Notice to Hospitals -
Health Canada Endorsed Important Safety Information on
St. Jude Medical Riata and Riata ST Silicone Endocardial Defibrillation Leads

ST. JUDE MEDICAL
MORE CONTROL. LESS RISK.

October 31, 2012

Dear Health Professional,

Please distribute to the relevant Departments of Cardiology, Cardiac Surgery, Radiology, and/or other Departments as required and other involved professional staff and **post this NOTICE** in your institution.

Subject: **St. Jude Medical Riata and Riata ST Silicone Endocardial Defibrillation Leads – Safety recommendations regarding lead insulation abrasion**
Riata models: 1560, 1561, 1562, 1570, 1571, 1572, 1580, 1581, 1582, 1590, 1591, 1592
Riata ST models: 7000, 7001, 7002, 7010, 7011, 7040, 7041, 7042

St. Jude Medical Inc., in collaboration with Health Canada, is providing this letter to re-iterate safety information and provide updated patient care resources and recommendations regarding insulation abrasion in Riata and Riata ST defibrillation leads.

- **Lead insulation abrasion may result in lead electrical malfunction potentially causing abnormal pacing or sensing, delivery of inappropriate shock therapy, or failure to deliver needed therapy, which could result in serious adverse events including death.**
- **Accelerated patient follow-up for both remote monitoring and in-person clinic visits is recommended. The exact diagnostic and alerting features will differ between pulse generator models and remote monitoring systems.**
- **Advise patients of the importance of contacting their follow-up clinic should they receive a vibratory or auditory alert from their device and to contact their physician or report to the nearest hospital should they experience any adverse events.**
- **At the next scheduled pulse generator replacement, consider performing fluoroscopic or x-ray imaging to identify potential insulation damage in order to facilitate the development of individualized patient care plans.**

Background Information
Riata and Riata ST leads were marketed in Canada from May 2002 to December 2010. According to hospital implant registration data, approximately 4,320 remain actively implanted

as of September 2012.

Insulation abrasions have been reported with Riata and Riata ST defibrillation leads. One form of lead abrasion known as 'externalized conductors' is observed when the outermost silicone insulation is breached, allowing individual conductor cables to become visible outside of the lead body. Preliminary results of the Riata Lead Evaluation Study (RLES) were reported in July 2012, based on 724 patients with Riata and Riata ST silicone leads enrolled at 20 sites in the US and Canada. The prevalence of externalized conductors reported in this study was 24% for Riata (8Fr) models and 9.3% for Riata ST (7Fr) models. These rates are consistent with other published data[1-5]. In the majority of reported cases of Riata and Riata ST leads with externalized conductors, the leads have continued to function normally, owing to a second layer of insulation on the individual conductor cables. The RLES will assess the long-term electrical performance of leads with and without externalized conductors during a minimum of three year follow-up.

Most instances of externalized conductors with Riata silicone leads that have been confirmed by laboratory analysis have been due to 'inside-out' abrasion. Inside-out abrasion refers to the mechanism whereby relative motion of the conductor cables within the silicone insulation leads to abrasion and possible breach of the outer silicone insulation layer. Externalized conductors can also occur due to lead friction with sources external to the lead (referred to as 'external abrasion'), such as calcified tissue or other implanted leads.

Insulation abrasion between a lead body and an implantable cardioverter defibrillator or ICD (i.e. lead-to-can abrasion) may result in short circuiting of lead components to the pulse generator. Based on returned product analysis, the overall rate of lead-to-can abrasion is 0.43% in Riata models and 0.35% in Riata ST models. Approximately 27% of confirmed lead-to-can abrasions exhibited abrasion of all layers of lead insulation, presenting the possibility of high voltage short circuits. Distinct from lead-to-can abrasion, internal abrasion may lead to short circuiting of internal lead components. In leads returned to St. Jude Medical for product analyses, the rate of internal short circuiting of high voltage lead components due to internal abrasion was approximately 0.08% in Riata models and 0.01% in Riata ST models. There have been international reports of patient deaths resulting from these types of short circuit malfunctions.

