Medtronic Announces FDA Approval of New Portfolio Of Next-Gen Cardiac Resynchronization Therapy Devices, Implantable Cardioverter-Defibrillators

Medtronic

Newly designed Devices Result in Fewer Hospitalizations for Patients, Deliver Increased Longevity, and Improved Comfort

Medtronic, Inc. has announced U.S. Food and Drug Administration (FDA) approval and U.S. launch of its newest cardiac devices: the Viva® portfolio of cardiac resynchronization therapy with defibrillation (CRT-D) devices, and the Evera® portfolio of implantable cardioverter-defibrillators (ICD).

The Viva CRT-D significantly improves response rate to the therapy for many indicated heart failure patients, with a demonstrated 21 percent reduction in overall heart failure hospitalizations within the first year after implant as compared to historical CRT trials. According to economic analyses presented at ISPOR Europe, with this device both payers and hospital providers will experience reductions in overall healthcare costs as compared to CRT-D devices with traditional programming.[i,ii]

The improved response is due to the device's ability to continuously adapt to individual patient needs and preserve each patient's normal heart rhythms. Called AdaptivCRT®, the algorithm improves heart failure patients' response rate to CRT-D therapy by 12 percent as compared to historical CRT trials.[iii]

The next-gen Viva CRT-D and Evera defibrillation devices are shaped for patient comfort with a new, contoured design that reduces skin pressure by 30 percent,[iv] deliver greater battery longevity and come equipped with the most advanced shock reduction technology available.

Building upon its industry-leading device longevity as proven by seven independent studies, Medtronic's Viva and Evera systems deliver up to a 25-percent increase in battery longevity (up to 11 years) compared to previous devices.[v-xii] In addition, both systems are paired with the reliable Sprint Quattro® Secure lead, the only defibrillator lead with 10 years of proven performance with active monitoring.[xiii]

"These devices offer patients and physicians advanced systems that can improve patients' overall quality of life, while reducing the cost burdens of unnecessary hospitalizations," said Jagmeet P. Singh, M.D., Ph.D., director of the resynchronization and advanced cardiac therapeutics program at Massachusetts General Hospital in Boston. "Patients can now experience a more comfortable fit due to less skin pressure, a longer lasting battery, and highly advanced CRT-D

algorithms."

The Viva and Evera portfolios include SmartShock™ 2.0, the next generation shock reduction algorithm that enables devices to better differentiate between dangerous and harmless heart rhythms, resulting in a 98-percent inappropriate shock free rate at one year.[xiv]

"These devices are designed to provide optimal therapy for patients, while providing economic benefits through fewer hospitalizations, fewer inappropriate shocks and increased longevity, which can result in lower healthcare costs," said David Steinhaus, M.D., vice president and general manager, Heart Failure, and medical director for the Cardiac Rhythm Disease Management business at Medtronic. "Patients suffering from debilitating heart rhythm disorders can rely on new treatment options that can significantly improve their quality of life."

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 [1]), headquartered in Minneapolis, is the global leader in medical technology – alleviating pain, restoring health, and extending life for millions of people around the world.

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[xiii] Medtronic Product Performance Report, 2012 Second Edition, Issue 66.
[xiv] Virtual ICD: A Model to Evaluate Shock Reduction Strategies. Presented at HRS 2010 (P03-125).

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