Cardiac Pacemaker	Yes C*	No	<p>The following guidelines have been set here at UCSF to scan a patient with a pacemaker or ICD:</p>  <ul style="list-style-type: none"> A risk- benefit ratio must be established and benefit from the MRI examination

MRI IMPLANT TABLE EDITED MARCH 2013

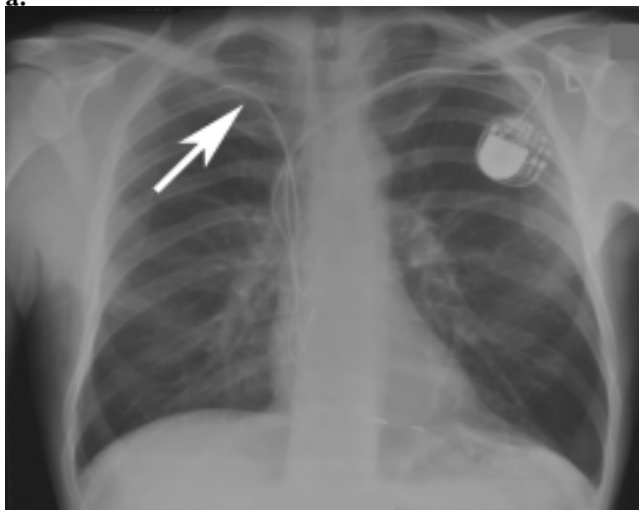
			<p>should clearly outweigh the risks of the procedure.</p> <ul style="list-style-type: none">• MR imaging in the thoracic region is subject to additional risk and this should be considered when evaluating the benefit to risk for a specific patient.• Multiple MR exams in a single patient should also be avoided, as there is potential for increased risk and this should needs to be considered when determining if the benefits clearly outweigh the risks.• The study should not be performed if similar clinical information could be obtained by a different image modality• The MRI scan must be approved by an attending radiologist and an electro-physiologist.• For Pacemaker patients: The patient must be non-pacemaker dependent.• For ICD patients: Risks associated with MR examination in patients with ICD are expected to be higher than in patients with pacemakers. Therefore, MR examination of patients with ICDs should not be performed unless there are highly compelling circumstances and when the benefits clearly outweigh the risks. ICD patients must be non-pacemaker dependent.• The patient must have the pacemaker/ ICD in place for more than 6 weeks.• The patient must be not at or near Elective Replacement Indicator (ERI).• Abandoned temporary epicardial (cut at skin) leads are not a contraindication for MRI (please see images a. and b. bellow). Abandoned/capped trans venous leads are a contraindication to MRI (please see image c. bellow).
--	--	--	--



a.



b.



c.


MRI IMPLANT TABLE EDITED MARCH 2013

		<ul style="list-style-type: none">• Prior to the scan date, a cardiology consult must be scheduled, where it will be determined if the pacemaker/ICD patient is safe to have an MRI. At this time, a written informed consent will be established. If a patient is referred from and outside physician, a visit to the UCSF device clinic should be scheduled before the MRI is acquired.• An electro-physiologist, or cardiologist or device nurse (with pacemaker/ICD monitoring experience) must be present before, during, and after the MRI exam to validate the performance integrity of the pacemaker/ICD prior to the MRI exam, monitor the patient during the exam, and check the pacemaker/ICD performance after the exam. An electro-physiologist should be carrying a pager and be within quick reach of the MRI scanner during the entire examination. For patients with ICDs, a physician with electrophysiological expertise should perform post scan device reprogramming and defibrillation threshold testing. Arrangements should be made for the patient to follow-up with electro physiologist at 3 months after the MRI.• The patient should be monitored continuously during the MR procedure (e.g., blood pressure, pulse rate, oxygen saturation, and ECG).• Appropriate personnel, a crash cart, and defibrillator must be available throughout the procedure to address an adverse event.• Maintain visual and voice contact throughout the procedure with the patient.• The patients must be able to communicate in case any complications arise.• Instruct the patient to alert the MR system operator of any unusual sensations or problems so that, if necessary, the MR system operator can immediately terminate the procedure.• The patients will only be scanned during normal workday hours (8A-5P) on 1.5T scanners, only in hospital setting with appropriate trained personnel. For urgent, on-call cases, scans may need
--	--	--

