Together, improving life

kolovoz 2025.

HITNO Sigurnosna korektivna mjera za medicinski proizvod /
Obavijest o sigurnosnoj korektivnoj mjeri na terenu
Vaskularni transplantat GORE® ACUSEAL

CILJNI KORISNICI: *Vaskularni kirurzi i drugi liječnici koji implantiraju ili revidiraju vaskularni transplantat GORE® ACUSEAL.*

Broj događaja 2017233.08/18/2025.002-C

Poštovani pružatelju zdravstvene skrbi:

W. L. Gore & Associates (Gore) želi vas obavijestiti o sigurnosnim informacijama vezanim uz **vaskularni transplantat GORE® ACUSEAL**, sve kataloške brojke. Pažljivo pregledajte ovo pismo i priloženi Sažetak izmjena Uputa za uporabu te ispunite i potpišite priloženi Obrazac za potvrdu povrata. Pojedinosti o proizvodu potražite u odjeljku DODATAK 1 – DODATNE INFORMACIJE O DOGAĐU.

Opis problema:

- Vaskularni transplantat GORE® ACUSEAL sastoji se od više slojeva. Pojam „delaminacija" se odnosi na razdvajanje tih slojeva. Ako dođe do delaminacije, odvojeni materijal može viriti u lumen.
- Od 1. siječnja 2020. do 30. lipnja 2025. godine, tvrtka Gore je primila 112 izvještaja o delaminaciji vaskularnog transplantata GORE® ACUSEAL. To odgovara globalnoj stopi pritužbi od 0,2 % u odnosu na broj prodanih proizvoda tijekom tog vremena. Ta stopa odražava događaje prijavljene tvrtki Gore ili koje je tvrtka Gore na drugi način identificirala. Izvještaji pojedinačnih centara opisali su veće stope delaminacije od onih koje su navedene u podacima o globalnim pritužbama. Najviša stopa objavljena po našem saznanju je iz nedavnog retrospektivnog ispitivanja koje su proveli Yu et al., u kojem je zabilježena učestalost od 10 % (7 od 70 transplantata).[1] Osim toga, tvrtka Gore je primila neobjavljen izvještaj od liječnika koji je uočio stopu incidencije delaminacije od 22 % (12 od 55 slučajeva) unutar svoje skupine.
- Štete povezane s delaminacijom mogu uključivati smanjen protok pristupa zbog stenoze, tromboze ili okluzije; poteškoće s kanulacijom; krvarenje ili modrice; i štete povezane s postupcima ponovne intervencije koje se provode radi rješavanja delaminacije.

[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.

W. L. Gore & Associates, Inc.
Medical Products Division
goremedical.com

Europe 00800 6334 4673
United States +1 800 437 8181
United States +1 928 779 2771

- Prijavljena liječenja za delaminaciju uključuju postavljanje stenta, djelomičnu ili potpunu zamjenu transplantata, balonsku angioplastiku (PTA), trombektomiju, kirurško praćenje i opažanje. Od 112 prijavljenih pritužbi, u 86 % slučajeva prijavljena je jedna ili više ponovnih intervencija, a za 46 % transplantata prijavljeno je da su u konačnici djelomično zamijenjeni ili napušteni.
- Vrijeme delaminacije je promjenjivo, a slučajevi su prijavljeni već na isti dan implantacije i do sedam godina nakon implantacije. Među pritužbama s dovoljno informacija za procjenu vremena do delaminacije, medijan prijavljenog intervala iznosio je približno sedam mjeseci.
- Kao uzroci delaminacije na koje se sumnja, obično se prijavljuju kanuliranje i postupci ponovne intervencije; međutim, delaminacija je prijavljena i u proizvodima koji nikada nisu bili podvrgnuti nijednom od navedenih postupaka.

Korektivne radnje tvrtke Gore:

Gore održava povjerenje u sigurnost i učinkovitost vaskularnog transplantata GORE® ACUSEAL kada se koristi u skladu s namjenom. Dosad istraga nije otkrila nikakve nedostatke u dizajnu ili proizvodnji povezane s delaminacijom.

Revizije Uputa za uporabu koje se odnose na delaminaciju:

- Tvrtka Gore će ažurirati svoje Upute za uporabu za vaskularni transplantat GORE® ACUSEAL kako bi uključio:
  - Izmjenu postojećeg upozorenja radi daljnjeg pojašnjenja tehnika koje mogu pridonijeti riziku od delaminacije
  - Dodavanje delaminacije u odjeljak o štetnim događajima povezanim s proizvodom

Dodatne pojedinosti potražite u priloženom Sažetku izmjena uputa za uporabu.

Neposredne preporučene radnje za liječnika:

- Pregledajte priloženi Sažetak izmjena uputa za uporabu i ispunite i potpišite priloženi OBRAZAC ZA POTVRDU POVRATA i vratite na adresu FieldActionTeam@wlgore.com u roku od 2 tjedna od primitka ove obavijesti. Ovo pismo i Sažetak izmjena uputa za uporabu također će biti dostupni na web-stranicama tvrtke Gore Medical.
- Ovu obavijest treba podijeliti s osobama koje bi trebale biti upoznate unutar vaše ustanove ili s bilo kojom organizacijom u kojoj su preneseni potencijalno zahvaćeni proizvodi (ako je primjenjivo).
- Tvrtka Gore potiče liječnike da se pridržavaju izmijenjenih informacija o upozorenjima i sigurnosti u Uputama za uporabu, kao i drugih trenutačnih upozorenja. Sve indikacije, kontraindikacije, upute, upozorenja i mjere opreza potražite u odobrenim uputama za uporabu, koje su dostupne na: https://eifu.goremedical.com/. Ažurirane potpune upute za uporabu bit će dostupne na internetskoj stranici.
- Nisu potrebne nikakve radnje za pacijente kojima je trenutačno ugrađen proizvod; međutim, imajte na umu delaminaciju kao potencijalni uzrok okluzije ako se u budućnosti pojave klinički problemi. Liječenje pacijenata sa suspektnom ili potvrđenom delaminacijom treba voditi kliničkom prosudbom liječnika, uz pažljivo razmatranje rizika i koristi svake mogućnosti liječenja u kontekstu pojedinačnih okolnosti.

