

May 16, 2006

Heart Device Makers Plan Enhanced Safety Reviews

By [BARRY MEIER](#)

Two major producers of heart devices, responding to a report by a medical group critical of industry's oversight of product safety, said yesterday that they planned to broaden how they conducted such reviews.

In separate statements, the two companies, [Medtronic Inc.](#) and St. Jude Medical, said they planned several steps to heighten their scrutiny of device safety and reliability, like increasing the number of outside doctors who serve as consultants reviewing such issues.

The statements were issued just before the start of a meeting tomorrow in Boston of a medical group that represents specialists who implant heart devices like [defibrillators](#) and pacemakers. Last month, the group, the Heart Rhythm Society, issued a report calling on device makers to create, among other things, independent panels of doctors and other specialists to review product safety.

The medical group's report was issued in response to a situation last year in which one producer, the [Guidant Corporation](#), did not alert doctors to life-threatening flaws in some defibrillators and allowed more than 4,000 suspect units to be implanted in patients when safer ones were available. While reports of device failures were relatively low, the consequences of such failures were life-threatening.

A group of doctors and other experts retained by Guidant to review its actions found that the company had failed to fully assess the patient consequences of its decisions because engineers, rather than doctors, were involved in making them. At least seven patients have died during episodes in which those devices short-circuited.

Last month, Guidant, which is now owned by [Boston Scientific](#), said it would adopt all the recommendations in the Heart Rhythm Society's report and urged that an industrywide safety monitoring panel be established. In their statements, Medtronic and St. Jude did not endorse that idea but said they were moving to adopt some of the medical group's proposals.

For example, Medtronic, which is the nation's biggest maker of heart devices, said that rather than creating a new safety panel, the company was expanding the number of outside physicians who consult with the company on device performance and safety issues. In addition, the company said that, along with notifying doctors of product recalls, it would send notices directly to patients, another step urged by the medical group.

For its part, St. Jude Medical, the country's third-biggest heart device maker behind Guidant, said it was planning to expand its existing board of outside advisers. The company said it would create a

board focusing specifically on the wires, or leads, that connect an implanted device to the heart. It said that it would also directly notify patients about product problems.

Also yesterday, a leading medical publication, *The New England Journal of Medicine*, released an article on its Web site by three physicians who participated in the Guidant-sponsored panel. In that article, the three doctors wrote that they believed that independent scrutiny of company safety data was vital.

"Voluntary, independent review at the level suggested is a notion both foreign and frightening to most corporations, whose perceived need is to protect business interests," the physicians wrote. "But corporate culture fosters a loyalty to corporate goals that may create unintended bias and distorted perceptions about product performance and patient safety."

One doctor involved in the report, Dr. Bruce D. Lindsay of the Washington University School of Medicine in St. Louis, said he was heartened by the steps announced by Medtronic and St. Jude. "My impression is that it is a positive response," he said.

But another specialist who helped write the report, Dr. Robert J. Myerburg of the University of Miami, said the companies ought to set up panels specifically devoted to product safety issues. "It has to be a go-to group that you can call on a Friday night," he said.

More Warnings on Defibrillators

By Bloomberg News

The Boston Scientific Corporation said yesterday that it had warned physicians that another 996 defibrillators made by its Guidant unit might quit prematurely, leaving patients unprotected from sudden cardiac death.

No deaths or injuries have been linked to the battery failures, the company said. The defect, a faulty low-voltage capacitor, was confirmed in 30 defibrillators removed from patients as of May 8, and is suspected in at least 46 devices still implanted, Boston Scientific said. The defect involves a single manufacturing batch of 996 defibrillators.

The company said it learned of the failures after purchasing Guidant in April 21 for \$27.5 billion.

Regulators imposed sanctions on Guidant in December because of quality-control flaws after the recall last year of 109,000 defibrillators linked to at least seven deaths. Many recalled devices were sold years after Guidant learned of the flaws.

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