





Keys to a Successful Pack Control Strategy Using Chemical Indicators

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LEARNING OBJECTIVES

1. Understand the Sterile Processing technician's responsibilities for ensuring the instrument tray/pack can maintain sterilization integrity
2. Explain the basic steps involved in preparing an instrument set for sterilization
3. Explain why the instrument tray/pack should have a chemical indicator

In the world of instrument processing, there are six steps involved in the process: transportation, cleaning/inspection, packaging, sterilization, storage/delivery, and quality assurance (QA). This lesson will focus on an aspect of QA – pack control – and why the presence of internal chemical indicators (CIs) is important.

Objective 1: Understand the Sterile Processing technician's responsibilities for ensuring the instrument tray/pack can maintain sterilization integrity

Maintaining standards and best practices when packing a tray is important in the sterilization process. Best practice is to use a Type 5 or Type 6 CI in the tray because they react to all critical parameters of the sterilization process. It is also critical to always follow the manufacturer's instructions for use (IFU).

It is the responsibility of the Sterile Processing (SP) technician to understand the process used to achieve the destruction of microorganisms as

it pertains to the instrument tray/pack. SP technicians are tasked with knowing how to prepare an instrument tray/pack for the end user, allowing them to verify sterilant penetration, while making sure that the instrument tray/pack is safely prepared for patient use.

Within that process, it is important to be aware of the tools needed to correctly put an instrument tray/pack together for sterilization. Each instrument tray/pack will need the following to produce a successful product: clean and functional instruments, the correctly-sized tray or basket, container/wrap, and the correct CI for the sterilization process to be used.

Objective 2: Explain the basic steps involved in preparing an instrument set for sterilization

Basic packing criteria for preparing an instrument set for sterilization includes checking for cleanliness of each instrument in the set, inspecting each individual instrument (this is critical to its use during surgery), and assembling the instrument tray/pack.



An instrument tray/pack should be built using the following essential steps:

Step 1: Ensure the instruments are clean. Instruments should be checked for any peeling of tape and for the presence of bioburden such as blood, bone, cement, excessive oil, rust and spotting. Ensuring the cleanliness of an instrument is an important first step in the packing process. No instrument should be placed into an instrument tray/pack for patient use until it has been fully checked and signed off as clean.

Workspaces should be prepared by ensuring the area is clean and free of clutter. Necessary tools should be readily available and within reach of the work area. Potentially needed tools may include a tape measure, lubricant, scissor/sharps testing materials, tip protectors, non-linting wipes, and access to a magnifying lamp, demagnetizer and insulation tester.

Step 2: Inspect instruments that will be used in the instrument tray/pack. Inspection of an instrument requires that each instrument in the tray be handled and critically checked for sharpness, clamp ability, punch ability, stiffness or rust. The serrations, box locks and ratchets should be checked on each instrument to ensure they are in good working condition and are free of any foreign material. Hinged instruments with stiff joints may be a sign of inadequate cleaning. It is important to handle each instrument to ensure it is working properly before beginning to build the instrument tray/pack. Instruments should be replaced, as needed. It is important that technicians have access to the instruments' IFU during the inspection process. Also, knowing how an instrument is used during a procedure will help make the inspection process

clearer for the technician. While performing instrument inspections, tip protectors should be applied to delicate and sharp instruments, as needed, and as required by the IFU. Attention must be given to the details. These check points are the final ones performed before that tray/pack will be processed for patient use.

Step 3: Assemble the tray/pack. This step requires that an instrument count sheet be available to provide a roadmap that allows the technician to account for all required instruments. It is very important to only place requested instruments accurately within the tray - never giving fewer or more than is required. The packing of a tray requires that the basket be the right size and depth to contain the instruments. Instruments should not overcrowd the tray or be able to slip and slide because the tray is too big; either scenario can cause damage. If a tray/pack is overcrowded and overweight, the sterilization process can be impacted. Each instrument should be identified and verified against the count sheet and then placed neatly inside the tray. The need to substitute instruments should be cleared with the appropriate specialty coordinator before a substitution is made. If a tray/pack is assembled missing any instrument, the item missing (as well as the quantity) should be clearly marked. Tray liners or towels used for cushioning or wicking should be cleared for use by the package manufacturer's IFU. Gauze sponges, raytec, and four by fours cannot be used in trays to protect instruments because they interfere with surgical counts. *Note: There is a weight limit guideline of 25 pounds (per ANSI/AAMI ST79:2017 and ANSI/AAMI ST77:2013). This weight limit includes the basket, instruments and container/wrap. Remember, the total weight should not exceed 25 pounds.*

