Is it Sterile? What is Sterility Assurance?

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Objectives

- Define the term “sterility assurance”
- Discuss the guidelines that relate to sterility assurance (SA) and biological indicator (BI) usage.
- Identify and discuss the value of using a BI designed by the sterilizer manufacturer
- Verbalize and review steps to be taken when a positive BI occurs

Bad

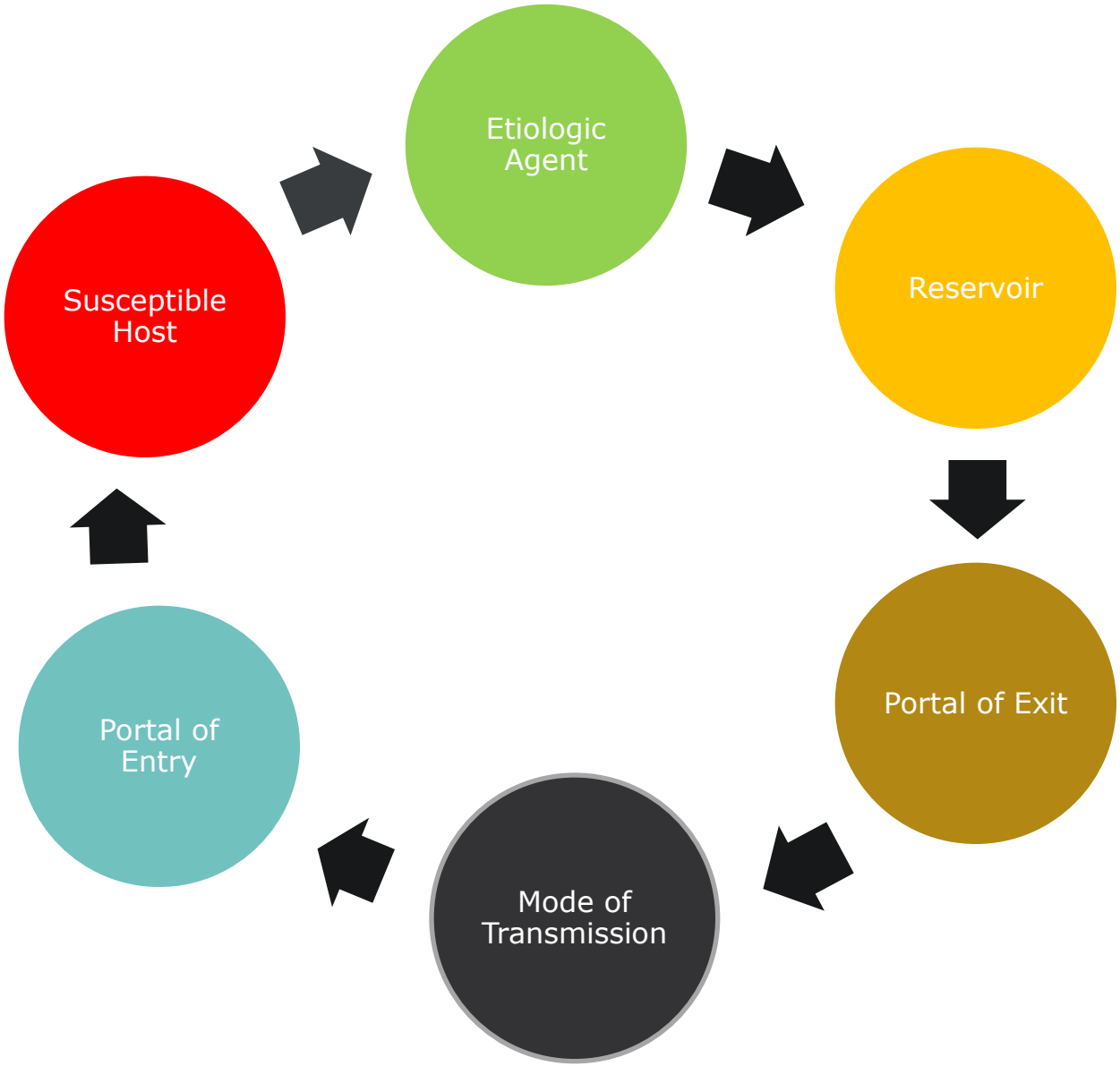
things

happen

to

Good People!

