

1 May 2020

GESA and GENCA Recommendations for Endoscope Reprocessing during the COVID-19 Pandemic

Benedict Devereaux, Vice President, GESA
Dianne Jones, GENCA
Sue Greig, Australasian College for Infection Prevention and Control
Kathryn Haberfield, CSSD, St Vincent's Hospital Melbourne
Cate Quoye, Australasian College for Infection Prevention and Control
Elizabeth Wardle, GENCA
Robyn Brown, GENCA
Andrew Taylor, GESA
Eugene Athan, Barwon Health, Deakin University
Karen Vickery, Microbiologist, Macquarie University

Introduction:

GESA's Infection Control in Endoscopy (ICE) Committee has been closely monitoring the COVID-19 pandemic. The ICE Committee is a multi-society, multidisciplinary Committee with expertise in GI Endoscopy, GI Endoscopy Nursing, Infection Prevention and Control, Infectious Diseases and Sterile Processing. Endoscopic reprocessing is at the core of safe and efficient endoscopy practice. The ICE Committee considers the safety of all patients in endoscopy units and personnel involved in instrument reprocessing a priority.

Key Points:

1. Existing protocols are adequate for the reprocessing of endoscopic instruments even if used on suspected or known SARS-CoV-19 positive patients. This document contains additional steps primarily related to consideration of environmental contamination and staff safety.
2. It is optimal for all reprocessing steps, including cleaning to be automated.
3. If manual cleaning is performed specific precautions need to be taken.
4. Just as in the endoscopy procedure room, specific attention needs to be paid to PPE during instrument reprocessing.
5. Reprocessing staff and decontamination areas should be clearly demarcated as "clean" and "dirty"
6. Each endoscopy unit should have a detailed plan for cleaning and disinfecting procedure rooms and reprocessing area including use of a viricidal agent due to the risk of infection following contact with contaminated surfaces.

Reprocessing Staff Personal Protective Equipment (PPE)

All staff working in the decontamination room should be wearing personal protective equipment. Use a buddy to assist with confirmation that PPE has been correctly and safely applied. For reprocessing of endoscopic instruments PPE will include:

1. Single use disposable gloves - change between each scope reprocessing activity and for environmental cleaning
2. Fluid resistant gown or apron - that offers good protection to the front of the worker and minimises the opportunity for moisture contamination with reprocessing and cleaning activities
3. Protective eyewear/face shield - fitted correctly and unless it is touched can be worn for continuous tasks. If touched, then it must be changed or cleaned and hand hygiene performed before replacing on face
4. Surgical masks should be used when there is a chance of droplet generation during the reprocessing process. Decontamination rooms should implement endoscopy reprocessing practices to eliminate or minimise droplet or aerosol generation
5. Surgical mask - fitted correctly and unless it is touched can be worn for continuous tasks. If touched, then it must be changed. Hand hygiene must be performed before and after removing the surgical mask and again before putting on a new surgical mask. If generation of aerosols is unavoidable as is likely during manual cleaning, a P2 / N95 respirator (mask) should be worn.

Removing PPE should be done with a buddy observing and assisting if required to minimise self-contamination at each step.

1. Remove gloves - perform hand hygiene
2. Gown/apron - perform hand hygiene
3. Remove overshoes if worn - perform hand hygiene
4. Remove protective eye wear/face shield immediately after leaving the room - perform hand hygiene
5. Remove mask also after leaving the room - perform hand hygiene
6. Remove hat/balaclava (if worn) - perform hand hygiene

It is important that masks and protective eye wear is removed after leaving the location where aerosol generation occurs, either the procedure room or the reprocessing area.

PPE may be in short supply and therefore when protective eye wear/face shield and mask is not moist, contaminated or has not been touched, it can remain in place for ongoing reprocessing of endoscopes for up to 4 hours

Steps of reprocessing

1. Immediate bedside decontamination

This is an essential step of the reprocessing regime to ensure the removal of gross contamination from the endoscope and must be performed immediately following completion of the endoscopic procedure.

Bronchoscopes do not have air/water channels but should otherwise be processed according to the steps below.

