URGENT DRUG RECALL

Product	NDC Number	Lot*	Expiration Date
0.9% Sodium Chloride Injection, USP, 250 mL	0409-7983-02	44-002-JT	1AUG2016

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

January 21, 2015

Dear Valued Customer:

Hospira, Inc. is voluntarily recalling one lot identified above of Sodium Chloride Inj. USP, due to one confirmed customer report of particulate in a single unit. The foreign particle was confirmed by Hospira as human hair, sealed in the bag at the additive port area.

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 September 2014 through November 2014. To date, Hospira has not received reports of adverse events associated with this issue for this lot. The root cause has not been determined and is under investigation.

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 1-877-877-0164 (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 user 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 user level. If additional copies of the letter and/or reply form are needed, please contact Stericycle at 1-877-877-0164 (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.

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

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

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