Boston Scientific

Boston Scientific Announces Voluntary Recall of iCross™ Coronary Imaging Catheters

NATICK, Mass., May 27, 2011 /PRNewswire/ -- Boston Scientific Corporation (NYSE: BSX) today announced that it is voluntarily recalling all of its iCross™ Coronary Imaging Catheters used in intravascular ultrasound (IVUS) imaging in patients who are candidates for transluminal coronary interventional procedures. These catheters are intended to operate with Boston Scientific's ClearView Ultra™, Galaxy™, Galaxy®2 or iLab® IVUS imaging consoles. This recall affects all iCross Coronary Imaging Catheters, approximately 29,664 units distributed in the United States, Puerto Rico, Trinidad, Tobago and the American Virgin Islands. The Company's Atlantis® SR Pro, Atlantis ICE, Atlantis Ultra ICE, Atlantis .018, Atlantis PV and Sonicath® Ultra 9 Catheters used with the iLab, ClearView and Galaxy IVUS imaging consoles are not impacted by this recall, with the Atlantis SR Pro available immediately as a substitute.

This corrective action is being taken due to confirmed occurrences of catheter tip detachments due to embrittlement of the catheter material. Between April 1, 2010 and May 10, 2011, Boston Scientific has confirmed eight occurrences of catheter tip detachments due to embrittlement in the U.S. and Puerto Rico. Based on available market data, this translates to a rate of 0.027 percent. Today's action does not affect patients who have already received treatment with the recalled devices because the potential problem occurs during the procedure. The Company has identified a solution and has submitted this information to the U.S. Food and Drug Administration (FDA) for approval.

Potential health risks associated with this type of failure include vessel wall injury, thrombotic events, retained foreign body, foreign body embolization, myocardial infarction and death. There are additional risks to health associated with retrieval attempts (percutaneous or surgical). To date, the majority of confirmed brittle tip detachments have been successfully retrieved (typically snared percutaneously). Because the potential for tip detachment is undetectable prior to use, modifications to the IVUS procedure will have little impact on the likelihood of occurrence of these events.

Products affected by this recall were distributed only to hospitals in the U.S. and its territories. Boston Scientific will replace, free of charge, all returned iCross Coronary Imaging Catheters with Atlantis SR Pro Coronary Imaging Catheters, which will operate with Boston Scientific's IVUS imaging consoles and are immediately available. The Company does not expect this recall to have a material financial impact.

Boston Scientific is notifying affected hospitals through detailed recall notification letters, including instructions on how to return recalled product. The notification and instructions may also be found on the Boston Scientific website. For additional information regarding this recall, please contact Boston Scientific at 1-800-811-3211.

The FDA has determined this action is a Class I recall. Any adverse reactions experienced with the use of this product and/or quality problems should also be reported to the FDA's MedWatch Program by phone at 1-800-FDA-1088, or on the MedWatch website at www.fda.gov/medwatch.

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 and launch cadence, regulatory approvals, clinical trials, product performance, embrittlement solutions 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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