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September XX, 2021

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

Event Number 3120 / 2017233.08/26/2021.001-R

Dear Recall Coordinator/Purchasing Team/Healthcare Professional:

This is to inform you that W. L. Gore & Associates, Inc. (Gore) has initiated a voluntary product recall related to expiration labeling for GORE® CARDIOFORM Septal Occluder (GSO Devices), Catalogue Numbers with prefixes GSX and GSXE. Gore has traced the device serial numbers affected and found that your institution may have received one or more of these devices. See APPENDIX 1 – ADDITIONAL EVENT INFORMATION for product details.

The GSO Devices subject to this voluntary product recall are incorrectly labeled with a three-year expiration date. GSO Devices are approved for a two-year expiration date; therefore, the mislabeled products indicate a longer expiration date than approved. Currently, all affected devices are within their approved two-year expiration date, and no affected devices will expire prior to September 2022.

The labeling error does not impact the safety and performance of devices used prior to their approved expiration. Gore has initiated this voluntary recall to remove and replace affected product before any affected devices reach their approved expiration. This action is intended to prevent any future risk of patient harm related to this labeling error.

This voluntary recall affects only GORE® CARDIOFORM Septal Occluder with device serial numbers starting with serial number 22689696 and ending with serial number 23569078 (see APPENDIX 1).

To comply with this voluntary recall, inspect your purchased product inventory and remove and return any affected product. For accounts with Gore consignment inventory, please allow a 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 **WLGore3120EMEA@sedgwick.com** within 3 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 **WLGore3120EMEA@sedgwick.com** within 3 weeks of receipt of this letter. No further action is needed.

As a reminder, there is no known additional risk to patients who have been treated with a GORE® CARDIOFORM Septal Occluder device that is subject to this recall. We regret any confusion or inconvenience this matter may cause to your product supply and we are working to replenish inventory as soon as possible. Please be assured that Gore is committed to ensuring top product quality and customer satisfaction.

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,

Devin Nelson
W. L. Gore & Associates, Inc.
Global Product Specialist

W. L. Gore & Associates, Inc.
Medical Products Division
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APPENDIX 1 – ADDITIONAL EVENT INFORMATION

Event Number:
3120 / 2017233.08/26/2021.001-R

Field Safety Notification Type:
New

Regulatory Representative:
Shannon Eggers
Global Regulatory Affairs
W. L. Gore & Associates, Inc.
32470 N. North Valley Parkway
Phoenix, AZ 85085
T +1 623 234 5951 M +1 480 220 8007
seggers@wlgore.com

Device Type:
Cardiac occluder

Commercial Name:
GORE® CARDIOFORM Septal Occluder

Primary Clinical Purpose of the Device:
The GORE® CARDIOFORM Septal Occluder is intended for use as a permanently implanted device indicated for the percutaneous, transcatheter closure of atrial septal defects (ASDs), such as ostium secundum and patent foramen ovale.

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

Affected Catalogue Numbers:

Region	Gore Catalogue Number	Item Description (Size)	GTIN/UDI-DI Number
US	GSX0020A	20 mm	00733132631018
	GSX0025A	25 mm	00733132631025
	GSX0030A	30 mm	00733132631032
EMEA	GSXE0020	20 mm	00733132617630
	GSXE0025	25 mm	00733132617647
	GSXE0030	30 mm	00733132617661
Canada & Australia	GSXE0025B	25 mm	00733132620111
	GSXE0030B	30 mm	00733132620128

Mexico	GSX0030H	30 mm	00733132648948

Affected Serial Numbers:

GSO Devices with Device Serial numbers starting with serial number 22689696 and ending with serial number 23569078.

Date of first shipment:

December 1, 2020

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 **WLGore3120EMEA@sedgwick.com** within 3 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 **WLGore3120EMEA@sedgwick.com** within 3 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® CARDIOFORM Septal 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:
Australia: +86 21 5172 8235, Fax +86 21 5172 8236
Canada and Mexico: +1 928 864 4922, Fax +1 928 864 4364
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.

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

MD185047 Attachment 6

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CUSTOMER RESPONSE FORM

GORE® CARDIOFORM Septal Occluder

URGENT Medical Device Recall/Field Safety Notice

Attn: Event Number 3120 / 2017233.08/26/2021.001-R

Please inspect all GSO 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 3 weeks of receipt, even if item(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, item(s) used, return paperwork only (see below)

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

AUSTRALIA, CANADA, MEXICO
W. L. Gore & Associates
Attn: Nathan Lee, NCR119156
4000 W Kiltie Lane
Flagstaff, AZ 86005
RA #: _____

EMEA
W. L. Gore & Associates
Attn: Leonie Grootzwagers, NCR119156
Dr. Paul Janssenweg 150
5026 RH Tilburg
The Netherlands
Contact Gore Customer Service for return information

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

☐ Replacement item(s) order placed with Gore Customer Service (Order No.: _____)

Return Paperwork and Questions:

Attn: Event Number 3120 / 2017233.08/26/2021.001-R

Email Address: WLGore3120EMEA@sedgwick.com

Person Responsible for Completing Information:

Print Name: _____
Signature: _____ Date: _____