ANZCDACC Product Defect Correction Notice August 2019

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

TGA Reference: RC-2019-RN-01242-1

Advisory grade TGA: Class III Safety Alert.

ANZDACC Advisory Grade: Routine

Number of CIEDs affected in Australia and New Zealand: 0

There were no devices supplied/implanted in Australia or New Zealand included in the advisory subset. Clinics may have inherited patients with affected devices however.

Description:

There are approximately 400 active worldwide EMBLEM S-ICDs manufactured in July 2017 that may result in a need for device replacement earlier than expected due to compromised performance of an electrical component causing accelerated battery depletion.

Risk:

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

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 subset available for implant.

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.

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.

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 implanted after June 2017, which may have been implanted outside Australia or New Zealand.

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