Welcome!

**Topic:** Biological Indicators – Do they make your life easier or harder?

**Facilitator:** Diane Koch, 3M

**Speaker:** Phil Schneider

**Housekeeping**
- Questions
- Mute feature (*7 = unmute; *6 = mute)
- "Chat" feature
- Technical difficulties
- Post session follow-up

For more information: www.3M.com/3MSterileU

How do I get a CE Certificate?

Next week, all of today’s meeting participants will be sent an email containing instructions for obtaining a CE Certificate for today’s meeting.

The email will be sent to the email address you provided when you logged-in to today’s meeting. If there are others listening with you today who did not log-on, you may forward the CE certificate email to them.
Disclosure Statement

Phil Schneider
LexaMed, Ltd. (Toledo, OH)
Retired from 3M
Consultant for 3M
Co-chair AAMI Biological indicator
Working Group
Co-chair AAMI Ethylene Oxide
Hospital Practices Working Group
Convener ISO Biological Indicator
Working group 4
pmschneider11@yahoo.com

Learning Objectives

1. Describe the rationale for the use of sterilization monitors.
2. Define a BI and discuss why they are considered the 'gold standard' for sterilization monitors.
3. Describe the evolution of biological indicators (BIs).
4. Define proper use of BIs in health care facility applications and discuss assessment of BI results.
5. Describe applicable standards for BIs and how they impact use applications.

Biological indicators (BIs)

New information…maybe

Insight,
perspective…hopefully
If you believe that what you don't know can't hurt you…
or
What you can't see won't hurt you…then

Harder!!

If you understand the nature and value of BIs
and
Want to be consistent with recommended practice
guidelines and your facility’s goal to provide the highest
level of patient care possible…then

Easier!!

If you understand the nature and value of BIs
and
Want to be consistent with recommended practice
guidelines and your facility’s goal to provide the highest
level of patient care possible…then

Easier!!
Biological indicators

Microorganisms

Sterilization monitoring
Physical monitors
Chemical indicators

Sterilization Assurance
Recommended practice guidelines

Antonie van Leeuwenhoek observed and described single celled organisms, now called microorganisms, in 1683

Joseph Lister proposed 'germ theory' linking microorganisms to infection and applied to surgical techniques in the 1860's
Microorganisms

- As microorganisms can cause disease it is intuitive that transmitting such organisms via medical items to patients, with potentially compromised immune systems must be avoided at all costs

- Sterilization is the only process that can consistently achieve sterility for medical items

Sterility

- Dr. Earl Spaulding proposed a scheme for classification and treatment of medical items based on how they were used and the subsequent risk of infection to the patient in the late 1960’s
  - Items that enter sterile tissue or the vascular system are categorized as critical devices and should be sterile
  - AORN 2011 Recommended Practices for Maintaining a Sterile Field: Recommendation III
    - Specifies that items contacting the vascular system, the neurological system, and/or sterile tissue pose the greatest risk of infection, are classified as critical and should be sterile

Sterilization

Definition: A process that eliminates all forms of microbial life (including bacterial endospores)

- Steam - Approximately 85% of medical item sterilization in healthcare facilities is achieved with saturated steam under pressure
- Dry heat
- Low temperature processes
  - Ethylene oxide
  - Hydrogen peroxide vapor gas plasma
  - Hydrogen peroxide vapor
  - Ozone
The goal of sterilization is to provide sterile, functional items at the point of use in the health care facility.

Disease Transmission Cycle

- Infectious Agent
- Susceptible Host
- Reservoir
- Portal of Entry
- Portal of Exit
- Mode of Transmission
- Sterilization/Disinfection

Sterilization assurance

As sterilization involves microorganisms, how do you determine its effectiveness??

