October 28th 2016

**Canadian Heart Rhythm Society**

**Device Committee**

**RE: ADVISORY: Battery Malfunction, St. Jude Medical NanoStim™ Leadless Cardiac Pacemaker System.**

**Nature of the Advisory:**

This advisory describes a battery malfunction with the St. NanoStim™ Leadless Cardiac Pacemaker (LCP) system. Affected LCP devices have been unable to communicate with the Programmer Link, not able to respond to the magnet, and are not able to provide pacing therapy. Destructive analysis of 3 returned products to date has identified that battery malfunction is the source of the problem, wherein the battery had reduced electrolyte availability causing dry cells with high battery resistance, resulting in a loss of pacemaker function.

**Scope of the problem:**

St. Jude Medical has received seven (7) complaints describing this phenomenon. In patients with devices affected by this issue, one had symptomatic bradycardia and the others were asymptomatic. No patient harm has been reported in patients with affected devices. The magnitude of this problem is unclear at present. A total of 1423 NanoStim leadless cardiac pacemaker devices have been inserted worldwide. All of the affected LCP devices had been implanted for at least 2 years. Of the total number of worldwide implants, 111 of these devices have been implanted for 2.5 years or longer.

There have been 99 devices implanted in Canada. 97 of these are in the NanoStim clinical study and 2 were implanted on a compassionate release basis.

**Response of the CHRS Device Committee:**

* Patients with affected LCPs 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 LCP interrogated in order to:
  + Establish whether the pacemaker can be communicated with
  + Assess the patient for pacemaker dependency
* This may include turning the pacing rate down to 30 beats per minute for up to 5 minutes to determine if a hemodynamically stable escape ventricular rate is present.
* PACEMAKER DEPENDENT patients should have a replacement pacemaker placed, with priority to patients who have had their devices more than 2 years
  + Where clinically appropriate, the LCP should be removed and returned to the manufacturer
  + If the LCP is not removed the new pacemaker lead should be inserted at a location remote to the LCP. The LCP should be programmed OFF after the new pacemaker is placed.
* Patients who are NOT PACEMAKER DEPENDENT should be followed monthly, especially if their devices have been implanted for 2 years or more. This should include assessment of an ECG signal or the pulse rate.
* Additional recommendations will be provided as new information becomes available.

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