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June 2023

URGENT MEDICAL DEVICE RECALL/ADVISORY NOTICE
GORE TIPS Set

Dear Recall Coordinator/Purchasing Team/Healthcare Provider:

This is to inform you that W. L. Gore & Associates, Inc. (Gore) is executing a voluntary recall on behalf of Creganna Medical* involving GORE TIPS Set devices, Catalogue Number TSET1016. Gore has traced the device lot 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 three lots of GORE TIPS Set devices that may be labeled with the incorrect expiration date. GORE TIPS Set devices are approved for a three-year expiration date; however, the mislabeled products may indicate a longer expiration date than approved. Currently, all affected devices are within their approved three-year expiration date, and no affected devices will expire prior to July 2024. As of the date of this letter, Gore has received no customer complaints in regard to this expiration date mislabeling.

The labeling error does not impact the safety and performance of devices used prior to their approved expiration date. Using the devices beyond the three-year expiration date could result in difficulty preparing, introducing, delivering, or removing the device as well as potentially compromise sterility. This may include inability or difficulty in executing percutaneous transjugular liver access as intended in patients undergoing a Transjugular Intrahepatic Portosystemic Shunt (TIPS) procedure. This could potentially result in, increased procedure time, clinical infection, air embolus, clinical consequences that are related to embolized material requiring additional procedures or removal, or clinical consequences that are related to re-intervention.

This voluntary recall is to remove and replace affected product before any affected devices reach their approved expiration. This action is intended to prevent any potential future risk of patient harm related to this labeling error. This voluntary product recall affects only the following device catalogue and lot numbers:

Regions	Gore Catalogue Number (GTIN/UDI-DI Number)	Product Description (Size)	Lot Numbers (UDI-PI)
Canada, EMEA, and United States	TSET1016 (25391526210028)	10Fr Introducer Sheath; 16 Gauge Needle	1V00099635 1V00166928 1V00199622

*Legal manufacturer of GORE TIPS Set: Creganna Medical, Parkmore West, Galway, H91 VN2T, Ireland

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

To comply with this voluntary product recall, please 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.

In the event that an adverse event occurs:

Any adverse event involving the GORE TIPS Set should be reported to W. L. Gore & Associates and the country specific regulatory authorities immediately. To report an event to W. L. Gore & Associates, email: medcomplaints@wlgore.com
or contact:
USA and Canada: 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

As a reminder, there is no known additional risk to patients who have been treated with a GORE TIPS Set 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,

[redacted]
Global Product Specialist
W.L. Gore & Associates, Inc.

APPENDIX 1 – ADDITIONAL EVENT INFORMATION

Event Number:
3004193842-06/22/2023-001-R

SRN of Manufacturer:
IE-MF-000002854, Creganna Medical – Manufacturer

Device Type:
Transjugular Liver Access Set

Commercial Name:
GORE TIPS Set

Primary Clinical Purpose of the Device:
The GORE TIPS Set, GORE® TIPS Sheath and GORE TIPS Needle, are intended to be used together for percutaneous transjugular liver access during diagnostic and interventional procedures in patients undergoing a Transjugular Intrahepatic Portosystemic Shunt (TIPS) procedure.

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

Date of first shipment:
Canada – October 23, 2021; EMEA – October 23, 2021; United States – July 26, 2021

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/DEVICE RECONCILIATION FORM

MD193182 Attachment 5

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CUSTOMER RESPONSE/DEVICE RECONCILIATION FORM

GORE TIPS Set

URGENT Medical Device Recall/Advisory Notice

Attn: 3004193842-06/22/2023-001-R

Please inspect all GORE TIPS Set inventory for the following lot number(s). 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 Lot Number(s) (UDI-PI)	Device Quantity Shipped to Above Location	**To be Completed by Recipient of this Notice**
			In Stock Quantity
TSET1016 / 25391526210028			

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 and CANADA
W. L. Gore & Associates
Attn: Nathan Lee, NCR121347
4000 W Kiltie Lane
Flagstaff, AZ 86005

RA #: _____

EMEA
W. L. Gore & Associates
Attn: Leonie Grootzwagers, NCR121347
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: _____ Job Title: _____

Signature: _____ Date: _____