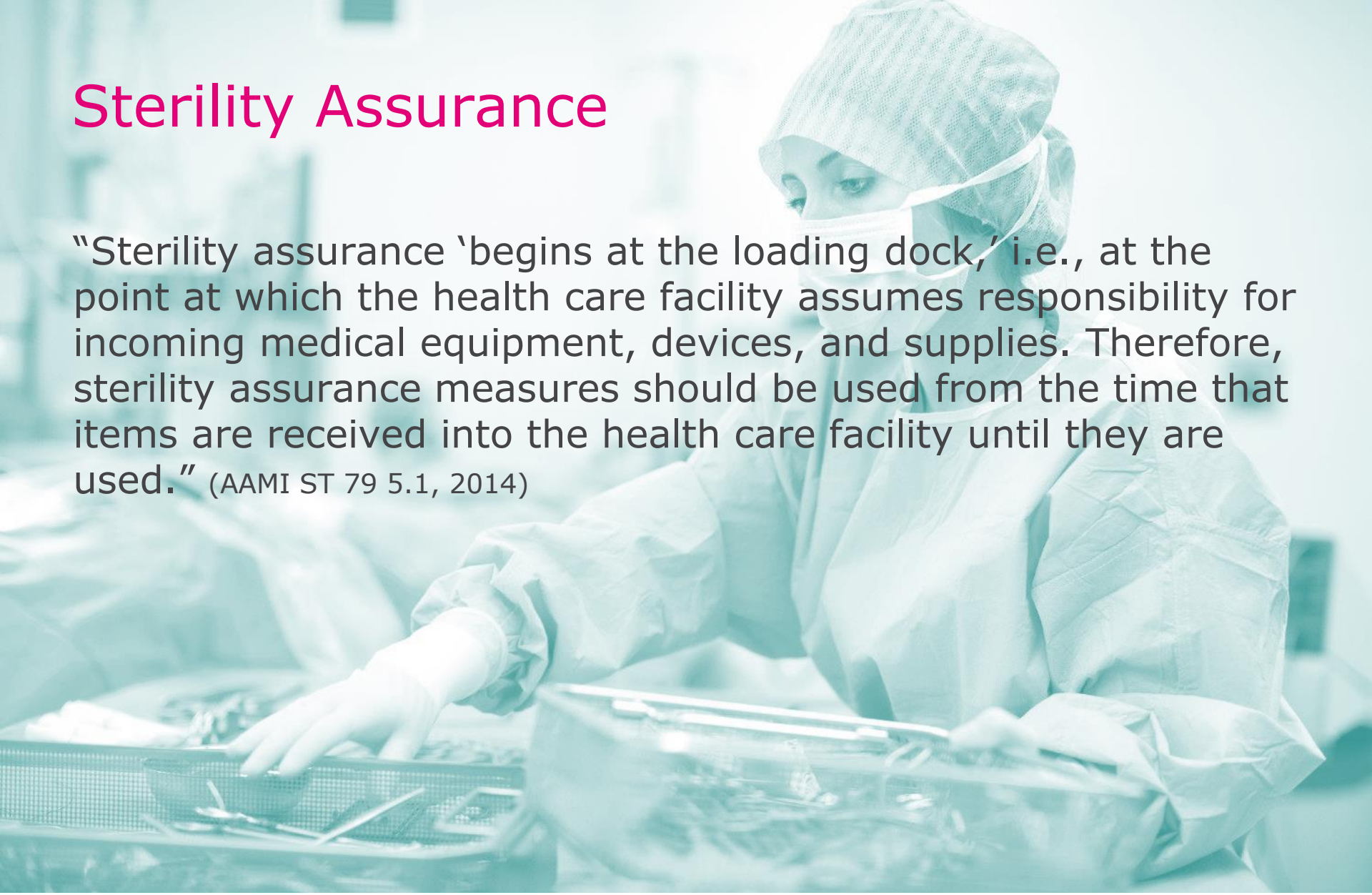
Chain of Infection[1]



Touch Points of an Instrument Set

- Transportation
- Receiving
- Wash-Disinfect
- Prep and pack
- Transfer to sterilizer
- Loaded in sterilizer
- Removed from sterilizer
- Placed on a cart
- Place on storage shelf
- Place on case cart
- Place on ringstand
- Open

Sterility Assurance



"Sterility assurance 'begins at the loading dock,' i.e., at the point at which the health care facility assumes responsibility for incoming medical equipment, devices, and supplies. Therefore, sterility assurance measures should be used from the time that items are received into the health care facility until they are used." (AAMI ST 79 5.1, 2014)

What are those guidelines?

American National Standard

ANSI/AAMI ST79:2010 & A1:2010 & A2:2011 & A3:2012 & A4:2013 (Consolidated Text: (R)2014)

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

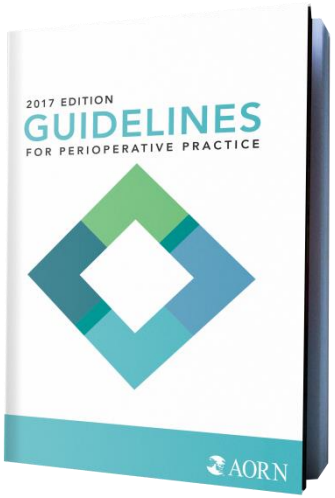
AAMI

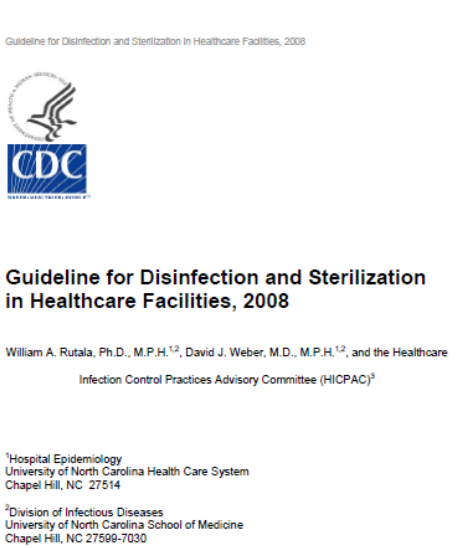
American National Standard

ANSI/AAMI ST58:2013

Chemical sterilization and high-level disinfection in health care facilities

AAMI




Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008

CDC

Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008

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American National Standard

ANSI/AAMI ST91:2015

Flexible and semi-rigid endoscope processing in health care facilities

AAMI

Overview of Sterility Process Monitoring*

An essential element of sterility assurance is sterilization process monitoring, which consists of:

- Monitoring of every package and sterilization load
- Routine monitoring of sterilizer efficacy
- Qualification testing of the sterilizer after installation, relocation, sterilizer malfunction, major repairs, and sterilization process failures
- Periodic product quality assurance testing

*AAMI ST 79 (10.4)

Measuring the Effectiveness of Sterilization

1.Physical Measures

- Sterilizer cycle parameters have been met (temperature, time, pressure).

2.Chemical Indicators

- Chemical indicators verify that one or more conditions necessary for sterilization have been achieved within the package and/or at a specific location within the load.

3.Biological Indicators

- Biological indicators verify that the conditions at a location within the load were adequate to kill a population of microorganisms resistant to the sterilization process and demonstrate the lethality of the sterilization process.

