FDA Safety Communication: Premature Insulation Failure in Recalled Riata Implantable Cardioverter Defibrillator (ICD) Leads Manufactured by St. Jude Medical, Inc.

U.S. Food & Drug Administration

Medical Specialty: Cardiology, Electrophysiology, Cardiac Surgery, Radiology, Internal Medicine; Family Medicine

Device:

Riata and Riata ST leads connect an implantable cardioverter defibrillator (ICD) to the heart in order to monitor heart rhythms. ICD's can detect life-threatening heart rhythms and deliver an electrical shock from the ICD through the lead to the heart. ICD leads typically have layers of insulation that protect electrical conductor wires inside the lead.

Riata's manufacturer, St. Jude Medical Inc., recalled these leads on Nov. 28, 2011, due to premature erosion of the insulation around the electrical conductor wires, known as insulation failure. St. Jude Medical stopped selling these leads in late 2010 but more than 227,000 Riata leads had been distributed worldwide. According to St. Jude Medical, as of 2011, approximately 79,000 Riata leads remained implanted in patients in the United States.

Purpose:

The Food and Drug Administration (FDA) is providing information and recommendations regarding safety concerns with the recalled Riata leads. These leads have an increased risk of premature insulation failure that can impact the lead's ability to function properly.

Summary of Problem and Scope:

Many factors contribute to the lifespan of an ICD lead, including the age and activity level of the patient. On average, an ICD lead is expected to last at least 10 years. The FDA is aware of an increase in frequency of reported Riata insulation failures, beginning approximately four years after implant. Insulation failure may cause some of the electrical conductors inside Riata leads to move within (migrate), or move entirely outside (externalize), the outer lead insulation. These changes may be detectable on X-ray or fluoroscopic imaging.

Lead insulation failure may cause the ICD lead to malfunction. ICD lead malfunction may cause abnormal sensing or pacing, or delivery of inappropriate or no shock therapy, which could result in serious adverse events, including death.

There is currently not enough information to determine:

- How frequently and how soon after implantation Riata insulation fails;
- How often and how soon both inner and outer layers of insulation fail and at what point migration or externalization of the electrical conductors cause ICD lead malfunction or other problems; and
- Risk factors that contribute to insulation failure or externalization of the electrical conductors.

The majority of Riata and Riata ST ICD leads, including those that show signs of electrical conductor migration or externalization on imaging, continue to function electrically and provide life-saving support. However, the FDA is concerned that Riata and Riata ST leads that show insulation abnormalities on imaging may be at greater risk of future electrical failure.

Recommendations for Health Care Providers:

Physicians should continue to closely monitor patients who have a Riata or Riata ST lead and notify patients if they have a recalled lead. Patients who have not had a recent evaluation and device interrogation should undergo those exams to assess for any electrical abnormalities. Physicians should consider remote monitoring for patients with a recalled lead to better detect electrical abnormalities.

St. Jude Medical recommends reprogramming [1] [2] the device to increase the chance for detection of a lead abnormality. The patient alert and remote monitoring alerts should also be turned on.

Imaging may detect visual abnormalities of the lead

The FDA is recommending that physicians image Riata and Riata ST leads implanted in patients to assess for externalization or other visible insulation abnormalities. Several studies have demonstrated that routine imaging of Riata and Riata ST leads may detect previously unrecognized visual insulation abnormalities. We believe that assessing the current condition of Riata and Riata ST leads is likely to help health care providers develop individualized plans for their patients, which may include recommendations on the frequency of remote monitoring and the necessity and frequency of repeat imaging.

We do not consider the additional exposure to radiation from imaging to be prohibitive for most patients, but physicians may need to consider additional factors, such as pregnancy, for individual patients.

Imaging can be done via fluoroscopy or a two-view chest X-ray. If leads have been imaged in the last three to six months, physicians may choose to review those images rather than ordering a new imaging study. It may be difficult to see lead insulation failure, including migration or externalization of the electrical conductors, so physicians should work closely with radiologists during the imaging process and in the review of previously ordered images. The utility of other imaging modalities, such as CT scans and ultrasound, has not been well-studied.

In addition to one-time imaging assessment of the Riata and Riata ST lead, physicians may consider performing fluoroscopy of the lead at the time of the generator replacement to check the lead condition. For Riata and Riata ST leads with identified visual insulation abnormalities, the FDA believes it is reasonable to consider repeat interval imaging to assess for progression.

The value of repeat imaging for leads initially assessed as intact is uncertain, and the FDA recommends individualized clinical management that takes into consideration the patient's specific risk factors.

Lead replacement and extraction
The FDA, St. Jude Medical, and the Heart Rhythm Society do not recommend routine removal of any leads due to the risks of explantation surgery.

Leads with normal imaging and normal electrical function
The FDA does not recommend routine replacement of leads with normal imaging and normal electrical function, although clinical management of patients should be individualized based on the patient's medical history and prognosis. Continue to monitor lead and device system performance.

