

Reprocessing Flexible Endoscopes

Avoiding Reprocessing Errors Critical for Infection Prevention and Control

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Flexible endoscopy procedures are now a routine part of patient diagnosis and treatment in hospitals and surgery centers in the United States. The demand for these safe and effective procedures continues to increase, with more than 15 million endoscopy procedures annually. Endoscopies are performed with sophisticated, reusable, flexible instruments that have specific requirements for cleaning, disinfection and sterilization. Because of this, adherence to recommended practices and guidelines for reprocessing is a critical component of infection control and reducing the risk of nosocomial infections.

Failure to follow established guidelines for reprocessing has resulted in the transmission of infectious agents causing serious patient injury and/or death.¹⁻³ Despite these incidents, concise manufacturer's reprocessing guidelines, and the development and publication of several recommended practice and guidance documents,⁴⁻⁸ appropriate cleaning, disinfection and/or sterilization of endoscopes continue to be a challenge for many facilities. This article presents some reprocessing

errors commonly identified in hospitals and surgery centers in the United States and discusses how these can be avoided.

Pre-cleaning

Pre-cleaning is an essential reprocessing step that removes patient biomaterial and microorganisms from the endoscope. Following an endoscopy, biomaterial from the patient is present on the insertion tube and within the internal channels of the endoscope. All channels must be cleaned, even if unused, due to fluid and debris entering these channels at the distal tip. Patient biomaterial provides a nutrient source that will promote the growth of potentially pathogenic microorganisms. Also, when this biomaterial is not removed immediately after a procedure, it will dry and harden. The surface of the hardened material functions as a barrier that prevents the penetration of disinfecting and sterilizing agents that kill microorganisms. In addition, patient biomaterial may inactivate disinfectants. The result is potentially infectious material still present on the endoscope or in the endoscope channels following reprocessing delays.

A reprocessing delay may occur when a patient has both upper and lower procedures performed during the same visit. The endoscope from the first procedure is kept in the procedure room until the second procedure is completed. If pre-cleaning is not initiated within an hour, the endoscope should be

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Reprocessing delays may be encountered if staff must come in and perform emergency procedures at night or over the weekend, leaving the endoscope to be properly reprocessed by the regular staff on the next workday. Delays may also occur in busy departments, especially when cases run longer than expected. In the rush to get to the next procedure, the pre-cleaning is often abbreviated or the endoscope is set aside until the next case is finished. The pre-cleaning process is not a long procedure, but is an essential step in the cleaning process. Pre-cleaning should be performed every time according to manufacturer's instructions.

To avoid additional delays, the endoscope insertion tube should be wiped down and all of the channels flushed with detergent and/or water (as specified by manufacturer's instructions) as soon after the procedure as possible, preferably immediately.

The mechanical action of wiping the endoscope, coupled with flushing all of the channels, removes biomaterial that harbors and provides nutrients for microorganisms. When delays in pre-cleaning do occur, additional reprocessing steps, which include an extended soak period, are required. Follow the manufacturer's instructions for delayed reprocessing of endoscopes.

Mechanical Cleaning

Guidelines from professional organizations consistently state that mechanical cleaning is critical for proper endoscope reprocessing. Mechanical cleaning is essential to reducing bioburden and preventing the risk of cross-contamination. Studies indicate that mechanical cleaning alone reduces bioburden by an average of 4 logs (99.99%).⁹⁻¹⁰ The *Multi-society Guideline for Reprocessing Gastrointestinal Endoscopes*⁵ identifies mechanical cleaning as "essential before manual or automated disinfection," and the guideline categorizes cleaning as a Class 1A recommendation, the strongest possible classification, stating: "strongly recommended for implementation and strongly supported by well-designed experimental, clinical, or epidemiologic studies."

Mechanical cleaning is a multi-step process that involves accessories for brushing and flushing the endoscope channels and openings. The multitude of detergents, disinfectants, and accessories specific for each endoscope may lead to improper cleaning. Some common areas to focus on include the following:

▶ Detergent Use

One of the most common errors during cleaning is improper dilution of the detergent. The "more is better" theory may work with some things in life, but detergents and liquid chemical germicides are not among them. The detergent is formulated to be effective at a specific dilution and temperature. Any deviation from the instructions for use may alter the effectiveness of the detergent, its ability to be properly rinsed, and possibly cause damage to the scope. As a result, the detergent should be used according to the manufacturer's instructions. Use of an enzymatic detergent is recommended to help breakdown and flush patient biomaterial from the scope.

According to all accepted reprocessing guidelines, enzymatic detergents are intended for single use. In general, detergents have little or no bacteriocidal activity. As a result, potentially infectious material will remain in the detergent following its use in endoscope cleaning. To prevent cross-contamination, dispose of the detergent after each use.

▶ Submersion

A common reprocessing error is the failure to fully submerge the endoscope in detergent or disinfectant for the required length of time. Contact time is a critical component to the efficacy of any detergent or disinfectant, especially for the disinfectant. Do not guess; use a timer. Anything less than the recommended time will not produce a "patient-ready" endoscope. Anything substantially over the recommended time may lead to endoscope damage. If portions of the endoscope are not submerged for the required contact time during exposure to either the detergent or disinfectant, infectious material may remain on the endoscope following reprocessing.

