

**Canadian Heart Rhythm Society
Device Committee**

Re: St. Jude Medical Riata and Riata ST High Voltage Leads

Dear CHRS Device Committee Members,

CHRS Class of Advisory: Class I

Urgency of Advisory: Semi-urgent

Nature of the Advisory: This advisory describes a unique form of lead failure in the Riata (8Fr) and Riata ST (7Fr) silicone endocardial defibrillation leads. This form of failure is due to an outer insulation breach resulting in externalization of conductor cables, contained within the body of the defibrillation lead. The breach results in the externalized conductors becoming visible on either X-ray or fluoroscopy outside the lead body. The cause of the insulation breach may be due to relative motion of the conductor cables within the lead insulation lumen, referred to as “inside-out” abrasion, or from external sources, such as lead-to-lead abrasion. The most common area of abrasion (75% of confirmed cases) occurs within 8 centimeters proximal to the RV shock coil, presumably due to increased stress from cardiac motion at this point.

Scope of the Problem: There have been ≈ 5300 silicone Riata and Riata ST leads sold in Canada, $\approx 227\,000$ worldwide. The Riata (8Fr) lead has been available since 2001, while the Riata ST (7Fr) lead became available in 2005. The overall rate of abrasion from worldwide complaints (including product not returned) and returned product analysis is 0.63%, with $\approx 15\%$ of these exhibiting externalized conductor cables. There have been a few single center studies reporting their experience with Riata externalized conductors, with one center in Belfast, Northern Ireland reporting a 15% rate of externalized conductors based on fluoroscopic screening (Kodoth V., Cromie N., Laue E. et al, reported at ESC 2011, <http://spo.escardio.org/abstract-book>), but only 3% that were associated with an electrical abnormality. There appears to be an increased rate of abrasion in the Riata (8Fr) lead over the Riata ST (7Fr) which the manufacturer has determined to be statistically significant using Kaplan-Meier analysis taking into account differences in follow-up duration between lead models, but the former has been implanted for four more years, so there may be temporal bias operating to account for some of the difference. In addition, the Single Coil models of the Riata (8Fr) have the highest incidence rate, statistically significantly higher than all other models. This issue may manifest solely as a structural abnormality, as seen in Figure A. Figure B depicts the X-ray manifestation of the externalized cables. The finding of a structural abnormality may not necessarily be associated with abnormal lead parameters. Over 80% of the returned Riata silicone leads have no evidence of breach of the ethylene tetrafluoroethylene (ETFE) insulation around the externalized cables themselves, which is likely why no electrical abnormalities may be observed. From reports associated with worldwide complaints (non-returns) and returns, the presentation of electrical abnormality was pacing or defibrillation impedance changes ($\approx 37\%$), inappropriate therapy ($\approx 36\%$), noise and oversensing ($\approx 18\%$) and threshold rise ($\approx 9\%$).

If this lead is found to have malfunctioned due to abrasion and externalization of conductor cables and lead extraction is planned, extreme caution must be used to extract these leads, due to the disruption of the lead. A larger sheath may be required to accomplish the extraction. There have been two deaths reported due to complications related to extraction of this lead. There have otherwise not been any reports of serious death or injury due to being unable to deliver high voltage therapy.

