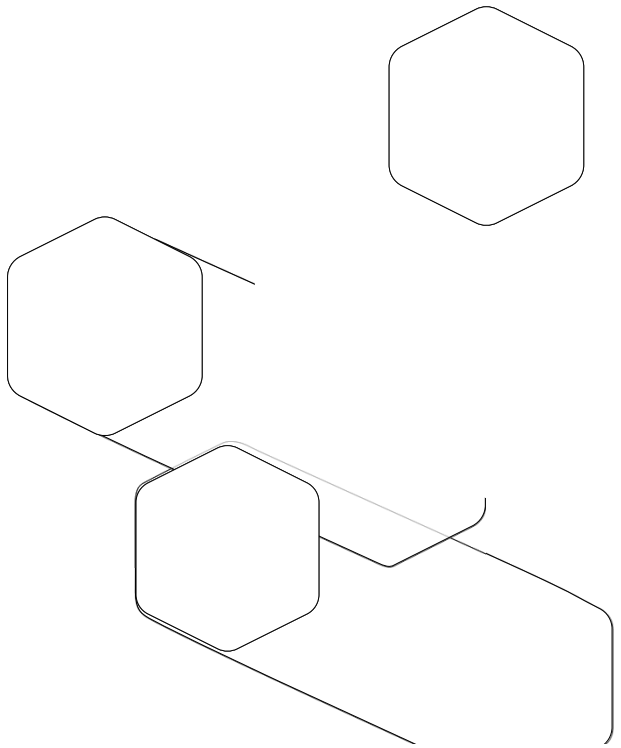
Why are Sterilization Indicators and Integrators So Important for Patient Safety?