Chemical Indicators

Class 1 › Process indicator

Class 2 › Bowie-Dick

Class 3 › Single variable indicator

Class 4 › Multiple variable indicator

Class 5 › Integrating indicator

Class 6 › Emulating indicator

Routine Testing of H_2O_2 sterilizers

Monitoring tool	Frequency	Acceptance	Record keeping
Physical Monitor	Every load	Printout is examined to verify cycle parameters were met	Printout is initialed and included in cycle documentation
Chemical indicators (CI)	External CI on outside unless internal is visible. Internal CI used inside every package, tray or container.	External and Internal CI Verification	Document any reports of CIs which did not meet their end-point

Routine Testing of H_2O_2 sterilizers

Monitoring tool	Frequency	Acceptance	Record Keeping
Biological Indicators (BI)	Test BI is run daily, preferably every cycle or cycle type Control BI with matching lot number each day	Negative result for test BI Positive result for control BI	Test BI results and lot numbers are documented Control BI results and lot numbers are documented

Common Factors Influencing the Effectiveness of Sterilization

- Improper cleaning of instruments
- Improper packaging
- Wrong packaging materials for the sterilization process
- Improper loading of a sterilizer
- Monitoring
- No separation between packages
- Sterilant quality and quantity

*CDC Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008. Pg 72.

History of BIs

- The concept of sterilization was born in the mid-19th century.
- Robert Koch conducted a series of experiments in which a roll of flannel contaminated with spores was exposed to dry heat.
- When exposed at 140-150°C for four hours, the spores survived and germinated.
- When exposed to moist heat at 120°C for 30 minutes, they did not.

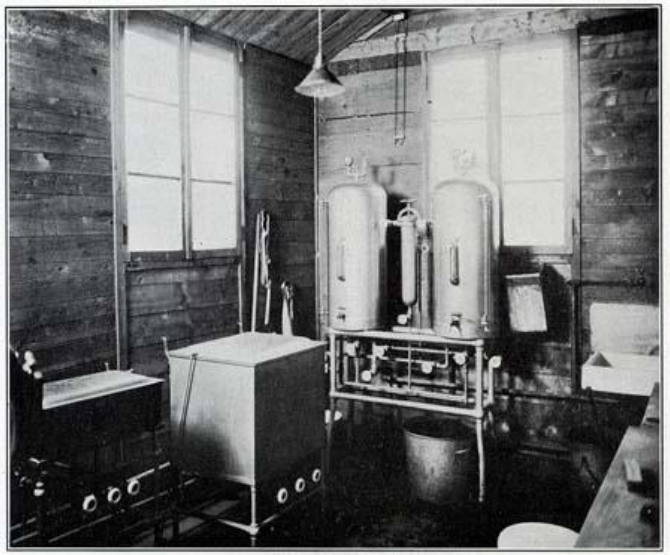


FIG. 96.—Sterilization room, Allerey hospital center

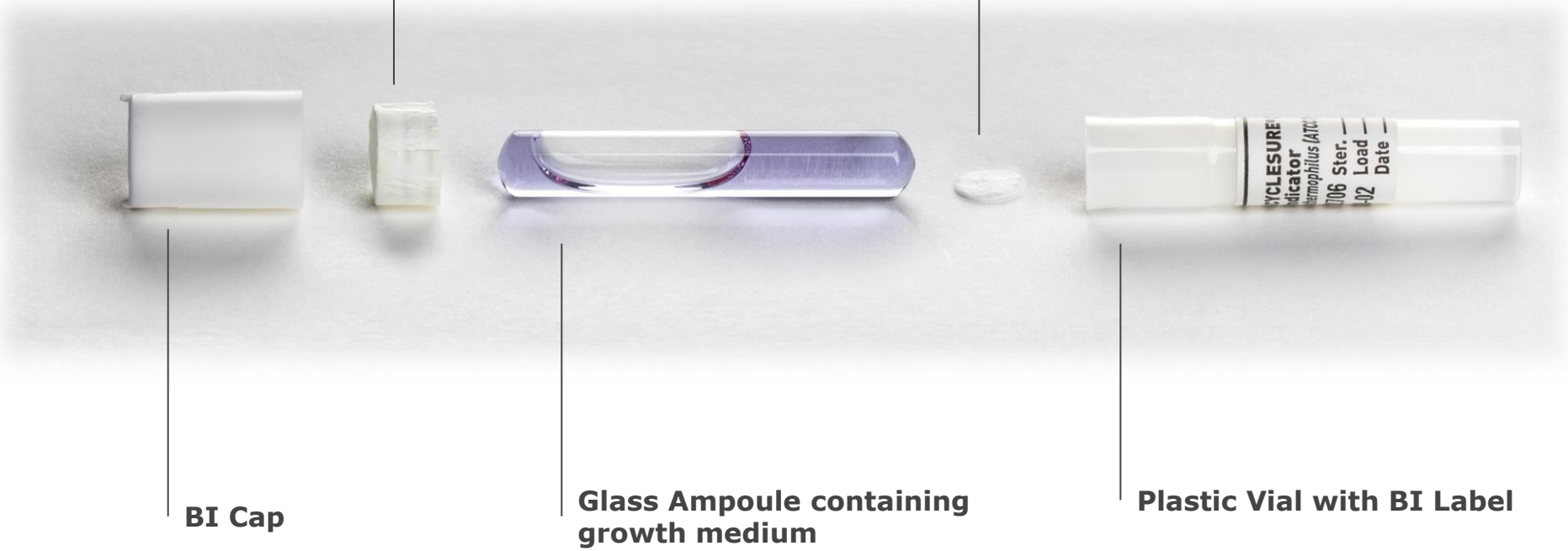
Evolution of BIs

Early BIs were primarily spore strips with a known organism.

