August 8, 2012 Advisory Response Notification - UPDATE

Canadian Heart Rhythm Society
Device Committee

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

Dear CHRS Device Committee Members,

Class of Advisory: Class I (classified in December, 2011)

Urgency of Advisory: Semi-urgent (as per prior advisory)

Nature of the Advisory: **This update provides additional information obtained from the Prospective Riata Lead Evaluation Study conducted by St. Jude Medical on over 700 Riata leads under advisory**. The original advisory described an unusual form of lead failure in the St. Jude Medical Riata (8Fr) and Riata ST (7Fr) 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 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 or lead-to-can 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 leads sold in Canada, and 227 000 worldwide. The Riata (8Fr) lead has been available since 2002, while the Riata ST (7Fr) lead became available in 2006. These products are no longer sold in Canada, replaced by other models in December, 2010. The overall rate of abrasion from returned product analysis is 0.63%, with ≈15% of these returned products exhibiting externalized conductor cables. **The data from the recent study found that the prevalence of externalized conductors in the 7Fr (7000 series) leads versus 8Fr (1500 series) is significantly lower (9.3% vs 24.0%, respectively, $p<0.001$). When implant duration is considered, this remains statistically significant (9.4% vs 17.9%, $p=0.02$). The second phase of the study will examine long term clinical performance. These rates are consistent with what was found by the Laval Group (personal communication Dr. Jean Champagne), as well as our national survey.**

The electrical failure mechanism for this lead remains undefined. Further work in this area may help elucidate the mechanism.

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 inability to deliver high voltage therapy.

Response of the Canadian Heart Rhythm Society
Updated Recommendations (based on Riata information to date) :

1. The CHRS-DC feels that patients should be informed of this issue at their next routine clinic visit.
2. Follow-up should be increased to every 1-3 months via remote monitoring; consider every 3 months for an in-clinic visit in patients where remote monitoring is not possible. In order to detect possible lead-can abrasion, manipulation of pocket and counter pressure maneuvers during a lead impedance and HVLI measurement may be considered at the time of an in clinic visit.
3. Some tips to increase the possibility of early detection of electrical lead failure or to avoid inappropriate shocks include: 1) Narrow the HVLI parameters. This programming change may result in increased frequency of alerts. 2) Increase VF detection to a longer detection time. 3) Review of the heart rate histogram to evaluate whether any short R-R intervals (>240 bpm) have occurred that may indicate sensed noise .
4. There is no data that routine radiographic evaluation of these leads is indicated. This is being evaluated in observational studies, and this recommendation will be updated as data becomes available.
5. The CHRS-DC does not recommend lead replacement for this issue unless electrical abnormalities are identified.
6. In patients who have not had a high voltage therapy in the prior two years, it is reasonable to consider performing some form of 'electrical stress test' of the high voltage system in those undergoing a pulse generator change. Using a test shock with at least 10 J may be reasonable to ensure absence of noise and good HV lead impedance; inducing VF is not necessary.
7. 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 detected, consideration to lead revision should be given, guided by the risk/benefit of doing so in that individual situation. Lead extraction of the affected lead should be considered, again guided by risk/benefit, as there is potential for further degradation of the ETFE around the lead, with resultant potential of a short-circuit between the new high voltage lead and the retained lead with exposed conductors.
8. If lead extraction is planned for this lead, it should be performed in a high volume extraction center, with precautions taken, as described above.

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