Hofspoor 3
3994 VZ Houten
The Netherlands
www.icumed.com

URGENT: FIELD SAFETY NOTICE

ChemoLock™ Port Connection Issue

23rd Sept 2022

Dear Valued Customers:
Director of Risk Management
Director of Nursing
Director of Pharmacy

ICU Medical, Inc. is issuing this Urgent Field Safety Notice to notify you of a potential for non-connection or disconnection issue with certain lots of products including the ChemoLock Port. This urgent Field Safety Notice details the issue and the required steps for you to perform.

Issue:

ICU Medical has identified the potential for certain lots of products containing the ChemoLock Port to have the inability to connect to or fully engage with the ChemoLock injector due to a variation in the spring inside the ChemoLock Port. This information pertains to the Port that is utilized as an access point on ICU Medical Vial Adaptors, Bag Spikes, and Administration Sets and is also available as a standalone connector to adapt any needle free connector to accept an infusion from a ChemoLock injector.

Potential Risk:

This issue may potentially cause delay of therapy and exposure to caustic substances. ICU Medical has received reports for the inability to connect or unintended disconnection associated with this issue. To date, there have been no reports of adverse events associated with this issue.

Affected Product:

Our records indicate that you may have received some of the affected products, which were distributed directly from ICU Medical to you in Estonia in May 2022. The affected item and lot number is provided in Table 1.

Required Actions for Users:

1) Please discontinue the use and distribution of the affected product immediately. Check your inventory and quarantine all affected product at your facility.

2) In the instances where the benefits of using the ChemoLock are greater than the potential risks for non-connection or disconnection, and you choose to utilize ChemoLock lot numbers listed in Table 1, ensure full engagement between the ChemoLock Port and ChemoLock Injector as shown in Picture 2. If full engagement is achieved (there will be an audible click), the device will work as intended. If full engagement cannot be achieved or is difficult to achieve (NO audible click), discard product and utilize a new device.

Picture 1. Not fully engaged

Picture 2. Fully engaged

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3) Inform potential users of the product in your organization of this notification and complete the attached response form below indicating what affected product you have and whether you intend to return this to ICU Medical or destroy it locally. Return the completed response form to the e-mail address on the form, even if you do not have any of the affected product.

4) ICU Medical has some lots of unaffected product available today and is actively increasing the amount of available inventory. Please contact ICU Medical customer service for product availability.

5) Upon receipt of the affected product, or upon receipt of a Certificate of Destruction, ICU Medical will credit you for any product returned/destroyed. You will only receive credit for product that you return or that you certify has been destroyed locally.
NOTE: Credits for product purchased through distributor will be credited by the distributor.

6) If you have distributed the product further, immediately notify your accounts that received the product identified in the Affected Product / Table 1 sections of this notification and ask your customers to complete a response form and return to you for overall completion.

Follow up Actions by ICU Medical:
Please contact Customer Service using the information provided below for assistance reordering replacement product.

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

ICU Medical Contact	Contact Information	Areas of Support
Global Complaint Management	ProductComplaintsPP@icumed.com	To report adverse events or product complaints
ICU Medical Customer Service	EMEAdistributor-support@icumed.com	Additional information or assistance

Ravimiamet have been notified of this action.

ICU Medical is committed to patient and clinician 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,

Corine Broekhuizen
Director, Quality and Regulatory Affairs
ICU Medical BV

Enclosures:

- Affected Product and Lot Numbers
- Response Form

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Table 1: Affected Product and Lot Numbers Distributed

Item Number	Product Description	Lot Number
011-CL-80S-5	ChemoLock™ Vial Spike, 20mm, 5 Units	5850506

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URGENT: FIELD SAFETY NOTICE RESPONSE FORM

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Please check your inventory and complete the information below, even if you do not have the affected product. *Failure to complete all sections of this page may result in improper, delayed or denied credit.*

Please return the completed form to EMEA-Quality@icumed.com, EMEAdistributor-support@icumed.com and your ICU Medical sales representative.

Hospital/Facility Name	
ICU Medical Customer # (if applicable)	
Address/City/Postal code	
Contact Name/Phone/E-mail Address	
Completed by: Printed Name/Signature/Date	

☐ I have **NO** affected product (complete and return this form to the e-mail addresses above).
☐ **YES**, I have affected product

If you have affected product on hand, please complete table below:

TABLE 1

List Number	Lot Number	Quantity in inventory	PO, debit memo or invoice

If you have distributed the product further, please complete table below with collated information received from your customers and respond to ICU Medical with the overall information.

TABLE 2

List Number	Lot Number	Quantity destroyed locally by customer	Quantity returned to distributor

☐ I have followed the instructions provided to me and I will **destroy** affected products on site (complete and return provided Certificate of Destruction to the email addresses on the certificate).

☐ I have followed the instructions provided to me and I will contact my ICU Medical CS Representative to make arrangement to **return** the affected products.

☐ I have chosen to **use** the affected product because _____(Please explain).

Adverse events and complaints associated with the use of these products should be reported and emailed to ICU Medical at the contact information provided.