- Spore strips – readout in 7 days
- Required operator to know aseptic technique
- Accidental contamination could cause a false positive result

Self contained BIs evolved in the late 90’s to what they are today.

Components of a Biological Indicator



Use of Biological Indicators

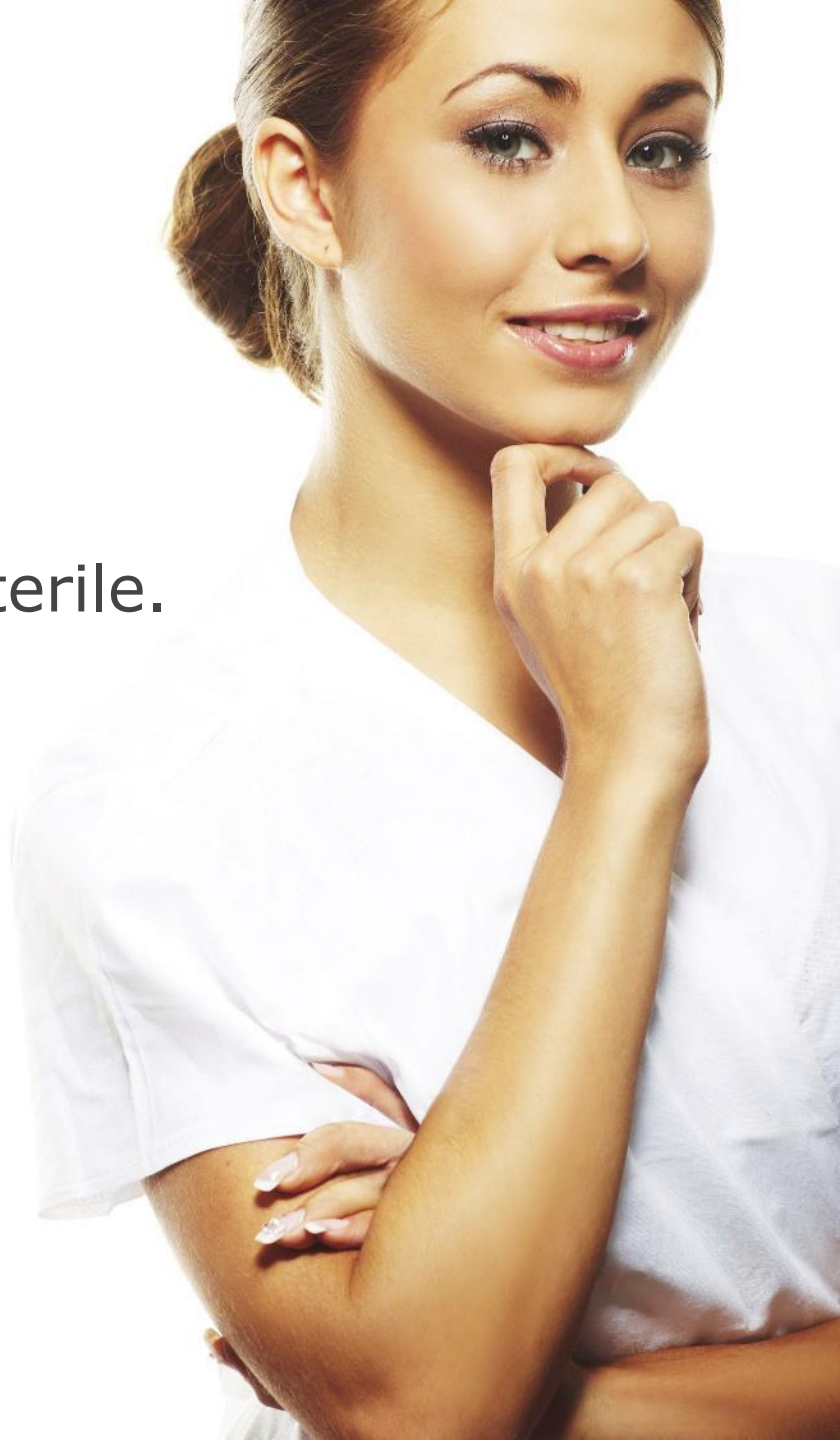
"Biological indicators should be used for load release purposes. For example, loads containing an implant should be monitored with a biological indicator and not released for use until the result of the test is available." (AORN Perioperative Standards VI.c.6, 2013)

Test Your Knowledge

True or False

A BI tells me if my load is sterile.

Answer: False



Organisms used in Biologicals

Steam/Hydrogen Peroxide/Ozone

*Geobacillus stearothermophilus (*used to be called *Bacillus stearothermophilus)*

Ethylene oxide (EO or ETO) and Dry Heat

*Bacillus atrophaeus (*formerly *Bacillus subtilis)*

General Considerations*

Biological indicators:

- Are intended to demonstrate if the sterilization conditions have been met.
- Consist of spores in or on a carrier, sometimes (as in the case of self-contained BIs) accompanied by incubation media.
- Provide the only direct measure of the lethality of the sterilization process.
- Must be incubated for various periods of time (depending on the specific product) until it is determined whether the microorganisms grow (i.e., they survived the sterilization process) or fail to grow (i.e., they were killed by the sterilization process).

*AAMI ST 79 (10.5.4.1)

How does a BI work?

- A BI is a test system containing viable microorganisms providing a defined resistance to a specified sterilization process.
- Biological indicators are the only sterilization process monitoring device that **provides a direct measure of the lethality of the process.**
- If the sterilization process is effective enough to kill a large population of highly resistant spores, it will also kill a lower number of less resistant organisms on the medical devices.

