





CIS Self-Study Lesson Plan

Lesson No. CIS 261 (Instrument Continuing Education - ICE)

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Human Factors That Impact Sterilization

LEARNING OBJECTIVES

1. Review general human factors that impact the sterilization process
2. Discuss the factors that may interfere with the sterilization process in the decontamination area
3. Discuss the factors that may interfere with the sterilization process in the preparation and packaging area
4. Discuss the factors that may interfere with the sterilization process in the sterilization area

Instrument Continuing Education (ICE) lessons provide members with ongoing education in the complex and ever-changing area of surgical instrument care and handling. These lessons are designed for CIS technicians, but can be of value to any CRCST technician who works with surgical instrumentation.

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STERILIZATION IS A KEY RESPONSIBILITY OF THE INSTRUMENT technician, and each phase of instrument processing impacts the sterilization of medical devices. Infections from improper cleaning and sterilization of medical devices have caught the attention of medical device manufacturers and the U.S. Food and Drug Administration (FDA). While some sterilization failures of medical devices are caused by equipment or other issues beyond the control of the instrument technician, many obstacles may be caused by the human factor.

The human factor is the behavior under the control of the technician. This means each instrument technician has the ability to change or improve that behavior.

This lesson will discuss the behaviors that may disrupt the sterilization process.

OBJECTIVE 1: REVIEW GENERAL HUMAN FACTORS THAT IMPACT THE STERILIZATION PROCESS

There are numerous factors that can affect the sterilization process, and these factors may occur in any area of the department. Instrument technicians should be aware of the factors and strive to eliminate them.

Dress code is an important factor in reducing instrument contamination. Technicians should be aware that their hair and body should be clean at all times, and that only clean scrub attire should be worn. Hair, including facial hair (except eye lashes and eye brows), can contribute to sterilization failure when the hair is allowed to fall into or onto sets and instruments. Beards, mustaches and sideburns should be completely covered at all times. Hair on head should be completely tucked under the surgical cap, even if the hair is very short. Bald heads should also be completely covered because they still slough skin cells, which can contaminate an instrument set. The use of skull-type surgical caps should be discouraged because they do not cover

all head hair. Technicians should wear long sleeves while assembling instrument sets to reduce the chance of skin cell and hair sloughing onto sets and instruments. Shoes should always be kept clean.

Poor hand hygiene can be a major contributing factor to instrument contamination. The Centers for Disease Control and Prevention (CDC) states hands should be scrubbed for at least 20 seconds and then completely rinsed and dried. Handwashing should occur at least at the beginning of the shift, before and after eating or using the toilet, any time hands are visibly soiled, or after removing gloves or personal protective equipment (PPE). Hand sanitizers should be used between handwashing in accordance with the manufacturer's Instructions for Use (IFU) and the facility's policy.

Fingernails should be kept clean and short with no nail polish or other decoration should not be worn. Soiled and/or artificial nails can promote the growth of bacteria and fungus.

Jewelry, including rings and watches, should not be worn. Jewelry harbors



bacteria, may damage packaged items, can fall into trays, and can cause holes in gloves.

Food and beverages, including candy, gum and water, should not be allowed in any area of the department at any time. Food alone can attract insects and rodents. Food residues on hands can contaminate instrument sets and the work area. Beverages can spill and contaminate the work area.

Strict adherence to device, product and equipment IFU is critical. Not following manufacturer's IFU can cause a sterilization failure due to unclean or unsterile instruments.

Although employee communication is beneficial and acceptable, excessive talking between technicians may be distracting and cause the technician to make mistakes (e.g., Placing items in the wrong sterilizer, forgetting to place peel pouch items on edge or placing a wrong instrument in a set).

