LOW-TEMPERATURE GAS PLASMA STERILIZATION

Low-temperature gas plasma (LTGP) was cleared by FDA in 1993 as an alternative to EO gas. It is a quick, low-temperature process that uses a combination of hydrogen peroxide vapor and gas plasma to effectively and safely sterilize packaged devices. It is an effective sterilant without the hazards or extended aeration times associated with EO. Devices sterilized by this process do not require aeration, and only a special electrical outlet is needed for installation.

Today, LTGP is used for many of the devices previously processed by EO (e.g., multiple- and single-channel flexible endoscopes, rigid endoscopes, endoscopic instruments, cameras, stereotactic devices, fiberoptic light cords). There are several models of LTGP sterilizers. The sterilizer manufacturer’s instructions for use of the specific available sterilizers and cycles, including any lumen and packaging restrictions, should be followed.

The STERRAD® 100S LTGP sterilizer (Figure 8-32) is limited in its ability to sterilize devices with long and narrow lumens or dead-end channels (channels open only at one end). Currently, lumened devices that meet the following criteria can be processed in this system:

**Single stainless steel lumens with**

- an inside diameter of 1 mm or larger and a length of 125 mm or shorter
- an inside diameter of 2 mm or larger and a length of 250 mm or shorter
- an inside diameter of 3 mm or larger and a length of 400 mm or shorter

**Teflon®/polyethylene lumens with**

- an inside diameter of 6 mm or larger and a length of 310 mm or shorter

The cycle time is approximately 55 minutes. During the sterilization cycle, the sterilizer operates at 113°F (45°C), and the temperature of the load does not exceed 131°F (55°C).
The STERRAD® NX sterilizer (Figure 8-33) has greater capacity than the STERRAD® 100S to sterilize a variety of instruments and accessories, including single-channel flexible endoscopes, semi-rigid ureteroscopes, cameras, light cords, batteries, power drills, and rigid endoscopes, including hysteroscopes and choledocoscopes.

This sterilizer provides two cycles:

- General surgical instruments and medical devices with the following characteristics can be processed in the 28-minute “STANDARD” cycle:
  - Stainless steel instruments without lumens
  - Single-channel stainless steel lumens having an inside diameter of 1 mm or larger and a length of 150 mm or shorter
  - Single-channel stainless steel lumens having an inside diameter of 2 mm or larger and a length of 400 mm or shorter
- Single-channel polyethylene and Teflon® medical tubing with an inside lumen diameter of 1 mm or larger and a length of 350 mm or shorter (up to 10 pieces of tubing can be sterilized at one time without any additional load)

- General surgical instruments and medical devices with the following characteristics can be processed in the 38-minute “ADVANCED” cycle:
  - Single-channel stainless steel lumens having an inside diameter of 1 mm or larger and a length of 500 mm or shorter
  - Single-channel polyethylene and Teflon® medical tubing with an inside lumen diameter of 1 mm or larger and a length of 1,000 mm or shorter
  - Single-channel flexible endoscopes with an inside diameter of 1 mm or larger and a length of 850 mm or shorter (only one endoscope per load, with no other items in the load)

  NOTE: There is a limit of 10 lumened devices per cycle. If the lumens do not conform to the above dimensions, contact the sterilizer manufacturer for guidance.

For both the “STANDARD” and “ADVANCED” cycles, the maximum load temperature is 131°F (55°C).

The STERRAD® 100NX sterilizer (Figure 8-34) has a greater capacity than the STERRAD® 100S to sterilize a variety of instruments and accessories, including single-channel flexible endoscopes, semirigid ureteroscopes, cameras, light cords, batteries, power drills, and rigid endoscopes, including hysteroscopes and choledoscopes.

![Figure 8-34 – LTGP sterilizer (STERRAD® 100NX)](image)

The STERRAD® 100NX provides three cycles:

- General surgical instruments and lumened medical devices (e.g., flexible endoscopes) with the following characteristics can be processed in the 47-minute “STANDARD” cycle:
• Single-channel stainless steel lumens having an inside diameter of 0.7 mm or larger and a length of 500 mm or shorter

• Single-channel flexible endoscopes with the following characteristics can be processed in the 42-minute “FLEX” cycle:
  ➢ Single-channel Teflon®/polyethylene medical tubing having an inside lumen diameter of 1 mm or larger and a length of 850 mm or shorter

• The 24-minute “EXPRESS” cycle can be used to process general and delicate instruments without lumens, rigid and semirigid telescopes/endoscopes (including da Vinci® 3-D Endoscopes), and rechargeable batteries.

