URGENT MEDICAL DEVICE INFORMATION

Cardiac Rhythm Management
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March 4, 2009

Subject: Expansion of the April 5, 2007 Product Advisory regarding the potential for reduced ERI to EOL time (shortened replacement window) due to low-voltage capacitor degradation

Dear Doctor:

In April 2007, Boston Scientific CRM communicated with physicians regarding the potential for reduced ERI to EOL time in a subset of implantable defibrillators, due to degradation of a low-voltage capacitor. Since that time, the April 2007 advisory population has not experienced any clinically significant changes to either the rate of occurrence or patient management recommendations.

This letter identifies a second population (March 2009) of 856 active ICDs and CRT-Ds manufactured with capacitors from the same supplier that may be subject to the same failure mechanism. No devices from this population have been registered as implanted after April 2007, and the mean age of those remaining implanted is 38 months. No devices in this subset remain available for implant.

Description of Issue
Specific low-voltage capacitors from a former supplier may be subject to degradation, which may cause accelerated battery depletion and may reduce the time between elective replacement indicator (ERI) and battery end of life (EOL) to less than three months. Should this occur, EOL device behaviors could be observed ***between*** the standard 3-month patient follow-up visits recommended in labeling. Device replacement indicators continue to function normally. There have been no patient deaths or serious injuries associated with this behavior, but some devices have required early replacement.

Rate of Occurrence
There has been one (1) confirmed report of shortened ERI to EOL time from the March 2009 population. Thirty-two (32) additional devices have exhibited accelerated battery depletion that could have resulted in shortened ERI to EOL time if the device had not been replaced when the device reached ERI. The cumulative failure rate for accelerated depletion within the March 2009 population is approximately 6% at 42 months and is projected to increase. However, recommendations described in the April 2007 product advisory have been 99.9% successful in identifying susceptible devices and ensuring replacement at ERI, and will minimize patient risk associated with a shortened replacement window.

Patient Management Recommendations
Recommendations described in the April 2007 product advisory should also be applied to the March 2009 population. The risk for reduced ERI to EOL time due to capacitor degradation may be assessed by examining the time from implant to a battery voltage of 2.65 volts (MOL2). For each patient:

1. Review battery voltage information within patient records.
2. If battery voltage is ***above*** 2.65 volts (MOL2), continue to follow the patient every three months per device labeling.
3. If battery voltage is ***at or below*** 2.65 volts (MOL2), determine the time between device implant and a battery voltage of 2.65 Volts (MOL2).
   a) If the time from implant to 2.65 volts (MOL2) is greater than 27 months (or 32 months for VITALITY® EL / 2 EL / HE devices), the patient is not at risk for a shortened ERI to EOL time, **and this advisory no longer applies.**
   b) If the time from implant to 2.65 volts (MOL2) is 27 months or less (or 32 months for VITALITY EL / 2 EL / HE devices), **the patient should be followed monthly until ERI**. For devices that require monthly follow-up, replace the device within 30 days after ERI is displayed because ERI to EOL time may be shortened.

   NOTE: *If it is not clear when a battery voltage of 2.65 volts (MOL2) was reached, conduct a memory "Save to Disk" and return (mail or e-mail) to Boston Scientific CRM for prompt analysis. Contact your local Boston Scientific representative or Technical Services for further assistance.*

In geographies where available, the LATITUDE® Patient Management System can facilitate remote patient monitoring and provide automatic notification when the device reaches a battery status of ERI.

Devices Affected
The potential for shortened ERI to EOL time due to low-voltage capacitor degradation is confined to a subset of devices within the CONTAK RENEWAL® 3 & 4, VITALITY and VITALITY 2 families. Enclosed is a list of patients at your clinic who were implanted with a device from the March 2009 population. In addition, a model/serial search tool is available to determine if a specific device is subject to this product advisory (go to the Boston Scientific CRM Product Performance Resource Center located at www.bostonscientific.com).

Warranty Program
With certain terms and conditions, warranty and unreimbursed medical expense programs are available for advisory devices.

Further Information
Boston Scientific recognizes the impact of this communication on you and your patients and wants to reassure you that patient safety remains our primary concern. Quarterly updates for both advisory populations will be provided in our Product Performance Report found at www.bostonscientific.com. If you have any questions regarding this communication, please contact your local Boston Scientific CRM representative, United States Technical Services at 1.800.CARDIAC (227.3422), or European Technical Services at +32 2 416 7222.

Sincerely,

William E. Young
Vice President, Reliability and Quality Assurance
Boston Scientific Cardiac Rhythm Management