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May 19, 2026

URGENT Medical Device Safety Correction / Field Safety Notice
GORE® TAG® Thoracic Branch Endoprosthesis Side Branch Component

TARGET AUDIENCE: *Vascular or Cardiothoracic Surgeons and other physicians implanting the GORE® TAG® Thoracic Branch Endoprosthesis Side Branch Component.*

Event Number 2017233.05/19/2026.004-C

Dear Health Care Provider:

W. L. Gore & Associates (Gore) would like to inform you of safety information related to the **GORE® TAG® Thoracic Branch Endoprosthesis Side Branch Component**, all Catalogue Numbers. Please carefully review this letter and complete and sign the enclosed Return Acknowledgement Form. See APPENDIX 1 – ADDITIONAL EVENT INFORMATION for product details.

Event Description: Catheter Separation

- Between February 24, 2026 and April 13, 2026, Gore received 5 reports involving catheter separation of the GORE® TAG® Thoracic Branch Endoprosthesis (TBE) Side Branch (SB) Component during clinical use. In all cases, the failure occurred at the interface between the main catheter shaft and an over molded transition near where the trailing end of the device is positioned on the catheter. In all cases, the catheters separated after the Side Branch device was deployed; see image below.
- In 4 of the events, the separated catheter component was successfully removed using an upper-extremity catheter advanced over a pre-existing through-and-through wire and retrieved through the femoral sheath. In the remaining event, the separation was identified on the back table following delivery system removal, and the timing of failure could not be definitively determined.
- In each case the patient tolerated the procedure, and no serious injuries or death have been reported to date. The only observed impact to patients to date has been increased procedure time.
- Potential harms associated with this type of catheter separation include stroke or ischemia due to embolization or premature deployment of the SB device if the separation were to occur prior to SB component deployment. Neither of these harms have been reported to date.
- Contributing factors in each of the 5 events included higher than typical force applied during delivery or removal of the delivery system and, in some instances, catheter rotation.
- Gore's investigation of these events remains ongoing.

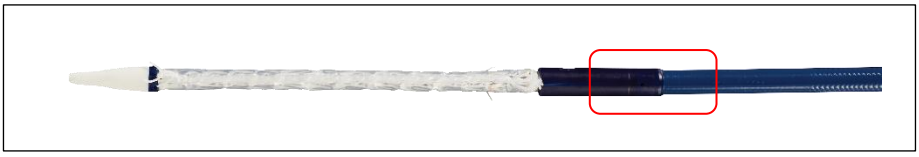

Figure 1. Example TBE SB device on catheter, red box showing location of catheter separation.

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

- Consistent with the Instructions for Use (IFU), Gore recommends use of a through-and-through side branch wire, where clinically and anatomically feasible.
    - As stated in the Patient Selection and Treatment section of the IFU: "For initial Zone 2 and all Zone 0/1 GORE® TAG® Thoracic Branch Endoprosthesis cases, through-and-through wire access is recommended to aid in side branch wire manipulation throughout the procedure."
    - Utilizing a through-and-through side branch wire provides the physician additional wire manipulation abilities and options for other devices (i.e., 5 Fr sheath) which can aid in side branch tracking and positioning. This may reduce the need for excessive forces or manipulation needed to position the SB device or to remove the delivery system, reducing the chance of catheter separation occurring.
    - Utilizing a through-and-through side branch wire reduces the likelihood that a separated catheter component can embolize as it would remain on the guidewire. Options for catheter component retrieval are also enhanced with a through-and-through guidewire, as has been employed in the 4 events where this has been required.
- Please note that, per the IFU, rotation of the SB delivery catheter is cautioned against: "Caution: Do not rotate the SB Component delivery catheter. Catheter breakage or inadvertent deployment has occurred."
    - In 2 of the 5 events described above, returned components exhibited evidence of failure consistent with catheter rotation.
- Additionally, the IFU states "Do not continue advancement or retraction of the … delivery catheter if resistance is felt. Stop and assess the cause of resistance. Vessel, endoprosthesis, or delivery catheter damage may occur."
    - If additional force is experienced during introduction or positioning of the device or is felt upon attempted removal of the delivery system, the following techniques should be considered:
        - Adjust pressure or tension on the side branch guidewire either via femoral access or via both ends of the guidewire if introduced through-and-through to change the position/approach of the side branch device or delivery system. Specifically, pushing on the wire and/or sheath from the arm has been successful in assisting delivery system removal when higher than expected force is experienced during attempted delivery system withdrawal.
        - Per the IFU, "Advance [a] catheter or sheath from the brachial access site to engage the tip of the SB Component to ease introduction of the SB Component through the internal portal and into the target branch vessel." and "**Note:** Catheter or sheath must be > 4 Fr to prevent tip from sliding under SB Component olive."
- Lastly, as is standard practice in TEVAR, the IFU states "Withdraw the delivery catheter using fluoroscopic guidance to ensure safe removal from the deployed endoprostheses." Physicians should be careful, as always, to recognize any anomalies in catheter / delivery system components during and after withdrawal (i.e. catheter is withdrawn, but the olive is still observed in place on fluoroscopy). Gore encourages physicians to inspect the SB

Component delivery system for integrity/separation after removal from patient to ensure all parts are removed as intended.

