Medtronic News

Medtronic Cardiac Devices Gain FDA Approval to Enable Patient Access to the Most Advanced Diagnostic Imaging

Patients with SureScan® Pacemakers, ICDs and CRT-Ds Now Can Receive 3 Tesla MRI Scans

DUBLIN - Oct. 13, 2016 - Medtronic plc (NYSE:MDT) is the first company to receive U.S. Food and Drug Administration (FDA) approval for its suite of cardiac rhythm and heart failure devices and leads to be scanned in both 3 and 1.5 Tesla (T) magnetic resonance imaging (MRI) machines. This advancement gives patients with Medtronic SureScan® MR-conditional pacemakers, implantable cardioverter-defibrillators (ICDs) and cardiac resynchronization therapy-defibrillators (CRT-Ds) and leads access to MRI scans on any part of the body.

Each year, approximately 12-16 percent of patients with cardiac devices have a condition in which MRI would normally be prescribed, but less than 1 percent receive a scan because of device or lead restrictions.1-4 Before the availability of MR-conditional technology, patients with cardiac devices were contraindicated from undergoing MRI scans to avoid a potential interaction between the MRI and the device function.

"The potential interaction between cardiac devices and MRIs has been a long-running concern for patients and physicians," said Marc Silver, M.D., cardiologist at WakeMed Heart and Vascular Physicians in Raleigh, N.C. "Fortunately, advancements in MR-conditional cardiac device technology give patients more access to this important diagnostic tool."

MRI is an important imaging technology to diagnose conditions such as stroke, cancer, Alzheimer's disease, and muscle, bone and joint pain. 3T MRI offers better image quality5,6, better diagnosis7-11 and reduced scan duration11,12 compared to 1.5T scans. In the next five years, the adoption of 3T MR systems is expected to reach approximately 30-40 percent of hospitals across the U.S.13

"While 1.5T scanners still comprise the majority of installations, 3T scanners are expected to comprise more than half of new units - with some centers having only 3T scanners - since they offer faster scans and higher resolution images," said Yair Safriel, M.D., neuroradiologist and chief medical officer at Pharmascan Clinical Trials and University of South Florida. "Approval for MRI conditional scanning at both 1.5 and 3T allows patients to have improved access to MRI at a time and place most appropriate for their care. And with 3T scanning, physicians and radiologists gain a clearer look into soft tissues, particularly critical when diagnosing serious conditions, often involving the brain and spine."

Patients in the U.S. with the following devices are now eligible for 1.5 and 3T MRI scans:

- Advisa MRI(TM) Pacemakers and Micra(TM) Transcatheter Pacemaker
- Amplia MRI(TM) and Compia MRI(TM) Cardiac Resynchronization Therapy Defibrillators
- Evera MRI(TM) and Visia AF(TM) MRI DF-1 and DF4 Implantable Cardioverter Defibrillators
- Reveal LINQ(TM) Insertable Cardiac Monitor
- SureScan® Pacing, Defibrillation and Left-Heart Leads

Additionally, Medtronic now offers more options for ICD patients undergoing device replacement surgery, enabling MRI access to an even broader base of patients.

"Our goal is to help patients get the cardiac device therapy they need while ensuring they also retain access to other needed tools, such as diagnostic MRI," said David Steinhaus, M.D., vice president and general manager of the Heart Failure business, and medical director for the Cardiac Rhythm and Heart Failure division of Medtronic. "We are proud to be the first and only company to offer a comprehensive suite of MR-conditional devices and leads in the U.S."

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 of the highest quality that deliver clinical and economic value to healthcare consumers and providers around the world.

About Medtronic

Medtronic plc (www.medtronic.com), headquartered in Dublin, Ireland, is among the world's largest medical technology, services and solutions companies - alleviating pain, restoring health and extending life for millions of people around the world. Medtronic employs more than 88,000 people worldwide, serving physicians, hospitals and patients in approximately 160 countries. The company is focused on collaborating with stakeholders around the world to take healthcare Further, Together.

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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The Revo MRI(TM) Pacemaker is labeled for 1.5T MRI only.

1 Data from 2010 MarketScan® Commercial and Medicare databases from Truven Health Analytics, Inc. were used to characterize non-pacemaker and pacemaker cohorts and utilization or radiology services. Cohorts were matched based on age, gender and comorbidities.

2 Medtronic data on file 2015: ICD data from MarketScan® 2012 Commercial and Medicare Database, Truven Health Analytics.

3 Nazarian S, Reynolds MR, Ryan MP, et al. Utilization and likelihood of radiologic diagnostic imaging in patients with implantable cardiac defibrillators. J Magn Reson Imaging. January 2016;43:115-127.

4 Medtronic data on file 2015: CRT data from MarketScan® 2012 Commercial and Medicare Database, Truven Health Analytics.

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13 2015 MR Market Outlook Report, IMV Medical Information Division, Inc.

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