INFECTION PREVENTION AND CONTROL GUIDELINE

for **Flexible Gastrointestinal Endoscopy** and **Flexible Bronchoscopy**

Public Health Agency of Canada
Agence de la santé publique du Canada

Canada

To promote and protect the health of Canadians through leadership, partnership, innovation and action in public health.

— Public Health Agency of Canada

Infection Prevention and Control Guideline for Flexible Gastrointestinal Endoscopy and Flexible Bronchoscopy is available on Internet at the following address: http://www.phac-aspc.gc.ca

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Introductory Statement

The Public Health Agency of Canada (PHAC) develops national infection prevention and control guidelines to provide evidence-based recommendations to complement provincial/territorial governments' efforts in monitoring, preventing, and controlling healthcare-associated infections. National guidelines support infection control professionals, healthcare organizations and healthcare providers in the development, implementation and evaluation of infection prevention and control policies, procedures and programs to improve the quality and safety of health care and patient outcomes.

The purpose of the PHAC Guideline *Infection Prevention and Control Guideline for Flexible Gastrointestinal Endoscopy and Flexible Bronchoscopy* is to provide a framework within which those responsible for endoscopes in all settings, where endoscopy is performed, may develop policies and procedures to ensure that the critical elements and methods of cleaning, disinfection, and/or sterilization of these devices between patient uses are consistent with national guidelines.

Guidelines, by definition, include principles and recommendations, and should not be regarded as rigid standards. This guideline, whenever possible, has been based on research findings. In some areas, where there is insufficient published research, a consensus of experts in the field has been used to provide recommendations specific to practice.

The information in this guideline was current at the time of publication. Scientific knowledge and medical technology are constantly evolving. Research and revisions to keep pace with advances in the field are necessary.

Target Users

This guideline is intended to assist infection prevention and control professionals and all other healthcare providers responsible for using and reprocessing flexible gastrointestinal endoscopes and flexible bronchoscopes in all settings in which endoscopy is performed, whether in hospitals, clinics, physician offices, or stand-alone endoscopy centres.

Guideline Working Group

The Public Health Agency of Canada's Infection Prevention and Control Program developed this guideline with expert advice from a working group. The Guideline Working Group was comprised of members representing clinical microbiologists, endoscopy nurses, gastroenterologists, hospital epidemiologists, infectious disease specialists, infection prevention and control professionals, biomedical technicians and the medical instrument reprocessing sector. The multidisciplinary Guideline Working Group reflected a balanced representation of the regions of Canada.

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Guideline Issuance and Review

This guideline was issued in 2011 and will be reviewed in 2013, or sooner if new evidence becomes available. Any amendments to this guideline in the interim period will be noted on the PHAC website. Comments are invited to assist the review process.

Please refer to Appendix A for a summary of the PHAC Infection Prevention and Control Guideline Development Process.

This document is part of the PHAC series of Infection Prevention and Control Guidelines and is intended to be used with the other Infection Prevention and Control Guidelines. The series is available at: www.phac-aspc.gc.ca/nois-sinp/guide/pubs-eng.php

For information regarding the Infection Prevention and Control Guidelines series, please contact:

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Infection Prevention and Control Guideline for Flexible Gastrointestinal Endoscopy and Flexible Bronchoscopy

Executive Summary

This document, *Infection Prevention and Control Guideline for Flexible Gastrointestinal Endoscopy and Flexible Bronchoscopy*, has been prepared by the Public Health Agency of Canada's Blood Safety Surveillance and Health Care Associated Infections Division of the Centre for Communicable Diseases and Infection Control. It is intended to assist infection prevention and control personnel and all other healthcare providers responsible for both using and reprocessing flexible gastrointestinal endoscopes and flexible bronchoscopes in all settings in which endoscopy is performed, whether in hospital clinics, physician offices, or stand-alone endoscopy centres. The recommendations provide a framework within which those responsible for endoscopy in any setting may develop policies and procedures to address their needs, and to ensure that the critical elements and methods of cleaning, disinfection, and/or sterilization of these devices between patient uses are consistent with national guidelines.

Numerous types of flexible endoscopes are available (e.g., gastrointestinal, bronchoscopic, urological, laparoscopic surgical, etc). **This Guideline will focus solely on flexible gastrointestinal and bronchoscopic endoscopes and their respective accessories.** Instruments such as transesophageal or rectal ultrasounds, cystoscopes, laparoscopes and others are examples of instruments that will not be addressed. For purposes of this document, 'patient' includes patient, client or resident. The Public Health Agency of Canada guidelines provide evidence-based recommendations. Where scientific evidence is lacking, the consensus of experts is used to formulate a recommendation. As new information becomes available, the recommendations in this document will be reviewed and updated.

Parts I and II describe the purpose of this Guideline and provide background information on the epidemiology, etiology, and pathogenesis of infections associated with flexible endoscopy, in order to bring an understanding of how disease can be transmitted by these instruments. Briefly, endoscopy-related infections can result from 1) the patient's own (endogenous) microbial flora, or 2) microorganisms acquired a) exogenously from a contaminated endoscope, and/ or b) transmitted between the patient and the healthcare provider. Each category is reviewed in the document, with a focus on the sources and modes of acquisition of exogenously acquired microorganisms and specific microorganisms and problems (e.g., breaches in disinfection or sterilization processes) associated with transmission of disease attributed to a contaminated endoscope.

Part II further elaborates on the factors that contribute to the survival of microorganisms in reprocessed endoscopes. Common errors in reprocessing are highlighted. The Guideline emphasizes the steps required to address these factors, and points out the critical need for appropriate training and ongoing competency assessment for staff in the reprocessing area.

Part III describes the structure and function of the endoscope with corresponding illustrations.

Part IV provides detailed instructions on the critical steps required for reprocessing endoscopes and describes the barriers to adequate reprocessing that may lead to transmission of infection. Endoscope reprocessing is a three-stage process that includes: 1) cleaning the endoscope and its detachable parts using a detergent solution and brushes; 2) high level disinfection or sterilization of the endoscope using a product, most often a liquid chemical agent, approved for use in Canada, followed by thorough water rinsing to remove residual product from the instrument; and 3) post-processing, which includes proper handling and storage of the endoscope. In Part IV, major attention is given to the safe use of automated endoscope reprocessors, the proper reprocessing of endoscopic accessories, and the storage requirements for flexible endoscopes.

Part IV also includes important sections on quality management, healthcare worker protection, health and safety considerations related to endoscopy and equipment reprocessing, appropriate endoscopy unit design, outbreak investigation and management, and finally, investigation and action required if a reprocessing problem is identified. These sections of the document are intended to provide the user with the knowledge and tools to ensure that the endoscopy working environment is safe for patients and staff, that staff are appropriately trained and competency assessment is ongoing, and that potential outbreaks of infection or reprocessing problems are identified and managed effectively and in a timely fashion.

Part V sets forth evidence-based recommendations for reprocessing flexible gastrointestinal endoscopes and flexible bronchoscopes, including recommendations for administrative policies and procedures, cleaning, leak testing, sterilization and high level disinfection, and storage and transportation. The recommendations in this Guideline take into account guidelines and recommendations published by other national and international societies and organizations[1-10].The recommendations elaborate on quality management, specifically, education and training requirements, worker health and safety considerations, and the quality assurance elements of a reprocessing program. Other recommendations deal with classic and variant Creutzfeldt-Jakob Disease, outbreak investigation and management, and endoscopy unit design.

Appendix A. The ***"PHAC Infection Prevention and Control Guideline Development Process"*** provides a summary of the guideline development process.

Appendix B. The ***"Glossary of Terms"*** provides definitions of terms used throughout these guidelines.

Appendix C. The ***"Spaulding Classification System"*** is used for making decisions about whether to use sterilization or high level disinfection on endoscopic equipment between each patient use.

Appendix D. The ***"Bioburden Test Method"*** describes a procedure for microbiologic testing of endoscopes that may be undertaken as part of an outbreak investigation.

Appendix E and F. These two sections, ***"Sample Audit Checklist/Tools for Reprocessing of Endoscopy Equipment/Devices"***, provide examples of quality assurance tools to audit reprocessing practices to verify that equipment/devices are being reprocessed according to established guidelines. They may be adapted for individual facility use.

Appendix G. The ***"Verification of Training Stages for Endoscope Reprocessing"*** provides an example of an audit tool to verify that staff training and education have been completed and that competency with procedures has been established. It may be adapted for individual facility use.

Appendix H. The ***"Guideline for Outbreak Investigation Related to Endoscopic Procedures"*** outlines steps to be taken if an outbreak investigation is undertaken. Some steps may be carried out concurrently and a thorough risk assessment should be conducted to determine if patient notification is required.

Appendix I. The ***"PHAC Guideline Rating System"*** describes the system for ranking the strength of the evidence used to support the recommendations made in this Guideline.

PART I. PURPOSE

Decades ago, the advent of flexible endoscopy heralded a new era in diagnostic and therapeutic medicine; not only was invasive surgery potentially avoidable, but it surpassed the spectrum of diagnostic and therapeutic options available at the time with rigid bronchoscopes and esophagoscopes. With improvements in technology, the sophistication and capabilities of these electro-mechanical devices have further increased, in turn leading to better tolerated and quicker procedures with less accompanying morbidity and mortality, and more efficient use of resources. At the same time, however, the complexity of the instruments has presented new challenges in reprocessing.

Flexible endoscopes are complex instruments with not only an external surface, but also internal channels (e.g., suction /biopsy, air/water and elevator channels) and accessories that are exposed to body fluids and other contaminants. These expensive instruments must be designed for reuse. They are difficult to disinfect and easy to damage because of their intricate design, including narrow long lumens, and delicate materials. For this reason, policies and procedures must be in place to ensure appropriate reprocessing of flexible endoscopes before the endoscope is used on subsequent patients. Research on disposable endoscopes is ongoing. There are some bronchoscopes that can be steam sterilized but most flexible endoscopes require low temperatures for disinfection/sterilization.

This document provides guidance for the development of policies and procedures that will eliminate preventable errors in the reprocessing of flexible endoscopes in all healthcare settings where endoscopy is performed. The document emphasizes the essential elements required and methods to be used for the safe handling, transportation and biological decontamination of endoscopes and their reusable accessories. Definitions used are in accordance with the Canadian Standards Association[11] and the Public Health Agency of Canada Infection Prevention and Control Guidelines[12;13].

Robust evidence upon which to formulate these guidelines is scarce as data from randomized trials are lacking or only preliminary results from clinical trials are available. Thus, these guidelines largely reflect the efforts of organizations and societies within Canada, Britain and the USA that have previously published guidelines on reprocessing flexible endoscopes[1;3-9], new literature, and current published opinions from experts in the field. The appendices of this document provide examples of audit tools for verification of staff training and competency, cleaning, disinfection, and safe storage of the equipment, and can be adapted for use as required.

Most reported cases of cross-transmission of infection related to endoscopy have identified breaches in proper instrument processing or use of defective equipment. It is therefore essential that all healthcare settings where endoscopy is performed have appropriate guidelines in place for endoscope reprocessing and handling. Adherence to these guidelines should minimize the potential for transmission of infection associated with use of the instrument.

PART II. TRANSMISSION OF INFECTION BY FLEXIBLE ENDOSCOPY

1. Background

1.1. Spaulding Classification for Medical Devices

In the 1960s, Spaulding developed a system to classify the cleaning, disinfection and sterilization requirements for equipment used in patient/client care[14]. The system divides medical devices into three categories based on the invasiveness of the procedure that the device will be used for. The three categories are non-critical, semi-critical, and critical. This classification system is widely accepted and used by professional organizations[1;4;6;7;15] to help determine the level of disinfection or sterilization required for various medical devices. Refer to Appendix C for the Spaulding Classification System and to Appendix B, Glossary of Terms, for definitions. The recommendations for reprocessing of endoscopes presented here are based on and consistent with the principles of Spaulding's classification.

2. Overview

Flexible endoscopic procedures are used for diagnostic (i.e., visualization and sample collection) as well as therapeutic purposes. The endoscopes that will be discussed in these guidelines are used for medical conditions involving the lungs (bronchoscopy), the esophagus, stomach and small intestine (gastroscopy and enteroscopy), the biliary tract and pancreas (duodenoscopy with endoscopic retrograde cholangiopancreatography (ERCP)), or the large bowel (colonoscopy). Also included are new modalities that continue to develop and evolve such as combined ultrasound transduodenoscopy, which provides endoscopic ultrasound to endoscopy (EUS).

Infections related to flexible endoscopic procedures are caused by either endogenous flora (the patient's own microorganisms) or exogenous microbes (microorganisms introduced into the patient via the flexible endoscope and/or its accessories). Microbial sources of infection and modes of acquisition of exogenous microorganisms causing infection are discussed in detail in Section 3 of this guideline. The post-procedure infection rate related to inadequate reprocessing is difficult to determine, as there are no prospective studies that differentiate endogenous from exogenous infections.

The incidence of infections caused by transmission of microorganisms between patients or from the environment following endoscopy is estimated to be very low. Twenty-eight reported cases of endoscopy-related transmission of infection were reported in the United States between 1988 and 1992[16]. During that period, approximately 40 million procedures were performed nationally, with the estimated incidence of transmission therefore in the order of approximately 1 infection per 1.8 million procedures[3;4;8;16]. The risk of infection from endogenous sources ranges from close to 0% with simple upper endoscopy or sigmoidoscopy to slightly greater than 1% in complicated ERCP[17]. Although rarely associated with clinical infection, bacteremia with various gastrointestinal endoscopic procedures is not uncommon. The mean frequency of post-procedure bacteremia has been reported to range from 0.5% for flexible sigmoidoscopy to 2.2% for colonoscopy, 4.2% for esophagogastroduodenoscopy (EGD) and 5.6% to11% for ERCP**.**

Performance of biopsy or polypectomy does not change the associated rates of bacteremia. Esophageal dilatation and sclerotherapy in conjunction with EGD have been reported to raise the incidence to 45% and 31% respectively[18;19], although recent prospective studies estimate that bacteremia rates for esophageal dilatation and sclerotherapy may be significantly lower than that, ranging between 12% and 22%[20].

There is even less information available on infection post-bronchoscopy. The apparent low incidence might reflect a truly uncommon occurrence, or infections may be under-recognized because they are easily masked by the primary signs and symptoms for which bronchoscopy is performed[9]. Although pneumonia appears to be a rare complication of bronchoscopy (<1%)[21], this procedure has been identified as an independent risk factor for healthcare-associated pneumonia[22]. Infections after bronchoscopies are commonly due to mechanical or structural defects in the device that lead to its inadequate reprocessing[23-25].

3. Microbial Sources

3.1. Endogenous

Endogenous infections after flexible endoscopic procedures arise when the patient's own microbial flora gain entry to the bloodstream or other normally sterile body sites as a result of mucosal trauma or instrumentation and are not related to instrument reprocessing problems. Examples of endogenous infections include pneumonia resulting from aspiration of oral secretions in a sedated patient or bacteremia resulting from microscopic tissue trauma occurring during endoscope insertion or removal.

In the lungs there is normally no resident flora. However, the mucosal surface of the upper respiratory tract has a substantial load (~ 10^6 cfu/gm) of microorganisms[26] that can be carried down into the lower respiratory tract when the insertion tube of the bronchoscope is introduced into the lung through the mouth. Oropharyngeal microorganisms include a wide range of viridans streptococci, *Moraxella* and *Neisseria* species, and anaerobic bacteria such as *Porphyromonas* species, *Fusobacterium* species and oral anaerobic spirochetes. The stomach and small intestine have only low levels of resident normal flora (10^{3-6} cfu/gm of tissue)[26], but again microorganisms from the oropharyngeal cavity and throat can be introduced when the insertion tube is passed through the mouth into the stomach or small intestine. The large bowel, on the other hand, has high numbers of normal flora (~ 10^{12}/gram of feces)[26]. Microorganisms found in the colon include anaerobic bacteria such as *Bacteroides fragilis*, *Porphyromonas* species, and *Clostridium* species as well as high numbers of *Enterobacteriaceae (Escherichia coli, Klebsiella* species, *Enterobacter* species, *Proteus* species, etc.*)* and *Enterococcus* species. In most immunocompetent patients bacteremia, which may occur during or after procedures, is usually transient and asymptomatic[19]. No published data demonstrate a conclusive link between procedures of the gastrointestinal (GI) tract and the development of infective endocarditis (IE) and there are no studies that demonstrate that the administration of antibiotic prophylaxis prevents IE in association with GI procedures. Therefore, antibiotic prophylaxis solely to prevent IE is no longer recommended for patients who undergo GI tract procedures, including diagnostic esophagogastroduodenoscopy or colonoscopy. However, patients with high risk cardiac conditions (prosthetic heart valve, previous infective endocarditis, certain types of congenital heart disease and cardiac transplant recipients who develop cardiac valvulopathy) are

candidates for prophylaxis before bronchoscopy, only if the procedure involves incision of the respiratory tract mucosa. For further details, the reader is referred to *Prevention of infective endocarditis: Guidelines from the American Heart Association*[27].

3.2. Exogenous

Exogenous infections arise from microorganisms introduced into the patient's body by the flexible endoscope or by the accessories used in the procedure and are the focus of this document. Such infections are preventable with strict adherence to accepted reprocessing guidelines. Exogenously acquired microorganisms may originate from a number of sources, which are outlined in Figure 1. These include:

1. A previously used endoscope, followed by inadequate cleaning and/or improper reprocessing technique.
2. Contamination of the endoscope, accessories, or automated endoscope reprocessor from the environment during reprocessing (e.g., environmental microorganisms, skin microorganisms, and water microorganisms).
3. Post-reprocessing contamination of the endoscope and accessories with water, environmental and/or skin microorganisms during final handling and/or storage.

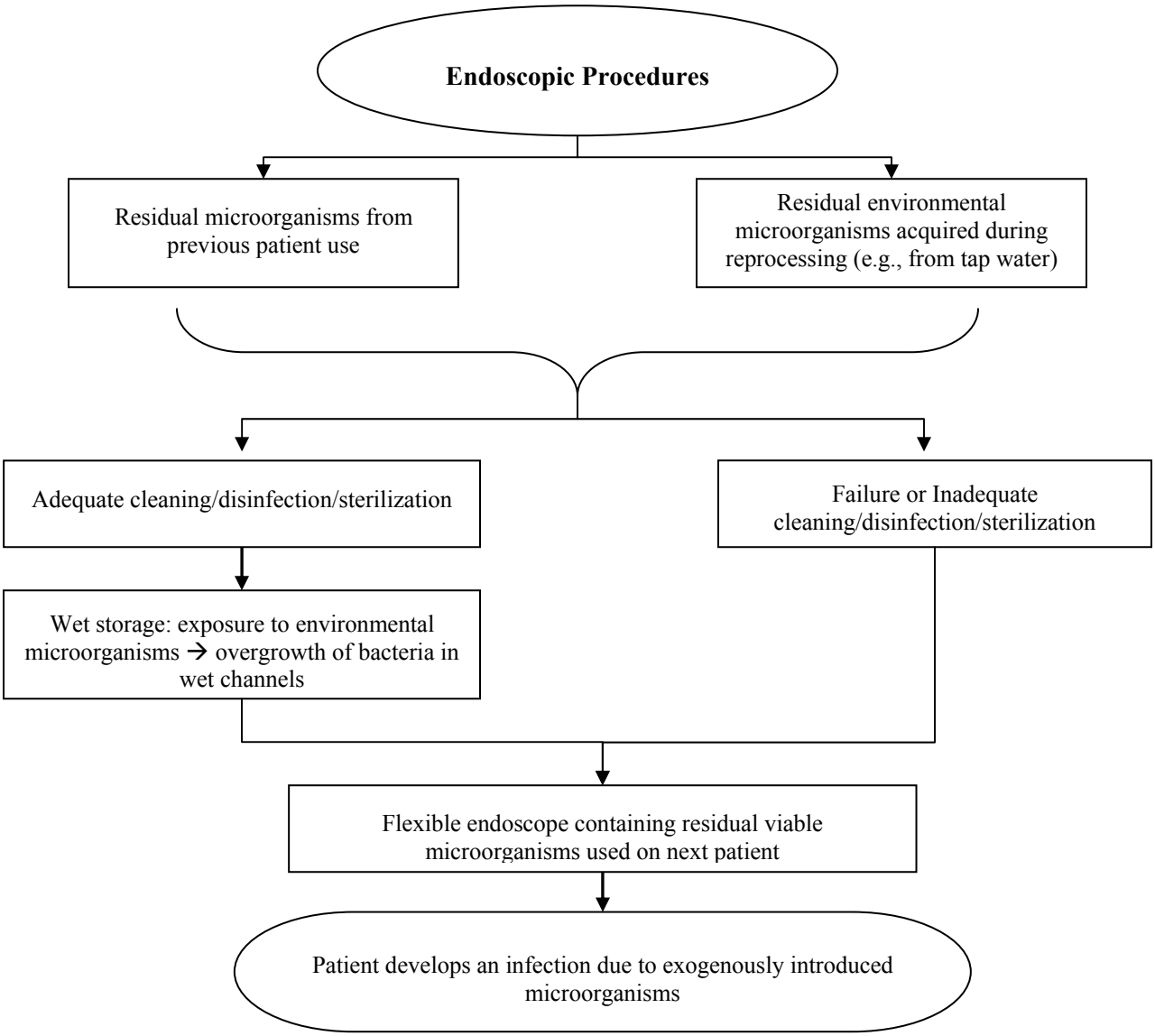
The reservoir for exogenous microorganisms within a flexible endoscope may be the suction/biopsy channel or any other channel in the flexible endoscope (e.g., elevator wire channel in side-viewing duodenoscopes, air/water channel in colonoscopes, or any auxiliary channels that may be present)[28-32]. In addition, the water bottle and tubing used for endoscopy procedures may also form a reservoir for exogenous microorganisms if these accessories are not properly reprocessed[33]. Components of the reprocessing procedure itself may serve as a reservoir, such as cleaning brushes if not inspected, cleaned and high level disinfected after each use; tap water diluted enzymatic detergent and tap water rinse that are not changed after each use; or if the water filtration system is not maintained as per manufacturers' instructions[34]. Enzymatic detergent and rinse water used during manual cleaning should be changed for each scope to ensure residual microorganisms are not introduced into the next endoscope that is immersed in the used solution. Diluted preparations of enzymatic detergents should never be stored overnight as tap water-derived microorganisms can multiply to unacceptably high levels.

