Steam Sterilization - A Carefully Monitored Process

Dr. Lynne Sehulster, Centers for Disease Control

A Webber Training Teleclass

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Disclaimer

The findings and conclusions in this presentation are those of the author and her information resources and do not necessarily represent any determination or policy of the Centers for Disease Control and Prevention (CDC).

Unofficial Mascot of Environmental Services!

It All Started With…

Sterility vs. Sterilization

- Sterile – free from living microorganisms
- Absolute state – it either is, or it isn't
- Sterilization – the process, a probability function
- Sterility Assurance Level (SAL) – the predictor of the efficacy of the sterilization process
- Application of sterilization – strategy that determines when sterilization is the appropriate form of terminal reprocessing
  - Example: the Spaulding Classification

From: Favero MS, Bond WW. Disinfection of Medical and Surgical Materials. In: Block SS ed. Disinfection, Sterilization, and Preservation, 5th Ed. 2001.

Operational Definition of Sterilization

A carefully designed and monitored process that will assure the probability that an item being contaminated to be equal to or less than one in one million (10^{-6})

Sterilization

- Kills all microorganisms, including HIGH numbers of bacterial spores
  - Heat (moist or dry)
  - Chemical gas or vapor
  - Radiation
  - Liquid chemical sterilizing agents (sporicides); 6-10 hours exposure time
    - aldehydes
    - hydrogen peroxide
    - peracetic acid

Factors Affecting Sterilization or Disinfection

- AMOUNT OF ORGANIC MATERIAL
- Number of microorganisms
- Type of microorganisms (resistance levels)
- Type of germicidal agent
- Concentration of germicidal agent
- Exposure time to germicidal agent
- Temperature of exposure
- pH of solution
- Presence or absence of moisture

Attributes of the Ideal Sterilant*

- Highly efficacious
  - Bacteriocidal, sporicidal, tuberculocidal, fungicidal, virucidal
- Rapid activity
  - Achieves sterilization quickly
- Strong permeability
  - Penetrates packaging materials and device lumens
- Materials compatibility
  - Negligible changes in either appearance or function of processed items

Attributes of the Ideal Sterilant*

- Non-toxic
  - Poses no health hazards to the operator, patient, or the environment
- Organic material resistance
  - Withstands reasonable organic challenge without loss of efficacy
- Adaptability
- Monitoring capability
  - Physical, chemical, or biological indicators
- Cost effective

* Source: Schneider, PM. Low-temperature sterilization in the 1990's. 1994. Tappi Journal 77: 115-121.

Factors Affecting The Efficacy of Any Sterilization Process

- Implementing a consistent system for lowering and limiting bioburden before sterilization
- Properly preparing items for sterilization
- Selecting the appropriate sterilization parameters
- Establishing and implementing controls to maintain the sterility of sterilized items until they are used

Source: ANSI/AAMI ST 79: 2006

Effective Sterilization: Controlled Conditions

- For all physical processes:
  - Time, temperature, relative humidity
- For liquid chemical processes:
  - Time, temperature, pH, concentration
- For gas or plasma processes:
  - Time, temperature, gas concentration, relative humidity, wrapping

Moist Heat Sterilization

- All moist heat sterilization processes consist of four phases in their cycles:
  - Heating phase
  - Sterilization phase
  - Evacuation and cooling phase
  - Drying phase

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Sterilization via Saturated Steam: Air Removal Mechanisms

- Air interferes with the ability of steam to make contact with items to be sterilized. Air is removed by:
  - Gravity displacement: incoming steam forces air to the bottom of the chamber for removal
  - Dynamic air removal (pre-vacuum or porous load): air is pumped out of the chamber mechanically in one or multiple cycles before steam enters

Key Definitions

- D value
  - Time necessary to reduce a microbial population by one log or 90% at a given temperature
- Z value
  - Slope of the thermal death time curve, or the number of degrees of temperature to change the D value by a factor of 10
- Energy of activation
  - Energy required to release spores from dormancy to germinate; also the energy required to initiate inactivation of microorganisms

Microorganisms on Death Row!

- Death of a microorganism
  - Failure to reproduce when suitable conditions for reproduction are available
- Death is a first order exponential, logarithmic function
- Spores have higher energy of activation thresholds
  - More energy required to inactivate dormant spores compared to actively growing vegetative cells

SAL and the Sterilization Cycle

- Determine the SAL using a BI (resistant spores)
  - Determine process parameters
  - Determine D value and construct inactivation curve
- A 6 log reduction is considered to be "half cycle"
- Extrapolate the inactivation curve to an additional 6 logs
- This results in a sterilization cycle with an SAL of 10^{-6}, meaning there is the probability of one chance in a million that one of the 10^6 spores used in the starting challenge survived.
- This approach is extraordinarily conservative

From: Favero MS, Bond WW. Disinfection of Medical and Surgical Materials. In: Block SS ed. Disinfection, Sterilization, and Preservation, 5th Ed. 2001.

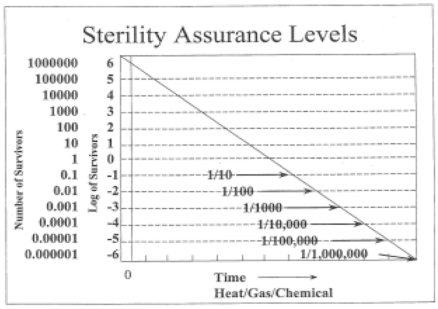

FIG. 43.2. Sterility assurance levels.

From: Favero MS, Bond WW. Disinfection of Medical and Surgical Materials. In: Block SS ed. Disinfection, Sterilization, and Preservation, 5th Ed. 2001.

Table: Inactivation of Bacterial Population

Time (mins.)	Initial Bacterial Count	Bacteria Killed in 1 Minute	Remaining Bacterial Count	Logarithm of Survivors
1	1,000,000	900,000	100,000	5
2	100,000	90,000	10,000	4
3	10,000	9,000	1,000	3
4	1,000	900	100	2
5	100	90	10	1
6	10	9	1	0
7	1	0.9	0.1	-1
8	0.1	0.09	0.01	-2
9	0.01	0.009	0.001	-3
10	0.001	0.0009	0.0001	-4
11	0.0001	0.00009	0.00001	-5
12	0.00001	0.000009	0.000001	-6

Adapted from: Favero MS, Bond WW. chapter in Block SS, 5th Ed, 2001

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Manufacturers' Considerations

- Assumption that the bioburden on a device is 10^6 bacterial spores most resistant to the process
- For challenge tests, placement of the spores in the least accessible location
- Spores contained in "soil"
- Simulated use conditions
- Document 6 log kill at half-cycle
- Document that a cycle produces 6 log kill with a 10^{-6} probability that one spore survives

From: Favero MS, Bond WW. Disinfection of Medical and Surgical Materials. In: Block SS ed. Disinfection, Sterilization, and Preservation, 5th Ed. 2001.

In Reality…

- Most medical devices have a bioburden of $<10^3$
- Cleaning can reduce the bioburden by 3 – 5 logs
- Bioburden on medical devices is largely composed of vegetative bacteria, viruses, and fungi, and <0.1% are spores, if any

From: Favero MS, Bond WW. Disinfection of Medical and Surgical Materials. In: Block SS ed. Disinfection, Sterilization, and Preservation, 5th Ed. 2001.

Perspective of FDA and AAMI

- An SAL of 10^{-6} is generally accepted as appropriate for items intended to come into contact with compromised tissue (i.e., tissue that has lost the integrity of the natural body barriers)
- An SAL of 10^{-3} is considered acceptable for items not intended to come into contact with compromised tissue.

From: ANSI/AAMI ST 79: 2006; ANSI/AAMI ST 67: 2003

Advice From an Indoor Environmental Microbiologist

"The proper method of reprocessing a heat-stable device is to AUTOCLAVE it! You COOK it!

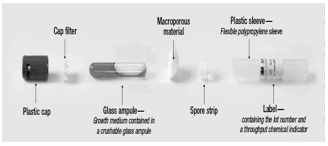
You don't gas it, you don't dunk it, YOU COOK IT!!!"

W.W. Bond, MS
CDC Microbiologist (Retired)

Life Was So Much Simpler Back Then…

The use of 3M products on this and subsequent slides is for example purposes only, not for endorsement.

Biological Indicators



A Biological Indicator (BI) is a characterized preparation of a specific microorganism that provides a defined and stable resistance to a specific sterilization process.

The example pictured here is a self-contained BI. Spores, together with self-contained growth medium are considered a system.

Biological Indicators

- A standardized preparation of bacterial spores on or in a carrier
- PCD – process challenge device
- Serves to demonstrate whether sterilizing conditions have been met
- Considered to be the only true measure of sterilization process lethality
- BI must be placed in the most difficult site for sterilant penetration
- A positive BI indicates a process failure

Types of Biological Indicators

- *Bacillus stearothermophilis*
  - Moist-heat systems
  - *Geobacillus stearothermophilis*
- *Bacillus subtilis*
  - EO, dry heat systems
  - *Bacillus atropheus*
- *Bacillus pumilus*
  - Radiation-based systems

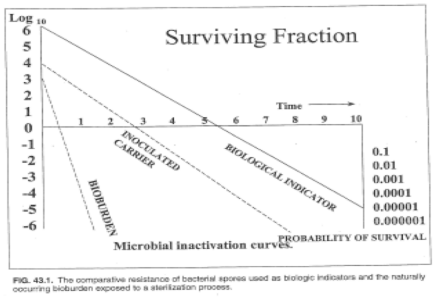


FIG. 43.1. The comparative resistance of bacterial spores used as biologic indicators and the naturally occurring bioburden exposed to a sterilization process.