Resistance of Microorganisms to Disinfection and Sterilization[10]

Resistant

Prions *(Czeutzfeldt-Jakob Disease)*

Bacterial spores *(Bacillus atrophaeus)*

Coccidia *(Cryptosporidium)*

Mycobacteria *(M. tuberculosis, M. terrae)*

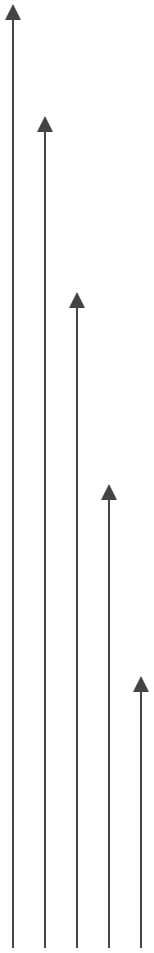
Nonlipid and small virus *(polio, Coxsackie)*

Fungi *(Aspergillus, Candida)*

Vegetative bacteria *(S aureus, P. aeruginosa)*

Lipid or medium-sized viruses *(HIV, herpes, hepatitis B)*

Susceptible



Level

Prion reprocessing

Sterilization

High-level Disinfection

Intermediate-level disinfection

Low-level disinfection

Rapid-Readout Indicators

"A rapid-readout biological indicator that detects the presence of enzymes of *G. stearothermophilus* by reading a fluorescent product produced by the enzymatic breakdown of a non-fluorescent substrate has been marketed for more than 10 years."

(CDC Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008)

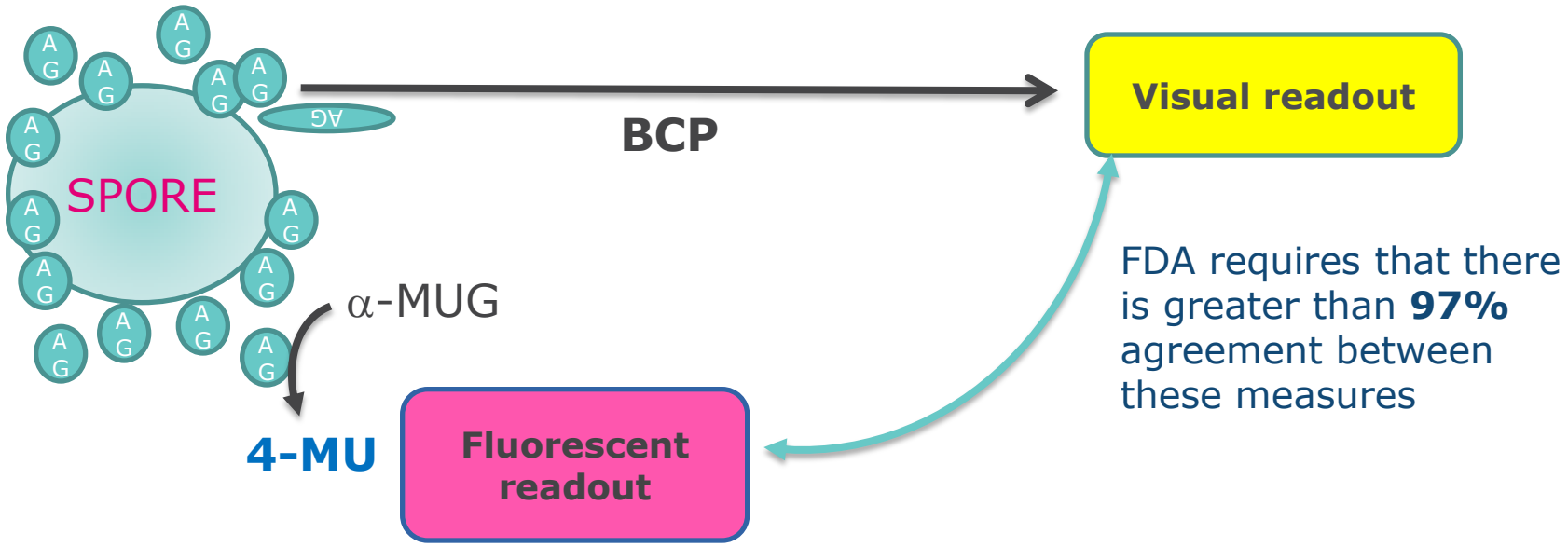
How do Biological Indicators Work?

Growth medium contains two substrates to measure spore germination:

1) **Bromocresol Purple (BCP),** a pH-sensitive, visual dye that responds to acidification of growth medium during growth (hours to days) by changing color from purple to yellow

2) **α-MUG**, a dye that becomes fluorescent when acted upon by α-glucosidase (AG) enzyme, released by germinating spores (minutes)

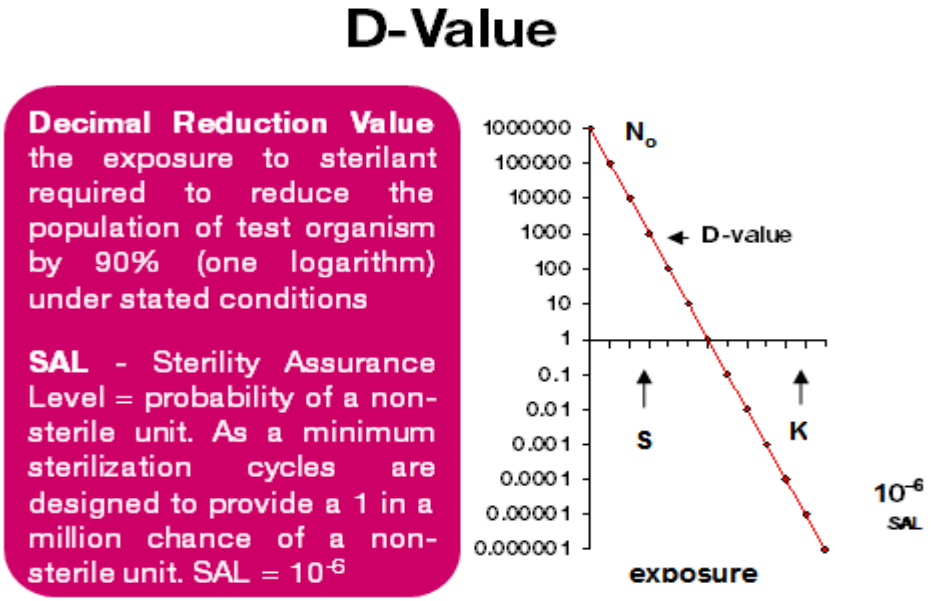
How do Biological Indicators Work?



