The following recommended practices for sterilization were developed by the AORN Recommended Practices Committee and have been approved by the AORN Board of Directors. They were presented as proposed recommended practices for comments by members and others. They are effective January 1, 2008.

These recommended practices are intended as achievable recommendations representing 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 recommended practices can be implemented.

AORN recognizes the various settings in which perioperative nurses practice. These recommended practices are intended as guidelines adaptable to various practice settings. These practice settings include traditional operating rooms, ambulatory surgery centers, physician’s offices, cardiac catheterization laboratories, endoscopy suites, radiology departments, and all other areas where surgery may be performed.

References to nursing interventions (I) used in the Perioperative Nursing Data Set, second edition, (PNDS) are noted in parentheses when a recommended practice corresponds to a PNDS intervention.1 The reader is referred to the PNDS for further explanation of nursing diagnoses, interventions, and outcomes.

**Purpose**

These recommended practices provide guidance for sterilizing items to be used in the surgical environment. The creation and maintenance of an aseptic environment has a direct influence on patient outcomes. A major responsibility of the perioperative registered nurse is to minimize patient risk for surgical site infection. One of the measures for preventing surgical site infections is to provide surgical items that are free of contamination at the time of use. This can be accomplished by subjecting them to cleaning and decontamination, followed by a sterilization process.2 Steam, ethylene oxide (EO), low-temperature hydrogen peroxide gas plasma, peracetic acid, ozone, and dry heat are sterilization methods that are used in the health care environment. Sterilization provides the highest level of assurance that surgical items are free of viable microbes.

### Recommendation 1

**Items to be sterilized should be cleaned, decontaminated, sterilized, and stored in a controlled environment and in accordance with AORN’s “Recommended practices for cleaning and caring of instruments and powered equipment”2 and the device manufacturer’s written instructions.**

Effective sterilization cannot take place without effective cleaning. The process of sterilization is negatively affected by the amount of bioburden and the number, type, and inherent resistance of microorganisms, including biofilms, on the items to be sterilized. Soils, oils, and other materials may shield microorganisms on items from contact with the sterilant or combine with, and inactivate, the sterilant.3,4

**I.a.** Functional workflow patterns should be established to create and maintain physical separation between the decontamination and sterilization areas. (PNDS: I81, I98)

Physical separation aids in environmental and microbial control. During manual cleaning of instruments, particulates, aerosolized matter, dust, and microbial counts are elevated. Physical separation and vented airflow to the outside minimizes contamination of processed items.

**I.a.1.** Attire, use of personal protective equipment (PPE), and limitations in personnel access and movement should be based on expected contamination levels (Table 1).

**I.a.2.** Functional workflow patterns should be established in the following order from potentially high contamination areas to:

- clean areas:
  - decontamination,
  - preparation and packaging,
  - sterilization processing,
  - sterile storage, and
  - clean distribution.

**I.a.3.** Traffic patterns should be established that define access restrictions, movement of personnel, and appropriate attire according to AORN’s “Recommended practices for traffic patterns in..."
the perioperative practice setting” to protect personnel, equipment, supplies, and instrumentation from sources of potential contamination.⁵

I.b. Room temperature, humidity, and ventilation should be controlled in accordance with local, state, and federal policy and regulation. Table 2 provides parameters for the controlled environment.³ (PNDS: I81, I98)

Bacteria and fungi thrive at warm temperatures; cooler temperatures may impede bacterial and fungal growth in the decontamination area. Regulated environmental controls in work areas are essential for the comfort of personnel wearing appropriate attire and PPE.³

I.c. Room temperature, humidity, and ventilation for each work area should be monitored and recorded daily.³ (PNDS: I98)

I.c.1. Organizations should monitor and record environmental controls in each area to ensure that, at minimum, recommended parameters are met and maintained.

I.d. Health care personnel should refer to the “Recommended practices for cleaning and care of surgical instruments and powered equipment” and must use standard precautions when performing decontamination activities.² (PNDS: I70, I98)

Standard precautions are designed to protect patients and health care workers from contact with recognized and unrecognized sources of infectious diseases.

**Recommendation II**

**Items to be sterilized should be packaged in accordance with AORN’s “Recommended practices for selection and use of packaging systems for sterilization.”⁶**

Appropriate packaging ensures that sterility can be achieved and maintained to the point of use.

II.a. Manufacturers of packaging systems should be consulted for package preparation, configuration, and sterilization.⁵,⁶ (PNDS: I70: I98)

II.b. The total weight of an instrument set should not exceed 25 lbs. (PNDS: I122)
Instrument sets weighing more than 25 lbs are known to be difficult to dry without lengthy drying times and present an increased risk of ergonomic injury.3,8

II.c. Combination paper/plastic peel pouches should not be placed in a container or wrapped set.3,6 (PNDS: I70, I122)

It may not be possible to position pouches to ensure adequate air removal, steam contact, or drying. The practice of using wraps or pouches inside container systems has not been validated by pouch or container manufacturers. Medical-grade, all-paper pouches may be used for this purpose.3

**Table 2**

<table>
<thead>
<tr>
<th>Functional area</th>
<th>Airflow</th>
<th>Minimum number of air exchanges per hour</th>
<th>All air exhausted directly to the outdoors</th>
<th>Temperature</th>
<th>Relative humidity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Soiled/ decontaminated</td>
<td>Negative (in)</td>
<td>10</td>
<td>Yes</td>
<td>60° F to 65° F (16° C to 18° C)</td>
<td>30% to 60%</td>
</tr>
<tr>
<td>Sterilizer equipment access</td>
<td>Negative (in)</td>
<td>10</td>
<td>Yes</td>
<td>75° F to 85° F (24° C to 29° C)</td>
<td>30% to 60%</td>
</tr>
<tr>
<td>Sterilizer loading/unloading</td>
<td>Positive (out)</td>
<td>10</td>
<td>Yes</td>
<td>68° F to 73° F (20° C to 23° C)</td>
<td>30% to 60%</td>
</tr>
<tr>
<td>Restrooms/ housekeeping</td>
<td>Negative (in)</td>
<td>10</td>
<td>Yes</td>
<td>≤ 75° F (≤ 24° C)</td>
<td>30% to 60%</td>
</tr>
<tr>
<td>Preparation and packaging</td>
<td>Positive (out)</td>
<td>10 (downdraft type)</td>
<td>No</td>
<td>68° F to 73° F (20° C to 23° C)</td>
<td>30% to 60%</td>
</tr>
<tr>
<td>Textile packaging room</td>
<td>Positive (out)</td>
<td>10 (downdraft type)</td>
<td>No</td>
<td>68° C to 73° F (20° C to 23° C)</td>
<td>30% to 60%</td>
</tr>
<tr>
<td>Clean/sterile storage</td>
<td>Positive (out)</td>
<td>4 (downdraft type)</td>
<td>No</td>
<td>≤ 75° F (≤ 24° C)</td>
<td>≤ 70%</td>
</tr>
</tbody>
</table>

**REFERENCE**


Saturated steam under pressure is the preferred sterilization method. It is an effective, inexpensive, and relatively rapid sterilization method for most porous and nonporous materials.9

III.a. Manufacturers’ written instructions for operating steam sterilizers should be followed. (PNDS: I98, I122).

Steam sterilizers vary in design and performance characteristics. A variety of steam sterilization cycles are used in health care organizations. Some examples are gravity-displacement cycles, dynamic air-removal (ie, prevacuum), steam flush pressure pulse cycles, flash cycles, and express cycles (ie, abbreviated steam sterilization cycles used for flash sterilization).9 In addition, some sterilizers may be designed to permit only one type of cycle. For example, some sterilizers are identified as gravity-displacement sterilizers because that is the only type of cycle this type of sterilizer permits.

