December 2nd 2015

# Urgent - Field Safety Notice
## MEDICAL DEVICE RECALL

Dear Valued GlideScope Customer,

Verathon Incorporated, manufacturer of GlideScope® Video Laryngoscopes, is conducting a Product Recall affecting certain models and serial numbers of the GlideScope GVL and AVL blades.

Our records indicate that your facility has 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(s).

This Product Recall is being conducted with the knowledge of the applicable Regulatory Authorities. Please report any suspected malfunction or adverse event related to any GlideScope GVL or AVL 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,

[redacted]

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

[redacted]

Christian Wulff
Operations Director, EMEA
Linnaeusweg 11
3401 MS IJsselstein
The Netherlands
verathon.com

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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.
Linnaeusweg 11 ♦ 3401 MS IJsselstein ♦ The Netherlands
+31.30.68.70.570 ♦ Fax +31.30.68.70.512

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# Urgent - Field Safety Notice
## 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**

| PRODUCT RECALL | Product Name | Part Number | Serial Numbers | Instructions/Actions |
|---|---|---|---|---|
| | GVL 3 | 0574-0007 | MD151685 – MD151932 | These serial numbers are being recalled due to the potential of the blades to separate, potentially resulting in breakage or delayed intubation. Refer to the instructions below for return and replacement of these Reusable Blades. |
| | GVL 4 | 0574-0001 | LG151858 – LG152232 | |
| | GVL 5 | 0574-0030 | XL151543 – XL151572 | |
| | AVL 3 | 0574-0115 | AD141603 – AD151535 | |
| | AVL 4 | 0574-0116 | AE141629 – AE151545 | |
| | AVL 5 | 0574-0117 | AF141570 – AF151525 | |

Verathon Incorporated has become aware of the potential for GlideScope® Video Laryngoscope blades to separate. If a blade separates during a procedure, it may result in failure of the intubation procedure, which could result in patient death or serious injury. Blade separation may also lead to cracking or breaking of the separated blade halves which, in turn, could result in laceration caused by aspiration of, or need for, a secondary procedure to retrieve a detached piece remaining in the patient airway. These affected serial numbers are being recalled due to the potential risk of separation in the blade tip that may not be readily visible during routine inspection before or after intubation.

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.



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Verathon Incorporated will, at no cost to you, replace your GlideScope® GVL or AVL blade(s) that fall within the serial number ranges identified above.

To comply with this Field Safety Notice for the affected models and serial numbers of GlideScope GVL and AVL blades, please complete steps 1-5 of the attached Field Safety Notice Reply Form and return it to Verathon. Please return the form even if you do not have any blades subject to the recall.

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



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Our records indicate that your facility has received a reusable GlideScope® Video Laryngoscope with the Serial 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® Video Laryngoscope blades with the following Serial Numbers | | | | | | |
| **Model Number** | GVL 3 | GVL 4 | GVL 5 | AVL 3 | AVL 4 | AVL 5 |
| **Part Number** | 0574-0007 | 0574-0001 | 0574-0030 | 0574-0115 | 0574-0116 | 0574-0117 |
| **Serial Number Ranges** | MD151685 - MD151932 | LG151858 - LG152232 | XL151543 - XL151572 | AD141603 - AD151535 | AE141629 - AE151545 | AF141570 - AF151525 |

1. **I have ensured that the Field Safety Notice was distributed to users throughout the facility.**

   ☐ YES ☐ NO If NO, please explain: _____

2. **I received notification of your recall and will contact Verathon Customer Care to arrange for replacement blades.**

3. **The following AVL/GVL device(s) are still in use at our facility, as per the provided list – please record Serial Number(s):**

| **GVL 3 Blade** PN 0574-0007 | **GVL 4 Blade** PN 0574-0001 | **GVL 5 Blade** PN 0574-0030 | **AVL 3 Blade** PN 0574-0115 | **AVL 4 Blade** PN 0574-0116 | **AVL 5 Blade** PN 0574-0117 |
|---|---|---|---|---|---|
| Ex: MD105000 | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |

4. **The following AVL/GVL device(s) are no longer in use at our facility, as per the provided list – please record Serial Number(s):**

| **GVL 3 Blade** PN 0574-0007 | **GVL 4 Blade** PN 0574-0001 | **GVL 5 Blade** PN 0574-0030 | **AVL 3 Blade** PN 0574-0115 | **AVL 4 Blade** PN 0574-0116 | **AVL 5 Blade** PN 0574-0117 |
|---|---|---|---|---|---|
| Ex: MD105000 | | | | | |
| | | | | | |

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

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

**Fax: +31.30.68.70.512**
**E-mail: CustomerCareEU@verathon.com**



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