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

URGENT: FIELD SAFETY NOTICE

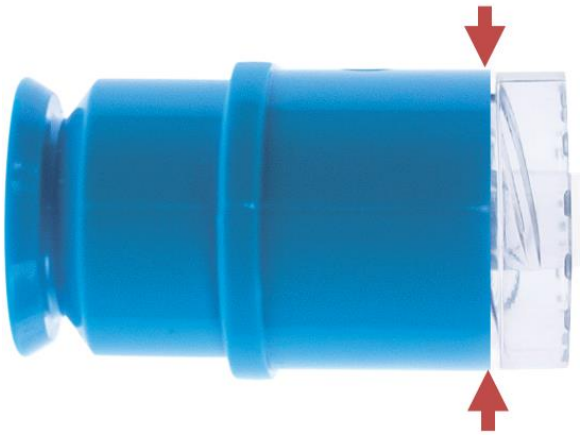
ChemoLock™ Port

18th September 2025

Dear Valued ChemoLock™ Port Customer:

ICU Medical is issuing this letter to notify you of a potential issue affecting specific lots of ChemoLock Closed System Transfer Device products. This notification details the issue and the affected items.

Issue:
ICU Medical has internally identified a lot-specific issue where the weld of the ChemoLock Port was not functioning as intended due to a manufacturing issue. Impacted products include the standalone ChemoLock Port, ChemoLock Vial Adapters, ChemoLock Bag Spikes, and ChemoLock administration sets that may include the ChemoLock Port. The malfunctioning port weld may separate or break during use and potentially result in a leak. Chemolock products that are affected may display the separation in the area shown below.



Potential Risk:
To date, ICU Medical has received zero (0) reports of serious injury, and zero (0) deaths associated with this issue. If the device separates during setup, this may result in a delay in therapy. If the device separates during use, this may result in interruption of therapy and/or fluid leakage.

Affected Items:
Our records indicate that you have received some of the affected items, which were distributed directly from ICU Medical on 12 June 2025. The affected item and lot number are shown below:

Table 1: Potentially Affected Product Models and Lots

SKU/List/Model Number	Product Description	Lot Number
011-CL-70S-20	ChemoLock™ Vented Vial Spike, 20mm, 20 Units	14401659

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Required Actions for Users:

There is no need to remove an affected ChemoLock™ device if it is already in use. However, when using the device, all instructions, including warnings and cautions contained in the IFU must be followed with heightened awareness. Please complete the following actions below.

1) Check all inventory locations within your institution for the affected products listed in Table 1 and discontinue use. Destroy all affected products following your institution's process for destruction. If destroying is not immediately possible at your facility, then the product should be quarantined until disposal.

2) Share this notification with all potential users of the device, to ensure they are aware of this notification. If the devices are used at another location, please ensure this communication is delivered there.

3) Complete and return the attached Customer Response Form to EMEA-FSN@icumed.com within 10 days of receipt to acknowledge your understanding of this notification.

4) **DISTRIBUTORS:** If you have distributed potentially affected products to your customers, please immediately forward this notice to them and request that they complete the response form and return it to **YOU**. Then the **DISTRIBUTOR** must complete a SINGLE form with the required details and return to EMEA-FSN@icumed.com

Follow up Actions by ICU Medical:

ICU Medical will provide full credit to affected customers upon receipt of a complete Customer Response Form to certify product destruction. Full credit shall be provided if the form is received within 120 days of receipt of this notification.

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	service.commandes@icumed.com	Additional information or assistance

Your local Competent Authority has 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 of Quality, ICU Medical BV

- See Response form below

icumedical
human connections

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URGENT: FIELD SAFETY NOTICE - RESPONSE FORM

ChemoLock™ Port

18th September 2025

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-FSN@icumed.com, If you have questions about this form please contact EMEA-FSN@icumed.com or your local sales representative.

Customer Number (Refer to the original email subject line for your CNXXXXXX /customer number)	
Name of Hospital / Facility	
Hospital / Facility Address	
Telephone Number	
Name and Title of Person Completing this Form	
Signature of Person Completing this Form	
Date	
If Purchased through a distributor, please list distributor name/location here for traceability purposes	

Please select one:

☐ I have **NO** affected products (complete and return this form to the e-mail address above)

☐ **YES**, I have affected products, I have notified users in my facility and I have followed the instructions provided to me and destroyed all affected items (see table below)

If you have affected product on hand, please complete table 1 below:

TABLE 1

Item / SKU Number	Lot Number	Quantity in inventory (Eaches)	Quantity Destroyed (Eaches)	Date of Destruction

If you have distributed the product further, please complete table 2 below with collated information received from your customers and respond to ICU Medical with the overall information.

TABLE 2

Item / SKU Number	Lot Number	Quantity destroyed locally (Eaches)	Date of Destruction

Adverse events and complaints associated with the use of this product should be reported and emailed to ICU Medical's Global Complaint Management Department at ProductComplaintsPP@icumed.com.