



**TITLE: Sterilization Equipment and Requirements for Endoscopy Equipment: A Review of the Clinical Evidence and Guidelines**

**DATE:** 19 January 2012

## **CONTEXT AND POLICY ISSUES**

Endoscopies are performed frequently in Canada; almost one million gastroscopies and colonoscopies were performed in Canada in 2002, and this number has likely increased since then given the aging population and increased screening for colorectal cancer.<sup>1</sup> Endoscopies are useful tools for the diagnosis and treatment of illness.<sup>2</sup> Given that endoscopes are reusable items exposed to bodily fluids, potentially transmitting pathogens, it is vital that the equipment used to perform endoscopies is appropriately reprocessed to prevent exposure to and transmission of communicable diseases to patients who undergo endoscopies.<sup>2</sup>

While it is very rare for infection to be transmitted during endoscopy (estimated to be 1 infection per 1.8 million procedures), nearly all transmissions have occurred as a result of improper cleaning and disinfection of endoscopy equipment.<sup>2-4</sup> Bacteria have been the major cause of infections acquired through endoscopy, but there are reports of hepatitis B and C transmission through endoscopy.<sup>2</sup> These rare but serious cases further highlight the need for thorough reprocessing of endoscopy equipment prior to patient exposure.

The Spaulding Classification for Medical Devices was developed to identify the level of cleaning, disinfection, or sterilization required for patient care equipment.<sup>5</sup> Based on the Spaulding classification, equipment is divided into three categories: non-critical (items that come into contact with intact skin), semi-critical (items that come into contact with mucous membranes), and critical (items that enter sterile tissue).<sup>5</sup> All items require manual cleaning initially.<sup>5</sup> Non-critical items require a minimum of low-level disinfection, whereas semi-critical items require a minimum of high-level disinfection and critical items require disinfection.<sup>5</sup> Appendix 1 provides the complete definitions for each category and level of cleaning required.

There are a number of clinical practice guidelines available on the reprocessing of endoscopy equipment, and some have conflicting recommendations. The purpose of this review is to evaluate the current evidence and recommendations surrounding reprocessing of endoscopy equipment.

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## RESEARCH QUESTIONS

1. What is the clinical evidence regarding sterilization and sanitation of endoscopy equipment?
2. What are the evidence-based guidelines regarding the appropriate type of sterilizer and sterilization procedures for endoscopy equipment?

## KEY MESSAGE

Gastrointestinal endoscopes are consistently classified as semi-critical items, and require a minimum of high-level disinfection. Inconsistent evidence exists regarding the processing of cystoscopes and bronchoscopes.

## METHODS

### Literature Search Strategy

A focused search (with main concepts appearing in title or major subject heading) was conducted on key resources including PubMed, The Cochrane Library (2011, Issue 12), University of York Centre for Reviews and Dissemination (CRD) databases, Canadian and major international health technology agencies, as well as a focused Internet search. No filters were applied to limit the retrieval by study type. Where possible, retrieval was limited to the human population. The search was also limited to English language documents published between January 1, 2006 and December 12, 2011.

### Selection Criteria and Methods

One reviewer screened the literature search results to identify relevant publications, including health technology assessments (HTA), systematic reviews (SR), randomized controlled trials (RCT), non-randomized studies, and clinical practice guidelines (CPG) based on publication title and abstract. Full-text articles were considered for inclusion based on the selection criteria listed in Table 1.

**Table 1: Selection Criteria**

<b>Population</b>	Endoscopy equipment - bronchoscopes, cystoscopes, colonoscopes, or gastroscopes
<b>Intervention</b>	Disinfection and sterilization equipment and standards
<b>Comparator</b>	Any comparator
<b>Outcomes</b>	Guidelines and best practice for sanitation versus sterilization requirements Clinical evidence to support practice Clarification regarding levels of sanitation and sterilization (semi-critical versus critical)
<b>Study Designs</b>	Health technology assessments, systematic reviews and meta-analyses, randomized controlled trials, non-randomized studies, evidence-based guidelines.

## Exclusion Criteria

Publications were excluded if there were duplications of the same study, if a more recent update was available, if they used a comparator that is not recommended for use, if they were non-systematic reviews, or if they did not meet the inclusion criteria.

## Critical Appraisal of Individual Studies

Clinical practice guidelines (CPGs) were appraised using the Appraisal of Guidelines for Research and Evaluation (AGREE II) instrument.<sup>6</sup> The items included in the AGREE instrument are scope and purpose of the guideline, stakeholder involvement, rigour of development, clarity and presentation, applicability, and editorial independence.<sup>6</sup> An overall numeric score was not calculated; instead, strengths and limitations were reviewed for available guidelines. No health technology assessments, systematic reviews, randomized controlled trials or non-randomized studies were identified for critical appraisal.

## SUMMARY OF EVIDENCE

For the purpose of this review, a list of definitions relating to endoscopy reprocessing is provided in Appendix 1.

## Quantity of Research Available

A total of 266 manuscripts were identified in the literature search. After screening of titles and abstracts, 29 potentially relevant articles were selected for full-text screening. An additional 11 potentially relevant articles were retrieved from the grey literature. Of the 40 potentially relevant reports, a total of 10 studies met inclusion criteria, and all are CPGs.<sup>2-4,7-13</sup> Appendix 2 describes the PRISMA flowchart of the included studies in the report.

## Summary of Study Characteristics

A summary of individual study characteristics is provided in Appendix 3

### *Country of origin*

The clinical practice guidelines included in this report are from a number of different countries including Canada,<sup>2,9,13</sup> United States of America (USA),<sup>3,10,12</sup> Japan,<sup>7</sup> Europe,<sup>4</sup> and United Kingdom.<sup>11</sup> One guideline from the World Gastroenterology Organisation/World Endoscopy Organization (WGO/WEO) involved individuals from a number of countries, including France, United Kingdom, USA, Chile, Switzerland, Japan, and the Netherlands.<sup>8</sup>

### *Interventions*

Three of the guidelines discussed disinfection of any endoscopy equipment,<sup>9,12,13</sup> whereas six guidelines focused specifically on gastrointestinal endoscopes,<sup>2-4,8,10,11</sup> one reviewed bronchoscopes,<sup>2</sup> and one guideline focused on cystoscopes.<sup>7</sup>

### *Grading of recommendations and levels of evidence*

Six guidelines graded the strength of their recommendations based on the quality of evidence, but each guideline used a different system to grade the evidence, except the 2011 guidelines from the American Society for Gastrointestinal Endoscopy and the guidelines from the Centers for Disease Control and Prevention, which used the same system.<sup>2,3,7,10-12</sup> Appendix 4 reports the methods used for grading recommendations provided in the guidelines.