OBJECTIVE 2: DISCUSS THE FACTORS THAT MAY INTERFERE WITH THE STERILIZATION PROCESS IN THE DECONTAMINATION AREA

Instrument cleaning is the first step in the instrument processing cycle. Human factors in the decontamination area that can affect improper cleaning include:

Disassembling instruments –

Instrumentation that is not completely disassembled can interfere with the cleaning process by not allowing technicians to properly clean all lumens, serrations, crevices and other hard-to-reach areas. The IFU should always be carefully followed to ensure the instrument has been properly disassembled (care should be taken not to disassemble parts that the manufacturer has meant to remain intact). Check the manufacturer's IFU for recommendations

for protecting small and delicate instrument parts during mechanical cleaning.

Manual cleaning – This process is recommended for most instruments prior to any type of mechanical cleaning or disinfection/sterilization. Some instruments may look clean enough to place directly into a washer-disinfector; however, manual cleaning is still required because contaminants may not always be visible.

Unopened instruments – Instruments should always be opened for proper manual or mechanical cleaning. Cleaning solutions and brushes cannot reach all surface areas through closed jaws or box locks.

Improper instrument placement – Several factors in instrument and tray positioning directly impact the ability to produce clean instrumentation. These include:

- Metal mass/weight – Placing too many heavy instruments or stacking lightweight instruments too high in trays keeps the cleaning solution from reaching all parts of all instruments in the tray. Always place heavy instruments on the bottom of the tray; lighter instruments should be placed on top.
- Lumens/cannulations – All lumened items must be properly brushed and flushed to allow for successful sterilization. Lumened items should be primed (completely filled with cleaning solution to remove air bubbles) before placing them into an ultrasonic cleaner. Some instruments require the use of an irrigating sonic or washer manifold to properly clean. IFU should be followed for specific cleaning instructions.
- Tray lids – Tray lids keep cleaning and rinsing solutions from contacting instruments inside the closed tray. If the solution gets into the tray, it

may not be completely removed and chemical residues will remain on the instrumentation. Unless otherwise stated in the IFU, lids should be removed for cleaning.

- Stacking of trays
 - » Multi-level trays – Unless otherwise stated by the manufacturer, each level of multi-level trays should be processed independently to help ensure the cleaning solution is in contact with all surfaces.
 - » Tray stacking – Trays should not be stacked on top of one another for mechanical cleaning; doing so prevents cleaning solutions from reaching all instrumentation.

Rigid Container systems – Although these containers look clean when returned from the Operating Room, they should be properly disassembled, completely cleaned and rinsed in accordance with the manufacturer's IFU. Careful inspection of the container prior to cleaning is recommended because items, such as pieces of suture, may be stuck to the bottom of the container or the inside surface.

Cleaning equipment – It is important to keep all cleaning equipment clean. Dirty chamber walls, sinks, manifolds, spray arms and working surfaces will affect the cleaning process.

OBJECTIVE 3: DISCUSS THE FACTORS THAT MAY INTERFERE WITH THE STERILIZATION PROCESS IN THE PREPARATION AND PACKAGING AREA

Work area cleanliness – Cluttered or dirty workspaces can contaminate clean instruments. Cluttered work areas may also increase the risk of having instrument technicians pull the wrong instrument or indicator and place it into



a tray or package. Dust and debris may also make their way inside the trays being assembled

Moisture – Moisture can affect many sterilization processes. Wet or moist instruments can cause some low-temperature sterilization cycles to abort. Wet instruments may also react in ethylene oxide (EtO) sterilizers and produce ethylene glycol. In the steam process, moisture from wet instruments can affect the steam quality, causing wet packs. Overloading instrument trays can cause excess moisture or not allow the sterilant to reach all instruments.

Silicone type mats – Mats should be dried before being placed into a tray. Placing wet silicone type mats on the bottom of trays may change the steam quality in the cycle, causing a wet pack. If the mat holes are not aligned with the holes in the tray, the mat can trap and hold moisture; this can also cause a wet tray. Figure 1 shows a mat improperly placed in the tray; the tray holes are covered by the mat, obstructing the flow of air and sterilant. Figure 2 shows a properly placed mat; the mat holes and the tray holes are properly aligned.

