Infection Prevention and Control.

Module 6. Processing Surgical Instruments and Medical Devices

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The authors have made every effort to check the accuracy of all information, the dosages of any drugs, and instructions for use of any devices or equipment. Because the science of infection prevention and control is rapidly advancing and the knowledge base continues to expand, readers are advised to check current product information provided by the manufacturer of:

- Each drug, to verify the recommended dose, method of administration, and precautions for use
- Each device, instrument, or piece of equipment to verify recommendations for use and/or operating instructions

In addition, all forms, instructions, checklists, guidelines, and examples are intended as resources to be used and adapted to meet national and local health care settings' needs and requirements. Finally, neither the authors, editors, nor the Jhpiego Corporation assume liability for any injury and/or damage to persons or property arising from this publication.

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Chapter 1. Overview of Processing Surgical Instruments and Medical Devices

Key Topics

- Level of disinfection or sterilization required
- General guidelines for handling and reprocessing items
- Overview of processing instruments and medical devices
- Methods used to process used instruments and medical devices
- Guidelines for reprocessing single-use medical devices

Key Terms

- **Bioburden** is the population of viable microorganisms on devices, instruments, equipment, or products. When measured, bioburden is expressed as the total count of bacterial and fungal colony-forming units per single item. (AAMI ST79 2010).

- **Cleaning** is the removal of visible dirt (e.g., organic and inorganic material) from objects and surfaces, normally accomplished manually or mechanically, using water with detergents or enzymatic cleaners. Cleaning is required before high-level disinfection or sterilization because tissue, blood, body fluids, dirt, and debris reduce the effectiveness of these processes.

- **Decontamination** is the process of removing pathogenic microorganisms from objects so they are safe to handle, use, or discard. It can be done using physical or chemical means.

- **High-level disinfection** is a process that kills all microorganisms but not necessarily all bacterial spores. HLD is achieved by soaking items in liquid chemicals classified as high-level disinfectants or by boiling or steaming for the appropriate time (20 minutes).

- **Instrument processing areas** are places anywhere in the health care facility where soiled instruments, equipment, and other items are cleaned and processed by means of either high-level disinfection or sterilization.

- **Log10 reduction and kill rate** is a quantitative (calculable) measurement describing the percentage of contaminants killed during instrument processing procedures. 1 log10 reduction means a 90% reduction in microbes on a given surface. For example, if there are 1 million microbes on a surface, 1 log10 reduction or kill rate will remove 90% of 1 million microbes, 2 log10 kill rate will remove 99% of microbes, and 5 log10 reduction or kill rate will remove 99.999%. Therefore, a 6 log10 reduction or kill rate will remove 99.9999% of microbes, which means that only 1 microbe will survive at the end of the procedure that has a kill rate of 6 log10 reduction.

- **Personal protective equipment (PPE)** items are the protective barriers and respirators used alone or in combination by a health care worker (HCW) to protect mucous membranes, airways, skin, and clothing from contact with harmful or infectious agents. PPE may also be used on an infectious patient to prevent the spread of infectious agents (e.g., surgical mask worn by a patient to control the spread of influenza or tuberculosis).

- **Point of use** refers to a place and time where equipment, instruments, and supplies are used on patients (e.g., the patients’ bedsides, procedure rooms, delivery rooms, operating theaters).

- **Sterilization** is the process used to render an item free from viable microorganisms, including spores.
Overview of Processing Instruments and Devices

**Background**

If surgical instruments or medical devices are not adequately cleaned, and then either high-level disinfected or sterilized, health care-associated infections can result, including surgical site infections, infections with bloodborne pathogens (e.g., hepatitis B and C, HIV), and ventilator- or catheter-associated infections. Therefore, it is critical that the HCWs who are responsible for processing instruments follow all steps carefully to provide adequately cleaned and high-level disinfected or sterilized instruments for patient care.

**Level of Disinfection or Sterilization Required**

A rational approach for processing medical devices and surgical instruments for patient care was first described by Earle H. Spaulding more than 45 years ago (Spaulding 1968) and it is still relevant in making decisions about the final approach to instrument processing. Spaulding classified instruments and patient care devices into three categories, based upon how the device is used. Items are classified as:

- Non-critical—come in contact with intact skin but not mucous membranes
- Semi-critical—come in contact with mucous membranes or non-intact skin
- Critical—come in contact with sterile areas of the body including the vascular system

Table 1-1 provides examples of non-critical, semi-critical, and critical items and the level of disinfection or sterilization required to make the instruments safe for use.

**Table 1-1. Spaulding’s Classification and Examples of Instruments and Processing Levels**

<table>
<thead>
<tr>
<th>Patient Contact</th>
<th>Spaulding’s Classification</th>
<th>Examples of Instruments and Devices</th>
<th>Level of Processing Required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intact skin</td>
<td>Non-critical</td>
<td>Blood pressure cuffs, stethoscopes</td>
<td>Cleaning and/or low-/intermediate-level disinfection</td>
</tr>
<tr>
<td>Mucous membranes or non-intact skin</td>
<td>Semi-critical</td>
<td>Endoscopes, specula</td>
<td>High-level disinfection</td>
</tr>
<tr>
<td>Sterile areas of the body, including blood contact</td>
<td>Critical</td>
<td>Surgical instruments</td>
<td>Sterilization*</td>
</tr>
</tbody>
</table>

* In limited-resource settings when sterilization is not possible and a critical procedure must be performed, high-level disinfection is acceptable.

Facilities should assess the intended use of the medical device, the manufacturer’s instructions for use on reprocessing, the heat and chemical tolerance of the device, and the available space and layout where reprocessing will be done to determine the appropriate method of high-level disinfection or sterilization.

**General Guidelines for Handling and Reprocessing Items**

Instruments or other reusable items require appropriate handling and processing to:

- Minimize the risk of injury to staff
● Minimize exposure to blood or body fluids for the housekeeping, transportation, and reprocessing staff

● Ensure that they are not vectors of health care-associated infections

Staff must wear appropriate PPE when handling contaminated instruments to protect themselves from exposure to blood or body fluids. This PPE includes:

● Gloves: utility gloves, which should have high cuffs when there is a chance hands will be submerged in cleaning solutions

● Gown: fluid-resistant gown

● Face protection: mask and integrated visor, full visor, or mask with goggles

● Footwear: with closed toes, and non-skid soles such as rubber boots or leather shoes. Shoe covers can be worn to protect shoes.

Contaminated instruments should be handled as little as possible to prevent accidental exposure to bloodborne pathogens.

Overview of Processing Instruments and Medical Devices

● During surgical or invasive procedures:
  ● Wipe items as needed with sterile surgical sponges moistened with sterile water to remove gross soil and prevent blood and body fluids from drying on surfaces.
  ● Irrigate cannulated instruments or items with lumens frequently with sterile water to prevent blood and body fluids from drying within the lumens.

● At the conclusion of the surgery or procedure (point-of-use cleaning):
  ● Separate items into reusable, single-use/disposable, and waste categories. See Module 6, Chapter 5, Reprocessing Single-Use Devices, for guidance on decisions to reuse items labeled as single-use.
  ● Dispose of sharps in a sharps container (see Module 5, Chapter 5, Waste Management in Health Care Facilities).
  ● Clean reusable instruments at the point of use to prevent blood and body fluids from drying on instruments:
    > Point-of-use cleaning is required (immediately after the end of the procedure) to remove blood and body fluids. If bioburden is allowed to dry on instruments, it becomes extremely difficult to remove. Bioburden that remains on surfaces prevents the penetration of steam or disinfection chemicals, which leads to incomplete disinfection or sterilization.
During transportation of items to the instrument processing area:
- Wear PPE, including gloves and gown, while transporting contaminated devices in order to prevent accidental exposure to blood and body fluids.
- Transport contaminated devices to the instrument processing area as soon as possible after the conclusion of the procedure.
- Transport contaminated items fully enclosed in a puncture-resistant container that prevents spills of liquid. The container must be labeled as biohazard using a biohazard symbol. (See Module 5, Chapter 5, Waste Management in Health Care Facilities, for examples of appropriate labeling.)
- Clean and disinfect transport containers after each use. (See Module 5, Chapter 2, Environmental Cleaning, for appropriate cleaning of contaminated surfaces.)
- Use predetermined, designated routes to transport contaminated items to the reprocessing area. Avoid high-traffic areas to prevent the risk of cross-contamination.
- Do not transport sterile and soiled devices together on the same trolley/cart.

Within the instrument processing area:
- Ideally, the reprocessing area should be divided into areas that are physically separated into decontamination, preparation and packaging, and sterilization areas. If physical separation is not feasible, these functions should be at least 4 feet from one another. If at least 4 feet is not possible, a barrier could be installed to prevent splashing from the decontamination area to the preparation and packaging or sterilization areas. (See Module 5, Chapter 1, Facility Design, Traffic Flow, and Work Practices in Health Care Facilities, for more information on appropriate layout of a reprocessing area.)
- Develop clear, unidirectional workflow (one direction only) from dirty to clean and ensure that no crossover from dirty tasks to clean/sterile tasks occurs.

Additional considerations
- Manufacturer’s instructions for use (IFUs):
  - Follow IFUs for cleaning agents, enzymatic products, devices, and instrument processing equipment.
- Policies:
  - Develop written policies outlining the steps for cleaning, transporting, disinfecting, sterilizing, and storing surgical instruments and devices.
- Location:
  - Perform all reprocessing, ideally, in a central location, such as a central sterilization unit. (See Module 5, Chapter 1, Facility Design, Traffic Flow, and Work Practices in Health Care Facilities.)
- Staff training and competency: This includes all staff performing reprocessing anywhere in the facility, including wards, labor and delivery, intensive care units, and any other places where instruments are reprocessed.
  - Ensure that HCWs are appropriately qualified for the work they will be doing.
  - Train HCWs upon hire on the tasks they will be performing and document competency.
Major Steps in Reprocessing Instruments and Medical Devices

Figure 1-1. Workflow for Processing Instruments and Medical Devices

Point-of-Use Cleaning
Point-of-use cleaning at the end of the procedure is a critical step in device reprocessing, and one that is often overlooked. It is important because:

- Contact with blood for long periods (> 30 minutes) is corrosive to instruments; it can cause pitting and staining.
- Once blood dries on instruments, it is difficult to remove, especially if blood has entered into hinges, sockets, or lumens.
- Blood and body fluid (bioburden) compromises the effectiveness of the disinfection or sterilization process if it is not removed prior to high-level disinfection or sterilization by thorough cleaning.
- Removing bioburden makes instruments and devices safer for handling in the reprocessing area.

Adapted from: Tietjen et al. 2003.
Therefore, properly clean instruments as soon as possible after they have been used to prevent bioburden from drying on the instrument or device.

**Cleaning Instruments in the Instrument Reprocessing Area**

The most important step in reprocessing reusable instruments is thorough cleaning and rinsing. Cleaning removes a number of microorganisms and other organic and inorganic materials. Studies have shown that a thorough manual cleaning results in a 4 log₁₀ (99.99%) reduction in microbial load on the instruments (Rutala and Weber 2004). Cleaning instruments using a mechanical washer-disinfector results in 5 log₁₀ (99.999%) reduction (Ransjo et al. 2001). However, cleaning does not remove or kill all microorganisms so subsequent disinfection or sterilization is required to render them safer for further use. Table 1-2 provides a list of microbes and the level of difficulty in killing them, with prions being the most resistant, and the level of processing needed to make surgical instruments and medical devices safe for use.

Rinsing removes the loose debris and residual detergent that can interfere with the subsequent disinfection or sterilization processes. Chapter 2, Cleaning and Preparing Surgical Instruments and Medical Devices for Disinfection or Sterilization, in this module describes the process of cleaning surgical instruments in detail.

**Table 1-2. Resistance of Microorganisms to Disinfection and Sterilization and the Level of Processing Needed to Kill the Microorganism**

<table>
<thead>
<tr>
<th>Resistance</th>
<th>Microorganism</th>
<th>Processing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Resistant</td>
<td>Prions</td>
<td>Prion reprocessing</td>
</tr>
<tr>
<td></td>
<td>Spores (<em>C. difficile</em>)</td>
<td>Sterilization</td>
</tr>
<tr>
<td></td>
<td>Coccidia (<em>Cryptosporidium</em>)</td>
<td>Sterilization</td>
</tr>
<tr>
<td></td>
<td>Mycobacteria (<em>M. tuberculosis</em>)</td>
<td>High-level disinfection</td>
</tr>
<tr>
<td></td>
<td>Nonlipid small viruses (poliovirus and coxsackie virus)</td>
<td>Intermediate-level disinfection</td>
</tr>
<tr>
<td></td>
<td>Fungi (<em>Aspergillus, Candida</em>)</td>
<td>Low-level disinfection</td>
</tr>
<tr>
<td></td>
<td>Large non-enveloped viruses (Adenovirus)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Vegetative bacteria (<em>S. aureus, P. aeruginosa</em>)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Lipid, or medium size viruses (<em>HIV, HBV, HSV</em>)</td>
<td></td>
</tr>
</tbody>
</table>

*Adapted from: Favero and Bond 2001.*

**High-Level Disinfection**

High-level disinfection is indicated for processing instruments and medical devices that come in contact with non-intact skin and mucous membranes, but, ideally, not those that contact sterile areas of the body, including the vascular system (see Table 1-1). High-level disinfection is widely used to process reusable endoscopes because most endoscopes are made of materials that cannot withstand high-temperature reprocessing.

For some health care facilities in many limited-resource settings, high-level disinfection may be the only option for processing instruments and medical devices in. Appendix 1-A outlines methods of high-level disinfection and sterilization commonly available in limited-resource settings for various instruments.
and medical devices. Health care facility teams should do a thorough review of available products, resources, and existing space and layout of the instrument reprocessing areas before selecting a method of high-level disinfection.

Chapter 3, High-Level Disinfection of Surgical Instruments and Medical Devices, in this module provides more details.

**Sterilization**

Sterilization is indicated for processing instruments and equipment that come in contact with sterile areas of the body, including the vascular system. Sterilization results in a $6 \log_{10}$ reduction in microbes on the surface being sterilized. A $6 \log_{10}$ reduction or kill rate will remove 99.9999% of microbes.

Methods of sterilization include:

- Physical methods: moist heat (e.g., steam sterilizer) and dry heat
- Chemical methods: liquids (e.g., ortho-phthalaldehyde [0.55%], glutaraldehyde [2.5%]), and gases (e.g., ethylene oxide)
- Physical chemical methods: hydrogen peroxide gas plasma (this method is usually not available at health care facilities in limited resource settings)

Sterilization is only as effective as the cleaning process prior to sterilization. Other factors impacting the effectiveness of sterilization include the types of microorganisms on the device, the number and location of microorganisms, and the type and amount of organic material surrounding the microorganism that may protect it from the steam or chemical sterility (biofilm). Additionally, the effectiveness of sterilization depends upon key parameters of the process, which, depending on the process used, include temperature, humidity, pH, water quality, contact time, pressure, and chemical concentration.

Steam sterilization and chemical methods are the most commonly employed methods for sterilization at health care facilities in low- and middle-income settings. Sterilization is described in Chapter 4, Sterilization of Reusable Surgical Instruments and Medical Devices, in this module.

A table to assist with choosing appropriate methods for processing instruments and other medical equipment used to provide health care services is presented in Appendix 1-A.

**Summary**

Applying Spaulding’s classification of non-critical, semi-critical, or critical items determines the method that should be used to process instruments. Health care facilities should review and choose the most appropriate method based on the intended use of the instruments (i.e., for non-critical, semi-critical, and critical procedures). No matter which methods are used, carefully follow each step of the process. The methods and steps for cleaning, high-level disinfection, and sterilization are described in detail in the other chapters in this module.
Appendix 1-A. Guidelines for Processing Surgical Instruments and Medical Devices in Limited-Resource Settings

The first column of this table lists categories of items according to the characteristics of the material from which they are manufactured. The other columns describe various methods of disinfection or sterilization. All items must first be cleaned to remove dirt and bioburden prior to carrying out disinfection or sterilization. HCWs can use this information to determine which method of disinfection or sterilization is appropriate.

Table A-1. Guidelines for Processing Surgical Instruments and Medical Devices in Limited-Resource Settings

<table>
<thead>
<tr>
<th>Object</th>
<th>STERILIZATION</th>
<th>DISINFECTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Critical items that will enter tissue or the vascular systems, or blood will flow through them</td>
<td>Procedure (exposure time ≥ 1 min)</td>
<td>Procedure (exposure time 12–30 min at ≥ 20°C [68°F])</td>
</tr>
<tr>
<td>Smooth, hard surfaces (heat-resistant)</td>
<td>Heat sterilization, including steam and hot air (MR [manufacturer’s recommendations])</td>
<td>Ethyl or isopropyl alcohol (70–90%)</td>
</tr>
<tr>
<td></td>
<td>• Heat sterilization, including steam and hot air (MR [manufacturer’s recommendations])</td>
<td>• Ethyl or isopropyl alcohol (70–90%)</td>
</tr>
<tr>
<td></td>
<td>• Ortho-phthalaldehyde (0.55%)</td>
<td>• Sodium hypochlorite (0.05%, &gt; 100 ppm available chlorine)</td>
</tr>
<tr>
<td></td>
<td>• Hydrogen peroxide 7.5%</td>
<td>• Phenolic germicidal detergent</td>
</tr>
<tr>
<td></td>
<td>• Hydrogen peroxide in combination with other chemical</td>
<td>• Iodophor germicidal detergent</td>
</tr>
<tr>
<td></td>
<td>• Boiling for 20 min</td>
<td>• Quaternary ammonium germicidal</td>
</tr>
<tr>
<td></td>
<td>• Single-use hypochlorite (&gt; 650–675 parts per million [ppm] active free chlorine generated on site)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Glutaraldehyde preparations</td>
<td></td>
</tr>
<tr>
<td>High-Level Disinfection (Semi-critical items [except dental devices] that will come in contact with mucous membrane or non-intact skin)</td>
<td>Procedure (exposure time ≥ 1 min)</td>
<td>Procedure (exposure time ≥ 1 min)</td>
</tr>
<tr>
<td>Intermediate-Level Disinfection (Some semi-critical items and non-critical items)</td>
<td>Ethyl or isopropyl alcohol (70–90%)</td>
<td>Ethyl or isopropyl alcohol (70–90%)</td>
</tr>
<tr>
<td>Low-Level Disinfection (Non-critical items that will come in contact with intact skin)</td>
<td>Sodium hypochlorite (0.05%, &gt; 100 ppm available chlorine)</td>
<td>Sodium hypochlorite (0.05%, &gt; 100 ppm available chlorine)</td>
</tr>
<tr>
<td></td>
<td>Phenolic germicidal detergent</td>
<td>Phenolic germicidal detergent</td>
</tr>
<tr>
<td></td>
<td>Iodophor germicidal detergent</td>
<td>Iodophor germicidal detergent</td>
</tr>
<tr>
<td></td>
<td>Quaternary ammonium germicidal</td>
<td>Quaternary ammonium germicidal</td>
</tr>
<tr>
<td>Object</td>
<td>STERILIZATION</td>
<td>DISINFECTION</td>
</tr>
<tr>
<td>--------</td>
<td>---------------</td>
<td>--------------</td>
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<tr>
<td>Critical items that will enter tissue or the vascular systems, or blood will flow through them</td>
<td>High-Level Disinfection (Semi-critical items [except dental devices] that will come in contact with mucous membrane or non-intact skin)</td>
<td>Intermediate-Level Disinfection (Some semi-critical items and non-critical items)</td>
</tr>
<tr>
<td>Procedure (exposure time)</td>
<td>Procedure (exposure time 12–30 min at ≥ 20°C [68°F])</td>
<td>Procedure (exposure time ≥ 1 min)</td>
</tr>
<tr>
<td>Smooth, hard surfaces (heat-sensitive)</td>
<td>• Glutaraldehyde preparations (10 hours at 20–25°C [68–77°F])</td>
<td>• Ethyl or isopropyl alcohol (70–90%)</td>
</tr>
<tr>
<td></td>
<td>• Hydrogen peroxide 7.5% (6 hours)</td>
<td>• Sodium hypochlorite (0.05%, &gt; 100 ppm available chlorine)</td>
</tr>
<tr>
<td></td>
<td>• Peracetic acid (12 min at 50–60°C [122–140°F])</td>
<td>• Phenolic germicidal detergent</td>
</tr>
<tr>
<td></td>
<td>• Hydrogen peroxide in combination with other chemical (3–8 hours)</td>
<td>• Iodophor germicidal detergent</td>
</tr>
<tr>
<td></td>
<td>• Ethyl or isopropyl alcohol (70–90%)</td>
<td>• Quaternary ammonium germicidal</td>
</tr>
<tr>
<td>Rubber tubing and catheters</td>
<td>Heat sterilization including steam and hot air (MR)</td>
<td>Ortho-phthalaldehyde (0.55%)</td>
</tr>
<tr>
<td></td>
<td>Glutaraldehyde preparations (10 hours at 20–25°C [68–77°F])</td>
<td>Hydrogen peroxide 7.5%</td>
</tr>
<tr>
<td></td>
<td>Hydrogen peroxide 7.5% (6 hours)</td>
<td>Hydrogen peroxide in combination with other chemical</td>
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<tr>
<td></td>
<td>Peracetic acid (12 min at 50–60°C [122–140°F])</td>
<td>Boiling for 20 min</td>
</tr>
<tr>
<td></td>
<td>Hydrogen peroxide in combination with other chemical (3–8 hours)</td>
<td>Single-use hypochlorite (&gt; 650–675 ppm active free chlorine generated on site)</td>
</tr>
<tr>
<td></td>
<td>Glutaraldehyde preparations</td>
<td>Glutaraldehyde preparations</td>
</tr>
</tbody>
</table>
### Overview of Processing Instruments and Devices

<table>
<thead>
<tr>
<th>Object</th>
<th>STERILIZATION</th>
<th>DISINFECTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Critical items that will enter tissue or the vascular systems, or blood will flow through them</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Procedure (exposure time)</strong></td>
<td><strong>High-Level Disinfection</strong>&lt;sup&gt;*&lt;/sup&gt; (Semi-critical items [except dental devices] that will come in contact with mucous membrane or non-intact skin)</td>
<td><strong>Intermediate-Level Disinfection</strong>&lt;sup&gt;8&lt;/sup&gt; (Some semi-critical items and non-critical items)</td>
</tr>
<tr>
<td><strong>Procedure (exposure time ≥ 1 min)</strong></td>
<td><strong>Low-Level Disinfection</strong>&lt;sup&gt;8&lt;/sup&gt; (Non-critical items that will come in contact with intact skin)</td>
<td></td>
</tr>
<tr>
<td>------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------------</td>
</tr>
<tr>
<td><strong>Polyethylene tubing and catheters&lt;sup&gt;2,3,6&lt;/sup&gt;</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Heat sterilization including steam and hot air (MR)</td>
<td>• Ortho-phthalaldehyde (0.55%)</td>
<td></td>
</tr>
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<td>• Glutaraldehyde preparations (10 hours at 20–25°C [68–77°F])</td>
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</tr>
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<td>• Hydrogen peroxide 7.5% (6 hours)</td>
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<td></td>
</tr>
<tr>
<td>• Peracetic acid (12 min at 50–60°C [122–140°F])</td>
<td>• Boiling for 20 min&lt;sup&gt;5&lt;/sup&gt;</td>
<td></td>
</tr>
<tr>
<td>• Hydrogen peroxide in combination with other chemical (3–8 hours)</td>
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<td></td>
</tr>
<tr>
<td>• Glutaraldehyde preparations</td>
<td>• Glutaraldehyde preparations</td>
<td></td>
</tr>
<tr>
<td><strong>Instruments with lenses&lt;sup&gt;3&lt;/sup&gt;</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Heat sterilization including steam and hot air (MR)</td>
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<tr>
<td>• Glutaraldehyde preparations (10 hours at 20–25°C [68–77°F])</td>
<td>• Hydrogen peroxide 7.5%</td>
<td></td>
</tr>
<tr>
<td>• Hydrogen peroxide 7.5% (6 hours)</td>
<td>• Hydrogen peroxide in combination with other chemical</td>
<td></td>
</tr>
<tr>
<td>• Peracetic acid (12 min at 50–60°C [122–140°F])</td>
<td>• Single-use hypochlorite (&gt; 650–675 ppm active free chlorine generated on site)</td>
<td></td>
</tr>
<tr>
<td>• Hydrogen peroxide in combination with other chemical (3–8 hours)</td>
<td>• Glutaraldehyde preparations</td>
<td></td>
</tr>
</tbody>
</table>
### Overview of Processing Instruments and Devices

<table>
<thead>
<tr>
<th>Object</th>
<th><strong>STERILIZATION</strong></th>
<th><strong>DISINFECTION</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Critical items that will enter tissue or the vascular systems, or blood will flow through them</td>
<td><strong>High-Level Disinfection</strong>&lt;br&gt;(Semi-critical items [except dental devices] that will come in contact with mucous membrane or non-intact skin)</td>
<td><strong>Intermediate-Level Disinfection</strong>&lt;br&gt;(Some semi-critical items and non-critical items)</td>
</tr>
<tr>
<td>Procedure (exposure time)</td>
<td>Procedure (exposure time 12–30 min at ≥ 20°C [68°F])&lt;sup&gt;1,2&lt;/sup&gt;</td>
<td>Procedure (exposure time ≥ 1 min)&lt;sup&gt;8&lt;/sup&gt;</td>
</tr>
</tbody>
</table>
| Thermometers (oral and rectal)<sup>7</sup> and hinged instruments<sup>3</sup> | • Heat sterilization including steam and hot air (MR)  
• Glutaraldehyde preparations (10 hours at 20–25°C [68–77°F])  
• Hydrogen peroxide 7.5% (6 hours)  
• Peracetic acid (12 min at 50–60°C [122–140°F])  
• Hydrogen peroxide in combination with other chemical (3–8 hours) | • Ortho-phthalaldehyde (0.55%)  
• Hydrogen peroxide 7.5%  
• Hydrogen peroxide in combination with other chemical  
• Boiling for 20 min<sup>5</sup>  
• Single-use hypochlorite (> 650–675 ppm active free chlorine generated on site)  
• Glutaraldehyde preparations | • Ethyl or isopropyl alcohol (70–90%) |

---

**Adapted from:** Rutala et al. 2008.

**Notes:**

1. The longer the exposure to a disinfectant, the more likely it is that all microorganisms will be eliminated. Ten-minute exposure is not adequate to disinfect many objects, especially those that are difficult to clean because they have narrow channels or other areas that can harbor organic material and bacteria. Twenty-minute exposure at 20°C (68°F) is the minimum time needed to reliably kill *M. tuberculosis* and nontuberculous mycobacteria with a 2% glutaraldehyde. Some high-level disinfectants have a reduced exposure time (e.g., ortho-phthalaldehyde at 12 minutes at 20°C [68°F]) because of their rapid activity against mycobacteria or reduced exposure time due to increased mycobactericidal activity at elevated temperature (e.g., 2.5% glutaraldehyde at 5 minutes at 35°C [95°F], 0.55% OPA at 5 minutes at 25°C [77°F] in automated endoscope reprocessor).

2. Tubing must be completely filled for high-level disinfection and liquid chemical sterilization; care must be taken to avoid entrapment of air bubbles during immersion.

3. Material compatibility should be investigated when appropriate.

4. A concentration of 1,000 ppm available chlorine should be considered where cultures or concentrated preparations of microorganisms have spilled (5.25–6.15% household bleach diluted 1:50 provides > 1,000 ppm available chlorine). This solution may corrode some surfaces.
Overview of Processing Instruments and Devices

5 Pasteurization (washer-disinfector) of respiratory therapy or anesthesia equipment is a recognized alternative to high-level disinfection. Some data challenge the efficacy of some pasteurization units.

6 Thermostability should be investigated when appropriate.

7 Do not mix rectal and oral thermometers at any stage of handling or processing.

8 All applicable label instructions on US Environmental Protection Agency-registered products must be followed.

Adapted from: Rutala et al. 2008.
References


Chapter 2. Cleaning and Preparing Surgical Instruments and Medical Devices for Disinfection or Sterilization

Key Topics

- Importance of pre-soaking and cleaning as initial steps in processing used medical instruments
- Factors that affect cleaning
- Steps in the instrument cleaning process
- Cleaning tips

Key Terms

- **Bioburden** is the population of viable microorganisms on devices, instruments, equipment, or products. When measured, bioburden is expressed as the total count of bacterial and fungal colony-forming units per single item. (AAMI ST79 2010).

- **Cleaning** is the removal of visible dirt (e.g., organic and inorganic material) from objects and surfaces, normally accomplished manually or mechanically, using water with detergents or enzymatic cleaners. Cleaning is required before high-level disinfection or sterilization because tissue, blood, body fluids, dirt, and debris reduce the effectiveness of these processes.

- **Decontamination** is the process of removing pathogenic microorganisms from objects so they are safe to handle, use, or discard. It can be done using physical or chemical means.

- **High-level disinfection** is a process that kills all microorganisms but not necessarily all bacterial spores. HLD is achieved by soaking items in liquid chemicals classified as high-level disinfectants or by boiling or steaming for the appropriate time (20 minutes).

- **Log$_{10}$ reduction and kill rate** is a quantitative (calculable) measurement describing the percentage of contaminants killed during instrument processing procedures. 1 log$_{10}$ reduction means a 90% reduction in microbes on a given surface. For example, if there are 1 million microbes on a surface, 1 log$_{10}$ reduction or kill rate will remove 90% of 1 million microbes, 2 log$_{10}$ kill rate will remove 99% of microbes, and 5 log$_{10}$ reduction or kill rate will remove 99.999%. Therefore, a 6 log$_{10}$ reduction or kill rate will remove 99.9999% of microbes, which means that only 1 microbe will survive at the end of the procedure that has a kill rate of 6 log$_{10}$ reduction.

- **Personal protective equipment (PPE)** items are the protective barriers and respirators used alone or in combination by a health care worker (HCW) to protect mucous membranes, airways, skin, and clothing from contact with harmful or infectious agents. PPE also may be used on an infectious patient to prevent the spread of infectious agents (e.g., surgical mask worn by a patient to control the spread of influenza or tuberculosis).

- **Sterilization** is the process used to render an item free from viable microorganisms, including spores.
Background

Cleaning is a critical step in instrument processing because:

- It makes instruments safer for additional processing, which reduces the risk of infection for the HCWs who handle the instruments.
- It reduces damage to instruments. At the end of a clinical or surgical procedure, surgical instruments and equipment are contaminated with tissue particles, body fluids, and blood. Long contact with blood is corrosive and can damage surgical instruments.
- It makes instruments easier to process. Once blood dries on an instrument, it is difficult to clean, especially if the blood has entered the hinges and sockets.

Bioburden and residual cleaning agents remaining on an item can inactivate chemical disinfectants or sterilants and protect microorganisms from destruction, which can result in disinfection and sterilization failures (Zuhlsdorf et al. 2004). Therefore, it is important to follow all the necessary steps to properly clean instruments prior to high-level disinfection or sterilization.

Before transport to the instrument processing area, HCWs should perform point-of-use cleaning—wiping instruments to remove tissue and blood immediately at the conclusion of the procedure. Once instruments are in the instrument processing area, cleaning involves thorough cleaning of them with water and a detergent and/or an enzymatic cleaner followed by thorough rinsing, and then drying before further processing.

Cleaning is done manually or mechanically using washer/disinfector machines. Health care facilities may practice only manual cleaning of contaminated instruments before further processing or may use a combination of manual cleaning and washer/disinfector machines.

All facilities should aim to clean and re-process all instruments in a central location. Large facilities where a high number of procedures are performed should have a central sterile supply department that is dedicated to cleaning, disinfection, and sterilization of the instruments and equipment. (See Module 5, Chapter 1, Facility Design, Traffic Flow, and Work Practices in Health Care Facilities.) However, many health care facilities operate within existing infrastructure and the ideal situation cannot be immediately achieved, so cleaning and packaging of instruments and devices may occur on wards or in the labor and delivery or operating theater areas.

Cleaning instruments is a dirty process and can lead to extensive contamination of sinks and surrounding areas, including surfaces, which increases the risk of cross-contamination of patients undergoing procedures in the area. Therefore, if more than point-of-use cleaning occurs in procedure areas, the following must be in place:

- All staff involved with cleaning of instruments and medical devices should be trained and have competencies for the procedures, chemicals, and equipment.
- Appropriate PPE should be available to all staff performing cleaning procedures.
- Written procedures and policies for the processes performed should be available to staff in the processing area.
- Procedures, chemicals, and methods of cleaning should be standardized across all areas as appropriate to the instruments and medical devices being processed.
- Infection prevention and control staff should monitor all instrument cleaning and reprocessing areas.
Cleaning and Preparing Instruments and Devices

Refer to Module 5, Chapter 1, Facility Design, Traffic Flow, and Work Practices in Health Care Facilities, for descriptions of workflow requirements and setting up suitable processing spaces.

Factors That Affect the Effectiveness of Cleaning

Mechanical washer-disinfectors remove more microbial load than manual cleaning. Studies have shown that a thorough manual cleaning results in $4 \log_{10}$ (99.99%) reduction (Rutala and Weber 2004) of microbial load on the instruments. Washing in a mechanical washer-disinfector results in $5 \log_{10}$ (99.99%) reduction in microbial load on instruments (Ransjo et al. 2001). In addition, mechanical washer-disinfectors allow control in the procedure and help avoid operator mistakes.

Factors that affect effectiveness of manual cleaning include:
- Quality of water
- Quality, concentration, and type of cleaning agent
- Cleaning methods
- Rinsing and drying methods

Factors that affect the effectiveness of mechanical cleaning include:
- Preparation of items for machine washing
- Exposure time
- Temperature
- Load capacity

Water quality

Water quality—physical, chemical, and biological characteristics—can affect the cleaning process, and health care facilities must be aware of this impact. Hard water, which contains higher level of minerals such as calcium, chlorides, and other chemicals, can damage instruments over time. Deposits can insulate instruments and may not allow them to reach the desired temperature.

Water without minerals and salts is called “soft water.” Soft, distilled, deionized, or reverse osmosed water is recommended for cleaning instruments. (See Module 5, Chapter 3, Managing Food and Water Services in Health Care Facilities, for more information and recommendations on water treatment.) If the cost of treating water is prohibitively high, the final rinse in the cleaning process should be done with soft water. (Acosta-Gnass and Stempliuk 2009; Spry and Conner 2008)

Cleaning agents

Cleaning products contain surfactants, which reduce the surface tension of water and allow dirt to become suspended in water and washed away. When choosing a cleaning agent, be sure it is compatible with the instruments being cleaned (review the manufacturer’s instructions). Cleaning agents should not be corrosive to either the instruments or automatic washers. They should not promote electrolytic reactions between the instruments and the containers. At a minimum, an ideal cleaning agent should:
- Be non-corrosive and non-abrasive
- Be low-foaming and free-rinsing
- Be biodegradable and non-toxic
Cleaning and Preparing Instruments and Devices

- Have a neutral pH
- Be cost-effective
- Have a long shelf life

(AORN 2013)

Not all detergents and cleaning agents available on the market meet these criteria. For example, commonly available products such as Vim or Comet are not appropriate for cleaning medical devices and instruments because these products may scratch instruments (Tietjen et al. 2003). If available, use detergents or enzymatic instrument cleaning products made in your country, such as Rapid Multi-Enzyme Cleaner by 3M. Enzymatic detergent uses several of the required mechanisms to loosen proteins and bioburden, which makes subsequent cleaning more effective. (Acosta-Gnass and Stempliuk 2009)

Personal Protective Equipment for Instrument Cleaning

HCWs who are responsible for cleaning instruments are at an increased risk of exposure to bloodborne pathogens such as HIV and hepatitis B and C viruses. It is essential that staff who handle contaminated instruments or devices:

- Wear PPE (including fluid-resistant gowns; heavy-duty, waterproof long-cuffed gloves; fluid-resistant face masks and eye protection; and footwear with closed toes, low heels, and non-skid soles, such as rubber boots or leather shoes/fluid-resistant shoe covers, as needed to protect against exposure to blood and body fluids. (OSHA 2012)
- Follow the facility guidelines for disposal of sharps, such as scalpel blades and needles, in puncture-resistant containers. (See Module 4, Chapter 1, Injection Safety.)
- Follow guidelines for potential exposures to bloodborne pathogens. (See Module 4, Chapter 2, Infection Prevention and Control Aspects of Occupational Health in Health Care Settings.)

Steps in the Instrument Cleaning Process

1. Perform tasks at the point of use (in the operating theater or procedure room)
2. Transport items to the processing area
3. Receive and classify items
4. Pre-soak instruments
5. Wash and rinse instruments
6. Dry instruments
7. Inspect, repair, and lubricate instruments

(Acosta-Gnass and Stempliuk 2009)

1. Perform tasks at the point of use

A scrub nurse, scrub technician, or assistant should perform the following tasks at the point of use (before taking surgical instruments to the reprocessing area):

- Dispose of all sharps in a biohazard sharps container.
Cleaning and Preparing Instruments and Devices

- Flush and fill channels and tubing of instruments with sterile water to prevent blood and body fluids from drying inside the lumens. Never use saline solution since it is corrosive to instruments.
- Place instruments in a basket or a tray in an orderly fashion with all box locks (hinges) open.
- Separate cannulated and sharp instruments and place them on top. Make sure delicate instruments are secured in their holders.
- If immediate cleaning is not possible, soak instruments in tap water or spray instruments with an enzymatic product. Make sure to spray an enzymatic cleaner down the lumens of instruments with lumens to prevent blood from drying inside the lumen.

2. Transport items to the processing area

- Place instruments in the instrument pan for transport to the instrument reprocessing area.
- Transport instruments in leak-proof containers with a biohazard label as soon as possible; keep them moist by covering them with a wet towel or using an enzymatic product to prevent drying of blood and body fluids.

(AORN 2015)

3. Receive and classify items

Staff in the reprocessing area who receive instruments should:

- Wear recommended PPE at all times when receiving used instruments. See the Personal Protective Equipment for Instrument Cleaning section in this chapter.
- Record details of instruments received, including counts, in receiving registers.
- Classify instruments into metal, polyethylene, rubber, plastic, and glass—they may need to be washed separately for manual and machine cleaning.

4. Pre-soak instruments

Pre-soaking instruments with enzymatic detergents is recommended (follow manufacturers’ instructions for dilution and soak time) because it moistens and loosens organic materials on the instruments and makes cleaning more effective.

Instruments should be soaked in 0.8% solution of enzymatic detergent in warm water (not above 45°C [113°F]) for 1 minute. Soak the instruments and devices until all organic matter is dissolved and eliminated but never for more than 5 minutes. Instruments should be rinsed in clean water after soaking until they are visibly clean. Enzymatic detergents selected for cleaning stainless steel surgical instruments should have a neutral pH once they are dissolved in water. (Acosta-Gnass and Stempliuk 2009)

5. Wash and rinse instruments

*Manual washing and rinsing*

Key elements of manual cleaning are friction, temperature, and detergent. Optimum temperature for water to clean instruments is 27–44°C (80–111°F) but never more than 60°C (140°F). This will help prevent coagulation of proteins. Water temperature from the tap is within 27–44°C (80–111°F), easily
achievable in most settings. However, it is advisable to use a thermometer to test this during different seasons to ensure that the water temperature will not coagulate proteins.

Health care facilities should have a dedicated sink/wash basin for washing instruments. It should not be used for other purposes such as handwashing or disposing of liquids.

