EXCELLENTIA ADVISORY GROUP | INFECTION PREVENTION STRATEGIES FOR AMBULATORY SURGERY CENTERS

Frequently Asked Questions About . . . Sterilization!

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3M Science. Applied to Life.™

Speaker has a commercial interest in this topic

Today's Learning Objectives

1. Understand the basic principles of the sterilization processes used in ASCs today

2. Learn answers to common questions about the sterilization of medical devices in ambulatory surgical centers

Sterilization Processes

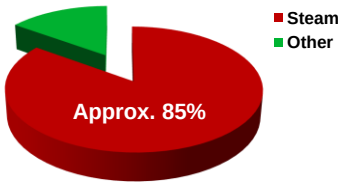
High Temperature

- Steam (autoclave)

Low Temperature

- Vaporized hydrogen peroxide
- Ethylene oxide
- Ozone/hydrogen peroxide combination

Sterilization Processes in Healthcare



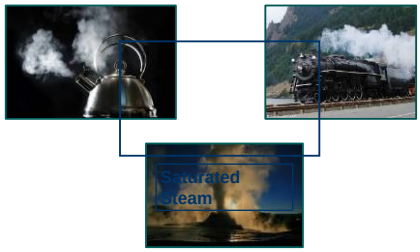
Steam Sterilizers

Google Images

"Moist heat in the form of saturated steam under pressure is the most dependable medium know for the destruction of all forms of microbial life."

"Principles of Steam Sterilization", John Perkins, 2nd Edition, p. 95, 1983.

Steam - Basics



Google Images

Critical Process Variables – Steam Sterilization

Parameters identified as being essential to the sterilization process (and require monitoring)

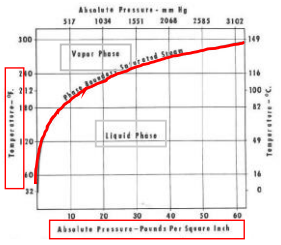
So, what are the critical variables for steam sterilization??

- Time (exposure time)
- Temperature
- Saturated steam

Saturated Steam

Water vapour in a state of equilibrium between condensation and evaporation

Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 17665-1:2006)



"Principles of Steam Sterilization", John Perkins, 2nd Edition, p. 101, 1983.

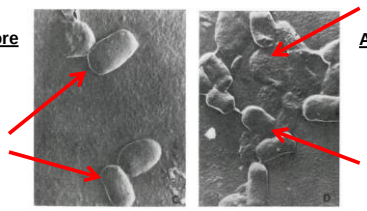
How Steam Kills . . .

Steam condensation on surfaces releases latent heat (energy) that damages and destroys large biochemical molecules required for life

- **Proteins denatured**
- **Nucleic acids damaged**

Effect of Steam Sterilization

Before



After

"Principles of Steam Sterilization", John Perkins, 2nd Edition, p. 101, 1983.

Moist Heat versus Dry Heat

Sterilization Exposure Times

	Dry Heat	Moist Heat
250°F (121°C)	360 minutes	30 minutes
285°F (140°C)	180 minutes	< 3 minutes

Steam Quality

Saturation is critical. If the steam is not saturated, there is less condensation (meaning less energy released) so the steam has less killing power.

So, how can steam become "un-saturated"?

Steam Quality - NCGs

Non-condensable gases (NCGs) in the steam or chamber will prevent uniform and effective condensation, resulting in inadequate sterilization conditions.

What is the most common non-condensable gas?

AIR!!

Steam Quality - NCGs

Potential Sources of NCGs

- Inadequate air removal - sterilizer
- Air leaks (valves or gaskets) - sterilizer
- Gasses entrapped in the supplied steam
- Boiler feed water
- Steam lines and valves

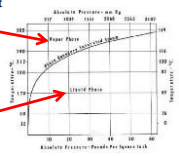
Other Steam Quality Issues

Superheated Steam

- Temperature above the equilibrium line, at same pressure
- Not saturated – less lethality
- Can be caused by jacket temperature too high, or dry materials

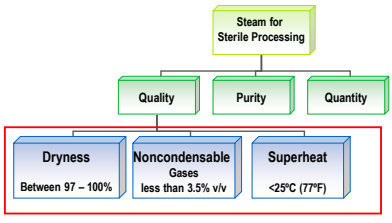
Wet Steam

- Not saturated – less lethality
- Residual moisture – wet loads
- Boiler/steam delivery system issues



"Principles of Steam Sterilization", John Perkins, 2nd Edition, p. 101, 1983.

Steam for Sterile Processing



ANSI/AAMI ST79:2010 & A1:2010 & A2:2011 & A3:2012 & A4:2013; Comprehensive guide to steam sterilization and sterility assurance in health care facilities.

How Air is Removed from the Sterilizer . . .

