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URGENT: DRUG RECALL
Attention: Update to previous communication

12 October 2018

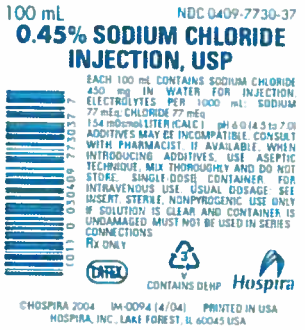
Dear Valued Customers:
Director of Risk Management
Director of Materials Management
Director of Pharmacy

On 06 June 2018, ICU Medical, Inc. issued an **Urgent: Drug Recall Notification** letter informing customers of the voluntary recall for certain lots of Hospira Intravenous (IV) solutions due to the potential for flexible container leaks

UPDATED INFORMATION: As a result of continued evaluation, ICU Medical is expanding the scope of the previously distributed Urgent: Drug Recall Notification to include additional lots of Hospira Intravenous (IV) Solutions. All product lots identified in this communication have the potential for flexible container leaks. This notification details the issue and the required steps for you to perform.

Affected Product:

UPDATED INFORMATION: Our records indicate you have received some of the additional affected products, which were manufactured between December 2017 and January 2018 and distributed in the United States between December 2017 and July 2018. All of the affected product lots are below with the additional lots highlighted in red:

NDC Number	Product Description	Lot Number*	Expiration Date	Configuration	Label Example
0409-7730-37	0.45% Sodium Chloride Injection, USP	85-023-JT	July 01, 2019	100mL Flexible Container	

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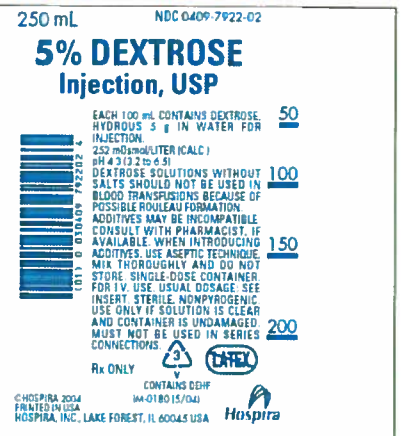
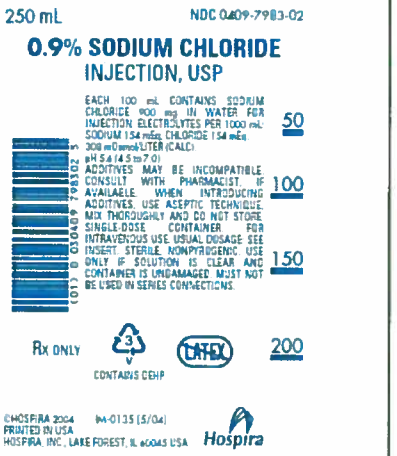
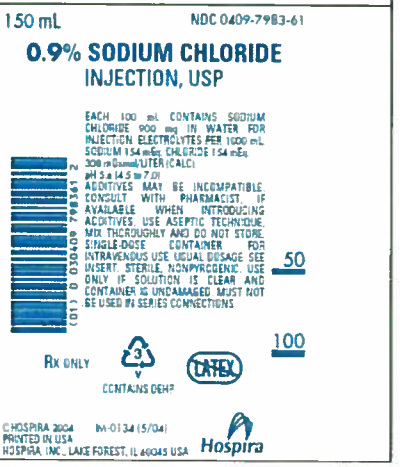
0409-7922-02	5% Dextrose Injection, USP	84-012-JT	June 01, 2019	250mL Flexible Container	
0409-7922-02	5% Dextrose Injection, USP	86-033-JT	August 01, 2019	250mL Flexible Container	
0409-7923-20	5% Dextrose Injection, USP	84-017-JT	December 01, 2019	25mL Flexible Container	
0409-7983-02	0.9% Sodium Chloride Injection, USP	84-011-JT	December 01, 2019	250mL Flexible Container	
0409-7983-02	0.9% Sodium Chloride Injection, USP	85-014-JT	January 01, 2020	250mL Flexible Container	
0409-7983-02	0.9% Sodium Chloride Injection, USP	85-018-JT	January 01, 2020	250mL Flexible Container	
0409-7983-02	0.9% Sodium Chloride Injection, USP	85-031-JT	January 01, 2020	250mL Flexible Container	
0409-7983-61	0.9% Sodium Chloride Injection, USP	84-015-JT	December 01, 2019	150mL Flexible Container	

