Class I Medical Device Recall: Fisher and Paykel Healthcare ? Reusable Breathing Circuit

U.S. Food & Drug Administration

Recall Class: Class I

Date Recall Initiated: January 3, 2013

Product: Reusable Breathing Circuit

Manufacturing Dates: August 2011 – October 2011

Distribution Dates: April 6, 2012 – September 27, 2012

Device Model: 900MR068

Lot Numbers: 110810 and 111020

Use: The Fisher & Paykel Healthcare reusable breathing circuit is a non-heated breathing circuit intended for oxygen therapy delivery for adult patients.

Recalling Firm:
Fisher & Paykel Healthcare Limited
15365 Barranca Parkway
Irvine, California 92618

Reason for Recall: The tubes used in the reusable breathing circuit have pinholes. If these pinholes are not detected during the standard leak test before patient use, it could potentially result in a gas leak in the breathing system, which may lead to a loss of pressure for the intended ventilation therapy. Usage of the defective device may result in patient death.

Public Contact: Questions should be directed to Fisher & Paykel Healthcare Limited at 1-800-446-3908 ext 5003, Monday through Friday from 6 am to 5 pm Pacific Time.

FDA District: Los Angeles

FDA Comments:
On Nov. 19, 2012, Fisher & Paykel issued an Urgent Medical Device Recall letter to inform customers of the problem and to provide them with a Product Recall Response form. Customers should examine their inventory and destroy and discard any affected circuits in their possession. Replacement circuits will be provided to customers upon receipt of the Product Recall Response form, which indicates the quantity of replacements required.

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 MedWatch: The FDA Safety Information and Adverse Event Reporting Program [1] either online, by regular mail or by FAX.

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[1] http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm