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Learning Objectives

1. Understand the role that each sterility assurance product plays
2. Identify the areas where healthcare professionals have a choice in monitoring products
3. Relate where the Class 6 emulating indicator fits on the sterility assurance monitoring team

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SELF-STUDY SERIES

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A winning team includes the best players

by Linda Clement and Heide Ames

Any good coach will tell you that their team's success comes from each member doing what he or she does best. A running back is not expected to be good at charging the quarterback and a quarterback would not be expected to kick the football through the goal every time. All members have specific functions that, when combined, make a winning team.

Sterile processing department (SPD) managers are playing to win a much more serious victory – the successful sterilization of critical surgical instruments. In this must-win game, sterility assurance monitoring tools are among the key players for a winning team. From the process indicator tape to the biological indicator, each team member has specific goals and expectations. The latest members to be added to the team roster are the Class 6 emulating indicators. Though this technology is new in the United States, it has been used in sterile processing departments throughout the world for several years.

Let's see how each sterility assurance monitoring member works to make a great team, and where the emulating indicator fits in the program.

The goal

The goal of sterility assurance monitoring is to ensure that medical devices are sterile when they arrive in the operating room. Each sterility assurance tool performs a critical function on the way to achieving this objective.

Preparation

It's critically important to start the game by properly preparing every dirty or contaminated medical device that comes into the SPD for reprocessing. The device must be clean, properly assembled and correctly packaged for the sterilization process being used. The monitoring goal at this point in the process is to oversee the device preparation activities and assure that they are correctly done.

The SPD professional is the first line of defense to ensure proper pre-cleaning and to visually inspect cleaned devices for any

residual debris and moisture. To monitor the cleaning process, SPD staff can use washing indicators, which are designed to validate specific washing processes. Washing indicators are used to ensure that an automated washer is functioning properly and that an appropriate amount and concentration of detergent is used.

After being cleaned, the devices are packaged for sterilization using trays, containers or peel pouches. Many sterilization processes have specific recommendations regarding the materials that should be used to encase, package or pouch the devices. The SPD professional is also the guardian of the packaging process, ensuring that cleaned devices are packaged according to the device and sterilizer manufacturer's instructions. To assist with identification, the packaging is labeled to identify load contents, and an appropriate external process chemical indicator is also attached or included (e.g., chemical indicator tape, indicators on peel pouches, or rigid sterilization container locks or data cards).

Process chemical indicators are defined as Class 1 indicators in the globally recognized ANSI/AAMI/ISO 11140 standard (See Table 1). Process indicators serve the important role of a segregator, identifying processed and unprocessed packs and indicating the sterilization process that is required. This basic role requires simple performance requirements for these indicators.

Sterilizer performance verification

Sterilization occurs when sterilant contacts all device surfaces and causes the death of microbes. This is accomplished using a preprogrammed sterilizer. The monitoring goal during sterilization is to track the performance of the sterilizer and to monitor the achievement of sterilization conditions inside each pack in the load.

A sterilizer's performance is confirmed in a variety of ways. The first validation occurs when the unit is first installed in the SPD, if it is relocated, or if it undergoes any major repairs. The second type of validation occurs periodically during

normal sterilizer operation. The third confirmation occurs when each load of items is sterilized.

When a unit is installed, relocated or repaired, it is tested before it is released for normal operation to ensure it is functioning properly. For this purpose, some sterilizers require a microbial challenge pack, which contains a biological indicator and is constructed of materials that are difficult for a particular sterilant to penetrate. The biological indicator contains viable bacterial spores that have the greatest kill resistance for a particular sterilization process. The typical number of spores ranges from 100,000 to 1,000,000 on each indicator. Some sterilizers, like the STERIS SYSTEM 1® Sterile Processing System, a low-temperature liquid process, do not require a challenge pack and use a biological indicator as their challenge.

Some sterilizers have critical processing steps that are verified at the time of installation. These include things like steam quality or air removal in steam sterilizers. Other systems may include verification of the electrical or water supply. Some even include verification of air supplies. All of these are confirmed at installation and whenever a major repair would affect these functions. Monitoring products used to evaluate these functions fall under the AAMI Class 2 classification of Indicators for Specific Tests. Currently, only one type of indicator is recognized under this category: the Daily Air Removal Test, also known as the Bowie-Dick Test.