- Place the items being cleaned in the sink and wash them with water between 27–44°C (80–111°F) and detergent or enzymatic product.
- Monitor the temperature according to the detergent’s or enzymatic product’s manufacturer’s IFU.
- Brush items under water to avoid exposure to blood and body fluids via aerosols, sprays, and splashes.
- Use brush sizes designated by the instrument manufacturer for cleaning lumens. If the bristle diameter is too small, the brush will not touch the sides of the lumen and will not clean it. If the diameter if too large, the bristles will flatten against the edges and will not clean properly. The brush should be long enough so that all bristles exit the tip of the distal end of the lumen being cleaned and the soil inside the lumen will be pushed out.
- Flush instruments and devices with lumens and channels with water under pressure, in addition to brushing, to remove soil and debris.
- Use non-metal soft brushes or a soft cloth and water to manually clean all surfaces of the instruments or devices. Some health care facilities use toothbrushes to clean non-lumened instruments:
  - Cleaning brushes or cloths can be single-use/disposable or reusable. Reusable brushes and cloths must be washed thoroughly using detergent and water, rinsed and dried, and disinfected at least once per day.

Once the instruments are visibly clean, rinse the items in another sink (not the sink used for cleaning) with plenty of clean running water to remove traces of cleaning solution. Ideally, water without minerals and salts (soft water) is recommended for cleaning instruments. A final rinse should be carried out, ideally with soft water, to ensure that all salt residues are removed to avoid damage to the instruments and ensure effectiveness of further processing.

If only one sink is available to clean instruments, follow all of the steps above with the addition of these:

- Remove the instruments from the sink.
- Drain the sink and wipe the sink surfaces with a combined detergent-disinfectant.
- Rinse the sink twice with tap water, preferably hot.

See Module 5, Chapter 1, Facility Design, Traffic Flow, and Work Practices in Health Care Facilities, for information on workflow when using a single sink.

**Mechanical washing**

Mechanical washing equipment, such as cart washers or washer-disinfectors, remove blood, tissues, and microorganisms through an automated cleaning and rinsing process. Various mechanisms are used for cleaning including heat, chemical, and ultrasonic methods.

When instruments are being loaded into a washer-disinfector, hinged instruments must be fully opened to allow adequate contact with the detergent solution; avoid stacking instruments. Disassemble
Cleaning and Preparing Instruments and Devices

instruments as much as possible. Heat-tolerant instruments can undergo multiple cycles of washing and rinsing followed by a drying cycle to remove all visible debris, which can result in a low to intermediate level of disinfection.

Ultrasonic cleaning is used to aid in the cleaning of small items with intricate parts and small lumens. Instruments requiring ultrasonic cleaning must be pre-cleaned and rinsed prior to ultrasonic cleaning. Mechanical cleaning equipment should be tested upon installation, weekly during routine use, and after major repairs.

6. Dry instruments
All instruments should be allowed to dry completely before further processing. Drying prevents further contamination of instruments by growth of microorganisms in wet/damp environments. Drying can be done manually using a lint-free soft cloth or cellulose material. When instruments are air-dried, the hinges, lumens, and crevices may still need to be dried with a cloth to achieve dryness. Some equipment with lumens and channels may come with specialized drying equipment. (Acosta-Gnass and Stempliuk 2009)

Verification of cleaning process
Following the cleaning process, at a minimum, all instruments should be visually inspected to detect any visible soil. For smaller areas, a magnifying glass should be used to detect any debris or instrument damage. Inspection of instruments should include the thoroughness of cleaning and drying, functionality of instruments and any visible damage, absence of lint or fibers, and appropriate assembly of parts.

7. Inspect, repair, and lubricate instruments
Following cleaning, instruments that have become rigid and difficult to operate may require lubrication before sterilization.

The lubrication solution should be approved for use on surgical instruments. Mineral, silicone, or machine oils should not be used because sterilizing agents may not be able to fully penetrate the lubricant, which might be contaminated by microorganisms. Use lubricating agents approved by the manufacturer and suitable for use with the chosen disinfection/sterilization process.

Cleaning tips
- Always wear appropriate PPE while handling contaminated instruments and equipment.
- Never allow tissues, blood, and body fluids to dry on the instruments.
- Wash instruments under water to prevent aerosols and splashes.
- Use non-metal, soft brushes to clean instruments.
- Use enzymatic detergent solution, if available; otherwise, use a low-foaming liquid soap with a neutral pH.
- At the end of cleaning, rinse all instruments ideally with soft, clean water; if possible, at least use soft, deionized, or reverse osmosed water for the final rinse.
- Develop comprehensive written cleaning protocols, train staff, and ensure competency in the appropriate way to clean surgical instruments and medical devices.

Note: For sterilization and high-level disinfection to be effective, thorough cleaning of instruments and equipment is vital.
More information can be found in Chapter 3, High-Level Disinfection of Surgical Instruments and Medical Devices, and Chapter 4, Sterilization of Reusable Surgical Instruments and Medical Devices in this module.

Summary
Cleaning is the most important step in instrument processing because it makes instruments safer for additional processing, which reduces the risk of infection for HCWs who handle the instruments; prevents bioburden from drying on instruments; and ensures that there are no residual bioburden or cleaning chemicals on the instruments that may interfere with the subsequent high-level disinfection or sterilization process. Cleaning is a complex procedure; policies should be in place and all HCWs who perform instrument cleaning throughout the facility should be trained and competent in the appropriate way to clean surgical instruments and other equipment.
References


Chapter 3. High-Level Disinfection of Surgical Instruments and Medical Devices

Key Topics

- Factors that affect the disinfection process
- High-level disinfection using liquid chemicals
- High-level disinfection using physical methods
- Reprocessing of endoscopes
- Recommendations for disinfection of various medical devices

Key Terms

- **Antiseptics** are chemical disinfectants applied to skin to reduce the number of microbial flora on the skin. These agents include alcohol (ethyl or isopropyl), dilute iodine solutions, iodophors, and chlorhexidine. They are used on skin only, not inanimate items and surfaces.

- **Disinfectants** are chemicals that destroy or inactivate microorganisms on inanimate (non-living) surfaces. Disinfectants are classified as low-, intermediate-, or high-level depending on their ability to kill or inactivate various classes of microorganisms. Disinfectants do not kill all spores. Glutaraldehyde, orthophthalaldehyde, peracetic acid, and hydrogen peroxides are used for high-level disinfection of surgical instruments and medical equipment.

- **Disinfection** is a process that eliminates many or all pathogenic microorganisms except bacterial spores, by chemical (i.e., a disinfectant) or physical (boiling, wet pasteurization) means.
  - **Low-level disinfection** is a process that destroy all vegetative bacteria (except tuberculosis bacilli), lipid viruses, some non-lipid viruses, and some fungi, but not bacterial spores. Low-level disinfection is carried out using chemicals that have been approved to achieve low-level disinfection.
  - **Intermediate-level disinfection** is a process that destroys all vegetative bacteria, including tuberculosis bacilli, all fungi, and most viruses (except some non-lipid viruses) but not bacterial spores. Intermediate-level disinfection is carried out using chemicals that have been approved as intermediate-level disinfectants or those that are approved as “tuberculocidal” in the national infection prevention and control guidelines.
  - **High-level disinfection (HLD)** is a process that kills all microorganisms but not necessarily high numbers of bacterial spores. HLD is achieved by soaking items in liquid chemicals classified as high-level disinfectants or by boiling or steaming for the appropriate time (20 minutes).

- **Pasteurization** is a disinfection process that uses hot water at temperatures of 65–77°C (149–170.6°F) for a contact time of at least 30 minutes to kill or markedly reduce the number of microorganisms other than bacterial spores.

- **Sterilization** is the process used to render an item free from viable microorganisms, including spores.
High-Level Disinfection

Background
Sterilization is the safest and most effective method for the reprocessing of surgical instruments because it kills all vegetative microorganisms and microbial spores. However, sterilization is not always suitable because some materials cannot withstand the high temperatures used during the sterilization process and sterilization may not be consistently available in some low-resource settings.

There are three levels of disinfection: low-level, intermediate-level, and high-level. The level of disinfection needed is based on how the item will be used. Per the Spaulding classification, devices that come in contact with intact skin are classified as non-critical items and should be processed by intermediate- or low-level disinfection. (See Chapter 1, Overview of Processing Surgical Instruments and Medical Devices, in this module.) Surgical instruments and medical devices that come in contact with non-intact skin or mucous membranes (classified as semi-critical devices) must, at a minimum, be high-level disinfected, though sterilization is always preferable when possible.

Factors That Affect the Effectiveness of the Disinfection Process

- **Quantity and location of the microorganisms.** As the quantity of microorganisms increases, longer exposure times as well as higher concentrations of chemical disinfectants are needed to effectively disinfect instruments and devices. Therefore, it is essential that health care workers (HCWs) thoroughly clean items prior to disinfection (see Chapter 2, Cleaning and Preparing Surgical Instruments and Medical Devices for Disinfection or Sterilization, in this module).

- **Quantity and location of organic matter.** The presence of organic matter such as tissue particles, blood, and other body fluids can inactivate some disinfectants and compromise their effectiveness. Also, biofilm formation makes it more difficult to adequately clean items. Thorough cleaning of instruments and devices is essential to reduce organic materials and biofilms prior to the disinfection process (Acosta-Gnass and Stempliuk 2009). (See Chapter 2, Cleaning and Preparing Surgical Instruments and Medical Devices for Disinfection or Sterilization, in this module.)

- **Concentration of the disinfectant.** The concentration of the disinfectant should be such that it effectively kills microorganisms and at the same time does not harm the instruments and devices being disinfected.

- **Physical and chemical factors.** Some disinfectants require a specific temperature or pH level to be effective. Always follow the manufacturer’s instructions for use.

- **Duration of exposure.** Each disinfection method and disinfectant is associated with a specific amount of time that is necessary for achieving the desired results.

- **Resistance of microorganism to the chemical agent.** Resistance of microorganisms to various disinfectants can occur; therefore, it is important to periodically review for documented or potential resistance of microorganisms to the disinfectant being used.

High-Level Disinfection Using Liquid Chemicals

Disinfectants are able to achieve different levels of disinfection based on the chemical and exposure time. The US Food and Drug Administration (FDA) has a process to approve and classify disinfectants as low-, intermediate-, or high-level. (See Table 3-1.) Several products can be used both as high-level disinfectants and sterilants based on the exposure time. It is critical to choose the appropriate disinfectant and exposure time to achieve the desired disinfection level. Disinfectants are not interchangeable, and incorrect selection and use can mean that the desired level of disinfection is not achieved.
### Table 3-1. Levels of Disinfection and Chemical Agents Approved as Disinfectants

<table>
<thead>
<tr>
<th>Level</th>
<th>Chemical Agent</th>
</tr>
</thead>
</table>
| **High-level disinfectants** (HLD) | • Orthophthalaldehyde (OPA) 0.55%  
• Glutaraldehyde 2% or higher  
• Hydrogen peroxide (7.5%)  
• Peracetic acid > 0.2% at 50–65°C (122–149°F)  
• Hydrogen peroxide (7.35%) and peracetic acid (0.23%)  
• Hypochlorite, chlorine generated onsite by electrolyzing saline containing more than 650–675 parts per million (ppm) of active free chlorine (will corrode metal instruments) |
| **Intermediate-level disinfectants** | • Ethyl or isopropyl alcohol (70–90%)  
• Sodium hypochlorite (5.00–5.25% household bleach diluted to 0.5–1.0%)  
• Phenolic germicidal detergent solutions  
• Iodophor germicidal detergent solutions |
| **Low-level disinfectants** | • All intermediate-level disinfectants  
• Quaternary ammonium (QUAT) germicidal detergent solutions |

*Adapted from: Rutala et al. 2008.*

### Properties of an Ideal Disinfectant

- Wide antimicrobial spectrum
- Rapidly kills microorganisms
- Active in the presence of organic matter and compatible with soaps, detergents, and other chemicals encountered in use
- Non-toxic
- Does not cause the deterioration of cloth, rubber, plastics, and other materials
- Leaves an antimicrobial film on the treated surface
- Easy to use with clear label instructions
- Pleasant odor or no odor to facilitate its routine use
- Not prohibitively high in cost
- Soluble in water
- Stable in concentrate and at use-dilution
- Good cleaning properties
- Environmentally friendly on disposal

(Rutala et al. 2008)
High-Level Disinfectant Liquid Chemical Products

High-level disinfectants (some may also achieve sterilization with longer disinfection times) are described below.

**Orthophthalaldehyde (OPA)** has a number of features that make it a good choice for high-level disinfecting instruments and medical devices. It is relatively fast-acting, it is non-irritating to eyes and nasal mucosa, and it does not require activation. It kills all vegetative bacteria, fungi, and non-enveloped and enveloped viruses (high-level disinfectant). It does not kill all bacterial spores; therefore, it cannot be used to achieve sterilization. It is compatible with most metals and plastics and can be used to process most endoscopes. However, there are reports of serious anaphylactic reaction in bladder cancer patients; therefore, OPA should not be used to process scopes for use in patients with bladder cancer.

Once OPA solution is poured into the disinfection container, it can be used for 14 days as long as the solution concentration meets the minimum effective concentration. The concentration must be tested using the approved test strips provided by the manufacturer before the first use and then regularly to assure that the minimum concentration is met. The manufacturer recommends testing the solution prior to each use, and it should be done at a minimum daily. A log should be kept to document the quality control results. OPA must be used within 24 months of the date of manufacture. Unopened bottles should be stored in a cool, dry place. Once the bottle of OPA is opened, it must be discarded within 75 days or by the bottle expiration date, whichever date comes first. HCWs handling OPA must wear personal protective equipment (PPE), including gloves and face and eye protection. OPA stains unprotected skin gray.

Items should be thoroughly cleaned and dried prior to OPA disinfection (See Chapter 2, Cleaning and Preparing Surgical Instruments and Medical Devices for Disinfection or Sterilization, in this module). The contact time for HLD using OPA is 12 minutes at 20°C (68°F). Ensure that all surfaces and lumens contact the disinfectant for the entire soaking time. This means lumens must be filled with disinfectant and free of air bubbles.

After disinfection time, items are removed from the disinfection solution and rinsed. OPA requires three complete rinses in water for 1 minute each. Items that may come in contact with non-intact skin and mucous membranes may be rinsed with clean, potable water. If the water quality is not reliable, a final rinse with 70% isopropyl alcohol will help eliminate any microbes and speed the drying process. When used for HLD of endoscopes, all lumens and channels should be rinsed with 70% alcohol after the third water rinse to help dry the channels. If items are not rinsed properly, the residual OPA can cause staining of patients’ and HCWs’ skin.

OPA can be safely disposed of in a sewerage system. No deactivation is required prior to disposal down the drain, though it should be accompanied with large amounts of water.

OPA is not approved for sterilization. If sterilization methods are not available and OPA is used to high-level disinfect items that will be used on sterile tissue, the three rinses should be done with sterile water.

**Glutaraldehyde** can be used to achieve both HLD or sterilization of surgical devices and medical devices, based on exposure time. Glutaraldehyde has some disadvantages that make it a less desirable high-level disinfectant than OPA. Glutaraldehyde is a known irritant to mucous membranes and can cause throat and lung irritation and asthma. HCWs must wear appropriate PPE, including mask, goggles, apron, and gloves. For extended exposure (> 5 minutes), nitrile or butyl rubber gloves must be worn; latex gloves do not provide adequate protection. The room where the product is used should have local exhaust with 10
air exchanges per hour. Ideally, the disinfection should be done under a fume hood. Soaking containers should be covered with a tight-fitting lid at all times except when adding or removing items or adding or disposing of the solution. The best practice is to monitor the concentration of glutaraldehyde in the environment and the allowable exposure for staff should not exceed 0.05 ppm in an 8-hour workday. In facilities with limited resources, the best option is to follow the guidelines for use of glutaraldehyde, including wearing PPE and ensuring appropriate ventilation.

Glutaraldehyde must be activated with an alkalizing agent before use. Once activated, it remains effective for 14 days. Some manufacturers have products that remain effective for 28 days. The minimum effective concentration should be tested on the first use and then daily to confirm that the concentration meets the minimum effective concentration. Use a log to document each soaking cycle and minimum effective concentration test results.

Contact time for achieving HLD using 2.5–3.5% solution is 20 minutes at 20°C (68°F) and 5 minutes at 35°C (95°F). Sterilization can be achieved in 8–10 hours at 20–25°C (68–77°F). Ensure that all surfaces remain fully submerged in the solution for the full contact time. Once removed from the solution, the items must be thoroughly rinsed with copious amounts of water. The expired solution must be neutralized following manufacturer’s instructions before it is disposed of in the sewerage system. (Acosta-Gnass and Stempliuk 2009; OSHA 2006; Rutala et al. 2008)

**Hydrogen peroxide** can be used to achieve HLD and sterilization. It has activity against a wide range of microorganisms including vegetative bacteria, fungi, and viruses. Hydrogen peroxide (3% solution) works effectively at lower pH and is stable at room temperature. Hydrogen peroxide does not damage glass and plastic articles and is safe on ventilators. It does have compatibility concerns with selected metals so approval from the device manufacturer should be obtained prior to use of this method on items where corrosion would be a concern. It has low toxicity and irritancy rating. No activation is required.

A 3% solution can achieve HLD using a contact time of 30 minutes at 20°C (68°F). To achieve sterilization, a higher concentration (7.5% solution) and a longer contact time are required (6 hours at 20°C [68°F]). Follow manufacturer’s instructions for product-specific contact time. After the first use, hydrogen peroxide can be used for a maximum of 21 days. The concentration of hydrogen peroxide must be monitored regularly by testing the minimum effective concentration. Items processed using hydrogen peroxide should be thoroughly rinsed with plenty of water. Chemical irritation has been identified in an endoscopy unit where endoscopes were disinfected with hydrogen peroxide.

**Hydrogen peroxide (1%) in combination with peracetic acid (0.08%)** is available for both HLD and sterilization. Contact time for HLD is 25 minutes at 20°C (68°F). The contact time for sterilization is 8 hours at 20°C (68°F). The concentration of both hydrogen peroxide and peracetic acid varies in different products. Always follow manufacturer’s instructions for use.

**Super-oxidized water** rapidly kills all forms of vegetative bacteria, viruses, and fungi, but not spores; therefore, it can be used for high-level disinfection of items. It is fast-acting, safe, non-toxic, non-corrosive, and does not have bleaching properties.

Super-oxidized water must be produced fresh when needed at point of use, and a fresh solution is needed for every use. It is produced by passing a saline solution over coated titanium electrodes in the presence of an electric current (9 amps). Technology allows maintaining a pH of 5–6.5 and reduction oxidation ratio of > 950 millivolts. At this pH, more hypochlorous acid is available than hypochlorite, which is less microbicidal than hypochlorous acid.
High-Level Disinfection

The microbicidal activity of super-oxidized water reduces in the presence of organic material, so as with all disinfection and sterilization, all items must be thoroughly cleaned prior to disinfection. Items, including endoscopes, should be soaked for 10 minutes at 30°C (86°F) for HLD. There is no need to wear PPE while using and handling super-oxidized water because it is safe for skin and mucous membranes.

Storage and Disposal of Disinfectants and Their Containers

Chemical disinfectants should be stored in their original containers provided by the manufacturers in a cool, dark area. Keep the top or lid on the container. Never store chemicals in direct sunlight or at a high temperature (> 50°C [122°F]).

For disposal, carefully pour waste chemical disinfectants down a utility sink drain or into a flushable toilet or latrine and rinse or flush with water. Glutaraldehyde requires neutralization prior to disposal.

Glass containers may be washed with soap, rinsed, dried, and reused. Alternatively, thoroughly rinse glass containers with water and dispose of by burying. Plastic containers used for toxic substances, such as glutaraldehyde or formaldehyde, should be rinsed with water and disposed of by burning or burying. (See Module 5, Chapter 5, Waste Management in Health Care Facilities.)

