Indiana State Department of Health
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Michael R. Pence
Governor

William C. VanNess II, MD
State Health Commissioner

**DATE:** October 17, 2013

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

**FROM:** A. Scott Gilliam, MBA, CP-FS
Director, Food Protection Program

**SUBJECT:** Hospira, Inc. Recall 2 [Drug]

**AFFECTED PRODUCT(S):** **1% Lidocaine HCl Injection, USP, 10 mg/mL, 20 mL Multiple-dose Fliptop Vial, NDC 0409 4276-01 Lot 25-090-DK (the lot number may be followed by 01 or 02).**

**SUMMARY:** **Voluntary Recall; Hospira, Inc. (NYSE: HSP), announced today it has initiated a voluntary nationwide recall of one lot of 1% Lidocaine HCl Injection, USP, 10 mg/mL, 20 mL Multiple-dose Fliptop Vial, NDC 0409-4276-01 Lot 25-090-DK (the lot number may be followed by 01 or 02). This action is due to one confirmed customer report of visible particulate, identified in the primary container, in the form of dark red/black particles. The particulate was identified as oxidized stainless steel. This lot was distributed March 2013 through June 2013.**

**SUGGESTED ACTION:** **Recommend notification of affected parties via phone, fax, or e-mail. Anyone with an existing inventory should stop use and distribution, quarantine the product immediately, and call Stericycle at 1-866-364-8812 between the hours of 8am to 5pm ET, Monday through Friday, to arrange for the return of the product. Replacement product from other lots is available.**

**For clinical inquiries, please contact Hospira by calling 1-800-615-0187, or medcom@hospira.com (Available 24 hours a day/7 days per week). Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program online, by regular mail, or by fax.**

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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 1% Lidocaine HCL Injection Due To The Presence Of Dark Particulate

**Contact**
Consumers:
1-800-615-0187

Media:
224-212-2357

**FOR IMMEDIATE RELEASE** - October 4, 2013 - LAKE FOREST, Ill., - Hospira, Inc. (NYSE: HSP), announced today it has initiated a voluntary nationwide recall of one lot of 1% Lidocaine HCl Injection, USP, 10 mg/mL, 20 mL Multiple-dose Fliptop Vial, NDC 0409-4276-01 Lot 25-090-DK (the lot number may be followed by 01 or 02). This action is due to one confirmed customer report of visible particulate, identified in the primary container, in the form of dark red/black particles. The particulate was identified as oxidized stainless steel.

In general, injected particulate matter may result acutely in local inflammation, phlebitis, and/or low-level allergic response through mechanical disruption of tissue or immune response to the particulate. Capillaries, which may be as small as the size of a red blood cell, may become occluded. Chronically, following sequestration, some granuloma formation may occur in the lungs.

The presence of oxidized stainless steel particulate may potentially put a patient at risk from a strong magnetic field exposure such as with magnetic resonance imaging (MRI). If a metal particle in the lung becomes dislodged and pulled through tissue, possibly causing a pneumothorax or hemothorax, urgent and significant medical intervention may be required.

Depending on the particle size, if undetected, it could block administration of the drug to the patient, causing a delay in therapy. Impact to the patient would depend on the time it would take to obtain a new vial, the condition being treated and the patient's status.

To date, Hospira has not received reports of any adverse events associated with this issue for this lot. The recall is being conducted as a precautionary measure. The root cause has not been determined and is under investigation. Hospira informed customers of the issue in a letter dated Sept. 16, 2013.

This lot was distributed March 2013 through June 2013.

Anyone with an existing inventory should stop use and distribution, quarantine the product immediately, and call Stericycle at 1-866-364-8812 between the hours of 8am to 5pm ET, Monday through Friday, to arrange for the return of the product. Replacement product from other lots is available.

For clinical inquiries, please contact Hospira using the information provided below.

| Hospira Contact | Contact Information | Areas of Support |
|---|---|---|
| Hospira Global | 1-800-441-4100 (8am-5pm CT, M-F) | To report adverse |

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| Complaint Management | (ProductComplaintsPP@hospira.com) | 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 |

Any adverse reactions or quality problems experienced with the use of this product may be reported to the U.S. Food and Drug Administration's (FDA) MedWatch Adverse Events Program either online, by regular mail or by fax.

- Online: www.fda.gov/medwatch/report.htm[1]
- Fax: 1-800-FDA-0178

**About Hospira**

Hospira, Inc. is the world's leading provider of injectable drugs and infusion technologies. 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 16,000 employees. Learn more at www.hospira.com[2] .

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