

Urgent Medical Device Recall and Hazard Alert

TGA Ref: RC-2015-RN-01086-1

Optisure™ Dual Coil Defibrillation Leads

Models: LDA220Q/52, LDA220Q/58, LDA220Q/65 and LDP 220Q/58

6 November 2015

Dear Doctor,

St. Jude Medical has become aware of a small number of Optisure™ Dual Coil 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 implanted or are currently managing one or more patients who have one of the impacted leads implanted.

This letter and the attached list of affected leads will provide you with important information related to this very limited group of Optisure™ leads and provide technical support as you plan the management of your patient(s) with the subject leads. St. Jude Medical identified that during the manufacturing process, a trim technique to remove excess medical adhesive around the SVC shock coil may have introduced damage to the lead's insulation.

**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 identified trim technique are very low, patient safety is the utmost 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 Rupa Kirubakaran, Product Sales Manager on (02) 9936 1214.

Sincerely,



Jeff Fecho
Vice President, Global Quality

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Issue description	Potential insulation damage at the interface of the termination sleeve and SVC shock coil in Optisure™ Dual Coil Defibrillation leads.
Devices affected	A total of 447 Optisure™ Dual Coil Defibrillation Lead Models LDA220Q/52, LDA220Q/58, LDA220Q/65 and LDP220Q/58 were impacted by the manufacturing process. Of these, 19 affected leads have been implanted and 2 are in hospital inventory in Australia.
Root cause	During the manufacturing process of a limited number of Optisure™ Dual Coil Defibrillation leads, a trim technique to remove excess medical adhesive around the SVC shock coil may have introduced damage to the lead's insulation.
Risk for the patient	<p>St. Jude Medical is not aware of any complaints or clinical incidents related to this matter.</p> <p>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.</p> <p>In the event that a subject Optisure™ lead is connected to a device without Dynamic Tx* technology, there is the potential for lead damage to result in loss of defibrillation therapy during attempted shock delivery when programmed to the RV to SVC and can high voltage therapy configuration.</p>
Prevalence	Probability of a high voltage short resulting from the insulation damage is 0.32%.
Product removal	All inventory of the limited number of affected leads subject to this advisory shall be immediately placed in quarantine and returned to St. Jude Medical. Refer to the serial number list provided.
Patient management	<p>Following discussions with our Medical Advisory Board, St. Jude Medical recommends the following actions depending on the implanted ICD/CRTD device the patient has implanted:</p> <ul style="list-style-type: none"> • For patients implanted with a potentially-impacted Optisure™ lead connected to a device with DynamicTx* technology programmed "On", if a short circuit is detected the device will automatically change the shock configuration by vector switch to enable high voltage delivery. For those patients, we recommend: <ol style="list-style-type: none"> 1. To review patient records 2. Ensure DynamicTx* is programmed "On" 3. Enrol these patients in Merlin.net, if available 4. Monitor patients as normal • For patients implanted with a potentially-impacted Optisure™ lead connected to a device WITHOUT DynamicTx*, the device will check for high current during HV delivery and abort the shock in the event of Over Current Detection.

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<p>Patient management (continued)</p>	<p>For those patients, we recommend:</p> <ol style="list-style-type: none"> 1. To review patient records 2. Enrol these patients in the Merlin.net network, if available 3. Where clinically appropriate, consider turning off the SVC coil (select RV-to-Can vector) 4. If dual coil shocking configuration is desired, consider performing a high voltage test using max. energy. <ol style="list-style-type: none"> a. If shock delivery is normal - no additional testing is required b. If shock delivery identifies a short circuit – consider lead replacement <p>* DynamicTx automatically adjusts shock configurations to ensure the delivery of high-voltage therapy even if an electrical short were to occur.</p> <ul style="list-style-type: none"> • For patients implanted with a potentially-impacted Optisure™ lead connected to a competitive device, we recommend: <ol style="list-style-type: none"> 1. To review patient records 2. Enrol these patients on remote monitoring system, if available 3. In case where competitive device does not switch vector in case of over current detection, we recommend: <ol style="list-style-type: none"> 3.1 Where clinically appropriate, consider turning off the SVC coil (select RV-to-Can vector if available) 3.2 If dual coil shocking configuration is desired, consider performing a high voltage test using max. energy <ol style="list-style-type: none"> a) If shock delivery is normal - no additional testing is required b) If shock delivery identifies a short circuit – consider lead replacement
<p>Additional Measures</p>	<p>For patients implanted with St. Jude Medical ICD/CRTD we recommend at your patient’s next follow up visit a St. Jude Medical representative be present to program an alert message in the implanted device.</p> <p>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 Programmer upon interrogation. This ensures that future caregivers assessing the diagnostics of these devices receive the latest information and are made aware of this corrective action.</p> <p>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.</p>
<p>For setting alert in Merlin™ Patient Care System</p>	<p>Please contact your local St. Jude Medical Representative.</p>
<p>For further information</p>	<p>If you have any questions about this notification, please contact your local St. Jude Medical Representative or Rupa Kirubakaran, Product Sales Manager on (02) 9936 1214.</p>