

**URGENT: DEVICE RECALL**  
**AC Power Cords**  
**LIST No. 16026 Symbiq™ One-Channel Infuser**  
**LIST No. 16027 Symbiq™ Two-Channel Infuser**



November 1, 2010.

Dear Healthcare Professional and Valued Hospira Customer:

**Hospira, Inc. has recently received customer reports of the Symbiq™ infuser experiencing AC power cord damage including bent, broken or missing prongs, charring, sparks, visible smoke, burnt smell, and one report of fire.** Hospira's initial investigation suggests that Symbiq™ power cords can exhibit significant damage over time, due to excessive mechanical stress. As a result, internal wiring can be fractured and prongs can be bent or severed potentially leading to overheating, burning of the plastic around the power cord, and an electrical fire.

Proper use and care of the power cord can significantly reduce potential damage. Included in this communication, Hospira is providing a Technical Service Bulletin to reinforce correct maintenance, inspection, general use and storage of the Symbiq™ Infusers and AC power cords. Please ensure the Technical Bulletin is circulated throughout your facility.

**In order to mitigate the risks associated with the current AC power cord, Hospira, with your cooperation, will perform the following corrective actions:**

**1. Replacement of Damaged Cords:**

- a. Hospira is recommending that you discontinue use of any damaged cords and call Hospira for an immediate replacement. Please take the following actions to immediately locate damaged Symbiq™ AC power cords:
  - i. For all Symbiq™ AC Power Cords, inspect for any bent, missing or cracked prongs, burnt plastic or excessive wear and tear.
  - ii. For those cords exhibiting bent, missing or cracked prongs, burnt plastic or excessive wear and tear, please immediately discontinue use and contact Hospira at 1-800-241-4002 to order replacement cords. Hospira will begin shipping replacements for damaged AC power cords at no cost the week of November 11, 2010
  - iii. For Symbiq™ AC power cords not exhibiting any of the characteristics described above, please continue to monitor those power cords closely until you receive replacement power cords. Hospira recommends that all power cords should be inspected prior to operating the device.

Hospira, Inc.  
275 North Field Drive  
Lake Forest, IL 60045  
www.hospira.com

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#### 2. Replacement of All Symbiq™ Cords with Current Design AC Power Cords

- a. Hospira is proactively replacing all existing hospital grade power cords used on Symbiq™ devices. The replacement power cords will be of the same design and manufacture as the original power cords.
  - i. Hospira will add a label to the AC power cords of the current design that will be sent as replacements that will serve as a visual aid to differentiate between older AC power cords and newer AC power cords.
  - ii. Hospira will be contacting you to schedule shipment of new AC Power cords to your facility at no charge. Hospira will begin shipment of the replacement cords with labels by January 15, 2011
  - iii. Hospira is recommending you replace the existing Symbiq™ power cords with these new cords. Please contact Hospira if you require any assistance with the replacement.

#### 3. Replacement of All Symbiq™ Cords with New Design AC power cords

- a. Hospira is currently developing a design improvement to make Symbiq™ AC Power Cord more robust.
- b. Once the redesign of the new AC power cord is completed and inventory is available, Hospira will notify you to schedule shipment of the new Symbiq™ power cord.

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 these actions may cause.

These corrections are being made with the knowledge of the U.S. Food and Drug Administration.

If you have distributed the product further, please notify your accounts and ask them to return the reply form to Hospira at the fax number on the form.

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

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Any adverse events experienced with the use of this product, and/or quality problems should also be reported to the FDA's MedWatch Program by:

- Linking to the MedWatch website at [www.fda.gov/medwatch](http://www.fda.gov/medwatch)
- Calling 1-800-FDA-1088
- Faxing at 1-800-FDA-0178
- Mailing to MedWatch, HF-2, FDA, 5600 Fishers Lane, Rockville, MD, 20852-9787

Sincerely,

A handwritten signature in black ink, appearing to read "Ileana Quinones", is written over a light blue horizontal line.

Ileana Quinones  
Vice President, Device Quality Operations

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**Recall Reply Form- RESPONSE REQUIRED**

**COMPLETE THE INFORMATION AND FAX THE COMPLETED FORM TO HOSPIRA AT  
(FAX: 408-782-8457).**

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**1. I have received the Recall Notification and Technical Service Bulletin and distributed it to users throughout the facility:**

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

**If NO, state reason:**

**2. I have inspected the Symbiq™ Devices in my facility and have identified \_\_\_\_\_  
number of damaged AC Power Cords that require immediate replacement.**

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**Replacement Cords Shipped To:**

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

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

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

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

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