Following initial qualification, SPD staff is responsible for periodic verification of the unit's performance. This verification consists of both microbial tests (using a combination of biological indicator products and chemical indicator products) and checks of key performance parameters. Periodic testing catches performance changes in the sterilizer over time. The same tests used to qualify the sterilizer are repeated at a frequency recommended by the sterilizer's manufacturer. For example, some recommendations include weekly (or preferably daily) microbial

challenges of steam or low-temperature liquid sterilizer systems.

In addition to the manufacturer's recommendations for periodic monitoring, many standards organizations also provide recommendations for this type of verification. It is important to know that an organization's stated frequency preferences may or may not align with what a manufacturer has recommended. It is the SPD manager's call to decide and document what the policy should be for periodic monitoring in their particular department.

Load sterilization performance verification

A sterilizer's function is also evaluated during the sterilization cycle itself. Each type of load requires a specific sterilization cycle with specific sterilization parameters (length of exposure time, temperature setting, and steam quality or sterilant concentration, for example). The goal of load monitoring is to ensure that the sterilization parameters for a specific cycle were achieved.

Standards organizations, manufacturers of sterilizers and manufacturers of load monitoring products all provide recommendations for load monitoring. The recommended practices will be different depending on the sterilization process being used. For example, AAMI recommends that every ethylene oxide load be monitored, while a steam sterilizer only has to be monitored when loads contain implantable devices. Monitoring device manufacturers may recommend something different for these situations. However, all

manufacturers and standards organizations agree that, prior to release of the load, the parameters must be met per the cycle printout, all process indicators in the load must pass and any load monitoring products used must pass. Each healthcare facility must review the recommendations that relate to their sterilization processes and decide which is most appropriate for them.

Load monitoring tools vary in performance and the types of loads they verify. The oldest player on this team is the previously mentioned microbial challenge pack. The microbial challenge pack consists of a biological indicator placed within a barrier to the sterilization process. This is typically a commercially available challenge pack, but SPD staff can also construct their own challenge pack following industry recommended practices. The same microbial challenge packs used for qualification and verification of sterilizer performance are often used as a load monitoring device. The main difference between the system verification testing and load testing is the cycle used. With verification testing, the cycle with the shortest time frame is used, while in load testing, all time frames are monitored, both short and long, using the same type of challenge pack. A biological challenge pack can be used across all sterilization processes to release all loads and all items in a load.

The second type of load monitoring device is the Class 5 integrating indicator. This chemical indicator mimics the behavior of a biological indicator when exposed to the sterilization process. It can be placed

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Table 1: Listing of ANSI/AAMI/ISO 11140 chemical indicator classifications			
Classification	Description	Examples of Sterility Assurance Monitoring Products	Examples of Performance Criteria for a 250° F, 30-Minute Steam Sterilization Cycle
Class 1	Process Indicator	• Indicator Tape	• PASS at 10.0 min. ± 5sec. at 250° F • FAIL at 3.0 min. ± 5sec. at 250° F
Class 2	Indicators for Specific Tests	• Daily Air Removal Test	Not applicable
Class 3	Single Variable Indicators	• Internal Indicator Strips	• PASS at 250° F • FAIL at 246.4° F
Class 4	Multi-variable Indicators	• Internal Indicator Strips	• PASS at 4.0 min. at 250° F • FAIL at 3.0 min. at 246.4° F
Class 5	Integrating Indicators	• Internal Indicator Strips • Integrator Challenge Packs	• PASS at 16.5 min. at 250° F • FAIL at 10.5 min at 250° F • Correlation to biological indicator kill • FAIL when exposed to dry heat for 30 minutes at 278.6° F
Class 6	Emulating Indicators	• Internal Indicator Strips • Emulating Indicator Challenge Packs	• PASS at 30.0 min. at 250° F • FAIL at 28.2 min. at 248.2° F • Correlation to biological indicator kill • FAIL when exposed to dry heat for 30 minutes at 278.6° F

Self-Test Answers: 1. B, 2. C, 3. D, 4. B, 5. A, 6. E, 7. D, 8. B, 9. C, 10. A



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within a challenge pack just like a biological indicator. However, at this time only steam and ethylene oxide processes have Class 5 indicators to verify their cycles.

