Date: June 3, 2021

Canadian Heart Rhythm Society
Device Committee

ADVISORY: INGENIO, VITALIO, and ADVANTIO pacemakers and INLIVEN, INTUA, and INVIVE cardiac resynchronization therapy pacemakers (CRT-Ps)

Nature of the Advisory:

Boston Scientific has observed malfunctions in a subset of INGENIO family devices manufactured in between 2011 and 2017. Affected dual chamber INGENIO family EL pacemakers and CRT-Ps may transition to Safety Mode during interrogation attempts by either a programmer or a LATITUDE communicator. This occurs when the battery exhibits high internal impedance, e.g. later in the device life-cycle but prior to reaching the Explant battery indicator. This increased battery impedance may cause a device to exhibit transient voltage decreases during periods of high-power consumption associated with telemetry communication via a programmer or a LATITUDE communicator. If the battery voltage drops below a minimum threshold during communication attempts, the device will temporarily halt telemetry, and a system reset will be performed. If three (3) system resets occur within a 48-hour period, the device will immediately enter Safety Mode to maintain back-up pacing with pre-defined, non-programmable settings. Although therapy is still provided when a device is in Safety Mode, replacement is required as the device is non-programmable.

Scope of the problem:

The advisory comprises approximately 48,000 active dual chamber INGENIO family pacemakers and CRT-Ps built with the Extended Life (EL) battery. Approximately **6700** devices were implanted in Canada. It is estimated that **one third or more of these devices will experience Safety Mode prior to reaching explant battery indicator.** Safety Mode non-programmable parameters involve unipolar RV (or BiV) sensing/pacing at VVI @ 72.5 ppm with high output (5.0V at 1.0 ms). This may result in adverse effects via myopotential oversensing-associated pacing inhibition, loss of AV/VV synchrony, and phrenic nerve stimulation.

To date there have been no identified serious adverse clinical events in the 65 reports associated with this anomaly. The most common clinical event has been early device replacement. No deaths have been reported due to this problem.

Response of the CHRS Device Committee:

- As part of this formal advisory, we recommend that patients be notified about this issue
- Patients should be followed according to their usual schedule, preferably in person as interrogation of the device is the trigger for reverting into safety mode in susceptible situations. In clinic interrogation will allow immediate recognition of reversion to safety mode rather than it occurring at home if triggered by the remote monitoring system.
- Recommended follow-up 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.
- In cases where Safety Mode is reached or inability to interrogate the device or to transmit data is encountered, replacement should be performed:
  - Pacemaker-dependent patients should be **admitted to hospital and their pacemaker replacement performed promptly**
  - In non-pacemaker dependent patients, replacement should be planned **in ≤ 1 week**.
- Prophylactic device generator replacement is not routinely recommended but may be considered in certain high-risk individuals or ones where safety mode may not be well tolerated, and discussed with patients as part of the decision-making process. Patients in whom prophylactic replacement may be considered are those where device reset to Safety Mode may result in clinical deterioration via myopotential oversensing-associated pacing inhibition, loss of AV/VV synchrony, or phrenic nerve stimulation.
  - For dual chamber EL pacemakers, consider replacement with a longevity remaining of 4 years (or less).
  - For CRT-Ps, consider replacement with a longevity remaining of 3 years (or less).
- The CHRS device committee may update these recommendations should more data become available

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