

**From:** FDA MedWatch <fda@service.govdelivery.com>  
**Sent:** Friday, January 23, 2015 8:12 AM  
**To:** Stratton, Samuel  
**Subject:** FDA MedWatch - 0.9 Percent Sodium Chloride Injection, USP, 250 mL by Hospira : Recall - Particulate Matter



**The FDA Safety Information and  
Adverse Event Reporting Program**

## **0.9 Percent Sodium Chloride Injection, USP, 250 mL by Hospira : Recall - Particulate Matter**

**AUDIENCE:** Pharmacy, Risk Manager

**ISSUE:** Hospira, Inc. announced 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.

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.

**BACKGROUND:** The affected 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.

**RECOMMENDATION:** 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.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: [www.fda.gov/MedWatch/report.htm](http://www.fda.gov/MedWatch/report.htm)

- [Download form](#) 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

Read the MedWatch alert, including a link to the press release, at:

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm430941.htm>

---

You are encouraged to report all serious adverse events and product quality problems to FDA MedWatch at [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm)

[Follow MedWatch on Twitter](#)



Update your subscriptions, modify your e-mail address, or stop subscriptions at any time on your [Subscriber Preferences Page](#). You will need to use your email address to log in. If you have questions or problems with the subscription service, please visit [subscriberhelp.govdelivery.com](http://subscriberhelp.govdelivery.com).

This service is provided to you at no charge by [U.S. Food & Drug Administration \(FDA\)](#).



---

This email was sent to [ssratton@ochca.com](mailto:ssratton@ochca.com) using GovDelivery, on behalf of: U.S. Food & Drug Administration (FDA) · 10903 New Hampshire Ave · Silver Spring, MD 20993 · 800-439-1420