### *Years of publication*

The years of publication ranged from 2006 to 2011.<sup>2-4,7-13</sup>

## **Summary of Critical Appraisal**

Results of critical appraisal are provided in Appendix 5.

Many CPGs noted the lack of rigorous prospective evidence identifying the incidence of pathogen transmission associated with endoscopy or comparing different methods of disinfection or sterilization, therefore the strength of evidence supporting recommendations within the guidelines is limited.<sup>2-4,7,8,11</sup> The majority of CPGs did not report the methods for the literature search to identify relevant publications, or how evidence was selected.<sup>3,4,7-9,11,13</sup> Most did not report whether members of the guideline committee had conflicts of interest to declare.<sup>4,7-13</sup> Lastly, only one guideline considered cost and organization barriers to implementing recommendations.<sup>8</sup> Strengths of some of the CPGs were inclusion of relevant professional societies for the creation of the guideline, unambiguous recommendations, and a clear link between the evidence discussed and the recommendations created by the guideline committee.<sup>2-4,11,12</sup>

## **Summary of Findings**

Individual study findings and a summary of author conclusions is provided in Appendix 6.

Gastrointestinal endoscopes typically come into contact with mucous membranes, but do not enter sterile tissue. As a result, the CPGs included in this report consistently recognized gastrointestinal endoscopes as semi-critical equipment that should at a minimum undergo high-level disinfection.<sup>2-4,8-13</sup> In addition, all guidelines recommended manual precleaning immediately following the endoscopic procedure to remove visible debris and prevent development of biofilm and disinfection failure.<sup>2-4,7-13</sup> All guidelines also stated that manufacturers' instructions regarding device-specific disinfection and proper use of high-level disinfectants should be closely followed.<sup>2-4,7-13</sup>

Endoscopes that enter sterile tissue such as arthroscopes and laparoscopes have been clearly identified as critical items, thereby requiring sterilization.<sup>9,12,13</sup> There is controversy, however, whether items like cystoscopes and bronchoscopes, because they enter sterile tissue, should be considered critical items and thereby be required to be sterilized prior to patient use. The controversy exists because some cystoscopes and bronchoscopes are not compatible with sterilization techniques, and can therefore only be disinfected. Guidelines from Japan focused on urological endoscopes recognized that because cystoscopes are inserted into a sterile environment, sterilization is preferred, but because there are compatibility issues with some flexible cystoscopes and sterilization, strictly monitored high-level disinfection is permitted.<sup>7</sup> The

Provincial Infectious Diseases Advisory Committee from Ontario, Canada also recognized that it is preferred to have cystoscopes and bronchoscopes sterilized, but many are not compatible with sterilization, so high-level disinfection is the minimum requirement when endoscopes are not compatible with sterilization.<sup>9</sup> Guidelines from the Centers for Disease Control and Prevention recommend that all heat-sensitive endoscopes, including bronchoscopes, be subjected to a minimum of high-level disinfection after each use.<sup>12</sup> Also, cystoscopes were considered semi-critical items in this guideline, thereby requiring a minimum of high-level disinfection for reprocessing.<sup>12</sup> Lastly, the Endoscopy Task Force from Ontario, Canada, recognized cystoscopes and other endoscopes that enter sterile tissue as critical items that should be sterilized when feasible.<sup>13</sup>

The recommendations discussing the use of automated endoscope reprocessors (AERs) also differed between guidelines. Guidelines from the British Society of Gastroenterology Endoscopy Committee stated that AERs should be used for all gastrointestinal endoscope disinfection and that manual disinfection is “unacceptable”.<sup>11</sup> Other European guidelines recommended the use of AERs for endoscope reprocessing.<sup>4</sup> North American CPGs, including three from Canada, do not provide a recommendation of AERs over manual disinfection,<sup>2,3,9,12,13</sup> and three highlight the potential risk of inadequate disinfection associated with incorrect use of AERs or poorly designed AERs, and inadequate disinfection has been reported with bronchoscopes processed in older AERs.<sup>2,12,13</sup>

Other recommendations that differed between guidelines included type of rinse water that should be used to rinse the endoscopes during reprocessing (tap water vs. sterile water vs. filtered water), and whether alcohol should be used to rinse the endoscope prior to drying. Most guidelines recommended the use of 70% to 90% ethyl or isopropyl alcohol prior to drying.<sup>2,3,8,10,12,13</sup> British and European guidelines do not recommend rinsing with alcohol because of little evidence suggesting that alcohol prevents the proliferation of waterborne bacteria, and the potential that proteins could be anchored to the endoscope channel because of alcohol's fixative properties, but the guidelines state that this is a theoretical risk, and there is no clinical evidence to suggest this is the case.<sup>4,11</sup>

## LIMITATIONS

No clinical studies were available to evaluate the sterilization and sanitation of endoscopy equipment. As many of the guidelines note, there was a lack of rigorous prospective evidence available to guide decision-making regarding the proper sterilization or high-level disinfection of endoscopy equipment. A number of guidelines had methodological flaws including no reported literature search strategy, no criteria for selecting evidence included in the guideline, no criteria for grading recommendations, and no conflict of interest statements from members of the guideline panel.<sup>3,4,7-11,13</sup> While the evidence regarding reprocessing of gastrointestinal endoscopy equipment was consistent, conflicting information was available for the recommended reprocessing of cystoscopes and bronchoscopes. Many guidelines were not from Canada, and therefore may not be generalizable to the Canadian population.<sup>3,4,7,8,10-12</sup> Little evidence exists to make a decision regarding the use of AERs or manual disinfection.<sup>2,3,9,12,13</sup>

## CONCLUSIONS AND IMPLICATIONS FOR DECISION OR POLICY MAKING

No evidence was available in terms of clinical studies assessing sterilization and sanitation of endoscopy equipment. Existing guidelines state that all endoscopes should be manually precleaned of visible debris immediately after the endoscopic procedure. The majority of

evidence available focused on gastrointestinal endoscopes, and these items were consistently classified by available guidelines as semi-critical items requiring a minimum of high-level disinfection prior to patient exposure. There were conflicting opinions about whether cystoscopes and bronchoscopes should be classified as semi-critical or critical items because they enter sterile tissue, and as a result should be sterilized prior to use. It was recognized that some flexible cystoscopes and bronchoscopes are not compatible with sterilization, so it was recommended that the non-compatible endoscopes should undergo a minimum of high-level disinfection.

