600 N. Field Drive
Lake Forest, IL 60045
www.icumed.com

URGENT: MEDICAL DEVICE RECALL

ChemoLock™ Products - Port Connection Issue
See Table 1 for affected products

27 June 2022

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

ICU Medical, Inc. is issuing this Urgent Medical Device Recall letter to notify you of a potential for non-connection or disconnection with certain lots of ChemoLock Port products. This letter 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.

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.

Potential Risk:
This issue may potentially cause delay of therapy and exposure to caustic substances.

Affected Product:
Our records indicate that you may have received some of the affected products, which were distributed directly from ICU Medical in the United States between February 10, 2022 and May 04, 2022. The affected item and lot numbers are 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, the device will work as intended. If full engagement cannot be achieved or is difficult to achieve, 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. Return the completed response form to the fax number or e-mail address on the form, even if you do not have the affected product.

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

5) Return affected product using the return label provided with this letter. Contact Sedgwick at 1-888-943-5190 (M-F, 8am-5pm ET) if you have not received a return label or require additional labels for returning the affected product. The return labels are for single use only. Please do not reproduce. Please visit http://expertezlabel.com to request additional labels for returning affected product. To ensure proper and timely credit, follow the instructions on the return label for returning product. Upon receipt of the completed response form and return of the affected product, ICU Medical will credit you for any product returned. You will only receive credit for product that you return. 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 them to contact Sedgwick at 1-888-943-5190 (M-F, 8am-5pm ET) to obtain a response form.

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	1-844-654-7780 or ProductComplaintsPP@icumed.com	To report adverse events or product complaints
Customer Service	1-866-829-9025, option 8 or customerservice@icumed.com (M-F, 8am-6pm CT)	Additional information or assistance
Sedgwick	1-888-943-5190 (M-F, 8am-5pm ET)	Questions about product return or to obtain additional copies of the Medical Device Recall letter

The U.S. Food and Drug Administration (FDA) has been notified of this action.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report **Online**: www.fda.gov/medwatch/report.htm
- **Regular Mail or Fax**: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

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,

Amy Giertych
Vice President, Global Regulatory Affairs

Jesus Cabrera, MD; PhD
Chief Medical Officer, Medical Affairs

Enclosures:

- Affected Product and Lot Numbers
- Response Form
- FAQs

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Table 1: Affected Product and Lot Numbers Distributed in the United States

Item Number	Product Description	Lot Number
CL-10-10	ChemoLock™ Bag Spike, 10 units	5872839 5891255
CL-12	ChemoLock BAG SPIKE w/ ADDITIVE PORT, DRY SPIKE	5819981 5856055 5873186
CL-13	APPX 1.5ml,ChemoLock BAG SPIKE WITH ADDITIVE PORT	5850811
CL2100	ChemoLock™ Port	5797867 5816334 5829882 5850510
CL2100-5	ChemoLock™ Port, 5 Units	5754377
CL2100T	ChemoLock™ Port	5816341 5842229 5850517
CL2150	Clave® Bag Spike w/ChemoLock® Port	5829900 5850507
CL3011	30" (76 cm) Appx 3.3 ml, 20 Drop Admin Set w/Integrated ChemoLock™ Drip Chamber, Spiros® w/Red Cap, Hanger	5829885 5842227
CL3364	9 IN(23cm)APPX 2.7ml,EXT SET,ChemoLock PORT,2 CLAMPS,2 GRADUATED CONN	5841261 5850805
CL-34	Syringe Transfer Set w/Clave™, ChemoLock™ Port	5754437 5829875
CL3511	30" (76 cm) Appx 3.6 ml, 20 Drop Admin Set w/Integrated ChemoLock™ Port Drip Chamber, ChemoLock™ w/Red Cap, Bag Hanger	5842231 5861991 5894477
CL3511T	30" (76 cm) Appx 3.6 ml, 20 Drop Admin Set w/Integrated ChemoLock™ Port Drip Chamber, ChemoLock™ w/Red Cap, Bag Hanger	5829831 5891263
CL3528	30" (76cm) Appx 6.3 ml, 20 Drop Admin Set w/Integrated ChemoLock™ Port Drip Chamber, 0.2 Micron Filter, ChemoLock™ w/Red Cap, Hanger	5850500 5872833 5883793 5894481 5909807
CL3535T	7" (18 cm) Appx .93 ml, Ext Set w/ChemoLock™, Y-Connector, Rotating Luer	5685350
CL3538	Oncology Kit w/5" (13 cm) Add-On Set w/ChemoLock™ Additive Port, Vented Cap; ChemoLock™; Spinning Spiros™ w/Red Cap	5935851
CL3900	Graduated Connector w/ChemoLock™ Port	5772697
CL3927	ONCOLOGY KIT, EXT,ChemoLock PORT, GRAD CONN,TRANSFER,ChemoLock,VIAL SPIKE,ChemoLock PORT	5842211
CL3946	Oncology Kit w/5" (13 cm) Add-On Set w/ChemoLock™ w/Red Cap, Vented Cap; ChemoLock™ Port w/Bag Spike; Spiros™ w/Red Cap	5829895 5861983