‘You can’t see sterility’

- You can’t inspect for sterility
- You can’t test for sterility in a practical manner
Sterilization assurance

- The sterilization processes for single-use, sterile medical items are validated by the product manufacturer and controlled by adhering to a rigid Quality System.
- Sterilization assurance in U.S. healthcare facilities is based on a combination of:
  - Recommended practice for reprocessing
  - Following device manufacturers instructions for reprocessing
  - Overkill sterilization cycles
  - Monitoring the sterilization process

Recommended practice guidelines

- AORN (Association of periOperative Registered Nurses) Perioperative Standards and Recommended Practices for Inpatient and Ambulatory Settings. 2011
- CDC (Centers for Disease Control and Prevention) Guideline for Disinfection and Sterilization in Health Care Facilities. 2008

Device manufacturer requirements

- 21 CFR Part 801 requirements for reusable devices
  - Developing and VALIDATING cleaning and disinfection or sterilization methods
  - Clear reprocessing instructions
- Draft Guidance Processing/Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling (May 2011)
  - Applicable to reusable medical devices AND single-use devices that are reused
  - Instructions for assembly and reassembly
  - Validation of reprocessing per FDA Quality System Regulation
  - Cleaning process
  - Sterilization or disinfection
You can follow:
- recommended practice
- manufacturers instructions for reprocessing, and
- use overkill cycles...BUT

You still need some type of feedback to demonstrate that you are ‘on track’
AAMI, AORN and CDC recommend monitoring of the sterilization process with:
- Physical monitors
- Chemical indicators
- Biological indicators

Three distinct types of monitoring are recommended because all of these monitoring methods have both advantages and limitations.

**Physical indicators**
- Integral component of the sterilizer
- Provide real time information
  - Cycle assessment
  - Malfunctions
- Provide historical record
- Generally monitor only one location in the sterilizer
- Require periodic calibration

**Chemical indicators (CIs)**
- Provide immediate information
  - External: differentiate processed vs. non-processed
  - Internal: demonstrate exposure to sterilant
- Allow multiple location placement
- May detect incorrect packaging, incorrect loading, sterilizer malfunctions or aid in the identification of procedural errors
- Results based on physical and/or chemical change providing an indication of sterilizer conditions but do not indicate lethality
• Definition: Test system containing viable microorganisms providing a defined resistance to a specified sterilization process (ANSI/AAMI ST79)
  - A negative BI does not prove that all items in the load are sterile or that they were all exposed to adequate sterilization conditions

- BIs are a tool – nothing more, nothing less
  - They are available to help you perform your job in the successful reprocessing of medical items
  - Like any tool, they must be used correctly to fulfill their intended function

- Affected by the same kinds of changes in cycle conditions that would affect the microorganisms commonly found on items being sterilized
- Not only provide an indication of sterilant exposure but also indicate that conditions are adequate to inactivate microorganisms
- Provide the only direct measure of sterilization cycle lethality – AAMI
- Recognized by most authorities as being closest to the ideal monitors of the sterilization process – CDC
- Require incubation period
**BI microorganisms**

- Bacterial spores are commonly used for BI microorganisms:
  - Highly resistant to physical and chemical agents
  - Stable for long periods of time
  - Easy to grow
  - Non-pathogenic
- Geobacillus stearothermophilus for steam, H₂O₂ & ozone
- Bacillus atrophaeus for ethylene oxide & dry heat

**BI rationale**

- Typical BIs contain a minimum of 100,000 – 1,000,000 spores per unit
- Studies have indicated that the microbial contamination on medical instruments after use (bioburden) ranges from 1 to 1,000 viable organisms (generally vegetative cells)
  - Consequently, a negative result with a BI, when used in a proper manner, strongly implies that the device bioburden has also been inactivated

**Use of BIs**

- Bioburden population & resistance
  - Unknown (cannot see or quantify)
  - Known (can see & quantify)

- Sterilant Exposure Time

- # Organisms/µl

- Bioburden population & resistance
  - Biological indicators

- Use of BIs
Use of small quantities of garden soil cultured after exposure to the sterilization process in the 1880’s believed to be the first ‘BIs’

Shortly thereafter, the German scientist Robert Koch refined the BI concept by using preparations of spores and other microorganisms on various carrier materials.

