Device: Medtronic Reveal LINQ™ with TruRhythm™ Cardiac Monitoring Systems

TGA Reference: RC-2021-RN-01276-1

Australian Register of Therapeutic Goods (ARTG): 218791

Advisory grade TGA: Class II

(Class II recall action occurs when the product deficiency could cause illness, injury or result in mistreatment, but are not class I.)

ANZDACC Advisory Grade: Routine

ANZCDACC Product Defect Correction and Implant Hazard Alert June 2021

Description:

Medtronic has identified that Reveal LINQ™ with TruRhythm™ Insertable Cardiac Monitors (ICMs) that undergo a partial electrical reset, appear to be programmed "ON," but are no longer able to detect and report Brady and Pause events.

A partial electrical reset is normal behaviour that can occur when the device detects a possible issue with the device software. However, an error in the partial electrical reset implementation is causing this unintended behaviour.

Medtronic's complaint data suggests the majority of electrical resets were associated with Electromagnetic Interference (EMI) due to cardioversion or electrocautery.

Potential harms include those associated with the risk of a delayed medical intervention or missed diagnosis for Brady and Pause events, and an explant procedure.

If a partial electrical reset occurs, CareLink™, Model 2090 and Encore programmer software and Reveal LINQ™ Mobile Manager (LMM) will continue to indicate that detection parameters are "ON;" however, Brady and Pause events will not be automatically collected.

The Patient Assistant (Patient Activator) will continue to function to manually trigger ECG collection, store the tracing, and mark symptoms.

Tachy and AT/AF detections are not affected by a partial electrical reset.

Medtronic's analysis of those Reveal LINQ™ ICMs enrolled on CareLink™ across Australia identified 2 devices impacted by this issue as of the 10 May 2021. For those clinicians with identified patients, a supplemental letter was sent. If you have not received a supplemental letter, then none of your patients who are actively transmitting on CareLink™ were identified as having a recorded electrical reset event during Medtronic's investigation.

Product Defect Correction:

Future Software Update Availability: Medtronic is developing a programmer-delivered software update to correct this issue for Reveal LINQ™ with TruRhythm™ ICMs currently

implanted or in distribution. Anticipated availability is early calendar year 2022. Medtronic representatives will inform you of the availability and work with you to install the software onto clinic and hospital 2090 and Encore programmers. LMM application software will be unable to deliver the software update for this issue. In order for patients with Reveal LINQ™ with TruRhythm™ ICMs to receive the update, the device will need to be interrogated with an updated 2090 or Encore programmer.

Number of devices affected in Australia and New Zealand:

Not supplied at time of publication.

Presentation:

- Following a partial electrical reset, there may be no stored ECG recorded following an episode of bradycardia which met the programmed detection criteria, if the patient did not record it with the Patient Assistant (Patient Activator).
- During in person or remote follow-up: If a device experiences an electrical reset, clinicians will be informed via programmer pop-up or CareLink display message.

Rate of occurrence:

Medtronic estimates that 0.049% of Reveal LINQ™ with TruRhythm™ ICMs have experienced a partial electrical reset resulting in the inability to detect Brady and Pause events. While there is a potential for underreporting due to lack of awareness that an electrical reset has occurred, there have been zero (0) serious or permanent harms or deaths reported as a result of this issue.

All Reveal LINQ™ with TruRhythm™ ICMs currently in distribution are susceptible to this issue. Through 10 May 2021, Medtronic has received 87 complaints related to an electrical reset. The projected rate of a Reveal LINQ™ with TruRhythm™ ICM experiencing a partial electrical reset that results in the inability to detect Brady and Pause events is 0.056% at 36 months.

Recommendation:

1. If an electrical reset has never occurred, all detection criteria are being monitored and recorded as programmed. Continue with normal follow-up per local clinic protocols for these patients.
2. All patients, including those on CareLink™, should be carefully monitored for reports of an electrical reset condition.
    1. Actively monitor for any electrical reset pop-up or Carelink™ display messages at each patient follow-up, and contact Medtronic Technical Services should you receive an alert. Note: Once cleared, electrical reset notifications are no longer accessible
3. If you need to determine whether an electrical reset has occurred:
    1. Review the Brady lifetime episode counter from the most recent session report (CareLink™ or in-office). If a report is not available, consider scheduling a follow-up for each patient being monitored for Brady or Pause events. Review the Brady lifetime episode counter:

1. If the lifetime count for Brady is ≥ 1, a partial electrical reset has not occurred.
2. If the lifetime count for Brady is zero, and the Brady detection parameter indicates it is "ON," a partial electrical reset may have occurred. Contact your local Medtronic representative for assistance verifying reset.

2. Patients with a confirmed partial electrical reset:
    1. ANZCDACC and Medtronic, recommends against device replacement for patients being monitoring for Tachy or AT/AF; continue normal patient follow-up.
    2. If patients require monitoring for Brady and/or Pause events, and it is not acceptable to wait for the software update to become available, or rely on patient activated events only (as patient activated recordings are unaffected by this issue), consider device replacement. Recognize that exposure to EMI could introduce this issue for new device implants that occur before the manufacturing update is implemented.

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