January 26, 2016

URGENT: MEDICAL DEVICE RECALL

GLIDESCOPE® TITANIUM SINGLE-USE VIDEO LARYNGOSCOPE BLADES

Radiance Medical Systems
10 Bukit Batok Crescent #07-01
The Spire, Singapore 658079

Dear Distributor:

Purpose of this letter:

The purpose of this letter is to advise you that Verathon® Inc. is voluntarily recalling all models of the GlideScope® Titanium Single-Use (SU) Video Laryngoscope blades. The GlideScope Titanium Single-Use systems are intended for use by qualified medical professionals to obtain a clear, unobstructed view of the vocal cords for medical procedures. **Serious injuries and/or deaths could occur due to the failure mode associated with this recall; however, we have not received any reports of deaths or serious injuries associated with this failure mode.**

Reason for the Voluntary Correction:

Verathon has completed an investigation and is issuing a field corrective action regarding a significant source of disruption (flickering) in the video laryngoscopy image when GlideScope® (GS) Titanium (Ti) Single Use (SU) (or GS Ti SU) video laryngoscope blades are used. Video "flickering" appears as the intermittent break-up of the on-screen video image, appearing as either distorted horizontal or vertical bars of displayed video signal. Flickering may be unnoticeable to the human eye; however, if it repeats frequently within a short time interval, it could interrupt the placement of an endotracheal tube and completion of the intubation procedure. Video flickering may not be readily visible prior to intubation without careful monitoring.

Verathon is aware of two (2) complaints reporting a near-harmful inability to complete an intubation procedure due to video flickering. Neither complaint reported a death or serious injury as a direct outcome of the flickering. In both instances, the user experienced a delay in intubation, but in both cases intubation was successfully achieved with a back-up device.

Global Headquarters
Verathon, Inc.
20001 North Creek Parkway, Bothell, WA 98011, USA
Toll-free: 800.331.2313 **Main:** 425.867.1348

European Headquarters
Verathon Medical Europe B.V.
Willem Fenengastraat 13, 1096 BL Amsterdam, The Netherlands
Main: +31(0)20.210.30.91 **Fax:** +31(0)20.210.30.92

verathon.com

Risk to Health:

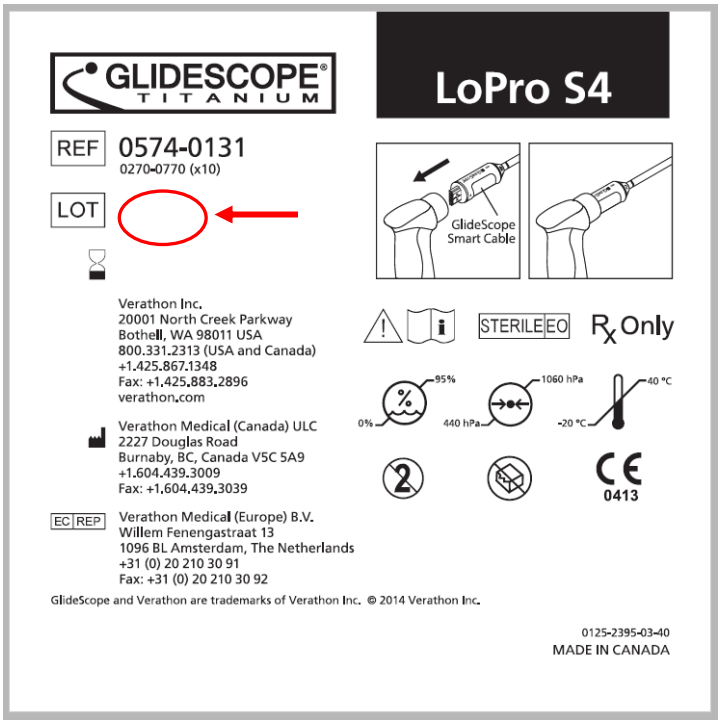
If a GlideScope Titanium SU blade causes image flickering during an intubation procedure, there may be a short delay while the physician completes the intubation with a disrupted video image. If flickering is so severe that the video image cannot be relied upon to complete the intubation, then the failure of the intubation procedure, and accompanying delay while a different SU blade or laryngoscope is located, could result in patient death or serious injury. At this time, Verathon is not aware of any instances of patient injuries or deaths attributed to this potential failure.