St. Jude Medical Canada Inc. has disseminated information and advisory letters in December 2010, November 2011 and July 2012 to healthcare professionals and hospital administrators regarding insulation abrasion in Riata and Riata ST silicone leads. If you have not reviewed these letters and may be involved in caring for a patient implanted with a Riata or Riata ST lead, please contact St. Jude Medical Canada Inc. to obtain a copy of the advisory letters, or visit www.riatacommunication.com/intl/physician-information.aspx.

Additional Important Safety Information

St. Jude Medical Inc. has published guidelines to assist with the radiographic visualization of externalized conductors. ("Guidelines for Identifying Externalized Conductors on Radiographic Images") at www.riatacommunication.com/intl/physician-information.aspx.

St. Jude Medical Inc. has developed updated considerations for device programming, lead integrity monitoring, and patient remote follow-up. ("Riata Lead Programming and Monitoring Considerations") at www.riatacommunication.com/intl/physician-information.aspx.

Particular attention should be directed to analyzing the electrical integrity of high voltage lead components as short circuiting of high voltage components can render the pulse generator unable to deliver needed shock therapy. Specific recommendations include the following (but are not limited to):

- In order to detect possible lead-to-can abrasion, manipulation of the pocket and counter pressure maneuvers during lead impedance measurement may be considered.
- For devices which do not have automatic high voltage lead impedance measurements (e.g. Atlas and Epic family devices), the high voltage impedance test (12 V) should be measured at each clinic visit.

Information Regarding Lead Revision

There is currently no evidence to recommend routine revision of leads without electrical dysfunction, although clinical decisions should be individualized based on specific patient conditions and circumstances. If a lead is revised, physicians should carefully consider the risks and benefits of abandoning the lead versus extracting the lead. The decision to extract a lead should be based on the individual patient conditions as well as the training and experience of the practitioner and the extraction team[6]. If a Riata or Riata ST lead extraction is planned, the following information should be considered:

- The presence of externalized conductors may result in increased difficulty and lengthened procedure for removing the lead using extraction tools, such as sheaths.
- Extraction of 8Fr Riata lead models (non-ST) may have added complexities owing to their round, non-backfilled shocking coils. These lead characteristics have been associated with fibrous tissue in-growth at the shock coils in lead models prior to the Riata ST which has flat wire technology and silicone backfill to help prevent such in-growth[7].

Reporting Adverse Incidents

Managing marketed health product-related adverse incidents depends on health care professionals and consumers reporting them. Reporting rates determined on the basis of spontaneously reported post-marketing adverse incidents are generally presumed to underestimate the risks associated with health product treatments. Any cases of adverse incidents in patients implanted with Riata or Riata ST leads should be reported to St. Jude Medical Canada Inc. or Health Canada at the following addresses:

Any suspected adverse incident should be reported to:
St. Jude Medical Canada Inc.
2100 Derry Road West Suite 400
Mississauga, Ont L5N 0B3 Canada
Telephone: 905-812-8600
Fax: 905-812-4295

Any suspected adverse incident can also be reported to:
Health Products and Food Branch Inspectorate
Health Canada
Address Locator: 2003D
Ottawa, Ontario, K1A 0K9
Telephone: 1-800-267-9675

The Medical Devices Problem Report Form and Guidelines (http://www.hc-sc.gc.ca/dhp-mps/compli-conform/info-prod/md-im/index-eng.php) can be found on the Health Canada Web site.
For other medical device inquiries related to this communication, contact Health Canada at:
Marketed Health Products Directorate (MHPD)
E-mail: MHPD_DPSC@hc-sc.gc.ca
Telephone: 613-954-6522
Fax: 613-952-7738

St. Jude Medical encourages physicians to report any case of lead failure and return devices to the manufacturer for further inspection and analysis to best ensure the company is able to validate and communicate information in the interest of patient safety.

If you have any questions or concerns, please contact St. Jude Medical Canada Inc. at the address, telephone or fax listed above, or our Technical Services Department at 800-722-3774.

A copy of this communication is available at www.riatacommunication.com/intl/physician-information.aspx along with several additional resources that can assist in managing patients with Riata and Riata ST silicone leads. A copy of this communication is also available on the Health Canada Website at www.hc-sc.gc.ca/dhp-mps/medeff/index-eng.php.

Original signed by

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St. Jude Medical Canada Inc.

References:

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