1.1 IMMEDIATELY after each procedure with the endoscope still attached to the light source, grasp the control head. Using a disposable cloth or sponge soaked in detergent solution wipe the control head and insertion tube to the distal tip. Discard cloth/sponge. Note: remove balloons from ultrasonic endoscopes and enteroscopes.

1.2 Place distal tip in detergent solution. Aspirate through suction channel - depress and release suction button rapidly to promote debris dislodgement. Alternately suction cleaning fluid and air by raising the instrument tip in and out of the cleaning solution. Continue aspiration until clear. NB: patient secretions from bronchoscopy are clear and may be difficult to identify when aspirating. The volume of fluid to be aspirated through the channel during the bedside clean is determined by the automated flexible endoscope reprocessor (AFER) manufacturer as this is the first step in the automated cleaning process.

1.3 Depress and release air/water button several times to flush water channel. Occlude air button to force air through the air channel.

1.4 Depending on the brand of endoscope, either

(a) insert the special air/water channel feed button and depress the button to flush with water then release for air flow to expel the water; OR (b) move the lever on the water feed connector to close off the water supply, then depress the water feed button until water is expelled. Disconnect the water bottle connector from the endoscope, taking care not to contaminate its end.

1.5 Flush the jet channel either by depressing the foot pedal or using a syringe flush.

1.6 Flush the forceps elevator (if present) with syringe of clean water (2ml)

1.7 Remove the endoscope from the light source. If applicable, ensure protective caps are applied before immersing in solutions.

After pre-cleaning, the endoscope is transferred to the reprocessing area in a manner that will not contaminate the environment and is clearly identified as contaminated equipment. Care should be taken to ensure that the exterior of the transport case is not contaminated when loading. Thus gloves used during the pre-cleaning need to be removed, hand hygiene performed and new gloves donned for the transfer.

Manual cleaning of the endoscope or commencement of the AFER cleaning cycle should occur without delay, ideally within 15 minutes but must be within 1 hour. Manufacturers' protocols for delayed processing should be followed if required.

2. Leak testing

Leak testing detects damage to the external surfaces and internal channels of the endoscope that can lead to inadequate disinfection and further damage of the endoscope. Leak testing should be performed after each use prior to manual cleaning or may be performed by the AFER at the commencement of the reprocessing cycle. Remove all valves and buttons prior to leak testing.

The risk of aerosol generation with wet leak testing is potentially significant. For this reason wet leak testing is not recommended. For manual reprocessing following a procedure on a suspected or confirmed COVID-19 patient, dry leak testing should be performed in the procedure room whilst staff are still in PPE consistent with standard plus transmission-based precautions. The risk associated with this recommendation is that a leak may go undetected by not completing a wet leak test. Confirmation of leak test process within the machine cycle should be confirmed.

3. Cleaning

Automated cleaning with chemical disinfection is recommended as the optimal process. When not using an AFER with automated cleaning, manual cleaning including brushing and flushing channels and ports consistent with the manufacturer's instructions for use (IFU) is required prior to high-level disinfection (HLD) or sterilisation. Some AFER with automated cleaning cycles may require some limited manual cleaning processes prior to cycle commencement eg duodenoscopes. To avoid omission of steps in this process one person should complete the full manual cleaning of the endoscope. If a change in personnel occurs, the process should be recommenced.

For any procedure where there is a risk of aerosol transmission, any items that are available as single use should be utilised to reduce risk of personnel and environmental contamination during cleaning.

- 3.1 Make up detergent solution as per manufacturer's instructions. Enzymatic or biofilm remover products should be used. Detergent solution should not be reused.
- 3.2 All brushing and flushing cleaning steps must be **completed underwater** to avoid generation of aerosols.
- 3.3 Brush and clean reusable buttons and biopsy caps, paying particular attention to internal surfaces. Once brushed, buttons should undergo ultrasonic cleaning prior to sterilisation. The lid of the ultrasonic cleaner must remain closed whilst the cycle is active. Disposable biopsy caps should be used unless they are not available for that particular endoscope. Single use buttons are available.

