ANZCDACC Product Hazard Alert August 2022

Device:
A SUBSET OF ASSURITY™, ENDURITY™ AND ZENEX™ PACEMAKERS MODELS PM2162, PM2172, PM2272, PM2282*
* TGA Approved but not currently commercially released
TGA Reference:
RC-2022-RN-01000-1

Australian Register of Therapeutic Goods (ARTG):
267517, 267514, 267513, 322001*
* TGA Approved but not currently commercially released

Wand Notification Reference:
Not supplied by Abbott

Advisory grade TGA:
Class I
(Class I recall action occurs when there is a reasonable probability that the use of or exposure to, the deficient therapeutic goods will cause serious adverse health consequences)

Description:
A manufacturing laser surface preparation subprocess, unique to a single assembly line in Malaysia subject to process variation, may not have properly prepared the device's metal housing potentially leading to abnormal device-to-header adhesion.

This in turn may allow moisture ingress into the pulse generator header.

This specific manufacturing process is no longer in use.

Based on data reviews, the functionality interruption may occur as soon as within a week from the last transmission date in Merlin.net.

Number of devices affected in Australia and New Zealand:
2211

Presentation:

The current reported clinical impact has included loss of pacing, reduced battery longevity, devices reverting to back-up mode, and/or loss of telemetry / communication. There have been no deaths to date.

Rate of occurrence:

To date, one hundred twenty-eight (128) complaints have been identified from approximately 83,000 specific serial numbers potentially susceptible to this issue. Functionality interruption was noticed on average after 749 days (~2.1 years) of implant duration. An overall rate of 0.15% loss of device function

Recommendation:

- Prophylactic generator replacement is NOT generally recommended.
- Assess each patient's risk. Consider individualised therapy up to and including generator replacement for patients who are at high risk if interruption of pacemaker function were to occur. Factors to be considered include:
    - Adequacy of intrinsic / underlying rhythm
    - Individual patient characteristics and circumstance, including access to emergency care
    - Ability to adequately monitor patients based on risk
- When possible, monitor patients using Merlin.net to benefit from compliance and alert monitoring, including Electronics Performance Indicator (EPI – see description below), between routine device checks.
- For patients enrolled in Merlin.net;
    - Remind them of the importance of using remote monitoring.
    - Consider reducing the "Disconnected Transmitter Thresholds" in the patient's profile to allow earlier notification of disconnected monitors. Promptly address disconnected monitors or DirectAlert™ Check status if they arise.
- Prompt replacement for devices that receive an EPI notification, reach ERI, or experience one of the clinical impacts listed above, unless particular patient circumstances preclude this.
- Ensure your clinic contact information in Merlin.net is current.

EPI (Electronics Performance Indicator) Description: The EPI tool assists in patient management in patients followed with Merlin.net. The EPI tool supplements ERI using data available on Merlin.net to identify abnormal electrical system behaviour resulting from loss of hermeticity. The EPI tool is an Abbott surveillance process that reviews data from all devices within this affected population communicating with Merlin.net. If an EPI signal is detected, Abbott will notify the clinic using the email contact information in Merlin.net.

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