


## IN THIS SECTION



## Terumo Medical Corporation Recalls SOLOPATH® Balloon Expandable TransFemoral System and Re-Collapsible Balloon Access System Due to Dislodgement of the Fairing Tip from the Sheath

*The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death.*

### Recalled Product

- SOLOPATH® Balloon Expandable TransFemoral System and Re-Collapsible Balloon Access System
- All model and lot numbers are affected. (See full list of affected devices in Terumo recall notice (<http://www.terumomedical.com/news-and-events/news/2019/terumo-solopath-product-recall-letter.html>)  (<http://www.fda.gov/about-fda/website-policies/website-disclaimer>).)
- Manufacturing Dates: June 22, 2016 to January 30, 2019
- Distribution Dates: July 22, 2016 to March 13, 2019
- Devices Recalled in the U.S.: 3,474
- Date Initiated by Firm: April 26, 2019

### Device Use

The SoloPath Balloon Expandable TransFemoral Introducer System (STFI) and the SoloPath Re-Collapsible Access System (SR) are sterile, single use devices designed to help insert and guide placement of catheters or other medical devices from a blood vessel to the large arteries in a patient's thigh or hip (femoral or iliac artery). The devices are designed to help reduce friction during insertion and to minimize trauma throughout the procedure.



Figure 1. Examples of expected smooth (left) and dislodged (right) fairing tip.

## Reason for Recall

Terumo Medical Corporation is recalling the SOLOPATH® Balloon Expandable TransFemoral System and Re-Collapsible Balloon Access System due to a potential for the tip to dislodge from the outer rim 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.

Use of the affected devices could cause vessel tears (dissection), false lumen, blood between the two outer layers of an artery (pseudoaneurysm), hemorrhage, inability to transition through the skin to the iliac artery in the hip area, vessel perforation, and vessel disruption, which may result in additional medical intervention, increased procedure time, or death.

The firm has received a total of 14 reports of related incidents in which the device has malfunctioned in this manner, including two injuries. No deaths have been reported.

## Who May be Affected

- Patients who underwent surgical procedures involving the SOLOPATH® Balloon Expandable TransFemoral System and Re-Collapsible Balloon Access System
- Health care providers using the SOLOPATH® Balloon Expandable TransFemoral System and Re-Collapsible Balloon Access System

## What to Do

On April 30, 2019, Terumo sent customers a product discontinuance notification (<http://www.terumo.com/news-and-events/company-news/2019/terumo-solopath-product-discontinuance-notice.html>) [↗](http://www.fda.gov/about-fda/website-policies/website-disclaimer) (<http://www.fda.gov/about-fda/website-policies/website-disclaimer>) and a voluntary recall notice to customers (<http://www.terumo.com/news-and-events/company-news/2019/terumo-solopath-product-recall-letter.html>) [↗](http://www.fda.gov/about-fda/website-policies/website-disclaimer) (<http://www.fda.gov/about-fda/website-policies/website-disclaimer>), which listed the following actions:

- Review the Product Recall Bulletin and the Required Actions.
- Assure that all users receive notice of this issue so that required actions can be performed.

- Assure that this notice is forwarded to applicable facilities if any affected products were further distributed outside of your facility.
- Review your SOLOPATH inventory immediately to identify and isolate affected inventory to prevent future use.
- Complete the Medical Device Recall Response Form. **The form is required even if you do not have product to return.**
- If you have product to return, contact Stericycle to obtain a credit and reference event number 10082. Phone Number: 855-205-2627 E-Mail: return to [terumo10082@stericycle.com](mailto:terumo10082@stericycle.com) (<mailto:terumo10082@stericycle.com>).
- E-mail the Recall Acknowledgement Form to [terumo10082@stericycle.com](mailto:terumo10082@stericycle.com) (<mailto:terumo10082@stericycle.com>) to arrange for product to be returned to Stericycle.

Terumo encourages customers to consider alternative suppliers.

## Contact Information

For questions or concerns regarding this notification, please call Terumo at 1-800-888-3786.

## Full List of Affected 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

## Additional Resources

- Solopath Product Recall (<http://www.terumo.com/content/dam/terumo-www/global-shared/Solopath-Recall-Direct-Customer-Communication.pdf>) [↗](#)  
(<http://www.fda.gov/about-fda/website-policies/website-disclaimer>) (PDF)
- Solopath Product Discontinuation Notice  
([http://www.terumo.com/content/dam/terumo-www/global-shared/Solopath-Product-](http://www.terumo.com/content/dam/terumo-www/global-shared/Solopath-Product-Discontinuation-Notice.pdf)

Discontinuation-Notice.pdf) [↗ \(http://www.fda.gov/about-fda/website-policies/website-disclaimer\)](http://www.fda.gov/about-fda/website-policies/website-disclaimer) (PDF)

## How do I report a problem?

Health care professionals and consumers may report adverse reactions or quality problems they experience using these devices to [MedWatch: The FDA Safety Information and Adverse Event Reporting Program](https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting_home) ([https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting\\_home](https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting_home)) either online, by regular mail or by FAX to 1-800-FDA-0178.

## More Information

- Class 1 Device Recall SOLOPATH Balloon Expandable TransFemoral System (<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=172421>)
- Class 1 Device Recall SOLOPATH ReCollapsible Access System (<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=172422>)