For all three cycles, the maximum load temperature is 131°F (55°C).

The following devices and materials should not be processed in any LTGP sterilizer: devices with dead-end lumens, cellulose-based materials (e.g., cotton, paper, gauze), liquids, items that do not meet the lumen length/diameter criteria, any organizing trays that contain cellulose-based materials, load-control stickers (unless they are made of Tyvek® plastic), count sheets (unless they are made of Tyvek® plastic), traditional adhesive labels (e.g., dust cover labels), and implants.

Before LTGP sterilization is considered for a particular medical device, the device manufacturer’s instructions should be checked to ensure that the device was validated for this sterilization method using the STERRAD® 100S, STERRAD® NX, or STERRAD® 100 NX sterilizer. If this information cannot be verified with the medical device manufacturer, the sterilizer manufacturer should be contacted.

LTGP STERILIZATION CYCLES

The parameters for LTGP sterilization are time, temperature, and hydrogen peroxide gas plasma:

• **Time:** Cycle time varies with the sterilizer model.

• **Temperature:** Cycle temperature varies from 113°F to 131°F (45°C to 55°C), depending on the sterilizer model.

• **Sterilant:** The sterilant is provided in a multi-dose cassette containing 10 single ampules of liquid hydrogen peroxide (H₂O₂) (nominal 59% concentration).

The phases of the sterilization process are as follows:

• **Vacuum:** All air is removed from the chamber and the packages until the pressure is reduced to below atmospheric pressure.

• **Injection:** After the correct pressure has been reached, a premeasured amount of concentrated (59%) H₂O₂ is pumped from the cassette into the vaporizer bowl where, depending on the cycle chosen, it may be concentrated. It is then vaporized into the chamber.

• **Diffusion:** During the diffusion phase, the chamber returns to atmospheric pressure and H₂O₂ vapor is driven into the small crevices and lumens of the devices in the chamber. Inactivation of microorganisms is initiated.

• **Plasma:** The chamber pressure is reduced by vacuum, and radiofrequency (RF) energy is radiated within the chamber from the electrode screen. The RF energy ionizes the
H₂O₂, creating H₂O₂ gas plasma and leading to the generation of free radicals and other chemical species that then recombine to form oxygen and water when the plasma power is turned off.

- **Injection, Diffusion, Plasma:** The injection, diffusion, and plasma phases are repeated a second time.

- **Vent:** At the end of the second sequence, the RF energy is turned off. Air is then vented into the chamber through bacterial HEPA filters, returning the chamber to atmospheric pressure.

At the end of the sterilization cycle, a 10-second continuous audible alarm sounds, alerting the operator that the cycle is complete and that the sterilized items can be removed from the sterilizer. A printout verifies that the process is complete.

**PREPARATION OF ITEMS FOR LTGP STERILIZATION**

Preparing items for LTGP sterilization is similar to preparing items for steam or EO sterilization. All hinged instruments should be opened, and multipart instruments should be disassembled if recommended by the device manufacturer. All devices processed in LTGP must be thoroughly cleaned and dried; any residual moisture can result in a cycle cancellation. Medical-grade compressed air can be used to assist with the removal of moisture from lumens and other difficult-to-reach places.

Items should be packaged according to departmental procedures, which should be based on the medical device, packaging, and sterilizer manufacturers’ instructions for use. Packages should be prepared in a manner that provides for aseptic handling and for the protection of the package contents until use. Packages must also allow for the adequate penetration of hydrogen peroxide. Trays for containing items should be perforated and should be placed flat in the sterilizer. Neither Tyvek® pouches nor additional absorbent material (e.g., silicone mats) should be placed inside trays unless their use has been validated by the packaging manufacturer and FDA-cleared for that use.

