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

URGENT DRUG RECALL

0.9% SODIUM CHLORIDE INJECTION, USP 100ML

09 November 2022

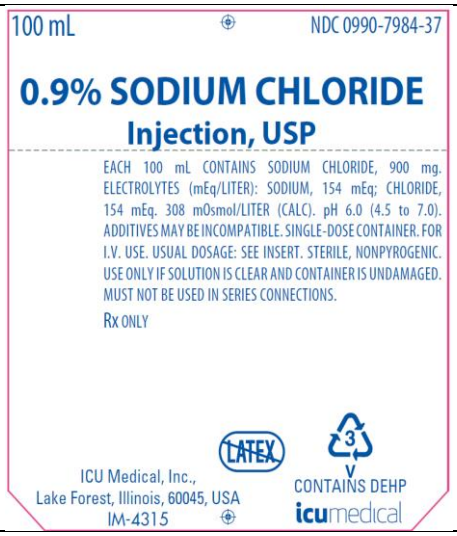
Dear Valued Customers:
Director of Risk Management
Director of Materials Management
Director of Pharmacy

ICU Medical, Inc. is issuing a voluntary recall for one lot of 0.9% SODIUM CHLORIDE INJECTION, USP 100ML due to the potential for leaks in the flexible container. This notification details the issue and the required steps for you to perform.

Issue:
ICU Medical has identified a potential for leaks related to a manufacturing issue.

Potential Risk:
Solution from a leaking flexible container may have compromised sterility and may potentially lead to delay of therapy, infusion of biologic and non-biologic contaminants, spillage, skin, and mucous membrane exposure to allergenic or hazardous substances, or inadequate or inconsistent solution/medication dosing. As instructed in the product labels, prior to administration, healthcare professionals should inspect the product and not administer the product if the container is damaged. The reported incidents were identified prior to use, and there have been no reports of adverse events associated with this issue to date.

Affected Product:
The affected product lot was manufactured on 01 April 2022 and distributed in the United States between 26 May 2022 and 08 July 2022. The affected product lot is:

NDC Number	List Number	Product Description	Lot Number	Expiration Date	Configuration	Label Example
0990-7984-37	079840456	0.9% SOD CHL INJ USP 100ML 4-1	5829936	31 March 2024	100mL Flexible Container	

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Required Actions:

1. **Because this product is on the critical drug shortage list,** please inspect the product prior to use, as indicated on the container, to determine if the container is damaged. If the container is damaged, please discontinue the use of the affected product immediately. Check your inventory to locate and quarantine all affected product at your facility.

2. If the container is not damaged, and the benefits of using this lot (lot 5829936) of product outweigh the potential risks outlined above associated with using this lot of product because this product is on the critical shortage list, periodically monitor the container for leakage during clinical use.

3. 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.

4. Return affected product using the return label provided with this letter. Contact Sedgwick at 1-888-943-5186 (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, Inc. 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.

5. If you have distributed the product further, immediately notify your accounts that received the product identified above of this notification and ask them to contact Sedgwick at 1-888-943-5186 (M-F, 8am-5pm ET) to obtain a response form.

To return affected product or if you require assistance, please contact Sedgwick at 1-888-943-5186 (M-F, 8am to 5pm ET) to obtain a return label.

For further inquiries, please contact ICU Medical using the information provided below.

ICU Medical Contact	Contact Information	Areas of Support
Global Complaint Management	1-844-654-7780 or ProductComplaintsPP@icumed.com	To report product complaints
Drug Safety	1-844-654-7780 or DrugSafety@icumed.com	To report adverse events for IV Solutions & Drugs
Medical Information	1-800-241-4002, option 6 or medinfo_us@icumed.com	Medical inquiries
Customer Care	1-877-946-7747, option 1	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.

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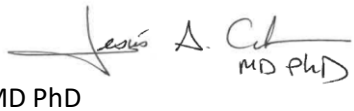
- Complete and submit the report **Online**: www.fda.gov/medwatch/report.htm
- **Regular Mail or Fax**: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

ICU Medical is committed to patient safety, 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,

Amy Giertych
Vice President, Global Regulatory Affairs



Jesús Cabrera, MD PhD
Chief Medical Officer, Medical Affairs

Enclosures:

- Response Form