

Important Medical Device Advisory - Update
Optisure™ Dual Coil Defibrillation Leads
Models: LDA220, LDA220Q, LDA230Q, LDP220Q
See the attached List for Your Affected Patients

January 22, 2016

Dear Doctor,

On November 3, 2015, St. Jude Medical issued a voluntary Medical Device Advisory, which the United States Food and Drug Administration (FDA) has subsequently determined to be a Class I advisory, to clinicians following patients with a specific subset of recently implanted Optisure Dual Coil Defibrillation leads. This update is being issued to expand upon the information provided in the November advisory.

St. Jude Medical has received no reports of lead failure or patient injury related to this issue and no new patients in your practice are subject to this advisory, but for your reference we have again included the list of your patients currently implanted with the potentially affected leads along with their respective serial numbers.

This letter provides important information related to this limited group of Optisure leads (447 leads distributed globally with 278 leads implanted in the United States) that will assist you in managing the patients in whom they are implanted.

Summary of Issue:

St. Jude Medical identified that during the manufacturing process of a limited number of Optisure leads, an unapproved trim technique (the use of a sharp blade) to remove excess medical adhesive around the Superior Vena Cava (SVC) shock coil, may have introduced cuts to the lead's insulation. Depending upon device programming and the depth of the cut, (see below), this could result in the inability to deliver high voltage therapy. The unapproved trim technique was used on a known and well-defined group of leads. Corrective actions and preventive measures have been put in place to eliminate any potential future occurrences of this practice in the manufacturing of any and all St. Jude Medical leads. There are no leads subject to this advisory remaining in hospital inventories.

A thorough investigation was undertaken of the leads subject to the unapproved trim technique, that were found in manufacturing to have cuts or surface discontinuities of varying levels. These leads are constructed with an outer layer of Optim material which overlays an inner layer of Silicone insulation.

The least prevalent and most relevant identified cut type that is through the Optim layer, Silicone insulation layer, as well as the ETFE (blue coating) of the conductor cable has been noted (5 out of 517 non-implanted devices tested = 0.97%). In the event that type of cut (through all three layers of insulation) occurs on one or both of the high voltage RV cables, the interruption of the ETFE insulation from the cut to the adjacent SVC coil could result in an arc and subsequent inability to deliver a high voltage shock if programmable mitigations (see Recommendations below) are not put into place. If the SVC shock coil is programmed “ON”, damage to the RV shock cable inner ETFE insulation can potentially lead to an electrical malfunction wherein the defibrillator cannot deliver appropriate high voltage therapy due to arcing from the damaged RV conductor body to the SVC shock coil surface. If this was to occur in a patient with an ICD with DynamicTx™ programmed on, the detected electrical abnormality would result in aborting the ineffective shock, automatically switching to the RV-to-Can vector and therapies could still be delivered to address shockable arrhythmias. A patient with an ICD without DynamicTx would present with an Over Current Detection (OCD) alert. Extensive standards-based flex testing has shown that if a lead is able to deliver high voltage therapy and contains a cut, the potential for a cut to progress further to cause a future failure, is not expected. Given that the SVC coil is connected to the SVC conductor cable, a cut exposing the SVC conductor cable will not cause arcing.

Based on the frequency of occurrence of these cuts from the undistributed population, we estimate that the probability of lead damage that could result in compromised high voltage therapy delivery as a result of this trim technique affecting the ETFE insulation is low (0.32% or less than 1 lead in the population of 278 leads subjected to the trim technique distributed in the United States). St. Jude Medical provided the Recommendations (on the following page) as a means to manage your patients. The company and its Medical Advisory Board believe that prophylactically explanting or replacing a lead can create risks to a patient that are greater than those posed by this issue.

Given the nature, size, and location of the potential cut, SJM believes that, based on engineering testing, the low voltage conductors used for pacing and sensing are not subject to electrical issues even if subjected to a cut consistent with the worst cut noted in our investigation. No Low Voltage (LV) conductor to High Voltage (HV) Shock Coil contact is expected nor has been demonstrated, therefore, the pacing output and sensing capabilities of the implanted device are not affected. This is because the pacing output will take the path of least resistance that is through the ring electrode due to its larger surface area in relation to the cut rather than arcing across an exposed pacing conductor to the lead electrodes.

The most prevalent levels of damage (surface or Optim layer) found during the analysis will yield no expected compromises in therapy or potential for progression leading to an electrical anomaly.

Based on current information, St. Jude Medical believes that following the recommendations (below) should mitigate any potential for patient adverse events from this issue. Furthermore, an analysis of data from patients implanted with the subject leads that are being actively monitored via Merlin.net™ and have delivered high voltage shocks has shown that none of these patients have experienced any recorded high voltage electrical issues.

It is important to note that although there are no reported adverse events at shock delivery, the occurrence of shocks in this cohort could be infrequent and take time to occur, and that any adverse events would not necessarily present in a way that would be obviously associated with the damage to the leads, as opposed to more routine causes of failed shocks.

Recommendations:

Following discussions with our Medical Advisory Board, St. Jude Medical recommends the following actions depending on the device the affected patients have implanted. These recommendations are unchanged from our November 2015 communication. The primary mitigation is to prevent electrical current from arcing from any insulation breach of the right ventricle (RV) coil conductors to the SVC coil either by programming the SVC coil “OFF” or by programming the DynamicTx feature “ON”. According to our records, all but 9 of the 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. Dynamic Tx™, which is nominally enabled, automatically checks the defibrillation system integrity at the onset of high voltage therapy and, if necessary, changes the output vector to ensure high voltage therapy delivery in the event a short circuit is detected.

We have included a patient list with this letter that identifies your affected patient(s) and whether or not they have a device with the Dynamic Tx™ feature, as well as if the feature is currently enabled based on an analysis of our Merlin.net database.

For patients implanted with one of the 269 leads (US) with a potentially-compromised Optisure lead connected to a device WITH DynamicTx™* technology, we recommend:

- Review Patient Records:
 1. Ensure DynamicTx™ is programmed “ON” (nominal setting is “ON”), which ensures high voltage therapy delivery in the event a short circuit is detected
 2. Enroll these patients in Merlin.net
 3. Monitor patients as normal, with no additional testing or follow-up needed.

For patients implanted with one of the 9 potentially-compromised Optisure leads connected to a device WITHOUT DynamicTx™* technology we recommend:

- Review Patient Records:
 1. Enroll patients in Merlin.net
 2. Where clinically appropriate, consider turning off the SVC coil (select RV-to-Can vector), which eliminates the potential for compromised high voltage therapy.
 3. If dual coil shocking configuration is desired, when clinically appropriate, 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

* The attached Patient List indicates which devices incorporate the DynamicTx feature. DynamicTx does not prevent breaks in the insulation. DynamicTx may help prevent complications in the event of the lead developing clinically significant damage by automatically

turning off the SVC coil. It is important to note that in the absence of the DynamicTx feature, reprogramming the device and turning off the SVC coil will ensure high voltage therapy delivery in a single coil configuration (RV coil to can) should the lead fail.

We also strongly recommend that 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 an impacted subject lead an alert message upon interrogation on the Merlin™ Programmer and Merlin.net remote care system, 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 at the internet address below:

www.sjm.com/optisureadvisory

In addition, should a patient require a replacement device it is strongly recommended to work with your St. Jude Medical representative to place the alert on any subsequent devices. We believe such actions will further the ability of clinicians to most optimally manage the care of these patients.

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