



COUNTY OF ERIE

MARK C. POLONCARZ

COUNTY EXECUTIVE

TO: All E.M.S. Providers

FROM: John Adolf, Deputy Commissioner / E.M.S.
Erie County Division of Emergency Medical Services

DATE: December 14, 2012

SUBJECT: Voluntary Recall of Certain GlideScope GVL Video Laryngoscope Reusable Blades

FOR IMMEDIATE RELEASE - November 29, 2012 - Verathon Inc., Bothell, Washington, is initiating a voluntary recall of GlideScope GVL Video Laryngoscopes reusable blades that were manufactured between December 2010 and August 2011. These laryngoscope blades have been found to be prone to developing cracks and/or breaking across the tip of the blade, which potentially could result in pieces of the blade breaking off in patient's mouths and obstructing the airway or being swallowed.

Healthcare facilities that have GlideScope GVL reusable blades that are being recalled should stop using the blades and contact Verathon Customer Care to obtain a replacement blade, if one has not already been provided. Customers should also contact Customer Care regarding any other questions about the recall. Customer Care can be reached at (800) 331-2313 (U.S. and Canada) or (425) 867-1348 (international), Monday through Friday from 6:00am to 5:00pm PST for the United States and 6:00am to 4:30pm PST outside of the United States. Customers may also email the company at cservice@verathon.com.

The recall includes the following models within the specified serial number ranges:

GlideScope GVL 3, 0574-0007: MD10500 to MD112387

GlideScope GVL 4, 0574-0001: LG105000 to LG112758

GlideScope GVL 5, 0574-0030: XL105000 to XL111798

The firm voluntarily recalled the products after learning about design characteristics leading to cracked and broken blades. FDA has been apprised of this action.

The affected GlideScope GVL blades are at risk of developing stress cracks at the blade tip that may not be readily visible during routine inspection prior to intubation. This cracking may eventually

cause the blade tip to break and the product to fail. To date, no patient injuries due to this issue have been reported to Verathon.

GlideScope GVL Video Laryngoscopes are used only by healthcare professionals and were distributed directly to hospitals and other healthcare facilities throughout the United States, Canada, and other foreign countries. Affected GlideScope GVL reusable blades can be identified by reference to the serial number engraved on the metal label on the handle of the GlideScope GVL blade.

Verathon has notified its distributors and customers by mail and by telephone or in-person visits and is arranging for return and replacement of all recalled products.

Any adverse reactions experienced with the use of this product and/or quality problems should 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/medwatch¹.

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Cc Commissioner Burstein
Commissioner Neaverth