



Society of Gastroenterology Nurses and Associates, Inc.

POSITION STATEMENT

Management of Endoscopic Accessories, Valves, and Water and Irrigation Bottles in the Gastroenterology Setting

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Definitions

For the purpose of this document, SGNA has adopted the following definitions:

Backflow-prevention valve refers to the valve that is intended to prevent the proximal water bottle and/or irrigation system from being contaminated by backflow of fluids from the patient (FDA, 2016).

Critical medical device refers to a device that enters normally sterile tissue or the vascular system. These devices must be sterilized. Examples include endoscopic cutting and biopsy devices (SGNA, 2017).

Endoscopic accessories refer to devices used with an endoscope for the purpose of diagnosis or therapy (e.g., biopsy forceps, snares, guidewires, irrigation tubes, and dilators).

High-level disinfection (HLD) refers to the destruction of all microorganisms with the exception of low levels of bacterial spores (Rutala, 2013).

Irrigation bottle refers to the water container and tubing (and accessories) that are used to flush water through the endoscope (e.g., auxiliary/forward water jet system).

Irrigation system refers to all devices and device components between the patient and the water bottle (including the bottle itself) that convey or contact water used for irrigation (FDA, 2016).

Medical devices refer to endoscopic accessories, valves, and water and irrigation bottles.

Multi-patient use device refers to a device that is intended to be used on multiple patients, either with reprocessing (for reusable devices) between patient uses or without reprocessing (for consumables) between patient uses (FDA, 2016).

Reprocessing refers to the validated process of cleaning then disinfecting or sterilizing endoscopes and accessories. In relation to endoscopy, it includes all the steps from pre-cleaning to drying (SGNA, 2016).

Reusable medical device refers to an item intended for use either on the same patient or different patients, following manufacturer's instructions for cleaning and reprocessing between uses (FDA, 2016).

Semi-critical device refers to a device that comes into contact with intact mucous membranes and does not ordinarily penetrate sterile tissue. These devices must follow manufacturers' instructions for cleaning and high level disinfection. Examples include gastrointestinal endoscopes (SGNA, 2017).

Single-use device refers to a device that is intended for one use or one patient. It is not intended to be reprocessed (cleaned/disinfected/sterilized) and used on another patient (FDA, 2016).

Sterilization refers to a process resulting in the complete elimination or destruction of all forms of microbial life, including bacterial spores. The Spaulding Classification identifies sterilization as the standard for medical devices that enter the vascular system or sterile tissue, such as biopsy forceps (Rutala & Weber, 2013; SGNA, 2017).

Valves refer to the air/water valve, suction valve, and biopsy port cover to the flexible endoscope.

Water bottle refers to the water container, cap, and tubing system used for insufflation of air or CO₂ and lens wash (American Society for Gastrointestinal Endoscopy [ASGE], 2017).

24-hour use device refers to the use of a device within a single 24-hour period with no reprocessing between patient uses. A device labeled "24-hour use" implies multi-patient use (FDA, 2016).

Background

Gastroenterology settings must employ best practices to ensure patient safety. Proper reprocessing is critical to the safe treatment of patients (Alvarado, Reichelderfer, & the 1997, 1998, and 1999 APIC Guidelines Committees, 2000; ASGE, 2008; SGNA, 2017; SGNA, 2013). Infection prevention should be a guiding factor in selecting endoscopic accessories, valves, and water bottles because cross-contamination can transmit infection.

Gastroenterology settings may employ both disposable and reusable medical devices. These decisions should be based on the most current infection prevention standards, evidence-based research, applicable standards and regulations, institutional policy, cost, optimal workflow, and management of operations.

The high-level disinfection or sterilization process may affect the device; therefore, the device's integrity and functionality must be visually inspected during all phases of care. If the medical device is damaged, it should be removed from service immediately (ASGE, 2017).

Waterborne infections in health care have been traced to the tap water supply (Dickey, 2014), contaminated reprocessing machines, and improper reprocessing of water bottles and endoscopic accessories (Beilenhoff et al., 2008; Kovaleva, Peters, van der Mei, & Degner, 2013). Facility water supplies have been found to be reservoirs for waterborne pathogens such as *Legionella* or *Pseudomonas aeruginosa* (CDC, 2017; Loveday et al., 2014; Kanamori et al., 2016). The Multisociety guideline on reprocessing flexible gastrointestinal endoscopes (ASGE, 2017) and the major endoscope manufacturers recommend the use of sterile water during endoscopy.

