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Medtronic recalls InSync III pacemakers due to battery issue

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Medtronic has recalled nearly 97,000 advanced InSync III pacemakers for treating heart failure, saying the globally distributed devices may have batteries that put out less power than they should.

In letters published over the extended holiday break, regulators in the U.S. and Germany said at least 22,000 of the battery-powered InSync III CRT implantable pacemakers made by Medtronic remain inside patients, and could fail earlier than expected. Medtronic's cardiac devices division in suburban Minneapolis is handling the worldwide recall.

"Due to the unpredictable nature of this issue, it is not possible to identify which devices might fail or when they might fail. The issue cannot be mitigated by programming changes or increasing patient follow-up frequency," Medtronic wrote to doctors, according to a copy of its "urgent field safety notice" published Nov. 26 in Germany.

The recall affects three models of the InSync III - models 8042, 8042B and 8042U.

Medtronic has stopped distributing InSync III CRT pacemakers. Current devices have a modified battery design that is not susceptible to this issue, according to the Thanksgiving Day field notice.

Cardiac resynchronization therapy, or CRT pacemakers, can apply small electric pulses to both sides of the heart to keep the left and right

chambers beating in proper sync. They're used to treat heart failure by improving the body's ability to pump blood and distribute oxygen.

The affected devices have a glitch involving battery impedance that may leave it without as much power as it needs to function properly.

Through Oct. 27, Medtronic confirmed that at least 30 devices have been impacted by the issue, including some units that are just over four years old. "Medtronic has received one report of a patient death, where it is possible, but unconfirmed, that this issue was a contributing factor," the field safety notice says.

The FDA's Nov. 27 alert - which classified Medtronic's action as a Class 2 recall - says the company will offer a supplemental device warranty.

"We regret any difficulties this may cause you and your patients," Medtronic's statement in the FDA recall says.

The letter published in Germany notes that doctors with affected patients who are considered "pacemaker-dependent" should carefully weigh the risks of getting a replacement device vs. the surgical risks from an early device replacement, which are comparable.