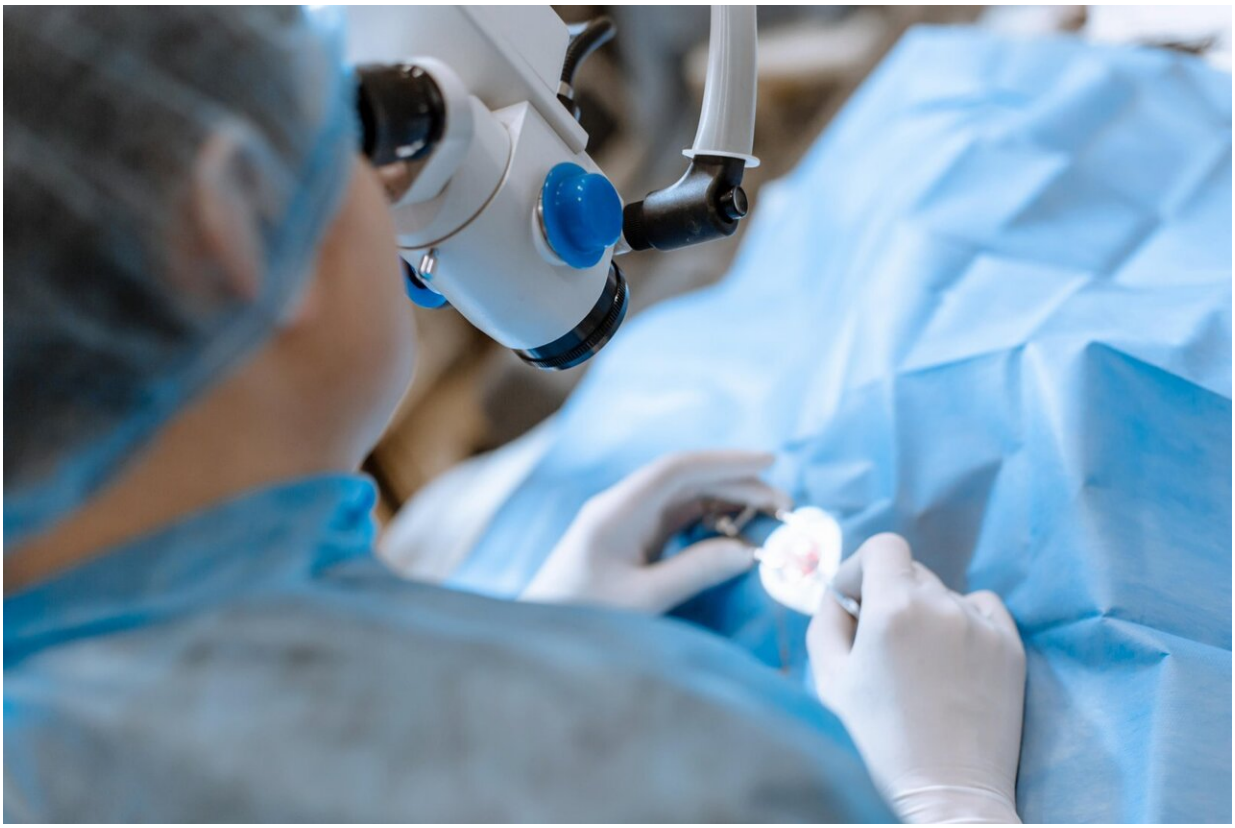
Medical Xpress

FDA recalls heart failure devices linked to injuries and deaths

April 17 2024, by Ernie Mundell



Two implanted heart devices used by patients in end-stage heart failure are now under a strict U.S. Food and Drug Administration recall, after being tied to 273 known injuries and 14 deaths, the agency said Tuesday.

The HeartMate II and HeartMate 3 are manufactured by Thoratec Corp., a subsidiary of Abbott Laboratories. About 14,000 of the devices are thought to be under recall, but as of now the two devices not being removed from the market.

"The HeartMate II and 3 are used for both short- and long-term support in adult patients with severe left ventricular heart failure," the FDA explained in a statement. "It can be used while waiting for a heart transplant, to help the heart recover, or as a permanent solution when a transplant isn't an option."

The devices replace the blood-pumping action of the heart's main pumping chamber, the left ventricle. They divert blood flow from that weakened chamber and propel it into the aorta, where it flows to the rest of the body.

However, in rare cases a type of clot can form from "biological material" that builds up in a particular area of the devices.

"This buildup can obstruct the device, making it less effective in helping the heart pump blood," the FDA explained. "It can trigger alarms indicating low blood flow and affect the device's ability to help the heart properly. The accumulation of biological material typically occurs over two years or more."

In the worst cases, this kind of obstruction can lead to injury or death, the agency said.

On Feb. 19, Thoratec "sent all affected customers an Urgent Medical Device Correction Letter," asking them to pay attention to low flow alarms linked to the devices, "as this is the first symptom of significant outflow obstruction," according to the FDA.

If alarms are reported to doctors, they could address the issue by either monitoring the patient closely, implanting a stent to improve blood flow or replacing the pump.

One study published in 2022 in the Journal of Thoracic and Cardiovascular Surgery found the blockages occurred in about 3% of patients with the devices, with the likelihood of obstructions rising over time.

Heart specialists are concerned about the issue, because patients in end-stage heart failure have few options if the HeartMate devices are removed from the market.

In the absence of these devices, "we are in trouble," Dr. Francis Pagani, a cardiothoracic surgeon at the University of Michigan, told KFF News.

"It would be devastating to the patients to not have this option. It's not a perfect option—no pump ever is—but this is as good as it's ever been," said Pagani, who also oversees a proprietary database of HeartMate II and HeartMate 3 implants.

More information: Find out more about the care of people in end-stage heart failure at the American Heart Association.