Designation: F 1518 – 00

Standard Practice for Cleaning and Disinfection of Flexible Fiberoptic and Video Endoscopes Used in the Examination of the Hollow Viscera[1]

This standard is issued under the fixed designation F 1518; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This practice covers the flexible fiberoptic and video endoscopes that are fully immersible in liquid and are used in the examination of the hollow viscera (that is, colonoscopes, gastroscopes, duodenoscopes, sigmoidoscopes, and enteroscopes). These endoscopes will be referred to as flexible gastrointestinal (GI) endoscopes.

1.1.1 It is strongly recommended that only immersible endoscopes be used in order to assure that all parts of the endoscope will be high-level disinfected; however, it is recognized that, in some instances, portions of endoscopes that neither contact patients nor patient fluids may not be immersible. In these instances, care must be taken to disinfect the nonimmersible portions to the highest degree with which they are compatible, according to the manufacturer's directions.

1.2 This practice is intended to complement, not replace the instructions and labeling provided by product manufacturers. Endoscope manufacturers must provide instructions and labeling necessary for users to know the basic design, specifications, nomenclature, and components of specific flexible GI endoscopes and to properly inspect, prepare, use, clean, disinfect, rinse, dry, and store these instruments.

1.3 Endoscopic technique and the medical aspects of gastrointestinal endoscopy are not covered in this practice.

1.4 This practice details the steps necessary to properly reprocess flexible GI endoscopes and render them patient-ready.

1.5 This practice details manual reprocessing as well as automated reprocessing of flexible GI fiberoptic and video endoscopes.

1.6 The application of all practices relating to endoscopic reprocessing will ultimately fall into the purview of the individual assigned to that task in an endoscopic area.

1.6.1 To ensure the proper adherence to this practice, those personnel should themselves meet certain requirements as specified in 4.8.

1.7 This practice does not detail the steps necessary for the reprocessing of endoscopic accessories.

1.8 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.* Specific precautionary statements are given in Note 1 and Note 2.

2. Terminology

2.1 *Definitions of Terms Specific to This Standard:*

2.1.1 *clean, adj*—visibly free from debris.

2.1.2 *endoscope, n—flexible GI endoscope*, flexible fiberoptic or video endoscopes used in the examination of the hollow viscera (that is, colonoscope, gastroscope, duodenoscope, sigmoidoscope, and enteroscopes).

2.1.3 *High-Level Disinfectant*—A liquid chemical sterilant used under the same contact conditions as for sterilization except for a shorter contact time. A sterilant is a liquid chemical germicide, which has passed the AOAC sporicidal test with no failures; therefore, to qualify for a high-level disinfection claim, a germicide must be a sterilant as defined by the AOAC sporicidal test. In addition, the claim should be supported by efficacy data from potency tests, simulated-use tests, and in-use tests.

2.1.3.1 *Discussion*—A high-level disinfectant is a liquid chemical germicide cleared by FDA for market with a claim for high-level disinfection.

2.1.4 *high-level disinfected, adj*—devoid of all vegetative bacteria, viruses, and fungal spores and some but not all bacterial endospores.

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2.1.5 *patient-ready endoscope*, *n*—an endoscope rendered clean after being subjected to a validated cleaning procedure, subjected minimally to a high-level disinfection process, and rinsed so that it does not contain residual chemicals in amounts that can be harmful to humans.

2.1.5.1 *Discussion*—It is recognized that in limited circumstances, portions of an endoscope that neither contact patient fluids nor contact the patient directly, may not be immersible (for example, ultrasound endoscopes). In these instances, care must be taken to disinfect the non-immersible portions of the endoscope to the highest degree with which they are compatible according to the manufacturer's directions.

2.1.6 *reprocessing*, *n*—the cleaning and high-level disinfection necessary to render an endoscope patient-ready.

2.1.7 *reprocessing chemicals*, *n*—detergents and liquid chemical germicides used for reprocessing endoscopes.

2.1.8 *residual chemical*, *n*—freely extractable residual reprocessing chemicals in amounts that can be harmful to humans.

3. Summary of Practice

3.1 Each brand, type, and model of endoscope has unique specifications, nomenclature, interior design, function, and components.

3.2 Endoscopes used in gastrointestinal endoscopy are considered semi-critical medical devices because they normally only come into contact with mucous membranes.

3.3 To prevent the spread of microorganisms during endoscopy, semi-critical medical devices must receive scrupulous manual cleaning followed minimally by high-level disinfection.

