

May 5, 2010

Subject: Product Advisory – Factory nominal value for programmable Lead Configuration does not match package labeling for a subset of ALTRUA[®] pacemakers distributed in Canada

Dear Doctor,

This letter contains important patient and device management information regarding Boston Scientific ALTRUA pacemakers manufactured for Canada since January 2010. Boston Scientific has determined that approximately 400 ALTRUA devices were distributed in Canada with Lead Configuration programmed to a factory nominal value of unipolar even though box labeling, the enclosed Physician Technical Manual, and the System Guide state that the nominal value is bipolar. Our records indicate that you may have implanted or are currently monitoring one of these devices or that your hospital may have remaining inventory. No geographies other than Canada are affected by this advisory.

Description

The ALTRUA pacemaker models shown in Table 1 include a programmable parameter referred to as “Lead Configuration”. This feature allows clinicians to program the device to match the type of lead implanted in the patient – either unipolar or bipolar. Because the type of lead preferred by physicians varies by geography, the factory nominal value for this parameter also varies by geography.

In January 2010, ALTRUA box labels, the Physician Technical Manual, and the System Guide for Canada were updated to reflect a proposed change in the nominal value for Lead Configuration from unipolar to bipolar. However, the actual nominal setting in the device remained factory preset to a value of unipolar. The device functions as intended, and Lead Configuration can be reprogrammed to bipolar if clinically indicated.

Health Canada has been notified of this mismatch between labeling and nominal value.

Clinical Implications

Unlike bipolar pacemakers, which will begin pacing immediately upon lead connection, ***the titanium case of a pacemaker programmed to unipolar becomes electrically active and must be positioned within the implant pocket to begin pacing.*** For this reason, if a physician attempts to implant a device that he/she thinks is configured to bipolar but is actually programmed to unipolar, the system will not begin pacing until the device case makes contact with patient tissue. If not diagnosed quickly, any potential confusion created by this mismatch between factory setting and labeling could result in a delay to the initiation of pacing.

Although this mismatch is primarily a concern during the implant procedure, it is possible that an implanted pacing system may be operating with a lead configuration that is different than the physician intended.

One clinical event has been reported to Boston Scientific. The patient experienced a short delay in initiation of pacing during the implant procedure. This was resolved without a prolonged asystolic pause or patient harm by quickly placing the titanium case in the body to begin pacing.

Recommendations

Prior to implanting affected ALTRUA pacemakers, interrogate each device and use programmer screens (rather than device labeling) to confirm current lead configuration values. As recommended in labeling, reprogram the device as needed to ensure that lead configuration and all other programmable values match the patient’s needs.

If an affected device has already been implanted, consider reevaluating the programmed setting for lead configuration at the next scheduled follow-up visit, and reprogram if indicated.

Devices Affected

Approximately 400 serialized devices with model numbers listed in Table 1 distributed in Canada since January, 2010 are affected by this advisory.

Table 1. Device models affected.

Family Name	Model Numbers
ALTRUA 20	S201, S206, S208, S209
ALTRUA 40	S403, S404
ALTRUA 50	S503, S504, S508
ALTRUA 60	S601, S602, S603, S606

NOTE: ALTRUA models S204 and S205 do not offer programmable lead configuration, and therefore are **not** included in this advisory

A serial number list is available from your local representative. In addition, a device model and serial number search tool is available in the Product Performance Resource Center at www.bostonscientific-international.com.

Further Information

Following appropriate validation and regulatory approval, the factory nominal value for Lead Configuration for devices distributed in Canada will be changed from unipolar to bipolar to match current labeling. Until that time, an additional label will be attached to each ALTRUA pacemaker package to clearly communicate current Lead Configuration.

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. Updates regarding this advisory will be provided in our quarterly **Product Performance Report**, found at bostonscientific-international.com. If you have any questions regarding this communication, please contact your local Boston Scientific CRM representative or Technical Services at 1.800.CARDIAC (227.3422).

Sincerely,



John Zagala
Quality Assurance Manager – Canada
Boston Scientific (Canada) Ltd.