Response of the Canadian Heart Rhythm Society

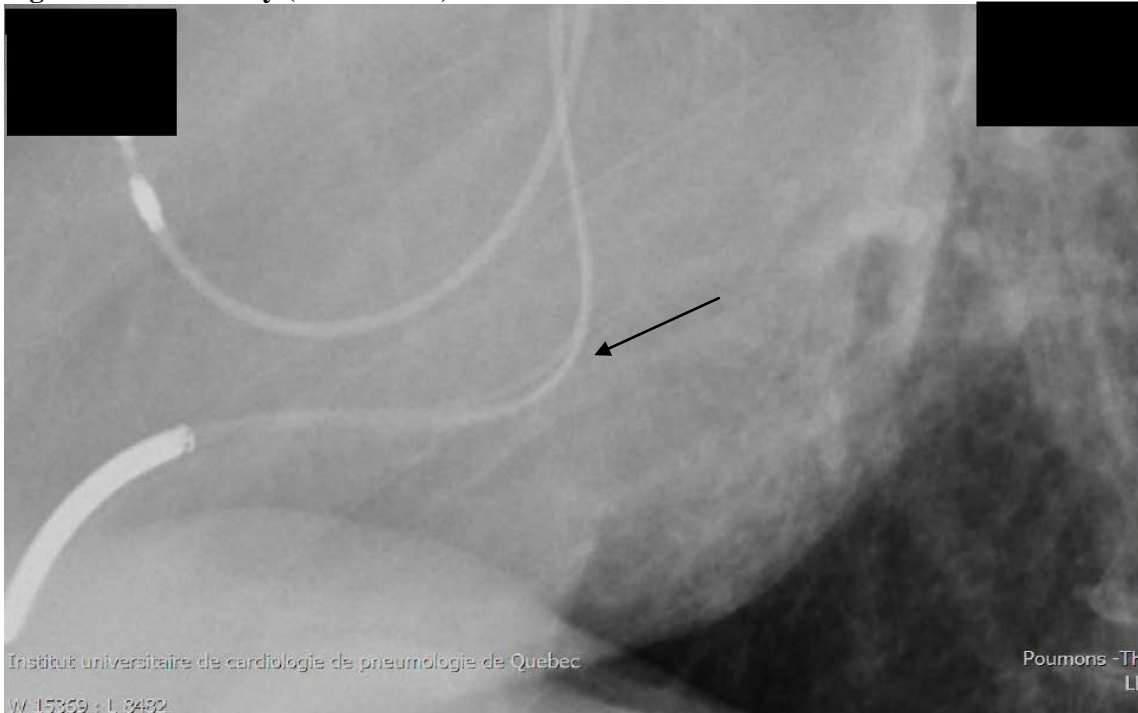
The CHRS-DC is in the process of conducting a national survey to better understand the scope of this advisory. In addition, a more detailed study of this issue using radiographic examination will be undertaken to assist in better understanding how this lead will behave over time. St. Jude Medical is also undertaking a prospective study to evaluate further the incidence and long term performance of leads with externalized conductors that do not exhibit electrical abnormalities. This study will commence in Dec. 2011, with participation from one Canadian center.

Figure A. Riata lead with externalization of conductor cables



Courtesy of St. Jude Medical

Figure B. Chest Xray (lateral view) of Riata lead with externalization of conductor cables



Courtesy of F. Phillipon, Laval University

Recommendations:

1. The CHRS-DC feels that patients should be informed of this issue at their next routine clinic visit.
2. Follow up visits as per the Canadian guidelines (Gillis et al. CJC 2002) should be continued, either in clinic or through remote monitoring.
3. The CHRS-DC does not recommend lead replacement for this issue unless abnormal electrical parameters are identified.
4. Routine screening with fluoroscopy or high quality chest radiographs from multiple angles may be useful in identifying an affected lead.*
5. The CHRS-DC does not recommend lead replacement for this issue at the time of system revision, but does recommend fluoroscopic screening at the time of system revision to identify an affected lead.* If found, consideration to lead revision should be given to a lead revision procedure, guided by the risk/benefit of doing so in that individual situation. Lead extraction for the affected lead should be considered, again guided by risk/benefit analysis, as there is possibility of further degradation of the ETFE around the lead, with resultant possibility of a short-circuit between the new high voltage lead and the retained lead with exposed conductors.
6. If lead extraction is planned for this lead, it should be done in a high volume extraction center, with precautions taken, as described above.

*These are recommendations of the CHRS-DC and are not included in the recommendations provided by the manufacturer, St. Jude Medical, or their Medical Advisory Board (see enclosed letter from St. Jude Medical: *Important Product Information Update*).

Ratika Parkash
CHRS DC Chair
parkashr@cdha.nshealth.ca