



## Important Information – Baxa Exacta-Mix® EVA Container

<i>Product</i>	<i>List Number</i>
<b>Baxa Exacta-Mix® EVA Container, 2000 mL</b>	<b>20696-04</b>

June 29, 2011

Dear Valued Customer:

Hospira, Inc. received the attached letter from Baxa Corporation regarding the Baxa manufactured 2000 mL Exacta-Mix EVA container. Baxa Corporation has learned that the retaining ring portion of the manual addition port on select Exacta-Mix bags may become detached upon removal of the additive port cap to access the septum. If this retaining ring becomes detached, the septum could dislodge and the bag may leak. Please read the attached Exacta-Mix® Bag Product Notice dated June 13, 2011 from Baxa and follow the instructions for continued use of the bags.

The impacted lot numbers distributed by Hospira are listed on the second page of this letter. These lots were distributed March 2009 through May 2011.

You do not need to return any bags unless they exhibit the issue identified in the letter from Baxa. Should the retaining ring portion of the manual addition port become detached, please complete the attached return form and send it to Stericycle at the fax number or e-mail address on the form. Stericycle will send labels to return the product. If you require additional return labels, call Stericycle at 1-800-913-4350. To ensure proper and timely credit, follow the instructions on the reply form for returning the product and include your Hospira customer number (if applicable) and information about your wholesalers/distributors from whom you purchased the affected product (if applicable). Include a copy of the completed form and your PO, Debit Memo or Invoice showing the purchase price on the outside of the package being shipped (e.g. case, pallet).

If you have distributed the product further, notify your accounts that received the product identified above and ask them to follow the instructions in the previous paragraph for returning defective bags.

Hospira will not continue distribution of the 2000 mL Exacta-Mix EVA container until Baxa notifies us that the problem has been corrected. In the meantime, you may continue to use the 2000 mL bags in your inventory that do not exhibit the problem described in Baxa's letter. Should you need additional bags, the 1000 mL bag (list number 20696-03) and 3000 mL bag (list number 20696-05) are available. Should you require additional bags, please contact Hospira Customer Care at 1-877-946-7747 or your Hospira representatives to determine a suitable replacement. We will notify you when corrected 2000 mL bags become available.

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,

Patrick Gondek  
Sr. Manager, Third Party  
Manufacturing Quality

Hospira, Inc.  
275 North Field Drive  
Lake Forest, IL 60045  
(224) 212-2000  
[www.hospira.com](http://www.hospira.com)  
2435\_01\_01AS

FA105-03 (4)



## Important Information – Baxa Exacta-Mix® EVA Container

<i>Product</i>	<i>List Number</i>
<b>Baxa Exacta-Mix® EVA Container, 2000 mL</b>	<b>20696-04</b>

Lot numbers potentially impacted:

<b>Lot</b>	<b>Expiration Date</b>
05500J3	01/1/2014
02500J3	11/1/2013
96502J3	9/1/2013
96501J3	9/1/2013
96500J3	9/1/2013
95502J3	8/1/2013
95501J3	8/1/2013
95500J3	8/1/2013
94512J3	8/1/2013
94511J3	8/1/2013
94510J3	8/1/2013
94501J3	6/1/2013
94500J3	6/1/2013
91502J3	02/1/2013
91501J3	02/1/2013
91500J3	02/1/2013
90502J3	02/1/2013
90501J3	02/1/2013
90500J3	02/1/2013
89502J3	01/1/2013
89501J3	01/1/2013
89500J3	01/1/2013
87502J3	01/1/2013

<b>Lot</b>	<b>Expiration Date</b>
87501J3	01/1/2013
87500J3	01/1/2013
86501J3	12/1/2012
86500J3	12/1/2012
85500J3	12/1/2012
83502J3	9/1/2012
83501J3	9/1/2012
83500J3	9/1/2012
82502J3	8/1/2012
82501J3	8/1/2012
82500J3	8/1/2012
78502J3	5/1/2012
78501J3	5/1/2012
78500J3	5/1/2012
77500J3	4/1/2012
76500J3	3/1/2012
74502J3	01/1/2012
74501J3	01/1/2012
74500J3	01/1/2012
73502J3	11/1/2011
72501J3	11/1/2011
72500J3	11/1/2011

**Baxa Exacta-Mix® EVA Empty Container, 2000 mL – Return Form**  
**List Number 20696-04**



Please complete this form and return it to Stericycle by fax at **1-866-915-5060** or email to **[hospira2435@stericycle.com](mailto:hospira2435@stericycle.com)**. Keep a copy of this form to include with the return. Stericycle will send you labels for returning the product.

If you have questions about this form call Stericycle at **1-800-913-4350**.

*Failure to complete all sections of this page may result in improper, delayed or denied credit.*

<b>Required Information</b>	
Business Name	Phone Number
Address/City/State/Zip	
Hospira Customer Number (ship to #) if applicable	Your reference # (e.g. PO, Debit Memo or Invoice #)
Completed by: Printed Name/Signature/Date	

\_\_\_\_ Number of return labels needed

Product was purchased directly from Hospira:

Yes (complete lot and quantity information below)     No (also complete the wholesaler/distributor information below)

Lot Number	Total Qty to be Returned	Wholesaler/Distributor Name <small>If you purchased from multiple Wholesalers/Distributors include name, address, city, state, zip, quantity from each, name, and invoice number. If you purchased directly from Hospira leave this section blank</small>	QTY	PO, Debit memo or Invoice)
		1.		
		2.		

