





Steam and Gas Plasma Sterilization Failures: What Technicians Need to Know

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LEARNING OBJECTIVES

1. Identify common causes and consequences of sterilization failures
2. Describe how sterilization verification processes promote patient safety
3. Explain how standard work, checklists and visual cues prevent failures

The mission of every healthcare Sterile Processing department (SPD) is to protect patients from hospital-associated infections (HAIs). Sterile Processing (SP) technicians are on the frontline of patient safety, providing sterility assurance by ensuring that disease-causing microorganisms are effectively removed from surgical instruments and medical devices through validated sterilization methods.

When sterilization failures occur, the consequences extend far beyond the department; patients may be exposed to harm, surgeries may be delayed or canceled, and trust in the sterilization process can be compromised due to the lack of available sterile instruments and devices.

Sterilization technologies and modalities have evolved significantly since the early 1900s, driven by advances in science, standardization and mistake-proofing. Today’s sterilization methods are faster, more sophisticated, and easier to operate, monitor and verify. Despite these advances, SPDs continue to experience sterilization

failures, most often related to equipment issues, process variations, or operator errors. This lesson addresses the common causes of such failures and explains how technicians can reduce the risks by applying proven processes and other vital practices.

Objective 1: Identify common causes of steam and gas plasma sterilization failure

Although multiple factors contribute to sterilization failures, there are common causes across both steam and hydrogen peroxide gas plasma processes. These can include exceeding tray weight limits, using incompatible packaging materials, and failing to follow the sterilizer manufacturer’s written instructions for use (IFU) for proper operation. Steam and gas plasma sterilizers have tray weight limits identified by the manufacturer’s IFU.¹ It is extremely important that technicians operating sterilizers understand the required weight limits to avoid potential sterilization failures.²

Sterilization packaging materials play a critical role in sterility assurance.



Each packaging system is validated for use with specific sterilization modalities and cycle parameters.² Using packaging materials that are not compatible with the selected sterilizer, cycle or device can prevent effective steam or sterilant penetration, resulting in sterilization failure.² Not following the manufacturer's written IFU can jeopardize sterility and, therefore, place patients at risk for harm.

Common causes of steam sterilization failures include, but are not limited to, equipment-related issues, improper load configuration, inadequate cooling, and incorrect placement of process challenge devices (PCDs) used to verify sterilization.^{1,2} These failures most often result from process variation that occurs when technicians deviate from recommended standards of practice.

Equipment-related issues pose a significant risk to sterility assurance. Sterilizers are often installed with initial education on operation; however, required preventive maintenance is frequently overlooked until a malfunction occurs. In some cases, critical components, such as specialized filters that require replacement every six months, may remain unchanged for years, ultimately causing a sterilizer malfunction. To reduce the risk of equipment-related failures, SP leaders should partner with the Facilities Maintenance and Clinical Engineering departments to establish a standardized preventive maintenance program.² This program should strictly follow the sterilizer manufacturer's IFU for routine inspections, cleaning, calibration, filter replacement, and other preventive maintenance requirements.

Pre-vacuum steam sterilizers are widely used in SPDs and require routine performance testing to ensure effective air removal and vacuum integrity.¹ Leak tests verify the sterilizer's ability to maintain a vacuum. In contrast, the

Bowie-Dick test, commonly used as a dynamic air removal test, evaluates the sterilizer's ability to remove air from the chamber.¹ These tests are typically programmed cycles within the sterilizer. Failure to perform leak and Bowie-Dick tests as required can result in undetected sterilization failures.¹ ANSI/AAMI ST79, section 10.7.6, states "*The Bowie-Dick test should be carried out each day the sterilizer is used, before the first processed load.*"¹

Improper load configuration is a frequent contributor to steam sterilization failure.^{1,2} Overloading the sterilizer or configuring packages to maximize the number of trays in a single load can restrict steam circulation, resulting in wet loads and inadequate steam penetration.¹ Loads must be arranged with visible space between packages to allow effective air removal and steam contact.² When multiple packaging types are processed in the same load, rigid containers should be placed on the bottom shelves of the sterilizer rack to prevent condensate from dripping onto wrapped sets below.² Paper/plastic pouches should be positioned on edge in a basket or holder, with paper facing plastic.¹ Failure to follow validated load configurations may result in retained moisture and compromised package integrity, rendering the load unacceptable for patient use.^{1,2}

Adequate cooling of steam-sterilized instrument packages is also essential for maintaining sterility.¹ Packages must be allowed to cool to room temperature before handling.¹ Handling hot packages can cause condensation to form within or on the packaging material, resulting in contamination.² The use of infrared thermometers or other temperature-sensing devices is strongly recommended to verify that packages have cooled sufficiently before they are handled or stored.¹

Proper placement of PCDs is critical to sterility assurance.¹ PCDs must be positioned in the sterilizer chamber that represents the greatest challenge to sterilization, as identified in the sterilizer manufacturer's IFU.¹ Correct placement ensures that steam penetration is adequate throughout the entire load, regardless of package location.² When PCDs are placed in areas where steam penetration is easiest, a false sense of security may occur, increasing the risk that a contaminated package is released despite a negative test result.¹

