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Hospitals Dispute Medtronic Data on Wires

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Some leading hospitals are reporting failure rates for Medtronic Inc.'s fracture-prone defibrillator wires—including among young people—that are significantly higher than what the company has publicly disclosed.

Medtronic, a medical-device maker, pulled the Sprint Fidelis defibrillator wires off the market in 2007 and substituted another type of wire with a lower failure rate. But an estimated 150,000 Sprint Fidelis wires, which are known as leads, remain implanted in U.S. patients. The company, and most doctors, generally advise patients not to have the leads surgically removed if they haven't fractured, because of the risk of complications.

Medtronic says its own research shows the Sprint Fidelis leads survive for three years at least 95.4% of the time, for a failure rate of 4.6%. Reports from hospitals including the University of Rochester in New York state, the Minneapolis Heart Institute, the Mayo Clinic and the University of Ottawa, say the overall failure rate for Sprint Fidelis leads is as much as two times as great as the company's own data indicate. Some of the hospitals also report that the rate of fracture accelerates as the leads age.

"The hazard of [Sprint] Fidelis lead fracture is increasing exponentially with time and, based on our data, occurring at a higher rate than the latest manufacturer's performance update," doctors at the University of Rochester concluded in findings published in January's *American Journal of Cardiology*. The report said the three-year survival rate of 426 Medtronic leads inserted in the hospital's patients was 90.8%, meaning 9.2% failed. Some of the researchers have received consulting fees or research grants from Medtronic and its competitors.

Medtronic says its own findings are more reliable because they come from multiple hospitals. "You have to be care-

ful of small-center studies," said David Steinhaus, medical director of Medtronic's cardiac-rhythm division. He called the company's data "very robust" and "as accurate as any data out there."

Defibrillators are metal-encased boxes implanted in the shoulder area and connected via leads threaded through veins to the heart. In the event of sudden cardiac arrest, a defibrillator is programmed to dispatch a powerful life-saving shock, akin to being kicked by a horse, people who have experienced it say. That jolt is supposed to correct the faulty heart rhythm.

When the Sprint Fidelis leads fracture, the defibrillator can fail to send a needed electrical jolt, and the patient can die. Or the defibrillator can send repeated, massive jolts, which themselves can be fatal. In a March 2009 statement, Medtronic said it had identified 13 deaths in which the Sprint Fidelis lead "may have been a possible or likely contributing factor."

The Wall Street Journal has identified from an FDA database at least 12 additional deaths allegedly linked to the leads that occurred and were reported to the FDA since last March. Most of these were reported by attorneys representing families. A Medtronic spokesman said the company hasn't yet interviewed medical professionals about those cases.

A number of studies have been performed since the Sprint Fidelis recall.

Last February, a joint report from the Minneapolis Heart Institute and the Mayo Clinic, published in the journal *HeartRhythm*, said the estimated rate of failure among 848 leads at three years of use was 12.1%. An October 2008 study by the University of Ottawa Heart Institute, also published in *HeartRhythm*, found that the fracture rate of Sprint Fidelis leads "increased significantly with time."

In November, a separate Mayo Clinic study showed the failure rate for Sprint Fidelis leads after two years was higher in patients younger than 50, at

20.4%, than in older patients, with a rate of 3.5%. There were 89 patients under 50 who received the leads, and 362 patients who were 50 or above.

Medtronic said the Mayo study of fractures by age had an especially small sample size of younger patients, and thus is open to question.

If an older patient's lead fails, the doctor may leave it there and slide a second lead through the vein to the heart. But younger and more physically active patients can require more than one replacement lead during their lifetime. Because veins are fairly narrow, doctors are more inclined to extract a faulty lead and replace it. This process can be fatal because scar tissue can tear and lead to profuse bleeding. Of course, for thousands of patients, the risk is much greater that they might die without the device.

Robert G. Hauser and colleagues from the Minneapolis Heart Institute searched the Food and Drug Administration's database seeking information about extractions of leads for defibrillators and pacemakers, another type of heart device. They found that extractions from 1995 through 2008 led to 57 reported deaths and 48 serious cardiovascular injuries. The total number of extractions wasn't contained in the data.

Medtronic, which is shielded from liability by various court decisions, says its data on Sprint Fidelis failure rates is based on "the largest sample size available" and that "therefore our numbers are more likely to be reflective of the overall population," according to a spokesman. The company said other independent studies, including an abstract presented at a medical conference last February by the U.S. Department of Veterans Affairs, as well as a survey of Canadian hospitals, showed failure rates comparable to its own findings.

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