**Recommendation III**

Saturated steam under pressure should be used to sterilize heat- and moisture-stable items unless otherwise indicated by the device manufacturer.
Table 3 and Table 4 provide typical minimum sterilization times for gravity-displacement and dynamic air-removal steam sterilization cycles.1

III.b. Cycle parameters recommended by the device manufacturer should be reconciled with the sterilizer manufacturer’s written instructions for the specific sterilization cycle and load configuration.3,10 Certain types of equipment and implants (eg, some pneumatically powered instruments; specialty orthopedic, neurosurgery, trauma instruments) may require prolonged exposure times or drying times.3,10 (PNDS: I98, I122)

III.c. Following steam sterilization, the contents of the sterilizer should be removed from the chamber and left untouched for a period of 30 minutes to two hours depending on the load contents.1 (PNDS: I70, I98, I122)

The potential for the formation of condensation is decreased by allowing the contents of the sterilizer to remain untouched until the equalization of the temperature differential between the chamber and outside environment has occurred.1

III.c.1. Steam sterilizer doors should not be left ajar to cool loads following a cycle.11

Removing the sterilizer load from the sterilizer as soon as possible after steam sterilization allows the cooling process to begin earlier.

Cracking the sterilizer door may hinder the drying process.

Wet packs may be a result of excessively wet steam, poor loading techniques, or a true sterilizer malfunction.

III.d. Warm or hot items should not be placed on cool or cold surfaces. (PNDS: I70, I98, I122)

When hot and cold surfaces are brought together, moisture condenses from both inside and outside the package. At the end of the steam sterilization cycle and after an appropriate drying time, items still may contain some steam vapor. Touching packages at this vulnerable stage could compromise the barrier properties of the packaging material by causing moisture and/or contaminants to wick through the package. Droplets inside or outside of the container can form because rigid container materials are nonabsorbent. Condensate can drip onto surrounding containers, compromising the sterility of other packages.3

III.e. Sterilized packages or containers that have formed condensate should be considered unsterile and none of the contents used.1 (PNDS: I70, I98, I122)

Moisture can compromise the integrity of barrier material and the sterility of the contents. Moisture may indicate problems with the packaging and sterilization process.3

Recommendation IV

Use of flash sterilization should be kept to a minimum. Flash sterilization should be used only in selected clinical situations and in a controlled manner.
Flash sterilization may be associated with increased risk of infection to patients because of pressure on personnel to eliminate one or more steps in the cleaning and sterilization process.

IV.a. Flash sterilization should be used only when there is insufficient time to process by the preferred wrapped or container method. Flash sterilization should not be used as a substitute for sufficient instrument inventories.1 (PNDS: I70, I98)

Proper decontamination is essential in removing bioburden and preparing an item for sterilization by any method. Failures in instrument cleaning have resulted in transmission of infectious agents.3

IV.a.1. Items to be flash sterilized should be subjected to the same decontamination processes as described in AORN’s “Recommended practices for cleaning and care of surgical instruments and powered equipment.”2

IV.a.2. Flash sterilization should be performed only if all of the following conditions are met:
  • The device manufacturer’s written instructions on cycle type, exposure times, temperature settings, and drying times (if recommended) are available and followed.
  • Items are disassembled and thoroughly cleaned with detergent and water to remove soil, blood, body fats, and other substances.
  • Lumens are brushed and flushed under water with a cleaning solution and rinsed thoroughly.
  • Items are placed in a closed sterilization container or tray, validated for flash sterilization, in a manner that allows steam to contact all instrument surfaces.
  • Measures are taken to prevent contamination during transfer to the sterile field.

Flash-sterilized items are to be used immediately and not stored for later use.3 Table 5 provides examples of typical flash sterilization parameters.

IV.b. Packaging and wrapping (eg, textiles, paper/plastic pouches, nonwoven wrappers) should not be used in flash sterilization cycles unless the sterilizer is specifically designed and labeled for this use. (PNDS: I70, I98)

Cycle parameters vary according to sterilizer design.

IV.b.1. Sterilizer manufacturers’ written directions should be followed and reconciled with the packaging manufacturer’s instructions for sterilization.3

IV.c. Process challenge devices (PCDs) should be used with routine process monitoring devices (ie, chemical indicators, biological indicators, physical monitoring devices).3 (PNDS: I70, I98)

Process challenge and process monitoring devices provide information to demonstrate that conditions for sterilization have been met.

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Table 4

<table>
<thead>
<tr>
<th>Item</th>
<th>Exposure time at 270° F (132° C)</th>
<th>Minimum drying time</th>
<th>Exposure time at 275° F (135° C)</th>
<th>Minimum drying time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wrapped instruments</td>
<td>4 min</td>
<td>20 to 30 min</td>
<td>3 min</td>
<td>16 min</td>
</tr>
<tr>
<td>Textile packs</td>
<td>4 min</td>
<td>5 to 20 min</td>
<td>3 min</td>
<td>3 min</td>
</tr>
<tr>
<td>Wrapped utensils</td>
<td>4 min</td>
<td>20 min</td>
<td>3 min</td>
<td>16 min</td>
</tr>
</tbody>
</table>

Table 5

**EXAMPLES OF TYPICAL FLASH STEAM STERILIZATION PARAMETERS**

<table>
<thead>
<tr>
<th>Type of sterilizer</th>
<th>Load configuration</th>
<th>Time</th>
<th>Exposure Temperature</th>
<th>Drying Times</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gravity displacement</td>
<td>Metal or nonporous items only (ie, no lumens)</td>
<td>3 minutes</td>
<td>270° F–275° F</td>
<td>0 to 1 minutes</td>
</tr>
<tr>
<td></td>
<td>Metal items with lumens and porous items (eg, rubber, plastic) sterilized together. Complex devices (eg, powered instruments requiring extended exposure times). Manufacturer instructions should be consulted.</td>
<td>10 minutes</td>
<td>270° F–275° F</td>
<td>0 to 1 minute</td>
</tr>
<tr>
<td>Dynamic air-removal (prevacuum)</td>
<td>Metal or nonporous items only (ie, no lumens)</td>
<td>3 minutes</td>
<td>270° F–275° F</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td>Metal items with lumens and porous items sterilized together</td>
<td>4 minutes</td>
<td>270° F (132° C)</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3 minutes</td>
<td>275° F (135° C)</td>
<td>N/A</td>
</tr>
</tbody>
</table>

- The sterilizer manufacturer’s instructions for use of express cycles should be followed. One sterilizer manufacturer provides an express flash cycle that permits flash sterilization with a single-ply wrapper to help contain the device to the point of use. This cycle is not recommended for devices with lumens. Express cycles should only be used if the sterilizer is designed with this feature.
- Steam-flush pressure-pulse: See manufacturers’ written instructions for time and temperature.
- This table does not include specific instructions for rigid flash sterilization containers. The container manufacturer’s instructions should be followed.

**REFERENCE**


**IV.c.1.** Each sterilization cycle should be monitored to verify that parameters required for sterilization have been met.³

**IV.c.2.** The sterilizer operator should use physical monitoring devices to verify cycle parameters for each load.³

Physical monitoring devices (eg, printouts, graphs, gauges) can indicate immediate sterilizer failure. Physical monitors record cycle parameters (ie, time, temperature) for each cycle.

**IV.c.3.** Biological (BI) and chemical indicators should be used to monitor sterilizer efficacy and assess compliance of monitoring standards established for gravity-displacement and dynamic air-removal sterilizers. Class 5 chemical integrating indicators should be used within each sterilizer container or tray.³

**IV.d.** Users should adhere to aseptic technique for flash-sterilized items during transport to the point of use. It is important that sterilization processing be carried out in a clean environment and that flash-sterilized devices are transferred to the point of use in a manner that prevents contamination.

**IV.e.** Rigid sterilization containers designed and intended for flash-sterilization cycles should be used. (PNDS: 170, 198)

Rigid flash-sterilization containers
- reduce the risk of contamination during transport to the point of use,
- facilitate ease of presentation to the sterile field, and
- protect sterilized items during transport.³
IV.f. Flash-sterilization containers should be used, cleaned, and maintained according to the manufacturer’s written instructions.1

IV.f.1. Flash-sterilization containers should be opened, used immediately, and not stored for later use.

IV.f.2. Flash-sterilization containers should be differentiated from other types of containers.

IV.g. Flash sterilization should not be used for implantable devices except in cases of emergency when no other option is available.12 (PNDS: I85, I138)

Implants are foreign bodies and they increase the risk of surgical site infection.12 Careful planning, appropriate packaging, and inventory management in cooperation with suppliers can minimize the need to flash sterilize implantable medical devices.

IV.h. In an emergency, when flash sterilization of an implant is unavoidable, a rapid-action BI with a Class 5 chemical integrating indicator (or enzyme only indicator) should be run with the load.3,12 (PNDS: I70, I98)

IV.h.1. The implant should be quarantined on the back table and should not be released until the rapid-action BI provides a negative result.

IV.h.2. If the implant is used before the BI results are known and the BI is later determined to have a positive result, the surgeon and infection prevention and control personnel should be notified as soon as the results are known.

IV.h.3. If the implant is not used, it cannot be saved as sterile for future use. Resterilization of the device is required if the implant is to be used later.3,12

IV.i. Documentation of cycle information and monitoring results should be maintained in a log (electronic or manual) to provide tracking of the flashed item(s) to the individual patient.3,12 (PNDS: I112)

Documentation allows every load of sterilized items used on patients to be traced.

IV.i.1. Sterilization records should include information on each load, including

- the item(s) processed;
- the patient receiving the item(s);
- the cycle parameters used (eg, temperature, duration of cycle);
- the date and time the cycle is run;
- the operator information; and
- the reason for flash sterilization.1

**Recommendation V**

Ethylene oxide (EO) sterilization is a low-temperature process that is appropriate for heat- and moisture-sensitive surgical items when indicated by the device manufacturer.

Ethylene oxide at sterilizing temperatures kills microbes in hard-to-reach areas, and it does so with no damage to devices. Ethylene oxide is an alkylating agent that results in microbial death under controlled parameters. Ethylene oxide substitutes for hydrogen atoms on molecules needed to sustain life and, by attaching to these molecules, EO stops these molecules’ normal life-supporting functions. Some of the key molecules that EO disrupts are proteins and DNA. Under low-temperature sterilizing conditions, so much EO is used that this disruption proves lethal to microbial life.13

V.a. Ethylene oxide should be used if alternate methods of sterilization are not available compatible with the medical devices being processed.14

Health care organizations use 100% concentrations of EO or EO in mixtures with inert diluent gases (eg, carbon dioxide, hydrochlorofluorocarbons [HCFC]) for EO sterilization procedures. Until the 1990s, chlorofluorocarbons (CFCs) were used as diluents for EO. Chlorofluorocarbons cause depletion of the ozone layer and are no longer produced in the United States. Hydrochlorofluorocarbons deplete the ozone layer, but to a lesser degree than CFCs.14

V.a.1. Users of HCFCs should be aware of and comply with federal, state, and local regulations regarding HCFC use in EO sterilizers.15-17

V.b. The manufacturer’s written instructions should be reviewed to determine if a heat- or moisture-sensitive item is compatible with EO sterilization before attempting sterilization by this method. (PNDS: I122)
V.c. Items, including all lumens, should be clean and dry before being packaged for EO sterilization. (PNDS: I75, I98, I122)

   Soil inhibits sterilization, and moisture may produce toxic by-products. The combination of water and EO results in the formation of ethylene glycol (ie, antifreeze).

V.d. Sterilizer manufacturers’ written instructions should be followed for EO sterilization parameters and placement of items within the sterilizer. (PNDS: I70, I75, I122)

   Ethylene oxide sterilizers differ in design and operating characteristics.

V.d.1. Items should be placed in EO sterilizers in baskets or on loading carts in a manner that allows free circulation and penetration of the EO.¹⁵

V.e. Physical monitors of EO sterilizers should record the essential parameters for sterilization including temperature, exposure time, pressure.¹⁵ (PNDS: I75, I98, I122, I138)

   Physical monitors provide real-time assessment and documentation of sterilization cycle parameters. Timely review of graphs, charts, and printouts enhance detection of sterilizer malfunctions and allows for implementation of corrective actions.³

V.f. Items sterilized in EO sterilizers should be properly aerated in a mechanical aerator to remove EO. (PNDS: I75, I122)

   Ethylene oxide residual absorbed into sterilized items represents a hazard to patients and personnel, if not removed. Ethylene oxide is a known human carcinogen and a chemical that has the potential to cause adverse reproductive effects in humans. The Occupational Safety and Health Administration (OSHA) has established exposure limits for EO in the workplace.¹⁶¹⁸

   Items not sufficiently aerated may cause patient or personnel injury (eg, chemical burns). Aeration is the only safe and effective way to remove EO.¹⁵¹⁶¹⁹

   Adequate aeration times reduce EO vapors and residue to a level safe for exposure of both patients and health care personnel.

   Rinsing an inadequately aerated item does not remove EO and can create hazardous by-products.

V.f.1. Sterilized items should be handled as little as possible before aeration to prevent health care personnel from breathing EO gas or coming in contact with EO residues.

   - Health care personnel should wear butyl rubber, nitrile, or neoprene gloves that provide protection to the skin when handling unaerated EO-sterilized items.¹⁵
   - Pulling, rather than pushing, sterilizer carts during transfer to aerators directs the flow of EO vapors and residues away from health care personnel.
   - When using a separate mechanical aerator, health care personnel should be protected from EO vapors and residue during transfer of sterilized items from the sterilizer to the aerator.
   - The transfer of products from a sterilizer to an aerator should be performed in as short a time as possible.

V.f.2. Required aeration times depend on many variables that include, but are not limited to,

   - item composition and size,
   - item preparation and packaging,
   - density of the load,
   - type of EO sterilizer used,
   - type of aerator used, and
   - temperature penetration pattern of the aerator’s chamber.¹⁵

V.f.3. All EO-sterilized items must be completely aerated before they can be used safely.

   - Aeration cycles should never be interrupted to remove items for use.
   - Items should remain in aerators until the aeration time has been completed.
   - Aeration requirements for the most difficult-to-aerate products may require increased time frames. Ethylene oxide vapors and residues diffuse from sterilized items over time. This aeration or degassing process can be expedited by raising the temperature and by increasing the flow of air around the item.
   - Whenever possible, EO-sterilized items should be processed in sterilizers that have an integrated aeration cycle.
V.f.4. The device manufacturers’ written instructions should be followed for specific aeration requirements.

V.f.5. All aeration cycle parameters should be documented and verified as to the accuracy of the correct aeration time and temperature.

V.f.6. A program for monitoring occupational exposure to EO must be established according to OSHA regulations to accurately determine the permissible airborne concentrations of EO within the health care setting.

Compliance with regulations promotes a safe work environment that is within federal and state mandated limits.18,20

V.g. Personnel who have the potential for exposure should wear EO-monitoring badges that meet the National Institute for Occupational Safety and Health standards for accuracy.15,21,22

V.g.1. The EO-monitoring program in each organization must comply with OSHA regulations.16

General environmental monitoring is not required, although it may provide an indicator of problems with the ventilation or EO system.15

Monitoring of short term exposures over a 15-minute period also is required while sterilizer and aeration activities are being performed.

V.h. Health and safety procedures should be developed for health care personnel.

Established procedures help to identify, eliminate, or minimize risk from exposure to hazards as well as facilitate timely response to accidental exposure and emergencies.

