Medtronic News

Medtronic Receives FDA Approval and Launches Two New Cardiac Resynchronization Therapy Quadripolar Leads

Additional Attain Performa® Quadripolar Leads Provide Physicians with More Options to Optimize Delivery of Proven Heart Failure Treatment

MINNEAPOLIS - Dec. 11, 2014 - Medtronic, Inc. (NYSE: MDT) today announced the U.S. Food and Drug Administration (FDA) approval and commercial launch of two additional Attain Performa® left ventricular (LV) quadripolar leads, which can be paired with the Medtronic Viva® Quad XT and Viva® Quad S cardiac resynchronization therapy defibrillators (CRT-D) to treat patients with heart failure. The newest additions to the Attain Performa lead portfolio, the S-shape and Straight leads, are designed to accommodate patients' varying vessel sizes and curvatures to enhance successful lead placement. Quadripolar leads (leads with four electrodes) help physicians optimize cardiac resynchronization therapy, which uses an implantable device to improve the pumping efficiency of the heart.

FDA approval for the additional quadripolar leads follows the August 2014 approval of the Attain Performa Model 4298 Dual Cant quadripolar lead. All three leads were studied in the multicenter Attain Performa Quadripolar Lead Clinical Study, involving more than 1,200 patients. Results featured at the 2014 American Heart Association Scientific Session demonstrate an excellent implant success rate (97.6 percent), and show that CRT with the Attain Performa family of LV quadripolar leads is associated with a low complication rate, and low, stable pacing capture thresholds (PCTs) through six months for all pacing polarities.i

"While optimal lead positioning has been shown to improve CRT response rates, every patient is different, making lead placement and stability a common challenge that can result in nonresponse to therapy," said George H. Crossley, M.D., F.A.C.C., F.H.R.S., associate professor, Vanderbilt Heart and Vascular Institute in Nashville, Tenn. "Having access to a range of lead shapes that work with one CRT-D system gives physicians the ability to help our heart failure patients, even if their cardiac anatomy is challenging."

The three Attain Performa lead shapes -Dual Cant Model 4298, Straight Model 4398 and S-Shape Model 4598 -were designed to accommodate various anatomies without compromising lead handling or stability. With 16 pacing configurations and shorter spacing between the two center electrodes, these quadripolar leads have been shown to reduce the incidence of phrenic nerve stimulation (PNS), a potential issue associated with CRT therapy that results in muscle twitching, hiccups or shortness of breath.ii Attain Performa leads also include steroid elution on all four electrodes for lower chronic pacing thresholds, which contribute to greater device longevity and reduce the likelihood of PNS.iii

"With the two new shapes, the Attain Performa quadripolar lead portfolio gives physicians more options than any other CRT-D system available in the United States," said David Steinhaus, M.D., vice president and general manager, Heart Failure, and medical director for the Cardiac Rhythm and Heart Failure Business at Medtronic. "We are committed to driving advancements in CRT, and designed these leads to give physicians tools to customize treatment for their patients."

All three Attain Performa leads are compatible with the company's newest portfolio of CRT devices, the Viva Quad XT and Viva Quad S CRT-D systems. The Viva Quad XT CRT-D features the Medtronic-exclusive AdaptivCRT® algorithm, which significantly improves heart failure patients' response rate to therapy by preserving normal heart rhythms and automatically adapting to patient needs, creating a customized therapy for each patient. AdaptivCRT is the only algorithm demonstrated to improve heart failure patients' response to the therapyiv (as compared to conventional biventricular therapy) and reduce the risk of atrial fibrillation, or AFv.

The system also includes VectorExpress(TM) technology, an automated in-office test that reduces lead programming time to

two minutes,vi and reveals clinically actionable information to help physicians select optimal pacing configurations for each patient.

About the Attain Performa Quadripolar Lead Clinical Study

The Attain Performa Quadripolar Lead Clinical Study is a global trial that evaluated the safety and effectiveness of the Attain Performa leads. The study demonstrated a 97.6 percent implant success rate and the PNS complication-free rate was 99.7 percent. Steroid on all four electrodes resulted in low, stable PCTs through six months for all pacing polarities. The study enrolled 1,201 patients indicated for a CRT-D from approximately 130 centers across the world. All implanted patients were followed at one, three, six and every subsequent six months post-implant.

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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i Crossley et al. A Novel Quadripolar Lead with a Narrow-Spaced Bipole Allows for Effective Left Ventricular Pacing While Avoiding Phrenic Nerve Stimulation - Attain® Performa(TM) LV Lead Study Primary Results. American Heart Association Scientific Sessions. 2014

ii 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.

iii Lunati MG, Gasparini M, Landolina M, et al. Long-Term Effect of Steroid Elution on the Electrical Performance of Coronary Sinus Leads for Cardiac Resynchronization Therapy. Presented at HRS 2012 (AB10-05).

iv Birnie D, Lemke B, Aonuma K, et al. Clinical outcomes with synchronized left ventricular pacing: Analysis of the adaptive CRT trial. Heart Rhythm. September 2013;10(9):1368-1374.

v Martin D, et al. Can Adaptive Cardiac Resynchronization Therapy Reduce Atrial Fibrillation Risk? Circulation. 2013;128(22S):A17740.

vi Demmer, W. VectorExpress Performance Results. Medtronic data on file. January 2013.

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