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Medtronic Announces CE Mark and European Launch of Attain Performa® Portfolio of Quadripolar Leads

New Lead Portfolio Provides Options for Physicians to Deliver CRT Optimally and Efficiently

Medtronic, Inc. announced on March 5 that it received CE (Conformité Européenne) Mark and will begin the European launch of the Attain Performa® portfolio of quadripolar leads. Paired with Medtronic Viva®/Brava® Quad cardiac resynchronization therapy defibrillators (CRT-D), Attain Performa left-heart leads provide additional options for physicians as they navigate different patient anatomies, optimizing therapy based on the individual needs of heart failure patients.

Attain Performa leads feature four electrodes with 16 pacing configurations. Compared to unipolar and bipolar leads, the additional pacing configurations offered by Medtronic quadripolar leads provide implanting physicians more options to optimize CRT delivery. Attain Performa leads are not approved for sale in the United States.

“This sophisticated new lead family provides physicians with the flexibility needed to effectively navigate diverse patient anatomies and help maintain optimal lead position, which has been proven to improve CRT response,” said Massimo Santini, M.D., FESC, FACC, FACA, director, Cardiovascular Department, S. Filippo Neri Hospital in Rome, and president, World Society of Arrhythmias.

The Attain Performa portfolio includes three distinct lead shapes, Dual Cant, S-Shape and Straight, each with 16 pacing configurations to better fit a patient’s anatomy and optimize CRT delivery. The leads are designed with shorter spacing between the two center electrodes to increase phrenic nerve thresholds and reduce phrenic nerve stimulation (PNS).[1] With unipolar and bipolar leads, PNS may require surgery to reposition the lead or disable the CRT, and occurs when a device’s electrical output inadvertently activates the diaphragm muscle, causing muscle twitching, hiccups or shortness of breath.

Attain Performa leads include steroid elution on all four electrodes for lower chronic pacing thresholds, which contribute to greater device longevity and reduce the likelihood of PNS.[2] The leads also utilize VectorExpress™ technology, an automated in-office test that provides information on physician-selected pacing configurations in less than three minutes to aid in selecting the optimal pacing configuration for stimulating the heart.

Attain Performa leads are compatible with the company’s newest portfolio of devices, Viva Quad CRT-Ds, which feature the AdaptivCRT® algorithm that significantly improves heart failure patients’ response rate to therapy by preserving normal heart rhythms and continuously adapting to patient needs.

“Our new quadripolar leads were designed with advancements that help physicians customize care for their heart failure patients so they receive the optimal therapy for their condition,” said David Steinhaus, M.D., vice president and general manager, Heart Failure, and medical director for the Cardiac Rhythm Disease Management business at Medtronic. “The Attain Performa portfolio builds upon years of Medtronic leadership driving advancements in CRT and significantly improving the lives of heart failure patients at every stage of care.”

Attain Performa Quadripolar Lead Study

The Attain Performa Quadripolar Lead study is a global clinical trial gathering additional safety and effectiveness data on Attain Performa leads in patients indicated for a CRT-D. Approximately 140 centers throughout the world, in regions including the United States, Canada, Europe, Australia and developing markets, will enroll up to 1,210 patients who will receive Attain Performa leads in this open-label, single-arm study. Enrollments have already occurred in Australia, Europe, South America and the United States.

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.

References:

1. 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.
2. 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).

Source: Medtronic

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