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**Appendix 1: Definitions of terminology relating to endoscopy reprocessing**<sup>2,9,12</sup>

**Automated endoscope reprocessor:** “a machine designed to assist with the cleaning and disinfection of endoscopes”.<sup>2</sup> page 74

**Cleaning:** the physical removal of visible foreign material such as blood or other organic material. Cleaning is completed with water, detergents and mechanical action.

**Critical items:** based on the Spaulding Classification System,<sup>5</sup> equipment that enters sterile tissue that confers a high risk for infection if they are contaminated with any microorganism. Examples include arthroscopes, laparoscopes, biopsy forceps, and other surgical instruments.

**Disinfection:** “the inactivation of disease-producing microorganisms”.<sup>2</sup> page 74 Disinfection is less lethal than sterilization because it destroys most recognized pathogenic organisms but not necessarily all microbial forms, such as bacterial spores.

**High-level disinfection:** the process of destroying vegetative bacteria, mycobacteria, fungi and viruses, but not necessarily bacterial spores. High-level disinfection chemicals must be capable of sterilization when used in sufficient concentration under suitable conditions. This is the level of disinfection required for processing semi-critical items.

**Low-level disinfection:** the process of destroying all vegetative bacteria (except tubercle bacilli), lipid viruses, some non-lipid viruses, some fungi, but not bacterial spores. This is the level of disinfection required for processing non-critical items.

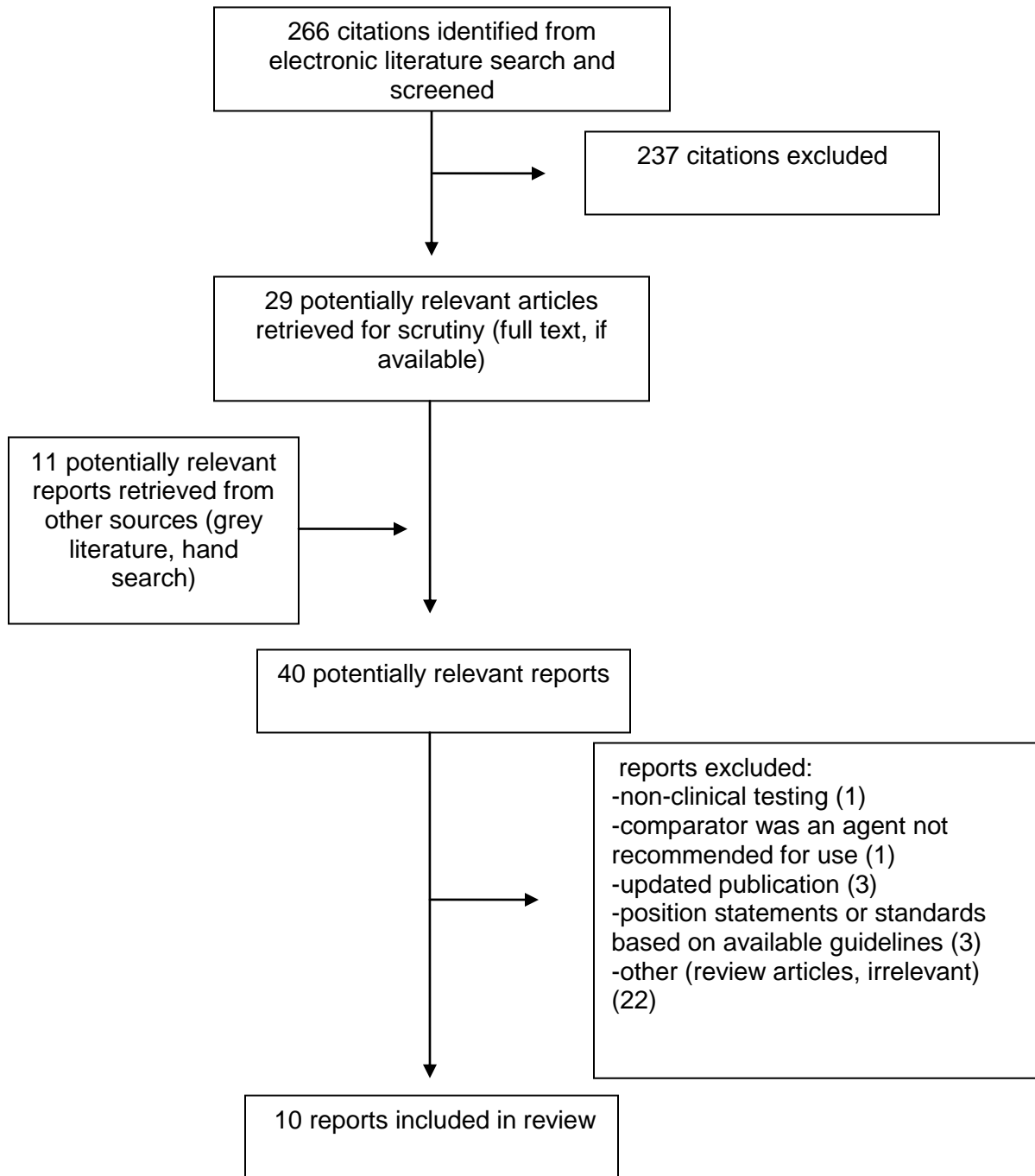
**Non-critical items:** based on the Spaulding Classification System,<sup>5</sup> equipment that touches intact skin. Examples include stethoscopes and blood pressure cuffs.

**Semi-critical items:** based on the Spaulding Classification System,<sup>5</sup> equipment that touches mucous membranes and non-intact skin. Examples include gastroscopes, bronchoscopes, and colonoscopes.

**Spaulding Classification System:** the classification of medical devices as critical, semi-critical, or non-critical based on the risk of patient safety from contamination of a device. In addition, three levels of germicidal activity have been established for the three classes of medical devices, including sterilization for critical items, high-level disinfection for semi-critical items, and low-level disinfection for non-critical items.

