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July 14, 2021

URGENT MEDICAL DEVICE RECALL/FIELD SAFETY NOTICE
GORE® Molding and Occlusion Balloon Catheters

Event Number 3007284313.07/07/2021.001-R

Dear Recall Coordinator/Purchasing Team/Healthcare Provider:

This is to inform you of a voluntary product recall involving GORE® Molding and Occlusion Balloon Catheters (MOB Devices), Catalogue Number MOB37. See APPENDIX 1 – ADDITIONAL EVENT INFORMATION for additional product details.

Between April 2, 2021 and June 30, 2021, W. L. Gore & Associates, Inc. (Gore) received 75 complaints regarding GORE® Molding and Occlusion Balloon Catheter (MOB Device) leakage from the guidewire lumen and the y-hub during preparation or use of the device, resulting in either insufficient inflation or an inability to inflate. Of all complaints received, 74 of 75 complaints reported the MOB Device being used for molding purposes. One of the 75 complaints reported the MOB Device being used as a temporary occlusion device for an emergent procedure. All reported complaints resulted in no immediate or long-term health consequences. In most cases an alternative balloon was used to successfully complete the procedure.

The GORE® Molding and Occlusion Balloon Catheter is intended for temporary occlusion of large diameter vessels or to assist the expansion of self-expanding endovascular prostheses (stent grafts) (also known as molding). In both clinical use scenarios, the most likely patient harm is increased procedure time to obtain an alternate device. When the MOB Device is used for occlusion (e.g. occlusion of the aorta due to a rupture), the increased procedure time could be associated with critical blood loss which may result in life-threatening harm to the patient. Patient harm associated with this device issue may increase in cases of emergent rupture, the device not being prepared per Instructions for Use, a lack of readily available additional occlusion balloon(s), and/or an inability to convert to open surgery.

Upon a thorough review, Gore has identified the source of the device failure mode as a manufacturing equipment change. Therefore, Gore has elected to conduct a voluntary recall of the distributed devices that may potentially exhibit this failure mode. This voluntary recall affects only the device serial number range listed in Appendix 1 with device expiration dates between December 7, 2022 and May 5, 2023 (2022-12-07 to 2023-05-05).

Gore has traced the device serial numbers potentially affected and found that your institution may have received one or more of these devices. To comply with this voluntary recall, please inspect your product inventory and remove and return any affected product.



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For accounts with Gore consignment inventory, please allow the Gore Field Sales Associate to arrange the retrieval of any potentially affected consignment inventory at your institution.

Actions to be taken by the customer/user:

- Identify and return any unused devices within the scope of this voluntary recall.
- Please complete and sign the enclosed CUSTOMER RESPONSE FORM and return to **{include appropriate email for customer return forms}** within 2 weeks of receipt of this notification.
- Please share this letter with others in your hospital or clinic as appropriate.
- If a listed device has been used, there is no patient-follow up needed and there are no further actions needed other than informing Gore the device was used. Please indicate the used devices on the CUSTOMER RESPONSE FORM and return to **{include appropriate email for customer return forms}** within 2 weeks of receipt of this letter. No further action is needed.

We regret any confusion or inconvenience this matter may cause to your product supply. Gore expects this supply issue to be a temporary disruption, and we will be working to replenish inventory as soon as possible. Please be assured that Gore is committed to ensuring top product quality and customer satisfaction.

Please feel free to contact Gore if you have questions or concerns regarding this voluntary recall.

Sincerely,

Kyle Marr
Global Product Specialist
W. L. Gore & Associates, Inc.

W. L. Gore & Associates, Inc.
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 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:
3007284313.07/07/2021.001-R

Field Safety Notification Type:
New

Regulatory Representative:
Michael Ivey
Aortic Regulatory Affairs
W. L. Gore & Associates, Inc.
3450 Kiltie Lane
Flagstaff, AZ 86004
T +1 928 864 3790
mivey@wlgore.com

Device Type:
Catheter, Intravascular Occluding, Temporary

Commercial Name:
GORE® Molding and Occlusion Balloon Catheter

Primary Clinical Purpose of the Device:
The GORE® Molding and Occlusion Balloon Catheter is intended for temporary occlusion of large diameter vessels or to assist the expansion of self-expanding endovascular prostheses (stent grafts).

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

Affected Catalogue Numbers:
Gore Catalogue Number: MOB37
GTIN/UDI-DI: 00733132639489

Affected Serial Numbers (UDI -PI):
MOB37 Devices with Device Serial Numbers between 22982051 and 23516741, with device expiration dates between December 7, 2022 and May 5, 2023 (2022-12-07 to 2023-05-05).

Date of first shipment:
March 2, 2021

Actions to be taken by the customer/user:
▪ Identify and return any unused devices within the scope of this voluntary recall.



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- Please complete and sign the enclosed CUSTOMER RESPONSE FORM and return to **{include appropriate email for customer return forms}** within 2 weeks of receipt of this notification.
- Please share this letter with others in your hospital or clinic as appropriate.
- If a listed device has been used, there is no patient-follow up needed and there are no further actions needed other than informing Gore the device was used. Please indicate the used devices on the CUSTOMER RESPONSE FORM and return to **{include appropriate email for customer return forms}** within 2 weeks of receipt of this letter. No further action is needed.

In the event that an adverse event occurs:

Any adverse event involving the GORE[®] Molding and Occlusion Balloon Catheter 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: +49 89 4612 3440, Fax: +49 89 4612 43440

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: CUSTOMER RESPONSE FORM



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CUSTOMER RESPONSE FORM

GORE® Molding and Occlusion Balloon Catheters

URGENT Medical Device Recall/Field Safety Notice

Attn: Event Number 3007284313.07/07/2021.001-R

Please inspect all MOB inventory for the following serial number(s). Indicate if item(s) was used or is still in customer inventory. Return any identified product for replacement. Please return this form within 2 weeks of receipt, even if item(s) is no longer in inventory.

Location	
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Catalogue Number / GTIN/UDI-DI	Device Serial Number(s) (UDI-PI)	CHECK ONE	
		Used	In Stock
MOB37 / 00733132639489			

{ add rows as needed }

Retrieval and Return of Affected Item(s):

- Not required, item(s) used, return paperwork only (see below)
- Affected item(s) removed from customer's location, ship device(s) to:

{ insert address for product returns }

Replacement Order: (Replace only if an item is retrieved and returned)

- Not required, item(s) used
- Replacement item(s) order placed with Gore Customer Service (Order No.: _____)

Return Paperwork and Questions:

Attn: Event Number 3007284313.07/07/2021.001-R

Fax: { insert fax number for paperwork return }

Email Address: { insert email for paperwork return }

Phone: { insert phone number for questions }

Person Responsible for Completing Information:

Print Name: _____

Signature: _____

Date: _____