

URGENT DRUG RECALL



<i>Product</i>	<i>NDC Number</i>	<i>Lot*</i>	<i>Expiration Date</i>
0.5% Bupivacaine HCl and Epinephrine 1:200,000 Inj., 50 mL, Multiple-dose Vial	0409-9046-01	32-484-EV	1FEB2015
		32-485-EV	1FEB2015

* Note: the lot number may be followed by 01

November 7, 2013

Dear Valued Customer:

Hospira, Inc. is voluntarily recalling two lots identified above of 0.5% Bupivacaine and Epinephrine Injection, USP, to the retail/user level, as a precautionary measure, due to results from our internal monitoring process where an equipment failure occurred during manufacturing resulting in a potential breach in the aseptic process. A potential breach in the aseptic process may have resulted in a potential breach of sterility with the possibility for microbial contamination. While there is no conclusive evidence to confirm a breach in sterility, as the data compiled exhibited no microbial contamination occurred, out of an abundance of caution Hospira is recalling these two lots.

Risk factors associated with microbial contamination may lead to serious infections including sepsis, which could potentially lead to death. Signs and symptoms could include injection site reactions, fever, shortness of breath, fast heart rate and feeling generally ill with nausea and vomiting. The most vulnerable patient populations would be immunocompromised patients.

These lots were distributed September 2013 through October 2013. To date, Hospira has not received reports of any adverse events associated with this issue for these lots. Hospira has notified the U.S. Food and Drug Administration.

Hospira has initiated an investigation to determine the root cause and corrective and preventive actions.

Please check your inventory and immediately 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 1-888-667-1508 (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.

If you have distributed the product further, notify your accounts that received the product identified above of this recall and ask them to contact Stericycle at 1-888-667-1508 (M-F, 8am to 5pm ET), to receive a reply form and return labels for returning the product.



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.

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.

- **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 address on the pre-addressed form.
- **Fax:** 1-800-FDA-0178

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,

Shane Ernst
Vice President, Quality
Rocky Mount, North Carolina

Urgent Drug Recall Reply Form – Response Required
Bupivacaine HCl and Epinephrine Injection, USP – Potential Microbial Contamination
November 7, 2013



Check your inventory and complete the information below, even if you do not have the affected product.
Failure to complete all sections of this page may result in improper, delayed or denied credit.

Fax the completed form to 1-877-406-5291 or e-mail the completed form to Hospira6656@stericycle.com.

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 product. If you have not received a return label or require additional assistance contact Stericycle at **1-888-667-1508** (M-F, 8am to 5pm ET).

Required Information	
_____	_____
Business Name	Phone Number
_____	_____
Address/City/State/Zip	DEA #
_____	_____
Hospira Customer Number (ship to #) if applicable	Your reference # (e.g. PO, Debit Memo or Invoice #)

Completed by: Printed Name/Signature/Date	

I have **NO** affected product (fill out and return this form to Stericycle at the fax/e-mail above).

YES, I have affected product (fill out and return this form to Stericycle via the fax/e-mail above and return the product per the instructions on the return label).

If affected product is not being returned, please explain:

- Have you distributed the product further to the retail/hospital level? YES___ NO___
 - If yes, have you notified your retail customers? YES___ NO___ (if no, explain below)

Urgent Drug Recall Reply Form – Response Required
Bupivacaine HCl and Epinephrine Injection, USP – Potential Microbial Contamination
November 7, 2013



Business Name _____ Hospira Customer No. _____

NDC and Lot Number	Quantity to be returned	Wholesaler/Distributor Name If you purchased from Wholesalers/Distributors include name, address, city, state, zip, quantity from each, and invoice number. If you purchased directly from Hospira leave this section blank.	PO, debit memo or invoice
0409-9046-01 32-484-EV*		1.	
		2.	
0409-9046-01 32-485-EV*		1.	
		2.	

* Note: the lot number may be followed by 01