- 3.4 Place endoscope in detergent solution and wash all outer surfaces. Discard cloth/sponge after use.
- 3.5 Brush all sections of the suction, biopsy channels and other channels as per manufacturer's instructions using a brush applicable for the channel size. Brushes for endoscopes may be bristle or bladed design. Some twin channel endoscopes require brushes of differing sizes. Endoscopes with elevators will require specific brushes. If the brush contains obvious debris, it should be cleaned before being withdrawn. Some brushes are designed to be used as a pull-through instead of withdrawing the brush. Each channel should be brushed until all visible debris is removed.

Using a soft brush, gently clean the distal tip.

Brush control wheels, around and in valve seats and biopsy port thoroughly. Check that all visible debris has been removed.

- 3.6 Fit cleaning adaptors. Thoroughly flush all channels with detergent, ensuring solution is obtained from a separate supply to that in which the endoscope is immersed. The volume of fluid to be flushed through the channels is identified in the manufacturer's IFUs. Ensure all air is displaced from the channels. Leave the detergent solution in contact for the specified time. Purge detergent solution from all channels.
- 3.7 Rinse outer surfaces. Flush all channels with clean (potable) water (this means tap water that has been freshly drawn and not used for any other instrument). It is essential that all detergent be removed prior to disinfection.
- 3.8 Purge channels with air to remove rinsing water.

After manual cleaning, the endoscope and its accessories are visually inspected. Some endoscopes may require the use of light magnification to assist with the inspection process. Borescopes provide capability to inspect the endoscope biopsy channel for damage, presence of foreign matter and identification of biological material.

4. Automated disinfection

Connect the endoscope to the AFER. Choose the relevant cycle (HLD or sporicidal).

At completion of the cycle, check that cycle parameters have been met and all channel adaptors are still connected. Staff should wear standard PPE when removing the endoscope from the AFER. If required for immediate use, remove the channel adaptors and dry exterior of the endoscope. Endoscopes to be dried in cabinets will require connectors specific to those cabinets and these may be those used in the AFER.

5. Drying

At completion of reprocessing, endoscopes are wet. Those to be used immediately will not require further channel drying. All others require forced air drying of the channels, either manually for 10 minutes with compressed air, or within a Therapeutic Goods Administration (TGA) approved endoscope drying cabinet. The parameters for drying are specific to each cabinet and will vary with type of endoscope, temperature, humidity and time. EN 16442 requires that the drying process is complete within 3 hours. Whilst alcohol 70% has traditionally been used to assist drying, the increasing emphasis on forced air drying of channels has concurrently de-emphasised the utility of alcohol flushes.

6. Endoscope Storage

Cabinets compliant with EN 16442 that are designed for drying of endoscopes must also be used for their storage. Manufacturer's instructions will state the length of time an endoscope can remain ready for patient use without requiring further reprocessing. Endoscopes should remain within the cabinet until required for use.

7. Transport of endoscopes ready for patient use

Endoscopes may be transported using the tray from the drying cabinet or in a closed container / wrap that will prevent contamination. Only endoscopes that have completed the drying time of the specific cabinet may be placed within a mobile storage device to allow for transfer of scopes to a procedural area where proximate access to the storage cabinet is not available. Endoscopes transferred and stored in this manner but not used must be reprocessed before return to the storage cabinet. The maximum time that these endoscopes can be used after placement in the mobile device is 12 hours.

8. Endoscope accessory equipment

The cleaning and disinfection or sterilisation of reusable endoscopic accessories is equally as important as that of the endoscope because endoscopic accessories have been implicated in the transmission of infection and pseudo-infections.

As with endoscopes, the cleaning of accessories as a pre-requisite to sterilisation is mandatory.

The Spaulding classification provides a system to determine the level of reprocessing necessary for reusable medical devices (RMDs) based on the item's intended use:

- (1) Critical RMDs require cleaning followed by sterilisation
- (2) Semi-critical RMDs require cleaning followed by high-level disinfection at a minimum; however, sterilisation of these items is strongly recommended if possible.

The requirements of AS/NZS4187:2014¹ are applicable to all health service organisations (HSOs). It is necessary for individual HSOs to develop their own workplace procedures based on the requirements of this Standard to ensure their reprocessing activities result in a safe RMD that is able to be used for diagnostic and treatment purposes and that is not hazardous to either staff or to the environment.

