

URGENT: MEDICAL DEVICE RECALL

Item No.	Description
CL-80S	ChemoLock™ Vial Spike, 20mm

03 January 2019

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 voluntary recall of one lot of ChemoLock™ Vial Spike, 20mm. This product notification details the issue and the required steps for you to perform.

Issue:

ICU Medical has identified the potential for burr particulate in one lot of ChemoLock™ Vial Spike, 20mm, 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 the United States between August 2018 and September 2018. 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) Inform potential users of the product in your organization of this notification and complete the attached response form. Return the completed response form to the fax number or e-mail address on the form, even if you do not have the affected product.
- 3) Return affected product using the return label provided with this letter. Contact Stericycle at 1-888-871-7114 (M-F, 8am-5pm ET) if you have not received a return label or require additional labels for returning the affected product. The return labels are for single use only. Please do not reproduce. Please visit <http://expertezlabel.com> to request additional labels for returning affected product. To ensure proper and timely credit, follow the instructions on the return label for returning product. 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.

- 4) 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 them to contact Stericycle at 1-888-871-7114 (M-F, 8am-5pm ET) to obtain a response form.

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	1-844-654-7780 (ProductComplaintsPP@icumed.com)	To report adverse events or product complaints
Medical Information	1-800-241-4002, option 6 or medinfo_us@icumed.onmicrosoft.com	Medical inquiries
Customer Care	1- 949-366-4208	Product Replacement Options

The U.S. Food and Drug Administration (FDA) has been notified of this action.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report **Online:** www.fda.gov/medwatch/report.htm
- **Regular Mail or Fax:** Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

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,



John Beard, MD
Medical Director, Medical Affairs

Enclosures:

- Affected Item and Lot Number
- Customer Response Form
- Return Label

Table 1: Affected Product and Lot Number Distributed in the United States

Item Number	Description	Lot Number
CL-80S	ChemoLock™ Vial Spike, 20mm	3757712