Items to be sterilized by LTGP must be packaged in non-cellulose-based materials; therefore, such materials as cloth, paper, and paper–plastic pouches cannot be used. Cotton gauze, cotton-tipped applicators, cotton balls, and towels cannot be used inside trays. Cellulose-based materials can absorb H₂O₂ and cause cycle cancellation and/or a sterilization process failure. In addition, it must be verified that any containment devices (containers that must be wrapped or rigid sterilization container systems) have been validated for use in LTGP. For rigid containers intended for use in LTGP, only non-cellulose filter material can be used. The following packaging materials are compatible with LTGP: trays provided by the sterilizer manufacturer, Tyvek® (all-plastic) pouches (but no paper–plastic pouches), and polypropylene-based wraps. However, it is important to follow the packaging manufacturer’s instructions for use and to verify that the packaging system has been validated for the STERRAD® process.

The CS/SPD technician should carefully review tray contents and packaging materials to ensure that they are compatible with LTGP before placing them in the sterilizer.

If traditional paper lot control labels are used at the facility, they should be applied immediately after items are removed from the sterilizer. Many CS/SPD departments have standardized with universal lot labels that can be used for items to be sterilized by steam or EO and other low-temperature processes. These labels can be applied to items before they are placed into the sterilizer. The label manufacturer should be requested to provide written verification that the label is compatible with the sterilization process to be used.
LOADING THE STERILIZER

The sterilizer chamber should be loaded according to the manufacturer’s recommendations; stacking of items is not recommended. The load should be arranged so that all metal items are in a single layer and do not touch the walls, doors, or electrode of the sterilizer. The most effective sterilizer performance is achieved when the load contains a mixture of metal and plastic items. The sterilizer chamber must not be overloaded. No paper or cellulose materials should be placed in the chamber. All Tyvek® pouches should be placed on their edge.

MONITORING THE STERILIZATION PROCESS

Routine Monitoring: Special chemical indicators are used to detect the presence of hydrogen peroxide. A chemical indicator should be placed inside and outside of each package. It is important to be able to recognize the correct color change. The chemical indicator provided by the sterilizer manufacturer is red when unprocessed; the red color changes to golden yellow or lighter after exposure to hydrogen peroxide. This color change occurs in both the external CI (indicator tape) and the internal CI. These indicators should be stored away from fluorescent light; otherwise, the color can fade. The CI manufacturer’s instructions for use (including color change interpretation) and storage (including the expiration date) should be followed.

If at the end of the sterilization cycle the indicator bar has not completely changed from red to yellow, introduction of hydrogen peroxide, an essential component of the STERRAD® sterilization process, might not have taken place. The load contents should not be considered sterile, and the department head should follow the departmental/facility policy on recalls. The recall decision should be based on the results of physical monitoring, other CIs in the load, and, if the load was biologically monitored, BIs.

According to the manufacturer, the LTGP process should be monitored with a BI PCD daily. ANSI/AAMI ST58 recommends BI testing at least daily, but preferably for each load. If testing is performed daily, each type of cycle (STANDARD, ADVANCED, FLEX) should be tested with a BI PCD. Monitoring every load with a BI and quarantining the load until the BI results are known to be negative reduces the potential for recalls (ANSI/AAMI ST48). The biological indicator for this process contains the spore Geobacillus stearothermophilus. The BI PCD should also contain a CI. If the BI PCD is prepared at the healthcare facility, it should consist of a BI and a CI in a Tyvek® pouch, package, or tray that is routinely processed and that is representative of the most-difficult-to-sterilize item in the load being processed (AAMI TIR31). The sterilizer manufacturer has products available for the preparation of PCDs in the healthcare facility; the manufacturer’s instructions for assembly should be followed. (Currently, there are no commercially available PCDs for this system.) The BI PCD is placed on the bottom shelf in the back, preferably on top of a tray.

The manufacturer’s instructions for activation/crushing of the BI vial and for incubation of the test BI and a control BI from the same lot should be followed. The BI is incubated at 55°C to 60°C (131°F to 140°F) for at least 24 hours but not longer than 72 hours. The temperature of the incubator should be verified and documented daily.

The BI manufacturer’s instructions for storage, handling, and expiration dates should be followed.

