OLYMPUS

URGENT: MEDICAL DEVICE PRODUCT REMOVAL

GORE® VIABIL® Biliary Endoprosthesis Products

Product Name	Catalogue Number	UDI-DI	Serial Number	Product Distribution Range
GORE[a] VIABIL[a] Short Wire Biliary Endoprosthesis Product – 8-mm diameter x 8-cm length with transmural drainage holes	VSWVH0808	00733132638772	30907025	February 13, 2026-August 26, 2026
			30907033	
			30907034	
			30907036	

Date: October 12, 2026

Attention: Endoscopy and Risk Management Departments

Dear Healthcare Professional:

W. L. Gore & Associates, Inc. ("GORE"), the manufacturer of a series of GORE VIABIL biliary endoprosthesis products that Olympus distributes, has initiated a voluntary product recall for four serial numbers of the VSWVH0808 catalogue number (see table above).

Reason for Action:

GORE notified Olympus of a potential labeling discrepancy in which the device contained within the packaging may not match the size and configuration indicated on the product label. See the attached Medical Device Recall letter from GORE for more information on the issue, the reason for action, and the risks.

Actions Required:

Our records indicate that your facility may have received product with the catalogue number and one or more of the serial numbers identified in the table above. Olympus therefore requests that you take the following actions:

1. Carefully read the content of the attached Medical Device Recall letter from GORE.
2. Examine the carton labels of all unused GORE VIABIL products in your inventory for the catalogue number and serial numbers indicated in the table above.
    a. If any products in your inventory match the catalogue number and one of the serial numbers indicated in the table above, immediately quarantine that product and contact Olympus Customer Service at 1-800-848-9024, option 2, to obtain a Return Material Authorization.
    b. A replacement product or a credit will be issued for each unused product with one of the affected serial numbers that is returned to Olympus.
3. Examine the medical records of your patients who have received a GORE VIABIL biliary endoprosthesis implant to determine whether the catalogue number and serial numbers indicated in the table above are among the

[a] 'GORE' and 'VIABIL' are trademarks of W. L. Gore & Associates, Inc.

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devices that have already been implanted. If so, see the "Implanting Physicians" instructions within the "Actions to be taken by the customer / user" section of the attached letter from GORE.

4. Acknowledge receipt of this letter through the Olympus recall web portal. **Note:** This request applies even if you have confirmed that you do not have any of the affected serial numbers currently in your inventory and have not already implanted devices with any of the affected serial numbers into a patient.
   a. Go to https://olympusamerica.com/recall
   b. Enter the recall number: 0511
   c. Complete the form as instructed.
   d. Indicate in your response whether you confirm having received one or more of the affected serial numbers. If so, indicate the affected serial number(s) you received and, for each, whether that product 1) remains unused and will be returned to Olympus or 2) has already been implanted into a patient.
5. If you have further distributed any products with the catalogue number and any of the serial numbers identified in the table at the start of this letter, forward this cover letter and the attached letter from GORE to other users who may now have affected products.

Olympus requests that you report any complaints to our Technical Assistance Center (TAC) at 1-800-848-9024, option 1, and the FDA. Adverse events experienced with the use of this product may also be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, or by fax.

Olympus fully appreciates your prompt cooperation in addressing this situation. If you require additional information, please do not hesitate to contact me by phone at (484) 553-1029 or by e-mail at Ashley.troiani@olympus.com

Sincerely,

Ashley Troiani

Ashley Troiani
Senior Manager, US FCA Lead

September 2026

URGENT MEDICAL DEVICE RECALL
GORE® VIABIL® Short Wire Biliary Endoprosthesis

Dear GORE® VIABIL® Short Wire Biliary Endoprosthesis Customer:

This is to inform you that W. L. Gore & Associates, Inc. (Gore) has initiated a voluntary product recall involving 4 GORE® VIABIL® Short Wire Biliary Endoprosthesis devices, Catalogue Number VSWVH0808 distributed by Olympus Corporation of the Americas (Olympus). Gore has identified the specific serial numbers affected and determined that your institution may have received one or more of these devices. Please refer to APPENDIX 1 – ADDITIONAL EVENT INFORMATION for detailed product information.

Gore received a complaint concerning 2 GORE® VIABIL® Short Wire Biliary Endoprosthesis (VIABIL SW) devices. Following a thorough investigation, Gore identified a potential labeling discrepancy in which the packaged device may not match the device specifications indicated on the product label. Gore's records indicate your facility may have received one or more of the impacted devices.

Description of Mislabeling Issue:
The device mislabeling resulted in 10 mm x 6 cm devices without transmural drainage holes labeled as an 8 mm x 8 cm device with transmural drainage holes.