Products That Are Not Disinfectants

Antiseptic solutions are sometimes used incorrectly as disinfectants. Antiseptics are used to cleanse skin before surgical or other clinical procedures; they are not appropriate for HLD of surgical instruments and equipment used for semi-critical or critical procedures. (See Module 7, Chapter 2, Use of Antiseptics in Health Care Facilities.) Antiseptics, for example Savlon (chlorhexidine gluconate with or without cetrimide), do not reliably kill bacteria, viruses, and fungi.

The following antiseptics should not be used as disinfectants:
- Acridine derivatives (e.g., gentian or crystal violets)
- Cetrimide (e.g., Cetavlon)
- Chlorhexidine gluconate and cetrimide in various concentrations (e.g., Savlon)
- Chlorhexidine gluconate (e.g., Hibiscrub, Hibitane)
- Chlorinated lime and boric acid (e.g., Eusol)
- Hexachlorophene (e.g., pHisohex)

Other products frequently used to disinfect equipment are 1–2% phenol (Phenol), 5% carbolic acid (Lysol), and benzalkonium chloride, a quaternary ammonium compound (Zephiran). These are low-level disinfectants and should be used only to disinfect environmental surfaces.

General Guidelines for Using Liquid Chemicals for High-Level Disinfection

- Wear appropriate PPE to protect eyes, face, and hands.
- Carry out HLD using liquid chemicals in a well-ventilated room with good airflow, appropriately sized bench tops, and if possible at least two sinks, one for HLD and a second for rinsing instruments. If two sinks are not available, clean and disinfect the sink between the HLD step and the rinsing step.
Make sure that instruments and equipment are thoroughly cleaned, dried, and inspected (see Chapter 2, Cleaning and Preparing Surgical Instruments and Medical Devices for Disinfection or Sterilization, in this module).

Ensure that all removable parts are disassembled and all joints are opened.

Check the expiration dates of the liquid chemical.

Use reactive strips (provided by the manufacturer or separately procured) to check that the solution can still be used (meets minimum inhibitory concentration [MIC]).

Prepare disinfectant solution following manufacturer’s instructions.

Use an appropriately sized container made from inert materials, such as medical-grade plastic, with a tight-fitting lid.

Ensure that the entire instrument is fully submerged in the chemical solution, including lumens filled with disinfectant and no air bubbles.

Start the timer and soak instruments and equipment for the time recommended by the manufacturer (e.g., OPA [0.55%] 12 minutes, 2.5% glutaraldehyde 20 minutes).

Remove instruments and equipment from the solution after the appropriate time and allow the solution to drain completely.

Rinse the items with plenty of water per the manufacturer’s instructions for use to remove any residual chemical.

Items coming in contact with non-intact skin and mucous membranes may be rinsed with clean, potable water. If the water quality is not reliable, a final rinse with 70% isopropyl alcohol will help eliminate any microbes and speed the drying process. Though it is not recommended only to high-level disinfect items that will come in contact with generally sterile tissues, if this is the only alternative available, then items should be rinsed with sterile water.

All lumens and channels of endoscopes should be thoroughly rinsed.

Allow items to dry and use them immediately or store them in a manner to protect them from contamination.

Discard the solution following the manufacturer’s instructions if it was the last permissible use of the liquid chemical.

**Physical Methods for High-Level Disinfection**

*Pasteurization* can be used to achieve HLD of instruments and medical devices. It is carried out by heating at 77°C (170.6°F) for 30 minutes or boiling at 100°C (212°F) for 20 minutes.

*Boiling* has been a common practice for HLD of instruments and equipment used for semi-critical and sometimes critical procedures as it was the only available option in some low-income countries.

**Instructions for HLD by Boiling**

- Clean all instruments and other items that are to be high-level disinfected.
- Start the heat to bring the water to boil. Turn down the heat to bring the water to a gentle, rolling boil.
High-Level Disinfection

- Immerse items completely, covered them with at least 1 inch of water, and ensure that there are no air pockets in the lumens of the items.

- For those items (manual vacuum aspiration cannula or other rubber items) that float on the surface of water, it is not necessary that they remain under the surface of the water.

- Cover the container with a lid.

- Start the timer. Boil all items for the required time: 30 minute at 77°C (170.6°F) or 20 minutes at 100°C (212°F).

- Remove all items after the recommended time with a high-level disinfected forceps. Never leave boiled instruments in water that has stopped boiling. As the water cools and steam condenses, air and dust particles are drawn down into the container and may contaminate the instruments.

- Use items immediately or, using high-level disinfected forceps or sterile/clean, non-sterile gloves, place the objects in an HLD container with a tight-fitting cover. Ensure that the instruments are completely dry before the container is tightly closed.

Boiling tips

- Always boil for the required time period in a container with a lid.

- Start timing when the water begins to boil.

- Make sure that metal instruments are completely covered with water during boiling.

- Do not add additional items to the pot after timing begins.

Protecting the life of instruments that are frequently boiled

Lime deposits may form on metal instruments that are frequently boiled. This scale formation, caused by lime salts in the water, makes subsequent disinfection difficult. Follow these steps to minimize the problem of lime deposits:

- Boil the water for 10 minutes at the beginning of each day before use. This precipitates much of the lime salt in the water onto the walls of the boiling container before objects are added.

- Use the same water throughout the day, adding only enough to keep the surface at least 1 inch above the instruments. Frequently draining and replacing the water increases the risk of lime deposits on instruments.

- Do not boil the water too vigorously as this increases the risk of lime deposits on instruments.

- Drain and clean the boiler or pot at the end of each day to remove lime deposits and prevent growth of bacteria.

Reprocessing Endoscopes

The use of endoscopes in low- and middle-income countries is rapidly growing. Because of their design and the types of body cavities they enter, flexible endoscopes acquire high levels of microbial contamination. Most endoscopes have several components that are heat-sensitive and therefore cannot be sterilized with heat.

There are several liquid chemicals that are approved for reprocessing endoscopes, either manually or with automated washers/disinfectors or sterilizers. OPA is recommended and is becoming more popular than glutaraldehyde for processing endoscopes as it is safer due to lower toxicity rating.
Cleaning is the most important first step in processing endoscopes (see Table 3-2). Point-of-use cleaning should be done in the procedure room to prevent bioburden from drying on the scope’s exterior and internal channels.

In the scope reprocessing area, the following supplies should be available for cleaning:

- PPE (gloves, eye protection, impervious gown, face shield or simple surgical mask that will not trap vapors)
- Leak-testing equipment
- Channel-cleaning adapters (per the manufacturer’s instructions)
- Large basin or sink
- Detergent solution prepared according to the manufacturer’s instructions and alcohol (60–75%)
- Appropriate-size channel-cleaning brushes and lint-free cloths

### Table 3-2. Processing Steps for HLD or Sterilization of Endoscopes Using Liquid Chemicals

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
</tr>
</thead>
</table>
| Pre-cleaning                | • Wipe all exterior and interior surfaces of the endoscope using a damp sponge or soft cloth to remove gross contamination. Use enzymatic solution that is approved by the manufacturer for pre-cleaning.  
• Remove suction valves, air water valves, and biopsy valves.  
• Discard those parts designated as disposable.                                                                                          |
| Leak test                   | • Conduct the leak test before immersing the scope in the disinfectant. Use clear water (no soap or detergent) for leak testing, following the manufacturer’s instructions. If no leak is detected, continue further processing.                                                                                      |
| Manual cleaning             | • Use manufacturer-recommended cleaning products and water for cleaning the endoscope. At a minimum, the cleaning solution should be a medical-grade, low-foaming, and neutral pH detergent specially manufactured for endoscopes.  
• Immerse the endoscope in the cleaning solution and perform all cleaning under the water to avoid splashes. Always use the tools and brushes provided or recommended by the manufacturer.  
• Flush all the channels and tubing to ensure thorough removal of debris.                                                                                                                      |
| Rinsing, drying, and inspection | • Rinse all channels and parts with clean water to remove any debris or residual detergent.  
• Visually inspect the endoscope for conditions that could affect the disinfection or sterilization process, such as cracks, corrosion, discoloration, or retained debris. (Magnification and adequate lighting assist with inspection.)  
• Repeat the cleaning steps if the endoscope is not visibly clean and send for repair if damage is identified.                                                                                               |
### High-Level Disinfection

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
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<tbody>
<tr>
<td><strong>HLD</strong></td>
<td></td>
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</table>
  - Prepare the disinfectant following the manufacturer’s instructions. Achieving HLD or sterilization depends upon the contact time with the disinfectant.  
  - Use a chemical indicator test strip to ensure that the HLD solution’s minimum effective concentration is adequate. OPA 0.55% and glutaraldehyde 2–4% are the most commonly used disinfectants for reprocessing endoscopes. Peracetic acid 0.2% is used for sterilization of endoscopes.  
  - If using a manual approach to HLD, follow the steps below:  
    - Completely immerse the endoscope and all removable parts in a large basin of disinfectant. Do not process any other instruments with the endoscopes and reprocess each scope one at a time.  
    - Ensure that all channels are filled with the chemical by flushing the channels and ensuring a steady flow out the other end.  
    - Cover the basin with a tight-fitting lid for the rest of the contact time and at the recommended temperature. Use a clock to verify the contact time; contact time will depend upon the solution used and whether HLD or sterilization is required.  
    - At the end of exposure time, purge all channels and tubes with air to ensure complete removal of the chemical. |
| **Rinsing** |  
  - Thoroughly rinse all surfaces, channels, and tubing with clean (if HLD) or sterile (if sterilization) water. Use fresh water for each rinse. Follow manufacturer’s instructions for use. If using tap water, rinse with alcohol as a final step. |
| **Drying** |  
  - Purge all channels with forced air to ensure complete drying of the inner tubes and channels. |
| **Storing** |  
  - Store the endoscope in such a way that it promotes drying and prevents recontamination. Ideally, the endoscope should be hung vertically in a closed cabinet. |

*Adapted from: AAMI 2010; Rutala et al. 2008; SGNA 2016.*
Recommendations for Disinfection of Various Devices Used in Patient Care

Manufacturers’ instructions for use should be followed. In some limited-resource settings, alternative practices are sometimes used. The goal is always to follow the manufacturers’ instructions for use and the Spaulding classifications.

- **Tonometers** should be high-level disinfected, following the recommendations of most manufacturers and the Centers for Disease Control and Prevention (CDC), by soaking them for 5–10 minutes in a 1:10 dilute bleach (0.5%) solution, 3% hydrogen peroxide, and 70% isopropyl alcohol. Dilute bleach at 1:10 concentration, 70% isopropyl alcohol, 3% hydrogen peroxide, ultraviolet lights, and even soaking in water can cause varying degrees of damage to tonometer prisms.

- **Diaphragm fitting rings** should be thoroughly washed with soap and water, dried, and soaked in 0.5% bleach solution for 20 minutes or in peracetic acid and rinsed with boiled, cool water.

- **Vaginal probes** should be high-level disinfected between patients even if they are covered with a removable probe cover or a condom, as per the manufacturer’s instructions for use. Sterile transvaginal ultrasound probe covers have a very high rate of perforations; using a condom as a cover is more effective than a sterile cover. Some manufacturers recommend disinfecting the vaginal transducer by mechanically removing the gel, washing with soap and water, wiping the transducer tip with 70% alcohol or soaking in 0.05% chlorine for 2 minutes, and rinsing with tap water and air-drying. Rinse all items following HLD, using sterile water, a filtered water rinse, or a tap water rinse followed by an alcohol rinse. Some manufacturers do not recommend the use of glutaraldehyde 2% for HLD of vaginal probes as it may shorten the life of the probe and may have a toxic effect on tissues. (Rutala and Weber 2013; Ryndock et al. 2016)

- **Cryosurgery equipment** should be high-level disinfected. If it is not possible to completely immerse some components of the equipment in disinfectant, the tip should be fully immersed in disinfectant for the recommended time. The other components of the equipment should be wrapped with a cloth soaked in a high-level disinfectant. Immersible probes are recommended for use in health care facilities. Immersible components should be properly washed before immersion in a disinfectant.

- **Dental instruments** that come in contact with intact mucous membranes of the oral cavity should be sterilized if they are heat-tolerant. Heat-sensitive items should undergo HLD, at a minimum.

Disinfection in Home Care Settings

It is a common practice in low- and middle-income countries to provide end-of-life care in home settings. The family member responsible for providing home care should be trained in proper cleaning and disinfection of equipment used in patient care at home. All semi-critical items should be cleaned with soap and water, soaked in 0.1% sodium hypochlorite solution, and rinsed with clean water. Since the items are used for a single patient at home, the risk of transmission of infection is very low.

Summary

All semi-critical instruments and devices that come in contact with mucous membranes and non-intact skin should be, at a minimum, high-level disinfected. HLD can be carried out by soaking in a high-level disinfectant or by boiling. Before HLD, all items must be properly washed and dried. Follow manufacturer’s instructions for preparation, activation, dilution, soak time, rinsing, and storage.
References


Chapter 4. Sterilization of Reusable Surgical Instruments and Medical Devices

Key Topics

- Sterilization methods
- Packaging instruments and equipment for steam sterilization
- Factors affecting the effectiveness of sterilization processes
- Steam sterilization
- Types of steam sterilizers
- Monitoring the quality of steam sterilization
- Dry-heat sterilization
- Chemical sterilization
- Sterilization of prion-contaminated instruments
- Handling sterile surgical instruments and medical devices
- Storing and transporting sterilized items

Key Terms

- **Bioburden** is the population of viable microorganisms on devices, instruments, equipment, or products. When measured, bioburden is expressed as the total count of bacterial and fungal colony-forming units per single item. (AAMI ST79 2010).

- **Biofilm** is an accumulated, thin layer of bacteria and extracellular material that tightly adheres to surfaces (e.g., skin drains, urinary catheters) and cannot be easily removed. The presence of biofilm can increase the resistance of the bacteria to antimicrobial drugs and reduce the effectiveness of disinfectants and sterilization because products cannot penetrate the surface.

- **Biological indicator** is 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. If the biological indicator fails, it indicates the sterilization cycle was not adequate.

- **Bowie-Dick test** is a diagnostic test used to detect air leaks, ineffective air removal, and the presence of non-condensable gases in dynamic-air-removal steam sterilizers.

- **Chemical indicators** are devices used to monitor one or more of the parameters required for a satisfactory sterilization process. There are six classes of chemical indicators:
  
  - **Class 1**: Process indicators demonstrate that a package was exposed to the sterilization process and distinguish between processed and unprocessed packages.
  
  - **Class 2**: Bowie-Dick type tests, see key term above.
  
  - **Class 3**: Process indicators that react to a single parameter of the sterilization process.
  
  - **Class 4**: Process indicators that react to two or more of the critical parameters of sterilization.
- **Class 5** (integrating indicators): Process indicators designed to react to all critical sterilization parameters over a specified range of sterilization cycles.

- **Class 6** (emulating indicators): Process indicators designed to react to all critical variables of a specified sterilization cycle; they are also called cycle verification indicators.

- **Cleaning** is the removal of visible dirt (e.g., organic and inorganic material) from objects and surfaces, normally accomplished manually or mechanically, using water with detergents or enzymatic cleaners. Cleaning is required before high-level disinfection or sterilization because tissue, blood, body fluids, dirt, and debris reduce the effectiveness of these processes.

- **Cycle time** is the total elapsed time of a sterilization cycle from the time the process is initiated until the cycle is complete. This includes start time, exposure time, and cooling or drying time. In pre-vacuum sterilizers, it also includes pre- and post-vacuum time.

- **D-value** is the time or dose required to achieve inactivation of 90% of a population of the test microorganism under stated conditions. The larger the D-value, the more resistant the microorganism is to destruction. The most heat-resistant but harmless bacteria, *Geobacillus stearothermophilus*, is used as a biological indicator to test sterilizers; it has a D-value of 2 minutes. It means that within 2 minutes of exposure time, 90% of the test microorganism will be killed. In order to achieve 6 log10 reduction in the microorganism, 12 minutes should be enough. Because in many countries the internal temperature-sensing devices are not available, extra time is added to increase the margin of safety. Therefore, a general guideline for unwrapped instruments is 20 minutes and for wrapped packages is 30 minutes.

- **Decontamination** is the process of removing pathogenic microorganisms from objects so they are safe to handle, use, or discard. It can be done using physical or chemical means.

- **Drying time** is the time required to dry steam-sterilized items before they are handled.

- **Dynamic-air-removal steam sterilizers** are sterilizers that use a series of mechanisms to remove air from the sterilizer chamber, which is critical for steam penetration.

- **Engineering controls** are methods that are built into the design of the environment, equipment, or a process to minimize the hazards associated with use. An example is a medical device that limits exposure to bloodborne pathogen hazards in the workplace, such as sharps disposal containers, self-sheathing needles (a barrel or cover that automatically slides over the needle and locks in place once the needle has been removed from the patient), sharps with injury protection, and needleless systems.

- **Exposure time** is the period during which items are exposed to saturated steam at the specified pressure and temperature to achieve sterilization.

- **FIFO** stands for first-in, first-out, meaning that the items that arrived first are issued first. For sterile products, it means that the oldest sterile packages are issued first before any other similar sterile package.

- **Gravity displacement steam sterilizer** uses incoming steam to displace residual air through a port or drain in or near the bottom of the sterilizer chamber.

- **High-level disinfection (HLD)** is a process that kills all microorganisms but not necessarily high numbers of bacterial spores. HLD is achieved by soaking items in liquid chemicals classified as high-level disinfectants or by boiling or steaming for the appropriate time (20 minutes).
- **Log$_{10}$ reduction and kill rate** is a quantitative (calculable) measurement describing the percentage of contaminants killed during instrument-processing procedures. 1 log$_{10}$ reduction means a 90% reduction in microbes on a given surface. For example, if there are 1 million microbes on a surface, 1 log$_{10}$ reduction or kill rate will remove 90% of 1 million microbes, 2 log$_{10}$ kill rate will remove 99% of microbes, and 5 log$_{10}$ reduction or kill rate will remove 99.999%. Therefore, a 6 log$_{10}$ reduction or kill rate will remove 99.9999% of microbes, which means that only 1 microbe will survive at the end of the procedure that has a kill rate of 6 log$_{10}$ reduction.

- **Personal protective equipment (PPE)** items are the protective barriers and respirators used alone or in combination by a health care worker (HCW) to protect mucous membranes, airways, skin, and clothing from contact with harmful or infectious agents. PPE may also be used on an infectious patient to prevent the spread of infectious agents (e.g., surgical mask worn by a patient to control the spread of influenza or tuberculosis).

- **Prions** are abnormal infectious protein particles that cause rare, progressive degenerative neurological disorders that affect both humans and animals. These disorders are known as transmissible spongiform encephalopathies, such as Creutzfeldt-Jakob disease, Gerstmann-Sträussler-Scheinker syndrome, fatal familial insomnia, and kuru in humans; scrapie in sheep and goats; bovine spongiform encephalopathy in cattle; and other transmissible encephalopathies of deer, elk, and mink. They are resistant to normal methods of disinfection and sterilization.

- **Process challenge devices (PCDs)** are items designed to constitute a defined resistance to a sterilization process and used to assess performance of the sterilization process. A PCD challenge pack or test tray contains a biological indicator or a Class 5 integrating indicator. A PCD may also contain only Class 5 indicators.

- **psi** is the abbreviation of “pounds per square inch,” a unit used to describe saturated steam pressure. More specific designations are pounds per square inch absolute (psia referenced to an absolute vacuum), pounds per square inch gauge (psig, referenced to atmospheric pressure), and kilopascals (kPa, referenced to absolute vacuum).

- **Recall of sterile packages** in the health care setting is the instruction to the wards and operating theater (OT) to return sterile packages that were found not to meet quality control tests such as biological indicators.

- **Saturated steam** is water vapor in a state of equilibrium between condensation and evaporation.

