

Immediate-Use Steam Sterilization

"Flash sterilization" has traditionally been used to describe steam sterilization cycles where unwrapped medical instruments are subjected to an abbreviated steam exposure time and then used promptly after cycle completion without being stored. This is in contrast to traditional "terminal sterilization" cycles, where instruments are sterilized within containers, wrappers, or primary packaging designed to maintain the instruments' sterility and allow the devices to be stored for later use. The term "flash" arose out of the abbreviated time of exposure of the unwrapped device.

Today, however, "flash sterilization" is an antiquated term that does not fully describe the various steam sterilization cycles now used to process items not intended to be stored for later use. Current guidelines may require longer exposure times and/or the use of single wrappers or containers designed to allow for aseptic transfer of an item to the point of use. The term "immediate-use steam sterilization" more accurately reflects the current use of these processes. The same critical reprocessing steps (such as cleaning, decontaminating, and transporting sterilized items) must be followed regardless of the specific sterilization cycle employed; a safe process does not include short-cuts or work-arounds.

"Immediate use" is broadly defined as the shortest possible time between a sterilized item's removal from the sterilizer and its aseptic transfer to the sterile field. Immediacy implies that a sterilized item is used during the procedure for which it was sterilized and in a manner that minimizes its exposure to air and other environmental contaminants. A sterilized item intended for immediate use is not stored for future use, nor held from one case to another. Immediacy, rather than being defined according to a specific time frame, is established through the critical analysis and expert collaboration of the health care team.

We agree that:

- Personnel involved in reprocessing should be knowledgeable and capable of exercising critical thinking and judgment, and should implement standardized practices. The supervising organization is responsible for ensuring appropriate training, education, and competency of staff and ensuring that the necessary related resources are provided.
 - Examples of education and certification resources include the Certification Board for Sterile Processing and Distribution (CBSPD) and the International Association of Healthcare Central Service Materiel Management (IAHCSMM).
 - Examples of standards and practices can be found with the Association for the Advancement of Medical Instrumentation (AAMI), the Association of periOperative Registered Nurses (AORN), and the Centers for Disease Control and Prevention-Healthcare Infection Control Practices Advisory Committee (CDC-HICPAC).

- Sterilization personnel should be educated regarding the different types of steam sterilizers (i.e., gravity-displacement and dynamic air removal—prevacuum, high vacuum, and steam-flush-pressure-pulse sterilizers) and the different types of steam sterilization cycles (i.e., gravity-displacement and dynamic air removal cycles) used in health care facilities.
- Sterilization cycles with little or no dry time are efficacious when used in compliance with validated written instructions provided by the device manufacturers, sterilization equipment manufacturers, and (if applicable) container manufacturers and when done in accordance with professional guidelines.
- Cleaning, decontamination, and rinsing are critical and users must follow and complete all required processing steps regardless of the sterilization exposure parameters being used.
- Aseptic transfer from the sterilizer to the point of use is critical to protect items from contamination.
- Only items sterilized and packaged in materials cleared by the FDA for maintenance of sterility can be stored.
- The device manufacturer's written instructions for reprocessing any reusable device must be followed. The cycle parameters required to achieve sterilization are determined by the design of an instrument, the characteristics of the load, the sterilizer capabilities, and the packaging (if used).

NOTE: The device manufacturer's instructions are not always compatible with the sterilizer instructions or the instructions for the container/wrapper. Device manufacturers' instructions are sometimes unclear, incomplete, or require processes or cycles that are not available in the health care facility. Where instructions conflict or are insufficient, the device manufacturer should be contacted for more information/guidance. If differing instructions cannot be resolved and the instrument is urgently needed, the device manufacturer's instructions must be followed.

- Survey personnel involved in evaluating organizations that sterilize medical items should be knowledgeable and capable of exercising critical thinking and judgment. The regulatory or accrediting agency should evaluate whether the organization's leaders ensure that training, education, and resources are provided and the competency of staff is validated.
- Quality management is important to ensure compliance with processes and relating those processes to outcomes.
- Sterilization process monitoring is essential to ensure that sterilization practices are efficacious.
 - Examples of process monitoring tools are physical indicators, biological indicators, and chemical indicators.
- Instrument inventories should be sufficient to meet anticipated surgical volume and permit the time to complete all critical elements of reprocessing.

Immediate-use sterilization should NOT be performed on the following devices:

- Implants¹, except in a documented emergency situation when no other option is available.
- Post-procedure decontamination of instruments used on patients who may have Creutzfeldt–Jakob disease (CJD) or similar disorders.
- Devices or loads that have not been validated with the specific cycle employed.
- Devices that are sold sterile and intended for single-use only.

¹ The FDA defines an implant as a "device that is placed into a surgically or naturally formed cavity of the human body if it is intended to remain there for a period of 30 days or more. FDA may, in order to protect public health, determine that devices placed in subjects for shorter periods are also 'implants.'" [21 CFR 812.3(d)]

Resources

Association for the Advancement of Medical Instrumentation. *ANSI/AAMI ST79: 2010—Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities*. Arlington, VA: Association for the Advancement of Medical Instrumentation, 2010.

Association for the Advancement of Medical Instrumentation. *ANSI/AAMI ST40—Table-top Dry Heat (Heated Air) Sterilization and Sterility Assurance in Health Care Facilities*. Arlington, VA: Association for the Advancement of Medical Instrumentation; 2004.

Recommended practices for sterilization in the perioperative setting. In: *Standards, Recommended Practices, and Guidelines*. Denver, CO: AORN, Inc; 2010.

Recommended practices for cleaning and care of surgical instruments and powered equipment. In: *Standards, Recommended Practices and Guidelines*. Denver, CO: AORN, Inc; 2010.

Centers for Disease Control, *Guideline for Disinfection and Sterilization in Healthcare Facilities*, 2008.