

PRINT



Star Tribune reports on problems with Medtronic's Sprint Fidelis leads

July 31, 2007 | Michael O'Riordan

Minneapolis, MN - Several cardiologists in the Minnesota area have stopped using the Sprint Fidelis lead, an implantable lead made by **Medtronic** that has previously been scrutinized for a "higher-than-expected" tear rate, according to a report in the Minneapolis-St Paul *Star Tribune* [1]. Last March, Medtronic issued a "Dear Doctor" letter to physicians to offer suggestions on how to implant the lead, but recently several cardiologists in the Twin Cities have stopped using them because of the risk of tearing. The company is also investigating the death of one patient implanted with the scrutinized lead, also known as model 6949.

According to reporter **Janet Moore**, 169 000 Sprint Fidelis leads have been used since the US **Food and Drug Administration** approved them in September 2004. Doctors, she writes, prefer it because it is thin and nimble, and the company says the overall fracture rate is "extremely low." Although Medtronic informed the FDA about the lead fractures, the letter was not considered an official advisory, nor has the FDA recalled the leads.

"Unlike its February 2005 defibrillator recall, Medtronic did not issue a news release, and a product performance report on its website lists no advisories associated with Sprint Fidelis leads," writes Moore. "Patients would likely hear of potential problems through their doctors."

Medtronic has conducted a review with an independent physician quality panel, all of whom received compensation for time and expenses, and this is the reason for the "Dear Doctor" letter sent in March. The company continues to "monitor and analyze" why leads tear, reports Moore. In addition, she notes that a study by **Dr Robert Hauser** (Minnesota Heart Institute Foundation, Minneapolis) found that six Sprint Fidelis leads failed of the 592 implanted at his institution between September 2004 and February 2007. An additional analysis of FDA data revealed 679 reports for the leads during a 30-month period, and that Medtronic found 77 of 125 returned leads defective, mainly with tears. Of seven deaths, one was attributed to shocks, but no details on the patient were provided, reports the *Star Tribune*.

Based on these data, Hauser concluded "that the Sprint Fidelis leads appear prone to early failure, probably because they are thinner and perhaps less robust," writes Moore. He did, however, praise Medtronic, noting that the company was candid and forthcoming with all requests for information.

Moore notes that specialists at different hospitals in the US, including the **St Paul Heart Clinic**, prefer using thicker, more robust leads; others have stopped using the leads because they experienced higher tear rates. **Dr Stephen Remole** (Metropolitan Cardiology Consultants, MN) told the *Star Tribune* that "until this thing gets straightened out, we need to put a halt on the [Sprint Fidelis lead] implants."

Source

1. Moore J. Medtronic device under scrutiny. *Star Tribune*, July 29, 2007. Available at: <http://www.startribune.com/535/story/1329342.html>.

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