Class 1 Recall
Multi Absorber Original, Disposable

See Related Information[21]

Date Posted	December 13, 2013
Recall Status[1]	Open
Recall Number	Z-0472-2014
Product Classification	Absorber, Carbon-Dioxide[22] - **Product Code** BSF[23]
Product	Multi Absorber Original, Disposable M1173310 Multi Absorber Original, Disposable, package of 6 pcs, GE Healthcare Finland Oy Kuortaneenkatu 2 FI-00510 Helsinki, Finland +358 10 394 11 Made in US Rx Only The GE Healthcare Multi Absorber Original, Disposable is a disposable product intended for use with the GE Healthcare Advanced Breathing System (later ABS), the GE Healthcare EZchange manifold, the GE Healthcare Compact Block, and the GE Healthcare Compact Block II (later Compact Block). The Multi Absorber should only be used with air, oxygen, nitrous oxide, halothane, enflurane, isoflurane, desflurane and sevoflurane. The device is intended to be used under constant attention of qualified professional healthcare personnel.
Code Information	510(k): Exempt The affected product number is M1173310 containing lot numbers 12001 through 13031. E218574 Active Exempt BSF ABSORBER, CARBON-DIOXIDE
Recalling Firm/ Manufacturer	GE Healthcare, LLC 3000 N Grandview Blvd Waukesha, Wisconsin 53188-1615
Manufacturer Reason for Recall	GE Healthcare has recently become aware of a potential safety issue due to air leakage associated with the CO2 Multi Absorber.
FDA Determined Cause [2]	DESIGN: Device Design
Action	GE issued an Urgent Medical Device Correction letter dated September 19, 2013, to all affected customers via Fed Ex overnight mail. The letter identified the product, the problem, and the action to be taken by the customer. Customers were instructed to not use the affected product, isolate all affected product and return the attached form via fax to 800-535-7923. Once the information is received, customers would be contacted with an RMA and replacement information. If product was distributed further the notice should be forwarded to those customers. For questions customers should call 1-800-345-2700, option 2 followed by ooption 2. For foreign customers 1-800-932-0760, option 2. For questions regarding this recall call 262-513-4122.
Quantity in Commerce	US: 59,721 boxes, 358,326 canisters; OUS: 3,724 boxes, 22,344 canisters
Distribution	Worldwide Distribution - USA (nationwide) Puerto Rico and Internationally to Canada, Costa Rica, Mexico, and Venezuela.
Total Product Life Cycle	TPLC Device Report[24]

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[25]
[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

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