The primary reasons for failure to fully submerge the endoscope are that the sink/basin is not large enough to accommodate the flexible endoscope, or not enough of the properly diluted detergent or disinfectant was added. The recommended sink/basin should be at least 16 inches by 16 inches by 8 inches. After placing the endoscope in the sink/basin, ensure that the scope is fully submerged. If not, add additional properly diluted detergent or disinfectant. If using an automated endoscope reprocessor, follow the manufacturer's instructions for loading the endoscope into the basin.

▶ Channel Reprocessing and Cleaning Accessories

The validated cleaning adapters supplied by the manufacturer are critical for properly reprocessing the endoscope channels. Some scopes have additional or unique channels, such as an auxiliary water channel (forward water-jet) or elevator wire channel, which require reprocessing. All channels must be cleaned and disinfected even if they are not used during the procedure. By not utilizing the correct, validated connection, there is a high probability that many or all channels will not be adequately reprocessed. To ensure that all channels are adequately reprocessed, refer to the manufacturer's instruction manual for scope reprocessing and, if applicable, contact the automated endoscope reprocessor (AER) manufacturer for the proper cleaning accessories.

▶ Channel Brushing

Channel brushes may seem like simple devices, but they are an important part of effective cleaning. For effective cleaning, the brush must contact the channel wall to produce mechanical abrasion of the surface, which results in the removal of biomaterial. Worn or damaged cleaning brushes may result in ineffective cleaning or channel damage. To avoid this, routinely inspect channel brushes for missing bristles, bends or kinks, and missing solder beads holding the twisted wires together. Also, keep an inventory of spare brushes in the event that one needs to be replaced. Reprocess and use the brush in accordance with the manufacturer's instructions.

▶ **Water Rinsing**

Manual cleaning is completed with a thorough rinse of the endoscope with fresh water. There is a common misconception that rinsing after cleaning is not critical because the scope will subsequently be terminally reprocessed; however, residual detergent may react with and inhibit the disinfectant or sterilant solution. This reaction may also result in insertion tube staining or peeling. It is equally important to ensure that the disinfectant or sterilant solution is thoroughly rinsed from the scope following terminal reprocessing. Failure to thoroughly flush disinfectant or sterilant from the endoscope following reprocessing has resulted in adverse patient outcomes including chemical irritation of tissue and patient anaphylaxis.¹¹ Contact your equipment and/or disinfectant manufacturer to determine the rinse volume and total number of rinses required.

Disinfection/Sterilization

High-level disinfection or sterilization of endoscopes is listed as a requirement in all guidance documents, with high-level disinfection being the standard and minimum requirement.

▶ **Disinfectant/Sterilant Use**

The Multi-society Guideline recommends that manual or automated reprocessing include use of “a high-level disinfectant/sterilant cleared by the FDA for high-level disinfection/sterilization.” All disinfectants and sterilants have expiration dating established by the manufacturer. For example, most glutaraldehyde solutions have both a shelf life printed on the container and a 14- or 28-day expiration following activation or first use. Expiration dating is based on the stability (expiration date and use life) of the product and minimum effective concentration (MEC) required to achieve the expected result of disinfection or sterilization. Reusable disinfectants and sterilants begin to degrade upon preparation. The addition of any debris or solution, such as water, will reduce the effective concentration. Therefore, it is recommended that the MEC be tested prior to each use according to the manufacturer’s instructions.

For many disinfectants and sterilants, the solution must be activated and the use period starts from the date of activation. A common misconception is that the addition of fresh disinfectant or sterilant to an existing solution will extend the duration of use or expiration of the older solution. This is incorrect, and mixing the two solutions will reduce the efficacy of the freshly prepared disinfectant or sterilant. Also, under no circumstances, including a passing MEC result, may the use period for a disinfectant/sterilant be extended beyond the manufacturer's recommendations. Facilities should maintain and routinely review MEC logs to ensure proper disinfectant/sterilant use.

Endoscopes should be stored in a clean, dry, and well-ventilated area to minimize the possibility of recontamination. Also, all valves and the water resistant cap should be removed during storage to facilitate drying.

▶ **Air Purge and Alcohol Flush**

An air purge should be completed immediately following the water rinse. Residual water, depending upon the quality used to rinse the scope, may contain waterborne organisms. If sterile water is not used to rinse the scope, an additional alcohol purge followed by a forced air purge is required to thoroughly dry the scope and prevent recontamination. An alcohol flush is recommended to enhance drying whether or not sterile water is used during the final rinse.¹²

Storage

Endoscopes should be stored in a clean, dry, and well-ventilated area to minimize the possibility of recontamination. Also, all valves and the water resistant cap should be removed during storage to facilitate drying. During storage, many facilities use distal tip protectors, most of which are essentially sponges. These protectors will absorb moisture and may harbor microorganisms. To minimize the risk of recontamination, these protectors are typically designed for single-use only.

The benefits of flexible endoscopic procedures for the detection, prevention and treatment of many diseases, such as cancer, are well established. There is no doubt that these procedures have improved healthcare and diagnostic capabilities. As discussed, these procedures require the use of

sophisticated equipment. Flexible endoscopes can be cleaned, disinfected and/or sterilized efficiently and effectively when the manufacturer's guidelines are followed. If there are concerns about the current procedures performed at your facility, contact the manufacturer and review the current published guidelines. †

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