As in other types of sterilization, all items processed by LTHP sterilization should be documented in a sterilization log. When the sterilization cycle is complete, the printout should be reviewed and, if all sterilization parameters were met, signed (the printout will state that the cycle is complete). If physical monitoring indicates any malfunction or a sterilization process failure, the load should not be used.
Recalls: When a positive BI indicates a sterilization process failure, the sterilizer manufacturer recommends the following: 1) Follow the current facility policy and procedures regarding retrieval of unused instruments and notification of physicians. 2) Repeat the BI test a second time. If the second BI test is negative, a third BI test should be run to confirm sterilizer performance. If two consecutive positive results are obtained, the facility’s policy and procedures for recalls should be followed. The positive BI results should be reported to the sterilizer manufacturer and arrangements made for service. The sterilizer should not be used until servicing has been completed. To shorten the BI testing time, the second and third BI tests may be performed back-to-back.

Sterilizer Qualification Testing: Sterilizer qualification testing is performed upon installation or relocation of the sterilizer in order to assess its performance in the environment in which it will be used. This type of testing is also performed after sterilizer malfunctions, after major repairs of the sterilizer or its utilities, and after sterilization process failures in order to ensure that the sterilizer is working properly before it is placed back into routine use. The sterilizer manufacturer should be consulted for assistance with testing after installation, relocation, or major repairs. The sterilizer manufacturer recommends that upon relocation of the sterilizer, product certification and validation using the appropriate validation kit should be performed before the sterilizer is placed into service. Any necessary planned or corrective maintenance actions identified during the product certification must be implemented before the sterilizer can be validated and put into service.

SAFETY PRECAUTIONS

The LTGP system uses liquid hydrogen peroxide at a concentration of a 59%. Therefore, basic safety precautions are necessary. Hydrogen peroxide is a skin, eye, nose, throat, lung, and gastrointestinal tract hazard and is listed as an animal carcinogen and as a Group 3 carcinogen (not classifiable as to carcinogenicity in humans). Personnel should always wear PPE (polyvinyl chloride or nitrile gloves) when removing items from the sterilizer and when handling the sterilant. The MSDS should be checked for more information. An area monitor is available to verify that employee exposures are below the OSHA PEL of 1 ppm TWA. Rooms in which hydrogen peroxide sterilizers are used should have an air exchange rate of 10 air exchanges per hour.
Peracetic acid is FDA-cleared as a liquid chemical sterilant. Because the peracetic acid processor is a wet system, it can only be used for immersible items. Devices to be processed are not packaged, so care must be taken to avoid recontamination after processing. Like immediate-use (flash) sterilization, the peracetic acid processing system is a point-of-use system. Therefore, the processor should be located as close to the point of use as possible. It is essential to follow the processor manufacturer’s written instructions for use.

The SYSTEM 1E Liquid Chemical Sterilant Processing System is an automated, table-top, microcomputer-controlled device designed to maintain process parameters necessary for standardized and effective liquid chemical sterilization. It is FDA-cleared for the liquid chemical sterilization of immersible semicritical and critical heat-sensitive medical devices, including multi-channel flexible endoscopes. At the completion of each cycle, a comprehensive printout documents the process and load information.

Before the liquid chemical sterilant processing system is considered for a particular medical device, the device manufacturer’s instructions should be checked to ensure that the device was validated for this processing method using the SYSTEM 1E. If this information cannot be verified with the medical device manufacturer, the processor manufacturer should be contacted.

THE PROCESSING CYCLE

The SYSTEM 1E Liquid Chemical Sterilant Processing System has two standard cycles:

- The liquid chemical sterilization cycle is used to process devices that have been properly cleaned, inspected, and tested for proper working condition in accordance with the device manufacturer’s instructions for use. The specific cycle parameters are discussed later in this section.

- The diagnostic cycle is designed to test the filter and the electromechanical systems of the SYSTEM 1E processor. The cycle consists of a series of internal tests that are
performed sequentially. A successful diagnostic cycle assures the operator that the system is operating as designed. If the diagnostic cycle fails, the processor must not be used until the problem is corrected and a successful diagnostic cycle is run. A diagnostic cycle takes approximately 14 minutes and should be run once every 24 hours.