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Item Number	Product Description	Lot Number
CL3947	Oncology Kit w/17" (43 cm) Bifuse Ext Set w/ChemoLock™ w/Red Cap, ChemoLock™ Port; ChemoLock™ Vented Vial Spike, 13mm; ChemoLock™	5782844
CL3952	Oncology Kit w/ChemoLock™ Port Closed Vial Spike; ChemoLock™; ChemoLock™ Port Bag Spike	5782863 5816379
CL3955	APPX 0.5ml, ChemoLock BAG SPIKE WITH ADDITIVE PORT,ChemoLock Port	5841209 5850839
CL3960	Oncology Kit w/60" (152 cm) Appx 2.2 ml, Smallbore Ext Set w/ChemoLock™ Port, Clamp, Anti-Siphon Valve, Spiros™; ChemoLock™; Syringe Transfer Set w/MicroClave™, ChemoLock™ Port	5816328 5842216
CL3963	Oncology Kit w/Appx 2.2ml, 5" (13 cm) Add-On Set w/ChemoLock™ w/Red Cap, Vented Cap; ChemoLock™ Port w/Bag Spike; Spiros™ Closed Male Luer w/Red Cap	5842214 5851775
CL4114	Oncology Kit w/ChemoLock™ Port; ChemoLock™; Spinning Spiros™ w/Red Cap	5754773 5782864 5816356
CL4130	30" (76 cm) Appx 3.9 ml, Admin Set w/20 Drop In-Line Drip Chamber, ChemoLock™ Additive Port, ChemoLock™ w/Red Cap	5850515
CL4131	30" (76 cm) Appx 3.6 ml, Admin Set w/20 Drop In-Line Drip Chamber, ChemoLock™ Additive Port, Spiros™ w/Red Cap	5895940
CL4136	Oncology Kit w/ChemoLock™ w/Red Cap, ChemoLock™ Port	5816325 5850661
CL4143	Oncology Kit, 5" (13 cm) Bag Spike Adapter w/ChemoLock™ w/Red Cap, Vented Cap; ChemoLock™ Bag Spike; ChemoLock™; ChemoLock™ Port	5782848 5873243 5891266
CL4146-5	30" (76 cm) 20 Drop Admin Set w/Integrated ChemoLock™ Port Drip Chamber, ChemoLock™; 5 Units	5872843 5883800 5909812
CL4153	ChemoLock™ Kit w/ 5" (13 cm) Bag Spike Adapter w/ChemoLock™ w/Red Cap, Vented Cap; ChemoLock™; ChemoLock™ Port Bag Spike	5816348
CL4159	8 IN (20 cm) APPX 2.1 ml, TRANSFER SET, ChemoLock PORT, ChemoClave, VENTED CAP	5881696
CL4179	Oncology Kit w/8.5" (22 cm) Transfer Set w/ChemoLock™ Port, ChemoClave™, Y-Connector, Vented Cap; ChemoLock™ w/Purple Cap	5872687
CL-62	ChemoLock™ Vial Spike, 13mm	5816320 5825248
CL-70	ChemoLock™ Universal Vented Vial Spike	5842228
CL-70-10	ChemoLock™ Universal Vented Vial Spike, 10 units	5816343 5851774
CL-70-10T	ChemoLock™ Universal Vented Vial Spike, 10 units	5816353
CL-70S	ChemoLock™ Vented Vial Spike, 20mm	5842225 5850512
CL-70S-5	ChemoLock® Vented Vial Spike, 20 mm, 5 Units	5816326 5851776

