



**Valiant Navion™ Thoracic Stent Graft System**  
**SAFE-N LIMITED WARRANTY**  
**(U.S. ONLY – O.U.S. COVERAGE TO BE ASSESSED AND DETERMINED LOCALLY)**  
**Effective February 17, 2021 until February 17, 2025**

**Requests for reimbursement of costs under the SAFE-N Limited Warranty will be processed by Syntactx/NAMSA, a third-party vendor retained by Medtronic for this purpose. Instructions on how to request reimbursement of costs under these SAFE-N Limited Warranty terms and conditions:**

1. Complete the Medtronic SAFE-N Limited Warranty Claim Form which can be found at [NavionSafety.syntactx.com](http://NavionSafety.syntactx.com).
2. Ensure the correct Warranty Type has been selected, "Additional Imaging" or "Reintervention."
3. E-mail the completed Warranty Claim Form to [SAFE-N-Reimburse@syntactx.com](mailto:SAFE-N-Reimburse@syntactx.com). Mailing address or facsimile for submission are provided below.

This SAFE-N Limited Warranty relates to the February 17, 2021 Medtronic communication announcing Medtronic's decision to voluntarily recall the Valiant Navion™ Thoracic Stent Graft System and alerting physicians to immediately stop using the Valiant Navion System in new patients. The Instructions for Use for the Valiant Navion Thoracic Stent Graft System included life-long annual surveillance of the implanted product to monitor performance. On May 21, 2021, Medtronic issued an updated recommendation that physicians proactively contact their Valiant Navion-implanted patients to schedule CT imaging with contrast every six (6) months, or as frequently as deemed appropriate by the physician's medical judgment. For patients with contraindications to contrast, a non-contrast CT is recommended (*e.g.*, MRI or X-Ray). In light of this, Medtronic is offering this SAFE-N Limited Warranty for the Valiant Navion System to offer financial assistance to all patients with a Valiant Navion System for out-of-pocket expenses directly relating to the need for additional imaging and/or reintervention (described below).

Under this SAFE-N Limited Warranty, Medtronic is offering the following:

- A. For **Additional Imaging**, *i.e.*, for the second or successive episodes of imaging in any 12-month period ("Additional Imaging") due to enhanced patient monitoring recommendations:
  - ✦ **Imaging.** If an insurance claim is denied or a patient is uninsured, warranty holders are eligible for reimbursement consistent with fair market value and/or the Medicare-specific facility payment for that procedure. In no instance shall a facility and a patient both be reimbursed for the same expenses.
  - ✦ **Patient Support.** Patients are eligible under Medtronic's SAFE-N Limited Warranty to apply for reimbursement for Unreimbursed Medical (URM) expenses associated with the patient's portion of costs of the additional imaging (inclusive of any co-pays, coinsurance or deductibles paid or owed by patients) and incidental expenses (*e.g.*, parking, meals, hotel, travel expenses, time away from work for patients).
  - ✦ **Uninsured Patients.** Uninsured patients are eligible to apply for reimbursement for URM expenses associated with two episodes of imaging in any 12-month period, or more where ordered by the patient's physician.
- B. For **Reintervention** procedures due to (i) Type IIIb endoleak, (ii) stent ring enlargement, or (iii) stent ring fracture, or (iv) due to the risk of those observations:

Pursuant to the HIPAA Privacy Rule (45 C.F.R. § 164.512(b)), covered entities may disclose protected health information without an authorization to a person or entity subject to FDA jurisdiction for public health purposes related to the quality, safety, or effectiveness of an FDA-regulated product.

Additional limitations may apply. Reimbursements are subject to review and approval. The SAFE-N Limited Warranty is limited to its express terms. The SAFE-N Limited Warranty is voluntary and does not constitute a representation, judgment, admission, or assumption of liability by Medtronic with respect to imaging, reintervention, and/or utilized thoracic stent graft systems. No action taken by Medtronic in connection with the Voluntary Product Recall, including this SAFE-N Limited Warranty, shall be construed as an admission of any fault or liability whatsoever to the patient, doctor, health care professional, or to any third party. Medtronic makes no representation with respect to any potential impact of reimbursements on a patient's eligibility to participate in a Health Savings Account or other tax-favored health plan; please consult with a tax advisor as necessary. All rights reserved.



