

November 28, 2011

**MEDICAL DEVICE ADVISORY  
IMPORTANT PRODUCT INFORMATION UPDATE**

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,**

The purpose of this letter is to provide updated estimates of failures associated with all cause insulation failure on our Riata® (8Fr) and Riata ST (7Fr) silicone endocardial defibrillation leads, with a specific emphasis on externalized conductors. The information provided is based on updates to worldwide complaints and returns analysis as well as new peer reviewed publications. 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 now estimated to be 0.63% for all cause abrasion versus the prior rate of 0.47% communicated in December 2010 (attached for your reference), with approximately 15% of those exhibiting externalized conductors.

Issuance of this letter is in conjunction with our recently released November 2011 Product Performance Report (available online at <http://simprofessional.com>). For your convenience the relevant sections of the November 2011 Product Performance Report (PPR), which provide details on the performance of our defibrillation leads and specific failure mechanisms, are also attached. Although returned product analysis is recognized to underestimate failure rates, the relative rates of failure from one model to another should be representative of the overall clinical experience.

**Lead Performance Summary**

Kaplan-Meier analysis, which takes into account differences in follow-up duration between the lead models, shows that the Riata ST (7Fr) silicone leads, which included conductor configuration design changes, exhibit significantly lower externalized conductor incidence rates than the Riata (8Fr) silicone leads ( $p=0.006$ ). As documented in our PPR, the large majority of implanted Riata and Riata ST silicone leads are expected to function normally. Also, Kaplan-Meier analysis shows at a highly statistically significant level that the Durata® and Riata ST Optim® leads that have the Optim insulation material are not prone to externalized conductors and have lower incidence rates for all cause abrasion compared to the Riata and Riata ST silicone leads (both  $p<0.0001$ ).

New peer reviewed literature from one single center site in Belfast, Northern Ireland, has indicated a 15% incidence rate of externalized conductors in Riata silicone leads (25 out of 165 patients) during fluoroscopic screening, including 5 leads (3%) that were associated with an electrical abnormality. One significant finding out of the Belfast experience is that a large percentage (35%) of the patients with Riata leads at the site had Riata (8Fr) single shock coil models. Analysis of worldwide complaint and returns information has identified that Riata (8Fr) single shock coil models exhibit a significantly higher incidence rate of externalized conductors than all other Riata (8Fr) and Riata ST (7Fr) models, which helps explain why the Belfast experience has shown such a high incidence rate.

**Root Cause**

Externalized conductors occur when an abrasion results in an outer insulation breach within the vascular or cardiac systems allowing the normally contained conductors to become visible outside the lead body. Externalized conductors can be a result of relative motion of the conductor cables within the lead insulation lumen, referred to as "inside-out" abrasion, or from external sources of abrasion, e.g. lead-to-lead abrasion, where the outer insulation is breached and as a result the conductor cables are observed to be outside the lead body. Approximately 85% of the leads confirmed through laboratory analysis to exhibit externalized conductors occurring in Riata silicone leads are due to the inside-out variety while approximately 15% are attributed to external sources of abrasion (i.e., outside-in). Also, the most common (approximately 75% of

the confirmed cases) location of the externalization along the lead body is within 8 centimeters proximal to the RV shock coil, as the stress on that area of the lead may be higher than other areas of the lead due to lead movement associated with a patient's heart beat.

**Clinical Implications**

The clinical implications of externalized conductors without electrical anomalies are not fully known or understood at this time. Externalized 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 externalized 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 externalized 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.

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

**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 externalized conductors, or 0.10%. The rates of externalized conductors reported in the PPR 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 standardized 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 recognized throughout the industry that not all leads are returned to manufacturers.

The table below summarizes the incidence rate of externalized conductors for the Riata and Riata ST family of silicone leads based on worldwide complaints and returns, along with estimated remaining active U.S. implants.

Riata Family	Shock Coil Configuration	Model Numbers	Worldwide Complaint and Returns Rate of Externalized Conductors	Estimated Remaining Active U.S. implants
Riata (8Fr)	Single	1562, 1572, 1582, 1592	0.64%	2,000
	Dual	1560, 1561, 1570, 1571, 1580, 1581, 1590, 1591	0.096%	48,000
Riata ST (7Fr)	Single	7002, 7042	0.081%	2,000
	Dual	7000, 7001, 7010, 7011, 7040, 7041	0.024%	27,000

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 externalized 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 externalized 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.

