

URGENT DRUG RECALL - Expanded



<i>Product</i>	<i>NDC Number</i>	<i>Lot</i>	<i>Expiration</i>
0.9% Sodium Chloride Injection, USP 1000 mL	NDC 0409-7983-48	90-035-JT*	1 JUN 2012

*Note: the lot number may be followed by 01

March 23, 2011

Dear Valued Customer:

Hospira, Inc. is voluntarily expanding the March 4, 2011 recall to include one additional lot of 0.9% Sodium Chloride Injection, USP in 1000 mL flexible plastic containers. On March 4, 2011 Hospira voluntarily recalled NDC 409-7983-09, Lot 95-070-JT in the LifeCare™ container because there is a potential for solution to leak from the bag. This could result in contamination of the fluid inside the bag. Additional investigation has identified the potential for this issue to also occur with lot 90-035-JT in the VisIV™ container and therefore as a cautionary measure Hospira is expanding the recall to include 90-035-JT. This lot was distributed July 2010 through August 2010. Only lots 90-035-JT in the VisIV™ container and 95-070-JT in the LifeCare™ container are impacted by this recall and replacement product is available.

The cause has been identified. Corrective and preventive measures have been implemented. 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 return 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 labels provided with this letter. Please call Stericycle at 1-877-244-8991 if you have not received return labels or require additional labels for returning the affected product or if you need a copy of the reply form. 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).

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".

Janet Stevens
Vice President, Parenteral Quality Operations

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

FA103-04(3)

2348_02_01AS

Urgent Drug Recall Reply Form – Response Required
0.9% Sodium Chloride Inj., USP
NDC 0409-7983-48, Lot 90-035-JT



Check your inventory and complete the information below, even if you do not have the affected product.
To ensure proper and timely credit be sure to include your Hospira customer number (if applicable) and provide information about your wholesaler/distributor from whom you purchased the affected product. *Failure to complete all sections of this page may result in improper, delayed or denied credit.*

Fax the completed form to 1-877-546-9069 or e-mail the completed form to Hospira2348@stericycle.com.

To obtain return labels or if you have questions about this form call Stericycle at 1-877-244-8991.

- I have **NO** affected product (fill out and return the form to Stericycle at the fax/e-mail number above)
- I have affected product (fill out and return the form to Stericycle via fax/email and contact them if you need return labels using the appropriate numbers above)

Quantity of stock on hand to be returned: BAGS _____ or CASES _____
(If affected product is not being returned, please explain)

- ✓ Did you receive this affected product from a wholesaler or distributor? YES ___ NO ___
- ✓ If yes, **you must** provide your wholesaler or distributor name and address below in order to receive credit.

Wholesaler or Distributor Name _____ Address/City/State/Zip (required for indirect customers) _____

- ✓ 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)

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 _____

- Once the return labels are received, package only the *affected product*, this completed reply form, and PO, Debit Memo or Invoice showing the purchase price and then return the product to Stericycle.
- Direct Hospira customers who purchased the product directly from Hospira must supply their Hospira customer number and reference # (e.g. PO, Debit Memo or Invoice #). Credit will be issued by Hospira.
- Indirect customers who purchased the product from a wholesaler or distributor must supply their wholesaler/distributor information and reference # (e.g. PO, Debit Memo or Invoice #). Credit will be issued through the wholesaler/distributor.

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FA103-04 (3)
ID / SEQ #
SAMPLE