Medtronic Announces Approval and Launch of Japan’s First MR-Conditional Pacemaker System

Medtronic

Medtronic Launches Advisa DR MRI™ SureScan™ Pacing System in Japan

Medtronic, Inc. (NYSE: MDT), today announced the Japanese regulatory approval and launch of the Advisa DR MRI™ SureScan™ pacing system. The Advisa MRI system is the first and only MR-Conditional pacemaker available to patients in Japan, the world’s second largest market for medical devices.

With the Advisa MRI system, pacemaker patients will have access to full body scans, without positioning limitations in the MRI scanner. MRI is the standard of care in soft tissue imaging, providing information not seen with X-ray, ultrasound or CT scan, and critical for early detection, diagnosis and treatment. Advisa MRI was specifically tested and approved for use as labeled with MRI scanners in Japan. The system includes an Advisa MRI device and two CapSureFix MRI™ SureScan® leads, which must be used together.

“Until recently there was a significant unmet need for patients with pacemakers to have access to MRI technology,” said Ken Okumura M.D., professor and chief, Department of Cardiology, Graduate School of Medicine, Hirosaki University and president of the Japanese Heart Rhythm Society. “Now physicians and patients have a choice of pacing systems that allow access to the invaluable benefits of MRI technology.”

The first SureScan pacemaker system was introduced in Europe in 2008 and its use in the MRI environment is supported by extensive computer modeling and clinical studies, as well as real-life data. To date, Medtronic has sold nearly 100,000 SureScan devices worldwide, and thousands of SureScan patients have been able to safely undergo an MRI that would have been denied to them with a standard pacemaker.

Approximately 400,000 people in Japan have implanted pacemakers. However, until the availability of Medtronic’s SureScan pacing systems, patients with pacemakers have been contraindicated in Japan from receiving MRI scans. There is the potential for pacemakers to interact with MRI machines in a manner that could negatively affect the device function or patient safety. According to estimates, 50 to 75 percent of patients worldwide with implanted cardiac devices are expected to need an MRI scan during the lifetime of their devices.[i]

The Advisa DR MRI™ SureScan™ pacing system is not yet available in the U.S. The Revo MRI™ SureScan® pacing system was FDA approved in February 2011.

Advisa MRI – The Most Advanced Pacing System from Medtronic

Medtronic's Advisa MRI pacing system provides patients with innovative exclusive technology, including the MVP™ (Managed Ventricular Pacing) algorithm, which is proven to reduce unnecessary ventricular pacing by 99 percent. Additional features include:

- Complete automaticity with Ventricular and Atrial Capture Management™ (VCM and ACM) and Anti-Tachycardia Pacing (ATP).
- Diagnostics such as the Cardiac Compass® Report, and tachyarrhythmia management tools that assist in the early detection of atrial fibrillation (AF).
- Remote follow-up via Medtronic's CareLink® Network, which transmits comprehensive arrhythmia and diagnostic device data to a physician's clinic.
- Rate Drop Response that identifies abrupt cardiac slowing and responds by pacing the heart at an elevated rate, which may reduce the frequency of syncopal (fainting) episodes in patients with apparent cardio-inhibitory vasovagal syncope.

In collaboration with leading clinicians, researchers and scientists worldwide, Medtronic offers the broadest range of innovative medical technology for the interventional and surgical treatment of cardiovascular disease and cardiac arrhythmias. The company strives to offer products and services that deliver clinical and economic value to healthcare consumers and providers around the world.

About Medtronic
Medtronic, Inc. (www.medtronic.com [1]), headquartered in Minneapolis, is the global leader in medical technology – alleviating pain, restoring health, and extending life for millions of people around the world.

[i] Gillis, AM, et al. Reducing Unnecessary Right Ventricular Pacing with the Managed Ventricular Pacing Mode in Patients with Sinus Node Disease and AV Block. PACE. July 2006; 29(7):697-705.

Source URL (retrieved on *06/20/2013 - 2:44am*):
http://www.mdtmag.com/news/2012/10/medtronic-announces-approval-and-launch-japan%E2%80%99s-first-mr-conditional-pacemaker-system?qt-recent_content=0

Links:
[1] http://www.medtronic.com/