THE WALL STREET JOURNAL. ONLINE

November 12, 2007

St. Jude Defibrillator Wire Gets Scrutiny

New Accounts of Patients With Heart Perforations Are Set to Be Published

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November 12, 2007; Page B7

In the wake of a heart defibrillator-wire recall by **Medtronic** Inc., reports are emerging that some defibrillator wires made by **St. Jude Medical** Inc. are in rare instances puncturing holes in the hearts of cardiac patients.

The devices in question, the Riata line of defibrillator leads from St. Jude, are wires that connect defibrillators to patients' hearts. They are affixed to the heart wall and are designed to sense when the heart's rhythm has gone haywire. The defibrillator then is supposed to dispatch an electric shock.

But in some reported cases, rather than staying attached to the heart, the Riata leads are poking holes through the heart and -- in some cases -- nearly poking through the patients' skin. Such events are potentially very serious. When the lead can't sense aberrant heart rhythms, the patient can die from the underlying medical condition. Or the heart can bleed into the pericardial sac surrounding it, causing a lethal condition called cardiac tamponade in which pressure builds around the heart and it can't beat effectively.

Such occurrences can happen with any defibrillator lead. St. Jude said in its own monitoring of the Riata's performance, it hasn't seen anything to suggest Riata leads are linked to more heart "perforations" than are any other defibrillator leads.

The most recent cases are the accounts of four patients -- in Nebraska, New York City and the Czech Republic -- expected to be posted online today by the medical journal Pace. These cases have been reported to St. Jude and to the Food and Drug Administration.

In one case at Montefiore Medical Center in New York, the tip of the lead was within seven millimeters of the surface of the skin, said an associate editor of the journal, Stephen C. Vlay. Dr. Vlay, a cardiologist and heart-rhythm specialist at Stony Brook University in Stony Brook, N.Y., described the case in an interview as "kind of scary."

"There is a legitimate concern that the problem may be more than physician misadventure and that there may be an inherent design flaw, at least in some models of the Riata lead," Dr. Vlay wrote in an editorial to be published online today.

St. Jude, of St. Paul, Minn., said it has created three "registries," or large studies of devices on the market, that focus on patients getting the Riata and others of St. Jude's cardiac devices. It has found, in one such registry, a rate of perforation of 0.33% in 1,207 patients implanted with all Riata leads.

Eric Fain, president of St. Jude's cardiac-rhythm management division, said perforation rates with the 121,000 Riata leads implanted so far are at or lower than those reported for other defibrillator leads. "You're looking at very low rates...," he said. "We've set up a system that actively encourages physicians to report" adverse events.

Heart doctors stress these patients face a far greater risk of death from their underlying disease than from the possibility their devices might not work properly.

Dr. Vlay, however, questioned whether manufacturers or the FDA get a true picture of perforations from leads because doctors don't always report these experiences.

Reports earlier this year, published in the journal Heart Rhythm, described higher perforation rates than those cited by St. Jude. In April, Massachusetts General Hospital reported a 3.8% rate of perforations -- five out of 130 -- with certain models of Riata leads. A subsequent letter to Heart Rhythm by Mass General doctors reported three more perforation cases with 115 other Riata leads. Doctors from New York Hospital Queens also reported in a Heart Rhythm letter that they saw five perforations out of 59 Riata leads implanted. Those doctors, Ranjit Suri and Seth Keller, wrote, "We have stopped using the Riata lead."

Some cases of perforations with Riata leads also were reported to the federal government's database of adverse events. At least four reports of patient deaths in the database mention perforations and Riata leads, though some of the problems may stem from doctors' actions. The database, which lacks detail in many cases, contains several dozen other reports involving the Riata and perforations.

In October, the Sprint Fidelis defibrillator lead, made by Medtronic, was pulled from the market after the company found it was fracturing at a higher rate than another Medtronic lead, the Sprint Quattro. The Sprint Fidelis is a thin-diameter model, as are some of the Riata leads. An FDA spokeswoman, Karen Riley, said, "We are actively looking at whether lead size and configuration pose unique safety and performance issues."

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