

# URGENT DEVICE RECALL



<i>Product</i>	<i>List Number</i>	<i>Lot</i>
<b>GemStar™ Pump Set</b>	<b>12640-01</b>	<b>682105H; 770815H</b>
<b>GemStar™ Pump Set</b>	<b>13261-01</b>	<b>691805H; 670695H; 760665H; 772085H</b>
<b>GemStar™ Pump Set - SL</b>	<b>13263-01</b>	<b>682095H</b>
<b>GemStar™ Pump Set - SL</b>	<b>13273-01</b>	<b>680295H; 770875H</b>
<b>GemStar™ Pump Set</b>	<b>19680-28</b>	<b>772075H</b>
<b>GemStar™ Pump Set</b>	<b>20634-01</b>	<b>682085H</b>
<b>GemStar™ Pump Set with Convertible Pin</b>	<b>20635-01</b>	<b>691825H; 701295H; 781565H</b>

August 12, 2010

Dear Valued Customer:

Hospira, Inc. is conducting a voluntary recall on specific lots of GemStar™ pump sets identified above. The affected lots were distributed between September 2008 and June 2010. No other lots are impacted by this recall and replacement sets are available. Please contact Hospira Customer Care at 1-877-946-7747 or your Hospira Account Manager to obtain replacement product.

Hospira is taking this voluntary action due to reports of under delivery occurring during clinical use. Our investigation determined that under delivery can occur under low rate settings (less than 10 mL/hour). We have not received any reports of adverse events resulting from this issue. This recall is being conducted as a precautionary measure. The root cause has been identified and preventive actions have been implemented.

Hospira has notified the U.S. Food and Drug Administration. This recall has not yet been assigned a class by the FDA.

**Please check your inventory and immediately quarantine any affected product.** Complete the attached Reply Form in its entirety and fax it to Stericycle at 1-877-523-9110, **even if you do not have the affected product.** To ensure proper and timely credit, be sure to include your Hospira customer number (if applicable) and supply information about your wholesaler/distributor from whom you purchased the affected product.

Please inform healthcare professionals in your organization of this recall. If you have distributed the product further, notify your accounts that may have received the product identified above of this recall and ask them to follow the instructions on the reply form.

Should you have any questions, please do not hesitate to contact Stericycle at 1-877-274-7163. For medical inquiries, please call Hospira Medical Communications at 1-800-615-0187.

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,

Ileana Quinones  
Vice President, Device Quality Operations



# Urgent Device Recall Reply Form GemStar™ Sets

Please check your inventory and quarantine any affected product. Complete the information below and fax this form to Stericycle at 1-877-523-9110, even if you do not have the affected product. To ensure proper and timely credit be sure to include your Hospira customer number (if applicable) and provide information about your wholesaler/distributor from whom you purchased the affected product. Failure to complete all sections of this page may result in improper, delayed or denied credit.

Please call Stericycle at 1-877-274-7163 if you have any questions regarding this form.

I have **NO** affected product (please fill out and fax back the first page only to Stericycle at 1-877-523-9110)

I have affected product (please fill out and fax back all pages to Stericycle at 1-877-523-9110)

- Contact Stericycle at 1-877-274-7163 to obtain pre-paid shipping labels.
- **Once labels are received, package *only* the affected product for return. Include in each box being returned all pages of this completed reply form and debit memo including debit memo number.**

✓ Did you receive this affected product from a wholesaler or distributor? YES \_\_\_ NO \_\_\_

✓ If yes, you must provide your wholesaler or distributor name and address below.

\_\_\_\_\_  
Wholesaler or Distributor Name

\_\_\_\_\_  
Address/City/State/Zip (required for indirect customers)

✓ Have you distributed the product further to the retail level? YES \_\_\_ NO \_\_\_

✓ If yes, have you notified your retail customers? YES \_\_\_ NO \_\_\_ (if no, explain)

### General Required Information

\_\_\_\_\_  
Business Name

\_\_\_\_\_  
Phone Number

\_\_\_\_\_  
Address/City/State/Zip

\_\_\_\_\_  
Hospira Customer Number (ship to #)

\_\_\_\_\_  
Debit Memo Number (for product being returned)

\_\_\_\_\_  
Completed by: Printed Name/Signature/Date

- Direct Hospira customers who purchased the product directly from Hospira must supply their Hospira customer number and debit memo number. Once the return is processed you will receive credit from Hospira.
- Indirect customers who purchased the product from a wholesaler or distributor must supply their wholesaler/distributor information and debit memo number. Once return is processed you will receive credit through your wholesaler/distributor.

**Urgent Device Recall Reply Form  
GemStar™ Sets**



Business Name \_\_\_\_\_

<i>List Number</i>	<i>Lot</i>	<i>Quantity of Sets to be Returned</i>
12640-01	682105H	
	770815H	
13261-01	670695H	
	691805H	
	760665H	
	772085H	
13263-01	682095H	
13273-01	680295H	
	770875H	
19680-28	772075H	
20634-01	682085H	
20635-01	691825H	
	701295H	
	781565H	