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Removing Medtronic Heart Cables Is Hard Choice

By BARRY MEIER

BOSTON — Pulling a medical device off the market is one thing. Removing it from the bodies of thousands of patients is a lot more complicated and dangerous.

Consider the Sprint Fidelis, a heart defibrillator cable. In 2007 its maker, Medtronic, stopped selling it after five patients who had the cables died.

But only now is the full scope of the public health problem becoming clear for the Sprint Fidelis, which is still used by 150,000 people in this country.

In the next few years, thousands of those patients may face risky surgical procedures to remove and replace the electrical cable, which connects a defibrillator to a chamber of the heart.

Medtronic estimates that the cable has failed in a little more than 5 percent of patients after 45 months of being implanted. But as a preventive measure, some patients with working cables are having them removed.

Already, four patients have died during extractions. Experts fear that the toll could quickly rise if such procedures are not performed by skilled doctors at medical centers that have performed many of the operations.

“I think we are just seeing the tip of the iceberg,” said Dr. Charles J. Love, a cardiologist at Ohio State University Medical Center in Columbus, who specializes in cable extractions.

For many of the patients around the country who may need the procedure, finding the right medical center will not be easy.

There is little publicly available data on the volumes and success rates of the procedures at the nation’s hospitals. Some hospitals disclose their own numbers, but many more do not.

“There are people who are doing this that don’t meet the criteria,” said Dr. Bruce Wilkoff, a cardiologist at the Cleveland Clinic.

Even experienced cardiologists at well-regarded hospitals, like Dr. Laurence M. Epstein at Brigham and Women’s Hospital here, consider the procedure challenging.

Dr. Epstein recently operated on a patient, a 63-year-old man, whose Sprint Fidelis cable had become so overgrown with tissue that it was stuck inside a major vein.
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To free it, Dr. Epstein cautiously threaded a catheter-guided laser through the blood vessel to dissolve the entrapping tissue. It was a risky move. The deaths of the four Sprint Fidelis patients at other hospitals apparently occurred when less practiced doctors damaged a vein or the heart, causing extensive bleeding.

Finally, Dr. Epstein pulled the cable out. “This was one of the more difficult ones,” said Dr. Epstein, who added that he had removed scores of the Sprint Fidelis cables in the last year without a major complication.

It is not unusual for heart cables, or leads as doctors call them, to eventually wear out or fail, which is why there are doctors who specialize in removing them. What makes the Sprint Fidelis situation stand out is the vast number of patients who got the cable before its recall. A quarter-million people around the world received a Sprint Fidelis in the three years from its introduction in 2004 to its recall in October 2007.

The cable's chief flaw is the tendency for it to crack, creating electrical problems. The defibrillator may fail to give a heart a life-saving jolt to disrupt a potentially fatal rhythm. Or it may repeatedly discharge, shocking patients for no reason.

Also, when a Sprint Fidelis is used with a device that combines a defibrillator with a pacemaker, the cable's flaw may interfere with the pacemaker's ability to keep a patient's heart beating at a steady rhythm.

Medtronic has given patients some guidance about extractions, like telling them to seek a hospital experienced in the procedure if they decide to have a Sprint Fidelis removed. Though the company has declined to indicate which medical centers have such experience, it recently compiled such a list. Last year, to win approval for a new heart cable from the Food and Drug Administration, the company agreed to provide the F.D.A. with future data from “10 experienced extraction centers,” according to agency records. But Medtronic says it does not plan to make such a list public.

“Medtronic believes that a patient’s physician is in the best position to make decisions related to patient care, including the most appropriate lead extraction center,” the company wrote, in response to a reporter's question.

Experts say patients should ask a hospital how many of the procedures it has performed, and go to medical centers that do at least 50 a year.

Medtronic has been shielded so far from legal claims over the recalled device. More than 1,000 patient lawsuits involving the Sprint Fidelis have been thrown out because of a ruling last year by the Supreme Court. The court held in a ruling involving a different medical device that federal law protects device makers from liability suits involving some products, as long as the F.D.A. has approved their products.

Some Democrats in Congress have vowed to pass legislation that would override the Supreme Court decision. They cite the Sprint Fidelis problem as one reason, also noting the F.D.A. let it onto the market without extensive testing.
Medtronic is supplying replacement cables, but the cost of the operation to implant a cable, which can run $15,000 to $20,000 is being borne by Medicare or private insurers.

A defibrillator cable can last 15 years or more — much longer than a defibrillator, whose built-in batteries may wear out in five years or so. When the cable does eventually wear out, or break, extracting it is not the only option. Often doctors will leave the old one in place, threading a new cable in place alongside.

Those options pose competing risks, experts say. While extracting a cable can be dangerous, leaving it in place can make it more difficult to remove later, because of in-grown tissue.

In the case of the Sprint Fidelis, doctors will be making decisions for a huge number of patients. Medtronic’s recent estimates indicate the cables are likely to stop working in thousands of people in the next few years.

Meanwhile, even tens of thousands of additional patients for whom the Sprint Fidelis is still working will need to undergo a procedure in the next few years to have the defibrillators themselves replaced, as the batteries wear out. During replacement procedures, doctors will need to weigh the risk of hoping the cables continue to work or replacing them.

Medtronic has said that whether the Sprint Fidelis is broken or is still working, it should be extracted only as a last resort. The company said it did not know how many Sprint Fidelis cables have been extracted.

Specialists take different approaches on the matter. Dr. Wilkoff of the Cleveland Clinic said he planned to reattach a working Sprint Fidelis when he replaces a defibrillator. Because of the clinic’s experience in implanting cable, he said, the failure rate at his hospital has been much lower than at other medical centers.

But other experts like Dr. Epstein, who are concerned about the failure rate, have started pre-emptively removing the cables in some patients. That was the approach he took with his 63-year-old patient, whose life depends on the reliable operation of his heart pacemaker.

Dr. Love of Ohio State, meanwhile, said he had begun routinely removing the Sprint Fidelis when changing defibrillators or pacemakers in younger, more active patients — typically those age 60 or less — because greater physical activity places more stress on a cable, raising the likelihood of its fracturing.

The Heart Rhythm Society, a group representing doctors who implant heart devices, plans to issue guidelines about cable extraction this year. They would urge doctors to perform at least 30 removals under the supervision of an experienced extraction surgeon before operating solo.

But some experts say that it is difficult for doctors to obtain that level of training. And they caution that even well trained physicians need to regularly perform significant numbers of extractions to remain proficient.

The group of device experts, which plans to urge doctors to collect more data about defibrillator cables, has not released a list of hospitals experienced in extractions.
Dr. Epstein said that two of his patients had died of complications during the first 200 extractions of various makes of cables he performed. Since then, he said he had performed 800 procedures without any deaths.

“Of all the procedures I do,” he said, “extraction probably has by far the largest learning curve.”