

[High Priority] - H0630 : [COVID-19] Recommendations for Reprocessing Flexible Endoscopes Used on COVID-19 Patients [ECRI Exclusive Hazard Report]
Medical Device Hazard Report

Published: Thursday, July 23, 2020

UMDNS Terms:

- Disinfectors, Liquid Germicide, Flexible Endoscope [11279]
- Bronchoscopes [10491]
- Colonoscopes [10950]
- Ureteroscopes [15788]
- Duodenoscopes [11359]
- Gastrosopes [11856]
- Sigmoidoscopes [13594]

Geographic Regions: Worldwide

Suggested Distribution: Clinical/Biomedical Engineering, Infection Control, OR/Surgery, Pulmonology/Respiratory Therapy, Urology, Gastroenterology, Otolaryngology, Central Sterilization Reprocessing

Summary: Please [CLICK HERE](#) for a brief ECRI Micro e-learning Module related to this Hazard Report. For more information regarding these modules, please contact hda@ecri.org.

Problem:

1. The COVID-19 pandemic has raised new challenges and changed workflows for facilities performing endoscopic procedures.
 1. Many healthcare facilities have postponed nonurgent endoscopic procedures.
 2. For urgent procedures, extra precautions have been required to protect patients and staff from exposure to the SARS-CoV-2 virus.
2. As facilities return to their pre-pandemic procedure loads, they may need to take steps to prepare their staff and equipment.
3. Failure to prepare staff and equipment for higher procedure loads may result in:
 1. Increased risk of infection by:
 1. SARS-CoV-2 for patients and staff
 2. Endoscope cross-contamination for patients
 2. Equipment failure because of nonuse, lack of preventive maintenance, expired materials, and damaged or lost accessories

ECRI Recommendations:

Endoscopic Nurses or Technicians

1. For each procedure, take steps to minimize staff exposure to patients and contaminated rooms and equipment.
 1. After the procedure, staff already in the procedure room should perform endoscope pre-cleaning. Because of their presence during the procedure, these staff members should already be wearing personal protective equipment (PPE) appropriate for their role, including face and eye protection against droplets.
 1. Staff at high risk of aerosol exposure should also wear an N95 respirator. When supplies allow, surgical N95 respirators or N95 respirators used with a droplet protection layer (e.g., surgical mask or face shield) may also be considered for all staff in the procedure room; however, these are not required for the purposes of manual cleaning.
 2. When endoscopes must be transported to a central location for reprocessing, place each endoscope in a fully enclosed, rigid, and labeled biohazard container for transport to the central processing department, according to facility policy.

Central Processing Department or Scope Processing Area

1. During times of outbreaks, closures, and limited procedure loads, consider limiting the number of reprocessing staff. When possible, rely on experienced staff with documented competency, and avoid trainees and novices. As procedure loads increase, bring staff back as needed, but emphasize proper training and procedures.
2. Train reprocessing staff on proper procedures.
 1. Reiterate the need to follow all instructions for use (IFU) including leak testing and proper manual cleaning protocols, even as workload pressures increase.
 2. Donning PPE that includes, gloves, gowns, face shields, and masks. When supplies allow, facilities may consider the use of surgical N95 respirators with fluid resistant properties, or N95 respirators underneath a surgical mask or face shield.
 3. Continue standard manual cleaning followed by high-level disinfection (HLD) or liquid chemical sterilization (LCS). Data shows this should be effective at eradicating SARS-CoV-2.
3. If endoscope reprocessors are being used infrequently as defined by the manufacturer (e.g., less than once every 14 days):
 1. Refer to manufacturer IFU for product-specific guidance on reprocessor maintenance. Manufacturers may suggest:
 1. Running periodic empty reprocessing cycles to keep the reprocessor clean and disinfected.

2. Preparing the reprocessor for long-term storage by draining fluids and performing an air/water purge. When procedure volumes increase, the reprocessor will then need to be prepared for use.
4. When preparing for increasing procedure volumes, or as needed based on current usage patterns, confirm that all components and accessories are ready for use.
 1. Return automated endoscope reprocessors (AERs) to operational condition, referring to manufacturer IFU.
 2. Check all filters and hoses; replace according to manufacturer recommendations or facility protocols.
 3. Review expiration dates for chemical solutions, solution test strips for solution MEC testing, detergents, and pre-cleaning kits. Discard expired items. Ensure inventory levels are appropriate.
 4. Test water quality to confirm compliance with the relevant AAMI TIR34 guidance document.
5. Develop procedures for long-term endoscope storage resulting from low procedure volumes:
 1. Ensure adequate drying before storage. Consider the use of drying verification, or choose an appropriate endoscope lumen drying time and method based on peer-reviewed literature.
 2. Leave scopes in hanging storage or drying cabinets. Scopes should not be stored in the procedure room.
 3. Develop a policy for reprocessing of endoscopes that exceed your facility's limits on hang time. This policy may require immediate reprocessing, or if procedure volume is low, the policy may not require the endoscope to be reprocessed until a scheduled procedure is approaching. Consider:
 1. How frequently endoscopes are expected to exceed long term-storage limits during normal procedure volumes and during times of low procedure volumes
 2. The expected frequency and urgency of procedures using each type of endoscope
 3. The ease of compliance with the updated reprocessing policy
 4. The additional wear on the endoscopes resulting from repeated reprocessing

