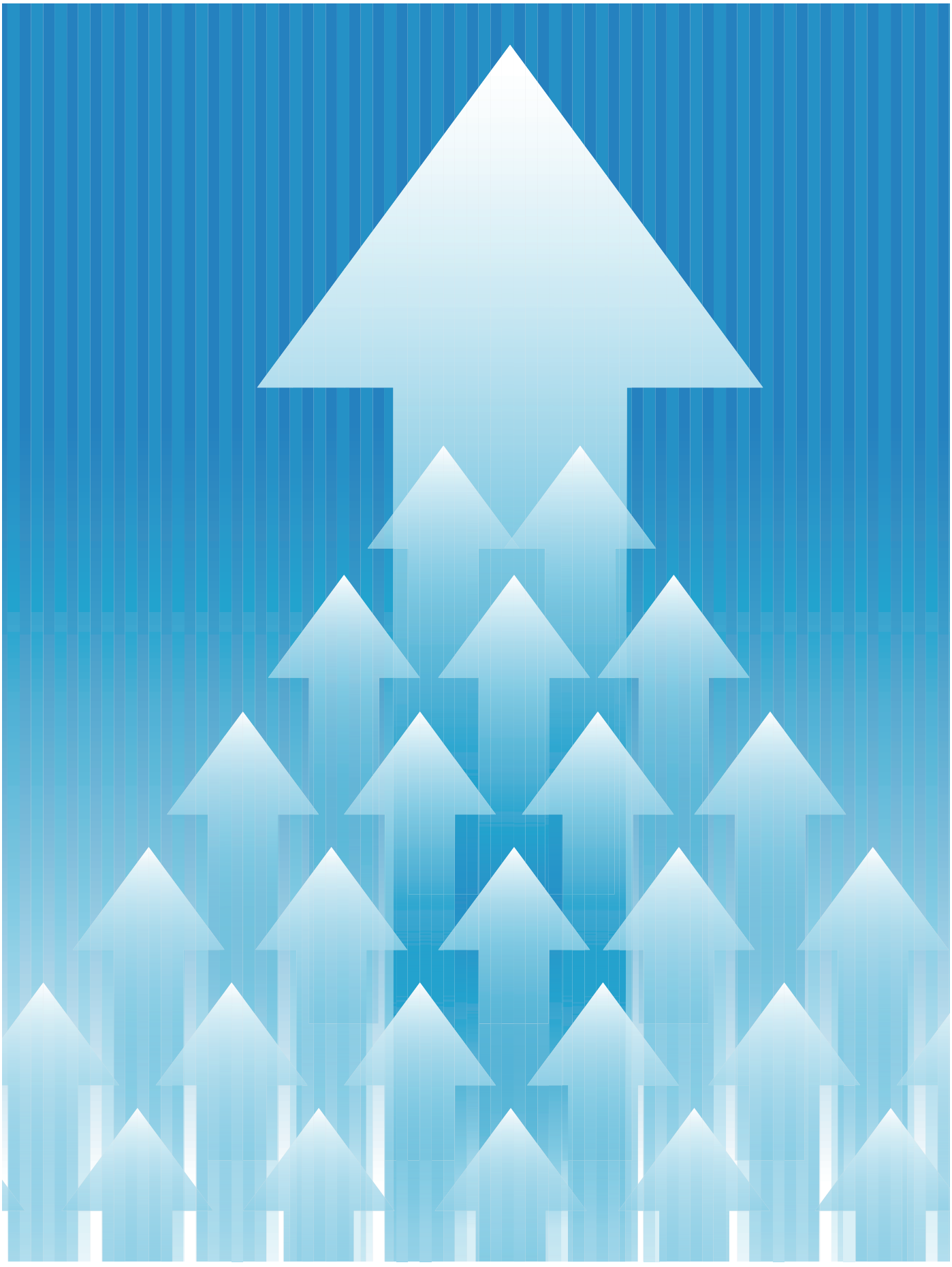

Elevating Knowledge About Sterilization Equipment and Processes

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LEARNING OBJECTIVES

1. Identify key differences between sterilizer types and understand how to properly prepare devices for sterilization
2. Understand how to monitor sterilization quality
3. Describe the unloading process to prevent load contamination

For the delivery of sterile medical devices, all processes before and after sterilization must be performed correctly, and all sterilizer parameters must be met. Dry, saturated steam is ideal for sterilization. Pressure serves to obtain the high temperatures necessary to quickly kill microorganisms. Specific temperatures and times are required to attain microbicidal activity.

