Society of Gastroenterology Nurses and Associates, Inc.

POSITION STATEMENT

Reprocessing of Endoscopic Accessories and Valves

Disclaimer

The Society of Gastroenterology Nurses and Associates, Inc. (SGNA) assumes no responsibility for the practices or recommendations of any member or other practitioner, or for the policies and procedures of any practice setting. Nurses and associates function within the limitations of licensure, state nurse practice act, and/or institutional policy.

Definitions

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

Critical Medical Devices refers 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], 2007) and/or come into contact with sterile tissue or the vascular system.

Endoscopic Accessories refer to devices used with an endoscope for the purposes of diagnosis or therapy (e.g. biopsy forceps, snares, guide wires, irrigation tubes, and dilators) (Rey, J.F., Bjorkman, D., Duforest-Rey, D. , Axon, A., Saenz, R., Fried, M., Mine, T., Ogoshi, K. & Krabshuis, J.H., 2005).

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

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, 2007; SGNA, 2008b).

Single Use Device (SUD) refers to an instrument designed for one-time use only, on one patient, and 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 (SGNA, 2008b ; United States Department of Health and Human Services [HHS], Food and Drug Administration [FDA], & Center for Devices and Radiological Health [CDRH], 2000). SUDs are also referred to as disposable devices (HHS, FDA, & CDRH, 2000).

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 Association for Professionals in Infection Control and Epidemiology [APIC] Guidelines Committees, 2000; American Society for Gastrointestinal Endoscopy [ASGE], 2008; SGNA, 2008a; SGNA, 2009). 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 FDA requires the manufacturers of reusable devices to provide instructions for cleaning and high-level disinfection or sterilization (ASGE, 2008; HHS, FDA, & CDRH, 2000).

Position

SGNA supports the following positions:

a. Accessories, valves, and tubings labeled as reusable must be reprocessed according to manufacturer's instructions.
b. Accessories, valves, and tubings labeled as single-use must not be reprocessed or reused (SGNA, 2008b).
c. Accessories that are classified as critical medical devices require sterilization.
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 must have been validated to reprocess the accessory, and the manufacturer's instructions regarding reprocessing of valves must be followed.
f. Channel cleaning adaptors, reusable cleaning brushes and other reprocessing accessories should be reprocessed according to manufacturer's instructions after each use.
g. Accessories, valves, and tubings should be inspected for integrity and cleanliness before, during and after use. Damaged or soiled items should be removed from service immediately (ASGE, 2011).

References

Alvarado, C. J., Reichelderfer, M., & the Association for Professionals in Infection Control and Epidemiology Guidelines Committees. (2000). APIC Guideline for infection prevention and control in flexible endoscopy. *American Journal of Infection Control*, *28*, 138-155.

American Society for Gastrointestinal Endoscopy (ASGE). (2011). Quality Assurance In Endoscopy Committee, Petersen,B. T., Chennat, J., Cohen, J., Cotton, P.B., Greenwald, D.A., Kowalski, T. E., Krinsky, M.L., Park, W.G., Pike, I.M., Romagnuolo, J.R., Society for Healthcare Epidemiology of America (SHEA), Rutala, W.A. Multisociety guideline on reprocessing flexible gastrointestinal

endoscopes: 2011. *Gastrointestinal Endoscopy*, 2011; 73 (6): 1075-1084 DOI: 10.1016/j.gie.2011.03.1183

American Society for Gastrointestinal Endoscopy. (2008). Infection control during GI. *Endoscopy,* 67(6), 781-790.

American Society for Testing and Materials. (2007). *Standard practice for reprocessing of reusable, heat-stable endoscopic accessory instruments (EAI) used with flexible endoscopes* [Standard]. West Consohocken, PA: Author.

Rey, J.F., Bjorkman, D., Duforest-Rey, D., Axon, A., Saenz, R., Fried, M., Mine, T., Ogoshi, K., Krabshuis, J.H. (2005). *WGO practice guideline endoscope disinfection, world gastroenterology organization (WGO*). Retrieved on September 10, 2011 from http://www.worldgastroenterology.org/assets/downloads/en/pdf/guidelines/09_endoscope_disinfection_en.pdf

Society of Gastroenterology Nurses and Associates, Inc. (2008a). *Gastroenterology nursing: A core curriculum* (4th ed.). Chicago, IL: Author.

Society of Gastroenterology Nurses and Associates, Inc. (2008b). *Reuse of single-use critical medical devices* [Position Statement]. Chicago, IL: Author.

Society of Gastroenterology Nurses and Associates, Inc. (2009). *Standards of infection control in reprocessing of flexible gastrointestinal endoscopes* [Standard]. Chicago, IL: Author.

United States Department of Health and Human Services, Food and Drug Administration, & Center for Devices and Radiological Health. (2000). *Guidance for industry and for FDA staff: Enforcement priorities for single-use devices reprocessed by third parties and hospitals* [Guidance]. Retrieved August 31, 2011 from http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM107172.pdf

Recommended Reading

Rutala, W. A., Weber, D. J., & the Healthcare Infection Control Practices Advisory Committee. (2008). *Guideline for disinfection and sterilization in healthcare facilities* [Centers for Disease Control Guideline]. Retrieved August 31, 2011 from http://www.cdc.gov/ncidod/dhqp/pdf/guidelines/Disinfection_Nov_2008.pdf

Adopted by the SGNA Board of Directors, May 2002
Revised 2005, May 2009, September 2011

SGNA Practice Committee 2011 – 12
Michelle Day, MSN BSN RN CGRN - Chair
Michelle R. Juan, MSN ACNS-BC RN CGRN – Co-Chair
Kathy Buffington, BSN RN CGRN
Rhonda Casey, RN BS MHA CGRN

Cynthia M. Friis, MEd BSN RN-BC
Ann Herrin, BSN RN CGRN
Judy Lindsay, MA BSN RN CGRN
Colleen Keith, MSN BSN RN CGRN
Marilee Schmelzer, PhD RN
Barbara Zuccala, MSN RN CGRN