Society of Gastroenterology Nurses and Associates, Inc.

POSITION STATEMENT

Reuse of Single-Use Critical Medical Devices

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 adopted the following definitions:

Critical Medical Devices refers to instruments that may be introduced directly into the bloodstream or into other normally sterile areas of the body (American Society for Testing and Materials [ASTM], 2007). These devices break the mucus membrane and/or come into contact with sterile tissue or the vascular system.

Original device refers to a new, unused single use instrument (United States Food and Drug Administration [FDA], 2009).

Reusable Medical Devices refers to instruments that are designed and labeled for multiple uses and are reprocessed by thorough cleaning and high level disinfection and sterilization between patients (FDA, 2011).

Reprocess refers to a method to ensure proper disinfection or sterilization; it can include cleaning, inspection, wrapping, sterilizing, and storing (Rutala, Weber, & the Healthcare Infection Control Practices Advisory Committee, 2008).

Reprocessed SUD (single use device) is defined as an original device that has previously been used on a patient and has been subjected to additional processing and manufacturing for the purpose of an additional single use on a patient (FDA, 2009).

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

Background

In order to save costs and reduce medical waste, the FDA (2002) established statutory requirements in 2002 for reprocessing of specific single use devices by approved reprocessors.

The Society of Gastroenterology Nurses and Associates, Inc. believes that patients deserve the same standard of care regardless of practice setting. The reuse of SUDs is a complex issue that must be balanced with the assurance of patient safety and the delivery of quality health care. These concerns cannot be overlooked when evaluating the legal, ethical, financial, and technical aspects of reusing

SUDs. SGNA supports further research to define risk and document benefits of reprocessing single use devices.

Position

In the absence of substantial scientific evidence to prove the safety and effectiveness of reprocessed critical medical devices in the endoscopy setting, SGNA maintains the position that critical medical devices originally manufactured and labeled for single use should not be reused.

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Recommended Reading

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