

Medtronic Sprint Fidelis® Lead Recall

Medtronic of Canada Ltd. (Medtronic) in consultation with Health Canada is advising patients that it has voluntarily suspended the distribution of the Sprint Fidelis® defibrillation leads (models 6930, 6931, 6948, 6949). Sprint Fidelis leads are thin wires that connect a defibrillator implanted near the shoulder to your heart. This action does not affect patients implanted with Medtronic pacemakers.

Medtronic has informed your doctor that there is a small chance of fractures in particular locations on the lead and has advised your doctor to stop implanting the leads and return the unused products to the firm. Medtronic has provided your doctor with detailed information on how to reduce the risks in affected patients.

The fracture of the leads could cause the defibrillator to deliver unnecessary shocks or, in very rare instances, to fail to deliver a shock. If you have one of the affected leads, your Patient ID card should contain one of the following four sets of numbers: 6930, 6931, 6948, and 6949, shown at the beginning of a longer set of numbers on your ID card. You will be contacted directly by your doctor for follow-up. Your doctor may choose to change the way your device is programmed to help reduce any potential problems. The suspension of distribution does not require your Sprint Fidelis Lead to be removed and replaced, because the risk of removal in most patients exceeds the small risk of lead fractures. In consultation with your doctor, you can decide what is best for you.

Sprint Fidelis Leads have been available in Canada since July 2004. Medtronic's decision to suspend distribution of the Sprint Fidelis Leads was made following a review of data available to us and recommendations by an Independent Physician Quality Panel. As of October 4, 2007, approximately 268,000 Sprint Fidelis Leads have been implanted worldwide. Medtronic is aware of 5 patient deaths in which a Sprint Fidelis lead fracture may have been a possible or likely contributing factor. None of these deaths are in Canada.

Please contact Medtronic at 1-800-268-5346 if you have any questions or concerns. Contact your physician if you experience anything unusual, including multiple shocks, fainting, or palpitations.

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 at:

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).