Hydrogen peroxide gas plasma is a low-temperature sterilization technology that is highly effective at inactivating microorganisms when used as validated.^{1,2} To achieve reliable sterility assurance, SP technicians must strictly follow the sterilizer manufacturer's written IFU and verify that each instrument or device is validated for gas plasma sterilization.²

Gas plasma sterilization is incompatible with liquids, powders or moisture-absorbing materials, such as tray liners, towels or cellulose-based products.¹ The presence of these materials can neutralize hydrogen peroxide and prevent effective sterilant contact.² For this reason, all items processed in a gas plasma sterilizer must be completely dry before loading. Even small amounts of residual moisture within lumens, hinges or packaging can result in cycle failure or incomplete sterilization.

A common misconception about hydrogen peroxide gas plasma sterilization is that all "blue wrap" packaging is universally compatible and can be used if the appropriate external indicators, such as locks or tape, are applied. In reality, not all blue wrap materials are validated for use in gas plasma sterilization cycles. When unvalidated wrapping



materials are used, gas plasma sterilizers may alarm and abort the cycle.² Without an understanding of the wrap manufacturer's IFU, technicians may incorrectly place the sterilizer out of service, assuming an equipment malfunction. This can result in unnecessary downtime of a fully functional sterilizer and delays in instrument availability.

To prevent these avoidable failures, SP leaders must review and confirm that wrapping materials are validated for the specific gas plasma cycles in use. Verifying compatibility not only prevents inadvertent sterilization failures but also avoids the unnecessary expense of purchasing packaging materials that cannot be used safely or effectively.

Proper load configuration is also critical to the effectiveness of gas plasma sterilization.² Sterilizers are designed to deliver a specific amount of hydrogen peroxide based on validated load parameters.² Overloading the sterilizer or loading devices in a manner inconsistent with the IFU can limit sterilant distribution and prevent hydrogen peroxide from reaching all device surfaces.¹ When the sterilant is absorbed or dissipated before full exposure is achieved, sterility assurance cannot be confirmed.²

Objective 2: Describe how sterilization verification processes ensure patient safety

Sterilization verification eliminates the assumption of sterility by continuously monitoring and testing sterilization processes.^{1,2} Both steam and hydrogen peroxide gas plasma sterilization require the use of chemical indicators (CIs) and biological indicators (BIs) to verify sterility assurance and ensure patient safety.^{1,2}

CIs are used both externally and internally, including indicator tape,

locks and tray indicator strips.² These indicators verify exposure to specific sterilization conditions, such as temperature, time or chemical presence, through a visible color change.¹ When indicator colors fail to change as expected, this may signal a potential sterilization failure. While CIs confirm exposure to sterilization conditions, they do not prove sterility; therefore, BI testing is required.¹

BIs are critical for confirming the destruction of microorganisms and validating the effectiveness of the sterilization process.² BIs are test devices containing live bacterial spores suspended in a growth medium.¹ *Geobacillus stearothermophilus* spores are commonly used because they are highly resistant to both steam and hydrogen peroxide gas plasma sterilization.¹ For this reason, BIs provide direct evidence that sterilization conditions were sufficient to kill microorganisms commonly found on surgical instruments and devices.²

BIs are placed within a PCD and positioned in the area of the sterilizer that presents the greatest sterilization challenge, as identified in the sterilizer manufacturer's IFU. After the sterilization cycle is complete, the BI is incubated to determine whether the spores have been successfully destroyed. This testing method provides the highest level of confidence that instruments and devices are safe for patient use.

Routine BI testing is strongly recommended, and SP leaders should evaluate the need for BI testing with every sterilization load based on sterilizer use and the frequency of implant processing.^{1,2} ANSI/AAMI ST79, Section 10.5.3.2, states, "*Biological indicators should be used within a PCD for routine sterilizer efficacy monitoring at least weekly, but preferably every day that the sterilizer is in use...and should be used to monitor every load containing implants.*"¹

Objective 3: Explain how standard work, checklists and visual cues reduce sterilizer failures

Regardless of a technician's experience level, sterilization failures can occur during any SP operation. Variability in practice, distractions and reliance on memory increase the risk of error. Developing standardized work for sterilization processes reduces this variability by promoting consistent, repeatable outcomes regardless of which technician performs the task. SP leaders and educators play a critical role in designing and implementing standard work supported by checklists and visual cues to minimize operator error and improve sterility assurance.

Standard sterilization checklists are simple yet highly effective tools for verifying critical steps before a sterilizer cycle is initiated. Checklists may be paper-based or electronic, depending on whether the department uses an instrument-tracking system. An effective checklist includes key verification points, such as correct cycle selection, proper load configuration, BI and PCD placement, implant identification, packaging integrity, locks, filters and any cycle-specific requirements. Checklists should be reviewed and updated regularly as part of a continuous improvement process to ensure alignment with current IFU and departmental practices.