V.h.1. Personnel should be informed about the health effects and potential hazards associated with exposure to EO.

V.h.2. Information on the EO health effects and potential hazards should be provided at the time of assignment to an area where EO is used and at least annually thereafter.

V.h.3. Periodic employee and environmental physical assessment and testing should be carried out and documented according to current OSHA regulations.15,21,23

V.h.4. Personnel should be familiar with the organization’s emergency spill plan.18

V.h.5. Personnel should be aware of safety procedures that should be implemented following exposure to EO.

People who have inhaled concentrated EO gas
• should seek fresh air immediately;
• may require the administration of oxygen; and
• may require cardiopulmonary resuscitation, if respiratory or cardiac collapse occurs.15,19

The material safety data sheet (MSDS) for the type of ethylene oxide used should be consulted for specific first-aid measures after exposure.

V.i. Documentation of employee breathing zone EO monitoring must be maintained in employees’ health records for the duration of employment plus 30 years after termination of employment.15,21

Documentation establishes a continuous history of the work environment.

Recommendation VI

Low-temperature hydrogen peroxide gas plasma sterilization methods should be used for moisture-sensitive and heat-sensitive items and when indicated by the device manufacturer.

Low-temperature hydrogen peroxide gas plasma sterilization uses a combination of hydrogen peroxide vapor and low-temperature hydrogen peroxide gas plasma.24 In this process, microbial life is disrupted when free radicals created from hydrogen peroxide gas plasma interact with microbial cell membranes, enzymes, or nucleic acids.16

Items processed using a low-temperature hydrogen peroxide gas plasma sterilization require no aeration because the residuals and by-products are oxygen and water in the form of humidity.16,25,26

Items are dry at the end of the cycle.

Hydrogen peroxide is a severe irritant, but it is considered nonmutagenic and noncarcinogenic.16,24,27
VI.a. The sterilizer manufacturer’s written instructions for use, monitoring, and maintenance should be followed when using a low-temperature hydrogen peroxide gas plasma sterilization system. (PNDS: I75, I98, I122)

VI.a.1. Written documentation of the acceptability of low-temperature hydrogen peroxide gas plasma sterilization for specific devices should be obtained from the instrument manufacturer.

VI.a.2. Devices with lumens should comply with the sterilizer manufacturer’s lumen specifications relating to diameter and length of the device.26,27,28

VI.b. Items to be gas-plasma sterilized should clean and dry and packaged in nonwoven polypropylene wraps, high-density polyethylene, or biaxially oriented polyethylene terephthalate polyester film (ie, Mylar) pouches.

Cellulose-based (eg, paper-based) packaging materials or products and liquids are not suitable for low-temperature hydrogen peroxide gas plasma sterilization.

VI.c. Trays designed and validated for use with low-temperature hydrogen peroxide gas plasma sterilization should be used.

VI.d. When loading a low-temperature hydrogen peroxide gas plasma sterilizer, the load configuration and placement of items inside the sterilizers should comply with the sterilizer manufacturer’s recommendations. (PNDS: I122)

Proper load configuration allows sterilant contact.3

Recommendation VII

Sterilization systems using peracetic acid as a low-temperature liquid sterilant is appropriate for heat-sensitive surgical items that can be immersed and when indicated by the device manufacturer.

Peracetic acid sterilization is a system that uses a chemical formula of acetic acid plus an extra oxygen atom. This extra oxygen atom is highly reactive, reacts with most cellular components, and causes cellular death. The ability of peracetic acid to inactivate many different critical cell systems is responsible for its broad spectrum antimicrobial activity. As peracetic acid returns to acetic acid (ie, vinegar) and the oxygen decomposes, it is rendered nontoxic and environmentally safe.

VII.a. Items sterilized by liquid peracetic acid sterilization should be used immediately. This sterilization technique should not be used for items to be stored for later use without additional processing. (PNDS: I70, I75, I98; I122)

VII.b. Sterilization systems using liquid peracetic acid should be used, monitored, and maintained according to the manufacturer’s written instructions. (PNDS: I70, I98, I122)

Peracetic acid is an effective sterilizing agent that does not leave toxic residues on sterilized items when items are rinsed properly. Serious injuries (eg, burns) may result if the chemical is not handled, neutralized, and rinsed properly. Peracetic acid is corrosive to the skin at concentrations of 3.4% or higher and corrosive to eyes at concentrations of 0.35% or higher.26-29

VII.c. Health care personnel should clean and process endoscopes and their accessories according to AORN’s “Recommended practices for cleaning and processing endoscopes and endoscope accessories,”30 and the manufacturer’s specific instructions when using peracetic acid, as with other sterilization/disinfection processes. (PNDS: I75, I98, I122)

Peracetic acid is an efficient, effective method for cleaning and disinfecting endoscopes and accessories with lumens in order to provide high-quality patient care, ensure equipment integrity, and facilitate rapid turn around on endoscopes and other items that need to be used quickly.26,29

VII.d. When using peracetic acid to sterilize items with lumens, health care personnel should verify proper selection of adapters and connect the device to the appropriate adapters.
as recommended by the manufacturer of both the device and sterilizer. (PNDS: I70, I75, I98, I122)

Failure to do so may result in failure to sterilize the lumen of the item.

VII.e. Items sterilized in an automated system using peracetic acid should be transported to the point of use and used immediately. (PNDS: I70, I98, I122)

Items sterilized with peracetic acid are wet and the cassette or container in which they are sterilized is not sealed to prevent contamination, thereby increasing the risk of contamination if not used immediately.

VII.f. The ability to successfully process devices intended for use with a peracetic acid system should be validated by the device manufacturer and comply with the sterilizer manufacturer’s written instructions. (PNDS: I122)

Exposure and cycle times are important factors in assessing the efficiencies of a decontamination or sterilization process.

VII.f.1. Appropriate use of sterilizers should be identified to ensure proper sterilization and prolong the life of instrumentation.

VII.f.2. Documentation of items that can and cannot be processed in peracetic acid should be obtained from the device and sterilizer manufacturers.

Peracetic acid can be corrosive to some items not meant for this type of processing.

Recommendation VIII

Sterilization systems using ozone should be used for moisture and heat-sensitive items when indicated by the device manufacturer.

Ozone is a strong oxidizer, which makes ozone sterilization an effective low-temperature sterilization process. Ozone is generated within the sterilizer using only oxygen and water. On completion of the sterilization cycle, ozone is exhausted through a catalytic converter, where it is converted back into the raw materials of oxygen and water. No aeration of sterilized items is necessary because these by-products are nontoxic. 10,28,29,31

VIII.a. Manufacturers’ written instruction for operating, monitoring, and maintaining ozone sterilizers should be followed. (PNDS: I122)

Ozone has been cleared by the US Food and Drug Administration (FDA) for use in the sterilization of metal and plastic surgical instruments, including some instruments with lumens.

VIII.a.1. All devices should comply with the sterilizer manufacturer’s specifications for lumen length and diameter.

VIII.b. Items to be processed in ozone should be packaged in nonwoven pouches or reusable rigid sterilization containers validated by the container manufacturer for use in ozone sterilizers. 28,31 (PNDS: I70, I98, I122)

Cellulose-based packaging materials and products are not suitable for ozone sterilization processes.

Recommendation IX

Dry-heat sterilization should be used to sterilize anhydrous (ie, waterless) items that can withstand high temperatures and when indicated by the device manufacturer.

Sharp instruments that would be damaged by the moisture of steam may be sterilized by dry-heat.9 Dental instruments, burrs, reusable needles, glassware, and heat-stable powders and oils are examples of items that can withstand the high temperatures generated by dry-heat sterilization. Dry heat is an oxidation or slow burning process that coagulates protein in microbial cells. There is no moisture present in a dry-heat process, so microorganisms are destroyed by a very slow process of heat absorption.