Leads with abnormal imaging and normal electrical function
The FDA does not recommend routine replacement of leads with abnormal imaging and normal electrical function, although clinical management of patients should be individualized based on the patient's medical history and prognosis, as well as the severity of the visual abnormality. Continue to monitor lead and device system performance.

Leads with abnormal imaging and abnormal electrical function
Physicians should consider replacing the lead if there is evidence of insulation failure in imaging and if there is abnormal electrical function. If the lead is replaced, physicians should carefully weigh the risks and benefits of extracting the old lead compared to capping it and leaving it in place. The decision to remove a lead should be based on the individual patient as well as physician experience and the capabilities of the health care facility where the extraction would be performed. Lead extraction is a procedure that carries significant risk of severe injury and death, especially when the lead has been implanted for a long period of time.

Report lead performance problems to St. Jude Medical and the FDA

Reporting from the physician community is crucial to gathering data to more accurately characterize long-term lead performance, identify risk factors that contribute to lead failure, and further develop advice for managing patients with Riata and Riata ST leads. The FDA encourages physicians to report concerns with lead performance to St. Jude Medical and to the FDA. If you suspect that an ICD lead

has premature insulation failure, externalized or migrated conductors, electrical malfunction, or other abnormal function, the FDA encourages you to file a voluntary report through MedWatch, the FDA Safety Information and Adverse Event Reporting program [3].

Explanted Riata or Riata ST leads should always be returned to St. Jude Medical for analysis.

Recommendations for Patients:

Patients should contact their cardiac physician to determine if they have the recalled leads and to request additional information regarding care and monitoring. Physicians and patients should discuss the best approach to take based on individual need.

The FDA encourages patients to work with their physician to participate in a clinical study, if available, to help understand and improve the care of all affected patients.

FDA Actions:

In December 2011, the FDA classified the Riata and Riata ST Silicone Endocardial Defibrillation Leads recall as a Class I recall, the most serious type of recall. St. Jude Medical stopped selling Riata and Riata ST leads in late 2010.

Since 2008, the FDA has required manufacturers to conduct five-year post-approval studies for new or substantially modified ICD leads. These studies are designed to detect early signs of poor device performance and will collect data for at least 1,000 patients for five years after implantation. These post-approval studies were not in place at the time the FDA approved the Riata and Riata ST leads.

In 2012, the FDA ordered St. Jude Medical to collect clinical data related to the potential for premature insulation failure in Riata and Riata ST leads. The FDA required St. Jude Medical to conduct three-year postmarket surveillance studies, or Section 522 studies [4] to address concerns related to premature insulation failure and to address important questions related to follow-up of affected patients.

The recommendations in this Safety Communication apply only to Riata and Riata ST Silicone Endocardial Defibrillation Leads. However, the FDA also required St. Jude to conduct post-market surveillance studies on:

- QuickFlex LV CRT leads
- QuickSite LV CRT leads
- Riata ST Optim and Durata ICD leads

St. Jude Medical voluntarily recalled and stopped selling its QuickSite [5] and QuickFlex [6] LV CRT Leads on April 3, 2012. The FDA classified this as a Class II recall.

In 2006, the FDA approved the Riata ST Optim lead, which St. Jude Medical renamed Durata in 2008. While Durata leads have not been the subject of a recall, the agency chose to include Riata ST Optim and Durata leads in the post-market surveillance study order to proactively obtain additional, detailed performance information.

The orders apply to the specified lead models, whether currently implanted in patients or implanted after the FDA issued the study orders.

Reporting Problems to the FDA:

Prompt reporting of adverse events can help the FDA identify and better understand the risks associated with medical devices. If you suspect that an ICD lead has premature insulation failure, externalized or migrated conductors, electrical malfunction, or other abnormal function, the FDA encourages you to file a voluntary report through MedWatch, the FDA Safety Information and Adverse Event Reporting program [3].

Health care personnel employed by facilities that are subject to the FDA's user facility reporting requirements [7] should follow the reporting procedures established by their facilities.

Please include the following information in your reports, if available:

- Manufacturer's Name
- Device Name (Brand Name)
- Model Number
- Device Implant and Explant Date
- Was the Device Returned to the Manufacturer?
- Details of Adverse Event and Medical and/or Surgical Interventions (if required), including how the device may have played a role in the adverse event. For implanted leads this may include details of lead interrogation, lead surgery, heart rhythm changes, symptoms and monitoring.

Contact Information:

If you have questions about this communication, please contact the Division of Small Manufacturers, International and Consumer Assistance (DSMICA) at DSMICA@FDA.HHS.GOV [8], 1-800-638-2041, or 301-796-7100.

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Links:
[1] http://www.riatacommunication.com/us/physician-information.aspx

[2] http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm
[3] http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm
[4] http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm072517.htm
[5] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=108650
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