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HAZARD ALERT

St. Jude Medical Riata and Riata ST Silicone Endocardial Defibrillation Leads
Riata (8Fr): Models 1560, 1561, 1562, 1570, 1571, 1572, 1580, 1581, 1582, 1590, 1591, 1592
Riata ST (7Fr): Models 7000, 7001, 7002, 7010, 7011, 7040, 7041, 7042

Dear Doctor,

St. Jude Medical, in consultation with the Therapeutic Goods Administration (TGA) is upgrading the November 30, 2011 "Update to December 2010 Safety Alert" on the Riata and Riata ST silicone endocardial defibrillation leads to a Hazard Alert in Australia.

This letter provides St. Jude Medical's estimation of failures as at November 2011 associated with all cause insulation failure on our Riata® (8Fr) and Riata ST (7Fr) silicone endocardial defibrillation leads, with specific details on externalised conductors based on worldwide complaints and returns analysis. Out of over 227,000 Riata and Riata ST silicone leads sold worldwide over the past 9 years, the incidence rate based on returns and complaints (reports from the field with no product returned) is estimated to be 0.63% for all cause abrasion versus the prior rate of 0.47% communicated in December 2010, with approximately 15% of those exhibiting externalised conductors.

A total of 3962 Riata and Riata ST leads have been supplied in Australia and the incidence rate based on returns and complaints to January 29, 2012 is estimated to be 1.2% for all cause abrasion with approximately 18% of those exhibiting externalised conductors.

The supply of St. Jude Medical Riata and Riata ST silicone leads was discontinued in Australia in December 2010 and the above models have been cancelled from the Australian Register of Therapeutic Goods (ARTG).

St Jude Medical's Product Performance Report (PPR) in relation to this issue is available online at http://sjmprofessional.com. Although returned product analysis is recognised to underestimate failure rates, the relative rates of failure from one model to another should be representative of the overall clinical experience. Additional information may be found on the Riata Communication website at http://riatacommunication.com/riata-intl.aspx.

Root Cause

There are several factors that can contribute to lead abrasion in implanted pacing and defibrillation systems, including physiological stresses placed on the lead due to patient anatomy, implant orientation, and mechanical stresses applied from concomitant devices in the body. The main causes of insulation abrasion are listed below:

- Lead to Can abrasion (in the pocket)
- Lead to Lead abrasion (in the vasculature or cardiac structure)
- Lead abrasion caused by something in the heart or vasculature that rubs against the outside of the lead resulting in exposure of the conductors
- Clavicular Crush
- Inside-out abrasion caused by movement of the conductors within the insulation. A more recently reported manifestation of inside-out abrasion involves conductors being visible outside the lead insulation body through x-ray or fluoroscopy.

Recommendations and Mitigations

In accordance with the Heart Rhythm Society's 2009 guidelines[2], St. Jude Medical recommends direct patient contact via telephone, letter or in person to advise patients of the issue with this lead. To support physicians in communicating with their patients St. Jude Medical has made available a template letter that may be adapted and is available at http://riatacommunication.com/riata-intl.aspx.

St. Jude Medical's Medical Advisory Board (MAB) has reviewed the available data and is providing the following recommendations which are consistent with standard best practice:

- Advise patients of the importance of contacting their physician should they experience any adverse events.
- Continue to monitor your patient's implanted system at regularly scheduled intervals with particular attention to diagnostic information related to defibrillation lead performance. The recommendations for frequency of in-person or remote monitoring are a follow-up period of every 3 - 6 months for ICD/CRT-D devices per the HRS/EHRA consensus.
- St. Jude Medical offers a vibratory patient notifier in response to out of range impedance measures from three High Voltage lead vectors (RVC to Can, SVC to Can, and RVC to SVC), as well as pacing and sensing electrodes. Data are displayed graphically to enable physicians to trend changes in impedance over time. The noise reversion feature protects against non-physiologic high rate event detection to avoid inappropriate shocks.
- Review lead measurements including pacing and high voltage lead impedances per your standard follow-up procedures in particular looking for significant changes from the patient's previous follow-up visits.
- If there is evidence of a lead electrical failure, manage the patient per standard practice[1,2]. This may include x-ray or fluoroscopy. Additional testing if necessary could include provocative methods such as shoulder and arm movements and deep respiration while looking at the surface ECG and intracardiac electrograms with the programmer, which may reveal an intermittent problem associated with any source of lead electrical failure if one exists.
- The value of routine x-ray or fluoroscopy for patients with leads having no electrical abnormalities is unknown at this time.
- In addition, prophylactic explant or replacement of a lead without electrical dysfunction is not recommended.
- Currently there is no expert consensus regarding whether patients undergoing pulse generator replacement should undergo fluoroscopy or lead replacement should an externalised conductor without electrical anomalies be present. This is, in part, because the risk versus benefit of replacing a lead in such a patient may vary from patient to patient and centre to centre. Clinical decisions in this setting should be individualised based on specific patient conditions and circumstances.

Based on input from the MAB, St. Jude Medical is conducting a prospective study to further evaluate the incidence and long-term performance of leads with externalised conductors that do not exhibit electrical abnormalities. The outcome of the study, along with any additional information we learn, will determine if updated recommendations are needed. Enrolment began in December, 2011 and the results will be communicated as soon as available.

