Endoscopy Facility Restart Check Points

Frequently Asked Questions: COVID-19 and Resuming Procedures

The current COVID-19 virus has created a need for providers to prepare and implement infection prevention and control measures in response to changes in the current healthcare environment.

Preparation is an essential step in the effort to mitigate the spread of COVID-19 and recover from this unprecedented event. Safe patient care is a core principle at Olympus and assisting our customers with answers to questions is one strategy in maintaining stewardship in that belief.

This document is intended as a resource for customer questions that may arise as a result of the COVID-19 pandemic and will be supported with an evidence base approach from product IFUs, the Olympus Technical Assistance Center (TAC) and regulatory and societal recommendations.

Continued on next page.

Endoscopy Facility Restart Check Points

SUITE DISINFECTION

Q: What are the current approved chemicals for surface disinfection or alternates that may be utilized on Olympus equipment?

A: Olympus has performed full material compatibility testing on disinfectants listed within our product instructions for use (IFUs).

- If using surface disinfectants outside of those recommended within the Olympus IFUs. Olympus has not performed full material compatibility testing specific to those products.

Olympus has performed material compatibility testing with limited product models on two (2) non-Olympus recommended surface disinfectants and confirmed favorable results: sodium hypochlorite-based and quaternary ammonium compound-based disinfectants.

- Surfaces of displays/screens and touch-panels were not included in this testing and therefore damage to these components may occur.

When using non-Olympus recommended surface disinfectants on Olympus products, damage such as peeling of paint or deterioration of materials may occur. Olympus recommends that users perform regular inspection of surfaces to detect potential damage. Surface disinfectants must be used according to the disinfectant manufacturer's instructions, including effective decontamination processes against COVID-19.

- Surface disinfectants should not be used on Olympus critical or semi-critical medical devices such as flexible or rigid endoscopes.

A customer letter referencing this information can be found at:
https://medical.olympusamerica.com/sites/default/files/us/files/pdf/Customer-Letter---Surface-Disinfection.pdf

Q: What chemicals can be safely utilized for surface disinfection of Olympus monitors and screens to prevent damage to the optical surface?

A: Olympus has performed full material compatibility testing on disinfectants listed within our product instructions for use (IFUs).

If using surface disinfectants outside of those recommended within the Olympus IFUs, please be aware that Olympus has not performed material compatibility testing specific to those products. Monitors and screens may be cleaned with 70% isopropyl or ethyl alcohol as described in the Olympus IFU(s) for those products. Do not spray disinfectant directly on the monitor or screen.

Q: How should procedure rooms be cleaned after each patient during the COVID-19?

A: Perform meticulous cleaning of room after each procedure, which includes cleaning of all high touch and horizontal surfaces in procedure rooms with an EPA approved surface disinfectant.[10]

Medical waste and linen should be removed from each room according to endoscopy unit policy. Staff involved in the cleaning of endoscopy rooms should utilize PPE. This should include: head cover, gown, surgical mask, eye-protection and gloves. Each endoscopy unit should have a plan in place for the cleaning and disinfecting of the entire unit at the end of the day.[4]

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Endoscopy Facility Restart Check Points

SUITE DISINFECTION (Continued)

Q: How should a procedure room be cleaned after a known COVID-19 case?

A: Perform meticulous cleaning as mentioned above.

Once the procedure is completed, extra time, as determined by your facility, should be allowed to permit air changes to remove potentially infectious particles within the room. Adequate aeration time will be determined by your facility. If negative pressure rooms are utilized, as has been advised by CDC, aeration time may be more abbreviated.[11, 4]

Q: What are the current society guidelines or recommendations for suite disinfection and cleaning?

A: Summary from the ASGE (American Society for Gastrointestinal Endoscopy) "GUIDANCE FOR RESUMING GI ENDOSCOPY AND PRACTICE OPERATIONS AFTER THE COVID-19 PANDEMIC" April 28, 2020:

1. No changes are recommended to established reprocessing procedures for endoscopes and accessories. Standard bedside pre-cleaning, followed by manual cleaning and high-level disinfection in the reprocessing facility should continue.[2,3]
2. Reprocessing staff should be donning personal protective equipment (PPE) that includes gloves, gown, face shield, bonnet and mask. While there are no data to support a requirement for the use of N95 respirators in the reprocessing room, their use should be considered, if available.[1]
3. EPA-registered hospital-grade disinfectant solutions and wipes should be used in procedure rooms to clean all high-touch and horizontal surfaces.[3]
4. Clorox™/bleach wipes can be used for kitchen and personal desk spaces.[3]
5. Desks, counters, keyboards, computer mice, phones, doorknobs, faucets, etc. should be disinfected at least twice daily.
6. Restrooms should be cleaned frequently, ideally after each patient.
7. No changes are recommended to 'terminal cleaning' procedures for cleaning and disinfecting the endoscopy unit at the end of the day.[2]

Continued on next page.

