TECHNIQUES OF STERILIZATION

3

The information in this section is intended as a general guide to steam sterilization techniques. For a more detailed description of this subject, refer to the following publications available from STERIS:

- Techniques Manual (MK-2085)
- Wet Pack Problem Solving Guide (MK-3099)

STERIS also recommends reference to the standards of Association for the Advancement of Medical Instrumentation (AAMI).

3.1 General

Prior to sterilization, all materials and articles must be thoroughly cleaned. After sterilization, most goods should be stored for no longer than 30 days, depending on wrapping materials.

For sterilization of articles or materials not covered in this section, contact the manufacturer of the article for recommended procedure. Cycle times and temperatures not covered in this manual should always be validated for efficacy before processing loads.*

* *For in-depth training, STERIS offers a wide range of education/training programs designed to meet the educational needs of scientific industries. Contact STERIS for details.*

3.2 Recommended Sterilization Variables

3.2.1 Prevacuum Cycle

Prevacuum cycle is recommended to process heat- and moisture-stabile goods, except liquids, which are capable of being sterilized with steam. This cycle can also be used to decontaminate wastes, including wastes containing liquids, provided the materials are properly contained.

Refer to Table 3-1 for recommended Prevacuum cycle parameters.

Table 3-1. Prevacuum Cycle Parameters

Temperature	Pressure Point psig (psia)	Minimum Recommended Sterilize Time* Minutes at Temperature
121°C (250°F)	12-14 (27-29)	15
132°C (270°F)	26-28 (40-42)	4

* *Minimum sterilize times are based on obtaining a 10^{-6} Sterility Assurance Level (SAL) with standard test loads. Your specific loads may require different sterilize times to achieve this level of sterility, or you may require a different SAL.*

3.2.2 Gravity Cycle

Refer to Table 3-2 for the type of items which can be processed in a Gravity cycle and the recommended cycle parameters.

Table 3-2. Gravity Cycle Parameters

Items	Minimum Recommended Sterilize Time at 121°C (250°F)	Minimum Recommended Sterilize Time at 132°C (270°F)	Dry Time
Glassware, empty, inverted, without closures*	15 minutes	3 minutes	0 minutes**
Instruments, metal combined with suture, tubing or other porous materials (unwrapped)	20 minutes	10 minutes	0 minutes**
Hard Goods, unwrapped	15 minutes	3 minutes	0 minutes**
Hard Goods, wrapped in muslin or equivalent	30 minutes	15 minutes	30 minutes***

* *If items which can trap air must be sterilized upright, they should be sterilized in a prevacuum cycle.*

** *Goods will be wet when removed from sterilizer.*

*** *Dry time can vary for wrapped goods depending on pack density, weight of goods, pack preparation technique including type of wrapping material used, and sterilizer loading procedures.*

3.2.3 Liquid Cycle

⚠ WARNING – EXPLOSION HAZARD: This sterilizer is not designed to process flammable liquids.

⚠ WARNING – BURN HAZARD: When sterilizing liquids, you must observe the following procedures:

- **It is inappropriate for a health care facility to sterilize liquids for direct patient contact.**
- **Use Liquid cycle only.**
- **Use only vented closures.**
- **Use only Type I borosilicate glass bottles.**
- **Do not allow hot bottles to be jolted.**

Refer to Table 3-3 for recommended Liquid cycle parameters. The recommended times indicated in Table 3-3 assume the use of vented bottles or Erlenmeyer flasks. The "minimum sterilization time" includes the time required to bring the solution up to the sterilize temperature plus the time required to achieve sterilization.

NOTE: Load probes and F_0 option will allow you to optimize cycle times.

Table 3-3. Liquid Cycle Parameters - No Load Probes

Volume of Liquid in One Container	Minimum Recommended Sterilize Time* at 121°C (250°F) minutes
75 mL	25
250 mL	30
500 mL	40
1000 mL	45
1500 mL	50
2000 mL	55
> 2000 mL	55 + 10 min/L

* *Minimum sterilize times are based on obtaining a 10^6 Sterility Assurance Level (SAL) with standard test loads. Your specific loads may require different sterilize times to achieve this level of sterility, or you may require a different SAL.*

3.3 Recommendations for Sterilizing Liquids

⚠ WARNING – EXPLOSION HAZARD: This sterilizer is not designed to process flammable compounds.