**Sterilization:** the validated process of destruction of all forms of microbial life including bacteria, viruses, spores, and fungi. This is the level of disinfection required for critical items.

Appendix 2: PRISMA Diagram: Selection of Included Studies



**Appendix 3: Summary of Included Guidelines**

<b>First Author, Publication Year, Country</b>	<b>Equipment Evaluated</b>	<b>Processes</b>
American Society for Gastrointestinal Endoscopy (ASGE) 2011 United States <sup>3</sup>	GI endoscopes	Reprocessing flexible GI endoscopes
Hamasuna 2011 Japan <sup>7</sup>	Urological endoscopes	Prevention of health care-associated infection in urological practice
Rey JF 2011 Multiple countries <sup>8</sup>	GI endoscopes	GI endoscope reprocessing
Guideline Working Group 2010 Canada <sup>2</sup>	Flexible GI endoscopes and bronchoscopes	Infection control and prevention for flexible GI endoscopes and flexible bronchoscopes
Provincial Infectious Diseases Advisory Committee (PIDAC) 2010 Canada <sup>9</sup>	All endoscopes	Cleaning, disinfection, and sterilization of endoscopes
ASGE Standards of Practice Committee 2008 United States <sup>10</sup>	GI endoscopes	Infection control during GI endoscopy
British Society of Gastroenterology Endoscopy Committee 2008 United Kingdom <sup>11</sup>	GI endoscopes	Decontamination of equipment for GI endoscopy
Rutala W 2008 United States <sup>12</sup>	All endoscopes	Disinfection and sterilization of endoscopes
Beilenhoff U 2008 Europe <sup>4</sup>	GI endoscopes	Cleaning and disinfection in GI endoscopy
Endoscopy Task Force 2006 Canada <sup>13</sup>	All endoscopes	Infection control and prevention for endoscopy procedures

GI: Gastrointestinal

Appendix 4: Grading of Recommendations and Levels of Evidence

Guideline Society/First Author, Publication year, Country	Level of Evidence	Recommendation Grade
American Society for Gastrointestinal Endoscopy (ASGE) 2011 United States <sup>3</sup>	<ul style="list-style-type: none"> <li>▪ None</li> </ul>	<ul style="list-style-type: none"> <li>▪ Category IA: Strongly recommended for implementation and strongly supported by well-designed experimental, clinical or epidemiologic studies</li> <li>▪ Category IB: Strongly recommended for implementation and supported by some experimental, clinical or epidemiologic studies and a strong theoretical rationale</li> <li>▪ Category IC: Required by state or federal regulations. Because of state differences, readers should not assume that the absence of an IC recommendation implies the absence of state regulations</li> <li>▪ Category II: Recommended for implementation and supported by suggestive clinical or epidemiologic studies or theoretical rationale</li> <li>▪ No recommendation: Unresolved issue. Practices for which insufficient evidence of no consensus regarding efficacy exists</li> </ul>
Hamasuna 2011 Japan <sup>7</sup>	<ul style="list-style-type: none"> <li>▪ I: Experimental evidence from at least one randomized controlled trial or meta-analysis</li> <li>▪ II: Experimental evidence from non-randomized controlled trial comparative studies or cohort studies</li> <li>▪ III: Case-series study or expert opinion</li> </ul>	<ul style="list-style-type: none"> <li>▪ A: Strongly recommended</li> <li>▪ B: Generally recommended</li> <li>▪ C: At your own discretion</li> </ul>
Guideline Working Group 2010 Canada <sup>2</sup>	<ul style="list-style-type: none"> <li>▪ I: Evidence from at least one properly randomized, controlled trial</li> <li>▪ II: Evidence from at least one well-designed clinical trial without randomization, from cohort or case-controlled analytic studies (preferably from more than one centre), from multiple time series, or from dramatic results in controlled experiments</li> <li>▪ III: Evidence from opinions of respected authorities on the basis of clinical experience, descriptive studies or reports of expert committees</li> </ul>	<ul style="list-style-type: none"> <li>▪ A: Good evidence to support a recommendation</li> <li>▪ B: Moderate evidence to support a recommendation</li> <li>▪ C: Insufficient evidence to make a recommendation</li> </ul>

Guideline Society/First Author, Publication year, Country	Level of Evidence	Recommendation Grade
ASGE Standards of Practice Committee 2008 United States <sup>10</sup>	<ul style="list-style-type: none"> <li>▪ 1A: Clear benefit; randomized trials without important limitations</li> <li>▪ 1B: Clear benefit; randomized trials with important limitations (inconsistent results, nonfatal methodologic flaws)</li> <li>▪ 1C+: Clear benefit; overwhelming evidence from observational studies</li> <li>▪ 1C: Clear benefit; observational studies</li> <li>▪ 2A: Unclear benefit; randomized trials without important limitations</li> <li>▪ 2B: Unclear benefit; randomized trials with important limitations (inconsistent results, nonfatal methodologic flaws)</li> <li>▪ 2C: Unclear benefit; observational studies</li> <li>▪ 3: Unclear benefit; expert opinion only</li> </ul>	<ul style="list-style-type: none"> <li>▪ 1A: Strong recommendation; can be applied to most clinical settings</li> <li>▪ 1B: Strong recommendation; likely to apply to most practice settings</li> <li>▪ 1C+: Strong recommendation; can apply to most practice settings in most situations</li> <li>▪ 1C: Intermediate-strength recommendation; may change when stronger evidence is available</li> <li>▪ 2A: Intermediate-strength recommendation; best action may differ depending on circumstances or patient or societal values</li> <li>▪ 2B: Weak recommendation; alternative approaches may be better under some circumstances</li> <li>▪ 2C: Very weak recommendation; alternative approaches likely to be better under some circumstances</li> <li>▪ 3: Weak recommendation; likely to change as data become available</li> </ul>
British Society of Gastroenterology Endoscopy Committee 2008 United Kingdom <sup>11</sup>	<ul style="list-style-type: none"> <li>▪ None</li> </ul>	<ul style="list-style-type: none"> <li>▪ A: Recommendation based on at least one meta-analysis, systematic review, or a body of evidence from RCTs</li> <li>▪ B: Recommendation based on high quality case control or cohort studies with overall consistency or extrapolated from systematic reviews, RCTs or meta-analyses</li> <li>▪ C: Recommendation based on lesser quality case control or cohort studies with overall consistency or extrapolated from high quality studies</li> <li>▪ D: Recommendation from case series or report and expert opinion including consensus</li> </ul>
Rutala W 2008 United States <sup>12</sup>	<ul style="list-style-type: none"> <li>▪ None</li> </ul>	<ul style="list-style-type: none"> <li>▪ Category IA: Strongly recommended for implementation and strongly supported by well-designed experimental, clinical, or epidemiologic studies.</li> <li>▪ Category IB. Strongly recommended for implementation and supported by some experimental, clinical, or epidemiologic studies, and by a strong theoretical rationale</li> <li>▪ Category IC. Required by state or federal regulations. Because of state differences, readers should not assume that the absence of an IC recommendation implies the absence of state regulations</li> </ul>

