

**IMPORTANT ADDITION TO AUGUST 13, 2010 RECALL NOTIFICATION**  
**Symbiq™ Syringe Administration Sets**

August 24, 2010

Dear Valued Customer:

This is an **addition** to our August 13, 2010 Recall Notification. After performing additional testing, **Hospira has determined the need to expand the recall of Symbiq™ microbore administration sets to include three additional set configurations.** These three administration sets are used for Symbiq™ syringe delivery only and descriptions are provided below:

Additional Symbiq™ Microbore Sets to be Recalled	
<u>List Number</u>	<u>Description</u>
16023-04-01	LifeShield, LATEX-FREE Symbiq™ Pump Syringe™ Microbore Set, 83 Inch With Syringe Holder, 2 Clave Ports And Option-Lok, Non-DEHP
16042-04-28	LifeShield LATEX-FREE Symbiq™ Pump Syringe Microbore Set, 84 Inch With Syringe Holder, 1 Clave Port, 1 Pre-Pierced Port And Option-Lok, Non-DEHP
16066-07-28	LifeShield, LATEX-FREE, Non-DEHP, Symbiq™ Syringe Set, Clave Syringe Holder, Clave Y-Site, 15 Micron Filter, Microbore Tubing, 84 Inch (For International Use Only)

**These three syringe sets will be replaced with identical sets except for the inclusion of an in line filter.**

**As outlined in Hospira's August 13, 2010 recall notification, a Hospira representative will contact you to schedule replacement of your Symbiq™ microbore administration sets.**

**Until Hospira can provide replacement inventory, please follow the "Required Actions for Continued Use of Symbiq™ Microbore Sets" included in Hospira's August 13, 2010 recall notification.**

Hospira has placed the highest priority and commitment to resolving this issue, and will contact you as soon as possible to schedule replacement of administration sets. We regret any inconvenience this may have caused your facility and ask your cooperation in this important matter.

This notification is being sent with the knowledge of the U.S. Food and Drug Administration.

Regards,



Ileana Quinones  
Vice President, Device Quality Operations



**Recall Notification UPDATED Reply Form - RESPONSE REQUIRED**

NOTE: THIS REPLY FORM IS COMPREHENSIVE AND COVERS ALL PRODUCT AFFECTED BY THIS RECALL. A COMPLETE LIST OF RECALLED PRODUCT IS PROVIDED BELOW.

**INSTRUCTIONS:**

1. Please provide ALL of the information requested below and fax completed reply forms to Stericycle at 877-523-9113.
  - a. **If you have already completed and returned the reply form** attached to Hospira’s August 13, 2010 recall notification, please also complete this comprehensive reply form and fax the completed form to Stericycle at 877-523-9113.
  - b. **If you have NOT completed and returned the reply form** attached to the August 13, 2010 recall notification, please only this comprehensive reply form and fax the completed form to Stericycle at 877-523-9113.
2. In order to expedite exchange of the administration sets, please send your completed reply form to Stericycle no later than September 3, 2010.

I have received the Recall Notification and distributed it to users throughout the facility:

YES\_\_\_ NO\_\_\_

If NO, state reason:

Check one of the following:

\_\_\_\_\_ Until receiving replacement sets, this facility will immediately discontinue use of recalled Symbiq™ microbore administration sets

OR

\_\_\_\_\_ Until receiving replacement sets, this facility will continue use of recalled Symbiq™ microbore administration sets using the required mitigations provided by Hospira

OR

\_\_\_\_\_ No affected product on hand

Have you distributed the product further? \_\_\_\_\_ YES \_\_\_\_\_ NO

If yes, have you notified your accounts? \_\_\_\_\_ YES \_\_\_\_\_ NO (if no, please explain):

**General Required Information**

_____ <b>Business Name</b>	_____ <b>Phone Number</b>
_____ <b>Address/City/State/Zip</b>	
_____ <b>Hospira Customer Number (ship to #)</b>	
_____ <b>Completed by: Printed Name/Signature/Date</b>	

