VERATHON

www.verathon.com

May 15, 2013

URGENT

SAFETY ALERT and MEDICAL DEVICE RECALL

Dear Valued GlideScope® Customer,

Verathon®, maker of GlideScope video laryngoscopes, is conducting a Safety Alert affecting all GlideScope Reusable Blades and a Product Recall affecting certain serial numbers of the Glidescope GVL and AVL blades. Our records indicate that your facility may have received one or more of the products affected by this notice. Please identify the serial number(s) of your GlideScope Reusable Blades located on the side of the handle and follow the instructions on the following pages that apply to your specific serialized device.

This Product Recall and Safety Alert are being conducted with the knowledge of the applicable Regulatory Authorities.

Thank you for your immediate attention to this matter. Verathon is committed to providing product 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.

Thank you,

[redacted]

VP of Quality & Regulatory Affairs
Verathon, Inc.

[redacted]

Sr. Manager, Regulatory Affairs/Quality Assurance
Verathon Medical (Canada) ULC

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VERATHON

May 10, 2013

URGENT - SAFETY ALERT

Affected products: GlideScope Reusable GVL, AVL, and Ranger Blades

Note: Does not apply to Single Use Systems, including Video Batons and STATS

Verathon is implementing this Safety Alert to increase awareness of the importance of monitoring the blade condition to prevent blade breakage. Visual inspection of the blades before and after each use is required to prevent injury to the patient.

Our records indicate that your facility may have received one or more of the products affected by this safety alert. Please identify the Serial Number(s) of your GlideScope Reusable Blades located on the side of the handle and follow the instructions below.

	Product Name	Serial Number range	Instructions/Actions
SAFETY ALERT	**GlideScope Reusable GVL, AVL, and Ranger Blades**	**All serial numbers**	Verathon is implementing a Safety Alert to provide additional Safety Information to remind users to carefully examine these blades before and after use and promptly replace any that show signs of wear or damage. **Please refer to the safety information included in this announcement for detailed instructions on how to inspect your product.**

It is critical to conduct routine inspections of the product before and after each use to identify any damage or wear such as cracks that may lead to breakage. Verathon is highlighting the following warning statement in the User Guide.

⚠ WARNING

To ensure patient safety, routinely inspect the GlideScope video laryngoscope blade before and after every use to ensure the blade is free of rough surfaces, sharp edges, cracks, protrusions, or any other indication of wear. If found, do not use the damaged or worn blade, otherwise blade breakage may occur which could cause patient injury or death.

- Always ensure that alternative airway management methods and equipment are readily available.

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- Please ensure that all personnel/users are made aware of this warning; retain this safety information with GlideScope user instructions.

- Please fill out the attached self-addressed response card and return it to Verathon. Your Verathon sales representative will contact you shortly regarding replacement of your product(s). All customers have the option to purchase a single use laryngoscope to replace their reusable blades.

Should you have any questions or concerns about this Safety Alert, please contact your Verathon representative or Verathon Customer Care at +31 30 68 70 570. You may also e-mail us at RecallEMEA@verathon.com and we will respond promptly.

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VERATHON

May 10, 2013

URGENT - MEDICAL DEVICE RECALL

Affected products: GlideScope Reusable GVL and AVL Blades

Note: Does not apply to Ranger Blades or Single Use Systems, including Video Batons and STATS

Verathon® has become aware of several patient incidents of a fracture/breakage of the laryngoscope blade resulting in a detached piece remaining in the patient airway requiring medical intervention to remove the component. These affected serial numbers are being recalled due to the potential risk of premature failure/breakage of the blade tip that may not be readily visible during routine inspection before or after intubation. We have received reports of laryngoscope blades breaking during use, which could potentially obstruct the patient's airway or be swallowed, and there are reports of serious adverse health consequences, including death.

Our records indicate that your facility may have received one or more of the products affected by this recall. Please identify the Serial Number of your GlideScope Reusable Blades located on the side of the handle and follow the instructions below.

	Product Name	Part Number	Serial Numbers	Instructions/Actions
PRODUCT RECALL	GVL 3	0574-0007	MD112388 - MD121908	**These serial numbers are being recalled due to the potential of premature failure resulting in cracking and breaking. Discontinue use of these products and refer to additional information below as well as instructions for return and replacement of these Reusable Blades.**
	GVL 4	0574-0001	LG112759 - LG122582	
	GVL 5	0574-0030	XL111799 - XL121759	
	AVL 2	0574-0118	AC111500 - AC121604	
	AVL 3	0574-0115	AD111500 - AD121688	
	AVL 4	0574-0116	AE111500 - AE121778	
	AVL 5	0574-0117	AF111500 - AF121666	

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- Please fill out the attached response card and return it to Verathon. Your Verathon sales representative will contact you shortly regarding replacement units.

- To minimize interruption in the availability of your GlideScope system, Verathon will replace each of your affected video laryngoscope blades with new product at no cost to you or we can replace your reusable blades with a Single Use laryngoscope configuration.

Should you have any questions about this Recall, please contact your Verathon representative or Verathon Customer Care at +31 30 68 70 570. You may also e-mail us at RecallEMEA@verathon.com and we will respond promptly.

