Past, Present and Future of Sterilization Technology and Sterility Assurance Monitoring
Continuing Education Contact Hours

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Learning Objectives

• Describe the science behind sterility assurance monitoring

• Review today’s sterility assurance monitoring challenges
Evolution of Sterilization

1880
Charles Chamberland’s pressure steam autoclave

1888
Ervin Von Esmarch recommends bacteriologic tests to validate sterilizers

1933
First automated steam sterilization process
1950 Ethylene oxide sterilization becomes popular in U.S.

1963 First standardized Bowie-Dick test

1977 FDA clears first chemical indicator

1980 First published standard biological test (AAMI ST1:1980)

1988 FDA clears SYSTEM 1® Sterile Processing System
1990
FDA clears steam flush pressure pulse cycle

1995
FDA clears Sterrad® Sterilizer

1990
3M Attest Rapid Read biological indicator cleared by FDA

1996
Class 5 integrators with challenge pack may be used to release loads (AAMI ST46:1996)
2003
FDA clears TSO$_3^\circledR$ Sterilizer

2007
Class 6 emulating indicators with challenge pack cleared for use to release all steam sterilization loads

2008
FDA clears V-Pro 1$^\circledR$ Sterilizer
What is Sterilization and Sterility Assurance?
Sterilization is the destruction of all living micro-organisms including bacterial spores.

Pathogenic Organisms
How Do You Prove An Item Is Sterile?

• Test Each Item!
  – Impractical
  – Renders device unusable

• Alternative
  – Use a scientific method to predict sterilization conditions and time
    • SAL of $10^{-6}$
    • Less than one in a million that a single viable organism is present
    • Acceptable for devices in contact with compromised tissue
Steam Sterilizer Validation

Step 1:

- Determine the time required to kill bacterial spores
- Use one million of the most resistant bacterial spores, $10^6$ *Geobacillus stearothermophilus* spores
Example 134°C Vacuum Assisted
1st Minute

Assumed Bioburden of $10^6$ Micro-organisms
Steam Sterilizer Validation

Step 2:

- Double the required time to kill the bacterial spores to establish the Sterility Assurance Level
- Perform “Half Cycle Testing” within the fully loaded steam sterilizer
Example 134°C Vacuum Assisted 2nd Minute

Assumed Bioburden of 10^6 Micro-organisms

SAL10^{-6}
Steam Sterilizer Validation

Step 3:

• Add additional exposure time for the “Safety Margin”
Example 134°C Vacuum Assisted Safety Time

Assumed Bioburden of $10^6$ Micro-organisms

SAL $10^{-6}$

Safety Margin
How is the Cycle Time Determined?

$\text{Sterility Assurance Level} + \text{Safety Margin} = \text{Exposure Time}$
Sterilization Cycle Times Depends on the Country

Vacuum Assisted Cycles:

<table>
<thead>
<tr>
<th>Country</th>
<th>Degrees</th>
<th># of Minutes</th>
</tr>
</thead>
<tbody>
<tr>
<td>UK</td>
<td>134</td>
<td>3.5</td>
</tr>
<tr>
<td>Germany</td>
<td>134</td>
<td>4</td>
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<td>5.3</td>
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<td>Spain</td>
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<td>France</td>
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<tr>
<td>Australia</td>
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</tr>
<tr>
<td>South Africa</td>
<td>134</td>
<td>5</td>
</tr>
</tbody>
</table>
Why are there different exposure times even when the Sterilization Parameters are exactly the same?

Example:

- 270°F / 132°C Prevacuum Cycle for 4 minutes
- 270°F / 132°C Prevacuum Cycle for 15 minutes
Gravity Sterilization
Gravity Sterilization
Vacuum Assisted (Prevacuum) Sterilization
Dynamic Air Removal; Vacuum Assisted
Steam Surrounds the Mass (Steam Flush)
Dynamic Air Removal; Vacuum Assisted Vacuum Pulse Removing Air
Dynamic Air Removal; Vacuum Assisted Attraction of Steam through Condensation
Dynamic Air Removal; Vacuum Assisted Vacuum Pulse Removing Air, Steam & Condensate

AIR, STEAM & WATER

MASS

AIR, STEAM & WATER

AIR, STEAM & WATER
Dynamic Air Removal; Vacuum Assisted Successful Penetration of Steam to Center of Mass
Preconditioning Comparisons

Gravity

- Poorest air removal
- Complicated by solid bottom trays and basins
- Not affected by leaks

Prevacuum

- Good air removal
- Air removal capabilities lessoned by leaks

All are affected by non-condensable gases and super heat
A Word on Sterilizer Lethality

• Lethality occurs whenever the conditions achieved can kill microorganisms

• The preconditioning phase of some sterilization processes will often result in the death of microorganisms prior to the actual start of the exposure time
How does Sterility Assurance Monitoring fit into all of this?
Sterility Assurance

- ✔ Identifies between processed and unprocessed
- ✔ Confirms sterilant penetration
- ✔ Verifies the proper functioning of sterilizers
Evolution of Sterility Assurance Monitoring
Biological Indicator Evolution

