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Medtronic recalls unused aortic stent device after patient dies in trial



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Medical device maker Medtronic, which has a large presence in North Haven, has voluntarily recalled unused batches of its Valiant Navion thoracic stent graft system after a patient died during a clinical trial.

The company announced the recall this week, informing doctors to immediately stop using the device until further notice.

The Dublin-based company said three patients in a global clinical trial were observed to have stent fractures, and one patient died.

An independent follow-up review of images from patients enrolled in the trial found seven out of 87 had "stent ring enlargement beyond the design specification."

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The company said it is conducting a comprehensive technical investigation, including further review of follow-up clinical trial imaging and commercial complaints.

The Valiant system treats thoracic aortic aneurysms through a minimally invasive procedure that reinforces the wall of the aorta to prevent the aneurysm from rupturing, according to the company.

“We treat matters of product safety with the highest priority and urgency,” said Nina Goodheart, senior vice president and president, Structural Heart & Aortic, which is part of Medtronic’s cardiac vascular group. “Our decision to implement this voluntary recall is necessary to ensure the utmost patient safety. As our investigation continues, we are committed to timely communication with physicians and regulatory bodies.”

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