URGENT DRUG RECALL

October 17, 2014

Product: Hospira's Flexible Intravenous Containers (Reference Table 1)

Subject: Potential Container Leaks

Dear Risk Manager, Materials Manager and Pharmacy Manager,

Hospira is issuing this voluntary recall letter to alert Health Care Providers of the potential for leakage in flexible containers containing intravenous solutions of the LifeCare product line. Several product lots are potentially impacted by this issue; refer to Table 1 for product lot information. In a Dear Health Care Provider letter issued earlier this year Hospira informed Health Care Providers of the potential of leaking primary containers which was identified during re-inspection of a manufactured product lot which identified a single puncture mark going through the overwrap and primary container. The root cause is attributed to a defect in a conveyance system and corrective actions have since been implemented to prevent reoccurrence. The manufacturing issue that caused this incident has been addressed. Hospira recommends customers check with their local Hospira representative or with Hospira Customer Care (1-877-946-7747, M-F, 7am to 6pm CT) regarding replacement product.

The puncture in the primary container may result in leakage that is difficult to detect. Leakage may result in an open system which has the potential for contamination, compromised sterility, drug waste, spillage, inadequate or inconsistent solution/medication dosing, and/or delay in therapy, all of which may require medical intervention and should be reported to Hospira and/or FDA (see reporting information below). Hazardous topical exposure may occur if a hazardous drug is added to the flexible container. Hospira's product insert packaged with LifeCare flexible intravenous containers recommends providers do not administer unless solution is clear and the container is undamaged.

The lots were originally distributed by Hospira to direct accounts September 2013 to October 2014. To date, Hospira has not received reports of any adverse events associated with this issue for these lots.

Please check your inventory and immediately stop use and 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. If you have not received a return label or require additional assistance contact Stericycle at 1-844-861-6221 (M-F, 8am to 5pm ET). To ensure proper and timely credit, follow the instructions on the return label for returning the product. *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.

This recall is being carried out to the medical facility/retail level (both human and veterinary). Please notify all users in your facility. If you have further distributed the recalled product please notify any accounts or additional locations which may have received the recalled product from you and instruct them if they have redistributed the product to notify their accounts, locations or facilities to the medical facility/retail level. If additional copies of the letter and/or reply form are needed, please contact Stericycle at 1-844-861-6221 (M-F, 8am to 5pm ET).

Please contact Hospira Customer Care at 1-877-946-7747 (M-F, 7am to 6pm CT) or your Hospira representative regarding product availability and for questions regarding this field action.

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

Hospira Contact	Contact Information	Areas of Support
Hospira Global Complaint Management	1-800-441-4100 (M-F, 8am to 5pm CT) (ProductComplaintsPP@hospira.com)	To report adverse events or product complaints
Hospira Medical Communications	1-800-615-0187 or medcom@hospira.com (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.

- 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

This recall is being made with the knowledge of the U.S. Food and Drug Administration.

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,

Robert Arnott
Vice President, Quality – US Pharma Operations

Urgent Drug Recall Reply Form – Response Required
Flexible Containers – Potential Leaks
October 17, 2014

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 1-844-861-6232 or e-mail the completed form to Hospira7120@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 product. If you have not received a return label or require additional assistance contact Stericycle at 1-844-861-6221 (M-F, 8am to 5pm ET).

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).

☐ **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:

- Have you distributed the product further to the medical facility/retail level? YES___ NO___
  - If yes, have you notified your medical facility/retail customers? YES___ NO___ (if no, explain below)

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

Urgent Drug Recall Reply Form – Response Required
Flexible Containers – Potential Leaks
October 17, 2014

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.

Customer Name _____ Customer Number _____

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 Hospira leave this section blank.	PO, debit memo or invoice
		1.	
		2.	
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		2.	
		1.	
		2.	
		1.	
		2.	

Hospira, Inc.
275 North Field Drive
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Table 1

Product	NDC Number	Lot*	Expiration Date
Normosol®-R pH 7.4 Multiple Electrolytes Injection Type 1, USP; 1000 mL container	0409-7670-09	32-082-JT	1AUG2015
Potassium Chloride in 5% Dextrose and 0.45% Sodium Chloride Injection, USP; 1000 mL container	0409-7902-09	34-017-JT	1OCT2015
		35-100-JT	1NOV2015
5% Dextrose Injection, USP; 1000 mL container	0409-7922-09	33-094-JT	1SEP2015
		35-028-JT	1NOV2015
5% Dextrose and 0.45% Sodium Chloride Injection, USP; 1000 mL container	0409-7926-09	33-095-JT	1SEP2015
		36-030-JT	1DEC2015
Lactated Ringer's and 5% Dextrose Injection, USP; 1000 mL container	0409-7929-09	34-134-JT	1OCT2015
		34-166-JT	1OCT2015
5% Dextrose and 0.9% Sodium Chloride Injection, USP; 1000 mL container	0409-7941-09	32-104-JT	1AUG2015
		34-136-JT	1OCT2015
		36-092-JT	1DEC2015
Lactated Ringer's Injection, USP; 1000 mL container	0409-7953-09	32-099-JT	1AUG2015
		32-103-JT	1AUG2015
		34-070-JT	1OCT2015
		34-086-JT	1OCT2015
		34-165-JT	1OCT2015
		35-085-JT	1NOV2015
		35-115-JT	1NOV2015
		35-121-JT	1NOV2015
		36-057-JT	1DEC2015
Normosol®-R Multiple Electrolytes Injection Type 1, USP; 1000 mL container	0409-7967-09	32-081-JT	1AUG2015
		34-115-JT	1OCT2015
0.9% Sodium Chloride Injection, USP; 1000 mL container	0409-7983-09	32-044-JT	1AUG2015
		32-072-JT	1AUG2015
		32-102-JT	1AUG2015
		33-028-JT	1SEP2015
		33-046-JT	1SEP2015
		33-049-JT	1SEP2015
		33-061-JT	1SEP2015
		33-085-JT	1SEP2015
		33-096-JT	1SEP2015
		33-101-JT	1SEP2015

Table 1 continued

Product	NDC Number	Lot*	Expiration Date
0.9% Sodium Chloride Injection, USP; 1000 mL container	0409-7983-09	33-102-JT	1SEP2015
		34-016-JT	1OCT2015
		34-085-JT	1OCT2015
		34-122-JT	1OCT2015
		34-123-JT	1OCT2015
		35-026-JT	1NOV2015
		35-030-JT	1NOV2015
		35-067-JT	1NOV2015
		36-002-JT	1DEC2015
		36-029-JT	1DEC2015
		36-049-JT	1DEC2015
		36-058-JT	1DEC2015
		36-103-JT	1DEC2015
		37-013-JT	1JAN2016
0.45% Sodium Chloride Injection, USP; 1000 mL container	0409-7985-09	33-027-JT	1SEP2015
		33-045-JT	1SEP2015
		33-097-JT	1SEP2015
		35-068-JT	1NOV2015
		36-112-JT	1DEC2015
		37-012-JT	1JAN2016
Sterile Water for Injection, USP; 1000 mL container	0409-7990-09	36-084-JT	1DEC2015

*Note: the lot number may be followed by additional numbers from 01 to 99