IX.a. Dry-heat sterilizers should be used, monitored, and maintained according to the manufacturer’s written instructions. (PNDS: I122)

Dry heat sterilizers may vary in design and performance characteristics.

IX.b. Only packaging and container materials designed to withstand the high temperature of the dry-heat sterilization should be used for this type of processing. (PNDS: I122)

If packaging is not formulated for dry-heat sterilization, pouches may char, compromising
IX.b.1. Closed containers or cassettes may extend the time needed to achieve sterilization; therefore, the use of such containers should be based on manufacturers’ instructions and biological indicator monitoring results.

IX.b.2. Manufacturers should be consulted to confirm the compatibility of the packaging material with sterilizer temperatures before packaging materials are selected for dry-heat sterilization.

IX.b.3. When possible, small containers should be used for items to be dry-heat sterilized, and package density should be as low as possible.

Most types of tape are not designed to withstand the high dry-heat sterilization temperatures. Tape adhesive melts when subjected to dry-heat sterilization and may leave a sticky residue on sterilized packages that degrades, leaving baked-on tape residue on the items, or can result in loss of tape adhesion.

IX.c. The operator should be aware of the hazards associated with dry-heat sterilization and use the appropriate protective equipment (eg, insulated gloves, transfer handles). Burns are the most common safety hazard associated with dry-heat sterilization.

IX.c.1. On completion of the sterilization cycle, both the sterilizer chamber and the items in the chamber are very hot and should not be touched.

IX.c.2. Packages should be cooled before being handled or removed from the dry-heat sterilizer.

IX.d. Presterilized oils and powders are commercially available and should be considered before purchasing a dry-heat sterilizer.

Dry-heat sterilizers are not commonly available in operating rooms or sterile processing departments. When used, the main purpose of a dry-heat sterilizer is to sterilize talcum powder for surgical procedures.

Recommendation X

A formalized program between health care organizations and health care industry representatives should be established for the receipt and use of loaner instrumentation.

Implementation of tracking and quality controls and procedures are necessary to manage instrumentation and implants brought in from outside organizations and companies.

X.a. Interdisciplinary collaboration between the health care organizations’ sterile processing, operative services and commercial health care industry representatives should be established.

The systematic management of loaner instrumentation reduces loss and ensures proper decontamination and sterilization through increased communication and accountability.

X.a.1. The loaner instrumentation process should include, but not be limited to,
- requesting loaner instrumentation or implant; (PNDS: I85)
- receiving loaner items, including a detailed inventory list; (PNDS: I85)
- obtaining manufacturers’ written instruction for instrument care, cleaning, assembly, and sterilization; (PNDS: I122)
- cleaning, decontaminating, and sterilizing borrowed instrumentation by the receiving facility, performed in accordance with AORN’s “Recommended practices for cleaning and care of surgical instruments and powered equipment;” (PNDS: I70, I98, I138)
- transporting processed loaner instrumentation to the point of use; (PNDS: I98)
- returning items to the sterile processing department following the procedure for decontamination, processing, inventory, and return to the health care industry representative; (PNDS: I98) and
- maintaining historical records of transactions.
X.b. Personnel should coordinate requests for loaner instrumentation in sufficient time for loaner items to be processed by conventional sterilization methods. (PNDS: I138)

Advance delivery of loaner items to the receiving health care organization ensures sufficient time to permit in-house disassembly, cleaning, packaging, quality assurance testing, and sterilization of the instruments before scheduled procedures.

X.b.1. Personnel requesting loaner items should specify quantities, estimated time of use and return, and restocking requirements to circumvent the need for flash sterilization.

X.b.2. Flash sterilization should not be used as a substitute for sufficient instrument inventory resulting from late delivery of loaner instrumentation.

X.c. Loaner instrumentation sterility assurance should begin on receipt at the point where the health care organization personnel assume responsibility for the items.3

Failures in instrument cleaning have resulted in transmission of infectious agents.

X.c.1. All loaner instruments should be considered contaminated and delivered directly to the decontamination area for processing. Instruments should be thoroughly cleaned and dried in a manner consistent with AORN’s “Recommended practices for cleaning and care of surgical instruments and powered equipment”2 and the standards of the Association for the Advancement of Medical Instrumentation before sterilization.3,15 (PNDS: I70, I98, I122, I138)

X.c.2. Newly manufactured loaner items should be properly decontaminated before sterilization to remove bioburden and substances (eg, oils, greases) remaining on the item during the manufacturing process.3

X.c.3. Clean or sterile items transported to sterile processing should be removed from external shipping containers.1

External shipping containers may have potentially high microbial contamination due to environmental exposures during transport.

X.c.4. Rigid sterilization containers should be thoroughly inspected on receipt and cleaned and decontaminated according to manufacturers’ instructions. Containers should be inspected for integrity and function.

X.c.5. Loaner items, type, and quantity should be inventoried and documented.

X.c.6. Implants and instruments should be visually inspected for damage.

X.c.7. Manufacturers’ instructions on processing and sterilizing loaner items should be followed.

X.c.8. Loaner items should be decontaminated and handled in accordance with organizational policy following the procedure.

X.c.9. Implantable devices should be sterilized with a BI and a Class 5 integrating indicator and documented in accordance with FDA regulations and AORN recommended practices.

Recommendation XI

Sterilized materials should be packaged, labeled, and stored in a manner to ensure sterility, and each item should be marked with the sterilization date.3,14

Limiting exposure to moisture, dust, excessive light or handling, and temperature and humidity extremes decreases potential contamination of sterilized items.3

XI.a. The shelf life of a packaged sterile item should be considered event-related. (PNDS: I70, I98, I122)

An event must occur to compromise package content sterility. Events that may compromise the sterility of a package include, but are not limited to,

– multiple handling that leads to seal breakage or loss of package integrity,
– moisture penetration, and
– exposure to airborne contaminants.3,15,32
NOTE: Ambulatory surgery centers should refer to the Centers for Medicare and Medicaid Services State Operations Manual for Ambulatory Services that states, “Sterilized materials should be packaged, labeled, and stored in a manner to ensure sterility and that each item is marked with the expiration date.”

XI.b. Sterile packages should be stored under environmentally controlled conditions.² (PNDS: I70, I98, I122)

Controlled conditions reduce the risk of contamination.

XI.b.1. The temperature in the sterile storage areas should not exceed 24° C (75° F).

XI.b.2. The storage area should have at least four air exchanges per hour.

XI.b.3. Relative humidity should be controlled, not to exceed 70%.

XI.b.4. Traffic should be controlled to limit access to those trained in handling sterile supplies. (PNDS: I81)

XI.b.5. Supplies should be stored in a manner that allows adequate air circulation, ease of cleaning, and compliance with local fire codes. (PNDS: I98)

XI.b.6. Sterile items should be stored at least eight to 10 inches above the floor, at least 18 inches below sprinkler heads, and at least two inches from outside walls.

XI.b.7. Outside shipping containers should not be allowed in the sterile storage area because they serve as generators of, and reservoirs for, dust. (PNDS: I98)

XI.c. Storage conditions should be evaluated before policies and procedures on event-related sterility are written for perioperative practice settings. (PNDS: I70, I98, I122, I138)

The shelf life of packaged sterile items is event-related and dependent on packaging material, storage conditions, transport and handling. Adequacy and quality of storage space are factors to be considered when writing policies and procedures.³

XI.c.1. All storage items should be rotated according to the principle of “first in, first out.”

Recommendation XII

Transportation of sterile items should be controlled.

Sterility is event-related and depends on the amount of handling, conditions during transportation and storage, and the quality of the packaging material.

XII.a. Sterile items should be transported in covered or enclosed carts with solid-bottom shelves. (PNDS: I70, I81, I98, I122)

Covered or enclosed carts will protect sterile items from exposure to environmental contaminants during transportation.

