ANZCDACC Safety Alert Notice 21 December 2020
Device:

1. Model A209 EMBLEM ™ Subcutaneous Implantable Cardioverter Defibrillators (S-ICDs)
2. Model A219 EMBLEM MRI™ Subcutaneous Implantable Cardioverter Defibrillators (S-ICDs)

ARTG:

1. 260382
2. 286705

Medsafe Reference Number: 26965

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

Advisory grade TGA: Class I (Class I recall action occurs when the product deficiency is potentially life threatening or could cause serious risk to health)
ANZDACC Advisory Grade: Routine
Number of CIEDs affected in Australia and New Zealand:
August 2019 safety alert: There were no devices supplied/implanted in Australia or New Zealand included in the advisory subset
December 2020 safety alert: TBA
Description:
Boston Scientific is expanding an August 2019 safety alert 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. 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, unexpected decrease in Remaining Battery Life to ERI (e.g., between follow-ups, an unexpected decrease from 60% at the preceding check to 18% at the check 3 months later). This unexpected decrease is a phenomenon of the S-ICD's battery monitoring algorithm response to accelerated battery depletion and the shift to solely using battery voltage later in life. 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 safety alert 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 safety alert population to include all EMBLEM S-ICDs built with original low voltage capacitors.

Risk:

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 behaviour, 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) safety alert 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.

Safety alert 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%)

Presentation:

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. Note: Any MRI scan may cause permanent loss of beeper volume in these devices due to the strong magnetic fields. If accelerated depletion is suspected, Boston Scientific Technical Services can use device data to confirm and provide a customised replacement interval.

Advice:

1. Check if you are following up any patients with advisory devices;

a) Check if you are following up any patients with either a A209 EMBLEM or a A219 EMBLEM MRI S-ICD.

b) If so, enter their device details into the following website to check if they are affected: BostonScientific.com/lookup

2. Evaluate Risk:

Schedule an in-clinic visit and demonstrate alert tone “beeper” to ensure it is functional, the patient can hear it and will appropriately respond if it alerts. The potential for life threatening harm due to accelerated depletion is greatest for patients:

a) with a history of life-threatening arrhythmias such as a secondary prevention indication or previous appropriate shock for VT/VF.
b) who are unable to reliably be followed up every 3 months (via Latitude Remote monitoring[1] and/or in-clinic check)
c) Who are not monitored via latitude[1] and are unable to hear beeping tones.

3. Follow-up

a) Consider enrolling and monitoring patients on Latitude remote monitoring[1] to facilitate prompt detection of ERI/EOL. If enrolled, ensure patients understand they are required to manually send weekly alert monitoring checks[1]and they are shown how.
b) Perform a device follow-up every 3 months via remote monitor 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 remote monitoring[1], 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 follow-up clinic if beeping tones are heard from their device as this may be an indication of ERI/EOL and;
c) Promptly investigate any suspected indication of accelerated depletion, contact Boston Scientific Technical Services for assistance as needed.

4. Replace as needed

a) Replace device within 21 days of ERI
b) Consider prophylactically replacing devices in high risk patients as indicated by the factors listed above.

[1] S-ICDs are unable to automatically transmit alerts via the Latitude remote monitor. Patients are required to manually press a button on their remote monitor to check for and send alert data. The patient, is in most cases, prompted to do this weekly by a flashing white button on the Wave Wireless Communicator.

The ANZCDACC encourage you to report any adverse event or near (potential) adverse event associated with the use of a medical device including any abnormal CIED or lead function. We encourage reporting to ANZCDACC directly via the Committee chair Dr Paul Gould drpgould@gmail.com and to the following regulators.

In Australia, report to the TGA:

Online: https://www.tga.gov.au/reporting-problems

In New Zealand, report to Medsafe:

Post	Compliance Management Branch, Medsafe, PO Box 5013, Wellington 6145.
Email	devices@moh.govt.nz
Fax	04 819 6806