Evolution of BIs

- BIs in the form of spore strips packaged in glassine envelopes became commercially available in the 1950’s.
- Self-contained BIs were introduced into the marketplace in the mid 1970’s.
- Rapid Readout self-contained BIs were first available in the early 1990’s.

My how you’ve grown!

• Today the manufacturing, labeling, performance requirements and testing of BIs (and CIs) are well characterized and standardized.
• Standards series specifying the various requirements for these indicators are published by AAMI in the U.S. and by ISO (International Organization for Standardization) on a global basis.
• Additionally, the U.S. FDA regulates the marketing of CIs and BIs in U.S. health care facilities through its 510(k) process.
ISO 11138 BI standards series

- Specifies general production, labeling and performance requirements for BIs and suspensions intended for use in the validation and monitoring of sterilization cycles
- ANSI/AAMI/ISO versions of these standards are identical to the ISO documents
  Part 1: General requirements
  Part 2, BIs for the ethylene oxide process
  Part 3, BIs for the moist heat process
  Part 4, BIs for the dry heat process

ISO 14161 guidance document

- Provides guidance regarding the selection, use and interpretation of results of BIs when used to develop, validate and monitor sterilization processes
- An ANSI/AAMI/ISO version of this standard is identical to the ISO document
Process challenge device (PCD)

Definition: Item designed to constitute a defined resistance to a sterilization process and used to assess performance of the process (ANSI/AAMI ST79)
- Used to assess the effective performance of a 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
- May be a user-assembled challenge test pack or test tray or a commercially available
- Can be a challenge test pack, a test tray or a rigid sterilization container that contains a BI (and/or CI)

Examples of PCDs

- User assembled PCD (BI challenge test pack) for steam
  - ANSI AAMI ST79
- Single-use PCD (BI challenge pack) for steam
- Single-use PCD (routine BI test pack) for EO
- PCD for Immediate Use Steam Sterilization (formally “FLASH” sterilization)

Proper use of BIs

Don’t mean much if it ain’t done right!
Improper use of BI

Proper use of BI (PCD)
Proper use of BI (PCD)

- Representative of items being processed
- Placement in worst case location in sterilizer (steam)

Rigid sterilization container systems
- Placement in worst case location in container (steam and LTS)
  - Locations that present the greatest challenge to air evacuation and sterilant penetration
  - Corners of the container system and the underside of the lid, away from the filters, are the likeliest locations for air pockets
  - Consult container manufacturer’s recommendations
Proper use of BI

• For each test BI that is run, at least one BI that is from the same lot and that has not been exposed to the sterilant should be incubated as a control (ANSI/AAMI ST79)

• Verifies
  - Viability of the test organisms
  - Ability of the media to promote growth of the test organisms
  - Proper incubation temperature

Recommendations for monitoring steam process with BI

Overview


• Routine monitoring
  - Implant loads (load quarantined until BI results obtained)
  - Non-implant loads
• Sterilizer qualification testing
• Periodic quality assurance testing
• Types of sterilizers
  - Sterilizers larger than 2 cubic feet
  - Flash sterilizers
  - Table-top sterilizers

Frequency

• Routine sterilizer efficacy monitoring
  - Every load containing an implant
  - At least weekly but preferably daily for non-implant loads
• Sterilizer qualification testing
  - After sterilizer installation, relocation, malfunctions, major repairs and sterilization process failures
• Periodic quality assurance testing
  - Ongoing basis for routinely processed items representing a product family
Recommendations for monitoring steam process with BI

**Type & application**
- BI contained in PCD
- Most difficult to sterilize location in chamber
- Routine sterilizer efficacy monitoring
  - Full load (normal load - sterilizers > 2 ft³ chamber & tabletop sterilizers)
  - Empty load (IUSS "FLASH" sterilization cycles)
  - Monitor each different type of cycle (even if same sterilizer)
  - Part of load release criteria
- Sterilizer qualification testing
  - Empty chamber (> 2 ft³ chamber and IUSS)
  - Full load (table-top sterilizer)
  - Three consecutive cycles

