IMPORTANT SAFETY INFORMATION

Product	**Lidocaine HCl Injection, USP, 2%, 20 mg per mL, 5 mL, Single-Dose Vial, Preservative-Free**
	Diltiazem Hydrochloride Injection, 25 mg/5 mL (5 mg/mL), 5 mL, Single-dose Fliptop Vial

Subject	**Potential for Embedded and Suspended Particulates**

ACTION REQUIRED

January 24, 2014

Dear Healthcare Professional,

Hospira is issuing this important Safety Information Letter to alert Healthcare Professionals to the potential for embedded metallic particulate in the glass vials containing the Lidocaine HCl Injection and Diltiazem HCl Injection product lots identified below. Hospira has confirmed one customer complaint for the presence of embedded particulate in the glass vial of a lot of Lidocaine HCl Injection. In that specific case, the presence of the embedded material caused the individual product container to be out of USP specification for the presence of particulates in the solution and/or discoloration. The product lot associated with this complaint was 32135DD recalled on December 27, 2013. The additional lots identified below were manufactured using the same glass vial lot as the Lidocaine lot which was recalled.

The additional product lots potentially impacted by this issue include the following and were distributed between November 2013 and January 2014:

Product Name	NDC	Lot	Expiration Date
Lidocaine HCl Injection, USP, 2%, 20 mg per mL, 5 mL Single-Dose Vial, Preservative-Free	**0409-2066-05**	**33035DD**	**1SEP2015**
Diltiazem Hydrochloride Injection, 25 mg/5 mL (5 mg/mL), 5 mL, Single-dose Fliptop Vial	**0409-1171-01**	**32095DD**	**1AUG2015**

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The root cause of embedded metal in molded glass relates directly to the process of the manufacture of the glass container. Information received from the glass supplier indicates that there is potential for this defect inherent in their manufacturing process. Hospira continues to work with the supplier to institute process controls that minimize the potential for these events.

There is the potential for patient injury in the event that dislodged particle(s) are small enough to pass through a syringe and needle. Injected visible particulate matter may result acutely in local inflammation, mechanical disruption of tissue, or immune response to the particulate. Chronically, following sequestration, local granuloma formation is possible but long term clinically meaningful impact is expected to be low. Metallic particulate may potentially put a patient at risk from a strong magnetic field exposure such as with magnetic resonance imaging (MRI). This may result in particulate being pulled through tissue, possibly causing mechanical disruption. Migration of the particles to the bloodstream could result in microthrombi and could require urgent and significant medical intervention. Given the small size of the particulate identified, this would be an extremely rare occurrence, once solutions are filtered with a 5 micron filter.

Directions for Healthcare Professionals

After opening the carton or box, the vial should be inspected visually to confirm there is no visible particulate matter. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution or container permits. This requirement is specifically stated in the package insert for the products which are subject to this notification.

A filter should be used when withdrawing solution from the vial for the two lots identified above. The following steps are recommended when using a filter with Lidocaine HCl Injection or Diltiazem HCl Injection product.

1. Perform a visual inspection of the vial prior to withdrawal of the solution. DO NOT USE IF PARTICULATES ARE VISIBLE OR IF THE SOLUTION IS DISCOLORED. USE A NEW VIAL.
2. Use a 5 micron filter needle to withdraw the required volume of drug.[1]
3. Remove the filter needle and attach a standard needle to the syringe.
4. Visually inspect the final solution prior to administration. DO NOT USE IF PARTICULATES ARE VISIBLE. USE A NEW VIAL.

1. Although Hospira does not have data to support the use of a specific filter type, a 5 micron filter is being recommended based on pharmaceutical literature, e.g. McKinnon BT and Avis KE. Membrane filtration of pharmaceutical solutions. *Am J Hosp Pharm*; 1993; 50:1921-193; Buchanan EC and Schneider PJ. *Compounding Sterile Preparations*. American Society of Health-System Pharmacists®; February 1, 2009; Third Edition.

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Important Safety Information

Lidocaine HCl Injection / Diltiazem HCl Injection
Potential for Embedded & Suspended Particulates
January 24, 2014

Upon inspection of the vial prior to administration, if visible matter is identified, **do not use the vial** and report the issue to Hospira by calling 1-800-441-4100 between the hours of 8am to 5pm CT, Monday through Friday, or e-mail ProductComplaintsPP@hospira.com. To report product complaints, such as particulate within a vial call 1-800-441-4100 (M-F, 8am to 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, seven days a week) or e-mail Medcom@hospira.com.

Adverse reactions or quality problems experienced with the use of these products may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, telephone, or 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: MedWatch, 5600 Fishers Lane, Rockville, MD 20857
- **Telephone**: 1-800-332-1088
- **Fax**: 1-800-FDA-0178

We thank you for your attention to this important matter.

Sincerely,

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