

Boston Scientific Recalls 200 TAXUS™ Stent Systems

(July 2, 2004) -- Boston Scientific Corporation (NYSE: BSX) announced today that it is voluntarily recalling nationwide approximately 200 units of its TAXUS™ Express²™ 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. Impeded balloon deflation can result in significant patient complications, including coronary artery bypass graft surgery and death. The characteristics were found in two manufacturing lots by the Company's quality monitoring program. The Company has notified the U.S. Food and Drug Administration (FDA). FDA has received reports of one death and 16 serious injuries associated with balloon deflation. In addition, the agency has received eight reports of balloon malfunction that were not associated with patient injury.

The stents had been shipped to 99 hospitals in the United States, and the Company is notifying these hospitals of the recall. Ten of the stents were shipped to three Canadian hospitals, and the Company is notifying these hospitals and Canadian officials. All these hospitals should immediately discontinue use of any affected units. The recall does not affect patients who have already received a TAXUS stent because the difficulty is with the delivery system and occurs at the time of insertion, not afterward.

The TAXUS system was launched domestically in March, and since then more than 222,000 stents have been implanted at more than 1,300 hospitals in the United States. The product was launched outside the United States in February 2003, and more than 445,000 stents have been implanted worldwide. Of these 445,000 implants, the Company has confirmed a small number of complaints (30 worldwide) about TAXUS balloons that did not deflate or were slow to deflate, and it has been closely monitoring these complaints.

The characteristics in the two lots were related to a narrowing in the area where the catheter and balloon are laser welded. This narrowing resulted in the potential for impeded deflation and removal of the balloon after stent placement.

"As with every one of our products, we have closely monitored the quality and performance of the TAXUS system since its launch, seeking to identify any and all issues," said Jim Tobin, President and Chief Executive Officer of Boston Scientific. "We will continue to monitor TAXUS and take appropriate action to ensure that we provide a safe and effective product for physicians and patients."

Information about the affected lots is described below:

Product Description

TAXUS™ Express²™ Paclitaxel-Eluting Coronary Stent System, Over-the-Wire

Catalog Number: H7493896812270

Lot Number: 6294706

Size: 2.75 x 12 mm

TAXUS™ Express²™ Paclitaxel-Eluting Coronary Stent System, MONORAIL™

Catalog Number: H7493897032350

Lot Number: 6365192

Size: 3.5 x 32 mm

Clinician and patient inquiries may be directed to Boston Scientific at 800-832-7822.

Boston Scientific officials will be discussing this press release with analysts on a conference call at 12:00 p.m. (ET) today. The Company will webcast the call to all interested parties through its website

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.

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.

<https://news.bostonscientific.com/news-releases?item=58761>