Tap water used for the final rinse after disinfection/sterilization may result in water microorganisms being left in the channels[30;35-37]. Most guidelines[1;3;4;9;38] now recommend that, preferably, the final rinse water be sterile, filtered or otherwise rendered free of bacteria. If tap water is used for the final rinse, flushing the channels with 70-90% alcohol after the rinse is critical, not only to facilitate drying, but also to help eliminate any residual water microorganisms introduced from the tap water rinse[37;39].

Bronchoscopic procedures involve substantial flushing of fluid through the biopsy-suction channel into the lung with subsequent aspiration from the lung back through the endoscope suction channel and into the side-trap. This "flushing process" through the endoscope channel, combined with the normally sterile lung environment, results in a higher likelihood of infection arising from any exogenously introduced microorganisms.

This is not to say that upper and lower GI endoscopy have lower rates of exogenously introduced microorganisms; it simply reflects the higher likelihood that exogenous microorganisms introduced into the lung in combination with a certain degree of trauma will result in an infection compared to the same event occurring in the gut.

Figure 1. Acquisition of Exogenous Microorganisms Causing Endoscopy Related Infection



4. Specific Microorganisms Transmitted or Shown to Contaminate Flexible Endoscopes

Bacteria have caused the vast majority of exogenously acquired endoscope-related infections reported in the literature. The bacteria involved have been either true pathogens, which always have the potential to cause infection (e.g., *Mycobacterium tuberculosis*), or opportunistic pathogens that cause infection if the microbial load is sufficient and/ or host-factors are permissive (e.g., *Pseudomonas aeruginosa*).

Transmission of viral pathogens via flexible endoscopic procedures is rare because these microorganisms are obligate intracellular microorganisms that cannot replicate outside viable human cells. This means that even if viral particles are present within a flexible endoscope channel after a patient procedure, the load of viruses cannot increase, as they are not capable of replication in vitro. Enveloped viruses (e.g., human immunodeficiency virus (HIV), hepatitis B virus (HBV), hepatitis C virus (HCV)) die readily once dried but non-enveloped viruses (e.g., enteroviruses, rotavirus) can survive in dry conditions. Furthermore, enveloped viruses are more readily killed by high-level disinfectants and/or sterilants compared to non-enveloped viruses. Viruses can, however, survive longer in the presence of organic material than they can on dry surfaces. Published studies have demonstrated the efficient removal of HBV and HCV from endoscopes with standard reprocessing regimens[40;41].

Although there is serious concern about the possibility of HIV transmission by flexible endoscopes, no cases have been identified. Thorough pre-cleaning has been shown to eliminate even high titres of HIV, and 2% alkaline glutaraldehyde has been found to inactivate the virus rapidly, even if the virus is dried in serum on a surface[41-43].

To date, only one case of clinically apparent HBV transmission, from an acutely viremic hepatitis B patient, via endoscopy has been documented[31]. A review of cleaning and disinfection procedures used at the time this case occurred revealed no breaches in reprocessing protocol. However, no disinfecting agent was being used to flush the air/water channel and standardized guidelines for reprocessing endoscopes were not yet available. These factors may have contributed to the hepatitis B transmission in this situation. A number of studies have followed patients who were exposed to endoscopes that had recently been used on HBsAg positive patients, without finding evidence of its transmission to others[44;45].

Eight cases of HCV transmission have now been attributed to gastrointestinal endoscopy[46]. Thorough investigation with genotyping was performed in only three cases, in which transmission was firmly established by nucleotide sequencing[47;48]. While both reports implicate inadequate disinfection of the colonoscope, they each also raised the possibility of contamination of syringes or multidose vials as the actual source of transmission. A recent investigation of an outbreak of acute hepatitis C in patients who underwent procedures at the same endoscopy clinic revealed that transmission likely resulted from reuse of syringes on individual patients and use of single-use medication vials on multiple patients at the clinic[49]. A multicentre cohort study by Ciancio et al.[50] followed 8260 HCV seronegative patients who were undergoing endoscopy. Follow-up serology was performed at 6 months, comparing them with a control population of healthy blood donors. There were no cases of seroconversion after endoscopy; in particular, none of the 912 patients who underwent endoscopy with the same instrument previously used on an HCV carrier showed anti-HCV seroconversion. There were four seroconversions in the

control group (indicating a background seroconversion rate of 0.042 per 1000 patient-years). These results strongly suggest that when currently accepted guidelines are followed, transmission of HCV does not occur. Other recent studies[51;52] provide further evidence of the safety of reprocessing protocols based on current accepted standards**.**

Parasites (e.g., C*ryptosporidium* sp.) do not replicate in moist environments in the same manner as bacteria and fungi, but the cysts and eggs of parasites can survive in such environments. Although there is a theoretical risk of *Cryptosporidium* cysts and *Clostridium difficile* spores surviving high level disinfection (HLD), transmission of such pathogens via endoscopy has not been reported[3;44]. The presence of fungi is associated with prolonged storage of flexible endoscopes, however, these microorganisms rarely cause infections in immunocompetent patients. Consequently, although transmission by a contaminated endoscope has occurred[32;53;54], outbreaks of fungal infection associated with contaminated flexible endoscopes have been infrequent.

A review article covering the years from 1966 to July 1992[44] reported 281 infections following gastrointestinal endoscopy and 96 infections following bronchoscopy[44]. Microorganisms associated with transmission of infection from contaminated flexible endoscopes are summarized in Table 1. Microorganisms associated with transmission, without infection, attributed to contaminated flexible endoscopes are summarized in Table 2.

Table 1. Microorganisms Associated With Transmission of Infection Attributed to Contaminated Flexible Endoscopes

Organisms	Endoscope Type	Problem Identified
Helicobacter pylori	Duodenoscope[55;56]	Transmission of microorganism to subsequent patients. Failure to use appropriate disinfectant between patients.
Pseudomonas aeruginosa	1) Bronchoscopes[24;25] 2) Duodenoscopes[30;39;44;57]	1) Microorganisms isolated from loose biopsy port caps due to design flaw, resulting in disinfection failure - multiple cases of cross-transmission. 2) Bacteremias/cholangitis post- ERCP caused by inadequate disinfection (e.g., endoscope flushed with tap water between patients and no disinfectant used[39], contamination of inner channels, or incomplete drying).
Salmonella species	Colonoscopes[44;58]	Inadequately disinfected colonic biopsy forceps in one outbreak; in most outbreaks, disinfectant used was not effective against *Salmonella* sp. N.B.: No reported cases since publication of cleaning/disinfection standards in 1988.
Enterobacteriaceae (range of genera including: *Escherichia coli, Serratia* sp.*)*	1) Colonoscopes/Duodenoscopes[44] 2) Bronchoscope[24]	1) High levels of bacteria within channels - Transient bacteremia after ERCP. 2) *Serratia* sp. sequestered in loose biopsy port due to design flaw –cross- transmission to multiple patients (one infection).
Mycobacterium tuberculosis	1) Bronchoscope[59] 2) Bronchoscope[60]	1) Failure to disinfect contaminated suction valve -cross-transmission to four patients (one infection). 2) Lack of routine Leak Testing- cross-transmission to eight patients.
Fungi	1) Duodenoscope[32] 2) Duodenoscope[53]	1) Trichosporon *beigelii* isolated from biopsy channel after disinfection failure – cross-transmission to nine patients. 2) *T.asahii* isolated from tip of endoscopic forceps and resistant to disinfectant –cross-transmission to one patient.
Hepatitis C	Colonoscope[47]	Failure to clean suction channel with brush and sterilize biopsy forceps- cross-transmission to two patients who subsequently developed hepatitis.
Hepatitis B	Duodenoscope[31]	No disinfecting agent used to flush air/water channel; standard guidelines not available – cross- transmission to one patient who subsequently developed hepatitis.
Strongyloides stercoralis	Duodenoscopes[61]	Circumstantial evidence for four cases of cross-transmission of parasite. No further cases following ETO sterilization.

Table 2. Microorganisms Associated With Transmission Without Infection Attributed To Contaminated Flexible Endoscopes

Organisms	Endoscope Type	Problem Identified
Bacillus sp.	Bronchoscope[62]	*Bacillus* sp. isolated from suction valves. Contamination related to improper disinfection and storage –microorganism detected in bronchial washing cultures obtained from asymptomatic patients.
Pseudomonas aeruginosa	Bronchoscopes[63]	*Pseudomonas aeruginosa* isolated from suction channel not cleaned prior to disinfection- microorganism detected in bronchoalveolar lavage fluid (BAL) samples from eight asymptomatic patients.
Mycobacterium sp.	1) Bronchoscopes[64] 2) Bronchoscope[65]	1) *M. chelonae* isolated from lidocaine sprayers used during bronchoscopy- acid-fast bacilli (AFB) detected in bronchial washings of asymptomatic patients. 2) *M. gordonae* isolated from tap water related to failure in filter replacement and maintenance-AFB detected in bronchial aspirates of asymptomatic patients.
Serratia marcescens *Pseudomonas aeruginosa*	Bronchoscope[66]	*Serratia marcescens* and *Pseudomonas aeruginosa* isolated from saline used to rinse disinfected scope. Procedure changed to use filtered water rinse with scheduled in-line filter changes- microorganism detected in bronchoalveolar lavage fluid (BAL) samples from 41 asymptomatic patients.
Fungus	1) Bronchoscope[67] 2) Bronchoscope[54]	1) *Aureobasidium* sp. isolated from re-use of stopcocks meant for single use in outpatient bronchoscopy unit –microorganism detected in BAL cultures from nine asymptomatic patients. 2) *B. dermatitidis* contamination related to ineffective mechanical cleaning- microorganism detected in samples from two asymptomatic patients.
Legionella pneumophila	Bronchoscope[36]	Contaminated tap water used to rinse scopes after disinfection. Problem recurred because of inadequate maintenance to filters –microorganism detected in BAL samples from three asymptomatic patients.

5. Occupational Infection Related to Endoscopy

Although transmission of infection is rare, endoscopy staff, like the patient, can become infected as a result of endoscopic procedures. Several studies have examined the prevalence of antibodies to *Helicobacter pylori* in the serum of gastroenterologists. Lin et al.[68] found that endoscopists had a 69% seropositivity rate compared to 40% among internists. Seroprevalence was similarly higher in two studies comparing endoscopists (about 52%) to blood donors (14-21%)[69;70]. It is unclear whether the subjects wore appropriate personal protective equipment. In contrast, another study reported no statistically significant difference in seropositivity between endoscopists and age-matched controls[71]. Although differences in methodology may explain some of the discrepant results, overall it appears that endoscopists do have higher seropositivity to *H. pylori*, suggesting that endoscopy can be a risk factor for acquiring *H. pylori*.

Catanzaro described transmission of *M. tuberculosis* to 10/13 (77%) of healthcare workers present at the bronchoscopy of an individual with undiagnosed tuberculosis[72]. The author calculated that during bronchoscopy and intubation of the patient, at least 249 infectious units/hour of mycobacteria were generated. One case of bacterial conjunctivitis from a splash during colonoscopy has been reported, highlighting the need for appropriate personal protective equipment[73].

6. Classic and Variant Creutzfeldt-Jakob Disease

Transmissible spongiform encephalopathies (TSEs) are caused by prions, which are protein particles that contain no nucleic acid, yet are capable of causing a transmissible disease. All prions are hardy, remain infectious for years in a dried state, and resist all routine sterilization and disinfection procedures commonly used by healthcare facilities[74-78]. Differences in the pathogenesis of classic (sporadic, familial and iatrogenic) Creutzfeldt-Jakob Disease (CJD) and variant Creutzfeldt-Jakob Disease (vCJD) are reflected in the different distribution of TSE-specific protein (PrP^{TSE}) in the bodies of patients with CJD versus vCJD. This means that different infection prevention precautions may be required during endoscopic procedures in patients with vCJD as compared to patients with classic CJD.

In classic CJD, prion infectivity is largely limited to the central nervous system (CNS) and only surgical instruments contaminated with prions from these high-risk tissues have resulted in iatrogenic transmission. In classic CJD, PrP^{TSE} is found less often in organs outside the CNS, such as the lung, spleen, and lymph nodes and these tissues are considered to have low infectivity. Much of the evidence for this conclusion comes from studies of the distribution of the abnormal prion protein and/or associated prion infectivity in tissues of individuals with prion diseases. The agent responsible for vCJD is different from the agent that causes sporadic CJD. With vCJD, PrP^{TSE} has been detected in a number of lymphoid tissues, as well as the intestinal tract and these tissues are considered to have a higher level of infectivity than similar tissues in patients with classic CJD. Experimental evidence suggests that the lymphoreticular system may contain significant levels of infectivity for most of the incubation period (mean 10-30 years). To support this, PrP^{TSE} was found in the germinal centres of an appendix that was removed eight months before the onset of neurological disease in a patient with vCJD. Lymphoid follicles and germinal centres are widely distributed in the gastrointestinal tract and are often biopsied; it is therefore possible that endoscopy on patients who have or are incubating vCJD may result in contamination of the instrument (and particularly the biopsy forceps) with PrP^{TSE}[79].

In a patient with vCJD, an endoscope can potentially be contaminated with PrP^{TSE} at several points during an endoscopy procedure. During upper GI endoscopy and bronchoscopy, the first potential point of contamination is the tonsils if they are traumatized during insertion of the scope. If a small bowel biopsy deep enough to encounter lymphatic tissue is obtained, it is possible to contaminate the biopsy/suction channel as the biopsy forceps are withdrawn. The biopsy channel is an issue with lower GI tract endoscopies if biopsies are obtained. An ileal biopsy is a higher risk procedure than duodenum or jejunum biopsy because of the higher concentration of Peyer's patches in the ileum[80].

With classic CJD, since PrP^{TSE} has not been found in the GI tract, GI endoscopy alone is unlikely to be a vector for its transmission.

Although lung and lymphoid tissues have been identified as low infectivity for CJD, the magnitude of infectivity is such that special precautions related to the procedure and reprocessing of equipment are not required[7;75;76].

Disinfection techniques to eliminate prion infectivity include prolonged steam sterilization, and extended soaks in concentrated sodium hydroxide, sodium hypochlorite, or formic acid[81] (Please refer to Public Health Agency of Canada Infection Prevention and Control Guideline: *Classic Creutzfeldt-Jakob Disease in Canada , Quick Reference Guide-2007*[75] and *Classic Creutzfeldt-Jakob Disease in Canada* (www.phac-aspc.gc.ca/piblicat/ccdr-rmtc/02vol28/28s5/index.html)[75;76;80]. Unfortunately, an endoscope cannot be reprocessed by any of these techniques without sustaining severe damage[81]. Therefore, endoscopes used on patients with vCJD must be single use or destroyed after use[7].

The risk of transmission of any pathogen from an endoscope depends on many factors including the susceptibility of the exposed individual, the infectivity load of the tissues, the amount of contaminating tissue (in part related to the type of procedure done) and the effectiveness of the decontamination processes[82]. The quantification of risk from asymptomatic individuals depends on the prevalence of disease. The total number of cases of vCJD reported in the UK, since 1990, was 166 as of December 31st, 2009 (www.cjd.ed.ac.uk/figures.htm) and 211 worldwide[81]. The risk in Canada is much lower than in the UK as reflected by only a single case reported to date[83]. This case occurred in 2002 and infection was likely acquired while the individual was living for a period of time in the United Kingdom. The transmission of CJD and vCJD via an endoscopic procedure, remains only a theoretical risk at this time, as no cases of such transmission have been reported[46;80].

7. Factors That Contribute to Survival of Microorganisms in Reprocessed Flexible Endoscopes

7.1. Wet Storage

Bacteria may replicate to substantive levels even after overnight storage at room temperature if there is adequate moisture in the endoscope channels. Some bacteria can survive drying (e.g., *M. tuberculosis* and Gram positive bacteria) whereas others, like Gram negative bacteria (e.g., *P. aeruginosa* and *E. coli*), die rapidly when dried. Gram negative bacteria replicate more easily in the presence of moisture and have been implicated in endoscope associated infections more frequently than have Gram positive bacteria[29].

Moisture remaining in the channels of flexible endoscopes is a major contributing factor to exogenous microorganisms being transmitted by flexible endoscopes and outbreaks related to inadequate drying and improper storage have been reported[30;37]. A survey by Kazmarek et al. in 1991[84] of stored flexible endoscopes found that 23.9% of samples taken from the devices' channels had > 10^5 cfu/channel. Alfa & Sitter 1991[29] demonstrated that overgrowth of bacteria in flexible endoscope channels during storage was most commonly associated with Gram negative organisms, rather than Gram positive organisms. Ensuring the endoscope channels are thoroughly dried can prevent this overgrowth.

7.2. Biofilm Formation and Organic Debris

The ability of bacteria to form biofilms is an important factor in their potential to cause endoscopy-related infections. During clinical use blood, feces, mucus, and other biological substances can adhere to the endoscope and its channels. If the channels are not properly cleaned, there may be high residual levels of organic material and microorganisms[85-89]. If the endoscope remains moist for extended periods, the residual bacteria can produce biofilm. Biofilms consist of colonies of microorganisms forming structures to maximize growth potential. Development of a biofilm begins when free-swimming bacteria attach to a surface. Substantial biofilm formation may result after overnight storage[90]. Microorganisms embedded within this biofilm are sheltered from the cidal activity of the disinfectant/sterilant. This protection is further enhanced if there is residual organic material post-cleaning; subsequent exposure to aldehyde based disinfectants leads to fixation of the matrix, but the microorganisms within the matrix (i.e., biofilm and/or residual patient secretions) may or may not be adequately killed[4;80;91]. Additionally, biofilm formation explains why flexible endoscopes should not be left soaking in enzymatic detergent overnight. Enzymatic detergents do not inhibit bacterial replication, and indeed, the microorganisms can use the enzyme proteins as an energy source. Therefore the most important step in endoscope reprocessing is bedside flushing, with subsequent manual cleaning and brushing of endoscope channels, **as soon as possible after the procedure.** This will reduce the likelihood that residual organic material or bioburden will be present during the disinfection/sterilization stage. The importance of timely flushing, and manual cleaning and brushing, cannot be overemphasized[92].

7.3. Equipment Design Flaws

Two studies[24;25] confirm that design flaws can contribute to, if not promote, microbial contamination despite adherence to proper reprocessing protocols. In both reports, the documented design flaw was a faulty biopsy port in a bronchoscope that could loosen, allowing patient secretions and microorganisms to become sequestered in a moist environment, inaccessible to adequate cleaning and disinfection. The problem was identified when an abnormally high rate of *P. aeruginosa* was detected in bronchoalveolar lavage (BAL) specimens. This illustrates how periodic review of microbiology reports from BAL samples may be a useful audit tool for bronchoscopy services. Such audits would not be possible for duodenoscopy and colonoscopy as cultures are generally not done as a part of these procedures. Correcting design flaws is beyond the ability of most endoscopy units and primarily the responsibility of manufacturers of equipment and their regulatory bodies. However, endoscopy users may be able to identify flaws that manufacturers should address.

8. Errors in Reprocessing

Outbreaks associated with flexible endoscopy have most often been associated with breaks in the cleaning and/or disinfection/sterilization stage of flexible endoscope reprocessing[92]. Cowan[45] has described how the currently used reprocessing protocols provide a very narrow margin of safety and any slight deviation from the recommended steps may result in an increased risk of infection transmission by flexible endoscopes. Tables 1 and 2 show that errors in reprocessing of flexible endoscopes are the most common underlying problems associated with endoscopy-

related transmission of infection. Some of the most common errors associated with reprocessing of flexible endoscopes have been identified by surveys of endoscopy units[84;93] and include:

- Failure to perform leak testing prior to cleaning,
- Failure to completely immerse scope during cleaning,
- Inadequate exposure time to enzymatic detergent during cleaning,
- Inadequate amount of active ingredient used for disinfection,
- Inadequate volume of water used for rinsing,
- Inadequate time for scope drying prior to storage, and
- Placement of the valves on the endoscope during storage.

In addition to these breaches in reprocessing, a Canadian survey reported that few healthcare facilities (30%) had written instructions for reprocessing of flexible endoscopes in their facility[93]. The introduction of Minimum Effective Concentration (MEC) testing of liquid chemicals (LC) has reduced the problem previously associated with an inadequate level of active ingredient due to inactivation or dilution.

Barriers to the proper reprocessing of flexible endoscopes are both the lack of appropriate initial training and of ongoing competency assessment for staff performing the reprocessing. A checklist that can be used to ensure competency of staff in the flexible endoscope reprocessing area has been included in Appendix G.

