ANZCDACC Advisory Notice 6th December 2020

Device:
EMBLEM™ Subcutaneous Implantable Cardioverter Defibrillators (S-ICDs) (Models A209 and A219) all Implanted from May 2015 to December 2017

Advisory grade TGA: TBA

ANZDACC Advisory Grade: Semi-urgent

Description:
Potential for electrical overstress and non-delivery of high voltage shock. Over time, due to variations in header assembly, a very small pathway may develop that allows moisture ingress, enabling a shorting condition to occur during delivery of high voltage therapy.

Number of devices affected in Australia and New Zealand:
Australia: and New Zealand: 50

Presentation:
Patient may present with failure of delivery high voltage therapies due to electrical short and subsequent necessity of device replacement post high voltage therapies which have shorted. Most common presentation is early device replacement and no clinical event. An occurrence of electrical overstress malfunction can be identified by the inability to perform a device interrogation (in-clinic or remotely via LATITUDE) or by device-based errors/alerts.

Rate of occurrence:
The current projected occurrence rate for this advisory is 0.3% at 5 years, and the most common clinical outcome is early device replacement. To date there have been no serious sequelae, the potential exists for life-threatening harm due to an inability to provide defibrillation therapy. It is estimated the probability of the hypothetical worst-case harm associated with loss of therapy resulting in death is 0.09% at 5 years. Six confirmed events resulting in early replacement have occurred, four were reported as inability to interrogate, one displayed prolonged charge time alerts, and one exhibited premature battery depletion.

Recommendation:

Increase device follow-up to 3 months in person or enrol appropriate patients into home monitoring with 3 monthly checks. Educate patients regarding beeping tones, if their device makes a beeping tone noise the patient must seek medical advice and device interrogation as soon as possible.

Patients at extremely high risk (i.e frequent appropriate device treatment events) and the patient cannot undergo increased monitoring as above the patient could be considered for device replacement at the physician's discretion, acknowledging the risks of complication associated with replacement are not insignificant.

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