Endoscopy staff should have a clear understanding of the risks and implications associated with waterborne infections, cross-contamination, and improper reprocessing.

For further information, consult SGNA's Standards of Infection Prevention in Reprocessing Flexible Gastrointestinal Endoscopes (2016).

Position

SGNA believes that patients deserve the same standard of care regardless of practice setting. SGNA supports the following positions:

- A. End users must have access to and understanding of the manufacturer's labeling and they must follow the instructions for use (IFU) of single, reusable, or multiuse devices.
- B. All reusable medical devices must be reprocessed according to validated manufacturers' instructions for use. Follow manufacturer's IFU outlining approved methods to achieve high level disinfection or sterilization, either by manual means or in FDA cleared AERs or sterilization systems (ASGE, 2017).
- C. All medical devices originally manufactured and labeled as single-use must not be reprocessed or reused (SGNA, 2015a).
- D. Medical devices that are classified as critical medical devices require sterilization.
- E. Sterile water must be used in the water and irrigation bottles for all endoscopic procedures (ASGE, 2017; Beilenhoff et al., 2008).
- F. Follow manufacturer's instructions on the use of simethicone with water and irrigation systems. Residue from these products has an effect on HLD and sterilization.
- G. Irrigation bottles intended for multiple patients must have a single use backflow prevention method in place and used according to the manufacturer's IFU (FDA, 2016).
- H. Water bottles, whether reusable or disposable, must be replaced as recommended by the manufacturer. Methods to ensure adherence to the recommendations must be employed (e.g., label with date and time).
- I. A comprehensive quality control program for reusable medical devices should be implemented and include, but not limited to the following:
 1. Visual inspection and equipment testing to identify conditions that may affect the cleaning or disinfection process (Ofstead et al., 2017; FDA, 2009). Damaged reusable items should be removed from use. Follow facility protocol for returning device.
 2. Procedures for monitoring the useful life of medical devices that include visual inspection, scheduled maintenance, and removal of equipment from use based on manufacturer's guidelines (FDA, 2009; CDC, 2015; Ofstead et al., 2017).

3. Protocols to ensure valves and other detachable reusable accessories are processed and identified as ready for use. Documentation should include the date of HLD; person(s) who performed reprocessing or sterilization; and may be cross-referenced with other records that can track the patient, date, and type of procedure (British Society of Gastroenterology, 2017).
4. Comprehensive training for staff to ensure they understand the methods and the importance of standard infection prevention measures and device-specific reprocessing instructions to carry out cleaning and high-level disinfection or sterilization procedures (Alfa et al., 2014; Muscarella, 2014; SGNA, 2015b).
5. Ongoing review of clinical practice guidelines and recommendations for infection prevention updates published by professional organizations and government agencies.
6. To ensure best practices and consistency of performance, reusable medical devices/ equipment used to reprocess should be maintained and repaired by or to original equipment manufacturer (OEM) specifications and standards. Failure to repair to OEM standards could invalidate an instrument/ equipment manufacturer's IFU and/or warranty.

Infection prevention principles should be a guiding factor in selecting medical devices because cross-contamination can transmit infection. There are advantages and disadvantages in using disposable or reusable medical devices. Facilities should make these decisions with the infection prevention team based on:

- a risk assessment of the device design, labeling, and handling after single use;
- evidence-based practice;
- policy, procedure, and regulatory requirements;
- waste stream management guidelines; and
- unit feasibility and financial impact.

Facilities should review manufacturers' instructions to ensure the device can safely and effectively be used as intended (FDA, 2016). If there are concerns regarding the device design, labeling, or instructions for use, it is up to the individual facility to reconcile those differences with the manufacturer, or consider a product that better supports the facility's intent of infection prevention and patient safety.

SGNA supports further research in the area of disposable versus reusable medical devices and their role in infection prevention and patient safety.

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Adopted by the SGNA Board of Directors, May 2002

Revised 2005, May 2009, September 2011, September 2014, December 2017, August 2018

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