Medtronic News

New Research Demonstrates Success of Shock Avoidance in Medtronic Defibrillators

"Shock-Less" Late Breaking Clinical Trial: Providing Clinicians with ICD Programming Reports Improves Adherence to Evidence-Based Guidelines, Reduces All-Cause Shocks
PainFree SST Trial: More Than 98 Percent of Patients with SmartShock(TM) Technology Are Free of Inappropriate Shock at One Year
ADVANCE III Trial: Waiting to Deliver ICD Therapy Combined with ATP During Charging(TM) Reduces the Rate of Inappropriate Shocks by 45 Percent and Reduces Rate of Hospitalization by 19 Percent

MINNEAPOLIS and DENVER - May 10, 2013 -Validating its leadership in shock reduction research and technology, Medtronic, Inc. (NYSE: MDT) today announced the results of three clinical trials, Shock-Less, PainFree SST and ADVANCE III, which successfully employed key strategies to dramatically reduce inappropriate and unnecessary shocks in patients with implantable cardiac defibrillators (ICD). The studies followed more than 7,000 patients on six continents; results were presented today at Heart Rhythm 2013, the Heart Rhythm Society's 34th Annual Scientific Sessions.

ICDs are sophisticated devices designed to provide lifesaving shocks or painless pacing (anti-tachycardia pacing, or ATP) to stop life-threatening fast or irregular heartbeats. While the majority of shocks delivered are necessary to treat potentially fatal arrhythmias, studies estimate that approximately 20 percent of patients with implantable defibrillators may experience inappropriate shocks in response to a benign arrhythmia or electrical noise sensed by the device.1 According to published literature, ICD shocks are associated with increased anxiety for the patient, as well as increased healthcare utilization1.

The studies presented today demonstrate that a combination of Medtronic-exclusive device algorithms and evidence-based programming strategies allow physicians to safely avoid unnecessary shocks and can reduce the number of patients who receive an inappropriate shock to less than two percent per year.

Shock-Less: Improved Adherence to Guidelines Reduces Inappropriate Shocks

Presented as a late-breaking clinical trial, results of Shock-Less demonstrated that in real-world practice, providing clinicians with reports that displayed ICD parameter settings in relation to evidence-based targets improved adherence to evidence-based shock reduction programming, which was associated with reduced risk of ICD shocks. The reports increased adherence to guidelines by up to 20 percent and reduced the relative risk of a shock by 27 percent. The Shock-Less prospective clinical trial enrolled 4,131 primary and secondary prevention ICD patients between 2009 and 2012 at 118 clinical sites.

"The results of this study are clear: When clinicians followed the evidence-based programming recommendations, the risk of all cause and inappropriate shocks was reduced," said Marc Silver M.D., lead investigator and cardiologist at WakeMed in Raleigh, N.C. "Establishing methods that improve and maintain clinician adherence to guidelines is therefore crucial to reducing ICD patient morbidity."

PainFree SST: SmartShockTM Technology Reduces Inappropriate Shocks

Primary results from the PainFree SST clinical trial demonstrated that treating patients with ICDs featuring Medtronic's exclusive SmartShockTM technology resulted in the delivery of life-saving shocks when needed to save lives, with more than 98 percent of patients free from inappropriate shocks during the first year of implant.

SmartShock Technology features six exclusive algorithms automatically "ON" that recognize life-threatening arrhythmias and deliver therapeutic shocks when appropriate2, therefore improving patient quality of life.3 PainFree SST is a multi-center international prospective clinical trial; this analysis encompassed 1,308 patients implanted with dual and triple chamber ICDs.

ADVANCE III: Prolonged Detection and ATP During Charging Reduce Hospitalizations and Inappropriate Shocks

The Shock-Less and PainFree SST results build on the findings of the ADVANCE III4 (Avoid DeliVering TherApies for Non-sustained Arrhythmias in ICD PatiEnts III) clinical trial, published in this week's edition of the *Journal of the American Medical Association*, which demonstrated reduced rate of hospitalizations by 19 percent when devices were programmed to wait longer to deliver therapy to patients, compared to devices with standard programming. ADVANCE III data presented at Heart Rhythm further identified that this prolonged detection also reduced the rate of inappropriate shocks by 45 percent.

"These data show that ICD programming matters, but real world clinical practice suggests that many ICDs are not currently programmed for optimal patient outcomes. By combining best practice programming with proprietary shock reduction technology, Medtronic has made it easier to achieve and sustain the patient outcomes reported in clinical trials with minimal programming changes," said Marshall Stanton, M.D., vice president and general manager, Implantable Defibrillator Business, Cardiac Rhythm Disease Management at Medtronic.

Medtronic has provided the broadest portfolio of scientific research focused on shock reduction, supporting 16 major clinical trials involving more than 15,000 patients worldwide-more than any other device manufacturer. Medtronic pioneered the use of ATP, and is the only company to offer ATP During Charging(TM), which automatically uses pacing pulses to painlessly stop fast, dangerous heartbeats while concurrently preparing to deliver a shock if needed, with no delay.

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 worldwide.

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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2 Volosin et. al. "Virtual ICD: A Model to Evaluate Shock Reduction Strategies." Heart Rhythm. Vol. 7, N. 5, May supplement 2010. (PO3-125).
3 Wathen MS, et al. *Circulation*. 2004; 110:2591-2596.
4 JAMA. 2013;309(18):1903-1911.

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