AORN Guidance Statement: Reuse of Single-Use Devices

Introduction

Today's economic environment has compelled health care organizations to explore methods to reduce health care costs. One prospective approach to controlling rising costs is to reprocess single-use medical devices. Reprocessing is rigorously regulated by the US Food and Drug Administration (FDA). AORN, the Association of periOperative Registered Nurses, recognizes the need for each health care facility to provide safe, cost-effective, quality care to patients and realizes that many facilities in today's marketplace are reprocessing and reusing devices labeled for single use. These devices are reprocessed either within the facility or by an external third party contracted to provide the reprocessing service.

Background

As surgery evolved and increased in complexity, the number of single-use devices utilized during surgery increased and continues to rise. In response to this trend, the practice of reprocessing and reusing single-use medical devices began during the 1970s.[1] As technology led to a wide variety of materials used in device manufacture and devices became more complex, concern for patient safety, informed consent, and ethical practice intensified. In the late 1990s, the FDA determined that increased regulation of reprocessing was needed to promote safe practice and protect the public's safety. Although original equipment manufacturers have been regulated for many years, the FDA determined that they, along with third-party reprocessors and hospital reprocessors, should be regulated uniformly according to the Food, Drug, and Cosmetic Act. The FDA sought the expertise of manufacturers, reprocessors, hospitals, users, and other interested parties in developing a regulatory document, and in August 2000, it published its rule governing the reprocessing/reusing of devices labeled for single-use only. The document is applicable to both hospitals and third-party reprocessors.

Reprocessing of single-use devices (SUDs) is additionally addressed in the Medical Device User Fee and Modernization Act of 2002 (MDUFMA), which establishes new statutory requirements for SUDs, including labeling to identify the devices as reprocessed, submission of validation data for many reprocessed SUDs, and submission of premarket notification (510[k]) with validation data for some SUDs that previously were exempt from 510(k) submission requirements. Firms and hospitals that are reprocessing are considered by the FDA as manufacturers and therefore must comply with statutory and regulatory requirements.[2] In addition, the FDA has published an approved list of single-use devices that are acceptable for reprocessing and a list of items that may not be reprocessed. In essence, the regulations regard reprocessors in the same way as original equipment manufacturers.[3,4]

Guidance Statement

Reprocessing single-use medical devices is chosen by some health care facilities as a cost containment effort and to reduce the amount of waste generated. It is the role and responsibility of each health care facility to determine whether and to what extent it will engage in such practice. As licensed professionals, perioperative nurses must demonstrate accountability to the nursing profession, to other members of the health care team, and to the public they serve.[5] AORN, the professional organization of and for perioperative nurses, believes certain basic tenets must underpin any reprocessing program. The foremost concern is for the patient's safety. Therefore,

- if a device cannot be cleaned, it cannot be reprocessed and reused;
- if sterility of a post-processed device cannot be demonstrated, the device cannot be reprocessed and reused;
- if the integrity and functionality of a reprocessed SUD cannot be demonstrated and documented as safe for patient care and/or equal to the original device specifications, the device cannot be reprocessed and reused; and
- if anything is opened it needs to be decontaminated before reprocessing.

Per requirements of the MDUFMA regulation, the FDA has published a list of reprocessed SUDs that have 510(k) approval/clearance; whose manufacturers have provided supplemental data on functionality, cleaning, and sterility; and which now are on the published list of devices that are acceptable for reprocessing.[2]