Glidescope AVL Single Use System; GVL Stat Reprocessing

April 28, 2020

IMPORTANT, PLEASE NOTE: THE FDA HAS NOT CLEARED THIS GUIDANCE, EVEN UNDER AN EUA*. THE PROCEDURE BELOW IS PART OF CRISIS RESPONSE DUE TO THE INABILITY TO OBTAIN REPLACEMENTS FROM THE MANUFACTURER AT HOSPITALS WHERE SUPPLY IS NOT ABLE TO MEET THE DEMAND FOR INTUBATION OF PUI OR THOSE WITH COVID-19. THIS PROCEDURE PROVIDES INSTRUCTIONS ON REPROCESSING OF SINGLE USE GVL® STATS.

The purpose of this document is to provide guidance for the reprocessing that includes the cleaning, disinfection and sterilization of the Glidescope AVL Single Use System's GVL® Stats. While reprocessing of single-patient use stats are not consistent with FDA clearance nor other requirements of processing of single use devices (SUDs), due to the high volume of intubations during COVID-19 pandemic, this guidance is provided for hospitals where replacements are unavailable from the manufacturer to support patient care.

- **Rationale:** The use of a video laryngoscope for intubating PUIs or those with COVID-19 is safer for both the patient and personnel as it provides real-time visualization of the patient's airway and therefore the intubation is more efficient and there is less risk of disseminating contaminated respiratory secretions.

There is not an IFU for reprocessing single use GVL stats. However, our subject matter experts applied the principles from the Operations and Maintenance Manual as well as recommendations for disinfection and sterilization from the CDC.¹ ²

This guide was reviewed and approved by an interdisciplinary group of Infectious Disease physicians, Infection Preventionists, Sterile Processing Department colleagues and clinicians, that use the Glidescope systems, as part of the MercyOne Incident Command response to COVID-19.

Applies to: Stats used with the Glidescope AVL Single Use System. See also Figure 1 below. These are used with the AVL system illustrated in Figure 2.

*Emergency Use Authorization
Figure 1. System Components. **GLIDESCOPE SYSTEM AVL SINGLE-USE**

<table>
<thead>
<tr>
<th>GlideScope Video Monitor</th>
<th>Video batons (for Single-Use system only)</th>
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<tbody>
<tr>
<td><img src="image1" alt="GlideScope Monitor" /></td>
<td><img src="image2" alt="Video Batons" /></td>
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*GVL* Stat sizes 0, 1, 2, 2.5, 3, and 4 (for Single-Use system only)

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Figure 2. GlideScope AVL Single-Use System

![GlideScope AVL Single-Use System](image3)
Key considerations:

1. These instructions are for the Glidescope AVL single-use GVL stats only
2. All hospitals should establish a process for collecting single use blades after use and transport to SPD for reprocessing as soon as possible in anticipation of continued unavailability and store reprocessed blades.
3. Hospitals must begin collecting used stats to support this process (see step 1, below)
4. The cleaned stats can be processed with other reusable surgical instruments in low temperature sterilizer cycles.
5. This process was created and tested with a STERRAD 100NX (ASP) and V-Pro (hydrogen peroxide vapor) manufactured by Steris using the lumened instrument cycle. The sterilization process monitoring devices used for each included physical monitors, chemical indicators and biologic indicators as recommended by the manufacturer of the sterilizers and consistent with SPD policies and procedures

Process:

1. After use of stats:
   - Place GVL single patient use stats in a collection container for transport to Decontamination, in SPD. that has a biohazard label or is color-coded (red).
   - Apply pre-cleanse (e.g. wetting agent) product to used stat to facilitate removal of bioburden.
   - Transport the stats collected to SPD Decontamination for reprocessing.
   - Disinfect cable and other parts of the Glidescope system with EPA registered disinfectant wipe according to the IFU from the Glidescope manufacturer, Verathon, Inc.

2. After arriving in SPD:
   - Receive transport container containing stats in Decontamination of SPD.
   - Manually wash stats with soft cloth in enzymatic solution.
   - Rinse and then dry.
   - Transport stats to clean side of SPD for packaging and sterilization. Inspect the stat for any damage prior placing in sterilization pouch. Place into sterilization pouch designed for low temperature sterilizer in use at the hospital, i.e. STERRAD or V-PRO.
   - Place chemical indicator (CI; can be an indicating or emulating integrator) and, if desired a biologic indicator (BI) to monitor the sterilizer according the the manufacturer’s IFU. The CI and/or BI can be placed into a remote, narrow area of the stat.
   - Place into appropriate sterilization container, if applicable.
   - Sterilize the stat run in a V-Pro using the lumen cycle. For STERRAD, use an appropriate cycle.
   - After sterilization, verify the sterilization process monitors meet requirements of the sterilizer manufacturer IFUs and SPD policies and procedures for low temperature sterilization. Biological indicators (Bis) verify that the conditions at a location within the load were adequate to kill a population of microorganisms resistant to the sterilization process and demonstrate the lethality of the sterilization process. Because the blades are not implantable there is no need to hold the load for final reading of the BI, if used.
   - Transport sterilized stats back to the point of care.
3. Prior to use, inspect for damage and test functionality
   - Before you use the reprocessed stat, perform the following functional check to ensure that the system is working properly.
     i. Assure the monitor battery is fully charged
     ii. Attach the video cable to the monitor.
     iii. Press the Power button. The monitor turns on.
     iv. Look at the monitor screen, and verify that the image displayed is being received from the video baton or GlideScope Direct blade
   - After removing the GVL Stat from the packaging used for sterilization, visually inspect the Stat to ensure that all exterior surfaces are free of unintended rough areas, sharp edges, protrusions, or cracks. If there is any evidence of damage or the system is not functioning properly – discard the stat, obtain another.
   - Follow cleaning and disinfection for the other components of the AVL system after the procedure and place used stat in the collection container for returning to Decontamination in SPD.

References: