

**Medtronic**  
Structural Heart and Aortic  
3576 Unocal Place  
Santa Rosa, CA 95403

**Valiant Navion™ Thoracic Stent Graft System**  
**SAFE-N Limited Warranty Claim Form**  
**Facility Graft Credit**

**SYNTAX**

Medtronic Site Account Number: \_\_\_\_\_ Clinical Site Name: \_\_\_\_\_

Patient First Name: \_\_\_\_\_ Patient Last Name: \_\_\_\_\_

Valiant Navion Serial Number: \_\_\_\_\_ Customer Facing Number (CFN): \_\_\_\_\_

Medtronic Representative Who Supports Account: \_\_\_\_\_

Date of Navion Implant	Date of Reintervention	Replacement Graft Type	If Valiant Captivia, Replacement Graft Serial Number
		<input type="checkbox"/> Valiant Captivia <input type="checkbox"/> Other	

**Authorized Signature:**  
\_\_\_\_\_

**Required for Standard and Supplemental Warranty Claims:**

By checking this box or signing this form, you agree to allow Medtronic to determine if a warranty credit is due. No warranty credit will be issued unless all eligibility criteria imposed by the applicable warranty have been met. Additional limitations may apply. Reimbursements and credits are subject to review and approval. 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. By checking this box or signing this form, you attest that you have not already received or submitted for payment for the product used, or will correct or remit payment received or submitted for the product. By checking this box and entering your initials or signing this form, you represent, after due inquiry, that the product(s) noted on this form functioned in a manner inconsistent with its or their intended operation or performance, or that you determined in the exercise of independent medical judgment that reintervention was warranted. All other warranty conditions have been met, all of the above information is correct and you are authorized to sign on behalf of the clinical site.

Name and Title of Authorized Representative of Medical Institution:  
\_\_\_\_\_

Initials or Signature of Authorized Representative of Medical Institution:  
\_\_\_\_\_

E-mail: \_\_\_\_\_ Telephone Number: \_\_\_\_\_

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.

**Within 90 days of the Reintervention Date:**

E-mail Completed Warranty Form to: [SAFE-N-Reimburse@syntactx.com](mailto:SAFE-N-Reimburse@syntactx.com)

Mailing or facsimile submission is also available at:

**Syntactx**

**RE: SAFE-N Project**

**4 World Trade Center**

**150 Greenwich Street, 44<sup>th</sup> Floor**

**New York, New York, 10007**

or

**Facsimile: 1 (800) 342-1401**

**Please allow between 45-60 days for processing any reimbursement request. Syntactx may need to contact you directly to obtain additional verification or information before payment may be processed. Please consult your financial and tax advisor regarding any reporting obligation for tax purposes.**

For questions, contact Medtronic through Syntactx:

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

Email: [SAFE-N-Reimburse@syntactx.com](mailto:SAFE-N-Reimburse@syntactx.com)

You may also visit [NavionSafety.syntactx.com](http://NavionSafety.syntactx.com)

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