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FSCA-ref: 1721504-03/01/22-002R

0X-MAR-2022

URGENT FIELD SAFETY NOTICE (FSN)

Name of Affected Products: Access-9™ and AccessPLUS™ Hemostasis Valves

Action Required: Return Devices to Merit

Merit Medical Systems, Inc. is voluntarily conducting a recall of the Access-9™ and AccessPLUS™ Hemostasis Valves due to a defect which is the result of a recent design change made to improve manufacturability. Access Hemostasis Valves manufactured after implementation of this change have an internal gap between the rotator and the Y-body where the guidewire can get caught, resulting in difficulty advancing the guidewire through the device (Figure 1). This recall affects 120 Merit lots and 61 Merit catalog numbers, as identified in the attached table.

This issue is unlikely to cause harm to the patient and does not result in additional risk to the patient or user. Additionally, the defect does not appear to affect the safety or performance of the device when used as intended but the potential of kinking or damaging the wire remains a possibility if the wire meets resistance and is advanced with extra manipulation or effort. This defect may result in a delay of procedure.

Merit has not received any reports of patient harm or injury relating to this issue; however, as of the date of this letter, Merit has received 17 customer complaints relating to this issue. Merit has chosen to remove these units from the market and requests that you immediately stop using or distributing the affected lots and return the units to Merit. Our records indicate you have received affected lots, as identified in the attached Customer Response Form.

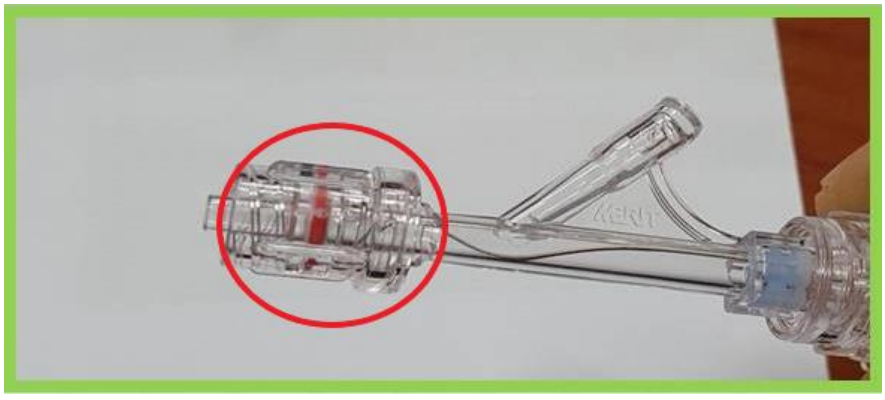

Figure 1.

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 seven (7) calendar 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.

Note, the relevant National Competent Authorities have been advised of this field safety corrective action.

If you have any questions concerning this communication, please don't hesitate to contact your Merit Sales Representative or Merit Customer Service at RESPONSE-EMEA@merit.com or by phone at 0031 – 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)