If a silicone finger mat is being used, the holes must be aligned with the drainage holes in the tray to help ensure proper air and water removal during steam sterilization. The instruments in a tray should be arranged in a predetermined configuration, and care should be taken to protect instruments from damage. Instruments that open, such as scissors and hemostats, should be placed with lock boxes in the open position to allow the sterilant to reach all parts. To ensure the IFU is being followed, devices such as stringers and racks can help keep instruments in the opened position. Instrument trays/packs should be arranged in a neat, functional, accurate and predetermined way that allows for ease of use by the surgical team as they provide patient care.

Objective 3: Explain why the instrument tray/pack should have a chemical indicator

The use of internal CIs in the assembly process is a standard part of tray setup. The CI is a visual tool that indicates whether the instrument tray has been subjected to a sterilization process. CIs have six different defined classifications or "types." Types 3, 4, 5 and 6 are all internal CIs. Type 3 indicators react to a single critical process variable, while Type 4 indicators react to multiple critical process variables.

ANSI/AAMI ST79:2017, *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*, recommends the use of a Type 5 or 6 indicator because these types of CIs react to all critical process variables. Type 5 indicators are often called integrating indicators because they integrate all the process variables into a single result. Type 6 indicators are referred to as emulating indicators because they are cycle specific. Type 5 indicators can be used in cycles with different parameters. All CIs should be



used for the cycle(s) for which they are labeled and used in accordance with the manufacturer's written IFU.

Once opened by the surgical team member, an internal CI with a passing result offers a visual notification that the tray was exposed to a sterilization process and passed the parameters the CI was designed to measure. A tray that is assembled without a CI is considered unusable and can potentially cause a delay in the surgical case while a replacement tray/pack is located. The absence of a CI is considered an error in the assembly process and the tray should be listed as not being processed accurately. When placing a CI in a tray/pack, it is recommended that the CI is placed in the most challenging area for steam to penetrate. ANSI/AAMI ST79:2017 notes the following for the placement of internal CIs:

- One CI must be visible to the person opening the package;
- The CI should be placed in the area or areas considered least accessible to steam penetration; and
- The CI should be placed in accordance with all applicable written IFU.

The CI should be retrieved from the tray and interpreted by a knowledgeable user to determine whether the criteria and characteristics were met to be a "pass" or "fail." If there are questions as to the interpretation of a CI, an appropriate supervisor should ensure the complete tray is returned for reprocessing. As part of the process, the supervisor must conduct research on the load to determine whether a recall is needed; this is typically done by checking the physical monitors and the biological indicator (BI) result, and opening other trays to check the internal CIs. If the surgical team opens a tray and finds the CI is missing, the entire tray

should be rejected. Because the sterility of individual instruments cannot be determined without the assistance of a microbiology laboratory, it is important (as part of the QA process) that an internal CI be present in each tray for retrieval and interpretation.

A robust sterility quality assurance program includes the use of a suite of monitoring products. Load release should be based on a careful review of the physical monitors, verification that the external CIs have turned color and, for implant loads, the BI result.

As a best practice, a BI PCD should be used to release every load. It is then up to the surgical team member to do the final check by verifying the internal CI has a "pass" result. Remember, the "pass" reading of a CI does not mean that the item or items in the sterilizer load are sterile; it means that the parameters for sterilization that the CI was designed to measure have been met.

Conclusion

In summary, the goal of any SP technician is to provide trays that are clean, sterile, functional and properly assembled with CIs.

Trays and packs should contain instruments that are free of bioburden and in good working order. Trays and packs should be organized and complete, and they should be assembled using a count sheet and/or template to ensure the contents are accurate. If items are unavailable or missing, the tray should not be placed into rotation without clearance from the surgical team members. Additionally, instrument trays should contain internal CIs because they are a visual indicator that sterilant has penetrated to the point of placement in the tray.