Back to Basics

What is a D-value?

- The D-value is a measure of the resistance of the BI. The D-value is the time required to achieve inactivation of 90% of a population of micro organisms under the stated exposure conditions. (CDC Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008.)



Why 10^{-6} for a sterility assurance level?*

"In the sterilization process, the nature of microbiological inactivation is described by an exponential function. The presence of a viable microorganism 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." (AAMI ST 58 2.72, 2013)

Sterility Assurance Level (SAL)

What does SAL tell us?

- The sterility assurance level (SAL) defines the probability of a non-sterile unit for a validated sterilization process.
- When the SAL is 10^{-6}, it means that there is one chance in a million that a device is not sterile.

Test Your Knowledge

True of False

A more resistant BI is better.

Answer: False

Per the CDC…

"Since the *Bacillus* spores used in biological indicators are more resistant and present in greater numbers than are the common microbial contaminants found on patient-care equipment, the demonstration that the biological indicator has been inactivated strongly implies that other potential pathogens in the load have been killed."

(CDC Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008)

All BIs are NOT created equal

Importance of using a BI made by the Sterilizer Manufacturer

1. Each sterilization cycle behaves differently and is optimized for certain classes of devices. Developing a single BI that satisfies performance requirements for all cycles is extremely challenging.
2. The sterilizer manufacturer has access to complete, proprietary sterilization cycle parameters and performance information.
3. The balance between these competing requirements (finding the "sweet spot") requires detailed knowledge of the sterilization cycle AND the instruments being processed through those systems.
4. Development of a BI requires that the resistance is neither too weak (potential false-negative) nor too strong (potential false-positive).

The Importance of Controls

"Each day BIs are run, one BI that is from the same lot and that has not been exposed to the sterilant should be incubated as a control to verify the presterilization viability of the test spores, the ability of the media to promote growth of the test spores, and the proper incubation temperature.

If the control BI from a lot fails to grow, it should be assumed that the test BIs from that lot are not viable or that improper incubation occurred. Therefore, the results from the test BIs should be considered invalid and the test should be repeated."

(AAMI ST 58 9.5.4.5.2, 2013)

False Negatives versus False Positives

False negatives

A “too weak” BI can lead to potential false-negatives (device is not successfully sterilized but BI reads negative) putting patient safety at risk

False-negative rates are extremely low and highly unlikely to occur.

False positives

A “too strong” BI could lead to potential false-positives

False-positives occur when a BI returns a positive biological reading despite a successful sterilization cycle.

An overly-resistant BI may unnecessarily challenge shorter sterilization cycles, or those with lower H_2O_2 concentrations, increasing the risk of false-positives.

False Positives

A “too strong” BI could lead to potential false-positives

- Loads recalled unnecessarily
- Antibiotics administered unnecessarily
- Sterile processing operations disrupted
- Waste of time and materials
- Confidence decreased

Positive BIs

What are true positive BIs?

- A positive result for a test BI indicates a sterilization process failure, can be caused by overloading the chamber.

What are false positives and why do they occur?

- False positives* occur when a device is sterilized but the BI reads positive.
- Can be caused by improper testing, faulty indicators, incubator related issue, improper storage, expired BI, or product contamination.

What protocol should the customer follow?

- Follow your hospital's policy/procedure and manufacturer's IFU.
- AAMI ST91 12.9.6 states: "Because a sterilization failure has occurred, items processed in that sterilizer since the sterilization cycle having the last negative BI should be considered non-sterile. They should be retrieved, if possible, and reprocessed."

*According to the CDC, "A biological indicator should not be considered a false-positive indicator until a thorough analysis of the entire sterilization process shows this to be unlikely." (CDC, 2008)

Positive Biological Indicator (BI)

Potential steps that can be followed for a positive BI*:

- Report results to supervisor
- Recall and re-sterilize all "suspected non-sterile" items
- Verify growth and perform gram stain
- Determine cause of failure and correct
- Retest sterilizer before using again

*According to the CDC, "A biological indicator should not be considered a false-positive indicator until a thorough analysis of the entire sterilization process shows this to be unlikely." (CDC, 2008)

