# New Analysis Suggests Lower Electrode-Related Complication Rate for Boston Scientific S-ICD® System Versus Transvenous ICD Leads

Paris (June 24, 2013) – The Boston Scientific Corporation (NYSE:BSX) S-ICD® (subcutaneous implantable defibrillator) System showed a significant reduction in major lead-related complications when compared with both single (VVI) and dual chamber (DDD) transvenous implantable defibrillator (TV-ICD) systems. The analysis was presented today at EHRA EUROPACE 2013, the annual meeting of the European Heart Rhythm Association in Athens, by Jens Brock Johansen, M.D., PhD, of Odense University Hospital, Odense, Denmark.

The authors of the poster presentation analysed the rate of surgical complications in S-ICD patients reported in the Boston Scientific EFFORTLESS S-ICD international post market registry compared to a nationwide cohort of first VVI and DDD TV-ICD implantations derived from the Danish ICD Register. More than 1,000 patients were analysed.

TV-ICDs require a lead to be connected to the heart to sense and defibrillate, whereas the S-ICD System utilizes an electrode that sits just under the skin, leaving the heart and vasculature untouched.

- Significantly lower rate of major lead complications (lead-related reintervention, pneumothorax, cardiac perforation) for the S-ICD System (1.4 percent) when compared with VVI TV-ICDs (4.3 percent), (p<0.05)
- Significantly lower rate of major lead complications for the S-ICD System (1.4 percent) when compared with DDD TV-ICDs (5.4 percent), (p<0.01)
- Fewer surgical complications for the S-ICD System (7.9 percent) when compared with conventional TV-ICDs (11.5 percent), (p=0.06)
- No difference in the rate of pocket revision or major hematoma

The benefits of the S-ICD System leaving the heart and vasculature untouched are becoming more evident," said Dr. Johansen. "These are very exciting outcomes, since implanting an S-ICD System is relatively new compared with implanting transvenous ICDs. Having supportive outcomes in the acute phase is incredibly important and I am optimistic about the potential benefits the S-ICD System may have in the long term.

#### **NICE Guidance**

In addition to the data presented at EUROPACE, The National Institute for Health and Care Excellence (NICE) in the United Kingdom recently issued guidance on the use of the S-ICD System to treat patients with ventricular arrhythmias. The guidance, from the Institute's Interventional Procedures Advisory Committee (IPAC) acknowledges that current evidence on the preventive role of S-ICD in sudden cardiac death is adequate in the short and mid-term.

This is very positive news for patients requiring protection against sudden cardiac death and ventricular arrhythmias," said Trudie Lobban MBE, founder and chief executive of the Arrhythmia Alliance, the heart rhythm charity.

"The NICE interventional procedure guidance on the insertion of the S-ICD System is a welcome step in the development of this new therapy," said Andrew Grace, M.D., consultant cardiologist at Papworth Hospital, Cambridge, United Kingdom. "The guidance complements the growing evidence supporting its application in a larger patient pool."

The S-ICD System has been available in European countries since July 2009 and was approved in the United States by the Food and Drug Administration in September 2012.

### **About Boston Scientific**

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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, clinical trials, product performance 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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