By following the steps outlined in this lesson, SP technicians will be able to provide critical instrumentation in a

timely manner to ensure a high standard of patient care for each person who undergoes surgery at their facility. **C**

RESOURCES

1. International Association of Healthcare Central Service Materiel Management. *Central Service Technical Manual*, Eighth Ed. 2016.
2. Association for the Advancement of Medical Instrumentation. ANSI/AAMI ST77:2013, *Containment devices for reusable medical device sterilization*.
3. Association for the Advancement of Medical Instrumentation. ANSI/AAMI ST79:2017, *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*.
4. Association of periOperative Registered Nurses. Guidelines for Perioperative Practice. *Guideline for selection and use of packaging systems for sterilization*. 2015.



CRCST Self-Study Lesson Plan Quiz - Keys to a Successful Pack Control Strategy Using Chemical Indicators

Lesson No. CRCST 173 (Technical Continuing Education - TCE) • Lesson expires July 2023

1. Internal chemical indicators must be placed:
 - a. In an area or areas considered least accessible to steam
 - b. In an area visible to the person opening the tray
 - c. In accordance with the manufacturer's instructions for use
 - d. All the above
2. The "pass" reading of a chemical indicator means that the item or items in the sterilizer load is/are sterile.
 - a. True
 - b. False
3. Once the instrument tray is received on the clean side of Sterile Processing:
 - a. The instruments should be carefully inspected
 - b. The instruments are ready for the sterilizer
 - c. Internal indicators should be immediately placed in the tray
 - d. The chemical indicator should be read before handling the instruments
4. Hinged instruments that have stiff joints indicate that the instrument:
 - a. Needs to be sharpened
 - b. Is dirty
 - c. Is ready to be placed in the tray
 - d. Needs to be removed from service
5. The twenty-five-pound weight limit for a tray refers to:
 - a. The total weight of the instruments
 - b. The weight of the instruments and the tray
 - c. The weight of the tray and container/wrap
 - d. The weight of the instruments, tray and container/wrap
6. If instruments are missing when assembling an instrument tray:
 - a. Always find a substitute to ensure the tray is complete
 - b. Try to locate the missing instruments and clear any suggested substitutes with the owning department
 - c. Never substitute instruments
 - d. Clearly label the tray as missing an instrument and set it on a holding rack
7. The important steps to prepare an instrument for sterilization include:
 - a. Cleanliness and sharpness inspection
 - b. Inspection for damage and following an approved count sheet
 - c. Instrument placement in the tray and total weight of the set
 - d. All the above
8. Internal chemical indicators should be used in cycles where the process parameters match the indicator's indications for use provided in the instructions for use.
 - a. True
 - b. False
9. Chemical indicators should be checked for a pass or fail by a member of:
 - a. The surgical team (internal and external)
 - b. The Sterile Processing team (internal and external)
 - c. The Sterile Processing team (internal)
 - d. Both A and B
10. Trays with a missing internal chemical indicator:
 - a. Can be used after the sterilizer monitors and process biological indicator are approved
 - b. Can be used if the external indicators have properly changed color
 - c. Should not be used in surgical procedures
 - d. Should trigger a recall of the entire load
11. Best practice is to use which type of indicator?
 - a. Type 3 indicator
 - b. Type 4 indicator
 - c. Type 5 or 6 indicator
 - d. None of the above
12. Sterile Processing technicians are responsible for knowing how to:
 - a. Properly prepare a tray for sterilization
 - b. Verify sterilant penetration inside a tray/pack
 - c. Provide clean and functional instruments
 - d. All the above
13. Industry standards for tray/pack assembly include:
 - a. Inspection of all instrument to be used in the tray/pack
 - b. Placement of the instrument count sheet inside the tray/pack
 - c. Proper use of external indicators inside the tray
 - d. All the above
14. If a tray/pack is overcrowded:
 - a. Tray liners and wicking material should be used
 - b. Items should be removed and marked on the count sheet
 - c. The instruments can become damaged
 - d. All the above
15. A "pass" reading on a processed chemical indicator indicates that:
 - a. A specific temperature and humidity level have been reached
 - b. The instruments are sterile
 - c. The sterilant has reached that area of the tray/pack
 - d. The sterilizer load can be released for use

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