Urgent FIELD SAFETY NOTICE

Device: **SOLOPATH® Balloon Expandable TransFemoral System & SOLOPATH® Re-collapsible Balloon Access System**

Reference: **FSN 1901 2019-05**

Action: **Return**

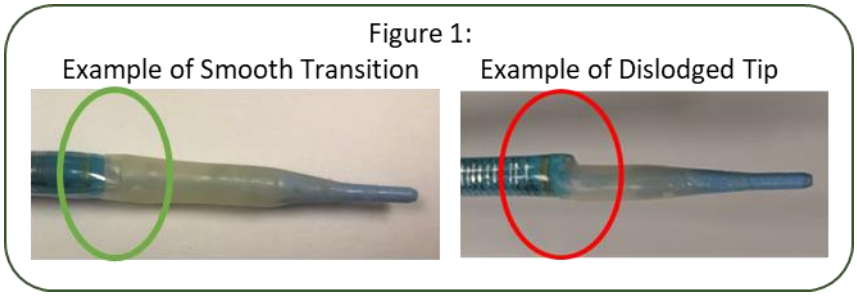
Attention: Chief of Hospital, Clinics, Pharmacy & Medical staff

Description of the problem

Terumo Medical Corporation is voluntarily recalling SOLOPATH® Balloon Expandable TransFemoral System and the SOLOPATH® Re-collapsible Balloon Access System.

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:



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

A SOLOPATH® product discontinuance notification will be provided to you under separate cover.

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.

Details on Recalled devices

Product Name	SOLOPATH® Balloon Expandable TransFemoral System	SOLOPATH® Re-Collapsible Balloon Access System
Product Models	STFI-1425 STFI-1435 STFI-1625 STFI-1635 STFI-1825 STFI-1835 STFI-1925 STFI-1935 STFI-2125 STFI-2135	SR-1925 SR-1935 SR-2025 SR-2035 SR-2225 SR-2235 SR-2425 SR-2435
Lot Numbers	All lots within expiry	All lots within expiry

Potential hazard

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, with two complaints resulting in serious injury for vascular damage.

Corrective actions

Terumo Medical Corporation is asking customers to immediately identify, segregate and return the remaining recalled units in their inventory to Terumo Europe.

Customer instructions

1) Review this Field Safety Notice and assure that all users are aware of this notice and the Required Actions.
2) Immediately identify and segregate the units of the recalled device population.
3) Indicate the number of remaining units per reference/lot number combination on the reply form and return this form as quickly as possible to the e-mail address or the fax number indicated on the form. **The form is required even if you do not have any product to return.**
4) The company representative will contact you to organize immediate pick-up and credit note.

We confirm that this *Field Safety Notice* has also been notified to your national Competent Authority.

We encourage you to contact us or your local Terumo representative with any questions or concerns.

Organisation (to be completed by the sales or dealer)
Contact name (function)
Contact phone, mobile, email

Fayez Abou Hamad - MD Vigilance Expert
Terumo Europe NV – Leuven, Belgium

Field Safety Notice - CUSTOMER REPLY FORM

Device: **SOLOPATH® Balloon Expandable TransFemoral System & SOLOPATH® Re-collapsible Balloon Access System**

Reference: **FSN 1901 2019-05**

Action: **Return**

Please complete, sign and e-mail or fax this back: To:

E-mail/Telefax:

Hospital/Customer Name	
City	
Country	

Our records indicate that you have received recalled devices.

By completion and return of this form, I am confirming receipt, reading and acting on this Safety Notice:

Have you experienced any adverse events associated with recalled product? Yes ☐ No ☐

If yes, please explain:

_____

☐ We have no physical inventory from the recalled population.

☐ We have the following recalled units ready to return:

SOLOPATH® Balloon Expandable TransFemoral System			SOLOPATH® Re-collapsible Balloon Access System		
Reference	**Lot**	**Number of units ready to return**	**Reference**	**Lot**	**Number of units ready to return**

Person Responding [Please Print]	
Title	
Phone Number	
Signature	
Date	

FSN1901A [EN]