S40 Sterilant Concentrate is a single-use chemistry labeled exclusively for use in the SYSTEM 1E Liquid Chemical Sterilant Processing System. Its active ingredient is peracetic acid, an effective liquid chemical sterilant. Other chemicals in the formulation minimize corrosion or degradation of the devices being processed. S40 contains peracetic acid in the inner cup and dry-powder inert ingredients in the outer cup. The peracetic acid is diluted with extensively treated potable water inside the processor chamber to create the use dilution. The minimum recommended concentration of use dilution for an effective cycle is 1,820 mg/L. A new container of sterilant is needed for each cycle. Filtered, UV treated water enters the processor and mixes with the sterilant to prepare the use dilution. The use dilution fills the chamber and is heated to a temperature of approximately 46°C to 55.5°C (115°F to 131°F). The exposure time at the exposure temperature is 6 minutes. The use dilution is then drained from the chamber, and the device and chamber are rinsed with filtered, UV treated water two times. Upon successful completion of the liquid chemical sterilization cycle (approximately 23 minutes in duration), devices are ready for immediate use.

NOTE 1: Actual cycle time might vary depending on water pressure, the temperature of the incoming water, and the status of the filter.

NOTE 2: The manufacturer recommends that at the completion of the cycle, the user verify that the S40 container is empty because the physical monitors do not measure the presence or concentration of peracetic acid.

It is important to monitor the filters and change them periodically as recommended by the manufacturer. Filter changes should be documented. It should be noted that the facility’s water quality can affect how frequently filters must be changed.

**PREPARATION OF ITEMS FOR PROCESSING**

Items to be processed must first be thoroughly cleaned according to the device manufacturer’s instructions for use. Items are immersed in the use dilution so no packaging is required.

The specific preparation steps are as follows:

- **Clean the device:** Heat-sensitive endoscopes, devices, cameras, and other devices must be cleaned according to the device manufacturer’s instructions.

- **Visually inspect and test the device:** Heat-sensitive endoscopes, devices, cameras, and other devices must be visually inspected and tested for proper working condition according to the device manufacturer’s instructions.

- **Place a water-resistant cap on the device, as required:** Certain devices, such as cameras, connectors, and light cables, might require use of a water-resistant cap. Failure to cap such devices could result in damage to the devices. The device manufacturer’s instructions should be consulted.

- **Place the device into the processor:** Devices must be positioned to ensure that all surfaces will be exposed to the sterilant use dilution. All devices should be completely disassembled into the smallest components possible, according to the device manufacturer’s instructions. Specially designed “Quick Connects” are available from the processor manufacturer for most devices with internal channels. Each Quick Connect includes processing instructions describing how to ensure proper sterilant flow through the specific device. These instructions should be followed to ensure proper device positioning. Failure to properly position devices in the processing container could cause
device-to-device contact sites, which might not be exposed to the sterilant use dilution during processing. See also “Loading the Processor,” below.

- **Use a processing container, as required:** The processor manufacturer recommends that critical devices be processed in a container, where possible. If the device does require processing in a container, the appropriate container should be used and the lid should be placed on the container. If handles are present, the lid is secured by rotating the handles up and over the lid. The fluid port on the bottom of the processing container should be aligned over the fluid port of the processing tray. The processing tray should rest on the rubber fluid port gasket. See also “Loading the Processor,” below.

**LOADING THE PROCESSOR**

Immersible, heat-sensitive critical and semicritical devices are placed in the processing chamber. If applicable, the appropriate connector (“Quick Connect”) is attached to the device and the processor is closed, creating a sealed environment.

The processor is a table-top unit with processing trays and containers to position devices such as multi-channel flexible endoscopes, rigid endoscopes, and associated instrumentation for processing. It is of paramount importance that when processing flexible endoscopes in the SYSTEM 1E processor, the user must be thoroughly familiar with the processor and know the correct “Quick Connect” to attach to the flexible endoscope. If an incorrect Quick Connect is used, the sterilant use dilution will not reach all areas of the endoscope for effective processing. The CS/SPD technician should carefully review the loading configuration to ensure effective processing.

**OPERATING THE PROCESSOR**

The procedure for operating the SYSTEM 1E processor is as follows:

- **Add S40 sterilant concentrate:** Wearing PPE, the operator should carefully inspect the carton containing the S40 sterilant concentrate container for evidence of damage or expiration. If the container is not damaged and the expiration date has not been exceeded, the sterilant container should be removed from the carton and placed into the sterilant compartment located in the lower right corner of the processing tray. The processor manufacturer’s specific instructions for insertion of the sterilant concentrate container should be followed.

