

## URGENT: Medical Device Recall Notification



### IMPORTANT INFORMATION UPDATE TO PREVIOUS CLINICAL BULLETIN

#### Affected Devices:

List No. 16026- Symbiq™ One-Channel Infuser

List No. 16027- Symbiq™ Two-Channel Infuser

PE-lined Microbore Segment Administration Sets (Listed in Table 1)

June 11, 2010

Dear Valued Customer:

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

This is a critical update to our April 2010 "Clinical Bulletin". Hospira continues to receive reports of its Symbiq™ Infusion System failing to detect air in line. Although to date Hospira has not received any reports of serious injuries, failure to detect air in line may result in the delivery of air to the patient, resulting in serious injury or death.

Although Hospira does NOT believe there is a need to remove or stop the use of Symbiq™ Infusion Pumps at this time; clinicians should weigh the risk/benefits to the patients before continuing the use of the device.

#### Recommended Mitigation Actions for Users

Hospira has identified the following temporary corrective steps which are intended to mitigate the risks associated with failure to detect air in line until a permanent fix is identified.

See **Table 1** included in the Appendix on page 4 for a complete list of PE-lined microbore segment administration set list numbers.

- **DO NOT:**

- Do not use PE-lined microbore segment administration sets if other sets are available.
- Do not run solution/medication containers dry.

- **DO:**
  - 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. NOTE: Hospira will continue to provide administration sets with air eliminating filters for use in clinically appropriate circumstances. 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

The root cause for the failure to detect air in line continues to be investigated. Hospira will provide additional corrective actions as they are identified.

**PLEASE PROMPTLY COMPLETE THE ATTACHED REPLY FORM IN ITS ENTIRETY AND FAX IT TO HOSPIRA AT FAX NUMBER 408-782-8457.**

Hospira has placed the highest priority and commitment to resolving this issue, and will continue to keep you updated on developments. We regret any inconvenience this may have caused your facility and ask your cooperation in this important matter.



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) ( <a href="mailto:ProductComplaintsPP@hospira.com">ProductComplaintsPP@hospira.com</a> ).	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

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-PE Lined Microbore Tubing Segment Administration Sets**

<b>Symbiq-PE Lined Microbore Tubing Segment Administration Sets</b>	
<b>List Number</b>	<b>Description</b>
160120401	LifeShield LATEX-FREE Symbiq® Pump Set, Convertible Pin, 105 Inch Piggyback with Backcheck Valve, 2 CLAVE Ports, Distal Microbore Polyethylene-Lined Tubing Segment and OPTION-LOK
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
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
160980728	LifeShield LATEX-FREE, Non-DEHP, Primary Symbiq® Set, 2 CLAVE® Y-Sites, Backcheck Valve, 267 cm / 14 mL
160990701	LifeShield LATEX-FREE, Non-DEHP Primary Symbiq® Set, Polyethylene Lined Tubing, 2 CLAVE® Y-Sites, Backcheck Valve, 0.2 Micron Filter, 267cm / 20 mL
161000701	LATEX-FREE, Non-DEHP Primary Symbiq® Set, Polyethylene Lined Tubing, 274 cm / 17 MI
161010728	LifeShield LATEX-FREE, Non-DEHP, Primary Symbiq® Set, 2 CLAVE® Y-Sites, Backcheck Valve, 0.2 mm Filter, 267cm / 17mL
161020728	LifeShield LATEX-FREE, Non-DEHP, Symbiq™ Blood Set, Nonvented, 200 Micron Filter, CLAVE Y-Site, 272 cm
161030401	LATEX-FREE Primary Symbiq® MICRODRIP Set, Polyethylene Lined Tubing, 109 inch, Non-DEHP

Symbiq-PE Lined Microbore Tubing Segment Administration Sets	
161040401	LifeShield LATEX-FREE HEMA <sup>®</sup> Primary Symbiq <sup>®</sup> Blood Set, 210 Micron Filter, Nonvented, CLAVE <sup>®</sup> Y-Site, 110 Inch
161050428	LifeShield LATEX-FREE Primary Symbiq <sup>®</sup> Set, 1.2 Micron Filter, CLAVE Y-Site, 103 Inch, Non-DEHP
161060428	LifeShield LATEX-FREE Primary Symbiq <sup>®</sup> Soluset, 150 mL Burette with CLAVE <sup>®</sup> Port, 2 CLAVE <sup>®</sup> Y-Sites, 115 Inch, Non-DEHP
161070428	LifeShield LATEX-FREE Primary Symbiq <sup>®</sup> Set, Piggyback with Backcheck Valve, 3 CLAVE Y-Sites, 106 Inch, Non-DEHP
161080428	LifeShield LATEX-FREE Primary Symbiq <sup>®</sup> Set, Sight Chamber with Ball, Piggyback with Backcheck Valve, 2 CLAVE Y-Sites, 105 Inch, Non-DEHP
161090401	LifeShield LATEX-FREE HEMA <sup>®</sup> Primary Symbiq <sup>®</sup> Y-Type Bood Set, 210 Micron Filter, Non-Vented, Pre-pierced Y-Site, 122 Inch
161100401	LifeShield LATEX-FREE Primary Symbiq <sup>®</sup> Set, CLAVE <sup>®</sup> Y-Site, 105 Inch, Non-DEHP
161110428	LifeShield LATEX-FREE Primary Symbiq <sup>®</sup> Set, Piggyback with Backcheck Valve, 2 CLAVE Y-Sites, 0.2 Micron Filter, 104 Inch, Non-DEHP
161120428	LifeShield LATEX-FREE Primary Symbiq <sup>®</sup> Soluset, 150mL Burette with CLAVE Port, 2 CLAVE Y-Sites, 0.2 Micron Filter, 116 Inch, Non-DEHP
161130428	LifeShield LATEX-FREE HEMOSET Primary Symbiq <sup>®</sup> Blood Set, 100mL Burette with CLAVE Port, Nonvented, 170 Micron Filter, 104 Inch, Non-DEHP

**Some medications that cannot be filtered:**

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<sup>®</sup>), Amphotericin Cholesteryl Sulfate Complex (Amphotec<sup>®</sup>), Denileukin diftitox (Ontak<sup>®</sup>), Doxorubicin Hydrochloride Liposome injection (Doxil<sup>®</sup>), and Liposyn<sup>®</sup> 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.

*Blood Administration:*

In addition to the Symbiq and MedNet mitigations that are listed above, AABB guidelines indicate a 170-260 micron blood filter is recommended to deliver blood products. NOTE: Blood filters are not designed to eliminate air.

Important Product information regarding air eliminating filters:

Filters for infusion have many functions. While maintaining high flow rates, these include venting of air and removing particulate matter. Hospira's 0.2 and 1.2 micron



filters are housed in clear modified acrylic housing with a polyethersulfone (PES) membrane. The filters are sterile, low protein binding, air-eliminating and can be used for either gravity or pump administration. The filter can be utilized with a standard pressure cuff which in general has a maximum pressure of 300mmHg or 5.8 PSI. The air eliminating filters are self-priming and the dual vent design allows the filter to prime in any position with a priming volume of up to 2.4mL.

These filters are designed to tolerate pressures generated by infusion pumps and act in a nonbinding fashion with medications. The Hospira air eliminating filters utilize a dual vent design that ensures air elimination and quick priming while providing a barrier to air passing through the wetted membrane. The major membrane is a hydrophilic (water loving) membrane that is easily wetted and helps pull the fluid forward in an I.V. administration. Any air that enters the filter body is released through the vent membrane, which is a hydrophobic (water hating) membrane. The hydrophobic membrane material does not lose its ability to vent air after priming or during use.

*Priming Air Eliminating Filter Sets:*

For optimal results, please follow the priming instructions on the labeling of the particular administration set you are using. Additionally, sets should be primed just prior to patient use. If this is not possible, close the sliding clamp distal to the filter to ensure the filter remains primed. Full priming of the filter housing should be verified prior to connection to the patient.



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

**Hospira Symbiq™ June 2010 URGENT: Medical Device Recall Notification**

**Complete the information and fax the completed form to Hospira at  
(Fax: 408-782-8457)**

**Thank you.**

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**The following action has been taken:**

**I have ensured that the Recall Notification was distributed to users throughout  
the facility:**

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

**If NO, state reason:**

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**General Required Information**

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

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

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

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

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