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July 28, 2026

URGENT Medical Device Field Safety Notice
GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis (TAMBE)

TARGET AUDIENCE: *Vascular Surgeons and other physicians implanting, reintervening and/or following patients implanted with the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis.*

INFORMATION REGARDING BRANCH COMPONENT OCCLUSION

Dear Health Care Provider:

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

Description of the Issue:

Gore is proactively communicating updated information regarding branch component occlusions observed during ongoing clinical follow-up of patients treated with the TAMBE device. These updates are intended to support physician awareness and reinforce considerations related to patient selection, procedural planning, and post-procedural surveillance.

Clinical study analyses and previously published clinical study outcomes for the TAMBE device have identified anatomical factors that may adversely influence renal branch patency outcomes in certain patients; specifically, those patients with renal arteries ≤5 mm in diameter [1]. The IFU has been updated to reflect these anatomical considerations and to provide the pivotal trial data through the currently available follow-up period (approximately 3 years).

Branch component occlusion remains a known risk associated with complex branched endovascular repair and is currently described within the TAMBE Instructions for Use (IFU). Since commercial approval, ongoing analyses from the TAMBE pivotal study[A] have provided further information regarding branch component occlusions, associated clinical sequelae, branch patency outcomes, and potential anatomical factors that may influence branch component performance over time.

[A] Clinicaltrials.gov NCT03728985 - Evaluation of the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis in the Treatment of Thoracoabdominal and Pararenal Aortic Aneurysms

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goremedical.com
Europe 00800 6334 4673

At the time of TAMBE US approval (Jan 2024), the TAMBE pivotal trial reported total occlusion of a device component had been reported in 14 of 95 evaluable subjects (14.7%) through the 12-month primary endpoint timeframe. The occlusions included renal, celiac and mesenteric branch vessels. Through the 12-month primary endpoint timeframe, reported clinical sequelae included mesenteric ischemia leading to multisystem organ failure and death in 1 of 95 (1.1%) evaluable subjects as well as renal failure requiring dialysis in 3 of 95 (3.2%) evaluable subjects.

Subsequent longer-term follow-up from the ongoing clinical study has indicated additional branch component occlusions beyond the 12-month primary endpoint timeframe. Through currently available follow-up (up to approximately 3 years), branch component occlusions have been reported in 22 of 80 evaluable subjects (27.5%). At the vessel level, freedom from occlusion estimates through 3 years were approximately 83.2%, 92.6%, 96.4 and 97.7%, and for the right renal, left renal, superior mesenteric and celiac arteries, respectively, with mesenteric vessels generally demonstrating higher long-term patency than renal branches. To date, no specific anatomical risk factors have been identified for mesenteric branch occlusions; however, smaller renal artery diameters have been associated with lower renal branch patency. Through longer follow-up, reported clinical sequelae includes mesenteric ischemia in 2 of 80 (2.5%) evaluable subjects and renal failure requiring dialysis in 5 of 80 (6.3%) evaluable subjects. Death related to branch occlusion or target vessel events occurred in 2 of 80 (2.5%) evaluable subjects.
Through the 12-month primary endpoint timeframe, 6 of 16 branch component occlusions (37.5%) underwent percutaneous reintervention; this proportion remained consistent through approximately 3 years of follow-up (9 of 27 branch component occlusions undergoing percutaneous reintervention, 33.3%), despite the greater number of occlusions observed over time.

These observations are generally consistent with previously published literature describing complex branched endovascular repair, in which renal branch vessels have demonstrated comparatively lower long-term patency relative to mesenteric vessels. Smaller renal artery diameters have also been described as important patient selection considerations for other off-the-shelf branch endovascular devices approved outside of the United States [2]. Gore believes these findings reflect the inherent anatomical and procedural complexity associated with branched endovascular treatment of thoracoabdominal and pararenal aortic aneurysms and further support the importance of individualized patient selection, procedural planning, and continued surveillance.

Gore Corrective Actions:

Based on currently available data, Gore believes the TAMBE benefit-risk profile remains favorable when used as intended. To date, investigation has not revealed any design or manufacturing deficiencies related to branch component occlusion. Gore will continue ongoing evaluation of clinical study data, post-market experience, and physician feedback to further characterize branch component performance and long-term clinical outcomes.

IFU Revisions relating to branch vessel component occlusion:

Gore will be updating the Instructions for Use (IFU) for the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis to include:

- Modification of existing warning to further clarify that branch component patency should be evaluated and monitored during follow-up
- Addition of warning to inform users of lower branch primary patency rates observed in certain patient subsets with renal artery diameters ≤5 mm compared to larger diameter renal arteries
- Update to 'Clinically Significant Reintervention' section to provide additional detail on branch component occlusions observed beyond the 12-month primary endpoint timepoint, through currently available follow-up (approximately 3 years)

See enclosed Summary of IFU Changes for further details.

