ST. JUDE MEDICAL

Important Medical Device Advisory
Optisure™ Dual Coil Defibrillation Leads
Models: LDA220, LDA220Q, LDA230Q, LDP220Q

November 3, 2015

Dear Doctor,

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 any impact to your patients is very low, you are receiving this letter because our records indicate you are currently managing one or more patients who have one of the impacted leads implanted.

This letter and the attached patient 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.

Summary:

St. Jude Medical identified that during the manufacturing process of a limited number of Optisure leads, a trim technique to remove excess medical adhesive around the SVC shock coil may have introduced damage to the lead's insulation.

A thorough investigation has determined the probability of a lead malfunction as a result of this trim technique is very low. A total of 447 leads subjected to the trim technique were distributed globally. Of those, 278 were implanted in the United States. St. Jude Medical is not aware of any adverse clinical events 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.

Recommendations:

Following discussions with our Medical Advisory Board, St. Jude Medical recommends the following actions depending on the device the affected patients have implanted. According to our records the vast majority of patients with the subject leads have devices with the DynamicTx™ feature that provides additional protection to help ensure therapy delivery in the case of a compromised lead. We have included a patient list with this letter that identifies your affected patient(s) and whether or not they have the DynamicTx feature active based on an analysis of our Merlin.net database.

For these patients implanted with a potentially-impacted Optisure lead connected to a device WITH DynamicTx™* technology, we recommend:

- Review the Patient Records:

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.

For patients implanted with a potentially-impacted Optisure lead connected to a device WITHOUT DynamicTx™* technology we recommend:

1. Enroll these patients in our Merlin.net network
2. Where clinically appropriate, consider turning off the SVC coil (select RV-to-Can vector)
3. If dual coil shocking configuration is desired, consider performing a high voltage test using maximum energy.
    a. If shock delivery is normal - no additional testing is required
    b. If shock delivery identifies a short circuit – consider lead replacement

* DynamicTx™ automatically adjusts shock configurations to ensure the delivery of high-voltage therapy even if an electrical short were to occur. The attached Patient List indicates which devices incorporate the DynamicTx feature.

We recommend at your patient's next follow-up visit a St. Jude Medical representative be present to program an alert message into the implanted device. This will provide clinicians following patients with impacted subject lead an alert message on the Merlin™ Programmer 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.

While the risks associated with the identified trim technique are very low, patient safety is the utmost priority of St. Jude Medical. If you have any questions about this advisory, please contact your local Sales Representative or St. Jude Medical Technical Services at 800-722-3774.

We thank you for your continued support.

Yours Sincerely,

Jeff Fecho
Vice President Global Quality