23 May 2013

VIA EMAIL

URGENT

SAFETY ALERT and MEDICAL DEVICE RECALL

Dear Valued GlideScope Distributor:

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 you may have imported one or more of the products affected by this notice in your territory. The list of the serial numbers is attached.

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.

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VERATHON

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 Inc., of Bothell, WA, has become aware that GlideScope Video Laryngoscope customers continue to use reusable laryngoscope blades even when the blades show signs of serious wear and tear. Using laryngoscope blades in a deteriorated condition could lead to incidents of cracking and breakage during use in intubation procedures. The statement instructing users to inspect and monitor the product is currently located in the middle of the User's Manual under General Maintenance Information. This statement may not be sufficiently prominent to ensure that users do, in fact, inspect blades for wear and tear. Therefore, Verathon has made the decision to initiate a voluntary correction to strengthen the product labeling for all GlideScope Reusable Blades.

This correction applies to all models of GlideScope Reusable Blades currently in the field: reusable GVL 2 0574-0010, GVL 3 0574-0007, GVL 4 0574-0001, and GVL 5 0574-0030; AVL Reusable 2 0574-0118, AVL Reusable 3 0574-0115, AVL Reusable 4 0574-0116, and AVL Reusable 5 0574-0117; and Ranger GVL 3 0574-0029, Ranger GVL 4 0574-0028, and Ranger GVL 4 with 2 foot cable 0574-0018. Please note the submission of this report does not reflect a conclusion and is not an admission that any affected device has caused or contributed to a death or serious injury. A Recall Report has also been submitted to the FDA (Ref: RCR#65157-2013/05/10-001-C) and to Health Canada (Ref: RCR# 65157-2013/05/10-001C).

	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.**

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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.

Safety Alert Strategy

Regulatory Authorities

Please notify the National Competent Authority as per local requirements.

Customers

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

- Please ensure that the correction information to customers include written notification, including a documented acknowledgement of response by the customer, to all customers that are identified as owning one of the affected GlideScope reusable laryngoscope blades. The notification must be sent via certified mail or other methods to all customers who have purchased affected product. The delivery confirmation must show the tracking number or the signature of the recipient.

Copies of the following documents are provided for customer information.

- 0900-4310-01-60 Safety Information

VERATHON

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

The affected GlideScope Video Laryngoscope Blades were manufactured between August 2011 and July 2012. In blades built during this time span, Verathon has identified a possible flaw induced along the seams of the plastic blades as a result of using a handheld plasma torch to clean the seam surfaces and camera location before bonding. During its operation to generate a plasma bond, the handheld plasma torch produced a localized intense heating of the plastic to a high temperature. That inadvertent spot heating of the plastic at the seam and the camera location induced unintended localized stress into the area surrounding the seam and camera.

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 you may have imported one or more of the products affected by this notice in your territory. The list of the serial numbers is detailed below. Please follow the instructions below

Verathon has made the decision to initiate a voluntary removal of the reusable laryngoscope blades provided with specific "builds" of the GlideScope Video Laryngoscope, model numbers GVL 3 0574-0007, GVL 4 0574-0001, and GVL 5 0574-0030; and AGVL 2 074-0118, AGVL 3 0574-0115, AGVL 4 0574-0116, and AGVL 5 0574-0117. These blades were manufactured between August 2011 and June 2012. Please note the submission of this report does not reflect a conclusion and is not an admission that any affected device has caused or contributed to a death or serious injury. A Recall Report has also been submitted to the FDA (Ref: RCR#3022472-05/07/13-002-R) and to Health Canada (Ref: RCR# 65157-2013/05/10-002R).

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PRODUCT RECALL	Product Name	Part Number	Serial Numbers	Instructions/Actions
	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	

Recall Strategy

Regulatory Authorities

Please notify the National Competent Authority as per local requirements.

Customers

Please ensure the removal action include written notification, including a documented acknowledgement of response by the customer, to all customers that are identified as owning one of the affected GlideScope reusable laryngoscope blades. The notification must be sent via certified mail or other methods to all customers who have purchased affected product. The delivery confirmation must show the tracking number or the signature of the recipient.

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Verathon is fully committed to compliance with all local requirements and regulations. Please feel free to contact us if you need further assistance or further information at +31 30 68 70 570.

Thank you,

Rod J. Rylands
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0014-0198-00-86

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