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September 21, 2020

URGENT Field Safety Notice
GORE® TAG® Conformable Thoracic Stent Graft
with ACTIVE CONTROL System

Inability to Complete Secondary Deployment

Event Number 2017233.09/09/2020.001-C

Dear Health Care Provider, Chief Executive or Risk Management:

W.L. Gore & Associates (Gore) would like to inform you of safety information related to the GORE® TAG® Conformable Thoracic Stent Graft with ACTIVE CONTROL System. These are devices with catalogue number prefixes TGM and TGMR. See Appendix 1 for a full list of Catalogue Numbers.

GORE® TAG® Conformable Thoracic Stent Graft with ACTIVE CONTROL System

These updates do NOT relate to the Conformable GORE® TAG® Thoracic Endoprosthesis (with the SIM-PULL delivery system), if available in your region. Catalogue numbers beginning with prefix TGU and TGE are not affected.

Please carefully review this letter and follow all recommended actions described below.

Event Description: Inability to Complete Secondary Deployment

From July 2018 to December 2019, Gore received 12 reports of the GORE® TAG® Conformable Thoracic Stent Graft with ACTIVE CONTROL System where the device remained at intermediate diameter after successful primary deployment. The secondary deployment line when removed did not actuate deployment of the device to full diameter and was not accessible via the Deployment Line Access Hatch. Of the 12 events, 11 reported minor health consequences (increased procedure time) and 1 reported serious health consequences (branch vessel occlusion, surgical revascularization). This represents a rate of 0.09% reported complaints of this type of deployment event over the last 3 years since commercialization.

In every case the patient tolerated the procedure, and the device was ballooned by the physician to full diameter from trailing end to leading end after removing all other deployment system components. Although these deployment events required endovascular intervention, the intended location was successfully treated and no re-interventions have

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been required. Device distal movement while ballooning the device open was reported in 4 events. Only one event, where an occlusion balloon (non-GORE® Tri-Lobe Balloon Catheter) was used, resulted in branch vessel coverage that required surgical and endovascular revascularization. No confirmed root cause was identified through comprehensive investigations into manufacturing and clinical activities.

New IFU Warning:

Based on these events, Gore will be updating its Instructions for Use (IFU) to include a new Warning:

> "Secondary deployment events have occurred where the device does not open to full diameter after Secondary Deployment Handle actuation, and the deployment line is not accessible via the Deployment Line Access Hatch. If this event occurs, Gore recommends using the GORE® Tri-Lobe Balloon Catheter to expand the device from trailing end to leading end after complete delivery system component removal. (Please refer to the GORE® Tri-Lobe Balloon Catheter Instructions for Use for pertinent recommended volume, directions and warnings.) Ballooning of a non-fully expanded stent graft may lead to improper placement of the stent graft and/or branch vessel occlusion or obstruction. Use of an occlusion balloon may lead to device distal displacement during deployment (windsock effect) and has been observed to lead to branch vessel occlusion or obstruction."

Reminder of Pertinent Instructions for Use (IFU) Information and Warnings:

Deployment events (e.g. deployment difficulties/failures) are known complications. For this type of deployment event, although the patient remains hemodynamically stable, attempts to resolve it may lead to potential adverse events per the IFU of harms associated with additional intraoperative procedure time; harms associated with additional intraoperative and/or secondary surgical or endovascular procedures; branch vessel occlusion or obstruction; improper placement of the stent graft; surgical conversion; ischemia; and stroke.

Additionally, the IFU provides that physicians must have appropriately trained staff, materials, and techniques in case there are any events that may require endovascular or surgical intervention. Specifically, Gore recommends that physicians be familiar with ballooning techniques and have a GORE® Tri-Lobe Balloon Catheter on-hand, the only recommended balloon to use with this device and specifically designed for use in the thoracic aorta.

Please refer to the approved IFU for full indications, contraindications, instructions, warnings, and precautions, available at: https://eifu.goremedical.com/. This letter will also be available on the Gore Medical website.

