Determining the Risks of MRI in the Presence of Pacemakers and ICDs

The MagnaSafe Registry is a multicenter study expected to begin enrollment in the Spring of 2009. We are conducting this research to determine the risks of performing MRI for patients with pacemakers and Implantable Cardioverter-Defibrillators (ICDs). The study will create a registry of patients with pacemakers and ICDs who undergo clinically indicated MRI and will document any adverse event or change in device parameters that may be associated with the imaging procedure.

This is a physician-initiated research study that will be coordinated by Scripps Clinic, Torrey Pines. Up to 35 sites will be recruited to participate in the registry. Sites will be required to obtain institutional review board (IRB) approval of the FDA-authorized protocol and consent form before allowing any subject to participate. Sites must complete a written investigator agreement to conduct the investigation in accordance with the investigational plan and FDA regulations.

The purpose of this notice is to obtain investigators. If you are interested in learning more about the MagnaSafe Registry, please contact us by email: info@magnasafe.org, phone: 858-554-5273, or visit our website at www.magnasafe.org.

Inclusion Criteria
- Male or female 18 years of age or older
- Able to provide informed consent
- Permanent pacemaker or ICD placement after 2001
- Strong clinical indication for MRI
- Scheduled for non-thoracic MRI

Exclusion Criteria
- Metallic objects or implanted devices that represent a contraindication to MRI
- ICD patients who are pacemaker dependent
- Abandoned pacemaker or ICD leads
- Abdominal device placement
- Device generator battery voltage at ERI
- Claustrophobia unresponsive to sedatives
- Morbid obesity (abdominal diameter >60 cm)

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