Canadian Heart Rhythm Society
Société canadienne de rythmologie

Date: March 9th, 2021

Canadian Heart Rhythm Society
Device Committee

ADVISORY:
Potential premature battery depletion in a subset of Biotronik ICD and CRT-D devices (Idova, Iforia, Ilesto / Inventra, Iperia, Itrevia / Ilivia, Inlexa, Intica / Ilivia Neo, Intica Neo)

Nature of the Advisory:

Premature battery depletion has been seen in a subset of these devices, which have been in distribution since 2013. This results from "lithium plating" which represents a certain mode of lithium deposition on the anodes of the batteries causing a higher rate of battery drain. No serious injury or death have been reported so far.

Scope of the problem:

This premature battery depletion could result in loss of high-voltage or pacing therapy. Inability to interrogate or transmit data can also be a manifestation of this problem. The mean interval from ERI to EOS could be reduced to a median of **58 days for high-voltage devices and 6 months for low voltage devices**. The onset for devices to experience this issue is about 2 years with a failure rate estimated at **0.0012%** with a 5-year probability of **0.17%**. The estimated risk for loss of high-voltage therapy is 0.0069% and 0.0015% for loss of pacing capability.

In Canada, there were 24 affected devices on consignment and 388 devices implanted.

Response of the CHRS Device Committee:

- As part of this formal advisory, we recommend that patients be notified about this issue
- All non implanted affected devices should be removed from hospital inventory and returned to Biotronik
- Patients should be followed every 3 months remotely or in person
- No prophylactic replacement is recommended at this stage
- All patients should be enrolled on the Biotronik home monitoring system where possible. This recommendation applies to all patients with CIEDs, but is especially important in this advisory patient group
- In cases where unexpected ERI is reached or inability to interrogate the device or to transmit data is encountered, replacement should be performed:
    - For pacemaker dependant patients or secondary prevention patients, they should be **admitted and replacement performed promptly**
    - In non-pacemaker dependent patients, primary prevention with no previous therapy delivered, replacement should be planned **in ≤ 1 week**.
- BIOTRONIK is working on a software update that reduces the probability of batteries developing this form of lithium plating. Please follow-up with your Biotronik representative for an update on the release date
- The CHRS device committee may update these recommendations should more data become available.

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