Date: June 3rd 2021

Canadian Heart Rhythm Society
Device Committee

ADVISORY: Medtronic Medical Device Recall

REVEAL LINQ Insertable Cardiac monitor (LNQ11)

LINQ II Insertable Cardiac monitor (LNQ22)

Nature of the Advisory:

During post market surveillance, Medtronic has observed malfunctions in a small fraction of these devices (<1%) which may result in a failure to automatically detect and store "Brady" and "Pause" events (LNQ11) and "Brady", "Pause" and "PVC" events (LNQ22) due to an error in the normal electrical reset function. Patient reported events continue to be stored normally despite this failure. Tachy/AF detections are unaffected by this advisory and continue to be detected and stored automatically. In the rare instance that this malfunction occurs the programmer will still indicate that detections are 'on' but these events will not be automatically stored. The most common trigger for an electrical reset is exposure to electromagnetic interference (EMI). It is anticipated that a software patch for devices already in use will be available for download in Spring 2022 and that devices manufactured in 2022 will be unaffected by this advisory.

Scope of the problem:

The inability of Reveal LINQ (LNQ11) to detect "Brady" and "Pause" events is projected to occur in **0.056%** of devices during their expected length of service (36 months). The inability of Reveal LINQ (LNQ22) to detect "Brady", "Pause" and "PVC" events is projected to occur in **0.73%** of devices during their expected length of service (36 months). No patients are known to have experienced harm associated with this failure. However, this advisory does describe a diminished functionality of these implanted cardiac monitors which could result in missing or underreporting of bradycardia and missed diagnoses.

Response of the CHRS Device Committee:

- As part of this formal advisory, we recommend that patients be notified about this issue.
- No prophylactic replacement is recommended at this stage, although if the detection of asymptomatic bradycardia is clinically imperative consideration of re/implantation with an alternative implantable cardiac monitor should be discussed.
- Patients should be followed according to their usual schedule, remotely or in person.
- Patients should be reminded to avoid exposure to EMI.
- At next follow up clinicians should seek to document if either a partial reset has occurred (pop up or indicator in Carelink) or if the "Brady" or "Pause" event log is empty indicating a potential problem. In this eventuality, clinicians should contact Medtronic Technical Services for assistance by emailing RS.LINQElectricalResetFCA@medtronic.com OR calling 1-800-929-4043.
- If an electrical reset has not occurred, all detection criteria are being monitored and recorded as programmed and follow up can continue as expected.
- The CHRS device committee may update these recommendations should more data become available.

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