Boston Scientific

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

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NATICK, Mass.
(NYSE:BSX)

NATICK, Mass., June 26 /PRNewswire-FirstCall/ -- Boston Scientific Corporation (NYSE: BSX) today announced that it is providing safety information and retrieving a specific subset of pacemakers, cardiac resynchronization pacemakers and implantable cardioverter defibrillators from its sales force and hospital inventories. The specific subset of devices includes INSIGNIA and NEXUS pacemakers, CONTAK RENEWAL TR/TR2 cardiac resynchronization pacemakers, and VENTAK PRIZM 2, VITALITY, and VITALITY 2 implantable cardioverter defibrillators. These products are manufactured by the Company's Cardiac Rhythm Management (CRM) Group, formerly Guidant's CRM business. Boston Scientific acquired Guidant on April 21.

Boston Scientific CRM has recently identified a supplier's low-voltage capacitor that is not performing to the company's expectations. A capacitor is an electrical charge storage component. Some capacitors from specific lots may perform in a manner that leads to device malfunction, including intermittent or permanent loss of therapy or premature battery depletion. To date, a total of five confirmed events have been reported out of approximately 27,200 implanted devices from this subset. One event involved a device malfunction discovered at the time of implant. The other four events involved devices that were implanted and subsequently required replacement.

Patients with affected pacemakers may experience intermittent or permanent loss of output or telemetry, or premature battery depletion. Patients with affected defibrillators may experience inappropriate sensing or premature battery depletion. There have been no reported patient deaths associated with this issue. There have been two reports of pacemaker patients experiencing syncope associated with loss of pacing output.

Engineering analysis is ongoing and the company will further communicate on this issue when it has additional information. Implanting and following physicians are being asked to schedule an in-clinic follow-up visit as soon as possible for all patients with implanted devices from this subset to assess device function. At this follow-up visit, physicians should look for behaviors that may be indicative of capacitor malfunction such as premature battery depletion, intermittent or permanent loss of therapy or telemetry, fault codes, pacing or sensing abnormalities, or loss of daily measurements.

"Boston Scientific believes in notifying physicians in a timely, transparent and responsible manner," said Jim Tobin, Boston Scientific President and Chief Executive Officer. "This action reflects Boston Scientific's industry-leading commitment to implementing recommendations made by both the Heart Rhythm Society and the Independent Panel Commission chaired by Dr Robert Myerberg. Boston Scientific is the only CRM company that has committed to implementing these recommendations, which it believes are in the best interest of patients and physicians."

Physician communications can be viewed in their entirety athttp://www.guidant.com/physician_communications/.

Boston Scientific will webcast a conference call on this topic at 11:00 a.m. ET today. The live webcast and archived replay of this call will be available at http://www.bostonscientific.com/ in the Investor Relations section.

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, 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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