Together, improving life

September 21, 2020

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

Difficulty Withdrawing Catheter

Event Number 2017233.09/09/2020.002-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: Difficulty Withdrawing Catheter

From August 2019 to January 2020, Gore received five (5) reports where difficulty withdrawing the delivery catheter was encountered due to a proximal stent apex being lodged within the delivery catheter leading olive. Of the five (5) events, four (4) reported health consequences related to increased procedure time and 1 related to surgical intervention. This represents a rate of 0.04% reported complaints of this type of deployment event over the last three (3) years since device commercialization. The investigation of these events determined that a proximal stent apex was unintentionally lodged within the delivery catheter leading olive during the manufacturing process. Gore is implementing manufacturing changes to reduce the possibility of these events. Based on the frequency of these events, Gore estimates that a very small number of the devices in the field globally may be potentially affected by this type of event.

In each event, the physician attempted endovascular techniques to free the stent apex from the leading olive. The techniques included delivery catheter manipulation/movement (e.g. twisting, pushing, and/or pulling) without the use of additional tools; ballooning to force the stent apex apart from the leading olive; and snaring of the catheter or device components.

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Four (4) of the five (5) events were resolved endovascularly using different combinations of these techniques and the remaining event was resolved with a surgical intervention. In two (2) events that were resolved endovascularly, significant manipulation of the catheter resulted in partial separation of the nitinol stent from the graft material requiring additional stent graft placement to reline and/or secure the separated nitinol stent segment with no additional reports of patient harm.

New IFU Warning:

Gore defers to the best medical judgement of physicians to determine the appropriate course of action for the patient if this type of event occurs. As reported, simple endovascular manipulation of the catheter may resolve the issue, but use of balloons, snares and other techniques may be necessary.

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

"Events have occurred where difficulty withdrawing the delivery catheter was encountered due to a proximal stent apex being lodged within the delivery catheter leading olive. Patient harms have been reported including surgical intervention; see ADVERSE EVENTS. If delivery catheter removal difficulty occurs, use best medical judgement to determine the appropriate course of action for the patient. Effective removal of the catheter component has been reported through both surgical and endovascular (catheter manipulation, ballooning, snaring) techniques."

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

Deployment events (e.g. removal difficulty) 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 surgical conversion; ischemia; stroke; dissection, perforation, or rupture of the aortic vessel and surrounding vasculature; harms associated with additional intraoperative and/or secondary surgical or endovascular procedures; and/or harms associated with additional intraoperative procedure time. Attempts at resolution of the event may also lead to catheter breakage; and/or improper placement, material failure, occlusion, and fracture of the stent graft.
The IFU currently warns: Do not continue advancement or retraction of the guidewire, sheath, or delivery catheter if resistance is felt. Stop and assess the cause of resistance. Vessel, stent graft, or delivery catheter damage may occur.
The IFU similarly warns: If resistance is felt, stop and assess the cause. Otherwise, device displacement may occur.

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.

Per the IFU, regular and consistent follow-up is a critical part of ensuring the safety and efficacy of aortic endovascular repair. Physicians should tailor patient follow-up to the needs

and circumstances of each individual patient.

Gore encourages physicians to adhere to all of the warnings in the IFU. 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

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

Attachment:
Return Acknowledgement Form

APPENDIX 1 – Additional Event Information

Event Number:

2017233.09/09/2020.002-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).

MD179044 Attachment 1 EU