icumedical
human connections

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

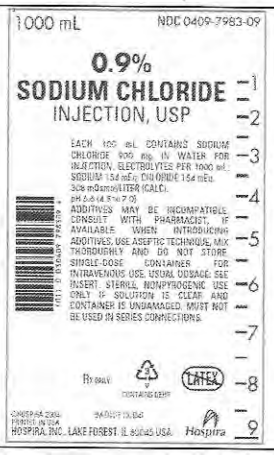
URGENT: DRUG RECALL

08 February 2019

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 Hospira intravenous (IV) solution due to a processing error. This notification details the issue and the required steps for you to perform.

Affected Product:
The affected product lot was manufactured July 2018 and distributed in the United States between August 2018 and November 2018. The affected product lot is:

NDC Number	Product Description	Lot Number*	Expiration Date	Configuration	Label Example
0409-7983-09	0.9% Sodium Chloride Injection, USP	91-016-JT	July 01, 2020	1000 mL Flexible Container	

* Note: The lot number on the shipping carton label may be followed by additional digits (Ex. 91-016-JT-XX)

Issue:
ICU Medical identified a deviation during manufacturing resulting in a portion of lot 91016-JT not meeting environmental control requirements which could result in subvisible particulate exceeding specifications. The affected portion of the lot was inadvertently released for distribution.

Potential Risk:
ICU Medical has not identified any product that has been compromised as a result of the event; however, ICU Medical is initiating this action out of an abundance of caution. As ICU Medical has no evidence of the affected portion of the lot exceeding specifications for subvisible particulate, infusion of product that has been compromised is unlikely to occur and extremely unlikely to lead to harm. Administration of the affected product associated with this issue is unlikely to lead to reversible or serious adverse health consequences. ICU Medical has not received any complaints or adverse event reports associated with this issue.

Required Actions for Users:
1. Please discontinue 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 1-888-879-4613 (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 1-888-879-4613 (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 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.onmicrosoft.com	Medical inquiries
Customer Care	1-877-946-7747, option 1	Product Replacement Options

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:

- Customer Response Form
- Return Label

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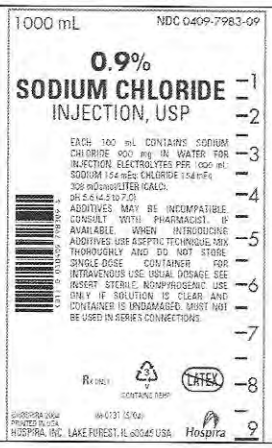
URGENT: DRUG RECALL RESPONSE FORM

NDC Number	Product Description	Lot Number*	Expiration Date	Configuration	Label Example
0409-7983-09	0.9% Sodium Chloride Injection, USP	91-016-JT	July 01, 2020	1000 mL Flexible Container	

* Note: The lot number on the shipping carton label may be followed by additional digits (Ex. 91-016-JT-XX)

08 February 2019

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 1-888-253-5702 or email it to icumedical8565@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 1-888-879-4613 (M-F, 8am - 5pm ET).

Name of Hospital / Facility	
Hospital / Facility Address	
Telephone Number	
Name and Title 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 and asked them to contact Stericycle at 1-888-879-4613 (M-F, 8am-5pm ET) to obtain a response form? YES___ NO___ (if no, explain below)

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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.	

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.

The below shipping label is not intended for multiple shipments. Please DO NOT duplicate or re-distribute.

Ship STERICYCLE
To:
2670 EXECUTIVE DRIVE SUITE A
INDIANAPOLIS IN 46241

RS
ID: 60067841
Event: 8565
Seq.# 419

IN 462 8-01

UPS GROUND
TRACKING: 1Z E38 010 06 4637 7749

PACKING INSTRUCTIONS:

1. Fill out this packing slip and photocopy it for your records. Return this original packing slip with your product shipment.

2. Affix prepaid UPS RS shipping label to shipping container (if reusing a shipping container, remove or mark out all labels, stickers, hazmat and ORM markings). Give directly to any UPS driver or deliver to UPS. (Do not enter this shipment in a UPS log book or apply any other UPS shipping label or bar code.)

3. Keep this for your records. All follow-up will be based on this shipping information.

TRACKING: 1Z E38 010 06 4637 7749

ID 60067841 Event 8565
LIFE ASSIST INC

GTY-04-12