Guideline Society/First Author, Publication year, Country	Level of Evidence	Recommendation Grade
		<ul style="list-style-type: none"> <li>▪ Category II. Suggested for implementation and supported by suggestive clinical or epidemiologic studies or by a theoretical rationale.</li> <li>▪ No recommendation. Unresolved issue. These include practices for which insufficient evidence or no consensus exists regarding efficacy.</li> </ul>

Appendix 5: Critical Appraisal of Included Studies

First Author, Publication Year, Country	Strengths	Limitations
American Society for Gastrointestinal Endoscopy (ASGE) 2011 United States <sup>3</sup>	<ul style="list-style-type: none"> <li>▪ Input was received from a number of stakeholders for the development of the guideline.</li> <li>▪ The criteria used for formulating recommendations were reported.</li> <li>▪ The guideline highlights unresolved issues that require further research before recommendations can be made.</li> <li>▪ Guideline authors provided conflict of interest statements.</li> </ul>	<ul style="list-style-type: none"> <li>▪ Only provides recommendations for GI endoscopy. Recommendations do not apply to other forms of endoscopy.</li> <li>▪ No description of literature search to identify evidence.</li> <li>▪ Patient views and preferences were not requested.</li> <li>▪ Methods for selecting evidence were not described.</li> <li>▪ No consideration of cost or organizational barriers to implementing recommendations.</li> </ul>
Hamasuna 2011 Japan <sup>7</sup>	<ul style="list-style-type: none"> <li>▪ Target audience is specified.</li> <li>▪ The criteria used for formulating recommendations were reported.</li> <li>▪ Overall objective of the guideline is specifically described.</li> </ul>	<ul style="list-style-type: none"> <li>▪ No description of literature search to identify evidence.</li> <li>▪ Methods for selecting evidence were not described.</li> <li>▪ Only provides recommendations for urological endoscopy. Recommendations do not apply to other forms of endoscopy.</li> <li>▪ All recommendations are based on case-series study or expert opinion.</li> <li>▪ No conflicts of interest recorded.</li> <li>▪ No consideration of cost or organizational barriers to implementing recommendations.</li> </ul>
Rey JF 2011 Multiple countries <sup>8</sup>	<ul style="list-style-type: none"> <li>▪ Different options are presented for different resource levels.</li> <li>▪ Cost implications of applying recommendations were considered.</li> </ul>	<ul style="list-style-type: none"> <li>▪ Only provides recommendations for GI endoscopy. Recommendations do not apply to other forms of endoscopy.</li> <li>▪ No description of literature search to identify evidence.</li> <li>▪ No criteria for selecting the evidence described.</li> <li>▪ No grades of evidence were provided.</li> <li>▪ No conflicts of interest recorded.</li> </ul>
Guideline Working Group 2010 Canada <sup>2</sup>	<ul style="list-style-type: none"> <li>▪ Overall objective of the guideline is specifically described.</li> <li>▪ Target users of the guideline are clearly described.</li> <li>▪ Input was received from a number of stakeholders for the development of the guideline.</li> <li>▪ Literature search was described.</li> <li>▪ Process for formulation of recommendations was described.</li> <li>▪ The guideline was reviewed by a number of societies and associations prior to widespread implementation.</li> <li>▪ All members of the working group declared no conflicts of interest.</li> </ul>	<ul style="list-style-type: none"> <li>▪ Only provides recommendations regarding flexible GI endoscopy and flexible bronchoscopy.</li> <li>▪ Most recommendations are based on insufficient to moderate evidence based on the guideline evidence grading system.</li> <li>▪ No consideration of cost or organizational barriers to implementing recommendations.</li> </ul>
Provincial Infectious	<ul style="list-style-type: none"> <li>▪ Overall objective of the guideline</li> </ul>	<ul style="list-style-type: none"> <li>▪ No description of literature search to identify</li> </ul>

First Author, Publication Year, Country	Strengths	Limitations
Diseases Advisory Committee (PIDAC) 2010 Canada <sup>9</sup>	<ul style="list-style-type: none"> <li>▪ is specifically described.</li> <li>▪ Target users of the guideline are clearly described.</li> </ul>	<ul style="list-style-type: none"> <li>▪ evidence.</li> <li>▪ Methods for selecting evidence were not described.</li> <li>▪ No grades of evidence were provided.</li> <li>▪ No conflicts of interest recorded.</li> <li>▪ No consideration of cost or organizational barriers to implementing recommendations.</li> </ul>
ASGE Standards of Practice Committee 2008 United States <sup>10</sup>	<ul style="list-style-type: none"> <li>▪ Overall objective of the guideline is specifically described.</li> <li>▪ Target users of the guideline are clearly described.</li> <li>▪ Grades of recommendations provided.</li> <li>▪ Search for identifying literature reported.</li> </ul>	<ul style="list-style-type: none"> <li>▪ Only provides recommendations for GI endoscopy. Recommendations do not apply to other forms of endoscopy.</li> <li>▪ No conflicts of interest reported.</li> <li>▪ All recommendations are based on observational evidence only.</li> <li>▪ No consideration of cost or organizational barriers to implementing recommendations.</li> </ul>
British Society of Gastroenterology Endoscopy Committee 2008 United Kingdom <sup>11</sup>	<ul style="list-style-type: none"> <li>▪ Grades of recommendations provided.</li> <li>▪ Key recommendations are easily identifiable.</li> <li>▪ The recommendations are specific and unambiguous.</li> </ul>	<ul style="list-style-type: none"> <li>▪ No target audience or clear objective reported in the guideline.</li> <li>▪ No description of literature search to identify evidence.</li> <li>▪ Methods for selecting evidence were not described.</li> <li>▪ Most recommendations are based on level C (lesser quality case control or cohort studies with overall consistency or extrapolated from high quality studies) or level D (case series or report and expert opinion including consensus) evidence based on the guideline evidence grading system.</li> <li>▪ Only provides recommendations for GI endoscopy. Recommendations do not apply to other forms of endoscopy.</li> <li>▪ No conflicts of interest recorded.</li> <li>▪ No consideration of cost or organizational barriers to implementing recommendations.</li> </ul>
Rutala W 2008 United States <sup>12</sup>	<ul style="list-style-type: none"> <li>▪ Overall objective of the guideline is specifically described.</li> <li>▪ Target users of the guideline are clearly described.</li> <li>▪ Search for identifying literature reported.</li> <li>▪ Grades of recommendations provided.</li> <li>▪ Key recommendations are easily identifiable.</li> <li>▪ The recommendations are specific and unambiguous.</li> </ul>	<ul style="list-style-type: none"> <li>▪ No conflicts of interest recorded.</li> <li>▪ No consideration of cost or organizational barriers to implementing recommendations.</li> </ul>
Beilenhoff U 2008 Europe <sup>4</sup>	<ul style="list-style-type: none"> <li>▪ Input was received from a number of stakeholders for the development of the guideline.</li> </ul>	<ul style="list-style-type: none"> <li>▪ No description of literature search to identify evidence.</li> <li>▪ No criteria for selecting the evidence described.</li> </ul>