Presented by:
Mary Govoni, MBA, CDA, RDH



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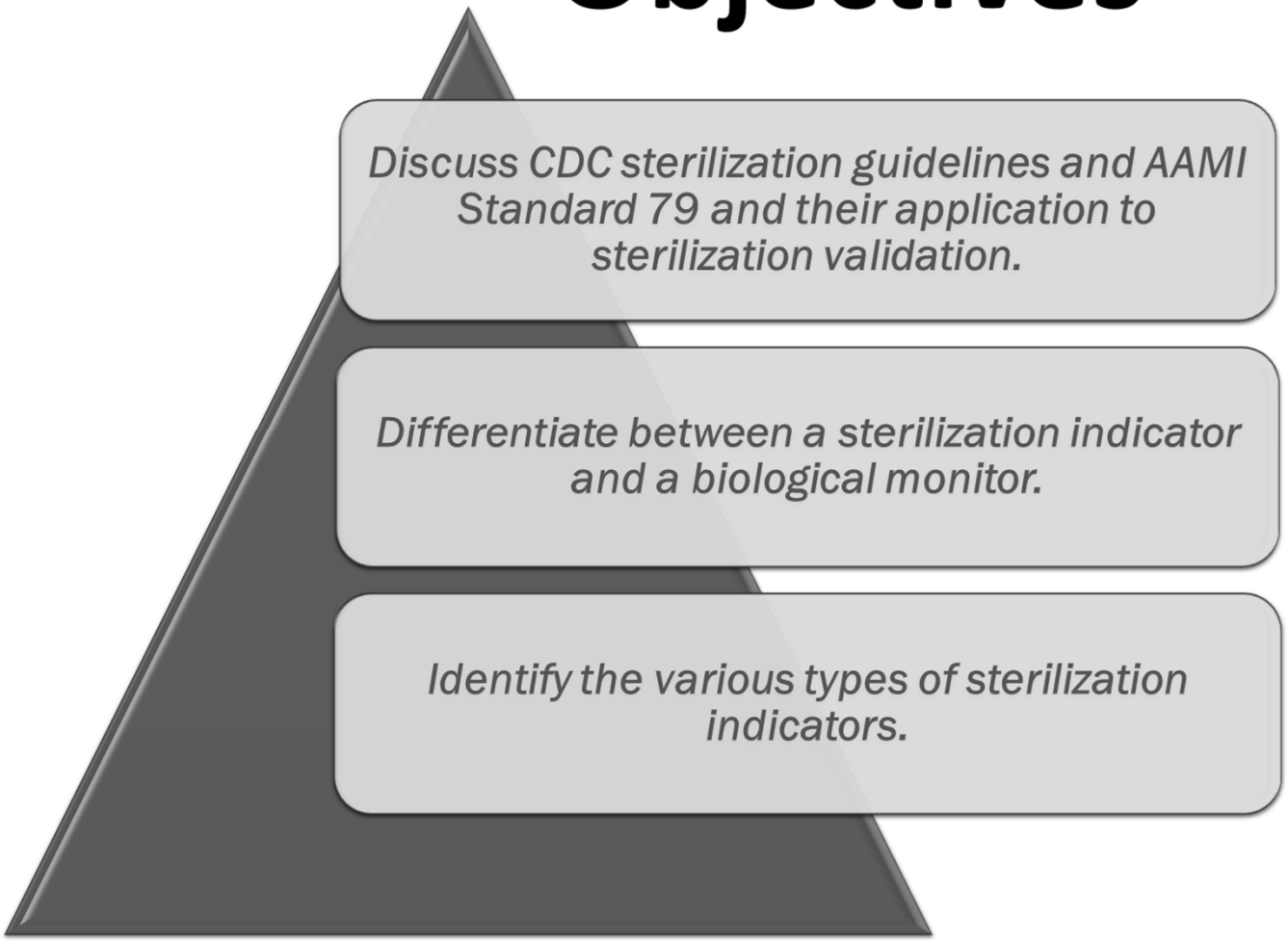
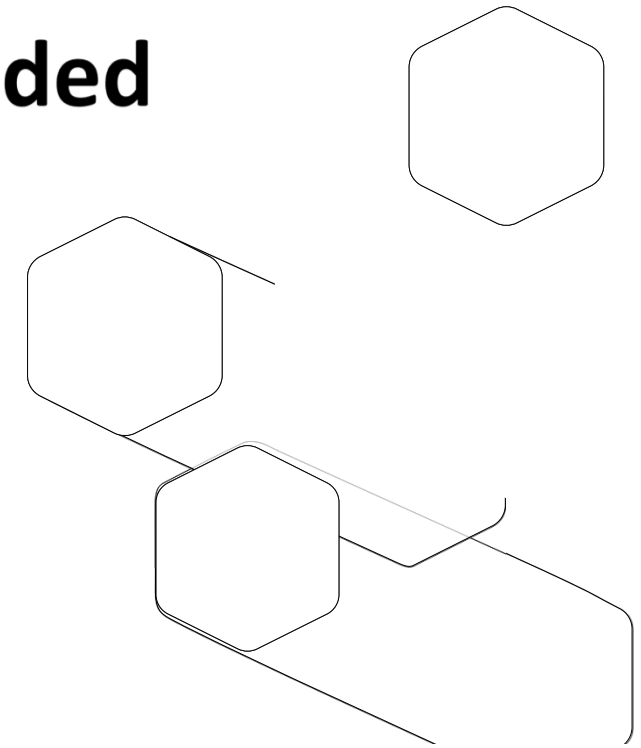
Objectives


Discuss CDC sterilization guidelines and AAMI Standard 79 and their application to sterilization validation.
Differentiate between a sterilization indicator and a biological monitor.
Identify the various types of sterilization indicators.

Most important objectives:

- ✓ Why and What
- ✓ Change protocols if needed



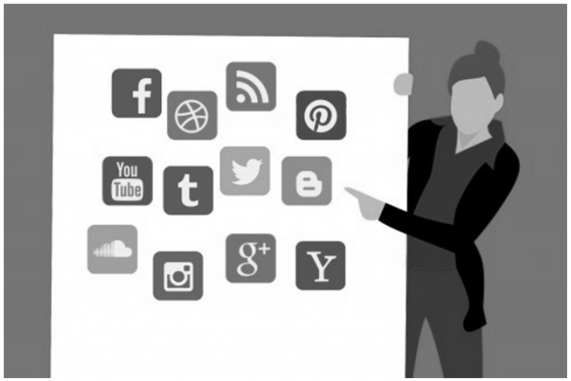
WHY???

