



## **Canadian heart rhythm specialists comment on Medtronic Sprint Fidelis lead issue**

Quebec City – Tuesday October 23 2007

Meeting at the Canadian Cardiovascular Congress in Quebec City, the Canadian Heart Rhythm Society (CHRS), a professional group representing Canadian heart rhythm specialists, issued a statement today (attached) on the recent concerns about the Medtronic Sprint Fidelis family of implantable cardiac defibrillator (ICD) leads (Models 6930, 6931, 6948 and 6949).

“The Canadian Heart Rhythm Society has been working with Medtronic Canada to communicate the perspective of our members on this issue, and to seek clarification regarding the nature of the concern, the risks posed to our patients, and potential solutions,” said Dr. Martin Gardner, President of CHRS.

Medtronic Canada sent a letter to Canadian doctors on October 15<sup>th</sup>, 2007 regarding an issue with the Medtronic Sprint Fidelis family of ICD leads (Models 6930, 6931, 6948 and 6949). The letter was sent in response to a growing concern regarding a small risk of a crack developing in the wire that connects the defibrillator to the patient’s heart. Five deaths worldwide are currently under review, in which the lead may have been a possible or likely contributing factor.

Medtronic estimates that 5,955 potentially affected leads have been implanted in Canadian patients since the leads were released in 2004.

“We don’t want to alarm patients unnecessarily,” said Dr. Andrew Krahn, Chair of the CHRS Working Group on Device Advisories. “New implantations of these leads have been suspended, and so far the reported leads affected in Canada are around 1% of the total implanted. That said, it’s important that patients be aware of the problem, and discuss the issue with their doctor/specialist.”

The CHRS has posted a suggested letter on its web site, [www.chrsonline.ca](http://www.chrsonline.ca), for physicians to use in notifying their patients, and is urging professionals to do so right away. They issued a summary and recommendations, targeting health professionals, which is also available on the web site.

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Dr. Charles Kerr of the Canadian Cardiovascular Society supported the CHRS efforts to inform professionals and their patients. “It’s very important that doctors and their patients have access to timely information on the problem, the risks and the solution. CHRS is providing an important service with this statement.”

The problem in question can cause inappropriate shocks, and much less frequent potential problems with the delivery of life-saving high-energy shocks. Routine monitoring may not detect the problem, but devices can be reset to improve the chances of detecting changes in lead performance before the patient experiences a shock.

“It’s also important that we recognize that for most patients, the risk of lead replacement would greatly exceed the risk of non-replacement unless there is evidence of lead malfunction,” noted Dr. Krahn. “Lead replacement is not generally recommended, but these decisions need to be made on a case by case basis by doctors.”

“The CHRS has been communicating with its members and working in collaboration with Medtronic and Health Canada to take action and get this message out broadly. The safety of our patients is our paramount concern,” said Dr. Gardner of the Society.

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Canada’s heart rhythm specialists, represented by the Canadian Heart Rhythm Society, are committed to the promotion of evidence-based practice in Canada. The full text of the CHRS statement on Medtronic Sprint Fidelis leads is available at [www.chrsonline.ca](http://www.chrsonline.ca)

**For interviews (Oct 23) please contact the media room at the Canadian Cardiovascular Congress at 418 649 5215**

or Dr. Andrew Krahn 519 318 8787 (cell)  
or Dr. Martin Gardner 902 221 4747(cell)

**Response of the Canadian Heart Rhythm Society to  
Medtronic Sprint Fidelis Lead Issue**

The Canadian Heart Rhythm Society (CHRS) is dedicated to the safety of our patients, to best practices and to the development of open, transparent processes.

While we are reassured that the risk posed by this particular defect is low, we believe that timely communication and assessment of patients is essential to addressing understandable concern, assessing lead performance and reconfiguring the detection and alarms in keeping with the recommendations included in the “Dear Doctor” letter from Medtronic.

We believe that physicians and patients have the right to know about these defects in a timely way, so that individualized decision-making can be undertaken by the doctor and his/her patient with all of the relevant information in hand.

1. *CHRS encourages physicians to promptly notify patients with potentially affected leads of this issue, being careful to emphasize the low rate of failure due to this defect and the likelihood of detection of lead failure with device reprogramming. A sample notification letter is available at [www.chrsonline.ca](http://www.chrsonline.ca) (coming online October 23<sup>rd</sup> at CCC 2007). Some patients may have heard about this issue in the lay press and will require reassurance.*
2. *CHRS recognizes that for most patients, the risk of lead replacement would greatly exceed the risk of non-replacement unless there is evidence of lead malfunction. As a result, lead replacement with or without lead extraction is not generally recommended. This may not be the case for all patients, such as the patient with borderline performance values and frequent device use. Decisions regarding lead replacement should be individualized.*
3. *CHRS encourages compliance in principle with the recommendations contained in the “Dear Doctor” letter to extend the NID for detection and redetection and lower the impedance thresholds for audible warning tones to maximize sensitivity for detection of out of range impedance values to maximize preclinical detection of lead failure. Specific programmed parameters are likely to be individualized based on Physician and Institution consensus.*
4. *CHRS encourages each centre to schedule follow-up visits according to Canadian guidelines (Gillis AM et al, Can J Cardiol 2003;19(1):21-37) or manufacturers recommendations at their discretion, since there is no evidence that increased follow-up will alter patient outcome in this situation.*
5. *CHRS acknowledges that preclinical detection of the defect by audible alerts will not be possible when the lead is connected to a generator that does not have this capability, or in patients that are unable to reliably hear and act upon the alert. Clinical decisions regarding lead replacement in this uncommon situation will need to be individualized, influenced by the patient’s reliance on the device; ie pacing dependence or previous ventricular arrhythmia.*

**Input from Health Canada**

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 serious or unexpected adverse incidents associated with the Medtronic Sprint Fidelis family of ICD leads should be reported to the marketing authorization holder or to Health Canada at the following address:

Health Products and Food Branch Inspectorate HEALTH CANADA  
Address Locator: 2003D  
Ottawa, Ontario K1A 0K9  
Tel: The Inspectorate Hotline 1-800-267-9675

The Reporting Form and Guidelines can be obtained from the Health Canada web site ([http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/rep\\_md\\_prob-rap\\_inc\\_im\\_tc-tm\\_e.html](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/rep_md_prob-rap_inc_im_tc-tm_e.html)).



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