Different types of steam sterilizers are used in healthcare facilities. A small clinic or dental office typically uses a tabletop sterilizer whereas a larger medical facility typically uses a larger hospital sterilizer. Both types of sterilizers provide an operator's manual with the sterilization parameters. This lesson details some key differences between the sterilizer types, while also addressing correct processes for preparation, quality monitoring and unloading of the sterilizer.

Objective 1: Identify key differences between sterilizer types and understand how to properly prepare devices for sterilization

Steam generated in a tabletop sterilizer differs from that in a hospital sterilizer. A noticeable difference is the equipment size. Tabletop sterilizers have a chamber volume less than or equal to 2 cubic feet; hospital sterilizers are larger and have a volume greater than 2 cubic feet.

Tabletop sterilizers generate their own steam by having water poured into the sterilizer, either manually or automatically, through a port or the bottom of the chamber. They are electrically heated until the water turns to steam. Water quality is an important factor and is specified in the sterilizer operator's manual. In a tabletop sterilizer cycle, steam rises to the chamber's top and as more steam is produced, cooler air is forced out through the drain near the bottom

of the chamber. When steam enters the drain, a thermostatic valve closes, causing the steam to build up pressure until the operating temperature is reached. When the proper temperature is reached, the timer is activated. At the end of the cycle, the relief valve opens to allow the steam to escape. The steam passes through the water reservoir where it condenses back to water. After the pressure has dropped to zero, the door can be opened.

There are two types of steam sterilization cycles available: gravity displacement and dynamic air removal. A gravity displacement cycle uses steam that enters the chamber from the top or sides. As the steam enters the chamber, it is heavier than air, which forces the air out the bottom of the chamber through the drain vent. Dynamic air removal sterilizers have a vacuum pump or ejector to remove air before the steam is admitted. This results in nearly instantaneous steam penetration.

A hospital steam sterilizer uses steam plumbed by the healthcare facility or perhaps an integral electric boiler. Both require a treated water supply to remove total dissolved solids. There are two methods of steam generation that healthcare facilities use to deliver steam to a steam sterilizer. The most common is derived from a centralized system used for other purposes throughout the facility. This is known as "plant" or "house" steam. The Sterile Processing department (SPD) might be located a lengthy distance from the central steam supply, resulting in the steam passing through an extensive distribution system before being delivered to the sterilizer. This steam can be produced with a high-purity water source and can be either "process" steam or "clean/pure" steam.

All items undergoing sterilization must be thoroughly cleaned and rinsed with critical water. Using critical water as the final rinse reduces the risk of pyrogenic reactions and removes organic pyrogens. The items must then be thoroughly dried using a clean, non-linting cloth. Lumened devices should be dried with instrument air or HEPA-filtered air from a flushing pump. The items should be prepared in a manner that allows steam to contact all surfaces. Items must be completely clean and dry. Also, unless otherwise stated in the instructions for use (IFU), all valves should be opened, and instruments should be disassembled.

Quality monitors should be included with all packages, and the medical devices should be packaged in a packaging system validated for the specific type of steam sterilization cycle. Packages include both external and internal chemical indicators (CIs). External process indicators include tape, load cards or labels on the outside of the packages. External CIs demonstrate that the package has undergone a sterilization cycle. These chemical indicators are reviewed by the sterilizer operator at the end of the cycle to ensure they have met their end point.

Internal CIs are placed inside a package and provide evidence that the sterilant penetrated the package. CIs can be either type 3, 4, 5 or 6. Type 3 CIs react to a single variable during a sterilization process. Type 4 are multicritical process variable indicators. They are designed to react to two or more of the critical variables and are intended to indicate exposure to a sterilization process. Type 5 is an integrating indicator designed to react to all critical variables. Type 6 is an emulating indicator designed to react to all critical variables of specified sterilization cycles. Types 5 and 6 are preferred because they provide more information about the critical steam sterilization parameters.

