



URGENT: Medical Device Recall Notification

IMPORTANT UPDATE TO PREVIOUS RECALL NOTIFICATION

ACTION REQUIRED: REPLACEMENT OF SYMBIQ™ MICROBORE ADMINISTRATION SETS

Affected Devices:

Symbiq Microbore Administration Sets (Listed in Table 1)

August 13, 2010

Dear Valued Customer:

Director of Nursing/ Clinical Nurse Educator
Director of Risk Management
Director of Biomedical Engineering
Director of Pharmacy

This is an update to our June 2010 Recall Notification. Hospira completed its investigation and determined the root cause of the Symbiq™ Failure to Detect Air in Line to be a liquid droplet randomly adhering to the inner wall of a Symbiq™ microbore administration set when the infusion continues past the point where the solution container is empty, and the liquid droplet is positioned directly in line with the air sensor, interfering with the air sensing algorithm's ability to trigger an alarm for the presence of air in line. (Symbiq™ microbore administration sets are either sets that are configured with straight microbore tubing (smaller inner diameter) or sets with a microbore tubing segment that extends distal to the cassette and aligned with the air sensor)

Once available, Hospira will be replacing Symbiq™ microbore administration sets with Symbiq™ macrobore sets (larger tubing inner diameter). For those situations in which microbore sets are required, once available, Hospira will provide Symbiq™ microbore sets with an integral air eliminating filter or Symbiq™ microbore sets with built in design feature(s) which will cause a proximal occlusion alarm when the bag is run past dry.

Hospira is currently accelerating production of replacement sets and will provide communication of specific dates for exchanging your recalled Symbiq™ microbore administration sets. A Hospira representative will be coordinating the distribution of these sets to your hospital as inventory becomes available. All exchanges are targeted to be complete by October 11, 2010.

See **Table 1** included in the Appendix on pages 4 and 5 for a complete list of Symbiq™ microbore administration sets to be recalled.

Replacement of Recalled Symbiq™ Microbore Administration Sets

A Hospira representative will contact you to schedule replacement of your Symbiq™ microbore administration sets. In addition, we will provide training for your staff on use of the replacements sets to help with the transition.

PLEASE PROMPTLY COMPLETE THE ATTACHED REPLY FORM IN ITS ENTIRETY AND FAX IT TO STERICYCLE AT 877-523-9113.

If you have distributed the product further, please notify your accounts of this recall, ask them to complete the reply form and fax it to Stericycle at 877-523-9113.

Required Actions for Continued Use of Symbiq Microbore Sets

Until Hospira can provide replacement inventory, per the previous recall notification, the following actions are required for your continued use of Symbiq microbore administration sets.

- **DO NOT:**
 - Do not use Symbiq™ microbore administration sets without an air eliminating filter if other sets are available.
 - Do not run solution/medication containers dry.
- **DO (per previous recall notification):**
 - When programming VTBI:
 - Take into consideration priming volume when determining volume to be infused. (VTBI)
 - Program pump for 95% of stated volume of container (minus the priming volume) or less.
NOTE: Symbiq™ system accuracy is +/- 5%.
 - Consider discarding the remaining volume when clinically acceptable.
 - For solutions/medications that have no impact on the patient's physiological status, enable "KVO" or "None" (rather than "Continue Rate" at end of infusion) from the default settings for each medication setting in the drug library or select "KVO" or "None" under "Options" on the pump. NOTE: Recommend setting KVO to the lowest clinically acceptable rate.
 - Enable Nearing End of Infusion Alarm
 - The Nearing End of Infusion Alarm is an audible and visual alarm that displays 10, 20, or 30 minutes prior to the end of the infusion
 - Nearing end of Infusion is available for Basic, Multi-step, Intermittent and Inter-channel Sequencing Therapies
 - Nearing End of Infusion Alarm can be enabled in the drug library or selected under "Options" on the pump.
 - Use an air eliminating filter if clinically appropriate. When using an air eliminating filter:
 - For appropriate medications, attaching a 0.2 micron or 1.2 micron air eliminating filter will reduce the possibility of air in line below the filter.
 - Add a "filter set use reminder" to the Clinical Note field in the Drug Library for each drug that is clinically acceptable to filter. Symbiq™ with Hospira MedNet Safety Software can support up to 1,000 clinical notes

Some medications that cannot be filtered (per previous recall notification):

Use of an in-line filter depends on the properties of the drug, filter material and filter pore size. For example, drugs such as Aldesleukin (Proleukin®), Amphotericin Cholesteryl Sulfate Complex (Amphotec®), Denileukin diftitox (Ontak®), Doxorubicin Hydrochloride Liposome injection (Doxil®), and Liposyn® III 10% and 20% have statements in their package inserts indicating that they should not be

filtered for intravenous use. Clinicians should consult the package insert or contract the drug manufacturer for information about whether filtering during administration is appropriate with a particular drug.

Please report a product problem any time and use the chart provided below for questions and support.

Hospira Contact	Contact Information	Areas of Support
Hospira Global Product Safety and Complaints	1-800-441-4100 (8am-5pm CST, M-F) (ProductComplaintsPP@hospira.com).	To report adverse events or product complaints
Hospira Technical Support Operations	1-800-241-4002 (8am-6pm CST, M-F)	Additional information Technical Assistance

We also encourage you to report any problem to FDA's MedWatch program by any of the following methods:

- Telephone: 1-800-332-1088
- Fax: 1-800-FDA-0178
- MedWatch Online:
<https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm>
- Regular Mail: Use postage-paid FDA Form 3500 which is downloadable at:
<http://www.fda.gov/downloads/Safety/MedWatch/HowToReport/DownloadForms/ucm082725.pdf>
- Mail to: MedWatch
5600 Fishers Lane
Rockville, MD 20852-9787

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

Appendix:

Table 1: Symbiq™ Microbore Administration Sets to be Recalled

Symbiq™ Microbore Administration Sets to be Recalled	
<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

Symbiq™ Microbore Administration Sets to be Recalled	
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
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



Device Recall Notification Reply Form- RESPONSE REQUIRED

Hospira August 2010 URGENT: Medical Device Recall Notification Symbiq™ Microbore Administration Sets

COMPLETE THE INFORMATION AND FAX THE COMPLETED FORM TO STERICYCLE AT 877-523-9113.

The following action has been taken:

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

Business Name

Phone Number

Address/City/State/Zip

Hospira Customer Number (ship to #)

Completed by: Printed Name/Signature/Date