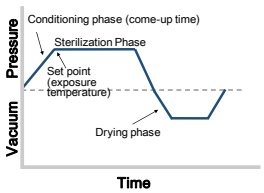
Gravity displacement

- Steam into the top of the chamber drives air out the bottom

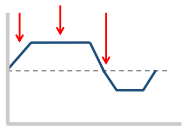
Dynamic air removal

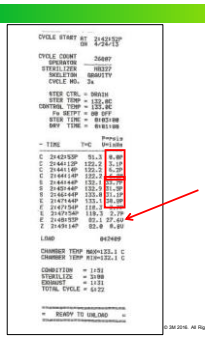
- Pre-Vacuum
  - Vacuum/pressure pulsing to drive air out
- Steam Flush Pressure Pulse (SFPP)
  - Positive pressure steam pulses with gravity flush

Profile of a Gravity Displacement Cycle

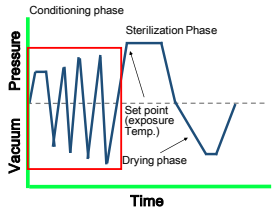


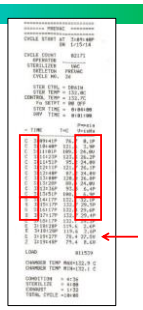
Gravity Displacement Cycle Printout



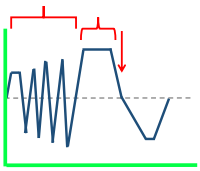


Profile of a Prevacuum Cycle





Pre-vacuum Cycle Printout



Typical Steam Sterilization Process Conditions – Gravity Displacement

Parameters for gravity displacement steam sterilization

Item	Exposure time at 121°C (250°F)	Exposure time at 132°C (270°F)
Wrapped Instruments	30 minutes	15 minutes
Textile Packs	30 minutes	25 minutes
Wrapped Utensils	30 minutes	15 minutes

ANSI/AAMI ST79:2010 & A1:2010 & A2:2011 & A3:2012 & A4:2013, Comprehensive guide to steam sterilization and sterility assurance in health care facilities.

Typical Steam Sterilization Process Conditions – prevacuum

Minimum cycle times for dynamic air removal steam sterilization

Item	Exposure time at 132°C	Exposure time at 135°C
Wrapped Instruments	4 minutes	3 minutes
Textile Packs	4 minutes	3 minutes
Wrapped Utensils	4 minutes	3 minutes
Unwrapped nonporous items	3 minutes	3 minutes
Unwrapped porous and nonporous (mixed load)	4 minutes	3 minutes

ANSI/AAMI ST79:2010 & A1:2010 & A2:2011 & A3:2012 & A4:2013; Comprehensive guide to steam sterilization and sterility assurance in health care facilities.

Table-top Sterilizers

Definition: "Compact steam sterilizer that has a chamber volume of not more than 2 cubic feet and that generates its own steam when distilled or deionized water is added by the user"

- Popular in office-based practices (medical, dental, and surgical) and ambulatory care clinics

https://statim.us/sterilization/statim/2000g4/#rely

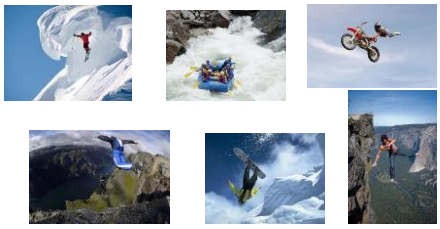
Image courtesy of Midmark Corporation

AAMI ST79, Introduction and Section 2.131

Steam Sterilization Process Standard

AAMI ST79 – Comprehensive guide to steam sterilization and sterility assurance in health care facilities

When steam is too *extreme* . . .



Low Temperature Sterilization

Sterilization processes using chemical gases or vapors at lower temperatures (below 60°C) to process heat and moisture sensitive instruments.

Low Temperature Sterilants Kill by . . .

Chemical action on the microorganisms:

Ethylene oxide: Alkylation of proteins and DNA

Hydrogen peroxide: Oxidation of proteins and DNA

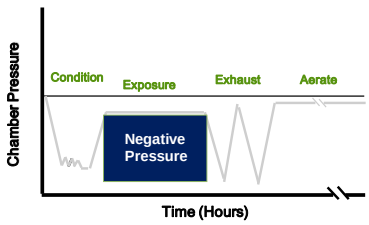
Low Temperature Sterilization Technologies Available Today . . .