0014-0199-00-86

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If you/your facility are using a reusable GlideScope Video Laryngoscope, please fill out and return the **Safety Alert Reply Form**.

If you/your facility are using a reusable GlideScope Video Laryngoscope with the Serial Number ranges listed in the second table, please fill out and return the **Blade Recall Notification Reply Form** and the **Safety Alert Reply Form**.

SAFETY ALERT REPLY FORM: RESPONSE REQUIRED

Affected Devices: GlideScope Video Laryngoscope blades											
Model Number	GVL 2	GVL 3	GVL 4	GVL 5	AVL 2	AVL 3	AVL 4	AVL 5	Ranger GVL 3	Ranger GVL 4	Ranger GVL 4 w/ 2 ft. cable
Part Number	0574-0010	0574-0007	0574-0001	0574-0030	0574-0118	0574-0115	0574-0116	0574-0117	0574-0029	0574-0028	0574-0018
Serial Number	All Serial Numbers										

☐ I received notification of your Safety Alert. I understand the need to inspect all GlideScope blades before and after use. I have ensured that the provided Safety Information is inserted into the GlideScope User's Manual.

BLADE RECALL NOTIFICATION REPLY FORM: RESPONSE REQUIRED

Affected Devices: GlideScope Video Laryngoscope blades with the following Serial Numbers							
Model Number	GVL 3	GVL 4	GVL 5	AVL 2	AVL 3	AVL 4	AVL 5
Part Number	0574-0007	0574-0001	0574-0030	0574-0118	0574-0115	0574-0116	0574-0117
Serial Number Ranges	MD112388 to MD121908	LG112759 to LG122582	XL111799 to XL121759	AC111500 to AC121604	AD111500 to AD121688	AE111500 to AE121778	AF111500 to AF121666

I have ensured that the Recall Notification was distributed to users throughout the facility.

☐ YES ☐ NO If NO, please explain: _____

☐ I received notification of your recall and will contact Verathon Customer Care or my sales representative to replace the blades listed below.

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

GVL 3 Blade PN 0574-0007	**GVL 4 Blade** PN 0574-0001	**GVL 5 Blade** PN 0574-0030	**AVL 2 Blade** PN 0574-0118	**AVL 3 Blade** PN 0574-0115	**AVL 4 Blade** PN 0574-0116	**AVL 5 Blade** PN 0574-0117
Ex: MD105001						

☐ We no longer have GlideScope GVL device(s) with the following Serial Numbers: _____

Business Name:	
Address (Including Country):	
Signature:	Phone:
Printed Name:	Date:

Please e-mail the completed form to Verathon. **E-mail:** RecallEMEA@verathon.com

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Retain this Safety Information with GlideScope User Instructions

GlideScope® Video Laryngoscopes

SAFETY INFORMATION

⚠ WARNING

To ensure patient safety, routinely inspect the GlideScope video laryngoscope blade before and after every use to ensure the blade is free of rough surfaces, sharp edges, cracks, protrusions, or any other indication of wear. If found, do not use the damaged or worn blade, otherwise blade breakage may occur and could cause patient injury or death.

- Always ensure that alternative airway management methods and equipment are readily available.

Inspection Instructions

1. Regularly inspect the GlideScope video laryngoscope reusable blade before and after every use to identify any damage or wear that may lead to breakage (see representative examples on reverse side). It is critical to conduct regular inspections throughout the life of the product to prevent any risk to patient safety.

2. Immediately discontinue use if inspection reveals any of the following defects:
   - Rough surfaces
   - Protrusions
   - Sharp edges
   - Surface delamination
   - Cracks
   - Shell separation

3. Report any suspected blade defects to Verathon Customer Care at:

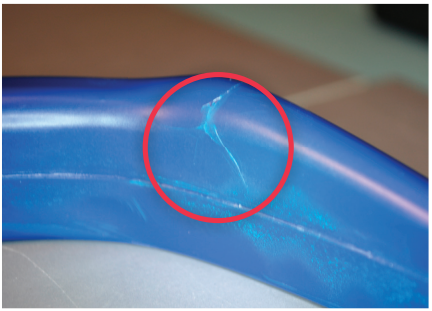
   Phone: +31 30 68 70 570
   E-mail: customercareEU@verathon.com

Visible Signs of Damage or Wear

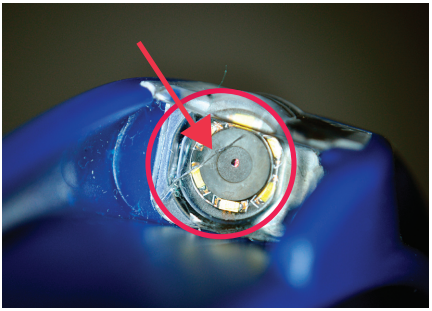
Damages and wear that may affect safety are shown inside the red circles and are the result of accelerated cycle-to-failure testing to simulate worst-case usage (end-of-life).

Surface Degradation

Cracking



Camera Window Cracking



For more detailed product information, see the GlideScope User's Manual.

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