PART III. FLEXIBLE ENDOSCOPES: STRUCTURE and FUNCTION

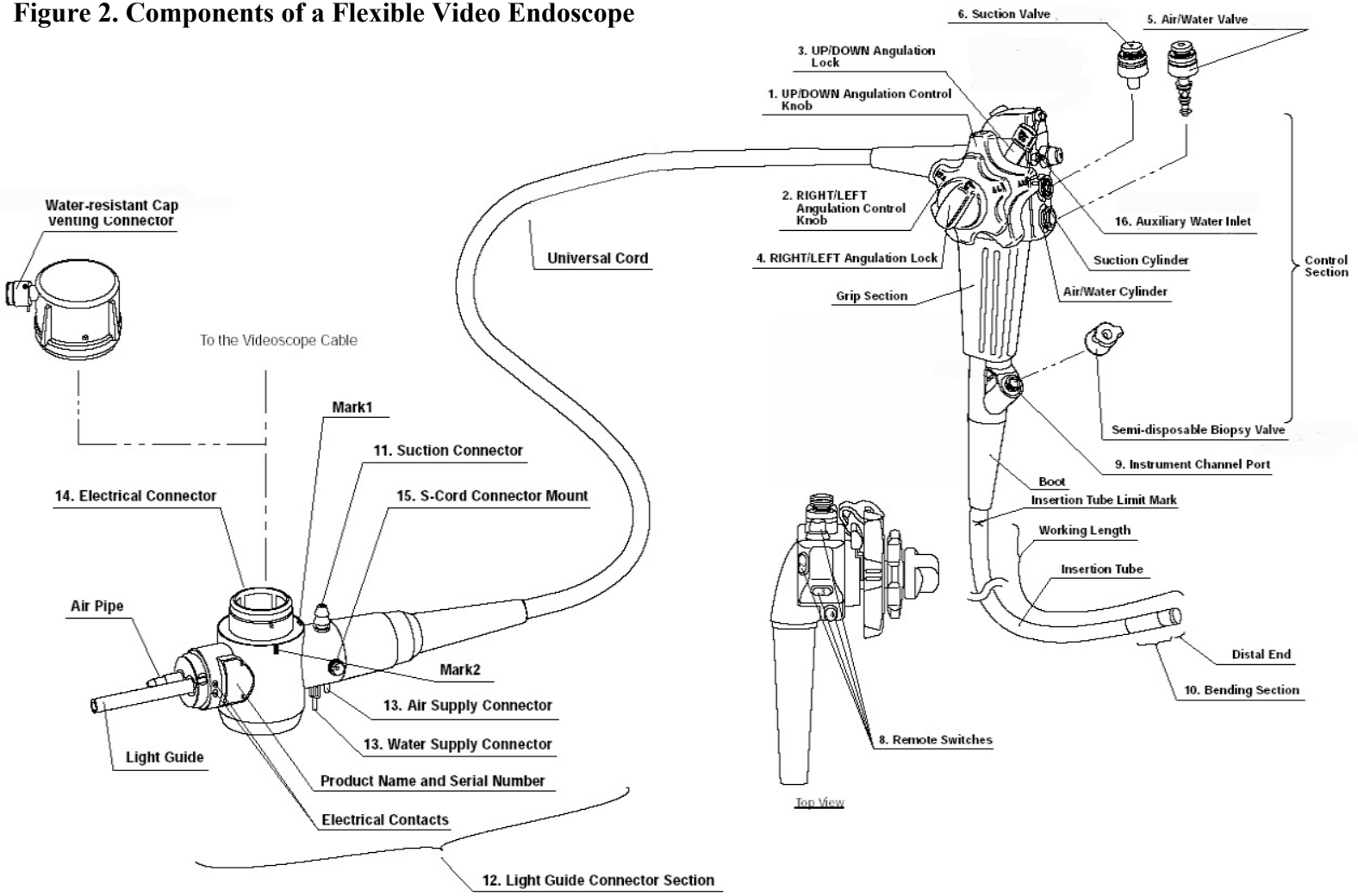
Endoscopes are very complex biomedical devices. The complexity results from the need for fiberoptic bundles and multiple long narrow channels to be contained within a tubular structure that is constrained by the limited dimensions of the body cavity opening (e.g., throat, intestine, trachea). The endoscope is only one element of the system. Other required elements are a light source, video processor, monitor and water bottle. For the purpose of describing an endoscope in these guidelines, we will refer to videoscopes, which represent a newer technology in endoscope development as compared to fiberoptic endoscopes. In videoscopes, the "viewing" fibre bundle is replaced by a miniature charged coupled device (CCD) video camera chip that transmits signals via wires. Certain endoscopes, particularly very narrow endoscopes used for direct viewing of the bile and pancreatic ducts, remain fiberoptic and require the same care in handling and reprocessing as videoscopes. Endoscopes that are not completely immersible are no longer acceptable. Videoscopes consist of three major sections: the connector section (sometimes referred to as the "umbilical" section), control section and the insertion tube. Endoscopes require a watertight internal compartment integrated through all components for electrical wiring and controls, which protects them from exposure to patient secretions during use and facilitates the endoscope being submerged for cleaning and subsequent disinfection.

The connector section (see figure 2.) provides connections for four systems:

1. Electrical System (figure 2. part 14): A cable with video signal, light control, and remote switching from the video processor is connected here. A watertight cap is required for leak testing and reprocessing. The electrical connector is the only opening to the internal components.
2. Light System (figure 2. part 12): The connector is inserted into the light source and directs light via the fiberoptic bundle in the light guide to the distal end of the insertion tube.
3. Air and Water System (figure 2. part 13): Air pressure is provided from a pump to the air pipe, and the water bottle is also connected here (there is no water channel or water connection for bronchoscopes). In some endoscope models, the separate air and water channels merge just prior to the distal end where they exit through a single channel. In other models, the air and water channels are totally separate and do not merge. The air and water channels are usually of 1mm internal diameter (I.D.), which is too small for brushing.
4. Suction System (figure 2. part 11): Portable or wall suction system is connected to the suction port. The Universal cord encases the electrical wiring and air, water and suction channels from the connector to the control section. Teflon® (PTFE) tubing is commonly used for channels, and advances in technology have led to more pliable and smooth materials for instrument channels with better anti-adhesion properties. The suction channel size can vary from 2mm to 4mm I.D. depending on scope make and model. There is a biopsy port (figure 2. part 9) on the side of the insertion tube that allows instruments to be passed down the insertion tube to the distal end (referred to as the instrument channel or biopsy/suction channel).

The control section (figure 2. parts 1-6, 8, 9, 16) has moveable knobs that allow the physician to control all scope functions. The angulation control knobs drive the angulation wires and control the bending section at the distal end of the insertion tube, thereby providing two-dimensional angulation. Locking mechanisms are provided to hold the bending section in a specific position. The suction cylinder and valve connects the suction channel to the instrument channel in the insertion tube. By pressing the valve button, suction can be provided to the instrument channel. The air/water cylinder and valve are similar to the suction cylinder/valve except that a two-way button valve is used in a dual channel cylinder thereby providing air or water to the lens at the distal end to wash and insufflate for better vision. Both valves are removable for cleaning. The air and water channels also require a cleaning adaptor valve that is to be used at the end of each procedure. Insertion of the cleaning adaptor initiates air flow through both air and water channels, and once activated, water is pumped through both channels. The instrument channel port (often referred to as the "biopsy port") is located on the lower part of the control section. It enters the instrument channel at a Y-piece union with the suction channel. A valve is required to close the port so that suctioning may be facilitated. Remote switches present on the top of the control section are usually programmable, allowing control of the video processor (i.e., contrast, iris and image capture functions).

Figure 2. Components of a Flexible Video Endoscope



Furthermore, some models have unique features that facilitate specific therapeutic applications.

Table 3. Examples of Specifications For Flexible Endoscopes

SCOPE TYPE	INSERTION TUBE O.D. (outer diameter)	WORKING LENGTH	INSTRUMENT CHANNEL I.D. (internal diameter)
Adults			
GASTROSCOPE	9.0 mm-11.4 mm	1030 mm-1050 mm	2.8 mm-3.8 mm
DUODENOSCOPE	10.8 mm-12.5 mm	1235 mm-1250 mm	3.2 mm-4.2 mm
COLONOSCOPE	12.9 mm-13.7 mm	1330 mm-1680 mm	3.7 mm-4.2 mm
SIGMOIDOSCOPE	12.8 mm-13.2 mm	700 mm-730 mm	3.7 mm-4.2 mm
ENTEROSCOPE	10.5 mm-11.7 mm	2200 mm-2500 mm	2.8 mm-3.8 mm
BRONCHOSCOPE	5.7 mm-6.0 mm	550 mm-600 mm	2.0 mm-2.8 mm
Pediatrics			
GASTROSCOPE	5.9 mm-6.0 mm	1030 mm-1050 mm	2.0 mm
COLONOSCOPE	11.5 mm-11.6 mm	1680 mm-1700 mm	3.2 mm-3.8 mm
BRONCHOSCOPE	4.4 mm-5.1mm	600 mm	2.0 mm

NB. Ranges of flexible endoscope manufactured by Olympus and Pentax, including diagnostic and therapeutic models are included in this table. These are provided as examples only and are not intended as an endorsement of a specific manufacturer's product.

Duodenoscopes have two unique features: a side viewing charged coupled device and an elevator lever that can manipulate an instrument at the distal end without moving the bending section. A cable system (elevator wire) connected to a lever at the angulation knobs in the control head is required for control. The cable is an 'external' component that is exposed to patient secretions during use. It is inside a separate channel that extends from the control head to the distal end. It is important that this channel is properly cleaned and disinfected after each use. Access to this channel is through the elevator wire port. The small inner diameter of this channel combined with the wire inside requires greater pressure to push fluids through this channel compared to the other channels. Some specialized therapeutic endoscopes such as the ultrasound endoscope may also have an elevator channel, which requires additional steps for manual cleaning and disinfection.

Therapeutic gastroscopes and colonoscopes provide options for auxiliary water channels or secondary instrument channels, each creating additional steps in the cleaning and reprocessing procedures. Therapeutic gastroscopes may have double therapeutic channels, each needing to be brushed, cleaned and disinfected. They may require additional adapters in order to effectively disinfect the endoscope.

Bronchoscopes have only an up-down angulation lever for one dimensional control of the bending section and they do not have an air water channel. Ancillary equipment required for the video system includes a video processor, monitor and light source. The video processor is solely for handling the signal from the CCD chip and this enables control for color, contrast, image enhancement and light intensity control. The light source commonly uses a 300-watt xenon lamp and provides the pump for the air/water system.

PART IV. ISSUES RELATED TO REPROCESSING FLEXIBLE ENDOSCOPES

1. Reprocessing of Flexible Endoscopes and Accessories

The complexity and temperature sensitivity of flexible endoscopes makes cleaning followed by sterilization/disinfection difficult. While sterilization may be optimal, the minimum acceptable standard for reprocessing endoscopes is high level disinfection (HLD). At all times, cleaning must precede high level disinfection. Endoscopic accessories do require sterilization.

Whenever flexible endoscopes are reprocessed, those involved in the reprocessing must adhere to the validated protocol recommended by the manufacturer of the endoscope. Table 4 provides detailed instruction, based on national and international guidelines, regarding both the specific steps and rationale for cleaning, disinfection, rinsing, drying and storage of endoscopes, regardless of the type/model. Figure 3 is a flow chart of the reprocessing steps described in Table 4.

TABLE 4. Critical Steps for Reprocessing Flexible Endoscopes[36;93-98]

NOTE: The following table is a summary guide of the critical steps for the reprocessing of flexible endoscopes. Please refer to the reprocessing manual provided by the manufacturer for each endoscope being reprocessed. Different types and models of endoscopes may require additional steps or different procedures to properly reprocess the device.
Personal protective equipment should be worn at all times during reprocessing.

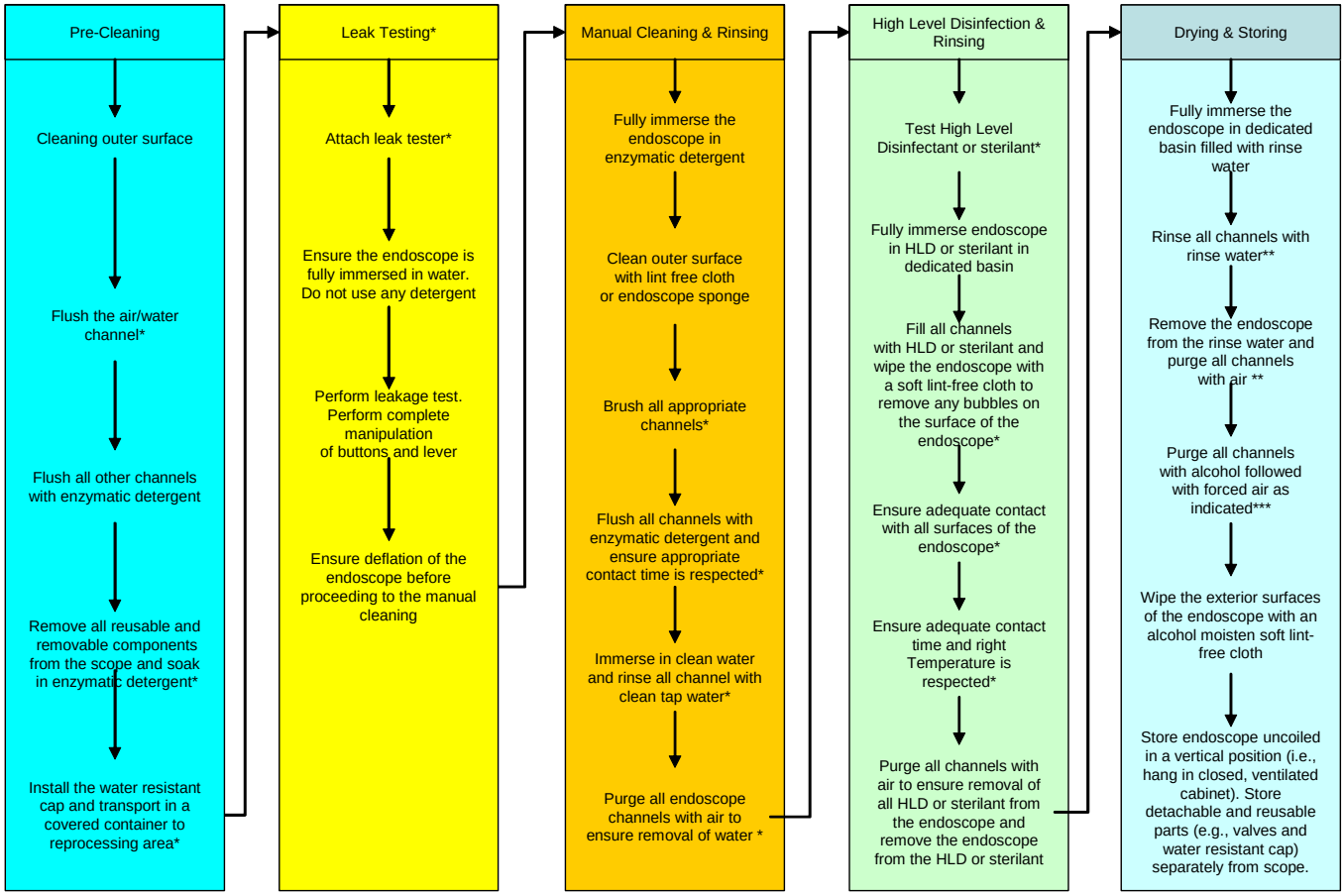
STEP OR PROCEDURE	RATIONALE	BARRIERS TO ADEQUATE REPROCESSING
Pre-Cleaning (Immediately after use in procedure room)		
1. Wipe down the insertion tube of the endoscope with a soft lint-free disposable cloth or endoscope sponge soaked in freshly prepared enzymatic detergent.	Reduces risk of worker and/or environmental contamination.	
2. Flush the air/water channels as per the manufacturer of the endoscope. Flush all other channels with enzymatic detergent solution at bedside immediately post procedure, followed by air.	Removes gross debris and ensures patient material is not allowed to dry, which will impair reprocessing.	The correct adaptors are to be used in order to properly flush all channels according to manufacturer's instructions.
3. Remove all detachable parts (e.g., valves) and reprocess accordingly. Attach the water resistant cap, if appropriate. Transport in a covered container rapidly to reprocessing area before drying of patient material occurs	Prevents patient material from drying on scope and prevents environmental contamination.	Reprocessing done off-site; may have long transit time so that secretions dry on device.
Leak Testing		
4. Perform leak testing as per manufacturer's instructions. **Note**: If a leak is detected, the endoscope must be repaired. Follow manufacturer's instructions.	If leaks are present, subsequent cleaning will allow fluid to enter the scope housing and cause damage.	Patient material can enter scope housing and will not be accessible to cleaning; sequestered soil inhibits disinfection; the residual soil acts as a source of contamination if scope used on another patient.
Manual Cleaning & Rinsing		
5. Completely immerse scope in enzymatic detergent solution.	Enzymatic detergent improves cleaning ability by breaking down proteins. Immersion reduces aerosols, thereby reducing the infectious biohazard risk to reprocessing staff.	1) Scope is not completely immersed, cleaning is not as well done. 2) Contact time with the enzymatic detergent is not adequate. 3) Full reprocessing of the endoscope is not completed promptly. If patient-used endoscopes are allowed to soak in enzymatic detergent or remain wet overnight, this will facilitate biofilm formation. 4) The enzymatic detergent is not properly diluted or the required temperature for activation of the product is not respected, which can lead to inadequate product performance.

STEP OR PROCEDURE	RATIONALE	BARRIERS TO ADEQUATE REPROCESSING
6. Clean all exterior surfaces of the endoscope using a soft lint-free cloth or endoscope sponge while keeping the endoscope immersed. Use endoscope brushes to clean ALL channels while the scope is immersed. (NOTE: not all channels can be brushed - follow manufacturer's recommendation for channel cleaning). Repeat until all debris has been removed.	Brushing greatly improves the efficiency of the cleaning process.	Inadequate brushing leads to residual patient material that can cause disinfection failure and lead to disease transmission between patients. Ensure that the brush used is appropriate for the type of endoscope and that the diameter of the bristle is adequate for the diameter of the channel. Inappropriate brushes may not dislodge biological materials or may damage the inside of the channels. Refer to the manufacturer of the endoscope for specifications of the channels.
7. Use manufacturer's cleaning adaptors to ensure adequate enzymatic detergent is flushed through ALL channels (including the elevator wire, forward jet, 2nd therapeutic channel, balloon channel), and soak in enzymatic detergent as directed by the manufacturer of the enzymatic detergent.	Residual material in any channel can pose a risk for transmitting infectious material to the next patient.	If a channel is blocked, fluid will flow preferentially through other channels. Therefore, ensure fluid is flowing through all channels. The preferred method of flushing the instrument is from umbilical end to distal end.
8. Remove the endoscope from the enzymatic detergent basin and place in a basin filled with clean water for rinsing	The enzymes are proteins and if not adequately rinsed off, can contribute to protein build-up within scope channels.	Adequate removal of detergent is not achieved when an insufficient amount of rinse water is used or with used rinse water. The pre-rinse cycle of some Automated Endoscopy Reprocessors (AERs) can be used to ensure the appropriate volume of rinsing is achieved.
9. Rinse all channels with an adequate volume of water to remove all detergent (At a minimum use approximately three times the total channel volume specific to the endoscope being reprocessed. Ensure a copious amount of water is used to remove all enzymatic detergent).	The enzymes are proteins and if not adequately rinsed off, can contribute to protein build-up within scope channels.	Adequate removal of detergent is not achieved when an insufficient amount of rinse water is used. The pre-rinse cycle of some AERs can be used to ensure the appropriate volume of rinsing is achieved.
10. Following the rinse, purge all endoscope channels with air to ensure removal of water. Wipe the exterior surfaces of the endoscope using a soft lint-free disposable cloth to remove excess moisture.	Residual water will dilute the high level disinfectant and reduce the concentration of the disinfectant.	A high level disinfectant diluted with residual water may reduce the efficacy of the disinfectant and not properly disinfect the device.
High-Level Disinfection		
11. Monitor minimal effective concentration (MEC) of the high level disinfectant or sterilant if reused. Rapid test strips specific to the product being used are available for this purpose.	The high level disinfectants that are reused can lose efficacy through excessive dilution and/or inactivation.	Lack of monitoring can result in use of ineffective high level disinfectant concentrations and inadequate microbial killing.