Immediate Recommended Actions for the Physician:

- Please review the enclosed Summary of IFU Changes, and please complete and sign the enclosed RETURN ACKNOWLEDGEMENT FORM and return to WLGore4100ous@sedgwick.com within 2 weeks of receipt of this notification. This letter and Summary of IFU Changes 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).
- Gore encourages physicians to adhere to the modified warning and safety information in the IFU, as well as other current warnings. Please refer to the approved IFU for full indications, contraindications, instructions, warnings, and precautions, available at: https://eifu.goremedical.com/. Updated full IFUs will be available on the website.
- When anatomical characteristics associated with increased branch occlusion risk are present, including smaller renal arteries, physicians should carefully assess the overall benefit-risk profile of available treatment options. In patients with Type IV TAAA who are not considered high surgical risk, surgical repair should be considered based on the physician's assessment of the individual patient's anatomy, clinical condition, and available treatment options.
- For patients who currently have the device implanted, continue to reference the IFU for recommended follow-up and please be aware of the anatomical characteristics that may influence branch patency outcomes in certain patient subsets. Management of patients within these subsets should be guided by the clinical judgment of the treating physician, with careful consideration of the risks and benefits of each treatment option in the context of the individual circumstance.
- Gore strongly encourages regular imaging surveillance with duplex ultrasound and/or CTA to facilitate early identification of occlusions and reinterventions to be performed before occlusion occurs, especially in patients identified as having the known anatomical risk factors influencing renal branch patency (e.g., renal arteries ≤ 5mm diameter).

In the event that an adverse event occurs:

Any adverse event involving the GORE® EXCLUDER® Thoracoabdominal 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:

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

Gore is providing physicians with this safety risk-related data and information so that appropriate risk-benefit related decisions can be made with the patient when considering the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis.

Please be assured that Gore is committed to ensuring the highest product quality and customer satisfaction and will be implementing 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,

James Chow, Ph.D.
Global Product Specialist
jchow@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.

References

1. Farber MA, Han S, Makaroun MS, Matsumura JS, Mendes BC, Oderich GS, Sanchez LA, Suckow BD, Timaran CH. One-year outcomes from the pivotal trial of a four-branch off-the-shelf solution to treat pararenal and extent IV thoracoabdominal aortic aneurysms. J Vasc Surg. 2025 Sep;82(3):740-749.e2.
2. Tsilimparis N, Oderich GS. Endovascular repair of TAAAs with the t-Branch stent graft. Endovascular Today. November 2015 (Cook Medical Supplement):4–8. https://evtoday.com/pdfs/et1115_Cook_supp_sec%204.pdf

APPENDIX 1 – ADDITIONAL EVENT INFORMATION

Event Number:
2017233.07/22/2026.006-C

Field Safety Notification Type:
New

SRN of Manufacturer:
US-MF-000001141

Regulatory Representative:
Phillip M. Lester
Product Pipeline Regulatory Leader
W. L. Gore & Associates, Inc.
1505 N Fourth Street
Flagstaff, AZ 86005
T +1 410 506 8148
plester@wlgore.com

Device Type:
Endovascular Stent Graft

Commercial Name:
GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis

Affected Device Catalogue Numbers:
Europe: ATAA43120160E, ATAA43720160E

Primary Clinical Purpose of the Device:
The TAMBE device is intended for endovascular repair of thoracoabdominal and pararenal aortic aneurysms. Specific anatomical considerations and device sizing criteria are described in the TAMBE Instructions for Use (IFU).

Risk Assessment:
Branch component occlusion remains a known risk associated with complex branched endovascular repair and is currently described within the TAMBE IFU and product risk management documentation. Reported clinical sequelae associated with branch component occlusions have included reintervention, renal failure, permanent hemodialysis, bowel ischemia, and death.

Ongoing clinical follow-up and analyses from the TAMBE pivotal study have provided additional longitudinal information regarding branch patency outcomes and anatomical characteristics that may influence branch component performance in certain patient subsets. Gore has evaluated these findings within the context of the overall TAMBE benefit-risk profile and ongoing clinical experience.

Based on currently available data, Gore believes the overall benefit-risk profile for TAMBE remains favorable within the approved indication for use in patients with thoracoabdominal and pararenal aortic aneurysms who have anatomy suitable for endovascular repair. These observations reinforce the importance of individualized patient selection, procedural planning, post-procedural surveillance, and physician assessment of available treatment options based on the totality of the patient's anatomy and clinical condition.

Additional Clinical Analyses:

Additional analyses from the ongoing clinical study identified lower Kaplan-Meier primary patency rates in the renal arteries among certain patients through 3 years; specifically, those patients having renal arteries with diameters ≤5 mm (74.1% vs. 88.2%; p=0.01).

