Boston Scientific

Urgent Field Safety Notice

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August 2019

Subject: **Important Medical Device Advisory** – Subset of approximately 400 worldwide active Model A209 EMBLEM™ Subcutaneous Implantable Cardioverter Defibrillators (S-ICDs) and Model A219 EMBLEM MRI S-ICDs with an elevated likelihood for early replacement - Ref: 92400926-FA.

Summary

- While EMBLEM S-ICDs demonstrate an overall cumulative device survival of 99.6% at 3 years[1], a subset of approximately 400 active worldwide devices exhibit an elevated likelihood (19% at 3 years) of an electrical component causing accelerated battery depletion.
- The most common outcome of this behaviour is early device replacement. There have been no other serious injuries reported for this behaviour.
- This behaviour can be detected by observing an unexpected decrease in battery capacity or an early Elective Replacement Indicator (ERI) or End of Life (EOL) battery status.
- Devices exhibiting this behaviour have been capable of providing therapy for a minimum of 21 days after ERI.
- Recommendations include enrolling/monitoring in the LATITUDE™ NXT Remote Patient Management System (LATITUDE), device checks every 3-months, device replacement within 21 days of ERI, and consideration of prophylactic device replacement for higher risk patients.
- The advisory subset comprises of approximately 400 active worldwide Model A209/A219 EMBLEM S-ICDs that were manufactured in July 2017 and are no longer available for implant.
  - Enclosed is a list of your devices from this subset (Appendix B).
  - 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,

[1]US Emblem S-ICD survival probability data published in the Q3 2019 PPR available online at www.BostonScientific.com/ppr.

International Technical Services
+32 2 416 7222 - intltechservice@bsci.com

Boston Scientific is informing you about the performance of approximately 400 active worldwide EMBLEM™ Subcutaneous Implantable Cardioverter Defibrillators (S-ICDs) that may result in a need for device replacement (ERI/EOL) earlier than expected due to compromised performance of an electrical component causing accelerated battery depletion. You are receiving this letter because you may be following one or more patients with an EMBLEM S-ICD. This letter provides important information about the detection and management of this behaviour for the advisory subset as well as a review of design and clinical premature battery depletion (PBD) mitigations for all EMBLEM S-ICDs (see Appendix A). **Please distribute this letter to all other physicians and healthcare professionals within your organization who need to be aware of this topic.**

Recommendations for managing the approximately 400 active worldwide EMBLEM S-ICDs in the advisory subset.

- Follow-Up.
  - Enroll and monitor patients in LATITUDE to facilitate prompt detection of ERI/EOL during the interval between in-office device checks.
  - Perform a device follow-up every 3 months via remote or in-office interrogation.
    - During the next in-office follow-up visit, demonstrate the 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;
    - Remind patients to promptly contact their physician if beeping tones are heard from their device as this may be an indication of ERI/EOL; and
  - Promptly investigate any suspected indication of accelerated depletion, contact Boston Scientific Technical Services for assistance as needed.
  - Append the patient's medical record with this letter to maintain awareness of this topic for the remaining service life of the device.

- 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 a secondary prevention indication or previous appropriate shock for VT/VF[2].
  - who are unable to be reliably followed every 3 months (via LATITUDE and/or in-clinic interrogation).
  - who are not monitored via LATITUDE and are unable to hear beeping tones.
  -
- Replace As Needed.
  - Replace device within 21 days of ERI.
  - Prophylactically replace devices in high risk patients as indicated by the factors listed above.

Clinical Impact

Approximately 56,000 EMBLEM S-ICDs (A209, A219) have been distributed and implanted. As a family, these devices demonstrate an overall cumulative survival of 99.6% at 3 years[3]; however, Boston Scientific has identified a subset of devices that is experiencing an elevated rate of accelerated depletion. The most common clinical outcome associated with this device behaviour is early replacement with a potential for life-threatening harm due to an inability to provide defibrillation therapy. None of the reported cases have resulted in permanent patient injury or death.

Advisory Subset

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

[3] US Emblem S-ICD survival probability data published in the Q3 2019 PPR available online at www.BostonScientific.com/ppr.

The advisory subset is comprised of approximately 400 active worldwide devices manufactured in July 2017. The advisory subset has a projected rate of accelerated depletion of 19% at 3 years. Because this behaviour is detectable through regular follow-up care, the projected potential for life-threatening harm in this subset is approximately 1 in 20,000 at 3 years. The projected potential for life-threatening harm for all other devices (non-advisory) is approximately 1 in 5,000,000 at 3 years. There are no devices within this advisory subset available for implant.

Behaviour Description

Accelerated depletion can be detected if an unexpected decrease in remaining battery capacity is observed between remote/in-clinic follow-ups. Progression of accelerated depletion eventually produces a battery status replacement indicator (ERI) which is detectable through ambulatory beeping tones, remote monitoring, or in-clinic follow-up. Devices exhibiting this accelerated depletion behaviour are capable of providing therapy for a minimum of 21 days after ERI independent of when EOL is initiated. If accelerated depletion is suspected, Technical Services can use device data to confirm and provide a customized replacement interval. Appendix A describes the design and clinical mitigations for PBD available to all EMBLEM S-ICDs.

