

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

Merit Medical Systems, Inc. is voluntarily conducting a recall of the PhD Hemostasis Valve™ due to a manufacturing defect. When used, the valve cap may remain depressed, leading to potential leakage. Use of this product may result in procedure inconvenience and/or hemorrhage. This affects the lots identified in the attached table.

Merit has not received any reports of patient harm or injury relating to this issue; however, Merit has received 113 complaints 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
PhD Hemostasis Valve

CATALOG ITEM	LOT NUMBER
IN7802/C	H3143753
	H3162387
	H3183068
	H3189446
	H3213617
IN9802	H3141573
	H3183200
IN9802/A	H3200469
	H3210336
IN4802/K	I3138883
	I3150031
	I3161209
	I3161210
	I3161211
	I3172451
	I3135188
IN4802/T	I3170171
	I3146050
IN4918/A	I3200779
	I3200779
IN7802/C	H3183068
MAP800/B	I3206933
	I3209939
	I3219792
	I3234557
MAP800/T	I3162931
MAP801/B	I3146099
MAP802/B	I3118322
	I3118324
	I3129725
	I3150110
	I3162942
MAP804/B	I3219785
	I3219785
	I3219785
	I3219785
	I3219785
MAP800/B	I3124454
	I3174736
	I3186951
	I3191334
	I3206933
	I3209939
	I3219784
	I3219792
	I3234557
	I3234558

CATALOG ITEM	LOT NUMBER
MAP800/T	I3162929
	I3162931
	I3186954
	I3186961
MAP801/B	I3146099
	I3186946
MAP802/B	I3209937
	I3118322
	I3118324
	I3129725
	I3129726
	I3150110
	I3150111
	I3162940
	I3162942
	I3174729
	I3174730
	I3192937
	I3200996
	I3209935
	I3215925
	I3215926
	I3215928
	I3219783
	I3219785
	I3219786
	I3230013
MAP802/CNB	I3174740
MAP802/T	I3162943
	I3192650
MAP804/B	I3192654
	I3146101
MAP852/B	I3161426
	I3187883

CATALOG ITEM	LOT NUMBER
SKY1802	H3079946
	H3141576
	H3141577
	H3149507
	H3149508
	H3155575
	H3155576
	H3155577
	H3155578
	H3168264
	H3168265
	H3182996
	H3183206
	H3183207
SKY1802	H3189428
	H3189451
	H3200416
SKY1802	H3200475
	H3219111
	H3219111
K12T-10798A	H3168264
	H3183206
K05-02166B	H3189451
	T3163727
K05-02166B	T3217266
	T3192808
	T3198985
	T3201276
IN8802/C	T3217490
	T3232335
	H3141570
	H3143769
	H3143770
	H3143771
	H3143772
	H3149478
	H3149480
	H3149483
	H3155549
	H3162422
	H3162627
	H3168247
	H3183054
	H3200495
	H3219087
	H3241812

Dear Merit Customer,

We appreciate your business and take great pride in helping you care for your patients, delivering the products you need, when you need them. With the recall of the PhD™ Hemostasis Valve, we understand how this interruption can affect your patient care. We anticipate a temporary supply shortage and intermittent unavailability of these products. To assist you during this time, please refer to the table below for impacted product codes and suggested alternatives as needed.

Hemostasis Valve Kits

PhD Product Code	Honor™ Alternative	MBA™ Alternative	AccessPLUS™ Alternative
MAP800	MAP300	MAP400	MAP150
MAP801	MAP301	—	MAP151
MAP802	MAP302	MAP403	MAP152
MAP804	—	—	MAP154
MAP850	MAP350	MAP450	—
MAP852	MAP352	MAP453	—

Inflation and Hemostasis Valve Kits

PhD Product Code	Honor Alternative	AccessPlus Alternative	Inflation Device Only Alternative
IN4802	IN4330	IN4530	IN4130
IN7802	IN7352	IN7152	IN7130
IN8802	IN8302	IN8152	IN8130
IN9802	IN9302	IN9152	IN9135
SKY1802	SKY1302	SKY1152	SKY1130

Alternative product codes may not be available in every country. Please contact your Merit Sales Representative to determine availability.

The following impacted product codes are custom offerings and do not have direct alternatives. Please contact your Merit Sales Representative for help finding a suitable alternative.

IN4918
K05-02166B
K05T-02138A
K12T-10798A

If you have any questions, please do not hesitate to contact your local Merit Sales Representative.

We look forward to continuing to serve you.