Medtronic News

Medtronic SureScan® Pacing Systems First to Be Approved for Full Body MRI Scans Without Positioning Restrictions

Data Verifies Safety of MRI Scans for Any Region of the Body in Patients with Medtronic SureScan®Pacing Systems

MINNEAPOLIS - January 22, 2014 - Medtronic, Inc. (NYSE: MDT), today announced that the Medtronic SureScan® pacing systems - the first and only pacing systems in the United States that have been approved by the U.S. Food and Drug Administration (FDA) for use with magnetic resonance imaging (MRI) - are now approved for MRI scans positioned on any region of the body. Patients implanted with the Advisa DR MRI® or Revo MRI® SureScan pacing systems now can have MRI scans without positioning restrictions, including the chest area, which previously had been restricted.

"This approval allows for a more streamlined MRI scanning process and makes scanning the chest easier and more accessible for patients with pacemakers," said Pat Mackin, president of the Cardiac Rhythm Disease Management business and senior vice president at Medtronic. "Because MRI is the standard of care for soft tissue imaging and is a critical component for early detection, diagnosis and treatment, this FDA approval will help more patients with SureScan pacemakers receive the MRI scans they need."

Until the availability of Medtronic's SureScan pacemakers, U.S. patients had been contraindicated from receiving MRI scans due to potential interactions between the MRI and device function. According to published literature, up to 75 percent of patients worldwide with implanted cardiac devices are estimated to need an MRI scan during the lifetime of their devices.[1]

The recent approval was made following the FDA review of computer modeling and clinical data confirming that MRI chest-positioned scans are safe for patients. The first MR-Conditional pacemaker available in the U.S., the Medtronic Revo MRI, was FDA approved in February 2011, and the second-generation Advisa MRI was approved by the FDA in January 2013.

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.

Contacts:

Joey Lomicky

Public Relations
+1-763-526-2494

Jeff Warren
Investor Relations
+1-763-505-2696

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