The sterilizer should be loaded to ensure complete steam contact, adequate air removal, penetration of steam into each package, and steam evacuation. This allows adequate air elimination and drainage of condensate. The following steps should be followed:

- Items capable of holding water, such as solid-bottomed pans, basins and trays, should be placed in the same direction so that water, if present, can drain. Orienting items, such as solid-bottomed pans, in the same direction allows rapid, even distribution of steam throughout the load. Items should not be stacked.
- Textile and paper-plastic pouches should be placed above metal items. Placing metal items below textile items allows condensate to drain out without wetting other items in the load.
- In some instances, absorbent, non-linting cart shelf liners are used to assist with load drying. Cart liners should be non-linting. Lint can transfer to the packaging and carry microorganisms into the surgical site, causing foreign-body reactions.
- Perforated instrument sets and sterilization containers should be placed on the sterilizer shelf or cart so the bottom of the tray or container system is parallel to the shelf. This maintains distribution of metal mass and allows air removal, sterilant penetration, condensate drainage, and drying.
- Paper-plastic pouches should be placed edge, with the paper side of one pouch next to the plastic side of the next pouch; using metal baskets or racks

designed specifically for paper-plastic steam sterilization allows them to be placed on edge and remain properly spaced in the sterilizer for adequate steam contact and drying.

Objective 2: Understand how to monitor sterilization quality

The sterilization cycle is monitored with a combination of physical, chemical and biological monitors. During the sterilization cycle, the sterilizer operator should monitor the cycle by reviewing the physical parameters (these include time, temperature, pressure recorders, displays, digital printouts, electronic recording/data capture, and gauges). These provide real-time assessment of the sterilization cycle.

Physical monitoring is needed to detect malfunctions as soon as possible so appropriate corrective actions can be taken. At the end of the cycle, the physical monitors should be reviewed to ensure the sterilization parameters were met. Before the packages are removed from the sterilizer, the sterilizer operator should examine and interpret the physical monitor to verify that all cycle parameters were met and initial the documentation; this identifies the sterilizer operator and provides a permanent record. If a process challenge device (PCD), such as a type 5 PCD or biological monitor PCD, are used, they should be removed and examined for end-point response—or incubated. Every sterilization load containing implants should be monitored with a biological monitor PCD containing a type 5 integrating CI. The type 5 integrating CI should be reviewed to determine whether it met its end point. Implants should be quarantined until BI testing results are available.

If "wet packs" are observed, they should not be released. Wet packs occur if there is visible moisture remaining in or on a package after sterilization and cooling. The moisture may be in the form of visible dampness, droplets or puddles of water on or within a pack. If there are two or more wet packs, the load should be considered "wet," and the entire load should be reprocessed.

If the interpretation of any monitor suggests inadequate steam processing, the load should not be released, and all items must be fully reprocessed. Sterilized textiles should be removed and replaced with freshly laundered textiles that have not been ironed. The sterilizer operator should inform the appropriate supervisor.

Objective 3: Understand the sterilizer unloading process to prevent load contamination

It is important to recognize that packages contain a significant amount of moisture after being exposed to steam. The moisture migrates out of the package as a gas or water vapor during the drying and cooling phases. Packages should not be touched until they are cool because hands can become a point of condensation for the warm water vapor coming from the package, thereby creating a moist area on the outside of the package. Further, moisture on packages can act as a wick to draw bacteria from the hands into the package.

An infrared gun or temperature-sensing device may be used to verify that sterilized items have reached room temperature. Cooling time should take into consideration the type of sterilizer being used, the design of the device being sterilized, the temperature and humidity of the ambient environment, and the type of packaging used. The cool-down period begins within the sterilizer chamber. The door may be opened slightly at the end of the cycle, with the items left inside for a period of time to reduce the potential for condensation formation. A minimum cooling time of 30 minutes is recommended although, in most instances, a longer cooling time is required. Wet packs should be reprocessed and repackaged in a manner that facilitates effective sterilization and does not cause excess moisture or condensation.

When sterilizing rigid sterilization container systems, they must be properly cooled to prevent recondensation of the steam vapor. Materials used for containers are not absorbent, and condensate can appear as small droplets on or within the container system. Condensate on the outside of a container system can flow downward toward the filter of another container and contaminate it. Condensate can also run down the sides to the items below them. Condensate within any container system can compromise the sterility of the contents if it comes in contact with outside contaminants. After sterilization, the containers can be very hot. Caution must be taken when handling sterilized items to reduce the risk of burning the operator.

When unloading the sterilizer cart, packages should be inspected to ensure the lot control labels are still attached to the packages, indicator tape is securely affixed to the package, and chemical change has occurred. Wrappers should be visually checked for rips, cuts, tears or moisture. Tamper-evident devices should also be checked on containers. Load contents should be verified, and records should be checked and filed according to departmental policy.

