Important Medical Device Advisory

Rhythm Management
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Summary

- Boston Scientific is expanding an August 2019 advisory device population to a total of approximately 38,350 active EMBLEM S-ICDs (Models A209 and A219) with an elevated likelihood of a low voltage capacitor causing accelerated battery depletion.
  - This depletion behavior can be detected by the healthcare professional observing an unexpected decrease in Remaining Battery Life to ERI or an earlier than expected ERI/EOL[1] battery status.
  - Analysis of returned devices that have experienced accelerated battery depletion indicates that at least three months of battery capacity remain before the battery reaches a depleted state and that the battery status monitor functions as intended.

- Recommendations to manage this behavior are included within this letter.

- To date, the most common and the most severe clinical impact of devices experiencing this malfunction has been accelerated battery depletion requiring premature S-ICD replacement. There have been no reported deaths associated with this behavior.

- In August 2018, Boston Scientific transitioned S-ICDs to an alternative low voltage capacitor. EMBLEM S-ICDs built with this low voltage capacitor have not exhibited this depletion behavior.

- All EMBLEM S-ICDs with the original low voltage capacitor are included in either the original or the expanded advisory population and none are available for implantation.

- Boston Scientific is actively developing a software enhancement intended to detect and provide healthcare professionals an alert to this depletion behavior.

- Enclosed is a list of devices from this advisory subset. To determine if a device is included in this or any other advisory, enter the model/serial number at www.BostonScientific.com/lookup.

[1]As an S-ICD's battery capacity approaches depletion, the battery monitoring algorithm indicates that it's time to replace the S-ICD through the Elective Replacement Indicator (ERI) and subsequently alerts that the battery is approaching End Of Life (EOL).

Dear Physician or Healthcare Professional,

This letter provides important information about the expansion of the August 2019 EMBLEM™ Subcutaneous Implantable Defibrillators (S-ICDs) (Models A209 and A219) advisory population to a total of approximately 38,350 active S-ICDs. These S-ICDs are demonstrating an elevated likelihood for accelerated battery depletion associated with compromised electrical performance of a low voltage capacitor. The most common clinical outcome of this malfunction is S-ICD replacement due to accelerated battery depletion. Recommendations to manage this potential battery depletion behavior are included below.

You are receiving this letter because you may be following one or more patients with an EMBLEM S-ICD built with an original low voltage capacitor. There are no affected devices still available for implantation. The EMBLEM S-ICDs currently being distributed (since August 2018) include a different low voltage capacitor, which has not exhibited this depletion behavior. Please distribute this letter to all other physicians and healthcare professionals within your organization who need to be aware of this topic.

Description

The EMBLEM S-ICD includes low voltage capacitors designed to support the system's power supply. Boston Scientific has determined that latent release of small amounts of hydrogen within the S-ICD may, in some devices, cause the function of the low voltage capacitor to become electrically compromised over time, which results in accelerated depletion of the battery. The susceptibility of an S-ICD to this hydrogen-induced accelerated battery depletion mechanism is dependent upon the amount of hydrogen accumulation within the S-ICD and the susceptibility of the low voltage capacitor to hydrogen.

In EMBLEM S-ICDs, battery capacity is determined with a two-phase battery monitoring algorithm. At the beginning of battery life, the algorithm determines battery capacity using both implant time and charging cycles and then transitions to using solely the battery's voltage to determine capacity later in life. Since the algorithm's early-life inputs are independent of battery voltage, the estimated percentage of Remaining Battery Life to ERI will decrease at the same rate whether the battery is depleting normally or in an accelerated fashion.

When the battery reaches the level at which the battery monitoring algorithm transitions to determining capacity solely using voltage, a device experiencing accelerated depleting battery will exhibit a relatively large decrease in Remaining Battery Life to ERI (e.g., between follow-ups, a decrease from 60% at the preceding check to 18% at the check 3 months later). This notable decrease in Remaining Battery Life happens as part of the design of the S-ICD's two-phase battery monitoring algorithm. It is not indicative of an actual abrupt change in Remaining Battery Life. The algorithm reflects the accelerated battery depletion when it shifts to solely using battery voltage later in life. The battery status monitor functions as intended.

Boston Scientific's ongoing manufacturing continuity program identified an opportunity to strengthen the low voltage capacitor supply chain and developed an alternative, functionally equivalent source of low voltage capacitors. The full transition of this currently used low voltage capacitor in the EMBLEM S-ICD occurred in August 2018 and precedes the formal investigation of this malfunction pattern.

