

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 (American Society for Testing and Materials [ASTM], 2000) and/or come into contact with sterile tissue or the vascular system.

Endoscopic Accessory Instruments refer to medical instruments designed for insertion into a flexible endoscope (ASTM, 2000). These are devices used during endoscopy other than the endoscope. These include, but are not limited to, biopsy forceps, snares, bite blocks, guide wires, irrigation tubes and dilators. These devices 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.

Reprocessing refers to the sequence of cleaning, lubricating (if necessary), and sterilizing (ASTM, 2000) or high-level disinfecting steps that will assure an endoscopic accessory is patient-ready (Society of Gastroenterology Nurses and Associates, Inc. [SGNA], 2003).

Reusable Device refers to an 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 following manufacturers' recommendations (ASTM, 2000; SGNA, 2003).

Single Use Device (SUD) refers to an instrument designed for one-time use only, on one patient, during a single procedure. SUDs are not designed by their manufacturers to be reprocessed and/or used on another patient. The manufacturer's labels on these devices do not include reprocessing instructions, and may or may not identify the device as single use (United States Food and Drug Administration [U.S. FDA], 2000). SUDs are also referred to as disposable devices (U.S. FDA).

Valves refer to the air/water valve, suction valve, and biopsy port cover to the flexible endoscope (ASTM, 2001).

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Background

Proper reprocessing of endoscopic accessories and valves is critical to the safe and successful treatment of patients (Alvarado, Reichelderfer, and the Association for Professionals in Infection Control and Epidemiology [APIC] Guidelines Committees, 2000; SGNA, 2005). 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.

The United States Food and Drug Administration requires the manufacturers of reusable devices to provide instructions for cleaning and high-level disinfection or sterilization (U.S. FDA, 1996).

Position

SGNA supports the following positions:

- A. All accessories labeled as reusable must be reprocessed according to manufacturer's instructions.
- B. Accessories that are classified as critical medical devices require sterilization.
- C. Critical items labeled for single-use should not be reprocessed and/or reused (SGNA, 2002).
- D. Following each use of the endoscope, valves must be removed, manually cleaned and high-level disinfected or sterilized according to the original equipment manufacturer's instructions. This must occur as part of the cleaning and disinfecting process for the endoscope.
- E. When using an automated endoscope reprocessor (AER), the AER manufacturer's instructions regarding reprocessing of valves must be followed.

References

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