First Author, Publication Year, Country	Strengths	Limitations
	<ul style="list-style-type: none"> <li>▪ Target audience is specified.</li> </ul>	<ul style="list-style-type: none"> <li>▪ No criteria for formulating recommendations are described.</li> <li>▪ No grades of evidence were provided.</li> <li>▪ Only provides recommendations for GI endoscopy. Recommendations do not apply to other forms of endoscopy.</li> <li>▪ No conflicts of interest recorded.</li> <li>▪ No consideration of cost or organizational barriers to implementing recommendations.</li> </ul>
Endoscopy Task Force 2006 Canada <sup>13</sup>	<ul style="list-style-type: none"> <li>▪ Overall objective of the guideline is specifically described.</li> <li>▪ Target users of the guideline are clearly described.</li> </ul>	<ul style="list-style-type: none"> <li>▪ No description of literature search to identify evidence.</li> <li>▪ Methods for selecting evidence were not described.</li> <li>▪ No grades of evidence were provided.</li> <li>▪ No conflicts of interest recorded.</li> <li>▪ No consideration of cost or organizational barriers to implementing recommendations.</li> </ul>

GI: Gastrointestinal

Appendix 6: Summary of Study Findings

First Author, Publication Year, Country	Main Study Findings	Authors' Conclusions
<p>American Society for Gastrointestinal Endoscopy (ASGE) 2011 United States <sup>3</sup></p>	<p>The guidelines note that there are no well-designed prospective studies evaluating the incidence of pathogen transmission during GI endoscopy, but based on available evidence (e.g. case reports), transmission of pathogens seems to be rare.</p> <p>The reported cases of pathogen transmission in GI endoscopy have been associated with lapses in accepted cleaning and disinfection guidelines.</p>	<p>“Flexible GI endoscopes should first be completely cleaned and then subjected to at least high-level disinfection.” – page 1076, Category IB</p> <p>“Users should always refer to manufacturers’ instructions for device-specific reprocessing guidance.” – page 1078, Category IB</p> <p>“Precleaning should be performed at the point of use, before bioburden has an opportunity to dry and before decontamination.” – page 1078, Category 1B</p> <p>“Select a liquid disinfectant or sterilization technology that is compatible with the endoscope.” – page 1079, Category 1B</p> <p>“If an automated endoscope reprocessor (AER) is used, ensure that the endoscope and endoscope components are compatible with the AER” – page 1079, Category IB</p> <p>“After high-level disinfection, rinse the endoscope and flush the channels with sterile, filtered or tap water to remove the disinfectant solution. Flush the channels with 70% to 90% ethyl or isopropyl alcohol and dry by using forced air.” – page 1080, Category IA</p>
<p>Hamasuna 2011 Japan <sup>7</sup></p>	<p>Urological endoscopes must be cleaned immediately after use to prevent residual protein development and a reduction in the efficacy of disinfection and sterilization.</p> <p>All rigid scopes are autoclavable and should be sterilized by autoclaving.</p> <p>If compatible, flexible scopes can be sterilized using low temperature hydrogen peroxide gas plasma sterilization or ethylene oxide gas sterilization.</p> <p>Ortho-phthalaldehyde is contraindicated in Japan due to reports of anaphylaxis</p>	<p>“Treat urological endoscopes with high-level or greater disinfection methods.” – page 500, Grade AIII</p> <p>“Because urological endoscopes inserted into a sterile area are classified as critical in the Spaulding classification system, sterilization is preferable. For flexible endoscopes, strictly monitored high-level disinfection is currently permitted because of compatibility issue.” – page 500, Grade AIII</p> <p>“The high-level disinfectants used for urological flexible endoscopes are peracetic acid and glutaral. Automatic machine washing is recommended.” – page 500,</p>

