Essentials of Healthcare Steam Sterilization

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Objectives:

• Understand the importance of cleaning and disinfection to effective sterilization

• Understand why sterilization is important

• Be capable of discussing two types of steam sterilizers and cycles

• Understand why steam is the most widely preferred sterilant

• Understand critical factors that affect sterilization efficacy

• Understand how a steam sterilizer works

• Understand why “flash” is now immediate-use steam sterilization or IUSS
Bioburden

Bioburden = microbiological “load” or the number of viable organisms in or on the surfaces of inanimate objects.

Bioburden can also refer to organic material on the object.

In the Healthcare environment, Bioburden usually refers to microorganisms that cause infection and diseases.
Transmission of Infectious Diseases

Infectious diseases are usually qualified as contagious.

Transmission may occur through one or more diverse pathways.

Infectious diseases can be transmitted through:

• Physical contact
• Liquids
• Food
• Body fluids
• Contaminated objects
• Airborne inhalation
Microbicidal Processes

Cleaning – process of removing dirt and other soils, but does not kill microorganisms and spores.

Disinfection – process capable of destroying all pathogenic microorganisms, but not bacterial spores.

Sterilization – process capable of destroying all forms of microbial life on inanimate surfaces, including bacterial spores.
Cleaning

Process used for removing dirt, soils, and other organic & inorganic bioburden from medical devices

Process capable of reducing the number of microbial contaminants by removing them, but is not intended to destroy organisms

Disinfection and sterilization processes will be ineffective without adequate cleaning

Manual cleaning in a detergent solution can be effective but is not consistently repeatable

Mechanical cleaning is preferred due to a consistent level of cleaning each time, the reduced risk to workers and thermal disinfection
Disinfection

The process of destroying vegetative, pathogenic microorganisms on medical devices via heat or chemical means

Two most common methods of disinfection are:

1. Moist Heat
2. Liquid Chemicals

Moist heat is preferred method because:

- Easily controlled
- Relatively safe
- Non-toxic
1. Cleaning
   • Removal of bio-burden
     • Rinsing
     • Mechanical removal of soils
     • Mechanical vs. manual scrubbing
     • Ultrasonic Energy
     • Chemistry

2. Disinfection
   – Chemical
   – Thermal

3. Sterilization
   • Chemical
     • Liquid or vapor
   • Thermal
     • Dry heat or moist heat
Define Sterilization

Sterilization is defined as:

“A process that destroys all microorganisms (including bacterial spores) on the surface of an article or in a fluid to prevent disease transmission associated with the use of that item.”
PRINCIPLES OF STERILIZATION
INTRODUCTION

**Sterilization:** *A process by which all forms of microbial life including bacteria, viruses, spores, and fungi are destroyed*

- **Note:** In a sterilization process, the nature of microbial death is described by an exponential function. Therefore, the presence of microorganisms on any individual item can be expressed in terms of probability. While this probability can be reduced to a very low number, it can never be reduced to zero. (ANSI/AAMI ST46)
Why Is Sterilization Important?

Cleaning is used to render medical devices “safe to handle” for further processing, including terminal sterilization.

Cleaning & disinfection protects workers and patients who come into contact with non-critical and semi-critical reusable medical devices.

Sterilization protects workers and patients from contracting diseases caused by bacteria and spores when exposed to reusable medical devices during sterile surgical procedures.

The most important role of sterilization is that the process will inactivate & destroy bacterial spores.
PRINCIPLES OF STERILIZATION
TYPES OF STERILIZERS

ETO (Ethylene oxide)
Gas Plasma
VHP
Formaldehyde
Ozone

Moist Heat (Steam)
Dry Heat (Air)

Low Temp
High Temp
Steam Sterilization Cycles

There are two basic steam cycles:

- Dynamic air removal (DAR) commonly known as Pre-vacuum
- Gravity-displacement

**Dynamic Air Removal** steam sterilizers work by actively removing air from the sterilizer chamber using a series of vacuums.

**Gravity Displacement** steam sterilizers work by building up an amount of steam to fill the chamber, then releases the steam into the chamber forcing the air out through the drain.
PRINCIPLES OF STERILIZATION
TYPICAL HEALTHCARE STERILIZATION CYCLES

Gravity:
• Typically used for individual unwrapped surgical instruments; or instruments protected for aseptic transfer

Vacuum:
• Typically used for large volumes of wrapped surgical instrument trays or containerized instrument sets
Steam Sterilization

Steam is a simple and inexpensive sterilization method with many benefits.

It produces little waste and is a very effective way to kill microbial organisms.

Steam sterilization is the oldest, safest, cheapest, and most understood method of sterilization.

Principles of steam sterilization have not changed during the past century – despite advancements in machine design and alternate sterilization methods (low temp for example).
Characteristics of Steam

Steam is water vapor and represents a physical state of water.