- Gore encourages physicians to adhere to information in the IFU described above. Please refer to the approved IFU for full indications, contraindications, instructions, warnings, and precautions, available at: https://eifu.goremedical.com/.

Immediate Actions for the Physician:

- Please complete and sign the enclosed RETURN ACKNOWLEDGEMENT FORM and return to FieldActionTeam@wlgore.com within 2 weeks of receipt of this notification. This letter will also be available on the Gore Medical website.
- This notice needs to be shared with those who should be aware within your institution or to any organization where potentially affected devices have been transferred (as appropriate).
- Physicians should consider this information as part of patient specific risk-benefit decision making, including whether use of the GORE® TAG® Thoracic Branch Endoprosthesis or an available alternative treatment option is appropriate based on the patient's clinical condition, anatomy, urgency of treatment, and available therapies.
- No action is required for patients who currently have the device implanted, as this failure mode is limited to the delivery system and, once removed from patient, the delivery system does not pose any ongoing harm due to the observed failures.

In the event that an adverse event occurs:

Any adverse event involving the GORE® TAG® Thoracic Branch Endoprosthesis 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: Phone: +1 800 528 1866 or +1 928 864 4922, Fax: 928 864 4364
Canada: Phone: +1 928 864 4922, Fax: +1 928 864 4364
EMEA: Phone: +49 89 4612 3440, Fax: +49 89 4612 43440
China: Phone: +86 21 5172 8237, Fax: +86 21 5172 8236
Japan: Phone: +81 3 6746 2562, Fax: +81 3 6746 2563

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

Based on currently available information, Gore believes the GORE® TAG® Thoracic Branch Endoprosthesis Side Branch Component continues to provide a favorable benefit-risk profile when used in accordance with the IFU and the additional considerations described in this notice. Gore's investigation remains ongoing, and Gore will continue to evaluate potential contributing factors and implement corrective actions as appropriate.

If you have any questions regarding the content of this notification, please contact me, Gore Customer Service (email: MPDCustomerCare@wlgore.com or by phone at 800-528-8763), or your local Field Sales Associate.

Sincerely,

Austin Byrne
Global Product Specialist
abyrne@wlgore.com
W. L. Gore & Associates, Inc.

Consult Instructions for Use
eifu.goremedical.com

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

Products listed may not be available in all markets.

APPENDIX 1 – ADDITIONAL EVENT INFORMATION

Event Number:
2017233.05/19/2026.004-C

Field Safety Notification Type:
New

SRN of Manufacturer:
US-MF-000001141

Regulatory Representative:

Michael Ivey
Global Regulatory Affairs
W. L. Gore & Associates, Inc.
3450 Kiltie Lane
Flagstaff, AZ 86005
+1 (928) 864-3790
mivey@wlgore.com

Device Type:
Aortic arch branch vessel endovascular stent-graft

Commercial Name:
GORE® TAG® Thoracic Branch Endoprosthesis

Primary Clinical Purpose of the Device:
For Zone 0-2: The GORE® TAG® Thoracic Branch Endoprosthesis is intended for endovascular repair of the aortic arch and descending thoracic aorta requiring a proximal landing zone including the brachiocephalic, left common carotid, or left subclavian artery while maintaining flow into a single aortic arch branch vessel.

For Zone 2: The GORE® TAG® Thoracic Branch Endoprosthesis is intended for endovascular repair of the descending thoracic aorta requiring a proximal landing zone including the left subclavian artery while maintaining blood flow into the left subclavian artery.

Depth of Communication:
Communication should be disseminated to the appropriate treating physicians and to hospital personnel managing device inventories.

Affected Catalogue Numbers:

- TSB080806X
- TSB081006X
- TSB081206X
- TSB081506X
- TSB121506X
- TSB081706X
- TSB121706X
- TSB122006X

X is a placeholder for enumeration code listed below:
E = EU, Australia; W = China, Taiwan; A = US, Canada; J = Japan

Affected Device Manufacturing Dates:

Products with a manufacturing date that falls within the dates of August 05, 2025 and April 20, 2026.

Date of first shipment:
Americas, Asia Pacific – December 05. 2025
Europe – December 08, 2025
Japan – December 12, 2025

The Regulatory Authority of your country has been informed about this communication to customers, as required by local regulations.

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

Enclosure: RETURN ACKNOWLEDGEMENT FORM