

Boston Scientific Announces European Approval of Next-Generation Implantable Defibrillator

PRNewswire-FirstCall
Natick, Mass.
(NYSE:BSX)

Natick, Mass., Oct. 9 [PRNewswire-FirstCall](#) -- Boston Scientific Corporation (NYSE: BSX) today announced CE Mark approval of its CONFIENT™ implantable cardioverter defibrillator (ICD). This approval represents the first Boston Scientific-branded cardiac rhythm management device to treat sudden cardiac death (SCD).

The CONFIENT ICD, with an enhanced AV Search Hysteresis feature, is designed to reduce unnecessary right ventricular pacing. This product also contains wireless capability that is designed to save physicians time during implant by allowing device programming during wound closure while also eliminating the need for the wand in the sterile field. It also saves time at follow-up with device interrogations that can be three times faster than the Company's wanded telemetry.

"The CONFIENT ICD is a tangible example of our Cardiac Rhythm Management group's ability to deliver meaningful product innovation," said Jim Tobin, President and Chief Executive Officer of Boston Scientific. "We look forward to making this ICD broadly available to physicians so they can offer this advanced therapy to patients who are at risk of sudden cardiac death."

Sudden cardiac death is the abrupt loss of heart function, usually due to an electrical rhythm dysfunction in the lower chambers of the heart, called ventricular fibrillation. Each year, sudden cardiac death claims the lives of as many as 350,000 people in Europe alone. More people die from sudden cardiac death each year than from lung cancer, breast cancer and AIDS combined.

An ICD is a small implantable device about the size of a box of matches. It's placed under the skin just below the collarbone. The device uses leads (wires threaded into the heart's chambers) to monitor every single heartbeat. If a potentially deadly rhythm is detected, a lifesaving shock is delivered, restoring normal heart rhythm and preventing sudden cardiac death.

The CONFIENT ICD is not available for sale in the United States.

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: <http://www.bostonscientific.com/>.

Cautionary Statement Regarding Forward Looking Statements

This press release contains forward-looking statements within the meaning of 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 our product performance, regulatory approval of our products, our growth strategy, and our market position. 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 thereafter. 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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