GUIDELINE FOR STERILIZATION

The Guideline for Sterilization has been approved by the AORN Guidelines Advisory Board. It was presented as a proposed guideline for comments by members and others. The guideline is effective September 1, 2018. The recommendations in the guideline are intended to be achievable and represent what is believed to be an optimal level of practice. Policies and procedures will reflect variations in practice settings and/or clinical situations that determine the degree to which the guideline can be implemented. AORN recognizes the many diverse settings in which perioperative nurses practice; therefore, this guideline is adaptable to all areas where operative or other invasive procedures may be performed.

Purpose

This document provides guidance for sterilizing reusable medical devices to be used in perioperative and procedural settings. Items that enter sterile tissue, including the vascular system, are categorized as critical using the Spaulding classification and should be sterile when used.[1] An important factor in preventing surgical site infections (SSIs) is the use of only sterile instruments and medical devices for operative and other invasive procedures. Surgical site infections are among the most common health care–associated infections, comprising 31% of all health care–associated infections among hospitalized patients.[2] Between 2006 and 2009, SSIs complicated an estimated 1.9% of surgical procedures in the United States.[3] The Centers for Disease Control and Prevention (CDC) health care–associated infection prevalence survey found there were an estimated 157,500 SSIs associated with inpatient surgeries in 2011.[2]

Surgical site infections may cause serious injury or death at enormous cost to patients, their families, and the health care organization. A systematic review of the literature on SSI from 1998 to 2014 found the estimated average cost of an SSI ranged between $10,433 (2005 dollars) and $25,546 (2002 dollars),[3] which equates to approximately $13,300 to $35,400 in 2018 dollars. Costs can exceed $90,000 per infection when the SSI involves a prosthetic joint implant or an antimicrobial-resistant organism.[3]

Sterility is accomplished through a multistep process. This process begins immediately after instrument use with the removal of gross soil, followed by further cleaning, decontamination, inspection, packaging, and finally sterilization. Each step is critical in producing sterile items and maintaining sterility until the item is opened and delivered to the sterile field for use. Effective sterilization cannot take place without effective cleaning, decontamination, and packaging. Substances such as bioburden, biofilm, plaques, soils, and oils inhibit sterilization. The degree to which sterilization is inhibited is correlated with the amount, number, type, and inherent resistance of these substances. Any of these substances may shield microorganisms on items from contact with the sterilant or combine with and inactivate the sterilant. Sterile barrier packaging increases the probability that sterility will be achieved and maintained until the package is opened at the point of use.

Sterility may be achieved by a variety of physical or chemical processes. The selection of the sterilization method is dependent on a number of factors including device design, material, packaging, compatibility with the sterilant, load limitations, safety requirements, and organization-specific considerations. The most common sterilization methods used in health care in the United States are addressed in this guideline. New sterilization technologies are being developed and may become commercially available in the future but are not yet cleared by the US Food and Drug Administration (FDA) for use in the United States. This document provides guidance only for sterilization processes commonly used in health care and currently cleared by the FDA.

The guideline addresses

- saturated steam under pressure;
- ethylene oxide;
- low-temperature hydrogen peroxide gas plasma;
- low-temperature hydrogen peroxide vapor;
- ozone combined with hydrogen peroxide;
- dry heat;
- liquid chemical sterilization using peracetic acid;
- loading the sterilizer and load configuration;
- transport of sterile items;
- quality control measures; and
- installation, care, and maintenance of sterilization equipment.

Guidance for the following topics is outside of the scope of this document:

- specific guidance for reprocessing of medical devices labeled as single use, criteria for evaluating the services of a third-party reprocessor, and identifying single-use items for reprocessing;
- cleaning and decontamination of surgical instruments;
- high-level disinfection;
- packaging;
- loaned instruments;
- facility design;