Boston Scientific

Boston Scientific Announces Physician Communications Related to Products in Its CRM Group

NATICK, Mass., May 15 /PRNewswire-FirstCall/ -- Boston Scientific Corporation (NYSE: BSX) today announced physician communications related to products in its Cardiac Rhythm Management (CRM) Group, formerly Guidant's CRM business. Boston Scientific acquired Guidant on April 21.

Following the close of the Guidant transaction, Boston Scientific initiated a comprehensive product performance review of its CRM products. This review, together with Guidant's existing product performance process, is designed to assess the safety and efficacy of its CRM products, as well as the process for determining field communications related to those products. To date, the combined review has resulted in the physician communications described in today's announcement. The product performance review process is ongoing, and the Company plans to continue communicating with physicians regarding future findings.

"A product performance review conducted by our CRM Group produced these findings, and we are notifying physicians in a timely, transparent and responsible manner," said Jim Tobin, Boston Scientific President and Chief Executive Officer. "This is part of an ongoing process to evaluate the field performance of our CRM products, and it reflects Boston Scientific's commitment to patient safety, quality and open communication. We believe these physician communications are in keeping with the spirit of the Independent Panel report as well as the Heart Rhythm Society draft recommendations, both of which are supported by Boston Scientific."

The recent physician communications include an advisory describing the potential for premature battery depletion identified in certain implantable cardioverter defibrillators (ICDs) and cardiac resynchronization therapy defibrillator (CRT-D) devices manufactured with a single lot of low-voltage capacitors from a single supplier. Only devices from this single manufacturer's lot -- 996 devices implanted worldwide (less than one percent of all implants from these device families) -- have exhibited an increased probability of premature battery depletion. As of May 8, the Company has confirmed premature battery depletion in 30 returned devices. The Company has received an additional 46 reports of devices that remain implanted and have also exhibited signs of premature battery depletion. The Company has provided a patient follow-up recommendation as well as a tool to help characterize and predict the potential for early battery depletion on an individual patient basis. No deaths or injuries have been reported in relation to this advisory.

In addition, the Company is providing physicians an advisory reporting two device malfunctions associated with RENEWAL 3, RENEWAL 4 and VITALITY HE devices whose implantation was subpectoral and reversed from the common positioning. Most devices are implanted subcutaneously rather than subpectorally. Testing has confirmed that repetitive mechanical stress applied to a specific area of the titanium case can induce component damage and device malfunction, if the device is implanted in this rarely utilized, uncommon manner. Physicians have been asked to review the specific implant positioning for each patient to determine if any of their patients are affected. The implant positioning of devices is not reported, so the number of devices implanted in this manner is not known. However, based on information available to the Company, it is estimated that the number of devices implanted in a susceptible position is likely less than one percent of the total population. Both patients whose devices malfunctioned underwent successful replacement procedures.

The Company has also published an updated CRM Product Performance Report. This quarterly report makes detailed product performance information publicly available by product family. This information contains descriptions of clinical manifestations and indicates situations in which product improvement has been implemented to mitigate further occurrences. The Product Performance Report includes a PRIZM 2 DR advisory update with information current as of April 6, in which patient management recommendations remain unchanged. The Company is also providing physicians an educational product update discussing techniques to remove leads from headers.

All physician communications, including the updated Product Performance Report, can be viewed in their entirety at http://www.guidant.com/physician_communications/.

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: http://www.bostonscientific.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 product development and commercialization, clinical trials, intellectual property, regulatory approvals, competitive offerings, integration of acquired companies, 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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