

FIELD SAFETY NOTICE

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

December 15, 2010

Attention: Doctors implanting or following patients with Riata[®] and Riata ST Silicone Endocardial ICD Leads, all serial numbers.

Dear Doctor:

This letter provides important product information regarding the St. Jude Medical Riata and Riata ST family of defibrillation leads which use silicone as the outer insulation material. As part of St. Jude Medical's commitment to transparency on device performance, we are bringing to your attention performance information regarding lead abrasion failures identified in the Riata silicone insulated defibrillation leads as compared to our newer lead models utilizing the Optim[®] insulation material (Riata ST Optim and Durata[®] family of defibrillation leads).

The Riata and Riata ST family of silicone defibrillation leads have exhibited an insulation abrasion rate of 0.47% over 9 years of use. Silicone rubber, while representing the industry's most commonly used defibrillation lead insulation material over the past 20 years, has been observed to be vulnerable to abrasion^{1,2,3}. Abrasion of silicone defibrillation leads is acknowledged within the clinical community as a well known clinical risk and is well documented in the literature as the number one cause of lead failure across the industry with reported failure rates ranging from 3 to 10%^{4,5,6}. Lead insulation damage and its possible effects are also described as a potential adverse event in all silicone defibrillation lead user's manuals, including Riata User's manuals.

In contrast, St. Jude Medical's newer generations of defibrillation leads utilizing the Optim insulation material have demonstrated a reduction in lead abrasion-related observations by greater than 80% ($p < 0.0001$) at 44 months of follow-up as compared to our silicone leads. In addition, the difference in the overall survival rate at 44 months for St. Jude Medical defibrillation leads using Optim insulation (98.8%) vs. the Riata and Riata ST silicone leads (98.4%) is attributable to the lower rate of abrasion reported for Optim leads. The November 2010 issue of the St. Jude Medical Product Performance Report that provides a section on Optim lead performance (pages 213-214) can be found at <http://www.sjm.com/professional>.

Clinical Implications

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^{7,8,9,10}. This represents a small portion (~10%) of all reported abrasions. Starting with the November 2010 issue of our Product Performance Report, we have added a sub-category entitled Externalized Conductors in the Defibrillation Malfunction Summary Section of the report (page 128).

Lead insulation abrasion can present with various clinical observations if the associated conductors become exposed and then come in contact with other leads or devices. Some of the potential clinical observations are listed below:

- Oversensing (leading to inhibition of pacing or inappropriate high voltage therapy)

- Undersensing
- Loss of capture
- Changes in pacing and/or high voltage lead impedances
- Inability to deliver high voltage therapy.

Rate of Occurrence

Since the initial commercial release in June 2001 through the end of October 2010 there have been approximately 227,000 silicone Riata and Riata ST defibrillation leads sold worldwide. A total of 782 returned Riata and Riata ST defibrillation leads were confirmed by laboratory analysis to have abrasion failures for a confirmed abrasion rate of 0.34%. A significant portion of these returns were not accompanied by a clinical observation or complaint, but were identified as having abrasion during our standard evaluation of returned product. In addition, there were 275 non-returned complaints that could not be verified by laboratory analysis where abrasion was noted to have been observed or was noted as a potential cause of an observed clinical symptom. Using the combined quantity of 1,057 reports associated with abrasion regardless of whether they were confirmed by return analysis resulted in an overall abrasion rate of 0.47% for Riata and Riata ST defibrillation leads over 9 years of use. Under-reporting of lead complications is well acknowledged throughout the industry, so these statistics should be taken in that context. The overall survival rate of the Riata and Riata ST family of leads using silicone insulation is 95.3% at 96 months of follow-up.

Analysis of reports related to lead abrasion shows that the majority of these abrasions occurred within 27 months of implant. Approximately 90% of these leads have been implanted longer than 27 months, with a median implant duration of 48 months. Since the observation of lead abrasion typically presents early in the implant life of these leads, the recommendations provided below for patient management are considered conservative.

Recommendations and Mitigations

Based on the above data and demonstrated superior abrasion resistance of defibrillation leads utilizing Optim insulation, St. Jude Medical is completing the planned phase-out of all models of Riata and Riata ST silicone leads by December 31, 2010.

If you are following any patients implanted with Riata and Riata ST silicone leads, St. Jude Medical makes the following recommendations, which are consistent with standard best practices:

- 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 consensus¹¹.
- 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 suspicion of a lead failure, consider provocative testing 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 if one exists, and/or consider further evaluation of the system (e.g., x-ray or fluoroscopy).
- Consider remote monitoring and advise your patients of the importance of contacting you if they experience any adverse events.
- Prophylactic lead explant is not recommended^{12,13}.

St. Jude Medical has reviewed our lead abrasion data with our Medical Advisory Board and they support the above set of recommendations.

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 Support Department at +46 8 474 4177.

Sincerely,



Kathleen M. Chester
Sr. Vice President, Regulatory Affairs and Quality Assurance

REFERENCE PAGE

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