August 1, 2022

Canadian Heart Rhythm Society - Device Committee

ADVISORY: Abbott Medical Device Recall

SUBSET OF ASSURITY™ & ENDURITY™ PACEMAKER MODELS PM2172, PM2272

Nature of the Advisory:
During post market surveillance, Abbott has observed malfunctions which may affect a subset of serial numbers of Assurity™ and Endurity™ pacemaker devices. The issue is connected to a laser surface preparation subprocess, performed during the manufacturing of these devices on a single assembly site production line. Due to process variation, this surface lasering may not have properly prepared the device's metal housing in some devices, potentially leading to abnormal device-to-header adhesion and allowing moisture ingress into the pulse generator header.

While this specific manufacturing process is no longer in use, devices manufactured on this assembly site production line are at risk of loss of pacing, reduced battery longevity, devices reverting to back-up mode, and/or loss of telemetry/communication.

Scope of the problem:
Approximately 83,000 devices are potentially susceptible to this issue. Approximately 2,995 devices were implanted in Canada.

Through June 2022, a total of 128 devices worldwide have been identified with this issue (0.15% of the at-risk population). The interruption of device functionality was observed, on average, after 749 days of implant duration **(~2.1 years post implant).** As a significant number of active devices are early in their lifecycle it is possible that the proportion of affected devices may increase with time.

The Abbott remote monitoring system (MERLIN.NET) routinely checks for ERI status. In the subset of affected devices analysed so far (62/128), the malfunction was noted to have occurred within 7 days of the last Merlin transmission date (i.e., the change in function may occur with little warning).

Of Note – Abbott has previously developed the Electronics Performance Indicator (EPI) tool to assist in management of patients followed with MERLIN.NET. The EPI tool supplements ERI using data available on MERLIN.NET to identify abnormal electrical system behavior resulting from loss of hermeticity. Abbott will notify the clinic if an EPI signal is detected.

Response of the CHRS Device Committee:
As part of this formal advisory, we recommend:

- Patients be notified about this issue
- Patients should be followed according to their usual schedule
- **All patients should be enrolled on the MERLIN.NET home monitoring system.** While this recommendation applies to all patients with CIEDs it is especially important in this advisory patient group. Clinic contact information should be current in Merlin.net.
- In cases where unexpected ERI is reached, EPI is triggered, or there is an inability to interrogate the device or transmit data, then pulse generator replacement should be performed:
    - Pacemaker-dependent patients should be **admitted to hospital and their pacemaker replacement performed promptly**
    - In non-pacemaker dependent patients, replacement should be planned in ≤ 1 week.
- Prophylactic device generator replacement is not recommended but may be considered in certain high-risk individuals and discussed with patients as part of the decision-making process (e.g., pacemaker dependent patients especially where there is an inability to use the MERLIN.NET system, those planning to undertake planned prolonged travel, or those living remote from medical facilities).
    - One should keep in mind the very low risk of failure when assessing the risks and benefits of an early generator change.
- The CHRS device committee may update these recommendations should more data become available

CHRS Device Committee
Jason Andrade, MD, FRCPC, FHRS, FCCS (Chair, Device Committee)
François Philippon, MD, FRCPC, FHRS, FCCS (Past Chair, Device Committee)
Larry Sterns, MD, FRCPC, FHRS, FCCS
Derek Exner, MD, FRCPC, FHRS
Clarence Khoo, MD, FRCPC
Ratika Parkash, MD, FRCPC, FHRS
Calum Redpath, MBChB, MRCP (UK), PhD
Raymond Yee, MD, FRCPC, FHRS