Endoscopy Facility Restart Check Points

OER AUTOMATED ENDOSCOPE REPROCESSORS (OER-PRO & OER-MINI)

Q: What is the procedure to resume operation of Olympus Automated Endoscope Reprocessors OER-Pro and OER-Mini following long term storage (more than 14 days)?

A: Once OER-Pro/OER-Mini operation is resumed, a separate process is followed for preparation of the OER-Pro/OER-Mini, prior to resuming use.

The IFU provides care and maintenance instructions for OER-Pro/OER-Mini following long-term storage. Please refer to the IFU, (OER-Pros Section 7.18) (OER-Mini Section 7.12) – Care and Maintenance After Long-Term Storage, for detailed instructions regarding resuming operation and related questions. When reprocessing operations are resumed following long-term storage, certain error code(s) may be displayed on the OER-Pro. For more information on this, as well as other questions, please refer to the IFU, Section 8.1 – Troubleshooting Guide. If you have any questions or need a copy of the IFU, please contact the Olympus Technical Assistance Center at **1-800-848-9024** (United States) or **1-800-387-0437** (Canada).

A customer letter referencing this information can be found at:
(OER-Pro) https://medical.olympusamerica.com/sites/default/files/us/files/pdf/Customer-Letter---OER-Pro-Long-Term-Storage.pdf

Q: Are Olympus supplied disinfectants (Acecide-C & Aldahol 1.8) efficacious in providing the high-level disinfection (HLD) necessary to prevent spreading COVID-19 between patients undergoing endoscopic procedures?

A: As per the germicidal manufacturers, Acecide-C and Aldahol 1.8 are effective in providing the acceptable level of HLD against enveloped viruses such as COVID-19 (Best Sanitizers, February 25 2020 & DFB Pharmaceuticals, March 16, 2020). Customer letters referencing this information can be found at:

- **Acecide-C:** https://medical.olympusamerica.com/sites/default/files/us/files/pdf/Acecide-versus-coronavirus.pdf
- **Aldahol 1.8:** https://medical.olympusamerica.com/sites/default/files/us/files/pdf/Aldahol-versus-coronavirusRAApproved-Final.pdf

Q: If my facility is not able to obtain 70% isopropyl alcohol as needed in the OER-Pro/Mini is there an Olympus sourcing resource available?

A: Olympus has collaborated with Best Sanitizers to manufacture Alpet7030 70% isopropyl alcohol which is available from Olympus for purchase.

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Endoscopy Facility Restart Check Points

OER AUTOMATED ENDOSCOPE REPROCESSORS (OER-PRO & OER-MINI) (Continued)

Q: What changes are needed to prevent the transmission of infection from patients to the reprocessing staff?

A: No changes have been recommended, pre-cleaning should commence in the procedure room per protocol, which is typically done by the staff already in the room.

Reprocessing staff should be donning personal protective equipment (PPE) that includes gloves, gown, face shield and mask.[5] 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. Place endoscope in a fully enclosed and labeled container for transportation to the decontamination room, as per institutional policy.[4]

Q: Are there any additional recommendation to consider before reopening?

A: Perform disinfection cycle of all AERs and automated flushing pumps per IFUs.

Clean and disinfect all plumbing lines feeding all equipment used for reprocessing, including sinks, hookups, channel adaptors, and AERs and if needed, test for water quality. Change all filters and pre-filters for all applicable equipment. Check expiration dates for all chemical solutions and detergents.[4] If high-level disinfected endoscopes have been stored for a time exceeding the facility-defined maximum storage interval ("hang time"), they must be fully reprocessed before clinical use.

ENDOSCOPES & DEVICES

Q: Is there any specific new guidance to the reprocessing steps as outlined in prior guidelines for COVID-19?

