URGENT: **Medical Device Voluntarily Recall**

SOLOPATH® Re-collapsible Balloon Access System
SOLOPATH® Balloon Expandable TransFemoral System

30th April 2019

Dear Valued Customers,
Cc: Chairman Medical Board and relevant Head of Departments

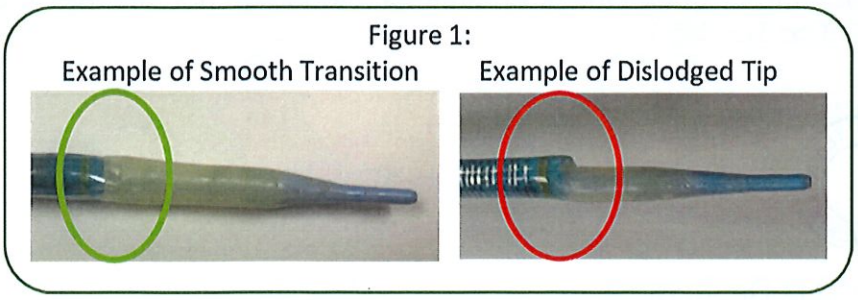
Terumo Singapore Pte Ltd is issuing this letter to inform a voluntarily recall on SOLOPATH® Balloon Expandable TransFemoral System and the SOLOPATH® Re-collapsible Balloon Access System.

Product Impacted by Recall:

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

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:



TERUMO SINGAPORE PTE. LTD.
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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.

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 suppliers. 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.

Advisory to Healthcare Professionals

1. Review this Product 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 SOLOPATH 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 to return.**

Reporting of Adverse Event

Healthcare professionals are advised to report any adverse events and/or suspected adverse reactions associated with these devices to Terumo Singapore Pte Ltd. Alternatively, healthcare professionals may report the adverse events to the Medical Device Branch, health Products Regulation Group, HSA at Tel: 6866 1048,or report online at www.hsa.gov.sg/ae_online. Events that are reported to Terumo Singapore Pte Ltd. will be investigated and subsequently reported to HSA.

If you have any further questions or comments, please do not hesitate to contact us at 6291 3606 (Office Tel. No.)

Yours Sincerely,

[redacted]

Joyce Soh
Regulatory Affairs Department

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