Urgent Field Safety Notice

September 2018

Subject: Urgent Field Safety Notice- Ref. 92289212-FA – Cardiac Resynchronization Therapy pacemakers (VISIONIST™, VALITUDE™,) and pacemakers (ACCOLADE™, PROPONENT™ and ESSENTIO™) – Potential for Hydrogen Induced Premature Depletion.

Device Family	Subset Population Model Numbers
ACCOLADE™ & ACCOLADE™ MRI	L300, L301, L321 & L310, L311, L331
PROPONENT™ & P POPONENT™ MRI	L200, L221 & L210, L211, L231
ESSENTIO™ & ESSENTIO™ MRI	L100, L101, L121 & L110, L111, L131
VISIONIST™ X4	U228
VALITUDE™ X4	U128

Dear Doctor,

Boston Scientific has identified a subset of approximately 2,900 active ACCOLADE™, PROPONENT™ and ESSENTIO™ pacemakers and VISIONIST™ and VALITUDE™ cardiac resynchronization therapy pacemakers (CRT-Ps) with an elevated potential for early pacemaker replacement due to hydrogen-induced accelerated battery depletion. There have been no reports of injury related to this behavior. You are receiving this letter because you or your center has implanted or follow one or more patients with a pacemaker in this subset.

This device behavior can be identified via the regular pacemaker follow-up process, either in-clinic or through the LATITUDE™ NXT Remote Patient Management System (LATITUDE). Therefore, a follow-up interval of no more than six (6) months is recommended and is consistent with existing international societal guidelines[1]. If accelerated depletion is suspected, Boston Scientific recommends consultation with Technical Services to review the pacemaker diagnostic data available from either a recent data upload in LATITUDE or a Save to Disk to confirm accelerated depletion and determine an appropriate timeframe for pacemaker replacement.

Description

The pacemaker manual describes how increases in pacing requirements or changes in programmed parameters may result in an expected longevity reduction and are considered normal battery depletion. However, hydrogen exposure within the pacemaker's circuitry may compromise the electrical performance of low voltage capacitors causing current leakage and a moderate acceleration in the rate of battery depletion. Because this accelerated depletion does not occur rapidly, a follow-up interval of no more than six months is recommended. Boston Scientific has determined a liner component to be the source of hydrogen and identified a subset of previously distributed pacemakers that have an elevated potential for exhibiting this behavior. Boston Scientific pacemakers include automated diagnostic tools, including battery status assessment and estimated longevity predictions, that dynamically adjust based on power consumption. It is important to emphasize that the accuracy of battery status and longevity estimates are not affected by this behavior.

[1]Wilkoff, B.L., Auricchio, A., Brugada, J. et al. HRS/EHRA Expert Consensus on the Monitoring of Cardiovascular Implantable Electronic Devices (CIEDS): description of techniques, indications, personnel, frequency and ethical considerations: etc. Heart Rhythm 2008; 5:907-925.

Recommendations

- Boston Scientific recommends following patients implanted with any affected pacemaker from the advisory subset at intervals no greater than every six (6) months either in-clinic or via LATITUDE in accordance with the best practices outlined in international societal guidelines[1]. Appendix A provides guidance for healthcare professionals in determining accelerated battery depletion.
- Promptly investigate any suspected indication of accelerated depletion. Before surgical intervention, contact Boston Scientific Technical Services for verification of accelerated depletion and to determine an appropriate timeframe for pacemaker replacement. Please note, if accelerated depletion is identified, the Save to Disk feature[2] or LATITUDE is necessary to perform an engineering assessment.
- Prophylactic replacement is NOT recommended for pacemakers with normal battery consumption as the risk of surgical replacement outweighs the risk of accelerated depletion.

Clinical Impact

Approximately 500,000 ACCOLADE, PROPONENT, ESSENTIO and ALTRUA 2 pacemakers and VISIONIST and VALITUDE CRT-Ps have been distributed and implanted. As a family, these pacemakers are meeting performance expectations with an overall cumulative survival of over 99% at 3 years[3]. However, Boston Scientific has identified a subset of pacemakers which have experienced an elevated rate of hydrogen induced depletion. The most common clinical outcome associated with this device behavior is early replacement. In all but two cases, the affected pacemakers were replaced with sufficient battery capacity for continued pacing therapy. None of the cases resulted in any patient injury.

Advisory Subset

Approximately 2,900 pacemakers within the advisory subset are active. The observed malfunction rate for hydrogen induced accelerated depletion within this advisory subset is 1.4% at 2.5 years which is 233 times higher than the non-advisory population. Because this behavior is highly detectable through regular pacemaker follow-up care, the projected potential for life-threatening harm is 0.0003% (1 in 333,333) at 5 years. There are no devices within this advisory subset that are still available for implant.

Advisory Pacemaker Subset

A model and serial number list of the affected advisory subset of ACCOLADE™, PROPONENT™ and ESSENTIO™ pacemakers; and VISIONIST™ and VALITUDE™ CRT-Ps implanted and/or followed by your clinic/center is available. An on-line search tool is also available at http://www.bostonscientific.com/en-US/pprc/device-lookup-tool.html to determine if a specific model/serial number combination is included within the advisory subset.

[2] To save data from a programmer, insert a pen drive into a USB port, within the programmer select Utilities>Data Storage>Save All
[3] Boston Scientific Product Performance Report Q3 2018 Edition available online at www.BostonScientific.com/ppr

Additional Information
An independent panel of physicians and safety advocates regularly reviews Boston Scientific's field performance data, including this device behavior and associated malfunction pattern. Boston Scientific will continue to include detailed, up-to-date product performance information within our Product Performance Report, published quarterly at www.bostonscientific.com.

Patient safety remains Boston Scientific's highest priority. Although Boston Scientific recognizes the impact of communications on both you and your patients, we are committed to transparent communication with our physician customers to ensure you have timely, relevant information for managing your patients. If you have additional questions regarding this information or would like to report a clinical event, please contact your Boston Scientific representative or Technical Services.

Sincerely,

Renold Russie
Vice President, Quality Assurance

Appendix A: Determination of Accelerated Battery Depletion

Approximate Time to Explant.

Instructions	Example
Review the patient's medical record and determine the date of the previous follow-up	Previous LATITUDE Follow-Up: 3 January 2018 Current Follow-Up: 3 July 2018
Calculate how many months since the last follow-up	6 months
Note the longevity remaining in the battery status report during the previous follow-up	Battery Status from 3 January 2018 Approximate time to explant 5.5 years
Note the current longevity remaining and calculate the reduction in longevity	Battery Status from 3 July 2018 Approximate time to explant 3.5 years
Compare the difference in follow-up time to the longevity reduction A. If these times are similar, battery consumption is normal complete the remaining follow-up steps and schedule the next follow-up B. If the longevity reduction exceeds the follow-up time significantly, contact Technical Services for further evaluation	Follow-up interval = 6 months Longevity reduction between follow-ups = 2 years In this example there is a significant reduction in longevity since the last follow-up, contact Technical Services for further evaluation.

Table 1 Determination of Premature Battery Depletion by comparing Approximate Time to Explant between two follow-up intervals

Appendix B – Impacted Devices

Boston Scientific has records indicating you didn't receive any advisory devices in scope of the Field Action. However, your location is a potential Following Site for patients implanted with potentially impacted devices. You can identify if a patient's device is impacted through the Device Lookup Tool available at http://www.bostonscientific.com/en-US/pprc/device-lookup-tool.html or ask your Boston Scientific representative for a list of the impacted devices.