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

Valiant Navion™ Thoracic Stent Graft System
SAFE-N Limited Warranty Claim Form
Patient or Provider Unreimbursed Medical Expenses

SYNTACTX

Patient Full Name: ________________________________ Telephone: ______________

Patient Address: ____

City: ____________________________ State: __________ Zip Code: __________

Medicare Beneficiary Identification (MBI) Number: __________ Patient Date of Birth: ______________

Primary Plan of Insurance: ______________________ Policy Number: ______________________

Secondary Plan of Insurance: ______________________ Policy Number: ______________________

Name of Insured (if not yourself): ______________________________________

Name of Person Filing Out Form (if not Patient): ______________________ Telephone: ______________

Relationship to Patient: ☐ Spouse ☐ Child ☐ Healthcare Provider ☐ Other: (Describe): ______________

If you are a family or non-family member authorized by and assisting the patient on their behalf, please have the patient complete and sign an **Authorization for Patient Caregiver** form, attached.

Status of Insurance (check as applies):

☐ I am submitting expenses (e.g., co-pays, coinsurance, or deductibles) that are unreimbursed.

☐ My Coverage was denied.

☐ I am uninsured.

☐ Other: (describe):

____

If you are uninsured, please complete and sign an **Uninsured Status Verification** Form.

Assignment of Insurance Benefits:
I hereby authorize and direct you to pay to Medtronic all benefits due to me or my covered dependent (s) as a result of this claim.

I understand that I am financially responsible for charges not covered by the policy.

Insured's Signature: ______________________ Date: ______________________

I am seeking reimbursement for the following types of medical expenses (check all that apply):

☐ Additional Imaging or Uninsured Imaging ☐ Reintervention ☐ Other (describe below)

If selecting additional imaging, I certify that I have received my routine, annual imaging and have not sought reimbursement for expenses related to the same from Medtronic, or that I am uninsured.

If you selected "other" above, please describe the type of medical expense you are requesting be reimbursed: ______________

Enclosed are the medical bills and insurance documents relating to my claim for reimbursement of unreimbursed medical expenses that are directly related to the Valiant Navion recall:

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.

Physician/Facility Name	Date of Procedure	Type of Procedure	Amount Billed	Amount Paid by Medicare or Insurance	Unpaid Balance
		TOTALS:			

Please refer to the Valiant Navion patient website to verify what qualifies for reimbursement. Additional limitations may apply. Reimbursements and credits are subject to review and approval. A social security number or Medicare number may be requested at a later date. For Unreimbursed Medical Expenses, required documentation is as follows:

	Required Documentation
All patients	• For reintervention, documentation of a diagnosis of recall-related observations or determination by a physician that reintervention is in the patient's best interests* • For more than once per 12-month period imaging, documentation of physician orders for more than twice annual monitoring, or, if the patient is uninsured, an Uninsured Status Verification Form

Patient **insured**, procedure allowed, patient has copay	• A copy of the Patient's Explanation of Benefits (EOB), which must include:
	  ○ Medical insurance overview of billing received
	  ○ Defines patient's final out of pocket responsibility (what the patient owes)
	  ○ Note that medical expenses incurred in this setting may entail two separate bills: one from a physician or imaging group and one from the facility. Both expenses are reimbursable.

Patient **insured**, procedure denied	• If insured with coverage denied, a copy of the insurance denial, which may appear on the EOB. Denial of pre-approval will not be considered. Reimbursement requires submitting the bill to insurance for the care once performed, along with documentation of its denial.

Patient **uninsured**	• Itemized final medical bills, which must include:
	  ○ A detailed list of all charges related to the date(s) of service to include the total amount
	  ○ Clearly defines patient's final out of pocket responsibility (what the patient owes)
	  ○ A "summary of charges" will not be considered
	  • Completed Uninsured Status Verification Form

Patient **paid** expenses	• If patient paid the medical provider's bills, proof of payment

* Documentation may consist of medical records or a physician statement, and is not required where observations were confirmed by Syntactx core lab.

I certify that the statements and information contained above are true, accurate, and complete. I certify that the above expenses were incurred by me, have not been reimbursed or are not reimbursable by any other insurance or benefit, are expenses related to coverage that has been denied or that I am uninsured.

Patient's or Authorized Person's Signature: ______________________________ Date: ______________

Within 90 days of the Imaging, Reintervention, or Treatment Date:

E-mail Completed Warranty Form to: 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, 44th Floor
New York, New York, 10007

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. Payments for medical expenses will either be via electronic funds transfer or via U.S. Mail to the patient's primary mailing address indicated on their patient account. Please consult your financial and tax advisor regarding any reporting obligation for tax purposes.

For questions, contact Medtronic through Syntactx at the U.S. SAFE-N reimbursement helpline: 1-833-256-2308 or email: SAFE-N-Reimburse@syntactx.com.

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