December 20, 2017

Canadian Heart Rhythm Society
Device Committee

RE: ADVISORY –LivaNova DF-4 Ring Connection Advisory

Nature of the Advisory:

This advisory describes an issue with a small group of LivaNova Platinium ICDs and CRT-Ds with DF-4 ventricular lead connectors. In a small group of these devices there has been a failure of a weld to adhere the spring ring connector to the contact in the header in the device. This has allowed for intermittent changes in measured lead impedance and non-physiologic 'lead noise' to be detected by the device.

Scope of the problem:

This problem has been seen in 6 of nearly 7,000 devices implanted worldwide. In those patients the presentations were as follows:

3 presented with inappropriate lead noise
2 of these received inappropriate shocks due to this apparent lead noise
3 presented with fluctuating lead impedances noted on daily measurements

All of these problems occurred within the first 35 days post implant, with no problems developing after that time with follow-up for up to 3 years in some centers.

There are 27 devices implanted in Canada, with only 3 of them less than 35 days post implant (all from one center).

LivaNova Canada has notified all affected centers of this advisory and will be removing all non-implanted devices at risk of this failure from shelves. Devices manufactured after October 2017 use a different manufacturing technique and are not subject to this advisory.

Response of the CHRS Device Committee:

- We recommend that the interrogations of all devices in this advisory be reviewed to look for any possible fluctuations in lead impedance or possible detections of apparent lead noise in case subtle signs of this failure may have been missed or dismissed as transient lead issues.

- If device reviews show any evidence of the above conditions, the company should be notified immediately and consideration made for device deactivation to prevent inappropriate shocks if this failure is suspected.
- If a device has shown no evidence of this inappropriate noise or impedance fluctuations, and is more than 35 days post implant, then we recommend no specific measures and routine clinical follow-up.

LivaNova will be reaching out to all centers with affected implanted devices and those with devices on the shelves. If there are any questions regarding this advisory, please contact your local LivaNova representative.

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