MRI IMPLANT TABLE EDITED MARCH 2013

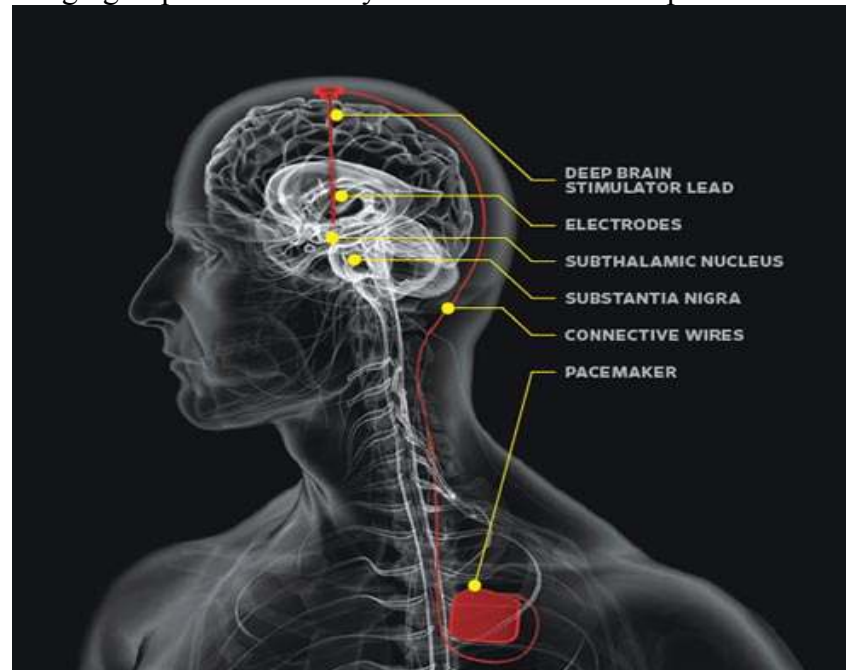
		<p>to be done after 5P or on weekends, although it is preferable to wait until normal workday hours if possible.</p> <ul style="list-style-type: none">• The MRI will only be scheduled during the day and appointments will be coordinated to ensure that an MRI physicist and an attending radiologist are involved to tailor the study for minimum SAR while obtaining the essential clinical information.• Patients with MR conditional Medtronic pacemaker (Revo MRI SureScan pacing system) can undergo an MRI study only if the MR isocenter is superior to the C1 vertebra or inferior to the T12 vertebra. In that case, Medtronic specific guidelines should be followed. In case MR isocenter is contained between C1 and T12, specific MR safety protocols described above should be followed.• The current protocol is effective now for cardiac imaging and neuroimaging studies. Additional clinical indications will be considered in the future. <p>http://www.mrisafety.com/safety_article.asp?subject=18 http://www.radiology.ucsf.edu/patient-care/patient-safety/mri http://www.medtronic.com/for-healthcare-professionals/products-therapies/cardiac-rhythm/pacemakers/revo-mri-pacing-system/index.htm</p>
		<p>C*=Conditional, see comments</p>

MRI IMPLANT TABLE EDITED MARCH 2013

Device	1.5 T C	3.0T C	Comments and Guidelines
Cochlear Implants	No	No	<p>Some types of cochlear implants employ a relatively strong cobalt samarium 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. Consequently, MR procedures are strictly contraindicated in patients with these types of implants because of the possibility of injuring the patient and/or damaging or altering the function of the cochlear implants.</p> 
Device	1.5 T C	3.0T C	Comments and Guidelines
Deep Brain Stimulator (DBS)	Yes C*	No	<ul style="list-style-type: none"> • Deep brain stimulation (DBS) is a surgical procedure used to treat a variety of disabling neurological symptoms—most commonly the debilitating symptoms of Parkinson’s disease. • The DBS system consists of three components: the lead, the extension, and the neurostimulator. The neurostimulator (the "battery pack") is usually implanted under the skin near the collarbone. In some cases it may be implanted lower in the chest or under the skin over the abdomen. • The greatest concern for electronically activated or electrically conductive implants in the brain is excessive MR imaging-related heating, which can cause irreversible tissue damage. • This may lead serious injury to the patient, including the possibility of transient dystonia, paralysis, coma, or even death. • The Deep brain stimulator must turn off and checked before the exam, and turned


on and checked after the exam. The primary contact is Monica Volz, Pg 443-5493.

- Patients with DBS implants can have MRI imaging of the brain with a head coil (transmit-receive head coil, where the RF is not transmitted by the body coil)
- Imaging of parts of the body other than the head is prohibited.