**Complete List of Symbiq™ Microbore Administration Sets to be Recalled**

Additional Symbiq™ Microbore Sets to be Recalled	
<u>List Number</u>	<u>Description</u>
16023-04-01	LifeShield, LATEX-FREE Symbiq™ Pump Syringe Microbore Set, 83 Inch With Syringe Holder, 2 Clave Ports And Option-Lok, Non-DEHP
16042-04-28	LifeShield LATEX-FREE Symbiq™ Pump Syringe™ Microbore Set, 84 Inch With Syringe Holder, 1 Clave Port, 1 Pre-Pierced Port And Option-Lok, Non-DEHP
16066-07-28	LifeShield, LATEX-FREE, Non-DEHP, Symbiq™ Syringe Set, Clave Syringe Holder, Clave Y-Site, 15 Micron Filter, Microbore Tubing, 84 Inch (For International Use Only)

<u>List Number</u>	<u>Description</u>
149600428	Symbiq™ Primary Set W/ 15 Microns Filter. No Injection Ports
160000401	LifeShield, LATEX-FREE Symbiq™ Pump Set, Convertible Pin, 106 Inch Piggyback with Backcheck Valve, 2 CLAVE™ Ports, Distal Microbore Tubing And Option-Lok™, Microdrip, Non-DEHP
160020401	LATEX-FREE Symbiq™ Pump Set, Yellow Striped Tubing, Convertible Pin, 108.5 Inch With Distal Microbore Tubing And Option-Lok
160040401	LifeShield, LATEX-FREE Symbiq™ Pump 50 mL Burette Set, Convertible Pin, 104 Inch With 3 CLAVE™ Ports, Distal Microbore Tubing And Option-Lok, Microdrip Soluset, Non-DEHP
160140401	LifeShield, LATEX-FREE Symbiq™ Pump 150 mL Burette Set, Convertible Pin, 124.5 Inch With 3 CLAVE™ Ports, Distal Microbore Tubing And Option-Lok™, Microdrip Soluset, Non-DEHP
160240401	LifeShield, LATEX-FREE Symbiq™ Pump Set, Convertible Pin, 105 Inch With Orange Polyethylene-Lined Light Resistant Tubing, CLAVE™ Port, Distal Microbore Tubing And Option-Lok™
160390428	LifeShield LATEX-FREE Symbiq™ Pump Set, Convertible Pin, 106 Inch Piggyback with Backcheck Valve, 2 Injection Sites, Distal Microbore Tubing and Option-Lok™, MICRODRIP, Non-DEHP
160520701	LifeShield, LATEX-FREE, Primary Symbiq™ Set, Orange Polyethylene Lined Light Resistant Tubing, CLAVE™ Y-Site, Distal Microbore Tubing, 269 cm/8.7 mL (For International Use Only)
160880428	LifeShield LATEX-FREE Primary Symbiq™ Set, Piggyback with Backcheck Valve, 2 Prepierced Y-Sites, 0.2 Micron Filter, 104 Inch, Non-DEHP
160890428	LifeShield LATEX-FREE Primary Symbiq™ Set, Piggyback with Backcheck Valve, 2 Prepierced Y-Sites, 105 Inch, Non-DEHP
160900428	LifeShield LATEX-FREE Primary Symbiq™ Set, Piggyback with Backcheck Valve, 2 CLAVE™ Y-Sites, 105 Inch, Non-DEHP
160900438	LifeShield LATEX-FREE Primary Symbiq™ Set, Piggyback With Backcheck Valve, 2 CLAVE™ Y-Sites, 105 Inch, Non-DEHP
160910401	LATEX-FREE HEMA™ Primary Symbiq™ Y-Type Blood Set, 210 Micron Filter, 111 Inch
160920401	LifeShield LATEX-FREE, HEMA™ Primary Symbiq™ Y-Type Blood Set, 210 Micron Filter, CLAVE™ Y-Site, 121 Inch
160930428	LifeShield LATEX-FREE, Primary Symbiq™ Set, Polyethylene-Lined Tubing, Piggyback with Backcheck Valve, 2 CLAVE™ Y-Sites, 0.2 Micron Filter, 104 Inch, Non-DEHP
160940428	LATEX-FREE Primary Symbiq™ Set, Polyethylene-Lined Tubing, 109 Inch, Non-DEHP
160950428	LATEX-FREE Primary Symbiq™ Set, 93 Inch, Non-DEHP
160960428	LifeShield LATEX-FREE Primary Symbiq™ Set, Piggyback with Backcheck Valve, 3 Prepierced Y-Sites, 106 Inch, Non-DEHP
160970728	LifeShield LATEX-FREE Non-DEHP Primary Symbiq™ Set, CLAVE™ Y-Site, 267 cm/ 14 mL