- **Shelf life**, when applied to a sterile package, is the period of time during which the item is considered safe to use.

- **Steam purity** is the degree to which steam is free of dissolved and suspended particles, water-treatment chemicals, and other contaminants.

- **Sterilization** is the process used to render an item free from viable microorganisms, including spores:
  - **Chemical sterilization** is a validated process that uses liquid chemicals to make surgical instruments and devices free of all forms of viable microorganisms.
  - **Dry-heat sterilization** is a validated process that uses dry heat to make instruments and equipment free of all forms of viable microorganisms. Dry heat is used for sterilization of devices that cannot be subjected to a chemical or steam sterilization process. The time to achieve sterilization depends on the temperature used for sterilization. The temperature used will depend on what is safe for the instruments being processed.
Sterilization

- **Steam sterilization** uses saturated steam under pressure, for a specified period of time and at a specified temperature, for sterilizing equipment and instruments. Typically required parameters include 121°C (250°F) temperature at 106 kPa (15.4 lbs/in², also called psi—pounds per square inch) pressure for 20 minutes for unwrapped instruments and 30 minutes for wrapped instruments and 132°C (270°F) at 207 kPa (30 lbs/in²) for 15 minutes for wrapped items.

**Background**

One of the key interventions for prevention of surgical site infections is to provide sterile instruments for surgeries. According to the Spaulding classification, medical devices and instruments used for surgery are considered critical items because they come in contact with generally sterile tissue in body cavities or the vascular systems. Other examples of critical items include cardiac and urinary catheters, implants, and ultrasound probes used in sterile body cavities. All such items should be sterile before they are used for procedures. All reusable critical items should be sterilized using appropriate methods following the manufacturers’ instructions for use so that all microbes, including bacterial spores, are eliminated. The method used will depend on the susceptibility of the microorganisms to be removed (see Chapter 1, Overview of Processing Surgical Instruments and Medical Devices, in this module).

**Methods of Sterilization**

Sterilization methods are classified into three categories (high temperature, low temperature, and liquid chemical immersion) (see Table 4-1).

**Table 4-1 Sterilization Types and Methods**

<table>
<thead>
<tr>
<th>Sterilization Type</th>
<th>Sterilization Methods</th>
</tr>
</thead>
<tbody>
<tr>
<td>High temperature</td>
<td>Steam sterilization, dry-heat sterilization</td>
</tr>
<tr>
<td>Low temperature</td>
<td>Ethylene oxide (ETO), H₂O₂ gas plasma, ozone, vaporized H₂O₂</td>
</tr>
<tr>
<td>Liquid chemical immersion</td>
<td>Peracetic acid, peracetic acid with H₂O₂, glutaraldehyde</td>
</tr>
</tbody>
</table>

*Source: APIC 2014.*

Steam sterilization and chemical methods using sterilant liquids are the most commonly employed methods for sterilization at health care facilities in limited resource settings.

**Packaging Medical Devices and Surgical Instruments for Steam Sterilization**

Generally, surgical instruments and equipment are sterilized well ahead of their use; therefore, they should be packaged properly before they are sterilized, and after sterilization they should be appropriately stored to maintain their sterility. Depending on the sterilization method, there are several approaches for packaging instruments. Select the appropriate packaging material (the wrapper or container in which the items will be sterilized) based on availability and the sterilization method. Steam sterilization with an autoclave is the most common method for sterilizing wrapped instruments.
General Principles of Packaging

The main purpose of packaging instruments is to maintain sterility by protecting them from moisture, dirt, dust, and microorganisms until they are opened and used. (For additional information on packaging, see Module 5, Chapter 1, Facility Design, Traffic Flow, and Work Practices in Health Care Facilities.)

- The instruments should be packaged in such a way that it is easy to remove them from the sterilizer without contamination.
- The packaging should allow steam and heat or other sterilizing agents to come in contact with all surfaces of the instruments.
- The packaged instruments should meet the users’ needs and safety during the procedure.
- The size of the packaging materials should properly cover all surfaces of the instrument.

(Acosta-Gnass and Stempliuk 2009)

Criteria for Selecting Packaging Material

Packaging material should maintain the sterility of the contents until use and be cost-effective. The following are criteria for choosing suitable and effective packaging materials:

- Permeability: Packaging materials should be permeable to the sterilizing agent and should maintain a highly effective barrier against microbial contamination. The flow of air or permeability is expressed in liters per minute every 100 cm². Good penetration of steam and the sterilizing agent ethylene oxide, for example, allows materials to be sterilized. Cotton, medical-grade papers, and polyethylene materials have good permeability to steam. Craft, crepe, parchment, and other similar types of papers are closely woven and do not allow adequate flow of the steam or gas used.

- Strength: Packaging materials should have a high resistance to bursting, tearing, and abrasion. Burst resistance is measure in units of psi of pressure required for materials to burst. Tear resistance is the force required to propagate the tear. Once a tear has occurred, it is easy for it to expand. Abrasion resistance also decreases the release of lint or micro particles.

- Lint or particles: Packaging materials should be such that they do not release lint. Materials with high lint releases increase the chances of infection, foreign body reaction, and embolism.

- Fluid-repellent: Packaging materials should be repellent to liquids such as water or normal saline. Water should not penetrate good-quality materials even after 30 minutes of contact, and 70% alcohol should not penetrate materials even after 5 minutes of contact time.

- Memory: Packaging material should have good memory; it should return to and remain in its normal position. The edges should not cave in onto the contents of the package.

- Ease of handling: Packaging materials should be soft and ductile, and permit packaging without any resistance.

(Acosta-Gnass and Stempliuk 2009)

Selecting Packaging Materials

Packaging materials should:

- Meet the national standards and guidelines or other regulatory requirements
- Meet the criteria described above
Be free of holes or perforations
Not react with sterilizing agents
Not release any odor
Be inexpensive and readily available
Not be metal drums or trays, or newspaper, or made from recycled materials

Types of Packaging Materials
There are several types of packaging materials on the market:

- **Woven cloth**: The density of the threads dictates the quality of the cloth. At a minimum, there should be 140 threads/inch². “Jeans” type cloth that has 160 threads/inch² should be used for double wrapping. A cloth barrier with 272–288 threads/inch² has good water repellency, allows good penetration by steam, and retains moisture. Most hospitals provide linens that are 160 thread/inch². Woven cloth should be free of lint. Woven cloth should be washed after each use, which will allow the cloth to maintain some moisture (about 8%) and prevent it from drying completely and deteriorating.

- **Unwoven cloth**: Unwoven cloths are a combination of cellulose and synthetic fibers or 100% synthetic fibers. They are joined by fusion and resins (glue-like chemicals). These cloths are disposable, allow penetration of steam and heat, and are water-resistant. Since they can retain moisture, the drying time should be increased for sterile packages.

- **Paper**: Only paper products approved for wrapping instruments for sterilization should be used. They should be free of toxic chemicals and not break easily. Newspapers and recycled papers should never be used for packaging instruments. Surgical-grade papers that have porosity of less than 0.3 microns, moisture of 8%, and less than 55% of long fibers are best suited for packaging surgical instruments. They are highly resistant to tearing and do not release lint, although they may release some fibers if the paper is broken while being opened. Surgical-grade papers are single-use items and can be used for ethylene oxide sterilization. Mixed papers are the most commonly used packaging materials. They have a transparent and an opaque sheet and are resistant to tension, bursting, and tearing. They are heat-sealable but easy to open and compatible with sterilization by steam and ethylene oxide. (Acosta-Gnass and Stempliuk 2009)

- **Polymers**: There are various types of polymers available for packaging surgical instruments:
  - **Polyethylene** is most appropriate for low-temperature sterilization such as ethylene oxide or ionizing radiation. Low-density polyethylene is most adequate. To allow entry of moisture required for ethylene oxide sterilization, a paper-plastic peel pouch is used, with one side film and one side paper. The films are made from a pure petroleum and are resistant to liquid, air, and gas and so protect the contents from microorganisms. Polyvinyl chloride (PVC) materials should never be used for wrapping surgical instruments for sterilization.
  - **Polypropylene and polycarbonates** are heat-resistant and are formed by three layers that are thermally joined. The long and short fibers used in the manufacturing process make them strong and provide an adequate microbial barrier. They can be used for steam sterilization but will need a longer time to dry compared to cloth and paper packs. They are the preferred packaging for sterilization with hydrogen peroxide plasma.
  - **Tyvek** is made from polyethylene fibers in a sheet, like paper. It is moisture-resistant as well as durable and flexible and suitable for gas sterilization. Tyvek does not retain gases and so does not need longer times for desorption of gas compared to other synthetic packaging materials.
Supplies for Packaging

Packaging materials: The health care facility team should make the decisions about the most appropriate packaging materials based on the sterilization methods available at their facility. Follow the national guidelines on infection prevention and control concerning recommendations for selecting packaging materials. The criteria for choosing appropriate packaging materials and the types of materials available are discussed earlier in this chapter. The following packaging supplies are recommended:

- Adhesive tape with an external chemical control according to the sterilization method used
- Adhesive tape for identification of the package
- Internal chemical indicators
- Gauze or protectors for sharp-pointed instruments
- Sealer in case of mixed or polyethylene packaging

(Acosta-Gnass and Stempiuk 2009)

Wrapping Methods

There are several methods for manually wrapping instruments. The methods described below are recognized worldwide for packaging of medical devices and surgical instruments.

- **Envelope fold** is appropriate for small, rounded, and light items. The steps for preparing packages using the envelope type of wrapping are described below (see Figure 4-1).
1. Place the wrap on the table to form a diamond shape. Place the device to be wrapped in the center of the wrap, parallel with the edge of the table.

2. Bring up the lower corner of the wrap to cover the contents and fold the tip back on itself to form a tab or flap (which is used later to assist in opening the pack aseptically).

3. Fold the left corner over the contents and fold the tip back to form a tab.

4. Fold the right corner over the left fold and fold the tip back on itself to form a tab.

5. Bring the top corner down over the contents and tuck the corner under the right and left folds, leaving a small tab visible for easy opening.

6. Apply the second wrap by placing the single wrapped device in the center of the remaining wrap and repeating the wrap sequence to form a package within a package. Bring up the lower corner to cover the single wrapped item and fold the tip back on itself to form a tab or flap.
7. Fold the left corner over the single wrapped item and fold the tip back to form a tab.
8. Fold the right corner over the left fold and fold the tip back on itself to form a tab.
9. Bring the top corner down over the single wrapped item and tuck the corner under the right and left folds, leaving a small tab visible for easy opening. Secure with chemical indicator tape.

**Rectangular/square fold** is recommended for large and heavy items. The steps for preparing packages using square folds are described below (see Figure 4-2).

**Figure 4-2. Square Fold for Wrapping Items for Steam Sterilization**

Sterilization

1. Place the edge of the wrapper parallel with the edge of the table. Place the device in the center of the wrapper parallel with the edge of the wrapper.

2. Fold the edge of the wrapper over the top of the contents, covering the lower half of the contents. Then fold the edge back over itself (back toward the technician) to form a cuff. This will facilitate aseptic opening of the pack when used.

3. Bring the upper edge of the wrap down over the upper half of the contents and fold it back on itself to form another cuff overlapping the original cuff to prevent a gap between the upper and lower folds.

4. Fold the left edge of the wrapper snuggly over the pack and back on itself to form a cuff.

5. Fold the right side of the wrapper over the pack, overlapping the previous fold, and fold it back to form a cuff.

6. The second wrap is applied by placing the single wrapped item in the center of the wrap and repeating the steps performed for the first wrap to create a package within a package. Fold the edge of the second wrapper over the single wrapped item, covering the lower half. Fold the edge back over itself (back toward the technician) to form a cuff.

7. Bring the upper edge of the wrap down over the upper half of the single wrapped item and fold it back on itself to form another cuff overlapping the original cuff to prevent a gap between the upper and lower folds.

8. Fold the left edge of the wrapper snuggly over the pack and back on itself to form a cuff.

9. Fold the right side of the wrapper over the pack, overlapping the previous fold, and fold it back to form a cuff. Secure with chemical indicator tape.

Whatever methods and materials are used, all packaging should allow easy approach to opening and transferring sterile items to the sterile field.

Factors Affecting the Effectiveness of the Sterilization Processes

The effectiveness of any sterilization process depends upon the following factors:

- **The type of microorganism present**: Some microorganisms are more difficult than others to kill. The requirements—time, temperature, moisture, steam contact, air removal, and drying for sterilization—sufficient to kill all microorganisms, including bacterial spores, using steam for sterilization. In decisions about the use of liquid chemicals for processing instruments and equipment, the concentration and exposure time are key parameters.

- **The number and location of microorganisms**: Given that all other conditions remain constant, the larger the number of microorganisms, the more time it takes for a disinfectant to kill them. For complex instruments and equipment, channels, lumens, crevices, and joints may not be easily reached by the sterilizing agent. Direct contact with a sterilant is a must for killing microbes. Disassembling and thoroughly cleaning instruments and equipment before sterilization are vital as they reduce the number of microorganisms and allow the sterilant to reach every surface of the instruments and equipment being processed.

- **Concentration and potency of disinfectant**: With an exception of iodophors, the higher the concentration of a disinfectant, the less time it takes to kill microorganisms. Some disinfectants may not kill microbial forms (e.g., spores) even within an extended period of time (orthophthalaldehyde will not kill bacterial spores even after hours of exposure).
The amount and type of organic material that protects the microorganism: Blood or tissue remaining on poorly cleaned instruments acts as a protective shield to microorganisms during the sterilization process. HCWs should ensure that instruments and equipment are thoroughly cleaned and dried before sterilization with steam or use of a chemical sterilant.

Physical and chemical factors: Several physical and chemical factors, including temperature, humidity, pH, and water hardness, influence the effectiveness of a liquid chemical sterilant.

Biofilms: Biofilms are microorganisms that are tightly attached to surfaces and are difficult to remove. Biofilms reduce the effectiveness of the sterilization process. They may form on different types of objects, including urinary catheters, central venous catheters, and endoscopes.

Steam Sterilization
Steam is an effective sterilant because:

- It is an extremely effective “carrier” of thermal energy. One gram of steam at 100°C (212°F) carries 540 more calories of heat than 1 gram of water at the same temperature. The principle is the same as for pressure cookers. Steam, especially under pressure, carries thermal energy more efficiently.

- The protective outer layers of microorganisms can be softened by moisture in steam, allowing coagulation of the sensitive inner portions, which kills the microorganism. For sterilization by steam to be effective, the items should be thoroughly cleaned and dried.

High-pressure steam sterilization is an effective method of sterilization but must be performed correctly to ensure that all required parameters are met. In addition, specialized equipment is needed requiring a reliable power source to run. In spite of its challenges, high-pressure steam remains the most popular approach for sterilizing medical devices and surgical instruments. Steam sterilizers are available in various sizes and may work on alternative sources of energy, including electric power and kerosene operated stoves. There are two types of high-pressure steam sterilizers: gravity displacement and pre-vacuum (dynamic-air-removal sterilizers).

Types of Steam Sterilizers
Gravity displacement sterilizers (see Figure 4-3) are available in various sizes to suit the needs of small health care facilities or large hospitals. They are made from metal, have a chamber with a lid or door to load instruments, and can withstand recommended pressure and temperature. Steam is either produced inside the chamber at the bottom or pumped from outside. As more and more steam enters the chamber, the cool air is forced out through the drain near the bottom of the chamber. Some sterilizers have a pool of water at the bottom, which is heated with electricity, kerosene, or gas.

Once the cool air is removed, the steam will enter the drain, triggering the thermally regulated valve to close. When the valve is closed, the steam continues to build up pressure until the operative temperature is reached. Typical ranges are 121°C (250°F) to 132°C (270°F) and pressure of 15.4 lbs/inch². The timer is then activated and timing begins. At the end of the cycle (typically 20 minutes for unwrapped and 30 minutes for wrapped items), the relief valve is opened, which allows steam to escape. Usually steam passes through the water reservoir, where it condenses back to water and thus does not enter the room. After the pressure gauge returns to zero, the operator should open the door slightly and allow items inside to cool for about 30 minutes. If steam is still present, condensation of the moist air may wet the items or packs if they are placed on a cool or cold surface; wet packages or instruments can become contaminated.
Gravity displacement sterilizers are not as effective on partially vented containers (stainless steel drums that hold instruments during sterilization, storage, transportation, and packaging). Gravity displacement sterilizers should be monitored for effectiveness of the sterilization cycle on a routine basis as recommended by the manufacturer. Use of various indicators to monitor the cycle quality is covered elsewhere in this chapter. (Tietjen et al. 2003)

**Figure 4-3. Simplified Diagram of a Gravity Displacement Steam Sterilizer**

**Pre-vacuum sterilizers** (also called dynamic-air-removal sterilizers) are similar to the gravity displacement sterilizers except that they have a vacuum pump system to remove the air in the chamber before the steam is let in. Typically, a series of alternating steam pressure injections and vacuum draws (called pulses) remove the air from the chamber. The absence of air in the chamber allows steam to penetrate the load more quickly, resulting in more reliable sterilization and shorter cycle time. Most pre-vacuum sterilizers are operated at the same temperature as gravity displacement sterilizers, but high-speed vacuum sterilizers operate at higher temperatures (134°C [273°F]) and pressure (27–28 lbs/in²) and require shorter exposure time. It is very important to monitor the functioning of pre-vacuum sterilizers (see the Monitoring the Quality of Steam Sterilization section in this chapter).

**Immediate-use sterilizers (IUSs)**, formally known as flash sterilizers, are small, table-top pre-vacuum sterilizers, usually located in OTs or in adjacent areas. They are used to rapidly sterilize items that are urgently needed. Items are unwrapped and sterilized at a higher temperature (134°C [273°F]), therefore allowing for the shorter cycle time. Though rapid sterilization can be achieved, this method should be limited to emergency situations only (e.g., an instrument is dropped where no sterile wrapped instrument is available, or an urgently needed item is not available sterile). An IUS is potentially a risk to patients as it is often associated with time constraints and may result in improper cleaning of instruments/medical devices. In addition, items are sterilized unwrapped so they are at higher risk of contamination, especially during transport from the IUS sterilizer to the OT. The HCW transporting the instruments to the point of use should wear sterile gloves, use a sterile towel to hold the tray, which is removed when still hot, and place the tray on the sterile field. Never place a tray containing sterilized instruments on a non-sterile surface. Of note, there are specially designed, validated IUS containers, which allow more rapid steam penetration and help protect items after flash sterilization, but concern about improper cleaning still exists. Therefore, the IUS should be reserved for urgent situations only.

**Note:** To be effectively sterilized, regardless of the sterilization method used, an item must be thoroughly cleaned and dried before beginning the process of sterilization.
Common IUS cycle time is 3 minutes at 27–28 lbs/in² pressure. Always consult the sterilizer manufacturer’s instructions for use and ensure that the instrument being sterilized is validated for an IUS cycle.

Gravity displacement sterilizers are more commonly used in medium to small health care facilities. In most countries, high-speed vacuum and flash sterilizers usually are used in larger hospitals.

**Operating Steam Sterilizers**

Staff who operate steam sterilizers should be appropriately trained upon hire and periodically (e.g., annually) in the use of the sterilizer in general as well as the specific steps, outlined by the manufacturer’s instructions, for operating a particular model of equipment. Training should include operation, routine maintenance, minor repair, and quality control and include a competency check-off system. A steam sterilizer will reliably sterilize items only if operated correctly and maintained according to the manufacturer’s instructions for use.