STEP OR PROCEDURE	RATIONALE	BARRIERS TO ADEQUATE REPROCESSING
12. Completely immerse the endoscope in a dedicated basin filled with an approved high level disinfectant or sterilant as per manufacturers' instructions. Use the endoscope cleaning adaptors to fill ALL channels with adequate high level disinfectant or sterilant (including the elevator wire, forward jet, 2nd therapeutic channel, balloon channel), and soak in the high level disinfectant or sterilant as directed by the manufacturer of the product. Wipe the endoscope with a soft lint-free cloth to remove any bubbles on the surface of the endoscope. (**NOTE: If an AER is used for reprocessing Endoscopic Retrograde Cholangiopancreatography (ERCP) scopes or other specialty endoscopes, ensure that all channels can be disinfected by the AER. Otherwise the affected channels MUST be manually cleaned/disinfected prior to placing in the AER)**.	Microbial killing needs to be effective; therefore, only disinfectants with antimycobacterial activity (e.g., high level disinfectant) or sterilants are appropriate.	Disinfectants other than those approved may result in inadequate microbial killing.
13. Adequate contact time and temperature are critical; therefore, temperature of the product should be monitored and contact time should be timed accurately as per manufacturer's recommendations. The use of a timer should be considered.	If less than the minimum effective exposure time or temperature are used, microorganisms may survive. This increases the risk of transmitting infections.	Problems with adequate timing are frequent when manual disinfection is done because timing of exposure to a high level disinfectant is often not performed. This is not an issue with AERs as long as the AER is programmed according to the manufacturer of the high level disinfectant or sterilant instructions. Temperature requirements still need to be respected while using an AER.
14. Following the disinfection, purge all channels with air to ensure removal of all high level disinfectant or sterilant from the endoscope and remove the endoscope from the high level disinfectant or sterilant.	Residual high level disinfectant and sterilants can cause tissue damage[99].	The correct adaptors are to be used in order to properly flush air through all channels according to manufacturer's instructions to remove all high level disinfectant or sterilant from the endoscope.
Rinsing		

STEP OR PROCEDURE	RATIONALE	BARRIERS TO ADEQUATE REPROCESSING
15. Immerse the endoscope in a dedicated basin filled with fresh bacteria-free or sterile water. Rinse all channels with an adequate volume of water to remove all high level disinfectant or sterilant (at a minimum use approximately three times the total channel volume specific to the endoscope being reprocessed. Ensure a copious amount of water is used to remove all high level disinfectant or sterilant). Refer to the high level disinfectant or sterilant manufacturer's recommendations for appropriate rinsing procedure. Some high level disinfectant or sterilants require several complete water exchanges. Most AERs rinse with several litres of water.	Residual high level disinfectant and sterilants can cause tissue damage[99]; therefore, adequate rinsing is critical to remove all residuals.	Problems with inadequate rinsing are possible when manual disinfection is done. Different endoscopes may require larger rinsing volume than others. Because the rinse volume in an AER is usually preset and cannot be reduced by the user unless initially programmed incorrectly, AERs provide more reliable rinsing, compared to manual methods where user variability is a problem.
16. Final rinse water should be sterile or bacteria-free. **Tap water can be used, but if it is, a subsequent 70-90% alcohol rinse is CRITICAL between each patient use and prior to storage.**	Tap water can contain *Mycobacteria, Pseudomonas* and other microorganisms. Therefore, the final rinse water should be bacteria-free (i.e., filtered through a 0.2 μm filters). Filtration can produce bacteria-free water provided there are no viruses in the water being filtered and the filters are patent.	Bacterial overgrowth within flexible endoscope channels may result from tap water microorganisms in moist channels. This has led to infection transmission between patients.
Drying		
17. Remove the endoscope from the rinse water and purge all channels with air to remove all remaining rinse water. Rinse all channels with 70% - 90 % alcohol (approximately 60 ml. flushed through all channels using the appropriate adaptors). **(NOTE: alcohol rinse and drying is not needed if scope is used immediately on another patient, unless the final rinse was with unfiltered tap water)**	This facilitates the drying of the channels and will also kill any tap water microorganisms that might be present.	Lack of drying has been associated with infection transmission between patients due to microbial overgrowth.
18. Following the alcohol rinse and prior to storing the endoscope, purge all channels with forced air. Wipe the exterior surfaces of the endoscope with an alcohol moisten soft lint-free cloth.	This facilitates the drying of the channels.	Lack of drying has been associated with infection transmission between patients due to microbial overgrowth. High pressured air (compressed air) may damage the inner structures of the endoscope. Consult the manufacturer of the endoscope for more information.
19. Store endoscope uncoiled in a vertical position (i.e., hang in closed, ventilated cabinet). Store detachable and reusable parts (e.g., valves and water resistant cap) separately from scope.	This facilitates drying of the scope during storage and reduces risk of recontamination.	Keeping valves on during storage increases the risk that residual moisture will remain, increasing the risk of microbial overgrowth and infection.

Figure 3. Flow Chart for Endoscope Reprocessing



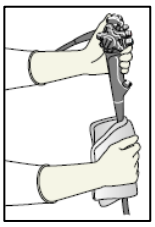
*** As per manufacturer of the product**
**** As prescribed by the manufacturer of the High Level disinfectant AND in accordance to the manufacturer of the endoscope**
***** Alcohol rinse and drying is not needed if scope is used immediately on another patient, unless the final rinse was with unfiltered tap water**

1.1. Pre-Cleaning

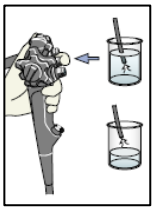
Meticulous manual cleaning of endoscopes and accessories is critical to the success of subsequent disinfection or sterilization. Manual cleaning refers to the physical removal of organic material and/or soil. The presence of residual organic material and/or soil may protect microorganisms from penetration and destruction by germicides, therefore contributing to disinfection or sterilization failure.

The initial steps in the cleaning process begin immediately after the patient procedure to prevent drying of secretions on both the exterior surface and inner channels of the endoscope[9;15]. At the conclusion of the procedure, and before transporting the endoscope to the reprocessing area, the following steps need to be performed:

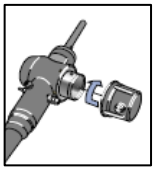
- Wipe the insertion tube with a soft lint-free cloth or endoscope sponge soaked in freshly prepared enzymatic detergent.
- Flush the air/water channels as per the endoscope manufacturer's instructions.



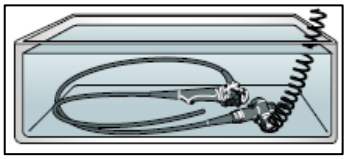
- Flush all other channels with enzymatic detergent solution at bedside immediately after the procedure, followed by flushing with air.
- Flush all the internal channels with freshly prepared enzymatic detergent to moisten and dilute organic debris.
- Remove all detachable parts and have them reprocessed accordingly.



- Attach the water resistant cap (if indicated).
- Immediately transport in a covered container to the reprocessing area.



1.2. Leak Test



The goal of performing a leak test is to detect any physical breaks to the exterior or interior of the endoscope[4;60]. These physical breaks compromise the integrity of the endoscope and will damage the internal structures (i.e., electrical wires, light bundle, manipulation cables) of the endoscope, which are not meant to be in contact with fluids. These breaks may also create a reservoir for microorganisms to proliferate[4]. Leak testing should be done after each procedure and prior to manual cleaning.

A leak test is performed by applying air pressure to the inside of the endoscope and by monitoring the presence of air bubbles coming from the endoscope[4] or by the inability to maintain adequate air pressure within the endoscope.

If a leak is detected, immediately remove the endoscope from service and have the device repaired or replaced. Refer to the manufacturer's instructions for proper decontamination and transportation of broken endoscopes. Always perform leak tests as per the manufacturer's instructions[4;60].

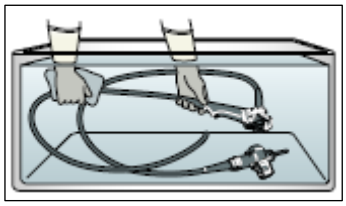
1.3. Manual Cleaning and Rinsing

Manual cleaning of flexible endoscopes is prone to error and must therefore be done with care.

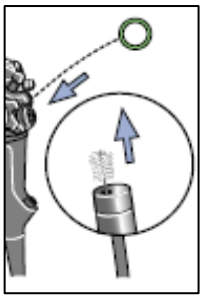
A problem that may be encountered by the reprocessing staff is unfamiliarity with all of the channels for the particular model of flexible endoscope being reprocessed. This highlights the need for staff training and ongoing competency testing and quality assurance. It is useful to have diagrams of type/models being reprocessed in the healthcare facility that clearly identify all the channels that must be cleaned and disinfected.

The enzymatic detergent used for cleaning flexible endoscopes (follow the manufacturer's recommendations for reconstitution and application) is a protein solution, and therefore if rinsing is not adequate after the cleaning process, there will be residual detergent protein remaining. If an inadequately rinsed endoscope is then placed in an aldehyde disinfectant, the residual detergent protein will be "fixed" within the channels and on the surface of the endoscope, possibly protecting underlying bacteria from exposure to the disinfectant.

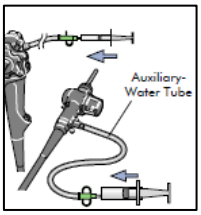
- After successfully carrying out the leak test, completely immerse the endoscope in a freshly prepared enzymatic detergent solution (prepared as per the manufacturer's instructions).



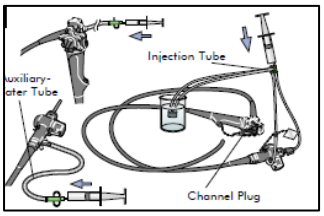
- Clean all exterior surfaces of the endoscope using a soft lint-free cloth or endoscope sponge while keeping the endoscope immersed.
- Use endoscope brushes to clean ALL channels while the scope is immersed. (**NOTE**: not all channels can be brushed - follow the manufacturer's recommendations for channel cleaning). **Repeat until all debris has been removed.** Flexible endoscopes have multiple channels with different diameters, so it is essential that a variety of brushes be available for use. Brushes should be of the correct diameter and length to ensure that the bristle will make contact (provide friction) with the walls of the lumens.



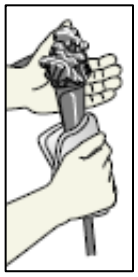
- Use the manufacturer's cleaning adaptors to ensure adequate enzymatic detergent is flushed through ALL channels (including the elevator wire, forward jet, 2nd therapeutic channel, balloon channel), and soak in enzymatic detergent as directed by the manufacturer of the enzymatic detergent.



- Remove the endoscope from the enzymatic detergent basin and place in a basin filled with clean water for rinsing.
- Rinse all channels with an adequate volume of water to remove all detergent (At a minimum use approximately three times the total channel volume specific to the endoscope being reprocessed. Ensure a copious amount of water is used to remove all enzymatic detergent). The use of potable tap water for rinsing after endoscope cleaning is acceptable.



- Following the rinse, purge all endoscope channels with air to ensure removal of water. Wipe the exterior surfaces of the endoscope using a soft lint-free disposable cloth to remove excess moisture.



All channels should be brushed and rinsed prior to disinfection[1;3;6;21;47;64;100].

Ideally, cleaning and disinfection of endoscopes should be performed immediately after use. There may be instances where this is difficult to achieve (e.g., emergency procedures after hours). If immediate cleaning is not possible, the endoscope may be flushed and soaked in an enzymatic detergent solution until properly reprocessed[101]. If the endoscope has been cleaned, but not disinfected, and left to soak, it should be thoroughly cleaned again prior to disinfection. If flexible endoscopes are inadvertently left overnight prior to cleaning, the manual cleaning stage must be performed thoroughly prior to disinfection/sterilization. As outlined in the previous discussion on biofilm formation, allowing a flexible endoscope to sit overnight with residual microorganisms and patient secretions in the channels will lead to biofilm formation that may be difficult to subsequently remove. Consult the manufacturer of the endoscope for special directives on delayed reprocessing.

Few published studies address whether washing by the automated endoscope reprocessor as part of flexible endoscope reprocessing can replace manual cleaning. One article found that the automated washing phase of the endoscope reprocessing system studied was equivalent to optimal manual cleaning for the makes and models of flexible endoscopes tested[95]. As new technological advances develop and Automated Endoscope Reprocessors (AERs) with a washing cycle are marketed, there will be the need to assess the cleaning efficacy of these new devices. Until such studies are completed, cleaning needs to be done manually.

1.4. Disinfection and Sterilization

Sterilization is considered optimal, however, the minimum acceptable standard for reprocessing endoscopes is high level disinfection (HLD). Currently, most of the available flexible endoscopes are temperature sensitive and cannot undergo steam sterilization. (**Note**: there are some makes of bronchoscopes that can be steam sterilized, but these are not widely used).

If a high level disinfectant is used, it is critical that exposure time, temperature and concentration of the active ingredient are consistently achieved and strictly controlled.

1.4.1. Selection of a High Level Disinfectant Product

The characteristics of an ideal liquid chemical (LC) agent used as a high level disinfectant should include broad antimicrobial spectrum, rapid onset of action, compatibility with delicate instruments, lack of toxicity for healthcare staff, patients and the environment, no odour, non-staining, unrestricted disposal, prolonged reuse and shelf life, ease of use, remains active in the presence of protein and organic material, ability to be monitored for concentration, and relatively low cost. No currently marketed product satisfies all these criteria. Major disadvantages include material incompatibility (e.g., peracetic acid, hydrogen peroxide) and human toxicity (e.g., glutaraldehyde)[102].

Despite their limitations, LC agents are convenient, relatively fast- acting, and universally used to reprocess flexible endoscopes and other instruments. When selecting a high level disinfectant product, infection prevention personnel should assess their institution's requirements (e.g., number of endoscopes processed per day, training, turnaround time required), obtain cost information, and know provincial and federal regulations regarding safe use and disposal requirements. It is important that healthcare workers who use any high level disinfectant, be familiar with and have readily accessible, product/brand-specific Material Safety Data Sheets (MSDS) for all chemicals used, and keep current with developments in products and practice. **Table 5** lists the currently approved low temperature products/methods for disinfection/ sterilization of flexible endoscopes and comments regarding appropriate use. For detailed information on advantages and disadvantages of available high level disinfectant products, the reader is referred to *Best Practices for Cleaning, Disinfection and Sterilization In All Health Care Settings*[2;12;102].

1.4.2. Liquid Chemical Agents

The most common method for disinfection/sterilization of flexible endoscopes is the use of liquid chemical (LC) agents including glutaraldehyde, ortho-phthalaldehyde (OPA), peracetic acid, and hydrogen peroxide (see **Table 5**). Glutaraldehyde has exposure threshold limit values as specified in provincial Occupational Health and Safety (OH&S) regulations and special air-handling requirements are necessary when this agent is used, due to its propensity to cause sensitization reactions in some healthcare workers. The correct contact time for the particular chemical agent used must be adhered to as indicated in **Table 5**. Glutaraldehyde (either alkaline or acidic) requires a minimum of 20 minutes contact time at room temperature. Although the manufacturer recommends 45 minutes contact time at 25°C, current guidelines and expert opinion confirm that 20 minutes at room temperature (20°C) is adequate provided that thorough pre-cleaning has been performed prior to exposure to the glutaraldehyde[1;3;38;40;90;103-105]. Ortho-phthalaldehyde (OPA) has the shortest exposure time at 10 minutes at room temperature (min 20°C), or a contact time of 5 minutes if used in AERs at a minimum temperature of 25°C.

The information listed in **Table 5** is current at the time of publication. Always refer to the manufacturer's instructions for product and for further details. Ensure that a Drug Identification Number (DIN), indication that the product is licensed by Health Canada for the Canadian market, is on the product container.

1.4.3. Low Temperature Gas and Gas Plasma Sterilization

Sterilization must be performed if the endoscope enters the body through an incision, as with intraoperative enteroscopy[12;14]. Low-temperature sterilization (<60 degrees C.) is required for temperature and moisture-sensitive critical medical devices. All currently developed sterilization processes have limitations and these must be understood to ensure the proper application of new sterilization technologies within medical facilities[106].

Regardless of the sterilization method used, scrupulous manual cleaning must precede sterilization to remove organic debris and salts[107-111]

Ethylene oxide (ETO) has been the most widely used low-temperature sterilization process. The compatibility of ETO with a wide range of materials has made it the most suitable process for the majority of heat and/or moisture-sensitive medical devices, however, there are potential toxic hazards to staff , patients and the environment, as well as risks associated with handling a flammable gas[112]. The International Agency for Research on Cancer (IARC) has upgraded its classification for ETO from 2A to a group 1 (known human carcinogen)[113]. A properly designed ventilation system dedicated to removing ethylene oxide, safe workplace practices and ongoing training can minimize the worker's exposure to the product[114].

Ethylene oxide (ETO) is an acceptable method of sterilizing flexible endoscopes, however, a lengthy aeration time is required for equipment post-exposure in order to allow desorption of all residual toxic gas from the endoscope to occur. In addition, additional steps must be taken (e.g., application of a venting valve or the removal of the water resistant cap) to ensure proper perfusion with the gas and to prevent damage due to pressure build-up. There are specific cases for holding flexible endoscopes during this process (manufacturer's recommendations should be followed). **Do not** place flexible endoscopes in their storage cases when being sterilized using ETO.

Low-temperature hydrogen peroxide gas plasma sterilization has been used in hospitals worldwide for over a decade[115]. Unlike ETO, hydrogen peroxide is not toxic and does not leave significant residue on the sterilized instruments. Alfa[107;116] demonstrated difficulty in achieving sterilization of narrow lumens in the presence of serum and salt with plasma-based sterilization systems. She also demonstrated that a lumen adaptor/booster, which supplies an additional source of hydrogen peroxide within the lumen, appears to improve the effectiveness of the plasma sterilization process. Newer gas plasma sterilization technologies have been found to be superior to older systems and improve the margin of safety of this sterilization process[109;117-119].

When reprocessing an endoscope with a hydrogen peroxide gas plasma sterilization process, ensure the lumens are made of Teflon® or polyethylene and that the lumens conform to the dimensions specified by the manufacturer for the specific sterilizer. Ascertain that the endoscope is made of materials that are compatible with this reprocessing method. Should the lumens or materials not conform to the manufacturer's recommendations, consult with the manufacturer of the endoscope for information on how to properly sterilize the device.

Table 5. High Level Disinfectants/Sterilization Methods Currently Used for Reprocessing Flexible Endoscopes

ACTIVE INGREDIENT	CONTACT TIME	COMMENTS
High Level Disinfection		
2% Glutaraldehyde	minimum of 45 minutes at 25ºC is indicated by the manufacturers (a minimum of 20 minutes at room temperature (20ºC) is adequate according to expert opinion and published guidelines)	• Aldehydes are protein fixatives, therefore it is critical that medical devices have been thoroughly cleaned and rinsed prior to exposing to glutaraldehyde as any residual protein will be fixed onto the surface by this high level disinfectant. Because of this protein fixing property, aldehydes should not be used for reprocessing scopes used in patients with suspect, possible, or proven prion infection. • Vapours from glutaraldehyde are sensitizing and work areas need to be properly ventilated to ensure levels are below threshold limit values (TLVs) specified in Occupational Health & Safety (OH&S) regulations. Use of an AER mitigates this aspect. • Recirculation of air in the area where the product is used is prohibited by OH&S regulations and ventilation must be to the exterior. The product Material Safety Data Sheet (MSDS) stipulates 10 fresh air exchanges/hour in the area where product is used. • Scheduled air quality monitoring is essential to ensure control of glutaraldehyde vapours. • Glutaraldehyde is reusable for 14 to 28 days (depending upon formulation). • Minimal effective concentration (MEC) testing is required. • Glutaraldehyde has a long history of use and is less expensive/gallon than other agents. • Disposal down the drain may be regulated in some areas.

ACTIVE INGREDIENT	CONTACT TIME	COMMENTS
Ortho-phthalaldehyde (OPA)	minimum of 10 minutes at room temperature (20°C); minimum of 5 minutes at 25°C (when used with an AER)	• OPA is an aldehyde and cross-links proteins similarly to glutaraldehyde, however it is much less active as a fixative compared to glutaraldehyde. Because of this protein fixing property, it should not be used for reprocessing scopes used in patients with suspect, possible, or proven prion infection. • Fumes may cause sensitization but there are fewer problems with air levels compared to vapours from glutaraldehyde. The product MSDS stipulate 10 fresh air changes/hour in the area where product is used. • No air quality monitoring for vapours is required. • OPA is reusable for 14 days. • MEC testing is required. • Rinsing after exposure to OPA is critical as OPA is hydrophobic and hard to rinse off flexible endoscopes. Use of AERs facilitates adequate rinsing post-exposure. • OPA is more costly than some products.
7.5% Hydrogen Peroxide (Some 3-4% formulations have also been validated for high level disinfectant-check manufacturer's label claims)	15 to 30 minutes at 21°C (depending upon formulation)	• Materials compatibility issues have been documented with brass and copper, thus the product is not widely used for flexible endoscopes. • MEC testing is required. • The product is reusable for 14 days.
0.2% Peracetic Acid	5 minutes at 30°C or 12 minute at 50-56°C depending on the formulation	• No vapour issues exist (except during accidental spills). • Product can be disposed of down the drain. • Product causes cosmetic changes to aluminum anodized coating.
Sterilization		
Ethylene Oxide (ETO) (100% formulation, or carrier gas that is not Freon® based)	30 minutes to 1 hour exposure (depending on sterilizer)	• 8-12 hours mechanical aeration is required at 50-60°C[120]. • Monitoring of ETO exposure levels for staff is required as per TLV in OH&S regulations. Federal regulations must be followed[114];[121]. • Recirculation of air in the area where the product is used is prohibited by OH&S regulations and ventilation must be to the exterior. • Special ETO approved cases are needed for flexible endoscopes.

ACTIVE INGREDIENT	CONTACT TIME	COMMENTS
Gas Plasma (vaporized hydrogen peroxide)	~ 50 minutes	• Product is safe for the environment, as there are no fumes. • Limitation due to poor penetration of the gas in long and narrow lumens • Limitation in material compatibility. • Only wraps appropriate for use with gas plasma can be used.

Note: Readers are advised to check the Health Canada – Therapeutic Product Directorate (TPD) website for updated licensing information.

