Verathon Inc. Recalls GlideScope Titanium Single-Use Video Laryngoscope Due to Potential Video Feed Disruption

The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death

Recalled Product:

- GlideScope Titanium Single-Use Video Laryngoscope
- Model Codes: LoPro S3; LoPro S4; MAC S3; MAC S4
- Lot Numbers: LoPro S3: 081814 - 093015; LoPro S4: 081114 - 090315; MAC S3: 080814 - 101315; MAC S4: 022514 – 082115
- Manufacturing Dates: November, 2014 to December, 2015
- Distribution Dates: November 14, 2014 to December 29, 2015
- Devices Recalled in the U.S.: 6,377 units nationwide

Device Use

The GlideScope Titanium Single-Use Video Laryngoscope is used to obtain a clear view of the vocal cords and to assist in the insertion of a tracheal tube used during other medical procedures (i.e. general anesthesia).

GlideScope Titanium Single-Use Video Laryngoscope

Reason for Recall

Verathon Incorporated is recalling the GlideScope Titanium Single-Use Video Laryngoscope because of a potential disruption in the video feed from the camera in the laryngoscope blades to the monitor. A disrupted or unstable video image may lead to delayed tracheal tube insertion, intubation failure and other serious adverse health consequences, including low levels of oxygen in the blood (hypoxemia), end organ damage or death.

Who May be Affected

- Health care providers using the GlideScope Titanium Single-Use Video Laryngoscope
- All patient groups undergoing procedures involving the GlideScope Titanium Single-Use Video Laryngoscope

What to Do

On January 29, 2016, Verathon Inc. sent a Customer Recall letter instructing customers to:

- Review the list of affected products and lots
- Fill out and return the attached Recall Response Form even if the inventory was free of affected products
- Return affected products along with the Recall Response Form, or to destroy them and provide evidence of destruction
- Contact the firm's customer care line at 1-800-331-2313 to arrange for delivery of replacement products

Report adverse events or quality problems experienced with use of the product to the FDA through:

- MedWatch Online
- Phone: 800-FDA-1088

Date Recall Initiated:

January 29, 2016

Contact Information:

Customers with additional questions about this recall can contact Verathon Inc. at 1-888-943-4207 or by email at verathon5165@stericycle.com

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Page Last Updated: 03/18/2016
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U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
1-888-INFO-FDA (1-888-463-6332)

Contact FDA