Irrespective of the manufacturer, a steam sterilizer requires adequate time, temperature, moisture, and contact to work effectively. However, sterilization failures in clinics and hospitals in limited resource settings are very common. (O’Hara et al. 2015)

**Time:** A specific amount of time is required to kill all microorganisms on all items being sterilized. The higher the temperature, the less time is required. Sterilization time is measured in D-values. A D-value is the amount of time required to kill 90% (1 log₁₀ reduction) of the microorganisms present. Different microorganisms need different lengths of time to be killed; therefore, each type of microorganism has a different set of D-values. The D-value depends on the temperature. Typical exposure time for routine cycles at 121°C (250°F) is 20 minutes for unwrapped instruments and 30 minutes for wrapped instruments once the recommended temperature and pressure have been reached. This is based on the ability of the process to kill the most heat-resistant microorganism, *Geobacillus stearothermophilus*, which is commonly used as a biological indicator to monitor the quality of a sterilization cycle. Always check the instrument or device manufacturer’s instructions for specific requirements.

**Temperature:** The most commonly used temperature for steam sterilization is 121°C (250°F). When an object at room temperature is placed in a sterilizer, the steam transmits thermal energy to the object until the object reaches the same temperature as the steam. Under normal conditions, this equilibrium occurs within a few minutes. If the steam is unsaturated (too dry) or if the steam is prevented from reaching all parts of the object, the temperature may never reach the level required for sterilization. The only way to be certain that all points inside the load reach the full operating temperature of 121°C (250°F) is to ensure that the sterilizer is working correctly by carrying out routine maintenance and process validation following the manufacturer’s instructions for use. The temperature of saturated steam is directly related to the pressure at which it is controlled. Achieving 121°C (250°F) will require 15–17 lbs/inch² gauge pressure (103–117 kPa) in the chamber. While sensing devices do give a good indication of overall sterilizer operation, they cannot detect air pockets within packs.

Steam sterilization of wrapped packages takes 30 minutes at 121°C (250°F); it takes 15 minutes at 132°C (270°F). Thus, achieving the recommended temperature is key to achieving sterilization (Rutala et al. 2008). Always follow manufacturer’s instructions for use for each device or instrument.

**Moisture:** An adequate moisture content of the sterilizer’s atmosphere is mandatory for effective sterilization by steam. The steam should have 100% humidity to be effective. When steam comes in
contact with objects placed in the sterilizer, it becomes cooler and thus supersaturated as water begins condensing on the surface of the object. This condensation produces two immediate effects:

- The volume of steam in the sterilizer chamber decreases as it (water vapor) changes to the liquid state and more steam is drawn into the chamber and into contact with the articles being sterilized.
- Very large amounts of thermal energy are transferred to the object, raising the object’s temperature significantly. When 1 gram of steam at 100°C (212°F) gets converted into 1 gram of water at the same temperature, it releases 540 calories of thermal energy, which is transferred to the object being sterilized.

**Contact between microorganisms (on instruments) and steam:** The most frequent reason for sterilization failure is the lack of direct contact between steam and the microorganisms. This failure may be related to human error or mechanical malfunction. Most common causes for steam contact failure include:

- Items have not been properly cleaned so that steam fails to penetrate the microorganisms in the tissue left on the instruments, reducing the effectiveness of sterilization.
- Instruments are closed, locked, or stacked touching each other, preventing effective contact with steam.
- Packages are wrapped too tightly for steam to be able to replace the air inside the packages.
- Packs are loaded in a higher volume than recommended. The exposure time and pressure may not be adequate to penetrate the packs because of the overloading.
- Containers are in the wrong position. The containers and bottles should be positioned on their sides with caps removed or held loosely. The containers should have vents that are open to allow steam to freely enter inside during the sterilization and can be closed at the end of the cycle.
- Strainers and exhaust lines are clogged due to lack of routine maintenance, which results in air being trapped inside the sterilizer and affects the quality of the cycle.

Most of the causes above are a result of human errors. Having required protocols, job aids, and mechanisms to address any problems related to operation of the sterilizer will help avoid these causes.

**Air removal:** Presence of air in the chamber can be the biggest barrier to steam sterilization. Air must be removed from the chamber and the load before direct steam contact and sterilization occurs. This is achieved by various mechanisms, such as gravity displacement or pre-vacuum methods. Only after all air from the sterilization chamber is removed can steam effectively come in contact with all surfaces and kill microorganisms.

**Drying:** Presence of moisture in the packages may result in recontamination of the items inside as microorganisms can enter the pack through moist wraps and multiply in moist environments; therefore, a steam sterilizer should dry the load after sterilization. Optimal drying times will be indicated by the manufacturer’s instructions for use. The density of the load and packaging will influence drying times and thus recommendations for these parameters must be carefully followed. (Dion and Parker 2013)
Instructions for Operating a Gravity Displacement Steam Sterilizer

The best practices for operating a gravity displacement steam sterilizer are to follow the manufacturer’s instructions for use.

General guidance includes the following:

- Ensure that items to be sterilized have been appropriately cleaned and inspected.
- Ensure that items have been wrapped and labeled according to the guidelines.
- Load the items in the sterilizer as described below:
  - The total weight of an individual pack should not exceed 11 kg (24 pounds).
  - At the time of loading, leave sufficient space for steam to circulate freely around the packs. Always leave 3 inches between the top-most pack and the top of the chamber. Items should not touch the chamber wall. Never overload the sterilization chamber.
  - Do not place packages on the floor of the chamber.
  - For trays or racks that have a mesh or perforated bottom, place instrument sets flat on the shelves or rack (see Figure 4-4 b).
  - Do not wrap paper-plastic peel pouches together in one pack unless approved by the manufacturer.
  - Load paper-plastic peel pouches in wire-type baskets to keep the packages in place (see Figure 4-4 d).
  - Place paper-plastic peel pouches on their edges such that the plastic side of one pouch faces the paper side of the adjacent pouch.
  - Load packages containing similar types of item in one load, when possible. For example, all textile packs should be sterilized in one cycle (see Figure 4-4 c).
  - Load instrument containers, such as drums, in a vertical position. Perforations on the side of the drum should be opened by releasing and moving the slotted belt with clamps to allow steam to enter the drum.
  - Do not exceed the allowable load size as per the manufacturer’s instructions.
  - Place linens on top shelves and trays on lower shelves in combination loads of cloth packs and instrument trays (see Figure 4-4 a).
  - Place items such as utensils and glassware that can hold water in a tilted position to avoid water collection.
  - Sterilize liquid and solution bottles separately from all other items. Containers specifically designed (borosilicate heat-resistant glass) for sterilizing liquid should be used. Only gravity displacement cycles are recommended for sterilizing liquids and solution bottles.
  - Follow the manufacturer’s instruction for loading carts and shelves.
    (Acosta-Gnass and Stempliuk 2009; AAMI 2013; Tietjen et al. 2003)
- Follow the recommended cycle parameters per the sterilizer and the items to be sterilized. Typical minimum cycle times for gravity displacement and dynamic-air-removal steam sterilizers are given in Tables 4-2 and 4-3.
Figure 4-4. Loading a Gravity Displacement Steam Sterilizer

Table 4-2. Recommended Cycle Times for Different Types of Packages for Gravity Displacement Steam Sterilizers

<table>
<thead>
<tr>
<th>Items</th>
<th>Exposure Time at 121°C (250°F)</th>
<th>Exposure Time at 132°C (270°F)</th>
<th>Exposure Time at 135°C (275°F)</th>
<th>Drying Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wrapped instruments</td>
<td>30 min</td>
<td>15 min</td>
<td></td>
<td>15–30 min</td>
</tr>
<tr>
<td>Textile packs</td>
<td>30 min</td>
<td>25 min</td>
<td></td>
<td>15 min</td>
</tr>
<tr>
<td>Wrapped utensils</td>
<td>30 min</td>
<td>15 min</td>
<td></td>
<td>15–30 min</td>
</tr>
<tr>
<td>Unwrapped, non-porous items</td>
<td>3 min</td>
<td>3 min</td>
<td></td>
<td>0–1 min</td>
</tr>
<tr>
<td>Unwrapped, non-porous items</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>and porous items in mixed</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>load</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Table 4-3. Recommended Minimum Cycle Times for Different Types of Packages for Dynamic-Air-Removal Steam Sterilizers

<table>
<thead>
<tr>
<th>Items</th>
<th>Exposure Time at 132°C (270°F)</th>
<th>Exposure Time at 135°C (275°F)</th>
<th>Drying Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wrapped instruments</td>
<td>4 min</td>
<td></td>
<td>20–30 min</td>
</tr>
<tr>
<td>Textile packs</td>
<td>4 min</td>
<td></td>
<td>5–20 min</td>
</tr>
<tr>
<td>Wrapped utensils</td>
<td>4 min</td>
<td></td>
<td>20 min</td>
</tr>
<tr>
<td>Unwrapped, non-porous items (e.g., instruments)</td>
<td>3 min</td>
<td></td>
<td>3 min</td>
</tr>
<tr>
<td>Unwrapped, non-porous and porous items in mixed load</td>
<td>4 min</td>
<td></td>
<td>3 min</td>
</tr>
</tbody>
</table>

Instructions for Operating Non-Electric Gravity Displacement (Pressure Cooker-Type) Steam Sterilizers

In small facilities such as primary health care centers in limited resource settings, pressure cooker-type steam sterilizers are sometimes the only options available for sterilization of reusable medical devices.
and surgical instruments (see Figure 4-5). These sterilizers have a small capacity. Follow the manufacturer’s instructions about load size.

Figure 4-5. Non-Electric Gravity Displacement Steam Sterilizer

To operate a non-electric gravity displacement steam sterilizer:

- Clean and dry all instruments to be sterilized.
- Put all jointed instruments in the opened or unlocked position. Disassemble instruments composed of more than one part or sliding parts.
- Wrap clean instruments or other objects as described earlier in this chapter. Instruments should not be held tightly together by rubber bands or any other means that will prevent steam contact with all surfaces. (See the Packaging Medical Devices and Surgical Instruments for Steam Sterilization section in this chapter.)
- Arrange packs loosely in the chamber to allow free circulation and penetration of steam to all surfaces. Follow the manufacturer’s instructions for load size.
- Bring water to boil until steam escapes from the pressure valve; turn down the heat but keep steam coming out of the pressure valve. Do not allow the sterilizer to boil dry. Steam should always be escaping from the pressure valve.
- Sterilize for 30 minutes for wrapped objects, 20 minutes for unwrapped objects. Time with a clock. Start timing only after the temperature and pressure have reached the required parameters.
- After the appropriate time, turn off the heat and wait about 30 minutes (or until the pressure gauge reads zero) to permit the sterilizer to cool sufficiently before opening the lid to allow steam to escape.
- Allow instrument packs to dry completely before removal; this may take an additional 30 minutes. (Damp packs act like a wick, drawing in microorganisms from the environment.) Wrapped instrument packs are considered unacceptable if there are water droplets or visible moisture on the outside of the package when removed from the sterilizer chamber.
- To prevent contamination by condensation, place sterile trays and packs on a surface padded with paper or fabric after removing them from the chamber. (Do not store trays or packs in a plastic dust cover until they reach room temperature; this usually takes about 1 hour.)
After sterilizing, objects wrapped in cloth or paper are considered sterile if they are kept dry and the package intact. Sealing packs in plastic bags can help to prevent damage to the packs and extend their shelf life. Unwrapped objects must be used immediately or placed in a sterile, covered container.

Allow the unwrapped instruments to cool inside the container of the sterilizer. Use the unwrapped, processed instruments immediately.

**Monitoring the Quality of Steam Sterilization**

Given the complexity of the processes and parameters for operating steam sterilizers and potential for human error, it is vital to have protocols for monitoring the quality of sterilization cycles using recommended indicators (O’Hara et al. 2015). Monitoring the quality of the sterilization cycle, at a minimum, should include:

- Monitoring of every package and sterilization load
- Routine monitoring of sterilizer functions
- Monitoring after a major repair or routine maintenance
- Periodic product quality-assurance testing

Achieving the quality of sterile processing depends upon validation of processes, including:

- Installing the sterilizer as per the standard recommended by the manufacturer
- Operating the sterilizer (gravity displacement or pre-vacuum autoclave) as per the manufacturer’s instructions for use
- Monitoring the performance of the sterilization cycle as per the recommended schedule (by the manufacturer or the facility)
- Monitoring the microbiological load on sterile instruments
- Documenting results of each monitoring process

There are three types of devices (see Table 4-4) available for monitoring sterilization cycle quality:

- **Physical monitors** record time, temperature, and pressure and print out the records. The operator should review and document the results at the end of each cycle before clearing the packages for use. The physical monitor installed in the sterilizer machine indicates the temperature at the drain or exhaust line and not in the center of the load:
  
  - Chemical indicators/tests are available in the form of packs, tape, and labels. Chemical indicators assist in detection of potential sterilization failures. There are external and internal indicators.
  
  - Process indicators (Class 1) differentiate between processed and unprocessed items and are available as sterilizer indicator tape and labels. They are generally affixed to each hospital-assembled package or rigid sterilization container system (instruments drums). They generally indicate that the package has been exposed to the physical conditions present in the steam sterilizer. They do not provide any information on the quality of the sterilization process.
  
  - Indicators for use in specific tests (Class 2), such as Bowie-Dick tests, are intended for specific test procedures such as testing for the presence of air pockets in pre-vacuum sterilizers.
Single or multiple variable indicators (Classes 3 and 4) are designed to monitor one or more of the critical variables and intended to indicate exposure to a sterilization process at a specific value of a chosen variable (pressure, temperature, moisture, etc.).

Integrated indicators (Class 5) are designed to react to all critical variables, with a stated value.

Emulating indicators (Class 6) are used to monitor all critical variables of a specified sterilization process.

Internal indicators are placed inside the package or the instrument container in the areas most difficult for the sterilization agent to reach. Depending on the type of internal indicator, it indicates whether a specific parameter or multiple parameters (contact with steam, temperature, humidity, and pressure) was/were achieved. Non-achievement of any of the parameters, specifically the failure of contact with steam, indicates the failure of the cycle, and the whole lot must be reprocessed. All items in the “failed” lot should be rewrapped before reprocessing. Use of biological indicators, described below, is the only option for verifying sterility, whereas chemical indicators measure the quality of the cycle. In facilities where biological indicators are not available, chemical indicators are the only option. One disadvantage of internal indicators is that they can be verified only at the point of use when the package is opened.

Biological indicators are the only method that directly measures the effectiveness (lethality) of the sterilization process. They are intended to demonstrate whether the conditions were adequate to achieve sterilization. They are the only indicators that provide evidence of efficacy by challenging the sterilizer with a large number of highly resistant bacterial spores.

The most commonly available biological indicator is spores of *Geobacillus stearothermophilus* bacteria, formerly called *Bacillus stearothermophilus*. Make sure that the instructions from the manufacturer of the biological indicator and the instructions for the autoclave are consistent in their recommendation on the use of the biological indicator for the autoclave. Follow the manufacturer’s written instructions for storage, handling, use, and microbiological testing of biological indicators. Biological indicators should preferably be used every day but at least every week.

Place a biological indicator in a container specifically designed for it. At the end of the sterilization cycle, send the indicator to the laboratory or central sterile processing area, where it is incubated and the results are interpreted.

Process challenge devices (PCDs) are used to assess the effective performance of the sterilization process by providing a challenge to the process that is equal to or greater than the challenge posed by the most difficult item routinely processed. The PCDs are commercially available but can also be assembled by the user. Depending on the application in sterilization process monitoring, the PCD may contain:

- A biological indicator
- A biological indicator and a Class 5 integrating chemical indicator
- A Class 5 integrating chemical indicator
- A Class 6 emulating indicator

Follow the manufacturer’s instruction while using a specific process challenge device or an indicator. (AAMI 2013)
The indicators mentioned above are use singly or in combination for the following:

- Monitoring of every package and sterilization load
- Routine monitoring of sterilizer efficacy
- Qualification testing of the sterilizer after installation, relocation, sterilizer malfunction, major repair, and sterilization process
- Periodic product quality-assurance testing

### Table 4-4. Types and Applications for Use of Sterilization Monitoring Devices

<table>
<thead>
<tr>
<th>Indicator/Monitor</th>
<th>Frequency of Use</th>
<th>Application (release of sterilizer, package, load)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Physical Monitors</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time, temperature, and pressure recorders, display, digital printout, and gauge</td>
<td>- Should be used for every load of every sterilizer.</td>
<td>- Part of load release criteria</td>
</tr>
<tr>
<td><strong>Chemical Indicators (CIs)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>External CIs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Class 1 (process indicators)</td>
<td>- Should be used on outside of every package unless the internal CI is available.</td>
<td>- Part of load and package release criteria</td>
</tr>
<tr>
<td><strong>Chemical Indicators (CIs)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Class 2 (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>
<td></td>
</tr>
<tr>
<td></td>
<td>- For sterilizer qualification testing (dynamic-air-removal sterilizers only), should be run, within a test pack, after sterilizer installation, relocation, malfunction, and major repairs and after sterilization process failure; test should be run three times consecutively in an empty chamber after biological indicator (BI) tests.</td>
<td></td>
</tr>
</tbody>
</table>
### Sterilization

<table>
<thead>
<tr>
<th>Indicator/Monitor</th>
<th>Frequency of Use</th>
<th>Application (release of sterilizer, package, load)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Internal CIs</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Should be used inside each package.</td>
<td>• Part of package release criteria at use site.</td>
<td></td>
</tr>
<tr>
<td>• Should be used in periodic product quality-assurance testing.</td>
<td>• Part of release criteria for changes made to routinely sterilized items, load configuration, and/or packaging.</td>
<td></td>
</tr>
<tr>
<td>• Part of package release criteria at use site.</td>
<td>• Release criteria should include BI results.</td>
<td></td>
</tr>
<tr>
<td><strong>Class 3 (single-variable indicators)</strong></td>
<td>May be used to meet internal CI recommendation.</td>
<td>• Part of package release criteria at use site.</td>
</tr>
<tr>
<td><strong>Class 4 (multi-variable indicators)</strong></td>
<td></td>
<td>• NOT to be used for release of loads.</td>
</tr>
<tr>
<td><strong>Class 5 (integrating indicators)</strong></td>
<td>May be used to meet internal CI recommendation.</td>
<td>• Part of package release criteria at use site.</td>
</tr>
<tr>
<td>• Within a PCD, may be used to monitor non-implant sterilizer loads.</td>
<td>• Part of load release criteria for non-implant loads.</td>
<td></td>
</tr>
<tr>
<td>• Within a PCD, should be used to monitor each sterilizer load containing implants. The PCD should also contain a BI.</td>
<td>• Part of release criteria for loads containing implants.</td>
<td></td>
</tr>
<tr>
<td>• Except in emergencies, implants should be quarantined until BI results are known.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Class 6 (emulating indicators)</strong></td>
<td>May be used to meet internal CI recommendation.</td>
<td>• Part of package release criteria at use site.</td>
</tr>
<tr>
<td>• Within a PCD, may be used to monitor sterilizer loads.</td>
<td>• Part of load release criteria for non-implant loads.</td>
<td></td>
</tr>
<tr>
<td>• Part of release criteria for loads containing implants.</td>
<td>• Implants should be quarantined until BI results are known, except in emergency situations.</td>
<td></td>
</tr>
</tbody>
</table>
### Biological indicators (BIs)

<table>
<thead>
<tr>
<th>Indicator/Monitor</th>
<th>Frequency of Use</th>
<th>Application (release of sterilizer, package, load)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Within a PCD, may be used to monitor non-implant loads.</strong></td>
<td>• Within a PCD, should be used in every load containing implants. The PCD should also contain a Class 5 integrating indicator. • Within a PCD, should be used for weekly, preferably daily (each day the sterilizer is used), routine sterilizer efficacy testing. (The PCD may also contain a CI.) Should be run in a full load for wrapped items; for table-top sterilization, should be run in a fully loaded chamber; for IUS, should be run in an empty chamber. • Within a PCD, should be used for sterilizer qualification testing (after sterilizer installation, relocation, malfunction, major repairs, sterilization process failures). (The PCD may also contain a CI.) Test should be run three times consecutively in an empty chamber, except for table-top sterilizers, where the test should be run three times consecutively in a full load. • Should be used for periodic product quality-assurance testing.</td>
<td>• Part of load release criteria. • Part of release criteria for loads containing implants. Implants should be quarantined until BI results are known, except in emergency situations. • Part of release criteria for loads containing implants. Except in emergencies, implants should be quarantined until BI results are known. • Part of sterilizer/load release and recall criteria. • Part of release criteria for placing sterilizer into service after qualification testing. • Part of release criteria for changes made to routinely sterilized items, load configuration, and/or packaging.</td>
</tr>
</tbody>
</table>

**Source:** AAMI 2013.

**Actions to take when process challenge tests fail:**

- Do not clear the load for use.
- If the cause of failure was human error, reprocess the load.
- If the cause of failure cannot be immediately identified, quarantine the load; if already released for use, arrange for immediate recall.
- Remove the sterilizer from the service.
- Identify the cause of failure, remove the sterilizer from service, correct the cause, and rerun the test using a PCD on an empty sterilizer three times to confirm the failure to achieve sterilization.
Sterilization

• Send the biological indicator from the failed test to the microbiology laboratory for testing to confirm the presence of test microorganisms on the biological indicator.