If my spore tests (BIs) are negative why do I need to do more?

- **The BI/spore test monitors a single load at a given point in time.**
- **The load may have reached all the parameters for sterilization, but was each package/cassette exposed to the parameters?**
- **The load settings may not be appropriate for the items being processed.**

Risk Management

- Violation of ethical standards
- Liability to the doctor individually
- Liability to the practice as a whole
- Negative publicity for the practice



What to Use?
And Who Says?

MMWR
Morbidity and Mortality Weekly Report
Recommendations and Reports December 19, 2003 / Vol. 52 / No. RR-17

Guidelines for Infection Control in Dental Health-Care Settings — 2003

Guidelines for Infection Control in Dental Health-care Settings - 2003

https://www.cdc.gov/mmwr/pdf/rr/rr5217.pdf

Accessible version: https://www.cdc.gov/infectioncontrol/guidelines/disinfection/

Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008

Update: May 2019

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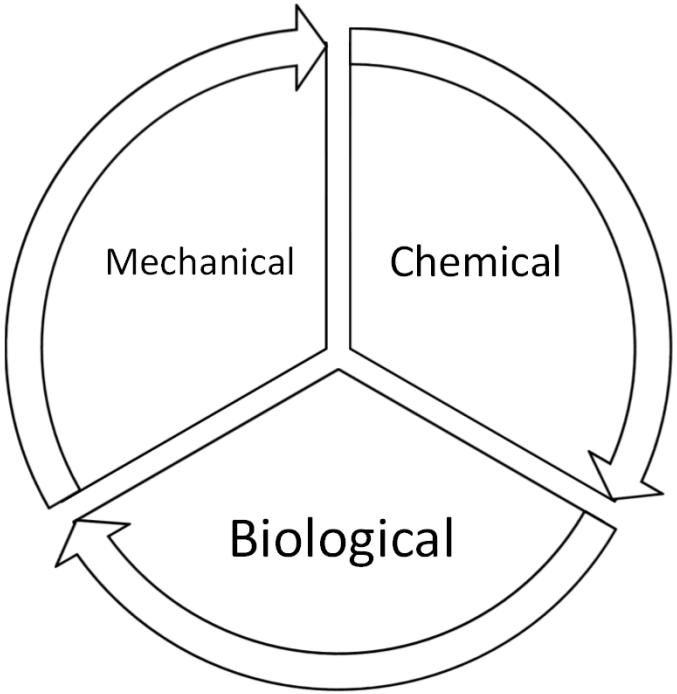
Guidelines for Disinfection and Sterilization in Healthcare Facilities 2008-2019

https://www.cdc.gov/infectioncontrol/pdf/guidelines/disinfection-guidelines-H.pdf

Sterilizer Monitoring

Combination of:



Biological Monitoring

- Upon installation of equipment
- Weekly – per CDC
- If a BI is positive
  - Take sterilizer out of service and retest
  - If second test fails – service sterilizer
- When equipment is moved
- When equipment has been serviced
- When major changes are made to packaging, wraps or load configuration

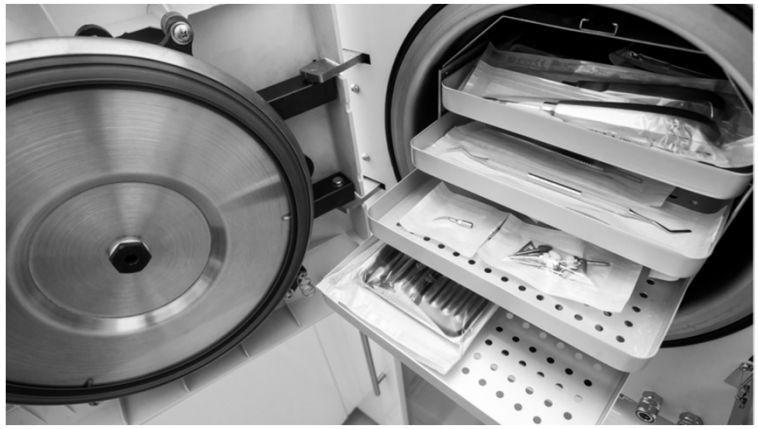


Image Source: HuFriedy Group

Biological Indicators/Spore Tests

Directly assess sterilizer effectiveness by determining if spore forming microorganisms are killed.

