Indiana State Department of Health
An Equal Opportunity Employer

Michael R. Pence
Governor

Jerome M. Adams, MD, MPH
State Health Commissioner

DATE: January 28, 2016

TO: All Local Health Departments
Attn: Chief Food Inspection Officer

FROM: Laurie Kidwell, RRT Supervisor
Food Protection Program

SUBJECT: St. Jude Medical, Inc. – CLASS 1 ADVISORY [Medical Device]

AFFECTED PRODUCT: **Optisure™ Dual Coil Defibrillation Leads**

SUMMARY: **Class 1 Advisory; The Class 1 Advisory has been initiated because the product may have been damaged during a manufacturing step.**

The advisory notification involves the worldwide distribution of 447 Optisure dual coil defibrillation leads manufactured and distributed by St. Jude Medical. The advisory relates to units within the following models: LDA220, LDA220Q, LDA230Q, and LDP220Q.

The product was distributed in the U.S.

SUGGESTED ACTION: **For consumer inquiry only. For more information, patients or their physicians can visit www.sjm.com/optisureadvisory or call the St. Jude Medical customer service team 24 hours a day at (800) 328-9634.**

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Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

FDA Classifies St. Jude Medical Field Action For 447 Of The Company's Optisure High Voltage Leads As A Class 1 Advisory In The U.S.

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

For Immediate Release

January 22, 2016

Contact

Consumers

St. Jude Medical
www.sjm.com/optisureadvisory
(800) 328-9634

Media

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Firm Press Release

St. Jude Medical, Inc. (NYSE:STJ), a global medical device company, today announced that a previously communicated voluntary global field safety action related to the company's Optisure™ Dual Coil Defibrillation Leads has now been classified as a Class 1 Advisory by the U.S. Food and Drug Administration. The Class 1 Advisory relates to a limited and well-defined group of 447 Optisure leads, 278 of which were distributed in the U.S., which may have been damaged during a manufacturing step. The company has received no reports of lead malfunction or patient injury related to this issue and all physicians with patients impacted by this advisory have been notified.

Optisure dual coil defibrillation leads are used in conjunction with implantable cardioverter defibrillators (ICDs), which monitor the heartbeat of patients suffering from heart rhythm disorders. An ICD's leads deliver electric current to the heart to help restore the heart to its normal rhythm when needed.

On November 3, 2015, St. Jude Medical began the global process of notifying physicians following patients who have been implanted with the 447 Optisure dual coil leads subject to this advisory. An investigation revealed a variation in the process to remove excess medical adhesive used in the assembly of the superior vena cava (SVC) shock coil in a limited and well-defined group of Optisure leads could result in cuts to the insulation of the lead. Depending on device programming and the depth of the inadvertent cut to the insulation, compromise of lead insulation can potentially lead to an electrical malfunction wherein the defibrillator cannot deliver appropriate high voltage therapy.

A St. Jude Medical internal investigation found the probability that a lead was damaged as a result of the manufacturing variation to an extent that it could result in the inability to deliver appropriate high voltage therapy is very low and that any associated risks can be prevented with device reprogramming. The patients' leads can also be monitored from home using the Merlin.net™ remote care system. The company has not received any reports of compromised performance of the impacted Optisure leads. St. Jude Medical is in the process of providing an updated advisory notice to physicians to further ensure physicians are aware of recommendations for managing their patients who may have been implanted with the impacted leads.

The advisory notification involves the worldwide distribution of 447 Optisure dual coil defibrillation leads manufactured and distributed by St. Jude Medical. The advisory relates to units within the following models: LDA220, LDA220Q, LDA230Q, and LDP220Q.

The vast majority of patients implanted with the Optisure leads compromised by the advisory have devices equipped with the St. Jude Medical DynamicTx™ feature that provides additional protection to help ensure delivery of appropriate high voltage therapy even in the case of a compromised lead. For these patients, physicians are advised to enroll patients in the Merlin.net patient care network, ensure the DynamicTx feature is programmed "on" and then monitor patients as per normal follow-up protocols.

Physicians following the 9 patients in the U.S. with compromised leads not connected to a device with the DynamicTx feature have been advised to enroll these patients in the Merlin.net patient care network and, where appropriate, consider turning off the SVC coil. If a dual coil shocking configuration is desired, physicians should consider performing a high voltage test when clinically appropriate to determine whether the lead has been

compromised. As of this letter all physicians following the 9 patients have been contacted and provided information about this event.

Patient safety is St. Jude Medical's highest priority, and the company will continue to work closely with customers and global regulatory agencies to ensure effective communication to our physician partners. The company has alerted all physician customers impacted by the advisory by letter, and all leads subject to this advisory have been accounted for and none remain in any field distribution. The U.S. Food and Drug Administration and other regulatory bodies have been notified. For more information, patients or their physicians can visit www.sjm.com/optisureadvisory or call the St. Jude Medical customer service team 24 hours a day at (800) 328-9634.

About St. Jude Medical
St. Jude Medical is a global medical device manufacturer dedicated to transforming the treatment of some of the world's most expensive epidemic diseases. The company does this by developing costeffective medical technologies that save and improve lives of patients around the world. Headquartered in St. Paul, Minn., St. Jude Medical has four major clinical focus areas that include cardiac rhythm management, atrial fibrillation, cardiovascular and neuromodulation. For more information, please visit sjm.com or follow us on Twitter @SJM_Media.

Forward-Looking Statements
This news release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that involve risks and uncertainties. Such forward-looking statements include the expectations, plans and prospects for the Company, including potential clinical successes, anticipated regulatory approvals and future product launches, and projected revenues, margins, earnings and market shares. The statements made by the Company are based upon management's current expectations and are subject to certain risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. These risks and uncertainties include market conditions and other factors beyond the Company's control and the risk factors and other cautionary statements described in the Company's filings with the SEC, including those described in the Risk Factors and Cautionary Statements sections of the Company's Annual Report on Form 10-K for the fiscal year ended January 3, 2015 and Quarterly Report on Form 10-Q for the fiscal quarter ended October 3, 2015. The Company does not intend to update these statements and undertakes no duty to any person to provide any such update under any circumstance.

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