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Peracetic Acid Sterilization

DISINFECTION AND STERILIZATION GUIDELINE
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Guideline for Disinfection and Sterilization in Healthcare Facilities (2008)

WHAT TO KNOW

Peracetic Acid Sterilization from the Guideline for Disinfection and Sterilization in Healthcare Facilities (2008).

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Overview

Peracetic acid is a highly biocidal oxidizer that maintains its efficacy in the presence of organic soil. Peracetic acid removes surface contaminants (primarily protein) on endoscopic tubing.^{711, 717} An automated machine using peracetic acid to sterilize medical, surgical, and dental instruments chemically (e.g., endoscopes, arthroscopes) was introduced in 1988. This microprocessor-controlled, low-temperature sterilization method is commonly used in the United States.¹⁰⁷ The sterilant, 35% peracetic acid, and an anticorrosive agent are supplied in a single-dose container. The container is punctured at the time of use, immediately prior to closing the lid and initiating the cycle. The concentrated peracetic acid is diluted to 0.2% with filtered water (0.2 mm) at a temperature of approximately 50°C. The diluted peracetic acid is circulated within the chamber of the machine and pumped through the channels of the endoscope for 12 minutes, decontaminating exterior surfaces, lumens, and accessories. Interchangeable trays are available to permit the processing of up to three rigid endoscopes or one flexible endoscope. Connectors are available for most types of flexible endoscopes for the irrigation of all channels by directed flow. Rigid endoscopes are placed within a lidded container, and the sterilant fills the lumens either by immersion in the circulating sterilant or by use of channel connectors to direct flow into the lumen(s) (see below for the importance of channel connectors). The peracetic acid is discarded via the sewer and the instrument rinsed four times with filtered water.

Concern has been raised that filtered water may be inadequate to maintain sterility⁸⁹⁶. Limited data have shown that low-level bacterial contamination may follow the use of filtered water in an AER but no data has been published on AERs using the peracetic acid system¹⁶¹. Clean filtered air is passed through the chamber of the machine and endoscope channels to remove excess water⁷¹⁹. As with any sterilization process, the system can only sterilize surfaces that can be contacted by the sterilant. For example, bronchoscopy-related infections occurred when bronchoscopes were processed using the wrong connector^{155, 725}. Investigation of these incidents revealed that bronchoscopes were inadequately reprocessed when inappropriate channel connectors were used and when there were inconsistencies between the reprocessing instructions provided by the manufacturer of the bronchoscope and the manufacturer of the automatic endoscope reprocessor¹⁵⁵. The importance of channel connectors to achieve sterilization was also shown for rigid lumen devices^{137, 856}.

The manufacturers suggest the use of biological monitors (*G. stearothermophilus* spore strips) both at the time of installation and routinely to ensure effectiveness of the process. The manufacturer's clip must be used to hold the strip in the designated spot in the machine as a broader clamp will not allow the sterilant to reach the spores trapped under it⁸⁹⁷. One investigator reported a 3% failure rate when the appropriate clips were used to hold the spore strip within the machine.⁷¹⁸ The use of biological monitors designed to monitor either steam sterilization or ETO for a liquid chemical sterilizer has been questioned for several reasons including spore wash-off from the filter paper strips which may cause less valid monitoring⁸⁹⁸⁻⁹⁰¹. The processor is equipped with a conductivity probe that will automatically abort the cycle if the buffer system is not detected in a fresh container of the peracetic acid solution. A chemical monitoring strip that detects that the active ingredient is >1500 ppm is available for routine use as an additional process control.

Mode of Action

Only limited information is available regarding the mechanism of action of peracetic acid, but it is thought to i.e., it denatures proteins, disrupts cell wall permeability, and oxidizes sulfhydryl and sulfur bonds in proteins, enzymes, and other metabolites^{654, 726}.

Microbicidal Activity

Peracetic acid will inactivate gram-positive and gram-negative bacteria, fungi, and yeasts in <5 minutes at <100 ppm. In the presence of organic matter, 200-500 ppm is required. For viruses, the dosage range is wide (12-2250 ppm), with poliovirus inactivated in yeast extract in 15 minutes with 1500 to 2250 ppm. Bacterial spores in suspension are inactivated in 15 seconds to 30 minutes with 500 to 10,000 ppm (0.05 to 1%).⁶⁵⁴

Simulated-use trials have demonstrated microbicidal activity^{111, 718-722} and three clinical trials have demonstrated both microbial killing and no clinical failures leading to infection^{90, 723, 724}. Alfa and co-workers, who compared the peracetic acid system with ETO, demonstrated the high efficacy of the system. Only the peracetic acid system was able to completely kill 6-log₁₀ of *Mycobacterium chelonae*, *Enterococcus faecalis*, and *B. atrophaeus* spores with both an organic and inorganic challenge.⁷²² Like other sterilization processes, the efficacy of the process can be diminished by soil challenges.⁹⁰² and test conditions.⁸⁵⁶

Uses

This automated machine is used to chemically sterilize medical (e.g., GI endoscopes) and surgical (e.g., flexible endoscopes) instruments in the United States. Lumened endoscopes must be connected to an appropriate channel connector to ensure that the sterilant has direct contact with the contaminated lumen.^{137, 856, 903} Olympus America has not listed this system as a compatible product for use in reprocessing Olympus bronchoscopes and gastrointestinal endoscopes (Olympus America, January 30, 2002, written communication).

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