



Urgent Field Safety Notice

Medtronic Valiant Navion™ Thoracic Stent Graft System UPDATED Patient Management Recommendations

May 2021

Medtronic Reference: FA960

Dear Doctor / Health Care Professional / Valued Customer,

This notification is to provide you with important updates to the voluntary global recall of the Medtronic Valiant Navion™ Thoracic Stent Graft System issued in February 2021.

In addition to providing an update on Valiant Navion observations, Medtronic is recommending physicians proactively contact patients implanted with the Valiant Navion Thoracic Stent Graft and perform computerized tomography (CT) imaging with contrast every six (6) months, or as frequently as deemed appropriate in the physician's medical judgment. CT imaging with contrast is necessary for a full evaluation of the stent graft; however, a non-contrast CT is recommended for patients with contraindications to contrast.

Moving forward, Medtronic is requesting physicians provide all prospective patient follow-up images for independent core lab review.

Medtronic will provide ongoing support for these recommendations, including a mechanism for physicians to upload prospective images and a physician and patient assistance program – all of which will be the subject of further communication.

Please share this information with anyone in your organization who needs to be aware or to whom you have transferred product.

UPDATE ON NAVION OBSERVATIONS

As part of a comprehensive investigation to assess device safety and quality, Medtronic continues performing CT imaging data analysis for patients implanted with the Valiant Navion™ Thoracic Stent Graft. As of May 10, 2021, 404 clinical trial and commercial patients' images have been analyzed by an independent core lab, from which a total of 17 patients had at least one device observation. CT observations include: Type IIIb endoleaks (8), stent fractures (5), and stent ring enlargements (15). Some patients had multiple observations. The overall observation rates in the worldwide Navion patient population are unknown at this time.

As reported in the February 2021 letter, one patient died four (4) days following reintervention after experiencing hypotension. No autopsy or films are available so cause of death is undetermined; the death was adjudicated by the trial's Clinical Events Committee as aneurysm related.

Based on the imaging data analyzed by the independent core lab, most of these observations were seen at the two-year or later follow-up timepoint; however, in some cases observations were seen as early as nine (9) months after implantation.

Details of the imaging findings from the Valiant Evo Global Clinical Trial were recently published in the *Journal of Vascular Surgery*¹ to help physicians recognize Type IIIb endoleak, stent fracture, and/or stent ring enlargement observations. The article includes the definitions and information on the best practices to identify the imaging observations described above.

Definitions of the imaging observations as applied by the independent Core Lab are included here:

1. Type IIIb endoleak: defined as blood flow through a fabric disruption confirmed with computed tomography angiography (CTA)
2. Stent fracture: stents are considered fractured if there is a visible gap in the stent ring and confirmed with CT or plain film X-ray
3. Stent ring enlargement: defined as an increase of the diameter of a nitinol stent ring beyond 1 mm of the nominal graft diameter as measured by CT

Medtronic is working diligently to assess the cause of the events observed with the Valiant Navion Thoracic Stent Graft. The preliminary analysis suggests a potential for loss of suture integrity, which could lead to separation of the longitudinal seam of the stent graft or stent ring detachment from the surface of the graft fabric. Further investigation is underway to understand these observations more completely.

UPDATED PATIENT MANAGEMENT RECOMMENDATIONS

Based on the totality of the available data and in consultation with an Independent Physician Quality Panel, Medtronic is recommending physicians proactively contact their Navion-implanted patients to schedule **CT imaging with contrast every six (6) months, or as frequently as deemed appropriate in the physician's medical judgment. CT imaging with contrast is necessary for a full evaluation of the stent graft; however, a non-contrast CT is recommended for patients with contraindications to contrast, as it would allow an assessment of device integrity with respect to stent fractures and stent ring enlargement.**

Moving forward, Medtronic is requesting physicians provide all prospective patient follow-up images for independent core lab review. Medtronic will provide details on the mechanism for physicians to upload prospective images in future communications.

