

May 28, 2015

Urgent Medical Device Safety Alert

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 following cleaning and disinfection agents as detailed in Table 1 and footnotes. 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.

- 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%)



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	Water temperature: 19–29°C (66–84°F) Exposure: 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. Rinse: Rinse for 3 minutes under running water.
ASP® Cidex® OPA †	High	Conditioning: 20–40°C (68–104°F) Exposure: Soak for 12 minutes, ensuring that all air bubbles are removed from the surface of the blade Rinse: (3) 1-minute immersions with agitation in pure water
Metrex® MetriCide® Plus 30 †	High	Conditioning: 20 ± 2°C (68 ± 4°F) Exposure: Soak for 20 minutes, ensuring that all air bubbles are removed from the surface of the blade Rinse: (3) 1-minute immersions with agitation in pure water
STERIS® Revital-Ox™ Resert® XL HLD † Revital-Ox™ Resert® HLD/Chemosterilant † Resert® XL HLD †	High	Conditioning: 20–60°C (68–140°F) Water Temperature: 20–60°C (68–140°F) Exposure: Soak for 8 minutes, ensuring that all air bubbles are removed from the surface of the blade Rinse: (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 +65 6408 6200.

You may also email SEA@verathon.com.

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