



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 device refers to a device that is introduced directly into the bloodstream or that contacts a normally sterile tissue or body space during use (U.S. Food and Drug Administration [FDA], 2015a).

Original device refers to a new, unused, single-use instrument (FDA, 2009).

Reusable medical device refers to an instrument designed and labeled for multiple uses and reprocessed by thorough cleaning and high level disinfection and sterilization between patients (FDA, 2015b).

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 single use device refers to an original device that has been used on a patient and then 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 SUDs by approved reprocessors.

SGNA believes that patients deserve the same standard of care regardless of practice setting. The reuse of single-use critical medical devices is a complex issue that must be balanced with the assurance of patient safety, the delivery of quality health care, and the cost. 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 critical medical devices.

Reuse of Single-Use Devices

Position

In the absence of substantial scientific evidence to prove the safety and effectiveness of reprocessed single-use 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.

References

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Recommended Reading

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Adopted by the SGNA Board of Directors, February 1998.

Revised May 2002, October 2005, August 2008, March 2012, May 2013, March 2015

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