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## Safety

### Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

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

##### Contact:

Customer Service, 1-800-975-7987

Representatives available M – F between 6 AM – 5 PM Arizona Standard Time

**FOR IMMEDIATE RELEASE** -- September 14, 2010 - Westmed, Inc., Tucson, AZ, is initiating a nationwide recall of 24,384 units of BagEasy Manual Resuscitation Devices. The select lots listed below 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 and return the product to Westmed or their distributor.

The recall includes the following part numbers and lot numbers:

Part Number	Description	Lot Number
		47952
		48174
		48320
		48489
		48718
562013	BagEasy, Adult Resuscitator, W/Mask	48893
		49093
		49179
		49353
		49567
		49685
		47772
		47896
		47971
		47972
		48319
562048	BagEasy, Adult Resuscitator, W/Peep and Mask	48449
		48577
		48807
		48892
		48970
		49092

		49178
		48321
		49225
562133	Child BagEasy Resuscitator w/Large and Regular Mask	49407
		47728
562136	Adult BagEasy Resuscitator w/Mask and CO2 EasyTM	49094
		49275
562080	BagEasy, Child Resuscitator, W/Peep and Mask	48719
		49144
562081	BagEasy, Child Resuscitator, W/Peep	49643
		49660
		48091
562082	BagEasy, Child Resuscitator, W/Mask	49274
		49386
		49487
		48119
		48578
562084	BagEasy, Infant Resuscitator, W/Peep and Mask	48733
		48941
		49042
		49254
		47895
562086	BagEasy, Infant Resuscitator, W/Mask	48071
		48488
		48823
562110	BagEasy, Neonatal/Infant Resuscitor, W/Mask	49486
		49611
562111	BagEasy, Neonatal/Infant Resuscitator, W/Peep and Mask	48276
		49273
		47769
		48140
		48141
32628	Manual Resuscitator Adult, PSS	48428
		48142
		48275
		48652
32629	Manual Resuscitator Pediatric, PSS	48429

The firm voluntarily recalled the products after learning of units disconnecting at user facilities. 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 setu 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 identified above.

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

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[Photo: Product Label](#)<sup>9</sup>

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