From: Favero MS, Bond WW. Disinfection of Medical and Surgical Materials. In: Block SS ed. Disinfection, Sterilization, and Preservation, 5th Ed. 2001.

Physical Indicators

- Equipment monitors that are engineered to detect any of these parameters:
  - Temperature, time
  - Pressure, gas concentration
  - Relative humidity
  - Steam purity
  - Delivered dose of sterilant

Chemical Indicators

- Measure key parameters of the sterilization process
- Visual change when the desired parameter has been achieved (e.g., color change with temperature)
- Single parameter indicators, multi-parameter indicators

Chemical Indicators

- Class 1: Process Indicators
  - Also known as throughput indicators. Intended for use on individual items to be sterilized. Demonstrate that the item has been exposed to a sterilization process
  - Helps to distinguish between those items that have been sterilized vs. those that have not
  - External application

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Chemical Indicators

- Class 2: Specific Test Indicators
  - Designed for a specific test procedure
  - Bowie-Dick Test: detects air leaks or inadequate vacuum and non-condensable gases in dynamic-air removal sterilizers (inadequate air removal and steam penetration
  - Internal; run daily in empty sterilizer

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Chemical Indicators

- Class 3: Single parameter indicators
  - Reacts to one of the critical process parameters of sterilization and indicate exposure to a sterilization cycle at state values of the chosen parameter (usually temperature)
  - Can be inserted into packs as an internal indicator

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Chemical Indicators

- Class 4: Multi-parameter indicators
  - More accurate than Class 3; can be used as an internal monitor
  - React to two or more critical parameters of the sterilization process and indicate exposure to the sterilization process at the stated values of the parameters
  - For steam: time and temperature

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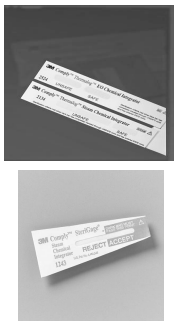
Chemical Indicators

- Class 5: Integrating indicators
  - Designed to react to all critical parameters over a specified range of sterilization cycles
  - Performance has been correlated to the performance of a BI under its labeled conditions for use
  - Can be used as an internal monitor



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Chemical Indicators

- Class 6: Emulating indicators
  - Suppose to emulate or mimic the behavior of a BI
  - Are cycle-specific: need an emulating indicator designed to validate a 10 minute/270º F cycle, and a different indicator to validate a 3 minute/270º F cycle
  - Dr. W.A. Rutala: No professional organization (e.g., AORN, AAMI) has as yet recommended the use of Class 6 emulating indicators as a substitute for BIs
  - No data that demonstrate it mimics a BI at suboptimal sterilization times

Use and Interpretation of Indicators

- Biological Indicators:
  - Use on each sterilizer periodically (e.g., at least weekly)
  - Use on each load of implantable devices
  - Control BIs (not processed) for comparison
- Chemical and Physical Indicators
  - External and internal indicators used for each item in the load
  - Class 3, 4, or 5 indicators can be used
- Results of external indicators and chemical integrator challenge packs can be read at the end of the sterilization cycle
- Internal indicators must be interpreted at time of use

ANSI/AAMI ST 79: 2006

Routine Load Release: Non-Implant Loads

- Use the following monitors and indicators:
  - Physical monitors
  - External process indicator (Class 1) on every package
  - Internal CI (Class 3, 4, or 5) inside every package
- Optional use of PCD for load monitoring:
  - BI, or a BI + a Class 5 integrator indicator, or a Class 5 integrator indicator
- Evaluate all monitoring data
- Do not distribute load if any data suggests a sterilization process failure

Slide info courtesy of M. Young, 3M

Flash Sterilization
AORN, CDC Guidelines

- In 1969, Perkins redefined flash sterilization of an unwrapped item to the current definition of 270ºF for 3 minutes in a gravity sterilizer.
- Flash used for items that must be used immediately
- Acceptable for processing items that cannot be packaged, sterilized and stored before use
- Because of the potential for serious infections, implanted surgical devices should not be flash sterilized unless unavoidable (e.g., orthopedic screws)
- Do not use flash sterilization for reasons of convenience, as an alternative to purchasing additional instrument sets, or to save time

Flash Sterilization
AORN 2009 Guidelines

- Recommends the use of rigid sterilization containers
  - Reduce risk of contamination during transport to point of use
  - Ease of presentation to sterile field
- AORN states that in flash sterilization a Class 5 integrating indicator should be used inside each sterilizer container or tray

