Indiana State Department of Health
An Equal Opportunity Employer

Michael R. Pence
Governor

Jerome M. Adams, MD, MPH
State Health Commissioner

DATE: January 26, 2015

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

FROM: Laurie Kidwell, RRT Supervisor
Food Protection Program

SUBJECT: Hospira, Inc. RECALL [Drug]

AFFECTED PRODUCT: **0.9% Sodium Chloride Injection, USP**

SUMMARY: **Unclassified Recall; The recall is due to one confirmed customer report of particulate in a single unit. Hospira has identified the particulate as a human hair, sealed in the bag at the additive port area.**

The recalled product is one lot of 0.9% Sodium Chloride Injection, USP, 250 mL (NDC 0409-7983-02, Lot 44-002-JT, Expiry 1AUG2016)

This lot was distributed nationwide from September 2014 through November 2014.

SUGGESTED ACTION: **For consumer inquiry only. For additional assistance, call Stericycle at 1-877-877-0164 between the hours of 8 a.m. to 5 p.m. 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 Issues a Voluntary Nationwide Recall of One Lot of 0.9% Sodium Chloride Injection, USP, 250 mL Due to Particulate Matter

Contact:
Consumer:
800-615-0187

Media:
224-212-2357

FOR IMMEDIATE RELEASE — January 20, 2015 — **LAKE FOREST, Ill.,** — Hospira, Inc. (NYSE: HSP), announced today it will initiate a voluntary nationwide recall of one lot of 0.9% Sodium Chloride Injection, USP, 250 mL (NDC 0409-7983-02, Lot 44-002-JT, Expiry 1AUG2016) to the user level due to one confirmed customer report

of particulate in a single unit. Hospira has identified the particulate as a human hair, sealed in the bag at the additive port area. To date, Hospira has not received reports of any adverse events associated with this issue for this lot.

In the unlikely event that the particulate breaks and pieces are able to pass through the intravenous catheter, injected particulate material may result in local inflammation, phlebitis, and/or low-level allergic response. Capillaries which may be as small as the size of a red blood cell, approximately seven microns in diameter, may become occluded. Patients with preexisting condition of trauma or other medical condition that adversely affects the microvascular blood supply are at an increased risk.

This lot was distributed nationwide from September 2014 through November 2014. Hospira has initiated an investigation to determine the root cause and corrective and preventive actions.

Anyone with an existing inventory of the recalled lot should stop use and distribution and quarantine the product immediately. Customers should notify all users in their facility. Customers who have further distributed the recalled product should notify any accounts or additional locations which may have received the recalled product and instruct them if they have redistributed the product to notify their accounts, locations or facilities to the consumer level. Hospira has notified its direct customers via a recall letter and is arranging for impacted product to be returned to Stericycle in the United States. For additional assistance, call Stericycle at 1-877-877-0164 between the hours of 8 a.m. to 5 p.m. ET, Monday through Friday. Hospira will provide allocation credits and make replacement product available for contracted customers.

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 (8am-5pm CT, M-F) (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 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. Learn more at www.hospira.com.

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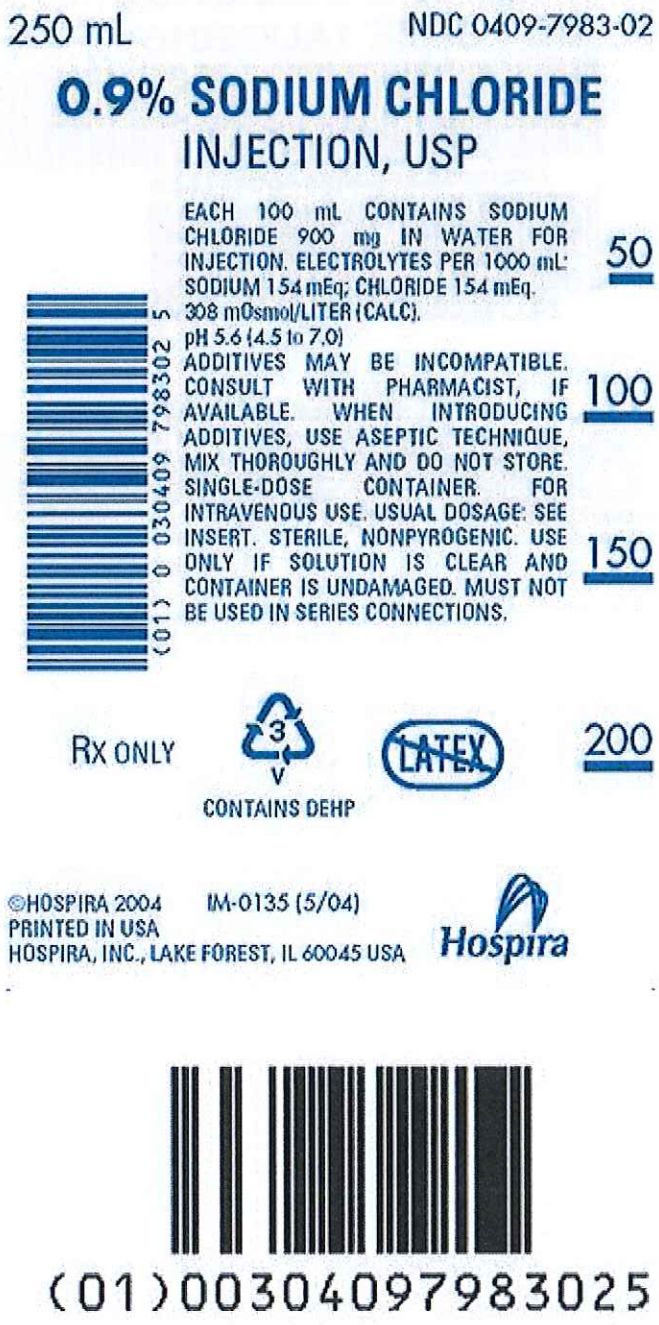
Photo



1-NDC 0409-7983-02

L/N 7983-02 LC 04 IC 63

CASE PACK 1 X 24-250 ML

0.9% SODIUM CHLORIDE

INJ., USP

LOT NO. 44-002-JT-01

EXP. DATE 1AUG2016

(22)80131608014400 2JT016

(01)30304097983026 (30)01

TO OPEN TEAR AT NOTCH

2 HDPE

DO NOT REMOVE FROM OVERWRAP UNTIL READY FOR USE. AFTER REMOVING THE OVERWRAP, CHECK FOR MINUTE LEAKS BY SQUEEZING CONTAINER FIRMLY. IF LEAKS ARE FOUND, DISCARD SOLUTION AS STERILITY MAY BE IMPAIRED. RECOMMENDED STORAGE: ROOM TEMPERATURE (25°C). AVOID EXCESSIVE HEAT. PROTECT FROM FREEZING. SEE INSERT.

98-4321-R14-3/98