### **New Peer Reviewed Publications**

In the December, 2010 product communication, St. Jude Medical referenced four case reports on Riata externalized conductors. Since then, we are aware of three more journal publications<sup>1,2,3</sup> as well as two single center studies<sup>4,5</sup>. A retrospective study from Frankfurt, Germany<sup>4</sup> reported that in their center, 2% (7 out of 332) of Riata and Riata ST silicone insulated leads exhibited externalized conductors. In this study, 6 of the 7 (86%) leads with externalized conductors were 8Fr, whereas one (14%) was a 7Fr lead. One single center screening study from Belfast, Northern Ireland, published as a European Society of Cardiology (ESC) 2011 abstract<sup>5</sup> indicated that at their center, externalized conductors were observed fluoroscopically in 15% of their Riata and Riata ST silicone insulated leads (80% of which were not associated with electrical abnormalities and 20% of which were associated with electrical abnormalities). In that study, 21 of the 25 (84%) leads with externalized conductors were 8Fr, whereas 4 (16%) were 7Fr leads. In addition, 35% of the patients in the Belfast study had Riata 8Fr single shock coil leads, which based on the analysis shown above, contributed to the high rate of observed externalized conductors.

### **Data on Optim Insulated Leads (Durata and Riata ST Optim)**

Durata and Riata ST Optim leads that employ Optim insulation have been on the market for over 5 years and over 278,000 have been sold worldwide. There have been no reports of externalized conductors in Durata and Riata ST Optim leads and 99.9% are free from abrasion of any type at approximately 5 years post-implant (see page 226 of the November PPR, US data through June 2011). Based on Kaplan-Meier statistical analysis, which factored in that the Optim defibrillation leads were introduced to the market 5 years after the silicone leads, the difference in the incidence of externalized conductors between Riata silicone leads and Durata Optim insulated leads (0.10% vs. none) is highly statistically significant ( $p < 0.0001$ ).

### **Recommendations and Mitigations**

Based on input from our Medical Advisory Board (MAB), St. Jude Medical is conducting a prospective study to evaluate further the incidence and long-term performance of leads with externalized 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. Enrollment is expected to begin in December, 2011 and we will communicate the results when they become available.

St. Jude Medical's MAB has reviewed the available data and is updating the recommendations from the December 2010 product communication below. If you are following any patients implanted with Riata and Riata ST silicone leads, St. Jude Medical and the MAB make the following recommendations, which are consistent with standard best practices and our December 2010 product communication:

- Whenever possible, monitor devices and leads remotely and advise your patients of the importance of contacting you should they experience any adverse events. St. Jude Medical remote monitoring features can be used to detect electrical changes early that may be associated with externalized conductors.
  - St. Jude Medical offers a vibratory patient notifier and daily remote monitoring capabilities through the Merlin@home transmitter in response to out of range impedance measurements 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. Customized DirectAlerts notifications allow physicians to monitor patient status between follow-ups. The noise reversion feature protects against non-physiologic high rate event detection to avoid inappropriate shocks.
- 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 are a follow-up period of every 3 - 6 months for ICD/CRT-D devices per the HRS/EHRA consensus.

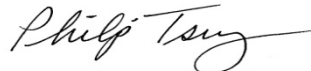
- Review lead measurements including pacing and high voltage lead impedances per your standard follow-up procedures in particular looking for significant changes from the patient's previous follow-up visits.
- If there is evidence of a lead electrical failure, manage the patient per standard practice <sup>6</sup>. 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 and is therefore not recommended.
- 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 externalized 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 center to center. Clinical decisions in this setting should be individualized based on specific patient conditions and circumstances. St. Jude Medical is conducting a study that will provide information that helps to inform the management of these patients.

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 our Technical Services Department at 800-722-3774. In addition, in the event you determine that it is appropriate to replace a Riata or Riata ST silicone lead that exhibits externalized conductors, we will provide a replacement Durata lead at no charge and up to \$600 in unreimbursed medical expenses.

Sincerely,



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



Philip Tsung  
Vice President, Quality Assurance

Attachments:

1. December 2010 Important Product Information
2. November 2011 Product Performance Report Defibrillation Leads Data
3. Physician Device Advisory Notice

## REFERENCE PAGE

<sup>1</sup> Krebsbach A. et al. Premature Failure of a Riata Defibrillator Lead without Impedance Change or Inappropriate Sensing: A Case Report and Review of the Literature, *J Cardiovasc Electrophysiol*, 2011

<sup>2</sup> Chan C.W. et al., An ICD Lead with Failure of Outer Insulation Goes Undetected by Regular Measurements, *PACE* 2011: 1-2.

<sup>3</sup> Yamamoto, N. et al. Noise oversensing and aborted shock therapies caused by an unusual insulation break of SJM-Riata implantable cardioverter-defibrillator lead, *Asia Pacific HRS* 2011.

<sup>4</sup> Erkapic D. et al. Insulation Defects of Thin High-Voltage ICD Leads: An Underestimated Problem? *J. Cardiovasc Electrophysiol*, 2011

<sup>5</sup> Kodoth, V. et al. Riata lead failure; A Report from Northern Ireland Lead Screening Programme, *ESC* 2011.

<sup>6</sup> 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.