

The basic steam sterilization cycle involves three primary steps:

1. Preconditioning the chamber and load within the chamber to remove air and replace it with saturated steam
2. The sterilization cycle
3. Removal of steam and release of pressure.

The removal of air and replacement with saturated steam is the most important technical aspect of steam sterilization. Removal of air depends on (i) the availability of moisture to displace air, (ii) the system used (e.g., vacuum) to displace air in an autoclave, (iii) the configuration of the load being sterilized, and (iv) the absence of air leaks.

The sterilization cycle is dependent on the ability of saturated steam to reach the innermost recesses of the load/materials being sterilized. This will dictate how much lag time is required before temperatures will reach levels where microbial destruction can occur. If it is finished, product being sterilized, for example, solutions in containers, is being terminally sterilized, the walls of each container must be heated to raise the temperature of the solution inside the container and this, in turn, generates steam inside the container. This points out that any container that is sealed or covered (e.g., rubber stoppers in cans, small pressure vessels, tubing sealed on both ends, any covered container) must have some degree of moisture inside the sealed/covered system. Otherwise, steam cannot penetrate container or vessel and temperature inside will only reach 100°C and not be saturated steam.

For solutions being sterilized inside containers, the pressure inside the container will be higher than the pressure outside. During sterilization, the vapor pressure from the solution in the container will increase to the same as the pressure in the chamber, but the partial pressure of the airspace in the container will increase and thermal expansion of the solution also will contribute to the increase in internal pressure. This increased internal pressure is safe for all glass containers (e.g., ampoules) and rubber-closed glass containers provided that the seal force torque of the rubber closure is adequate. However, for plastic containers, syringes, or any kind of container without a firm closure or cap, traditional steam sterilization is unsafe and must be replaced by using counterpressure steam sterilization methods.

The third stage of a steam sterilization process is the poststerilization stage where steam is replaced by air and pressure is reduced. There are several different designs of autoclaves differing primarily in how the poststerilization stage is accomplished (Table 17-5).

Autoclave with Vacuum and Time-Controlled Vacuum Maintenance

The batch or load after the sterilization cycle is dried and cooled by vacuum purges. Solid materials, both porous and nonporous, can be sterilized with this kind of autoclave.

Autoclave with Circulating Cold Water in the Jacket

With cold water circulating within the jacket of the autoclave, steam is removed through the introduction of compressed sterile air at pressures equal to the sterilization pressure. This prevents solutions from boiling and improves the heat exchange between the load in the autoclave and the autoclave jacket. Culture media used for sterility testing and media fills are sterilized using this type of autoclave.

Autoclave with Nebulized Spray Water

Cool water is nebulized and sprayed onto the load, producing rapid condensation of steam and sudden pressure drops. Pressure inside the containers remains high because the solution

Table 17-5 Poststeam Sterilization Possibilities

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1. Autoclave with vacuum and time-controlled vacuum maintenance
 2. Autoclave with circulating cold water in the jacket
 3. Autoclave with nebulized spray water
 4. Autoclave with superheated water spray (water cascade)
 5. Autoclave with air over steam counter pressure
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