

URGENT: Field Safety Notice

Affected Device(s): I.V. Administration Sets with NanoClave® manifold

Date: 01-June-2017

Dear Valued Customer:

Director of Risk Management Director of Nursing Director of Pharmacy

ICU Medical Inc. has identified the potential risk of leakage with certain I.V sets containing NanoClave® manifold. In these sets, the connection between the Female Luer and the Nanoclave manifold 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 listed above.			
	If	Then		
	No affected devices are found:	Complete sections A & B of the Recall Response Form and return to ICU Medical, see Step 2 below.		
	Affected devices are found:	 Quarantine any affected devices Complete sections A through C of the Recall Response Form as applicable and return to ICU Medical, see Step 2 below. Contact ICU Customer Care for a Return Goods Authorization. Call: (866) 829-9025 and select option 2 or 		
		- E-mail: <u>ProductReturns@icumed.com</u>		



Step	Action	
2	Return completed Recall Response Form to ICU Medical, Inc. via	
	- FAX: (801) 264-1755	
	or	
	- E-mail: <u>recall@icumed.com</u>	

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. NOTE: Credits for product purchased through distributor will be credited by the distributor.

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: 866-829-9025 and select option 2, or e-mail the following address: Productreturns@icumed.com. For customers in Europe please contact: Customerserviceeurope@icumed.com or call on numbers listed below.

Country	Language	Phone Number	
France	French	+33 4 9913 30 34	
Belgium	Flemish	+32 2 7007177	
Belgium	French	+32 2 7007177	
Germany	German	+49 2349 7849009	
Italy	Italian	+39 0687 500833	
Others and distributors	English	+44 203 564 3377	

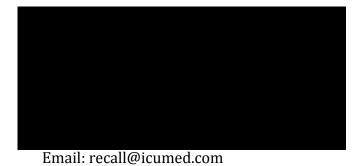
This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

Please complete the attached Medical Device Recall Response Form and fax to (801) 264-1755 or e-mail to recall@icumed.com. Please include the words "I.V. Administration Sets with NanoClave® manifold" 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,



Enclosures:

- Affected Product and Lot Numbers
- Response Form



Table 1. Affected Product and Lot Numbers

Item No.	Description	Lot No.
011-	18 cm (7") PUR Smallbore Ext Set w/6-Port	3172948
AM6111	NanoClave® Manifold, Check Valve, NanoClave®,	3192947
	Rotating Luer	3224228
	-	3246765
		3260270
011-	168 cm (66") Appx 2.6 ml, PVC/PUR Smallbore Ext Set	3297341
AM6115	w/6-Port NanoClave® Manifold, Check Valve,	3354442
	MicroClave® Clear, Rotating Luer	3388890
011-	28 cm (11") PUR Bifuse Ext Set w/6-Port NanoClave®	3303906
AM6116	Manifold, Check Valve, 2 NanoClave®, Rotating Luer	
011-	28 cm (11") PUR Smallbore Ext Set w/6-Port	3296247
AM6117	NanoClave® Manifold, Check Valve, NanoClave®,	
	Rotating Luer	
011-	PROXIMALE - 28 cm (11") Smallbore Ext Set w/6-Port	3316827
AM6118	NanoClave® Manifold, Check Valve, NanoClave® (Red	
	Rings), Rotating Luer	
011-	Kit w/3 Ext Sets, 3 Drop-In MicroClave® Clear	3320753
AM6123		



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Product: I.V. Administration Sets with NanoClave® manifold

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.:

Item #	Lot #	Quantity Returned (please specify if quantity returned is each device or cases)	ICU RGA Number

Please return to:

ICU Medical Recall Coordinator

E-mail: Recall@icumed.com, Please include the words "I.V. Administration Sets with NanoClave® manifold" in

the subject line

Or FAX: (801) 264-1755.