1.4.4. Automated Endoscope Reprocessors (AERs)

Automated endoscope reprocessors (AERs) standardize the disinfection process and decrease personnel exposure to a high level disinfectant and sterilants[122;123]. The AER manufacturer is to provide a list of the flexible endoscopes that have been validated for reprocessing in their specific AERs, and a list of chemical disinfectants/ sterilants that can be used with the AER[124]. Some AERs use dedicated single-use liquid chemical agents whereas other AERs may accommodate a range of reusable high level disinfectants. In each case, the AER manufacturer's device-specific instructions must be followed and only endoscopes that are compatible with the AER (as indicated by the endoscope and AER manufacturer) should be reprocessed by these methods.

If the AER manufacturer recommends that connectors be used for flexible endoscopes reprocessed in the AER, then the correct connector for the specific endoscope being reprocessed must be used[124-126]. Current AERs will always have disinfection and rinse cycles. In addition to these basic disinfection and rinse cycles, they may also have one or more of the following capabilities: leak testing, cleaning cycle, alcohol rinse, and drying cycle.

Regardless of the AER used, manual cleaning (including thorough rinsing) must be performed prior to placing the flexible endoscope into the AER (even if the AER cleaning cycle is used)[123;124].

Utilization of the AER cleaning cycle provides an extra margin of safety by providing additional cleaning, **but it does not replace the absolute requirement for thorough manual cleaning**. Also, even if the AER has leak testing capacity, manual leak testing should still be performed prior to manual cleaning. If an alcohol rinse is not part of the AER cycle, this step needs to be performed prior to manual forced air-drying when the flexible endoscope is going into storage.

Investigations of infections following bronchoscopy have revealed breaches in the reprocessing procedure associated with the AER[34;65]. Reports have also identified inconsistencies between the reprocessing instructions provided by the AER manufacturer and the endoscope manufacturer leading to bronchoscopes being inadequately reprocessed when inappropriate channel connectors were used[126;127]. In Canada, awareness of microbial growth in critical components of the AER even when recommended AER maintenance had been followed has further added to the concern over problems with AERs. As a result, the Therapeutic Product Directorate (formerly the Health Product and Food Branch) of Health Canada has issued recommendations for selecting an AER[124]. The criteria listed in **Table 6** are also detailed in Part V. Recommendations for Endoscopy and Endoscopy Decontamination Equipment, Section 2.0 (f) i-vii of this guideline.

Table 6: Selection of an Automatic Endoscope Reprocessor[124]

When purchasing an AER, ensure the following criteria are met:
• the AER is licensed for sale in Canada, • there are no potential reservoirs of infection - areas in the AER where water or disinfectant can stagnate, • the AER can effectively irrigate all channels of any endoscope to be reprocessed in the AER, ensuring effective contact between the chemical disinfectant and the channel walls, • for wash cycles ensure that all wash fluids (water and chemicals) are completely drained and discarded following each wash cycle ensuring that there are no potential reservoirs of infection (areas in the AER where water can stagnate) and reuse of contaminated wash fluid is not possible, • for the disinfection cycle, ensure that water and chemicals are completely drained between cycles, • if the AER uses a single-use disinfectant ensure that the disinfectant is completely drained and discarded after each cycle, • if the AER uses a reusable disinfectant, ensure that the minimum effective concentration (MEC) is monitored daily using test strips available from the supplier of the disinfectant. Discard the disinfectant in accordance with local regulations at the end of the disinfectant's specified reuse life (as specified by the disinfectant supplier) or following a failed MEC test, whichever comes first, • the cycle length and temperature can be adjusted to ensure high-level disinfection or sterilization based on the disinfectant/sterilant used, • the cycle length can be adjusted to ensure adequate rinsing based on the type of endoscope being reprocessed, • the manufacturer of the AER identifies by brand and model each endoscope that may be effectively reprocessed in the AER and the limitations of the AER in reprocessing certain models of endoscopes and accessories (e.g.: the lumen diameter of the elevator wire channel in a duodenoscope may not permit adequate fluid flow to effectively reprocess this are of the endoscope).

1.4.5. Reprocessing Endoscopic Accessories

Because of their complex nature, attention and adherence to a validated protocol is critical for reprocessing endoscope accessories. Accessories such as biopsy forceps, papillotomes, sphincterotomes and cytology brushes may be available as single-use (disposable) or reusable instruments. All reusable endoscopic accessories that breach mucosal barriers are considered critical and require cleaning with an ultrasonic cleaner followed by sterilization between patients[4;12;14;47]. Manufacturer's guidelines for the care and usage of reusable products must be strictly followed[11;128].

It is important that each institution be fully aware of the issues involved in accessory device selection. For instance, if reusable accessory devices are used, the institution must have appropriate cleaning equipment (e.g., ultrasonic cleaner) to accommodate proper reprocessing.

Contaminated or damaged medical devices pose a potential source for cross-contamination, infection and injury to patients and personnel. In an outbreak of 8 cases of *Salmonella newport* infection among patients undergoing colonoscopy, the epidemic strain was not recovered from the four colonoscopes used during the outbreak but was recovered from the spiral-wound spring of a pair of biopsy forceps, which are difficult to clean mechanically[58]. Presently the only method that effectively penetrates the metal coils of the spring is steam under pressure[4;101].

Although still controversial, the reuse of critical and semi-critical single-use devices (SUDs) has been commonplace in many institutions, and undertaken primarily for economic reasons[129]. The results of a recent survey show that Canadian hospital practices have not changed much in the last decade and that a minority of hospitals reprocess SUDs[130]. In the US, guidelines stipulate that the reprocessing of single-use devices must conform to the same standard as the manufacturer provides. While there are some third party companies that provide this service, it must be rigorous and controlled. Currently there are no licensed third party reprocessors in Canada[2;131].

In circumstances where the manufacturer does not approve of reuse, the facility will be legally responsible in establishing when and under what conditions the reuse of medical devices presents no increased risk to patients and that a reasonable standard of care was maintained during reuse of the device. All institutions that choose to reuse single-use accessory devices need to validate the sterility and integrity of the reprocessed devices, and have in place detailed protocols that include mechanisms for ongoing evaluation and quality assurance monitoring. This includes the training and retraining of staff, as well as policies and standards to determine the maximum number of uses for the device and to track their usages[132-134]. In general, the reuse of single use medical devices is discouraged.

Table 7 - Health Canada Recommendations[124]

I. Reusable Medical Devices

- Healthcare facilities and healthcare providers should review instructions provided by the manufacturer prior to the purchase of reusable medical devices to ensure that the device can be adequately reprocessed with available equipment.
- Healthcare facilities and healthcare providers should require that manufacturers include complete instructions for use, disassembly, cleaning, reassembly and sterilization with all reusable devices, and that they provide appropriate training to users where such training is essential to the safe use of the device.
- Healthcare facilities and healthcare providers should establish procedures and provide training for staff to ensure that reusable devices are, cleaned, and sterilized according to the manufacturer's instructions. These instructions should be filed so that they can be easily retrieved and consulted by users.
- Healthcare facilities and healthcare providers should validate and regularly review their sterilization procedures and ensure that they are being followed.

- Healthcare facilities and healthcare providers should report to Health Canada any cases in which the manufacturer does not provide adequate instructions for use, cleaning and sterilization of a reusable device.

II. Single-Use Medical Devices

- Health Canada is concerned that reusing single-use devices may be hazardous to patients. Health Canada is addressing this issue in consultation with the Provinces, Territories, and stakeholders.

1.4.6. Valves and Water Bottles

Outbreaks involving removable parts such as suction valves[59] have been reported. Following each endoscopic procedure, valves must be removed from the endoscope, manually cleaned, and high level disinfected or sterilized according to the manufacturer's instructions. It is imperative that all crevices be stringently cleaned so as to be free of debris. The use of an ultrasonic cleaner to enhance soil removal is recommended. Adequate rinsing must be done after sonication to remove any loosened soil. Water bottles and their connecting tubing should be sterilized or, at a minimum, high level disinfected at least daily and sterile water only should be used to fill the bottles[1;33;85;135].

Note: Each ERCP procedure requires a fresh sterile bottle filled with sterile water[1;135].

2. Sheathed Endoscopes

One approach that has been proposed to avoid the need for an elaborate reprocessing procedure is to use a sheathed endoscope. The sheathed endoscope includes a reusable endoscope without channels, and a sterile sheath set comprising a single disposable unit: a sheath; air, water, and suction channels; a distal window; and a cover for the endoscope's control body. All contaminated surfaces, including the channels, are then discarded, thereby eliminating any concern for cross-transmission of infectious agents from the previous patient[136]. There are few studies concerning the use of sheathed instruments for upper and lower endoscopy. In one prospective study[137], investigators found that the reprocessing turn-around time of the sheathed instrument was significantly faster (i.e., 9.6 minutes versus 47 minutes) than for a conventional gastroscope. Other studies[138;139] have reported similar results with reduced instrument turn-around time, but there are concerns about the functional ability of the sheathed endoscopes as well as the cost of the sheath compared to the cost of reprocessing the endoscope[140].

3. Storage of Flexible Endoscopes

Flexible endoscopes should be stored in a designated cabinet with a door, in a manner that prevents recontamination or damage[141].

Storage cabinets should meet the following criteria:

- made of material that can be disinfected weekly with an approved low-level disinfectant,
- ventilated when doors are closed,
- not situated in a procedure room, reprocessing area, or a high traffic area,
- easily accessible to ensure scopes can be placed inside without damage and without putting the HCW at risk (e.g., HCW must reach a high shelf where endoscope is stored),
- should accommodate a sufficient number of endoscope to support the patient volume,
- designed to allow scopes to be stored in the vertical uncoiled position to facilitate drying.

There are storage cabinets available with connections that provide airflow through the endoscope channels, thereby ensuring thorough drying of the channels[142]. Such special storage cabinets are not necessary if adequate manual drying is achieved prior to storage. If a flexible endoscope is to be stored without being used for more than a week, it must be reprocessed prior to use[143-146].

It is critical that the valves are stored separately from the endoscope. They may be placed in a mesh bag and hung on the scope but should not be positioned in the valve port of the endoscope. Storage of endoscopes with the valves in place can trap moisture within the channels and lead to microbial growth and biofilm formation within the channels[141].

The carrying case used to transport clean and reprocessed endoscopes outside of the healthcare environment should not be used to store an endoscope or to transport the instrument within the healthcare facility. An endoscope placed in its transport case will require reprocessing before use on a patient. Should the transport case become contaminated, contact the manufacturer for further instructions. In some instances, the transport case may need to be discarded[85;147].

4. Quality Management

Proper reprocessing of flexible endoscopes is mandatory to ensure safety of patients undergoing pulmonary and GI endoscopy. A quality management program should include the following elements[4;6;11;101;148].

Staff training

- The assigned staff must have received sufficient training to safely and properly perform the reprocessing process. The training should be ongoing and includes hands on training with the specific endoscopes used in the facility and should be documented by the supervising educator.

- The introduction of new equipments should be preceded by adequate training of the staff. An annual recertification program should be considered.
- The use of written protocols with frequent reminders to staff to not deviate from written instructions.

Administrative

- Equipment monitoring including visual inspection to identify conditions that may affect the cleaning or disinfecting process.
- Maintain a record of each endoscopic procedure, including but not limited to: the type of procedure with date & time, model and serial number of the endoscope used, patient information, staff involved with the procedure, information on the reprocessing method (e.g., AER serial number or identifier, chemical used, staff performing the reprocessing). This information will facilitate the ability to retrospectively link the scope used for each patient procedure.
- Annual audits of the reprocessing processes and infection prevention and control practices.
- A preventative maintenance program should be in place for all medical devices (i.e., endoscopes, AER, leak tester).
- A surveillance system capable of detecting clusters of infections or pseudo-infections associated with endoscopic procedures.
- Inform infection prevention and control personnel of any suspected or identified infection.
- **Ensure infection prevention and control personnel are consulted when reviewing, changing or updating the reprocessing procedure or policy.**

4.1. Staff Training

The reprocessing of flexible endoscopes has a narrow safety margin due to the complexity of the devices and the processes used. Deviation from the manufacturer's recommendations for reprocessing could potentially lead to residual microorganisms being left on the device and thus increase the risk of infection[95]. The reprocessing of flexible scopes, like all human endeavours, is prone to error as it is a multi-step process relying on both humans and automated or manual cleaning equipment. Inexperienced or untrained staff handling flexible endoscopes during reprocessing increases the likelihood of errors. A major element of quality management is ensuring the provision of device-specific training for endoscopy staff and ongoing competency testing to ensure compliance with protocols.

Competent personnel that maintain consistent excellence in practice are crucial to proper cleaning and disinfection of endoscopes[2-4;6;7;9;11;16;45;85;91;149].

Infection Prevention and Control education is a critical part of the orientation and continuing education for all personnel, including physicians, nurses, and technical staff who work in the endoscopy setting[6;9]. The orientation and continuing education program should include, but not be limited to, the following topics:

- Mechanisms of disease transmission,
- Routine Practices and Additional Precautions,
- The appropriate use of personal protective equipment,
- Occupational health and safety regulations,
- Reprocessing procedures for flexible endoscopes and accessories,
- Safe work practices,
- Safe handling of chemicals used in reprocessing,
- Safe waste management.

See **Appendix G** for sample training protocol.

4.2. Preventative Maintenance and Repair

Periodic assessments of the endoscopes by qualified personnel can reduce both patient risk and repair costs. Manufacturers will provide trained technical personnel for such assessments and in-house service. Repairs should always meet or exceed the manufacturer's original specifications and Original Equipment Manufacturer (OEM) parts should be used. Detecting the need for minor repairs before further damage occurs can prevent use of a substandard endoscope on a patient, and may also prevent unnecessary major repairs and cost.

During the manual cleaning process, trained personnel should inspect devices for functionality and damage[4;11]. If an endoscope requires repairs, it is important to ensure proper disinfection; if disinfection is not possible, then handling precautions as specified by the service vendor must be followed when shipping a contaminated endoscope, and according to provincial and federal guidelines for the transportation of dangerous goods[11]. When an endoscope requires repairs by a party other than the original manufacturer (i.e., third party repairs), the provider of the service should provide information that the new or repaired product meets or exceeds the specifications of the original product (e.g., if the suction channel is changed or repaired, the material used should be physically compatible with the high level disinfectant used).

> Repairs must be performed by a party knowledgeable on the various materials used for repairs and on the mechanical complexity of the flexible endoscope being repaired.

4.3. Monitoring Microbial Bioburden in Flexible Endoscope Channels

There are two potential problems that may arise during the reprocessing of flexible endoscopes: i) persistence of organic material if cleaning is inadequate, and ii) presence of residual microorganisms if high-level disinfection /sterilization are suboptimal or if endoscopes are not dried before storage. The role of ongoing environmental endoscopic surveillance cultures to monitor the effectiveness of routine cleaning and disinfection techniques remains controversial. Australian[10], French[150], and the European Society of Gastrointestinal Endoscopy (ESGE) and the European Society of Gastroenterology and Endoscopy Nurses and Associates (ESGENA)[151] guidelines advocate routine culturing of flexible endoscopes and AER for specific pathogens.

North American guidelines, for the most part, do not recommend routine monitoring of endoscope channels unless infection transmission, an outbreak, or a reprocessing error has been identified[3;4]. Routine bioburden monitoring of flexible endoscope channels may be useful as a "process monitor" by providing a valuable quality assurance tool to help identify previously unknown problems with the reprocessing process[135;136;152-154]. The results of this monitoring could be used to reinforce staff compliance with proper reprocessing techniques or identify a need to revise reprocessing policies and procedures. Bioburden monitoring should not be used to identify a specific endoscope in need of better reprocessing before use. Whether patient disclosure is required post-endoscopy if deficiencies in reprocessing are identified through the process monitor is controversial. **Appendix D** provides an outline of how bioburden testing could be performed as part of an outbreak investigation.

5. Healthcare Worker Protection During Endoscopy/Bronchoscopy and During Equipment Reprocessing

5.1. Hazards During Endoscopy

Endoscopy and bronchoscopy procedures can put both the patient and the healthcare worker (HCW) performing the procedure at risk for infection. Although transmission of a blood borne pathogen from patient to HCW during endoscopy has not been documented, it is possible. A needlestick or "sharp" injury involving an infected patient represents the greatest risk of transmission of a blood borne pathogen to HCWs. The probability of transmission from a needlestick/sharp injury has been estimated at up to 30% for HBV, 4% for HCV, and 0.25% for HIV[19;155]. The likelihood of percutaneous exposure to blood borne pathogens relates primarily to injury with sharp, contaminated endoscopic accessories (e.g., snares, biopsy forceps). However, the possibility of mucous membrane exposure to contaminated secretions is real if personal protective equipment (PPE) is not worn[13;46]. It is essential that all HCWs working in the endoscopy unit follow Routine Practices to minimize the risk of infection.

Of equal concern is the risk for transmission of tuberculosis (TB) from infected patients who are undergoing bronchoscopy[72]. Infection prevention and control precautions stipulate staff use of N95 respirators when patients with a potential respiratory infection are undergoing bronchoscopy.

5.2. Hazards During Reprocessing

Reprocessing procedures present the potential risk of biological (e.g., infectious agents) and chemical (e.g., high level disinfectant) exposures. HCW infection can occur during improper handling of patient contaminated instruments, such as the endoscope or accessories after the procedure. Prior to undertaking any cleaning of a flexible endoscope, personnel should put on the appropriate PPE. Reprocessing staff need to recognize that even after the flexible endoscope has been manually cleaned, there may still be viable infectious microorganisms in or on the endoscope (the cleaning process does not disinfect the endoscope) and appropriate use of PPE is still necessary for handling the endoscope after cleaning.

Cleaning and disinfecting endoscopes involves the use of chemicals that can emit toxic fumes and exacerbate allergies. To avoid danger to staff, patients, and the environment, prudent use as

well as established safety precautions are required. Refer to the product label of each product or the MSDS associated with each product for appropriate handling.

5.3. Infection Prevention and Control Practices and Precautions

The most important ways to prevent acquiring an infection are to perform good hand hygiene and wear the appropriate PPE. In addition, proper removal of PPE after the procedure is essential, as the PPE itself can be a source of infection. All personnel involved in the endoscopic procedure and/or reprocessing the endoscope after use require education in the basic principles of 'Routine Practices'[13] and 'Hand Hygiene'[12]. Hand hygiene should be performed before and after every contact with a patient and his/her surroundings[12;156]. Gloves and a fluid resistant gown should be worn during an endoscopic procedure and while cleaning endoscopes. Gowns should be changed between patient procedures, after cleaning instruments, and/ or when they are dirty[157]. Although rare, there have been case reports of HCV transmission from a blood splash to the conjunctiva of HCWs[158;159], as has a case of bacterial conjunctivitis following a splash during colonoscopy[73]. Therefore, facial protection (i.e., mask and eye protection/ face shield) should be worn to protect the mucous membranes of the eyes, nose and mouth during all endoscopic procedures and while reprocessing instruments. Eyeglasses are not sufficient to protect from splashes. For endoscopy procedures, in general, a surgical/procedure mask will suffice. If an infection is suspected a NIOSH certified N95 respirator should be worn during bronchoscopy[160-163]. PPE should not be worn outside the room in which the procedure takes place or outside the room in which the instruments are cleaned.

5.4. Occupational Health and Safety Considerations

Healthcare workers working in environments where endoscopes are handled should receive all vaccines as recommended by the *National Advisory Committee on Immunization*[164] including the hepatitis B vaccine. HCWs should also have regular tuberculin skin tests (TST), as per *Health Canada: Guidelines for preventing the transmission of tuberculosis in Canadian health care facilities and other institutional settings*[165]. The frequency of TST will depend on the burden of patients with TB actually seen in the clinic (e.g., annually or every 6 months for high risk facilities)[165]. In the event of an exposure to a patient with infectious TB, the hospital's protocol for post exposure management should be followed. Similarly, if there is a percutaneous or mucous membrane exposure to blood or body fluids during the procedure, follow-up through Occupational Health and Safety is required.

Exposure to glutaraldehyde can cause headaches, conjunctivitis, dermatitis, asthma-like responses and nasal irritation[21]. This can be minimized with appropriate point-of-use ventilation in accordance with the MSDS for the product used[11]. Less toxic high level disinfectants (e.g., 0.55% ortho-phthalaldehyde) are now available, but no option is ideal[166]. While cleaning endoscopes, to protect against contact with chemicals that can cause caustic injuries, personnel should wear gloves, facial protection (i.e., mask and eye protection/face shield) to protect the eyes, mucous membranes and face from splashes, and moisture-resistant gowns or aprons that protect the body[157]. All chemicals must be stored and handled appropriately and all personnel who handle chemicals need to be aware of the hazards associated with the materials and how to manage spills. Refer to the product label of each product, or the MSDS associated with each product for appropriate handling.

5.5. Environmental Controls

Certain microorganisms are transmissible by the airborne route (e.g., TB), and thus environmental controls are required. A negative pressure room is required for all bronchoscopy procedures and in the area where the patient is recovering from the procedure[165;167]. A minimum total air exchange rate of 12 per hour is recommended for newly constructed bronchoscopy suites with 6 exchanges per hour for existing facilities. The direction of air should be inward (negative pressure) and the air should be exhausted to the outdoors through a dedicated system or HEPA filtered[9;167-169]. The endoscopic instrument reprocessing room should be under negative pressure and requires an air exchange rate of, at minimum, 8 per hour to protect personnel from toxic vapours generated by cleaning or disinfecting agents, and covered containers should be used for additional control of vapours[167;170].

