

## **Boston Scientific to Recall Additional Coronary Stent Systems**

(July 16, 2004) -- Boston Scientific Corporation (NYSE: BSX) announced today that it is expanding its voluntarily worldwide recall to include certain additional units of its TAXUS<sup>™</sup> Express<sup>2™</sup> Paclitaxel-Eluting Coronary Stent Systems. The Company is also beginning a voluntary recall of certain units of its Express<sup>2™</sup> Coronary Stent Systems (bare metal stents). The Company has notified the U.S. Food and Drug Administration (FDA) and plans to notify officials in other affected countries.

On July 2, the Company announced the recall of approximately 200 TAXUS Express<sup>2</sup> Paclitaxel-Eluting Coronary Stent Systems, due to characteristics in the delivery catheters that have the potential to impede balloon deflation during a coronary angioplasty procedure. Since then, the Company has conducted further analysis and investigation of the TAXUS Express<sup>2</sup> (paclitaxel-eluting) and Express<sup>2</sup> (bare metal) stent systems, both of which share the same delivery catheter, and has identified additional production lots which may exhibit these characteristics. While the number of customer reports of balloon deflation difficulty is extremely small, patient safety is the Company's paramount concern, and therefore it has chosen to initiate this broader recall. Impeded balloon deflation can result in significant patient complications, including coronary artery bypass graft surgery and death. The Company has received reports of one death and 18 serious injuries associated with balloon deflation for the TAXUS stent system, and two deaths and 25 serious injuries associated with balloon deflation in the Express<sup>2</sup> (bare metal) stent system. The units being recalled were manufactured at the Company's Galway, Ireland and Maple Grove, Minnesota facilities.

The recall will involve approximately 85,000 TAXUS stent systems and approximately 11,000 Express<sup>2</sup> stent systems. Overall, the Company has shipped more than 500,000 TAXUS stent systems and more than 600,000 Express<sup>2</sup> stent systems. The recall does not affect the Express<sup>™</sup> SD and LD biliary stent systems.

The Company implemented review of its manufacturing process, additional inspections, and an FDA-approved modification to the manufacturing process for these products. The current and future production are not expected to experience similar balloon deflation problems.

"Patient safety continues to be our highest priority," said Jim Tobin, President and Chief Executive Officer of Boston Scientific. "We have every confidence these products are safe and effective, and we expect that these measures will go a long way toward reducing the occurrence of these events. We regret any disruption this recall may cause to physicians and their patients. We're fortunate that current TAXUS inventory levels will minimize service disruption in the United States, but we do expect some disruption internationally. We will continue to monitor the quality and performance of the affected products, and we will take appropriate action to ensure patient safety."

Today's action does not affect patients who have already received these stents, because the difficulty is with the delivery system and occurs at the time of insertion, not afterward.

Institutions with affected units will be receiving packages outlining the recall process and should immediately discontinue use of these units. Clinician and patient inquiries may be directed to Boston Scientific at 800-832-7822.

The Company expects that the recall will impact the financial results for the second quarter. On a preliminary basis, it is expected that the impact will include the reversal of sales related to the recalled products of approximately \$45 million (pre-tax) and a write-down of inventory of approximately \$50 million (pre-tax).

In light of today's announcement, the Company will postpone the announcement of its financial results for the second quarter, originally scheduled for Monday, July 19, so that it may finalize the adjustments necessitated by the recall. The Company plans to reschedule the call for Monday, July 26, at a time to be announced next week.

Boston Scientific officials will be discussing this press release with analysts on a conference call at 3:45 p.m. (ET) today. The Company will webcast the call to all interested parties through its website [www.bostonscientific.com](http://www.bostonscientific.com). Please see the website for details on how to access the webcast. The webcast will be archived and available for 10 days on the Boston Scientific website.

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](http://www.bostonscientific.com).

This press release contains forward-looking statements. The Company wishes to caution the reader that actual results may differ from those discussed in the forward-looking statements and may be adversely affected by, among other things, risks associated with the regulatory process, litigation, competitive product offerings and

other factors described in the Company's filings with the Securities and Exchange Commission.

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