Medical Device Hazard Report

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UMDNS Terms:
- Laryngoscope Blades [23534]
- Laryngoscope Blades, Fiberoptic [24023]
- Laryngoscopes, Rigid [15076]

Product Identifier:
[Consumable]
Single-Use Video Laryngoscope Blades

Geographic Regions: Worldwide

Suggested Distribution: Anesthesia, Clinical/Biomedical Engineering, Critical Care, Emergency/Outpatient Services, Infection Control, Nursing, OR/Surgery, Pulmonology/Respiratory Therapy, Diagnostic Imaging, Risk Management/Continuous Quality Improvement, Internal Medicine, EMS/Transport, Central Sterilization Reprocessing, Materials Management

Problem:
1. Hospitals are reporting difficulty getting single-use blades and transparent blade sheaths from their video laryngoscope suppliers.
2. Since many COVID-19 patients require intubation, hospitals that intubate with single-use video laryngoscopes are depleting their inventory much faster than normal.
3. Video laryngoscopy is preferred to direct laryngoscopy for known or suspected COVID-19 patients for a number of reasons.
   1. Compared to direct laryngoscopy, video laryngoscopy may be faster and more likely to succeed on the first attempt at intubation.
   2. Compared to direct laryngoscopy, the clinician performing the intubation may have reduced exposure to aerosolized virus with video laryngoscopy because their face does not need to be as close to the patient's mouth.
4. Laryngoscope blades are considered semi-critical according to the Spaulding classification scheme. Reuse without proper cleaning and sterilization or high-level disinfection exposes patients to significant risk of cross-contamination.

ECRI Recommendations:
1. Locate and secure all single-use video laryngoscope blades available.
   1. This includes the operating room, emergency department, catheterization lab, imaging, ambulatory surgery centers, and other locations in the hospital system.
   2. Nonaffiliated ambulatory surgery centers in your area may be another source of single-use video laryngoscope blades, since elective procedures have been cancelled.
2. Facilities should contact vendors to see if reusable devices are available. Karl Storz and Verathon have reusable models that are similar to their single-use devices.
3. Consider direct laryngoscopy in the interim while awaiting supplies.
   1. This should be done with caution as video laryngoscopy is preferred to direct laryngoscopy for known or suspected COVID-19 patients for the reasons listed above.
   2. In addition, there may be training considerations. Some clinicians may have minimal training or recent experience intubating patients using direct laryngoscopy.

Manufacturer’s Perspectives/Comments:
1. ECRI has reached out to three vendors of single-use video laryngoscopes: Verathon, Karl Storz, and Medtronic. All three vendors state that they have no validated method of reprocessing their single-use blades and/or blade sheaths.
2. Verathon (which makes GlideScope) states that it is "executing extensive supply chain expansion plans that enable them to scale to keep pace with clinical demand during these unprecedented times. The executed plans will meet the current and future clinical needs for all GlideScope products. They are shipping partial allotments to customers in the meantime, and have emergency stock for those customers that need products quickly."
3. Karl Storz states that it is "committed to providing our frontliners the tools they need to take care of their patients." The firm states that it has ramped up production across its entire airway management portfolio to ensure supply continuity.
4. Medtronic states that manufacturing is fully operational and that the firm is working with suppliers to minimize disruption and increase manufacturing capacity.

Discussion:
- ECRI is aware that some facilities are reprocessing single-use video laryngoscope blade sheaths.
- The facilities that we have spoken to are cleaning the blades and using low-temperature vaporized hydrogen peroxide sterilizers for decontamination.
The facilities that we have spoken to have not reported any noticeable degradation in the material or other obvious problems with the reprocessed blade sheaths.

However, ECRI has several concerns about this process:

- Reprocessing using any method that has not been validated could affect strength and/or transparency of the blade materials.
- There is a potential for residue on the blade sheaths, which is especially problematic because of the caustic nature of hydrogen peroxide.
- There is no clear process for tracking reprocessing cycles. None of the facilities that we have spoken to have determined an effective way to track cycles.

Comments:
- For information on a Karl Storz communication recommending against reprocessing C-MAC single-use video laryngoscope blades, see Alert A34912.
- For information on a Medtronic communication recommending against off-label use of McGrath MAC video laryngoscopes and blades, see Alert A34867.
- This alert is a living document and may be updated when ECRI receives additional information.

Source(s):
- 2020 Apr 27. ECRI