Visual cues provide an additional layer of mistake-proofing by guiding technicians toward correct actions at the point of use. Examples include color-coded tray tags, labels, or alerts that identify instruments requiring non-standard sterilization cycles. In departments that use tracking systems, trays can be programmed so that scanning triggers a visual or electronic warning, prompting technicians to confirm the correct cycle parameters.




The purpose of visual cues is to reduce reliance on memory and protect against errors caused by repetitive tasks, interruptions, distractions or fatigue, all of which are common contributors to sterilization failures.

Conclusion

While modern sterilization technologies are highly effective, they cannot compensate for inadequate training, improper loading, incompatible materials, or inadequate or overlooked preventive maintenance. SP professionals play a critical role in protecting patients from harm. That responsibility extends beyond running a sterilizer; it must also include ensuring that every step of the

process is performed as validated by the manufacturer's IFU.

The implementation of standard work, checklists and visual cues provides a practical and sustainable approach to reducing variability and minimizing operator error. These tools support consistency, reinforce compliance, and create a culture of accountability and continuous improvement within SPDs.

Sterility assurance is not achieved through technology alone but rather through knowledgeable professionals, disciplined processes and a commitment to doing the work correctly every time. 

REFERENCES

1. Association for the Advancement of Medical Instrumentation. ANSI/AAMI ST79:2017/(R)2022 *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities*.
2. Society of Gastroenterology Nurses and Associates. *Sterile Processing Technical Manual*, 9th ed. 2021.

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CRCST Self-Study Lesson Plan Quiz: Steam and Gas Plasma Sterilization Failures: What Technicians Need to Know

Lesson No. CRCST 208 (Technical Continuing Education – TCE) · Lesson expires June 2029

1. Sterilization packaging materials play a minimal role in sterility assurance.
 - a. True
 - b. False
2. Leak tests for prevacuum sterilizers:
 - a. Verify the sterilizer's ability to maintain a vacuum
 - b. Evaluate the sterilizer's ability to remove air from the chamber
 - c. Are unnecessary
 - d. None of the above
3. Which factor most commonly contributes to sterilization failures despite modern technology?
 - a. Advanced sterilizer design
 - b. Excessive cycle monitoring
 - c. Equipment issues, process variation, and operator error
 - d. Overuse of biological indicators (BIs)
4. Tray weight limits for sterilizers are established by which source?
 - a. Departmental policy
 - b. Sterile Processing leadership
 - c. The sterilizer manufacturer's instructions for use (IFU)
 - d. ANSI/AAMI ST79
5. Using packaging materials validated for a specific sterilization modality is critical because:
 - a. It improves instrument appearance
 - b. It prevents excessive drying times
 - c. It helps ensure effective sterilant penetration
 - d. It simplifies load configuration
6. Which of the following is a common cause of steam sterilization failure?
 - a. Excessive BI testing
 - b. Improper load configuration
 - c. Use of stainless steel trays
 - d. Excessive cooling time
7. Preventive maintenance for sterilizers:
 - a. Is often unnecessary for modern units
 - b. Must be performed by the manufacturer at least quarterly to preserve the warranty
 - c. Is often overlooked until a malfunction occurs
 - d. Should be performed by Biomedical Engineering staff every month or more if needed
8. According to ANSI/AAMI ST79, when should the Bowie-Dick test be performed?
 - a. Weekly
 - b. Monthly
 - c. With every implant load
 - d. Each day the sterilizer is used, before the first load
9. Improper load configuration in steam sterilizers may result in:
 - a. Faster cycle completion
 - b. Retained moisture and wet loads
 - c. The sterilizer manufacturer voiding the warranty
 - d. Shortened cooling times
10. Why must steam-sterilized packages be allowed to cool before handling?
 - a. To prevent packaging discoloration
 - b. To reduce staff exposure to heat
 - c. To prevent condensation and contamination
 - d. To meet tracking system requirements
11. Process challenge devices (PCDs) should be placed:
 - a. Near the chamber drain
 - b. In the area easiest for steam penetration
 - c. Wherever space is available
 - d. In the location representing the greatest challenge to sterilization
12. Which material is **not** compatible with hydrogen peroxide gas plasma sterilization?
 - a. Stainless steel instruments
 - b. Moisture-absorbing materials
 - c. Rigid containers validated for gas plasma
 - d. Non-cellulose packaging
13. Blue wrap is universally compatible with gas plasma sterilization.
 - a. True
 - b. False
14. What is the primary purpose of BIs in sterilization monitoring?
 - a. To confirm exposure to cycle parameters
 - b. To detect equipment malfunction
 - c. To demonstrate the destruction of microorganisms
 - d. To replace chemical indicators
15. Standard work, checklists and visual cues improve sterilization outcomes by:
 - a. Increasing the sterilizer's cycle time
 - b. Reducing reliance on memory and minimizing error
 - c. Eliminating the need for training
 - d. Replacing manufacturers' IFU

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