ANZCDACC Advisory Expansion June 2021

Device: Boston Scientific ACCOLADE, PROPONENT, ESSENTIO & ALTRUA 2 pacemakers and VISIONIST and VALITUDE CRTPs.

Model numbers: L100, L101, L110, L111, L121, L131, L200, L201, L209, L210, L211, L231, L300, L301, L310, L311, L321, L331, S701, S702, S722, U125, U128, U225, U226, U228.

TGA Reference: RC-2021-RN-01304-1
Australian Register of Therapeutic Goods (ARTG): 280319, 280316, 280315, 279330, 279331 and 279332

Advisory grade TGA: Class I
(Class I recall action occurs when the product deficiency is potentially life-threatening or could cause a serious risk of health).

ANZDACC Advisory Grade: Routine

Description:
In September 2018, Boston Scientific advised physicians about a population of pacemakers and CRT-Ps (collectively pacemakers) exhibiting hydrogen-induced accelerated battery depletion. Since that time, additional confirmed depletion events have been reported and described within Boston Scientific's Product Performance Report (PPR) for both the 2018 advisory and the non-advisory population. Latent release of small amounts of hydrogen within the pacemaker may cause a low voltage capacitor to become electrically compromised over time resulting in accelerated battery depletion and associated progression of displayed battery depletion indicators. Boston Scientific's ongoing investigation has determined that any pacemaker built with a specific, discontinued low voltage capacitor is potentially susceptible to this behaviour. Therefore, Boston Scientific is expanding the advisory population to make customers aware of all potentially susceptible pacemakers to this behaviour. The production of pacemakers from these advisory populations ceased in November 2017, and therefore they are no longer available for implantation. Pacemakers built with contemporary low voltage capacitors have not exhibited this behaviour and are not included in this expansion.

Number of devices affected in Australia and New Zealand:
1100

Presentation:
Patients are most likely to present with an unexpected drop in estimated battery longevity as compared to the previous check.

Rate of occurrence:
Ongoing monitoring, aligned with labelled instructions for use, has continued to validate the high degree of detectability and low risk of life-threatening harm due to

this behaviour. To date, 99.5% of the total 1,776 pacemakers confirmed to have exhibited this behaviour were replaced before the battery reached a depleted state. The likelihood of this behaviour occurring in the 2021 expanded population is an order of magnitude lower which contributes to a proportionally lower potential for life-threatening harm of a battery reaching a depleted state: 1 in 500,000 at 5 years for the approximate 2,100 active devices in the 2018 population and 1 in 5,000,000 at 5 years for the approximate 125,000 active devices in the expanded 2021 population. As communicated in the 2018 advisory, the most common clinical impact of this behaviour is early device replacement. There have been no reported deaths associated with this behaviour.

Recommendation:

1. Follow-up interval. Per labelling, perform a system follow-up via remote or in-office interrogation at least every 12 months until One-Year-Remaining and then 3 months thereafter until replacement is indicated. Note: this is a change to the recommendations originally communicated for the 2018 population.
2. During follow-ups. Assess battery for accelerated depletion by comparing the device's 'Approximate Time to Explant' between two follow-up intervals. If the change in longevity significantly exceeds the interval between follow-ups, the device may be exhibiting accelerated depletion. Contact Boston Scientific Technical Services for assistance verifying if there is accelerated depletion or if the observed change in longevity remaining is expected based on changes in device power usage.
3. Replacement. Replace and return to Boston Scientific any affected pacemakers suspected of exhibiting accelerated battery depletion within 90 days of the Explant battery status indicator. Alternatively, Boston Scientific Technical Services can provide a recommended replacement interval specific to an individual device by using data from the programmer or LATITUDE. Prophylactic replacement is not recommended for pacemakers with normal battery consumption as the risk of surgical replacement outweighs the risk of accelerated battery 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