

Medtronic Launches Advisa MRI Pacemaker System



Medtronic has announced U.S. Food and Drug Administration (FDA) approval and the U.S. launch of its Advisa DR MRI™ SureScan® pacing system. The Advisa MRI system is Medtronic's second-generation MR-Conditional pacemaker and is the first system to combine the most advanced pacing technology with proven MRI access.

Advisa MRI was specifically tested and approved for use as labelled with MRI scanners in the U.S. Of the 156 patients scanned in the Advisa MRI Clinical Trial, none showed any MRI-related complications. The new system includes an Advisa MRI device and two CapSureFix MRI™ SureScan® leads, which must be used together.

"Your physician can implant a pacemaker with advanced options that will allow for broad access to MRI scanning," said Dr. J. Rod Gimbel of Cardiology Associates of East Tennessee in Knoxville, Tenn. "MRI is just so very important and traditional pacemakers not FDA approved for MRI scanning often prevent the patient from having an MRI when they need it. With more than 85 percent of pacemaker patients being at least 65 years old and having multiple comorbidities for which MRI may be needed, it's key that physicians and patients have a pacing system that allows MRI imaging as a diagnostic procedure."

Until the availability of Medtronic's SureScan pacing systems, patients with pacemakers in the U.S. have been contraindicated from receiving MRI scans because of potential interactions between the MRI and device function. According to published literature, up to 75 percent of patients worldwide with implanted cardiac devices are expected to need an MRI scan during the lifetime of their devices.

Medtronic's Advisa MRI pacing system provides physicians with innovative technology that will benefit their patients, including the MVP® (Managed Ventricular Pacing) algorithm, which is proven to reduce unnecessary ventricular pacing. This system is the latest addition to a growing number of Medtronic devices which are designed for MRI access including the SynchroMed® II programmable drug infusion system available worldwide, and the SureScan® neurostimulation systems for the management of chronic pain which are available in Europe. In addition, SureScan® pacing systems – including Advisa MRI – are available worldwide.

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