Immediate Actions for the Recipient:

- Take note of amendment/reinforcement of Instructions For Use (IFU)
- Please respond to the enclosed acknowledgement

- Please share this letter with others in your hospital or clinic as appropriate

Gore is providing physicians with this information so that appropriate risk-related decisions can be made with the patient when considering the GORE® TAG® Conformable Thoracic Stent Graft with ACTIVE CONTROL System. Gore maintains its confidence in the safety and efficacy of the device and will not be removing GORE® TAG® Conformable Thoracic Stent Graft with ACTIVE CONTROL System from the market.

There are no actions required for patients already implanted with a GORE® TAG® Conformable Thoracic Stent Graft with ACTIVE CONTROL System.

This safety information serves as a supplement to the GORE® TAG® Conformable Thoracic Stent Graft with ACTIVE CONTROL System training in which you participated, and any related educational material you received.

Reference Appendix 1 for additional event information. Please contact Gore Customer Service (email: MPDCustomerCare@wlgore.com or by phone at 800-528-8763) with any questions related to this letter.

Sincerely,

Lena Borbouse, Ph.D.
Global TAG Conformable Product Specialist

Attachment:
Return Acknowledgement Form

APPENDIX 1 – Additional Event Information

Event Number:

2017233.09/09/2020.001-C

Field Safety Notice Type:

New

Local representative:

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Device Type:

System, Endovascular Graft, Aortic Aneurysm Treatment

Commercial Name:

GORE® TAG® Conformable Thoracic Stent Graft with ACTIVE CONTROL System

Primary Clinical Purpose of the Device:

The GORE® TAG® Conformable Thoracic Stent Graft is indicated for endovascular repair of the descending thoracic aorta.

Device Catalog Part Numbers:

TGM212110X*	TGM313110X*	TGM404010X*	TGMR313115X*
TGM212115X*	TGM313115X*	TGM404015X*	TGMR313120X*
TGM212120X*	TGM313120X*	TGM404020X*	TGMR312610X*
TGM262610X*	TGM343410X*	TGM454510X*	TGMR373710X*
TGM262615X*	TGM343415X*	TGM454515X*	TGMR373715X*
TGM262620X*	TGM343420X*	TGM454520X*	TGMR373720X*
TGM282810X*	TGM373710X*	TGM262110X*	TGMR404010X*
TGM282815X*	TGM373715X*	TGM312610X*	TGMR404015X*
TGM282820X*	TGM373720X*	TGMR313110X*	TGMR404020X

*X is a placeholder for enumeration code E=EMEA, Australia, New Zealand, J=Japan

Lot Number(s):

All lot numbers

Date of First Shipment:

EMEA – June 21, 2017
Australia/New Zealand – March 6, 2018
Japan – April 3, 2019
USA – June 14, 2019

Actions to be taken by the User:

- Take note of amendment/reinforcement of Instructions For Use (IFU).
- Please respond to the enclosed acknowledgement as soon as possible but no later than two weeks after receipt of this notification.
- Please share this letter with others in your hospital or clinic as appropriate.

In the event that an Adverse Event Occurs:

Any adverse event involving the GORE® TAG® Conformable Thoracic Stent Graft with ACTIVE CONTROL System should be reported to the manufacturer and the country specific regulatory authorities immediately. To report an event to W. L. Gore & Associates, email: medcomplaints@wlgore.com or contact:
EMEA: +49 89 4612 3440, Fax: +49 89 4612 43440

Depth of Communication:

Communication should be disseminated to the user level - Cardiothoracic Surgeons, Vascular Surgeons, Interventional Cardiologists, Interventional Radiologists, and other physicians implanting endovascular aortic devices

The Regulatory Authority of your country has been informed about this communication to customers.

This notice needs to be passed on to all those who need to be aware within your organization or to any organization where potentially affected devices have been transferred (as appropriate). Please transfer this notice to other organization on which this action has an impact (as appropriate).

MD179043 Attachment 1 EU