**IMPORTANT RETURN INSTUCTIONS:**

<p><b>Direct Customer</b> (purchased directly from Hospira)  <i>Credit will be issued by Hospira</i></p> <p><b>Step 1</b> Package only the <i>affected product</i>.  <b>Step 2</b> Include a PO, Debit Memo or Invoice showing the purchase price on the outside of the package being shipped (e.g. case, pallet).  <b>Step 3</b> Ship to Stericycle using the prepaid return label.</p>	<p><b>Indirect Customer</b> (purchased from a wholesaler/distributor)  <i>Credit will be issued through the wholesaler/distributor</i></p> <p><b>Step 1</b> Supply information for each wholesaler/distributor.  <b>Step 2</b> Package only the <i>affected product</i>.  <b>Step 3</b> Include a PO, Debit Memo or Invoice showing the purchase price on the outside of the package being shipped (e.g. case, pallet).  <b>Step 4</b> Ship to Stericycle using the prepaid return labels.</p>
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2435\_01\_03AS  
 Hospira, Inc.  
 275 North Field Drive  
 Lake Forest, IL 60045  
 (224) 212-2000  
[www.hospira.com](http://www.hospira.com)

CID / SEQ

SAMPLE

FA105-03 (4)

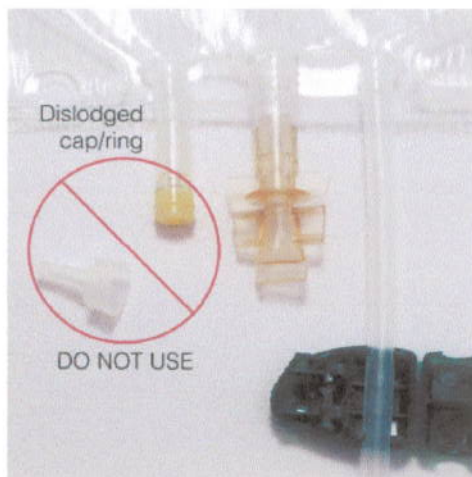
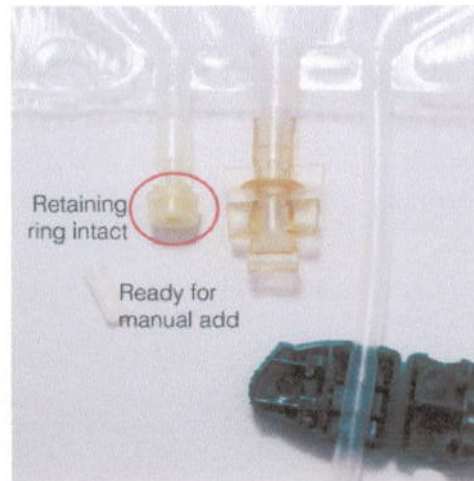
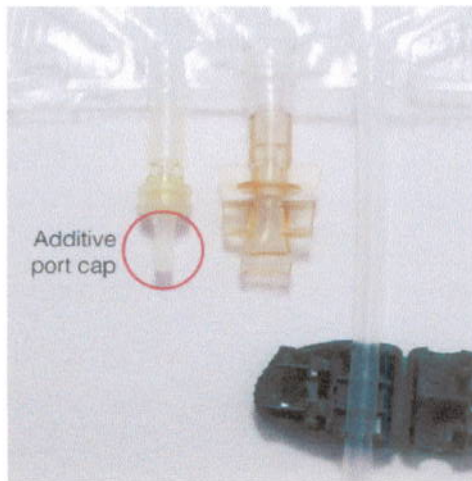
6/13/2011

## ExactaMix® Bag Product Notice

<b>Order No.</b> 20696-04	<b>Product Description</b> ExactaMix Empty EVA Container, 2000 mL
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Dear Hospira:

Through recent customer feedback, Baxa Corporation has learned that the retaining ring portion of the manual addition port on select ExactaMix Bags may become detached upon removal of the additive port cap to access the septum. If this retaining ring becomes detached, the septum could dislodge and the bag may leak.



If your customers **do not** intend to use the manual addition port, verify that the cap is firmly seated onto the port by gently tugging on the cap. **If you intend to use the manual addition port, we recommend that they snap off the additive port cap prior to compounding the bag.** This will ensure the integrity of the port. Removing the additive port cap does not affect bag sterility.

6/13/2011



Baxa is working to address this issue as quickly as possible. If your customers have this product in inventory, they should inspect individual packages prior to use to ensure add port integrity.

Please notify your customers and ask that they return any defective bags to you.

Sincerely,

A handwritten signature in black ink that reads "Joe Tsiakals". The signature is written in a cursive style with a prominent loop at the end of the last name.

Joe Tsiakals  
**Sr. Vice President, Quality and Regulatory**  
303.400.2838  
[Joe.Tsiakals@baxa.com](mailto:Joe.Tsiakals@baxa.com)