

URGENT: MEDICAL DEVICE RECALL

Item No.	Description
CH-80S	ChemoClave® Vial Spike, 20mm

21 February 2019

To: Medquest Marketing Pte Ltd

Dear Valued Customers:

ICU Medical, Inc. is issuing this Urgent Medical Device Recall letter to notify you of a voluntary recall of certain lots of ChemoClave® Vial Spikes. This product notification details the issue and the required steps for you to perform.

Issue:

ICU Medical identified the potential for plastic burr particulate in certain lots of ChemoClave® Vial Spikes, originating from the protective cap used in the assembly of the device. Out of an abundance of caution, ICU Medical is issuing this notification.

Potential Risk:

Burr particulate originating from the protective cap have the potential to detach. In uncommon circumstances a detached burr could enter the fluid path with potential to be infused into an intravenous line, which could potentially enter the patient and lead to an embolism. To date, ICU Medical has not received any reports of adverse events related to this issue.

Affected Product:

Our records indicate that you have received some of the affected products, which were distributed in Singapore between November 2018 and January 2019. The affected item and lot number are provided in Table 1.

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) Please complete the attached response form and return it to the e-mail address on the form, even if you do not have the affected product. In addition, this notification should be carried out to the user level and passed on to all those who need to be aware within your organization or to any other organization the device may have been transferred. If you have distributed the product further, notify your accounts that received the product identified in Table 1 of this notification.
- 3) 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.

Follow-up Actions by ICU Medical:

Product replacement options are available. Please contact Customer Care representatives using the information provided below.

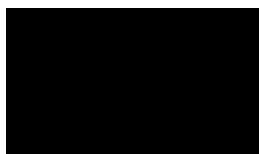
For further inquiries, including product replacement options, please contact ICU Medical using the information provided below.

ICU Medical Contact	Contact Information	Areas of Support
Global Complaint Management	apac.pumpcomplaints@icumed.com	To report adverse events or product complaints
ICU Commercial Lead For Singapore	rhoda.nifras@icumed.com	General inquires / Product replacement
Asia QA Team	AsiaQuality@icumed.com	General inquires / Return of Customer response form

This has been assessed to be reportable action to Singapore 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,



21 FEB 2019

Quality Manager Asia

Enclosures:

- Affected Item and Lot Number
- Customer Response Form

cc Chairman Medical Board and Relevant Head of Departments



04 MAR 2019

Table 1: Affected Product and Lot Number

Item Number	Description	Lot Number
CH-80S	ChemoClave® Vial Spike, 20mm	3826647, 3854001 3826844, 3827598 3839689, 3839690 3866761, 3873006