Public Communication -
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.

November 05, 2012

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, has issued a Notice to Hospitals regarding insulation abrasion in Riata and Riata ST defibrillation leads.

St. Jude Medical Canada Inc. has previously communicated this issue in letters to healthcare professionals in December 2010, November 2011 and July 2012. The purpose of this current notice is to re-iterate safety information and provide some updated patient care resources and recommendations.

A defibrillation lead is the wire that connects the defibrillator device (usually implanted in the chest near the shoulder) to the heart. These leads may become damaged over time, which in some cases may cause the leads to malfunction.

- **Lead insulation abrasion may result in therapy being delivered at the wrong time, or not being delivered when it is needed, which could result in serious adverse events including death.**
- **Patients should contact their follow-up clinic as soon as possible at the onset of any vibratory or audible alert from their defibrillator device.**
- **Any patient experiencing an adverse event should contact their physician or report to the nearest hospital emergency department.**
- **Patients can identify if they have one of the subject leads by consulting their St. Jude Medical Patient Identification Card that was issued shortly after their device was implanted, and determining if any of the following model numbers are listed on their card under the heading 'MODEL NUMBER':**
  - **1560, 1561, 1562, 1570, 1571, 1572, 1580, 1581, 1582, 1590, 1591, 1592, 7000, 7001, 7002, 7010, 7011, 7040, 7041 or 7042**

  Patients may also consult with their doctor or clinic to determine if they have a Riata or Riata ST defibrillation lead, or contact St. Jude Medical Canada at (905) 812-8600 and select '2' on the automated attendant.

Background and Additional Safety Information
The internal electrical components of defibrillation leads are protected by two or more layers of

insulation material. The term 'insulation abrasion' describes damage to the insulation material and could include damage ranging from abrasion of the outermost layer alone (where the internal electrical components of the lead continue to function normally) to complete abrasion of all layers of the insulation material, which can expose bare wires and cause the lead to malfunction. In a recent patient study, it was observed that approximately 1 in 4 Riata leads and 1 in 10 Riata ST leads exhibit abrasion to the outermost insulation layer. Most leads with this type of insulation abrasion have continued to function normally.

The frequency of complete abrasion of both the inner and outer layers of lead insulation is difficult to estimate. Based on presently available data from returned product analyses by St. Jude Medical Inc., and the most recent results of the aforementioned patient study, it is estimated that approximately 3 out of 100 Riata and Riata ST leads exhibited abrasion of all layers of insulation, which could, under certain circumstances, create the potential for inappropriate shock therapy or failure to deliver needed therapy.

It is understood that clinical decisions regarding patient management need to be individualized based upon specific patient conditions and circumstances. Physicians may decide to place patients, who are implanted with one of these leads, on accelerated follow-up schedules and may perform additional diagnostic tests. During follow-up visits, physicians may re-program the defibrillator device in order to provide optimal detection of potential malfunctions.

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

A copy of this communication is available at www.riatacommunication.com/intl/patient-

communication.aspx . *Riatacommunication.com* is a dedicated resource for providing the latest information on Riata 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.

Patients should address any health-related concerns directly with their physician. For other questions, please contact St. Jude Medical Canada Inc. at the address or telephone number listed above.

Original signed by

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