3.4 Upon removal of the endoscope from the patient, the instrument should be manually cleaned followed by high-level disinfection, rinsing, and drying. If due to time constraints, it is not possible to complete the reprocessing immediately, the endoscope should be leak-tested, flushed, brushed, and allowed to soak in a detergent solution until it can be thoroughly reprocessed.

3.4.1 Follow the endoscope manufacturer's recommendations for the maximum liquid exposure time.

3.5 After cleaning and high-level disinfection, endoscopes must be stored in a manner that allows air to circulate around the endoscope.

3.6 Refer to the endoscope manufacturer's instructions for proper storage.

4. Significance and Use

4.1 Because endoscopes are used to diagnose disease in immunocompetent and immunocompromised individuals, care must be taken to ensure that only endoscopes that are patient-ready are used for each examination.

4.2 Endoscopy of patients with diagnosed or suspected infections such as hepatitis B or human immunodeficiency virus is not contraindicated. Further, endoscopes do not need to be dedicated for use in only these patients.

4.3 By nature of their design requirements, endoscopes are more difficult to reprocess than other medical instruments.

4.4 Endoscopes have long narrow internal channels making inspection for cleanliness difficult if not impossible.

4.5 Endoscopes made from elastomeric materials cannot be subjected to heat sterilization, thus requiring high-level disinfection or sterilization with compatible chemical agents. Contact the endoscope manufacturer for liquid chemical sterilant compatibility.

4.6 Each user needs to understand the specifications, nomenclature, function of component parts, and interior channel design of endoscopes in order to render them patient-ready.

4.7 Persons responsible for the reprocessing of endoscopes should follow this practice and associated labeling and instructions from manufacturers after each endoscopic procedure to ensure that the endoscope is patient-ready for the next patient.

4.8 Reprocessing of endoscopes should be the specific responsibility of appropriately trained personnel. Temporary employees without the requisite training should not be given these responsibilites.

4.8.1 The responsibility for this activity should not be delegated from person to person unless each has the appropriate credentials for the position.

4.8.2 Persons responsible for processing the endoscopes should have the ability to read, understand, and implement instructions from manufacturers and regulatory agencies as they relate to endoscopic disinfection.

4.8.3 Reprocessing personnel should have the opportunity to become completely familiar with the mechanical aspects of the endoscopic equipment. This should be done by study of the manufacturer's information, and demonstration by the manufacturer's representatives.

4.8.4 Reprocessing personnel should participate in an institutionally developed, competency-based training program dedicated to endoscope reprocessing.

4.8.4.1 The competency-based training program should incorporate currently published national standards, such as ASTM, SGNA, APIC, and ASGE.

4.8.5 Reprocessing personnel should be made fully aware of the potential chemical and infectious hazards for patients and health care personnel associated with the reprocessing of the endoscope.

4.8.5.1 Training should include a thorough background regarding the potential for negative patient outcomes resulting from lapses in compliance with written reprocessing guidelines.

4.8.5.2 Training should include a thorough background in infection control principles and concepts based on written in-house infection control procedures.

4.8.5.3 Training should include familiarization with Occupational Safety and Health Administration (OSHA) regulations and in-house policies regarding the appropriate and safe handling of liquid chemical reagents and equipment used during the reprocessing of the endoscopes. OSHA guidelines are directed only toward healthcare worker safety and health but also may benefit patient safety.

4.8.5.4 Training should include information on the safe handling of endoscopes contaminated with patient tissue and fluids. This should include familiarization with principles and practices of standard (Universal) precautions.

4.8.6 Each endoscopic unit should have appropriately motivated individuals with the proper educational background or

experience, or both, to assume the responsibility for the reprocessing of endoscopes. Temporary employees without the requisite training should not be given this responsibility.

4.9 This practice is not intended to replace the cleaning and disinfection instructions provided by the manufacturers of the endoscope, endoscope disinfector, or chemicals used for cleaning and disinfection. Rather, it is to be used together with the manufacturer's instructions that provide specific instructions for specific products.

4.10 This practice is not intended to cover the endoscopic techniques, patient care, or other medical aspects of gastrointestinal endoscopy.

4.11 This practice does not include instructions for the use or reprocessing of endoscopic accessories.

5. Reagents

5.1 *Alcohol*—seventy percent isopropyl or seventy percent ethyl alcohol. Keep alcohol in a closed container. Alcohol stored in an open container is a fire hazard and may not remain effective because of evaporation. Do not reuse.