XII.a.1. Carts and reusable covers should be cleaned after each use because contaminants are picked up from the environment during transport.¹

XII.b. Written policies and procedures should address prevention of physical damage and maintenance of package sterility during transport.

Procedures for transporting sterile items can help preserve the quality of sterile packages and maintain the integrity of processed items until the time of use.³,¹⁵

XII.b.1. Transportation conditions should be evaluated before policies and procedures for the transportation of sterile items are written for perioperative practice settings.³,¹⁵,³² (PNDS: I70, I81, I98, I122, I138)

Recommendation XIII

Competency

An introduction and review of policies and procedures should be included in personnel orientation to sterile processing of surgical instruments in the perioperative setting. Continuing education should be provided for employees when new equipment, instruments, and processes are introduced. (PNDS: I11)

Operator and processing errors are minimized with regularly scheduled education, training, and competency demonstration.¹⁵

XIII.a. Sterilization-specific education and competency assessment of personnel should encompass all sterilization methodologies in use in the organization, to include
– operation and maintenance of sterilization equipment;
– selection and monitoring of sterilization cycles;
– use of chemical, biological, and physical monitoring measures; and
– documentation requirements.

XIII.b. Education should address, but not be limited to,
– orientation programs to equipment and work area;
– infection control policy and procedure, including exposure plans;
– potential hazards in the environment and methods of hazard protection;
– safe ergonomic practices; and
– use and location of MSDS.

**Recommendation XIV**

**Documentation**
Sterilization records should be maintained for a time specified by the health care organization’s policies and in compliance with local, state, and federal regulations.\(^{3,15,32}\)

Accurate and complete records are required for process verification and used in sterilizer malfunction analyses. Documentation establishes accountability.

XIV.a. Every sterilization cycle and modality, including steam (eg, wrapped, unwrapped), EO, hydrogen peroxide gas plasma, liquid peracetic acid, ozone, and dry heat should be documented. Documentation should include
– the assigned lot number;
– contents of each load; and
– results of physical, chemical, and biological monitors.

**Recommendation XV**

**Policies and Procedures**
Policies and procedures for sterilization processes should be developed, reviewed periodically, and readily available in the practice setting. (PNDS: I1)

Policies and procedures establish authority, responsibility, and accountability and serve as operational guidelines. Policies and procedures also assist in the development of continuous quality improvement activities.

XV.a. Policies and procedures for routine cleaning of sterilizer chambers, carts, and exterior surfaces should be developed and implemented. (PNDS: I122)

XV.b. These recommended practices for sterilization should be used to guide the development of policies and procedures within individual perioperative practice settings.

XV.c. The sterilizer manufacturer’s written instructions for cleaning should be followed.

XV.d. An introduction and review of policies and procedures should be included in the orientation and ongoing education of health care personnel to assist in the development of knowledge, skills, and attitudes that affect patient outcomes.

XV.e. User manuals for all sterilization equipment should be readily available to the sterilizer operators. (PNDS: I122)

As new technologies are introduced for use in perioperative practice settings, it is imperative that health care personnel strictly follow manufacturers’ written instructions for the operation and maintenance of sterilization equipment and are aware of the occupational hazards that different sterilants may pose to patients, health care personnel, and the environment. Compliance with the Safe Medical Device Act of 1990, which was amended in 2000, is required and will contribute to patient safety.\(^{36}\)

XV.e.1. Equipment manuals should be retained for the life of the sterilizer.

XV.f. When selecting a new sterilization technology, perioperative nurses and nurse managers should follow AORN’s “Recommended practices for product selection in perioperative practice settings.”\(^{37}\)

Capital equipment and medical device procurement are collaborative processes requiring clinical, business, financial, and legal acumen. Goals of product standardization and value analysis processes are to select functional and reliable products that are safe,
cost-effective, and environmentally conscious and that promote quality care and avoid duplication or rapid obsolescence.

**Recommendation XVI**

**Quality**
A quality control program should be established and maintained. (PNDS: I1)

Quality control programs that enhance personnel performance and monitor sterilization efficacy are established to promote patient and employee safety.

XVI.a. The health care organization should establish quality control and improvement programs to monitor the workplace environment and practices associated with cleaning, disinfection, and sterilization of surgical instruments.

Monitoring the sterilization process allows results to be compared to a predetermined level of quality. Reviewing the findings provide a method of identifying problems and trends to change and improve practice.

XVI.b. All sterilizer failures and corrective actions should be documented and reported to the infection control professional and/or quality assurance committee, and to administration.

XVI.c. All BI test results, including results from controls, should be interpreted by qualified personnel in the time frame specified by the BI manufacturer and should be included in the sterilization records. (PNDS: I70, I98, I122, I138)

Accurate interpretation and reporting of positive results promotes safe patient care.

XVI.c.1. Positive BI test results should be reported immediately so that appropriate action can be taken.

- The sterilizer printout should first be checked to determine if the cycle parameters were met.
- If retrievable, items processed in the suspect sterilizer (ie, back to the last known negative BI test) should be recalled and reprocessed before use.
- The positive BI vial should be sent to the laboratory for subculturing for bacilli (the recall should not be delayed during this testing).
- All actions taken in response to a positive BI test should be documented.
- A positive control should be placed in each incubator each day a test vial is run and incubated.

XVI.c.2. All control vials should be from the same lot number as the BI test vial for the test to be considered valid.

XVI.d. Processed items should be labeled with lot control numbers to identify the sterilizer used, the cycle or load number, and the date of sterilization. (PNDS: I122)

Lot control numbers allow items to be identified or retrieved in the event of a sterilizer failure or malfunction.

XVI.d.1. Information should be recorded from each sterilization cycle and should include, but not be limited to,

- identification of sterilizer (eg, “sterilizer #1”);
- type of sterilizer and cycle used;
- lot control number; load contents (eg, major set, Kelly clamps);
- critical parameters for the specific sterilization methodology (eg, exposure time, temperature for steam sterilization);
- operator’s name; and
- results of sterilization process monitoring (ie, biological, chemical, physical).

XVI.e. Physical monitors should be used to verify time, temperature, and pressure recordings for steam sterilization cycles. (PNDS: I70, I98, I122)

Physical monitoring provides real-time assessment of cycle conditions while providing historical records by means of graphs, printouts, or charts. Reviewing data from physical monitoring can readily identify sterilizer malfunctions to expedite corrective actions.

XVI.e.1. Recordings of physical data should be used, when available, for all sterilization methodologies to ascertain that
sterilization systems function within manufacturers’ specifications.3,15

XVI.e.2. The printout should be reviewed at the end of each cycle and signed by the sterilizer operator verifying that all sterilization parameters were met.

XVI.f. A sterilization chemical indicator should be used inside and outside each package and load sterilized. (PNDS: I122)

The purpose of the external chemical indicator is to differentiate between processed and unprocessed items.

Internal chemical indicators do not establish whether the item is sterile, but they do demonstrate that the contents were exposed to the sterilant.

XVI.f.1. Although external chemical indicators do not verify sterility, they help detect procedural errors and equipment malfunctions; therefore, the color change should be verified before opening.

XVI.f.2. An external chemical indicator should be used on the outside of each package unless the internal chemical indicator is visible.

XVI.f.3. Chemical indicators should be reviewed for a proper endpoint response (eg. color, migration or other change).

XVI.f.4. If the interpretation of the external or internal process monitors suggests inadequate processing, the item should not be used.1,15,18 (PNDS: I70, I98, I122, I138)

XVI.f.5. The internal chemical indicator should be reviewed for a proper end point response (eg, color, migration, other change) before placing the items or tray on the sterile field.

