Disposable Glidescope Spectrum Single Use Blade Reprocessing

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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 NOTABLE TO MEET THE DEMAND FOR INTUBATION OF PUI OR THOSE WITH COVID-19. THIS PROCEDURE PROVIDES INSTRUCTIONS ON REPROCESSING OF SINGLE USE GLIDESCOPE® SPECTRUM™ SINGLE-USE VIDEO LARYNGOSCOPES.

WHAT'S NEW: CLARIFIED WORDING IN IMPORTANT NOTE ABOVE, ADDED REFERENCE TO OTHER LOW TEMPERATURE STERILIZATION & ADDITIONAL ILLUSTRATIONS

The purpose of this document is to provide guidance for the reprocessing that includes the cleaning, disinfection and sterilization of the Glidescope Spectrum™ single-use video laryngoscopes. While reprocessing of single-patient use Glidescopes is 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 Glidescope blades. However, our subject matter experts applied the principles from the Operations and Maintenance Manual described for the GlideScope Titanium reusable system to the Spectrum single-use system.1

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: the angulated LoPro S1, S2, S2.5, S3 and S4 Spectrum single use blades. See also Figure 1 below. These are used with the Titanium Spectrum system illustrated in Figure 2.

*Emergency Use Authorization
Key considerations:

1. Recommend all hospitals begin a process for collecting single use blades after use and transport to SPD for reprocessing immediately in anticipation of continued unavailability and store reprocessed blades.
2. The cleaned blades can be processed with other reusable surgical instruments in sterilizer cycles.
3. Follow the same procedure in the IFU for the reusable Glidescope (Titanium system).
4. The process below was created and tested with a STERRAD 100NX using sterilization process monitoring devices that include physical monitors, chemical indicators and biologic indicators as recommended by the manufacturer of STERRAD (ASP). Hospitals can run the blades through other low temperature sterilizers, e.g. VPRO (Steris) using the physical, chemical and biologic indicators recommended in the IFU for this sterilizer. Refer to Glidescope Titanium IFU if using Steris VPRO for recommended settings.
5. These instructions are for the Glidescope Spectrum Single-use only.
6. Hospitals must begin collecting used Glidescopes to support this process (see step 1, below)
7. Hospitals should test a single Glidescope Spectrum Single-use prior to beginning batch processing.
Process:

1. After use:
   - Place Glidescope Spectrum Single patient in biohazardous waste bin
   - Spray or apply an appropriate pre-cleanse, wetting agent to facilitate removal of bioburden
   - Transport to SPD Decontamination in appropriate, biohazard labeled or color-coded container
   - Disinfect cable with EPA registered disinfectant wipe

2. After arriving to SPD:
   - Receive transport container in Decontamination of SPD.
   - Place blade(s) into premixed enzymatic, follow IFU for manufacturer's instructions (included below) and perform manual cleaning.
   - Rinse according to manufacturer's instructions/IFU.
   - Wipe window with soft cloth.
   - Rinse again.
   - Disinfect outside, may use EPA registered disinfectant or alcohol, per normal practice of handwash only items. **Do not place in washer/sterilizer – the high temperature in this device is too high for the blade.**
   - Transport to clean side for processing.
   - Place into sterilization pouch.
   - Place into appropriate sterilization container, if applicable.
   - Review IFU-see below
   - 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.
   - Transport sterilized blades back to the point of care.

3. **Prior to use, clinical colleagues need to inspect the blade for any damage and test functionality.** If there is any noticeable damage or the blade is not functioning – discard and obtain a replacement.

References: