

Boston Scientific

## **Boston Scientific Increases Longevity Projections for Its U.S. Defibrillators Devices Projected to Have Nearly Twice the Longevity of Comparable Products**

NATICK, Mass., May 31, 2012 [/PRNewswire/](#) -- The U.S. Food and Drug Administration (FDA) has approved revised product labeling for the Boston Scientific Corporation (NYSE: BSX) INCEPTA™, ENERGEN™, PUNCTUA™, COGNIS® and TELIGEN® implantable cardioverter defibrillators (ICDs) and cardiac resynchronization therapy defibrillators (CRT-Ds), to reflect increased longevity projections for these devices. The longevity projections are based on data submitted to the FDA and vary for each device dependent on the model type and settings.

Projected device longevity exceeds 10 years for some models of Boston Scientific ICDs, and approaches eight years for its CRT-D devices, and nearly double that of comparable competitive device models (1,2,3). The company backs these devices with warranties of up to 10 years\* in the U.S. and many other international markets. Depending on the model, the device warranties are also up to twice as long as other currently-marketed comparable devices.

"We're pleased with the new labeling for our U.S. defibrillator products which provides doctors and patients with additional assurance about the longevity and reliability of these devices," said Kenneth Stein, M.D., chief medical officer of Boston Scientific's Cardiac Rhythm Management Group. "Boston Scientific ICDs and CRT-Ds benefit from our proprietary advanced battery technology. The new battery was first introduced in the COGNIS and TELIGEN devices in 2008 and has now been incorporated into our newest devices with up to a 10-year warranty."

"The Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT) long-term follow-up study results, which were recently presented at the Heart Rhythm Society annual meeting in Boston, demonstrates that ICD therapy continues to benefit patients for a median follow-up of 11 years. Particularly in New York Heart Association Class II patients, it appears that an ICD may prolong a patient's life for at least a decade by rescuing the patient from sudden cardiac death," said Jeanne Poole, M.D., director, Arrhythmia Service and Electrophysiology Laboratory at the University of Washington Medical Center in Seattle. "By helping to mitigate the frequency of replacing an ICD or CRT-D device, this technology provides us with the potential to reduce the complications associated with replacement procedures and to reduce healthcare costs. Not only does the patient benefit from fewer surgeries, but the financial benefit can be significant."

*\*INCEPTA & ENERGEN VR ICD: 10 years; INCEPTA & ENERGEN DR ICD: 8 years; PUNCTUA & TELIGEN ICD: 7 years; INCEPTA & ENERGEN CRT-D: 6 years; and PUNCTUA & COGNIS CRT-D: 5 years.*

### **About Boston Scientific**

Boston Scientific is a worldwide developer, manufacturer and marketer of medical devices that are used in a broad range of interventional medical specialties. For more information, please visit: [www.bostonscientific.com](http://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, regulatory approvals, clinical trials, clinical outcomes, financial savings associated with the use of our products, 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.

(1) PUNCTUA™ ICD, ENERGEN™ ICD, INCEPTA™ ICD - PHYSICIAN'S TECHNICAL MANUAL

Part Number: 358362-006, 5-22-12; TELIGEN® 100 - PHYSICIAN'S TECHNICAL MANUAL

Part Number: 357449-010, 5-22-12; PUNCTUA™ CRT-D, ENERGEN™ CRT-D, INCEPTA™ CRT-D - PHYSICIAN'S TECHNICAL MANUAL Part Number: 358373-007, 5-22-12; COGNIS® 100-D - PHYSICIAN'S TECHNICAL MANUAL Part Number: 357483-012, 5-22-12.

(2) Based on Boston Scientific calculations using 17-26% current drain for Onset EGMs ON and one additional max energy charge per year.

(3) Medtronic Protecta XT CRT-D D314DRG Clinician Manual, M930564A001 2010-02-19; Medtronic Protecta XT ICD DR D314DRG Clinician Manual, M930566A001 2010-10-19; Medtronic Protecta XT ICD VR D314VRG Clinician Manual, M930568A001 2010-10-19.

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