Medtronic News

Medtronic Receives FDA Approval for Attain Performa® Quadripolar Lead and Viva® Quad CRT-Ds in United States

New System Helps Physicians Deliver Cardiac Resynchronization Therapy Optimally and Efficiently to Heart Failure Patients

MINNEAPOLIS - Aug. 7, 2014 - Medtronic, Inc. (NYSE: MDT) today announced it has received United States Food and Drug Administration (FDA) approval for the Attain Performa® Model 4298 quadripolar lead, and the Viva® Quad XT and Viva® Quad S cardiac resynchronization therapy defibrillators (CRT-D). The quadripolar lead and devices will be broadly available to physicians in mid-September.

With 16 pacing configurations and shorter spacing between the two center electrodes, the Attain Performa Model 4298 left-heart lead provides additional options for physicians to treat different patient anatomies. The new quadripolar lead reduces the incidence of phrenic nerve stimulation (PNS)1, a potential side effect that results in muscle twitching, hiccups or shortness of breath. The Viva Quad XT device is equipped with the proprietary AdaptivCRT feature, which preserves normal heart rhythms and automatically adjusts to patients' needs to customize therapy. The system includes VectorExpress(TM) technology, which reduces lead programming time to two minutes2 by providing physicians with clinically actionable information to help them select optimal pacing configurations for each patient.

Quadripolar leads (leads with four electrodes) help physicians optimize cardiac resynchronization therapy delivery. The Attain Performa lead addresses the clinical challenges that can compromise lead position, offering implanting physicians more options to maintain lead position and optimize CRT therapy3. The Model 4298 lead has a canted shape, and steroid on all four electrodes for lower pacing thresholds4,5.

"Compared to conventional leads, the additional pacing configurations offered by this system provide implanting physicians more options to optimize CRT delivery, which results in better patient care. Likewise, the narrow-spaced bipole helps avoid phrenic nerve capture," said George H. Crossley, M.D., F.A.C.C., F.H.R.S., associate professor, Vanderbilt Heart and Vascular Institute, in Nashville, Tenn.

About the AdaptivCRT Algorithm

The AdaptivCRT algorithm is the first significant advance to improve patient response rates to CRT since the advent of the therapy more than 10 years ago. The benefits of the algorithm were demonstrated in the Adaptive CRT Trial, a prospective, multicenter, randomized, double-blind clinical trial. Key findings from the original trial, sub-analyses and economic models:

- For patients with normal AV conduction, AdaptivCRT showed an increase in CRT response rate of 12 percent6 at six months
- Patients with AdaptivCRT demonstrated a 21 percent reduction in heart failure hospitalizations7 as compared to historical CRT trials
- Patients with the AdaptivCRT technology demonstrated a 46 percent reduced risk of AF8, and a 61 percent lower risk of AF-related problems9
- AdaptivCRT demonstrated a reduction in 30-day hospital readmissions for heart failure of 47 percent10

"Medtronic continues to advance the care of heart failure patients, as it has since it first commercialized cardiac resynchronization therapy in the U.S. With the previously available AdaptivCRT algorithm, and now the new Attain Performa canted lead and Viva Quad devices, Medtronic is delivering a top-notch system for patients with heart failure," said David Steinhaus, M.D., vice president and general manager, Heart Failure, and medical director for the Cardiac Rhythm and Heart Failure Management business at Medtronic.

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.

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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