



**Indiana State  
Department of Health**  
An Equal Opportunity Employer

**Michael R. Pence**  
Governor

**William C. VanNess II, MD**  
State Health Commissioner

**DATE:** October 15, 2014

**TO:** All Local Health Departments  
Attn: Chief Food Inspection Officer

**FROM:** *Laurie Kidwell*  
Laurie Kidwell, RRT Supervisor  
Food Protection Program

**SUBJECT:** Hospira, Inc. – RECALL [Drug]

**AFFECTED  
PRODUCT:** Several products in its LifeCare™ line of flexible intravenous solutions.

**SUMMARY:** Unclassified Recall; The recall is due to the potential for leakage.  
The recalled products were distributed nationwide.

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
		34-017-JT	1OCT2015
Potassium Chloride in 5% Dextrose and 0.45% Sodium Chloride Injection, USP; 1000 mL container	0409-7902-09	35-100-JT	1NOV2015
		33-094-JT	1SEP2015
5% Dextrose Injection, USP; 1000 mL container	0409-7922-09	35-028-JT	1NOV2015
		33-095-JT	1SEP2015
5% Dextrose and 0.45% Sodium Chloride Injection, USP; 1000 mL container	0409-7926-09	36-030-JT	1DEC2015
		34-134-JT	1OCT2015
Lactated Ringer's and 5% Dextrose Injection, USP; 1000 mL container	0409-7929-09	34-166-JT	1OCT2015
		32-104-JT	1AUG2015
5% Dextrose and 0.9% Sodium Chloride Injection, USP; 1000 mL container	0409-7941-09	34-136-JT	1OCT2015
		36-092-JT	1DEC2015
		32-099-JT	1AUG2015
Lactated Ringer's Injection, USP; 1000 mL container	0409-7953-09	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		

Product	NDC Number	Lot	Expiration Date
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
		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

**SUGGESTED**

**ACTION:** For consumer inquiry only. For additional assistance, call Stericycle at 1-844-861-6221 between the hours of 8am to 5pm ET, Monday through Friday.

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**Recall -- Firm Press Release**

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

## HOSPIRA ANNOUNCES VOLUNTARY NATIONWIDE RECALL OF CERTAIN LOTS OF SEVERAL LIFECARE PRODUCTS DUE TO POTENTIAL FOR LEAKAGE

**Contact:**

Consumer:  
1-800-615-0187  
Media:  
224-212-2357

**FOR IMMEDIATE RELEASE** - October 14, 2014 - Hospira, Inc. (NYSE: HSP), today announced the voluntary recall of certain lots of several products in its LifeCare™ line of flexible intravenous solutions due to the potential for leakage. The issue, which Hospira notified customers about in a Dear Health Care Provider letter issued earlier this year, was identified during re-inspection of a manufactured product lot in which a single puncture mark was identified going through the overwrap and primary container.

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 the U.S. Food and Drug Administration (FDA). 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 root cause is attributed to a defect in a conveyance system, and corrective actions have since been implemented to prevent a reoccurrence. To date there have been no reports of adverse events associated with this issue for the impacted lots. The manufacturing issue that caused this incident has been addressed. Hospira recommends impacted customers check with their local Hospira representative or with Hospira Customer Care regarding replacement product.

The affected lots (see table below) were originally distributed by Hospira to direct accounts from September 2013 through October 2014.

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
		34-017-JT	1OCT2015
Potassium Chloride in 5% Dextrose and 0.45% Sodium Chloride Injection, USP; 1000 mL container	0409-7902-09	35-100-JT	1NOV2015
		33-094-JT	1SEP2015
5% Dextrose Injection, USP; 1000 mL container	0409-7922-09	35-028-JT	1NOV2015
		33-095-JT	1SEP2015
5% Dextrose and 0.45% Sodium Chloride Injection, USP; 1000 mL container	0409-7926-09	36-030-JT	1DEC2015
		34-134-JT	1OCT2015
Lactated Ringer's and 5% Dextrose Injection, USP; 1000 mL container	0409-7929-09	34-166-JT	1OCT2015
		32-104-JT	1AUG2015
5% Dextrose and 0.9% Sodium Chloride Injection, USP; 1000 mL container	0409-7941-09	34-136-JT	1OCT2015
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<b>Product</b>	<b>NDC Number</b>	<b>Lot</b>	<b>Expiration Date</b>
Lactated Ringer's Injection, USP; 1000 mL container	0409-7953-09	32-099-JT	1AUG2015
		32-103-JT	1AUG2015
		34-070-JT	1OCT2015
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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
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		33-101-JT	1SEP2015
		33-102-JT	1SEP2015
		34-016-JT	1OCT2015
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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

Anyone with an existing inventory of the recalled lots should stop use and distribution and quarantine the product immediately. 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. In addition, customers should inform potential users of these products in their organizations of this notification. Hospira will be notifying its direct customers via a recall letter and will arrange for impacted product to be

returned to Stericycle. For additional assistance, call Stericycle at 1-844-861-6221 between the hours of 8am to 5pm ET, Monday through Friday.

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-5pm CT) ( <a href="mailto:ProductComplaintsPP@hospira.com">ProductComplaintsPP@hospira.com</a> )	To report adverse events or product complaints
Hospira Medical Communications	1-800-615-0187 or <a href="mailto:medcom@hospira.com">medcom@hospira.com</a> (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](http://www.fda.gov/medwatch/report.htm)
- **Regular Mail or Fax:** Download form [www.fda.gov/MedWatch/getforms.htm](http://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 conducted with the knowledge of the U.S. Food and Drug Administration.

### About Hospira

Hospira, Inc. is the world's leading provider of injectable drugs and infusion technologies, and a global leader in biosimilars. Through its broad, integrated portfolio, Hospira is uniquely positioned to Advance Wellness™ by improving patient and caregiver safety while reducing healthcare costs. The company is headquartered in Lake Forest, Ill., and has approximately 17,000 employees. Learn more at [www.hospira.com](http://www.hospira.com).

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