

Boston Scientific Launches World's Longest Lasting ICD

MARLBOROUGH, Mass., Feb. 2, 2015 /PRNewswire/ -- Boston Scientific Corporation (NYSE: BSX) announces the launch and first U.S. implant of its line of Extended Longevity (EL) implantable cardioverter defibrillators (ICD), including DYNAGEN™ EL and INOGEN™ EL device models. The first EL ICD was implanted at The University of Pittsburgh Medical Center (UPMC) by Dr. Samir Saba. The device features [EnduraLife™ battery technology](#) that was developed with high-performance chemistry and advanced manufacturing capabilities to provide up to double the battery capacity of other ICDs. Devices with similar technology have been shown to outperform competitors' device longevity in several recent clinical studies,^{1,2,3,4} and the EL ICD is projected to last nearly 12 years.⁵

"Battery longevity has a direct impact on patient outcomes and the cost of care," said Dr. Saba. "The EL ICD is an important advancement that can help minimize the frequency of avoidable replacement procedures to help reduce costs and the potential for replacement-related complications."

The EnduraLife battery technology delivers the industry's longest projected longevity, and is packaged in a device up to 11 percent smaller and 24 percent thinner than devices from other manufacturers⁶. Increased device longevity can reduce the risk of infection and other complications over time, minimize out-of-pocket patient expenses for avoidable replacement procedures, and decrease other healthcare system costs associated with device therapy.^{7,8,9,10}

"Boston Scientific is proud to build upon the world's most innovative ICD technology with the world's smallest ICD, the world's longest-lasting ICD and the world's only subcutaneous ICD," said Joe Fitzgerald, executive vice president and president, Rhythm Management. "By providing a device with greater battery capacity, physicians are now able to offer patients a longer lasting device and increased peace of mind, while administrators and payors have new options to more effectively manage healthcare costs and minimize unexpected complications."

About Boston Scientific

Boston Scientific transforms lives through innovative medical solutions that improve the health of patients around the world. As a global medical technology leader for more than 35 years, we advance science for life by providing a broad range of high performance solutions that address unmet patient needs and reduce the cost of healthcare. For more information, visit www.bostonscientific.com and connect on [Twitter](#) and [Facebook](#).

Cautionary Statement Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Forward-looking statements may be identified by words like "anticipate," "expect," "project," "believe," "plan," "estimate," "intend" and similar words. These forward-looking statements are based on our beliefs, assumptions and estimates using information available to us at the time and are not intended to be guarantees of future events or performance. These forward-looking statements include, among other things, statements regarding new product launches and launch cadence, regulatory approvals, markets for our products product performance and impact and competitive offerings. If our underlying assumptions turn out to be incorrect, or if certain risks or uncertainties materialize, actual results could vary materially from the expectations and projections expressed or implied by our forward-looking statements. These factors, in some cases, have affected and in the future (together with other factors) could affect our ability to implement our business strategy and may cause actual results to differ materially from those contemplated by the statements expressed in this press release. As a result, readers are cautioned not to place undue reliance on any of our forward-looking statements.

Factors that may cause such differences include, among other things: future economic, competitive, reimbursement and regulatory conditions; new product introductions; demographic trends; intellectual property; litigation; financial market conditions; and future business decisions made by us and our competitors. All of these factors are difficult or impossible to predict accurately and many of them are beyond our control. For a further list and description of these and other important risks and uncertainties that may affect our future operations, see Part I, Item 1A – Risk Factors in our most recent Annual Report on Form 10-K filed with the Securities and Exchange Commission, which we may update in Part II, Item 1A – Risk Factors in Quarterly Reports on Form 10-Q we have filed or will file hereafter. We disclaim any intention or obligation to publicly update or revise any forward-looking statements to reflect any change in our expectations or in events, conditions or circumstances on which those expectations may be based, or that may affect the likelihood that actual results will differ from those contained in the forward-looking statements. This cautionary statement is applicable to all forward-looking statements contained in this document.

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¹ J. Williams, R. Stevenson. [Contemporary cardiac resynchronization implantable cardioverter defibrillator battery longevity in a community hospital heart failure cohort](#). Presented at HFSA 2014.

² Ellis C, Markus T, Dickerman D, Orton J, Hassan S, Good E, Okabe T, Greenspon A. [Ampere Hour as a Predictor of CRT ICD Pulse Generator Longevity: A Multi-Center Study](#). Presented at HFSA 2014.

³ J, Hjortshoj S, Johansen J, Jorgensen O, Nielsen J, Petersen H. Device Longevity in Cardiac Resynchronization Therapy Implantable Cardioverter Defibrillators Differs Between Manufacturers: Data from the Danish ICD Registry. Presented at HRS 2014.

⁴ Alam MB, Munir MB, Rattan R, Flanigan S, Adelstein E, Jain S, Saba S. [Battery longevity in cardiac resynchronization therapy implantable cardioverter defibrillators](#). *Europace* (2014) 16, 246-251. Kaplan Meier curves depicting survival of CRT devices free from battery depletion by device manufacturer. Battery Longevity in Cardiac Resynchronization Therapy Implantable Cardioverter Defibrillators is an independent, single-center, retrospective observational study comparing battery longevity of contemporary cardiac resynchronization therapy defibrillators (CRT-Ds) of all patients implanted with CRT-ICDs from January 1, 2008 to December 31, 2010 at University of Pittsburgh Medical Center hospitals. The initial study population included 746 patients: 94 were excluded at the onset because they were lost to follow-up within a month of implant, 6 others were excluded because they had a Biotronik CRT-D and that number of devices precludes meaningful comparison. Survival rate calculated using device replacements for battery depletion as indicated by ERI. Medtronic = 416 patients, Boston Scientific = 173 patients, St. Jude = 57 patients.

⁵ DYNAGEN EL ICD/INOGEN EL ICD Physician's Technical Manual – VR models, 0% pacing, 60 ppm, 2.5 V RA/RV amplitude, 0.4 ms pulse width; RA/RV Impedance 500 Ω; sensors On

⁶ Medtronic Evera XT DR/VR Manual

⁷ Hauser R. [The growing mismatch between patient longevity and the service life of implantable cardioverter-defibrillators](#) *JACC* 2005; 45; 2022-5.

⁸ Boriani G, Braunschweig F, Deharo JC, Leyva F, Lubinski A, Lazzaro C. [Impact of extending device longevity on the long-term costs of implantable cardioverter-defibrillator therapy: a modelling study with a 15-year time horizon](#). *Europace* (2013) 15, 1453-1462.

⁹ Ramachandra. [Impact of ICD Battery Longevity on Need for Device Replacements](#) *PACE* 2010; 33:314–319.

¹⁰ Thijssen et al. [Cost-Effectiveness of Primary Prevention Implantable Cardioverter Defibrillator Treatment: Data from a Large Clinical Registry](#). *PACE* 2014; 37:25–35.

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