Since the original August 2019 advisory communication, the number of non-advisory hydrogen-induced accelerated battery depletion malfunctions has increased significantly. These malfunctions are all associated with devices built using the original low voltage capacitor. Boston Scientific is therefore expanding the advisory population to include all EMBLEM S-ICDs built with original low voltage capacitors.

Clinical Impact

There have been no serious injuries or deaths reported beyond early device replacement. The median implanted age range of devices with confirmed hydrogen-induced accelerated battery depletion events is approximately 41 months with a range of 3 to 60 months. Using save-to-disk or LATITUDE™ data, Boston Scientific Technical Services can provide a recommended replacement interval specific to an individual device. Based on an analysis of returned devices exhibiting this depletion behavior, projections indicate that at least 21 days of therapy is available after the battery status indicates ERI, independent of subsequent EOL initiation.

Table 1 identifies the projected rate of occurrence for hydrogen-induced accelerated battery depletion in each EMBLEM S-ICD (Model A209 and A219) advisory subset. The potential for life-threatening harm is determined based on the projected occurrence rate, likelihood the battery reaches a depleted state and is unable to provide therapy between follow-ups, and a subsequent untreated ventricular arrhythmia leads to death.

Advisory Population	Approximate Active Implanted Population Size	Projected Occurrence Rate at 5 years	Potential for Life-Threatening Harm at 5 years
August 2019	350	15.1%	1 in 50,000 (0.002%)
December 2020	38,000	3.7%	1 in 250,000 (0.0004%)

Table 1. Statistics of EMBLEM S-ICD (Model A209 and A219) advisory populations for hydrogen-induced accelerated battery depletion.

To date, there have been zero confirmed malfunctions reported for this depletion behavior in EMBLEM S-ICD devices manufactured with the currently used low voltage capacitors, which have been available for distribution since August 2018.

Recommendations

1. Remote monitoring**.** Enroll and monitor patients through the LATITUDE NXT Patient Management System to facilitate prompt detection of accelerated depletion or alert conditions such as ERI or EOL during the interval between in-office device checks. Instruct patients to comply with remote checks and interrogations.

2. Follow-up interval. Perform a system follow-up every 3 months per labeling via remote or in-office interrogation.

3. During follow-ups. Promptly investigate any suspected indication of accelerated battery depletion, and contact Boston Scientific Technical Services for assistance as needed.

4. Demonstrate beeping tones. During the next in-office follow-up visit, demonstrate the device beeper to the patient using the programmer's Test Beeper function available from the Beeper Control screen within the Utilities menu.
   - For patients not monitored by LATITUDE, repeat the beeper demonstration following any MRI scan as strong magnetic fields may cause permanent loss of beeper volume; and
   - Remind patients to promptly contact their physician if beeping tones are heard from their device as this may be an indication of ERI.

5. Evaluate risk. The potential for life-threatening harm due to accelerated depletion is greatest for:
   - Patients with a history of life-threatening ventricular arrhythmias such as secondary prevention indication or previous appropriate shock for VT/VF[2];
   - Patients who are unable to be reliably followed remotely or in person every 3 months; or
   - Patients who are not monitored via LATITUDE and are unable to hear beeping tones.

6. Replacement. Replace any affected EMBLEM S-ICD suspected of exhibiting accelerated battery depletion within 21 days of ERI. Alternatively, Boston Scientific Technical Services can provide a recommended replacement interval specific to an individual device by using data from the programmer or LATITUDE.
   - In other cases of high risk, as indicated by the factors listed above, consider prophylactic device replacement after taking individual patient preferences and circumstances into account through a process of shared decision-making.
   - Return explanted devices to Boston Scientific. A no cost Return Product kit is available from your local Boston Scientific representative.

7. Records. For each patient with an affected EMBLEM S-ICD, append their medical record with this letter to maintain awareness of this topic for the remaining service life of the device.

Adverse reactions or quality problems experienced with the use of this device may be reported to Boston Scientific or FDA's MedWatch Adverse Event Reporting program.

Additional Information
We will be submitting an enhancement to EMBLEM S-ICD's Battery Depletion Alert to detect this behavior earlier. Up-to-date product performance information, including this topic, and a device lookup tool is available within our Product Performance Resource Center at www.bostonscientific.com/ppr. Patient safety remains our highest priority. Although we recognize the impact of communications on both you and your patients, we are committed to transparent communication with our physicians and healthcare professionals 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,

Alexandra Naughton
Vice President, Quality Assurance

[2] VT: Ventricular Tachycardia; VF: Ventricular Fibrillation