Abiomed heart pumps linked to 49 deaths

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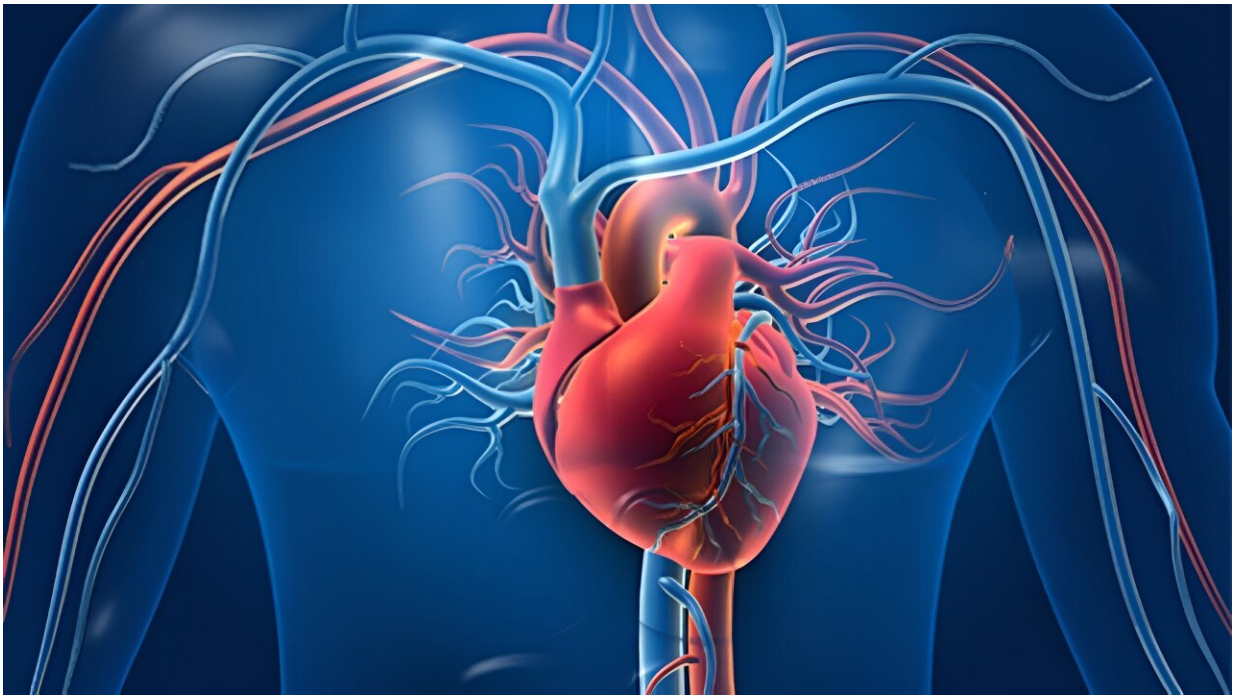

A new warning is being issued over a heart pump whose use could perforate the heart.

The device has already been linked to over 100 injuries and 49 deaths.

These left-sided Impella heart pumps are made by Abiomed, a subsidiary of Johnson & Johnson MedTech. Abiomed posted the new

warning on the devices on the U.S. Food and Drug Administration's website.

"The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death," the statement said, although it adds that "this recall is a correction, not a product removal."

The advisory informs those implanting the Impella devices about revised instructions for use, including "carefully position the pump catheter during operative procedures."

These Impella pumps resemble a long straw inserted into the heart. They are used during high-risk cardiac procedures (for example, during certain types of heart attack), to help maintain proper blood flow from the heart to the body.

The pump is threaded through major heart vessels and into the heart's left ventricle, the organ's main pumping chamber.

"Abiomed is recalling its Impella Left Sided Blood Pumps because the pump catheter may perforate [cut] the wall of the left ventricle in the heart," the company warned in its statement. "During operations, the Impella device could cut through the wall of the left ventricle."

"The use of the affected Impella pumps may cause serious adverse health consequences, including left ventricle perforation or free wall rupture, hypertension, lack of blood flow and death," the warning added.

So far, 129 patients have reported serious injuries linked to the devices, and 49 patients have died.

The issue was first disclosed in a technical bulletin to physicians back in

October 2021, but the FDA wasn't informed at the time. An FDA spokesman has told CNN that failing to do so violated agency protocols.

FDA followed up with an inspection of Abiomed's facility in September of 2023, and issued its own warning letter to the firm soon after.

According to the latest Abiomed advisory, anyone undergoing a procedure using Impella Left Sided Blood Pumps should be aware of the new instructions for use, especially people with heart disease, the elderly and women.

But Public Citizen, a consumer advocacy group, issued a statement calling for a full ban on the devices.

Despite dozens of severe injuries and deaths, "the FDA has allowed them to remain in use," the group said. "Moreover, there are serious and ongoing concerns about whether there are clinically meaningful survival benefits that outweigh the risks of these left ventricular assist devices."

Dr. Robert Steinbrook directs Public Citizen's Health Research Group.

"Given the ongoing safety concerns about Impella left ventricular assist devices and this new recall, it is woefully inadequate to revise an instruction manual and to tell cardiologists to be more careful," Steinbrook said in a statement. "The use of these left ventricular assist devices should be stopped."

"Better treatments are urgently needed," Steinbrook added, and "in the future, these devices should only be used in patients enrolled in a randomized, controlled trial that compares the devices to medical [drug] management."

More information: Find out more about heart attacks and their treatment at the Cleveland Clinic.