Steam is an ideal sterilant because it is:

- Nontoxic
- Readily available
- Economical
- Easy to control
- Highly Effective

Saturated steam kills microorganisms by denaturing the protein.

This is a fast and efficient method and is the most common form of sterilization used in Healthcare facilities.
Steam Sterilization

- Four factors are required to ensure effective steam sterilization:
  - adequate exposure time
  - correct exposure temperature
  - presence of moisture
  - removal of air
- Adherence to these basic principles ensures safe and efficacious steam sterilization outcomes by health care facilities and device manufacturers.

Surfaces to be sterilized must be heated to and maintained at a high enough temperature with adequate moisture present for a prescribed time.
PRINCIPLES OF STERILIZATION
PROCESS EFFICACY

• **Steam Quality (Moisture)**
  • **Wet Steam**
    • Dryness value should be between 97% - 100%
    • i.e. 98% steam 2% water
    • Excess moisture can cause wet packs and uneven temperature distribution on non-porous loads
  • **Superheated steam**
    • May occur during sterilization of extremely dry packs
    • Causes dry heat conditions
    • Hampers sterilization
    • Can damage textiles
• **Presence of non-condensable gases**
  • Inhibits steam penetration
Steam and Sterilization

The saturated steam temperature of 212°F (100°C) is not high enough to kill heat resistant microorganisms.

In order to kill these microorganisms, we need to increase the saturation temperature.

Using a pressurized container, we can increase the saturation temperature at pressures of 15-30 PSI to 250 – 275°F (121°C – 135°C), the temperature needed to kill the heat resistant microorganisms.

The first steam sterilizer consisted of a pressure cooker, safety valve, and means for expelling air.

*Consider a wet towel in a microwave oven*
Why Is Saturated Steam Important?

Heat is used to disrupt hydrogen bonds and non-polar hydrophobic interactions. This occurs because heat increases the kinetic energy and causes the molecules to vibrate so rapidly and violently that the bonds are disrupted.

The protein in eggs denature and coagulate during cooking. Other foods are cooked to denature proteins to make it easier for enzymes to digest them.

Medical devices and instruments are sterilized because the saturated heat during exposure will DENATURE proteins in bacteria and destroy the bacteria – even as endospores.
PRINCIPLES OF STERILIZATION
PROCESS EFFICACY

• Importance of Air Removal
  o Air is 1.6 times denser than steam
  o Air and steam do not mix
    o Impedes steam penetration
    o Inhibits steam contact
  o Caution - Load type, wrapper & density
  o Caution - Lumens devices

• Results of inadequate temperature, and moisture conditions at the desired sterilization sites.
  o Steam condenses on cool spots
  o Packs can become wet
# PRINCIPLES OF STERILIZATION

## STEAM STERILIZATION EFFICACY

### Table 5—Minimum cycle times for dynamic-air-removal steam sterilization cycles

<table>
<thead>
<tr>
<th>Item</th>
<th>Exposure time at 132°C (270°F)</th>
<th>Exposure time at 135°C (275°F)</th>
<th>Drying times</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wrapped instruments</td>
<td>4 minutes</td>
<td></td>
<td>20 to 30 minutes</td>
</tr>
<tr>
<td>Textile packs</td>
<td>4 minutes</td>
<td>3 minutes</td>
<td>16 minutes</td>
</tr>
<tr>
<td>Wrapped utensils</td>
<td>4 minutes</td>
<td></td>
<td>5 to 20 minutes</td>
</tr>
<tr>
<td>Unwrapped nonporous items (e.g., instruments)</td>
<td>3 minutes</td>
<td>3 minutes</td>
<td>NA</td>
</tr>
<tr>
<td>Unwrapped nonporous and porous items in mixed load</td>
<td>4 minutes</td>
<td>3 minutes</td>
<td>NA</td>
</tr>
</tbody>
</table>

**NOTE**—This table represents the variation in sterilizer manufacturers’ recommendations for exposure at different temperatures. For a specific sterilizer, consult only that manufacturer’s recommendations.

Source: AAMI ST79:2010
Time & Temperature

When a large number of microorganisms are exposed to saturated steam at constant temperature, all do not die at the same time.

During each one-minute period, 90% reduction in surviving population.

**D-value** specifies time required for 90% reduction in population.

The D-value varies from one microorganism to another.
Time & Temperature

Understanding the survivor curve and D-value concept allows quantifiable Sterility Assurance Levels (SALs).

By extrapolating D-value below one surviving microorganism, we can determine “probability” of a surviving microorganism.

SAL of $10^{-6}$
Summary

In this lesson, you learned about the critical factors that contribute to effective steam sterilization:

- Surfaces to be sterilized must be kept at a high enough temperature with adequate moisture for a prescribed time.

