November 4, 2018

Canadian Heart Rhythm Society
Device Committee

RE: ADVISORY: Battery Malfunction, Boston Scientific First Generation Model 101 SICD.

Nature of the Advisory:

This advisory describes a possible battery malfunction with the first-generation Boston Scientific Subcutaneous ICD (SICD) system. Due to a potential issue with the battery in these devices there is the possibility of more abrupt battery depletion than expected. This can lead to a shortened time between ERI notification and functional battery depletion.

The cause is a malfunction in one of the 3 cells that compose the battery pack which powers high voltage therapy in the device. This malfunction happens later in device life and can cause an earlier than expected ERI and can shorten the time from ERI to the device being unable to deliver shock therapy. This is **not** an issue in the second-generation EMBLEM SICD devices due to different battery sourcing in the newer devices.

If the battery depletes to ERI, the device delivers an audible tone. With the condition described in this advisory the time from the audible tone for ERI until loss of shock ability can be as short as 20 days rather than the usual 3 months. The depletion to ERI could also be sooner than expected based on usual battery depletion trends in the case of this malfunction.

The SICD delivers an audible alert for 3 reasons:

1 The Battery Depletion alert may have been triggered due to a rapid rate of battery depletion. The device may not be able to deliver therapy if this is the cause of the alert.

2 There may be a prolonged charge time noted with a capacitor reformation. If this happens the device may not be able to deliver therapy from that point forward.

3 The device has reached ERI without any Battery Depletion or Charge Time alert. In this case there may be as few as 20 days to end of service in case of a malfunctioning battery.

Because the audible alert could indicate any of the above issues, patients hearing the alert should have their device interrogated promptly upon noticing the alert. Recommendations for the urgency of that interrogation vary with patient risk.

Scope of the problem:

There are approximately 9000 1st generation SICD devices in current service worldwide, with 108 known to be in service in Canada. At this point there is a failure rate estimated at 2% at 5 years. No patients are known to have been harmed by this advisory, and the risk of harm varies with the risk of arrhythmias in individual patients. At this point all device failures have triggered the patient alert. There are no reports of the device developing complete battery failure without triggering the notification.

Response of the CHRS Device Committee:

- Patients with affected SICDs should be informed of this issue at an in person visit as soon as possible, preferably in less than 1 month.
- At that in person visit, patients should have their SICD interrogated to confirm proper function
- The patient alert tones should be demonstrated to the patients to ensure they are able to hear them
    - Patients should be notified to seek device interrogation promptly if they hear the tones
    - In some high-risk individuals (e.g. Secondary prevention with recent events) it may be appropriate to have them present to emergency if they hear the tone for monitoring until the device can be interrogated due to the possibility of device non-function if the prolonged charge time indicator is the cause of the alert
    - In lower risk patients, waiting until the next working day after hearing the tone to have the device checked may be safe
- As there is no remote monitoring available for these devices, in clinic 3 monthly follow-up is recommended
- In certain high-risk individuals device replacement may be indicated
    - E.g. frequent arrhythmic events, unable to hear device tones, planned prolonged travel, living remotely from medical facilities
- Additional recommendations will be provided as new information becomes available.

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