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Medtronic Recalls Sprint Fidelis Cardiac Leads Questions and Answers for Consumers

What are Sprint Fidelis Leads?

Manufactured by Medtronic, Inc., Sprint Fidelis Leads are specific models of cardiac electrodes (thin wires) that connect an implantable cardioverter-defibrillator (ICD) or cardiac resynchronization therapy defibrillator (CRT-D) directly to the heart. ICDs and CRT-Ds are devices that protect patients when life-threatening heart rhythms occur.

How do defibrillators work?

Defibrillators monitor heart rhythms. They deliver an electrical shock or rapid pacing to restore normal rhythm when life-threatening, irregular heartbeats are detected. These devices keep the heart from going too fast. They are surgically implanted for patients who are at risk of sudden cardiac arrest.

What is Medtronic announcing about the Sprint Fidelis Leads?

Medtronic, Inc., is announcing that it is voluntarily suspending worldwide distribution of the Sprint Fidelis family of defibrillation leads. This includes four Sprint Fidelis Models: 6930, 6931, 6948, and 6949. FDA considers this removal action to be a medical device recall. Medtronic is advising physicians to stop implanting the leads and to return unused products to the firm.

How do I know if I have a Sprint Fidelis lead?

You may have a patient card that identifies the implanted devices you have. If you have any uncertainty about your devices, you should contact your physician.

Does this action affect other Medtronic devices?

This action does not affect patients who have Medtronic devices that are pacemakers. While defibrillators keep the heart from going too fast, pacemakers keep the heart from going too slowly. This action also does not affect patients who have Medtronic ICDs or CRT-Ds without a Sprint Fidelis lead.

What is a medical device recall?

A recall is an action taken when a medical device is defective, when it could be a risk to health, or when it is both defective and a risk to health. A recall for an implantable medical device does not always mean that the device has to be removed.

Why are the Sprint Fidelis Leads being recalled?

The devices are being recalled because of the potential for lead fractures. These electronic wires are prone to fracture in a small number of patients. This could cause the defibrillator to deliver unnecessary shock or to not operate at all. Some deaths and other serious injuries have been reported in which a fracture in a Sprint Fidelis lead may have been a possible or likely contributing factor.

How many people have had this device implanted?

As of October 4, 2007, there have been approximately 268,000 Sprint Fidelis leads implanted worldwide, including 172,000 Sprint Fidelis leads implanted in the United States.

What should patients do if they have had a Sprint Fidelis lead implanted?

- Patients who have had the Sprint Fidelis lead implanted should contact their physician, especially if they have experienced multiple shocks, lightheadedness, fainting, or palpitations.
- Patients should not routinely seek removal of the device. The risks of removal in most patients exceed the small risk of lead fractures. Therefore, it is generally recommended to leave functioning leads in place. There are two alternatives to removing the lead. One is to continue using the lead while monitoring closely for signs of fracture. A second is to surgically add a replacement lead. Adding a replacement lead does not require removing the Sprint Fidelis lead. If the Sprint Fidelis is left in a patient without being used,

it must be “capped”, which means covering the tip with a small plastic insulation.
- Patients can call Medtronic at this toll-free number: 1-800-551-5544, ext. 41835.

What additional advice has been given to protect patient health?

Medtronic has provided guidance to physicians on how to reduce the risks in affected patients and ensure that devices are set to more effectively monitor for potential fractures. These patient management recommendations are available at http://www.medtronic.com/fidelis/

How should problems with Sprint Fidelis leads be reported?

Problems should be reported to FDA's MedWatch Adverse Event Reporting program.

- Online (www.fda.gov/medwatch/report.htm)
- Fax (800-332-0178)
- Regular mail (use postage-paid FDA form 3500 available at: www.fda.gov/MedWatch/getforms.htm and mail to MedWatch, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787).

FDA Statement
http://www.fda.gov/bbs/topics/NEWS/2007/NEW01724.html

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