Together, improving life

September X, 2022

URGENT MEDICAL DEVICE RECALL/FIELD SAFETY NOTICE
GORE® CARDIOFORM ASD Occluder

Company Name
Address Line 1
Address Line 2

Dear GORE® CARDIOFORM ASD Occluder Customer:

This is to inform you that W. L. Gore & Associates, Inc. (Gore) has initiated a voluntary product recall involving thirty-six (36) GORE® CARDIOFORM ASD Occluder devices, Catalogue Numbers ASD37A, ASD44A, and ASD44E. Gore has traced the device serial numbers affected and found that your institution has received one or more of these devices. See APPENDIX 1 – ADDITIONAL EVENT INFORMATION for product details.

Gore has identified one batch of GORE® CARDIOFORM ASD Occluder devices that was incorrectly released following a documented failure of a subset of quality tests. A failure of this subset of quality tests could potentially result in increased risks during the release of the device from the delivery system for the affected devices.

This issue is limited to the affected devices listed below and does not impact the safety and performance of implanted GORE® CARDIOFORM ASD Occluder devices. The potential risks would only be present during the release of the device from the delivery system and would be limited to the index procedure. The most severe potential harm that may result from the increased risks is anoxic brain injury due to occluder embolization during the release of the device which may be life-threatening. If occluder embolization occurs during the index procedure, it would be immediately observable by the implanting physician and the embolized device must be removed per the *Instructions for Use*. There have been no reported instances of occluder embolization, anoxic brain injury, or any other immediate or long-term health consequence associated with the affected devices, and it has been determined the probability of these risks occurring is low.

Gore has elected to remove the thirty-six (36) distributed devices that are affected. This voluntary product recall affects only the following device catalogue and serial numbers:

Region	Gore Catalogue Number (GTIN/UDI-DI Number)	Product Description (Size)	Serial Numbers (UDI-PI)
Europe	ASD44E (00733132636617)	44 mm	24305083

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

Region	Gore Catalogue Number (GTIN/UDI-DI Number)	Product Description (Size)	Serial Numbers (UDI-PI)
United States	ASD37A (00733132636501)	37 mm	24468090, 24468092, 24468093, 24468096, 24468097, 24468098, 24468099, 24468103, 24468104, 24480314, 24480315, 24480316 24480318
	ASD44A (00733132636518)	44 mm	24281498, 24281499, 24281500, 24281501, 24281502, 24281507, 24281509, 24281511, 24281512, 24429270, 24429271, 24429276 24429278, 24429279, 24480351, 24480352, 24480353, 24545359, 24550148, 24550149, 24578446, 24578447

To comply with this voluntary product recall, inspect your purchased 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 recall.
- Please complete and sign the enclosed CUSTOMER RESPONSE FORM and return to FieldActionTeam@wlgore.com within 2 weeks of receipt of this notification.
- Please share this letter with others in your institution as appropriate. Please transfer this notice to other organization(s) as appropriate.
- If a listed device has been used, there is no patient follow-up needed and no further actions required other than informing Gore the device was used. Please indicate the used device(s) on the CUSTOMER RESPONSE FORM and return to FieldActionTeam@wlgore.com.

As a reminder, there is no known additional risk to patients who have been treated with a GORE® CARDIOFORM ASD Occluder device that is subject to this voluntary recall. 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 actions as appropriate.

Please contact your local Gore Field Sales Associate with any questions regarding this notice, and to coordinate the return and replacement of any unused affected devices. Additionally, you may also contact Gore Customer Service (Email: MPDCustomerCare@wlgore.com).

Sincerely,

Tom Biggerstaff
Global Product Specialist
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.

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

APPENDIX 1 – ADDITIONAL EVENT INFORMATION

Event Number:
2017233.09/15/2022.001-R

Field Safety Notification Type:
New

Regulatory Representative:
Sharon Alexander
Global Regulatory Affairs
W. L. Gore & Associates, Inc.
32470 N. North Valley Parkway
Phoenix, AZ 85085
T +1 623 234 5440 M +1 480 550 1076
salexand@wlgore.com

Device Type:
Cardiac occluder

Commercial Name:
GORE® CARDIOFORM ASD Occluder

Primary Clinical Purpose of the Device:
The GORE® CARDIOFORM ASD Occluder is intended to be used for percutaneous, transcatheter closure of ostium secundum atrial septal defects (ASDs).

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

Affected Catalogue Numbers:

Refer to table on Pages 1 and 2 for a list of affected Catalogue Numbers

Affected Serial Numbers:

Refer to table on Pages 1 and 2 for a list of affected Serial Numbers

Date of first shipment:
Europe – December 1, 2021
United States – November 24, 2021

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 FieldActionTeam@wlgore.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 FieldActionTeam@wlgore.com.

In the event that an adverse event occurs:

Any adverse event involving the GORE® CARDIOFORM ASD Occluder 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: 800 528 1866 Ext. 44922 / 928 864 4922, Fax 928 864 4364
EMEA: +49 89 4612 3440, Fax +49 89 4612 43440

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

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

MD190567 Attachment 5

CUSTOMER RESPONSE FORM

GORE® CARDIOFORM ASD Occluder

URGENT Medical Device Recall / Field Safety Notice

Attn: 2017233.09/15/2022.001-R

Please inspect all GORE® CARDIOFORM ASD Occluder inventory for the following serial numbers. Indicate if product(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 product(s) is no longer in inventory.

Location	

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

Retrieval and Return of Affected Item(s):

☐ Not required, product(s) used, return paperwork only (see below)

☐ Affected product(s) removed from customer's location, ship device(s) to:

UNITED STATES
W. L. Gore & Associates
Attn: Nathan Lee, NCR120433
4000 W Kiltie Lane
Flagstaff, AZ 86005

RA #: _____

EUROPE
W. L. Gore & Associates
Attn: Leonie Grootzwagers, NCR120433
Dr. Paul Janssenweg 150
5026 RH Tilburg
The Netherlands
Contact Gore Customer Service for return information

Return Completed Customer Response Form to:

Email: FieldActionTeam@wlgore.com

Person Responsible for Completing Information:

Print Name: _____

Signature: _____ Date: _____