ICU MANAGEMENT & PRACTICE

Teleflex Incorporated Announces Worldwide Voluntary Recall of Hudson RCI® LIFESAVER®

Teleflex Incorporated announced today that the U.S. Food and Drug Administration (FDA) has classified the voluntary medical device recall of Hudson RCI® LIFESAVER® Neonate Manual Resuscitator as a Class 1 recall. FDA defines Class I recalls as, “a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death.”

Teleflex is recalling the products referenced above because the intake port may be blocked, which can cause the bag to fail to fill. No patient injury or harm has been reported, however, a delay in treatment may occur while another resuscitator is obtained. A delay in treatment may potentially lead to adverse consequences such as hypoxia.

Teleflex notified both domestic and foreign hospitals and distributors via an Urgent Medical Device recall letter dated May 14, 2015. This recall involves the retrieval of unused product in the field.

At this time, there have been 3 complaints of this issue. There have been no reports of patient injury as a result of this issue. Forty-two (42) lots across five (5) product codes are affected by this recall for a total of 9,333 units distributed to the field.

The original recall notice can be found at Teleflex’s website:

http://www.teleflex.com/en/recall/Hudson-Lifesaver-Resuscitator-1st-Customer-Notification.pdf

Consumers with questions may contact the company at 1-866-246-6990; 8am to 8pm, ET, Monday through Friday.

Any adverse reactions experienced with the use of this product, and/or quality problems can also be reported to the FDA’s MedWatch Program by phone at 1-800-FDA-1088, by Fax at 1-800-FDA-0178, by mail at MedWatch, HF-2, FDA, 5600 Fishers Lane, Rockville, MD 20852-9787, or on the MedWatch website at www.fda.gov/medwatch.

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