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Medical Device Product Correction

EMBLEM S-ICD Model A209 and EMBLEM MRI S-ICD A219

WAND Numbers: 150406-WAND-6JKS7N and 160811-WAND-6MIDF3

Medsafe Reference Number 31906

October 2023

Subject: Product Defect Correction – Important EMBLEM™ Subcutaneous Implantable Cardioverter Defibrillator (S-ICD) software update to address transient sensing behavior. Boston Scientific Field Action Reference: 92892652-FA.

Summary

- Boston Scientific has launched a software update for Model 3300 LATITUDE™ and Model 3200 EMBLEM™ programmers to address a rare, transient sensing behavior in the EMBLEM S-ICD.

- There have been three (3) reported occurrences of this behavior out of 136,000 EMBLEM S-ICDs (none of these events occurred in New Zealand). In all cases, the S-ICDs remained in service with no associated patient injury reported.

- Boston Scientific recommends patients with EMBLEM S-ICD models listed in Table 1 who are enrolled in the LATITUDE™ Remote Patient Management System be checked in person at the next scheduled follow-up using an updated Model 3300 LATITUDE or Model 3200 EMBLEM programmer. Please complete and return the enclosed verification form.

- Boston Scientific plans to launch this software where the EMBLEM S-ICD has been distributed.

Table 1. All EMBLEM S-ICDs enrolled in LATITUDE have the rare potential for transient sensing behavior.

Product Name	Model	GTIN
EMBLEM S-ICD	A209	00802526544101, 00802526548406, 00802526575105, 00802526575112, 00802526575129, 00802526575136, 00802526575143, 00802526575167, 00802526575181, 00802526575204, 00802526575211, 00802526575228, 00802526599002
EMBLEM MRI S-ICD	A219	00802526581519, 00802526584404, 00802526584411, 00802526590405, 00802526590429, 00802526590436

Dear Physician or Healthcare Professional,

We are writing to inform you that a software update for the EMBLEM S-ICD is available to correct the potential for a rare interaction between the EMBLEM S-ICD and LATITUDE communicator, which may cause S-ICD sensing disablement for a 24-hour interval. The potential for this behavior is fully addressed upon interrogation by an updated programmer.

Background

During an EMBLEM S-ICD system impedance measurement, low energy pulses are automatically sent every three (3) days. When this test is performed, sensing is momentarily disabled to prevent non-cardiac artifacts from being over-sensed by the device or displayed on the S-ECG.

Description of Unanticipated Behavior

If telemetry from a LATITUDE communicator is initiated within a 700 msec interval during an automatic system impedance check, the impedance measurement will cease and be postponed for a 24-hour interval. During this postponement interval, sensing will be temporarily disabled until the rescheduled impedance measurement is completed. This software update prevents postponement of the system impedance measurement so sensing resumes in approximately one cardiac cycle as intended.

Clinical Impact

As of 16 June 2023, Boston Scientific has received three (3) reports of this rare behavior and associated transient device operating state out of approximately 136,000 EMBLEM S-ICDs. One of these events has been reported in the literature.[1] In all of these instances, the S-ICDs remained in service with no reports of associated patient injury. If sensing becomes disabled during the 24-hour interval, shock therapy will not be delivered. Prior to the software upgrade, the cumulative one-year likelihood for the theoretic worst-case harm of death due to failure to treat a life-threatening arrhythmia because of this behavior is 1 in 45 million.

Customer Actions

Please distribute this letter to all HCPs who manage follow-ups of S-ICD patients.

- **In-person follow-up**. Perform the next scheduled device check in-person using a Model 3300 LATITUDE programmer with Model 3877 v1.04 software or Model 3200 EMBLEM programmer with Model 2877 v4.10 software to address any potential for this rare S-ICD behavior.
- **Complete verification**. Please complete and return the enclosed verification form to ANZ_Incident_Report@bsci.com. A completed form is required from every facility who receives this letter.

[1]Grace A, Fogoros RN, Gordon MJ, Huddle T, Kennergren C, Soejima K, Stambler BS, Shorofsky S, Patient Safety Advisory Boards and Risk Evaluation, Heart Rhythm (2023), doi: https://doi.org/10.1016/j.hrthm.2023.04.020.

- **Medical records**. Append the patient's medical record with this letter to maintain awareness until the device has been interrogated by an updated programmer.

Additional Information

This action is being conducted following consultation with Medsafe, Ministry of Health.

Patient safety remains our highest priority. Although we recognize the impact of this type of communications on both you and your patients, we are committed to transparent communication with physicians and healthcare professionals to ensure you have timely, relevant information for managing your patients. Up-to-date product performance information and a device lookup tool[2] are available within our Product Performance Resource Center at www.bostonscientific.com/ppr. If you have additional questions regarding this information or need to report an adverse event, please contact your Boston Scientific representative or Technical Services.

Yours sincerely,

Seamus Gallagher

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Quality Assurance Manager

Boston Scientific Pty Ltd Australia
and New Zealand

[2]Available at www.BostonScientific.com/lookup