Together, improving life

July, 2021

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

Event Number 4731 / 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.

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 **WLGore4731@stericycle.com** 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 **WLGore4731@stericycle.com** 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.
Medical Products Division
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APPENDIX 1 – ADDITIONAL EVENT INFORMATION

Event Number:
4731 / 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

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.

Date of first shipment:
March 2, 2021

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- 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 **WLGore4731@stericycle.com** 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:
USA: +1.800.528.1866, Ext. 44922, +1.928.864.4922, Fax: +1.928.864.4364
China: +86 21 5172 8237, Fax: +86 21 5172 8236
Japan: +81 3 6746 2562, Fax: +81 3 6746 2563
EMEA: +49 89 4612 3440, Fax: +49 89 4612 43440

Healthcare professionals and consumers may report adverse events or quality problems by regular mail, fax or directly to FDA using the FDA MedWatch Website: https://www.accessdata.fda.gov/scripts/medwatch/index.cfm.

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

MD185090 Attachment 5