Table 1 – Summary Detail of Potentially Mislabeled VIABIL SW Devices

Mislabeled Device Configuration (incorrect) Diameter x Length; Holes/No Holes	**Actual Device Configuration Diameter x Length; Holes/No Holes**
8 mm x 8 cm; holes	10 mm x 6 cm; no holes

Gore has assessed the following potential for patient harm:

Scenario 1 – Discovery Before Deployment
The physician identifies the discrepancy before the stent is deployed. The affected device lacks the expected third radiopaque marker that demarcates the end of the holed region and is shorter than labeled (6 cm instead of the expected 8 cm), making accurate positioning difficult and potentially revealing the labeling/configuration error during placement. The most likely outcome is that the physician removes the undeployed device and replaces it with the intended device size and/or configuration. The primary impact is an increase in procedure time while another device is obtained and implanted.

Scenario 2 – Discovery Post-Deployment
If the difference in stent length or the absence of transmural drainage holes is identified after deployment, the physician may elect to remove the device. Because devices are not intended for removal in the U.S. there is no IFU guidance. This could lead to procedural difficulty and unintended interaction

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with the bile duct or duodenal tissue, including potential delamination or unraveling of the device lining. Potential clinical consequences include irritation or inflammation, bleeding (hemobilia), ulceration, bile leak, pain and extended procedure time. These outcomes are generally considered treatable and manageable through standard medical care, and the likelihood of occurrence is reduced because the device design supports removability.

Scenario 3 – Device Implanted
The discrepancy is not recognized, or the physician elects to leave the device implanted. Because the implanted device is shorter than expected and lacks transmural drainage holes, there is a potential risk of inadequate stricture coverage, side branch encroachment or obstruction, reduced drainage effectiveness, or stent occlusion. Device oversizing (10-30%) compared to duct diameter is recommended; however, an overly large stent could impart significant radial expansion force on the bile duct wall. Possible patient impacts include pain, cholangitis, cholecystitis, the need for an additional procedure, irritation or inflammation of the bile duct, ulceration, or bile leak. In some cases, a second stent may be implanted to achieve adequate stricture coverage. If removal is planned at a later date, the same removal-related risks described in Scenario 2 may apply. Overall, these events are considered unlikely, and any resulting complications would generally be manageable within the scope of standard medical care.

Gore has elected to remove four (4) devices distributed by Olympus that are potentially affected. To comply with this voluntary recall, we ask that you inspect your purchased product inventory for the serial numbers listed below and remove and return any affected product.

Catalogue Number: VSWVH0808
Description: 8 mm x 8 cm device with transmural drainage holes
Serial Numbers:
30907025
30907033
30907034
30907036

Actions to be taken by the customer/user:

- Identify and return any unused devices within the scope of this recall for replacement. Please acknowledge receipt of this letter according to the instructions provided by our distributor, Olympus.
- 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).
- Implanting Physicians: If you have implanted one of the potentially mislabeled GORE® VIABIL® Short Wire Biliary Endoprosthesis devices, please be mindful of the potential health outcomes and plan to take the needed measures that could minimize any potential health hazards associated with this mislabeling. If a listed device has been used, please indicate the device(s) used when you acknowledge receipt according to the enclosed instruction from our distributor, Olympus

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In the event that an adverse event occurs:
Any adverse event involving the GORE® VIABIL® Biliary Endoprosthesis should be reported to the manufacturer and the country specific regulatory authorities immediately. To report an event to Olympus, please contact their Technical Assistance Center at (800) 848-9024, option 1.

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

We regret any confusion or inconvenience this matter may cause. Please be assured that Gore is committed to ensuring top product quality and customer satisfaction and will be implementing corrective actions as appropriate.

Please contact me if you have any questions or concerns regarding this notice.

Sincerely,

Julie Skaife
W. L. Gore & Associates, Inc.
Global Product Specialist & Brand Manager
juskaife@wlgore.com

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APPENDIX 1 – ADDITIONAL EVENT INFORMATION

Device Type:

Polymeric-metal Biliary Stent

Commercial Name:

GORE® VIABIL® Short Wire Biliary Endoprosthesis

Primary Clinical Purpose of the Device:

The GORE® VIABIL® Short Wire Biliary Endoprosthesis is intended for use as a stent in the biliary tree.

Depth of Communication:

Communication should be disseminated to the user level – gastroenterologists and other physicians implanting biliary endoprostheses, as well as to hospital personnel managing device inventories.

Date of first shipment:

United States – September 3, 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 shared with those who should be aware within your institution or to any organization where potentially affected devices have been transferred (as appropriate).

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