## Pharmacy_Subscriberlist@DCA

**From:** Board of Pharmacy <pharmacy.subscriberlist@DCA.CA.GOV>
**Sent:** Tuesday, January 26, 2016 1:33 PM
**To:** PHARM-GENERAL@DCALISTS.CA.GOV
**Cc:** Pharmacy_Subscriberlist@DCA
**Subject:** Optisure Dual Coil Defibrillation Leads by St. Jude Medical: Class I Recall - Damage May Prevent Patient Therapy

**AUDIENCE**: Risk Manager, Patient

**ISSUE**: St. Jude is recalling the Optisure leads due to a manufacturing error that may have caused damage to the insulation layer of one of the shock coils. Depending on device programming and the depth of the cut, this could result in the inability of the defibrillator to deliver electrical therapy to the patient. The use of affected products may cause serious adverse health consequences, including patient injury or death. See the Recall Notice for a listing of affected product codes.

Manufacturing dates: March 12, 2014 to March 22, 2015
Distribution dates: April 9, 2014 to October 20, 2015

**BACKGROUND**: The Optisure Dual Coil Defibrillation Leads are implanted wires that connect a defibrillator to a patient's heart. The defibrillator system senses the patient's heart rhythm and delivers electrical pulses or shocks when it detects a faster than normal heart rate (tachycardia) or completely disorganized electrical activity (fibrillation).

**RECOMMENDATION**: Customers with questions about this recall may contact their sales representative of St. Jude Medical technical services at 1-800-722-3774

St. Jude Medical provided the recommendations below in their updated January 22, 2016, letter to health care providers:

- Review the patient's record and Identify if the patient is implanted with an Optisure lead connected to an implantable defibrillator that uses DynamicTx technology. To view a list of devices that incorporate the DynamicTx feature, please see the medical device advisory
- If the implantable defibrillator uses DynamicTx technology, follow the setting instructions provided by St. Jude Medical in their medical device advisory to doctors, dated January 22, 2016
- If the implantable defibrillator does not use DynamicTx technology, follow the extra steps outlined by St. Jude Medical in the same medical device advisory
- Enroll patients in Merlin.net

Patients should ask their doctor if the implantable defibrillator uses DynamicTx technology. This technology allows doctors to control the device and ensures that the defibrillator delivers patient therapy even if the lead is damaged.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report

- Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

[01/26/2016 - Recall Notice - FDA]