Maintenance of Steam Sterilizers

To effectively operate a steam sterilizer and ensure the quality of sterilization, it is important to carry out routine maintenance of the sterilizer based on the results of monitoring of cycle quality. Sterilization process monitoring should be conducted every time a new machine is installed in a health care facility. For routine maintenance of a steam sterilizer, follow the manufacturer’s instructions. The engineering staff at the health care facility should be trained in routine maintenance and minor troubleshooting of the equipment. Health care facilities should have access to a private agency with the capacity to promptly carry out major repairs and maintenance of the machine. A backup machine should be available to continue to provide uninterrupted services.

Dry-Heat Sterilizers

Dry-heat sterilizers are used only for materials that might be damaged by moist heat or that are impenetrable to moist heat (e.g., heat-stable powder, petroleum products, sharp instruments, and heat-stable glassware). Dry-heat sterilizers do not harm the environment but they have a slow rate of heat penetration and microbial killing, which makes this a time-consuming method. To reduce time, higher temperatures are required, but that may damage the items being processed. There are two types of dry-heat sterilizers: the static-air or oven type, which takes a longer time, and the forced-air type, in which air is circulated, via a motorized fan, at high velocity for faster circulation of hot air. Dry-heat sterilizers are used in processing culture plates and other glass items in the laboratory, as well as before destroying pathological samples.

Conditions for Effective Use of Dry-Heat Sterilizers

• Adherence to specific instructions: Instructions about the load, volume, and thermal resistance of the material must be considered at all times.

• Airflow rate and distribution: Irrespective of how airflow and air distribution are managed, they affect heat energy transfer efficiency. The heated air must be distributed uniformly within the load. Optimum air speed reduces microbial resistance by dehydrating cells and thus reduces sterilization time.

• Load configuration and distribution: The size and density of the load as well as the number and shape of the instruments affect airflow and air distribution.

• Temperature: The higher the temperature, the shorter the exposure time (see Table 4-5). The range is from 121–180°C (250–356°F), but 160–170°C (320–338°F) is the optimum.

• Time: The time depends upon the temperature chosen.
Table 4-5. Relationship between Temperature and Time for Sterilization Using Dry Heat

<table>
<thead>
<tr>
<th>Temperature</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>170°C (338°F)</td>
<td>60 minutes</td>
</tr>
<tr>
<td>160°C (320°F)</td>
<td>120 minutes</td>
</tr>
<tr>
<td>150°C (302°F)</td>
<td>150 minutes</td>
</tr>
<tr>
<td>140°C (284°F)</td>
<td>180 minutes</td>
</tr>
<tr>
<td>121°C (250°F)</td>
<td>Overnight</td>
</tr>
</tbody>
</table>

Start timing once the required temperature is reached. Follow the manufacturer’s instruction on temperature and exposure time.

Packaging Items for Dry-Heat Sterilizer
Packaging materials for dry-heat sterilization should allow easy heat penetration, provide an adequate barrier to microorganisms after sterilization, resist tearing or puncturing before and after sterilization, have proven seal integrity, allow for ease of aseptic presentation, be free of toxic ingredients, be low-linting or lint-free, and be cost-effective and readily available. The material should have been approved for use with dry-heat sterilization.

Packaging Materials for Dry-Heat Sterilizer
- Medical-grade paper, bleached crepe paper, cellulose, and synthetic fibers
- Aluminum foil (thicker than domestic use foil)
- Glass bottles, vials, and ampoules for liquids
- Non-perforated glass or metal containers
- Transparent peel pouches approved by the manufacturer for use in dry-heat sterilizers

Steps for packaging materials for dry-heat sterilizers:
- Clean, dry, and inspect all instruments and other items to be sterilized.
- Check the items’ instructions for use to ensure that each item can withstand a temperature from 150–180°C (302–356°F) and will not be damaged at the temperature and exposure time required for sterilization.
- Prepare pouches as described earlier in the chapter.
- Appropriately label the package (product name, lot number, date of processing, expiration statement label, etc.) according to the facility requirements and standards. Use pens that are specially purposed for labeling the pouches.
- If using stainless steel containers, make sure that they are small enough to easily fit in the interior compartment of the dry-heat sterilizer.
- Do not use any item that cannot withstand high temperatures.
- Do not use tape or rubber bands as they do not withstand high temperatures.
Operating a Dry-Heat Sterilizer

- Place the instruments in the dry-heat oven and close the door of the oven. Follow the manufacturer’s instructions for loading the sterilizer, including load size.

- Use Table 4-5 to select exposure time based on the temperature selected. For instruments with sharp edges, select lower temperatures because higher temperatures dull sharp edges.

- Start counting the exposure time after the required temperature is reached. Keep the door of the sterilizer closed throughout the procedure.

- Remove the packs and/or containers from the sterilizer and allow enough time for cooling. Ideally, all items should be wrapped or in containers during sterilization. If not, use sterile forceps to handle any loose items.

- Use loose items immediately or store them in a sterile container. Items that are not wrapped or in sterilization trays are at higher risk for contamination. The trays containing open items should be transported directly from the sterilizer to the point of use. Any item that becomes contaminated should be removed, cleaned, and reprocessed.

Preventing Errors

- Sterilization equipment should be calibrated and processes should be validated.

- The coldest point should have a minimum temperature of 170°C (338°F) for sterilization to be effective.

- Instruments should be wrapped in materials that can withstand high temperatures (aluminum foils, stainless steel containers, peel pouches).

- Do not stack the packages tightly; leave enough room between surfaces.

- Carry out chemical and biological controls on a regular basis as per the manufacturer’s instructions.

Monitoring Quality of Dry-Heat Sterilization Process

- All dry-heat sterilizers should be monitored using biological indicators following installation, relocation, sterilizer malfunction, major repairs, or sterilization process failure. Generally, one test is enough but performing more than one test could provide additional information about any minor issues with the cycle.

- Use a biological indicator containing a process challenge device and place it in the coolest area of the chamber as identified by the manufacturer.

- Appropriately document the test results. Presence of microorganisms on the biological indicator test at the end of the sterilization cycle is the sign of cycle failure and should be investigated.

Sterilization Using Liquid Chemicals

An alternative to high-pressure steam or dry-heat sterilization is chemical sterilization (often called cold sterilization). If objects need to be sterilized, but high-pressure steam or dry heat would damage them, they can be sterilized using chemicals (see Table 4-6).

Many chemicals, both in liquid and gas form, are available for processing instruments. Chemicals that are approved as sterilants can also be used as high-level disinfectants but those approved only for HLD cannot be used as sterilants. Formaldehyde is no longer included as a sterilant or a high-level disinfectant due to its toxicity.
### Table 4-6. Liquid Chemicals Used for Sterilization

<table>
<thead>
<tr>
<th>Chemical</th>
<th>Sterilant</th>
<th>Soak Time for Sterilization</th>
<th>High-Level Disinfectant</th>
<th>Soak Time for HLD</th>
<th>Effective Life</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glutaraldehyde 2–4%</td>
<td>Yes</td>
<td>10 hrs at 20–25°C (68–77°F) or 7 hrs, 40 min at 35°C (95°F)</td>
<td>Yes</td>
<td>20–90 min at 20–25°C (68–77°F)</td>
<td>14 days</td>
</tr>
<tr>
<td>Glutaraldehyde 3.4% and isopropanol 20.1%</td>
<td>Yes</td>
<td>8 hrs at 20°C (68°F)</td>
<td>Yes</td>
<td>10 min at 20°C (68°F)</td>
<td>14 days</td>
</tr>
<tr>
<td>Hydrogen peroxide 7.5%</td>
<td>Yes</td>
<td>6 hrs at 20°C (68°F)</td>
<td>Yes</td>
<td>30 min at 20°C (68°F)</td>
<td>21 days</td>
</tr>
<tr>
<td>Peracetic acid 0.31–0.38%</td>
<td>Yes</td>
<td>2 hrs at 20°C (68°F)</td>
<td>Yes</td>
<td>5 min at 25°C (77°F)</td>
<td>5 days</td>
</tr>
<tr>
<td>Hydrogen peroxide 8.3% and paracetic acid 7%</td>
<td>Yes</td>
<td>5 hrs at 25°C (77°F)</td>
<td>Yes</td>
<td>5 min at 25°C (77°F)</td>
<td>5 days</td>
</tr>
<tr>
<td>Hydrogen peroxide 1.0% and paracetic acid 0.08%</td>
<td>Yes</td>
<td>8 hrs at 20°C (68°F)</td>
<td>Yes</td>
<td>25 min at 20°C (68°F)</td>
<td>14 days</td>
</tr>
</tbody>
</table>

Adapted from: FDA 2015; Rutala et al. 2008.

The exposure time and concentrations may vary based on manufacturers’ instructions for use as approved by the FDA. Test strips must be used to determine if the solution has an adequate concentration of the active ingredient to ensure sterilization.

The liquid chemical sterilization process can be carried out manually (see Table 4-7) or using a dedicated mechanical device.
Sterilization

Table 4-7. General Guidelines for Chemical Sterilization Using a Manual Approach

<table>
<thead>
<tr>
<th>Guidelines for Chemical Sterilization: Manual Approach</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Choose the most appropriate chemical sterilant from those approved for use in your country. Consider health and safety, effectiveness, cost-effectiveness, and compatibility with the instruments being processed.</td>
</tr>
<tr>
<td>• Ensure that the area where chemical sterilization is to take place is well-ventilated, is freestanding, or has a vented chemical-fume hood.</td>
</tr>
<tr>
<td>• Clean, dry, and inspect the instruments. Follow cleaning instructions (see Chapter 2, Cleaning and Preparing Surgical Instruments and Medical Devices for Disinfection or Sterilization, in this module).</td>
</tr>
<tr>
<td>• Identify if the chemical is single-use or reusable.</td>
</tr>
<tr>
<td>• Check the expiry date on the container.</td>
</tr>
<tr>
<td>• Prepare chemical sterilant solution following the instructions for use.</td>
</tr>
<tr>
<td>• Use test strips or chemical monitoring to assess the effectiveness of the solution.</td>
</tr>
<tr>
<td>• Use an appropriately sized container made from inert materials, such as medical-grade plastic, with a tight-fitting lid.</td>
</tr>
<tr>
<td>• Label the container with the date of first use (opening of the container for the first time).</td>
</tr>
<tr>
<td>• Verify that any solution that is being reused is within the expiry date (confirm from the date the solution was activated or the expiry date).</td>
</tr>
<tr>
<td>• Immerse instruments in the chemical for the recommended period of time at a set temperature.</td>
</tr>
<tr>
<td>• Remove instruments from the chemical and put them in a container with sterile water. There should be at least two containers to rinse items. Follow the manufacturer’s instructions on the type of water used and the rinsing steps. Flush smaller lumens and canals with a syringe to push water through them.</td>
</tr>
<tr>
<td>• Follow specific instructions for number of rinses and rinsing solution (boiled, cooled, and filtered water or rinsing with alcohol).</td>
</tr>
<tr>
<td>• Allow instruments to dry completely.</td>
</tr>
<tr>
<td>• Use immediately or place in a sterile container until used.</td>
</tr>
</tbody>
</table>

Storage and Disposal of Liquid Chemical Sterilants

• The storage containers should be narrow and deep rather than large and shallow.
• Reusable solutions should be stored in closed containers in a well-ventilated area.
• The containers for soaking should always be covered with lids and clearly labeled.
• Follow manufacturer’s instructions for disposing of solution that is not effective or has expired.

Liquid Chemical Sterilants

Glutaraldehyde

Glutaraldehyde is an aqueous solution available as acidic solution in 2–4% concentration. It must be activated by the addition of an alkalinizing agent so that it becomes sporicidal. Once activated it has a shelf life of 14 days. The effective life of activated solution is a function of time and not the number of times it is used; however, if instruments are not thoroughly dry, the effectiveness will reduce before the 14 days of shelf life. Glutaraldehyde kills microorganisms by altering protein synthesis processes. It kills all microbes including bacterial spores. The soak time depends upon the temperature of the solution (see Table 4-6). Use chemical strips to test the effectiveness of the solution. Frequency of testing depends upon frequency of use, for example, testing daily, weekly, or when used, or every 10 uses, etc.
It is also used in combination with other liquid chemicals. Since glutaraldehyde has several side effects, the HCW carrying out instrument processing using glutaraldehyde should wear recommended PPE and work in a well-ventilated area with a minimum of 7–15 air exchanges per hour. Expired solutions must be neutralized per manufacturer’s instructions for use, but once neutralized can be discarded in a normal drainage system. (Acosta-Gnass and Stempiuk 2009; OSHA 2006; Rutala et al. 2008)

**Hydrogen peroxide**

Hydrogen peroxide can be used to achieve both HLD and sterilization. It has activity against a wide range of microorganisms including vegetative bacteria, fungi, and viruses. Hydrogen peroxide does not damage glass and plastic articles and is safe on ventilators. There are concerns about its compatibility with selected metals, so approval from the device manufacturer should be obtained prior to use of this method on items where corrosion would be a concern. It has low toxicity and irritancy rating. No activation is required.

To achieve sterilization, a higher concentration (7.5% solution) and a longer contact time (6 hours at 20°C [68°F]) are required. Follow the manufacturer’s instructions for product-specific contact time. After the first use, hydrogen peroxide can be used for a maximum 21 days. The concentration of hydrogen peroxide must be monitored regularly by testing the minimum effective concentration. Items processed using hydrogen peroxide should be thoroughly rinsed with plenty of sterile water. Chemical irritation has been identified in an endoscopy unit where endoscopes were disinfected with hydrogen peroxide.

Fully immerse the instruments in the solution. Use a test strip to make sure that the concentration of the solution is appropriate for the next cycle. Solution that evaporates below the level that permits immersion of the device should not be topped off. Instead, the entire solution should be discarded and new solution should be prepared. (Rutala et al. 2008)

**Peracetic acid**

Peracetic acid is a highly biocidal agent that is effective in the presence of organic substances. It is used in automated machines to sterilize medical devices, including different types of endoscopes and arthroscopes. A 35% solution with an anticorrosive agent is commonly used as a low-temperature sterilization agent. It needs to be diluted to 0.2% using filter water at a temperature of 50°C (122°F) with exposure time of 12 minutes. The contact time depends upon the concentration and temperature. Peracetic acid can be used in automated systems and manually in a tray. Some manufacturers do not recommend using peracetic acid for their endoscopes. Always refer to the manufacturer’s instructions for use.

Inhalation of vapors may cause irritation of the eyes, nose, throat, and lungs. Vapors may result in coughing and breathing difficulty and pulmonary edema as a result of long-term exposure to higher concentrations.

General instructions for use are the same as for other chemical sterilants. Solutions should be diluted with at least 20 parts of water before disposal. Undiluted material should not be allowed to enter storm or sanitary sewer systems nor should they be mixed with hypochlorite solutions. (Rutala et al. 2008)

Hydrogen peroxide (1%) in combination with peracetic acid (0.08%) is available for both HLD and sterilization. The contact time for sterilization is 8 hours at 20°C (68°F). The concentration of both hydrogen peroxide and peracetic acid varies in different products. Always follow the manufacturer’s instructions for use.
Sterilization

Chemical Gas Sterilization
Since the 1950s, ethylene oxide (ETO) gas has been widely used to sterilize heat- and moisture-sensitive devices in high-income countries and the pharmaceutical industry. ETO gas sterilizers are available in multiple sizes including a small, table-top version with small capacity. Machines use specifically designed ETO cartridges. These cartridges are refillable. The availability and use of ETO gas sterilizers has grown in limited-resource settings in recent years.

The ETO gas sterilization process can be used for sterilizing the following items:

- Electronic items (cameras, electrocautery cords, thoracic ventilator valves, laptop computers, and flashlights)
- Implants and invasive items (contraceptive implants, in vitro fertilization materials, needle holders, ventricular leads, and skin staplers)
- Plastic and paper (drape material, catheters, endotracheal tubes, plastic bottles, syringes, etc.)
- Heat-sensitive surgical instruments (electronics, drills, sharps, temperature probes, wire cutters, etc.)
- Disposable and reusable items (anesthesia masks, cannula, catheters, feeding sets, etc.)

ETO is a colorless gas that is flammable and explosive. Four essential parameters for using ETO are gas concentration (450–1,200 mg/L), temperature (37–63°C [98.6–145.4°F]), relative humidity (40–80%), and exposure time (1–6 hours). The average cycle time is much longer than the steam sterilization cycle. It kills microorganisms by alkylation of proteins.

Basic sterilization cycle using ETO gas consists of five stages:
1. Preconditioning and humidification
2. Gas introduction
3. Exposure
4. Evacuation
5. Air wash

All five stages take about 2–2.5 hours and do not including aeration time. The aeration time is generally 8–12 hours at 50–60°C (122–140°F).

ETO is an irritant to skin, eyes, and mucous membranes of the mouth and gut. It is considered to be a carcinogen to humans.

Packaging for Ethylene Oxide Sterilization
- Many porous materials and sealing styles may be used in ETO sterilization, except polyester/cotton textile. Sealed containers should not be used. Use packaging materials recommended by the manufacturer.
- Place an internal chemical indicator inside each package.
- Place an external chemical indicator outside of each package.
Loading and Unloading the Ethylene Oxide Gas Sterilizer

- Follow the manufacturer’s instruction for loading. Avoid overloading the chamber.
- Allow the recommended aeration time before opening the sterilization chamber.
- Do not open the chamber during aeration time to remove any package.

Monitoring the Quality of the Ethylene Oxide Sterilization Process

Monitoring the quality of the sterilization cycle using ETO should be carried out at the time of installation, before the first use, and on a routine basis as per the recommendations of the manufacturer. Monitoring should include both microbiological and physical performance of the equipment.

For the purpose of routine monitoring and control, use a biological indicator with each load and a chemical indicator with each package. Use biological indicators with 4 hours of read-out time.

Sterilization of Prion-Contaminated Instruments

Prion diseases, such as Creutzfeldt-Jakob disease (CJD), are a family of neurodegenerative diseases that affect humans and animals (dogs, cows, and primates). They have long incubation periods and are typically rapidly fatal once symptoms develop. Most cases of CJD are sporadic with unknown modes of transmission; 10–15% are inherited, and a small number have been transmitted via medical procedures. In humans, CJD remains rare with an incidence of less than 1 per million in the general population (CDC 2017). CJD poses a unique infection prevention problem because prions, which are protein-containing infectious agents, can survive the standard heat or high-pressure steam sterilization processes. In addition, chemical disinfectants, including sterilants such as glutaraldehydes and formaldehyde, do not eliminate prion infectivity on contaminated instruments and other items. Therefore, special treatment is required for surgical instruments and other critical devices contaminated with high-risk tissue (i.e., brain, spinal cord, and eye tissue) from patients with known or suspected CJD. (Rutala and Weber 2010)

Basic guidelines for known or suspected prion disease cases:

- Standard Precautions should be practiced all the time for all patients, including patients with known or suspected CJD.
- Environmental surfaces and equipment not in use should be covered with disposable, permeable sheets (e.g., plastic) during cases involving known or suspected prion disease.
- Environmental surfaces and non-critical equipment (as per the Spaulding classification) should be cleaned with 0.5–1% sodium hypochlorite solution with a contact time of 15 minutes.
- Immediate-use sterilization (flash sterilization) should never be used.
- Single-use devices and equipment should be used as much as possible.
- All single-use devices and devices that are very difficult to sterilize due to their design should be discarded after use on patients with prion diseases.
- If any reusable devices are used, they should be processed following recommended guidelines (see the section below). If this is not possible, they must be discarded.
Decontamination of Prion-Contaminated Medical Devices

- **Incineration:**
  - Incinerate all disposable instruments, materials, and waste. It is the preferred method for all instruments exposed to high-infectivity tissue.