Work areas need to be properly ventilated to ensure product levels are below threshold limit values (TLVs) specified in provincial OH&S regulations. Recirculation of air in the area where the product is used is prohibited by OH&S regulation and ventilation must be to the exterior. Use of an AER helps to reduce vapour concentration and the risk from splashes.

Ethylene oxide (ETO) is a designated substance under the Canadian Environmental Protection Act**.** Healthcare facilities that use 10 kg. or more of ETO per year for sterilization must comply with *Environment Canada*: *Guidelines for the Reduction of Ethylene Oxide Releases from Sterilization Applications*[121] and *Canadian Standards Association Z314.9-01: Installation, Ventilation, and Safe Use of Ethylene Oxide Sterilizers in Health Care Facilities*[114].

6. Endoscopy Unit Design

The design of an endoscopy unit is important to facilitate proper infection prevention and control and occupational health and safety. Major considerations in design and use of space for patient procedures, equipment reprocessing and storage include: i) patient volume, ii) traffic flow, and iii) types of endoscopic procedures performed[4]. The main objective is to create an efficient flow of patients and personnel through the unit, from reception to procedure and then to recovery, while maintaining a distinct separation between patient care areas and contaminated space and equipment. Providing comfortable working conditions for clinical staff, as well as support personnel, will promote an environment where proper procedures are routinely exercised. An ideal endoscopy unit would permit a one-way or circular flow for patients and endoscopes.

In procedure rooms, the workflow should be from clean to dirty. A dedicated clean area should be provided for charting, dictation and supplies. A separate soiled holding area must be provided for pre-cleaning of scopes and handling of contaminated instruments. The procedure room should have a separate dedicated hand washing sink with hands-free controls.

An appropriate airborne precautions environment should be available for patients with confirmed or suspected infectious airborne diseases if they cannot be immediately transported to an appropriately ventilated room[13;165].

In designing an endoscopy unit, consideration should be given to providing patients with private bathroom and change room. A staff lounge should be made available as eating, drinking, personal hygiene (e.g., cosmetic application, contact lenses) activities should be prohibited from all patient care areas and the reprocessing room[4;171].

Instrument reprocessing space should be physically separate from patient procedure rooms, maintained as a restricted access area, and enable personnel to respect the one-way work-flow[11;167]. Reprocessing functions can be broken down into 3 general areas: cleaning, decontamination, and storage. The workflow should be unidirectional from the contaminated or 'dirty' area to the clean assembly area and then to storage. Adequate space should be provided for each function with dedicated storage space in a separate room[167]. Reprocessing areas should have dedicated plumbing and drains[11], and if AERs are used, the area should be designed with adequate space and utility connections specific to the machine being used[4;167]. Adequate space for storage of chemical disinfectants should be considered near the AER. Other considerations for an endoscope reprocessing area include monolithic or joint free flooring[167] and stainless steel counters. Sinks should have rounded edges and enough depth to facilitate complete immersion of the endoscope. The size of the sink should be adequate to ensure the endoscope can be positioned without tight coiling as this could damage the fiberoptic bundles. Any other design features that promote easy cleanup are desirable. Hands-free doors and sinks will improve workflow and reduce risk of cross contamination. Separate, dedicated hand washing sinks must be at each entrance or exit.

Appropriate ventilation (see Section 5.5) must be provided to remove toxic vapours of disinfection chemicals and to handle any aerosolized particles or microbes. The manual cleaning and disinfection space should be under negative pressure in relation to the adjoining rooms, whereas the endoscope storage space should be under positive pressure[170]. Ventilation in the storage area should be adequate to ensure dry storage of clean endoscopes.

7. Surveillance and Outbreak Investigation and Management

Few healthcare settings have routine post-procedure surveillance programs in place to monitor the incidence of endoscopy-associated infections. Many endoscopies are now carried out in outpatient clinics and follow-up of patients in the community is difficult. In addition, some infections, such as hepatitis B and tuberculosis, have long incubation periods, and thus clinical infection developing later may not be linked to an earlier endoscopy. It has been suggested that infection surveillance programs be implemented, at least periodically, for high risk procedures such as Endoscopic Retrograde Cholangiopancreatography (ERCP)[45].

An outbreak is defined as an increase in the rate of infection or disease above the usual. This requires that ongoing surveillance for potential complications be in place so that the background rate is known or can be calculated, or alternatively that a retrospective review could be performed to obtain baseline data. There have been numerous reported outbreaks of infection related to endoscopic procedures (See **Table 1**) as well as transmission of microorganisms without disease related to contaminated endoscopes (See **Table 2**).

Any occurrence of infection after an endoscopy procedure should be reviewed since it might be a sentinel event that signals the occurrence of an outbreak. If an outbreak is suspected, an investigation should be initiated[4;172]. **Appendix H** outlines steps to be taken during an outbreak investigation. Many of these steps may be performed concurrently.

8. Investigation of a Reprocessing Problem

Potential exposure events due to breaches of disinfection and sterilization guidelines[57;173], and failures in the disinfection or sterilization processes[25] are not uncommon in healthcare settings.

The purpose of investigating a potential reprocessing problem is to discover the factor(s) that led to the potential exposure and to protect patients from adverse events, and not to assign blame to a particular person or persons.

Any investigation should be undertaken using a standardized approach. Rutala et al.[174] have described a process for exposure investigation after potential failure of a disinfection/sterilization procedure. **Table 8** outlines steps to be taken to investigate a reprocessing problem. Every situation is unique, therefore steps taken in the investigation should be adapted to the specific situation. In addition, the American Society for Gastrointestinal Endoscopy (ASGE) has recently published guidelines for patient notification and follow-up when a significant breach in reprocessing has been discovered[175].

Table 8. Investigation of a Reprocessing Problem

1. Confirm disinfection or sterilization reprocessing failure (e.g., review time and date of possible failure, sterilization method used, process parameters, and physical, chemical, biological indicators).
2. Impound any improperly disinfected/sterilized items.
3. Do not use the questionable disinfection/sterilization unit (e.g., sterilizer, AER) until proper functioning can be assured.
4. Inform key personnel (e.g., medical and nursing director of involved unit, risk management).
5. Conduct a thorough evaluation of the cause of the disinfection/sterilization failure (e.g., review exact circumstances of failure: dates and results of process measures, physical, chemical, biological indicators).
6. Prepare a line listing of potentially exposed patients (e.g., name, identification number), date of exposure, contaminated device used, underlying risk factors for infection, development of any healthcare-associated infections, or other adverse events.
7. Assess whether disinfection/sterilization failure increases patient risk for infection.
8. Inform expanded list of personnel of the reprocessing issue (e.g., administration, public relations, legal department).
9. Develop a hypothesis for the disinfection/sterilization failure and initiate corrective action.
10. Develop a method to assess potential adverse patient events (e.g., laboratory tests for source patients and exposed persons to blood borne pathogens).
11. Consider notification of provincial and federal authorities.
12. Consider patient notification.
13. Develop long term follow-up plan (e.g., long-term surveillance, changes in current policies and procedures).
14. Prepare after action report.

Adapted from Rutala[174]

PART V. RECOMMENDATIONS FOR REPROCESSING FLEXIBLE ENDOSCOPES

1. Administrative Recommendations

1.1. Policies and Procedures

a. All healthcare settings where endoscopies are performed should have detailed written policies and procedures for the cleaning, reprocessing, and handling of flexible endoscopes that are based on current recognized standards and recommendations. Policies and procedures should include responsibilities of management and staff and the qualification, education and training of personnel involved in reprocessing[1;2;6;11;12;16;91;128].

B II

b. All healthcare settings in which endoscopies are performed should have ongoing access to infection prevention and control expertise[176-178].

B II

c. All healthcare facilities in which endoscopies are performed should have ongoing access to and collaboration with an Occupational Health and Safety Program[11].

C II

d. All healthcare facilities where endoscopy is performed should have sufficient resources to support training and education programs for personnel assigned to reprocess endoscopes and accessories[6;9;11].

B II

e. Policies and procedures for cleaning and reprocessing endoscopes, endoscope accessories, and related equipment should be reviewed at least annually, revised as necessary and readily available in the practice setting. Procedures/modifications should be documented and reviewed by the facility or organization's Infection Prevention and Control Committee, infection prevention and control personnel or other individual(s) responsible for infection prevention and control in the setting[1;6;11;91].

C II

f. A procedure should be established for the recall of improperly reprocessed equipment (e.g., incorrect reprocessing method was used on equipment). The recall procedure should include assessment of patient risk, and a procedure for subsequent notification of patients, other facilities, and /or regulatory bodies if indicated[2;12].

C II

g. Healthcare settings where endoscopy is performed should have written policies regarding the use of single-use medical/equipment/devices[2;4;67;130;131;179].

B II

h. The bronchoscopist is responsible for notifying those involved in the endoscopic procedure as well as those involved in equipment reprocessing as to whether a patient undergoing bronchoscopy may have tuberculosis.

C II

2. Recommendations for Endoscopy and Endoscopy Decontamination Equipment

a. Medical equipment/devices that cannot be cleaned and reprocessed according to the recommended standards should not be purchased[2].

B I

b. All medical equipment/devices intended for use on a patient that are being considered for purchase should be assessed by infection prevention and control personnel and should meet established quality reprocessing parameters[2;11]. The manufacturer must supply the following:

i) Information about the design of the equipment/device and clearly indicate which parts need to be disassembled for reprocessing,

ii) Manuals/directions for use,

iii) Device-specific recommendations for cleaning and reprocessing of equipment/device,

iv) Education for staff on use, cleaning and the correct reprocessing of the equipment/device,

v) Recommendations for auditing the recommended process.

B II

c. The manufacturer's recommendations regarding the installation, care, use, and maintenance of decontamination equipment should be followed including establishment of a preventive maintenance schedule. This includes but is not limited to cleaning, lubrication, checking for leaks, the changing of filters, and verification of settings and calibrations.

B I

d. Qualified personnel only should perform equipment maintenance and repairs.

C II

e. Original Equipment Manufacturer (OEM) parts should be used to repair equipment[11;34;36].

C II

f. Proper planning and assessment is necessary for the selection and purchase of automatic endoscope reprocessors (AERs) used to reprocess endoscopes and accessories[124].

i) The AER must be licensed for sale in Canada[124].

ii) The manufacturer of the AER must identify by brand and model each endoscope that may be effectively reprocessed in the AER and the limitations of the AER in processing certain models of endoscopes and accessories[3;124;125].

B II

iii) The reprocessing instructions provided by the endoscope manufacturer and the AER manufacturer's instructions should be compared and any conflicting recommendations should be resolved prior to first reprocessing[3;85;125].

B I

iv) The AER should effectively irrigate all channels of the endoscope. All channel connectors should be attached according to the AER manufacturer's instructions to ensure exposure of all internal surfaces with the high-level disinfectant/chemical sterilant[3;85;124;126;127].

B I

v) The AER should have no potential reservoirs for microbial growth, i.e., areas in the AER where water or disinfectant can stagnate. For wash cycles, ensure that all wash fluids (water and chemicals) are completely drained and discarded following each cycle[6;124;180].

B I

vi) If the AER uses a single-use disinfectant, the disinfectant should be completely drained between cycles

C II

vii) If the AER uses a reusable disinfectant, the MEC should be monitored daily using test strips available from the supplier of the disinfectant[6;16].

B II

g. If an AER cycle is interrupted, high-level disinfection or sterilization cannot be ensured and the process should immediately be repeated[3;6].

C II

h. Because design flaws have compromised the effectiveness of AERs, infection prevention and control personnel (or other appropriate personnel) affiliated with the facility should routinely review Health Canada's advisories, warnings and recalls about marketed health products, Emergency Care Research Institute (ECRI) reports, manufacturer alerts, and the scientific literature for reports of AER deficiencies that may lead to infection[3;34;127;181].

C II

i. If an automatic endoscope reprocessor manufacturer identifies a defect that may impact on effectiveness of the disinfection/sterilization process, it has an obligation to provide information to the user detailing the likely impact on disinfection/sterilization.

C II

j. If an endoscope requires repairs, proper disinfection should be performed prior to repair, or, if disinfection is not possible, then handling precautions as specified by the service vendor/equipment manufacturer should be followed when shipping a contaminated endoscope. Preparation and shipping of the endoscope should conform to the applicable jurisdictional requirements for the transportation of dangerous goods[1;11].

C II

3. Recommendations for Reprocessing Endoscopes and Accessories

3.1. Preparing the Endoscope for Cleaning

a. Immediately after removal from the patient, the exterior surface of the endoscope should be wiped down with a soft lint-free cloth or endoscope sponge soaked in a freshly prepared enzymatic detergent solution[1;6;11;101;125].

C II

b. The biopsy/suction and air/water channels should be flushed with an enzymatic detergent solution. For endoscopes with an elevator wire, manual flushing of this channel with an enzymatic detergent followed by rinsing is required[1;11;101;125].

B II

c. The endoscope should be transported to the reprocessing area in an enclosed container. Do not transport contaminated and clean endoscopes in the same container at the same time[6;11;101].

C II

3.2. Leak Testing

a. Pressure/leak testing should be performed according to manufacturer's instructions after each use and prior to immersion of the endoscope in the reprocessing solution. Remove from clinical use any instrument that fails the leak test and have it repaired[1;3;4;6;11;60;85].

C II

3.3. Manual Mechanical Cleaning in the Reprocessing Area

a. Non-immersible endoscopes should not be used[3;4;8;11;16;85].

C II

b. The endoscope and its disassembled components (e.g., suction valves) should be completely immersed in a freshly prepared enzymatic detergent cleaner[1;3;6;11;15;59;85;182].

C II

c. The entire endoscope, including valves, channels, connectors and all detachable parts should be meticulously cleaned with an enzymatic detergent compatible with the endoscope, according to the manufacturer's instructions[1;3;5;6;9;11;12;15;43;54;85;90;100;153;183;184].

B I

d. All accessible channels should be flushed and brushed to remove all organic (e.g., blood or tissue) and other residues. Repeatedly actuate the valves during cleaning to facilitate access to each surface[1;3;5;6;9;11;28;44;47;85;90;91;100;127;185].

B I

e. Cleaning brushes appropriate to the size of the endoscope channel or port should be used (i.e., bristle should contact surfaces). Disposable cleaning items are preferred. Reusable cleaning items should be thoroughly cleaned, inspected for damage and subjected to, at a minimum, high-level disinfection after each use. Cleaning items should be discarded if worn or damaged[3;6;9;11;85;90;186].

C II

f. The external surfaces of the endoscope and accessories should be cleaned using a soft, lint- free cloth, sponge or brushes. Use of a soft bristle toothbrush to clean the lens end is acceptable[6;11;101].

C II

g. Enzymatic detergents should be discarded after each use as these products are not microbicidal and will not retard microbial growth[3;6;9;11;85;90].

B II

h. The endoscope and all the channels should be rinsed thoroughly with copious amounts of tap water (minimum of three times the lumen volume) to remove residual enzymatic detergent. To decrease the possibility of diluting the disinfectant solution, excess water from the rinse should be removed from the channels by purging with forced air[1;6;11;12;93;101].

C II

3.4. Sterilization and High Level Disinfection

a. Flexible gastrointestinal endoscopes and bronchoscopes and accessories that come in contact with mucous membranes are classified as semi-critical items and should receive, at a minimum, high-level disinfection after each use[1;3;5;7;9;11;12;21;85;90;187].

B I

b. Endoscope accessories that penetrate mucosal barriers (e.g., biopsy forceps or other cutting instruments) are considered critical items and should be sterile before use[1;3;11;12;47;58;85;181;187-189]. **See Section 3.5 *Recommendations for Accessories.***

B II

c. A Health Canada approved (possesses a drug identification number (DIN)) sterilant or high level disinfectant should be used for sterilization or high-level disinfection[1;11;12].

d. For cleaning, disinfection and sterilization, only products that are confirmed by the manufacturer to be compatible with the endoscope and accessories should be used[3-5;9;11;12;85].

C II

e. Formulations containing glutaraldehyde, glutaraldehyde with phenol/phenate, ortho-phthalaldehyde, hydrogen peroxide, peracetic acid and both hydrogen peroxide and peracetic acid can be used to achieve high level disinfection if the products are used as directed (e.g., proper concentration), and objects are properly cleaned, disinfected, rinsed and dried *Refer to Table 5 for specific product recommendations for achieving high level disinfection and sterilization*[1;3;15;43;85;102;118;190-193].

B I

f. If manually reprocessed, the endoscope should be completely immersed in the high level disinfectant/sterilant and all channels should be filled with high level disinfectant. Non-immersible endoscopes should be phased out[1;3;6;11;15;16;28;85;90;126;127].

C II

g. Endoscopes should not soak overnight. If cleaning and disinfection/sterilization cannot be performed immediately, soak the endoscope in enzymatic detergent until final reprocessing can be carried out. Consult the manufacturer's instructions for delayed reprocessing[11;101].

C II

h. The exposure time and temperature for disinfecting semi-critical patient care equipment varies among high level disinfectants. The label claim for high level disinfection should be followed unless several well-designed experimental scientific studies, endorsed by infection prevention and control, and/or regulators, and/or guidelines committees, demonstrate an alternative exposure time is effective for disinfecting semi-critical items[1;6;7;9;16;100;105;191].

B I

i. If an automatic endoscope reprocessor (AER) is used, the endoscope and endoscope components should be placed in the reprocessor and all channel connectors should be attached to the AER according to the AER and endoscope manufacturer's instructions to ensure exposure of all internal surfaces to the high-level disinfectant/sterilant. **NB: See Recommendations Section 2. (f) for further AER recommendations**[3;4;6;11;85;124;126;127].

B I

j. If an automatic endoscope reprocessor (AER) cycle is interrupted, high-level disinfection or sterilization cannot be assured and the cycle should be repeated[3;6].

C II

k. After high-level disinfection, the endoscope should be rinsed and all channels flushed to remove the disinfectant/sterilant. The use of sterile or bacteria-free water is preferred but tap water can be used. If tap water is used, a subsequent 70-90% alcohol rinse is critical between each patient use. Discard the rinse water after each use/ cycle[3;5;9;11;15;32;36;66;85;93;100;194-197]. **NB: If a final alcohol rinse is not included in an automatic endoscope reprocessor, this step should be done manually followed by forced air-drying prior to storage**[37;181]**.**

B II

l. Prior to storage, flush the channels with 70%-90% ethyl or isopropyl alcohol[11;37;39].

B II

m. After flushing all channels with alcohol, the channels should be dried using forced 'medical grade' air.[1;3;4;9;11;12;15;29;85;93;198;199].

C II

n. No recommendation can be made about the routine use of sheathed endoscopes[137-140;200].

C II

3.5. Recommendations for Accessories

a. Ultrasonic cleaning should be used for reusable endoscopic accessories to remove soil and organic material from hard to clean areas[1;3;4;11;85;129;201].

C II

b. Biopsy forceps are classified as critical items. If reusable, they must be steam sterilized after cleaning. Chemical sterilization does not penetrate the coils and is not effective. If disposable items are used, discard after use[1;3;4;47;58;85;129;189].

B II

c. Other accessories that penetrate mucosal barriers (i.e., papillotomes, cytology brushes) should either be disposable or sterilized between patient use (high level disinfection is not appropriate)[3;4;11;85;129].

B II

d. The water bottle used to provide intra-procedural flush solution and its connecting tubing should be sterilized or receive high-level disinfection at least daily. The water bottle should be filled with sterile water[1;3;4;11;36;85].

B II

e. Each Endoscopic Retrograde Cholangiopancreatography (ERCP) procedure requires a fresh sterile bottle filled with sterile water[1;11;33;101].

B II

3.6. Storage and Transport

a. Valves and other components should be detached from the endoscope as per manufacturer's instructions, thoroughly dried and stored separately[1;9;11;93;141].

B II

b. Endoscopes should be stored uncoiled, hanging vertically in a clean, dry, ventilated area that prevents recontamination or damage[1;3;4;6;9;11;16;85].

C II

c. The storage area should be cleaned weekly with an approved low level disinfectant/cleaner[1;11].

C II

d. The maximum allowable storage time before reprocessing is required is 7 days[11;143-146;202].

B II

e. A carrying case should be used exclusively to transport the used instrument and not used for storage. Once placed in the carrying case, the instrument will be considered not patient ready and will require reprocessing before being used[9;11;85].

C II

f. If a case is needed to transport the processed endoscope, it should be designated for this purpose and well marked. Do not use the same case to transport used and reprocessed scopes[147].

C II

4. Recommendations for Endoscopy Unit Design

a. All settings where endoscopes are used and disinfected should be designed to provide a safe environment for patients and healthcare workers. Design should accommodate proper workflow from dirty to clean with adequate separation to minimize risk of cross contamination[4;11;167].

C II

b. Reprocessing areas should be physically separate from patient procedure rooms[6;8;11;16;167].

C II

c. The procedure room should have a separate, dedicated hand-washing sink with hands-free controls. A separate hand washing station should be provided in the reprocessing area[11;167].

C II

d. Air-exchange equipment (ventilation system, exhaust hoods) should be used to minimize the exposure of all persons to potentially toxic vapours and air quality should be monitored regularly[3;11;85]. See ***Recommendations Section*** 5.2 (e).

