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600 N. Field Drive
Lake Forest, IL 60045
(224) 212-2000
www.icumed.com

URGENT: DRUG RECALL

July 31, 2017

Dear Valued Customers:

ICU Medical is issuing a voluntarily recall for one lot of Normal Saline (0.9% Sodium Chloride Inj., USP) due to a confirmed customer complaint of particulate matter identified as stainless steel within a single flexible container. 0.9% Sodium Chloride Injection, USP 1000 mL is an intravenous solution indicated for parenteral replenishment of fluid. The affected product lot was manufactured in the U.S. by Hospira, a Pfizer company, on February 01, 2016 and was distributed nationwide to Hospira customers between April 14, 2016 and February 02, 2017. The affected product is:

0.9% Sodium Chloride Injection, USP

NDC Number	Lot Number*	Expiration Date	Configuration/Count
0409-7983-09	61-841-FW	January 01, 2018	1000mL Single Dose Flexible Container

* Note: The lot number on the shipping carton label may include additional digits (Ex. 61-841-FW-XX)

Potential Risk:
Injection of particulate matter could potentially lead to limited adverse events such as allergic reactions, local irritation and inflammation in organs or tissues or other serious adverse health consequences. Prior to administration, healthcare professionals, as instructed in the product label, should visually examine the product for particulate matter and discoloration and should discard if a defect is identified. The reported incident was 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.

2. Inform potential users of the product in your organization of this notification and complete the attached response form and return it 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 1-844-491-7872 (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.

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4. If you have distributed the product further, notify your accounts that received the product identified above of this notification and ask them to contact Stericycle at 1-844-491-7872 (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	1-800-441-4100 (M-F, 8am-5pm CT) (drugproductcomplaints@pfizer.com)	To report adverse events or product complaints
Medical Information	1-800-241-4002, Option 6 (M-F, 8am-5pm CT)	Medical Inquiries

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,

Amy Giertych
Vice President, Global Regulatory Affairs

JW Beard MD
John Beard, MD
Medical Director

Enclosures:

- Response Form
- Return Label

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URGENT: DRUG RECALL RESPONSE FORM
0.9% Sodium Chloride Inj., USP 1000mL – Particulate Matter

July 31, 2017

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 1-844-265-7383 or email it to ICUmedical8242@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 1-844-491-7872 (M-F, 8am - 5pm ET).

Customer Information

_____ _____
Hospital/Facility Name ICU Medical Customer # (if applicable)

_____
Address/City/State/Zip

_____
Contact Name/Phone/E-mail Address

_____
Completed by: Printed Name/Signature/Date

☐ I have **NO** affected product (fill out and return this form to Stericycle at the fax/e-mail above).

☐ **YES**, I have affected product (fill out 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
NDC #: 0409-7983-09 *Lot #: 61-841-FW *Note: The lot number on the shipping carton label may include additional digits (Ex. 61-841-FW-XX)		1.	
		2.	
		3.	
		4	