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Implantable Electronic Systems Division

July 8, 2013

Re: Update - information regarding Riata® & Riata® ST silicone defibrillation leads

Dear Colleague,

St. Jude Medical remains committed to providing you with the latest information on Riata and Riata ST silicone defibrillation leads. This letter is an update to a letter from July 2012 and addresses three topics: (1) key studies and updated management considerations for patients with Riata and Riata ST silicone leads; (2) the most recent Riata Lead Evaluation Study results; and (3) the 2013 1st edition Product Performance Report (PPR).

1. *Key Study Results and Patient Management*

Updated data available through SJM-sponsored and independent studies[1-12] continue to validate the following key points:

a) Based on fluoroscopic screening, the occurrence of externalized conductors is approximately 25% for Riata 8F silicone leads and 10% for Riata ST 7F silicone leads.
b) The rate of externalized conductors in Riata 8F silicone leads when compared to Riata ST 7F silicone leads remains higher even after accounting for the longer implant duration of the Riata 8F silicone lead. These data indicate that design changes to reduce lead diameter and enhance extractability also decreased the overall abrasion and conductor externalization rates of Riata ST 7F silicone leads.
c) A majority of studies have shown no correlation between the presence of externalized conductors and electrical failures.[1-5, 8]

Based on the available data and in consultation with the SJM Medical Advisory Board, the patient management recommendations as communicated in our December 2010 Important Product Information letter and November 2011 Advisory remain appropriate and unchanged.

We invite you to a dedicated website, www.RiataCommunication.com, which is updated on a regular basis and contains detailed data on Riata and Riata ST silicone leads as well as additional resources that assist in managing patients with Riata silicone leads, including:

- St. Jude Medical patient management recommendations
- Guidelines from various regulatory authorities on patient management recommendations
- Review of studies published on Riata and Riata ST silicone lead performance
- Product Performance Report
- Riata and Riata ST silicone lead model survival curves and performance rates
- Compilation of Device Programming and Alerting Considerations for Monitoring and Managing Leads. For your convenience a link to this document is provided below. *Updated considerations can be found under Section II titled "Specific Considerations at Generator Replacement."*
- Riata Lead Management Webinar and Riata Lead Summit summary and presentation.

View Compilation of Device Programming and Alerting Considerations for Monitoring and Managing Leads Document

2. *Update on the SJM Riata Lead Evaluation Study*

The Riata Lead Evaluation Study, initiated in 2011, includes 776 patients implanted with Riata silicone leads enrolled in 23 sites in the United States, Canada, and Japan (517 8F and 259 7F).

Phase I of the Study was designed to determine the prevalence of externalization in these leads. Patients underwent cinefluoroscopy from three views. The table below provides updated results indicating that externalized conductors were present in 24.2% of Riata 8F leads and 9.3% of Riata ST 7F silicone leads. Patients will undergo cinefluoroscopy annually for three years.

Lead Type	Prevalence of Externalized Conductors N (%)	Implant Duration (All Leads)
7F Single (N = 47)	2 (4.3%)	4.4 ± 1.0 years
7F Dual (N = 212)	22 (10.4%)	4.9 ± 0.8 years
8F Single (N = 53)	16 (30.2%)	6.3 ± 1.4 years
8F Dual (N = 464)	109 (23.5%)	6.5 ± 1.6 years

Phase II will evaluate lead electrical performance through three years following enrollment. To date, three leads exhibited electrical anomalies at the time of patient enrollment and seven leads were subsequently found to have electrical malfunctions during study follow-up. Of the 10 leads that have exhibited electrical malfunction, three had externalized conductors and seven did not.

3. *The recently released 2013 1st edition of our Product Performance Report (PPR) and results from studies*

This new edition of the PPR can be found at www.RiataCommunication.com. For your convenience, a summary of the Riata 8F and Riata ST 7F silicone lead insulation failure rates presented on page 256 of the 2013 1st edition of the PPR is provided below.

Riata (8F) and Riata ST (7F) Insulation Abrasion Failure Mechanisms from Complaints and Returns

Insulation Failure Mechanism	Abrasion Type	Riata (8F) Worldwide (WW) Incidence Rate (WW Sales = 156,100)	Riata ST (7F) Worldwide (WW) Incidence Rate (WW Sales = 70,600)
Intravascular – External*	External Abrasion	0.21%	0.17%
Externalized Conductors – External **	External Abrasion	0.20%	0.09%
Lead-to-Can*	External Abrasion	0.52%	0.43%
Insulation Damage*	External Abrasion	0.06%	0.03%
Intravascular – Inside Out*	Internal Abrasion	0.24%	0.10%
Externalized Conductors – Inside Out**	Internal Abrasion	1.44%	0.56%
Internal Abrasion Short Under RV Shock Coil*	Internal Abrasion	0.06%	0.02%
Internal Abrasion Short Under SVC Shock Coil*	Internal Abrasion	0.05%	0.003%

*Determined by returned product analysis.
**Includes cases determined by product analysis as well as cases identified only by fluoroscopy or visualization of explanted leads.

I hope you find this information and other documents on www.RiataCommunication.com helpful in managing patients with Riata and Riata ST silicone leads. We will continue to provide updates periodically and strongly encourage you to register to receive updated email notifications as new information is posted to the site.

As always, please feel free to contact me, your St. Jude Medical representative, or any member of the St. Jude Medical team with any additional questions or concerns.

Sincerely,

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Chief Medical Officer and Sr. VP – Clinical Affairs
St. Jude Medical, IESD

List of References

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7. Abdelhadi RH, et al. Independent multicenter study of Riata and Riata ST implantable cardioverter-defibrillator leads. Heart Rhythm. 2013 Mar;10(3):361-5.
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10. Parvathaneni SV, et al. High Prevalence of Insulation Failure with Externalized Cables in St. Jude Medical Riata Family ICD Leads; Fluoroscopic Grading Scale and Correlation to Extracted Leads. Heart Rhythm. 2012 Aug;9(8):1218-24.
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12. Zhu DW, et al. High Incidence of Externalized Conductors in SJM Riata Leads: Results of Fluoroscopic Surveillance From A Single Center in US. Heart Rhythm 2012;9(5):S445. PO06-20.