Sterilmed Reprocessed Agilis Steerable Introducer Sheath recalled due to improper seal of the sheath hub

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

- Name: Sterilmed Reprocessed Agilis Steerable Introducer Sheath
- Product codes: PNE
- Model numbers and lot numbers: STJ408309, STJ408310, STJG408324; All product lots
- Manufacturing and Distribution Dates: January 1, 2017 to May 5, 2017
- Number of Affected Devices: 112

Device Use

The Agilis Steerable Introducer Sheath is used to insert and position various cardiovascular catheters in the heart, including on the left side of the heart through the wall of tissue that separates the right and left chambers of the heart (interatrial septum).

Reason for Recall

The Agilis Steerable Introducer Sheath's hemostatic valve, which prevents blood from flowing back through the valve, may fail due to an improper seal of the sheath hub. Improper seals can allow blood to leak through the hub, cause the cap to fall off during the procedure, or can create a difference in pressure that allows air into the circulatory system (air embolism).

The improper seal occurs when not enough glue is used to reattach the cap to the hub after reprocessing. Too much glue can also block the sheath valve and make the device unusable.

The use of affected products may cause serious health consequences for patients, including death.

Who May be Affected

Hospital clinicians using these devices for cardiac catheterization procedures.

Patients undergoing cardiac catheterization procedures. Patients with a lower body mass index (BMI) may be more at risk if blood loss occurs. Smaller patients and patients with pre-existing decreased pulmonary reserve may be more susceptible to air embolism.

What to Do

Sterilmed has provided the following instructions for health care facilities and providers:

- Examine inventory immediately to determine if you have this product.
- Do not use any of the affected products, and return any unused product to the company.
- Share this information with the appropriate staff at your facility.
- Continue to monitor patients treated with the Sterilmed Reprocessed Agilis Steerable Introducer Sheath as normal.

Contact Information

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Date Recall Initiated

June 12, 2017

How do I report a problem?

Health care professionals and consumers may report adverse reactions or quality problems they experienced using these devices to **MedWatch: The FDA Safety Information and Adverse Event Reporting Program (https://www.accessdata.fda.gov/scripts/medwatch/)** either online, by regular mail or by fax at 1-800-FDA-0178.

More in Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/default.htm)

2018 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm590900.htm)

2017 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm535289.htm)

2016 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm480134.htm)