Update Sept 2021:
This is the same alert (RC-2019-RN-01641-1) which has been reclassified by the TGA to an "implant hazard alert". No change from previous advice or risk: Latent shorting mechanism resulting from lithium plating between annode and cathode causing rapid battery depletion

Updated 4 Feb 2021 **(see purple text below).**

Link to previous 2019 notification: ANZCDACC Product Notification Notice 22 November 2019

Device:

Product	**ARTG**
Claria MRI™ CRT-Ds	280183; 280186 ; 281607; 281608
Amplia MRI™ CRT-Ds	280182; 280184 ; 281606
Compia MRI™ CRT-Ds	280181 ; 280185
Viva™ CRT-Ds	203210 ; 203211; 203212; 203840; 219221; 219222; 230204
Brava™ CRT-Ds	219220
Visia AF™ ICDs	280351; 280352; 280353
Visia AF MRI™ ICDs	280354; 280355; 282960; 282961
Evera™ ICDs	206324; 208024; 208025; 208026; 208027; 208028; 208029; 208030
Evera MRI™ ICDs	208030; 230019; 230020; 230021; 230022; 281609; 281610; 281611; 281612
Primo MRI™ ICDs	312640 ; 312641; 312642; 312643
Mirro MRI ™ ICDs	Not sold in Australia

TGA Reference: RC-2019-RN-01641-1

Advisory grade TGA: Implant Hazard Alert

ANZDACC Advisory Grade: Routine

Number of CIEDs affected in Australia and New Zealand: TBA

Description:

Medtronic identified a rare failure mechanism in the battery design of specific implantable cardioverter defibrillator (ICD) and cardiac resynchronization therapy defibrillator (CRT-D) models that could result in rapid battery depletion. The rapid depletion is caused by a latent

shorting mechanism resulting from lithium plating between the anode and cathode elements of the battery. If lithium bridges between a positive (cathode) and a negative (anode) element in the battery, an internal short will develop and the battery will deplete rapidly. If this occurs, the device may not meet expected longevity or provide at least three months of device operation between the Recommended Replacement Time (RRT) and End of Service (EOS).

In response to this potential issue, Medtronic implemented battery design enhancements. All products currently in distribution contain the battery enhancement.

All events have occurred during the mid-portion of device life; typically, 1-4 years after implant. Note, there have been no reports of this issue occurring after RRT has triggered under normal conditions. Therefore, when a device reaches RRT based on its programmed settings and use conditions, the device is likely performing as expected and time between RRT and EOS should be as labelled.

Risk:

Approximately 339 900 devices susceptible to this issue are estimated to be active worldwide. Through January 2021, confirmed events (observed rate 0.07% - previously estimated at 0.04%) have involved a rapid drop in battery voltage ranging from days to months, with unexpected RRT as one of the primary reported observations. For those devices in which RRT triggered earlier than expected, the median time from RRT to the EOS observation was 14 days. In a small number of cases, no output/no telemetry was reported prior to device replacement. Medtronic projects approximately 0.22% of the affected device population may experience this issue during their service life.

The rapid depletion is caused by a latent shorting mechanism involving lithium plating, resulting from a thermal gradient between the anode and cathode components of the battery. Devices with higher pacing outputs and high pacing percentages (e.g. CRT-D devices) 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**. Importantly, the probability of this issue developing is constant after approximately three years of service time.

There have been no reports of permanent harm to patients as a result of this issue.

Presentation:

Patients may present with symptoms related to pacemaker failure from bradycardia, loss of CRT pacing or untreated ventricular arrhythmia.

The battery longevity estimates, and voltage measurement may show a rapid unexpected drop in between routine follow up. This may also present as a low battery voltage alert on remote monitoring or as the inability to interrogate the device / transmit data.

Advice:

1. Identify. Identify the patients in your clinic who may be affected by this issue by searching their serial number at the following website: https://wwwp.medtronic.com/productperformance/
2. Evaluate risk*. Patients who are pacemaker dependent, those with secondary prevention indications and/or those who have experienced previous therapy for ventricular arrhythmias are at an increased risk. Those with a higher projected battery life (9-12 years) in the first 3 years following implant are at a higher risk of the rapid drop in battery voltage.

Additionally, those who are unable to hear the device alarm and are not on remote monitoring are also at an increased risk.

Medtronic and ANZCDACC do not recommend prophylactic replacement.

3. Follow-Up.
   a) Where possible, add these patients onto remote monitoring, especially those at higher risk*.
   b) During the next follow-up visit, demonstrate the low battery alert tone and confirm whether the patient can hear it or not. Ensure this alert is turned on in the device (shipped On with high urgency toning for low battery voltage indicator). If they can't hear their device alert, remote monitoring is highly recommended.
   c) Remind patients to promptly contact their physician if alert tones are heard from their ICD as this may be an indication of impending battery failure.
   d) Consider 3 monthly follow up for those who will not be on remote monitoring, can't hear the device alert tones and are at higher risk*.
   e) At each follow up, document the battery measurements and longevity estimates. Monitor for unexpected changes and contact a Medtronic representative immediately if there are any concerns or the described behaviour is observed. Further device analysis may be warranted to determine if immediate replacement is necessary.
   f) Respond to device alert tones as a matter of urgency to minimise the risk of battery failure.
   g) If there is evidence of rapid battery voltage drop, patients may need to have their devices replaced urgently as device failure may lead to intended therapy not being delivered.

4. If unexpected RRT is observed; prompt replacement of the device should occur according to the underlying clinical situation of the patient.
   a) For non-pacing dependent patients or for primary prevention ICD patients, replacement within 1 week of an unexpected RRT notification.
   b) For pacing dependent patients, immediate replacement is recommended following an unexpected RRT notification.

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