- **Autoclave/chemical methods for heat-resistant instruments:**
  - Immerse in sodium hydroxide (NaOH) and heat in a gravity displacement autoclave at 121°C (250°F) for 30 minutes; clean; rinse in water; and subject to routine sterilization.
  - Immerse in NaOH or sodium hypochlorite for 1 hour; transfer instruments to water; heat in a gravity displacement autoclave at 121°C (250°F) for 1 hour; clean; and subject to routine sterilization.
  - Immerse in NaOH or sodium hypochlorite for 1 hour; remove and rinse in water; then transfer to an open pan and heat in a gravity displacement (121°C [250°F]) or porous load (134°C [273°F]) autoclave for 1 hour; clean; and subject to routine sterilization.
  - Immerse in NaOH and boil for 10 minutes at atmospheric pressure; clean; rinse in water; and subject to routine sterilization.
  - Immerse in sodium hypochlorite (preferred) or NaOH (alternative) at ambient temperature for 1 hour; clean; rinse in water; and subject to routine sterilization.
  - Autoclave at 134°C (273°F) for 18 minutes.

- **Chemical methods for surfaces and heat-sensitive instruments:**
  - Flood with 2N NaOH (1 N NaOH is a solution of 40 grams [1.4 ounces] NaOH in 1 liter [4.2 cups] of water) or undiluted sodium hypochlorite; let stand for 1 hour; mop up; and rinse with water.
  - Where surfaces cannot tolerate NaOH or hypochlorite, thorough cleaning will remove most infectivity by dilution.

- **Autoclave/chemical methods for dry goods:**
  - Small dry goods that can withstand either NaOH or sodium hypochlorite should first be immersed in one or the other solution (as described above) and then heated in a porous-load autoclave at ≥ 121°C (250°F) for 1 hour.
  - Bulky dry goods or dry goods of any size that cannot withstand exposure to NaOH or sodium hypochlorite should be heated in a porous-load autoclave at 134°C (273°F) for 1 hour.
  - Staff processing instruments should wear recommended PPE (gown, mask, face shield, and utility gloves). There is no need for additional PPE.
  - Clean instruments using enzymatic detergent and thoroughly dry them.

(WHO 2000)

Handling Sterile Surgical Instruments and Medical Devices

**Shelf Life of Sterile Packages**

The shelf life of a sterile item depends on the following factors:

- Quality of the wrapping materials, wrapping methods, and use of the container
- Number of times a package is handled (limit to three or four times)
Sterilization

- Whether the package is stored on open or closed shelves
- Condition of the storage area (e.g., temperature, humidity, and cleanliness)
- Stacking of packs on top of each other and overcrowding of shelves and cabinets
- Use of plastic dust covers and method of sealing
- Events occurring in the storage area (e.g., water/steam leaks, splashes)

(AORN 1992)

- Most packages are contaminated as a direct result of frequent or improper handling or storage. (Gruendemann and Mangum 2001) (See the Storing Sterile Surgical Instruments and Medical Devices and Handling Sterile Surgical Instruments and Medical Devices sections in this chapter for detailed information on the recommended techniques.)

The shelf life of an item after sterilization can be managed by predetermined expiry dates or an event-related system can be used:

- Expiry-date shelf-life method: Sterile packs and drums are labeled with an expiry date after which the items must be reprocessed. This process serves as a reminder but does not guarantee sterility of the packs within the given date. Sterility within the expiry date can be compromised by many factors.

- Event-related shelf-life method: The item remains sterile until something causes the package or container to become contaminated; time elapsed since sterilization is not the determining factor. An event can be a tear or worn area in the wrapping, the package becoming wet, adverse conditions in the storage area, or anything else that could possibly enable microorganisms to enter the package or container. These events can occur at any time. For supplies included in the sterile pack that degrade over time (e.g., latex-containing products), an expiration date will be needed to indicate when these particular contents will no longer be able to be used (based on the expiration date of the supplies).

In many health care facilities resources for, and availability of, high-quality disposable supplies are limited; cloth is used for wrapping sterile packs; drums with dents, scratches, and rust are used; and sterilizing equipment, processes, and monitoring are not always reliable. In the presence of any of these issues, an expiry-date system for determining shelf life (e.g., 1 month) is recommended as a safety margin. Likewise, if plastic covers (bags) are unavailable for slow turnover sterilized supplies, limiting the shelf life with an expiry date may be a reasonable decision.

If appropriate packaging is used (i.e., medical-grade paper, polyethylene/polypropylene pouches, or well-maintained drums in excellent condition) and sterile packages are sealed in polyethylene bags and stored in a closed cabinet in a dedicated storage area, the instruments can remain sterile for long periods (up to 2–5 years) if not handled. (Acosta-Gnass and Stempiuik 2009)

**Storing Sterile Surgical Instruments and Medical Devices**

It is essential to store sterilized surgical instruments and medical devices in such a way that the sterility of the items is maintained until the time they are used. (See the Design and Space Requirements of Central Sterile Supply and Instrument Processing Areas section in Module 5, Chapter 1, Facility Design, Traffic Flow, and Work Practices in Health Care Facilities.) Below are key measures to maintain the shelf life of sterile items (i.e., for how long items can be considered sterile):
Sterilization

- Store sterile items in a cool, dry, and well-ventilated place, either:
  - In a closed cabinet, or
  - On an open shelf in a room for clean/sterile supplies.

To protect them from splashes and contamination, sterile items should never be stored in the open in areas where patient care is provided. This includes patient care areas such as wards and OTs.

- Entry to the sterile supply storage room/cabinet should be limited to authorized staff only. (For details on the sterile storage area, see the Central Sterile Supply Department section of Module 5, Chapter 1, Facility Design, Traffic Flow, and Work Practices in Health Care Facilities.)

- For items stored on open shelves:
  - Sterile packs should be covered with plastic dust covers to maintain sterility. Use covers (polyethylene bags) to protect items from dust and humidity and prolong storage time. These covers should be self-sealing for covering the sterile packs and are not materials for packaging items for sterile processing. Use the covers only after the packs are completely dry and cool. Dust covers should be removed at the time of use.
  - Shelves need a solid top (to protect from dust and drips from above) and a solid bottom shelf to protect from dirt and splashes from below.

- Store all sterile items away from the floor, ceiling, and outside walls to allow for adequate air circulation, ease of cleaning, prevention of condensation, and compliance with local fire codes. Sterile items should be stored at least 20–25 cm (8–10 inches) above the floor, at least 46 cm (18 inches) below the ceiling (or the level of fire sprinkler heads if any), and at least 5 cm (2 inches) from outside walls.

- Do not use cardboard boxes for storage. Cardboard boxes shed dust and debris and may harbor insects.

- Manage the sterile supply stock:
  - Rotate the supplies following a first in/first out (FIFO) method to ensure that the oldest items get used before the newly sterilized stock.
  - Develop a system to ensure that items in which the sterility has been compromised or the expiry date is past do not reach the patient. These items must be routinely identified and sent for reprocessing.

(AAMI 2013)

Transporting and Preparing Sterile Surgical Instruments and Medical Devices for Use

In large hospitals, there should be dedicated elevators and transportation routes for sterile items from the central storage area to the OT and other areas of the hospital performing procedures. (For a sample floorplan of the cleaning, HLD, and sterilization areas of a health care facility, See Module 5, Chapter 1, Facility Design, Traffic Flow, and Work Practices in Health Care Facilities.)

- Perform hand hygiene before touching and handling sterile packages.
- Use trolleys for transporting volumes of sterile packs to the operating area. Use trolleys dedicated solely to transporting sterile supplies.
- Do not stack heavy packs on top of each other during transport as this may damage the integrity of the wrappers.
• Hold sterile packs parallel to the floor if transported by hand.

• Use a protective cover to protect packages during transportation.

• Open sterile packages carefully:
  • Open sterile packs in the procedure area just prior to the procedure. (See the Procedure Area Design and Space Requirements section in Module 5, Chapter 1, Facility Design, Traffic Flow, and Work Practices in Health Care Facilities.)
  • Do not leave open packs unattended. Unattended opened sterile packs are considered contaminated (as sterility may have been compromised while unobserved).
  • Place the pack on a sterile surface at or above the level of the sterile field nearest to the person who will open it.
  • Inspect sterile packages for integrity before opening and observe the presence of an indicator that shows that the package has been processed.
  • Remove the seal or the tape to open the sterile pack and unfold the package layer by layer without touching the contents.
  • Inspect any internal process indicator if it was placed inside the package.

• Transfer sterile items to the sterile field:
  • Ensure that the person removing the sterile items from the package wears appropriate PPE for the location and procedure being performed. (See Module 3, Chapter 1, Personal Protective Equipment.)
  • Do not touch the edges and the outer side of the package or the surface while transferring sterile items to the sterile field.

(Acosta-Gnass and Stempliuk 2009)

Summary

Sterilization of medical devices and surgical instruments plays a vital role in reducing surgical site infections and infection as a result of other invasive procedures. Steam under pressure at a high temperature is the most widely used method of sterilization. The quality of the sterilization process depends upon several parameters, including that HCWs conduct the sterilization procedure correctly. Monitoring the quality of the sterilization process as well as appropriately following recommendations will assist health care facilities in optimizing the safety of sterile medical devices and surgical instruments used for patient care.
References


FDA. 2015. FDA-Cleared Sterilants and High Level Disinfectants with General Claims for Processing Reusable Medical and Dental Devices – March 2015.


Sterilization
Chapter 5. Reprocessing Single-Use Devices

Key Topics
- Single-use devices (SUDs) that should not be reprocessed
- Recommendations for developing guidelines for reprocessing SUDs
- Reprocessing SUDs in limited resource settings

Key Terms
- **Medical device** is an item that is used to diagnose, treat, or prevent disease, and is not a drug.
- **Reprocessing** involves decontaminating, disassembling (if necessary), cleaning, inspecting, functional testing, repackaging, relabeling, and sterilizing or high-level disinfecting an SUD after it has been used on a patient for its intended purpose.
- **Single-use device (SUD)** is a medical device designated by the manufacturer to be used on one patient for one procedure and then discarded.

Background
Standards and recommendations for safe reprocessing of SUDs exist in some high-income countries, but for many countries there are no legislation or quality standards for reprocessing SUDs. Patterns of reprocessing SUDs differ according to the setting. SUDs reprocessed in high-income countries tend toward the more expensive, complex devices; in limited resource settings, reprocessed SUDs typically include less expensive medical devices (e.g., syringes, needles, gloves, urinary catheters, stomach and rectal tubes, drains, lancets, and indwelling venous cannula). Therefore, practices in the reprocessing of SUDs vary widely across countries or regions within countries and individual facilities.

In limited-resource settings, 25–80% of health care facilities reprocess SUDs. In these settings, SUDs are commonly reused for a variety of reasons, including cost constraints, lack of replacements, and community beliefs. Reporting on adverse outcomes associated with the reprocessing of SUDs is voluntary and therefore data on adverse outcomes are also limited. (Popp et al. 2010; Shuman and Chenoweth 2012; WHO 2003b).

The ideal way to prevent adverse outcomes, protect patient safety, ensure device performance, and preserve the public’s confidence in the quality of medical devices is through regulation, policy guidance, and standardized practices for reprocessing SUDs. These are absent in many settings. Ministries of health, professional institutions, and organizations should support the needs of facilities by developing and implementing regulations and guidelines using global, evidence-based recommendations. (Collier 2011; Popp et al. 2010; WHO 2003b)

This chapter provides some basic infection prevention and control (IPC) considerations for health care facilities in limited resource settings on decisions about reprocessing SUDs. Safety of the patient must always be the primary consideration.
Developing Guidelines for Reprocessing Single-Use Devices at Health Care Facilities: Recommendations

National-level regulatory bodies within ministries of health should make every effort to provide health care facilities within their jurisdictions with appropriate guidance for the reprocessing of SUDs. This can be achieved by establishing a national multidisciplinary workgroup to review issues involving reprocessing of SUDs.

In the absence of national efforts, health care facilities will need to develop their own guidelines for reprocessing of SUDs. This can be achieved by establishing a multidisciplinary workgroup at the facility level.

The following guidance can assist in the process of developing guidelines for reprocessing of SUDs:

- Identify “reprocessing champions” who are in a leadership position and can offer technical guidance on reprocessing and advocate for appropriate approaches.
- Develop a multidisciplinary workgroup that includes ministry of health staff, health care facility managers, legal advisors, and administrative and IPC staff.
- Charge the multidisciplinary workgroup with the task of preparing guidelines that are in compliance with national legal provisions (where existing) and policies for health care facilities in the reprocessing of SUDs.
- Provide guidelines that include:
  - The types of SUDs and the number of times each device can be reprocessed
  - The recommended procedures for reprocessing
  - The quality assurance and control measures that should be taken
  - Conditions under which a device should not be reprocessed and should be discarded
- Ensure inclusion of methods to show that the devices are functioning properly after each reprocessing cycle.
- Provide recommendations for the training of staff at health care facilities on how to reprocess SUDs, including cleaning, testing for functionality, disinfection/sterilization, and storage.
- Consider cost factors, including staff compliance with the guidelines, types of SUDs that can be reused, risk assessment findings and the cost of these risks, and how quickly the guidelines can be implemented.
- Follow the device manufacturer’s recommendations for use when making decisions about reprocessing any SUD.
- Develop methods for tracking the use of reprocessed SUDs.
- Include reporting of adverse events that are related to the SUDs in surveillance of health care-associated infections and other adverse events.

(APIC 2014; AORN 2013; FDA 2003; WHO 2003b)
Reprocessing Single-Use Devices

Risk Assessment and Classification of Single-Use Devices

Risk Assessments for Reprocessing Single-Use Devices

A risk assessment should be conducted for each SUD that is being considered for reprocessing. The assessment should look into the likelihood of adverse events and hazards to the patients and health care workers (HCWs) before decisions on reprocessing any SUD are made (WHO 2003b). Cost savings and the availability of resources must not, in any way, supersede safety when it comes to deciding whether to reprocess SUDs.

Ideally, the risk assessment should be conducted at the national level by a national regulatory body such as a division or technical working group of the ministry of health. In absence of national regulation and guidelines, to assist decision-making for each SUD, a risk assessment should be conducted by the health care facility prior to reprocessing.

The decision to reprocess a specific SUD should be based on a standardized risk assessment that includes the complexity of the device and the procedure for which it is used.

Spaulding Categories

SUDs should be divided into non-critical, semi-critical, or critical devices depending on their contact with intact skin, mucous membranes, or normally sterile tissues and body cavities. This classification system was developed by Earle H. Spaulding as a strategy that could be used to determine the level of processing for medical devices:

- **Non-critical**: contact with intact skin
- **Semi-critical**: contact with intact mucous membranes but no penetration of normally sterile tissues of the body
- **Critical**: contact with normally sterile tissues or body spaces

Risk Assessment Categories

The complexity of the device can also be assigned to a risk category:

- **Category 1**: lowest risk
- **Category 2**: moderate risk
- **Category 3**: highest risk

An SUD may be low risk even if it is used for a critical procedure. Two considerations—contact with the body and complexity of the device—can help to determine potential risk of infection to the patient and HCWs (see Table 5-1). (FDA 2003)

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1 High-risk devices include equipment at high risk of being infected with the causative agents of Creutzfeldt-Jakob disease. (FDA 2003; FDA 2006)
Reprocessing Single-Use Devices

Table 5-1. Risk Assessment Categories for Reprocessing SUDs

<table>
<thead>
<tr>
<th>Criticality</th>
<th>Category 1: Low Risk</th>
<th>Category 2: Moderate Risk</th>
<th>Category 3: High Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-critical</td>
<td>Blood pressure cuff, breathing mouth piece</td>
<td>Laparoscopic insufflator, respiratory gas mask</td>
<td>Oximeter</td>
</tr>
<tr>
<td>Semi-critical</td>
<td>Surgical knife</td>
<td>Urological catheter, respiratory therapy and anesthesia breathing circuit, airway connector</td>
<td></td>
</tr>
<tr>
<td>Critical</td>
<td>Needle holder, blood lancet, episiotomy scissors, umbilical scissors, orthopedic surgical drill, needle holder</td>
<td>Gastro/urology biopsy punch, laparoscopic scissors and dissectors, ophthalmic surgical drape, endoscopic blade</td>
<td>Angiography catheter, cardiac guide wire, vascular clamp, dental needle, bronchoscopy biopsy forceps, hypodermic needle, endotracheal tube</td>
</tr>
</tbody>
</table>

Adapted from: FDA 2003.

Classes of Risk
Medical devices are also classified as Classes I, II, and III. Class I devices present the lowest potential risk to the patient and carry the fewest regulations when it comes to reprocessing and reusing. Class III devices pose the greatest potential risk and require the greatest number of regulations. Currently, in the United States, only SUDs in the low- to medium-risk categories (Classes I and II) have been approved by the regulatory body for reprocessing. No Class III SUDs have been approved for reprocessing. (APIC 2014; FDA 2006; FDA 2014)

Single-Use Devices That Should Never Be Reprocessed

Syringes and Needles
The reprocessing and reuse of syringes and needles is never recommended. This practice should not be encouraged or allowed in medical practice anywhere in the world. The literature and public health organizations warn against the risk of transmitting bloodborne diseases by using reprocessed, single-use syringes and needles (see Module 4, Chapter 1, Injection Safety). (WHO 2003a)

Disposable Gloves
Reprocessing of gloves, except for heavy-duty utility gloves, is also never recommended and should be avoided despite historic practices in many health care settings where glove supply is limited (see Module 3, Chapter 1, Personal Protective Equipment). (WHO, World Alliance for Patient Safety 2006)

Reprocessing Single-Use Devices in Low- and Middle-Income Countries
Procedures for reprocessing SUDs are the same as those for reprocessing reusable devices (see Module 6, Processing Surgical Instruments and Medical Devices). The steps include:

- Point-of-use processing: prompt, initial treatment to remove and/or prevent drying of soil and contaminants
- Disassembling (if necessary)
- Thorough cleaning
- Inspection and functional testing to ensure the item remains functional
- Repackaging and relabeling (if possible)
- Disinfection (high-, intermediate-, or low-level, based on the intended use) or sterilization

All steps should be carried out in compliance with IPC policies and guidelines and be performed by trained HCWs who understand the risks to both patients and HCWs.

**Summary**

Globally, practices in the reprocessing of SUDs vary widely. Ministries of health and health care facilities should review evidence-based guidance, regulations, and proper resource allocation when considering the reuse of SUDs. Guidelines for reprocessing SUDs should be developed, ideally at the national level. All countries should increase attention to safety priorities and standardization of regulatory practices for the reprocessing of SUDs.

Reprocessing of SUDs is risky but possible if supported by a risk assessment and appropriate processing guidelines are followed. Cost savings and the availability of resources must not supersede safety when it comes to deciding whether to reprocess SUDs. The reprocessing of SUDs should be guided by IPC principles and performed by trained HCWs who understand the risks to both patients and HCWs.
Reprocessing Single-Use Devices

References


