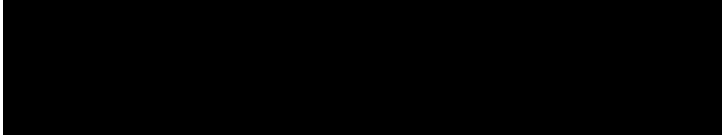


URGENT FIELD SAFETY NOTICE

Affected Device(s): I.V. Administration Sets with ChemoLock® Port

Date: 02-March-2016

Dear Valued Customer:



ICU Medical Inc. has identified an issue with a connection in an isolated number of I.V. Infusion administration sets that incorporate the ChemoLock additive port. In these sets, the connection between the Drip Chamber or Bag Spike and the ChemoLock port has the potential for developing a leak.

Out of an abundance of caution, ICU Medical Inc. is voluntarily recalling the affected devices. The company has not received reports of any patient injury associated with this issue.

Product Affected

Our records indicate that you have received some of the affected products. The affected item numbers and lots are provided in Table 1.

Action Required

To assure that the affected devices are accounted for, removed from use and returned to ICU Medical, Inc.: Please follow the instructions below:

Step	Action	
1	Inspect your inventory for the specific product and their lot numbers.	
	If...	Then...
	No affected devices are found:	<ul style="list-style-type: none"> • Complete sections A & B of the Recall Response Form and return to ICU Medical.
	Affected devices are found:	<ul style="list-style-type: none"> • Quarantine any affected devices • Complete sections A, C or D of the Recall Response Form as applicable and return to ICU Medical. • Contact ICU Customer Care for a Return Goods Authorization. <ul style="list-style-type: none"> - Call: +1-829-9025 and select option 8 or - E-mail: product_returns@icumed.com

Step	Action
2	Return completed Recall Response Form to ICU Medical, Inc. via <ul style="list-style-type: none">- FAX: +1-801-264-1755or- E-mail: recall@icumed.com

On receipt of the completed Response Form and return of the devices, ICU Medical, Inc. will credit you for any product returned. You will only receive credit for recalled product that you return.

This recall should be carried out to the user level and passed on to all those who need to be aware within your organization or any other organization the device may have been transferred to. Please forward this letter to your customers and on to any end users of the devices.

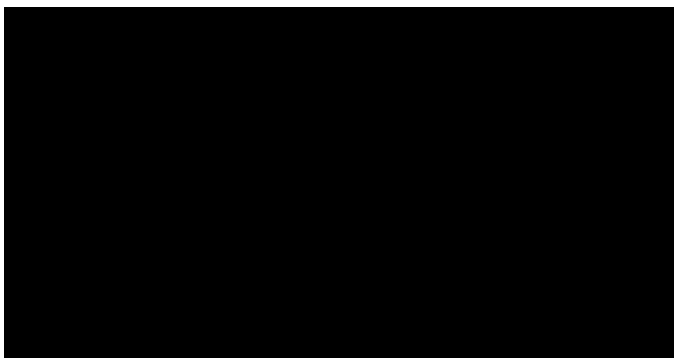
Should you have any questions or require assistance relating to this recall please contact ICU Customer Service Monday through Friday between the hours of 8:30 AM and 4:00 PM Pacific time: +1-866-829-9025 and select option 8, or e-mail the following address:
productreturns@icumed.com

There is confirmation that the relevant National Competent Authorities have been advised of the FSCA.

Please complete the attached Medical Device Recall Response Form and fax to +1-801-264-1755 or e-mail to recall@icumed.com. Please include the words "**ChemoLock Port**" in the subject line.