5.2 *Air*—Air flow provided by an air pump or compressor. Refer to the endoscope manufacturer's instructions and avoid using excessively high air pressure.

5.3 *Detergent*—Low-sudsing detergent formulations recommended by the manufacturer of the endoscopes.

5.4 *High-Level Disinfectant*—A liquid chemical germicide as defined in 2.1.3.

5.4.1 A high-level disinfectant is a liquid chemical sterilant used under the same contact conditions as for sterilization except for a shorter contact time. A sterilant is a liquid chemical germicide, which has passed the AOAC sporicidal test with no failures; therefore, to qualify for a high-level disinfection claim, a germicide must be a sterilant as defined by the AOAC sporicidal test. In addition, the claim should be supported by efficacy data from potency tests, simulated-use tests and in-use tests.

5.4.2 A high-level disinfectant is a liquid chemical germicide cleared by the FDA for market with a claim for high-level disinfection.

Subject valves and other removal parts to high-level disinfection by soaking in a basin of disinfectant, or if possible, place the valves and other removable parts in the designated accessory basket of the automated disinfector.

5.5 *Water*—Clean, potable water or potable water that has been filtered by passage through a 0.2-µm filter or otherwise treated by a method documented to improve the microbiological quality of the water.

6. Equipment and Supplies

6.1 *Reprocessing Adapters*—Adapters provided by the endoscope or disinfector manufacturer specifically for injecting fluids through the internal lumens of the endoscope, or for partially restricting or capping a lumen opening.

6.2 *Brushes*, must be high-level disinfected or disposed of after each use.

6.2.1 Cleaning brushes, of appropriate size and configuration, designed for use with specific endoscopes, and

6.2.2 Soft toothbrush or similar brush used for cleaning the exterior of the endoscope.

6.3 *Basin(s)*, must be large enough to totally immerse the endoscopes without coiling them too tightly. See the endoscope manufacturer's instructions for maximum coiling of specific endoscopes:

6.3.1 Cleaning basin, and

6.3.2 Disinfectant basin for soaking:

6.3.2.1 Nonmetal, and

6.3.2.2 Must include a tight-fitting lid to minimize escape of disinfectant vapors. This lid should be kept in place at all times except when transferring instruments into or out of the solution.

6.3.3 *Automated Disinfector*, must include a tight-fitting lid to minimize the escape of disinfectant vapors.

6.4 *Cloth*—Soft, lint-free cloth or sponge for wiping the exterior of the endoscope.

6.5 *Personal Protective Equipment*:

6.5.1 *Gloves*:

6.5.1.1 High-quality, impervious latex, butyl or nitrile rubber gloves should fit properly and be of adequate length to prevent skin exposure.

6.5.1.2 Gloves must be changed regularly as needed or as recommended by the manufacturer. They must be discarded if they are cracked, pealing, punctured, or when their ability to function as a barrier is compromised.

6.5.2 *Gowns*:

6.5.2.1 Impervious protective clothing must be worn when handling contaminated endoscopes and when working with liquid chemical germicides.

6.5.2.2 Gowns used during endoscope reprocessing must be removed prior to leaving the decontamination area.

6.5.3 Face masks or shields and protective eye gear should be worn to protect the face and eyes from contact with reprocessing chemicals and infectious material.

6.6 *Adequate Air Ventilation*—A large well-ventilated area with eight to ten air exchanges per hour is necessary to help protect personnel from chemical vapors.

7. Procedure

7.1 *Cleaning*:

7.1.1 Put on all necessary personal protective equipment.

7.1.2 Prepare detergent in accordance with the manufacturer's specifications.

7.1.3 Immediately after removing the endoscope from the patient:

7.1.3.1 Wipe all debris from the insertion tube using a soft lint free cloth and water to which you have added a lowsudsing detergent recommended by the endoscope manufacturer and diluted in accordance with the detergent manufacturer's instructions.

7.1.3.2 Place the distal end of the endoscope into the water and detergent solution and suction through the biopsy/suction channel until the exiting solution is visibly clean. Alternate suctioning detergent solution and air several times. Finish by suctioning air.

7.1.3.3 Flush or blow out air and water channels in accordance with the endoscope manufacturer's instructions.

7.1.4 Detach the endoscope from the light source and suction pump.