ANZCDACC Advisory Notice 2nd August 2018

Device:
Limited subset of Platinium ICD and CRTD
(Platinium VR 1210, Platinium VR 1240, Platinium DR 1510, Platinium DR 1540, Platinium CRT-D 1711, Platinium CRT-D 1741, Platinium SONR CRT-D 1811, Platinium SONR CRT-D 1841.)
Serial numbers of affected devices in Australia: 629DL05C, 650DL087, 638DD149, 639DD140, 639DD15E, 624DF096

TGA Reference: RC-2018-RN-00929-1
Australian Register of Therapeutic Goods (ARTG): 282817, 282816, 282818, 282819, 282820, 282821, 282822, 282823 respectively.

Advisory grade TGA: TBA

ANZDACC Advisory Grade: Semi-Urgent

Description:
On a subset of Platinium ICD and CRTD devices, a specific hardware configuration was identified as potentially defective over time, leading to overconsumption, immediately followed by loss of pacing and sensing capabilities in all cavities. As a result of the loss of sensing capability, the device can't identify an arrhythmia that would require a defibrillation shock therapy.

MicroPort CRM has not identified a specific time frame during which the problem is more likely to occur. Nevertheless, all five (5) events were detected within the first year after implantation. In only one (1) case, the patient reported feeling "weakness". All five devices were replaced.

The time between the first alert and complete device failure is unknown. In one (1) case this may have been as long as 4 months. The defibrillation system is potentially ineffective however from the time of the first alert.

Number of devices affected in Australia and New Zealand:
Australia: 6; New Zealand: 0

Presentation:
If one or more of the items listed below is/are observed during follow-up or via remote monitoring, then hardware failure may have occurred. *

1. The warning "Technical issue" indicates that overconsumption was detected. A steep decrease of the battery voltage may be visible on the battery curve
2. Warnings on high lead impedances in all cavities
3. Loss of sensing capability will result in flat EGMs and 100% pacing in the statistics.

Note: There is no audible or vibratory alert on Platinium ICD and CRT-D devices.

In the event of device failure patients may also present with the signs and symptoms resulting from bradycardia or untreated tachyarrhythmias including presyncope, syncope, serious injury and sudden death.

Rate of occurrence:
As of 30th of June 2018, MicroPort CRM has received five (5) reports on Platinium devices about this issue out of the 1637 released for distribution that may be subject to the issue (0.31%).

Recommendation:

1. Perform patient follow-up every three months. Pay particular attention to the battery status, the occurrence of system warnings, lead impedance and satisfactory sensing and pacing thresholds.
2. If one or more of the 3 items listed above* are observed then hardware failure may have occurred. Without delay, please contact your MicroPort CRM representative.
3. If not already done so, enrol patients on remote monitoring and verify that the "*RF for Remote Monitoring*" setting and the *"high lead impedance and continuity alerts"* are programmed ON.
    a. System alert checks are automatically performed daily. Integrity alerts cannot be deactivated, such as the overconsumption alert and the battery depletion alert. Clinics will automatically receive notification of such alerts overnight.
4. On the SmartView remote monitoring website, verify that the *"Monitoring Interruption"* notification is activated (in the "Clinic Notification Settings" tab), so that the clinic receives a notification in case of interruption in the communication between the server and the Platinium device for 14 consecutive days.
5. For patients currently enrolled in SmartView™, remind them of the importance of using remote monitoring.

It is not generally recommended physicians prophylactically replace the Platinium device. However, special consideration should be given in the following circumstances:

1. If patients are unable or unwilling to be on remote monitoring.
2. For pacing dependent patients or those with high ventricular arrhythmia burden the relative risk of device failure versus that associated with device replacement should be assessed on an individual patient basis.
3. In case of a surgical procedure involving the patient's defibrillation system, already scheduled for other causes than the one related to the Platinium device (*e.g.* lead revision), it is recommended physicians prophylactically replace the Platinium device, if subject to this advisory, during the same procedure.

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