

URGENT MEDICAL DEVICE RECALL NOTICE

Name of Affected Products: HP9 Tubing

Action Required: Return Device(s) to Merit

Merit Medical Systems, Inc. is voluntarily conducting a recall of specific lots of its High Pressure Tubing due to a manufacturing defect. Specifically, the tubing may relax over time causing it to partially separate from the connector resulting in a void that can trap air in the line. Use of the affected product may result in the trapped air being introduced into the patient. This issue impacts the lot numbers identified in the affected lots table attached.

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.

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 within 7 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 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)

Affected Lots Table

HP9 Tubing

CATALOG_ITEM	LOT_NUMBER
502211002	I3116954
HP9720E/C	I3116059
	I3127321
	I3137220
	I3116060
HP9721E/C	I3116060
K04-00417	I3114667
	I3147550
K04-00963	H3117053
	H3138590
	H3154108
	H3154786
	H3162244
	H3166789
	H3173526
	H3117059
K04-01029	H3154112
	H3159017
	H3166777
	H3181994
	H3111528
K09-02239C	H3157165
	H3116232
K09-02249UP	H3156392
	H3173422
	H3178693
	H3190348
	H3195871
	H3205105
	H3163891
	H3169190
K09-09110B	H3163891
K09-10294A	H3169190
K09-11227A	H3156393
	H3157208
K09-11456B	H3112605
	H3156272
K09-12123B	H3167049
K09-13342AP	H3119448
	H3127766
	H3152497
	H3152498
	H3157249
	H3170462
	H3196372
	H3205117

CATALOG_ITEM	LOT_NUMBER
K09-13391BP	H3128003
	H3152494
	H3170418
	H3173459
	H3184951
	H3190567
K09-13548	H3156627
K09-14000A	H3125122
	H3136598
K09T-12020D	T3147714
	T3163752
K09T-12275B	T3186397
K10-00353K	H3127803
	H3166061
	H3172299
K10-01603C	H3163984
	H3176777
K10-01694Q	H3116890
	H3152493
	H3177622
K10-05159B	H3116922
	H3119571
	H3127907
	H3152490
	H3152491
	H3152492
K10-05743	H3122012
	H3128429
	H3177446
K10-05825AP	H3112585