

URGENT MEDICAL DEVICE RECALL NOTICE

Name of Affected Products: Workstation Sheath and Dilator: Surfacer® Inside-Out® Access Catheter System

Action Required: Destroy at Point of Use

Purpose:

Merit Medical Systems, Inc. (Merit) is conducting a voluntary recall of the **Workstation Sheath and Dilator** due to the radiopaque tip of the sheath detaching. To date, 4 (four) product complaints have been reported; 2 (two) of these product complaints were adverse events. Merit requests that you immediately discontinue use of the **Workstation Sheath and Dilator** and remove these two components from the point of use and properly dispose of them.

The remaining components of the Surfacer® Inside-Out® Access Catheter System, including the Surfacer Device, two Exit Targets, and the Exit (Peelable) Introducer, may continue to be used with one of the alternative sheath products identified below in **Table 1**.

Manufacture	Product Name	Catalog Codes
Merit Medical	Prelude Roadster	PG7F65SX
Terumo	PINNACLE DESTINATION Guiding Sheath	RSP02 / RSP04, 7F x 65 cm
Additional guide sheaths may be considered acceptable for use with the Surfacer Device when deemed appropriate, provided they have a minimum internal diameter between 0.098 – 0.102 inches and a length of 65 cm.		

Table 1. Alternative Sheath Products

Warning #8 in the Surfacer Device IFU states, in relevant part:

“The Surfacer Device should only be inserted through the recommended Workstation Sheath to avoid damage to the patient or the device during its use.”

Merit requests that customers disregard this warning and proceed with using the replacement products identified in **Table 1** above.

Risk to Health:

Merit has received customer complaints related the radiopaque tip of the sheath detaching. Separation of the sheath introducer tip may result in vascular foreign body, additional procedure, thrombosis, hemorrhage, and soft tissue injuries.

Affected product table:

Catalog Code	GTIN	Product Description	Lot Number
600200/C	00884450762158	Surfacer® Inside-Out® Access Catheter System.Merit Medical.ETO.	3404290000
			3404290000R
			3405380000
			3405380000R
			3405410000R
			3405410000R1
			3409530000
			3414970000
			3416110000
			3417220000
			3434780000
600200/F	00884450762158	Surfacer® Inside-Out® Access Catheter System.Merit Medical.ETO.	H3410062
			H3561463

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.
2. Please place this notice near affected inventory and use **Image A** below to identify the **Workstation Sheath and Dilator**.

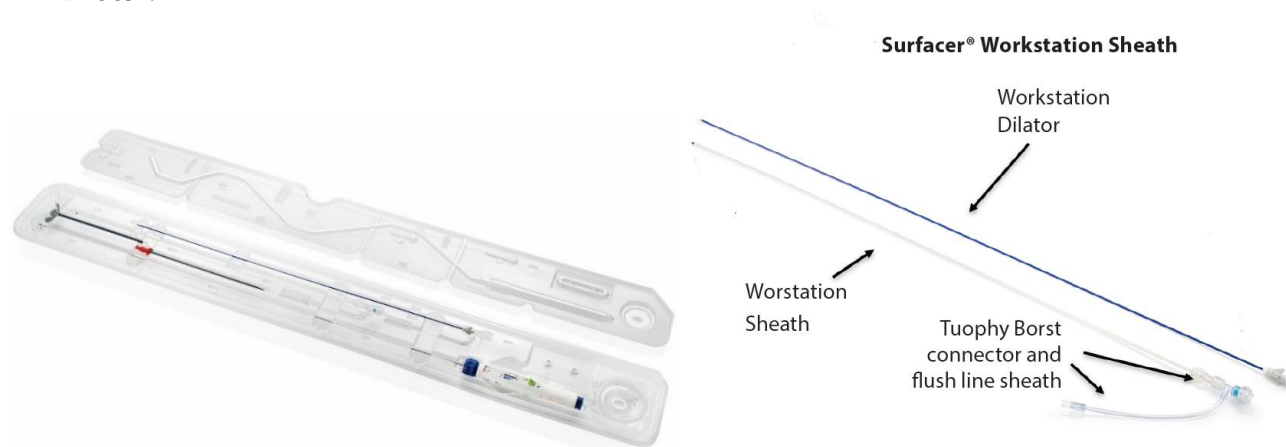


Image A: Surfacer Workstation Sheath and Dilator

3. In addition to placing this notice near the affected Merit product, you also need to place the labels we provided in this mailing on the kits to ensure awareness of the recall. See **Image B** below.

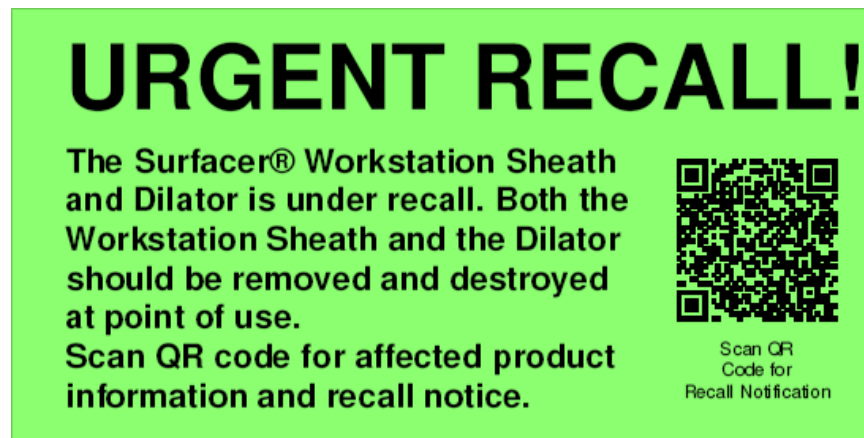


Image B: Surfacr recall label

- a. Using the label shown in **Image B**, apply one label to the exterior of each affected product packaging pouch and one label to the exterior of the corresponding carton.
- b. Place each label on a clean, dry, flat surface where it is clearly visible, without covering the product identification, lot number, expiration date, or other required labeling.
- c. Press the entire label firmly to ensure it is securely attached. See **Image C** below for suggested placement.
- d. If the quantity of provided labels is insufficient for your applicable inventory, please contact RESPONSE@merit.com for additional labels.



Image C: Label Placement

4. Please immediately discontinue the use of the Workstation Sheath and Dilator: destroy the components at the point of use. Only the Workstation Sheath and Dilator should be destroyed at the point of use; the rest of the finished good components remain safe for clinical use.

a. NOTE: The Workstation sheath and Dilator are sealed within the sterile barrier and cannot be removed or destroyed at the inventory level. Opening the unit packaging would compromise the sterility of the remaining components and therefore should occur at the point of use.

5. Ensure that applicable personnel within your organization are made aware of this field action.
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.
6. Please fill out, scan and email the completed Customer Response Form to Customer Service at RESPONSE@merit.com within 10 business days. All affected product shipped to you must be accounted for on the CRF.
7. If requesting alternative standalone Roadster Guide Sheath and dilator to support kits, please use Product code: **PG7F65SX** and contact RESPONSE@merit.com, along with the completed Customer Response Form.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, or by fax.

Web: MedWatch website at www.fda.gov/medwatch

Phone: 1-800-FDA-1088 (1-800-332-1088)

Mail: MedWatch, HF-2, FDA, 5600 Fisher's Lane, Rockville, MD 20852-9787

If you have any questions concerning this communication, please don't hesitate to contact your Merit Sales Representative or Merit Customer Service via email at RESPONSE@merit.com or via phone at +1 800 356 3748 | Hours: 6 am to 6 pm MST | Mon-Fri.

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

Enclosure(s)