Boston Scientific

Boston Scientific Announces Nationwide Recall of 51 Mach 1 Guide Catheters

NATICK, Mass., Dec. 15 /PRNewswire-FirstCall/ -- Boston Scientific Corporation (NYSE: BSX) today announced that it is voluntarily recalling certain lots of the Mach 1® Guide Catheter in the United States. The affected lots of Guide Catheters are 687532, 687586, 687593, 687596, 687654, 687753, 687754, 688035, 687877, 687878, 687879 and 688002. The total number of devices involved in this recall is estimated at 51.

The Guide Catheter is a tube that is thread through the body and allows delivery of medical devices to the heart to treat coronary artery disease. The Company is initiating this recall because it has determined, through internal inspections, that in some product units, excess strands of resin may exist in the inner lumen near the hub of the guide catheter. If the excess resin is present in the catheter and detaches during a procedure, there is the potential for embolization, in which strands of resin could obstruct a blood vessel. An obstruction of a small blood vessel by an embolism may not cause tissue damage; however, an obstruction of a major blood vessel or multiple small blood vessels could result in serious complications such as stroke, heart attack or kidney problems. To date, no product complaints have been reported to Boston Scientific related to this issue, and there have been no reported injuries.

The products affected by this recall were distributed only to hospitals in the United States. Boston Scientific is notifying affected hospitals through detailed recall notification letters requesting that use of the product affected by this recall should cease immediately. Instructions on how to return product are included in the notification letters. Replacement product will be available for all affected product. To arrange for return of affected product, please contact Boston Scientific at 1-800-811-3211.

The Company has notified the U.S. Food and Drug Administration (FDA) of this action.

Boston Scientific is a worldwide developer, manufacturer and marketer of medical devises whose products are used in a broad range of interventional medical specialties. For more information, please visit: http://www.boston.scientific.com/.

This press release contains forward-looking statements. Boston Scientific wishes to caution the reader of this press release 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 new product development and commercialization, clinical trials, intellectual property, regulatory approvals, competitive offerings, Boston Scientific's overall business strategy, and other factors described in Boston Scientific's filings with the Securities and Exchange Commission.

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