

FAULTY ELECTRICAL LEADS

IMPLANTABLE CARDIOVERTER DEFIBRILLATOR WIRES



Anapol Schwartz | Attorneys at Law

FAULTY ELECTRICAL LEADS - IMPLANTABLE CARDIOVERTER DEFIBRILLATOR WIRE LAWSUITS

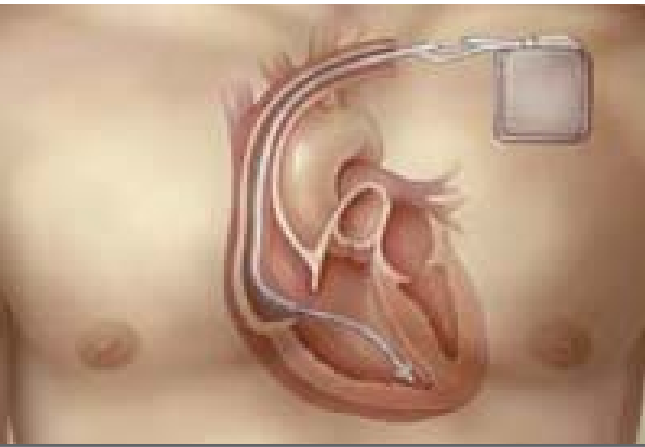
CONTACT LAWYER: THOMAS R. ANAPOL, ESQ.

EMAIL: TAnapol@anapolschwartz.com

CALL: 215-735-1130 OR 866-735-2792

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IMPLANTABLE CARDIOVERTER DEFIBRILLATOR LEAD WIRES:

The electronic wires, known as Sprint Fidelis leads, that are attached to implanted heart devices such as ICDs (implantable cardioverter defibrillators) appear to be prone to fracture. These faulty electrical lead wire fractures are failing to provide the correct shock (either no shock or too many shocks) to certain patients who have Medtronic heart devices implanted since 2004.

AT ISSUE ARE MEDTRONIC MODELS 6930, 6931, 6948 AND 6949 LEADS.

Warning from Medtronic:

Medtronic recently advised doctors, and now patients have been warned by Medtronic of this risk of the leads failing. The defibrillators with Sprint Fidelis leads are implanted devices with a least one lead connecting the patients heart and the device. The affected Sprint Fidelis leads can often be identified by the Patient ID card which would contain any of these numbers: 6930, 6931, 6948, 6949. (The number usually appears at the start of a long set of numbers on the patient ID card.)

What are the Chances of Failure? Medtronic reports a small chance of fractures on the Sprint Fidelis leads. The FDA says the risk is 1%, but that is based on past adverse event reports. The risk could prove to be much higher now that the public is being made aware and doctors know what to look for.

Should your doctor remove the lead? Patients with Sprint Fidelis leads face a risk in handling this problem as well. While there is a problem with the lead, Medtronic advises that it is even more likely that a patient will experience complications from removal than from a problem with a Sprint Fidelis lead. So it seems that patients are stuck in a dilemma, whether to leave the recalled leads in the body or remove them and face the risks attached with removal. Medtronic says that an independent panel of physicians that they have obtained information from recommends against removing Sprint Fidelis leads except in very unusual circumstances.



BROKEN LEAD WIRES

Broken lead wires are at the “heart” of a new controversy involving Medtronic. Medtronic cardiac electrodes that were sold under the model name Sprint Fidelis have been recalled. These cardiac electrodes connect the cardiac resynchronization therapy defibrillator to the heart. Used in CRT-D devices implanted into defib patients, these wires have been used over 268,000 times. Thus, there are a frighteningly large number of patients at risk. The failure rate has been reported at 1%, but past FDA statistics show that adverse events can be 10 times greater than reported. This means that many people may not receive the protective corrective shocks when life-threatening heart rhythms occur.

Attorneys at our office, familiar with the previous defibrillator class actions, consolidated Medtronic cases, and the Medtronic multi district litigation for the heart device recalls have begun working now of defibrillator lawsuits for the recent recall related to the wires breaking. While we have suspected for a long time that this could be a problem, our suspicions are now being confirmed as the FDA has issued a warning about these defibrillator wires and Medtronic has issued a worldwide suspension of distribution of these thin wires.

WHAT WENT WRONG?

Most implantable cardioverter defibrillators (ICDs) and Cardiac Resynchronization Therapy-Defibrillators (CRT-Ds) function fine. They are used to treat abnormal heart rhythms that can cause the heart to stop suddenly. ICDs and CRT-Ds put the heart back into normal rhythm by delivering a pulse of energy (electric shock) through an electrode wire or lead that is connected to the heart.

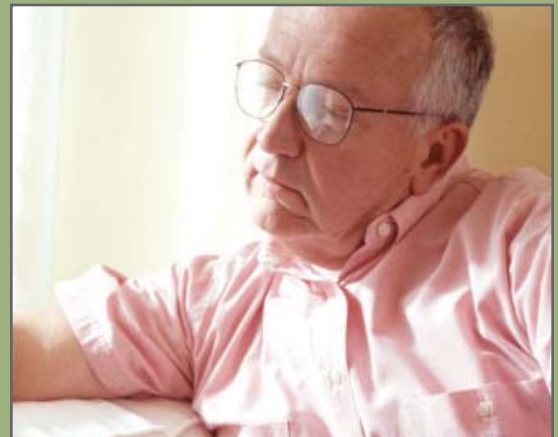
Some of these wires have been found to have broken. Luckily, not every wire breaks. In fact, according to Medtronic, most leads function well. But, where a lead actually breaks, or “fractures,” the lead may send false signals. These signals can result in too many or too few shocks.

