Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. 2021-1242

08 JUN 2021

TO: **ALL HEALTHCARE PROFESSIONALS AND ESTABLISHMENTS**

SUBJECT: **Voluntary Recall of Medtronic Valiant Naviation™ Thoracic Stent Graft System**

The Food and Drug Administration (FDA) warns all healthcare professionals and establishments on the voluntary recall of affected lots of Medtronic Valiant Naviation™ Thoracic Stent Graft System with FDA registration numbers, MDR-10572A, manufactured by Medtronic Inc., imported and distributed by Medtronic Philippines, Inc.:

Product Name	Model #/ CFN	Product Name	Model #/ CFN
Stent Graft	VNMC2020C94TE	Stent Graft	VNMC4646C95TU
	VNMC2020C94TJ		VNMF2020C96TE
	VNMC2020C94TU		VNMF2020C96TU
	VNMC2222C180TE		VNMF2222C185TE
	VNMC2222C180TJ		VNMF2222C185TU
	VNMC2222C180TU		VNMF2222C96TE
	VNMC2222C94TE		VNMF2222C96TJ
	VNMC2222C94TJ		VNMF2222C96TU
	VNMC2222C94TU		VNMF2520C185TE
	VNMC2520C186TE		VNMF2520C185TJ
	VNMC2520C186TJ		VNMF2520C185TU
	VNMC2520C186TU		VNMF2525C185TE
	VNMC2525C180TE		VNMF2525C185TJ
	VNMC2525C180TJ		VNMF2525C185TU
	VNMC2525C180TU		VNMF2525C96TE
	VNMC2525C94TE		VNMF2525C96TJ
	VNMC2525C94TJ		VNMF2525C96TU
	VNMC2525C94TU		VNMF2822C173TE
	VNMC2822C207TE		VNMF2822C173TJ
	VNMC2822C207TJ		VNMF2822C173TU
	VNMC2822C207TU		VNMF2828C174TE
	VNMC2828C182TE		VNMF2828C174TJ
	VNMC2828C182TJ		VNMF2828C174TU
	VNMC2828C182TU		VNMF2828C97TE
	VNMC2828C90TE		VNMF2828C97TJ
	VNMC2828C90TJ		VNMF2828C97TU
	VNMC2828C90TU		VNMF3125C173TE

Stent Graft	VNMC3125C207TE	Stent Graft	VNMF3125C173TJ
	VNMC3125C207TJ		VNMF3125C173TU
	VNMC3125C207TU		VNMF3131C174TE
	VNMC3131C182TE		VNMF3131C174TJ
	VNMC3131C182TJ		VNMF3131C174TU
	VNMC3131C182TU		VNMF3131C229TE
	VNMC3131C223TE		VNMF3131C229TJ
	VNMC3131C223TJ		VNMF3131C229TU
	VNMC3131C223TU		VNMF3131C97TE
	VNMC3131C90TE		VNMF3131C97TJ
	VNMC3131C90TJ		VNMF3131C97TU
	VNMC3131C90TU		VNMF3428C173TE
	VNMC3428C207TE		VNMF3428C173TJ
	VNMC3428C207TJ		VNMF3428C173TU
	VNMC3428C207TU		VNMF3434C174TE
	VNMC3434C182TE		VNMF3434C174TJ
	VNMC3434C182TJ		VNMF3434C174TU
	VNMC3434C182TU		VNMF3434C229TE
	VNMC3434C223TE		VNMF3434C229TJ
	VNMC3434C223TJ		VNMF3434C229TU
	VNMC3434C223TU		VNMF3434C59TE
	VNMC3434C52TE		VNMF3434C59TJ
	VNMC3434C52TJ		VNMF3434C59TU
	VNMC3434C52TU		VNMF3434C97TE
	VNMC3434C90TE		VNMF3434C97TJ
	VNMC3434C90TJ		VNMF3434C97TU
	VNMC3434C90TU		VNMF3731C173TE
	VNMC3731C207TE		VNMF3731C173TJ
	VNMC3731C207TJ		VNMF3731C173TU
	VNMC3731C207TU		VNMF3737C174TE
	VNMC3737C182TE		VNMF3737C174TJ
	VNMC3737C182TJ		VNMF3737C174TU
	VNMC3737C182TU		VNMF3737C229TE
	VNMC3737C223TE		VNMF3737C229TJ
	VNMC3737C223TJ		VNMF3737C229TU
	VNMC3737C223TU		VNMF3737C59TE
	VNMC3737C52TE		VNMF3737C59TJ
	VNMC3737C52TJ		VNMF3737C59TU
	VNMC3737C52		VNMF3737C97TE
	VNMC3737C90TE		VNMF3737C97TJ
	VNMC3737C90TJ		VNMF3737C97TU
	VNMC3737C90TU		VNMF4034C185TE
	VNMC4034C200TE		VNMF4034C185TJ
	VNMC4034C200TJ		VNMF4034C185TU
	VNMC4034C200TU		VNMF4040C103TE
	VNMC4040C175TE		VNMF4040C103TJ
	VNMC4040C175TJ		VNMF4040C103TU
	VNMC4040C175TU		VNMF4040C183TE
	VNMC4040C218TE		VNMF4040C183TJ

