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Heart Rhythm Journal Data Clarification and Our Continuous Focus on Device Performance
By Dr. Mark Carlson, Chief Medical Officer, St. Jude Medical Cardiac Rhythm Management

At St. Jude Medical, we take our role as a leading provider of medical devices very seriously. Patient safety and device quality have always been and continue to be our highest priorities. Our ongoing focus is on developing the next generation of products to perform even more reliably than the last.
We develop our products to save lives. And indeed, our products, as well as those of our competitors, have saved countless lives. A cardiac rhythm management lead is asked to survive in the harsh environment of the bloodstream and beating heart. Its energy source, the defibrillator can, contains miniature electronics developed, tested and also implanted in the human body. As much as we continue to strive to reduce the risk of anything ever going wrong, sometimes it does.

A manuscript entitled, “Deaths Caused by the Failure of Riata and Riata ST Implantable Cardioverter-Defibrillator Leads,” was accepted for publication in the *Heart Rhythm Journal* and made available online this week. This article is based on a search of the Food and Drug Administration’s Manufacturer and User Facility Device Experience (MAUDE) database of reported complaints and failure of our older generation silicone leads. The review compared lead-related deaths in patients with an older generation silicone-insulated St. Jude Medical Riata® and Riata ST lead to the current generation of a competitive product that uses a polyurethane outer insulation, which was added for a similar reason that we added our newer insulation technology to our current generation leads.

In December 2010, St. Jude Medical voluntarily and proactively sent a letter to physicians to communicate a significant reduction in all-cause abrasion with our newer Optim® insulation, as compared to silicone-only insulated leads. At that time, we also stopped selling our Riata silicone leads. Abrasion of silicone leads is acknowledged within the clinical community as a well-known risk and is clearly documented in the literature as the number one cause of lead failure with reported failure rates ranging from 3 to 10% for older-generation technologies across manufacturers. While we recognize this is an acknowledged risk, we do not find any failure rate acceptable. We continue to strive to reduce the risk of lead failure.

We are committed to ensuring that the clinical community and broader stakeholders have all of the information necessary to asses our device performance. As the manuscript noted, the MAUDE database often contains incomplete reports that do not fully reflect the conclusions following testing and review of the reported device malfunction. For this reason, it is often not possible to draw conclusions on the root cause of a failure mode based on a review of this source.

Our Analysis of the Devices in the MAUDE Reports
Given this understanding of the lack of information and reliability of the MAUDE database, it is not surprising that the manuscript published this week is not entirely accurate. We were not asked to review the information the author found in the MAUDE database prior to publication. Based on our analysis of the reports listed in the manuscript and our investigations, where possible, of the returned device, we have concluded:

- 2 of the 22 reports are duplicates
- 7 are the result of lead-to-can abrasion, which is the most common cause of abrasion for all leads
- 2 are the result of lead-to-lead abrasions
- 2 are due to internal electrical "shorts"
    - These "shorts" resulted from previously referenced and published abrasion of the silicone material
    - There were no cases of internal "shorts" on the Riata ST leads
    - The internal shorts were limited to Riata 8F leads in this MAUDE analysis, which supports our data that the flat-wire shock coil and silicone backfill design improvements introduced in the Riata ST 7F leads have significantly reduced an already low incidence of "shorts" under the shock coil

The remaining nine leads in this analysis were not returned to the company and as a result we cannot assign a specific failure mechanism to these reports; however, it is likely that the failure rates would be similar to those that were returned to the company. Therefore, the majority of these remaining reports are likely related to lead-to-can abrasion. We continue to enroll patients in our 500 patient Riata Lead Evaluation study to further understand the electrical failures associated with these silicone-only insulated leads. We will share information resulting from that study as soon as it is available.

Update on St. Jude Medical Actions
We remain confident that the design evolution of our lead models, coupled with the addition of our Optim insulation, have reduced the potential for abrasion-related issues. The data from the *Heart Rhythm Journal* manuscript and the recent update of the Belfast data at the American College of Cardiology meeting support this conclusion as well. We now have more than five years of experience and data with our Optim/Durata® lead family, and we are experiencing significantly reduced abrasion rates. We are meeting our goal to have our newer generation products perform more reliably than the last.

We announced this week as well that we have appointed Population Health Research Institute (PHRI), an academic health science research institute, to analyze data from three combined prospective, actively monitored registries involving over 10,000 patients that are documenting the performance of our current generation leads. The analysis will be entirely under the control of PHRI, who will complete a review of the raw data and report their findings independent of the company.

Conclusions
We are absolutely committed to the highest levels of device performance and public transparency. We have taken a number of actions to reflect this commitment related to Riata over the past two years. We remain focused on ensuring that we deliver the highest quality products possible to patients who rely on a St. Jude Medical device.