Date: June 3, 2021

Canadian Heart Rhythm Society
Device Committee

ADVISORY: Boston Scientific ACCOLADE, PROPONENT, ESSENTIO, and ALTRUA 2 pacemakers and VISIONIST and VALITUDE cardiac resynchronization therapy pacemakers (CRT-Ps)

Nature of the Advisory:

Boston Scientific has observed malfunctions in a subset of all ACCOLADE family devices manufactured in between November 2016 and December 2017. Affected devices may exhibit hydrogen-induced accelerated battery depletion, whereby latent release of small amounts of hydrogen within the pacemaker may cause a low voltage capacitor to become electrically compromised over time. This results in accelerated battery depletion leading to a need for early device replacement.

Scope of the problem:

The advisory comprises approximately 125,000 active ACCOLADE family pacemakers and CRT-Ps. Approximately **1600** devices were implanted in Canada. The most common clinical impact of this behavior is early device replacement. **For the 2018 advisory subset the observed malfunction rate is 11.3% at 5 years, with an observed malfunction rate of 1.3% at 5 years for the expanded 2021 advisory subset.** To date, 99.5% of the total 1,776 pacemakers confirmed to have exhibited this behavior were replaced before the battery reached a depleted state. The production of pacemakers from these advisory populations ceased in November 2017.

Beginning in 2018 a polymer material was added within the pulse generator to mitigate the hydrogen-induced accelerated battery depletion, and improvements were made to the liner components in 2021. Over 800,000 pacemakers built with contemporary low voltage capacitors have not exhibited this behavior.

There have been no reported deaths associated with this behavior.

Response of the CHRS Device Committee:

- As part of this formal advisory, we recommend that patients be notified about this issue
- All patients should be enrolled on the LATITUDE home monitoring system where possible. This recommendation applies to all patients with CIEDs but is especially important in this advisory patient group.
- Patients should be followed according to their usual schedule, remotely or in person.
    - Recommended follow-up via remote or in-office interrogation should occur at least every 12 months until the device reaches One-Year-Remaining and then follow-up every three (3) months thereafter until replacement is indicated.
- During follow-up, assess for accelerated depletion by comparing the device's "Approximate Time to Explant" with the previous estimate. Accelerated depletion may be occurring if the change in longevity significantly exceeds the interval between follow-ups. Boston Scientific Technical Services may be contacted to verify accelerated depletion.
- In cases where accelerated battery depletion is observed then the follow-up schedule should be intensified as the device approaches ERI, and replacement should occur within 90 days of the Explant battery status indicator.
- Prophylactic device generator replacement is not recommended.
- The CHRS device committee may update these recommendations should more data become available

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