U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

St. Jude Medical Recalls Optisure Dual Coil Defibrillation Leads Due to Damage that May Prevent Patient Therapy

The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death.

Recalled Device

- Optisure Dual Coil Defibrillation Leads
- **Product code information (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=141537)**
- Model numbers: LDA220, LDA220Q, LDA230Q, LDP220Q
- Manufacturing dates: March 12, 2014 to March 22, 2015
- Distribution dates: April 9, 2014 to October 20, 2015
- Devices recalled in the U.S.: 281 units

Device Use

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).

Reason for Recall

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.

Who May be Affected

- Health care providers who implanted St. Jude Optisure leads
- Patients who have implanted St. Jude Optisure leads

What to Do

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 (http://professional.sjm.com/resources/product-performance/optisure-important-info/physician-communication)
- If the implantable defibrillator uses DynamicTx™* technology, follow the setting instructions provided by St. Jude Medical in their medical device advisory (http://professional.sjm.com/resources/product-performance/optisure-important-info/physician-communication) 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 (http://professional.sjm.com/resources/product-performance/optisure-important-info/physician-communication)
- Enroll patients in Merlin.net

Patients with Optisure Dual Coil Defibrillation Leads:

Ask your doctor if your 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.

Contact Information

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

Date Recall Initiated: November 3, 2015

Full List of Affected Devices

- Product code information (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=141537)

Additional Resources:

- St. Jude January 22, 2016 November 3, 2015, Medical Device Advisory (http://professional.sjm.com/resources/product-performance/optisure-important-info/physician-communication)

How Do I Report a Problem?

Health care professionals and consumers may report adverse reactions or quality problems they experienced using these devices to MedWatch: The FDA Safety Information and Adverse Event Reporting Program (https://www.accessdata.fda.gov/scripts/medwatch/) either online, by regular mail or by FAX.

More in Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/default.htm)

2016 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm480134.htm)

2015 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm429489.htm)

2014 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm384921.htm)