

URGENT MEDICAL DEVICE RECALL NOTICE

Name of Affected Products: Centros® & CentrosFLO® Hemodialysis Catheters, ProGuide™ Chronic Dialysis Catheters, DuraMax® Chronic Hemodialysis Catheter, The BioFlo DuraMax® Hemodialysis catheter, and 16F Dual Valved Splittable Sheath Introducer (bulk, non-sterile): 16F Dual-Valved Splittable Sheath Introducer

Action Required: Destroy at Point of Use

Revised Notice: The initial notice was issued on February 12, 2026 with a supplemental notice on February 27, 2026.

Merit Medical Systems, Inc. (Merit) is conducting a voluntary recall of the Merit 16F Dual-Valved Splittable Sheath Introducer due to a design defect. Specifically, the sheath introducer may not split as intended. This sheath introducer is used in several Merit finished devices, a complete list of affected products and lots can be found in the table attached or can be accessed at "<https://www.merit.com/products/documents/product-notices/16FDualValvedSheath-recall/>".

Merit has received customer complaints regarding this issue, some of which involve patient injury. Failure of the sheath introducer to split as intended may result in hemorrhage, foreign bodies, and procedure delay, embolization/thrombosis, impaired catheter function, loss of vessel for future vascular access.

Merit is requesting that you immediately discontinue the use of the 16F Dual-Valved Splittable Sheath Introducer and destroy the sheath introducer at point of use. The other products included with the sheath introducer may continue to be used.

Actions required of you:

- a. Please immediately determine if any of the devices identified in the attached Customer Response Form (CRF) are within your facility.
- b. A picture of the 16F Dual-Valved Splittable Sheath Introducer is attached to help you identify the product. Please place this notice and the picture near the affected Merit product in your inventory (if applicable).



- c. In addition to placing this notice near the affected Merit product, you also need to place the stickers we provided in this mailing on the kits to ensure awareness of the recall. If the quantity of provided stickers is insufficient for your applicable inventory, please contact RESPONSE@merit.com for additional stickers.
- d. Please immediately discontinue the use of the 16F Dual-Valved Splittable Sheath Introducer and destroy the sheath introducer at the point of use. Only the 16F Dual-Valved Splittable Sheath

Introducer component should be discarded at the point of use; the rest of the finished good components remain safe for clinical use.

- a. Note: The introducer is 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.
- e. Ensure that applicable personnel within your organization are made aware of this field action.
- f. 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.
- g. 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.
- h. If requesting alternative standalone single valve sheaths to support kits, please use Product code: DCVP1600, and contact RESPONSE@merit.com, along with the completed Customer Response Form.
- i. In addition to Merit Medical's product offering, other products which may suit your clinical use are:
 - a. **BD** – GlidePath™ tunneled dialysis catheters
 - b. **Mozarc Medical** – Palindrome™ tunneled dialysis catheters offerings
 - c. **Medcomp** – Tunneled / chronic hemodialysis catheter kits
 - d. **Medcomp** - MCVS116: Valved Peelable Introducer

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 at www.fda.gov/medwatch, by regular mail, or by fax.

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)