MERITMEDICAL

Understand. Innovate. Deliver.™

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merit.com

FSCA-ref: 1721504-01/27/23-001R

01-JAN-2023

URGENT FIELD SAFETY NOTICE (FSN)

Name of Affected Products: Merit Procedure Packs Containing B. Braun Original Perfusor® Line Products

Action Required: Return Device(s) to Merit

In response to a voluntary Field Safety Corrective Action (FSCA) initiated by B. Braun Medical, Merit Medical Systems, Inc. is voluntarily conducting an FSCA of specific Merit procedure pack lots containing Original Perfusor® Line products. B. Braun has communicated the following:

> In the course of our Post Market Surveillance activities, we identified the risk for holes and leakages in the listed article/batch combinations of Original Perfusor® Line. *(See attached list Appendix 1)*
>
> The deviation might harbor the risk for the patient of microbial contamination, under supply, open patient access, or air infusion. A potential consequence for the healthcare worker is given by contact to hazardous drugs.
>
> In view of the identified risks, we have decided to recall all affected devices from the market.

This recall affects the Merit lot(s) and catalog number(s) identified in the below table. Merit has not received any reports of patient harm or injury as a result of this issue. Merit is removing the affected product from the market and requests that you immediately stop using or distributing the affected lots, place them in quarantine and return them to Merit.

Catalog Code	Lot Number
K12T-11877	K2505264

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.

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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 business 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 +31 – 43 3588233.

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

Enclosure(s)

B BRAUN

B. Braun Medical Ltd.
3 Naas Road Industrial Park
Dublin 12
e-mail:
productcomplaints.ie@bbraun.com
http://www.bbraun.com

Date:
January 16, 2023

Ref: FSCA-2023-01-12

URGENT Field Safety Corrective Action – Original Perfusor® Line

Dear Sir/Madam,

B. Braun Melsungen AG has decided to proactively recall the article/batch combinations of Original Perfusor® Line listed within Appendix 1 in the course of a Field Safety Corrective Action from the market.

Reason for the Recall
In the course of our Post Market Surveillance activities, we identified the risk for holes and leakages in the listed article/batch combinations of Original Perfusor® Line.

The deviation might harbour the risk for the patient of microbial contamination, under supply, open patient access, or air infusion. A potential consequence for the healthcare worker is given by contact to hazardous drugs.
Based on internal controls and available post market data, the effect can be limited to the listed article/batch combinations.
In view of the identified risks, we decided to recall all affected devices from the market.

Actions to be taken
Our records have shown that your institution has received one or more of the affected article/batch combinations.

We kindly ask you to initiate the following activities immediately and with priority:

- Review this Field Safety Notice in its entirety and ensure that all users of the above mentioned product in your organisation and other concerned persons are informed about this Field Safety Notice.
- If you are a distributor, please forward this correction notification to your customers.
- Identify, quarantine and return affected articles.
- Do not use affected devices anymore.
- It is recommended to exchange devices from the above mentioned batches, which are currently in use.
- Confirm receipt of this information by completing and signing the attached Confirmation Form and return this to B. Braun using the contact details provided.

*Please return the completed form by **Friday 20th January 2023**, or sooner if possible.*

A member of B. Braun Medical will then be in touch with you to organise collection of any quarantined units. Please enclose a copy of the Confirmation Form with this collection.

Credit will be provided for any affected product returned.

The Health Products Regulatory Authority has been informed of this action.

If more information is needed please contact:

Declan Burke
Hospital Solutions Consultant
B. Braun Medical Ltd
Tel: 086 2529912
Email: declan.burke@bbraun.com

We believe in improving people's health through everything we do. Patient and user safety is our highest priority. Kindly accept our apologies for any inconveniences caused and thank you in advance for your cooperation to resolve this matter quickly.

Yours sincerely,

mcguciie Digitally signed by mcguciie Date: 2023.01.16 10:50:17 Z

[redacted]

Digital Health & Healthcare Technology Lead

eganroie Digitally signed by eganroie Date: 2023.01.16 10:36:05 Z

[redacted]

Regulatory Affairs Manager

Appendix 1 – List of affected article/batch combinations

Article Number	Article Name	Batch
8255067	PERFUSOR LINE, PE, LL, 100 CM	22B02E8SC6
		22C06E8SC6
		22D02E8SC6
		22E09E8SC6
		22F04E8SC6
8722935	PERFUSOR LEITUNG, PE, LL, 150 CM	22B11E8SC6
		22B18E8SC6
		22B23E8SC6
		22D30E8SC6
		22E04E8SC6
		22E20E8SC6
		22E30E8SC6
		22F12E8SC6
8723060	PERFUSOR LINE, PE, LL, 200 CM	22B20E8SC6
		22D06E8SC6
		22E22E8SC6

Customer Response Form

Merit Medical Systems, Inc.
Merit Sales Rep: XXXXXXXXXXXX
Affected Product: Merit Procedure Packs Containing B. Braun Original Perfusor® Line Products

Customer Name Ship to Address	Customer Contact:
	Title:
	Phone Number:
Customer Number	RGA #: XXXXX

Please provide status on the following:

Lot #	Part #	Qty Merit Shipped to You	Qty You Further Distributed	Qty Used	Qty Unused and Being Returned

Return the affected products to Merit via Federal Express Ground Shipping (Account #680121095). Include the assigned RMA number (see above table) on the outside of the box and ship to:

ATTN: Receiving & Customer Service
Merit Medical Systems, Inc.
Amerikalaan 42, 6199 AE
Maastricht Airport, The Netherlands
RMA#

I certify that I received and understood this notice. I certify that the above listed products have been used, distributed, or returned to Merit Medical Systems, Inc. according to the notification instructions. Furthermore, if I have further distributed product listed on this form, I certify that a copy of this notice was provided to said consignee(s).

_____ _____

Signature of Customer Contact **Date**