Medtronic News

Medtronic Receives CE Mark for Its Next Generation Cardiac Resynchronization Therapy-Pacemakers

Suite of Smart Heart Failure Devices Offers More-Effective Pacing, Expanded MRI Access

DUBLIN - Feb. 24, 2017 - Medtronic plc (NYSE:MDT) today announced that it has received CE (*Conformité Européenne*) Mark for a suite of quadripolar cardiac resynchronization therapy pacemakers (CRT-Ps) that also allow patients to receive MRI (magnetic resonance imaging) scans in either 1.5 or 3 Tesla (T) machines. This complete line of CRT-Ps, available in Europe in March, includes the Percepta(TM) Quad CRT-P MRI SureScan(TM), Serena(TM) Quad CRT-P MRI SureScan(TM) and Solara(TM) Quad CRT-P MRI SureScan(TM), and enables proactive heart failure management alongside industry-leading pacing technology and patient access to the most advanced diagnostic imaging procedures available. *These devices are not yet approved for sale in the United States.*

"Quadripolar devices, such as these new pacemakers, allow more pacing programming options, which allows us to better optimize CRT delivery," said Dr. Massimo Mantica of Istituto Clinica Sant'Ambrogio, Milano, Italy. "Advanced technology continues to give us smarter devices that enable more personalized treatment for patients."

The Percepta Quad CRT-P features the EffectivCRT(TM) Diagnostic, which automatically determines the effectiveness of each left ventricular pace, and the EffectivCRT(TM) during AF algorithm, which automatically adjusts pacing rates during atrial fibrillation (AF), without adversely affecting the average heart rate. It also includes VectorExpress(TM) 2.0, an automated in-office test that reduces lead programing to two minutes,1 and reveals clinically actionable information to help physicians select optimal pacing configurations for each patient.

The Percepta Quad and Serena Quad CRT-Ps also feature the Medtronic-exclusive AdaptivCRT(TM) algorithm, which reduces a patient's odds of a 30-day heart failure readmission by 59 percent,2 and has demonstrated a 46 percent reduction in AF risk compared to echo-optimized biventricular pacing.3 Both devices also feature Multiple Point Pacing, which can stimulate two sites on the left ventricle (lower chamber) simultaneously or sequentially.

Additional features available in all three devices include:

- Attain(TM) Perfoma(TM) MRI SureScan(TM) Quadripolar Leads, which include short bipolar spacing to reduce phrenic nerve stimulation occurrence,4 steroid on all electrodes, and three shapes for varying patient anatomies.
- SureScan(TM) MR-conditional labeling for full-body scans without positioning restrictions. Medtronic now offers MR-conditional pacemakers, implantable cardioverter defibrillators, insertable cardiac monitors, cardiac resynchronization therapy defibrillators (CRT-Ds) and CRT-Ps.

"With the addition of quadripolar CRT-P devices to our heart failure portfolio, we now offer a comprehensive line of CRT devices to further meet the needs of patients throughout Europe," 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. "Our new quadripolar CRT-P devices include advanced, smart technologies that allow physicians to provide each patient with the appropriate therapy specific to his or her individual needs, all while offering access to advanced life-saving MRI technologies."

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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1 Demmer, W. VectorExpress performance results. Medtronic data on file. January 2013.
2 Starling RC, Krum H, Bril S, et al. Impact of a Novel Adaptive Optimization Algorithm on 30-Day Readmissions: Evidence From the Adaptive CRT Trial. *JACC Heart Fail*. July 2015;3(7):565-572.
3 Martin D, et al. Clinical outcomes with adaptive cardiac resynchronization therapy: Long-term outcomes of the Adaptive CRT Trial. HFSA Annual Scientific Meeting. September 23, 2013.
4 Biffi et al. Effort of bipolar electrode spacing on phrenic nerve stimulation and left ventricular pacing thresholds: An acute canine study. *Circulation Arrhythmia and Electrophysiology*. 2012.

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