

Medtronic

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URGENT: MEDICAL DEVICE NOTIFICATION

UPDATE on Clinical Observations

Medtronic Valiant Navion™ Thoracic Stent Graft System

Global Voluntary Product Recall

03 June 2022

Dear Doctor / Health Care Professional,

This letter is in follow-up to Medtronic's communications dated 24 May 2021 and 11 May 2022, which provided important updates to the voluntary global recall of the Valiant Navion™ Thoracic Stent Graft System issued on 18 February 2021. **This letter provides physicians with an update on the Valiant Navion observations as of 13 May 2022, including important new information on existing failure modes and an update on the root cause investigation.**

UPDATE ON ROOT CAUSE INVESTIGATION

Medtronic currently is working diligently to further investigate and assess the cause of the events observed with the Valiant Navion Thoracic Stent Graft. To date, the root cause analysis suggests a 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. The loss of suture integrity is likely caused by the combined effect of decrease in strength over time due to sterilization and higher than anticipated mechanical stresses from in-vivo loading conditions. This suture-sterilization process combination is unique to Valiant Navion products. **Additionally, the Valiant Navion patient imaging available to date suggests that stent ring detachment may be a precursor to the development of endoleak and/or stent fracture.** Further investigation is underway to understand these observations more completely.

With this in mind, if stent ring detachment and/or stent fracture without presence of an endoleak are detected, please consider when developing an appropriate treatment and/or monitoring plan, that **stent ring detachment may be a precursor to the development of endoleak and/or stent fracture.** If an 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.

UPDATE ON VALIANT NAVION OBSERVATIONS

Approximately 14,000 patients have been implanted with Valiant Navion Thoracic Stent Graft globally. As of 13 May 2022, images from 751 clinical trial and commercial patients have been analyzed by an independent core lab, from which a total of 48 patients had at least one observation. Some patients had multiple observations, and the table below summarizes these data.

Type of observation	Number of patients with confirmed observations**
Stent ring detachment*	37
Stent ring fracture	12
Type IIIb endoleak	28

*Stent ring detachment can be observed as stent ring enlargement and/or stent ring migration.

**Some patients had multiple observations

Most of these observations to date have been first seen at the two-year or later follow-up timepoint; however, in some cases, observations were first seen as early as nine (9) months after implantation. A higher event rate has been observed in the clinical trial patients, a population that is generally later in their clinical follow-up, compared to the commercial patients. Of the approximately 14,000 patients that have been implanted with Valiant Navion globally, only a limited number of patient images have been analyzed by the core lab. Therefore, the overall observation rates are unknown at this time. Details of the initial imaging findings were previously published in the *Journal of Vascular Surgery*¹.

PREVIOUSLY COMMUNICATED RECOMMENDATION

On 18 February 2021, Medtronic issued a voluntary recall of the Valiant Navion Thoracic Stent Graft System. On 24 May 2021, Medtronic issued an update and recommended that 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. **These recommendations remain unchanged.**

To support physicians and to promote the safety of patients, Medtronic implemented the SAFE-N (Safety Assessment for Everyone - Navion) program. The goal of the program is to provide resources to review patient images by an independent core lab, deliver feedback to individual physicians of any graft failure observations, facilitate interaction with an Independent Physician Advisory Committee (IPAC), and provide financial assistance related to the Valiant Navion recall.

IMPORTANT CONTACT INFORMATION

Medtronic is committed to patient safety and appreciates your detailed review of the information contained in this update. If you have any questions regarding this communication, please contact your local Medtronic Field

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)
CVG-21-Q4-32_G

Representative or Medtronic directly to be connected with the appropriate Medtronic resources based on your and your patients' needs.

Issue	Medtronic Contact
Treating and/or monitoring imaging observations	Medtronic Aortic Medical Affairs: rs.aorticmedicalaffairs@medtronic.com
SAFE-N information	SAFE-N@syntactx.com or rs.safe-n@medtronic.com
Report imaging observations	local Medtronic field representative
Returning unused product	
Information for patients	www.medtronic.com/NavionSafety

CUSTOMER INSTRUCTIONS:

Medtronic requests that you take the following actions:

- Please complete the enclosed Confirmation Form then hand or scan and email back to your local Medtronic field representative

As always, please notify Medtronic of any adverse events or quality problems associated with your use of this product. Adverse reactions or quality problems experienced with the use of this product should be reported to your local Medtronic field representative.


For more information, please refer to Medtronic’s Urgent Medical Device Recall Notification letters dated 18 February 2021, 24 May 2021, and 11 May 2022.


Medtronic will notify all applicable regulatory agencies about this matter.

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

Sincerely,

DocuSigned by:




 Signer Name: Diana Teo
 Signing Reason: I approve this document
 Signing Time: 02 June 2022 | 16:39 SGT
 05FB18D83D7745D787A6E905DEAE1FD1

Medtronic QRA Lead
Singapore & Malaysia

Medtronic

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Physician Confirmation Form
Urgent Medical Device Notification
UPDATE on Clinical Observations
Medtronic Valiant Navion™ Thoracic Stent Graft System
Global Voluntary Product Recall

For completion by Medtronic Customers Only - Please complete all fields below and return immediately

Customer Contact Details	Medtronic Contact Details
Distributor/HCP/Patient name:	Name:
	Contact:
Address:	Email:
Phone no:	
E-mail:	

Medtronic is asking that you sign and date to acknowledge receipt of the enclosed letter on this form.

By signing this form, I confirm that I have read the Urgent Medical Device Notification Letter, dated 03 June 2022, from Medtronic and taken appropriate action.

Name (print): _____ Signature: _____ Stamp: _____ Date:

DD	

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For more information, please refer to Medtronic's Urgent Medical Device Recall letters dated 18 February 2021, 24 May 2021, and 11 May 2022 and the information available to physicians on Medtronic's website:

For questions, please contact your Medtronic Field Representative.