C II

e. The reprocessing area should be under negative pressure and have an air-exchange rate of, at minimum, 10 per hour[11].

f. Bronchoscopy procedures and patient recovery post bronchoscopy must be performed in a negative pressure room with a minimum air-exchange rate of 12 per hour in newly constructed isolation rooms or 6 per hour in existing facilities[168-170].

g. Clean storage space, which is physically separate from decontamination and cleaning areas, should be provided. Storage space should have adequate positive pressure ventilation[11;167;170].

C II

5. Recommendations for Quality Management

5.1. Personnel Education and Training

a. All healthcare personnel in any setting where gastrointestinal endoscopy and bronchoscopy are performed should be trained in and adhere to *Health Canada Guidelines: Routine Practices and Additional Precautions for Preventing the Transmission of Infection in Health Care*[13],which includes the correct use and requirement to wear personal protective equipment to protect both patients and healthcare workers, and *Hand Washing, Cleaning, Disinfection and Sterilization in Health Care*[12]. **For detailed recommendations, refer to *Health Canada Guidelines: Routine Practices and Additional Precautions for Preventing the Transmission of Infection in Health Care*[13] and *Hand Washing, Cleaning, Disinfection and Sterilization in Health Care*[12].**

B I

b. Personnel assigned to reprocess endoscopes and accessories should receive hands-on training with written device-specific reprocessing instruction for every endoscope model and automatic endoscope reprocessor in their area of responsibility[3;4;6;7;11;85;91;125;127].

B II

c. Personnel should meet the healthcare setting's written endoscope reprocessing competency requirements. Documented competency testing should be carried out initially after completion of training and subsequently on a regular basis (e.g., at least annually). Additional training with documented competency should be provided for new models of endoscopes or automatic endoscope reprocessors as they are introduced into the practice setting;[11].

B II

d. Temporary personnel should not be allowed to reprocess endoscopes until competency has been established[3;4;6;8;11;16;85;91;125;127].

B II

e. All personnel using chemicals should be educated about the biological and chemical hazards present while performing procedures that use disinfectants/sterilants. Occupational health and safety training should include the workplace hazardous materials information system (WHMIS)[13].

5.2. Worker Health and Safety

a. Personal protective equipment (e.g., gloves, gowns, eye protection with visors or goggles, and respiratory protection devices) should be readily available and should be used routinely to protect workers from exposure to chemicals, blood or other potentially infectious material. **For detailed recommendations, refer to *Health Canada Guidelines: Routine Practices and Additional Precautions for Preventing the Transmission of Infection in Health Care*[13;159] and *CSA Standard Z314.8-08: Decontamination of Reusable Medical Devices*[1-5;11;13;73;85;158;165].**

b. A N95 respirator should be used during an endoscopic procedure if pulmonary or laryngeal tuberculosis is suspected[5;101;165;203;204].

C II

c. All susceptible personnel should receive immunizations as recommended by the *National Advisory Committee on Immunization (NACI)*[164] and receive tuberculin skin testing in accordance with Public Health Agency of Canada guidelines[11;168].

B I

d. Established written protocols, in accordance with the healthcare facility's Occupational Health and Safety Program, should be in place to prevent and manage worker exposure to infectious agents (e.g., HBV, TB) and toxic chemicals[3;4;12;85;124;128].

B I

e. Wherever chemical disinfection/sterilization is performed using products that produce toxic vapours (e.g., glutaraldehyde), work areas need to be properly ventilated to ensure levels are below threshold limit values (TLVs) specified in provincial and federal Occupational Health and Safety (OH&S) regulations. Recirculation of air in the area where the product is used is prohibited by OH&S regulation and ventilation must be to the exterior)[11;34;65;101;114;121;128].

5.3. Reprocessing Program

a. Manufacturer's written recommendations for use of sterilants/chemical disinfectants and instructions for reprocessing should be followed[11;101;125;128].

B I

b. All manufacturer's written recommended maintenance schedules and services for endoscopes and automatic endoscope reprocessors used in the facility should be adhered to[3;4;9;11;15;16;85;91;101].

C II

c. Visual inspections of equipment should be conducted to ensure that it is in proper working order in accordance with the endoscope manufacturer's recommendations and to identify conditions that may affect the cleaning or disinfection processes[3;11].

B II

d. Routine testing of the liquid sterilant/high-level disinfectant should be performed to ensure minimum effective concentration (MEC) of the active ingredient. Product-specific test strips should be used. The solution should be checked at the beginning of each day of use (or more frequently) and the results documented. If the chemical indicator shows that the concentration is less than the MEC, the solution should be discarded. A log of test results should be maintained[3;4;6;11;85;101].

B II

e. The liquid sterilant/high level disinfectant should be discarded at the end of its reuse life (which may be single-use), regardless of the minimum effective concentration [6;11;23;205].

B II

f. Healthcare facilities should develop protocols to ensure that users can readily identify whether an endoscope is contaminated or is ready for patient use[3].

C II

g. A permanent record of reprocessing shall be completed and retained according to the policy of the facility. The record shall include but not be limited to the patient's name and medical record number, the endoscopist, identification number and type of endoscope (and automatic endoscope reprocessor, if used), date and time of the clinical procedure, results of each individual inspection and leak test and the name of the person reprocessing the endoscope[3;4;6;9-11;85;101;135;136;153;154;172;205-208].

B I

h. A surveillance system capable of detecting clusters of infections or pseudo-outbreaks associated with endoscopic procedures should be established[76;205].

B I

i. Routine microbiologic testing of endoscopes for quality assurance purposes is not recommended. If endoscope cultures are indicated (e.g., outbreak investigation), see Appendix D for sample collection method and interpretive criteria[3;4;85;124;172].

C II

6. Recommendations for Outbreak Investigation and Management

a. If a cluster of suspected or confirmed endoscopy-related infections occurs, an investigation should be initiated to determine the potential routes of transmission (e.g., person-to-person, common source) and reservoirs. Use standard methods for outbreak investigation. **Refer to Appendix H, *Guideline for Outbreak Investigation Related to Endoscopic Procedures*[76].**

B I

b. If a breach in protocol is recognized, a risk assessment should be initiated to determine if patient notification is required[5;80;82;83;174].

B I

c. If a breach in protocol is recognized, an assessment and investigation should be performed to determine why this happened and how to prevent a recurrence[174].

B I

d. Outbreaks of endoscope-related infections should be reported to persons responsible for infection prevention and control, risk management and all involved department heads. If there are public health implications, notify local public health authorities and Health Canada. Where appropriate, notify the manufacturer(s) of the endoscope, disinfectant/sterilant, and automatic endoscope reprocessor[3-5;9;11;23;80;85;101;122;205].

B I

7. Recommendations for Classic and Variant Creutzfeldt-Jakob Disease (CJD and vCJD))

Refer to Health Canada/Public Health Agency of Canada Infection Prevention and Control Guideline, Classic Creutzfeldt-Jakob Disease in Canada-Quick Reference-2007[75] and ***"Classic Creutzfeldt-Jakob Disease in Canada"***[209] ***for definitions of high risk patient, high and low infectivity tissues, risk assessment tools and special recommendations for cleaning and decontamination of instruments and surfaces that have been exposed to tissues considered infective for CJD. The recommendations for gastrointestinal and bronchoscopic endoscope reprocessing found in this section are updated from those in the earlier Canadian CJD guidelines. The general procedures for reprocessing endoscopes already outlined in this guideline should be followed. In addition, the following are recommended for CJD.***

a. Channel cleaning brushes and, if a biopsy has been taken, the valve on the endoscope biopsy/instrument channel port should be disposed of as clinical waste after each use. Single use biopsy forceps should be used[7].

C II

b. Disinfectants with fixative properties (e.g., aldehyde disinfectants) should not be used on flexible scopes used for any procedure on patients with a diagnosis of definite, probable, or possible CJD/vCJD, or where the diagnosis of CJD/vCJD is unclear[7].

B I

c. Following the decontamination of the endoscope, the automatic endoscope reprocessor (AER) should be run through an empty cycle. Any solid waste or tissue remaining in the AER should be removed together with the outlet strainer and disposed of by incineration. Liquid waste should be disposed of safely by normal direct discharge from the AER. The usual self-disinfection cycle should be run as per recommended routine. Endoscopic accessories and cleaning aids should be disposed of by incineration[7].

C II

d. Endoscopes used for invasive (e.g., biopsy) procedures in individuals with definite, probable, or possible vCJD, or where the diagnosis of vCJD is unclear, should be removed from use or quarantined to be re-used exclusively on that same individual if required. The endoscope should be fully cleaned and decontaminated alone using an automatic endoscope reprocessor immediately after use, before being quarantined[7].

C II

e. If there is a risk that the endoscope could become contaminated with olfactory epithelium, a single use endoscope should be used if possible. If this is unavailable the endoscope should be removed from use[7].

C II

f. If it has been found retrospectively that an invasive endoscopic procedure was performed on a patient suspected to have vCJD, endoscopy equipment should be managed as in 7d. The instrument should be stored in a dated, leak proof, puncture-resistant container, labelled "biohazardous". The container should then be stored in a secure area and a monitoring system should be in place to ensure that the instrument is not re-circulated into the system until the diagnosis has been confirmed by neuropathological examination. If the diagnosis is positive for vCJD, the instrument should be incinerated. If an alternative diagnosis (i.e., not vCJD) is made, the instrument does not require CJD precautions, and routine cleaning and sterilization/disinfection may be initiated[7;210].

C II

g. If it has been found retrospectively that an invasive endoscopic procedure was performed on a patient suspected to have vCJD, reusable cleaning brushes that are still in use should be disposed of by incineration.

C II

h. A record should be kept of each endoscope used for each patient. **Refer to *Recommendation 5.3 (g) for details***. This is important for any future contact tracing when possible endoscopic disease transmission is being investigated.

C II

i. Outbreaks of endoscope-related prion infections should be reported to persons responsible for infection prevention and control, risk management, all involved department heads **and the Public Health Agency of Canada CJD Surveillance Unit (phone 1-888-489-2999).** If patient and physician notification and follow-up are required, **refer to *Appendix H, Guideline for Outbreak Investigation Related to Endoscopic Procedures***.

C II

APPENDIX A –PHAC IP&C Guideline Development Process

Literature Search – Inclusions/Exclusions

A thorough literature search was performed by the Public Health Agency of Canada reference librarian in collaboration with the nurse consultant and the writer. The search results were reviewed, and articles that did not meet the criteria for the guideline were eliminated. Abstracts of remaining articles were examined; those that were not appropriate study designs or that failed to meet specific methodological criteria were eliminated. As the essence of the guideline was further defined, additional searches were conducted to ensure all relevant literature was captured. All searches covered the period from 1996 onwards.

Formulation of Recommendations

This Guideline provides evidence-based recommendations. Guideline recommendations were graded to differentiate between those based on strong evidence and those based on weak evidence. Grading did not relate to the importance of the recommendation, but to the strength of the supporting evidence and, in particular, to the predictive power of the study designs from which that data were obtained. Assignment of a level of evidence and determination of the associated grade of recommendation was done by the writer and was reviewed and approved by the co-chairs and all Guideline Working Group members. When recommendations were not unanimous, difference of opinion was formally recorded and the reasons for disagreement noted for the information audit trail. It is important to note that no real divergence of opinion occurred for this guideline, however when a difference of opinion occurred, debate took place and a solution was found and accepted.

Where scientific evidence was lacking, the consensus of experts was used to formulate a recommendation. The grading system is outlined in Appendix I.

External Review by Stakeholders

This Guideline was reviewed by a group of societies and associations for feedback on the quality and content of the document and grading of recommendations for further validation before widespread implementation. The reviewers were:

- Association of Medical Microbiology and Infectious Disease Canada
- Canadian Association of Clinical Microbiology and Infectious Diseases
- Canadian Association of General Surgeons
- Canadian Association of Thoracic Surgeons
- Canadian Nurses Association
- Canadian Standards Association
- Canadian Thoracic Society
- Central Service Association of Ontario
- Community and Hospital Infection Control Association - Canada
- Healthcare Infection Control Practices Advisory Committee
- Network of Networks Interest Group, Community and Hospital Infection Control Association-Canada
- The Canadian Association of Gastroenterology

- The Canadian Society of Gastroenterology Nurses and Associates
- The Hospital for Sick Children

Editorial Independence

This guideline was funded by the Public Health Agency of Canada. Financial contribution was provided by the Canadian Association of Gastroenterology for travel and hospitality costs for non-public servants attending the expert working group meeting.

All Members of the Guideline Working Group have declared no competing interest in relation to the guideline. It was incumbent upon each member to declare any interests or connections with relevant pharmaceutical companies or other organizations if their personal situation changed.

The guidelines outlined herein are part of a series that has been developed over a period of years under the guidance of the 2008 Steering Committee on Infection Prevention and Control Guidelines. The following individuals formed the Steering Committee on Infection Prevention and Control Guidelines:

- Dr. Lynn Johnston, (Chair), Hospital Epidemiologist & Professor of Medicine, QEII Health Science Centre, Halifax, Nova Scotia
- Nan Cleator, National Practice Consultant, VON Canada, Huntsville, Ontario
- Brenda Dyck, Program Director, Infection Prevention and Control Program, Winnipeg Regional Health Authority, Winnipeg, Manitoba
- Dr. John Embil, Director, Infection Control Unit, Health Sciences Centre, Winnipeg, Manitoba
- Karin Fluet, Director, Regional IPC&C Program, Capital Health Region, Edmonton, Alberta
- Dr. Bonnie Henry, Physician Epidemiologist & Assistant, Professor, School of Population & Public Health, UBC, BC Centre for Disease Control, Vancouver, British Columbia
- Dany Larivée, Infection Control Coordinator, Montfort Hospital, Ottawa, Ontario
- Mary LeBlanc, Carewest Infection Prevention & Control Coordinator, Tyne Valley, Prince Edward Island
- Dr. Anne Matlow, Director of Infection Control, Hospital for Sick Children, Toronto, Ontario
- Dr. Dorothy Moore, Infection Control, Division of Infectious Diseases, Montreal Children's Hospital, Montreal, Quebec
- Dr. Donna Moralejo, Associate Professor, Memorial University School of Nursing, St. John's, Newfoundland
- Deborah Norton, Infection Prevention and Control Consultant, Regina, Saskatchewan
- Filomena Pietrangelo, Occupational Health and Safety Manager, McGill University Health Centre, Montreal, Quebec
- JoAnne Seglie, Occupational Health Nurse OC RN, University of Alberta Campus, Office of Environment Health/Safety, Edmonton, Alberta
- Dr. Pierre St-Antoine, Professor of Medicine, Centre Hospitalier de l'Université de Montréal, Campus Notre-Dame, Microbiology, Montreal, Quebec
- Dr. Geoff Taylor, Professor of Medicine, Department of Medicine, Division of Infectious Diseases, Edmonton, Alberta
- Dr. Mary Vearncombe, Medical Director, Infection Prevention & Control, Sunnybrook Health Sciences Centre, Toronto, Ontario

APPENDIX B – Glossary of Terms

Automated Endoscope Reprocessor (AER): Machine designed to assist with the cleaning and disinfection of endoscopes.

Antimicrobial agent: A product that kills or suppresses the growth of microorganisms.

Bacteria-free water: Water that has been filtered through a 0.2 micron filter to remove bacteria.

Bioburden: Population of viable microorganisms on a raw material, a component, a finished product and/or a package.

Biofilm: The process of irreversible adhesion initiated by the binding of bacteria to a surface by means of exopolysaccharide material (glycocalyx). The development of adherent microcolonies eventually leads to the production of a continuous biofilm on the colonized surface. Bacteria within biofilms tend to be more resistant to biocides than cells in batch-type culture.

Biomedical waste: Defined by the Canadian Standards Association (CSA) as waste that is generated by human or animal healthcare facilities, medical or veterinary settings, healthcare teaching establishments, laboratories, and facilities involved in the production of vaccines.

Cleaning: The physical removal of foreign material, e.g., dust, soil, and organic material such as: blood, secretions, excretions and microorganisms. It is accomplished with water, detergents and mechanical action. The terms "decontamination" and "sanitation" may be used for this process in certain settings, e.g., central service or dietetics. Cleaning reduces or eliminates the reservoirs of potential pathogenic microorganisms.

Contamination: The presence of microorganisms on inanimate objects (e.g., clothing, surgical instruments) or microorganisms transported transiently on body surfaces such as hands, or in substances (e.g., water, food, milk).

Critical items: Instruments and devices that enter sterile tissues, including the vascular system. Critical items present a high risk of infection if the item is contaminated with any microorganisms including bacterial spores. Reprocessing critical items involves meticulous cleaning followed by sterilization.

Decontamination: The removal of disease-producing microorganisms, to leave an item safe for further handling.

Disinfection: The inactivation of disease producing microorganisms. Disinfection does not destroy bacterial spores. Disinfectants are used on inanimate objects; antiseptics are used on living tissue. Disinfection usually involves chemicals, heat or ultraviolet light. Levels of disinfection vary with the type of product used.

Drug Identification Number (DIN): In Canada, disinfectants are regulated as drugs under the Food and Drug Act and Regulations. Disinfectant manufacturers must obtain a drug identification number from Health Canada prior to marketing, which ensures that labelling and supporting data have been provided and that it has been established by the Therapeutic Products Directorate that the product is effective and safe for its intended use.

Endoscope accessory instruments: Medical instruments designed for insertion into a flexible endoscope. These devices (other than the endoscope) are used during endoscopy and include, but are not limited to, biopsy forceps, snares, bite blocks, guide-wires, irrigation tubes, and dilators. Devices may or may not have lumens, porous or loosely joined surfaces or access ports for flushing, and may or may not be capable of being completely disassembled during reprocessing.

Endoscope-Flexible: Flexible fiberoptic or video endoscope used in the examination of hollow viscera (bronchoscope, colonoscope, duodenoscope, gastroscope, sigmoidoscope).

Enzymatic detergent: Low-sudsing cleaning formulations containing protease, lipase, amylase, alone or in combination, that aid in the removal of proteinaceous material on medical equipment/devices.

High level disinfection: Level of disinfection required when reprocessing semi-critical items. High level disinfection processes destroy vegetative bacteria, mycobacteria, fungi and enveloped (lipid) and non-enveloped (non-lipid) viruses, but not necessarily bacterial spores. High level disinfection chemicals (also called chemisterilants) must be capable of sterilization when contact time is extended. Items must be thoroughly cleaned prior to high level disinfection.

Infection: The entry and multiplication of an infectious agent in the tissues of the host.

a) Inapparent (asymptomatic, subclinical) infection: an infectious process running a course similar to that of clinical disease but below the threshold of clinical symptoms
b) Apparent (symptomatic, clinical) infection: one resulting in clinical signs and symptoms (disease).

Manufacturer: Any person, partnership or incorporated association that manufactures and, under its own name or under a trademark, design, trade name or other name or mark owned or controlled by it, sells medical equipment/devices.

Material Safety Data Sheet (MSDS): Descriptive sheet that accompanies a chemical or chemical mixture, providing the identity of the material; physical hazard, such as flammability; acute and chronic health hazards associated with contact or exposure.

Medical Device: Any instrument apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

a) Diagnosis, prevention, monitoring treatment, or alleviation of disease.
b) Diagnosis, monitoring treatment or alleviation of or compensation for an injury, or handicap.
c) Investigation, replacement, or modification of the anatomy or of a physiological process or control of conception; and that does not achieve its principal intended action in or on the human body by pharmacological, immunological, or metabolic means, but that may be assisted in its function by such means.

Minimum effective concentration (MEC): Lowest concentration of active ingredient necessary to meet the label claim of a reusable high-level disinfectant/sterilant.

Non-critical items: Those that either touch only intact skin but not mucous membranes or do not directly touch the patient. Reprocessing of non-critical items involves cleaning with or without low level disinfection.

Outbreak: An excess over the expected incidence of disease within a geographic area during a specified time period; synonymous with epidemic.

Patient-ready endoscope: An endoscope rendered visibly free from debris after being subjected to a validated cleaning procedure and, at minimum, a high level disinfection or sterilization process. If liquid chemicals are used for disinfection, the endoscope must also be rinsed to ensure that it does not contain residual chemicals in amounts that can be harmful to humans.

Personal protective equipment: Specialized clothing or equipment worn by staff for protection against hazards.

Reprocessing: The steps performed to prepare a used medical device for reuse.

Reusable device: A device that has been designed by the manufacturer, through the selection of materials and/or components, to be reused.

Risk Class: Classification assigned to a device involved in patient care based on the risk of infection involved with the use of the device. Classes are critical, semi-critical and non-critical.

Single use/disposable device: A device designated by the manufacturer for single use only.

Sterilant: Chemical germicide that has been cleared by the Therapeutic Product Division of Health Canada as capable of destroying all viable microorganisms, including bacterial spores.

Sterile: The state of being free from all living microorganisms.

Sterilization: The destruction of all forms of microbial life including bacteria, viruses, spores and fungi. Items must be cleaned thoroughly before effective sterilization can take place.

Threshold limit value - Time-Weighted Average (TLV-TWA): Airborne concentration of a substance to which all workers may be exposed day after day without experiencing any adverse health effects.

Ultrasonic Washer: A machine that cleans medical devices by agitation caused by sound waves which produce vigorous microscopic implosions of tiny vapour bubbles on the surface of objects immersed in the cleaning chamber.

Use - life: Statement by the manufacturer of maximum number of days a reusable high-level disinfectant/sterilant might be effective.

Validation: A documented procedure for obtaining, recording, and interpreting the results required to establish that a process will consistently yield product complying with predetermined specifications.

Verification: Confirmation by examination and provision of objective evidence that specified requirements have been fulfilled.

