

Medtronic Sprint Fidelis Lead Issue

October 17th, 2007

Dear Colleagues:

On October 15th, 2007, Medtronic Canada sent a letter to Canadian doctors regarding an issue with the Medtronic Sprint Fidelis family of ICD leads (Models 6930, 6931, 6948 and 6949). The letter (see links at end of this document) has been sent as a response to a growing concern regarding conductor fractures that was first reported in *Heart Rhythm* in July (Hauser et al, *Heart Rhythm* 2007;4(7):892-896). There have been 5 deaths worldwide that are currently under review where the lead may have been a possible or likely contributing factor. We are currently seeking further information regarding the specifics of these cases.

The Canadian Heart Rhythm Society (CHRS) has been working closely with Medtronic Canada to communicate the perspective of our members on this issue, and to seek clarification from Medtronic regarding the nature of the concern, the risks posed to our patients, and some potential solutions.

Lead Details

The problem in question is a conductor fracture that typically occurs in either the distal portion of the lead or near the anchoring sleeve. This most often presents with artifactual high rate detection with non-physiologic rates associated with inappropriate shocks and high lead impedance. Preliminary information suggests a reported but much less frequent fracture in the high-voltage coil that may affect delivery of high-energy shocks. The problem appears to be much more common in the 6.6 Fr family of leads than in the larger 8.2 Fr 6947 lead. Lead failure is most commonly relatively abrupt, and not detected by gradual changes in pacing or impedance parameters. In 89 patients with confirmed lead fracture, the median time from impedance change to presentation with inappropriate shocks was 2 days, with only 4 patients having an impedance change more than 40 days prior to experiencing a shock. Thus frequent routine surveillance of impedance of the lead is unlikely to identify preclinical lead failure, whereas alert tones are likely to provide short term warning to the patient to present to medical attention before lead failure becomes symptomatic. Medtronic has recommended suspension of implantation of the leads and removal of existing inventory. In patients with the lead implanted, they have recommended specific settings of the detect and redetect NID, activation of the patient alert feature with specific impedance settings to maximize sensitivity for detection

of out of range impedance values, and use of the CareLink network where available to maximize preclinical detection of lead failure. Retrospective evidence suggests that this strategy would have been effective in averting inappropriate shocks in the about 50% of patients. At this point, Medtronic has not advocated more frequent follow-up or routine lead replacement or extraction.

Scope of the Problem

Between September 2004 and October 2007, Medtronic made and sold 268,000 of the potentially affected leads worldwide. To date, Medtronic has identified 665 confirmed fractures in returned leads. Estimates from several mechanisms suggest 97.7% lead survival at 30 months, compared to 99.1% for the 6947 lead. The risk of failure may be higher in pediatric patients. Medtronic estimates that 5955 potentially affected leads have been implanted in Canadian patients since the 6949 and 6931 were released November 11, 2004, and the 6948 and 6930 were released July 9, 2004. Preliminary response to an e mail survey of Canadian ICD implant centers suggests that 47 out of 4140 leads are affected (1.14%), with symptoms in 30 of the 47 (64%), and failures in 11 of the 14 centers that responded (range 0.0-4.8%).

Response of the Canadian Heart Rhythm Society

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 (coming online October 23rd 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:

Medtronic of Canada Ltd.
6733 Kitimat Road
Mississauga, Ontario, L5N 1W3

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).



Andrew Krahn, MD
Chair, Special Advisory Committee
Canadian Heart Rhythm Society



Martin Gardner, MD
President,
Canadian Heart Rhythm Society

Important Links Related to the Fidelis Advisory:

Canadian Heart Rhythm Society Website: Device Advisory and Recall Section

<http://www.chrsonline.ca/members/advisories.htm>

Medtronic Site including Physician Letter:

<http://www.medtronic.com/fidelis/physician-letter.html>

Health Canada site including Physician Letter:

http://www.hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/prof/2007/leads-sondes_hpc-cps_e.html