XVI.g. Quality assurance testing of rigid containers should be performed before initial use, and periodically, according to manufacturers written instructions.1 (PNDS: I122, I138)

Rigid sterilization container systems vary widely in design, mechanics, and construction. These variables can affect the performance of characteristics and suitability of containers with sterilization methods.

XVI.g.1. The following measures should be evaluated when conducting periodic product quality assurance testing of sterilization containers for each sterilizer type used:

- sterilization efficacy, and
- drying effectiveness.

Health care organizations are responsible for obtaining and maintaining manufacturers’ documentation of methodology and performance testing of the container system.

Health care personnel are responsible for ensuring that container systems are suitable for proposed sterilization uses and are compatible with existing sterilizers.

XVI.g.2. Personnel should perform product testing to verify and collaborate with the sterilizer manufacturer for resolution of technological concerns.

XVI.h. Sterilization conditions such as exposure time should be evaluated with physical, biological, and chemical monitoring by strategically placing monitors alongside each other at locations that present the greatest challenge to air evacuation and sterilant penetration. (PNDS: I70, I122, I138)

Table 6 indicates types and applications of sterilization monitoring devices.

XVI.h.1. Monitors should be used for routine load release, routine sterilizer efficacy monitoring, sterilizer qualification testing (eg. after installation, relocation, malfunctions, major repairs, sterilization process failures) and periodic product quality assurance testing for all sterilization processes. Table 7 provides recommendations for sterilizer testing process monitoring.1,15,32,33,39

XVI.h.2. Steam sterilizers: Geobacillus stearothermophilus biological indicators should be used for routine load release, routine sterilizer efficacy monitoring, sterilizer qualification testing, and periodic product quality assurance testing.

Routine sterilizer efficacy monitoring should be done weekly, preferably daily, as follows:
each load containing an implantable device should be monitored with a BI and quarantined until the results of the BI testing are available, and

- one BI PCD should be run in three consecutive empty cycles for sterilizer qualification testing.

If a steam sterilizer is intended to be used for multiple types of cycles (eg, gravity-displacement, dynamic air-removal, flash), each sterilization mode should be tested.3

XVI.h.3. Ethylene oxide sterilizers: Bacillus atrophaeus (formerly Bacillus subtilis) spore testing should be performed with every load.

XVI.h.4. Low temperature hydrogen peroxide gas plasma sterilizers: Geobacillus stearothermophilus biological indicators are used for routine load release, routine sterilizer efficacy monitoring, sterilizer qualification testing and periodic product quality assurance testing.28

Routine sterilizer efficacy monitoring should be done weekly, preferably daily, as follows:

- each load containing an implantable device should be monitored with a BI and quarantined until the results of the BI testing are available,
- one BI PCD should be run in three consecutive empty cycles for sterilizer qualification testing, and
- the sterilizer manufacturer should be consulted for the specific monitoring product(s) to use and the appropriate placement of the product within the sterilizer.

XVI.h.5. Ozone sterilizers: Geobacillus stearothermophilus biological indicators should be performed daily for routine sterilizer efficacy monitoring.

- The test product used should be designed specifically for use with liquid peracetic acid processes.
- The sterilizer manufacturer's written instructions for use should be followed.

XVI.h.6. Liquid peracetic acid sterilizers: Geobacillus stearothermophilus biological indicators should be used for routine load release, routine sterilizer efficacy monitoring, sterilizer qualification testing and periodic product quality assurance testing.

- Routine sterilizer efficacy monitoring should be done weekly, preferably daily, as follows:
- each load containing an implantable device should be monitored with a BI and quarantined until the results of the BI testing are available;
- sterilizer qualification testing one BI PCD should be run in three consecutive empty cycles;
- mechanical convection (ie, forced air) dry-heat sterilizers should be monitored according to the manufacturer's recommendations, additional monitoring of three consecutive sterilization cycles should be performed after installation, major repair, redesign, or relocation of sterilizers; and
- this testing is performed in an otherwise empty sterilizer.

XVI.h.7. Dry-heat sterilizers: Bacillus atropheus biological indicators should be used for routine load release, routine sterilizer efficacy monitoring, sterilizer qualification testing and periodic product quality assurance testing.

- Routine sterilizer efficacy monitoring should be done weekly, preferably daily, as follows:
- each load containing an implantable device should be monitored with a BI and quarantined until the results of the BI testing are available;
- sterilizer qualification testing one BI PCD should be run in three consecutive empty cycles;
- mechanical convection (ie, forced air) dry-heat sterilizers should be monitored according to the manufacturer's recommendations, additional monitoring of three consecutive sterilization cycles should be performed after installation, major repair, redesign, or relocation of sterilizers; and
- this testing is performed in an otherwise empty sterilizer.
<table>
<thead>
<tr>
<th>Monitor</th>
<th>Frequency of Use</th>
<th>Application</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical Monitors</td>
<td>Should be used for every load of every sterilizer.</td>
<td>Part of load release criteria.</td>
</tr>
<tr>
<td>Time, temperature, and pressure recorder displays; digital printouts; and gauges</td>
<td></td>
<td></td>
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</tbody>
</table>

**Chemical Indicators (CIs)**

<table>
<thead>
<tr>
<th>Class</th>
<th>Application</th>
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</thead>
<tbody>
<tr>
<td>Class 1 (process indicators)</td>
<td>Should be used on outside of every package.</td>
</tr>
<tr>
<td>External CIs</td>
<td>Test of sterilizer efficacy of air removal and steam penetration; part of release criteria for using sterilizer for the day.</td>
</tr>
<tr>
<td>Bowie-Dick-type indicators</td>
<td>For routine sterilizer testing (dynamic air-removal sterilizers only): Should be run within a test pack each day in an empty sterilizer before the first processed load.</td>
</tr>
<tr>
<td>Class 2 (Bowie-Dick)</td>
<td>For sterilizer qualification testing (dynamic-air-removal sterilizers only): Should be run within a test pack after sterilizer installation, relocation, malfunction; after major repairs; and after sterilization process failures. Test should be run three times consecutively in an empty chamber after biological indicator (BI) tests.</td>
</tr>
<tr>
<td></td>
<td>Part of release criteria for placing sterilizer into service after qualification testing.</td>
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<tr>
<td>Internal CIs</td>
<td>Should be used inside each package.</td>
</tr>
<tr>
<td></td>
<td>Part of package release criteria at use site.</td>
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<tr>
<td>Class 3 (single-variable indicator)</td>
<td>Should be used in periodic product quality assurance testing.</td>
</tr>
<tr>
<td>Class 4 (multi-variable indicator)</td>
<td>Part of release criteria for changes made to routinely sterilized items, load configuration, and/or packaging. Release criteria should include BI results.</td>
</tr>
<tr>
<td>Class 5 (integrating indicator)</td>
<td>May be used to meet internal CI recommendation.</td>
</tr>
<tr>
<td>Enzyme-only indicator</td>
<td>Part of package release criteria at use site; NOT to be used for release of loads.</td>
</tr>
<tr>
<td></td>
<td>Part of load release criteria for nonimplant loads.</td>
</tr>
<tr>
<td></td>
<td>Part of release criteria for loads containing implants. Except in emergencies, implants should be quarantined until BI results are known.</td>
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<tr>
<td></td>
<td>Part of sterilizer/load release and recall criteria.</td>
</tr>
<tr>
<td>Biological Indicators</td>
<td>May be used to meet internal CI recommendation.</td>
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<tr>
<td></td>
<td>Within a process challenge device (PCD), may be used to monitor nonimplant sterilizer loads.</td>
</tr>
<tr>
<td></td>
<td>Within a PCD, should be used to monitor each sterilizer load containing implants. The PCD should also contain a BI.</td>
</tr>
<tr>
<td></td>
<td>Part of package release criteria at use site; Part of load release criteria for nonimplant loads.</td>
</tr>
<tr>
<td></td>
<td>Part of release criteria for loads containing implants. Except in emergencies, implants should be quarantined until BI results are known.</td>
</tr>
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<td></td>
<td>Part of sterilizer/load release and recall criteria.</td>
</tr>
<tr>
<td></td>
<td>Part of release criteria for placing sterilizer into service after qualification testing.</td>
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<tr>
<td></td>
<td>Part of release criteria for changes made to routinely sterilized items, load configuration, and/or packaging.</td>
</tr>
</tbody>
</table>

