

Boston Scientific Announces FDA Approval and First Implant for New Devices to Treat Heart Failure and Sudden Cardiac Death

NATICK, Mass., Nov. 30, 2011 [PRNewswire/](#) -- Boston Scientific Corporation (NYSE: BSX) announces FDA approval of its INCEPTA™, ENERGEN™ and PUNCTUA™ cardiac resynchronization therapy defibrillators (CRT-Ds) and implantable cardioverter defibrillators (ICDs) to treat heart failure and sudden cardiac death. The new devices offer enhanced therapy options, advanced battery longevity and a DF4 universal connector system in the industry's smallest and thinnest platform. The first implant of the Company's next-generation INCEPTA ICD occurred yesterday at the University of Washington Medical Center in Seattle by Jeanne E. Poole, M.D., FHRS, FACC, Professor of Medicine and Director, Arrhythmia Service and Electrophysiology Laboratory.

To view the multimedia assets associated with this release, please visit: <http://www.multivu.com/mnr/43511-boston-scientific-fda-approval-incepta-energen-punctua-heart-cardiac>

(Photo: <http://photos.prnewswire.com/prnh/20111130/MM12324>)

"Boston Scientific is providing physicians a choice of premium high-energy devices that are the world's smallest and thinnest, offer advanced battery technology with excellent longevity, and are backed by the longest warranty in the industry of up to 10 years," said Joe Fitzgerald, Senior Vice President and President of Boston Scientific's Cardiac Rhythm Management Group. "This new portfolio of products, built on our tradition of innovation, will provide physicians with flexible therapeutic options designed to match specific patient needs."

"These devices are a direct response to what patients tell us they want the most -- small, thin, long-lasting devices that provide appropriate therapy when necessary," said Dr. Poole. "Additionally, these devices are designed to streamline the implant procedure with Boston Scientific's 4-SITE™ DF4 connector system."

"The DF4 connector system makes the industry's smallest devices even smaller, potentially increasing patient comfort and making the implant procedure quicker and easier for physicians, while the new features will offer even more options for customizing patient care," said Kenneth Stein, M.D., Chief Medical Officer of Boston Scientific's Cardiac Rhythm Management Group. "The 4-SITE lead is built on the RELIANCE® family of defibrillation leads, which has a demonstrated survival probability of 99 percent at seven years."

The 4-SITE DF4 connector system reduces the volume of Boston Scientific's single-chamber ICDs to 30.5cc and CRT-Ds to 32cc, while maintaining a thickness of less than 10mm. The system is also designed to simplify and reduce the time needed for the implant procedure by combining three separate lead terminals into one integrated connection and leveraging the new EZ-4™ Connector Tool which allows physicians to reduce the number of steps required during implant.

These next-generation devices also include options to promote appropriate therapy, reduce right ventricular pacing, and improve patient management through the availability of the LATITUDE® Heart Failure Management weight scale and blood pressure cuff sensors.

"Including remote monitoring as a standard for patients will assist physicians involved in the management of this very complex disease. By involving patients in that process, it could also motivate them to become more engaged in their own care," said Leslie A. Saxon, M.D., Chief of Cardiovascular Medicine at University of Southern California, and Committee Chair of the ALTITUDE Clinical Program sponsored by Boston Scientific. "In the ALTITUDE Survival study, patients with remote monitoring had a lower mortality rate."

About Boston Scientific

Boston Scientific is a worldwide developer, manufacturer and marketer of medical devices whose products are used in a broad range of interventional medical specialties. For more information, please visit: www.bostonscientific.com.

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, regulatory approvals, 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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