

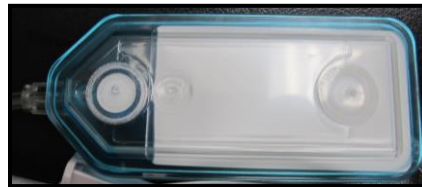
URGENT: MEDICAL DEVICE CORRECTION
Plum & Sapphire Microbore Infusion Sets with Inline Filters

05 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 air-in-line. To date, ICU Medical has not received any reports of serious injury or death associated with this issue.

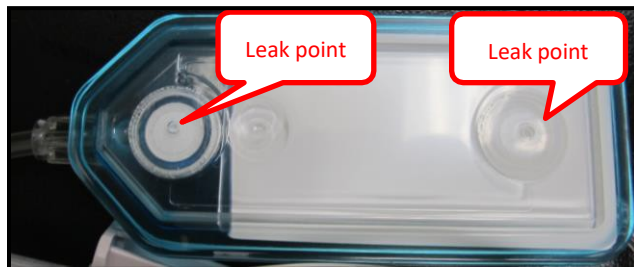
Affected Product:

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

Required Actions for Users:

1. ICU Medical recommends that customers evaluate the benefits and risks of filter usage in individual clinical applications that utilize filtered microbore sets. In instances where the benefits of filter use exceed the potential risks of a leak, additional awareness and monitoring for leaks during the infusion should be considered as described below.
2. In applications where filter use is desired, consider using macrobore sets in place of microbore sets. Please contact ICU Medical for alternate macrobore sets with filters.
3. If no alternative macrobore set is available and a filter is deemed medically necessary, please contact ICU Medical. You may need to consider a non-filtered set along with an add on filter or filtered extension set.
4. In applications where the use of a filter is not deemed necessary consider the option of utilizing an administration set which does not contain a filter. Please contact ICU Medical for alternate sets without filters.

5. When utilizing filtered sets, 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
Global Complaint Management	ProductComplaintsBucharest@icumed.com	To report adverse events or product complaints
Customer Service	EMEA-Quality@icumed.com	Additional information or assistance

The competent authorities have 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 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,

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ICU Medical BV

Enclosures:

- Affected Products
- Response Form
- FAQ

Table 1: Affected Products

Item Code	Product Description - PlumSets	Lot #
140099290	Primary PLUM Set 15 Micron Filter in Sight Chamber, CLAVE Secondary Port, 0.2 Micron Filter, CLAVE Y-Site, Polyethylene Lined Light Resistant Tubing, Distal Microbore Tubing, Secure Lock 272 cm / 15 mL	855575H
		865265H
		876065H
		885425H
		896175H
		918685H
		925775H
		929095H
		936455H
		945745H
		3845287
3849199		
3864779		
140099291	Primary PLUM Set 15 Micron Filter in Sight Chamber, CLAVE Secondary Port, 0.2 Micron Filter, CLAVE Y-Site, Polyethylene Lined Light Resistant Tubing, Distal Microbore Tubing, Secure Lock 272 cm / 15 mL	3981726

Item Code	Product Description - Sapphire Sets	Lot #
163359255	SAPPHIRE Primary 1.2 Micron Filter Set Non-Vented, Microbore 311 cm / 8.4 mL	855875H
		866155H
		876265H
		887125H
		905965H
163459255	SAPPHIRE Primary 0.2 Micron Filter Set Non-Vented, Microbore, 293 cm / 8.1 mL	945565H
		855755H
		876275H
163639255	SAPPHIRE Epidural Set Yellow-Striped Microbore, 0.2 Micron Filter 301 cm / 8.3 mL	897465H
		866165H
240119201	SAPPHIRE Epidural Set with NRFit Connector Yellow-Striped Microbore, 0.2 Micron Filter 301 cm / 8.3 mL	897465H
		916205H

URGENT MEDICAL DEVICE CORRECTION: RESPONSE FORM

Plum & Sapphire Microbore Infusion Sets with Inline Filters

05 August 2019

Check your inventory and complete the information below, even if you do not have the affected product. Please return the completed for to EMEA-Quality@icumed.com or your ICU Medical sales 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 Stericycle at the fax/e-mail above).
- 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 e-mail)
- 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 EMEA-Quality@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 to the competent authorities at the contact information provided.