Device Malfunction Casts Doubt on Industry Pledge

By BARRY MEIER and KATIE THOMAS

As doctors scramble to understand the risks posed by a flawed heart device component made by St. Jude Medical, the episode is raising a bigger question — whether the $10 billion heart device industry has fully embraced promised safety reforms.

The industry was shaken in 2005 by disclosures that a major maker of heart defibrillators, Guidant, had not warned doctors about a potentially fatal flaw in its products.

Subsequently, Guidant and other device makers promised to set up independent medical advisory boards, to quickly investigate malfunctions in their products and to alert doctors to potential problems. The key to preventing a repeat episode, specialists say, was for manufacturers to scrutinize every death to see if it pointed to an underlying flaw that could kill or injure other patients.

But now the same issues that dogged device makers seven years ago are resurfacing amid a controversy over how St. Jude Medical has handled disclosures about a problem component, a wire — or lead — that connects a defibrillator to a patient’s heart.

Last month, an outside researcher, Dr. Robert Hauser of Minneapolis, released a study indicating that short-circuits and other failures of the St. Jude lead might have played a role in some 20 patient deaths.

His report followed several studies showing that the lead, called the Riata, was also prone to another malfunction, a tendency for internal wires to break through the protective outer coating
and cause electrical problems like unintended shocks in some patients. An estimated 128,000 patients worldwide still use the Riata lead, which the company stopped selling in late 2010.

St. Jude executives, including the chief executive, Daniel J. Starks, quickly reacted to Dr. Hauser’s report by unleashing a public relations campaign aimed at discrediting the study’s accuracy and Dr. Hauser. But left unanswered amid the noise was the question: how closely had St. Jude been examining those deaths for signs pointing to a broader problem involving the Riata lead?

“Someone in the company should have been watching this,” said Dr. Robert J. Myerburg, who led an independent investigation into Guidant’s decision not to warn doctors that some of its defibrillators could short-circuit. A defibrillator emits an electrical jolt to interrupt a potentially fatal heart rhythm and restore the normal heartbeat.

In a statement issued in response to questions from The New York Times, Amy Jo Meyer, a St. Jude spokeswoman, said the company regularly updates a panel of outside safety specialists about patient deaths potentially tied to lead failure. But the company declined to disclose how many deaths involving short-circuits and other electrical failures involving the Riata had been presented to that panel.

One member of St. Jude’s lead safety panel, Dr. Bruce Wilkoff of the Cleveland Clinic, said in an e-mail that he did not “have specific recollections of how many patient scenarios” had been presented but added that he was aware of the conditions that could result in a patient’s death. Four other specialists on that board either did not respond to repeated requests for comment or declined to comment on the number of patient deaths St. Jude officials had presented to the panel.

In a telephone interview last week, the company’s chief medical officer, Dr. Mark D. Carlson, said that some patient deaths were inevitable because defibrillators occasionally fail; he added that the types of insulation problems with the Riata were common.
However, other heart device specialists said they were disturbed by St. Jude’s explanations, adding that the number of Riata-related deaths appeared unusually high compared with other leads and pointed to a troubling pattern.

“I would hope that anybody looking at that data would say, hey, something is not right here,” said Dr. Edward J. Schloss of Cincinnati, “I think if you saw 20 high-voltage fatalities with a pretty clear pattern of insulation abrasion, that should get your attention.”

It was not supposed to be this way. The safeguards that the major defibrillator makers — Medtronic, St. Jude and Boston Scientific, which acquired Guidant’s heart unit in 2006 — adopted in recent years were supposed to arm doctors with facts rather than opinions.

St. Jude is not the first producer to have encountered product problems since then. In 2007, Medtronic recalled a widely used lead called the Sprint Fidelis after reports emerged that it was cracking and failing in patients.

However some specialists questioned why St. Jude reacted as it did to Dr. Hauser’s recent report, since that study was based on reports of possible Riata-related deaths that St. Jude had filed with the Food and Drug Administration.

“I would have expected that they would have done his study in advance,” said Dr. Jeffrey N. Rottman, a heart device specialist at Vanderbilt University.

The Riata, specialists say, has had what appears to be a unique failure. Wires in the cable can work through its insulation and become exposed. The wires have continued to function properly in most patients. But in others, electrical problems have occurred.

Since 2010, the company had been receiving reports about the problem, and in a letter to doctors late that year it made a passing reference to the issue. Then, in 2011, a cardiologist at Royal Victoria Hospital in Belfast, Northern Ireland, alerted St. Jude that growing numbers of exposed Riata wires were occurring among patients there. That cardiologist, Dr. Ernest W. Lau, also urged St. Jude executives to immediately alert cardiologists about the seriousness of the problem.
“I am sorry to say this,” Dr. Lau wrote in an e-mail to company officials that he provided to The Times. “I believe there should and will be a much more serious advisory.”

Last April, Dr. Carlson, the company’s top doctor, discussed the problem of protruding wires with the lead safety panel. By then, German researchers had also reported that the Riata lead failed in 8 percent of the patients they had examined. Dr. Wilkoff of the Cleveland Clinic said that the St. Jude lead safety board decided at that time that it was premature to specifically alert doctors about the exposed wire problem, as Dr. Lau had urged. Instead, the panel recommended that St. Jude gather more data.

Still, St. Jude’s ability to gather that data quickly was limited. Even though the F.D.A. now requires device makers to track the performance of newer leads in patients, companies like St. Jude do not give the same level of scrutiny to older leads. Also, to understand the extent of the exposed wire problem, patients need to be screened using a diagnostic technique called fluoroscopy.

In November, the company finally sent an alert to doctors about the exposed wires and said it would start a study of the problem. The F.D.A. reviewed that letter and categorized it as a “Class I recall,” the most serious designation. But as doctors tried to figure out how to manage affected patients, Dr. Hauser’s report appeared, pointing to a separate and potentially more serious problem, the likelihood that the Riata’s insulation could wear away, short-circuiting the device.

Today, specialists say they are still groping for answers, not knowing all of the risks that the Riata lead poses to patients and whether it was limited to the external wires or if there was also a short-circuiting risk.

In a recent study at Vanderbilt, researchers found that about a third of Riata leads in patients they examined showed signs of protruding wires. Nearly a third of those showed electrical failures.

“Every patient you are seeing you have in the back of your mind whether the device is causing them harm,” said Dr. Christopher R. Ellis, one of the Vanderbilt researchers.