A: Consider limiting the number of reprocessing staff. Limit reprocessing to experienced staff with documented competency (avoid trainees and novices at this time).

All endoscopes should undergo full standard reprocessing prior to return to the endoscope manufacturer for maintenance, as per usual practice.[4]

Q: Does standard manual cleaning followed by high-level disinfection eradicate COVID-19?

A: Based on available evidence, standard manual cleaning followed by high-level disinfection (HLD) should be effective at eradicating COVID-19.[6]

There are no recommended changes to the reprocessing of GI endoscopes at this time.[2,3]

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Endoscopy Facility Restart Check Points

ENDOSCOPES & DEVICES (Continued)

Q: Is there any special handling of endoscopes, telescopes or other surgical devices for known COVID-19 cases?

A: There is no evidence that any special handling of endoscopes used on known COVID-19 positive patients is required at this time.[4]

Q: Are there any changes to the process needed to prevent transmission from staff to patients via handling of fully reprocessed endoscopes post high-level disinfection?

A: No changes are recommended to existing processes. Studies show that fully drying endoscopes may prevent outbreaks of waterborne organisms.[7,8]

Dry the exterior of endoscopes using a clean, lint free cloth. Facilities may choose to dry the interior of an endoscope with prolonged flow of medical grade air through all accessible channels for at least 10 minutes.[9] Ensure that all endoscopes are dried after reprocessing and before use per the Olympus IFU(s) and best practices recommended by the society guideline followed by your facility. Transport dry endoscopes to storage or drying cabinet wearing clean gloves.[4]

RESUMPTION OF CARE

Q: What first steps should be considered for prioritizing, scheduling, and managing the backlog of elective cases in a COVID-safe environment?

A: Facility policies, and multi-disciplinary professional medical society recommendations should be followed. Current literature suggest assembling a multi-disciplinary leadership group.

The mission of this "COVID Operations Group" (COG) is to restart elective surgery in a safe and patient and staff-friendly environment. The COG's membership should include representatives from: infection control, nurse management, anesthesia, medical directors, charge nurses and others as needed. Responsibilities may include daily assessment of supplies, patient flow, staffing capacity, monitoring all PPE usage of staff and patients, tracking room times and utilization, training and re-training staff and procedure monitoring.[12, 13, 14]

https://www.facs.org/COVID-19/clinical-guidance/triage

Q: Are there any tools to help project what our PPE usage need may be?

A: The CDC has developed a spreadsheet to calculate the average consumption (burn rate) and estimates how long remaining supply will last. This can be utilized to help make order projections for future needs:

https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/burn-calculator.html

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Endoscopy Facility Restart Check Points

RESUMPTION OF CARE (Continued)

Q: What are the recommendations to vendors such as Olympus for re-entry into health care facilities?

A: Olympus is adhering to facility, society, regulatory guidelines.

Considerations: Facility policies for medical device representatives in all areas should account for the following: Medical device representatives should work with facilities and providers to deliver services, information, and support remotely whenever possible. Medical device representatives needing facility access for servicing medical equipment should follow the same social distancing and access policies applicable to staff with access to the equipment.

Medical device representatives entering all areas of the facility should take safety precautions in accordance with Centers for Disease Control and Prevention (CDC) community recommendations, state and/or local public health recommendations, regarding hand washing and face coverings, both to protect the individual and others in the facility. Medical device representatives should have an understanding of CDC infection prevention recommendations for COVID-19, FDA guidance for PPE, CDC guidance for PPE donning and doffing and facility policy related to COVID-19 safety principles.[15]

Q: Are there any recommendations from professional medical societies for the utilization of tele collaboration?

A: Facilities with videoconferencing capabilities in their operating rooms should work with medical device representatives and clinicians to utilize virtual supporting surgical cases where remote attendance does not compromise patient safety or privacy.

Proper respiratory protection (e.g., fit tested N95 respirators with face shield or surgical N95 respirator) should be provided to all individuals, including medical device representatives, who are present for aerosol-generating procedures for patients who are not confirmed negative for COVID-19 at the time of the procedure.[15]

Q: What considerations should be made when scheduling and managing the case load?

A: Facilities should consult their management team and follow local policies. As per Hedman, (2020) establishing a Collaborative Daily Huddle that will use the prioritized list of backlogged elective cases to build and actively manage the daily schedule and the flow of patients across rooms.