What are the symptoms?

It is not so simple to know whether this has occurred since there are multiple clinical presentations. For example, it may present clinically as increased impedance, oversensing, increased interval counts, multiple inappropriate shocks, and/or loss of pacing output.

How dangerous is this?

Medtronic is aware as of Oct 15, 2007, of five patient deaths in which a Sprint Fidelis lead fracture may have been a possible or likely contributing factor.





HOW CAN YOUR DOCTOR REDUCE THE RISK?

Medtronic recommends that doctors conduct routine follow-up for each patient and possibly that changes be made to the settings to help the doctor detect if a fracture has occurred.

These steps, Medtronic believes, can reduce the risk of inappropriate detection and therapy due to over-sensing. These steps may also help optimize effectiveness of the lead impedance alerts. Medtronic believes that doctors taking the right actions can increase the likelihood that a fracture will be detected by Patient Alert and/or Medtronic CareAlert notifications and decrease the likelihood of inappropriate therapies.

As of October 2007, based on Medtronic's review of available data, they have told doctors that there does not appear to be a benefit to more frequent follow-up. You should consult your doctor to find out if they have reviewed the most recent information from Medtronic and to give you advice accordingly.

FDA ACTION

To read about the FDA recall, see the [FDA frequently asked questions page](#), located on the FDA web site. Doctors are being advised by Medtronic to stop implanting these leads. The FDA considers this action to be a medical device recall. The FDA is advising patients to check their patient device ID card to determine if these leads were used. If patients are uncertain, they should check with their physician immediately.



DO YOU HAVE A DEFIBRILLATOR LAWSUIT?

If you or someone you know has received a defibrillator with Sprint Fidelis leads (implants since 2004) please [contact our offices](#) for a free case evaluation. There is never an obligation to continue and all conversation and information is strictly confidential.

Call (toll-free):

1-866-735-2792

or use the [online consultation form](#).



DEFIBRILATOR LEADS

Medtronic now faces lawsuits from patients who have a Sprint Fidelis lead attached to their heart and defibrillator. Medtronic lead lawsuits are now being filed in many states, and attorneys familiar with this medtronic recall are providing counsel to these patients. The FDA considers this to be a medical device recall and has put a warning out to patients.

Update on Lead Recall

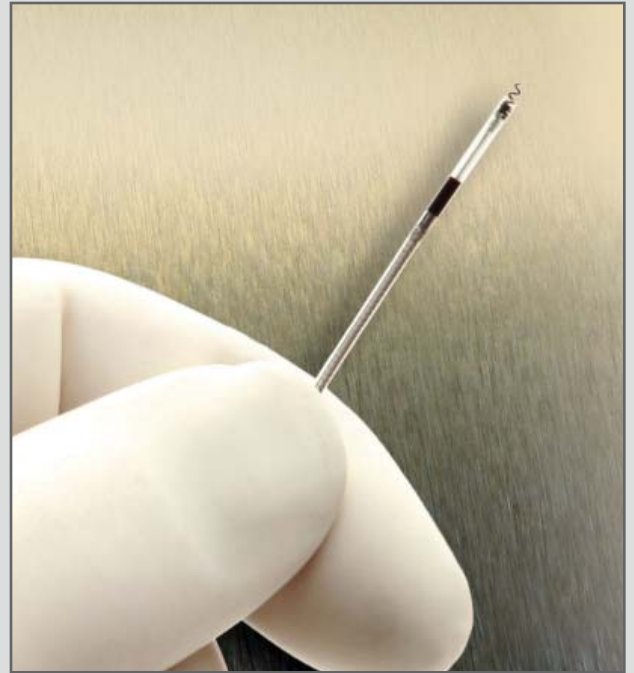
In a statement released to the public, Medtronic advises that a voluntary marketing suspension Sprint Fidelis Defibrillator Leads has taken place.

Medtronic decided to voluntarily remove its Sprint Fidelis defibrillation leads from the market. According to adverse event reports, the electronic wires are prone to fracture and can cause the defibrillator to deliver unnecessary shocks or not operate at all. These failures have resulted in deaths and major complications.

Patient Fear of Defect in Device

While defibrillators are life-saving products, it is scary for a patient who needs the device to monitor and correct heart rhythm abnormalities to know that there is a defect in that device that could cause serious injury. Medtronic has admitted that it is "frightening for a patient to learn that a product they rely on so much might have a serious defect."

Since the Sprint Fidelis defibrillation leads fractures have been detected, no more of these defective leads will be sold or manufactured and Medtronic is advising that any remaining product should be pulled from inventory and returned to the company.



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Anapol Schwartz | Attorneys at Law

ANAOPOL SCHWARTZ WEISS COHAN FELDMAN & SMALLEY
1710 Spruce Street
Philadelphia, PA 19103

CONTACT LAWYER: Thomas R. Anapol, Esq.
EMAIL: TAnapol@anapolschwartz.com
CALL: 215-735-1130 or 866-735-2792
READ MORE INFORMATION ONLINE AT: www.anapolschwartz.com

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