Conclusion

There are different types of steam sterilizers with which the sterilizer operator must demonstrate competency to prevent process failure. Equally important is the operator's understanding and use of quality monitors to ensure sterilization parameters have been met as well as knowing how to prepare devices for sterilization and remove them safely from the sterilizer to prevent load contamination. P

RESOURCES

1. ANSI/AAMI ST79:2017 & 2020 Amendments A1, A2, A3, A4 (Consolidated Text) *Comprehensive guide to steam sterilization and sterility assurance in healthcare facilities.*
2. Healthcare Sterile Processing Association. 2023. *Sterile Processing Technical Manual,* Ninth Ed.

CIS Self-Study Lesson Plan Quiz: Elevating Knowledge About Sterilization Equipment and Processes

Lesson No. CIS 305 (Instrument Continuing Education – ICE) · Lesson expires October 2027

1. Which is used to obtain the high temperatures necessary to quickly kill microorganisms?
   a. Altitude
   b. Pressure
   c. Density
   d. Water

2. How is steam generated in a tabletop sterilizer?
   a. From a steam generator
   b. With a measured cup of hot water
   c. By placing a bottle of sterile water in the sterilizer
   d. Water is electrically heated until it turns to steam

3. What are two types of steam sterilization cycles?
   a. Gravity displacement and dynamic air removal
   b. Gravity displacement and pressure mounted
   c. Pressure mounted and steam pressure flush
   d. Gravity displacement and spatial steam

4. What occurs when a steam sterilizer is located a lengthy distance from the central steam supply?
   a. It produces super-saturated steam
   b. The steam becomes contaminated
   c. The steam passes through an extensive distribution system
   d. The steam is used to heat the facility

5. During the cleaning process, why is critical water recommended for the instruments' final rinse?
   a. It reduces the risk of pyrogenic reactions and removes organic pyrogens
   b. Critical water is the same type of water used to make steam
   c. It prevents rust from forming on instruments
   d. It dries easily, thus preventing wet packs

6. Which type of air is used to dry lumened devices?
   a. Syringe air
   b. Instrument air
   c. Medical air
   d. Nitrogen

7. Indicator tape, load cards or labels are classified as which type of indicator?
   a. Internal indicators
   b. Process challenge devices
   c. External indicators
   d. Product testing

8. Which type of chemical indicator is an integrating integrator designed to react to all critical variables?
   a. Type 3
   b. Type 4
   c. Type 5
   d. Type 6

9. Which type of chemical indicator is an emulating indicator designed to react to all critical variables of specified sterilization cycles:
   a. Type 3
   b. Type 4
   c. Type 5
   d. Type 6

10. Why should solid-bottomed pans, basins and trays be placed in the same direction?
   a. It allows rapid, even distribution of steam throughout the load
   b. It allows for easier stacking
   c. It allows more of the items to be loaded on the sterilizer cart
   d. It prevents super-heated steam

11. What is reviewed at the end of a sterilization cycle to ensure the sterilization parameters were met before the packages are removed from the sterilizer?
   a. Surgery schedule
   b. Physical monitor
   c. Biological monitor
   d. Type 5 chemical indicator

12. What should occur if moisture is observed on packages upon completion of the sterilization cycle?
   a. Use a non-linting towel to absorb the moisture and inform the appropriate supervisor
   b. Leave the items in the sterilizer longer to dry fully
   c. Immediately re-sterilize the load, extend the dry time and inform the appropriate supervisor
   d. The items should be fully reprocessed, and the appropriate supervisor should be informed

13. How can a technician determine when packages in a sterilization load can be removed from a sterilizer cart?
   a. Touch a few items on the cart to see if they are warm
   b. Touch a few items on the cart to see if they are dry
   c. Use an infrared temperature-sensing device to verify the items have reached room temperature
   d. Place a thermometer on the packages until it reaches the acceptable temperature of 68°F

14. Implants should be quarantined:
   a. Until Bowie-Dick test results are reviewed and signed off by the manager
   b. For at least 24 hours
   c. Until biological indicator (BI) testing results are available
   d. None of the above

15. Before running a sterilizer, the sterilizer operator must show:
   a. Competency
   b. Compassion
   c. That they are certified
   d. Their employee identification

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