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St. Jude Defibrillator Leads: Is Another Recall on the Way?

When writing about the Medtronic lead recall last month, we wrote that the St. Jude Medical Riata defibrillator leads might also be suspect, noting that either St. Jude similar leads were technologically superior or that data had not caught up to the problem because St. Jude has less market share than Medtronic. Both the Medtronic Sprint lead and the St. Jude Riata lead are smaller than other defibrillator leads. Certainly, they are easier for cardiac surgeons who are threading the defibrillator leads through the patient's blood vessels than the Quattro lead or other available leads. The question is whether these newer and thinner defibrillator leads are safe. The Medtronic lead recall and the reports we are getting from clients all over the country make clear that the Medtronic Sprint lead is defective.

Now, the question is whether the St. Jude Riata lead is similarly flawed. According to a Wall Street Journal article last week, reports are emerging that some St. Jude defibrillator wires may be defective. As opposed to staying attached to the heart where they belong, there are reports that the St. Jude leads are puncturing holes in the hearts of defibrillator patients. The punctures are not insignificant; some reportedly are nearly poking through the patients' skin.

If the lead is not attached to the heart, it creates the same (failure to shock the heart) concerns we now have with the Medtronic Sprint leads. Even more problematic, the detached wires can cause the heart to bleed, creating a potentially life-threatening condition.

There is no question that in rare cases this can happen to any defibrillator lead. St. Jude claims that there is no evidence that Riata leads are more likely to perforate the heart than any other defibrillator leads.

But the medical community is not so sure. The medical journal Pace reported last week on four women with perforations from St. Jude Riata defibrillator leads. The patients (from Nebraska, New York, and the Czech Republic) all had their defibrillator leads removed. Cardiologist Dr. Stephen C. Vlay wrote that if the leads perforate, the problem is often not uncovered until the lead goes through the heart wall.

Dr. Vlay also voiced the concern that there has been an underreporting of defective leads, because doctors did not believe the problem they faced was anything other than an isolated incident. This comment makes you wonder if St. Jude has been fully forthright about the problems with its leads, particularly in light of Medtronic's apparent failure to disclose the relevant problems with its leads until they had been implanted in the chest of over 250,000 people.

The Pace article is consistent with an article published earlier this year by the medical journal Heart Rhythm, which described a 3.8% perforation rate, much higher than that offered by St. Jude. A subsequent letter to Heart Rhythm by Mass General doctors reported three more perforation cases with 115 other Riata leads. Doctors in New York also reported that they saw five perforations out of 59 Riata leads implanted. The doctors making the report, Dr. Ranjit Suri and Dr. Seth Keller, have stopped using the St. Jude Riata lead.

Our St. Jude defibrillator lead lawyers are reviewing defective St. Jude leads around the country now, in addition to the Medtronic Sprint leads. If you want to

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