

FSCA-ref: 1721504-11/02/23-005R

07-NOV-2023

URGENT FIELD SAFETY NOTICE (FSN)

Name of Affected Products: Merit Maestro™ Microcatheter, Merit Pursue™ Microcatheter, and Fountain® Infusion Systems

Action Required: Return Device(s) to Merit

Merit Medical Systems, Inc. is voluntarily conducting a recall of specific Merit Maestro™ Microcatheter, Merit Pursue™ Microcatheter, and Fountain® Infusion System lots due to a supplier packaging defect. Specifically, the gold foil pouch holding the catheter may contain a small hole along the pouch seal. This hole may impact the sterility of the device. This defect affects the lots and part numbers identified in the attached table. Merit has not received any reports of patient harm/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 CRF to Customer Service at RESPONSE-EMEA@merit.com within seven (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.

Note, the relevant National Competent Authorities have been advised of this field action.

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

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

Merit Maestro™ Microcatheter, Merit Pursue™ Microcatheter, and Fountain® Infusion System

Merit Maestro™ Microcatheter	
Catalog Code	Lot Number
28MC2111045/B	H2775120
28MC21110ST/B	H2750697
	H2775121
28MC2113045/B	H2750699
	H2763805
	H2775122
28MC21130SN/CNB	H2747446
28MC21130ST/B	H2750708
28MC2115045/B	H2750484
28MC2115045/C	H2750714
28MC21150SN/B	H2750715
	H2769214
28MC21150ST/B	H2750719
28MC2411045/D	H2750721
	H2769962
28MC24110SN/D	H2750518
28MC24110ST/D	H2750733
28MC2413045/D	H2766010
28MC24130SN/F	H2750372
28MC24130ST/D	H2750747
	H2779460
28MC24130ST-W/A	H2777603
28MC2415045/D	H2750756
	H2766011
	H2769993
28MC24150ST/D	H2750768
28MC24150ST/F	H2749681
28MC28110ST/D	H2770003
28MC2813045/D	H2770016
28MC28130SN/D	H2770029
	H2785162
28MC28130SN/F	H2750378
28MC28130ST/D	H2752481
	H2766013

Merit Maestro™ Microcatheter	
Catalog Code	Lot Number
28MC28150SN/D	H2756905
	H2765969
28MC28150SN/F	H2750387
29MC2911045/D	H2758290
29MC29130SN/F	H2750390
29MC29130ST/D	H2750599
29MC29150ST/CNB	H2756603
29MC29150ST/D	H2749336
	H2765976
	H2770087

Merit Pursue™ Microcatheter	
Catalog Code	Lot Number
28HC17130SN	H2769793
28HC17150ST/A	H2767389
29HC2015045/A	H2750582
29HC20150SN/A	H2750587
29HC20150ST	H2765980

Fountain® Infusion Systems	
Catalog Code	Lot Number
IS4-135-30	H2765720
IS4-90-10	H2765603