Designation: F1992 – 99(Reapproved 2007)

Standard Practice for Reprocessing of Reusable, Heat-Stable Endoscopic Accessory Instruments (EAI) Used with Flexible Endoscopes[1]

This standard is issued under the fixed designation F1992; 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 reusable, heat-stable endoscopic accessory instruments (EAI) designed to be inserted into flexible endoscopes and clearly defined in the user instructions as devices intended for reuse among patients. The EAIs covered by this practice may or may not have lumens or loosely joined surfaces, may or may not have access ports for flushing, and may or may not be capable of being completely disassembled prior to reprocessing.

1.2 This practice is not intended to be applied to the reprocessing of single-use, disposable EAIs specifically designed and labeled as such by their manufacturers.

1.3 This practice is not intended to address reprocessing of heat-sensitive EAIs, for example, those not capable of withstanding heat sterilization. Reprocessing of each heat-sensitive EAI must be considered on an individual basis according to specific instructions from the manufacturers of the EAI and the low-temperature sterilization device.

1.4 This practice is intended to complement, not replace, the instructions provided by product manufacturers. EAI manufacturers should provide properly validated instruction and labeling necessary for users to understand the basic design, specifications, nomenclature, and components of specific accessories and to properly inspect, prepare, use, reprocess, and store these instruments.

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

1.6 This practice details the basic steps necessary to reprocess a heat-stable EAI and render it patient-ready.

1.7 A patient-ready EAI is one that has been thoroughly cleaned using a validated cleaning procedure, rinsed with water to remove residual detergent, lubricated (if necessary) and drained to remove excess lubricant, dried, packaged, heat sterilized and stored to prevent from being compromised sterility before use.

1.8 This practice describes only manual reprocessing and does not address cleaning of an EAI by an automated reprocessing device.

1.9 To ensure the proper adherence to this practice, reprocessing personnel should meet certain requirements as specified in 5.5 to 5.7.

1.10 This practice does not address the steps necessary for the reprocessing of flexible endoscopes (see Practice F1518).

1.11 *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 to determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

F1518 Practice for Cleaning and Disinfection of Flexible Fiberoptic and Video Endoscopes Used in the Examination of the Hollow Viscera (Withdrawn 2009)[3]

3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*

3.1.1 *clean, adj*—visibly free from external debris after a thorough, manufacturer-validated regimen.

3.1.2 *critical medical device, n*—an instrument that may be introduced directly into the bloodstream or into other normally sterile areas of the body, that is, an invasive device.

3.1.3 *endoscopic accessory instrument, EAI, n*—medical instrument designed to be inserted into a flexible endoscope.

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[2] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

[3] The last approved version of this historical standard is referenced on www.astm.org.

3.1.3.1 *Discussion*—EAIs may be critical- or semi-critical devices. EAIs 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.

3.1.4 *flexible endoscope, n*—a flexible tubular instrument that utilizes fiberoptic or video imaging technology to examine the interior of a canal or hollow viscus.

3.1.5 *heat-stable medical device, n*—an instrument capable of withstanding sterilization using a heat-based process.

3.1.6 *lubrication, n*—the application of a substance used to reduce friction or wear.

3.1.7 *manual cleaning, n*—removal of debris from an instrument by hand using detergent solution, cleaning devices such as brushes, cloths, and irrigating devices, and water for rinsing.

3.1.8 *patient-ready, adj*—term used to describe endoscopic accessory instrument that, following prior patient use, has undergone an appropriate reprocessing protocol, including heat sterilization, to render it safe, as established by contemporary professional standards, for use on a subsequent patient; an operational check to ensure proper functionality is an essential component of preparing the EAI for reuse.

3.1.9 *reprocessing, n*—the precise sequence of cleaning, lubricating (if necessary), and sterilizing steps that, when performed properly and completely, will assure an endoscopic accessory instrument is patient-ready.

3.1.10 *reusable, adj*—instrument designed and validated by the manufacturer to be used more than once, provided that after each use, an appropriate reprocessing protocol and functionality check is performed.

