



Society of Gastroenterology Nurses and Associates, Inc.

POSITION STATEMENT

Reprocessing of Endoscopic Accessories and Valves

Disclaimer

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Definitions

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

Critical medical devices refer to those instruments that may be introduced directly into the bloodstream or into other normally sterile areas of the body. These devices break the mucus membrane (ASTM International, 2007) and/or come into contact with sterile tissue or the vascular system.

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) (World Gastroenterology Organisation, 2005).

Reprocessing refers to the validated process of cleaning, disinfecting, or sterilizing endoscopes and accessories.

Reusable medical devices refer to instruments that are designed and labeled for multiple uses and are reprocessed by thorough cleaning and high-level disinfection and sterilization between patients (U. S. Food and Drug Administration, 2011).

Single-use device (SUD) refers to an instrument labeled by the manufacturer for one-time use or use on a single patient during a single procedure (FDA, 2009a).

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

Background

Proper reprocessing of endoscopic accessories and valves is critical to the safe and successful treatment of patients (Alvarado, Reichelderfer, & the 1997, 1998, and 1999 APIC Guidelines Committees, 2000; American Society for Gastrointestinal Endoscopy, 2008; Society of Gastroenterology Nurses & Associates, Inc., 2012; SGNA, 2013a). The number of reuses should be based on manufacturer guidelines (ASTM International, 2007; SGNA, 2013b).

The U. S. Food and Drug Administration (FDA) requires the manufacturers of reusable devices to provide instructions for cleaning and high-level disinfection or sterilization (ASGE, 2008, 2011; FDA, 2009b). Accessories must be compatible with reprocessing equipment and supplies (FDA, 2009b). The high-level disinfection or sterilization process may affect the device; therefore, the device's integrity and functionality must be inspected prior to use.

Reusable endoscopic accessories (e.g., biopsy forceps, other cutting instruments) designed to break the mucosal barrier must be mechanically cleaned and sterilized (ASGE, 2011).

Position

SGNA supports the following positions:

- A. Endoscopic accessories and valves labeled as reusable must be reprocessed according to manufacturer's instructions.
- B. Endoscopic accessories and valves labeled as single-use must not be reprocessed or reused (SGNA, 2013b).
- C. Endoscopic accessories that are classified as critical medical devices require sterilization.
- D. Valves must be removed, cleaned manually, and high-level disinfected or sterilized in accordance with the original equipment manufacturer's instructions.
- E. Automated endoscopic reprocessors (AER) must be certified for the intended use of reprocessing accessories and valves in accordance with manufacturer's instructions.
- F. Channel cleaning adaptors, reusable cleaning brushes, and other reprocessing accessories should be reprocessed according to manufacturer's instruction after each use.
- G. Endoscopic accessories and valves should be inspected for integrity and cleanliness before, during, and after use. Damaged items should be removed from service immediately and soiled items should be reprocessed (ASGE, 2011).
- H. A comprehensive quality control program should be implemented that includes visual inspections and equipment testing to identify conditions that may affect the cleaning or disinfection process (FDA, 2009b).
- I. Procedures for monitoring the useful life of accessory equipment and valves should be implemented which include inspection, scheduled maintenance, and removal of equipment from use based on the manufacturer's guidelines (FDA, 2009b).

SGNA supports increased research in the areas of accessory and endoscope design in an effort to manufacture devices that can be easily disassembled, cleaned, high-level disinfected, and/or sterilized.

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Recommended Reading

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SGNA Practice Committee 2014-2015

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