



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.

Medtronic

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.

Medtronic

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