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Medtronic Sprint Fidelis Lead Defect Can Be More Of A Problem For Certain Patients

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POSTED: Tuesday, December 18, 2007

FROM BLOG: [Drug Injury Watch](#) - Prescription Drug Side Effects News and Information from Attorney Tom Lamb

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People With Hypertrophic Cardiomyopathy And Those With Defibrillator-Pacemaker Dual Unit Implants May Be More In Need Of Lead Wire Replacement After Medtronic Recall

(Posted by Tom Lamb at [DrugInjuryWatch.com](#))

As presented in a December 13, 2007 *New York Times* (NYT) article, "[Patients Wonder Whether to Replace a Wire That Might Fail](#)", for thousands of people the October 2007 Medtronic recall of its Sprint Fidelis lead wires has created confusion and doubt on various levels about what they can or should do, now:

Their defibrillators are meant to deliver electric shocks to restore normal rhythms if their hearts start beating chaotically. Should they have the potentially faulty wire, or lead, removed — or leave it in place and hope it does not fail?

And if they do have it extracted, how will they pay for it? Medtronic is limiting its contribution to only a replacement lead and \$800 toward each procedure, which can cost \$12,500 or more. So far insurers are deciding whether to cover the replacement operation on a case-by-case basis, unless the lead has already fractured....

From the December 13 article by NYT reporter Barnaby J. Feder we learn that this confusion and doubt about whether to have their Sprint Fidelis defibrillator lead wires removed (or explanted or extracted) and replaced is more profound for some people than it might be for others. This is because some patients may have more of a need to get their Sprint Fidelis lead wires replaced given the medical condition for which their heart implant device was required.

Returning to this December 2007 NYT article about Sprint Fidelis patients trying to decide what to do:

One potentially vulnerable group includes patients with a congenital thickening of the heart muscle known as hypertrophic cardiomyopathy.

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Their condition can put more stress on the lead, which may increase the likelihood a lead fracture. And they are usually younger than the typical heart-failure patient, so they face higher odds of eventual fractures simply because they are likely to have the leads in place longer....

Doctors are also concerned about patients who have dual-purpose implants that serve as both defibrillators and pacemakers and that rely on Fidelis leads for both functions....

For such patients, a fracture that stops Fidelis from gently pacing the heart is an even more certain death sentence... than a fracture that stops it from delivering a defibrillating shock.

For many patients, however, the real determination about whether to have replacement surgery before their Sprint Fidelis lead wires possibly fail is a financial matter controlled by, in the first instance, Medtronic (\$800 doesn't get you too far in a hospital these days) and, thereafter, the patient's health insurance company (if any).

Medtronic should be ashamed of its offer of an \$800 "contribution" to help these patients after [the FDA issued a Class 1 Recall of Sprint Fidelis Defibrillator leads in October 2007](#).

Certainly, this is a predicament no one would want to be in, especially someone with a heart condition.

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