Test Your Knowledge

True or False

Hydrogen Peroxide Gas Plasma is a contact sterilant

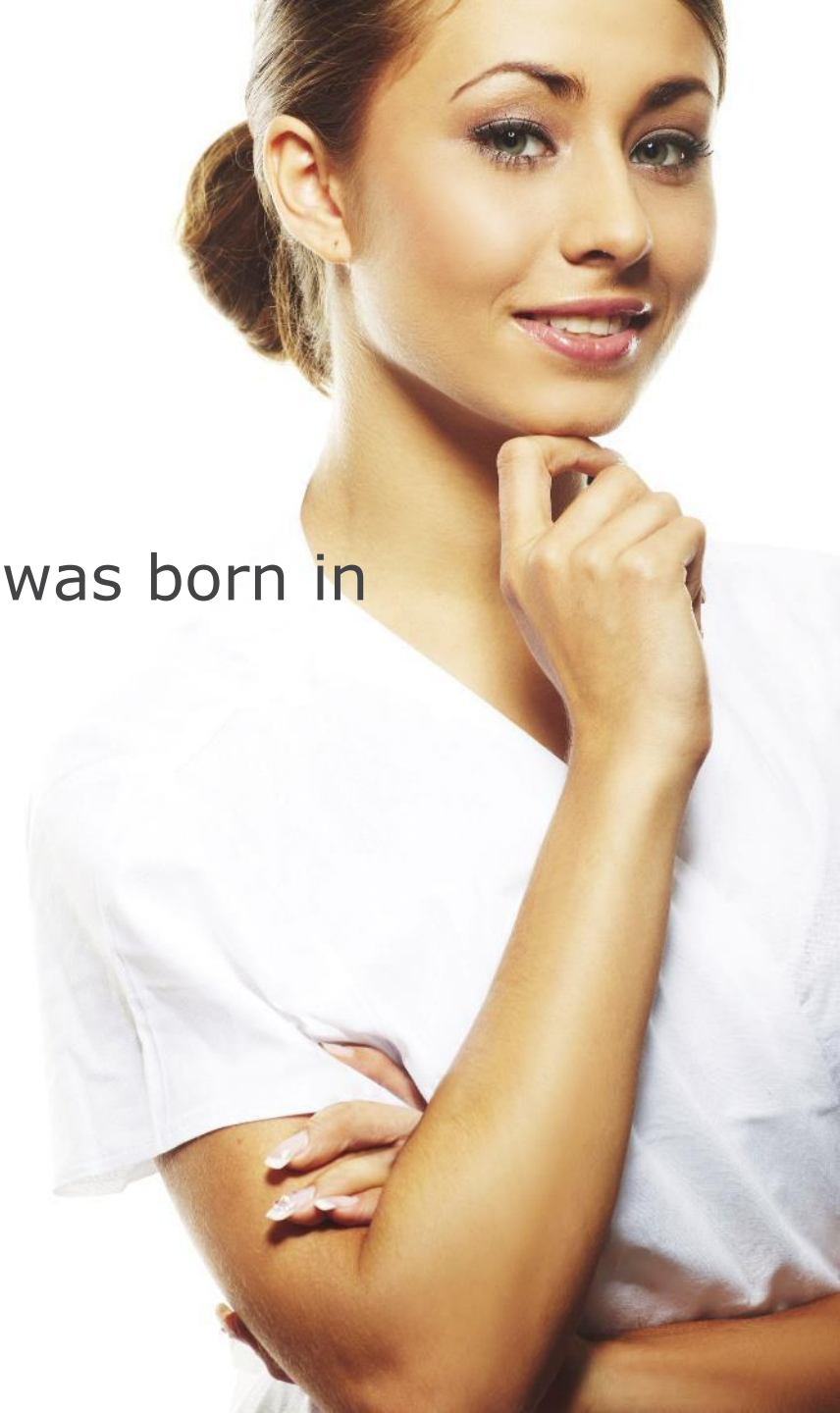
Answer: True

Test Your Knowledge

True or False

The concept of sterilization was born in mid 1900’s

Answer: False

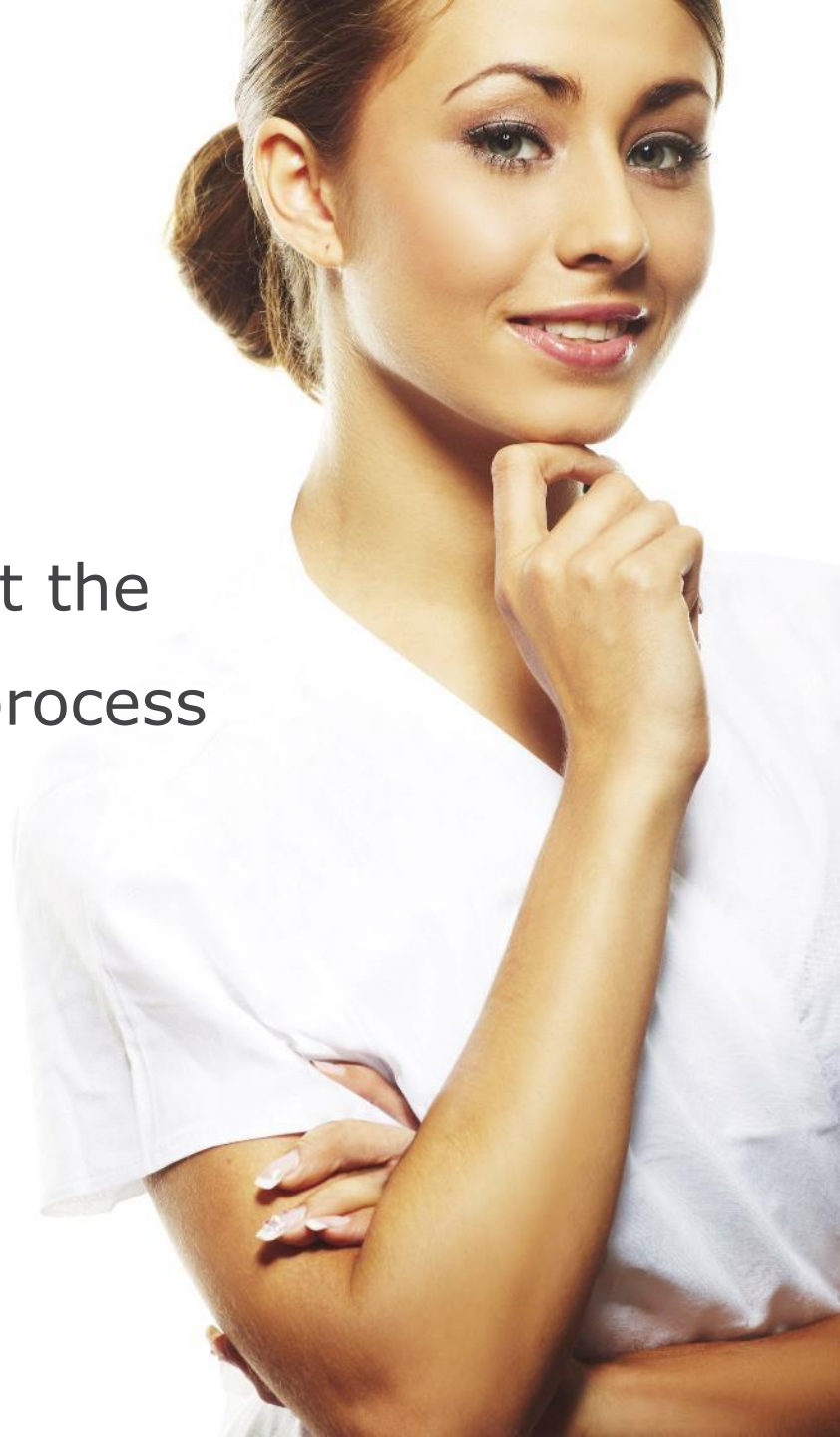


Test Your Knowledge

True or False

Improper cleaning can affect the efficacy of the sterilization process

Answer: True



Test Your Knowledge

True or False

The BI spore used for Low Temperature Gas Plasma sterilization is Geobacillus Stearothermophilus