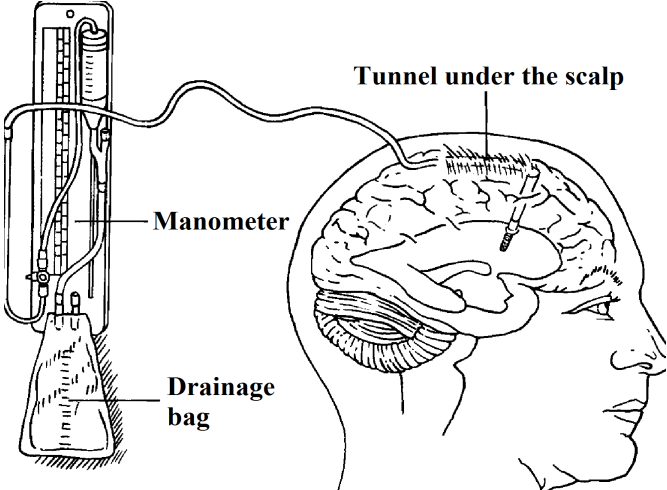


<http://www.medtronic.com/your-health/parkinsons-disease/therapy/our-dbs-therapy-products/activarc/index.htm>

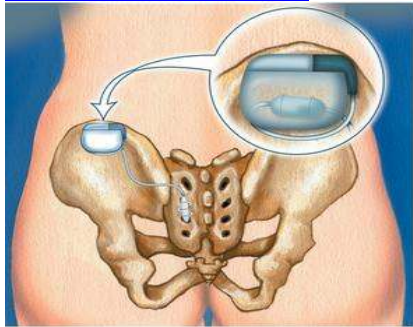

MRI IMPLANT TABLE EDITED MARCH 2013

Device	1.5 T C	3.0T C	C* = Conditional, see comments Comments and Guidelines
Drug Infusion Pump	Yes C*	No	<p>A drug infusion pump is used for automatic delivery of antineoplastic agents, morphine, or narcotics. The infusion pump has a motor that may have ferromagnetic properties, a magnetic switch, and is programmed by telemetry. Potential issues pertaining to MRI imaging of patients with a drug infusion pump include the following:</p> <ol style="list-style-type: none"> 1) Stopping of needed medication 2) Temporary or permanent stall of the motor 3) Local tissue heating adjacent to implant during imaging 4) Increase potential for Peripheral nerve stimulation (PNS) <p>Although many drug infusion pumps are contraindicated for MRI, there are currently some pumps that can be exposed to the MRI environment during imaging under strict conditional requirements. Always review the manufacturer guidelines for the specific pump before introducing the patient into the magnet room and proceeding with the exam. Strictly adhere to the manufacturer's conditional requirements for managing the pump prior to, during, and post imaging. The following are examples of conditional drug infusion pumps:</p> <p>AccuRx Constant Flow Implantable Pump (St. Jude Medical, Plano, TX) www.sjm.com</p> <p>SynchroMed (II,EL) , implantable drug infusion device (Medtronic Inc.) http://www.medtronic.com</p> 

MRI IMPLANT TABLE EDITED MARCH 2013

Device	1.5 T C	3.0T C	C* = Conditional, see comments Comments and Guidelines
External Ventricular Drain	Yes	Yes	<ul style="list-style-type: none"> An external ventricular drain (EVD) is a device used in neurosurgery that relieves raised intracranial pressure and monitors CSF fluid levels. The EVDs utilized here at UCSF is the Integra Limitorr, and the Integra MoniTorr. Both are safe to use on either the 1.5 or 3.0T. This device does not cause artifacts.  <p>http://www.integra-ls.com//PDFs/NeuroCriticalCare/Limitorr%20Sales%20Brochure.pdf</p>
Integra Camino Bolt	No	No	<ul style="list-style-type: none"> Camino Bolt catheter is an intracranial pressure monitoring device. It consists of a cranial bolt surgically implanted into the skull in which a pressure transducer is placed. At the end of the pressure transducer is a transducer connector, which is attached to a cable that is attached to a monitor. The Camino Bolts utilized here at UCSF is made by Integra Neurosciences. Currently, the FDA

MRI IMPLANT TABLE EDITED MARCH 2013

			<p>has requested that Integra revalidate their results concerning the Camino Bolt and its MR compatibility. Until such time that the manufacturer has completed their revalidation process and can produce a document that states that Camino Bolt and the various models are MRI safe in a 1.5T and or a 3.0T MR environment, Camino Bolts will be contraindicated for both the 1.5T and 3.0T.</p> <p>www.integra-ls.com/PDFs/Camino/Camino%20110-4HM%20PI.PDF</p>
Device	1.5 T C	3.0T C	Comments and Guidelines
InterStim Therapy	Yes C*	No	<ul style="list-style-type: none"> • InterStim Therapy is similar to a pacemaker for the bladder. The implantable device uses mild electrical pulses to target the communication problem that exists between the sacral nerves and the brain to tell the bladder to work correctly. • The therapy treats urinary retention and the symptoms of overactive bladder, including urinary urge incontinence and significant symptoms of urgency-frequency. • As with any neurostimulator, only the brain can be imaged using a transmit-receive head coil. <p>http://www.mrisafety.com/safety_article.asp?subject=158</p> <p>http://professional.medtronic.com/pt/uro/snm/prod/interstim/manuals-technical-resources/index.htm</p> <div style="display: flex; justify-content: space-around;">   </div>

