

Mark Carlson, MD, MA  
Chief Medical Officer and Sr. VP – Clinical Affairs  
Cardiac Rhythm Management Division

July 13, 2012

Re: Updated information regarding Riata® & Riata ST silicone defibrillation leads

Dear Colleague,

St. Jude Medical is committed to providing you with the latest information on our Riata silicone defibrillation leads. We are sending this letter to inform you that the results from Phase 1 of our multi-center Riata Lead Evaluation Study are now available, and a summary is being posted to our online resource center at [www.RiataCommunication.com](http://www.RiataCommunication.com). As a reminder, Phase 1 of this study was designed to more precisely determine the prevalence of externalized conductors in Riata 8F and Riata ST 7F silicone defibrillation lead models. Phase 2 of the study will assess the long-term electrical performance of leads with and without externalized conductors during a minimum of two year follow-up.

The Riata Lead Evaluation study enrolled 724 patients with Riata 8F and Riata ST 7F silicone leads at 20 sites in the US and Canada (an additional 51 patients have been enrolled at three sites in Japan and are awaiting adjudication; therefore, those data are not included in the presented study results). An experienced physician panel using predefined criteria adjudicated analyzable fluoroscopic images from 718 patients (259 7F and 459 8F leads) for the presence or absence of externalized conductors.

Key findings from Phase 1 include:

- The prevalence of externalized conductors was significantly lower in 7F (7000 series) leads as compared to 8F (1500 series) leads (9.3% vs. 24.0%,  $p < 0.001$ ) and the prevalence of externalized conductors in 7F leads remained significantly lower than that in 8F leads after accounting for implant duration (9.4% vs. 17.9%,  $p = 0.02$ ).
- This prevalence rate reflects a visual anomaly of externalized conductors only and not electrical failures. These data will be collected as part of Phase 2 of the study.
- These rates are consistent with other published data<sup>1,2,3,4</sup> on this topic and indicate that the design changes in the Riata 7F silicone leads provide additional resistance to conductor externalization.
- The St. Jude Medical independent Leads Medical Advisory Board has reviewed the data and recommends no changes to existing patient management recommendations.

Please visit [www.RiataCommunication.com](http://www.RiataCommunication.com) for a detailed summary of the data and several additional resources that can assist in managing patients with Riata silicone leads, including:

- An updated review of studies published on Riata silicone lead performance
- Riata lead model survival curves and performance rates

- Riata Patient Management Considerations reviewed by the independent Medical Advisory Board
- Riata Lead Management Webinar (available July 16, 2012) – Drs. Bruce Wilkoff, Neal Kay, Roger Carrillo, and Charles Love share their perspectives and insights regarding the Riata lead, lead designs and patient management.

I hope you find the information on [www.RiataCommunication.com](http://www.RiataCommunication.com) helpful in managing patients with Riata leads. We will continue to provide periodic updates via the website and encourage you to sign up to receive email updates as new information is posted to the site.

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

Sincerely,



Mark Carlson, MD  
Chief Medical Officer and Sr. VP, Clinical Affairs  
St Jude Medical, CRMD

1. Kodoth V et al. European Heart Journal ( 2011 ) 32(Abstract Supplement), 310.
2. Hodkinson E et al. JACC ( 2012 ) vol. 59(13s1):E585.
3. Schmutz M et al. International Journal of Cardiology, 2012 Jan 9 (Epub).
4. Parvathaneni SV et al. Heart Rhythm 2012 Mar 23 (Epub).