APPENDIX C – Spaulding Classification System

CLASS	USE	EXAMPLES OF DEVICES	REPROCESSING METHOD (MINIMUM REQUIREMENT)
NON-CRITICAL	Touches intact skin	-Stethoscopes -Blood pressure cuffs	Cleaning followed by intermediate or low level disinfection, depending on degree of contamination
SEMI-CRITICAL	Touches mucous membranes and non-intact skin	-Gastrointestinal endoscopes -Bronchoscopes -Cystoscopes	Cleaning followed by high level disinfection (HLD)
CRITICAL	Enters sterile tissue, vascular system or body space	-Biopsy forceps -Snares / Loop -Surgical instruments: -Arthroscopes -Laparoscopes	Cleaning followed by sterilization

APPENDIX D – Bioburden Test Method

Sample collection usually requires two people. It may be feasible to have a staff person from Infection Prevention and Control work with a staff person in the endoscope reprocessing area to collect the samples. If Infection Prevention and Control staff are not available, reprocessing personnel can perform the sampling, however, care must be taken to ensure aseptic technique during sample collection.

1. Sample Collection

Staff should wear appropriate personal protective equipment (gloves, gowns, face shields).

Supplies

1. Sterile tubing connector suitable to attach to the umbilical suction barb (or other channels if tested)
2. Sterile syringes; one for each channel to be sampled (30 cc for suction/biopsy channel and air/water channel, 20 cc for other smaller channels)
3. Sterile container for collecting the sample (sterile urine specimen containers work well)
4. Sterile reverse osmosis (RO) water (adequate total volume to collect samples from each channel; e.g., for a colonoscope ~ 50 mls, for a bronchoscope ~ 30 mls, for a duodenoscope ~ 50 mls will be needed). Ideally separate 20 mls aliquots of sterile RO water should be used for each channel sampled (this ensures that the risk of contaminating the sterile RO water as a result of aspirating several samples from the same container is reduced).

Ensure the specimen collection container is properly labelled. It will be necessary to ensure that the suction valve and biopsy port are closed so that the fluid used to collect the sample is flushed through the suction/biopsy channel (the air/water valve needs to be closed to collect the sample from the air/water channel). Use sterile RO water to collect the sample from the channel. This ensures that the optimal sample will be collected as RO water is very “active” and will “strip” surface material more efficiently than buffer or both media. In addition, it will not have to be cleaned away and as such will not interfere with subsequent use of the scope on patients.

Method

1. Aspirate 10 mls of sterile RO water into a sterile 30cc syringe.
2. Attach this syringe via a piece of sterile tubing (e.g., manufacturer’s recommended connector) to the suction/biopsy barb of the umbilical end and flush 10 mls of sterile RO water through the channel.
3. Collect the channel sample from the distal end of the endoscope by holding the end of the insertion tube in a sterile plastic container (urine specimen container can be used).
4. Use a syringe of air to flush out any residual fluid sample from the channel.

The sterile tubing used for sample collection should be packaged and steam sterilized prior to next usage. The air/water channel can be sampled in a similar fashion by attaching a sterile piece of tubing (e.g., manufacturer's recommended connector) to the air/water barb on the umbilical end and flushing 10 mls of sterile RO water through the air/water channel. For other smaller channels that may be present on some flexible endoscopes (e.g., elevator wire channel and auxiliary water channel) the same process can be performed using 3 mls of sterile RO water instead of 10mls, injected using a sterile 10cc syringe.

Once the channel sample(s) have been collected, and adequately labelled, they should be sent immediately to the microbiology laboratory for culture. If transit time is anticipated to be more than 30 minutes, the sample(s) should be held on ice or refrigerated until cultured (samples should not be held in the refrigerator longer than 24 hours prior to culture). This ensures that microbial growth does not occur during storage.

2. Bacterial Culture

Method

1. Mix the sample well (e.g., vortex mixer)
2. Inoculate 0.1 mls of the sample onto a blood agar (BA) plate and a Sabaroud agar (SA) plate.
3. Spread the inoculum over the entire surface of the media to allow quantitation of any colonies that grow.
4. Incubate the BA plate aerobically at 35°C for 48hrs (the BA plate will detect a wide range of organisms that might come from humans and/or the environment)
5. Incubate the SA plate aerobically at 30°C for 5 days (the SA plate at the lower temperature will detect the presence of Methylobacter species, which is commonly found in potable water).

If no growth is detected after 5 days of incubation the sample should be reported as having no detectable organisms. If growth of organisms is detected, the number of colonies should be counted and the colony forming units (cfu)/ml determined (cfu/ml = total number of colonies on the entire plate/0.1 mls (e.g., If 10 colonies are detected, the cfu/ml = 10/0.1 = 100 cfu/ml).

3. Interpretation

How to interpret the presence of any detectable bioburden is controversial. One published interpretation criterion is that endoscope channels would be expected to have bioburden levels that are no worse than 200 cfu/ml, which represents the cut-off of viable microorganisms for dialysis water and is within the 500cfu/ml or less cut-off (heterotrophic plate count, excluding coliforms) accepted by Canadian guidelines for potable water[93]. If there are 20 or more colonies on the plate (e.g., 20 colonies per 0.1 mls = 200 cfu/ml), this is considered unacceptable and would be reported as 200 cfu/ml. If 1 - 19 colonies are detected, this is considered acceptable, as a few organisms may be present due to the collection method. This result would be reported as < 200 cfu/ml. If no growth is detected the result would be reported as "no growth".

4. Actions for Unacceptable Bioburden Levels

If the level of bioburden is ≥200 cfu/ml, then the scope should be removed from use and re-tested. If the second testing shows no problem, then the scope can be returned to use (i.e., the elevated bioburden level was an isolated situation that is not due to an ongoing process problem). If the bioburden level is ≥200 cfu/ml. on the second evaluation, then infection prevention and control needs to be contacted to identify what the problem might be and recommend solutions. At this stage testing of all scopes may be necessary to determine how wide-spread the problem is. Items to be assessed (not an exhaustive list) when unacceptable bioburden levels are repeatedly detected include:

- Was there residual moisture in the channels during storage (review the procedure for alcohol rinsing and forced air drying prior to storage)? ***This is the most common reason for sporadic unacceptable bioburden levels.***
- Was the cleaning being done properly (review cleaning process to ensure fresh detergent was prepared for each scope)?
- Is the high level disinfectant still effective (review daily minimum effective concentration (MEC) testing results)?
- Was the final rinse post-high level disinfection (HLD) contaminated (check filter integrity if using an AER, take samples of the final rinse water from the distal side of the filters to determine bioburden levels)?
- Is there a problem with the high level disinfectant? To evaluate whether this is a problem, bioburden testing should be performed (sample collected as described previously) immediately after HLD to assess if the disinfection stage is ineffective.

If HLD problems are identified, Infection Prevention and Control should review the charts of patients on whom this scope had been used since the time of the last testing to evaluate if there have been any potential patient-related problems. If potential patient infections are identified, an assessment should be performed to determine the need for further outbreak investigation and/or patient notification.

The data from bioburden testing and any follow-up investigations should be reviewed with Infection Prevention and Control at the time of the occurrence.

APPENDIX E – Sample Audit Checklist for Reprocessing of Medical Equipment/Devices

NOTE: This checklist was adapted from Sunnybrook Health Sciences Centre

Purpose:

All medical equipment/devices used in healthcare settings in Ontario are to be reprocessed in accordance with both the Ministry of Health and Long-Term Care *"Best Practices for Cleaning, Disinfection and Sterilization"*, Public Health Agency of Canada infection prevention and control guidelines and current CSA standards.

Definition:

Reprocessing refers to the steps performed to prepare used medical equipment/devices for reuse.

Responsibility:

Each Physician Program Head and/or department manager is responsible to verify that all medical equipment/devices reprocessed in the area for which he/she is responsible is being reprocessed according to the Ministry of Health and Long-Term Care *Best Practices for Cleaning, Disinfection and Sterilization in All Health Care Settings*.

Checklist: Department/Area to be Audited

ITEM	YES	NO	PARTIAL	COMMENTS
Reprocessing occurs in the area *(if no – sign off checklist is complete)*				
Single-use medical equipment/devices are not reprocessed.				
Personal protective equipment is worn when cleaning reprocessing *(eye protection, mask, gown and gloves)*				
Cleaning				
Equipment/devices are cleaned using an enzymatic cleaner prior to reprocessing				
Is cleaning done in a separate area from where the instrument will be used *i.e., designated dirty area)*				
High Level Disinfection				
Equipment/devices are subjected to high-level disinfection according to manufacturer's instructions, using an approved, high-level disinfectant (do *not keep high-level disinfectant for more than 2 weeks even if test strip is still okay)*				
High-level disinfectant concentration is checked daily				
Quality Control on test strips is carried out as per company guideline				
Test strip bottle is dated when opened				

ITEM	YES	NO	PARTIAL	COMMENTS
Test strips are not used past the manufacturer's expiry date				
Log is kept of results of high-level disinfectant quality control				
Log is kept of instruments that receive high-level disinfection				
Log is kept of dates when high-level disinfectant is changed				
Two staff sign off that the correct solution was used when high-level disinfectant is changed				
Automated reprocessor has preventive maintenance program				
Log is kept of all preventive maintenance				
Log is kept of all maintenance associated with reprocessor				
Using checklist for reprocessing of endoscopes				
Sterilization				
Equipment/devices are sterilized by an approved sterilization process				
Bowie Dick – done daily – high vacuum sterilizer				
Sterilizer physical parameters are reviewed after each run				
Log is kept of physical parameters				
Sterilizers monitored with biologic monitor daily *(each type of cycle, i.e., flash, long loads)*				
Log is kept of biologic monitors				
Sterilizer has a preventive maintenance program				
Log is kept of preventative maintenance				
If biologic monitor is positive, loads are recalled and the positive test is investigated				
Log is kept of all maintenance associated with a positive biologic monitor				
Indicator tape is used on outside each wrapped package				
Multi-parameter indicator used on inside each wrapped package containing 2 or more instruments				
Log is kept of each loan and items in load				
If flash sterilization is used, a log is kept of flash sterilizer use				
Flash sterilized equipment/devices are noted in the patient's chart along with reason				

ITEM	YES	NO	PARTIAL	COMMENTS
All logs are to be retained according to facility policy.				
All reprocessed equipment/devices are stored in a manner to keep them clean and dry.				
Chemical indicators are checked before equipment/devices are used				
Is there a process in place that clearly identifies a non-reprocessed instrument from one that has been reprocessed to prevent use on a patient				
Purchasing and Reprocessing Instructions				
Manager/purchaser is aware of purchasing policy for all medical equipment/devices requiring reprocessing.				
There are explicit written reprocessing instructions from the manufacturer on each equipment/device to be reprocessed.				
Policy & procedure for reprocessing are written. These are compatible with current published reprocessing standards and guidelines.				
Education				
Manager and staff are educated on how to reprocess instruments when: ▪ First employed ▪ Minimum of annually ▪ Any authorized change in process ▪ When new equipment is purchased – reprocessor ▪ When new equipment is purchased – medical equipment/devices requiring reprocessing				
Managers and staff have completed a recognized certification course in reprocessing or there is a plan to obtain this qualification with 5 years				
There is an audit and follow-up process in place for ongoing evaluation of reprocessing. Appropriate people and Infection Prevention & Control are notified when follow-up is required.				
Compliance with the Occupational Health and Safety Act R.S.O. 1990, c.O.1 and associated Regulations including the Health Care and Residential Facilities – O.Reg. 67/93 Amended to O.Reg. 631/05.				

Checklist Auditor: **Date:**

APPENDIX F- Sample Audit Tool for Reprocessing of Endoscopy Equipment/Devices

Adapted from Kingston Hospitals

	Recommendation	Specific Procedure	Yes/No/NA	MRP	Comment/Strategy for Improvement
1.	There is compliance with endoscope manufacturer's recommendations for cleaning	A. Endoscope is wiped and flushed immediately following procedure B. Removal of debris collected in scope (brushing) C. Removal of debris collected on the scope (surface cleaning) D. Perform a Leak test E. Visually inspect the scope to verify working properly			
2.	Verify that endoscope can be reprocessed in site's automated endoscope reprocessor (AER)	A. Documentation from endoscope's manufacturer confirming compatibility of each scope with AER B. Documentation from AER manufacturer confirming testing of individual scope in system. C. Specific steps before reprocessing endoscope's in AER			
3.	Compare reprocessing instructions provided by AER manufacturer and scope manufacturer and resolve conflicts.	A. Conflicts identified and resolved. B. Compliance with manufacturer's recommendations for hospital approved chemical germicide			
4.	Adhere to endoscope manufacturer's instructions for manual reprocessing in the absence of specific technical information on AER reprocessing.	A. Manual procedures in place for endoscopes not compatible with AER B. Compliance with manufacturer's recommendations for hospital approved chemical germicide.			
5.	Reprocessing protocol incorporates a final drying step.	A. All channels of reprocessed endoscopes are flushed with alcohol followed by purging with air.			
6.	Staff adheres to facility's procedures for preparing endoscope for patient.	A. Confirm AER's processes are applicable to specific endoscope's models. B. Ensure endoscope-specific reprocessing instructions from AER mfg are correctly implemented. C. Written, device-specific instructions for every endoscope's model available to reprocessing staff. D. Written instructions for reprocessing system are available to reprocessing staff.			

	Recommendation	Specific Procedure	Yes/No/NA	MRP	Comment/Strategy for Improvement
7.	Comprehensive and intensive training is provided to all staff assigned to reprocessing endoscopes	A. New reprocessing staff receives thorough orientation with all procedures. B. Competency is maintained by periodic (annual) hands on training with every endoscope model and AER used in the facility. C. Competency is documented following supervision of skills and expertise with all procedures. D. Frequent reminders and strict warnings are provided to reprocessing staff regarding adherence to written procedures. E. Additional training with documented competency for new endoscope models or AER			
8.	A comprehensive quality control program is in place.	A. Periodic visual inspections (monthly) of the cleaning and disinfecting procedures. B. A scheduled endoscope's preventive maintenance program is in place and documented. C. Preventive maintenance program for AER is in place and documented. D. Preventive maintenance program for all reprocessing system filters is in place and documented. E. AER process monitors are utilized and logged. F. Chemical germicide effectiveness level is monitored and recorded in a logbook. G. There are records documenting the use of each AER which include the operator identification, patient's chart record number, physician code, endoscope serial # and the type of procedure. H. There are records documenting the serial # of scopes leaving the Endoscope reprocessing area (e.g., repairs, loaners, O.R., etc.) I. There is a surveillance system that detects clusters of infections/pseudoinfections associated with endoscopic procedures.			

	Recommendation	Specific Procedure	Yes/No/NA	MRP	Comment/Strategy for Improvement
9.	Staff adheres to Routine Practices.	A. Ensure correct hand hygiene technique is performed in appropriate situations. B. There is compliance with procedures for wearing clean, non-sterile gloves. C. PPE (masks, eye protection, gown, plastic apron) is worn during procedures and patient care activities that are likely to generate splashes or sprays. D. Appropriate PPE is worn during scope cleaning and reprocessing. E. Heavily soiled linen is placed into plastic bag prior to depositing in linen hamper. F. Procedures are in place to prevent sharps injury. G. Staff is knowledgeable regarding protocol for follow-up for blood/body fluid exposure.			
10.	Endoscope reprocessing policies and physical space are in compliance with workplace regulations and standards.	A. All procedures are in compliance with federal/provincial Occupational Health and Safety regulations/legislation B. The reprocessing physical space is in compliance with the Canadian Standards association standards and federal/provincial Occupational Health and Safety regulations/legislation.			

APPENDIX G – Verification of Training Stages for Endoscope Reprocessing

Date(s) of Training:

Name of Trainee:

Name of Trainer:

Information or Procedure in Endoscope Reprocessing Training	**Verification that procedure training was provided**		**Verification of competency with procedure**	
	Trainer:	**Trainee:**	**Trainer:**	**Trainee:**
1. Basic tutorial on: • Use of flexible endoscopes • Mechanics/handling of scopes				
2. Infection prevention and control tutorial on: • Basic microbiology of endoscopy • Disease transmission, staff protection (reduce aerosolizing) • Prevention of infection transmission - (patient to patient, environment to patient transmission)				
3. Chemical and detergent usage and safety				
4. Review of reprocessing manuals: • Manufacturer's procedure manual • Site/unit procedure manual (including diagrams)				
5. Leak testing: • How • Why • When • What to do if leak test fails				

Information or Procedure in Endoscope Reprocessing Training	Verification that procedure training was provided		Verification of competency with procedure	
	Trainer:	Trainee:	Trainer:	Trainee:
6. Disassembling of endoscopes: • Remove all buttons, valves, caps and other removable parts • Processing of disassembled parts • Appropriate capping for video endoscopes • Visual inspection • Correctly dispose of parts that are deemed single use				
7. Manual cleaning procedure: • Bedside suction • Detergent used • Brushing • Appropriate size • Appropriate reprocessing • Water for rinsing (volume) • Elevator wire of Endoscopic Retrograde Cholangiopancreatography (ERCP) scopes and other specialty channels • Consistency of process and why this is critical • Visual inspection				
8. Manual high-level disinfectant procedure: • Appropriate preventive clothing/risk of aerosols • Hazards of chemical exposure • Appropriate high-level disinfectant • Testing • Minimal effective concentration of disinfectant • Maximum in disinfectant expiratory date • Appropriate immersion techniques • Critical minimum timing parameters for high level disinfectant exposure • Rinsing techniques (water issues) of endoscopes • Alcohol rinse of endoscopes • Drying of reprocessed endoscopes				

Information or Procedure in Endoscope Reprocessing Training	Verification that procedure training was provided		Verification of competency with procedure	
	Trainer:	**Trainee:**	**Trainer:**	**Trainee:**
9. Automated endoscope reprocessor equipment: • Manual pre-cleaning shall be done • Appropriate protective clothing • Hazards of chemical exposure • Review of reprocessor manual/use of machine • Correct connection of endoscope • Issues related to the use-dilution of high level disinfectant or sterilant • Alcohol rinsing of endoscope • Drying of reprocessed endoscope				
10. Storage of dried scopes				
11. Accessory devices: appropriate cleaning and disinfection				
12. Quality assurance program for endoscopy: • Reprocessing damaged endoscopes • References • Templates				

Adapted from M. Alfa[211].

APPENDIX H – Guideline for Outbreak Investigation Related to Endoscopic Procedures[90;172;174;205]

The steps below may be done simultaneously and do not always follow the order listed.

1. Identify the duration and nature of exposure (identify microorganism(s) of concern).
2. Identify which scope, and/or scope accessories were used and quarantine if necessary.
3. Notify all involved personnel (e.g., infection prevention and control, endoscopy director and nurse manager, administration, microbiology, clinical department heads, communications department and family MDs).
4. Advise laboratory to save all relevant patient and endoscope isolates.
5. Identify and count cases or exposures.
    a. Create a case definition.
    b. Develop a patient line listing: sort according to the procedure, endoscope used, and chronological order in which accessories are used.
    c. Perform chart review of cases for risk factors related to suspect procedure(s) or other known risk factors for the infection under consideration; if review indicates endoscopy-related infection, perform retrospective chart review of all patients undergoing the procedure(s) for linked cases of post-endoscopy infection.
6. Tabulate and orient the data in terms of time, place, and person.
7. If indicated, perform environmental sampling of endoscopes, rinse water, fluid from automated endoscope reprocessor (AER) and other. relevant items (e.g., water bottles, I.V. sedatives). Save environmental isolates and compare with patient isolates to determine strain relatedness.
8. Formulate hypothesis for suspected outbreak.
9. Implement control and preventive measures.
10. Evaluate epidemiological data on the strength of causal association.
11. Initiate surveillance for new cases as well as continued microbiologic culturing of endoscopy equipment.
12. Re-evaluate specific control and preventive measures and revise if necessary
13. Communicate findings.
    a. Notify local public health and the Public Health Agency of Canada if there are public health implications.
    b. Prepare written reports for administration, involved department heads, and other requesting authorities.
    c. Provide information and debriefing sessions to involved personnel.
    d. Notify the communications department and advise if patient follow-up is required.
14. Assess risk to the patient.
15. Develop plan for patient follow-up (only if required).
    a. Organize a small notification team.
    b. Develop a telephone script, contact letters, and fact sheets for patients and physicians (family and attending).
    c. Initiate telephone contact with the patient followed by written confirmation with fact sheet.
    d. Provide information to the patient regarding required blood work and arrangement for follow-up testing if necessary.
    e. Notify diagnostic laboratory if a large volume of tests is necessary; may be advantageous if lab requisitions for required tests are filled out for each patient and faxed/delivered to lab.
    f. Plan for managing patients who test positive.

APPENDIX I – PHAC Guideline Rating System

PHAC Guideline Rating System[212]

Categories for the strength of each recommendation	
Category	**Definition**
A	Good evidence to support a recommendation.
B	Moderate evidence to support a recommendation.
C	Insufficient evidence to support a recommendation.

Categories for the quality of evidence on which recommendations are made	
Grade	**Definition**
I	Evidence from at least one properly randomized, controlled trial.
II	Evidence from at least one well-designed clinical trial without randomization, from cohort or case-controlled analytic studies (preferably form more than one centre), from multiple time series, or from dramatic results in controlled experiments.
III	Evidence from opinions of respected authorities on the basis of clinical experience, descriptive studies or reports of expert committees.

When regulations are quoted, no rating is given as they are legislative requirements.

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