Boston Scientific Corporation
Building 1, Level 6, Connect Corporate Centre
191 O'Riordan Street
Mascot NSW 2020

EMBLEM™ Subcutaneous Implantable Cardioverter Defibrillators (S-ICDs) (Models A209 and A219) Update

ARTG #: 260382 and 286705

TGA Reference Number: RC-2020-RN-01312-1

Subject: Update to the 2020 Implant Hazard Alert - Low Voltage Capacitor Causing Accelerated Battery Depletion (BD) (Boston Scientific Field Action Reference: 92400926E-FA).

July 2022

Dear Health Care Professional,

In December 2020, Boston Scientific committed to developing a software enhancement that detects and alerts healthcare professionals (HCPs) if an EMBLEM S-ICD exhibits hydrogen-induced accelerated battery depletion. This enhanced software allows clinicians to identify EMBLEM S-ICDs exhibiting hydrogen induced accelerated battery depletion sooner and is now regulatory approved. Boston Scientific is preparing to launch software in July 2022 for installation on the Model 3200 and 3300 Programmers.

When an EMBLEM S-ICD is first interrogated by an upgraded programmer, the user will be notified via the programmer screen of the initiation of the update and a status bar will display indicating the progress of the update. This software update enhances the current BD alert to detect hydrogen-induced accelerated depletion between in-office visits or LATITUDE™ remote interrogations. If depletion conditions are met, a BD alert is initiated, and the device emits 16 beeping tones every 9 hours (if beeping tones are enabled). For devices enrolled/active on LATITUDE, HCPs will be notified of a BD alert after a successful transmission from the patient's in-home LATITUDE communicator.

Current Status: Since the December 2020 communication, the malfunction rates for the approximately 28,000 active devices that compose the combined August 2019 and December 2020 advisory populations have converged to approximately 11.9% at 5 years. This behaviour continues to be highly detectable. 99.5% of the 3,611 S-ICDs that have exhibited this behaviour were replaced before the battery reached a depleted state. Based on the malfunction rate and detectability of hydrogen-induced accelerated battery depletion, the theoretical potential for life-threatening harm is projected at 1 in 250,000 at 5 years. The most common associated clinical outcome is early replacement and there have been no deaths associated with this behaviour.

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

Recommendations: The December 2020 ongoing follow-up recommendations for managing devices with the potential for hydrogen-induced accelerated depletion are unchanged. Specific to this software update, Boston Scientific recommends:

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- Programmer Software Upgrade. Confirm programmers at your center have been upgraded.
    - Model 3300 LATITUDE Programmers are supported with Model 3877 v1.03 application
    - Model 3200 EMBLEM Programmers are supported with Model 2877 v4.09 application
- Next Follow-up. Boston Scientific continues to recommend 3-month device follow-ups per labeling. Bearing in mind the risk versus benefits of in-person visits in the setting of the global COVID-19 pandemic, consider an in-person visit at the next scheduled follow-up, so the enhanced BD alert can be enabled in each affected device.
    - When an EMBLEM S-ICD is first interrogated by an upgraded programmer, an S-ICD software update will be performed. Per labeling, monitor the patient and have external defibrillation equipment available as tachycardia therapy is suspended during a S-ICD software update.
    - If a BD alert occurs, follow screen prompts and contact Technical Services. Using device data, Technical Services can provide a replacement interval.
- Update 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.
- Distribute This Letter. Please distribute this update to all other physicians and healthcare professionals within or outside your organization who need to be aware of this topic.

Up-to-date product performance information about this topic, including a device lookup tool, is available within our Product Performance Resource Center at www.bostonscientific.com/ppr. 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.

Yours Sincerely

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