1 Cycle Status Indicator
2 Pressure Indicator
3 Power Switch
4 Sterilization Timer
5 Water Pump Switch
6 Drying and Sterilization timer
7 Night Mode Switch
8 Temperature Selector

Image Source: Tuttenauer

Mechanical Indicators

Assess whether the physical conditions necessary for sterilization were achieved.

Chemical Indicators

Use chemicals to assess whether the physical conditions necessary for sterilization were achieved – 1 to 3 parameters measured.

Chemical Indicators in Pouches

Image Source: Halyard

Image Source: Duraline

Biological indicators (BIs) (i.e., spore tests) are the most accepted method for monitoring the sterilization process (*278,279*) because they assess it directly by killing known highly resistant microorganisms (e.g., *Geobacillus* or *Bacillus* species), rather than merely testing the physical and chemical conditions necessary for sterilization (*243*). Because spores used in BIs are more resistant and present in greater numbers than the common microbial contaminants found on patient-care equipment, an inactivated BI indicates other potential pathogens in the load have been killed (*280*).

Guidelines for Infection Control in Dental Health-care Settings - 2003

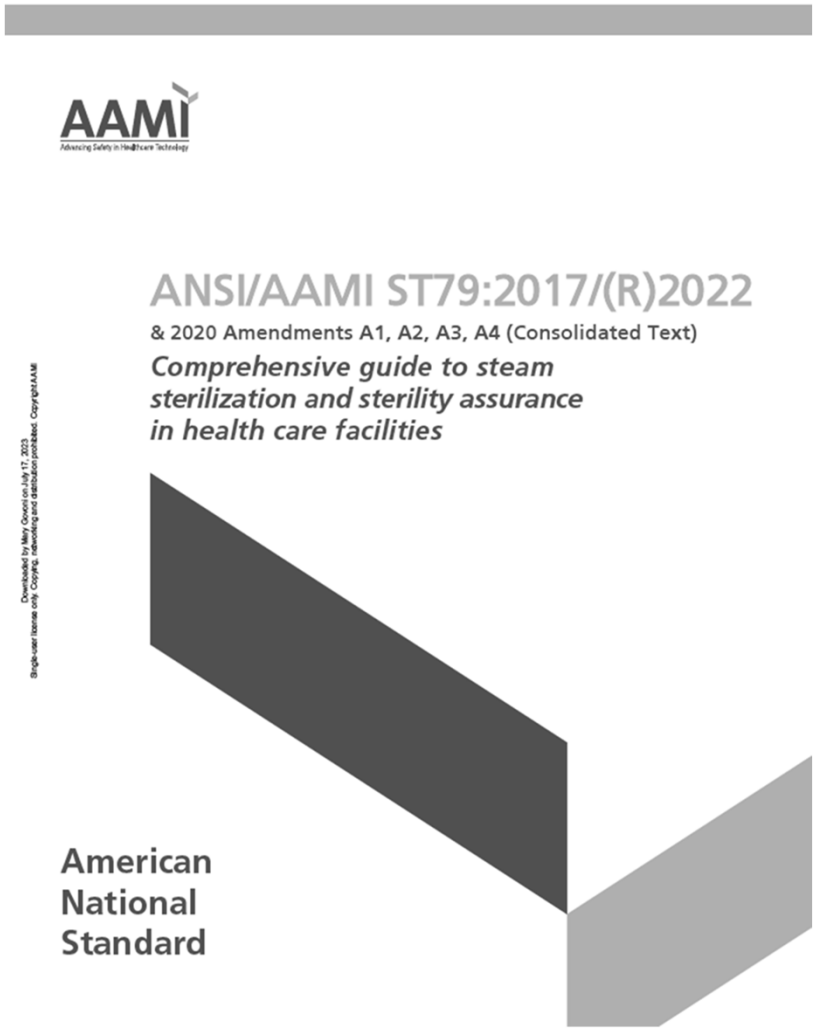
Chemical indicators, internal and external, use sensitive chemicals to assess physical conditions (e.g., time and temperature) during the sterilization process. Although chemical indicators do not prove sterilization has been achieved, they allow detection of certain equipment malfunctions, and they can help identify procedural errors. External indicators applied to the outside of a package (e.g., chemical indicator tape or special markings) change color rapidly when a specific parameter is reached, and they verify that the package has been exposed to the sterilization process. Internal chemical indicators should be used inside each package to ensure the sterilizing agent has penetrated the packaging material and actually reached the instruments inside. A single-parameter internal chemical indicator provides information regarding only one sterilization parameter (e.g., time or temperature). Multiparameter internal chemical indicators are designed to react to ≥2 parameters (e.g., time and temperature; or time, temperature, and the presence of steam) and can provide a more reliable indication that sterilization conditions have been met (*254*). Multiparameter internal indicators are available only for steam sterilizers (i.e., autoclaves).

