

Boston Scientific

Boston Scientific Announces Three FDA Product Approvals for Its Cardiac Rhythm Management Business

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(NYSE:BSX)

NATICK, Mass., Feb. 25 [/PRNewswire-FirstCall/](#) -- Boston Scientific Corporation (NYSE: BSX) today announced U.S. Food and Drug Administration (FDA) approval for three products in its Cardiac Rhythm Management business. They are:

- The CONFIENT™ implantable cardioverter defibrillator (ICD), which helps protect patients at risk of sudden cardiac death
- The LIVIAN™ cardiac resynchronization therapy defibrillator (CRT-D), which provides cardiac resynchronization and defibrillation therapies in one device
- An upgraded LATITUDE® Patient Management System, with enhanced remote monitoring capabilities

"Our Cardiac Rhythm Management (CRM) team is refocused on delivering therapy systems that meet physicians' needs for safety, reliability and better patient outcomes," said Jim Tobin, President and Chief Executive Officer of Boston Scientific. "These and other recent approvals are tangible examples of the team's revitalized commitment to quality and innovation."

CONFIENT ICD

The CONFIENT ICD features an enhanced AV (atrial ventricular) Search Hysteresis feature designed to reduce unnecessary right ventricular pacing. The device is equipped with wireless capability designed to save physicians time during implant by allowing device programming during wound closure and eliminating the need for the programming wand in the sterile field. Wireless capability also saves time at follow-up visits by offering device interrogations that can be three times faster than the Company's wanded telemetry.

LIVIAN CRT-D

The LIVIAN CRT-D enables physicians to provide patients with individualized therapy using the following features:

- SmartDelay™: quickly proposes programmable device settings, which enables physicians to tailor individualized pacing therapies for their patients
- Bi-V Trigger with ventricular rate regulation: helps physicians manage heart failure patients with frequent atrial arrhythmias

Upgraded LATITUDE Patient Management System The upgraded LATITUDE Patient Management system has enhanced remote monitoring capabilities that include:

- A new alert in the CONFIENT ICD that notifies physicians if a patient's percentage of right ventricular pacing increases above a programmable threshold
- A new alert in the LIVIAN CRT-D that notifies physicians if a patient's percentage of biventricular pacing falls below a programmable threshold
- A programmable atrial arrhythmia burden alert in the CONFIENT ICD and the LIVIAN CRT-D that enables physicians to detect and manage arrhythmias. Patients with atrial fibrillation, particularly those with heart failure, are at risk of stroke. By identifying arrhythmias earlier, physicians can intervene with treatments to decrease this risk.

Both the CONFIENT ICD and LIVIAN CRT-D enable physicians to manage their patients wirelessly on the LATITUDE Patient Management System. The LATITUDE system helps physicians impact patient outcomes by notifying them of changes in a patient's clinical status between normally scheduled follow-ups, enabling them to intervene earlier in a patient's care.

"These technologies are welcome improvements that are designed to provide earlier insight into changing patient conditions and enable me to devote time to patients who need me the most," said Brian Olshansky, M.D., Professor of Medicine, University of Iowa Hospitals.

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, competitive offerings, 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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