

URGENT DEVICE RECALL – Expanded



0.9% Sodium Chloride Flush Syringe List Number 1078-20

Lot	Expiration	Lot	Expiration	Lot	Expiration
95-182-5E	Oct 2012	94-224-5E	Oct 2012	94-233-5E	Oct 2012
94-230-5E	Oct 2012	93-232-5E	Sept 2012	93-230-5E	Sept 2012
93-229-5E	Sept 2012	93-211-5E	Sept 2012	92-133-5E	Aug 2012
92-131-5E	Aug 2012	02-157-5E	Feb 2013	01-170-5E	Jan 2013
01-168-5E	Jan 2013				

January 31, 2012

Dear Valued Customer:

Hospira, Inc. is expanding our November 18, 2011 voluntary recall to include thirteen additional lots of 0.9% Sodium Chloride Injection, USP flush syringes. The additional lots, identified above were distributed January through September 2011. On November 18, 2011 Hospira initiated a recall of six lots due to particulate matter in the fluid pathway. This particulate matter has been identified as the same material as the rubber tip. If injected intravenously, the particulate could result in significant injury to the patient.

This issue was discovered during an internal periodic review of the product. Hospira has not received any reports of this issue or adverse events associated with this issue involving these lots. This recall is being conducted as a precautionary measure. Hospira has notified the U.S. Food and Drug Administration.

Additional product of other lots is available. Please contact Hospira Customer Care or your Hospira representative to order replacement product.

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 866-470-3293 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.

Please contact Hospira Customer Care at 1-877-946-7747 or your Hospira representative for information regarding product availability.

2591_01_01AD

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

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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

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 cursive script, appearing to read "Ileana Quinones".

Ileana Quinones
Vice President, Device Quality Operations

2591_01_01BD

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Expanded Urgent Device Recall Reply Form – Response Required
Sodium Chloride Injection, USP Flush Syringe - List Number 1078-20



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 **1-888-912-2181** or e-mail the completed form to **hospira2591@stericycle.com**.
 To obtain a return label or if you have questions about this form call Stericycle at **1-866-470-3293**.

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 (fill out and return this form to Stericycle at the fax/e-mail above).

I have affected product (fill out and return all pages of the 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:

- ✓ 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)

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
		1.	
		2.	
		1.	
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		1.	
		2.	