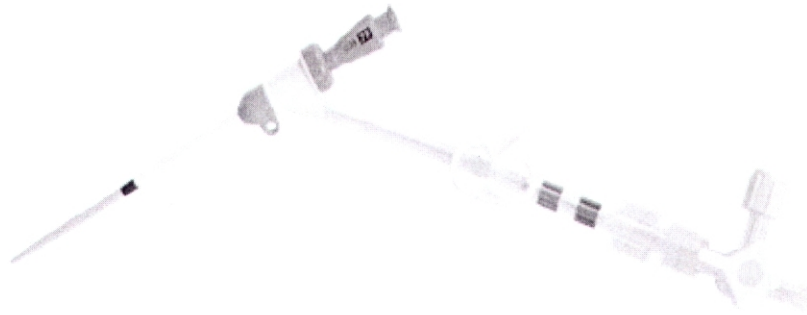


# Merit Medical Systems, Inc. Recalls the Prelude® Short Sheath Introducer - Sheath May Separate During Use

*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: Merit 7F Prelude® Short Sheath Introducers
- Lot Numbers: H1041469, H1041473, H1036880, H1041464
- Catalog Numbers: K15-00070, K15-00170, PSS-7F-4-035MT, PSS-7F-4MT
- Manufacturing Dates: November 23, 2016 to November 30, 2016
- Distribution Dates: December 15, 2016 to January 18, 2017
- Devices Recalled in the U.S.: 1,265 units



## Device Use

The Merit Prelude® Short Sheath Introducer is used to guide the placement of [catheters](https://en.wikipedia.org/wiki/Catheter) (<https://en.wikipedia.org/wiki/Catheter>), grafts, and other medical devices into the veins and arteries. The device is also used during temporary hemodialysis, a treatment for kidney failure.

## Reason for Recall

Merit Medical Systems Inc. is recalling the Prelude® Short Sheath Introducer due to a manufacturing defect which may cause the tip to separate from the sheath during the insertion procedure. If this occurs, the tip could enter the patient's bloodstream. This may result in prolonged procedure times, additional surgery to remove the tip from the patient, blood clots, internal tears and perforation to arteries or veins, excessive bleeding, and death.

## Who May be Affected

- Health care providers using the Prelude® Short Sheath Introducer
- All patients undergoing procedures involving these sheaths

## What to Do

On February 16, 2017, Merit Medical Inc. sent an Urgent Product Recall Notice to affected customers. The notice also asked customers to:

- Ensure appropriate staff is aware of the notice.
- Quarantine any affected products and discontinue use.
- Complete the Customer Response Form attached to the notice and return by email at [response@merit.com \(mailto:response@merit.com\)](mailto:response@merit.com).
- Return all affected lots in possession to Merit Medical Inc. per the instructions found in the Customer Response Form.

## Contact Information

Customers are instructed to contact their Merit Sales Representative or Merit Customer Service by telephone at 801.208.4381 with any questions related to this recall.

## Date Recall Initiated

February 16, 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/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 in [Medical Device Recalls](/MedicalDevices/Safety/ListofRecalls/default.htm)  
(</MedicalDevices/Safety/ListofRecalls/default.htm>)

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

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