Wicking material – Failing to use wicking material, when appropriate, can cause excess condensation in trays during the sterilization process. Excess condensation may not completely dry during the cycle, causing a wet pack.

Towels – Using huck (surgical) towels is not recommended in some container systems because they may retain rather than wick moisture.

Multi-part instruments – Assembling multi-part instruments, unless otherwise stated in the IFU, may cause a sterilization failure. The sterilant must contact all

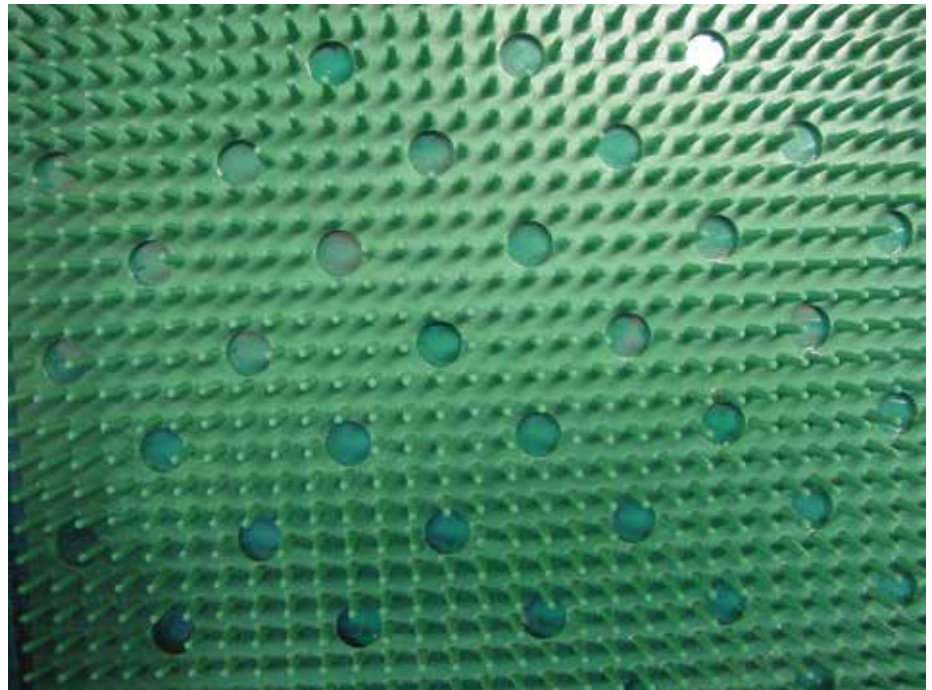


Figure 1: Silicone mat improperly placed



Figure 2: Silicone mat properly placed



Attention must be paid to packaging type and size. Using the wrong type of peel pouch or flat wrap for the sterilization method in use may cause instruments to be unsterile and may damage the instruments because of the melting of the packaging material.

parts of each instrument; this may not be possible with assembled instruments.

Packaging also plays a role in sterilization outcomes. When using rigid container systems, it is important not to overload the container trays; doing so may cause excess moisture or not allow the sterilant to reach all instruments. Lack of or improper filter placement can also cause a sterilization failure.

Placing a peel pouch inside a container or tray may also cause a failure. Because there is no way to properly secure a peel pouch on edge for sterilization inside a tray or container, the peel pouch may fall flat and not allow for proper sterilization.

Attention must be paid to packaging type and size. Using the wrong type of peel pouch or flat wrap for the sterilization method in use may cause instruments to be unsterile and may damage the instruments because of the melting of the packaging material. Packaging that is too small or too large can also cause a sterilization failure. Using too small a wrap or pouch may cause the instruments to break through the packaging or prevent circulation of the sterilant. Peel packs that are too large can allow instruments to move freely inside the package, which may potentially

damage the package. Flat wrappers that are too large can trap moisture in the folds, causing a wet pack.