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,



German Contact for this Recall:
MDSS GmbH
Tel.: +49-511-62628630
vigilance@mdss.com

Enclosures:

- Affected Product and Lot Numbers
- Response Form

Table 1. Affected Product and Lot Numbers

Item No.	Description	Lot No.
011-CL3341	74" (188 cm) Appx 9.0 ml, 20 Drop Admin Set w/Integrated ChemoLock™ Port Drip Chamber, Rotating Luer, Bag Hanger	2912285
011-CL3511	30" (76 cm) Appx 3.6 ml, 20 Drop Admin Set w/Integrated ChemoLock™ Port Drip Chamber, ChemoLock™, Bag Hanger	2860408, 2903727, 2938260, 3048128, 3072971
011-CL3528	30" (76 cm) Appx 6.3 ml, 20 Drop Admin Set w/Integrated ChemoLock™ Port Drip Chamber, 0.2 Micron Filter, ChemoLock™, Hanger	2938262
AHCL3300	110" (279 cm) Appx 13.8 ml, 20 Drop Admin Set w/Integrated ChemoLock™ Port Drip Chamber, Clave®, Rotating Luer, Bag Hanger	3114044, 3118069, 3124607, 3128408, 3183022
AHCL3511	30" (76 cm) Appx 3.6 ml, 20 Drop Admin Set w/Integrated ChemoLock™ Port Drip Chamber, ChemoLock™, Bag Hanger	2976071
AHCL3536	110" (279 cm) Appx 13.9 ml, 20 Drop Admin Set w/Integrated ChemoLock™ Port Drip Chamber, ChemoLock™, Bag Hanger	3045156
CL3011	30" (76 cm) Appx 3.3 mL, Admin Set w/20 Drop Integrated ChemoLock™ Drip Chamber, Spiros®, Hanger, Drop-In Red Cap	2603990, 2638178, 2648080, 2650789, 2651575, 2707143 2758814, 2775922, 2807999 2812304, 2822505, 2935268 2959788, 2981443, 2996455 3004510, 3004872, 3014970 3021774, 3031244, 3036751 3042661, 3050748, 3062734 3066394, 3070408, 3090587 3093069, 3095818, 3099253 3104787, 3106886, 3113237 3116568, 3124603, 3128411 3150731, 3160102, 3168416 3175643, 3179949, 3184510
CL3511	30" (76 cm) Appx 3.6 ml, 20 Drop Admin Set w/Integrated ChemoLock™ Port Drip Chamber, ChemoLock™, Hanger	2775926, 2812305, 2817810 2822507, 2869949, 2906006 2935267, 2956661, 3000036 3021000, 3022814, 3050749 3093071, 3106072,3112028 3113234, 3116570, 3122924 3124606, 3128409, 3146957 3154612, 3158607, 3160103 3172391, 3179951, 3182579
CL3528	30" (76cm) Appx 6.3 ml, 20 Drop Admin Set w/Integrated ChemoLock™ Port Drip Chamber, 0.2	2770706

	Micron Filter, ChemoLock™, Hanger	
SL3011	31" (79 cm) Appx 3.4 ml, 20 Drop Admin Set w/Integrated ChemoLock Drip Chamber, Spiros®, Bag Hanger	3132625, 3136286, 3158761

URGENT: Medical Device Recall Response Form

Product: I.V. Administration Sets with ChemoLock Port

Section A

Name of Hospital / Facility	
Hospital / Facility Address	
Telephone Number	
Name	
Signature	
Date	
If Purchased through a distributor, please list distributor name/location here for traceability purposes	

Section B

I have read and understood the contents of this recall notice and confirm that our inventory has been checked and we have no inventory of the listed products.

Section C

I have read and understood the contents of this recall notice and confirm that our inventory has been checked, Quarantined, and returned to ICU Medical Inc.:

Section D

I have read and understood the contents of this recall notice and confirm that our inventory has been checked and destroyed in accordance with site procedures:

Item #	Lot #	Quantity Returned	ICU RGA Number

Please return to:

ICU Medical Recall Coordinator

E-mail: Recall@icumed.com, Please include the words "**ChemoLock Port**" in the subject line

Or FAX: +1-801-264-1755.