3.1.11 *semi-critical medical device, n*—an instrument intended to contact only mucous membranes or non-intact skin during use.

3.1.12 *sterilization, n*—the complete elimination or destruction of all forms of microbial life, including high numbers of bacterial spores.

3.1.12.1 *Discussion*—In this standard, the only methods of sterilization considered are heat-based, for example, saturated steam under pressure (a steam autoclave) or a forced-air dry heat oven certified for medical use.

3.1.13 *ultrasonic cleaning, n*—a process in which ultra-high frequency sound waves are converted into mechanical vibrations capable of cleaning via a process called cavitation.

3.1.13.1 *Discussion*—During cavitation, microscopic bubbles in the cleaning solution implode (burst inward), resulting in a vacuum action that pulls soil and debris away from the surface of items being cleaned.

4. Summary of Practice

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

4.2 Most EAIs are critical medical devices because they come into direct contact with the bloodstream, enter normally sterile areas of the body, or break normally intact mucosal surfaces.

4.3 To prevent patient-to-patient transmission of infection, heat-stable EAIs should be thoroughly cleaned, rinsed, lubricated if necessary, dried, packaged, and sterilized using a heat-based process, for example, a steam autoclave or a forced-air dry heat oven.

4.4 After sterilization, a packaged EAI should be stored in a limited-access, well-ventilated area that provides protection from dust, moisture, and extremes of temperature and humidity so as not to compromise sterility before use.

4.5 Before use, the EAI should be tested for functionality.

5. Significance and Use

5.1 EAIs may have design features such as coiled metal sheaths, pivoting joints, opposed surfaces, and internal lumens or wires which make visual inspection for cleanliness difficult if not impossible.

5.2 By nature of their design requirements, EAIs are more difficult to reprocess than many other types of medical instruments.

5.3 Because EAIs are used to diagnose and treat disease in both immunocompetent and immunocompromised individuals, care must be taken to ensure that only patient-ready devices are used for examination.

5.4 The use of EAIs in patients having diagnosed or suspected infections such as hepatitis B, hepatitis C, or human immunodeficiency virus (HIV) is not contraindicated. Further, EAIs need not be dedicated for use only in these patients.

5.5 Persons responsible for reprocessing must understand the specifications, nomenclature, function of component parts, and interior design of EAIs in order to render them patient-ready.

5.6 Persons responsible for reprocessing EAIs should follow this practice and associated labeling and instructions from manufacturers after each endoscopic procedure to ensure that the EAI will be patient-ready.

5.7 Reprocessing of EAIs should be the specific responsibility of appropriately trained personnel. Temporary employees without the requisite training should not be given these responsibilities.

5.7.1 The responsibility for reprocessing of EAIs should not be delegated from person to person unless each has the appropriate training for the position.

5.7.2 Reprocessing personnel should have the ability to read, understand, and implement instructions from manufacturers and regulatory agencies as they relate to EAI reprocessing.

5.7.3 Reprocessing personnel should have the opportunity to become completely familiar with the mechanical aspects of the devices. They may gain this knowledge through study of the manufacturer's information and demonstration by representatives.

5.7.4 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 EAIs. Training should include:

5.7.4.1 A thorough background in infection control principles and concepts based on written in-house infection control procedures.

5.7.4.2 A thorough background regarding the potential for negative patient outcomes resulting from lapses in compliance with written reprocessing guidelines,

5.7.4.3 Familiarization with Occupational Safety and Health Administration (OSHA) regulations and in-house policies regarding the appropriate and safe handling of chemical reprocessing agents and equipment used during reprocessing of EAIs, and

5.7.4.4 Information on the safe handling of EAIs contaminated with patient tissue and fluids after use, including familiarization with principles and practices of standard (universal) precautions.

NOTE 1—Although healthcare workers and patients may benefit from adhering to the regulatory guidelines issued by federal and state OSHA agencies, these guidelines are directed only toward healthcare worker safety and health. They may not be sufficiently inclusive for optimum safety and health of patients. Therefore, contemporary infection control guidelines should be consulted in addition to OSHA guidelines.