⚠ WARNING – BURN HAZARD: When sterilizing liquids, you must observe the following procedures:

- **It is inappropriate for a health care facility to sterilize liquids for direct patient contact.**
- **Use Liquid cycle only.**
- **Use only vented closures.**
- **Use only Type I borosilicate glass bottles.**
- **Do not allow hot bottles to be jolted.**

⚠ CAUTION: Sterilization of chloride-containing solutions (e.g., saline) can cause chamber corrosion and is not recommended by the manufacturer. If, however, chloride-containing solutions must be processed, clean the chamber after each use.

IMPORTANT: Please read the following paragraphs before sterilizing any liquids in your sterilizer. It is inappropriate for a health care facility to sterilize liquids for direct patient contact.

Borosilicate glass is required because it is a superior glass capable of resisting thermal shock. If glass not as thermally resistant is used, a greater potential for bursting exists.

Vented closures are required because, by design, they release internal pressure build-up by automatically venting the containers, whereas pressure in unvented containers remains until the contents have cooled. Examples of vented closures are shown in Figure 3-1.

Sterilizing liquids in any other type of container or with the use of non-vented closures requires a sterilizer specifically designed for that purpose.

When loading, place small bottles in a separate basket to minimize sliding. Always use side rails on the loading car to prevent containers or baskets from falling off.

For extremely large liquid loads, a DART warm-up cycle may be required.

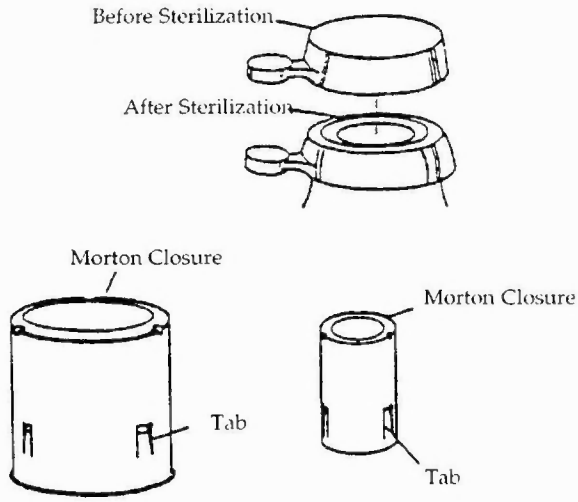

Figure 3-1. Vented Closures

3.4 Recommendations for Enhancing the Sterilization Process

Saturated steam is a well controlled, reliable method for processing items which can withstand the temperatures and pressures associated with steam sterilization. The requirements for achieving reproducible results are well known by many users, but are not always understood by all users.

The condition most likely to result in sterilization problems is a failure to remove all of the air from the items being processed. For example, placing an empty beaker or bowl in an upright position in a gravity displacement sterilizer may result in the object not being sterilized, or may require exceptionally long sterilization times. This problem is due to the fact air has almost twice the density as does saturated steam under the same conditions. Thus, the air sits in the bottom of the container, and the steam forms a stable layer over the air. This effect is similar to oil forming a stable layer over water. As long as there is no mechanism for actively mixing the two, the bottom of the container will only see dry heat, which is not an effective sterilization method at the temperatures typically used in steam processes.

There are two methods for enhancing the sterilization of solid bottom containers in gravity displacement cycles. These are:

- Place 1 to 2 mL of water in the bottom of each container. The expansion of the water into steam as the product is heated will force most of the air out of the object, thus allowing steam to reach all surfaces and effect sterilization.
- The better, more reliable method is to orient all objects in a manner which would allow water to flow out. When the steam enters the chamber, it will tend to layer over the air. However, the object is now oriented so the air can flow out. As the air flows out of the container, it will be replaced by the steam. The steam can now reach all surfaces and effect sterilization.

The best type of cycle for assuring sterilization of containers, and of objects which contain lumens or tortuous paths, is the prevacuum cycle. In this process, several vacuum pulses remove all of the air from the load. The steam can then immediately contact all surfaces. This immediate contact results in dramatically shorter sterilization times than are required when complete air removal cannot be assured. Items which take 15 to 30 minutes to sterilize in a gravity displacement cycle can be sterilized in 4 minutes or less at 132°C (270°F).

