



LATEST NEWS BANGLADESH STORM TOLL OVER 3,000, MILLIONS SUFFER



Were you there?

Share the news you capture with Reuters and the world.

[Submit your photos](#)



You are here: [Home](#) > [Investing](#) > [News](#) > Article

HOME

BUSINESS

INVESTING

News

- [Market News](#)
- [Economic News](#)
- [Mergers/Acquisitions](#)
- [Hot Stocks](#)
- [New Issues & IPO's](#)
- [Regulatory News](#)
- [Bonds News](#)

Markets

Industries

Stocks

Stock Buzz

Funds

ETFs

Options

Commodities

Bonds

Currencies

Analyst Research

Portfolio

NEWS

Do More With Reuters

[RSS](#)

[Mobile](#)

[Podcasts](#)

[Newsletters](#)

[My Headlines](#)

[You Witness News](#)

Partner Services

[CareerBuilder](#)

[Affiliate Network](#)

Professional Products

Is This What Medtronic's March 21, 2007 "Dear Doctor" Letter Said About Sprint Fidelis Lead Problems?

powered by BlogBurst

POSTED: Friday, October 26, 2007

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

The following blog post is from an independent writer and is not connected with Reuters News. The opinions and views expressed herein are those of the author and are not endorsed by Reuters.com.

One Person Took The Impression That Medtronic Was Trying To Lay Blame For Lead Wire Failures On Those Physicians Who Were Doing The Defibrillator Implants

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

To start, our thanks to a fellow in Florida who was kind enough to share with us what he found as a result of some investigation into [that hard-to-find March 21, 2007 "Dear Doctor" letter about problems with Medtronic's Sprint Fidelis defibrillator leads](#).

Unfortunately, his motivation came from the fact that he has one of the recalled Sprint Fidelis leads implanted currently.

The following material comes from [an April 8, 2007 article posted on a somewhat obscure blog called *Random Thoughts on Pacemakers & Personal Finance*](#) that this fellow found after some looking-around on the Internet:

... On March 21st, Medtronic issued a "Dear Doctor" letter concerning higher than expected conductor fracture rates with the Sprint Fidelis lead. The Sprint Fidelis is Medtronic's premium defibrillation lead. It is the first sub-7 french ICD to be released (St Jude Medical released the Riata ST lead approximately 18 months after the Sprint Fidelis).

The body of the letter is as follows:

Dear Doctor,

Medtronic has received reports from a limited number of implanting physicians indicating they have experienced higher than expected conductor fracture rates in their centers with Sprint Fidelis leads. While current overall Sprint Fidelis performance is consistent with other leads, Medtronic is actively investigating these reports, has reviewed them with our Independent Physician Quality Panel, and would like to share what we know at this time.

Through detailed assessment of reported fractures, we have identified two primary locations where conductor fractures have occurred: 1)

[Financial](#)[Media](#)[Support \(Customer Zone\)](#)

[About Reuters](#)

distal portion of the lead and 2) near the anchoring sleeve tie down. The distal conductor fractures affect the anode (ring electrode) and fractures that occur around the anchoring sleeve affect the cathode (helix tip electrode). Fractures at both locations appear to present clinically as over-sensing, increased interval counts and inappropriate shocks. Medtronic has worked closely with physicians who have experienced fractures and conducted significant bench testing in an attempt to reproduce the fractures and identify root cause. At this point, our investigation suggests that variables within the implant procedure may contribute significantly to these fractures.

For distal conductor fractures, our investigation has identified severe bending or kinking of the distal end of the lead over the lead body while passing through tortuous vasculature as a significant contributing factor. If the lead is severely bent or kinked at the distal end, the conductor may be compromised such that the conductor may fracture after implant due to chronic fatigue from natural cardiac motion. The venous structure or pathway, venous access location, length of introducer sheath and lead insertion force are all factors that may contribute to severe bending or kinking of the lead. Medtronic recommends avoiding severe bending or kinking of the lead during implantation. If you encounter excessive resistance resulting in severe bending or kinking while advancing the lead, please remove the lead and return it to Medtronic.

For conductor fractures that occur around the suture sleeve, our preliminary investigation suggests that under certain implant techniques, the lead appears to be exposed to severe bending or kinking in the pectoral area. We are still investigating and actively partnering with physicians to better understand this type of fracture. If excessive kinking or bending is observed during lead suturing and/or pocket formation, Medtronic recommends the lead be re-sutured and/or pocket reassembled per guidelines in the Medtronic lead implant manual. In addition, positioning the anchoring sleeve against or near the vein may be helpful.

Sprint Fidelis lead models 6949, 6948, 6931, and 6930 were market released in the U.S. and internationally in September and October 2004. Performance of model 6949, the Sprint Fidelis lead currently followed in our System Longevity Study, indicated survival is 98.9% at two years. Sprint Fidelis 6949 performance based upon return product analysis shows 99.86% chronic fracture-free survival at two years. Both evaluation methods suggest performance is in line with other Medtronic leads and consistent with lead performance publicly reported by other manufacturers.

The unknown person who posted this April 8 article on the *Random Thoughts on Pacemakers & Personal Finance* blog then went on to make these comments regarding this March 2007 Dear Doctor letter from Medtronic about its Sprint Fidelis lead failures:

This letter was sent to all implanting U.S. physicians and nowhere was there any request for confidentiality. That is why I posted it.


Well, the lead fails and they state, "variables within the implant procedure may contribute significantly to these fractures." It's the implanter's fault. Of course, that makes perfect sense. The same physician who has implanted endocardial defibrillation leads since 1992 now suddenly doesn't know how to operate one of these new-fangled

leads. Are they suggesting that for patients with a tortuous anatomy a different lead should be used - possibly a Sprint Quattro Secure? I don't know. What's going to happen if physicians get nervous and every time they try to implant the lead and "excessive kinking" occurs, they abandon the lead a try a different lead? Will returns to Medtronic increase?

Of course, if and when we learn that the (said-to-be) text of this March 21 Dear Doctor Sprint Fidelis letter from Medtronic which was posted on the *Random Thoughts on Pacemakers & Personal Finance* blog back in April 2007 is not accurate or correct somehow, we will let you know, immediately.

Until then, this fellow in Florida seems to have found one of the pieces that might help us further fit together an evolving Sprint Fidelis story.

[Read more from this blogger at Drug Injury Watch](#) | [Let us know what you think of this feature](#)

Reuters.com: [Help and Contact Us](#) | [Advertise With Us](#) | [Mobile](#) | [Newsletters](#) | [RSS](#)  | [Interactive TV](#) | [Labs](#) | [Reuters in S](#)
Reuters Corporate: [Copyright](#) | [Disclaimer](#) | [Privacy](#) | [Professional Products](#) | [Professional Products Support](#) | [About Reuters](#) |

International Editions: [Africa](#) | [Arabic](#) | [Argentina](#) | [Brazil](#) | [Canada](#) | [Chinese Simplified](#) | [Chinese Traditional](#) | [France](#) | [Gerr](#)
[Russia](#) | [Spain](#) | [United Kingdom](#) | [United States](#)

Reuters is the world's largest international multimedia news agency, providing investing news, world news, business news, technology news, headline market, and mutual funds information available on Reuters.com, video, mobile, and interactive television platforms. Reuters journalists are subject to the disclosure of relevant interests.