Information Regarding the SAFE-N (Safety Assessment for Everyone – Navion) Program
Medtronic Valiant NavionTM Thoracic Stent Graft System
Global Voluntary Product Recall

October 18, 2021

Dear Doctor / Health Care Professional / Valued Customer,

This letter is in follow-up to Medtronic’s UPDATED Patient Management Recommendations letter dated May 21, 2021, which provided important updates to the voluntary global recall of the Valiant NavionTM Thoracic Stent Graft System issued on February 17, 2021. In the May 21, 2021 letter, Medtronic 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 by the physician’s medical judgment. Moving forward, Medtronic also requested that physicians provide all prospective patient follow-up images for independent core lab review.

In order to provide support for these updated patient management recommendations, Medtronic implemented the SAFE-N (Safety Assessment for Everyone – Navion) program through its vendor Syntactx/NAMSA. The goal of the SAFE-N program is to provide resources to physicians, practice groups, and hospitals to collect patient imaging and information, and to provide patients implanted with the Valiant Navion Thoracic Stent Graft System with access to support resources and financial assistance, as needed. Through the SAFE-N program, Syntactx/NAMSA is also coordinating review of submitted patient images by the independent core lab, providing feedback to physicians of any graft failure observations, and facilitating physician interactions with the Independent Physician Advisory Committee (IPAC).

This letter provides information on the SAFE-N program and the process for submitting data and information for review through Syntactx/NAMSA, as well as more specific details on physician and patient support, the IPAC, and available financial assistance related to the Valiant Navion recall.

BACKGROUND, IMAGING REVIEW, AND DATA COLLECTION

On February 17, 2021, Medtronic issued a voluntary recall of the Valiant Navion Thoracic Stent Graft System. The recall was initiated in response to observations in the Valiant Evo Global Clinical Program of Type IIIb endoleaks, stent fracture, and stent ring enlargement. Type IIIb endoleaks, if untreated, can potentially lead to aneurysm rupture. On May 21, 2021, Medtronic issued an updated recommendation that physicians proactively contact their 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. Moving forward, Medtronic also requested physicians provide all prospective patient follow-up images for independent core lab review.

As part of its commitment to patient safety and to regulatory authorities, Medtronic is conducting a comprehensive technical root cause investigation, including independent core lab review of clinical trial and commercial follow-up imaging of patients implanted with the Valiant Navion Thoracic Stent
Graft System. To facilitate this investigation and promote patient safety, Medtronic has created the SAFE-N program to interface with implanting physicians and support patient data collection.

Through the SAFE-N program, Medtronic is collecting information for implanted patients, including imaging and data from follow-up visits submitted by physicians and facilities. This information includes basic demographic information for all patients (e.g., gender, age, hospital, procedure, indication, implanter) and more detailed information for patients with confirmed device-related observations (e.g., medical history related to aortic disease, secondary procedures and outcomes). Medtronic believes this information will help inform the root cause analysis, guide future recommendations, and allow the independent core lab to identify and communicate observations to submitting physicians.

- Applicable privacy laws and regulations allow health care providers to provide patient images and other relevant information to a manufacturer for treatment purposes and for activities related to the quality, safety, and effectiveness of a regulated product, including a product recall. (See 45 CFR 164.506(c)(1); 45 CFR 164.512(b)(1)(iii).)
- Those laws and regulations cover disclosure to a manufacturer and to vendors acting on that manufacturer’s behalf.
- Patient consent is not generally required for recall-related disclosures and use of data.
- Medtronic and Syntactx/NAMSA will share the results of independent core lab review with physicians. Imaging observations related to graft failure will be communicated quickly; the absence of observations will be communicated in follow up, as soon as reasonably practical.

PHYSICIAN AND PATIENT SUPPORT IS AVAILABLE

In Medtronic’s UPDATED Patient Management Recommendations letter dated May 21, 2021, Medtronic recommended that physicians proactively contact their Valiant Navion-implanted patients. To help support physicians in this effort, Medtronic provided physicians with an optional patient letter template that could be used to assist in the communication with patients. Medtronic has also developed the SAFE-N program that includes, among other things, logistical support for physicians, practice groups, and hospitals, who are working to contact their Valiant Navion patients. Examples include assistance with mailing patient letters or identifying additional contact information for patients lost to follow up. Please reach out to Syntactx/NAMSA for such support.

Additionally, Medtronic has created a patient webpage. This webpage is intended to provide patients with the same patient management recommendations that are communicated to their physicians and to direct patients to contact their physician for issues related to their Valiant Navion device.

INDEPENDENT PHYSICIAN ADVISORY COMMITTEE (IPAC)

As part of the SAFE-N program, an IPAC was created to provide support to the physician community and promote the safety of patients implanted with the Valiant Navion device. The IPAC will be utilized to provide input and guidance to Medtronic and the physician community as needed for inquiries related to the Valiant Navion recall. Examples of such input include providing expert scrutiny and

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critical interpretation of clinical findings, responding to physician inquiries related to patient management and treatment considerations, and advising on individual and collective patient treatment recommendations. Please contact Syntactx/NAMSA for IPAC support.

FINANCIAL ASSISTANCE

Medtronic is offering a limited warranty to provide financial assistance to Valiant Navion patients for out-of-pocket expenses directly related to the need for additional imaging or reintervention, both in terms of unreimbursed medical expenses and other incidentals. In addition, device credits may be available to facilities, with savings to be passed along to the patient, under certain circumstances.

Costs that are directly related to patients’ medical care in connection with the use of Valiant Navion, including imaging, should be billed to the patient or the patient’s health insurance provider in the usual manner. In the event the patient’s claim is denied by insurance or the patient is uninsured, or if the patient has related out-of-pocket costs (such as insurance co-payments, coinsurance, deductibles, travel expenses, incidentals, or other unreimbursed medical expenses), please contact Syntactx/NAMSA for assistance.

The SAFE-N Limited Warranty and Patient Reimbursement Guide, enclosed herein, provide additional information on the financial assistance that is available for Valiant Navion patients and the process for requesting reimbursement for out-of-pocket expenses related to imaging and treatment.

PLEASE REFER TO MORE COMPLETE INFORMATION PROVIDED IN MEDTRONIC’S URGENT MEDICAL DEVICE RECALL NOTIFICATION LETTERS.

Not all information related to the recall is reiterated here. For more information, please refer to Medtronic’s Urgent Medical Device Recall Notification letters dated February 17, 2021, and May 21, 2021, and the information available to physicians on Medtronic’s website. In addition, if you have a patient who was a clinical trial subject, please reach out to your Medtronic study team representative.

IMPORTANT CONTACT INFORMATION

Syntactx/NAMSA site manager(s):
SAFE-N@syntactx.com

Syntactx/NAMSA 24/7 helpline:
1-833-256-2308

Syntactx/NAMSA reimbursement:
SAFE-N-Reimburse@syntactx.com
NavionSafety.syntactx.com

Medtronic imaging and observation support:

rs.navionimage@medtronic.com

Medtronic support regarding this program:
rs.safe-n@medtronic.com

Kind regards,

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

ENCLOSURES

Enclosed please find:

1. SAFE-N Limited Warranty, including related claim forms and authorizations