Rate of Occurrence from Complaints and Returns

As of September 30, 2011, the overall worldwide rate of all-cause abrasion on Riata silicone leads (based on complaints and returns analysis) is 0.63%, approximately 15% of which are associated with the observation of externalised conductors, or 0.10%. The rates of externalised conductors reported in the Product Performance Report (PPR) released in November 2011 by individual model are lower than the worldwide rate of 0.10% due to the following reasons:

- Different data cut-off dates (June 30, 2011 vs. September 30, 2011)
- AdvaMed (US medical devices industry association) standardised PPR reporting methods require that only U.S. implants that have been returned and confirmed through laboratory analysis be included in the PPR lead malfunction tables
- It is recognised throughout the industry that not all leads are returned to manufacturers.

The table below summarises the incidence rate of externalised conductors for Riata and Riata ST family of silicone leads based on worldwide and Australian complaints and returns of explanted leads to St. Jude Medical where laboratory analysis has confirmed lead malfunction.

Riata Family	Shock Coil Configuration	Model Numbers	Worldwide Complaint and Returns Rate of Externalised Conductors to Sept. 30, 2011	Australia Complaint and Returns Rate of Externalised Conductors to Feb. 29, 2012
Riata (8Fr)	Single	1562, 1572, 1582, 1592,	0.64%	0.0%
	Dual	1560, 1561, 1570, 1571, 1580, 1581, 1590, 1591	0.096%	0.29%
Riata ST (7Fr)	Single	7002, 7042,	0.081%	0.0%
	Dual	7000, 7001, 7010, 7011, 7040, 7041	0.024%	0.0%

Kaplan-Meier statistical analysis was used to account for the fact that Riata ST 7Fr leads were introduced to the market four years after Riata 8Fr. Results of the analysis show that compared to Riata 8Fr, the Riata ST 7Fr leads exhibit lower incidence rates of externalised conductors, demonstrating that this particular failure mechanism is not a function of smaller diameter lead size:

- Riata 8Fr combined (0.14%) vs. Riata ST 7Fr combined (0.03%); p=0.006
- Riata 8Fr dual shock coil (0.096%) vs. Riata ST 7Fr dual shock coil (0.024%); p=0.037
- Riata 8Fr single shock coil (0.64%) vs. Riata ST 7Fr single shock coil (0.081%); p=0.023
- Riata 8Fr single shock coil (0.64%) vs. all other Riata models combined; p<0.001

Although the Riata 8Fr and Riata ST 7Fr leads have the same insulation wall thicknesses, the 7Fr size was achieved by reducing the diameter of the inner coil and the diameter of the central lumen of the multi-lumen tubing. As a result, the conductor cables in Riata ST 7Fr are closer to the center of the lead body which reduces cable tension and the risk of externalised conductors. In addition, the Riata 8Fr single shock coil models have two lumens directly opposed to one another while the other Riata and Riata ST models have three lumens that are equally spaced around the inner coil, which reduces stress.

Clinical Implications

The clinical implications of externalised conductors without electrical anomalies are not fully known or understood at this time. Externalised conductors can present as just a visual observation on X-ray or fluoroscopy without any associated clinical or device-related observations. Over 80% of the returned Riata silicone leads exhibiting externalised conductors have not shown evidence of compromised ethylene tetrafluoroethylene (ETFE) insulation on the conductor cables and thus have no associated electrical abnormalities. Based on our review of complaints and returns information for leads reported to exhibit externalised conductors with associated electrical abnormalities, the electrical presentations were:

- pacing or defibrillation impedance changes (~37%)
- inappropriate therapy (~36%)
- noise and oversensing (~18%)
- threshold rise (~9%).

Additionally, if electrical integrity of a lead were to be compromised, failure to deliver appropriate therapy could potentially occur.

Worldwide reports to St. Jude Medical associated with extraction of a Riata lead with externalised conductors include two patient deaths and one serious injury (effusion requiring thoracotomy). In addition, one patient death and one serious injury in patients with externalised conductors were reported, but were determined not to be due to the presence of externalised conductors.

St. Jude Medical is committed to keeping customers informed about product performance. If you have any questions or concerns, please do not hesitate to contact your local St. Jude Medical representative or James Ramshaw, CRM High Voltage Senior Product Manager on (02)9936 1213 or 0410 330 278. In addition, in the event you determine that it is appropriate to replace a Riata or Riata ST silicone lead that exhibits externalised conductors, we will provide a replacement St. Jude Medical lead at no charge.

Sincerely,

Mark Carlson, MD
Chief Medical Officer & Sr. Vice President
Research and Clinical Affairs

Philip Tsung
Vice President, Quality Assurance

REFERENCES

1. Epstein, A.E. "Troubleshooting of Implantable Cardioverter-Defibrillators." Clinical Cardiac Pacing, Defibrillation, and Resynchronization Therapy, 3rd ed. Eds. Ellenbogen, K.A., Kay G.N., Lau, C-P., Wilkoff, B.L. Philadelphia: Elsevier, 2007, pp. 1063-1086.
2. Recommendations from the Heart Rhythm Society Task Force on Lead Performance Policies and Guidelines, 2009.