Understand. Innovate. Deliver.™

1600 West Merit Parkway
South Jordan, UT 84095 USA
PHONE 801.253.1600
FAX 801.253.1688
merit.com

URGENT FIELD SAFETY NOTICE (FSN)

Name of Affected Products: DTX Safedraw® Kits and Meritrans DTXPlus® Devices

Action Required: Return Device(s) to Merit

Merit Medical Systems, Inc. is voluntarily conducting a recall of specific lots of DTX Safedraw® Kits and Meritrans DTXPlus® devices due to the potential for the bond between the drip chamber and the tubing to separate. Merit has received complaints from the field indicating that the tubing has separated from the drip chamber.

This failure may result in complications ranging from user dissatisfaction, a delay in procedure, or (in the case of an infant) blood loss. If separation occurs, fluid administration is interrupted, and blood may flow from the patient into the tubing. However, the risk of blood loss is very low as one configuration of the product has a transducer with an integrated flush device between the drip chamber and the patient, which maintains a very low flow rate (3mL/hr.) in either direction (blood out or saline in). The other, less common, configuration of the product has the drip chamber assembled within a manifold system. There is no risk of blood loss with the manifold system configuration as manifolds are used in the presence of a clinician who would notice if separation of the bond occurred. Merit has not received any reports of patient harm or injury as a result of this issue.

Merit has identified the affected lots and catalog numbers as detailed in the table below. Merit has chosen to remove the affected units from the market and requests that you immediately stop using the affected lots and return them to Merit.

Catalog Numbers	Lot Numbers		Catalog Numbers	Lot Numbers		Catalog Numbers	Lot Numbers
686164	C1312287		688627	C1308939		689153	512157
				C1321046			604273
686758	C1349808			C1353808			603238
	C1325434			C1329677			601016
	C1349807			C1363116			507686
	C1361514			C1392339			510600
	C1479895			C1446782			511599
	C1498221			C1399281			C1304789

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	C1512192			C1441251			C1478322
	C1527613			C1477276			C1537074
	C1555329			C1489868		689154	512158
	C1581292			C1502077			507687
	C1544085			C1544081			510601
687514	C1379976			C1531887			601677
687915	C1313306			C1560021			602411
	C1257621		688791	C1508913			604426
	C1286100			C1541515			611142
	C1263971		688929	C1581276			702186
	C1329675			C1321129			703566
	C1294738			C1349728			612300
	C1356140		689056	C1440455			7070427
	C1370481			C1353077			705528
	C1391523			C1396815			507688
688626	C1399273			C1643132		689155	510602
	C1453256		689057	C1330602			511601
	C1476569			C1330603			512678
	C1487010			C1349730			610378
	C1504368		689069	C1379919			C1206772
	C1518877			C1394593			C1209155
	C1531061			C1401756			C1326296
	C1554075			C1446687			C1353065
	C1560082		689095	C1515402			C1560014
	507685			507684		689156	507689
	510599			510598		689158	507691
	510606		689151	601011		689462	C1551880
	512365			601014		689464	C1564214
689152	601012			601696		689603	C1641609
	512156						
	601015						
	602412						
	604147						

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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 10 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, via UPS Standard Account 7619AE. Please include a copy of the CRF with the returning product, reference the assigned RMA number on the outside of the box (see CRF), and ship to:

Merit Medical, Customer Service, Amerikalaan 42, 6199 AE Maastricht Airport, The Netherlands

The Health Products Regulatory Authority (HPRA) has been notified of this Field Safety Corrective Action (FSCA).

If you have any questions concerning this communication, please don't hesitate to contact your Merit Sales Representative or Merit Customer Service at XXXX.

Merit Medical is committed to providing high quality products to you and apologizes for any inconvenience this field action may cause.

Enclosure(s)