- Ethylene oxide
- Vaporized hydrogen peroxide
  - With and without plasma phase
- Ozone/hydrogen peroxide combination

Ethylene Oxide Sterilization Process

Critical Variables
- Time
- Temperature
- Relative humidity
- Ethylene oxide concentration

100% Ethylene Oxide Cycle



Ethylene Oxide Sterilization - Endoscopes

- Several outbreaks related to the use of duodenoscopes
- Epidemiology and investigations published in peer reviewed literature
  - Northeastern Illinois Hospital
  - University of Pittsburg Medical Center
  - Milwaukee Wisconsin
  - UCLA Los Angeles CA
- No breach in reprocessing with HLD identified

"No new infections after starting ethylene oxide sterilization"

"after EtO sterilization of all duodenoscopes, no additional cases of CRE infection were diagnosed"

"no additional healthcare-associated infections have been noted since ERCP/EUS scope reprocessing included ETO"

Vaporized Hydrogen Peroxide (H_2O_2) Sterilization Systems

- Vaporized Hydrogen Peroxide (with plasma)
- Vaporized Hydrogen Peroxide (without plasma)
- Vaporized Hydrogen Peroxide and Ozone

Vaporized Hydrogen Peroxide

Critical Variables
- Time
- Temperature
- H_2O_2 Concentration

Vaporized Hydrogen Peroxide with Gas Plasma

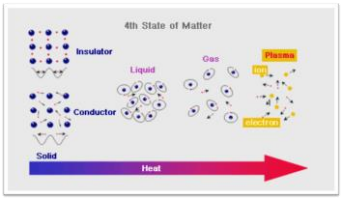
Examples

- Sterrad® Systems
  - NX®, 100NX®, 100S

(Source: www.aspjj.com)

Sterrad™ is a registered trademark of Advanced Sterilization Products, a Johnson and Johnson Company.

Plasma – 4th State of Matter



Primary role – destruction of residual hydrogen peroxide

Source: www.hmmdt.com

Vaporized Hydrogen Peroxide Systems without Plasma

Examples:

Amsco® V-PRO™ Systems

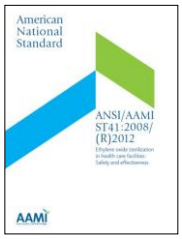
- V-PRO™ 1
- V-PRO™ 1 Plus
- V-PRO™ maX

Sterilucent™ PSD-85 Sterilizer

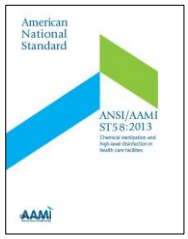
STERIZONE® VP4 Sterilizer

Amsco® and V-PRO™ are registered trademark of Steris Corporation. STERIZONE® is a registered trademark of TSOS Inc.

Great References!



AAMI ST 41 – Ethylene oxide sterilization



AAMI ST 58 – Chemical sterilization

Now, some sterilization related questions from health care facilities . . .

3M STERILIZATION TECH LINE

Tier 2 Technical support of 3M Sterilization products

1-800-441-1922 OPTION 2

What is the proper way to use biological indicators (BIs) to monitor routine performance of large and small (table top) steam sterilizers?

For all Steam Sterilizers . . .

Biological indicators – use in a Process Challenge Device (PCD)

- **Provides challenge to the sterilizer, as if the BI was inside the packs**

BI in a PCD weekly, preferably daily

All loads containing an implant

Test each cycle type that will be run (i.e. defined by temperature, air removal process)

ANSI/AAMI ST79:2010 & A1:2010 & A2:2011 & A3:2012 & A4:2013; Comprehensive guide to steam sterilization and sterility assurance in health care facilities.

(NOTE: Many facilities are moving to monitoring every load. This reduces the chance of monitoring mistakes, and provides uniform patient care.

For steam sterilizers with chamber size larger than 2 cu. ft.

- **User assembled PCD (AAMI 16-towel pack) OR commercially available FDA-cleared disposable BI PCD from manufacturer**
- **Full load, on bottom shelf over the drain**

For steam sterilizers with chamber size smaller than 2 cu. ft. (table top)

- **User assembled, representative of package or tray routinely processed and most difficult to sterilize.**
- **Full load in cold point (check with sterilizer manufacturer)**

What is the best way to get instrument sterilization information into the patient records?

Answer

1. Instrument tracking systems will provide this information linkage automatically
2. If there is no instrument tracking system, then the record must be created manually
   - Link sterilization load sticker information (load ID, date, etc.) to records that list the trays and sets used on the patient

How do I handle biological monitoring of IUSS cycles?

What is IUSS??

Immediate Use Steam Sterilization ("Flash", in the old days)

Key points:

- Items properly cleaned before sterilization
- Cycle type (gravity, prevacuum, temperature) consistent with IFUs
- Little or no dry time
- Must be able to transport aseptically to immediate point of use (container or covered tray)
- No storage
- No implants

Monitoring IUSS cycles

Test each type of tray configuration that is used

- For sterilizers >2 cubic feet - place the BI PCD on bottom shelf over the drain in an otherwise, empty chamber

Representative BI PCD using one or more BIs and one or more CIs - empty tray configuration

- *Rigid sterilization container system*
- *Perforated, mesh bottom, open surgical tray*
- *Protective organizing case*
- *Single-wrapped surgical tray*

When should I use internal chemical indicators?