First Author, Publication Year, Country	Main Study Findings	Authors' Conclusions
<p>Rey JF 2011 Multiple countries<sup>8</sup></p>	<p>associated with ortho-phthalaldehyde-disinfected equipment.</p> <p>The guidelines highlight the lack of well-designed prospective studies evaluating pathogen transmission during gastrointestinal endoscopy.</p> <p>The steps of the endoscope processing sequence are: cleaning, rinsing, disinfection, rinsing, drying, and storage.</p> <p>Precleaning should be performed immediately following the procedure.</p> <p>The guidelines recommend AERs for those with extensive resources, whereas manual disinfection is recommended for those with limited resources.</p> <p>Recommended disinfectants are glutaraldehyde, ortho-phthalaldehyde, peracetic acid, or electrolyzed acid water.</p>	<p>Grade BIII</p> <p>“Recommendations for effective disinfection with a liquid chemical germicide include:</p> <ul style="list-style-type: none"> <li>· Using an automatic endoscope reprocessor</li> <li>· Performing disinfection in a dedicated area with atmospheric extraction facilities</li> <li>· Flushing high-level disinfectant or chemical sterilant throughout the endoscope at the correct temperature and for the correct duration</li> <li>· Concluding disinfection by rinsing with sterile or filtered water or 70 – 90% ethyl or isopropyl alcohol</li> <li>· Drying each endoscope properly with forced air.” – page 6 - 7</li> </ul>
<p>Guideline Working Group 2010 Canada<sup>2</sup></p>	<p>Typically sterilization cannot be performed on flexible endoscopes because of temperature sensitivity.</p> <p>Reprocessing protocols should always adhere to manufacturers' recommendations.</p> <p>Critical steps for reprocessing flexible endoscopes: precleaning immediately after use, leak testing, manual cleaning and rinsing, high-level disinfection, rinsing with bacteria-free filtered water, drying after rinsing all channels with 70% to 90% alcohol and purging with forced air.</p> <p>The most commonly used liquid disinfectants include 2% glutaraldehyde, ortho-phthalaldehyde, 0.2% peracetic acid, and 7.5% hydrogen peroxide.</p> <p>Ethylene oxide gas or gas plasma vaporized hydrogen peroxide are recommended for sterilization for equipment that is compatible.</p> <p>If using an AER, it is important that the</p>	<p>“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.” – pages 29,62, Grade BI</p> <p>“Investigations of infections following bronchoscopy have revealed breaches in the reprocessing procedure associated with the AER. 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. 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.” – pages 44,60, Grade CII</p>

First Author, Publication Year, Country	Main Study Findings	Authors' Conclusions
	<p>AER is licensed for sale in Canada, can effectively irrigate all channels of any endoscope, there are no potential reservoirs of infection, and the manufacturer identifies endoscopes that are compatible and effectively reprocessed in the AER.</p>	
<p>Provincial Infectious Diseases Advisory Committee (PIDAC) 2010 Canada <sup>9</sup></p>	<p>High-level disinfection should occur after the device has been thoroughly cleaned, rinsed, and excess rinse water is removed from the device. Cleaning should take place immediately following the completion of the endoscopy procedure.</p> <p>Recommended high-level disinfectants include 2% glutaraldehyde, 6% hydrogen peroxide, 0.2% peracetic acid, 7% accelerated hydrogen peroxide, and 0.55% ortho-phthalaldehyde. A disinfectant should be chosen based on compatibility with the endoscope, and manufacturers directions regarding duration of contact and ambient temperature should be carefully followed. After disinfection, the endoscope should be rinsed with bacteria-free or sterile water.</p> <p>“For equipment/devices that cannot withstand heat sterilization, some examples of chemical sterilants include 6% hydrogen peroxide, 2% glutaraldehyde (&gt; 10 hours), hydrogen peroxide gas plasma, 0.2% peracetic acid, 7% accelerated hydrogen peroxide, and 100% ethylene oxide.” – page 45</p>	<p>“Critical endoscopes shall be sterilized prior to use.” – page 40</p> <p>“Semi-critical endoscopes require a minimum of high-level disinfection prior to use.” – page 40</p> <p>“Opinions differ regarding the reprocessing requirements for flexible bronchoscopes and cystoscopes. Since they are entering a sterile cavity, it is preferred that bronchoscopes and cystoscopes be sterilized; however, if the cystoscope or bronchoscope is not compatible with sterilization, high-level disinfection is the minimum requirement.” – page 40</p> <p>“If an AER is used, ensure that the endoscope and endoscope components are compatible with the AER.” – page 44</p> <p>“The preferred method for decontamination of heat-resistant critical medical equipment/devices is steam sterilization (pre-vacuum sterilizers are preferred).” – page 45</p>
<p>ASGE Standards of Practice Committee 2008 United States <sup>10</sup></p>	<p>The first step in endoscope reprocessing is manual cleaning of the endoscope with detergent solution and brushed based on manufacturers' recommendations for each type of endoscope.</p> <p>High-level disinfection is the standard of care for processing of GI endoscopes. Sterilization of endoscopes is indicated if used in an open surgical procedure,</p>	<p>“High-level disinfection is the standard of care recommended by governmental agencies and all pertinent professional organizations for the processing of flexible GI endoscopes.” – pages 785,787, Level 1C+</p> <p>“To date, there have been no demonstrable benefits to the further reduction in endoscope bacterial spore counts achieved by sterilization instead of high-level</p>

First Author, Publication Year, Country	Main Study Findings	Authors' Conclusions
	<p>where there is a potential for contamination.</p> <p>The endoscope should be rinsed following high-level disinfection, followed by a 70% alcohol flush to inhibit the growth of organisms and promote drying. Endoscopes should then be stored in an upright hanging position based on manufacturers' recommendations.</p>	<p>disinfection." – page 785</p>
<p>British Society of Gastroenterology Endoscopy Committee 2008 United Kingdom <sup>11</sup></p>	<p>Flexible endoscopes that do not enter normally sterile areas of the body (e.g. gastrointestinal endoscopes) are reprocessed by high-level disinfection rather than sterilization.</p> <p>The reprocessing process involves two basic components: manual cleaning, and automated disinfection using a liquid chemical germicide.</p> <p>Recommended disinfectants include 0.55% ortho-phthalaldehyde, 0.2% to 0.35% peracetic acid, electrolysed acid water, or chlorine dioxide.</p>	<p>"Thorough manual cleaning with a compatible enzymatic detergent, including brushing and flushing of all accessible endoscope channels, must be undertaken before automatic endoscope disinfection." – pages 1, 23, Grade C</p> <p>"Units should move away from using aldehyde- and alcohol-based disinfectants because of their fixative properties, which in theory could anchor prion and other protein within endoscope channels." – pages 1,23, Grade D</p> <p>"Automated endoscope reprocessing (AER) machines should be used for all endoscope decontamination following manual cleaning. Manual disinfection is unacceptable." – page 1, 23, Grade D</p> <p>"Filtered air should be used as part of the drying process at the end of the working day prior to endoscope storage. An alternative is to dry and store endoscopes in cabinets that are designed to deliver high efficiency particulate filtered air to the internal channels at the appropriate temperature and flow rate. Because of its fixative properties the use of isopropyl alcohol is no longer recommended." – page 1</p> <p>"Water used in AER should be free of particulate contamination and of microorganisms. This can be achieved either by using bacteria-retaining filters or by other methods, for example reverse osmosis." – page 1, 24, Grade D</p>
<p>Rutala W 2008</p>	<p>Food and Drug Administration (FDA) recommended high-level disinfectants</p>	<p>"To prevent the spread of health-care-associated infections, all heat-sensitive</p>

