

WHAT DO YOU KNOW ABOUT CHEMICAL INDICATORS?

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Objectives:

1. List the 6 different types of indicators.
2. Describe the differences between indicators and integrators.
3. Discuss what chemical indicators are.

Chemical indicators have been around as long as life itself. For example, hydrangeas bloom blue in acidic soil and pink in basic soil so they are an excellent indicator of soil conditions. That being said, chemical and biological indicators were not used routinely until the late 1940s and early 1950s to monitor sterilization processes. At that time, it was stated no single quality-assurance monitoring method assures that any item is sterile; rather it assures the conditions for sterilization to occur have been met. This statement is still true in today's sterilization practices.

Chemical indicators are either physical or chemical devices used to monitor one or more of the process parameters of the sterilization cycle. Currently they are divided into 6 classifications. They are as follows:

- a. **Class 1:** Process indicators are intended for use with individual items, e.g., containers, to indicate that the unit has been directly exposed to the sterilization process and to distinguish between processed and non-processed items. Indicator tapes, indicator

labels and load cards are examples of externally visible chemical indicators that are on the outside on the packages.

- b. **Class 2:** Indicators are intended for use in specific test procedures as defined in relevant sterilizer/sterilization standards. Bowie-Dicks are one type of specific testing most are familiar with. These are used to show the efficacy of air removal and steam penetration.
- c. **Class 3:** A single variable indicator that is designed to solely show the exposure to one sterilization process at a stated value (SV) of the chosen variable. One example of a single variable is a temperature tube that houses a chemical pellet which melts at a specific temperature.
- d. **Class 4:** These are considered as multiple variable indicators. They are designed to react with two or more of the critical variables and are intended to indicate exposure to a sterilization cycle at SVs of the chosen variable. Examples of these class 4s would be the paper strips with a color change chemical indicator. These are usually used inside each package.
- e. **Class 5:** Integrating indicators are designed to react with all critical variables. These can be used as internal chemical indicators in all packs and con-

tainers for pack control monitoring. They can also be used as an additional monitoring tool in order to be able to release loads that do not contain implants based on the appropriate Process Challenge Device. These indicators can also be used in implant loads **IF** a Biological Indicator is run with the class 5 integrator. The load can **NOT** be released until the BI result is known except in emergencies.

- f. **Class 6:** These are called emulating Indicators which are cycle verification indicators which are designed to react to all critical variables for specified sterilization cycles. In other words they are considered to be indicative of a complete cycle by showing the presence or absence of specific time and temperature parameters during a cycle. They are currently only available in the US for steam sterilization.

Chemical indicators are convenient, are inexpensive, and indicate that the item has been exposed to the sterilization process. In one study, chemical indicators were more likely than biological indicators to inaccurately indicate sterilization at marginal sterilization times (e.g., 2 minutes).

Chemical indicators should be used in conjunction with biological indicators, but based on current studies should not replace them because they indicate sterilization at marginal sterilization time and because only a biological indicator consisting of resistant spores can measure the microbial killing power of the sterilization process. Chemical indicators are affixed on the outside of each pack to show that the package has been processed through a sterilization cycle, but these indicators do not prove sterilization has been achieved. Preferably, a chemical indicator also should be placed on the inside of each pack to verify sterilant penetration. Chemical indicators usually are either heat- or chemical-sensitive inks that change color when one or more sterilization parameters (e.g., steam-time, temperature, and/or saturated steam; ETO-time, temperature, relative humidity and/or ETO concentration) are present. Chemical indicators have been grouped into five classes based on their ability to monitor one or multiple sterilization parameters. If the internal and/or external indicator suggests inadequate processing, the item should not be used⁸¹⁵. An air-removal test (Bowie-Dick Test) must be performed daily in an empty dynamic-air-removal sterilizer (e.g., prevacuum steam sterilizer) to ensure air removal.

The definitions listed above were taken from the ANSI/AAMI/ISO 11140-1:2005 definitions.

Definitions:

Chemical indicator: device for

monitoring a sterilization process. The device is designed to respond with a characteristic chemical or physical change to one or more of the physical conditions within the sterilizing chamber. Chemical indicators are intended to detect potential sterilization failures that could result from incorrect packaging, incorrect loading of the sterilizer, or malfunctions of the sterilizer. The “pass” response of a chemical indicator does not prove the item accom-



panied by the indicator is necessarily sterile. The Association for the Advancement of Medical Instrumentation has defined five classes of chemical indicators: Class 1 (process indicator); Class 2 (Bowie-Dick test indicator); Class 3 (single-parameter indicator); Class 4 (multi-parameter indicator); and Class 5 (integrating indicator).

Process challenge device (PCD): item designed to simulate product to be sterilized and to constitute a defined challenge to the sterilization process and used to assess the effective performance of

the process. A PCD is a challenge test pack or test tray that contains a biologic indicator, a Class 5 integrating indicator, or an enzyme-only indicator. This is a term now used by AAMI in their Recommended Practices.

Now that we have discussed all the technical definitions of the different types of indicators, what exactly does that mean to us? Indicators are first put inside wrapped packs or peel-packs. These are considered to be harder to sterilize to represent a challenge to the indicator. What are the needs of the department based on the types of equipment being sterilized?

Other questions to ask are:

- Are the indicator results easy to interpret?
- Can the indicators be easily stored for a set period of time without damage? Is there a shelf life?
- What sterilization parameters will the indicator detect?
- Is it biologically correlated? If so, what are the specifics?

Only by understanding the needs of the department as well as the composition of the individual chemical indicators/integrators can the department make an informed choice as to the indicator best for them.

Resources:

ANSI/AAMI/ISO 11140-1:2005
AAMI Standards 2005

What Do You Know About Chemical Indicators?
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1. Chemical Indicators have been in use since the early 1900's. **True False**
2. There are 8 different classifications of chemical indicators. **True False**
3. Chemical indicators are either physical or chemical devices used to monitor one or more of the process parameters of the sterilization cycle.
True False
4. Class 3 chemical indicators are considered as multiple variable indicators.
True False
5. Chemical indicators can be used to replace biological indicators.
True False
6. The "pass" response on a chemical indicator does not prove the item accompanied by the indicator is necessarily sterile.
True False
7. Chemical integrators can be used as an additional monitoring tool in order to be able to release loads that do not contain implants based on the appropriate Challenge Device.
True False
8. Process Challenge Devices are items designed to simulate the product to be sterilized and are used to assess the effective performance of the process.
True False
9. A class one (I) chemical indicator is only used to indicate the item has been exposed to the sterilization process and to differentiate between processed and non-processed.
True False
10. A chemical indicator can be used to indicate sterilization has occurred.
True False

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