ISO 11140 – Performance Requirements for Chemical Indicators

New terminology . . . "Class" is now "Type"

So . . .	**Class 1**	**Type 1**
	Class 2	**Type 2**
	Class 3	**Type 3**
	Class 4	**Type 4**
	Class 5	**Type 5**
	Class 6	**Type 6**

Pack Monitoring – Chemical Indicators

An internal CI should be used within each package, tray, or rigid sterilization container system to be sterilized… the CI should be placed in the area of the package, tray, or containment device… considered least accessible to steam penetration.

"For a containment device, the manufacturer's written IFU for placement of the CI should be consulted. This location might or might not be the center of the package, tray, or containment device."

ANSI/AAMI ST79:2010 & A1:2010 & A2:2011 & A3:2012 & A4:2013, Section 10.5.2.2.2

Chemical Indicator Placement

Wrapped fabric packs

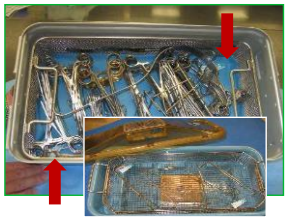
Wrapped instrument sets

- **Place CI in geometric center, not on the top**

Chemical Indicator Placement

Rigid container

- Place two CIs inside rigid containers
- Place one in each of two opposite corners

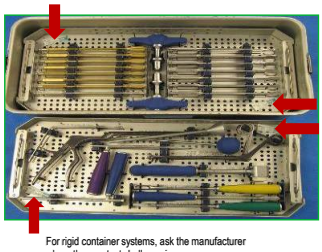


For rigid container systems, ask the manufacturer where the greatest challenge is

Chemical Indicator Placement

Multi-layer rigid container

- Place two CIs in each level of multi-level rigid container
- Place one in each of two opposite corners on each level

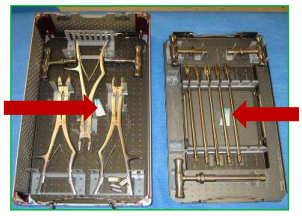


For rigid container systems, ask the manufacturer where the greatest challenge is

Chemical Indicator Placement

Multi-level container

- Supplied by the manufacturer
- Holes in tray
- Has to be wrapped
- Place a CI in center of each level



For all these trays, ask the medical device manufacturer where the greatest challenge is

What is the proper way to monitor hydrogen peroxide sterilizers?

ANSI/AAMI ST 58

Answer

Recommended practices related to hydrogen peroxide sterilization processes are covered by ANSI/AAMI ST58

Chemical Indicators (CIs)

- **Internal chemical indicator** inside every package, tray, & containment device

"….An internal CI should be used inside each package, tray, containment device (rigid sterilization container system, instrument case, cassette, or organizing tray) to be sterilized. The CI should be placed in that area of the package, tray, or containment device that creates the greatest challenge to sterilant penetration."

AAMI ST58, Section 9.5.3.2; AAMI ST41, Section 10.5.2.2.2

AAMI ST58 Recommended BI Frequency of Use *"A PCD with the appropriate BI should also be used at least daily, but preferably in every sterilization cycle"*

"Rationale: The condition of the sterilizer equipment, the expertise of the sterilizer operator, and other factors determining the success or failure of a sterilization cycle could vary from one cycle to another"

AAMI ST58:2013, Section 9.5.4.3

Commercial Hydrogen Peroxide BIs – Readout Times – Monitoring Frequency

Biological Indicator	Sterilizers	Readout Time (hrs)	
ASP Sterrad® CycleSure®	Sterrad® 100S, 100NX®, NX®	24	
Steris Verify® V24	Steris VPRO®, ASP Sterrad®	24	
3M Attest™ Rapid Readout 1295	Sterrad® 100S, 100NX®, NX®	4	

How should I monitor a load that contains an implant?

What is an implant?

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

ANSI/AAMI ST79:2010 & A1:2010 & A2:2011 & A3:2012 & A4:2013. Clause 2.63

"Every sterilization load containing implants should be monitored with a PCD containing a BI (a BI challenge test pack). A Class 5 integrating CI should be included in this PCD. Implants should be quarantined until the results of the BI testing are available (CDC, 2008)."

"A Class 5 CI should be included with the BI in the PCD so that if an implant must be released on an emergency basis, additional information about the critical parameters of the sterilization process will be available and documented."

ANSI/AAMI ST79:2010 & A1:2010 & A2:2011 & A3:2012 & A4:2013. Clause 10.6.1

Summary

1. **High temperature (steam) and low temperature (EO, H_2O_2) options for sterilization of instruments**
2. **AAMI recommended practices provide excellent references for proper sterilization procedures**

3M Sterilization Tech Line
1-800-441-1922 OPTION 2

Thank you!!