<b>List Number</b>	<b>Description</b>
160980728	LifeShield LATEX-FREE, Non-DEHP, Primary Symbiq™ Set, 2 CLAVE™ Y-Sites, Backcheck Valve, 267 cm / 14 mL (For International Use Only)
160990728	LifeShield LATEX-FREE, Non-DEHP Primary Symbiq™ Set, Polyethylene Lined Tubing, 2 CLAVE™ Y-Sites, Backcheck Valve, 0.2 Micron Filter, 267cm / 20 mL (For International Use Only)
161000728	LATEX-FREE, Non-DEHP Primary Symbiq™ Set, Polyethylene Lined Tubing, 274 cm / 17 mL
161010728	LifeShield LATEX-FREE, Non-DEHP, Primary Symbiq™ Set, 2 CLAVE™ Y-Sites, Backcheck Valve, 0.2 Micron Filter, 267cm / 17mL
161030428	LATEX-FREE Primary Symbiq™ MICRODRIP Set, Polyethylene Lined Tubing, 109 Inch, Non-DEHP
161040401	LifeShield LATEX-FREE HEMA™ Primary Symbiq™ Blood Set, 210 Micron Filter, Nonvented, CLAVE™ Y-Site, 110 Inch
161050428	LifeShield LATEX-FREE Primary Symbiq™ Set, 1.2 Micron Filter, CLAVE™ Y-Site, 103 Inch, Non-DEHP
161060428	LifeShield LATEX-FREE Primary Symbiq™ Soluset, 150 mL Burette with CLAVE™ Port, 2 CLAVE™ Y-Sites, 115 Inch, Non-DEHP
161070428	LifeShield LATEX-FREE Primary Symbiq™ Set, Piggyback with Backcheck Valve, 3 CLAVE™ Y-Sites, 106 Inch, Non-DEHP
161070438	LifeShield LATEX-FREE Primary Symbiq™ Set, Piggyback With Backcheck Valve, 3 CLAVE™ Y-Sites, 106 Inch, Non-DEHP
161090401	LifeShield LATEX-FREE HEMA™ Primary Symbiq™ Y-Type Blood Set, 210 Micron Filter, Non-Vented, Prepierced Y-Site, 122 Inch
161100428	LifeShield LATEX-FREE Primary Symbiq™ Set, CLAVE™ Y-Site, 105 Inch, Non-DEHP
161110438	LifeShield LATEX-FREE Primary Symbiq™ Set, Piggyback With Backcheck Valve, 2 CLAVE™ Y-Sites, 0.2 Micron Filter, 104 Inch, Non-DEHP
161120428	LifeShield LATEX-FREE Primary Symbiq™ Soluset, 150 mL Burette with CLAVE™ Port, 2 CLAVE Y-Sites, 0.2 Micron Filter, 116 Inch, Non-DEHP
161130428	LifeShield LATEX-FREE HEMOSET Primary Symbiq™ Blood Set, 100 mL Burette with CLAVE™ Port, Nonvented, 170 Micron Filter, 104 Inch, Non-DEHP
196650428	LATEX-FREE Symbiq™ Pump Nitro Set, Conv. P.P, PE-Lined Tubing, 111 In, Non-DEHP Fluid Path & OI
196720428	LATEX-FREE Symbiq™ Pump Nitro Set, Conv. P.P, PE-Lined Tubing, 111 In, Non-DEHP Fluid Path & OI
197120428	Symbiq™ Primary Set. No Injection Ports
197160428	Symbiq™ Primary Set. No Injection Ports