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

URGENT: MEDICAL DEVICE RECALL

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

25 July 2022

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

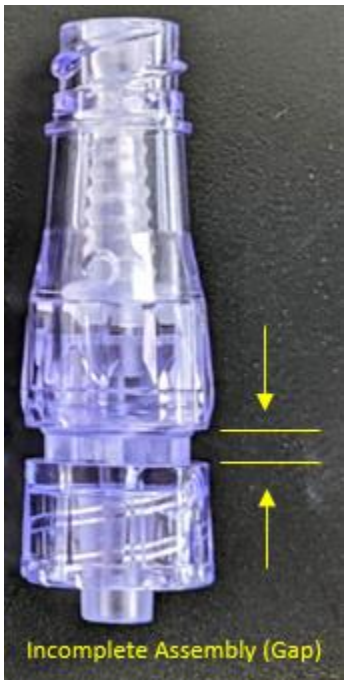
ICU Medical, Inc. is issuing this Urgent Medical Device Recall letter to notify you of a potential defect with the MicroClave Clear connector. This letter details the issue and the required steps for you to perform.

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.

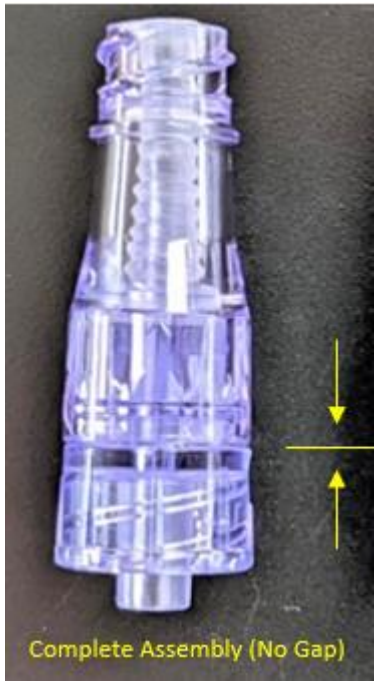
Potential Risk:
Inadequate connection between the MicroClave Clear connector's top and bottom housings may potentially cause fluid leak, blood loss, air ingress, or contamination. To date, ICU Medical has not received any reports of serious injury or death associated with this issue.

Affected Product:
Our records indicate that you may have received some of the affected products, which were distributed to Malaysia between 31 December 2021 to 10 March 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. If you have distributed the product further, immediately notify your accounts that received the product identified in the Affected Product in Table 1 sections of this notification. Return the completed response form to the e-mail address on the form, even if you do not have the affected product.

4) 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.

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Follow up Actions:
Please contact commercial lead 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
Commercial Lead for Malaysia	Vincent.fernandez@icumed.com	General inquiries/Product replacement
Asia Quality	Asiaquality@icumed.com	General inquiries/Return accomplished response form

This has been assessed to be a reportable action to Malaysia Health Authority. Please proceed to perform notification and keep us in loop of their response and any additional support needed.

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,

25 Jul 2022

Leodigard (Gary) Montefalcon Jr.
QA Manager Asia

Enclosures:

- Affected Product and Lot Numbers
- Response Form
- External FAQs

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Table 1: Affected Product and Lot Numbers

List Number	Product Description	Lot Number
066-MC100	SURPLUG MICROCLEAR CONNECTOR	5735598