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Item Number	Product Description	Lot Number
CL-70T	ChemoLock™ Universal Vented Vial Spike	5816350
CL-72	ChemoLock™ Vented Vial Spike, 13mm	5829832 5849740 5816312
CL-72T	ChemoLock™ Vented Vial Spike, 13mm	5841181 5849748
CL-76	ChemoLock™ Vial Spike, 20mm w/0.2 Micron Filter	5816323 5842218
CL-80	ChemoLock™ Closed Vial Spike	5804034 5842200
CL-80S	ChemoLock™ Vial Spike, 20mm	5808063 5816306 5829020 5829023 5841982 5845354 5862839
CL-80S-10	ChemoLock™ Vial Spike, 20mm, 10 units	5804045 5816315
CL-80S-10T	ChemoLock™ Vial Spike, 20mm, 10 units	5804051 5816310 5829022 5841994 5849630 5850497 5871336
CL-80S-5	ChemoLock™ Closed Vial Spike w/Skirt, 5 Units	5667054 5829021 5829024 5841980 5849474 5849631 5849632 5849713 5849714 5849715 5849716
CL-80SL	ChemoLock™ Vial Spike, 28mm	5816317
CL-82	ChemoLock™ 13mm Closed Vial Spike	5804065
CLH-12	8 IN (20cm) APPX 1.2ml, ADD-ON, Clave ADDITIVE PORT, ChemoLock Port, DRY SPIKE ADAPT	5842212

27 June 2022

ChemoLock™ Port Connection Issue

Urgent: Medical Device Recall
Frequently Asked Questions

ICU Medical is issuing a medical device recall letter informing affected customers of a potential lot-specific issue with the ChemoLock Port. As a part of this notification, ICU Medical is notifying each affected customer and authorized distributor of this issue.

1. Q What is the 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.

2. Q What is the 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.

3. Q What products are affected?

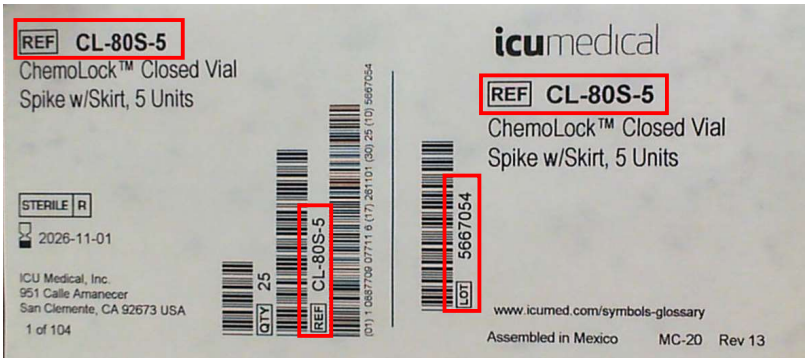
Refer to Table 1 of the Urgent Medical Device Recall notice for the affected products and lot numbers.

4. Q When was product distributed?

Affected products were distributed directly from ICU Medical in the United States between February 10, 2022 and May 04, 2022.

5. Q How can customers identify which devices are affected?

The list number and lot number are printed on every box and individual packaging. Refer to below example:

Product box	Product individual packaging
	

6. Q What action is ICU Medical taking?
ICU Medical is notifying affected customers via the attached letter and requiring removal of the affected products from the market.

7. Q Can devices at my facility continue to be used?
No. Please discontinue the use and distribution of the affected product immediately. Check your inventory and quarantine all affected product at your facility. Please follow the instructions provided in the customer letter to return your affected products.

8. Q Does ICU Medical have product replacement /alternatives?
Non-impacted lots of the affected list numbers may be available in limited quantities and ICU Medical is focused on increasing the available inventory of non-impacted product in the coming weeks. Customers are asked to place new orders for the replacement product.

9. Q Should I return affected products?
Yes. As communicated in the attached Urgent Medical Device Recall letter, you should discontinue use and distribution of the affected product immediately. You should also check your inventory and quarantine all affected product at your facility. 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 of the Recall Letter, ensure full engagement between the ChemoLock Port and ChemoLock Injector as shown in Picture 2 of the Recall Letter. If full engagement is achieved, the device will work as intended. If full engagement cannot be achieved or is difficult to achieve, discard product and utilize a new device.

10. Q How do I order replacement product?
Please contact Customer Service using the information provided below for assistance ordering replacement product.

11. Q Will ICU Medical credit customer accounts for impacted product returned?
Yes, ICU Medical will credit customers for any product returned.

12. Q How is the customer communication sent?
The notifications are being sent to the Director of Risk Management, Director of Nursing and Director of Pharmacy at each facility. Each customer and distributor will receive a letter, response form, and return label via courier.

13. Q Is the information available online?
Yes. The letter and FAQs distributed in the US can be found on ICU Medical's website.

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

15. Q Has FDA been notified?
Yes.

16. Q Where can I find more information?

ICU Medical Contact	Contact Information	Areas of Support
Global Complaint Management	1-844-654-7780 or ProductComplaintsPP@icumed.com	To report adverse events or product complaints
Customer Service	1-866-829-9025, option 8 or customerservice@icumed.com (M-F, 8am-6pm CT)	Additional information or assistance
Sedgwick	1-888-943-5190 (M-F, 8am-5pm ET)	Questions about product return or to obtain additional copies of the Medical Device Recall letter