- **Initiate the cycle:** The cycle cannot be initiated until the SYSTEM 1E lid is closed and the UV lamp is warmed up. The lid of the processor should be closed and, when the UV lamp is warmed up (typically in 5 minutes), the START touch pad should be pressed to run the cycle.

The System 1E critical parameters include temperature, time, and sterilant concentration. The sterilant temperature is monitored throughout the cycle. If the temperature is out of specification at any time during the cycle, the cycle will abort. The exposure time for all critical steps is also monitored by the controller. If any step is not within the specified time, the cycle will abort.

**MONITORING THE PROCESS**

**Routine Monitoring:** According to ANSI/AAMI ST58, a chemical indicator recommended by the processor manufacturer should be used in each cycle. The SYSTEM 1E chemical indicator cleared by FDA for use with the system provides additional confirmation of the appropriate use dilution concentration under actual use conditions. The CI manufacturer’s instructions for use (including interpretation of the color change) and storage (including the expiration date) should
be followed. If at the end of the process a CI suggests inadequate concentration of the use dilution, the contents of the load should not be used.

Use of the SYSTEM 1E CI in every processing cycle provides additional assurance that the concentration of the sterilant use dilution is always above the minimum recommended concentration of 1,820 mg/L. The use of the CI augments the process monitoring provided by the SYSTEM 1E processor itself.

The SYSTEM 1E MaxPure Filter Integrity test and the UV light provide additional verification that a successful cycle has been achieved. A failure associated with either the filter integrity test or the UV light will cause the processor to abort the cycle.

“Biological indicators are not appropriate or required for monitoring liquid chemical sterilization processes. They are generally used for monitoring traditional sterilization processes where a SAL of 10^6 is achieved. FDA has not cleared any biological indicators for monitoring liquid chemical sterilization processes. Chemical indicators are appropriate and are required for monitoring the minimum required concentration of most liquid chemical sterilants. FDA has cleared many chemical indicators for monitoring the concentration of liquid chemical sterilant. Refer to the manufacturer's instructions for a compatible chemical indicator that is cleared by the FDA for use with the liquid chemical sterilant.” (FDA, 2011)

The SYSTEM 1E printout provides the following information for completed cycles: current date; cycle start time; start time of the load's exposure to liquid chemical sterilant; temperature range throughout the exposure time; concentration, as equivalent units of the use dilution; actual exposure time; time in minutes of the longest fill phase; inlet temperature of the water after the chamber is filled and just before the heater goes on; serial number of the processor; cycle count, not including diagnostic cycles; time of cycle completion; and time that the lid seal is deflated to open the processor. The printout should be reviewed and signed at the completion of the cycle if all parameters were met. The printout should be saved with the processing records. Documentation of all items processed in the unit should be retained with the processing records. If physical monitoring indicates any malfunction or a processing failure, the load should not be used.

**Diagnostic Cycle:** As stated previously, a 14-minute diagnostic cycle should be run every 24 hours to ensure that the MaxPure™ filter and the electromechanical systems are functioning correctly. The processor should not be used if the diagnostic cycle shows a failure. The problem must be corrected and a successful diagnostic cycle performed before the processor can be returned to routine use. The testing information should be documented and retained with the processing records.

**Inadequate Processing:** When monitoring of a cycle indicates inadequate processing, the processor should be removed from service and the cause of the processing failure determined and corrected. The processor should be retested according to the processor manufacturer's written instructions for use. The processor manufacturer should be consulted as to whether a diagnostic cycle should be run before the processor is placed back into routine use. The CIs and physical monitors should show correct processing conditions before the processor is placed back into routine use.

**SAFETY**

The SYSTEM 1E Liquid Chemical Sterilant Processing System uses S40 sterilant concentrate, which contains 35% peracetic acid. Under normal use conditions, users are not exposed to the sterilant concentrate. Although it is unlikely that the user could be exposed while inserting the sterilant container into the SYSTEM 1E processor, it is recommended that PPE be worn as a
precautionary measure. Recommended PPE consists of chemical-resistant gloves, goggles, and an apron, preferably with arm protection.

