Canadian Heart Rhythm Society
Société canadienne de rythmologie

Date: February 3, 2021

Canadian Heart Rhythm Society
Device Committee

ADVISORY: POTENTIAL FOR PREMATURE BATTERY DEPLETION IN A SUBSET OF MEDTRONIC ICD AND CRT-D DEVICES:

Claria MRI™/Amplia MRI™/Compia MRI™/Viva™/Brava CRT-Ds™/Visia AF™/Visia AF MRI™/Evera™/Evera MRI™ ICDs

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Nature of the Advisory:

Medtronic has identified a rare failure mechanism leading to rapid battery depletion. This is present in the battery design of specific implantable cardioverter defibrillator (ICD) and cardiac resynchronization therapy defibrillator (CRT-D) models. The rapid depletion is caused by a latent shorting mechanism resulting from lithium bridges between a positive (cathode) and a negative (anode) element in the battery. This internal short between the anode and cathode elements of the battery causes the battery to deplete rapidly. **If this occurs, the device may trigger the Recommended Replacement Time (RRT) warning sooner than expected, and the time between the RRT indicator and End of Service (EOS) may occur in a matter of days, rather than the normally expected three (3) months of device operation**.

Scope of the problem:

It is estimated that approximately 15,000 susceptible devices implanted from 2013 to February 2019 are still active in Canada. Of these devices it is estimated that **0.22%** may experience this issue during their service life.

Clinical Observations:

The affected devices manifest as a rapid unexpected change in the remaining longevity estimate that cannot be attributed to programming changes or changes in use conditions, or with unexpected RRT alert. The inability to interrogate the device, or to transmit data, may be an indicator that the device has experienced this issue.

For those devices where RRT triggered earlier than expected, the median time from RRT to the EOS observation was 14 days (inter-quartile range: 5-73). Importantly, devices with higher pacing outputs and high pacing percentages have the lowest probability of occurrence. Conversely, devices with low current drain (evidenced by a longer overall service time from implant to RRT) have a higher probability of experiencing this issue. The probability of this issue developing is constant after approximately three years of service time.

Response of the CHRS Device Committee:

- As part of this formal advisory, we recommend that patients be notified about this issue.
- Patients should be followed in-person or via remote monitoring every **3 months**.
- No prophylactic replacement is recommended at this stage.
- Patients should be enrolled on the CareLink™ system where possible. While this recommendation applies to all patients with CIEDs, it is especially important in this advisory patient group.
- Device alert tones should be demonstrated to patients at each in-person follow-up to ensure patients are able to hear them.
    - Patients should be instructed to notify their follow-up device clinic as soon as possible if they hear the alert tone.
    - The device should be interrogated or a CareLink™ transmission initiated within **72 hours** after an alert tone.
- In cases where unexpected RRT is reached or an inability to interrogate the device or to transmit data is encountered, **replacement should be performed**.
    - Patients with a high percentage of pacing, pacemaker dependent or with prior ventricular arrhythmias should be **admitted to hospital and replacement performed promptly.**
    - Patients without a need for pacing and those without prior ventricular arrhythmias should have replacement planned **in ≤ 1 week**.
- The CHRS device committee may update these recommendations should more data become available.

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