

**URGENT MEDICAL DEVICE RECALL NOTICE****Name of Affected Products:** 10Fore™ Hemostasis Valve**Action Required:** Return Device(s) to Merit

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Merit Medical Systems, Inc. is voluntarily conducting a recall of the 10Fore™ Hemostasis Valve due to a manufacturing defect. Specifically, the o-ring between the y-body and the rotator may be damaged during assembly and a portion of the o-ring may remain loose or detach. Use of the affected product may result in a foreign body in the fluid path. This affects all lots distributed to date, as identified in the table below.

Merit has not received any complaints or reports of patient harm or injury relating to this issue. Merit has chosen to remove the units from the market and requests that you immediately stop using or distributing the affected lots and return the units to Merit.

CATALOG ITEM	LOT NUMBER
MAPTEN4	H3098831
	H3111155
	H3152503
	H3155611
	H3186901
MAPTEN42	H3076189
	H3111156
	H3152504
	H3155614
	H3173674
MAPTEN452	H3098829
	H3111162

**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 Customer Response Form to Customer Service at [response@merit.com](mailto:response@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.

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.

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](mailto: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)