Together, improving life

September 21, 2020

URGENT Field Safety Notice

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

Event Numbers 2017233.09/09/2020.001-C and 2017233.09/09/2020.002-C

PLEASE ENSURE THIS DOCUMENT IS DELIVERED TO THE APPROPRIATE PERSONNEL IN YOUR FACILITY RESPONSIBLE FOR ADDRESSING RECALLS/FIELD SAFETY CORRECTIVE ACTIONS.

The following document contains two notifications requiring your attention. One return acknowledgement form is provided with our request that it be returned acknowledging both notifications have been received and understood.

W. L. Gore & Associates, B.V.
Ringbaan Oost 152-A
5013 CE Tilburg, NEDERLAND
T +31 (0)13 507 47 00
F +31 (0)13 543 87 36
gore.com

GORE, *Together, improving life* and designs are trademarks of W. L. Gore & Associates

BTW Nr. NL006938140B01 BTW Nr. BE0465 846 557
Bank of America N.A.
Amsterdam 026 6577911
S.W.I.F.T. BOFANLNX
IBAN NL23 BOFA 0266 5779 11

Handelsregister: KvK Midden-Brabant,Tilburg 16050821
Bank of America N.A.
Antwerpen 685-7119012-56
S.W.I.F.T. BOFABE3X
IBAN BE20 6857 1190 1256

Directie: Frank Fuhrhop, Guy D'haeseleer

Together, improving life

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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IBAN BE20 6857 1190 1256

Directie: Frank Fuhrhop, Guy D'haeseleer

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:

Claire van den Nieuwenhof
EMEA Regulatory Affairs
W. L. Gore & Associates B.V.
Ringbaan Oost 152-a
5013 CE Tilburg
The Netherlands
EU-AR@wlgore.com
T +31 13 5074728 M +31 629450726

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

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.

W. L. Gore & Associates, B.V.
Ringbaan Oost 152-A
5013 CE Tilburg, NEDERLAND
T +31 (0)13 507 47 00
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gore.com

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BTW Nr. NL006938140B01 BTW Nr. BE0465 846 557
Bank of America N.A.
Amsterdam 026 6577911
S.W.I.F.T. BOFANLNX
IBAN NL23 BOFA 0266 5779 11

Handelsregister: KvK Midden-Brabant,Tilburg 16050821
Bank of America N.A.
Antwerpen 685-7119012-56
S.W.I.F.T. BOFABE3X
IBAN BE20 6857 1190 1256

Directie: Frank Fuhrhop, Guy D'haeseleer

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.

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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:

Claire van den Nieuwenhof
EMEA Regulatory Affairs
W. L. Gore & Associates B.V.
Ringbaan Oost 152-a
5013 CE Tilburg
The Netherlands
EU-AR@wlgore.com
T +31 13 5074728 M +31 629450726

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:

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TGM212110X*	TGM313110X*	TGM404010X*	TGMR313115X*
TGM212115X*	TGM313115X*	TGM404015X*	TGMR313120X*
TGM212120X*	TGM313120X*	TGM404020X*	TGMR312610X*
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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:

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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

Return Acknowledgement Form

URGENT Field Safety Notice

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

Please return this completed Return Acknowledgement Form via fax or E-mail to Stericycle using the information listed below within two weeks of receipt of this letter.

Attn: Event Number 6654 / 2017233.09/09/2020.001-C and 2017233.09/09/2020.002-C

Email Address: WLGore6654EMEA@stericycle.com

Fax: 0800-1802509 (Germany); +44-203-318-3198 (all other countries)

Please check and complete the following box to acknowledge receipt of the two documents listed below in reference to the Field Safety Notice of the GORE® TAG® Conformable Thoracic Stent Graft with ACTIVE CONTROL System.

- Field Safety Notice for inability to complete secondary deployment
- Field Safety Notice for difficulty withdrawing catheter

☐ I have read and I understand the documents

Print Name of Person Completing Form:	Facility/Business Name:
Date the notification was received:	Telephone Number:
Signed*	Date:
**Your signature provides confirmation that you have received and understood these Field Safety Notices.*	

It is important that your organization takes the actions detailed in these Field Safety Notices and that you confirm you have received the included documents.

Your organization's reply is the evidence we need to monitor the progress of the corrective actions.