

Boston Scientific Announces Ship Hold and Inventory Retrieval of ICD and CRT-D Devices

NATICK, Mass., March 15 [PRNewswire-FirstCall](#)/ -- Boston Scientific Corporation (NYSE: BSX) announced today that it has stopped shipment and is retrieving field inventory of all its implantable cardioverter defibrillators (ICDs) and cardiac resynchronization therapy defibrillators (CRT-Ds).

The Company has determined that some manufacturing process changes were not submitted for approval to the U.S. Food and Drug Administration (FDA). At this time, the company has identified two instances of changes that, while successfully validated, were not submitted to the FDA. Boston Scientific has informed the FDA and plans to work closely with the agency to resolve this situation as soon as possible.

The Company has no indication that the manufacturing process changes pose any risk to patient safety, and it is not recommending explantation of the devices.

Product families included in this advisory include: COGNIS®, CONFIENT™, LIVIAN™, PRIZM™, RENEWAL®, TELIGEN® and VITALITY™. The Company's pacemakers and other products are not affected by this advisory.

"A planned process review revealed that two manufacturing process changes were not submitted for FDA approval," said Ray Elliott, President and Chief Executive Officer of Boston Scientific. "We are acting voluntarily and expeditiously to resolve this situation, and we have seen no evidence of any risk to patient safety. We apologize for the inconvenience these actions will cause patients and physicians."

The Company plans to fully evaluate the impact of these actions on its financial results and provide an update when the evaluation is completed. Given the financial uncertainty involved, these actions could have a material impact on the Company's previously issued guidance, including revenue, operating profit and cash flows for the first quarter and full year of 2010.

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 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 regulatory approvals, product performance and financial results. 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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