Sterilization Cycle Verification. A sterilization process should be verified before it is put into use in healthcare settings. All steam, ETO, and other low-temperature sterilizers are tested with biological and chemical indicators upon installation, when the sterilizer is relocated, redesigned, after major repair and after a sterilization failure has occurred to ensure they are functioning prior to placing them into routine use. Three consecutive empty steam cycles are run with a biological and chemical indicator in an appropriate test package or tray. Each type of steam cycle used for sterilization (e.g., vacuum-assisted, gravity) is tested separately. In a prevacuum steam sterilizer three consecutive empty cycles are also run with a Bowie-Dick test. The sterilizer is not put back into use until all biological indicators are negative and chemical indicators show a correct end-point response[811-814, 819, 958].

Biological and chemical indicator testing is also done for ongoing quality assurance testing of representative samples of actual products being sterilized and product testing when major changes are made in packaging, wraps, or load configuration. Biological and chemical indicators are placed in products, which are processed in a full load. When three consecutive cycles show negative biological indicators and chemical indicators with a correct end point response, you can put the change made into routine use[811-814, 958]. Items processed during the three evaluation cycles should be quarantined until the test results are negative.

https://www.cdc.gov/infectioncontrol/pdf/guidelines/disinfection-guidelines-H.pdf

https://www.aami.org/standards/ansi-aami-st79



10.2.2 Sterilization cycles

The sterilizer manufacturer's written IFU should be followed for operation of the sterilizer and indications for use.

a) Differences between the programmed cycle and the cycle parameters recommended by the device manufacturer should be investigated and, if possible, reconciled before the items are sterilized. If differing instructions cannot be resolved, the device manufacturer's IFU should be followed.

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13.5.1 Physical monitors

Physical monitors should be used to monitor sterilizer performance. These include time, temperature, and pressure monitors. The output of these monitors may be recorded by way of charts, printouts, or digital data. The operator should

a) verify that the recording device is functioning properly; and

b) examine and interpret the chart, printout, or data to verify that all cycle parameters were met.

Confirmation that the cycle parameters were met should be documented by the operator signing the chart or printout or by suitable electronic means for data (see 13.3.3).

Sterilizers that do not have recording devices should not be used, with the exception of sterilizers used together with accessory recording devices or printouts.

https://www.aami.org/standards/ansi-aami-st79

13.5.2 Chemical indicators

13.5.2.1 General considerations

Chemical indicators should be

a) used to assist in the detection of potential sterilization failures that could result from incorrect packaging, incorrect loading of the sterilizer, or malfunctions of the sterilizer;

b) used in accordance with the CI manufacturer's written IFU;

c) used as part of an effective quality assurance program; and

d) used in conjunction with physical monitors and BIs to demonstrate the efficacy of the sterilization process. The "pass" response of a CI does not prove that the item monitored by the indicator is sterile.

