Medtronic News

Medtronic Launches Advisa and Ensura SR MRI(TM) SureScan® Pacemaker Systems in Europe

Single-chamber Devices Receive CE Mark for Full Body MRI Scans Without Positioning Restrictions

MINNEAPOLIS - June 2, 2014 - Medtronic, Inc. (NYSE: MDT), today announced CE (Conformité Européenne) Mark and commercial launch of the Advisa® and Ensura SR MRI(TM) SureScan® single chamber pacemaker devices in Europe. Both pacemakers are approved for magnetic resonance imaging (MRI) scans positioned on any region of the body. These devices are not approved in the United States.

MRI is the standard of care in soft tissue imaging, providing information not seen with X-ray, ultrasound, or CT scan, and without exposing patients to ionizing radiation. MRI is therefore critical for the early detection, diagnosis and treatment of many diseases, including stroke, cancer, Alzheimer's disease, muscle, bone and back pain - all of which are prevalent among older adults.

Until the approval of MR-conditional pacemakers, patients with these implanted devices were denied access to MRI procedures because of the potential for harmful interaction between the device and the MRI scanner. It is estimated that 50 - 75 percent of patients with an implantable cardiac device will need an MRI scan over the lifetime of their device.[1]

"For patients with chronic atrial fibrillation and intermittent AV block, the availability of the Advisa or Ensura MRI single chamber pacemakers provides physicians with more options when determining the best treatment plan for their patients," said Prof. Juerg Schwitter, M.D., director of the CMR Center at the University Hospital Lausanne in Lausanne, Switzerland. "It's imperative that patients with pacemakers receive access to MRI scanning for any region of the body."

Advisa and Ensura SR MRI pacemakers deliver single chamber pacing engineered with the same SureScan technology used in other Medtronic MR-Conditional pacemakers and implantable cardioverter-defibrillators (ICDs), while adding features such as improved diagnostic information and storage, as well as a 35 percent improvement in battery longevity (when compared to the Adapta single chamber pacing system). The new systems include an Advisa or Ensura SR MRI device with any SureScan labeled lead, which must be used together to be considered MR-conditional.

"This approval allows single-chamber pacemaker patients two new options that allow them to have full-body MRI access with no scanning or positioning restrictions," said Pat Mackin, president of the Cardiac Rhythm Disease Management business and senior vice president at Medtronic. "Medtronic has remained committed to developing devices that are approved for MRI since our release of the world's first MR-conditional pacing system in 2008, and still today we offer the only pacemaker system FDA-approved for MRI scans positioned on any region of the body."

The Advisa and Ensura single chamber pacemakers are the latest addition to a growing number of Medtronic devices that are designed for MRI access including the Advisa MRI(TM) and Revo MRI(TM) dual chamber SureScan® pacing systems, the Reveal LINQ(TM) Insertable Cardiac Monitoring (ICM) system and the SynchroMed® II programmable drug infusion system which are available worldwide. In addition, the Evera MRI(TM) SureScan® ICD systems and SureScan neurostimulation systems are available in Europe.

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), headquartered in Minneapolis, is the global leader in medical technology - alleviating pain, restoring health and extending life for millions of people around the world.

Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.

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[1] Kalin R and Stanton MS. Current clinical issues for MRI scanning of pacemaker and defibrillator patients. *PACE* 2005;28:326-328.

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