

URGENT DRUG RECALL



Product	NDC Number	Lot	Expiration Date
0.9% Sodium Chloride Inj., USP, 250mL	0409-7983-02	94-833-KL*	1OCT2012
0.4% Lidocaine HCl and 5% Dextrose Inj., USP, 250mL	0409-7931-32	92-643-KL*	1FEB2012

* Note: the lot number may be followed by 01, 02, or 03

January 20, 2012

Dear Valued Customer:

Hospira, Inc. is voluntarily recalling one lot of 0.9% Sodium Chloride Injection, USP and one lot of 0.4% Lidocaine Hydrochloride and 5% Dextrose Injection, USP, both identified above due to confirmed out of specification results for in-process chemical assay during lot specific protocol testing.

These lots were distributed November 2010 through September 2011. Replacement product from other lots is available for both products. Hospira has not received reports of any adverse events associated with this issue for these lots. This recall is being conducted as a precautionary measure. Hospira has notified the U.S. Food and Drug Administration.

Hospira has initiated an investigation to determine the root cause and corrective and preventive actions.

Please check your inventory and immediately quarantine any affected product. Complete the attached reply form and return it to the fax number or e-mail address on the form, even if you do not have the affected product. Inform healthcare professionals in your organization of this recall.

Return affected product to Stericycle using the label provided with this letter. Please visit <http://expertezlabel.com> to request additional labels for returning affected product. Call Stericycle at 1-866-204-6110 if you have not received a return label or require additional assistance. To ensure proper and timely credit, follow the instructions on the return label for returning the product.

If you have distributed the product further, notify your accounts that received the product identified above of this recall and ask them to contact Stericycle to receive a reply form and return labels for returning the product.

Replacement product for both products is available from other lots. Please contact Hospira Customer Care at 1-877-946-7747 or your Hospira representative for information regarding replacement product.

For clinical inquiries, please contact Hospira using the information provided below.

Hospira Contact	Contact Information	Areas of Support
Hospira Global Product Safety and Complaints	1-800-441-4100 (8am-5pm CST, M-F) (ProductComplaintsPP@hospira.com)	To report adverse events or product complaints
Hospira Medical Communications	1-800-615-0187 (Available 24 hours a day/7 days per week)	Medical inquiries

2579_01_01AD

Hospira, Inc.
275 North Field Drive
Lake Forest, IL 60045
(224) 212-2000
www.hospira.com



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.

- **Online:** www.fda.gov/medwatch/report.htm
- **Regular Mail:** use postage-paid, pre-addressed form FDA 3500 available at: www.fda.gov/MedWatch/getforms.htm. Mail to address on the pre-addressed form.
- **Fax:** 1-800-FDA-0178

Hospira is committed to providing our customers with the highest level of service and product quality. We appreciate your cooperation and we regret any inconvenience this action may cause.

Sincerely,

A handwritten signature in black ink, appearing to read "Janet Stevens".

Janet Stevens
Vice President, Parenteral Quality Operations

Urgent Drug Recall Reply Form – Response Required
0.9% Sodium Chloride Inj., USP
0.4% Lidocaine Hydrochloride and 5% Dextrose Inj., USP



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 1-888-410-7506 or e-mail the completed form to Hospira2579@stericycle.com.
 Please visit <http://expertezlabel.com> to request additional labels for returning affected product. Call Stericycle at 1-866-204-6110 if you have not received a return label or require additional assistance.

Required Information	
Business Name	Phone Number
Address/City/State/Zip	DEA #
Hospira Customer Number (ship to #) if applicable	Your reference # (e.g. PO, Debit Memo or Invoice #)
Completed by: Printed Name/Signature/Date	

- I have **NO** affected product
- I have affected product (Return the product per the instructions listed below. Contact Stericycle at the number above if a shipping label is needed.)

NDC and Lot Number	Quantity to be returned	Wholesaler/Distributor Name <small>If you purchased from Wholesalers/Distributors include name, address, city, state, zip, quantity from each, name and invoice number. If you purchased directly from Hospira leave this section blank.</small>	PO, debit memo or invoice
NDC: 0409-7983-02 Lot: 94-833-KL*		1.	
		2.	
NDC: 0409-7931-32 Lot: 92-643-KL*		1.	
		2.	

* Note: the lot number may be followed by 01, 02, or 03

If affected product is not being returned, please explain:

- ✓ 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)

IMPORTANT RETURN INSTRUCTIONS:

Direct Customer (purchased directly from Hospira) <i>Credit will be issued by Hospira</i>	Indirect Customer (purchased from a wholesaler/distributor) <i>Credit will be issued through the wholesaler/distributor</i>
<ul style="list-style-type: none"> ▪ Include a PO, debit memo or invoice showing the purchase price on the outside of the package being shipped (e.g. case, pallet). ▪ Ship only the <i>affected product</i> to Stericycle using the prepaid return label. 	<ul style="list-style-type: none"> ▪ Supply information for each wholesaler/distributor. ▪ Include a PO, debit memo or invoice showing the purchase price on the outside of the package being shipped (e.g. case, pallet). ▪ Ship only the <i>affected product</i> to Stericycle using the prepaid return label.

2579_01_02AS

CID/SEQ

Hospira, Inc.
 275 North Field Drive
 Lake Forest, IL 60045
 (224) 212-2000
www.hospira.com