Stent Graft	VNMC4040C218TJ	Stent Graft	VNMF4040C183TU
	VNMC4040C218TU		VNMF4040C223TE
	VNMC4040C55TE		VNMF4040C223TJ
	VNMC4040C55TJ		VNMF4040C223TU
	VNMC4040C55TU		VNMF4040C62TE
	VNMC4040C95TE		VNMF4040C62TJ
	VNMC4040C95TJ		VNMF4040C62TU
	VNMC4040C95TU		VNMF4337C185TE
	VNMC4337C200TE		VNMF4337C185TJ
	VNMC4337C200TJ		VNMF4337C185TU
	VNMC4337C200TU		VNMF4343C103TE
	VNMC4343C175TE		VNMF4343C103TJ
	VNMC4343C175TJ		VNMF4343C103TU
	VNMC4343C175TU		VNMF4343C183TE
	VNMC4343C218TE		VNMF4343C183TJ
	VNMC4343C218TJ		VNMF4343C183TU
	VNMC4343C218TU		VNMF4343C223TE
	VNMC4343C55TE		VNMF4343C223TJ
	VNMC4343C55TJ		VNMF4343C223TU
	VNMC4343C55TU		VNMF4343C62TE
	VNMC4343C95TE		VNMF4343C62TJ
	VNMC4343C95TJ		VNMF4343C62TU
	VNMC4343C95TU		VNMF4640C185TE
	VNMC4640C200TE		VNMF4640C185TJ
	VNMC4640C200TJ		VNMF4640C185TU
	VNMC4640C200TU		VNMF4646C103TE
	VNMC4646C175TE		VNMF4646C103TJ
	VNMC4646C175TJ		VNMF4646C103TU
	VNMC4646C175TU		VNMF4646C183TE
	VNMC4646C218TE		VNMF4646C183TJ
	VNMC4646C218TJ		VNMF4646C183TU
	VNMC4646C218TU		VNMF4646C223TE
	VNMC4646C55TE		VNMF4646C223TJ
	VNMC4646C55TJ		VNMF4646C223TU
	VNMC4646C55TU		VNMF4646C62TE
	VNMC4646C95TE		VNMF4646C62TJ
	VNMC4646C95TJ		VNMF4646C62TU

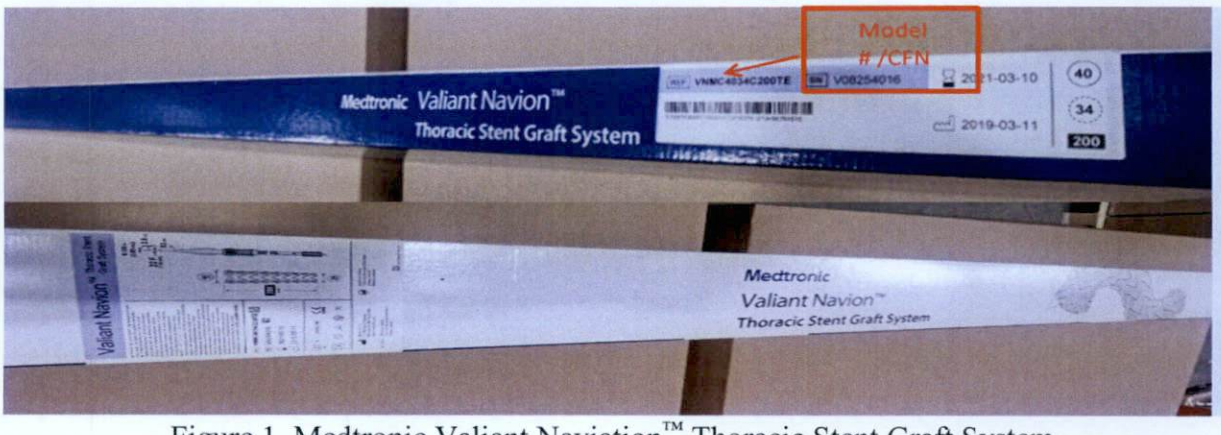

Figure 1. Medtronic Valiant Naviation™ Thoracic Stent Graft System

Medtronic International, Ltd. initiated the voluntary recall of the above-mentioned specific lots/batches of Medtronic Valiant Naviation™ Thoracic Stent Graft System. The recall is being initiated in response to information identified in the Valiant Evo Global Clinical Program, which studied the performance of the above-mentioned product. A total of 110 subjects were enrolled in the Valiant Evo Global Clinical Program. The information received indicated that there were three (3) subjects with stent fractures of which (2) confirmed Type IIIb endoleaks, and seven (7) core lab analysis findings showing stent ring enlargement. Type IIIb endoleaks, if untreated, can potentially lead to aneurysm rupture.

In light of the foregoing, all concerned healthcare professional, establishments, and the general public are warned to discontinue further use, sale, and distribution of the said affected lots/batches of Medtronic Valiant Naviation™ Thoracic Stent Graft System.

All FDA Regional Field Offices and Regulatory Enforcement Units, in coordination with law enforcement agencies and Local Government Units, are requested to ensure that product is not sold or made available in the market or areas of jurisdiction.

Any suspected adverse reaction experienced from the use of the medical device but not limited to the lot numbers stated above should be reported immediately to FDA.

For more information and inquiries, kindly contact the FDA Center for Device Regulation, Radiation Health, and Research through e-mail at **cdrrhr@fda.gov.ph**, or call **(02) 8857-1900 loc. 8301.**

Dissemination of this advisory to all concerned is hereby requested.

ROLANDO ENRIQUE D. DOMINGO, MD
Director General

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