- When a large number of microorganisms are exposed to saturated steam at a constant temperature, all do not die at the same time.

- It is important to understand the survivor curve and D-value concept to establish quantifiable sterility assurance levels (SALs).

- A steam sterilization process should be so effective that less than one item out of one million might be unsterile.

- Increasing temperature will reduce the time needed for sterilization.
Steam Sterilizers

• Although the principles of steam sterilization haven’t changed during the past century, steam sterilizers and sterilization technologies have dramatically changed.
Sterilizer Basics

• Pressure Vessel

• Jacket
  • Keeps Chamber hot to reduce Steam Condensation during cycle

• Air Removal
  • Air is an insulator
  • Unless steam touches an item, it does not receive the correct amount of
    Time, Temperature (Heat) and moisture to provide sterilization.

• Steam
  • Saturated steam (97%)
  • Sterilant

• Water
  • Cools Sterilizer discharge (<140 F)
  • With an ejector, is the mechanism for active air removal and “Pulling a
    Vacuum”.
PRINCIPLES OF STERILIZATION

CYCLE DYNAMICS

Steam

Water

Vacuum by Water-Ejector

Vacuum by Pump
Steam Sterilization Cycle Phases

The phases for a cycle are the same for both prevacuum and gravity-displacement steam sterilization cycles, its just the method of removing air that is different.

The phases for a steam sterilization cycle include:

• Conditioning Phase
• Exposure (Sterilization) Phase
• Exhaust Phase
• Drying Phase
Steam Sterilization Cycle Phases

**Conditioning Phase** – Air is removed from the sterilizer chamber and steam is injected into the chamber. The length of the conditioning phase varies with the types the loads and is controlled by the sterilizers program.

**Sterilization Phase** – This phase includes the prescribed exposure temperature and is maintained for the prescribed amount of time. The temperature must be maintained throughout the selected duration.

**Exhaust Phase** – After the exposure time is completed, the steam is exhausted from the sterilizer through the chamber drain.

**Drying Phase** – After the steam is exhausted, the sterilizer goes into a drying phase and typically lasts for 30 minutes. The sterilizer uses air and radiant heat to perform the drying process.
**PRINCIPLES OF STERILIZATION**

**TYPICAL PRE-VACUUM CYCLE PHASE DIAGRAM**

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**Pre-vacuum Cycle Phases**

1. **Start** – door seals, jacket warms chamber
2. **Purge** – steam enters chamber, while air is purged through the chamber drain
3. **Conditioning** – positive pressure and negative vacuum pulses continue to heat load and purge air
4. **Heat Up** – steam pressure builds to selected exposure temperature and pressure
5. **Exposure** – timing begins for selected exposure time and temperature
6. **Exhaust** – chamber drain opens and ejector water creates vacuum in chamber to exhaust steam
7. **Drying** – ejector water controls vacuum in chamber for selected dry time
8. **Air-in** – chamber returns to atmospheric pressure
9. **Cycle Complete** – door can be opened

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![Diagram showing the phases of a pre-vacuum cycle](image-url)
Steam sterilization is the best method for items that can withstand high moisture and temperatures of 250°F (121°C) to 275°F (135°C).

The four factors required for effective sterilization are:

- Exposure Time
- Exposure Temperature (Sterilization)
- Presence of Moisture
- Removal of Air

Healthcare uses Prevacuum and Gravity-displacement steam sterilization cycles.

Use of these basic principles allows health care facilities and device manufacturers to ensure that safe and efficacious steam sterilization processes are carried out.
What Happened to Flash Sterilization?

Objectives

- To discuss the new terminology associated with flash sterilization
- To identify the major reasons for the emphasis on IUSS
- To understand the standards for IUSS
What Happened to Flash Sterilization?

• Flash” has traditionally been used to describe steam sterilization cycles where:
  - Unwrapped medical instruments are subjected to an abbreviated steam exposure time
  - Then used promptly after cycle completion without being stored
• This is in contrast to the traditional “terminal sterilization” cycles where instruments are sterilized within wrappers or containers designed to maintain the instruments’ sterility and allow the devices to be stored for later use
Reasons for FLASH Sterilization

• Inadequate inventory of instrumentation
• Booking cases back-to-back
• Not aware of the turn-around time required for wrapped sterilization from SPD
• Items not available from SPD when needed
• Dropped contaminated items
Unacceptable Reasons for FLASH Sterilization

• Insufficient instrumentation for scheduled cases
• Items not available from SPD as requested
• Putting surgeons’ schedules ahead of patient safety
What Happened to Flash Sterilization?

• “Flash” is an antiquated term that does not fully describe the various steam sterilization cycles now in use to terminally process items NOT intended to be stored for later use.

• Current guidelines may require longer exposure times and/or use of single wrappers or containers designed to allow for aseptic transfer of an item from the sterilizer to the point of use.