Slide info courtesy of M. Young, 3M

Routine Load Release: Implant Loads

- Include these monitors and indicators:
  - Physical monitors
  - External process indicators (Class 1) on every package
  - Internal CI (Class 3, 4, or 5) inside every package
  - A PCD including a BI and a Class 5 integrating indicator
- Implant loads should be quarantined until the BI results are known

Slide info courtesy of M. Young, 3M

Early Release and Emergencies: Implant Loads

- AORN 2009: Flash sterilization should not be used for implantable devices except in cases of emergency when no other option is available
- If flash is necessary for an implant load:
  - Use a rapid-action BI and a Class 5 CI integrator (or enzyme-only indicator)
  - Quarantine implant and release only when the rapid-action BI provides a negative result
  - Document the items processed, cycle parameters, patient receiving the item(s), day/time of cycle run, operator info

Slide info courtesy of M. Young, 3M

To Recall or Not: AAMI and AORN

- Question: If a BI is positive, only that load needs to be recalled. FALSE
- If determined to be an operator error:
  - Using incorrect sterilization cycle
  - No recall, don't use load
- If the reason is not known or it's not operator error:
  - Recall all items processed since the last negative BI
  - Reprocess all retrieved items

Slide info courtesy of M. Young, 3M

Use and Interpretation of Indicators

- Check the mechanical parametric readings (e.g., time, pressure) and internal/external chemical indicators (e.g., temperature) first
- When these suggest that the sterilizer is functioning properly, a single positive BI may not indicate process failure
- Take sterilizer out of service, review process of operation to determine possible error

Use and Interpretation of Indicators

- Repeat BI testing with controls on three consecutive sterilization cycles, empty chamber
- If all processed BI's are negative, return the unit to service
- If any of the processed BI's are positive:
  - Recall the processed items from that unit, rewrap, and re-sterilize these items
  - Have the equipment repaired and repeat the BI challenge series

Extended Steam Sterilization Cycles

- Cycles recommended by the medical device manufacturer (MDM) that are longer than the minimum sterilizer manufacturer FDA cleared cycles
- Example: Synthes instruments and implants (wrapped)
  - 270-275ºF (132-135ºC) gravity steam sterilization cycle: 15 minutes
  - 270-275ºF (132-135ºC) pre-vacuum steam sterilization cycle, 3 pulse vacuum: 4 minutes
- Check with MDM for current instructions for all instruments
- Ensure that cycle indicators are appropriate for the extended cycle

Slide info courtesy of M. Young, 3M

Monitoring Extended Steam Sterilization Cycles

- No PCDs for monitoring extended cycles
- Include BIs and CIs inside trays
- Physical monitors:
  - Mark with correct date and sterilizer identification at the beginning of the cycle
  - Check cycle printout to verify cycle parameters were met and initial
  - If not correct, do not release

Slide info courtesy of M. Young, 3M

Standards and Other Resources

- AORN 2009 Perioperative Standards and Recommended Practices (www.aorn.org)
- ANSI/AAMI ST79:2006 (www.aami.org)
- CDC/HICPAC Guidelines for Disinfection and Sterilization in Healthcare Facilities 2008 (www.cdc.gov/ncidod/dhqp/)
- FDA guidance documents (www.fda.gov/cdrh/guidance.html)
- ISO 11140-1: 2005(E) (www.iso.org)
- AS/NZS 4815-2006
- UK: Medical Device Agency documents

Thank You!

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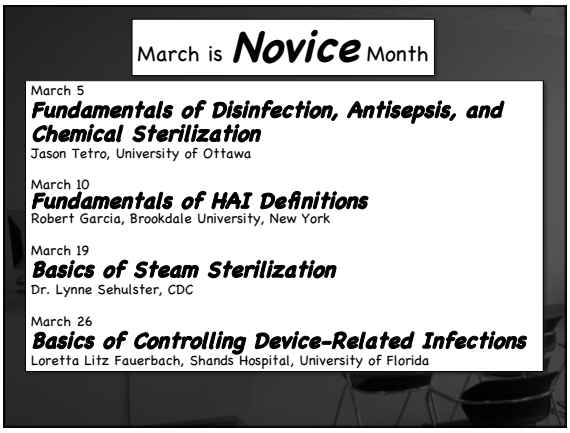
"Protect patients, protect health-care personnel, and promote safety, quality, and value in the health-care delivery system"


March is Novice Month
March 5
Fundamentals of Disinfection, Antisepsis, and Chemical Sterilization
Jason Tetro, University of Ottawa
March 10
Fundamentals of HAI Definitions
Robert Garcia, Brookdale University, New York
March 19
Basics of Steam Sterilization
Dr. Lynne Sehulster, CDC
March 26
Basics of Controlling Device-Related Infections
Loretta Litz Fauerbach, Shands Hospital, University of Florida