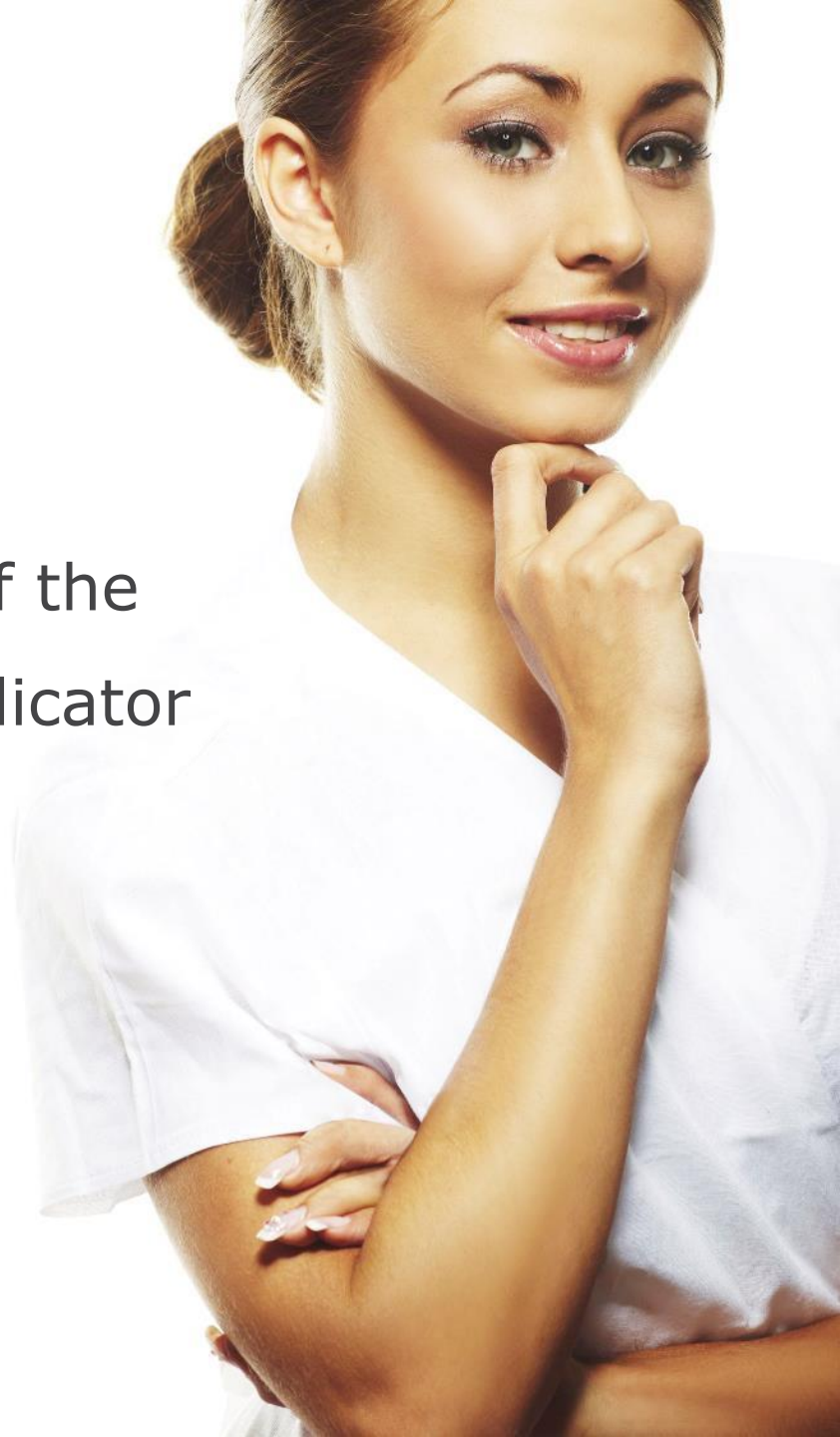
Answer: True

Test Your Knowledge

True or False

The D-Value is a measure of the resistance of a chemical indicator

Answer: False



Test Your Knowledge

True or False

If a control BI does not show growth at the specified time, the test BI's may not contain viable organisms

Answer: True

Bad

things

happen

to

Good People!

Questions?

Thank you for attending!

Protecting Lives Against Infection

ADVANCED STERILIZATION PRODUCTS

Division of Ethicon, Inc.

a Johnson & Johnson company


RECEIVING
BAX