• Uses
  – Validation of the sterilization process
  – Microbial verification of equipment functionality
  – Microbial challenge of sterilization loads

• Factors of evolution
  – Ease of use
  – Speed of results
  – New sterilization processes
Biological Indicator Strips

- Spore Suspension
- Glassine Envelope
- Adhesive Seal
- Filter Paper Carrier

Diagram:

- Spore Suspension
- Glassine Envelope
- Adhesive Seal
- Filter Paper Carrier

- Filter Paper Carrier
- Spore Suspension
Self-Contained Biological Indicators

- Cap
- Vial
- Media Ampoule
- Filter Paper Carrier
- Spore Bar
- Spore Suspension
Enzyme-Based Early-Readout

Cap

Vial

Media Ampoule

Media containing Alpha Glucosidase with attached 4-Methylumbelliferyl

Filter paper carrier with spores
Comparison of Growth Indicators

Conventional

Utilizes nutrients, grows and replicates

Waste builds changing pH making media turn yellow

Enzyme-based Early-readout

Spore Enzyme works on modified nutrient, by-product glows

Bacteria replicates

Waste builds changing pH making media turn yellow
Chemical Indicator Evolution

• Uses
  – Visual identification – processed vs. unprocessed
  – Verify sterilant penetration
  – Verify air removal (prevacuum sterilizers)
  – Load monitoring with limited load release
Recent Changes in Chemical Indicators

- FDA cleared Class 6 emulating indicators in 2006

- AAMI recognizes Class 6 emulating indicators – ANSI/AAMI/ISO 11140-1:2005
  - ST79:2010, Section 10.4: As new technology progresses, new sterilization process monitoring devices may be cleared by FDA…
Chemical Indicators

Class 1:

- External indicators
- Shows exposure to sterilization process
Chemical Indicators

Class 2:

- Indicators used in specific tests
  - Bowie-Dick Test
Chemical Indicators

Class 3:

- Internal indicators
- Single-parameter indicators
Chemical Indicators

Class 4:

- Internal indicators
- React to two or more critical parameters
Chemical Indicators

Class 5 – Integrators:

- Internal indicators and challenge packs
- Respond to all critical parameters
- Performance correlated to the BI over several temperatures
- For gravity and pre-vacuum cycles
Chemical Indicators

Class 6 – Emulating Indicator:

• Respond to all critical parameters

• Performance correlated to sterilization cycle

• Internal indicators and challenge packs

Next Stage in Chemical Indicator Evolution
Class 6 Indicator Configurations

- Indicator strips
  - Placed in most challenging area of packs
  - Uses thermochromic ink

- Challenge packs
  - Thermochromic ink printed on test sheet in process challenge device (PCD)
  - Barrier specific to conditions used in sterilization loads
Today’s Practices

• Instrumentation is released twice
  – Following sterilization in the CS or OR using biological indicators, chemical indicators and challenge packs
  – Just prior to actual use of the instrumentation in the OR using internal chemical indicator strips
Class 6 Emulating Indicators
FDA Cleared Use and Applications

Load Control

Pack Control
Verify SixCess Indicators

Example...

- Proprietary ink formulation
- Two chemical reactions
- Tight control of the color change
Total Color Change

Unexposed

Pass
One Size Does Not Fit All!

- 15 minute Emulating Indicator Ink
- 10 minute Emulating Indicator Ink
- 4 minute Emulating Indicator Ink
- 3 minute Emulating Indicator Ink

Minutes of Exposure to 270°F Steam Time
Challenges That Need Solutions

• Prions
• Extended Cycles
Infectious Particles

Prions – short for proteinaceous infectious particle (-on) that lacks nucleic acid – is a type of infectious agent composed only of protein (Wikipedia, 2007).
Infectious Particles

• Prions
  – CJD, Mad Cow Disease
  – Non-living
  – Harder to denature than bacterial spores
  – Prion diseases
    • Affect the structure of the brain or other neural tissue
    • All are untreatable and fatal
Extended Cycles

• Causes for extended cycle
  – Packaging design requires more time to achieve steam penetration
  – Device design requires more time for steam contact
Causes of Extended Cycles

• Regulatory situation
  
  – Extended cycles cleared for the medical device or set
  
  – Steam sterilizers capable of longer sterilization times but these are not recognized as “cleared” for the sterilizer
  
  – Biological indicators were never designed to withstand the challenges of extended cycles
Action Plan

• Develop sterility assurance monitoring plan for quality control

• Reference the recommended guidelines and practices

• Educational tools for staff members
Evaluation and Registration

- Thank you for attending this CE activity
- Please complete and submit the evaluation form
- For more information on the CE credentialed programs offered, go to http://university.steris.com
References

Association for the Advancement of Medical Instrumentation, “Comprehensive guide to steam sterilization and sterility assurance in health care facilities” ANSI/AAMI-ST79:2010, Arlington VA

Perkins, John J., “Principles and Methods of Sterilization in Health Sciences”, second edition, eighth printing, 1983
