

URGENT Medical Device Advisory

Rhythm Management
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December 2020

Summary

- Boston Scientific has confirmed six (6) events of electrical overstress (i.e., damage to the device caused by electrical shorting) during delivery of high voltage therapy by EMBLEM S-ICDs (Model A209 and A219).
- These six devices are included in a subset of approximately 3,350 EMBLEM S-ICDs manufactured between May 2015 and December 2017 that may have variations in the header assembly allowing a very small pathway for moisture ingress, enabling shorting.
- It is possible that either all or a portion of programmed defibrillation shock energy may not actually be delivered in the event of an electrical overstress malfunction.
- Immediately following this behavior, these six devices presented with device alerts or were unable to be interrogated, indicating an inability to deliver programmed therapy.
- No patient harm has been reported due to this behavior other than early device replacement.
- There is no method to detect whether devices included in the advisory subset will develop this condition.
- No affected S-ICDs remain available for implant.
- Recommendations to manage this behavior are included within this letter.
- Enclosed is a list of affected EMBLEM S-ICDs associated with your patients. To determine if a device is included in this or any other advisory, enter the model/serial number at www.BostonScientific.com/lookup.

Dear Physician or Healthcare Professional,

Boston Scientific is informing you about the potential for a specific subset of approximately 3,350 EMBLEM™ Subcutaneous Implantable Cardioverter Defibrillators (S-ICDs) (Model A209 and A219) to experience a malfunction during high voltage therapy delivery, necessitating device replacement due to electrical overstress (i.e., damage to the device caused by electrical shorting). You are receiving this letter because you may be following one or more patients with an affected EMBLEM S-ICD that is included within this identified subset. No affected S-ICDs remain available for implant. This letter provides important information about the detection and management of this potential device malfunction. Please distribute this letter to all other physicians and healthcare professionals within your organization who need to be aware of this topic.

Description

Boston Scientific has confirmed six (6) events of EMBLEM S-ICD electrical overstress malfunctions that have occurred in association with delivery of high voltage therapy. These events manifested clinically by the subsequent inability to interrogate the device or by display of device-based errors/alerts. Boston Scientific Technical Services recommended device replacement in each instance, and no serious patient injury or death has been reported.

Laboratory analysis of the returned devices confirmed evidence of electrical overstress damage in the device feedthrough area. Investigation has shown that, over time, variations in header assembly allowed a very small pathway for moisture ingress enabling a shorting condition to occur during delivery of high voltage therapy. Each of the devices exhibiting electrical overstress were built within a specific timeframe (between May 2015 through December 2017); a header assembly subprocess was found to be subject to process variations directly contributing to this behavior. There is no available method to detect whether an individual device is vulnerable to this condition prior to its occurrence. It is important to note that not all S-ICDs built during this timeframe were exposed to these process variations.

Clinical Impact

The projected occurrence rate for this electrical overstress behavior is 0.3% at 5 years, and the most common clinical outcome is early device replacement. Although there have been no serious injuries reported to date, the potential exists for life-threatening harm due to an inability to provide needed defibrillation therapy, as it is possible that either all or a portion of programmed defibrillation shock energy may not actually be delivered in the event of an electrical overstress malfunction. We estimate that the probability of the hypothetical worst-case harm associated with loss of ambulatory ventricular tachycardia/ventricular fibrillation therapy resulting in death is 0.09% at 5 years. An occurrence of electrical overstress malfunction can be identified by the inability to perform a device interrogation (in-clinic or remotely via LATITUDE) or by device-based errors/alerts. Of the six confirmed events resulting in early replacement, four were reported as inability to interrogate, one displayed prolonged charge time alerts, and one exhibited premature battery depletion. Boston Scientific Technical Services was consulted for troubleshooting guidance and recommended prompt device replacement in each case.

Recommendations

1. Follow-up interval. In the next 6 weeks, discuss this advisory with your patient to ensure awareness, to review their individual clinical status and perspective, and to determine their individual risk status. Perform a system follow-up every 3 months per labeling thereafter via remote or in-office interrogation.

2. Remote monitoring. Enroll and monitor patients through the LATITUDE NXT Remote Patient Management System to facilitate prompt detection of accelerated battery depletion or device-related alert conditions during the interval between in-office device checks. Instruct patients to comply with remote checks and interrogations, as well as to inform their clinic if they are unsuccessful in interrogating their device.
3. During follow-ups. Promptly investigate any suspected indication of inability to interrogate, premature battery depletion, or prolonged charge time alerts. Contact Boston Scientific Technical Services for assistance as needed.
4. Shocks, beeping tones, and counseling. 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, if a shock is delivered, or if any LATITUDE communicator transmissions are unsuccessful.
 - Reinforce that your patient should promptly report any new or unexpected symptoms suspicious for a ventricular tachyarrhythmia by contacting their clinic and, if applicable, perform a remote interrogation via LATITUDE.
5. Evaluate risk. The potential for life-threatening harm due to this device malfunction is greatest for:
 - Patients with a history of life-threatening ventricular arrhythmias such as secondary prevention indication or previous appropriate shock for ventricular tachycardia/ventricular fibrillation;
 - Patients who are unable to be reliably followed remotely or in person every three months; or
 - Patients who are not monitored via LATITUDE and are unable to hear beeping tones.
6. Replacement. Promptly replace any affected EMBLEM S-ICD suspected of exhibiting electrical overstress.
 - Boston Scientific does not recommend routine prophylactic device replacement.
 - In cases of high risk (as indicated by the factors listed above) or other relevant considerations, 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 a copy of this letter to maintain awareness of this topic for the remaining service life of the device.

Any adverse events or quality problems experienced with use of this product should be reported to Boston Scientific or FDA's MedWatch Adverse Event Reporting program.

Additional Information

Patient safety remains Boston Scientific's highest priority. As such, we are committed to transparent communication with our physician customers to ensure you have timely, relevant information for managing your patients. Boston Scientific will publish detailed, up-to-date product performance information for this topic within our Product Performance Report at www.BostonScientific.com. 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