

URGENT DRUG RECALL



Product	NDC Number	Lot	Expiration
0.9% Sodium Chloride Injection, USP 1000 mL	NDC 0409-7983-48	96-094-JT*	1 Dec 2012

*Note: the lot number may be followed by 01, 02, 03 or 04.

April 6, 2011

Dear Valued Customer:

Hospira, Inc. is voluntarily recalling one lot of 0.9% Sodium Chloride Injection, USP in 1000 mL in VisIV™ containers identified above because there is a potential for solution to leak from the additive port seal. In the unlikely event that the fluid seeps back into the bag, the fluid in the bag could become contaminated.

This lot was distributed in January through March 2011. No other lots are impacted by this recall and replacement product is available.

Hospira has initiated an investigation to determine the cause and preventive actions. We have not received any reports of patient involvement, adverse events or delay in critical therapy related to this issue. This recall is being conducted as a precautionary measure. Hospira has notified the U.S. Food and Drug Administration.

Please check your inventory and immediately quarantine any affected product. Complete the attached Reply Form and return it to the number on the form, even if you do not have the affected product. Please inform healthcare professionals in your organization of this recall. **If you have distributed the product further, notify your accounts that received the product identified above** of this recall and ask them to fax the reply form to the number on the form and follow the instructions provided on the form for returning product.

Return affected product to Stericycle using the label provided with this letter. Please call Stericycle at 1-866-792-5452 if you have not received a return label or require additional labels for returning the affected product. To ensure proper and timely credit, follow the instructions on the reply form for returning the product and include your Hospira customer number (if applicable) and information about your wholesaler/distributor from whom you purchased the affected product (if applicable). Include a copy of your PO, Debit Memo or Invoice showing the purchase price on the outside of the package being shipped (e.g. case, pallet).

For medical inquiries, please call Hospira Medical Communications at 1-800-615-0187.

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", with a stylized flourish at the end.

Janet Stevens
Vice President, Parenteral Quality Operations

2396_01_01AS
Hospira, Inc.
275 North Field Drive
Lake Forest, IL 60045
(224) 212-2000
www.hospira.com

FA104-01 (4)

Urgent Drug Recall Reply Form – Response Required
0.9% Sodium Chloride Inj., USP
NDC 0409-7983-48, Lot 96-094-JT



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.

Required Information	
Business Name	Phone Number
Address/City/State/Zip	
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 (fill out and return the form to Stericycle at the fax/e-mail below.)
- I have affected product (fill out and return the form to Stericycle via the fax/email below. Contact them at the number below to obtain return labels.)

Quantity to be Returned	Wholesaler/Distributor Name <small>If you purchased from multiple 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>	QTY	PO, Debit memo or Invoice
1.			
2.			

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)

Fax the completed form to 1-866-912-9548 or e-mail the completed form to hospira2396@stericycle.com.
To obtain return labels or if you have questions about this form call Stericycle at 1-866-792-5452.

IMPORTANT RETURN INSTUCTIONS:

<p>Direct Customer (purchased directly from Hospira) <i>Credit will be issued by Hospira</i></p> <p>Step 1 Package only the <i>affected product</i>.</p> <p>Step 2 Include a PO, Debit Memo or Invoice showing the purchase price on the outside of the package being shipped (e.g. case, pallet).</p> <p>Step 3 Ship to Stericycle using the prepaid return label.</p>	<p>Indirect Customer (purchased from a wholesaler/distributor) <i>Credit will be issued through the wholesaler/distributor</i></p> <p>Step 1 Supply information for each wholesaler/distributor.</p> <p>Step 2 Package only the <i>affected product</i>.</p> <p>Step 3 Include a PO, Debit Memo or Invoice showing the purchase price on the outside of the package being shipped (e.g. case, pallet).</p> <p>Step 4 Ship to Stericycle using the prepaid return label.</p>
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CID/SEQ

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SAMPLE