ANZCDACC Product Hazard Alert October 2023

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

TGA Reference:
RC-2023-RN-00850-1

Australian Register of Therapeutic Goods (ARTG):
399595 and 399599

Medsafe Notification Reference:
31906

Advisory grade TGA:
Class II

Description:
During an EMBLEM S-ICD system, low energy pulses are automatically sent every 3 days. Sensing is momentarily disabled when this test is performed to prevent non-cardiac artifacts from being over-sensed by the device.

If telemetry from a LATITUDE communicator is initiated within a 700 millisecond 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 next rescheduled impedance measurement is completed.

Number of devices affected in Australia and New Zealand:
1868

Presentation:
This advisory only affects EMBLEM S-ICD devices that are enrolled in the LATITUDE Remote Patient Management System. As sensing becomes disabled during the 24-hour postponement interval, there is a risk that shock therapy will not be delivered during this period.

Rate of occurrence:
Three reports of this rare behaviour have been reported out of approximately 136,000 EMBLEM S-ICD devices, none of which have occurred in Australia. The one-year likelihood for the

theoretical risk of death due to failure to treat a life-threatening arrhythmia because of this behaviour is 1 in 45 million.

Recommendation:
Boston Scientific Has launched a software update for Model 3300 LATITUDE and Model 3200 EMBLEM programmers to address this rare, transient sensing behaviour in the EMBLEM S-ICD.

All patients with the EMBLEM S-ICD models A209 and A219, who are enrolled in the LATITUDE Remote Patient Management System, should be checked in-person at next scheduled follow-up using an updated Model 3300 LATITUDE or Model 3200 EMBLEM programmer.

Ensure that the software version (S-ICD Support App Model 3877) is updated to version 1.04. This information can be found under the 'About' menu on the start-up screen of the programmers.

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@health.govt.nz**