FDA alerts Class I recall, most serious type of recall

Posted by MJ On 05/31/2019

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 noticeExternal Link 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.
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 notificationExternal Link Disclaimer and a voluntary recall notice to customersExternal Link 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.

- E-mail the Recall Acknowledgement Form to 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.

Additional Resources
Solopath Product RecallExternal Link Disclaimer (PDF)
Solopath Product Discontinuation NoticeExternal Link 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 either online, by regular mail or by FAX to 1-800-FDA-0178.

More Information
Class 1 Device Recall SOLOPATH Balloon Expandable TransFemoral System
Class 1 Device Recall SOLOPATH ReCollapsible Access System