Implement a system of safety protocols to prepare patients for their procedures. Under the sponsorship and oversight of the COG, the Patient Preparation and Scheduling Team should include representatives from anesthesia, pre-admission testing, scheduling, admitting, physician office personnel and day-of-procedure representatives. They should be responsible for building a streamlined coordinated patient-centric process.[13]

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Endoscopy Facility Restart Check Points

RESUMPTION OF CARE (Continued)

Q: What are some considerations for staff and workflow post reopening?

A: Multi-disciplinary professional medical societies suggests the following considerations:

- **FRONT/INTAKE:** Pre-Op screening may take additional time, attempt to limit face-to-face contact exposure, additional staff requirements for PPE are required, pre-procedure calls will require more detail, consider upfront payment of deductibles prior to procedure date
- **INTRA-PROCEDURAL:** Extra personnel may be required for in room assistance
- **POST PROCEDURE:** Discharge nurse/ escort will also require proper PPE [12,14]

Q: What are the possible impacts to revising block time flow?

A: Multi-disciplinary professional medical societies suggests the following possible impacts:

Lower caseloads, more PPE requirements, increased patient flow time to allow for terminal cleaning and allowing for airflow exchange in ASCs without negative pressure rooms. Terminal cleaning of rooms will also generate a greater consumption of supplies that should be considered.[12, 14]

Q: What is important when establishing a new day-of-procedure process?

A: Facilities should consult their management team and follow local policies.

Suggested recommendations is to have a clear patient communication process in place for the day of procedure. The patient and their families must know they are going to be in a safe environment to be comfortable going forward with their procedure. Given the media coverage about COVID-19, patients will be skeptical about coming to the hospital or ambulatory surgery center. On the day of the procedure, patients should already know to expect different entrances, COVID testing, a limit on family members, etc. Patients should also be told to expect triage questions or biometric temperature screening before entering the facility.[13]

Q: What are some potential avenues that can be pursued for a facility reopening?

A: Facilities should consult their management team and follow local policies. The following is a short list of considerations to help reestablish communication:

Update your facility website/patient portal; this is one of the most important actions and one of the first sources of information. Provide a live or updated phone hub for questions and patient support. Engage in a social media barrage of all forms: Facebook, Twitter, Instagram. Provide letters to referring physicians, personal calls or letters to patients that include COVID-19 instructions and facility protocol changes to reassure safety. Engage in Public Service Announcements when possible. Share a virtual guided tour of the hospital or ASC to ease discomfort and woo your patients back with confidence and trust.[12]

Continued on next page.

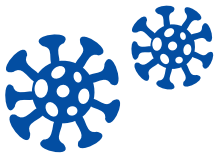
Endoscopy Facility Restart Check Points

OLYMPUS RESOURCES

Olympus America COVID-19 Resource Landing Page

Dedicated to serving healthcare services.

https://medical.olympusamerica.com/covid-19



Technical Assistance Center

Olympus has a highly-trained team that is available to address technical issues.

Phone: 800-848-9024 (United States) or 1-800-387-0437 (Canada)

Email: tac.support@olympus.com

Medical Customer Portal

Access to technical assistance and resources.

https://www.olympusconnect.com/

COVID-19 Webinars

Olympus America Informational webinars provide guidance about COVID-19:

- Addressing Surgical Customer Needs During the COVID-19 Pandemic: https://youtu.be/F0fjCBylnEE
- Addressing Endoscopy Customer Needs During the COVID-19 Pandemic: https://youtu.be/1vkEiCslhD0
- Bronchoscopy in the Era of COVID-19: A Global Perspective. Coming soon and accessible here: https://medical.olympusamerica.com/covid-19

Education

A variety of educational opportunities for medical and surgical healthcare professionals

https://medical.olympusamerica.com/customer-resources/learning-opportunities

MedPresence

Olympus aims to help customers with existing integration surgical suites and image/video recorders to reduce PPE consumption while enhancing clinical collaboration with three months of MedPresence software at no charge.

https://medical.olympusamerica.com/medpresence-covid-19-emergency-response

Olympus PSA: COVID-19 Signs

Digital and printable signs available for healthcare facilities to download.

- Digital Version for Monitors
- Printable Version

Olympus now offering Alpet7030 70% Isopropyl Alcohol

To order contact your local Olympus representative

Continued on next page.

Endoscopy Facility Restart Check Points

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