ANZCDACC Safety Alert Notice March 21st 2021

Device:
Subset Biontronik : Ilesto™, Inventra™, Iperia™, Itrevia™, Ilivia™, Intica™, Intica Neo™ ICDs and CRT-Ds implanted since 2013

TGA Reference: RC-2021-RN-00667-1

Advisory grade TGA: Class I

(Class I recall action occurs when the product deficiency is potentially life threatening or could cause serious risk to health)

ANZDACC Advisory Grade: Routine

Number of CIEDs affected in Australia and New Zealand:

Australia Approximately 2000

New Zealand Approximately 500

Description:

There is an increased likelihood of premature battery depletion in a subset of devices of the following models of Implantable Cardioverter Defibrillators and CRT-D distributed since 2013:

Ilesto, Inventra, Iperia, Itrevia, Ilivia, Intica, Intica Neo ICDs and CRT-Ds

The premature battery depletion is due to lithium plating in the battery which leads to rapid depletion of the battery. Analyses of returned devices by Biotronik has revealed the potential for a certain mode of lithium deposition on the anodes of the batteries, known as lithium plating, to occur. Lithium plating is a very rare phenomenon that may cause a battery drain at a higher rate than under typical use. The observed onset for devices experiencing this issue is about 2 years with a failure rate of 0.0012%. The projected failure rate at 5 years after implantation is estimated to be 0.17%. The current observed rate of confirmed premature battery depletion events is 0.1% of all devices susceptible to this issue.

Risk:

There have been no serious injuries or deaths reported currently. There is a very low risk that premature battery depletion could result in sudden loss of high-voltage or pacing therapy. Biotronik analyses of returned devices indicate that the risk for loss of high-voltage therapy is 0.0069% and the risk for loss of pacing therapy is 0.0015% on a per month basis. Due to the identified issue, the interval between the elective replacement indicator (“ERI”) being triggered and the loss of ability to provide therapy may be shorter than expected. Biotronik analyses demonstrate, that for impacted devices, the median interval from ERI to loss of high voltage therapy was 58 days. The median

interval until loss of pacing therapy was 6 months. Defibrillation shocks and multiple capacitor reformations can accelerate the plating process.

Presentation:

Accelerated depletion can be detected if an unexpected decrease in remaining battery capacity is observed between remote/in-clinic follow-ups. Progression of accelerated depletion eventually produces a battery status replacement indicator (ERI) which is detectable through remote monitoring, or in-clinic follow-up. Loss of pacing in CRT-D could present as worsening heart failure or syncope in pacing dependent and loss of defibrillation capacity could present as SCD.

Advice:

We do not advise prophylactic device replacement for functioning devices but ongoing monitoring as follows:

Biotronik's programmer and Home Monitoring system have a battery depletion detector. This feature allows a battery depletion, including any premature depletion, to be detected early and displayed by an ERI during in-office follow-up, or via daily remote monitoring using Home Monitoring. Where possible patients should be placed on Home Monitoring. Home Monitoring provides timely ERI warnings to reduce the risk of sudden loss of therapy. Please note that unresponsive devices or those that are not transmitting data may be experiencing this advisory. Biotronik will provide CardioMessenger devices free of charge to monitor implants affected by this advisory

Otherwise, continue with the standard patient follow-up schedule in office. During follow-ups: Verify the status of the device and battery during in-office or Home Monitoring follow-ups

If there is an unexpected ERI notification for a device that is subject to this advisory, a timely replacement should be considered based on the patient's underlying conditions:

For patients that are not pacemaker dependent, or patients with a primary prevention ICD, device replacement within one week after ERI notification is recommended.

For pacemaker dependent patients, replacement of the device is recommended immediately after ERI notification.

Biotronik is working on a software update which reduces the probability of batteries developing this form of lithium plating and as such mitigate premature depletion.

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