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After Report Of Death, FDA Warns Patients To Keep A Sharp Eye On Medtronic Pacemaker Batteries

by Shawn M. Schmitt

The US FDA is cautioning people implanted with particular Medtronic pacemakers to pay close attention to their device's battery level after the agency received reports of unexpected battery depletion – including one that led to a patient's death. The problem stems from cracked capacitors that can create an electric short in the pacemakers, causing their battery to quickly drain. The FDA says more than 130,000 of the pacemakers have been sold in the US.

The US Food and Drug Administration on 7 May warned people implanted with particular *Medtronic PLC* pacemakers to keep an eye on their device's battery level after the agency received reports of unexpected battery depletion – including one that led to a patient's death.

The problem stems from the device's capacitor, an electronic component in a pacemaker that stores electricity. When the capacitor is cracked, it can create an electric short that causes the device's battery to quickly drain.

Clinicians aren't able to communicate with the pacemaker if the battery is depleted. The FDA says three adverse event reports stood out in relation to the battery problem, including one that resulted in a death. A second patient experienced dizziness – resulting in the pacemaker being replaced – while trouble with a third pacemaker was identified before it was implanted.

Despite being designed to last anywhere between six to 15 years, the batteries noted in the three reports depleted within an average of seven months after implantation.

"While the number of adverse event reports associated with today’s safety communication is

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small and we expect very low rates of early battery depletion with this device, it's important that patients and health-care professionals who rely on these devices know to pay close attention to device performance given the pacemaker's important lifesaving functions and discuss appropriate steps to reduce any potential safety risks to an individual patient," William Maisel, director of the *new Office of Product Evaluation and Quality* within the FDA's Center for Devices and Radiological Health, said in a *release*.

Medtronic Pacemaker Models To Watch

- Azure: W1DR01, W2DR01, W3DR01, W1SR01, W2SR01, W3SR01
- Astra: X1DR01, X2DR01, X3DR01, X1SR01, X2SR01, X3SR01
- Percepta: W1TR01, W1TR04, W4TR01, W4TR04
- Serena: W1TR02, W1TR05, W4TR02, W4TR05
- Solara: W1TR03, W1TR06, W4TR03, W4TR06

Maisel, who also is CDRH's chief medical officer, said the agency recently approved improvements to Medtronic's manufacturing process to nip future battery problems in the bud. And, he noted, different capacitors are being used in the company's newly manufactured pacemakers.

"We'll continue to work with Medtronic to monitor impacted devices for any related adverse events and will keep the public informed should new information become available," Maisel said.

The FDA does not recommend that people with the affected pacemakers explant the devices. Instead, the agency says, patients and caregivers can use home-monitoring systems such as Medtronic's MyCareLink Monitor to observe battery status.

"Due to the low frequency of device failure, the FDA believes these are appropriate mitigations for most patients, as patients could be at greater risk of complications from the surgical procedure required to replace the device," the agency said.

The FDA says more than 130,000 of the pacemakers have been sold in the US.

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