As anatomical characteristics differ across disease types, publications reporting renal primary patency in branched endovascular devices stratified by disease may provide general clinical context regarding anticipated results in thoracoabdominal and complex abdominal/pararenal aortic aneurysm populations. For branched endovascular devices, reported renal artery primary patency rates at the vessel-level through 3 years have generally ranged from the high-80% to mid-90% in thoracoabdominal aortic aneurysm populations [3,4] and from the low-to-middle 80% range in complex abdominal aortic aneurysm populations [3]. These reports are not intended for direct comparison as limitations exist due to differences in study design and data oversight, patient characteristics, surveillance intensity, and operator experience.

These analyses are intended to provide additional longitudinal clinical context regarding branch patency outcomes and anatomical considerations that may influence branch component performance over time. Gore will continue ongoing evaluation of available clinical follow-up data as additional information becomes available.

References

3. Tenorio ER, et al; U.S. Fenestrated and Branched Aortic Research Consortium. Mid-term Renal and Mesenteric Artery Outcomes During Fenestrated and Branched Endovascular Aortic Repair for Complex Abdominal and Thoracoabdominal Aortic Aneurysms in the United States Aortic Research Consortium. Ann Surg. 2023 Oct 1;278(4):e893-e902
4. Tsilimparis N, et al. Two-year target vessel-related outcomes following use of off-the-shelf branched endografts for the treatment of thoracoabdominal aortic aneurysms. J Vasc Surg. 2023 Aug;78(2):289-298.

Depth of Communication:

Communication should be disseminated to the user level—implanting physicians and hospital personnel supporting procedures.

Date of first shipment:

European Union – March 2026

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

This notice needs to be shared with 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).

Enclosures:
IFU Summary of Changes for the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis
RETURN ACKNOWLEDGEMENT FORM

MD210567 Attachment 6c

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IFU Summary of Changes
GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis (TAMBE)

Gore is updating the TAMBE IFU to include additional information related to branch component occlusion observations identified during ongoing clinical follow-up. Updates include the following:

Section 'Warnings'

- **Modified:** Stent graft, including branch component, patency should be evaluated and monitored during follow-up. If reduced blood flow through any device or occlusion of a device is observed, a secondary intervention or surgical procedure may be required to re-establish flow if clinically necessary.
- **New:** Lower branch primary patency rates were observed in certain patient subsets with renal artery diameters ≤5 mm compared to larger diameter renal arteries. Appropriate patient selection, procedural planning, and post-procedural surveillance are important considerations when treating smaller target vessels.

Section 'Clinically Significant Reintervention'

- **Modified:** Fourteen Subjects (14/95; 14.7%) experienced total occlusion of a device component, with more noted in PAAA than Type IV TAAA anatomies. Based on this observation and the higher percentage of PAAA subjects who experienced target-lesion growth >5 mm the indications for use are limited to PAAA in high-surgical risk patients. The occlusions included 16 Branch Components, including one celiac and one superior mesenteric artery, six left renal arteries and eight right renal arteries; no occlusions were reported for any other TAMBE Device components. No surgical interventions were performed for treatment of any Branch Component occlusions, five Subjects underwent percutaneous reinterventions on six renal branches, with restoration of branch patency in four of the six targeted Branch Components. The remaining ten occluded Branch Components had no reintervention attempted. One Subject with a SMA Branch Component occlusion experienced mesenteric ischemia and three Subjects with renal Branch Component occlusions required hemodialysis treatment within 12 months. ~~A root cause investigation for Branch Component occlusions did not identify a singular root cause; however, diameters in the landing zone of renal Branch Component with occlusions tended to be near the lower end of the treatment range (4 mm), disproportionately relative to the overall study population.~~

  Additional branch component occlusions have been observed beyond the 12-month primary endpoint timepoint. Through currently available follow-up (up to approximately 3 years), branch component occlusions have been reported in an additional 8 subjects (22/80; 27.5%) through POD 1275, and have been observed in both renal and mesenteric branch vessels. Subsequent analyses of the clinical study data demonstrated lower Kaplan-Meier estimates of renal branch primary patency among renal arteries with diameters ≤5 mm compared to renal arteries >5 mm in certain patient subsets. Reported clinical sequelae associated with branch component occlusions have included renal failure, permanent hemodialysis, bowel ischemia, and death.

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RETURN ACKNOWLEDGMENT FORM

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Please return this completed Return Acknowledgment Form via email or fax to Sedgwick using the information listed below within two weeks of receipt of this letter.

Attn: Event Number 4100: 2017233.07/22/2026.006-C
Fax: +44 20 8834 9587
Email: WLGore4100ous@sedgwick.com

Please check and complete the following boxes to acknowledge receipt of this document sent in reference to the Medical Device Field Safety Notice of the GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis.

☐ I have read and I understand the documents

Print Name and Title of Person Completing Form:	Facility/Business Name:
Date the notification was received:	Telephone Number: Email:
Signed*	Date:
**Your signature provides confirmation that you have received and understood this Medical Device Field Safety Notice.*	

It is important that your organization takes the actions detailed in this Medical Device Field Safety Notice 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.

MD210567 Attachment 7c

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