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12 Deaths Prompt Another Class I Recall For Medtronic's HeartWare – The Firm's Fourth In Recent Weeks

by Shawn M. Schmitt

The medtech giant has racked up yet another high-risk class I recall designation from the US FDA, this time for HeartWare Ventricular Assist Device (HVAD) cables and controller ports. It's also the second class I recall action for the HeartWare device in a little more than six weeks, and the company's fourth overall.

Only a little more than six weeks separates two high-risk class I designations by the US Food and Drug Administration for recalls of *Medtronic PLC*'s HeartWare device.

The latest class I, announced by the agency on 15 April, comes because of "risk of wear and tear of the connector plugs (power sources, data cable, and alarm adapter), which could cause damage to the controller port metal pins (for example, bent pins)" for HeartWare Ventricular Assist Device (HVAD) battery cables, data cables, adapter cables and controller 2.0 ports.

Those components are part of the HeartWare HVAD System, an intrapericardial centrifugal left-ventricular assist device (LVAD) for advanced heart-failure patients.

"Damaged controller ports may prevent power cables and data cables from being connected to the controller and lead to a full or partial stop of the pump," the FDA said. "This could cause serious patient harm, including loss of consciousness, hospitalization, heart attack or death."

Twelve deaths and eight serious injuries have been reported, the agency said. Overall there have been 855 complaints about the device, which has been manufactured and distributed since 2006. More than 106,000 of the devices were recalled.

Medtronic sent an urgent notice to customers on 26 February to alert them to the problem and

offer guidance, including a variety of patient management recommendations, as noted *here*.

> ***The two HeartWare recalls represent only half of Medtronic's recent class I's.***

HeartWare's other class I came on 1 March. In that case, the problem was with the device's pump implant kits. The FDA said at the time that the kits, also part of the HeartWare HVAD System, could cause the device to "fail to initially start, restart or have a delay in restarting after the pump was stopped."

Two deaths and 19 serious injuries were reported. (Also see "*Recall Of Medtronic's HeartWare Pump Kits Labeled Class I By FDA; Deaths, Injuries Reported*" - Medtech Insight, 1 Mar, 2021.)

The two HeartWare recalls represent only half of the company's recent class I's. In a 12 April action, a recall of a laundry list of implantable cardioverter defibrillators (ICDs) and cardiac resynchronization therapy defibrillators (CRT-Ds) made by Medtronic was designated as high risk by the FDA.

The ICDs and CRT-Ds could experience an "unexpected and rapid decrease in battery life," the agency said. There were no deaths in relation to that recall, but there were 18 serious injuries. (Also see "*Another Class I Recall For Medtronic, This Time For Defibrillators*" - Medtech Insight, 12 Apr, 2021.)

And on 9 April the FDA gave a recall of Medtronic's Valiant Navion Thoracic Stent Graft System a class I designation. The agency said the device was recalled because of "stent fractures and endoleak concerns."

Two serious injuries and one death – a clinical trial participant – were reported in that case. (Also see "*It's Class I For Medtronic's Valiant Navion Recall*" - Medtech Insight, 9 Apr, 2021.)