UNDERSTAND. INNOVATE. DELIVER.

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URGENT FIELD SAFETY NOTICE (FSN)
16F Dual-Valved Splittable Sheath Introducer
-Component in Centros® Hemodialysis Catheters and BioFlo DuraMax® hemodialysis catheter

	1. Information on Affected Devices*
1.	1. Device Type(s)*
	Sterile, 16F Dual valved, splittable sheath introducer and dilator assembly. This device is a component in Merit Medical's Centros® Hemodialysis Catheters and BioFlo DuraMax® hemodialysis catheter finished goods and is not supplied as a standalone device.
1.	2. Commercial name(s)
	16F Dual-Valved Splittable Sheath Introducer: Centros® Hemodialysis Catheters and BioFlo DuraMax® hemodialysis catheter
1.	3. Primary clinical purpose of device(s)*
	The 16F Dual Valved Splittable Sheath Introducer is intended to provide percutaneous access to the vascular system for the purpose of delivering various types of catheters.
1.	4. Device Model/Catalogue/part number(s)*
	See attached affected lots table.

	2 Reason for Field Safety Corrective Action (FSCA)*
2.	1. Description of the product problem*
	In some cases, the splittable sheath introducers may not separate or “split” as intended, due to insufficient scoring of the sheath material.
2.	2. Hazard giving rise to the FSCA*
	Failure of the sheath to split as intended may result in hemorrhage, foreign bodies, and procedure delay.
2.	3. Probability of problem arising
	The Likelihood of the “Failure to split” defect occurring is 1/1675.087.
2.	4. Predicted risk to patient/users
	Failure of the sheath to split as intended may result in hemorrhage, foreign bodies, and procedure delay.

	3. Type of Action to mitigate the risk*
3.	**1. Action To Be Taken by the User***

☐ Identify Device ☐ Quarantine Device ☐ Return Device ☒ Destroy Device

☐ On-site device modification/inspection

☐ Follow patient management recommendations

☐ Take note of amendment/reinforcement of Instructions For Use (IFU)

☒ Other ☐ None

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. 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 on or near the affected Merit product in your inventory (if applicable).

3. 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.
4. Ensure that applicable personnel within your organization are made aware of this field action.
5. 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-EMEA@merit.com within 10 business days. All affected product shipped to you must be accounted for on the CRF.		
3.	2. By when should the action be completed?	Immediately, upon use of the kit	
3.	3. Is customer Reply Required? * (If yes, form attached specifying deadline for return)		Yes

	4. General Information*	
4.	1. FSN Type*	New
4.	2. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	3. List of attachments/appendices:	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/

	Transmission of this Field Safety Notice
	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.