Plum & Sapphire Microbore Sets with Inline Filters

Urgent: Medical Device Correction
Frequently Asked Questions

ICU Medical is issuing a medical device correction letter informing affected customers about a potential risk associated with Plum and Sapphire microbore infusion sets that contain an inline filter. As a part of this notification, ICU Medical is notifying each affected customer and authorized distributor of this issue.

If you have any further questions, please contact ICU Medical Global Complaint Management at ProductComplaintsPP@icumed.com.

1. Q What is the issue?
   Customer complaints report small amounts of fluid leaking out of air vents on inline filters on Plum and Sapphire microbore infusion sets.

2. Q What is the 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.

3. Q What products are affected?
   Refer to Table 1 of the Medical Device Correction notice for the affected products and lot numbers.

4. Q What is the difference between macrobore and microbore sets?
   Microbore infusion pump sets have distal tubing with a smaller Inner Diameter. The type of tubing is identified in the product description on the packaging. If not stated, the set has macrobore tubing.

5. Q How can you identify if a particular set is affected?
   The list number and lot number are printed on every box and individual packaging:

   ![Image of product packaging]
6. Q What actions are required for users?
   Please quarantine the sets that are affected by this notice and return them to ICU Medical as indicated in
   the attached Response Form. Additionally:
   
   i) 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.
   ii) 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.
   iii) 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.

7. Q Can the affected sets continue to be used?
   Yes. 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 the customer 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 in the customer letter. 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.

8. Q Have there been any complaints related to this issue?
   Yes.

9. Q Has there been any patient harm related to this risk?
   No. To date, ICU Medical has not received any reports involving a serious injury or death related to this
   issue.

10. Q What action is ICU Medical taking?
    ICU Medical is notifying affected customers via the attached notice. Additionally, ICU Medical is working
    with the filter manufacturer to identify the root cause of this issue.

11. Q How is the customer communication sent?
    The notifications are sent via courier to the Director of Risk Management, Director of Pharmacy and Director
    of Nursing of each facility. Each customer and distributor will receive a Letter, FAQs and Response Form.

12. Q Why is ICU Medical issuing this notice?
    ICU Medical is committed to patient safety and is focused on providing exceptional product reliability and
    the highest level of customer satisfaction. To that end, ICU Medical is issuing this notice to be proactive
    with our customers and provide you with the best information available.
13. Q Is the information available online?  
   Yes. The letter and FAQs distributed in the US can be found on ICU Medical website at http://www.icumed.com/support/customer-communications.aspx

14. Q Is this a voluntary action?  
   Yes. ICU Medical is voluntarily taking this action.

15. Q Can I return affected sets?  
   Yes. You may choose to return affected product if you can use alternate sets as recommended in the medical device correction letter. If you experience leaks through the air vent on the filter, please register a complaint with ICU Medical Global Complaint Management and return those sets to ICU Medical.

16. Q Will ICU Medical offer any compensation to customers for the corrective action?  
   ICU Medical will be providing replacement product or issue a credit for returned sets.

17. Q Has FDA been notified?  
   Yes.

18. Q Does this result in inability to ship the affected Plum and Sapphire sets?  
   No. Due to the very low frequency and sporadic nature of the issue, ICU Medical will make the affected product available where clinically necessary.

19. Q Where can I find more information?  

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<th>ICU Medical Contact</th>
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<tr>
<td>Global Complaint Management</td>
<td>1-844-654-7780 or <a href="mailto:ProductComplaintsPP@icumed.com">ProductComplaintsPP@icumed.com</a></td>
<td>To report adverse events or product complaints</td>
</tr>
<tr>
<td>Customer Service</td>
<td>1-866-829-9025, option 8 or <a href="mailto:customerservice@icumed.com">customerservice@icumed.com</a> (M-F, 8am-6pm CT)</td>
<td>Additional information or assistance</td>
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