The standards organizations have different recommended practices for Class 5 indicators as well. However, manufacturers of integrating indicators agree that whatever the sterilization process, integrating indicators within challenge packs may be used to monitor and release loads that do not require a biological challenge pack. They also recommend using an integrating indicator within a biological challenge pack for those times when loads are released prior to knowing the biological indicator's results.

The third load monitoring device is the Class 6 emulating indicator challenge pack, the newest addition to the team. This chemical indicator is designed to emulate the sterilization cycle. Like the integrating indicator, the emulating indicator's performance must correlate to a biological indicator. It must also monitor the sterilization parameters that should be achieved by the sterilizer. For example, if a cycle requires three minutes of steam contact, then the emulating indicator will need to be able to show a change after three minutes. If a different cycle requires the same temperature with 10 minutes of steam contact, then a different emulating indicator designed to validate 10-minute cycles is used. The emulating indicator differs from the integrating indicator because it is cycle-specific.

The emulating indicator is placed within a sterilization barrier, just like a biological indicator. Not every sterilization process has a Class 6 emulating indicator available at this time, and since this classification is so new, there are no recommendations available as of yet from the various standards organizations. Currently, only one manufacturer in the United States and Canada supplies a Class 6 emulating indicator challenge pack and it is only for steam sterilization processes. Based on the recommendations from this company, the Class 6 emulating challenge pack can be used to release all loads and all items in the load.

The SPD team has several choices of load monitoring devices. They can work individually or in combination to provide a high level of confidence that the sterilizer performed as intended during each cycle.

Internal pack monitoring

So far, all the sterility assurance devices and monitoring activities have worked together to ensure that the sterilizers functioned as intended. This results in a high level of probability that items in the load are also sterile. But how can SPD professionals really know that sterilant made it through the packaging and reached the medical devices inside? The only way to be sure is to monitor the internal confines of every pack. Since each type of tray, container and pouch represents a different challenge to the sterilization process, this is the most critical role played by sterility assurance devices.

The sterility assurance product best suited for this challenge is the chemical indicator strip. Chemical indicator strips perform in a variety of ways. They range from the simple Class 1 process indicator to the more complex Class 6 emulating indicator.



Verify® SixCess 4 minute indicator from STERIS

Class 1 process indicator strips provide the simplest level of performance. Each strip confirms the presence of sterilant but is not related to a biological indicator's performance or a sterilization cycle's performance. The same type of Class 1 indicator may be used for more than one set of sterilization cycle parameters (different exposure times, for example) as long as it meets the minimum performance criteria, such as those in Table 1. Some process indicators may be used in different sterilization processes (steam, ethylene oxide, for example). These indicators have two chemical reactions that produce a unique color change for each type of sterilization process.

Class 3 single variable indicator strips provide confirmation that at least one of the critical parameters of sterilization was achieved. That parameter is either linked to the biological indicator's performance or the sterilization cycle's performance, but it monitors only one of the several critical parameters for successful sterilization. For example, a single-parameter indicator may show the concentration of ethylene oxide to kill a biological indicator but would not detect if the temperature, humidity or time were wrong. The Class 3 indicator strips can be used for multiple sterilization cycles

but must be used for one type of sterilization process. For example, a steam indicator is for steam sterilization but not for dry heat sterilization.

Class 4 multi-variable indicator strips provide confirmation that two or more of the critical parameters were achieved. Like the Class 3 indicator strips, the Class 4 indicator strips do not monitor all critical sterilization cycle parameters.

