URGENT: MEDICAL DEVICE NOTIFICATION
UPDATE on Clinical Observations
Medtronic Valiant Navion™ Thoracic Stent Graft System
Global Voluntary Product Recall

May 31, 2022

Dear Doctor / Health Care Professional,

This letter is in follow-up to Medtronic's communications dated May 21, 2021 and October 18, 2021, which provided important updates to the voluntary global recall of the Valiant Navion™ Thoracic Stent Graft System issued on February 17, 2021 [Recall Reference Number Z-1201-2021]. **This letter provides physicians with an update on the Valiant Navion observations as of May 13, 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 [See Society for Vascular Surgery guidelines https://www.jvascsurg.org/action/showPdf?pii=S0741-5214%2820%2931521-4]. 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 May 13, 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.

<table>
<thead>
<tr>
<th>Type of observation</th>
<th>Number of patients with confirmed observations**</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stent ring detachment*</td>
<td>37</td>
</tr>
<tr>
<td>Stent ring fracture</td>
<td>12</td>
</tr>
<tr>
<td>Type IIIb endoleak</td>
<td>28</td>
</tr>
</tbody>
</table>

*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 Surgery1.

PREVIOUSLY COMMUNICATED RECOMMENDATION

On February 17, 2021, Medtronic issued a voluntary recall of the Valiant Navion Thoracic Stent Graft System. On May 21, 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 Medtronic Field Representative or Medtronic directly to be connected with the appropriate Medtronic resources based on your and your patients’ needs.

CUSTOMER INSTRUCTIONS:

Medtronic requests that you take the following actions:

- Please complete the enclosed Customer Confirmation Form and email to rs.fcanavion@medtronic.com.

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 may also be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm
- Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form or submit by fax to 1-800-FDA-0178.

For more information, please refer to Medtronic’s Urgent Medical Device Recall Notification letters dated February 17, 2021, May 21, 2021, and October 18, 2021 and the information available to physicians on Medtronic’s website.²

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,

Eliezer de Jesus Hernandez
Vice President, Quality
Medtronic, Structural Heart & Aortic

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