Class I Medical Device Recall: Symbiq One and Two-Channel Infusers

U.S. Food & Drug Administration

Recall Class: Class I

Date Recall Initiated: March 26, 2010

Product: Symbiq Infusion System

Brand Name:
Symbiq One-Channel Infuser
Symbiq Two-Channel Infuser

Model Numbers:
16026 Symbiq One-Channel Infuser
16027 Symbiq Two-Channel Infuser

Dates of Distribution: December 23, 2006 – January 22, 2010

All lots are affected and can be found in the following List Number Configurations:

Model Number-Country/ Language Code-Inventory Code	**Model Number-Country/ Language Code-Inventory Code**
16026-04-01/03/04	16027-04-01/03/04
16026-04-51/52	16027-04-51/52
16026-04-53/54	16027-04-53/54
16026-04-79/80	16027-04-79/80
16026-04-81/82	16027-04-81/82
16026-04-83/84	16027-04-83/84
16026-04-87/88	16027-04-87/88
16026-04-89/90	16027-04-89/90
16026-13-25/26	16027-13-25/26
16026-13-53/54	16027-13-53/54
16026-27-89/90	16027-27-89/90

Use: The Symbiq One and Two-Channel Infusers are infusion pumps intended for the delivery of fluids, solutions, drugs, agents, nutritionals, electrolytes, blood and blood products via parenteral, enteral, intravenous, intra-arterial, subcutaneous, epidural, or irrigation routes of administration.

The systems are available as a one-channel or a two-channel infuser and may be connected to configure a three or four channel pump. The cassette-based system is powered by either AC power or can be powered by a rechargeable battery. The

Symbiq Infusion Systems deliver basic therapy or advanced therapies such as multi-step, intermittent, and inter-channel sequencing.

Recalling Firm:
Hospira Inc.
775 Jarvis Drive
Morgan Hill, California 95037

Reason for Recall: There is potential for unrestricted flow of fluid or medication if the administration set (cassette) is removed before the cassette carriage fully opens and the slide/roller clamp is not closed. Additionally, when unrestricted flow occurs, the “Check Flow Stop” alarm, which is designed to notify users of a free flow condition, may not function as intended and may not provide appropriate warning to users. **Unrestricted flow of medication an/or other therapy has the potential to cause life-threatening effects and/or critical patient injury, especially in specific patient groups such as critically ill patients, patients with congestive heart failure and/or neonates.** The design of this device is being evaluated. The actions required under this recall will be supplemented with a long term solution to the “Check Flow Stop” alarm malfunction on a later date.

Hospira is reinforcing that it is imperative that clinicians using the Symbiq devices adhere to the operating instructions for removing the cassette from the infuser in order to mitigate free flow until a final correction is implemented. According to the firm, proper procedure for cassette removal is as follows:

1. Confirm the infusion pump is in “Stop” mode, and close the administration set roller clamp, and/or slide clamp, prior to removing the cassette from the infuser.
2. Press the “Load/Eject” button to open the cassette carriage. **Ensure the cassette carriage is fully opened. Do not remove the administration set until movement of the cassette carriage has stopped.**
3. Grasp the tubing above and below the cassette. Slide the cassette upward and out of the cassette carriage.
4. The cassette carriage will close automatically in approximately 10 seconds. Alternatively, press the “Load/Eject” button to close the cassette carriage sooner.
5. To discontinue use of the device, press and hold the “On/Off” button for one second to power down.
6. Discard the administration set and fluid container per Centers for Disease Control, hospital, or healthcare provider guidelines.

Public Contact: Questions should be directed to Hospira, Inc. at 1-800-241-4002 Monday through Friday from 8:00 a.m. to 6 p.m. Central Time.

FDA District: San Francisco

FDA Comments:

Hospira mailed clinical bulletins to affected customers on March 26, 2010 directing them to remove the administration set (cassette) only after the roller/slide clamp has been closed and the cassette carriage is fully open. Hospira sent additional information to customers through an Urgent Product Recall letter on September 13, 2010. Distribution of this product has stopped pending corrective actions.

Class I recalls are the most serious type of recall and involve situations in which there is a reasonable probability that use of these products will cause serious adverse health consequences or death.

Health care professionals and consumers may report adverse reactions or quality problems they experienced using these products to the MedWatch: The FDA Safety Information and Adverse Event Reporting Program [1] either online, by regular mail or by FAX.

Useful Links:

- Hospira Symbiq Unrestricted Flow Recall (September 13, 2010) [2] [3]
- Hospira Symbiq Clinical Bulletin and Recall Notice (March 2010) [4] [3]
- FDA Infusion Pump Initiative Webpage [5]

SOURCE [6]

Source URL (retrieved on *10/20/2014 - 6:09pm*):
http://www.mdtmag.com/news/2010/09/class-i-medical-device-recall-symbiq-one-and-two-channel-infusers

Links:
[1] http://www.fda.gov/Safety/MedWatch/default.htm
[2] http://www.hospira.com/Files/ClinicalBulletin/Symbiq%20Unrestricted%20Flow%20Recall%20Notification.pdf
[3] http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm
[4] http://www.hospira.com/Files/ClinicalBulletin/Clinical%20Bulletin%20March%202010.pdf
[5] http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/GeneralHospitalDevicesandSupplies/InfusionPumps/ucm205424.htm
[6] http://www.fda.gov/MedicalDevices/Safety/RecallsCorrectionsRemovals/ListofRecalls/ucm226594.htm