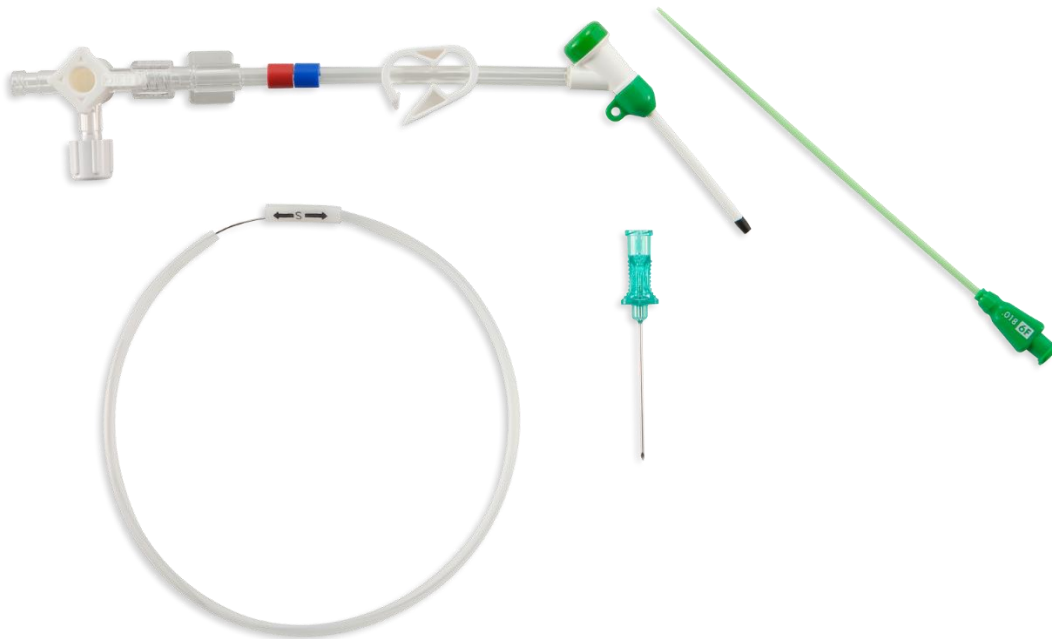


FSCA Ref: 1721504-07/07/21-007R

Date: DD-MMM-YYYY

## **URGENT FIELD SAFETY NOTICE (FSN)**

**Name of Affected Products:** Prelude® Short Sheath Introducer



### **Action Required:** Return Device(s) to Merit

Merit Medical Systems, Inc. is voluntarily conducting a recall of the Prelude® Short Sheath Introducer due to the inclusion of an incorrect dilator. This affects catalog number PSS-6F-4-018MT, lot H2069291. This catalog number should include a 6F dilator compatible with a 0.018" (0.46mm) guidewire; however, a 6F dilator compatible with a 0.038" (0.97mm) guidewire was incorrectly included in the affected lot. Use of the affected product may result in a delay of the procedure while actions are taken to compensate for the incorrect dilator.

Merit has not received any reports of patient harm or injury relating to this issue; however, Merit has received complaints relating to this issue. As of 28-JUN-2021, Merit has received 12 complaints. Merit has chosen to remove the units from the market and requests that you immediately stop using or distributing the affected lot and return the units to Merit.

**\*Note:** The relevant National Competent Authorities will be notified of this Field Safety Corrective Action (FSCA).

**Actions required of you:**

1. Please immediately determine if any of the devices identified in the attached Customer Response Form (CRF) are within your facility, quarantine them, and discontinue use and distribution.
2. Ensure that applicable personnel within your organization are made aware of this field action.
3. If the product has been further distributed to other facilities, institutions, or manufacturers, please ensure this notice is immediately shared with them and note the quantity distributed on the CRF. Additional distribution details may be required by health authorities.
4. Please fill out, scan, and email the completed CRF to Customer Service at [RESPONSE-EMEA@merit.com](mailto:RESPONSE-EMEA@merit.com) within 10 business days. All affected product shipped to you must be accounted for on the CRF.
5. Please immediately return all affected lots in your possession to Merit, per the instructions in the attached CRF.

If you have any questions concerning this communication, please don't hesitate to contact your Merit Sales Representative or Merit Customer Service at [+31 – 43 3588233](tel:+31-43-3588233).

Merit Medical is committed to providing high quality products to you and apologizes for any inconvenience this field action may cause.

Enclosure(s)