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

URGENT: FIELD SAFETY NOTICE

MicroClave Incomplete Assembly
See Table 1 for Affected Product and Lot Numbers

15th August 2022

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

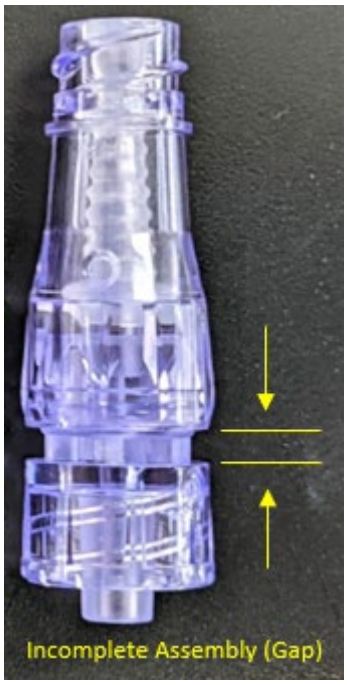
ICU Medical, Inc. is issuing this Urgent Field Safety Notice to notify you of a potential defect with the MicroClave Clear connector. This urgent Field Safety Notice details the issue and the required steps for you to perform.

Issue:
ICU Medical has identified the potential for a manufacturing defect within specific lots of MicroClave Clear sets, which may result in a visible gap between the MicroClave Clear connector's top and bottom housings.

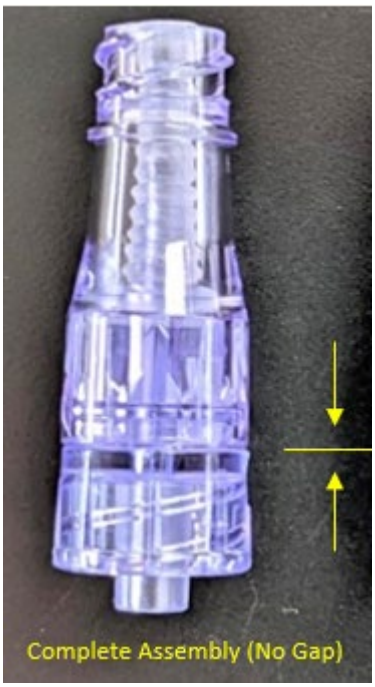
Potential Risk:
Inadequate connection between the MicroClave Clear connector's top and bottom housings may potentially cause fluid leak, blood loss, air ingress, or contamination. To date, ICU Medical has not received any reports of serious injury or death associated with this issue.

Affected Product:
Our records indicate that you may have received some of the affected products, which were distributed in Sweden in January 2022. The affected item and lot numbers are provided in Table 1.

The images below depict a MicroClave Clear connector with a visible gap versus a MicroClave Clear connector with no gap:



Picture 1 with Gap



Picture 2 with No Gap

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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) If you choose to utilize MicroClave Clear lot numbers listed in Table 1, you may utilize the photographs above to identify units with a visible gap. Inspect the MicroClave prior to use and if a gap is present as shown in Picture 1, do not use the product.

3) Inform potential users of the product in your organization of this notification and complete the attached response form below indicating what affected product you have and whether you intend to return this to ICU Medical or destroy it locally. Return the completed response form to the e-mail address on the form, even if you do not have any of the affected product.

4) Upon receipt of the affected product, or upon receipt of a Certificate of Destruction, ICU Medical will credit you for any product returned/destroyed. You will only receive credit for product that you return or that you certify has been destroyed locally.
NOTE: Credits for product purchased through distributor will be credited by the distributor.

5) 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 your customers to complete a response form and return to you for overall completion.

Follow up Actions:
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	ProductComplaintsPP@icumed.com	To report adverse events or product complaints
Customer Service	EMEAdistributor-support@icumed.com	Additional information or assistance

The Swedish Medical Products Agemcy (Läkemedelsverket) has been notified of this action.

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,

Corine Broekhuizen
Director, Quality and Regulatory Affairs
ICU Medical BV

Enclosures:

- Affected Product and Lot Numbers
- Response Form

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Table 1: Affected Product and Lot Numbers

Item Number	Product Description	Lot Number
011-MC100	MicroClave™ Clear Connector	5740714

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URGENT: FIELD SAFETY NOTICE RESPONSE FORM

MicroClave Incomplete Assembly

15th August 2022

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-Quality@icumed.com, EMEAdistributor-support@icumed.com and your ICU Medical sales representative.

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	

☐ I have **NO** affected product (complete and return this form to the e-mail addresses above).
☐ **YES**, I have affected product

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

TABLE 1

List Number	Lot Number	Quantity in inventory	PO, debit memo or invoice

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

TABLE 2

List Number	Lot Number	Quantity destroyed locally by customer	Quantity returned to distributor

☐ I have followed the instructions provided to me and I will **destroy** affected products on site (complete and return provided Certificate of Destruction to the email addresses on the certificate).

☐ I have followed the instructions provided to me and I will contact my ICU Medical CS Representative to make arrangement to **return** the affected products.

☐ I have chosen to **use** the affected product because _____ (Please explain).

Adverse events and complaints associated with the use of these products should be reported and emailed to ICU Medical at the contact information provided.