

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			C1308939			512157
686758	C1349808		688627	C1321046		689153	604273
	C1325434			C1353808			603238
	C1349807			C1329677			601016
	C1361514			C1363116			507686
	C1479895			C1392339			510600
	C1498221			C1446782			511599
	C1512192			C1399281			C1304789

686758	C1527613	688627	C1441251	689153	C1478322	
	C1555329		C1477276		C1537074	
	C1581292		C1489868		512158	
	C1544085		C1502077		507687	
687514	C1379976	688791	C1544081	689154	510601	
687915	C1313306		C1531887		601677	
688626	C1257621	688929	C1560021	689155	602411	
	C1286100		C1508913		604426	
	C1263971	689056	C1541515		611142	
	C1329675		C1581276		702186	
	C1294738	689057	C1321129		703566	
	C1356140		C1349728		612300	
	C1370481		C1440455		7070427	
	C1391523		C1353077		705528	
	C1399273		C1396815		507688	
	C1453256		C1643132		510602	
	C1476569		689069		C1330602	511601
	C1487010				C1330603	512678
	C1504368	C1349730			610378	
	C1518877	C1379919			C1206772	
	C1531061	C1394593	C1209155			
	C1554075	C1401756	C1326296			
C1560082	C1446687	C1353065				
689152	507685	689095	C1515402	689603	C1560014	
	510599	689151	507684		689156	507689
	510606		510598		689158	507691
	512365		601011		689462	C1551880
	601012		601014		689464	C1564214
	512156		601696		689603	C1641609
	601015					
	602412					
604147						

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)