



Standard Practice for Cleaning and Disinfection of Flexible Fiberoptic and Video Endoscopes Used in the Examination of the Hollow Viscera¹

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.

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.

¹ This practice is under the jurisdiction of ASTM Committee F-4 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.35 on GI Endoscopes.

Current edition approved April 10, 2000. Published July 2000. Originally published as F 1518 – 94. Last previous edition F 1518 – 94.