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August 26, 2025

URGENT Medical Device Correction
GORE® ACUSEAL Vascular Graft

TARGET AUDIENCE: *Vascular Surgeons and other physicians implanting or revising the GORE® ACUSEAL Vascular Graft.*

Event Number 2017233.08/18/2025.002-C

Dear Health Care Provider:

W. L. Gore & Associates (Gore) would like to inform you of safety information related to the **GORE® ACUSEAL Vascular Graft**, 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:

- The GORE® ACUSEAL Vascular Graft is composed of multiple layers. Delamination refers to the separation of these layers. If delamination occurs, the separated material may protrude into the lumen.
- From January 1, 2020, to June 30, 2025, Gore received 112 reports of delamination of the GORE® ACUSEAL Vascular Graft. This corresponds to a global complaint rate of 0.2% relative to the number of devices sold during this time. This rate reflects those events reported to Gore or otherwise identified by Gore. Single-center reports have described higher rates of delamination than those reflected in global complaint data. The highest published rate to our knowledge is from a recent retrospective study by Yu et al., which reported an incidence of 10% (7 out of 70 grafts).¹ Additionally, Gore received an unpublished report from a physician, who observed a delamination incidence rate of 22% (12 out of 55 cases) within his practice group.
- Harms associated with delamination may include reduced access flow due to stenosis, thrombosis, or occlusion; cannulation difficulties; bleeding or bruising; and harms related to reintervention procedures performed to address the delamination.
- Reported treatments for delamination include stent placement, partial or total graft replacement, balloon angioplasty (PTA), thrombectomy, surgical tacking, and observation. Of the 112 reported complaints, one or more reinterventions were

¹ Yu C, Li M, Lee H. Delamination of Acuseal graft is the main cause of secondary patency loss– Early unicenter experience. Ann Vasc Dis. 2025;18(Suppl):S113–S114.



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reported in 86% of cases and 46% of grafts were reported to have ultimately been partially replaced or abandoned.

- The timing of delamination is variable, with cases reported as early as same day of implant and as late as seven years after implantation. Among the complaints with sufficient information to estimate the time to delamination, the median reported interval was approximately seven months.
- Cannulation and reintervention procedures are commonly reported as suspected causes of delamination events; however, delamination has also been reported in devices that have never undergone either procedure.

Gore Corrective Actions:

Gore maintains confidence in the safety and efficacy of the GORE® ACUSEAL Vascular Graft when used as intended. To date, investigation has not revealed any design or manufacturing deficiencies related to delamination.

IFU Revisions relating to delamination:

- Gore will be updating its Instructions for Use (IFU) for the GORE® ACUSEAL Vascular Graft from MD183888 Revision 4 to MD183888 Revision 5 to include:
 - Modification of existing warning to further clarify techniques that may contribute to the risk of delamination
 - Addition of delamination to device-related adverse event section

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 wlgore3081@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.
- No action is required for patients who currently have the device implanted; however, please be aware of delamination as a potential cause of occlusion should clinical issues arise in the future. Management of patients with suspected or confirmed delamination 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.



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In the event that an adverse event occurs:

Any adverse event involving the GORE® ACUSEAL Vascular Graft 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>

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® ACUSEAL Vascular Graft.

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,

Alyssa J. Huntington, Ph.D.

Global Product Specialist

ahunting@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. ^{Rx} Only

Products listed may not be available in all markets.

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APPENDIX 1 – ADDITIONAL EVENT INFORMATION

Event Number:

2017233.08/18/2025.002-C

Field Safety Notification Type:

New

SRN of Manufacturer:

US-MF-000001141

Regulatory Representative:

Sarah Pastrnak
Product Pipeline Regulatory Leader
W. L. Gore & Associates, Inc.
1505 N Fourth Street
Flagstaff, AZ 86005
T +1 928 864 4146
spastrna@wlgore.com

Device Type:

VASCULAR GRAFT

Commercial Name:

GORE® ACUSEAL Vascular Graft

Device Catalog Part Numbers:

ECH050020J ECH050020W ECH050050J ECH050050W ECH060010A ECH060020A
ECH060020J ECH060020W ECH060040 ECH060040A ECH060040W ECH060050A
ECH060050J ECH460045A ECH460045J ECH470045 ECH470045A

Serial Numbers:

Product with a serial number that includes and falls within the range of
6597081PP001 and **9853822PP024**.

Primary Clinical Purpose of the Device:

The GORE® ACUSEAL Vascular Graft is intended for use as a vascular prosthesis in patients requiring vascular access.

Depth of Communication:

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

Date of first shipment:

February 7, 2020



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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® ACUSEAL Vascular Graft
RETURN ACKNOWLEDGEMENT FORM

MD206058 Attachment 5a



IFU Summary of Changes for the GORE® ACUSEAL Vascular Graft

This document summarizes the changes made to the Instructions for Use (IFU) for the GORE® ACUSEAL Vascular Graft. Table 1 provides comparison of verbiage found in the current version and in the updated version.

Table 1: Summary of Changes

Section	Current IFU Text	Updated IFU Text	Reason for Change
Warning	"When using the GORE® ACUSEAL Vascular Graft, avoid using traumatic instruments, handling the graft with excessive force or high rates of force, cutting the graft incorrectly, or placing the graft in an undersized tissue tunnel. These actions may lead to separation of graft layers. Potential consequences include partial or complete occlusion due to hemodynamically significant stenosis or thrombosis and related serious harms, including additional interventions to resolve."	"When using the GORE® ACUSEAL Vascular Graft, avoid using traumatic instruments, handling the graft with excessive force or high rates of force, cutting or suturing the graft incorrectly, or placing the graft in an undersized tissue tunnel. When performing reinterventions on the GORE® ACUSEAL Vascular Graft, avoid the use of oversized balloons. These actions may lead to separation of graft layers (delamination) . Potential consequences include partial or complete occlusion due to hemodynamically significant stenosis or thrombosis and related serious harms, including additional interventions to resolve."	Suturing incorrectly (ie – not passing suture through all layers of the graft wall) and the use of oversized balloons may lead to delamination.
Potential Device or Procedure Related Adverse Events	No reference to delamination	" A possible complication which may occur with the use of the GORE® ACUSEAL Vascular Graft is delamination. Delamination may result in partial or complete occlusion due to hemodynamically significant stenosis or thrombosis and related serious harms, including additional interventions to resolve. "	Delamination is a potential device related adverse event.