

Response to New England Journal of Medicine Perspective Editorial
By Dr. Mark Carlson, Chief Medical Officer, St. Jude Medical

In Dr. Robert G. Hauser's Perspective editorial titled, "Here we go again – Another failure of postmarketing device surveillance," he highlights the need for additional post-market device data across the industry and outlines how this issue is illustrated by the recall of the St. Jude Medical Riata and Riata ST silicone-only defibrillation leads.

First and most importantly, we take very seriously our responsibilities as a leading medical device company and treat product quality as our highest priority at St. Jude Medical. In this response, we would like to comment on the topic of our Riata silicone-only leads as we believe that there were inaccuracies and omissions in the editorial that are important to recognize in order to more fully understand this issue. Secondly, there is no evidence to suggest any similar issue with our new generation Durata lead and St. Jude Medical has the most active post-market surveillance program in the industry for these leads. We have explained these programs below as well.

Riata Silicone Leads

We agree with Dr. Hauser that additional data are needed to better understand the failure mechanism apparent with the Riata silicone-only leads. Specifically, St. Jude Medical, in consultation with our independent leads Medical Advisory Board (MAB), voluntarily communicated proactively to physicians and the Food and Drug Administration (FDA) regarding externalized conductors in Riata silicone-only leads and our decision to no longer sell these products beginning in December 2010. We again proactively communicated our updated experience in November 2011, and that communication was classified by the FDA as a product recall.

In reviewing the anomaly of externalized conductors in Riata silicone leads, we worked with our independent MAB to develop patient management guidelines. A Heart Rhythm Society panel of experts as well as the FDA have reviewed and independently agreed with these recommendations. Whereas these guidelines have been provided to assist physicians in managing their patients, we understand and agree that clinical decisions regarding patient management need to be individualized based upon specific patient conditions and circumstances and that patient management ultimately is a physician-patient decision.

The Perspective article states, "During the past year, neither St. Jude Medical nor the FDA has instituted the clinical studies that would be required to answer critical questions..." In fact, in December 2011, St. Jude Medical began enrolling in a 500-patient, multi-center, prospective Riata Lead Evaluation Study to further evaluate the incidence of externalized conductors and more importantly to evaluate the electrical performance of the Riata silicone-only leads that have externalized conductors over time. These results will help guide any additional future recommendations regarding patient management. Patients in the study will be monitored for any electrical abnormalities every three months for two years.

Newer Generation Durata Leads with OPTIM coating

Regarding St. Jude Medical's newer generation Durata lead with Optim coating, the article states, "St. Jude Medical is marketing the Durata ICD lead, which has an outer sleeve made of silicone and polyurethane but is otherwise similar to the Riata ST lead." This is incorrect as the Durata lead

incorporated substantial design changes from the prior generation Riata silicone-only leads that we believe significantly reduce the risk of externalized conductors and improve overall reliability. The changes include:

- The conductors' position in Durata was moved toward the center lumen thereby reducing cable tension.
- The Durata lead defibrillation coils were changed to flat wire with silicone backfill.
- Durata leads utilize an outer layer of Optim insulation, a material shown to be 50 times more abrasion resistant than silicone insulation.
- Durata leads have approximately 50% more insulation thickness relative to the Riata silicone-only leads.

Further, during the more than five years it has been on the market with approximately 250,000 leads implanted worldwide, the Durata lead has continued to meet our very high expectations in terms of safety and reliability, and continues to demonstrate excellent performance by any measure.

The Perspective article states that “we do not have a surveillance system in place that can detect low-frequency failures or adverse clinical events involving Durata leads.” However, this is simply not true. We have regularly communicated that St. Jude Medical began prospective, actively monitored registries assessing the performance of our Optim/Durata leads more than five years ago. Collectively, those studies now include 10,836 leads implanted at 292 sites by 571 physicians and represent the largest post-market surveillance program in the history of implantable stimulation devices. In these active registries, participating centers are required to complete a case report form for all patient follow-up visits (scheduled or unscheduled) and report the occurrence of any adverse events. In addition, a dedicated group of field employees perform on-site monitoring of these centers to ensure that the data being sent to the company is accurate and complete. This represents best practice for clinical studies and is very different than passive registries that rely solely on complaints and return information, and as the author points out, are known to have a certain amount of underreporting. To date, the studies have over 24,000 patient-years of follow-up data, which continue to confirm the excellent reliability of the Durata lead.

This investment in post-market surveillance is unprecedented in our industry and exemplifies our commitment to providing physicians and patients with the information they need to make clinical decisions.

Conclusions

We take our responsibilities related to communication of any product issue and the performance of our current products very seriously. Information about Riata silicone-only leads, the Riata Lead Evaluation Study, the lead design changes in our current generation of devices and our prospective, actively monitored studies have been communicated in a variety of ways, including at the Riata Summit on January 20, 2012, which was hosted by the Minneapolis Heart Institute Foundation. We have worked closely with our independent MAB, the FDA and the Heart Rhythm Society to address the issues with Riata silicone leads. In addition to our biannual Product Performance Report, we have launched the Riata Communication website (riatacommunication.com) as another resource for physicians to find all available information on our silicone-only Riata leads and will use this resource to continue to share additional information as it becomes available.

St. Jude Medical has a strong history of product safety and reliability, and we remain dedicated to developing technology and products that save and improve the lives of patients. We take our responsibilities as a leading manufacturer of cardiac rhythm management devices very seriously and recognize our primary responsibility as a global medical device manufacturer is to ensure that our devices are of the highest quality and function safely and properly.

