

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:	<ul style="list-style-type: none"> • Complete sections A & B of the Recall Response Form and return to ICU Medical, see Step 2 below.
	Affected devices are found:	<ul style="list-style-type: none"> • 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. <ul style="list-style-type: none"> - Call: (866) 829-9025 and select option 2 or - E-mail: ProductReturns@icumed.com

Step	Action
2	Return completed Recall Response Form to ICU Medical, Inc. via <ul style="list-style-type: none"> - FAX: (801) 264-1755 or - 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. 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,



Email: recall@icumed.com

Enclosures:

- Affected Product and Lot Numbers
- Response Form

Table 1. Affected Product and Lot Numbers

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

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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.