Recall # STE00143

Terumo Medical Corporation

May 2, 2019

URGENT: MEDICAL DEVICE RECALL

Portico Solo ™ Re-Collapsible Access System

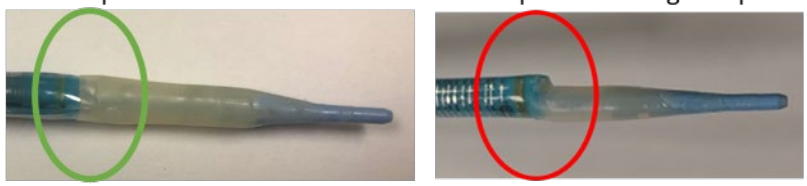
Customer Name
Device Name
Street Address
City, State, Zip Code

Dear Valued Customer,

The purpose of this letter is to advise you that Terumo Medical is voluntarily recalling the Solopath product family, including the Portico Solo™ Re-Collapsible Access System, distributed by St. Jude Medical, a subsidiary of Abbott Laboratories.

The recall has been initiated in response to confirmed reports of dislodgement of the tip from the outer diameter of the sheath resulting in a loss of the smooth transition from the surface of the tip to the outer surface of the expandable sheath. (see fig.1)

Figure 1:



The “Instructions for Use” instruct the user to visually inspect the device prior to use in order to ensure a smooth transition exists between the distal end of the sheath and the balloon expander. However, inadvertent use of a device with this condition may result in procedural complications and vascular damage. Terumo Medical has received fourteen complaints related to this issue on the Solopath product family, with **two complaints resulting in serious injury for vascular damage**.

Actions to be taken by the Customer:

1. Review this Urgent Medical Device Recall Bulletin and the Required Actions.
2. Assure that all users receive notice of this issue so that required actions can be performed.
3. Review your Portico Solo™ inventory immediately to identify and isolate affected inventory in order to prevent future use.
4. Complete the enclosed Medical Device Recall Response Form. **The form is required even if you do not have product on hand.**

5. If you have product on hand and would prefer to return the product, contact Stericycle to obtain a return label. If you have product on hand and would prefer to destroy the product on site, provide a certificate of destruction for the affected product.
   International Toll: +44 208 099 7960
   E-Mail: porticosolorecall@stericycle.com
6. E-mail the completed Recall Acknowledgement Form to porticosolorecall@stericycle.com to arrange for product to be returned to Stericycle. If destroying product on site, email the completed Recall Acknowledgement Form and Certificate of Destruction to porticosolorecall@stericycle.com. Credits will be issued upon receipt of product at Stericycle or upon receipt of the Certificate of Destruction at Stericycle.

Product Impacted by Recall:

PRODUCT RECALLED	
Product Name	**Portico Solo™ Re-Collapsible Access System**
Product Models	PRTSOLO-19, PRTSOLO-20
Lot Numbers	All lots within expiry

In response to declining demand for this product, accelerated by this field action, Terumo Medical and Abbott Laboratories has made the decision to permanently discontinue the manufacturing of SOLOPATH® product line including the Portico Solo™ As a result, effective immediately no future restocking orders or new orders for SOLOPATH® or Portico Solo™ will be fulfilled. Please plan accordingly with alternative suppliers.

Please be assured that we take the safety and quality of our products very seriously. Our customers are our top priority and we want to ensure that you have a high-quality product, which meets your daily needs. We greatly appreciate your understanding and prompt assistance and apologize for any inconvenience this may have caused.

Please contact the Stericycle recall support team with any questions or concerns regarding this process:

International Toll: +44 208 099 7960

Authorized by:
Name: (Print) John Boselli

Signature:

Title: Sr. VP Quality & Regulatory Affairs

cc Chairman Medical Board and Relevant Head of Departments