

URGENT: UPDATED FIELD SAFETY NOTICE
Plum & Sapphire Microbore Infusion Sets with Inline Filters

XX August 2019

Dear Valued Customers:

Director of Risk Management
Director of Nursing
Director of Biomedical Engineering

ICU Medical, Inc. is issuing this Urgent Medical Device Correction letter to notify you of a potential issue with Plum and Sapphire microbore infusion sets that contain an inline filter (pictured below). Out of an abundance of caution, ICU Medical is issuing this notice while we are investigating the root cause for this issue.



Issue:

ICU Medical has received reports of small amounts of fluid leaking out of air vents on inline filters on Plum and Sapphire microbore infusion sets.

Potential Risk:

Fluid leakage may potentially cause delay of infusion, medication under-delivery, contamination of the fluid path, exposure to hazardous medications, or fluid path air-in-line. To date, ICU Medical has not received any reports of serious injury or death associated with this issue.

Benefits of Filtered Microbore Infusion Sets:

Administration sets enabling the use of an infusion pump bring benefits to the patient including controlled delivery of fluids and medications at a range of infusion rates. Microbore infusion sets have low priming volumes and are of benefit for patients who are fluid sensitive or for infusions delivered at low flow rates. In-line filters remove substances from the fluid path, as directed by the labeling for the medication being administered, while also providing benefit for patients sensitive to fluid path microemboli.

Affected Product:

Our records indicate that you have received some of the affected product. The affected list and lot numbers are provided in Table 1.

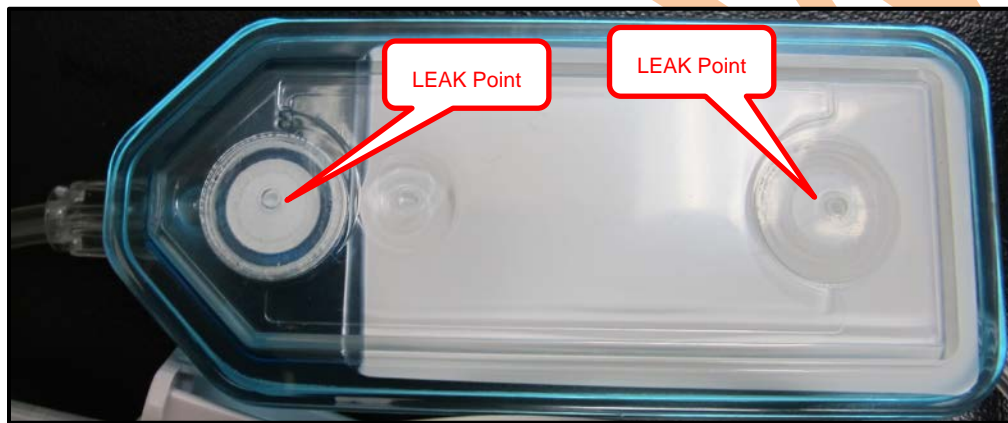
UPDATED INFORMATION: Required Actions for Users:

1. Please quarantine the sets that are affected by this notice and return them to ICU Medical as indicated in the attached Response Form. Additionally:
 - a) *In applications where the use of a filter is not deemed necessary*, consider utilizing an administration set which does not contain a filter. Please contact ICU Medical for alternate sets without filters.
 - b) In applications where filter use is desired and microbore tubing is not required, consider using filtered macrobore sets in place of microbore sets. Please contact ICU Medical for alternate macrobore sets with filters.

UPDATED INFORMATION: Required Actions for Users (continued):

2. In cases where a filtered macrobore set is desired but no alternative macrobore set is available, please contact ICU Medical. You may need to consider a non-filtered set along with an add on filter or filtered extension set from another vendor.

3. In instances where the benefits of a filtered microbore infusion set are greater than the potential risks of a filter leak, the product affected by this issue may be utilized out of medical necessity. In these cases, an individualized assessment of benefits and risks should be undertaken with consideration of the unique characteristics of the patient and the infusion itself. The risks and benefits described in this letter provide example inputs for conducting an analysis and are not an exhaustive list of considerations. When the benefits exceed the risks and the set is deemed medically necessary, users should periodically monitor the vented filter area for leakage as illustrated below. If leaking is observed, consider changing to a new infusion set as soon as clinically appropriate. Please contact ICU Medical Global Complaint Management to report the event.



For further inquiries, please contact ICU Medical using the information provided below.

ICU Medical Contact	Contact Information	Areas of Support
EMEA Complaint Management	EMEA-Quality@icumed.com	To report adverse events or product complaints
Customer Service	GermanSupport@icumed.com	Additional information or assistance

BfArM has been notified of this action.

Please Inform potential users in your organization of this notification, complete the attached response form and return it to the e-mail address on the form, even if you do not have the affected product. If you have distributed the product further, notify your accounts that received the product identified above of this notification and ask them to complete and return a reply form.

ICU Medical is committed to patient safety and is focused on providing exceptional product reliability and the highest level of customer satisfaction. Thank you for your prompt support on this important matter. We appreciate your cooperation.

Sincerely,


ICU Medical BV

Enclosures:

- Affected Products
- Response Form

REVIEW

Table 1: Affected Products

Item Code	Product Description - Sapphire Sets	Lot #
163359255	SAPPHIRE Primary 1.2 Micron Filter Set Non-Vented, Microbore 311 cm / 8.4 mL	855875H
		876265H
		887125H
163459255	SAPPHIRE Primary 0.2 Micron Filter Set Non-Vented, Microbore, 293 cm / 8.1 mL	855755H

Review

URGENT FIELD SAFETY NOTICE: RESPONSE FORM
Plum & Sapphire Microbore Infusion Sets with Inline Filters

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Check your inventory and complete the information below, even if you do not have the affected product. Email the completed form EMEA-Quality@icumed.com, GermanSupport@icumed.com or your ICU Medical representative.

Customer Information

Hospital/Facility Name ICU Medical Customer # (if applicable)

Address/City/State/ZIP

Contact Name/Phone/E-mail Address

Completed by: Printed Name/Signature/Date

- I have **NO** affected product (complete and return this form to the above email address).
- YES**, I have affected product, I have notified users in my facility, I have followed the instruction provided to me and I am not going to return the affected product (complete and return this form to the above email address)
- YES**, I have affected product, I have notified users in my facility, I have followed the instruction provided to me and I am going to contact GermanSupport@icumed.com to make arrangement to return my affected product.
- Have you distributed the product further to the retail level? YES___ NO___
 - If yes, have you notified your retail customers? YES___ NO___ (if no, explain below)

Lot Number	Quantity to be returned	Wholesaler/Distributor Name If you purchased from Wholesalers/Distributors include name, address, city, state, zip, quantity from each, and invoice number. If you purchased directly from ICU Medical leave this section blank.	PO, debit memo or invoice
		1.	
		2.	
		3.	

Adverse events and complaints associated with the use of these products should be reported and emailed to ICU Medical or BfArM.