The MSDS should be consulted for additional information on necessary PPE and emergency plans for spills. The PEL for acetic acid, which is a component of peracetic acid, is 10 ppm as an 8-hour TWA. Rooms in which liquid peracetic acid processors are used should have an air exchange rate of 10 air exchanges per hour.

ROUTINE MAINTENANCE AND CLEANING OF HEALTHCARE FACILITY STERILIZERS

Sterilizers are expensive pieces of equipment. They need to be maintained and cleaned on a regular basis according to the sterilizer manufacturer’s instructions. Preventive maintenance agreements permit ongoing maintenance of the sterilizer to help reduce downtime. All maintenance should be performed by trained personnel and documented. All service logs should be saved as evidence of the upkeep of the sterilizer and to assist in diagnosing sterilization process failures.

The inside chamber of a steam sterilizer should be routinely cleaned to remove deposits from the sterilization cycle. The steam supply needs to be shut off during cleaning so that the chamber walls are cool. The sterilizer manufacturer’s instructions for frequency of cleaning and for recommended cleaning products and implements should be followed. It is important to rinse off all detergents thoroughly to prevent deposits on devices during sterilization.

Two of the most important parts of a steam sterilizer (for CS/SPD personnel) are the drain-line basket and the door gasket. The drain-line basket, which is located on the floor of the sterilizer (usually near the door), should be removed and cleaned daily. A clogged drain line can cause problems with wet packs. The basket should be held under running water so that the contents flow out. A soft brush can be used, if necessary, to remove debris. After cleaning, the basket should be inspected for holes or other damage; if it is intact, it should be returned to the drain line. If it is damaged, it should be replaced. One sterilizer manufacturer recommends that the chamber drain be flushed weekly. The instruction manual for the sterilizer will indicate whether this needs to be done and, if so, how often and which cleaning products are recommended.

The door gasket should also be cleaned daily, using water and a non-linting towel. The gasket should be carefully inspected for cracks and other defects that could cause a steam leak. If deficiencies are seen, the gasket should be replaced.

The outside of the sterilizer (especially the top of the door) should be cleaned daily, and the sterilizer carriage should be wiped off. Oils and grease accumulate on the carriage and can be deposited on packs when loads are removed from the sterilizer.

Most sterilizers today are equipped with an automated recorder for documentation of cycle parameters. It is important to verify that the recorder is printing clearly and that the printout is dark enough for the cycle parameters to be read. Paper and ink cartridges should be replaced as needed.

Ethylene oxide sterilizer–aerators, other types of low-temperature sterilization equipment, and dry heat sterilizers should also be routinely cleaned according to the sterilizer manufacturer’s recommendations.

PERIODIC PRODUCT QUALITY ASSURANCE TESTING OF ROUTINELY PROCESSED ITEMS

Periodic product quality assurance testing is done because the PCDs used to monitor sterilization cycles might not provide the same challenge as all items that are routinely processed. Product testing ensures the effectiveness of the sterilization process and can identify problems that could cause wet packs. See ANSI/AAMI ST79 for additional information.
“Quality assurance testing of routinely processed items representing a product family should be performed on an ongoing basis” (ANSI/AAMI ST79). Routinely sterilized products should be tested periodically and when “major changes are made in packaging, wraps, or load configuration, such as dimensional changes, weight changes, or changes in the type of material of packaging or wrapper” (ANSI/AAMI ST79). Not every instrument tray supplied by the manufacturer needs to be tested. Medical device manufacturers divide instrument sets into families of products on the basis of similarities such as mass, material, construction, shape, lumens, and packaging systems. The most difficult-to-sterilize tray (called the “master product”) from each family of instrument sets should be chosen for testing. The device manufacturer can assist in identifying families and master products.

Newly purchased or loaner sets should be evaluated to determine if the existing product testing is applicable to these sets. The device manufacturer can be helpful in determining whether the newly purchased or loaner set is a greater challenge to sterilization than the master product previously tested in that family. If the newly purchased or loaner set is less of a challenge, no product testing need be performed; the sterilization cycle presently used for that product family may be used. If the newly purchased or loaner set is a greater challenge, than a new master product for the family has been identified and product testing should be done.

