

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

August 22, 2012

Re: FDA Safety Communication on Riata® and Riata® ST silicone leads

Dear Colleague,

On August 16th, the FDA issued a Safety Communication regarding Riata and Riata ST silicone lead patient management recommendations. In this communication, the FDA recommended:

“that physicians image Riata and Riata ST leads implanted in patients to assess for externalization or other visible insulation abnormalities.”

“Imaging can be done via fluoroscopy or a two-view chest X-ray. If leads have been imaged in the last three to six months, physicians may choose to review those images rather than ordering a new imaging study.”

“The value of repeat imaging for leads initially assessed as intact is uncertain, and the FDA recommends individualized clinical management that takes into consideration the patient’s specific risk factors.”

Other FDA recommendations for management of patients with Riata leads were consistent with the St. Jude Medical recommendations in our November 2011 communication (attached and available at www.RiataCommunication.com).

We acknowledge the FDA’s decision to recommend imaging in patients with Riata silicone leads and have strongly supported efforts to collect additional data on the incidence rate and clinical implications of externalized conductors. In July 2012, we announced the results of the first phase of the multicenter, prospective Riata Lead Evaluation Study identifying the incidence rates of externalized conductors in 718 patients with Riata and Riata ST silicone-only leads. This study, which will be supplemented by an additional 51 patients from Japan, will continue to evaluate the performance of these leads, both those with and without externalized conductors, over a minimum of two years with particular focus on electrical performance. Continued follow-up will determine how these leads function over time and should help inform patient management considerations going forward.

We will also continue to consult with our Medical Advisory Board (MAB) on any updates to their original recommendations and will communicate further if there are any changes. We recognize that the ongoing management of patients with Riata silicone-only leads, including the use of imaging, is complex and needs to take into account individual patient circumstances. We will continue to support your medical judgment on the need for imaging and other treatment decisions for your patients.

The FDA communication also discussed post-market monitoring of our leads. We have aggressively supported post-market lead surveillance programs on all of our products and currently have the largest post-market lead surveillance registries in the industry. Beginning six years ago, 10,950 Riata ST Optim® and Durata leads have been enrolled in actively monitored, post-market registries at almost 300 centers. The overall accumulation of data continues to support the safety and reliability of these leads, which have undergone significant design changes since the Riata lead was originally introduced. We will continue to collaborate with the FDA to understand the ongoing performance of our leads.

Other FDA recommendations for management of patients with Riata leads were consistent with the St. Jude Medical recommendations in our November 2011 communication (available at www.RiataCommunication.com). In particular, the FDA did not recommend the preemptive replacement or removal of a functioning Riata lead. St. Jude Medical recognizes that an externalized conductor may present complex patient management considerations for physicians, but it is important to note that in published studies, the majority of leads with externalized conductors have continued to function properly.

If x-ray or fluoroscopic screening is performed, please consider the following:

- The Riata Lead evaluation study employed fluoroscopic imaging in three views (RAO at 45 degrees, AP, and the LAO view closest to 45 degrees available).
- Adjudication of externalized conductors may be difficult for a reviewer inexperienced in evaluating these leads. Normal leads (without externalized conductors or other abnormalities) have been extracted when externalized conductors were erroneously thought to exist.
- As a resource we have posted the specific criteria used by experienced physicians to adjudicate the presence or absence of externalized conductors in the Riata Lead Evaluation Study (“Guidelines for Radiographic Assessment of Externalized Conductors”) at www.RiataCommunication.com.
- In light of the FDA’s Safety Communication, St. Jude Medical will provide assistance to patients with the patient’s share of the unreimbursed medical costs for imaging and interpretation of initial X-rays or fluoroscopy, where Warranty program requirement are met.

Additional considerations for device programming, monitoring lead integrity, remote follow-up using Merlin.net for patients with Riata leads are attached and also available at the www.RiataCommunication.com website.

Our field representatives and Technical Services are available for support and can provide you with a list of your Riata and Riata ST patients if needed.

I hope you find the information on www.RiataCommunication.com helpful in managing patients with Riata and Riata ST silicone leads. We will continue to provide you with periodic updates via the website and encourage you to enroll 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,

A handwritten signature in cursive script that reads "Mark D. Carlson".

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

Appendix A – Recommendations and Mitigations extracted from St. Jude Medical November 28, 2011 “Medical Device Advisory” Physician Letter

Recommendations and Mitigations

Based on input from our Medical Advisory Board (MAB), St. Jude Medical is conducting a prospective study to evaluate further the incidence and long-term performance of leads with externalized conductors that do not exhibit electrical abnormalities. The outcome of the study, along with any additional information we learn, will determine if updated recommendations are needed. Enrollment is expected to begin in December, 2011 and we will communicate the results when they become available.