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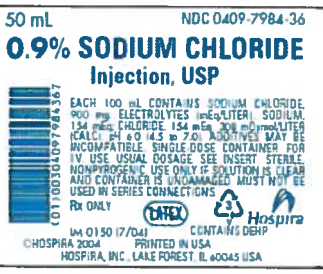
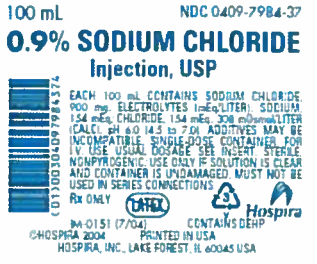
0409-7984-23	0.9% Sodium Chloride Injection, USP	85-016-JT	January 01, 2020	100mL Flexible Container	
0409-7984-36	0.9% Sodium Chloride Injection, USP	84-016-JT	June 01, 2019	50mL Flexible Container	
0409-7984-37	0.9% Sodium Chloride Injection, USP	84-005-JT	December 01, 2019	100mL Flexible Container	
0409-7984-37	0.9% Sodium Chloride Injection, USP	84-014-JT	December 01, 2019	100mL Flexible Container	
0409-7984-37	0.9% Sodium Chloride Injection, USP	85-021-JT	January 01, 2020	100mL Flexible Container	
0409-7984-37	0.9% Sodium Chloride Injection, USP	86-001-JT	February 01, 2020	100mL Flexible Container	

* Note: The lot number on the shipping carton label may be followed by additional digits (Ex. 85-023-JT-XX)

Issue:

ICU Medical identified flexible container leaks, potentially related to a manufacturing issue, in returned complaint samples and in ICU Medical reserve samples.

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.

Required Actions:

1. Please stop the use and distribution of the affected product immediately. Check your inventory to locate and quarantine all affected product at your facility. The NDC number, lot number, and expiration date can be found on the individual product or shipping case.

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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 1-877-523-9106 (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.

4. The recall is being carried out to the Hospital / User level. 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 Stericycle at 1-877-523-9106 (M-F, 8am-5pm ET) to obtain a response form.

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	Global Complaint Management
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.onmicrosoft.com	Medical inquiries

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, 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

John Beard, MD
Medical Director, Medical Affairs

Enclosures:

- Response Form
- Return Label

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URGENT: DRUG RECALL RESPONSE FORM
UPDATE TO PREVIOUS COMMUNICATION ISSUED 06 June 2018
Potential for Leaking Flexible Containers

12 October 2018

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.*

Fax the completed form to 1-877-244-1979 or email it to ICUmedical6625@stericycle.com. The return label provided in this notification is for single use only, please DO NOT reproduce. Please visit http://expertezlabel.com to request additional labels for returning affected product. If you have questions about this form please call Stericycle at 1-877-523-9106 (M-F, 8am - 5pm ET).

Name of Hospital / Facility	
Hospital / Facility Address	
Telephone Number	
Name 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 Stericycle at the fax/e-mail above).

☐ **YES**, I have affected product (complete and return this form to Stericycle via the fax/e-mail above and return the product per the instructions on the return label).

If affected product is not being returned, please explain below:

- Have you distributed the product further to the retail level? YES___ NO___
  - If yes, have you notified your retail customers? YES___ NO___ (if no, explain below)

NDC and Lot Number	Quantity to be returned	Wholesaler/Distributor Name If you purchased from Wholesalers/Distributors include name, address, city, state, zip, quantity from each, and invoice number. If you purchased directly from ICU Medical leave this section blank.	PO, debit memo or invoice
		1.	
		2.	
		3.	

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