• The term ”immediate-use steam sterilization” more accurately reflects the current requirements of this process.
“Flash” Sterilization is now “Immediate Use Steam Sterilization”

• AAMI, AORN, APIC and other health & safety organizations have endorsed the name change from “flash” to IUSS – Immediate Use Steam Sterilization.

“Immediate use” is broadly defined as the shortest possible time between a sterilized item’s removal from the sterilizer and its aseptic transfer to the sterile field.

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

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

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

We agree that:

• Personnel involved in reprocessing should be knowledgeable and capable of exercising critical thinking and judgment and should implement standardized practices. The supervising organization is responsible for ensuring appropriate training, education, and competency of staff and ensuring that necessary related resources are provided.

Examples of education and certification resources include the Certification Board for Sterile Processing and Distribution (CBSPD) and the International Association of Healthcare Central Service Material Management (IAHCSMM).
Immediate-Use Steam Sterilization

- Immediacy implies that a sterilized item is used during the procedure for which it was sterilized and in a manner that minimizes its exposure to air and other environmental contaminants.

- A sterilized item intended for immediate use is not stored for future use, nor held from one case to another.

- Immediacy, rather than being defined according to a specific time frame, is established through the critical analysis and expert collaboration of the health care team.
Immediate-Use Steam Sterilization

• Personnel involved in reprocessing should be knowledgeable and capable of exercising critical thinking and judgment, and should implement standardized practices.

• The supervising organization is responsible for ensuring appropriate training, education, and competency of staff and ensuring that the necessary related resources are provided.
  
  o Examples of education and certification resources include the Certification Board for Sterile Processing and Distribution (CBSPD); and the International Association of Healthcare Central Service Material Management (IAHCSMM).

  o Examples of standards and practices can be found with the Association for Advancement of Medical Instrumentation (AAMI); the Association of periOperative Registered Nurses (AORN) and the Centers for Disease Control and Prevention-Healthcare Infection Control Practices Advisory Committee (CDC-HICPAC).
Immediate-Use Steam Sterilization

• Sterilization personnel should be educated regarding the different types of sterilizers (i.e. D.A.R. pre-vacuum and gravity displacement) and the different types of steam sterilization cycles (including IUSS cycles) used in health care facilities.

• Cleaning, rinsing and disinfection are critical for effective sterilization. Users must follow the manufacturer’s written instructions for use (IFU) and complete all required processing steps regardless of the sterilization exposure parameters being used.

• Sterilization cycles with little or no dry time can be efficacious when used in compliance with validated written instructions provided by the device manufacturers, the sterilization equipment manufacturer, and (if applicable) the manufacturer of the wrapper or container.
Immediate-Use Steam Sterilization

- The device manufacturer’s written instructions for reprocessing any reusable device must be followed. The cycle parameters required to achieve sterilization are determined by the design of an instrument, the characteristics of the load, the sterilizer’s capabilities and the packaging (if used).

- Only items sterilized and packaged in materials cleared by the FDA for maintenance of sterility can be stored.

- Sterilization process monitoring is essential to ensure that sterilization practices are efficacious. Examples of process monitoring tools are:
  - Physical indicators – cycle records and logs
  - Chemical indicators, or CI’s
  - Biological indicator, or BI’s
Immediate-Use Steam Sterilization

• The aseptic transfer from the sterilizer to the point of use is critical to protect items from contamination.

• Instrument inventories should be sufficient to meet anticipated surgical volume and permit the time to complete all critical elements of reprocessing.

• Quality management is important to ensure compliance with processes and relating those processes to outcomes.

• The regulatory or accrediting agency should evaluate whether the organization’s leaders ensure that training, education and resources are provided and the competency of staff is validated.
Immediate-Use Steam Sterilization

. . . should NOT be performed on the following devices

• Implants* except in a documented situation when no other option is available.

• Post procedure decontamination of instruments used on patients who may have Creutzfeldt-Jakob disease (CJD) or similar disorders.

• Devices or loads that have NOT been validated with the specific cycle intended.

• Devices that are sold sterile and intended for single-use only.

* FDA defines an implant as a “device that is placed into a surgical or naturally formed cavity of the human body if it is intended to remain there for a period of 30 days or more. FDA may, in order to protect public health, determine that devices placed in subjects for shorter periods are also ‘implants’.” [21CFR 812.3(d)]
Essentials of Healthcare Steam Sterilization

References & Resources


• Association of periOperative Registered Nurses, AORN Recommended Practices for Sterilization (2009)

• Certification Board for Sterile Processing and Distribution (CBSPD), 2 Industrial Park, Suite 3, Alpha, NJ 08865

• International Association of Healthcare Central Service Materiel Management (IAHCSMM), 213 West Institute Place, Suite 307, Chicago, IL 60610