Utilisation of single use medical devices may provide HSOs with efficiencies particularly in the setting of equipment used in emergency endoscopy after hours. For any procedure where there is a risk of aerosol transmission, any items that are available as single use should be utilised. Consideration should be given to difficult to clean RMDs, labour intensive procedures, access to and high cost of reprocessing equipment, and control of inventory when risk assessing RMDs vs single use sterile devices as best practice AS/NZS4187:2014, 5.1.3 (f)

Medical devices labelled as or intended for single use and that have been used, shall not be reprocessed or reused. A medical device labelled with the symbol in Figure 1 shall be deemed to be a medical device intended for single use.



Figure 1. Do Not Reuse Symbol¹

All reusable medical devices (used and unused) returned to the sterilising service (CSSD) from the operating theatre, wards, clinics and other procedure rooms are considered contaminated and must be reprocessed before further use

8.1 Cleaning

- 8.1.1. All equipment should undergo bedside cleaning with all visible soiling removed.
- 8.1.2. Any multi component equipment should be dismantled as far as possible.
- 8.1.3. Any complex-structured accessories should be placed in an ultrasonic cleaner and processed according to manufacturer's recommendations.
- 8.1.4 Items should then be processed through a washer/disinfector prior to packaging for sterilisation.
- 8.1.5 Specific processes may be required for individual items eg. manual cleaning and flushing channels of water bottle connectors

- 8.1.6.** Accessory items that have been manually cleaned should be thoroughly rinsed and dried prior to high level disinfection or sterilisation.

8.2 Disinfection and sterilisation

- 8.2.1** Critical accessories that enter sterile tissue or the vascular system must be sterile
- 8.2.2.** Non-critical accessory equipment used in gastroenterological procedures requires high-level disinfection as a minimum. Non-sterilisable reusable accessories should not be used where a sterilisable alternative exists
- 8.2.3** High-level disinfection should not be used for equipment that can be sterilised.

8.3 Some accessory items require specific comment

8.3.1 Water bottles and connectors.

Water bottles by virtue of their design are difficult to clean and reprocess. AS/NZS4187:2014, 5.1.3 (f)¹. These accessory items should be steam sterilised according to manufacturer's instructions and a new bottle used for each session as they have been implicated in the transmission of infection. The use of single use bottles and accessory tubing will be required if steam sterilisation is not available.

Note: Following a procedure conducted under standard plus contact and airborne precautions single use bottles and connectors should be used to avoid removing contaminated equipment from the procedure room.

8.3.2 Reusable graduated dilators have a small diameter wire channel which is difficult to clean. The reprocessing of these dilators should be equivalent to an endoscope's high-level disinfection. Recommendation is that single use dilators be used.

8.3.3 Reprocessing of cleaning equipment

Most cleaning equipment such as brushes are single use and should be disposed of after use.

Channel connectors used during manual cleaning should undergo steam sterilisation daily.

Flushing pumps that have internal channels require disinfection as per manufacturer's instructions. This is required to be performed daily. The

channel connectors and intake tubing of these pumps will be disinfected as part of the daily process. Some models have external tubing that is single day use.

8.3.4 Reprocessing of connectors to drying cabinets

Many cabinets utilise the same channel connectors that are used in the AFER. As such, these are reprocessed during each cycle of use. For connectors that do not get processed with the endoscope in the AFER, cleaning and sterilisation/HLD will be required. These should be processed as per the manufacturer's IFU and most commonly on a weekly basis.

References:

1. AS/NZS4187:2014 Reprocessing of reusable medical devices in health service organisations. Standards Australia.

Disclaimer

The Gastroenterological Society of Australia (GESA) provides advice to endoscopists and endoscopy facilities during the COVID-19 pandemic. It should be noted that this advice is general in nature and thought to be correct at the time of posting. The user should have regard to any information, research or other material which may have been published or become available subsequently. It is recommended that this advice be considered in the context of the specific endoscopic facility and within the framework provided by the Departments of Health and Local Health Districts.