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May 12, 2021

MEDICAL DEVICE RECALL/ADVISORY NOTICE

GORE® PROPATEN® Vascular Graft configured for Pediatric Shunt

Company Name
Address Line 1
Address Line 2

Dear Recall Coordinator/Healthcare Professional:

This is to inform you of a voluntary product recall involving 47 distributed devices of GORE® PROPATEN® Vascular Graft configured for Pediatric Shunt, Catalogue Numbers HPT050010A, HPT050010, HPT060015A, and HPT060015. W. L. Gore & Associates, Inc. (Gore) has traced the device serial numbers potentially affected and found that your institution may have received one or more of these devices.

Gore received feedback through post market surveillance and confirmed that a GORE® PROPATEN® Vascular Graft configured for Pediatric Shunt, 5 mm x 10 cm device (HPT050010A) measured as an inner diameter (ID) of 6 mm. Upon a thorough review, Gore has identified that 47 GORE® PROPATEN® Vascular Graft configured for Pediatric Shunt devices may have been labeled with the incorrect Catalogue Number and ID size. Specifically, GORE® PROPATEN® Vascular Graft configured for Pediatric Shunt devices with Catalogue Numbers HPT050010A and HPT050010 from three work orders are labeled as 5 mm ID devices (HPT050010*); however, the packaging may contain a 6mm ID device inside. In addition, GORE® PROPATEN® Vascular Graft configured for Pediatric Shunt devices with Catalogue Numbers HPT060015A and HPT060015 from three work orders are labeled as 6 mm ID devices (HPT060015*); however, the packaging may contain a 5 mm ID device inside.

Gore has assessed the following potential for patient harm for either of the mislabeling situations. For pediatric shunting procedures, physicians choose a device size based on patient anatomy/weight at the time of the procedure. If the physician determines that the selected device is appropriate for the patient anatomy and chooses to implant a device that was labeled incorrectly, Gore is not aware of any foreseeable harm to the patient beyond those inherent to the procedure. If the physician notices the size difference prior to the procedure and decides to use a different device, there is the potential for an increase in procedure time associated with the selection of another device. However, the clinical implications of this increased procedure time are negligible, and it is unlikely that the situation would result in adverse health consequences.

Because of Gore's commitment to the highest product standards, Gore has elected to recall the 47 distributed devices that are potentially mislabeled. This voluntary recall affects only the following device catalogue and serial numbers:

Catalogue Number and (GTIN)	Description	Serial Numbers		
HPT050010A (00733132606337)	5mmX10cm Ped Shunt Heparin	6185494PP001	6185494PP002	6185494PP004
		6185494PP006	6185494PP008	6185494PP009
		6185494PP010	6185494PP011	6185494PP012
		6185495PP001	6185495PP002	6185495PP004
		6185495PP005	6185495PP006	6185495PP007
		6185495PP009	6185495PP010	6185495PP011
		6185495PP012	6185495PP014	
HPT050010 (00733132606320)	5mmX10cm Ped Shunt Heparin	6185497PP001	6185497PP005	6185497PP006
		6185497PP007	6185497PP008	6185497PP009
		6185497PP010	6185497PP011	6185497PP012
HPT060015A (00733132606375)	6mmX15cm Ped Shunt Heparin	6185496PP001		
HPT060015 (00733132606368)	6mmX15cm Ped Shunt Heparin	6185502PP001	6185502PP002	6185502PP003
		6185502PP004	6185502PP006	6185502PP007
		6185502PP009	6185502PP010	6185503PP001
		6185503PP002	6185503PP004	6185503PP005
		6185503PP006	6185503PP007	6185503PP008
		6185503PP009	6185503PP010	

To comply with this voluntary recall, we ask that you inspect your purchased product inventory for the above serial numbers 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 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 RETURN 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. Please transfer this notice to other organization(s) as appropriate.

As a reminder, patients who may have received a GORE® PROPATEN® Vascular Graft configured for Pediatric Shunt from the affected devices are not at risk. 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 appropriate corrective actions.

In the event that an adverse event occurs:

Any adverse event involving the GORE® PROPATEN® Vascular Graft configured for Pediatric Shunt 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
EMEA: +49 89 4612 3440, Fax +49 89 4612 43440
Brazil: +55 11 5502-7953, Fax: +55 11 5502-7965

For US Customers only: 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

Please feel free to contact Gore Customer Service (email: MPDCustomerCare@wlgore.com) or myself if you have questions or concerns regarding this voluntary recall.

Sincerely,

[redacted]

Medical Device Recall/Advisory Notice: 2017233.05/10/2021.001-R

MD183933 Attachment 5

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Medical Products Division
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USA

T +1 928 864 2927
goremedical.com

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CUSTOMER RETURN FORM

Medical Device Recall/Advisory Notice: 2017233.05/10/2021.001-R

Please inspect all inventory for the following serial numbers. 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				
Catalogue Number(s)	Product GTIN(s)	Serial Number(s)	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:

UNITED STATES, CANADA, BRAZIL
W. L. Gore & Associates
Attn: Nathan Lee, NCR118804
4000 W Kiltie Lane
Flagstaff, AZ 86005

RA #: _____

EMEA
W. L. Gore & Associates
Attn: Leonie Grootzwagers, NCR118804
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:

Email to: FieldActionTeam@wlgore.com or include with returned device(s)

Person Responsible for Completing Information:

Print Name: _____
Signature: _____
Date: _____

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For Gore Field Sales Associates Only:

Field Sales Associate: _____ Customer Communication Completed on: _____