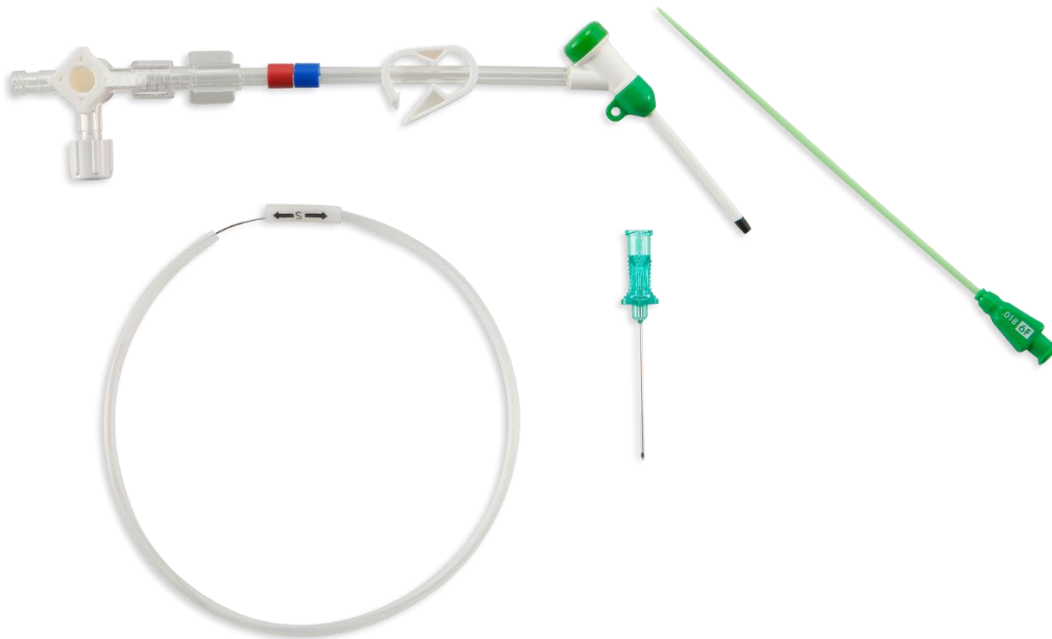


FSCA Ref: 1721504-07/07/21-007R

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 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)



Customer Response Form

Merit Medical Systems, Inc.

Merit Sales Rep: XXXXXXXXXXXXX

Affected Product: Prelude® Short Sheath Introducer

Customer Name Ship to Address Customer Number: XXX	Customer Contact:
	Title:
	Phone Number:
	RMA #: XXXXX

Please provide status on the following:

Lot #	Part #	Qty Merit Shipped to You	Qty You Further Distributed	Qty Used	Qty Unused and Being Returned

Please fill out and sign this Customer Response Form and complete the following steps. Merit may contact you regarding incomplete information. It is very important that you complete these steps in order to assist Merit in complying with applicable government regulations.

1. Scan and email the completed Customer Response Form to Merit Customer Service at RESPONSE-EMEA@merit.com within 10 days.
2. If you are returning product, place the original completed form with the products to be returned. This form must accompany all products being returned to Merit.

Product Return Instructions

Return the affected products to Merit via UPS Standard Account 7619AE; include the assigned RMA number (see above table) on the outside of the box and ship to:

ATTN: Receiving & Customer Service
Merit Medical Systems, Inc.
Amerikalaan 42, 6199 AE
Maastricht Airport, The Netherlands
RMA# (found in contact information table)

If you have further questions, please contact Merit Customer Service at XXX or by phone at XXX.

I certify that I received and understood this notice. I certify that the above listed products have been used, distributed, or returned to Merit Medical Systems, Inc. according to the notification instructions. Furthermore, if I have further distributed product listed on this form, I certify that a copy of this notice was provided to said consignee(s).

Signature of Customer Contact

Date