St. Jude Medical’s MAB has reviewed the available data and is updating the recommendations from the December 2010 product communication below. If you are following any patients implanted with Riata and Riata ST silicone leads, St. Jude Medical and the MAB make the following recommendations, which are consistent with standard best practices and our December 2010 product communication:

- Whenever possible, monitor devices and leads remotely and advise your patients of the importance of contacting you should they experience any adverse events. St. Jude Medical remote monitoring features can be used to detect electrical changes early that may be associated with externalized conductors.
 - St. Jude Medical offers a vibratory patient notifier and daily remote monitoring capabilities through the Merlin@home transmitter in response to out of range impedance measurements from three High Voltage lead vectors (RVC to Can, SVC to Can, and RVC to SVC), as well as pacing and sensing electrodes. Data are displayed graphically to enable physicians to trend changes in impedance over time. Customized DirectAlerts notifications allow physicians to monitor patient status between follow-ups. The noise reversion feature protects against non-physiologic high rate event detection to avoid inappropriate shocks.
- 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 are a follow-up period of every 3 - 6 months for ICD/CRT-D devices per the HRS/EHRA consensus.
- 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 evidence of a lead electrical failure, manage the patient per standard practice⁶. This may include x-ray or fluoroscopy. Additional testing if necessary could include provocative methods 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 associated with any source of lead electrical failure if one exists.
- The value of routine x-ray or fluoroscopy for patients with leads having no electrical abnormalities is unknown at this time and is therefore not recommended.
- In addition, prophylactic explant or replacement of a lead without electrical dysfunction is not recommended.
- Currently there is no expert consensus regarding whether patients undergoing pulse generator replacement should undergo fluoroscopy or lead replacement should an externalized conductor without electrical anomalies be present. This is, in part, because the risk versus benefit of replacing a lead in such a patient may vary from patient to patient and center to center. Clinical decisions in this setting should be individualized based on specific patient conditions and circumstances. St. Jude Medical is conducting a study that will provide information that helps to inform the management of these patients.

⁶ Epstein, A.E. “Troubleshooting of Implantable Cardioverter-Defibrillators.” *Clinical Cardiac Pacing, Defibrillation, and Resynchronization Therapy*, 3rd ed. Eds. Ellenbogen, K.A., Kay G.N., Lau, C-P., Wilkoff, B.L. Philadelphia: Elsevier, 2007, pp. 1063-1086.

Appendix B – Programming and Alerting Considerations

St. Jude Medical Device Programming and Alerting Considerations for Monitoring and Managing Leads

Programming Considerations

- **To clearly identify a patient with a Riata® or Riata ST Lead:**
 - Add Riata Lead descriptor to patient profile 'Notes' box
- **To use SecureSense™ RV lead noise discrimination* to monitor for noise:**
 - Set the discriminator to *On* (nominal) in order to detect and inhibit therapy for lead noise
 - Set the discriminator to *Passive* to only monitor and detect lead noise but not inhibit therapy
- **To use an EGM channel to monitor for HV lead noise:**
 - Set an unused EGM channel to '*RV Coil to SVC*' under Stored EGM Configuration settings
- **To program upper and lower limits for Pacing Lead Impedance (PLI) and High Voltage Lead Impedance (HVL):**
 - Set the PLI 'Upper Limit' to 1000 Ohms and 'Lower Limit' to 200 Ohms
 - Set the HVL 'Upper Limit' and 'Lower Limit' to 25 Ohms above and below the settled impedance trend rate
- **To ensure episode triggers for EGM storage, as available per device type:**
 - Verify priority is set to 'Low' for *Atrial AMS/AT/AF* episodes
 - Verify priority is set to 'High' for *VT* and *VF* episodes
 - Verify priority is set to 'Low' or 'High' for *Non-sustained VT/VF* episodes*
 - Verify priority is set to 'Low' or 'High' for *Non-sustained V Lead Noise* episodes*
 - Verify priority is set to 'Low' for *Noise Reversion* episodes.
(Note: Stores EGM but does not trigger device transmission to Merlin.net® PCN)
- **To enable appropriate patient notifications, program these vibratory patient alert triggers:**
 - RV Lead Impedance Out of Range
 - Therapy is inhibited due to Lead Noise
 - Episodes of Non-sustained Lead Noise are Detected
 - HV Lead Impedance Out of Range
 - Possible HV Circuit Damage
- **To monitor pacing thresholds**
 - Turn RV AutoCapture™ pacing to On or RVCap® Confirm to On or Monitor, if available and as appropriate for individual DR and CRT-D patients
- **To help avoid tachy episode detection of potentially brief lead noise episodes:**
 - Change Detection Criteria for the number of VF Detection Intervals to 24 or 30 intervals

* Available in all St. Jude Medical Ellipse® and Assura™ family ICDs & CRT-Ds

St. Jude Medical Device Programming and Alerting Considerations for Monitoring and Managing Leads

