

**URGENT FIELD SAFETY NOTICE (FSN)****Name of Affected Products:** Peritoneal Dialysis Catheter**Field Safety Corrective Action (FSCA) Identifier:** 1721504-09/19/17-004R**Action Required:** Return Affected Device(s) to Merit

25 September 2017

**ATTENTION:** Hospital Administrator/General Surgery/Risk Manager

Dear Sir or Madame,

Merit Medical Systems, Inc. is voluntarily conducting a recall of specific lots of Peritoneal Dialysis Catheters. 1 Cuff catheters were incorrectly configured as 2 Cuff product and 2 Cuff catheters were incorrectly configured as 1 Cuff product. The only difference between the two configurations is 1 Cuff versus 2 Cuff. This could result in a potential delay in procedure with no other identified risks, since the catheters can be used interchangeably. The Indications for Use for both products are also the same. Merit has received no 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 units from the market and requests that you immediately stop using the affected lots and return them to Merit.

| <b>Catalog Numbers</b> | <b>Lot Numbers</b>   |
|------------------------|----------------------|
| CF-4235                | H1136644<br>H1139640 |
| K14-00078              | H1190932             |
| K14-00079              | H1190448<br>H1193585 |

Our records indicate that you have received affected lots.

Actions required of you:

1. Please immediately determine if any of the devices identified in the attached Customer Response Form are within your facility, quarantine them, and discontinue use.
2. Ensure that all individuals within your organization are made aware of this field action.
3. Please fill out, scan and email the attached Customer Response Form to RESPONSE-EMEA@merit.com within 5 days. All affected product shipped to your company must be accounted for on the Customer Response Form.
4. Please return all affected lots in your possession to Merit within 10 days, per the instructions found in the Customer Response Form.

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

If you have any questions concerning this communication, please don't hesitate to contact your Merit Sales Representative or Michelle Savelkoul at +31 43 3588247 (Ext. 9007) or msavelkoul@merit.com.

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

Kind Regards,



Mark Mullaney  
Director, Regulatory Affairs  
Merit Medical Ireland Ltd.

Enclosure