Objects which do not allow easy passage of steam or air cannot be effectively sterilized with any steam process. For example, pipette cans with lids in place do not allow all the air to flow out, or the steam to flow in, even with prevacuum cycles. In a gravity cycle, these items have a high probability of being non-sterile. In a prevacuum cycle, these items may be crushed by the steam pressure because the chamber pressure changes much faster than does the pressure inside the canister.

Items which are hermetically sealed (e.g., empty screw cap bottles) cannot be sterilized by any steam process because the steam cannot get into the device, and air cannot get out. If you must process these items, make certain the screw caps are loosened at least one half turn (more would be better). Verify your process is capable of sterilizing these objects by running biological indicators in the bottom of the bottle. If the biological indicators are not killed, the caps need to be loosened even further, or the bottles need to be sterilized separately from the caps (cover the bottles with Kraft paper, peel pouches or some other steam permeable material).

3.5 Control Measures For Verifying Sterilization Process

3.5.1 Biological Monitors

As part of the operator's verification of the sterilization process, biological indicators may be used to demonstrate that sterilization conditions have been met.

NOTE: Contact your STERIS representative for information on specific biological indicators recommended for use with this sterilizer.

A live spore test utilizing *B. stearothermophilus* is the most reliable form of biological monitoring. This type of product utilizes controlled populations of a controlled resistance, so that survival time and kill time can be demonstrated.

To verify the process, insert the biological indicator in a test pack and place pack on the bottom shelf. Run test pack through a typical cycle. On completion, forward test pack and monitor to appropriate personnel for evaluation. Refer to AAMI guidelines to conduct routine biological monitoring.

3.5.2 Testing for Prevacuum Efficiency

⚠ WARNING – STERILITY ASSURANCE HAZARD: Load sterility may be compromised if the biological indicator or air leak test indicates a potential problem. If these indicators show a potential problem, refer the situation to a qualified service technician before using the sterilizer.

Run a DART (Bowie-Dick test) cycle daily before processing any loads. The first prevacuum cycle of each day should be used to test the adequacy of air removal from the chamber and load, so that steam can penetrate the load. It is not a test for adequate exposure to heat in terms of time-at-temperature.

Tests such as the Bowie-Dick or the DART® (Daily Air Removal Test)* are designed to document the removal of residual air from a sample challenge load.

In the case of these tests, following exposure in a prevacuum sterilizing cycle, the pack is opened, the indicator examined and conclusions are drawn as to the pattern of residual air, if any, that remained in the pack during the sterilizing cycle. Any indication of a malfunction must be reported to the supervisor, who will take appropriate action to determine the cause of the problem. Sterilizer should not be used during this time.

3.6 Dart (Bowie-Dick) Test

Conduct a residual air test (e.g., Bowie-Dick test) at the beginning of each day according to the AAMI standard ST-46. STERIS can provide a product called DART® (Daily Air Removal Test), designed to be as sensitive as the standard AAMI Bowie-Dick test pack in detecting air leaks. Refer to instructions for running DART test given in Section 4 of this manual. If a DART is not available, construct Bowie-Dick test package in accordance with instructions given in AAMI standard ST-8.

3.7 Vacuum Leak Test

⚠ WARNING – STERILITY ASSURANCE HAZARD: According to AAMI standards, a measured leak rate greater than 1 mm Hg/minute indicates a problem with the sterilizer. Refer the situation to a qualified service technician before using the sterilizer.

Run the Vacuum Leak test cycle daily or weekly. This test measures the integrity of the sealed pressure vessel and associated piping to assure air is not being admitted to the sterilizer during the vacuum draw downs. Refer to appropriate cycle description in Section 5 of this manual.

After running a vacuum leak test, a value or leak rate will be printed on the printer tape. This value will help define a trend over a period of time if the integrity of the system begins to deteriorate (i.e., allowing air to enter the system). By running a vacuum leak test cycle daily or weekly, the operator or maintenance personnel can always monitor the air tightness of the system and make repairs or adjustments when necessary.

NOTE: A leak rate of greater than 1 mmHg per minute indicates a problem with the sterilizer that must be addressed.