Medtronic News

Medtronic Announces Voluntary Recall of Unused Valiant Navion™ Thoracic Stent Graft System

DUBLIN, Feb. 17, 2021 /PRNewswire/ -- Medtronic plc (NYSE:MDT), the global leader in medical technology, has voluntarily issued a global recall of unused Medtronic Valiant Navion™ thoracic stent graft system and informed physicians to immediately cease use of the device until further notice.

In accordance with its commitment to patient safety – and in consultation with independent physicians – Medtronic initiated this action in response to information recently obtained from the Valiant Evo Global Clinical Trial indicating that three patients in the Valiant Evo Global Clinical Trial were observed to have stent fractures, two of which have confirmed type IIIb endoleaks. One patient death was reported.

Following these observations, an independent imaging laboratory reviewed all available images from patients enrolled in the Valiant Evo Global Clinical Trial. Upon further analysis of the images, seven (7) out of 87 patients were observed to have stent ring enlargement beyond the design specification. Those observations require further assessment to determine potential clinical importance.

Medtronic is currently conducting a comprehensive technical root cause investigation, including further review of follow-up clinical trial imaging and commercial complaints and imaging.

"There is nothing more important than the safety and well-being of patients," said Nina Goodheart, senior vice president and president, Structural Heart & Aortic, which is reported as part of the Cardiac Vascular Group at Medtronic. "We treat matters of product safety with the highest priority and urgency. 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."

Medtronic has contacted the U.S. Food and Drug Administration (FDA), along with other regulatory bodies around the world, to share information related to this issue. Medtronic will continue working directly with regulatory authorities on this global voluntary recall.

Patient Management Recommendations

Patients with a Medtronic Valiant Navion thoracic stent graft system should consult their physician with any questions.

As part of the voluntary recall of unused product, physicians were sent written communication from Medtronic directing them to immediately cease use of the Medtronic Valiant Navion thoracic stent graft system and instructions for returning unused product to Medtronic.

Medtronic advises physicians to retrospectively review all available images of patients treated with Valiant Navion thoracic stent graft system with specific attention to stent fractures and type IIIb endoleaks and contact Medtronic if any imaging findings are observed.

Medtronic urges physicians to follow best clinical practices and evaluate patients with at least annual follow-up according to the imaging recommendations in the Medtronic Valiant Navion thoracic stent graft system Instructions for Use (IFU).

As always, physicians are asked to notify Medtronic of any adverse events or product safety issues associated with use of any Medtronic product, which also should be reported to the FDA's MedWatch Adverse Event Reporting program. Outside of the U.S. adverse events or product safety issues associated with use of any Medtronic product should be reported to the appropriate competent authority.

About Medtronic

Medtronic plc (www.medtronic.com), headquartered in Dublin, Ireland, is among the world's largest medical technology, services and solutions companies – alleviating pain, restoring health and extending life for millions of people around the world. Medtronic employs more than 90,000 people worldwide, serving physicians, hospitals and patients in more than 150 countries. The company is focused on collaborating with stakeholders around the world to take healthcare Further, Together.

Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.

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