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United States <sup>12</sup>	<p>include <math>\geq 2.4\%</math> glutaraldehyde, 0.55% ortho-phthalaldehyde, 0.95% glutaraldehyde with 1.64% phenol/phenate, 7.35% hydrogen peroxide with 0.23% peracetic acid, 1.0% hydrogen peroxide with 0.08% peracetic acid, and 7.5% hydrogen peroxide.</p> <p>Meticulous cleaning must be completed prior to high-level disinfection because failure to clean can result in disinfection failure.</p> <p>Cystoscopes are considered a semi-critical item in this guideline.</p>	<p>endoscopes (e.g. gastrointestinal endoscopes, bronchoscopes, nasopharygoscopes) must be properly cleaned and, at a minimum, subjected to high-level disinfection after each use.” – pages 13,84, Category 1A</p> <p>“AERs need further redevelopment and design, as do endoscopes, so that they do not represent a potential source of infectious agents.” – page 15</p> <p>“In general, endoscope disinfection or sterilization with a liquid chemical sterilant involves five steps after leak testing:</p> <ol style="list-style-type: none"> <li>1. Clean: mechanically clean internal and external surfaces, including brushing internal channels and flushing each internal channel with water and a detergent or enzymatic cleaners (leak testing is recommended for endoscopes before immersion).</li> <li>2. Disinfect: immerse endoscope in high-level disinfectant (or chemical sterilant) and perfuse (eliminates air pockets and ensures contact of the germicide with the internal channels) disinfectant into all accessible channels, such as the suction/biopsy channel and air/water channel and expose for a time recommended for specific products.</li> <li>3. Rinse: rinse the endoscope and all channels with sterile water, filtered water (commonly used with AERs) or tap water (i.e., high-quality potable water that meets federal clean water standards at the point of use).</li> <li>4. Dry: rinse the insertion tube and inner channels with alcohol, and dry with forced air after disinfection and before storage.” – pages 16, 86, Category 1A</li> </ol>
Beilenhoff U 2008 Europe <sup>4</sup>	<p>Sporadic reports of infections have been associated with GI endoscopy, and the majority of these infections were caused by nonadherence to recommended reprocessing guidelines.</p> <p>The reprocessing procedure should include the following steps: precleaning, manual cleaning, rinsing, disinfection,</p>	<p>“All endoscopes and accessories used in endoscopy should be reprocessed following every endoscopic procedure, using a uniform, standardized reprocessing protocol.” – page 942</p> <p>“Most flexible endoscopes used in gastrointestinal endoscopy are classified as semi-critical devices, as they come into</p>

First Author, Publication Year, Country	Main Study Findings	Authors' Conclusions
	<p>rinsing, drying, and storage.</p> <p>Recommended disinfectants include 2% to 3.4% glutaraldehyde, 0.55% ortho-phthalaldehyde, peracetic acid, and chlorine dioxide.</p> <p>Sterile water is recommended for the final rinse after disinfection and before drying.</p>	<p>contact with mucous membranes. Semi-critical devices require disinfection, but sterilization is not necessary.” – page 942</p> <p>“Endoscopy accessories which penetrate the mucosal barrier (e.g. biopsy forceps, guide wires, etc) are classified as critical devices and therefore must be sterile at the point of use.” – page 942</p> <p>“The most important step in the reduction of microorganisms is the manual cleaning. It is impossible to disinfect or even sterilize an inadequately cleaned instrument.” – page 943</p> <p>“ESGE and ESGENA strongly recommend the use of washer-disinfectors covering cleaning and disinfection.” – page 943</p> <p>“There is no clear evidence that flushing with alcohol is effective in either drying endoscopes or preventing the proliferation of waterborne bacteria.” – page 951</p>
<p>Endoscopy Task Force 2006 Canada <sup>13</sup></p>	<p>All endoscopes should be reprocessed immediately after use, and not allowed to dry prior to manual cleaning to minimize development of biofilm.</p> <p>Following disinfection, rinsing should be performed with sterile water, but tap water can be used. A rinse step with 70% alcohol and drying with compressed air follow disinfection.</p> <p>The guidelines do not make a clear recommendation of use of AERs over manual disinfection, but highlight some issues with AERs, particularly associated with bronchoscopes.</p>	<p>“Gastrointestinal endoscopes come into contact with mucous membranes and are considered semi-critical items. High level disinfection between each patient use is the current minimum reprocessing standard of practice.” – page 25</p> <p>“Endoscopes that enter sterile body spaces (i.e. cystoscopes) should be sterilized before each use. There are some references that suggest when sterilization is not feasible, endoscopes should receive at least high-level disinfection.” – page 25</p> <p>“Transmission of organisms from contaminated bronchoscopes have illustrated problems associated with automated reprocessing machines. Some bronchoscope models are not compatible with certain automated reprocessing systems. Appropriate connector systems, both device and model-specific are essential.” – page 25</p> <p>“Endoscopes have been implicated in the transmission of disease when appropriate cleaning, disinfection or sterilization</p>

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		<p>procedures were not employed. Of particular significance is the need to thoroughly manually clean equipment prior to any manual or automated disinfection or sterilization process.” – page 25</p> <p>“At all stages of handling, the endoscope should be inspected for damage.” – page 34</p> <p>“Endoscopes that enter sterile body cavities (i.e. cystoscopes, biopsy forceps, polysnares) are classified as critical items and require meticulous cleaning and sterilization between uses.” – page 35</p> <p>“Endoscopes that come in contact with mucous membrane (i.e. laryngoscopes, flexible endoscopes including bronchoscopes, colonoscopes, duodenoscopes) require high-level disinfection between use.” – page 35</p> <p>“Endoscopy unit cleaning/disinfection processes may be standardized by the use of an automated endoscope reprocessor. This equipment may be useful in circulating germicides, containing vapors and decreasing exposure of personnel to contaminated equipment and disinfectants. Operating of this equipment should be limited to those individuals trained in its proper use.” – page 37</p>

AER: automated endoscope reprocessor; ESGE: European Society of Gastrointestinal Endoscopy; ESGENA: European Society of Gastroenterology and Endoscopy Nurses and Associates; GI: Gastrointestinal