Medtronic News

Medtronic First to Receive FDA Approval for MR-Conditional Quadripolar Cardiac Resynchronization Therapy-Pacemakers

Portfolio of Next Generation Heart Failure Devices Offers Effective Pacing and Access to the Most Advanced Diagnostic Imaging Procedures

DUBLIN - May 10, 2017 - Medtronic plc (NYSE:MDT) has received U.S. Food and Drug Administration (FDA) approval for a portfolio of quadripolar cardiac resynchronization therapy-pacemakers (CRT-Ps) that improve therapy delivery for patients with heart failure. These devices also allow patients to receive MRI (magnetic resonance imaging) scans in either 1.5 or 3 Tesla (T) machines. 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)are expected to be available commercially in the United States in early summer 2017.

"These new pacemakers allow clinicians to provide more personalized therapy treatment options," said Anne B. Curtis, M.D., chair of the Department of Medicine, University at Buffalo, NY. "Their ability to automatically adjust pacing to meet the patient's needs, even those who are among the most difficult to treat, is an example of how advanced implanted heart device technology has become."

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). It also includes VectorExpress(TM) 2.0, an automated in-office test that reduces lead programing to two minutes1, 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 percent2, and has demonstrated a 46 percent reduction in AF risk compared to echo-optimized biventricular pacing3. Multiple point pacing, which can stimulate the left ventricle (lower chamber) at two sites, is also available on both devices, as well as on the company's Claria MRI(TM) Quad CRT-D SureScan(TM) and Amplia MRI(TM) Quad CRT-D SureScan(TM).

All three CRT-Ps also are compatible with Attain(TM) Performa(TM) MRI SureScan(TM) Quadripolar Leads, which include short bipolar spacing to reduce the occurrence of phrenic nerve stimulation4, steroid on all electrodes, and three shapes for varying patient anatomies. They also employ the Medtronic-exclusive PhysioCurve(TM) contoured design, which reduces overall skin pressure compared to non-contoured devices5, for enhanced patient comfort6 and improved cosmetic appearance of the implant site7. This CRT-P portfolio received CE (*Conformité Européenne*) Mark in February 2017.

"Developing cardiac devices so physicians have the best treatment options to meet the individual needs of their patients is at the core of everything we do," said David Steinhaus, M.D., vice president and general manager of the Heart Failure business, which is part of the Cardiac and Vascular Group at Medtronic. "With FDA approval of these quadripolar CRT-P devices, we can offer the most innovative pacing technology for improved patient outcomes and enhanced design for their comfort."

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.
5 Flo D, et al. IS4/DF4 Device Shape Analysis. Medtronic data on file. January 2013.
6 Ceelen KK, et al. *J Biomech*. 2008;41:3399-3404.
7 Gold MR, et al. *J Am Coll Cardiol*. 1996;28;1278-1282.

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