Class 5 integrating indicators monitor all the critical parameters of sterilization and are linked to biological indicator performance. In simple terms, the indicator must show passing conditions when the same conditions would have killed a biological indicator and failing conditions when the sterilization parameters would have resulted in a living biological indicator. For example, if a biological indicator exposed to 270°F saturated steam dies in 1.5 minutes and survives at 1.0 minutes, a Class 5 indicator would need to show a pass at 1.5 minutes or longer of exposure and failing at 1.0 minutes of exposure.

Class 6 emulating indicators monitor all the critical parameters of sterilization, are correlated to biological indicators, and emulate a specific sterilization cycle. A different indicator strip would be used for each cycle exposure time. For example, a 270°F cycle may have a 4 minute or 15 minute exposure; the goal being to deliver either 4 minutes or 15 minutes of steam in the pack. A 4-minute indicator strip would be used for 4-minute cycles and a 15-minute indicator used for the 15-minute cycles, which will ensure that the sterilizer delivers the steam intended.

Though there are six indicator classifications, not all classifications are available for a given sterilization process. As new sterilization processes are developed, they are launched with accompanying process indicators that can be used to monitor them. As the processes become more accepted, more complex indicators with higher performance standards are developed for them. In addition, regulatory bodies such as FDA require specific performance criteria. Today, FDA only recognizes the Class 1 and Class 6 indicator strips (as defined by ANSI/AAMI/ISO 11140-1). This means that all new indicator strips brought to the US must meet either the Class 1 or Class 6 performance criteria.

Go team!

In the life-saving game of sterility assurance, each SPD team can only succeed by combining its people and the right moni-

toring devices to assure the delivery of sterile instruments. The Class 1-6 monitoring tools provide the team with varying levels of capabilities, and each plays a contributing role in achieving the goal. The newest players, Class 6 emulating indicators, fit well on this team because they offer the healthcare professional an even higher level of performance and assurance

for monitoring packs and releasing sterilized loads. [HPN](#)

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Circle the one correct answer:

- 1) The only types of sterility assurance monitors are biological indicators.
 - a. True
 - b. False
- 2) What is the goal of sterility assurance monitoring?
 - a. Protect devices from moisture
 - b. Kill microorganisms that cause disease
 - c. Ensure that devices arrive sterile to the operating room
 - d. Ensure that sterilant killed the microorganisms
- 3) Which sterility assurance monitoring devices are used when preparing devices for sterilization?
 - a. Washing indicators and the SPD professional
 - b. Washing indicators and chemical indicator strips
 - c. Detergent volume monitor and container data cards
 - d. Washer indicators and Class 1 process indicators
- 4) Which of the following checks are not required for a sterilizer verification?
 - a. Microbial challenge using a biological challenge pack
 - b. Confirmation that all process indicators are passing
 - c. Confirmation of electrical voltage delivered to the sterilizer
 - d. Confirmation of critical process steps
- 5) When would a sterilizer be re-qualified?
 - a. When the sterilizer is moved
 - b. After preventative maintenance is performed
 - c. Whenever a new maintenance person has repaired the sterilizer
 - d. All of the above
 - e. None of the above
- 6) Which sterility assurance products are reviewed prior to releasing a sterilization load?
 - a. Process indicators
 - b. Integrating indicator challenge packs
 - c. Biological indicator challenge packs
 - d. Emulating indicator challenge packs
 - e. All of the above
 - f. None of the above
- 7) Which products are used to monitor and release all loads and all items in those loads?
 - a. Biological Indicator Challenge Pack
 - b. Integrating Indicator Challenge Pack
 - c. Emulating Indicator Challenge Pack
 - d. A and C only
- 8) Only integrating indicator strips may be used as an internal pack indicator.
 - a. True
 - b. False
- 9) Which is the main difference between Class 3, Class 4, Class 5 and Class 6 indicators?
 - a. Each classification monitors a different sterilization process
 - b. Each classification is used with a specific type of sterile packaging
 - c. Each classification provides a different level of performance
- 10) When would an emulating indicator or emulating indicator challenge pack be used?
 - a. To monitor all sterilization loads and as an internal indicator strip
 - b. To monitor some sterilization loads and as an internal indicator strip
 - c. To monitor all sterilization loads and as an external process indicator
 - d. To monitor no sterilization loads and as an internal process indicator

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