H&H Medical Corporation

Issues Nationwide Recall of Emergency Cricothyrotomy Kit

FDA Recall Action No. Z-0006-2014

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On August 27, 2013, H&H Medical Corporation initiated a nationwide recall of 6,619 units of the H&H Emergency Cricothyrotomy Kit. The product has been found to show the potential for a defective cuff balloon on the provided endotracheal airway.

Consumers who have product should stop using the product and return them to their original place of purchase for immediate credit. Distributors are instructed to return all recalled items meeting the lot numbers listed below for return credit or for immediate replacement.

The recalled version of the H&H Emergency Cricothyrotomy Kit was produced between August 16, 2012 and July 29, 2013. The following lot numbers have been recalled:

Lot # of kits manufactured	Quantity Shipped In Market	Expiration Date
CKBD033 CKBE033	1,802 198	August 2015
CKBD034 CKBF034 CKBG034	653 326 254	August 2015
CKBP045	248	November 2015
CKBP047 CKBQ047	172 201	November 2015
CKBR060	125	February 2016
CKBT065	125	April 2016
CKBV070 CKBW070 CKBX070	150 101 385	May 2016
CKBX071	247	May 2016
CKBX076	510	June 2016
CKBX078	125	July 2016
CKBX079	125	July 2016

Lot # of kits manufactured	Quantity Shipped In Market	Expiration Date
CKBY079	125	
CKBY080 CKBZ080 CKCA080	164 368 215	July 2016

The product lot number can be identified by a lot number and manufacture label applied at the top opening of the kit.

H&H Medical Corporation is voluntarily recalling this product after becoming aware of the issue with the defective cuff. H&H Medical Corporation has notified the FDA of this action.

The cuff balloon may be defective due to a very particular set of circumstances (a reduction in package density, a higher than average dose of gamma sterilization, and the occasional slippage of a protective silicon sleeve during shipping used to shield the cuff balloon at the end of the endotracheal airway). To date, no injuries or deaths have been reported to H&H or to the FDA.

H&H Medical Corporation is notifying its distributors and customers by letter and email as well as posting this notice on our website at http://www.gohandh.com. Users should quarantine this product from inventory and return it to the original source of sale for credit or to request immediate replacement. Distributors and resellers are to return recalled product to H&H by contacting Michelle Morgan at 804-642-3663 or by email at mmorgan@gohandh.com. Please indicate whether replacement kits or purchase credit is requested. All return shipping costs will be paid by H&H Medical Corporation.

H&H Medical Corporation distributed this product within the Continental United States, primarily for U.S. military sale and use.

Consumers with questions may contact H&H Medical Corporation via telephone at 800-326-5708 between the hours of 8 a.m. and 4:30 p.m. (Eastern Time Zone). Consumer may also contact the company via e-mail at mmorgan@gohandh.com.

Adverse reactions or quality problems experienced with the use of this product must be reported to the FDA:

- Online at http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm (form available to fax or mail), or
- Call FDA 1-800-FDA-1088