



Together, improving life

URGENT MEDICAL DEVICE SAFETY CORRECTION
GORE® TAG® Conformable Thoracic Stent Graft with ACTIVE CONTROL System
INABILITY TO COMPLETE SECONDARY DEPLOYMENT

Event Number 2017233.09/09/2020.001-C

September 2020

Dear Health Care Provider:

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 successfully 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 one 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 three 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 reinterventions have been required. Device distal movement while ballooning the device open was reported in four 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*

W. L. Gore & Associates, Inc.
Medical Products Division
P.O. Box 2400
Flagstaff, AZ 86003-2400
USA

Asia Pacific +65 67332882
Europe 00800 6334 4673
United States +1 800 437 8181
United States +1 928 779 2771
goremedical.com



Together, improving life

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 surgical conversion; ischemia; stroke; branch vessel occlusion or obstruction; improper placement of the stent graft; harms associated with additional intraoperative and/or secondary surgical or endovascular procedures; and/or harms associated with additional intraoperative procedure time.

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 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 acknowledgment**
- 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,

A handwritten signature in black ink that reads "Lena Borbouse".

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

Attachment:
Return acknowledgment form



Together, improving life

APPENDIX 1 – Additional event information

Event number: 2017233.09/09/2020.001-C

Field safety notification type: New

Local representative: John Malone
Global Regulatory Affairs
W. L. Gore & Associates, Inc.
3450 West Kiltie Lane
Flagstaff, AZ 86005
T +1 928 864 3882 M +1 928 864 7251
jmalone@wlgore.com

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 catalogue 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



Together, improving life

Actions to be taken by the user:

- Take note of amendment/reinforcement of *Instructions For Use* (IFU).
- **Please respond to the enclosed acknowledgment** 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:

USA: +1.800 528 1866, Ext. 44922, +1 928 864 4922, Fax: +1 928 864 4364

China: +86 21 5172 8237, Fax: +86 21 5172 8236

Japan: +81 3 6746 2562, Fax: +81 3 6746 2563

Brazil: +55 11 5502-7953, Fax: +55 11 5502-7965

EMEA: +49 89 4612 3440, Fax: +49 89 4612 43440

Healthcare professionals and consumers may report adverse events or quality problems directly to FDA using the FDA MedWatch website: <https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home>

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



Refer to *Instructions for Use* at goremedical.com for a complete description of all warnings, precautions and contraindications for the markets where this product is available. Rx Only

Products listed may not be available in all markets.

GORE, *Together, improving life*, ACTIVE CONTROL, TAG and designs are trademarks of W. L. Gore & Associates.
© 2020 W. L. Gore & Associates, Inc. AZ1767-EN1 SEPTEMBER 2020