

POSITION STATEMENT

Reuse of Single-Use Critical Medical Devices

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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], 2000). These devices break the mucus membrane and/or come into contact with sterile tissue or the vascular system.

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 (ASTM, 2000).

Reuse refers to the repeated use or multiple use of any medical device including devices intended for reuse or single-use, with reprocessing (cleaning, disinfection, or sterilization) between uses (United States Food and Drug Administration [FDA], 2001).

Reprocessed is defined as the following: The term “reprocessed”, with respect to a single-use device, means 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. The subsequent processing and manufacture of a reprocessed single-use device shall result in a device that is reprocessed within the meaning of this definition (FDA, 2002, p. 116).

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 label on these devices does not include reprocessing instructions, and may or may not identify the device as single use (FDA, 2000). SUDs are also referred to as disposable devices (FDA, 2000).

Background

Cost-containment concerns led health care facilities to consider reuse of single-use medical devices (SUDs) (Alfa, 2000; Association of periOperative Registered Nurses [AORN], 2006; Hambrick, 2001; Wilcox, 2000). This statement is intended to address the reuse of critical medical devices manufactured and labeled for single use.

Reuse of Single-Use Devices

Original equipment manufacturers (OEMs) are required to conduct stringent testing processes for reusable products. In order for a device to be labeled "reusable" the OEM must meet FDA criteria to validate a device can be cleaned and, if necessary, re-sterilized.

In 2002, the FDA established new statutory requirements for SUD reprocessors and hospitals engaging in reprocessing of SUDs (FDA, 2002). The FDA requires reprocessors also submit data ensuring the reprocessed device is, "substantially equivalent to newly manufactured devices" (Emergency Care Research Institute [ECRI], 2006).

SGNA 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.

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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