

June 19, 2015

## Urgent - Field Safety Notice

**Subject: Important Safety Information for Verathon GlideScope GVL /AVL Reusable Video Laryngoscope Blades**

To our Valued GlideScope Customers,

Verathon®, manufacturer of GlideScope® video laryngoscopes, is revising the Instructions For Use for certain GlideScope GVL® and AVL Reusable Laryngoscope Blades (serial numbers noted below).

Our records indicate your facility may have received one or more of the products affected by this notice. Serial numbers of GlideScope Reusable Blades are located on the side of the handle; please identify the relevant serial numbers on your devices and follow the instructions below as applicable.

This Safety Alert is being conducted with the knowledge of the applicable Regulatory Authorities.

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

Sincerely,



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June 19, 2015

## Urgent - Field Safety Notice

### Affected products: GlideScope Reusable GVL and AVL Blades

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

Please ensure all personnel/users are made aware of this warning.

Retain this information with GlideScope user instructions.

Affected Product	Product Name	Part Number	Serial Number Range
	GVL 3	0574-0007	MD131860 - MD151622
	GVL 4	0574-0001	LG131995 - LG151773
	GVL 5	0574-0030	XL131578 - XL151524
	AVL 2	0574-0118	AC131852 - AC151510
	AVL 3	0574-0115	AD131589 - AD151506
	AVL 4	0574-0116	AE131587 - AE151558
	AVL 5	0574-0117	AF131504 - AF151500

For users of GlideScope® GVL and AVL video laryngoscopes with serial numbers noted above, Verathon is implementing a Safety Alert regarding updates to the following Operations and Maintenance Manuals (OMM):

- GVL Operations and Maintenance Manual: 0900-1204-08-60
- AVL Operations and Maintenance Manual: 0900-4200-02-60

The new Operations and Maintenance Manuals (OMM) specifically state compatibility limitations of the reusable video laryngoscope validated through simulated use cycles, using the cleaning and disinfection agents listed below and also detailed in Table 1 and footnotes.

- ASP® Cidex® OPA
- Metrex® MetriCide® Plus 30
- STERIS® Revital-Ox™ Resert® HLD

For the purpose of cleaning/disinfecting reusable blades, the following chemicals have been removed from the OMMs:

- Bleach (sodium hypochlorite)
- Isopropyl alcohol solution
- Liquid hydrogen peroxide (7.5%)

There is no change to the safety information provided in the OMM regarding inspection of the laryngoscope blade before and after every use to ensure patient safety.

The revised approved Cleaning and Disinfection Methods for GlideScope GVL and AVL video laryngoscopes with serial numbers noted above are:

**Table 1**

CHEMICAL	DISINFECTION LEVEL	CONDITIONS
Enzymatic debridement agent/detergent	Cleaner	As per chemical manufacturer’s instructions
Metrex® EmPower™ †	Cleaner	<b>Water temperature:</b> 19–29°C (66–84°F) <b>Exposure:</b> Prepare solution at 1 ounce/gallon. Soak component for 3 minutes. Before removing from solution, brush all surfaces and pay special attention to hard-to-reach areas. <b>Rinse:</b> Rinse for 3 minutes under running water.
ASP® Cidex® OPA †	High	<b>Conditioning:</b> 20–40°C (68–104°F) <b>Exposure:</b> Soak for 12 minutes, ensuring that all air bubbles are removed from the surface of the blade <b>Rinse:</b> (3) 1-minute immersions with agitation in pure water
Metrex® MetriCide® Plus 30 †	High	<b>Conditioning:</b> 20 ± 2°C (68 ± 4°F) <b>Exposure:</b> Soak for 20 minutes, ensuring that all air bubbles are removed from the surface of the blade <b>Rinse:</b> (3) 1-minute immersions with agitation in pure water
STERIS® Revital-Ox™ Resert® XL HLD † Revital-Ox™ Resert® HLD/Chemosterilant † Resert® XL HLD †	High	<b>Conditioning:</b> 20–60°C (68–140°F) <b>Water Temperature:</b> 20–60°C (68–140°F) <b>Exposure:</b> Soak for 8 minutes, ensuring that all air bubbles are removed from the surface of the blade <b>Rinse:</b> (1) 1-minute immersion with agitation in pure water. Ensure the connector is properly rinsed.
STERIS® S40™ or S20™ ‡	High/ Sterilization	Standard cycles in the following processors: STERIS® SYSTEM 1® (outside U.S.) SYSTEM 1E® (in U.S.) SYSTEM 1 EXPRESS (outside U.S.) SYSTEM 1 PLUS (outside U.S.)
STERIS® Vaprox® HC *	Sterilization	Non-lumen cycle in any STERIS® Amsco® V-PRO® low-temperature sterilization system.
ASP® Hydrogen Peroxide Gas Plasma*	Sterilization	STERRAD® 100S (in U.S.), STERRAD® 100S short cycle (outside U.S.), STERRAD® NX standard cycle, or STERRAD® 100NX standard cycle

\* Compatible with ≤ 250 cycles. Exceeding 250 cycles may affect the potential life of the product.

† Compatible with ≤ 2000 cycles.

‡ Compatible with ≤ 500 cycles. Exceeding 500 cycles may affect the potential life of the product.

If you have any questions regarding the Operations and Maintenance Manuals revisions noted above, please contact your Verathon representative or Verathon Customer Care at +31.30.68.70.570.

You may also email [customercareEU@verathon.com](mailto:customercareEU@verathon.com).

For a copy of the most recent GVL® or AVL Operations and Maintenance Manual, please visit <http://verathon.com/support>.

If you/your facility are using 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**.

For users of GlideScope® GVL and AVL video laryngoscopes with serial numbers noted below, Verathon is implementing a Field Safety Notice regarding updates to the following Operations and Maintenance Manuals (OMM):

- GVL Operations and Maintenance Manual: 0900-1204-08-60
- AVL Operations and Maintenance Manuals: 0900-4200-02-60

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 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	MD131860 - MD151622	LG131995 - LG151773	XL131578 - XL151524	AC131852 - AC151510	AD131589 - AD151506	AE131587 - AE151558	AF131504 - AF151500

I received notification of your Field Safety Notice. I understand the need to provide the revised cleaning and disinfection processes to the appropriate personnel.

For a copy of the most recent GVL® or AVL Operations and Maintenance Manual that includes the revised cleaning and disinfectant information, please visit <http://verathon.com/support>.

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

YES       NO    If NO, please explain:

We confirm that we have all the GlideScope device(s) within the stated Serial Numbers range, as per the provided list, with the following exception(s): \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

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

Please fax or e-mail the completed form to Verathon. **Fax:** +31.30.68.70.512 **E-mail:** [customercareEU@verathon.com](mailto:customercareEU@verathon.com)