ANSI/AAMI/ISO 11140-1, *Sterilization of health care products—Chemical indicators—Part 1: General requirements*, defines six types of CIs and specifies performance requirements for them. This document provides recommendations for the following types of CIs.

CIs marketed in the United States must be cleared by FDA. The requirements in FDA's guidance document (FDA, 2003) differ in some aspects from ANSI/AAMI/ISO categories and the performance requirements described in ANSI/AAMI/ISO 11140-1. Annex N provides information explaining the differences between the two sets of performance requirements. For the purposes of this document, ANSI/AAMI/ISO categories are used to refer to the various types of chemical indicators, including use and application guidance.

Health care personnel should

a) use CIs that are labeled for use in the selected sterilization cycle (see the written IFU of the CI manufacturer and the sterilizer manufacturer); and

b) obtain data from the manufacturer on the reliability, safety, performance characteristics, and use of their products (e.g., how to interpret indicator results, the reliability of the indicator in maintaining endpoint response during storage of sterilized items, the sterilization conditions that the indicator will detect, the shelf life of the indicator, and the storage requirements for the indicator itself before and after sterilization).

Some CIs, such as Type 1 and Type 3 chemical indicators, are sensitive only to certain variables (e.g., temperature); others, such as Type 5 integrating indicators and Type 6 emulating indicators, integrate all critical variables. Manufacturers of CIs are required to provide written IFU on the storage, handling, and use of their products. See also ANSI/AAMI/ISO 11140-1.

Type 4 multicritical process variable CIs, Type 5 integrating CIs, and Type 6 emulating CIs provide more information about the process than Type 3 single critical process variable CIs and can provide additional quality assurance for the individual monitoring of such items as complex devices, surgical trays, and rigid sterilization container systems. When used within a PCD (see 13.5.4), Type 5 integrating indicators and Type 6 emulating indicators may be used for release of nonimplant loads (see 13.6). In this application, they provide additional information about the critical parameters of the sterilization process to supplement the results of physical monitors and Type 1 process indicators. A Type 5 integrating CI within a PCD (that also contains a BI) should be used to monitor each load containing implants and may be used as a basis for early load release in documented emergency situations only; however, loads containing implants should always be biologically monitored. Implants should be quarantined until the BI results (early readout or spore growth) are available. In an emergency situation, implants may be released before the BI results are available (see 13.6.3); however, the BI should continue to be incubated. A Type 6 emulating indicator

Indicator	Description	Example
Type 1 Process indicator	Measures one or more variables in the sterilization process – packs have been directly exposed to the sterilization process	Autoclave tape or chemical indicator strips, located inside or attached to the outside of the packs
Type 2 Specific-use indicator	Used when sterilization standards require a specific test procedure	Bowie-Dick air removal test for prevacuum steam sterilizers
Type 3 Single-variable indicator	Measures one critical variable in the sterilization process – exposure to a stated value of the variable e.g., temp.	Chemical pellet that melts at a specific temperature.
Type 4 Multi-variable indicator	Measures two or more critical variables in the sterilization process	Chemical indicators that change color when exposed to a given temp. for a specified time in a steam sterilizer -
Type 5	Integrating indicator (integrator)	Moving front indicators – respond to all critical process parameters
Type 6	Emulating indicators (cycle verification indicators)	Cycle-specific indicators – typically placed in a pack, pouch or container, responds to all critical process parameters in the specific sterilization cycle

