By BARRY MEIER and KATIE THOMAS
Aug. 21, 2012

The New York Times

Cardiologist Issues Alert on St. Jude Heart Device

A cardiologist who studies the safety of heart devices said surgeons should stop using a component sold by St. Jude Medical until more is known about the long-term safety of the device.

The cardiologist, Dr. Robert G. Hauser of Abbott Northwestern Hospital in Minneapolis, made his comments as a study he conducted was published online. His research suggests that a proprietary material used by St. Jude to coat wires that connect an implanted defibrillator to a patient's heart is breaking down prematurely and, in some cases, leading to failure of the device. The study was published by EP Europace, a British cardiology journal.

St. Jude began using the coating, which is known as Optim, several years ago as a means of better protecting its leads from abrasion. But Dr. Hauser said a troubling number of cases had been reported to the Food and Drug Administration in which the Optim coating appeared to fail.

"There is no need to use this lead until we have more confidence in its performance," he said in an interview Monday.

The company has vigorously defended the safety of Optim and its current defibrillator lead, which is known as the Durata and has been implanted in an estimated 278,000 patients worldwide, according to St. Jude.

In a statement Tuesday, the company noted that leads from all manufacturers can fail and said the Optim coating is 50 times more resistant to abrasion than silicone, the standard coating. St. Jude also said its product registries are monitoring 11,000 patients with the company's current generation of leads, and it recently announced that it would follow patients in the registry with Optim-coated leads "indefinitely."

"St. Jude Medical is committed to continuing to make significant investments in technologies and post-market surveillance studies to further advance our insight into the performance of our leads, and to improve patient safety," the company said in the statement.

The release of Dr. Hauser's report has been highly anticipated by doctors and Wall Street analysts.

Last week, the F.D.A. took the unusual step of recommending that patients who had received an earlier generation of St. Jude leads undergo imaging tests to determine if the device is beginning to fail. It also ordered St. Jude Medical to conduct additional studies on both the older generation of leads, called the Riata, and the new generation of Durata leads.

The company has said its studies had shown that the Optim coating protected the leads from abrasion in 99.9 percent of cases.

Dr. Hauser focused on reports that suggested an abrasion problem with both the Durata and another model

that also carries the newer coating, the Riata ST Optim. He found 15 such reports for the Riata ST Optim and 37 for the Durata. He also found the abrasion had occurred within four years of being implanted.

“I think it is a red flag,” he said. “I think we need more data. But fundamentally, I’m afraid that this material is not going to perform as advertised.”

Still, Dr. Hauser said, patients who have been implanted with the lead should not be “unduly concerned,” adding that more research is needed. “We do believe that patients with these leads should be evaluated regularly, as recommended by their physicians,” he said in a news release. That mirrors the advice that the F.D.A. gave patients and their doctors last week about the earlier Riata lead.

Implanted heart defibrillators have two major components: a power generator that also monitors the heartbeat, and the lead, which transmits data from the heart and is used to send a high-energy jolt of electricity when a patient develops a potentially fatal heart rhythm. The power generators need to be replaced every five or six years, when the battery runs out. But the industry’s goal has been to make long-lasting leads because removing them can be dangerous.

For months, heart specialists have been scrambling to figure out how to treat an estimated 128,000 patients worldwide who have the Riata implant, which was recalled last November and has been shown to jolt the heart unnecessarily or to fail to work when needed. A study by the company found that wires had protruded from the leads in about 19 percent of cases, and other researchers have reported higher rates.

St. Jude has said that it has found no cases of “externalized conductors,” the problem that has plagued the Riata, in the approximately 278,000 leads with Optim that have been implanted in patients.

Dr. Laurence M. Epstein, a heart device expert at Brigham and Women’s Hospital in Boston, questioned the value of Dr. Hauser’s findings because he said the F.D.A. data used in the study was notoriously prone to inaccuracies. Dr. Epstein said he had already stopped using the Durata in all but a handful of specialized cases because the long-term safety was unknown. “I had these concerns anyway,” he said.

Dr. Hauser and St. Jude have clashed before. In April, the company challenged an earlier study by him and unsuccessfully tried to get a medical journal to retract the report.

Dr. Hauser identified three cases that appeared to show the coating on Durata leads had worn away because the wires had pushed through from the inside. In two of the cases, the reports initially described the problems as “inside out” abrasion — a term often used to describe the Riata flaw — but the wording was later changed by St. Jude to describe the problem differently.

Wall Street analysts have anxiously monitored coverage of the Riata for signs that the Durata could be prone to the same failures. St. Jude’s stock fell more than 4 percent Thursday after the F.D.A. announced it was ordering the company to perform additional studies on the safety of the Riata and the Durata, but has largely recovered since then. On Tuesday, shares of St. Jude fell 21 cents, to $37.96.

Bruce Nudell, an analyst for Credit Suisse, said Dr. Hauser’s most recent article didn’t provide any conclusive evidence of flaws with the Durata lead. “I think all the scrutiny that has gone into the Durata over the last six to nine months really has failed to unveil any smoking gun,” he said.

Dr. Hauser noted that the study was limited because the F.D.A. database he used to collect the data was problematic. Information is often missing or incomplete, and the agency relies on doctors or hospitals to report

voluntarily problems with medical devices. “Therefore, the number of lead failures in this study likely underestimates the actual number that has occurred,” he wrote in the study.