EL DORADO COUNTY
HEALTH AND HUMAN SERVICES AGENCY *Emergency Medical Services*

Daniel Nielson, M.P.A.
Director

Richard Todd
EMS Agency Administrator

EMS Safety Bulletin #2014-01

Date:	February 24, 2014
To:	All EDC ALS Personnel
From:	EDC EMS Agency
Subject:	Leaking Supply Containers

Please see the attached documents regarding leaking IV bag containers.

MESSAGE CONFIRMATION:
☐ NOT REQUIRED ■ REQUIRED ☐ ACKNOWLEDGEMENT BY ALL PERSONNEL REQUIRED

Life-Assist
Helping Heroes Save Lives

IMPORTANT SAFETY INFORMATION ENCLOSED

Tuesday, February 11, 2014

Dear Valued Life-Assist Customer,

According to our records you have purchased an item that is affected by an important safety notification issued by the manufacturer.

Life-Assist, Inc. Product Code	NDC	Item Description	Affected Lots
SL7983-09	0409-7983-09	0.9% Sodium Chloride Injection, USP 1000 mL Container	SEE ATTACHMENT
SL7953-09	0409-7953-09	Lactated Ringer's Injection, USP 1000 mL Container	SEE ATTACHMENT

Please review the enclosed safety notice from Hospira. Please direct any questions or concerns to Hospira by calling 1-800-441-4100, Monday through Friday 8am to 5pm CT, or emailing ProductComplaintsPP@hospira.com.

We apologize for any inconvenience.

RECEIVED FEB 19 2014

11277 Sunrise Park Drive
Rancho Cordova, CA 95742
(800) 824-6016 Phone
(800) 290-9794 Fax
customerservice@life-assist.com
www.life-assist.com

February 5, 2014

Important Safety Information

ACTION REQUIRED

Product: Hospira's Flexible Intravenous Containers

Subject: Potential Container Leaks

Dear Health Care Provider,

Hospira is issuing this Important Safety Information letter to alert Health Care Providers of the potential for leakage in flexible containers containing intravenous solutions of the LifeCare product line. Health Care Providers should inspect the flexible containers as described under the ACTION REQUIRED section of this letter. Hospira identified leaking primary containers during a re-inspection process of a manufactured product lot and 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. Several product lots are potentially impacted by this issue; refer to Table 1 for product lot information.

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 exposure is a potential for the patient and/or health care provider in the event a hazardous drug is added to the flexible container. Regardless, if used on a patient or in an inpatient care setting, these compromised solutions have the potential to result in injury requiring medical intervention for the patient and/or health care provider.

ACTION REQUIRED: All the containers of affected lots in Table 1 should be checked for leaks by a Health Care Provider prior to use.

Assessing for Leaks:

- Per the instructions on the overwrap container, visually inspect the overwrap for tears or holes. If damage to an overwrap or a leaking container is detected, the product should not be used and the incident should be reported to Hospira (see information below). Include the specific product information and lot number.
- If there is no visual damage, remove the primary container from the overwrap.
- After removing the overwrap, squeeze the primary container firmly to check for any leaks prior to use as indicated on the primary container instructions.

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

- If leaks are found, the flexible container should be returned to Hospira for evaluation (see information below).
- Use the product only if the solution is clear and the container is undamaged.
- The product should be used immediately once the overwrap is opened.
- Note: Due to terminal sterilization of the product, a small amount of liquid is normally present between the primary container and the overwrap. This is normal and does not indicate a leak.

REPORTING LEAKS OR ADVERSE EVENTS:

To report product complaints, such as leaking containers or adverse events, call 1-800-441-4100 (M-F, 8am-5pm CT) or e-mail ProductComplaintsPP@hospira.com.

For medical inquiries, please contact Hospira Medical Communications at 1-800-615-0187 (24 hours a day/7 days per week), or e-mail Medcom@hospira.com.

Adverse events 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

This letter is being issued with the knowledge of the U.S. Food and Drug Administration.

We thank you for your attention to this important matter.

Sincerely,

Claudio E. Rodriguez, MD
Global Medical Director
Global Pharmacovigilance and Product Safety

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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
		35-118-JT	1NOV2015
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

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Table 1 con't

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
		37-012-JT	1JAN2016
		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
Sterile Water for Injection, USP; 1000 mL container	0409-7990-09	36-084-JT	1DEC2015

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