ANZCDACC Advisory Notice 7th September 2017

Device: LivaNova (Formerly Sorin Group) Platinium™ ICDs and CRTDs

TGA Reference: RC-2017-RN-00913-1

Advisory grade TGA: TBA

ANZDACC Advisory Grade: Routine

Description: There are 2 issues in this advisory which are as follows;

1. An electronic component used in a specific hardware version of Platinium devices has been found to be sensitive to electrostatic discharge (ESD) potentially generated during the implant surgery. The discharge can trigger overconsumption of current, leading to reduced device longevity (5% longevity loss per month). The overconsumption is detectable upon interrogation of the device during follow-up visit and it can be stopped if the device is reset in clinic by a LivaNova representative. Although the overconsumption is stopped after this reset, the residual longevity displayed by the programmer may temporarily be underestimated.
2. If a device is exposed to a MRI's magnetic field, overconsumption can occur and the battery voltage will decrease to 2.80V. At this level, the device remaining longevity is 25% of the initial longevity.

Neither of the issues described above affect the therapeutic functions of the device. All sensing, pacing and shock delivery capabilities will remain functional.

Since 18th of May 2017 Livanova has stopped releasing the devices which are potentially affected and Platinium devices with a new version of this electronic component have been made available.

A software patch has been created and has either been uploaded to programmers or in the process of being uploaded. Devices are automatically upgraded upon device interrogation. This patch is reported to eliminate the risk of premature battery depletion as a result of an MRI scan. The patch does not however eliminate the risk premature battery depletion as a result of ESD if this occurs.

Risk: No permanent injury or death has occurred as a result of these issues.

As of 16th of June 2017 there have been 18 reports of overconsumption associated with ESD exposure at implant (0.19% of alert devices).

There are 4 reports attributed to MRI scans. It was not reported however how many patients with the alert devices had MRI scans so an accurate risk cannot be calculated. All 4 cases reported after MRI led to premature device replacement. 1 of these patients reported feeling a sensation of heat in the area of the device.

Number of devices affected in Australia and New Zealand: 8 devices affected in Australia and 0 in New Zealand. All the implanting physicians of these affected devices have been made aware of the issues and all devices are accounted for.

Presentation: Upon interrogation of the affected device, the warning "(A3) Technical issue" is displayed.

Advice:

- Standard follow up as per physician routine practice (increased follow up is not recommended)
- If the "(A3) Technical issue" is displayed, contact your LivaNova representative who will organise the reset of the device. A second reset may be necessary in order to correct the estimation of the residual longevity displayed by the programmer.

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