

SAMPLE LETTER TO PATIENTS
SPRINT FIDELIS LEAD PROBLEM

Dear ICD patient,

This letter is to inform you of a potential problem with your implanted defibrillator. The company that makes it (Medtronic) has made us aware that the lead (cable) of your defibrillator system may develop a crack or "fracture" which could cause the defibrillator to react in several different ways. A small number of patients may potentially be affected. Most patients will not experience symptoms but some may receive an unnecessary shock from the device and in very rare instances it might fail. In most patients, changing the settings on the device will result in an audible warning that the lead may not be performing normally before the patient feels anything.

? Health Sciences Centre plans to meet with and assess all of our patients with this lead in the near future and monitor them carefully (see below). The reported risk of having a problem with this lead is approximately 1 in 50 in the first 2 years, compared to 1 in 100 for other standard leads.

We will have an information session on October 27th at 1:30 pm at the University Hospital on the 3rd floor in Auditorium A. At that time, doctors will review the details of the issue, and provide answers to your questions. Parking at the hospital will be paid for on that day, and refreshments will be served. After the information session, we would like to check your device to reassure you that it is working correctly, and turn on several patient alarms that will notify you with a beep if there is a potential problem with the lead.

Please plan to attend the information session on October 27th. Please RSVP to ? at ?.

If you have questions regarding your device or do not plan to attend the information session, please call the ICD clinic at ?. We will make arrangements for you to come in to speak to the ICD nurses and one of the doctors and have your defibrillator checked. If you normally have follow-up in another centre, please contact that centre to determine what arrangements they have made.

Thank you for your understanding. We look forward to seeing you on October 27th at 1:30 p.m.

Sincerely,