U slučaju pojave štetnog događaja:

Svaki štetni događaj koji uključuje vaskularni transplantat GORE® ACUSEAL treba odmah prijaviti proizvođaču i regulatornim tijelima specifičnim za državu. Za prijavu događaja tvrtki W. L. Gore & Associates, pošaljite poruku e-pošte na adresu medcomplaints@wlgore.com ili kontaktirajte:

SAD: Telefon: +1 800 528 1866 ili +1 928 864 4922, telefaks: 928 864 4364
Kanada: Telefon: +1 928 864 4922, faks: +1 928 864 4364
EMEA: Telefon: +49 89 4612 3440, telefaks: +49 89 4612 43440
Kina: Telefon: +86 21 5172 8237, faks: +86 21 5172 8236
Japan: Telefon: +81 3 6746 2562, telefaks: +81 3 6746 2563

Zdravstveni djelatnici i korisnici mogu prijaviti štetne događaje ili probleme s kvalitetom izravno FDA-u putem internetske stranice FDA MedWatch: https://www.accessdata.fda.gov/scripts/medwatch/index.cfm

Tvrtka Gore pruža liječnicima ove podatke i informacije u vezi sa sigurnosnim rizikom kako bi se pacijentu mogle donijeti odgovarajuće odluke o rizicima i koristima pri razmatranju vaskularnog transplantata GORE® ACUSEAL.

Budite sigurni da je tvrtka Gore predana osiguravanju najveće kvalitete proizvoda i zadovoljstva korisnika te da će provesti korektivne radnje prema potrebi.

Ako imate bilo kakvih pitanja u vezi sa sadržajem ove obavijesti, obratite se meni, iz Službe za korisnike tvrtke Gore (e-pošta: MPDCustomerCare@wlgore.com ili telefonom na 800-528-8763) ili lokalnom prodajnom suradniku.

S poštovanjem,

Alyssa J. Huntington, dr. med.
Global Product Specialist
ahunting@wlgore.com
W. L. Gore & Associates, Inc.

Consult Instructions for Use
eifu.goremedical.com

Potpuni opis svih primjenjivih indikacija, upozorenja, mjera opreza i kontraindikacija za tržišta na kojima je ovaj proizvod dostupan potražite u *Uputama za uporabu* na eifu.goremedical.com. ℞ Only

Navedeni proizvodi možda neće biti dostupni na svim tržištima.

DODATAK 1 – DODATNE INFORMACIJE O DOGAĐAJIMA

Broj događaja:
2017233.08/18/2025.002-C

Vrsta obavijesti o sigurnosnoj korektivnoj mjeri na terenu:
Nova

SRN proizvođača:
US-MF-000001141

Regulatorni zastupnik:
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

Vrsta proizvoda:
VASKULARNI TRANSPLANTAT

Komercijalni naziv:
Vaskularni transplantat GORE® ACUSEAL

Kataloški brojevi dijelova proizvoda:
ECH050020J ECH050020W ECH050050J ECH050050W ECH060010A ECH060020A
ECH060020J ECH060020W ECH060040 ECH060040A ECH060040W ECH060050A
ECH060050J ECH460045A ECH460045J ECH470045 ECH470045A

Serijski brojevi:
Proizvod sa serijskim brojem koji je unutar raspona od **6597081PP001** i **9853822PP024**.

Primarna klinička svrha proizvoda:
Vaskularni transplantat GORE® ACUSEAL namijenjen je za uporabu kao vaskularna proteza u pacijenata kojima je potreban vaskularni pristup.

Dubina komunikacije:
Komunikacija treba biti proslijeđena korisnicima – liječnicima koji ugrađuju implantate i bolničkom osoblju koje sudjeluje u izvođenju zahvata.

Datum prve pošiljke:
7. veljače 2020.

Regulatorno tijelo vaše zemlje obaviješteno je o ovoj komunikaciji s korisnicima, u skladu s lokalnim propisima.

Ovu obavijest treba podijeliti s osobama unutar vaše ustanove koje trebaju biti upoznate s njom, kao i s bilo kojom organizacijom kojoj su preneseni potencijalno zahvaćeni proizvodi (ako je primjenjivo). Prenesite ovu obavijest drugoj organizaciji (organizacijama) na koju ova radnja utječe (ako je primjenjivo).

Prilog:
Sažetak izmjena uputa za uporabu vaskularnog transplantata GORE® ACUSEAL
OBRAZAC ZA POTVRDU POVRATA

Together, improving life

August 2025

URGENT Medical Device Safety Correction / Field Safety Notice
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.

W. L. Gore & Associates, Inc.
Medical Products Division
goremedical.com

Europe 00800 6334 4673
United States +1 800 437 8181
United States +1 928 779 2771

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 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 FieldActionTeam@wlgore.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.

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. ℞ Only

Products listed may not be available in all markets.

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 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

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

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.