February 9, 2016

Urgent - Field Safety Notice
MEDICAL DEVICE RECALL
GLIDESCOPE® VIDEO LARYNGOSCOPE TITANIUM SINGLE-USE BLADES

Dear Valued GlideScope Customer,

The purpose of this letter is to advise you that Verathon® Incorporated is voluntarily recalling all sizes of GlideScope® Video Laryngoscope Titanium Single-Use (SU) Blades.

Our records indicate that your facility has received one or more of the products affected by this notice. Please identify the lot number(s) of your GlideScope® Video Laryngoscope Titanium Single-Use (SU) Blades located on the packaging as described on page 3 of this letter and follow the instructions on the following pages that apply to your device(s).

This Field Safety Notice is being conducted with the knowledge of the applicable Regulatory Authorities. Please report any suspected malfunction or adverse event related to any GlideScope device to Verathon Customer Care at CustomerCareEU@verathon.com.

Thank you for your immediate attention to this matter. Verathon is committed to providing products of the highest quality and we regret any inconvenience these actions may cause. We encourage you to contact us if you need assistance or further information.

Sincerely,

Mary K. Moore
Vice President,
Regulatory Affairs & Quality Assurance
Respiratory and Surgical Solutions
20001 North Creek Parkway
Bothell, WA 98011
verathon.com

Christian Wulff
Operations Director, EMEA
Willem Fenengastraat 13
1096 BL Amsterdam
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MEDICAL DEVICE RECALL

Affected products: GlideScope® Video Laryngoscope Titanium Single Use Blades
Note: Does not apply to GlideScope Titanium Reusable Systems

Product Recall	Product Name	Part number		Lot Number Ranges	Lot Number Count	Dates of Distribution
		Single Blade	Box of 10			
	LoPro S3	0574-0130	0270-0769	081814-093015	18	November 2014 - December 2015
	LoPro S4	0574-0131	0270-0770	081114-090315	13	
	MAC S3	0574-0132	0270-0771	080814-101315	10	
	MAC S4	0574-0133	0270-0772	022514-082115	10	

The GlideScope Video Laryngoscope systems are intended for use by qualified medical professionals to obtain a clear, unobstructed view of the airway and vocal cords for medical procedures. Serious injuries and/or deaths could occur due to the failure mode associated with this Field Safety Notice; however, we have not received any reports of deaths or serious injuries associated with this failure mode.

Reason for the Voluntary Correction:

Verathon Incorporated has become aware of the potential for 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 displaced video signal. Flickering may be imperceptible 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 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.

CORPORATE HEADQUARTERS
20001 North Creek Parkway ♦ Bothell, WA 98011 ♦ USA
425.867.1348 ♦ 800.331.2313 (US & Canada Only) ♦ Fax 425.883.2896

VERATHON MEDICAL (EUROPE) B.V.
Willem Fenengastraat 13 ♦ 1096 BL Amsterdam ♦ The Netherlands
+31 (0) 20 210 30 91 ♦ Fax +31 (0) 20 210 30 92

Risk to Health:

If a GlideScope Video Laryngoscope 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:

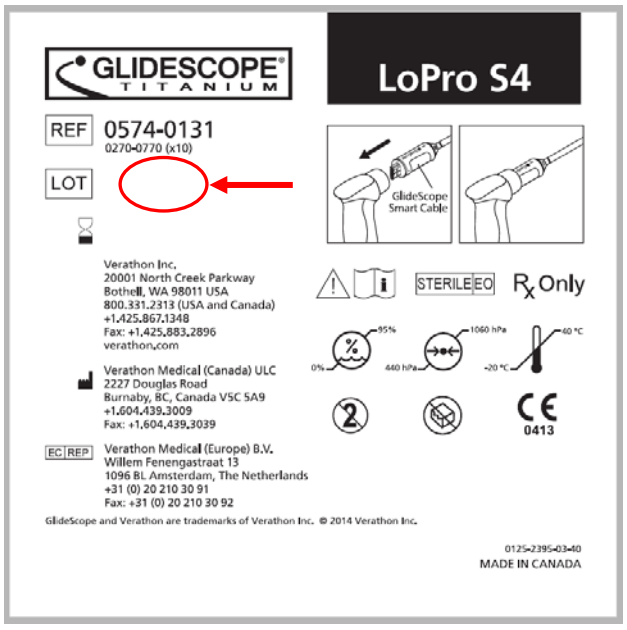
Our records indicate that your facility has received one or more GlideScope Video Laryngoscope Titanium SU blades affected by this Field Safety Notice. The blades are available in four (4) models; each blade is sterile-pouched with a three-year expiration, and is packaged and distributed in a box of ten (10). Verathon will replace all affected GlideScope Video laryngoscope Titanium SU blades that remain in your facility's inventory with new products that has been tested for video flickering.

The lot number for your GlideScope Video Laryngoscope Titanium Single Use (SU) blades 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:



To comply with this Field Safety Notice for the affected models and lot numbers of GlideScope Video Laryngoscope Titanium SU blades, please take the following actions:

- Fill out the attached Field Safety Notice Reply Form and return it to Verathon by fax: +31 (0) 20 210 30 92, or email: CustomerCareEU@verathon.com. Please return the form even if you do not have any blades subject to this Field Safety Notice.

- Contact Customer Care to arrange for delivery of replacement blades for affected GlideScope Video Laryngoscope Titanium SU blades that remain in your facility's inventory.

- To arrange for the destruction of your recalled blades, Customer Care will issue you an RMA number for the return of the devices to Verathon.

Action to Be Taken by Verathon:

Verathon is voluntarily taking this Field Safety Notice action to address the video flickering issue reported in connection with a small number of GlideScope Video Laryngoscope Titanium SU blades. As a corrective action, 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.

Should you have any questions about this Field Safety Notice, please contact your Verathon representative or Verathon Customer Care at **CustomerCareEU@verathon.com**.

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Field Safety Notice Reply Form: Response Required

Please complete this form

Our records indicate that your facility has received one or more boxes of GlideScope® Video Laryngoscope Titanium SU Blades with the LOT Number ranges listed in the table below. Please fill out and return this **Field Safety Notice Reply Form**.

FIELD SAFETY NOTICE REPLY FORM: RESPONSE REQUIRED					
Affected Devices: GlideScope® Titanium Single UseVideo Laryngoscope blades with the following Lot Numbers:					
Model Number		LoPro S3	LoPro S4	MAC S3	MAC S4
Part Number	**Single Blade**	0574-0130	0574-0131	0574-0132	0574-0133
	Box of 10	0270-0769	0270-0770	0270-0771	0270-0772
Lot Number Ranges		081814 – 093015	081114 – 090315	080814 – 101315	022514 – 082115

1. **I have reviewed and understand this Field Safety Notice, and have received a customized list of products shipped to me.**

   ☐YES ☐NO If NO, please explain: _____

2. ☐ **I will contact Verathon Customer Care to return the blades with Lot Numbers listed below and arrange for replacement blades.**

   List the number affected devices in your possession, by lot number, in the table below. Please attach a second page if necessary.

LoPro S3 PN 0574-0130		LoPro S4 PN 0574-0131		MAC S3 PN 0574-0132		MAC S4 PN 0574-0133	
LOT number	**Number of Blades**	**LOT number**	**Number of Blades**	**LOT number**	**Number of Blades**	**LOT number**	**Number of Blades**
Ex. 010101	*5*						

3. ☐ **We no longer have GlideScope Titanium Single Use blades in our inventory.**

Business Name:	
Address, City, State/Prov., Post Code:	
Signature:	Phone:
Printed Name:	Date:

4. **Please e-mail or fax the completed form to Verathon:**

Fax: +31 (0) 20 210 30 92
E-mail: CustomerCareEU@verathon.com

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