OBJECTIVE 4: DISCUSS THE FACTORS THAT MAY INTERFERE WITH THE STERILIZATION PROCESS IN THE STERILIZATION AREA

Human factors that can influence the sterilization process include incorrect loading of a sterilizer cart or shelf, and using the incorrect sterilizer or sterilization cycle.

Placing metal containers above non-metal items, such as wrapped items, can cause condensate from the metal containers to fall on the wrapped items, causing wet packs. Peel packs should be placed on their edge (plastic facing paper) to allow for adequate air removal and sterilant contact. Basin sets and other items that hold water should be placed on edge to allow for air and condensate removal. Overloading the sterilizer cart or shelf, allowing items to touch the sterilizer chamber walls, or stacking containers or trays on top of one another, unless approved by the IFU, also impedes sterilant contact and air removal.

It is important to not use a shorter cycle than is recommended by the device manufacturer because the shorter cycle may not be sufficient to properly sterilize the devices. Running an extended cycle for items not approved for extended cycles can also cause a sterilization failure and lead to instrument damage.

CONCLUSION

The success or failure of every sterilization process depends on the instrument technician following proper preparation of the items to be sterilized. Human factors play a vital role in the success or failure of the sterilization process.

Every method of sterilization relies

on the expertise of the instrument technician. Even the most sophisticated sterilizer cannot compensate for poor preparation and sterilization practices. **C**

RESOURCES

Association for the Advancement of Medical Instrumentation. ANSI/AAMI ST79, *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*, Section 4.5, Attire. 2013.

Association of periOperative Registered Nurses. *Guidelines for Perioperative Practice*. Guideline: Surgical Attire. 2017.

International Association of Healthcare Central Service Materiel Management. *Instrumentation Resource Course: Identification, Handling and Processing of Surgical Instruments*. Chapter 6. 2005.

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CIS Self-Study Lesson Plan Quiz - Human Factors That Impact Sterilization

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1. Proper dress code includes:
 - a. Keeping hair and body clean
 - b. Wearing clean scrub attire
 - c. Keeping all facial hair, except eyebrows and eyelashes, completely covered
 - d. All the above
2. Although food should not be allowed in the CS department, it is acceptable to have gum and water at the workstation.
 - a. True
 - b. False
3. Hands should be washed for a minimum of:
 - a. 10 seconds
 - b. 15 seconds
 - c. 20 seconds
 - d. 30 seconds
4. Manual cleaning should be performed:
 - a. Before mechanical cleaning
 - b. Before disassembling the instruments
 - c. Manual cleaning is not necessary if the instruments look clean and unused
 - d. All the above
5. During mechanical cleaning, tray lids should be left on sets containing small instruments.
 - a. True
 - b. False
6. Rigid containers that have not had bloody or obviously soiled instruments inside do not need to be cleaned after each use.
 - a. True
 - b. False
7. If properly manually cleaned, multi-level trays may be mechanically cleaned with the tray layers together as a single set.
 - a. True
 - b. False
8. Silicone mats should not be used because they cause wet packs.
 - a. True
 - b. False
9. Using a wrapper that is too large may cause a wet pack.
 - a. True
 - b. False
10. When packaging instruments for sterilization, it is important to not place wet instruments inside the tray or package because doing so may cause a wet pack.
 - a. True
 - b. False
11. Placing assembled multi-part instruments into a package or set may cause a sterilization failure.
 - a. True
 - b. False
12. Improper filter placement in a rigid container may cause a wet pack.
 - a. True
 - b. False
13. When loading a steam sterilizer, it is acceptable to stack rigid containers, but not wrapped trays.
 - a. True
 - b. False
14. When loading a low-temperature sterilizer, basin sets should be placed upside down on the cart or rack.
 - a. True
 - b. False
15. During the sterilization process, condensate can form on wrapped packages when placed under rigid containers.
 - a. True
 - b. False

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