November 5th, 2015

Canadian Heart Rhythm Society
Device Committee

RE: St-Jude Medical, Optisure™ Dual Coil HV Leads Model # LDA220, LDA220Q, LDA230Q, LDP220Q.

Nature of the Advisory:

St-Jude Medical has issued a "Dear Doctor Letter" on November 2nd 2015. The CHRS Device committee nucleus group had a teleconference on November 2nd with St-Jude medical to be informed of the scope of this advisory.

St-Jude Medical has issued the following statement: *"St. Jude Medical has become aware of a limited number of dual coil Optisure defibrillation leads that may have been compromised during the manufacturing process…St. Jude Medical identified that during the manufacturing process of a limited number of Optisure™ Dual Coil HV leads, a trim technique used to remove excess medical adhesive around the SVC shock coil may have introduced damage to the lead's insulation. St. Jude Medical is not aware of any clinical incidents related to this matter. Furthermore, an analysis of patients implanted with the subject leads that are being actively monitored via Merlin.net has shown that none of these patients have experienced any recorded electrical issues."*

Scope of the problem:

We were informed that only 2 leads were distributed in Canada. Only one has been implanted and the other lead was removed from the hospital inventory before implantation. Thus, the only two affected hospital received the official letter. The CHRS device committee felt important to inform all members since you may be asked by patients or your hospital administration or see information about that specific advisory. For your information, we are also posting the St-Jude Medical letter for reference.

Response of the CHRS Device Committee:

- The only patient in Canada affected by this advisory will be followed according to St-Jude Medical recommendations
- The CHRS device committee will follow with St-Jude Medical to monitor this issue
- No other action for the time being

François Philippon, MD, FRCPC, FHRS
Chair
Device Committee, CHRS

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Important Medical Device Information

Optisure™ Dual Coil HV Leads
Model # LDA220, LDA220Q, LDA230Q, LDP220Q

2 November 2015

Dear Customer,

St. Jude Medical has become aware of a limited number of dual coil Optisure defibrillation leads that may have been compromised during the manufacturing process. While the likelihood of an impact to your patients is very low, you are receiving this letter because you are currently managing one or more patients who have one of the impacted leads implanted or there may be affected inventory on your hospital shelf.

This letter and the attached model/serial number list will provide you with important information related to this limited group of Optisure leads and provide technical support as you plan the management of your patient(s) with the subject leads.

This document contains important information for the continued safe and proper use of your equipment

Please review the following information with all members of your staff who need to be aware of the contents of this communication. It is important to understand the implications of this communication.

While the risks associated with the manufacturing anomaly are very low, patient safety is the top priority of St. Jude Medical. We apologize for any inconvenience that this may cause you and your patients. If you have any questions or concerns, please do not hesitate to contact your local St. Jude Medical representative or St. Jude Medical's Technical Support 1-800-722-3774.

Sincerely,

Jeff Fecho
Vice President, Global Quality

IMPORTANT MEDICAL DEVICE INFORMATION

Issue description	Potential insulation damage at the interface of the termination sleeve and SVC shock coil in Optisure™ Dual Coil HV leads
Devices affected	A limited number of Optisure™ Dual Coil HV Leads model number LDA220, LDA220Q, LDA230Q, LDP220Q were impacted by the manufacturing anomaly.
Root cause	St. Jude Medical identified that during the manufacturing process of a limited number of Optisure™ Dual Coil HV leads, a trim technique used to remove excess medical adhesive around the SVC shock coil may have introduced damage to the lead's insulation.
Risk for the patient	St. Jude Medical is not aware of any clinical incidents related to this matter. Furthermore, an analysis of patients implanted with the subject leads that are being actively monitored via Merlin.net has shown that none of these patients have experienced any recorded electrical issues. According to our records the affected unit is associated with a device with the DynamicTx™ feature that provides additional protection to help ensure therapy delivery in the case of a compromised lead. The DynamicTx algorithm will prevent delivery of HV shocks into a damaged lead by automatically changing shock configuration and ensuring HV shock delivery. Alerts associated with this detection will be delivered to the patient (vibratory notifier) and may be delivered to the physician through alerts on the Merlin.net. Following detection of a potential lead issue, permanent reprogramming or replacement of chronically implanted defibrillation lead may be pursued.
Prevalence	The probability of a HV short resulting from the insulation is 0.32%.
Product removal	All inventory of the affected lead shall be immediately placed in quarantine and returned to St. Jude Medical.
Patient management	**Following discussions with our Medical Advisory Board, St. Jude Medical recommends the following:** **For these patients implanted with a potentially-impacted Optisure lead connected to a device with DynamicTx* technology, we recommend to review patient records and:** 1. Ensure DynamicTx is programmed "On." 2. Enroll these patients in Merlin.net 3. Monitor patients as normal, with no additional testing or follow-up needed. * Dynamic TX automatically adjusts shock configurations to ensure the delivery of high-voltage therapy even if an electrical short were to occur.

IMPORTANT MEDICAL DEVICE INFORMATION

Additional measures	**We recommend that your patient's next visit be on-site and a St. Jude Medical representative be present to apply an alert message in the Merlin™ Patient Care System**. When set up, this alert will enable Clinicians following patients with impacted subject leads to receive the alert message on the Merlin™ Patient Care System upon interrogation, ensuring that future caregivers assessing the diagnostics of these devices receive the latest information and be made aware of this corrective action. The programmer alert will direct clinicians to this letter for additional information. We believe such actions will further the ability of our clinician partners to most optimally manage the care of their patients.
For setting alert in Merlin™ Patient Care System	Please contact your local St. Jude Medical Representative
For further information	If you have any questions about this notification, please contact your local Sales Representative or St. Jude Medical Technical Services at 1-800-722-3774.