MRI IMPLANT TABLE EDITED MARCH 2013

Device	1.5 T C	3.0T C	Comments and Guidelines
<p>Linux Reflux Management System</p>	<p>No</p>	<p>No</p>	<ul style="list-style-type: none"> • Consists of a series of titanium beads, each with a magnetic core, connected together with titanium wires to form a ring shape. It is implanted around the lower end of the esophagus to help control gastro esophageal reflux (GERD). • Patients who have the LINX device should not be exposed to , or undergo, an MRI. Exposure to MRI could cause serious injury to the patient and the device may damaged. <div data-bbox="758 500 1335 889" data-label="Image"> </div> <p>http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm300790.htm</p>

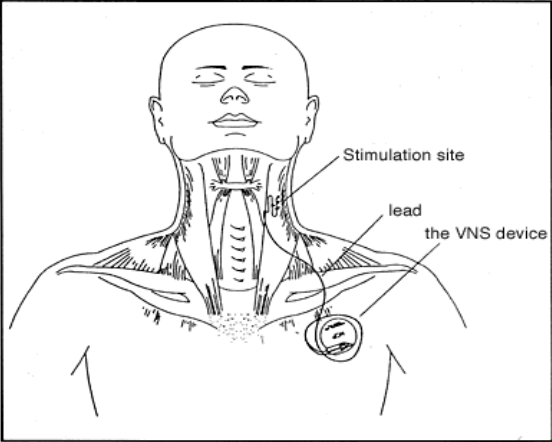
MRI IMPLANT TABLE EDITED MARCH 2013

Device	1.5 T C	3.0T C	C* = Conditional, see comments Comments and Guidelines
Magniimplant Magnatract Sternum Implant	No	No	<p>Magniimplant” and “Magnatract” in a combined system to correct for pectus excavatum or sunken chest deformity, in pediatric patients. As part of the system “Magniimplant” is an internal magnet that is surgically placed behind the sternum, and “Magnatract” is an external brace with a magnet implanted. The devices combine to exert a defined magnetic force to the chest wall.</p> <p>This device system is totally contraindicated for MRI at any field strength.</p>

MRI IMPLANT TABLE EDITED MARCH 2013

Device	1.5 T C	3.0 T C	Comments and Guidelines
Programmable Ventricular Shunt	Yes C*	Yes C*	<p>Programmable Valves are implantable devices that provide constant Intra-ventricular pressure and drainage of CSF for the management of hydrocephalus.</p> <ul style="list-style-type: none"> • Subjecting the valve to strong magnetic fields may change the setting of the valve(shunt) The use of Magnetic Resonance (MR) systems up to 3-Tesla will not damage the valve mechanism, but may change the setting of the valve. Confirm the valve setting after an MRI procedure. • The performance level setting should always be checked before and after MRI exposure. Contacts to check shunt: Pedi – Carolyn 443-4726, Adult – Gwen 443-4769 • The following programmable shunts have been approved for the 3.0 Tesla MRI: Codman Hakim (Johnson and Johnson), Delta Shunt (Medtronic), proGAV programmable valve (Aesculap), Pulsar Valve (Sophysa USA), Strata (Medtronic), Sophy Adjustable pressure valve (Sophysa USA) • Due to the increased artifacts generated by the 3 Tesla, the 1.5Tesla should be the scanner of choice, unless specific high resolution imaging is needed and has been approved by the radiologist. • <p>http://www.mrisafety.com/safety_article.asp?subject=175</p>

MRI IMPLANT TABLE EDITED MARCH 2013

Device	1.5 T C	3.0 T C	Comments and Guidelines
<p>Vagus Nerve Stimulator</p>	<p>Yes C*</p>	<p>Yes C*</p>	<ul style="list-style-type: none"> • The VNS Therapy generator is an implantable, programmable pulse generator that delivers a precise pattern of stimulation to the left vagus nerve. • MRI procedures should not be performed on patients with VNS Therapy Systems who have a Lead break. A broken Lead should be removed prior to MRI. Suspected Lead breaks should be confirmed by performing appropriate diagnostic procedures and consultation with Cyberonics. Broken Lead wires present increased risk of thermal injury to patients during MRI procedures • Magnetic resonance imaging (MRI) should not be performed with a magnetic resonance body coil in the transmit mode. The heat induced in the Lead by an MRI body scan can cause injury. • Imaging restricted to brain or head imaging utilizing a transmit-receive head coil. • The device must be turned off (Pulse generator output programmed to 0.0 mA) prior to the exam and the device checked and reset after the exam. See below. 

MRI IMPLANT TABLE EDITED MARCH 2013

			http://us.cyberonics.com/en/vns-therapy/healthcare-professionals/manuals/ http://www.mrisafety.com/safety_article.asp?subject=41
			•