Actions to be Taken by the Customer/Distributor:

Our records indicate that your facility has received one or more GlideScope Titanium SU blades affected by this recall. The blades are available in four (4) models; each blade is sterile-pouched with a three-year expiration and is packaged and distributed in a box of ten (10). You may determine whether or not you have affected devices by reviewing the Lot number for your GlideScope Titanium Single Use blades, which is located in two places:

1) on the outer carton/packaging label for a box of ten (10) blades and
2) on the immediate sterile packaging label for each individual SU blade.

The lot number is a six (6) digit numerical number located on the upper left corner of the label next to the lot number symbol "LOT". The red circle and arrow in the figure below will assist you in locating the lot number:



Verathon will replace all affected GlideScope Titanium SU blades that remain in your facility's inventory with new product that has been tested to screen out any units prone to disruptive flickering.

Due to the fact that single use blades are in boxes containing 10 individual blades, we will replace existing boxes of 10 (even if partial) with a full replacement box. For example, if you originally purchased two (2) boxes (i.e., twenty (20) blades) and only have twelve (12) blades left, then we'll send out two (2) replacement boxes.

Product and Distribution Information (for recalled devices) includes:

Product	Model		Lot Numbers Ranges (format is MMDDYY)
	Single Blade	Box of 10	
LoPro S3	0574-0130	0270-0769	081814 – 093015
LoPro S4	0574-0131	0270-0770	081114 – 090315
MAC S3	0574-0132	0270-0771	080814 – 101315
MAC S4	0574-0133	0270-0772	022514 – 082115

Actions to be Taken by the Customer/Distributor (continued):

To comply with this recall notice for the affected devices and lot numbers of GlideScope Titanium SU blades, please take the following actions:

- **Respond to Recall Response Form**: Fill out the attached Recall Response Form and return it **by email to, verathon5165@stericycle.com, or fax, (888) 943-5170**. Please return the form even if you do not have any blades subject to the recall. The Recall Response Form will indicate:
  - That you have reviewed the Recall Notification and understand it.
  - That you no longer have GlideScope Titanium Single Use blades in inventory, or
  - That you do have GlideScope Titanium Single Use blades in inventory and are requesting a replacement, and will hold the blades in quarantine and await further instructions from Verathon regarding their destruction or return.

- **Next, Verathon will initiate product replacement**: Verathon Customer Care will contact you via the information you supply on the Recall Response Form to arrange for delivery of replacement blades for the affected GlideScope Titanium SU blades that remain in your facility's inventory, in addition to discussing your options for destruction or return.

If you should need to expedite a product replacement **contact your Verathon representative or Verathon Customer Care at (800) 331-2313 (U.S. and Canada)**. We have live agent support Monday through Friday from 8:00am to 5:00pm Eastern Time. **You may also email us at CCTechSupport@verathon.com** and we will respond promptly.

Action To Be Taken by Verathon:

Verathon is voluntarily taking this recall action to address the video flickering issue reported in connection with a small number of GlideScope Titanium SU blades. Therefore, we have implemented an enhanced screening test for all newly produced Titanium SU blades. Only blades that pass this screening test will be provided to you as replacement blades, through the process described in the "Actions to be Taken by the Customer/Distributor" section above.

CONTACT INFORMATION:

Should you have any questions about this Product Recall, please contact your Verathon representative or call (888) 943-4207 (U.S. and Canada). We have live agent support Monday through Friday from 8:00am to 5:00pm Eastern Time. You may also email us at **verathon5165@stericycle.com** and we will respond promptly.

This field action is being conducted with the knowledge of the U.S. Food and Drug Administration and other regulatory authorities. Please report any suspected malfunction or adverse event related to any GlideScope Video Laryngoscope devices to Verathon Customer Care at the telephone numbers above or to FDA's MedWatch Program (1-800-FDA-1088 or www.fda.gov/medwatch).

Thank you for your immediate attention to this matter. We regret any inconvenience this recall action may cause. We encourage you to contact us if you need assistance or further information.

Sincerely,

[redacted]

Mary K. Moore
Vice President, Regulatory Affairs and Quality Assurance

Encl: Recall Response Form