Recommendations for monitoring LTS processes with BI

**Frequency**
- Routine sterilizer efficacy monitoring
  - EO - Every load (AAMI, AORN)
  - H₂O₂ gas plasma, H₂O₂ vapor, ozone -
    - Daily (preferably every load) and every load containing an implant (AORN)
- Sterilizer qualification testing (AAMI, AORN)
  - After sterilizer installation, relocation, malfunctions, major repairs and sterilization process failures (three consecutive cycles in an empty chamber)

Positive BI result
Recommendations for steam process monitoring with BI

Positive BI result

• If cause of failure identified and confined to one load - correct failure and reprocess load
• If cause not identified - quarantine load AND recall all loads back to the last negative BI
• Take sterilizer out of service
• If cause of failure has been determined to be a sterilizer malfunction and major repair is required – rechallenge the sterilizer after repair with a BI PCD in three consecutive cycles

Positive BI result

Easier because you have been alerted to a potential problem that may compromise attainment of your goal

OR

Harder because you now have extra work to do

And… one final thought…
And…one final thought…

So…

You decide –

Do biological indicators make your life easier or harder?

Summary

• Sterilization of medical items prevents transmission of microorganisms to patients via medical items
• Assurance of sterilization includes following recommended practice guidelines, manufacturers instructions for reprocessing and routine efficacy monitoring of the sterilization process
• Sterilization monitoring with physical, chemical and biological monitors provides feedback on the sterilization process (can’t see or test sterility)
• BIs not only provide an indication of sterilant exposure but also indicate that conditions are adequate to inactivate microorganisms
• The performance characteristics and use applications of BIs (and CIs) are specified in various industry standards
Thank you!

Next 3M™ Sterile U Web Meeting:
- October 13, 2011
- Ask the Experts! A Panel Discussion with Infection Prevention and CSSD Leaders

Register at www.3m.com/SterileU/WebMeetings

Evidence-Based Guidelines

Association for the Advancement of Medical Instrumentation (AAMI)
- Comprehensive guide to steam sterilization and sterility assurance in health care facilities,

How to Purchase AAMI Standards for Your Reference Library

AAMI documents can be purchased through AAMI by credit card using the following four options:
- Internet: http://marketplace.aami.org
- Call: 1-877-249-8226
- Fax: 301-206-9789
- Mail: AAMI Publications, P.O. Box 0211, Annapolis Junction, MD 20701-0211

A free PDF of future amendment(s) may be downloaded by visiting http://www.aami.org/publications/standards/st79.html, which also includes information on how to update your copy of ST79.
Print and save to your hard drive.
How to obtain CDC Guideline for Your Reference Library

A free PDF may be downloaded by visiting http://www.cdc.gov/hicpac/pdf/guidelines/Disinfection_Nov_2008.pdf
Print and save to your hard drive.

Evidence-Based Guidelines

Association of periOperative Registered Nurses (AORN)
Perioperative Standards and Recommended Practices (2011)
• Recommended Practices for Practices for Sterilization in the Perioperative Practice Setting
• Recommended Practices for Selection and Use of Packaging Systems for Sterilization

How to Purchase AAMI Standards for Your Reference Library

AORN Standards can be purchased through AORN using the following options:
• Internet: www.aorn.org/bookstore/ordering.htm
• Call: 1-800-755-2876 x 1 or 303-755-6304 x 1 (Monday-Friday, 8AM to 4:30PM mountain standard time)
• Fax: 303-750-3212
• By mail: AORN, Inc., Customer Service/Book Orders, 2170 South Parker Road, Suite 300, Denver, CO 80231-5711, USA
References

Recommended practice


Device reprocessing


Sterilizer testing