



Urgent Field Safety Notice
Medtronic Valiant Navion™ Thoracic Stent Graft System
Recall

February 2021

Medtronic Reference: FA960

Dear Doctor / Health Care Professional / Valued Customer,

Medtronic is issuing a global voluntary recall of the Medtronic Valiant Navion™ Thoracic Stent Graft System. The recall is being initiated in response to information identified in the Valiant Evo Global Clinical Program, which studied the performance of the Valiant Navion Thoracic Stent Graft System. A total of 100 subjects were enrolled in the Valiant Evo Global Clinical Program. The information received indicated that there were three (3) subjects with stent fractures of which two (2) have confirmed Type IIIb endoleaks, and seven (7) core lab analysis findings showing stent ring enlargement. Type IIIb endoleaks, if untreated, can potentially lead to aneurysm rupture.

Physicians should immediately cease use of the Valiant Navion Thoracic Stent Graft System and return any unused product to Medtronic.

This letter contains a description of the information known to date and patient management recommendations.

BACKGROUND

Medtronic has been informed of two (2) patients in the Valiant Evo Global Clinical Program who were observed to have stent fractures and Type IIIb endoleaks upon review of the two- and three-year follow-up CT images. The first patient event was reported on 21-December-2020 and the second patient event was reported on 27-January-2021. The first patient died following reintervention, and the death was adjudicated by the trial's Clinical Events Committee as aneurysm-related.

Following these two (2) events, the independent core lab for the clinical trial reviewed all additional available images from patients enrolled in the Valiant Evo Global Clinical Program. As of 13-February-2021, this review resulted in the identification of seven (7) patients with stent ring enlargement beyond the design specification and one (1) stent fracture, which requires further assessment to determine potential clinical sequelae.

As of the date of this letter, Medtronic has received two (2) complaints for patients treated outside the original clinical trial with the Valiant Navion Thoracic Stent Graft System: one (1) for Type IIIb endoleak and one (1) for Type IIIb endoleak with stent fracture. These two complaints were reported out of approximately 14,000 patients implanted with Valiant Navion Thoracic Stent Graft globally. Medtronic performed an explant analysis on the first complaint and confirmed no stent graft defects. The device related to the second complaint remains implanted, so Medtronic has not been able to confirm whether the complaint is related to device performance.

Medtronic is currently conducting a comprehensive technical root cause investigation, including full review of follow-up clinical trial imaging, as well as commercial complaint and imaging data analysis. Given these observations, the ongoing technical root cause investigation, and Medtronic's commitment to patient safety, Medtronic is proactively implementing a voluntary recall of all Valiant Navion Thoracic Stent Graft System globally.

PATIENT MANAGEMENT RECOMMENDATIONS

Medtronic engaged an Independent Physician Quality Panel (IPQP) composed of thoracic aortic specialists to advise on appropriate patient management. At this time, based on information collected to-date and IPQP input, Medtronic recommends physicians follow best clinical practices and make best efforts to evaluate patients with at least annual follow-up according to the imaging recommendations in the IFU. We also advise retrospectively reviewing all available images of patients treated with Valiant Navion Thoracic Stent Graft with specific attention to stent fractures and Type IIIb endoleaks.

Please contact Medtronic if any imaging findings are identified (e.g., stent fractures or Type IIIb endoleaks).

CUSTOMER ACTIONS

Medtronic is requesting customers with affected product on hand to take the following actions:

1. Identify and quarantine all unused affected Medtronic Valiant Navion™ Thoracic Stent Graft Systems.
2. Return all unused affected product in your inventory to Medtronic. Your local Medtronic Field Representative can assist you as necessary in initiating the return of this product.

ADDITIONAL COMMUNICATION

The Competent Authority of your country has been notified of this action. Please share with anyone in your organization that needs to be aware or to whom you have transferred product.

If you have any questions, please contact your local Medtronic Field Representative

Medtronic considers patient safety and customer satisfaction our top priorities. We appreciate your time and attention in reading this important notification and will continue to inform you of any additional recommendations.

Sincerely,

Youssef Wahidi

Sales Manager

Cardiovascular Operating Unit