ANZCDACC Field Safety Notice 15th of March 2021

Device: A subset of Abbott / St Jude Medical Assurity ™ and Endurity ™ Pacemakers Models: PM1160, PM1172, PM1240, PM1272, PM2160, PM2172, PM2240, PM2260*, PM2272

TGA Reference: RC-2021-RN-00728-1
Australian Register of Therapeutic Goods (ARTG): 216288, 267515, 216284, 267512, 216289, 267514, 216285, 216287*, 267513
*TGA listing cancelled in June 2019

Advisory grade TGA: TBA

ANZDACC Advisory Grade: Routine

Description:

Abbott's post market surveillance process has identified a subset of Assurity ™ and Endurity ™ pacemakers that have an increased chance of moisture ingress into the pulse generator header, caused by intermittent, incomplete mixing of epoxy during manufacture on specific equipment between 2015 and 2018. These units were from a manufacturing process which is no longer in use. No affected devices remain available for implant.

There have been no reports of serious harm to patients as a result of this issue.

Number of devices affected in Australia and New Zealand:
There have been 70 devices in Australia and 28 in New Zealand which are included in the identified subset.

Presentation:
The reported clinical impact has included loss of telemetry / communication, reduced battery longevity, loss of pacing, and/or shortened duration between Elective Replacement Indicator (ERI) and End of Service (EOS). Forty-eight (48) devices were returned with an associated report suggesting loss of pacing. Additionally, twenty-one (21) returned devices reached ERI earlier than expected with an average of 17 days from ERI to EOS.

Rate of occurrence:

Abbott has identified a subset of approximately 95,000 devices within the referenced timeframe that are potentially susceptible to this issue.

Due to the intermittent nature of the incomplete epoxy mixing, the potential for affected devices is inconsistently dispersed between 2015 and 2018. To date, 135 devices have been observed with this issue. A low observed rate (0.049%) of malfunctions has been detected among the identified subset of devices.

Recommendation:

Prophylactic generator replacement is not recommended by Abbott or ANZCDACC due to the very low rate of occurrence and the low potential for harm when prompt replacement is performed following an unexpected ERI/EOS alert.

1. If possible, monitor patients via remote monitoring to benefit from alert monitoring between routine device checks. (ERI and EOS alerts are currently monitored daily).
    a. If remote monitoring is not possible, 3 monthly in-clinic checks are recommended for those who are pacemaker dependent.
    b. If remotely monitored and pacemaker dependent;
        i. Reduce the disconnected transmitter thresholds on Merlin.net, in the transmitter section of the patient profile, to the minimum option of 7 days.
        ii. Promptly respond to disconnected transmitter (monitor) and patient's DirectAlert™ Check status alerts, summarised each week in the "Communication Centre."
2. During follow-up, document battery longevity measures in the medical record as normal and review any impact to device function including measured battery voltage or any unexpected change in battery consumption.
3. Prompt replacement for devices that reach ERI or EOS unexpectedly or experience one of the clinical impacts listed above commensurate with the patient's underlying clinical condition.

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