Multiple BIs and CIs (Class 3, Class 4, Class 5, or Class 6 chemical indicators) should be placed within the product to be tested. The number of BIs and CIs used will depend on the size and configuration of the package being tested. The device manufacturer should be consulted to determine the most challenging areas for placement of the BIs and CIs. For example, the BIs and CIs might be placed inside each layer in multiple locations, such as the corners of rigid sterilization containers and next to lumens and heat sinks (instruments having a large metal mass). The placement of the BIs and CIs should be recorded. (A photograph documenting the placement of the BIs and CIs will assist in recording the results according to the BI and CI locations.) The product test samples should be labeled and placed among other products in a full load. After the sterilization process, the package is sacrificed and the test BIs are retrieved and incubated with a control BI from the same lot. The BI and CI results should be recorded.

In addition, the packages should be inspected for evidence of moisture. “If moisture is observed, steps should be taken to remedy the problem” (ANSI/AAMI ST79). Such steps could include changing the packaging, adjusting the load configuration, reducing the amount of metal in the load, selecting a longer sterilization time and/or drying time, and modifying the unloading and cooling procedure.

Examples of products that should be tested include the following:

- **Wrapped textile packs**: Place BIs and CIs between multiple layers of draping material or surgical towels.
- **Basin sets**: Place BIs and CIs in locations where air could be trapped (e.g., between nested basins).
- **Instrument sets**: Place BIs and CIs at each end of the tray and among the instruments.
- **Containment devices**: Place BIs and CIs in each corner, the center, and in any other areas recommended by the containment device manufacturer.
- **Multi-layered instrument trays in containment devices**: Place BIs and CIs in the locations determined by the product manufacturer to create the greatest challenge to the sterilization process.
- **Other types of items:** Place BI and CIs in the area of the load least accessible to steam penetration.

If any test results indicate a problem, the cause of the problem should be investigated, the problem should be corrected, and the products should be retested. “It might be necessary to change the configuration of the load and/or items within the package or to service the sterilizer” (ANSI/AAMI ST79). The product being tested should not be placed into routine use until the BI, CI, and physical monitoring results verify that the sterilization process is effective.

To perform product quality assurance testing:

- a) Follow the medical device manufacturer’s instructions for processing the device.
- b) Place CIs and BIs in the areas of the product determined to be the least accessible to steam penetration.
- c) Label as a test.
- d) Place in a standard load.
- e) Run the cycle.
- f) Retrieve the CIs and BIs.
- g) Read and record the results of the CIs.
- h) Incubate the BI test and control vials. Read and record the results.
- i) Place the product into routine use if the monitoring results are acceptable and there is no evidence of moisture.

**SUMMARY**

Sterilization is a multistep process requiring great attention to detail. Proper identification of items, lot control, documentation, selection of the correct cycle time and temperature, compliance with the device manufacturer’s written instructions, and proper loading and unloading all have an impact on a successful outcome. Quality control using physical monitors, CIs, and BIs assists in the detection of sterilization process failures.

Effective sterilization begins with thorough and effective cleaning. All steps of the process must be followed from initial receipt until distribution after processing. CS/SPD technicians need to be competent in all practices pertaining to disinfection and sterilization. They should be familiar with the IFU provided by the manufacturers of the following products:

- The medical device
- Cleaning products (e.g., detergents) and implements (e.g., brushes)
- High-level disinfectants
- Cleaning equipment
- Sterilizer equipment
- Packaging
- Chemical and biological indicators
Up-to-date policies and procedures that are based on the recommended practices published by organizations such as AAMI, AORN and CDC; certification of personnel; and competency testing will assist in preparing CS/SPD employees to be competent in the cleaning, disinfection, and sterilization of medical devices and will improve patient care.

REFERENCES AND SUGGESTED READING


**NOTE: YOU HAVE COMPLETED STERILIZATION. IT IS NOW TIME TO TAKE THE QUIZ.**

Please click on the link below to go to the quiz.

[https://secure.netsolhost.com/spdceus.com/modules/fourth/ambu/module_18_22_quiz.htm](https://secure.netsolhost.com/spdceus.com/modules/fourth/ambu/module_18_22_quiz.htm)

Good Luck!