Patient Diagnostic Reports Inspection

What to look for to monitor implanted lead integrity -

- **Stored EGMs / Rhythm Episodes:**
 - Check presenting rhythms / stored EGMs for noise or artifact deviations on far field sensing vectors that include RV Coil, SVC Coil, and RV Ring to compare with near field sensing
- **Ventricular Heart Rate Histogram:**
 - Check histogram for counts in the high rate bins faster than 250ms (>240 bpm) that are likely non-physiologic
- **Ventricular Lead Impedance (PLI) Trend Report:**
 - Check pacing lead impedance for variations and changes in trend since last follow-up
- **HV Lead Impedance (HVLI) Trend Report:**
 - Check high voltage lead impedance on all vectors for variation of >25% since last follow-up
 - For Atlas and Epic family devices which do not have automatic HVLI measurements, the HV lead impedance test can be performed manually through the programmer screen. Be aware that some patients may notice discomfort during the 10V stimuli required to measure the impedance.
- **Ventricular Amplitude Trend Report:**
 - Check trend for signs of decreasing amplitude or fluctuations in trend
- **RV AutoCapture™ Pacing Trend Report / RV Cap® Confirm Trend Report:**
 - Check trend for increases in pacing threshold / changes over time, if RV AutoCapture Pacing or RV Cap Confirm feature is available and enabled
- **Non-sustained VT/VF episodes and diagnostics**
 - Check episodes and diagnostics for the number of non-sustained episodes detected and any associated stored EGMs to examine for lead noise that may have been responsible for these episodes
- **SecureSense RV Lead Noise Detected and Non-Sustained Lead Noise Detected episodes and diagnostics**
 - Check '**VT/VF Episodes**' for RV Lead Noise detected EGM episodes and diagnostics, and examine for lead noise that may have been responsible for these episodes
 - Check '**Other Episodes**' for Non-sustained RV Lead Noise EGM episodes detected, and examine for short bursts of lead noise that may have been responsible for these episodes

Note: Every case is unique; therefore physicians should decide the best treatment option for their patient

If you have any questions or concerns about available device features or programming options, please do not hesitate to contact St. Jude Medical Technical Services (1-800-PACEICD) or your local St. Jude Medical representative.

St. Jude Medical Device Programming and Alerting Considerations for Monitoring and Managing Leads

Merlin.net® Patient Care Network (PCN) Remote Patient Monitoring

- **To ensure that patients are identified as having a Riata or Riata ST lead for ease of lead surveillance via remote monitoring:**
 - Add Riata lead descriptor to patient profile / record.

- **To ensure that remote monitoring alerts are received, possibly related to the presence of lead noise, program the following DirectAlerts® notifications**
 - Set the following Alert Types to **'Urgent'** or **'Standard'**, as available per device type
 - RV Pacing Lead Impedance Out of Range
 - High Voltage Lead Impedance Out of Range
 - Possible High Voltage Lead Issue
 - Sustained RV Lead Noise Detected
 - Non-sustained RV Lead Noise Detected
 - Ventricular Noise Reversion

- **To ensure that the clinic receives the alerts on Merlin.net PCN**
 - Patients need to have their Merlin@home® transmitters connected via landline, cellular adapter or broadband connectivity to receive software updates that will enable the new alert types on Merlin.net PCN and transmit these alerts to Merlin.net PCN.

- **To ensure that appropriate clinic personal receive remote monitoring alerts which could be related to the presence of lead noise:**
 - Revise 'Clinic Preferences' for DirectAlerts® distribution, as appropriate

St. Jude Medical Device Programming and Alerting Considerations for Monitoring and Managing Leads

Merlin.net[®] PCN – Patient Diagnostic Reports Inspection

Review the **Recent Transmissions** screen on Merlin.net PCN for the list of patients with alert conditions and associated device report transmissions

What to look for to monitor implanted lead integrity -

- **Merlin.Net PCN 'Alert Summary' report**
 - Check list of device triggered alerts and or remote monitoring alerts for episodes pertaining to potential RV lead related issues
- **Stored EGM episode reports**
 - Check EGMS for the presence of lead noise on each of the available channels, especially episodes identified as **VT/VF**, episodes identified as **Non-sustained VT/VF**, and **Sustained RV Lead Noise Detected** and **Non-Sustained RV Lead Noise Detected** episodes.
- **'Ventricular Heart Rate Histogram' report display**
 - Check histogram for counts in the high rate bins faster than 250ms (>240 bpm)
- **'Ventricular Lead Monitoring' Impedance (PLI) Trend report display**
 - Check for impedance changes from baseline trend
- **'HV Lead Monitoring' Impedance (HVL) Trend report display**
 - Check for impedance changes from baseline for all 3 vectors
- **'Ventricular Amplitude' trend report display**
 - Check for changes in pacing amplitude and trends
- **RV AutoCapture™ Pacing Trend / RV Cap[®] Confirm Trend report display, if available and enabled**
 - Check for increases in pacing threshold and changes over time

Note: Every case is unique; therefore physicians should decide the best treatment option for their patient

If you have any questions or concerns about available device features or programming options, please do not hesitate to contact St. Jude Medical Technical Services (1-800-PACEICD) or your local St. Jude Medical representative.