

September 16, 2010

BagEasy Manual Resuscitation Devices by Westmed, Inc.: Class I Recall



Westmed, Inc. Issues Nationwide Recall of BagEasy Manual Resuscitation Devices

FOR IMMEDIATE RELEASE: September 14, 2010 – Westmed, Inc., Tucson, AZ, is initiating a nationwide recall of 24,384 units of BagEasy Manual Resuscitation Devices. Select lots of the BagEasy device have been found to have a potential for disconnection at the retention ring of the patient port manifold. Disconnection causes the unit to be inoperable, which potentially could result in treatment delays while another unit is obtained or technician switches to a different method of resuscitation. This recall is classified by the FDA as a Class I Recall.

Consumers who have units from the identified lots of BagEasy manual resuscitation devices which are being recalled should stop using them and return the product to Westmed or their distributor. To obtain the full listing of part numbers and lot numbers, visit the FDA website (www.fda.gov), or contact Westmed customer service at 1-800-975-7987.

Westmed voluntarily recalled these products after learning of units disconnecting at user facilities. The FDA has been apprised of this action. Westmed has become aware of a potential for disconnection at the patient port retention ring assembly of the BagEasy manual resuscitation device after receiving reports from three separate facilities regarding units disconnecting during setup or use. The healthcare providers obtained another unit and continued with setup or treatment.

The BagEasy manual resuscitation device was distributed to other medical device distribution companies as well as directly to hospitals and other treatment facilities. It can be identified by product labeling that contains part and lot numbers. Westmed is notifying its distributors and customers by certified mail and direct contact by sales representatives and is arranging for return of all recalled products.

Consumers with questions may contact the company at 1-800-975-7987 (Monday through Friday, 6 AM to 5 PM Arizona Standard Time).

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Online: www.fda.gov/medwatch/report.htm
- Regular Mail: use postage-paid FDA form 3500 available at: www.fda.gov/MedWatch/getforms.htm
- Mail to MedWatch 5600 Fishers Lane, Rockville, MD 20852-9787
- Fax: 1-800-FDA-0178

Read the complete MedWatch Safety Alert at:

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm226014.htm>

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www.kcercoalition.com/alerts.htm