- ✦ *Reline Graft System.* Facility warranty holders are eligible under Medtronic's SAFE-N Limited Warranty for a warranty credit in the amount of the cost of a Valiant™ Captivia™ Thoracic Stent Graft System, regardless of which graft system was used in the procedure, the savings related to which should be passed on to the patient as a no-charge, deleted line item, or credit to the patient's bill. Warranties for product possessed by patients are for the benefit of the patient and any value received under such warranty should be credited to the patient's account. You may also be required to report the amounts received to the patient's payor, including Medicare. The Medicare procedure for reporting may be found online at: <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Fast-Facts/Cardiac-Device-Credits>. Other payors may follow other rules, requiring you to contact them to confirm their process for reporting credits.
- ✦ *Unreimbursed Medical Expenses.* If an insurance claim is denied or a patient is uninsured, warranty holders are also eligible for reimbursement consistent with fair market value and/or the Medicare-specific facility payment for that procedure. In no instance shall a facility and a patient both be reimbursed for the same expenses.
- ✦ *Patient Support.* Patients are eligible under Medtronic's SAFE-N Limited Warranty to apply for reimbursement for Unreimbursed Medical (URM) expenses associated with the patient's portion of costs of the reintervention procedure (inclusive of any co-pays, coinsurance or deductibles paid or owed by patients) and incidental expenses (e.g., parking, meals, hotel, travel expenses, time away from work for patients).

As part of this SAFE-N Limited Warranty, pursuant to all terms and conditions, facilities should bill all recall-related medical care and costs relating to the additional imaging and/or reintervention through their ordinary course of action.

Warranty eligibility requirements for additional imaging and/or reintervention under this SAFE-N Limited Warranty are as follows:

- The patient is implanted with a Valiant Navion Stent Graft System.
- The additional imaging or reintervention must have occurred between February 17, 2021 (additional coverage may be available) and February 17, 2025 (the expiration date of this SAFE-N Limited Warranty).
- Reintervention includes procedures with and without placement of another endovascular graft and regardless of which graft system is used. Reintervention also includes procedures for patients without observation of (i) Type IIIb endoleak, (ii) stent ring fracture, or (iii) stent ring enlargement. Such procedures are eligible for reimbursement where the patient's physician determines in the exercise of independent medical judgment that reintervention due to the risk of those observations (but not the underlying disease state, progression of the disease, or unrelated conditions) is medically necessary.
  - Type IIIb endoleak, stent ring fracture, and stent ring enlargement are defined as:
    - Type IIIb endoleak: defined as blood flow through a fabric disruption confirmed with computed tomography angiography (CTA)
    - 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
    - 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
- For Unreimbursed Medical and Incidental Expenses, the patient or authorized person must complete, sign, and

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Additional limitations may apply. Reimbursements are subject to review and approval. The SAFE-N Limited Warranty is limited to its express terms. The SAFE-N Limited Warranty is voluntary and does not constitute a representation, judgment, admission, or assumption of liability by Medtronic with respect to imaging, reintervention, and/or utilized thoracic stent graft systems. No action taken by Medtronic in connection with the Voluntary Product Recall, including this SAFE-N Limited Warranty, shall be construed as an admission of any fault or liability whatsoever to the patient, doctor, health care professional, or to any third party. Medtronic makes no representation with respect to any potential impact of reimbursements on a patient's eligibility to participate in a Health Savings Account or other tax-favored health plan; please consult with a tax advisor as necessary. All rights reserved.



# Medtronic

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submit to Syntactx, the SAFE-N Limited Warranty Claim Form, and enclose the required documentation.

- For Facility Graft Credits, the facility must complete, sign, and submit to Syntactx, the SAFE-N Limited Warranty Facility Graft Credit Claim Form, and enclose the required documentation.
- Additional limitations may apply. Reimbursements and credits are subject to review and approval.

This SAFE-N Limited Warranty will be reassessed for renewal and may be republished for use on February 17, 2025.

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**By filling out and signing the SAFE-N Limited Warranty Claim Form, the patient confirms that:**

- All expenses for which the patient requests reimbursement have been incurred by and are the financial responsibility of the patient, have not been reimbursed and are not reimbursable by any other insurance or benefit.
- All expenses for which the patient seeks reimbursement have been incurred by the patient in obtaining medical care that is directly related to the recall of the Valiant Navion Stent Graft System.

**By filling out and signing the SAFE-N Limited Warranty Facility Graft Credit Claim Form, the physician confirms that:**

- The physician has made the medical judgment based on the patient's individual circumstances that the additional imaging, reintervention or reintervention to reline the Valiant Navion Stent Graft System with another stent graft covered under the SAFE-N Limited Warranty is in the best interests of the individual patient.

**By filling out and signing the SAFE-N Limited Warranty Facility Graft Credit Claim Form, the facility confirms that:**

- Any credit extended because of this SAFE-N Limited Warranty is for the sole benefit of the patient and will be credited in full to the patient's account; and
- Claims for reimbursement to third party payors will be submitted in accordance with all applicable payor requirements, including any such requirements relating to reporting either free or reduced-price products or warranty credits.

**For warranty-related questions, contact Medtronic through Syntactx at the**

**U.S. SAFE-N reimbursement helpline: 1-833-256-2308**

**or**

**Email: [SAFE-N\\_Reimbursement@syntactx.com](mailto:SAFE-N_Reimbursement@syntactx.com)**

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