5.8 This practice is not intended to replace the reprocessing instruction provided by the manufacturers of EAIs or suggest specific equipment or chemical reagents to be used for reprocessing. Rather, it is to be used together with manufacturers' instructions that provide specific instructions for specific products. See Appendix X1.1.

5.9 This practice is not intended to cover endoscopic techniques, patient care, or other medical aspects of flexible endoscopy.

5.10 This practice does not include instruction for reprocessing flexible endoscopes.

6. Reagents

6.1 *Air*—Air flow provided by a syringe or compressed air source. (Refer to the EAI manufacturer's instruction to avoid the use of excessively high air pressure.)

6.2 *Detergent*—A low foaming, neutral pH detergent, with or without enzymes, used for initial soaking and manual cleaning that is compatible with EAIs and is specifically formulated for use with medical devices.

6.3 *Ultrasonic Cleaning Detergent*—A detergent that is compatible with EAIs and specifically formulated for use in an ultrasonic cleaner.

6.4 *Water*—Fresh, potable water.

NOTE 2—In areas where water hardness may result in scaling or corrosion of metal instruments, the use of distilled, deionized, or softened water should be considered as appropriate for rinsing and preparation of cleaning reagent dilutions.

6.5 *Lubricant*—A lubricant that is compatible with EAIs that require lubrication before sterilization and is specifically formulated for use with medical devices.

7. Equipment and Supplies

7.1 *Basins*—Must be large enough to totally immerse the EAIs without coiling too tightly. See the EAI manufacturer's instruction for minimum radius of coiling of specific accessories. Basins needed are:

7.1.1 Cleaning basin, and

7.1.2 Lubrication basin.

7.2 *Cleaning Tools*—Soft, lint-free cloth, brushes, adapters, sponges, syringes, and other manufacturer-recommended cleaning items.

7.3 *Personal Protective Equipment:*

7.3.1 *Gloves*—High-quality latex, butyl, or nitrile rubber gloves that fit properly and are of adequate length to prevent skin exposure to liquids.

7.3.1.1 Gloves must be changed at appropriate times to limit cross contamination and must be removed prior to leaving the designated reprocessing area. They must be discarded if they are cracked, peeling, punctured, or when their ability to function as a barrier has been otherwise compromised. Hands must be washed thoroughly with soap and water before each donning and after removal of gloves.

7.3.2 *Gowns*—Fluid impervious protective clothing must be worn when handling contaminated EAIs and when working with reprocessing chemicals.

7.3.2.1 Gowns used during EAI reprocessing must be removed prior to leaving the designated reprocessing area.

7.3.3 *Protective Eye Wear*—Face masks and protective eyewear or face shields should be worn to protect the face and eyes from contact with reprocessing chemicals and potentially infectious material.

7.4 *Ultrasonic Cleaner*—Must be large enough to totally immerse the EAIs without coiling them too tightly, and must be able to operate within a frequency and power range that will not damage the instruments. See the EAI manufacturer's instructions for specifications regarding the minimum radius of coiling of specific models, the required frequency range of the ultrasonic cleaner, and the maximum power of ultrasonic transducers.

7.5 *Sterilizer*—Must be a heat-based process (for example, a steam autoclave or forced-air dry heat oven) and capable of meeting the conditions for the sterilization cycle validated by the EAI manufacturer.

7.5.1 The sterilizer also should be used to dry the packaged EAIs at the conclusion of a moist heat sterilization cycle.

7.5.2 Biological and chemical (temperature/color change) monitoring of the sterilizer should be done routinely according to the facility's protocol or national standards, or both.

7.5.3 General operation, maintenance, and calibration of the sterilizer should be done according to the sterilizer manufacturer's instructions.

7.6 *Air Ventilation*—A well-ventilated area with between eight and ten air exchanges per hour to protect personnel from potentially hazardous fumes or chemical or biological aerosols.

8. Procedure

8.1 *Cleaning:*

8.1.1 *Manual Cleaning:*

8.1.1.1 Don all necessary personal protective equipment.

8.1.1.2 Prepare fresh aqueous detergent solutions for manual cleaning in accordance with the manufacturer's