December 4th, 2020

Canadian Heart Rhythm Society
Device Committee

NEW EXTENDED ADVISORY: Premature Battery Depletion, Boston Scientific SICD Models A209 and A219.

NOTE: The CHRS device committee released a performance note in July 2020 related to an increased risk of premature battery depletion. This notification elevates this to a formal advisory that includes a larger number of EMBLEM model A209 and A219 subcutaneous ICD (S-ICD) devices manufactured before mid-2018.

Nature of the Advisory:

In August 2019, Boston Scientific reported that a subset of 400 worldwide S-ICD devices had an increased risk of accelerated battery depletion approaching 15% at 5 years. It has subsequently been determined by Boston Scientific that this issue may affect other S-ICD devices, produced with similar manufacturing techniques prior to a change made in mid-2018.

The risk of premature battery depletion in this larger group was initially estimated at < 1%. With further follow-up the estimated risk of premature depletion in these devices is now estimated to be **3.7% at 5 years**. Therefore, a formal device advisory has been extended to cover this wider population of S-ICDs that are at risk of this anomaly.

The mechanism of this premature battery depletion is described in the July 2020 CHRS performance note. Affected devices can be identified by an abrupt decrease in the estimated longevity on serial interrogations. The time to early replacement indicator (ERI) status could be as brief as 60 days. Once the device reaches ERI it will trigger an audible patient alert and send an alert via the Latitude remote monitoring system. If the battery is depleting quickly, the subsequent time from ERI to end of service (EOS) could be as little as 21 days. Therefore, once devices enter this end of life phase, prompt generator replacement is recommended.

Scope of the problem:

Worldwide, over 38,000 devices are included in this advisory, with 605 devices presently being followed in Canada. Devices potentially at risk of this issue were manufactured prior to a change

in the low voltage capacitor that occurred in the middle of 2018, and devices manufactured after that date have not been found to be impacted by this issue.

Response of the CHRS Device Committee:

- As part of this formal advisory, we recommend that patients be notified about this issue and reassured that with close follow-up the risk of harm due to this malfunction is low.
- Patients with S-ICDs should be followed according to manufacturer's guidelines every 3 months either in person or via remote monitoring.
- All patients with S-ICDs should be enrolled on the Latitude system where possible. This recommendation applies to all patients with CIEDs, but is especially important in this advisory patient group. Note: this requires that patients with an S-ICD to interact with the bedside Latitude Communicator in order to transmit the data.
- The patient alert tones should be demonstrated to patients at each in-person follow-up to ensure they are able to hear them. Patients should be instructed to notify their follow-up device clinic as soon as possible if they hear the alert tone.
- If the device shows a sudden decrease in estimated longevity between 3 monthly follow-ups, then more intensified follow-up (every 1 month or less) or plans for prompt generator replacement should be made. Note: Consultation with Boston Scientific technical services may be considered to better define the anticipated EOS time for a given device.
- Prophylactic device generator replacement is not recommended, but may be considered in certain high-risk individuals (e.g., inability to use the Latitude system, secondary prevention indication with multiple arrhythmic events, those unable to hear device tones, with planned prolonged travel, or those living remote from medical facilities).

If you have any questions, please contact your local Boston Scientific representatives. Contact Boston Scientific Technical Services for assistance as needed 1-800-227-3422.

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