In addition to the updated patient management recommendation, Medtronic continues to emphasize the importance of retrospectively reviewing all available images of Valiant Navion patients to identify signs of Type IIIb endoleak, stent fracture, and/or stent ring enlargement. If a stent fracture and/or stent ring enlargement without presence of a Type IIIb endoleak are detected, it is recommended that physicians use their best clinical judgment to develop an

¹ Verzini, F., et. al. (April 19, 2021) "A Preliminary Analysis of Late Structural Failures of the Navion Stent Graft in the Treatment of Descending Thoracic Aortic Aneurysms" *Journal of Vascular Surgery* located at [https://www.jvascsurg.org/article/S0741-5214\(21\)00640-6/fulltext](https://www.jvascsurg.org/article/S0741-5214(21)00640-6/fulltext)



appropriate treatment and/or monitoring plan. The company recommends paying particular attention to Type IIIb endoleaks, which, if untreated, can potentially lead to aneurysm rupture. It is important to note that Type IIIb endoleaks are not detectable with non-contrast CT imaging. If a Type IIIb endoleak is detected, please treat in accordance with your standard of care practices or refer to your medical society guidelines. If you have questions about treating or monitoring these observations, please contact the Medtronic Aortic Medical Affairs team who will triage your query to an Independent Physician Advisory Committee.

Please refer to the [Journal of Vascular Surgery](#)¹ for imaging findings from the Valiant Evo Global Clinical Trial to help physicians recognize Type IIIb endoleak, stent fracture, and/or stent ring enlargement observations. This full article is available online and a hard copy is also enclosed. **Note Medtronic's updated patient management recommendation of CT imaging with contrast every six (6) months is a more specific and frequent imaging cadence than that provided in the article.**

As per standard process, please contact your local Medtronic Field Representative if any imaging findings are identified.

The Competent Authority of your country has been notified about these updated patient management recommendations detailed in this FSN.

ONGOING MEDTRONIC SUPPORT

Medtronic considers patient safety its top priority and takes all adverse events seriously. As part of this commitment, Medtronic is developing a program to provide assistance to physicians and their patients upon eligibility verification, further details of which are forthcoming.

For support in identifying imaging observations (e.g., Type IIIb endoleak, stent fracture, and/or stent ring enlargement) through retrospective review of your patient images, including any CT performed without contrast, please contact Medtronic and we will refer those images for independent core lab review.

Medtronic will also institute an Independent Physician Advisory Committee to monitor progress, review data provided by physicians for existing Valiant Navion patients and advise on any further changes to patient management recommendations.

Medtronic has developed a website [www.medtronic.com/NavionSafety] to help patients access the updated patient management recommendations. Patients are recommended to consult their physician with concerns following implant of the Valiant Navion Thoracic Stent Graft System and to discuss the best approach for their ongoing care.

REMINDER OF PHYSICIAN ACTIONS FROM INITIAL PRODUCT RECALL COMMUNICATION

Per the initial product recall communication in February 2021, Medtronic continues to request physicians with affected product take the following actions:

1. Identify and quarantine all unused affected Medtronic Valiant Navion™ Thoracic Stent Graft Systems.



2. Return all unused product in your inventory to Medtronic. Contact Medtronic Customer Service to initiate a product return. Your local Medtronic Representative can assist you as necessary in initiating the return of this product.

Medtronic is committed to patient safety and appreciates your prompt attention to this matter. If you have any questions regarding this communication, please contact your Medtronic Field Representative to be connected with the appropriate Medtronic resources based on your and your patients' needs.

Sincerely,

Enclosed:

- Copy of the April 19, 2021, "A Preliminary Analysis of Late Structural Failures of the Navion Stent Graft in the Treatment of Descending Thoracic Aortic Aneurysms" from the *Journal of Vascular Surgery*
- Copy of the original consignee communication dated February 2021



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 at <XXXXX>.

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,