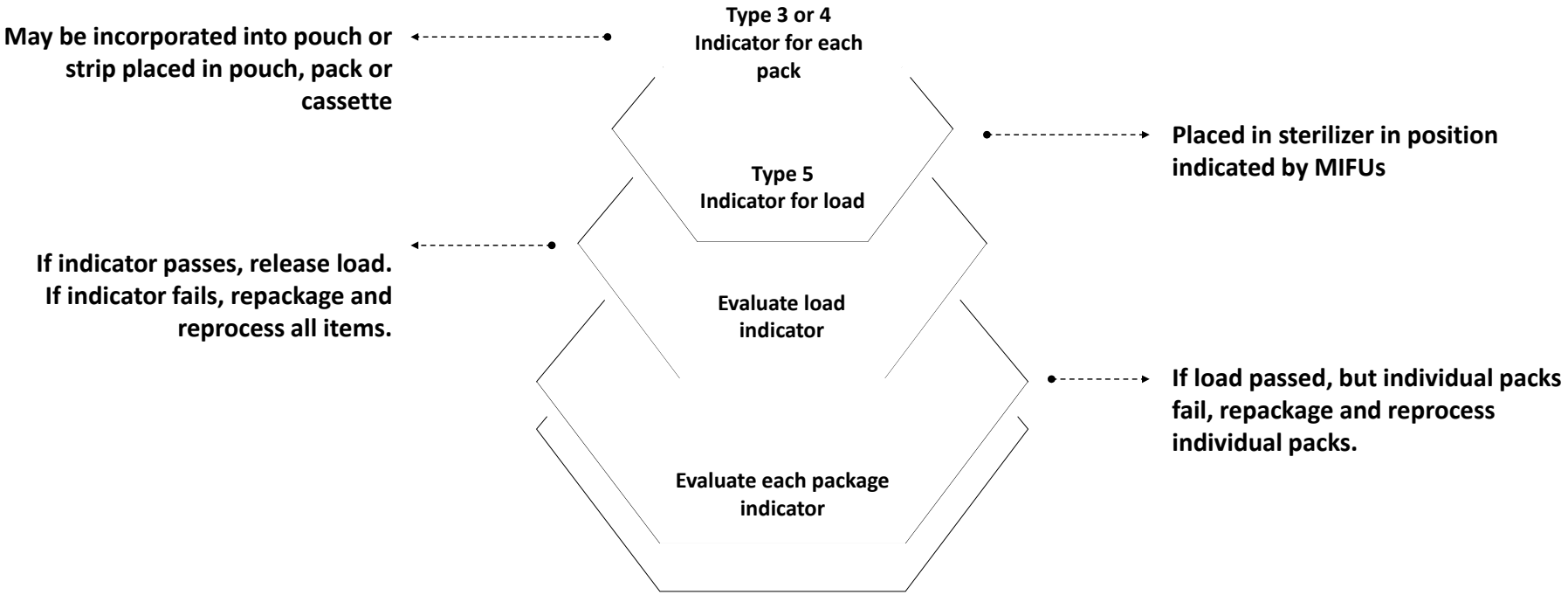
Type 1

Type 4

Type 5

Type 3 or 4

Sterilization Monitoring of Each Load



Common Errors with Sterilization Indicators

- Substituting them for BIs/spore tests
- Failure to place Type 5 indicator in each load
  - Using the wrong type of indicator – must measure all parameters
- Failure to repackage and re-sterilize items in the load if the indicator shows failure
- Purchasing indicators (and packaging materials) from unverified sources
  - i.e., not from a dental distributor

Additional Errors with Sterilizers

- Failure to follow sterilizer or device manufacturer's IFUs for type of sterilization cycle

- Use of same sterilization cycle for all items
  - Packaged – pouches vs. wraps
  - Instruments vs. handpieces

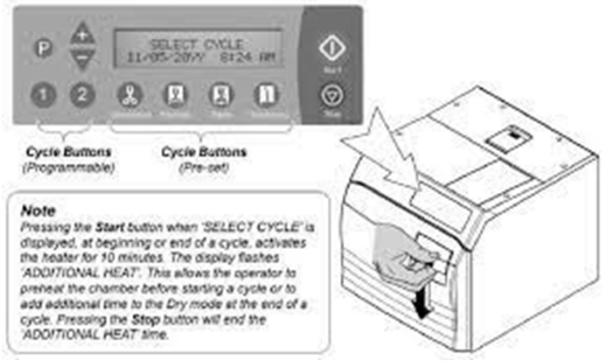


Image source: Midmark

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Questions???