Additional Information

Your Competent Authority is being notified of this Field Safety Notice.

Patient safety remains our highest priority. Although Boston Scientific recognizes the impact of this letter 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. Boston Scientific will publish detailed, up-to-date product performance information for this behaviour within our Product Performance Report, published quarterly 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.

Instructions:

- **Please distribute this letter to all other physicians and healthcare professionals within your organization who need to be aware of this topic.**
- **Append the patient's medical record with this letter to maintain awareness of this topic for the remaining service life of the device.**
- **Please complete the attached acknowledgement form. It is mandatory for each customer to return this form to Boston Scientific. When completed, please return the Form to «Customer_Service_Fax_Number» on or before xx September 2019.**

Yours sincerely,

Renold J. Russie
Vice President, Quality Assurance
Boston Scientific Rhythm Management

Attachment: Acknowledgment Form

Appendix A

Boston Scientific

EMBLEM S-ICD Family
Design and Clinical Mitigations for Premature Battery Depletion (PBD)

The EMBLEM S-ICD system's design, in combination with international societal accepted practice of care, can facilitate earlier detection of PBD and thus mitigate the potential harms associated with PBD. These system design and patient care elements/recommendations are aligned with information contained in the S-ICD manual and are summarized as follows:

- Remote Monitoring. The LATITUDE NXT Remote Patient Management System is a wireless home monitoring system designed to facilitate prompt notification of ERI and EOL battery replacement indicators in between in-office device checks. Boston Scientific supports the published societal guidelines to enroll and monitor all patients using available home monitoring technologies like LATITUDE.[4]
- Alert Conditions. The EMBLEM S-ICD includes a Battery Depletion (BD) monitor which actively monitors voltage to identify devices that could be experiencing rapid battery depletion. If battery voltage is not consistent with other monitored parameters, the device will initiate an audible beep and display a red programmer screen alert message. Note, the battery depletion rate for the behaviour described herein is moderate and therefore, by design, is not detected by the BD alert.
- Follow-Ups. Monitor the condition of the patient and evaluate device function, including battery status, one month after implant and every 3 months thereafter.
- Audible Beeper. The EMBLEM S-ICD is designed to emit beeping tones[5] when the battery status indicates ERI or EOL. Patients should be instructed to contact their physician if they ever hear beeping tones from their device. For patients not enrolled in LATITUDE, the EMBLEM S-ICD's beeper is an important tool for detecting PBD, so physicians and healthcare professionals may consider the following:
  - Assess beeper audibility through the programmer's Test Beeper function available from the Beeper Control screen within the Utilities menu.
  - Evaluate competing risks before performing an MRI scan[6]. Before an MRI procedure is performed, review with the patient the benefit of the procedure against the risk of losing the beeper with exposure to strong magnetic field of an MRI scanner. After an MRI procedure and exiting MRI Protection mode, manually re-enable the beeper and assess whether the beeper is audible. If it is not audible, disable the beeper and monitor device via LATITUDE.

Investigate and report any indications of PBD to your local Boston Scientific sales professional or Technical Services.

Appendix B

[4] Slotwiner D, Varma N, Akar JG, etal. HRS Consensus Statement on Remote Interrogation and Monitoring for Cardiovascular Implantable Electronic Devices: Developed in collaboration with and endorsed by ACC, PACES, AHA, APHRS, EHRA, and SOLAECE. Heart Rhythm 2015;12:e69-e100. http://dx.doi.org/10.1016/j.hrthm.2015.05.008

[5] The beeper emits 16 tones/second every 9 hours until the device is interrogated by a programmer.

[6] MRI: Magnetic Resonance Imaging

List of Affected Devices

Note: Boston Scientific has NO records of shipping devices impacted by this Field Action to your facility. If you have/start following a patient that did not receive an implant at your clinic, please use the Device Lookup Tool at www.BostonScientific.com/lookup to determine if a specific model/serial number combination is included within the advisory subset device population

Please complete the form & Send it to:
«Customer_Service_Fax_Number»

«Unique_Account_Number__Sold_To» - «Account_Name_Sold_To» - «Sold_To_City_SAP» - «Country__TRaC_II»

Acknowledgement Form – Product Advisory

EMBLEM S-ICDs with elevated likelihood for early replacement

92400926-FA

By signing this form, I confirm that

I have read and understood the Boston Scientific Field Safety Notice

dated August 2019 for the

EMBLEM S-ICDs with elevated likelihood for early replacement.

NAME* _____Title _____

Telephone _____ Department _____

SIGNATURE* _____ **DATE*** _____
* Required field dd/mm/yyyy