

Company warns of heart device malfunctions

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Implanted heart device manufacturer Medtronic of Minneapolis is asking doctors to discontinue use of a component in its newest defibrillator models.

Medtronic said the component, an electrical wire that connects the defibrillator to a patient's heart, is prone to defect and has been linked to hundreds of malfunctions and may have been involved in five fatalities, The New York Times reported Monday.

The company also urged the approximately 235,000 patients who have been outfitted with the devices to have them immediately examined by doctors to ensure they are properly reading heart rhythm data.

The move was welcomed by Daniel Schultz, director of the Center for Devices and Radiological Health at the U.S. Food and Drug Administration.

"Medtronic's decision to voluntarily remove its Sprint Fidelis defibrillation leads from the market is in the best interest of patient safety," Schultz said in a statement.

"These electronic wires are prone to fracture in a small number of patients which can cause the defibrillator to deliver unnecessary shocks or not operate at all. Based on our initial review of reported adverse events, some deaths and major complications have occurred after the leads have fractured," he said.

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