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Table 7

<table>
<thead>
<tr>
<th>Sterilization Process Monitoring Recommendations1</th>
<th>Routine load release</th>
<th>Routine sterilizer efficacy monitoring</th>
<th>Sterilizer qualification testing (after installation, relocation, malfunctions, major repairs, sterilization process failures)</th>
<th>Periodic product quality assurance testing</th>
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</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>External and internal chemical indicator monitoring of packages.</td>
<td>External and internal chemical indicator monitoring of packages.</td>
</tr>
<tr>
<td></td>
<td>Optional monitoring of the load with a process challenge device (PCD) containing one of the following:</td>
<td>Physical monitoring of cycle.</td>
<td>Monitoring of every load with a PCD containing a BI and a Class 5 integrating indicator or a PCD containing a BI and an enzyme-only indicator.</td>
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<tr>
<td></td>
<td>• a biological indicator (BI),</td>
<td>Physical monitoring of cycle.</td>
<td>Weekly, preferably daily (or each day the sterilizer is used), monitoring of a full load with a PCD containing a BI (The PCD may also contain a chemical indicator [CI]). In flash sterilization cycles, monitoring is done in an empty chamber. For dynamic air-removal sterilizers, daily Bowie-Dick testing in an empty chamber.</td>
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<tr>
<td></td>
<td>• a BI and a Class 5 integrating indicator,</td>
<td>Monitoring of every load with a PCD containing a BI and an enzyme-only indicator.</td>
<td>For sterilizers larger than 2 cubic feet and for flash sterilization cycles, monitoring of three consecutive cycles in an empty chamber with a PCD containing a BI. (The PCD may also contain a CI.) For table-top sterilizers, monitoring of three consecutive cycles in a fully loaded chamber with a PCD containing a BI. (The PCD may also contain a CI.) For dynamic air-removal sterilizers, monitoring of three consecutive cycles in an empty chamber with a Bowie-Dick test pack.</td>
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<tr>
<td></td>
<td>• a BI and an enzyme-only indicator</td>
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<tr>
<td></td>
<td>• a Class 5 integrating indicator,</td>
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<tr>
<td></td>
<td>• an enzyme-only indicator.</td>
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<tr>
<td>Implants</td>
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Reference

XVI.h.8. **Dynamic air-removal steam sterilizers:** A Bowie-Dick air removal test should routinely be performed daily in an empty chamber.

- The air-removal test is designed to detect residual air in the sterilizer chamber.
- The test should be run in accordance with the test manufacturer’s instructions before the routine biological indicator testing.

Whenever a dynamic air-removal sterilizer is installed, relocated, malfunctions, undergoes a major repair, or has a sterilization process failure, three consecutive cycles in an empty chamber should be tested with a BI PCD followed by three consecutive cycles in an empty chamber with a Bowie-Dick test.

XVI.i. Preventive maintenance on sterilizers should be performed by qualified personnel on a scheduled basis. (PNDS 1122)

- Periodic inspections, maintenance, and replacement of components subject to wear (eg, recording devices, steam traps, filters, valves, drain pipes, gaskets) help maintain proper functioning of sterilizers.

XVI.i.1. Inspection and cleaning should be performed as outlined in the manufacturer’s written instructions.3,10,15

Proper inspection and cleaning minimizes sterilizer downtime and helps prevent sterilizer malfunctions.

XVI.i.2. Preventive maintenance and repairs should be performed by qualified personnel as specified in the manufacturer’s written instructions.

XVI.i.3. Maintenance records should be kept for each sterilizer. Accurate and complete records are required for sterilization process verification. Information should include, but not be limited to,

- date of service;
- sterilizer model and serial number;
- sterilizer location;
- description of malfunctions;
- name of person and company performing maintenance;
- description of service and parts replaced;
- results of biological indicator testing, if performed;
- results of Bowie-Dick testing, if performed;
- where appropriate, the name of the person requesting the service; and
- the signature and title of the person acknowledging the completed work.

**Glossary**

Aeration: Method by which absorbed ethylene oxide (EO) is removed from EO-sterilized items by circulating warm air in an enclosed cabinet specifically designed for this purpose.

Anhydrous: Items that are free of water.

Bioburden: The degree of microbial load; the number of viable organisms contaminating an object.

Biofilm: A thin coating containing biologically active organisms that have the ability to grow in water, water solutions, or in vivo and that coat the surface of structures (eg, teeth, inner surfaces of catheters, tubes, implanted or indwelling devices, instruments, other medical devices). Biofilms contain viable and nonviable microorganisms that adhere to the surface and are trapped within a matrix of organic matter (eg, proteins, glycoproteins, carbohydrates), which prevents antimicrobial agents from reaching the cells.

Biological indicator: A sterilization process-monitoring device commercially prepared with a known population of highly resistant spores that tests the effectiveness of the method of sterilization being used. The indicator is used to demonstrate that conditions necessary to achieve sterilization were met during the sterilizer cycle being monitored.

Chemical indicator: A sterilization-monitoring device used to monitor the attainment of one or more critical parameters required for sterilization. A characteristic color or other visual change indicates a defined level of exposure based on the classification of the chemical indicator used.

Class 5 chemical integrating indicator: A chemical indicator designed to react to all critical parameters over a specified range of sterilization cycles and whose performance has been correlated to the performance of the stated test organism under the labeled conditions of use.
Decontamination: Any physical or chemical process that removes or reduces the number of microorganisms or infectious agents and renders reusable medical products safe for handling or disposal; The process by which contaminants are removed, either by hand cleaning or mechanical means, using specific solutions capable of rendering blood and debris harmless and removing them from the surface of an object or instrument.

Dynamic air-removal: Mechanically assisted air removal from the sterilization chamber. Includes prevacuum and steam-flush pressure-pulse steam sterilizers.

Dynamic air-removal test (ie, Bowie-Dick test): A diagnostic test to determine the adequacy of air removal from the chamber of a dynamic-air-removal steam sterilizer. The air-removal test is not a test for sterilization.

Downtime: A period of time when an item or device is not operational.

Emergency spill plan: A plan of action for any unanticipated release of ethylene oxide or other hazardous chemicals into the workplace.

Flash sterilization: A process designed for the steam sterilization of patient care items for immediate use.

Gravity-displacement sterilizer: Type of sterilization cycle in which incoming air displaces residual air through a port or drain near the bottom of the sterilizer chamber.

Physical monitor: Automated devices (eg, graphs, gauges, printouts) that monitor sterilization parameters for the sterilization method in use.

Process challenge device: A predetermined item/package (ie, test pack) designed to simulate the product to be sterilized and that is used to assess the efficacy of the sterilization process.

Prevacuum steam sterilizer: A steam sterilization cycle in which air is removed from the chamber and load via a series of pressure and vacuum excursions.

Shelf life: The length of time an item is considered sterile and safe to use.

Short-term exposure limits: Durations of exposure to a potentially toxic or harmful substance lasting for less than 15 minutes that cannot be repeated more than four times per day.

Steam-flush pressure-pulse (SPPP): A steam sterilization cycle in which air is removed from the chamber and load via a series of steam flushes and pressure pulses.

Sterilization process monitoring device: A device used to monitor sterilization processes. Sterilization monitoring devices can be biological, chemical, or physical.

References


RESOURCES