

Studies Show Benefits of Medtronic SmartShock(TM) Technology and Physician Reports in Protecting Patients from Inappropriate Shocks

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New Results from PainFree SST, Shock-Less Studies, Involving Nearly 7,000 Patients, Published in HeartRhythm

DUBLIN and MINNEAPOLIS - Jan. 29, 2015 - Medtronic plc (NYSE: MDT) today announced new results from the PainFree SST and Shock-Less clinical studies published in the journal *HeartRhythm*. The data show that treating patients with Medtronic implantable cardiac devices equipped with SmartShock™ Technology, and that providing clinicians with proactive reports, help physicians deliver lifesaving therapy while avoiding inappropriate and unnecessary shocks.

The studies evaluated cardiac resynchronization therapy-defibrillators (CRT-Ds) and implantable cardioverter defibrillators (ICDs), which stop life-threatening fast or irregular heartbeats by shocking or pacing the heart. While most ICD-delivered shocks are needed, previous studies estimated that approximately 20 percent of patients with ICDs may experience inappropriate shocks in response to benign arrhythmias or electrical noises sensed by their devices. The new PainFree SST study results show that the rate of inappropriate shocks for patients with the Medtronic SmartShock Technology was 1.5 percent with a dual/triple chamber defibrillator and 2.5 percent for single chamber ICD at one year after implant. At two years post-implant, 2.8 percent of dual/triple chamber and 3.7 percent of single chamber device patients experienced inappropriate shocks.

These results are consistent with earlier findings that showed 98 percent of patients with SmartShock technology are inappropriate shock-free at one year.¹

"The new results from PainFree SST reinforce that SmartShock technology streamlines programming to help deliver shocks only when necessary to save a life, and that ICD programming truly matters in improving patient outcomes," said Angelo Auricchio, M.D., Ph.D., FESC, Fondazione Cardiocentro Ticino, Lugano, Switzerland.

While PainFree SST data show the benefits of SmartShock Technology, the results from the Shock-Less clinical study demonstrate the importance of programming devices to improve "real world" patient outcomes. Most implanted ICDs are programmed to the manufacturers' default settings; however, the Shock-Less study showed that patients had better outcomes when their clinicians received guideline-based programming recommendations and periodic programming compliance reports prior to ICD implants. Patients who received ICD implants after their clinicians received these reports were up to 20 percent more likely to have their ICDs programmed according to guidelines, and to have a lower risk of inappropriate shocks. Based upon the results of these studies, Medtronic modified the initial settings of its ICDs, thereby simplifying programming for physicians and optimizing outcomes for patients.

In addition to providing better patient care, previous studies have shown that preventing inappropriate shocks also can lower the rate of hospitalizations, resulting in cost savings (Medtronic ADVANCE III Trial).²

"For decades, ICDs have proven effective in treating dangerous heart rhythms that lead to sudden cardiac death, and now new features and best-practice programming help physicians further reduce the rate of unnecessary shocks in their patients," said Marshall Stanton, M.D., vice president and general manager of the Tachycardia Business at Medtronic. "These innovations ensure that shocks are delivered only when needed to save lives, offering peace of mind for patients and physicians, and reducing costs to the healthcare system."

About the Studies

PainFree SST is a prospective, multicenter study that enrolled 2,790 patients at 126 centers across the globe, all of whom received a new device implant, system upgrade or generator replacement. Patients were followed for up to four years, with

visits every six months.

Shock-Less is a prospective clinical study that enrolled 4,131 primary- and secondary-prevention patients with ICDs between 2009 and 2012 at 118 clinical sites. After first enrollments in the trial, clinicians received reports that displayed ICD parameter settings in relation to evidence-based targets (including number of intervals to detect Ventricular Fibrillation (VF), longest treatment interval, supraventricular tachycardia (SVT) discriminators, Lead Integrity Alert(TM) and anti-tachycardia pacing).

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 plc (www.medtronic.com), headquartered in Dublin, Ireland, 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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¹ Volosin KJ, Exner DV, Wathen MS, Sherfese L, Scinicariello AP, Gillberg JM. Combining shock reduction strategies to enhance ICD therapy: a role for computer modeling. J Cardiovasc Electrophysiol. 2011 Mar;22(3):280-9.

² Proclemer A, Arenal A, Lunati M, Ferrer JB, Hersi A, Manotta L, Gasparini M. Association of long vs standard detection intervals for implantable cardioverter-defibrillators with hospitalizations and costs. JAMA. 2014;312(5):555-7

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