Manufacturer's Perspectives or Comments:

Endoscope and automated endoscope reprocessor manufacturers have published guidance on proper handling of their products. Some resources include:

1. [Custom Ultrasonics](#)
 1. Log in and proceed to the Product Documentation page. Refer to PSB-001 and other service bulletins relevant to your AERs.
2. [Medivators](#)
 1. [COVID-19](#)
 2. [COVID-19 Guidance for Recommissioning Cantel/Medivators AERs](#)
 3. [COVID-19 Guidance for Shutting Down Cantel/Medivators AERs](#)
 4. [COVID-19 Guidance for High Level Disinfection](#)
3. [Olympus](#)
 1. [Long Term Storage of Olympus Flexible Endoscopes](#)
 2. [OER-Pro Long-Term Storage](#)
 3. [Reprocessing Bronchoscopes During COVID-19](#)
4. STERIS
 1. [Startup Checklist](#)
 2. For AERs, Steris also recommends:
 1. Inspect gaskets, connectors, hoses, and accessories for cleanliness and function.
 2. Check expiration dating on all disposables including chemicals, filters, chemical indicators (CIs), and spore test strips and replace as needed.
 3. Perform qualification testing (where applicable).
 4. Perform decontamination cycle as instructed by IFUs.
 5. Verify printer paper is present (where applicable).
 6. Run a test print to confirm print density (where applicable).
 7. Verify equipment connectivity to data management systems.

Background:

1. Multiple gastrointestinal endoscopy organizations have published joint guidance on [management of endoscopes, endoscope reprocessing, and storage areas during the COVID-19 pandemic](#). Many of ECRI's recommendations are based on this guidance.
 1. Although these organizations focus on gastrointestinal procedures, their guidance for high-level disinfection or liquid chemical sterilization of endoscopes applies to all flexible endoscopes.
 2. They state, "While there is no data to support a requirement for the use of N95 respirators in the reprocessing room, their use should be considered, if available." ECRI believes that the regular use of N95 respirators is reasonable when supplies allow, but cautions facilities that:
 1. Endoscope reprocessing is not considered an aerosol-generating procedure, and therefore the risk of airborne SARS-CoV-2 transmission from endoscopes is low. During shortages, N95 supplies should be prioritized for staff at greater risk of aerosol exposure.

2. The primary risk to reprocessing staff is presented by droplets. At a minimum, staff should therefore use PPE that is rated for droplet transmission, such as surgical masks, surgical N95 respirators, or N95 respirators used with a droplet protection layer (e.g., surgical mask or face shield). Note that N95 respirators that are not rated for surgical use do not have fluid resistant properties; they are insufficient on their own. For details, refer to FDA article [N95 Respirators, Surgical Masks, and Face Masks](#) .
3. If N95 respirators are used, staff must be trained and fit tested according to CDC and OSHA guidelines: [The Need for Fit Testing During Emerging Infectious Disease Outbreaks](#) .
2. Professional organizations have also provided independent guidance, including:
 1. [American Gastroenterological Association](#)
 2. [American Society of Gastrointestinal Endoscopy](#)
 3. [American Association for Bronchology & Interventional Pulmonology](#)
 4. International Association of Healthcare Central Service Material Management (IAHCSCMM) [Sterilization and COVID-19 Town Hall](#) (audio file)
3. ECRI has also published guidance on COVID-19 considerations for the endoscopy department, providing recommendations for procedures and room cleaning.
4. There is no recognized consensus on the maximum time interval (“hang time” or shelf life) for the storage of reprocessed endoscopes before they can no longer be considered safe for patient use.
 1. Endoscopy units have previously been advised to conduct a risk assessment to determine the maximum storage time for an endoscope. Endoscopes that exceed this storage time need to be completely processed before use on the next patient.
5. In recent years, much research has been done on endoscope reprocessing workflows and effectiveness. Under normal circumstances, complex reprocessing procedures and workload pressures can cause reprocessing staff to inadvertently miss or intentionally skip steps in the precleaning, manual cleaning, reprocessing, and drying procedure. As procedure loads and reprocessing workloads increase, staff may feel pressure to reprocess endoscopes as quickly as possible; this may be exacerbated in facilities with reduced staffing levels. Endoscopy departments and reprocessing departments should be aware of the pressures on their staff, and consider steps to improve outcomes.
 1. Allow sufficient time between procedures for endoscopes to be reprocessed following all the steps in the scope manufacturer’s IFU.
 2. Retrain staff on proper reprocessing procedures as necessary.
 3. Provide the needed tools, recommended cleaning brushes, staffing, and accessories to perform reprocessing effectively.

Comments:

- This alert is a living document and may be updated when ECRI receives additional information.

Source(s):

- 2020 Jul 2. ECRI researched report