

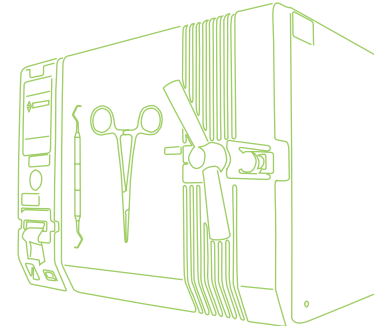
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Sterilization — Monitoring

- * *How is the sterilization process monitored?*
- * *How often should I perform biological monitoring (BI) (spore testing)?*
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How is the sterilization process monitored?

Sterilization procedures should be monitored through a combination of mechanical, chemical, and biological techniques designed to evaluate the sterilizing conditions and the procedure's effectiveness.

- ▶ Mechanical techniques for monitoring sterilization include assessing the cycle time, temperature, and pressure of sterilization equipment by observing the gauges or displays on the sterilizer. Some tabletop sterilizers have recording devices that print out these parameters. Correct readings do not ensure sterilization, but incorrect readings could be the first indication that a problem has occurred with the sterilization cycle.
- ▶ Chemical indicators, internal and external, use sensitive chemicals to assess physical conditions such as temperature during the sterilization process. Chemical indicators such as heat sensitive tape change color rapidly when a given parameter is reached. An internal chemical indicator should be placed in every sterilization package to ensure the sterilization agent has penetrated the packaging material and actually reached the instruments inside. An external indicator should be used when the internal indicator cannot be seen from outside the package. Single-parameter internal indicators provide information on only one sterilization parameter and are available for steam, dry heat, and unsaturated chemical vapor. Multiparameter internal indicators measure 2–3 parameters and can provide a more reliable indication that sterilization conditions have been met. Multiparameter internal indicators are only available for steam sterilizers (i.e., autoclaves). Refer to manufacturer instructions for proper use and placement of chemical indicators.

Indicator test results are shown immediately after the sterilization cycle is complete and could provide an early indication of a problem and where the problem occurred in the process. If the internal or external indicator suggests inadequate processing, the item that has been processed should not be used. Because chemical indicators do not prove sterilization has been achieved, a biological indicator (i.e., spore test) is required.

- ▶ Biological indicators (BIs) are the most accepted means of monitoring the sterilization process because they directly determine whether the most resistant microorganisms (e.g., *Geobacillus* or *Bacillus* species) are present rather than merely determine whether the physical and chemical conditions necessary for sterilization are met. Because spores used in BIs are more resistant and present in greater numbers than are the common microbial contaminants found on patient care equipment, an inactivated BI indicates that other potential pathogens in the load have also been killed.

How often should I perform biological monitoring (BI) (spore testing)?

Correct functioning of sterilization cycles should be verified for each sterilizer by the periodic (at least weekly) use of BIs. Users should follow the manufacturer's directions concerning the appropriate placement of the BI in the sterilizer. A control BI (not processed through the sterilizer) from the same lot as the test indicator should be incubated with the test BI. The control BI should yield positive results for bacterial growth. In addition to conducting routine biological monitoring, equipment users should perform biological monitoring.

- * Whenever a new type of packaging material or tray is used.
- * After training new sterilization personnel.
- * After a sterilizer has been repaired.
- * After any change in the sterilizer loading procedures.

If sterilizing an implantable device, should users perform biological monitoring (spore testing) more frequently?

Any load containing implantable devices should be monitored. Ideally, implantable items should not be used until the results of tests are known to be negative. As previously noted, the manufacturer's directions concerning the appropriate placement of the biologic indicator (BI) in the sterilizer must be followed. A control BI (not processed through the sterilizer) from the same lot as the test indicator should be incubated in the same manner as the test BI. The control biological indicator should yield positive results for bacterial growth.

What should I do if a spore test result is positive?

If the mechanical (e.g., time, temperature, pressure) and chemical (internal or external) indicators suggest that the sterilizer is functioning properly, a single positive spore test result probably does not indicate sterilizer malfunction. Items other than implantable items do not necessarily need to be recalled; however, sterilizer operators should repeat the spore test immediately using the same cycle that produced the positive BI. The sterilizer should be removed from service and sterilization operating procedures reviewed to determine whether operator error could be responsible.

If the result of the repeat spore test is negative and operating procedures were correct, then the sterilizer can be returned to service. If the repeat spore test result is positive, do not use the sterilizer until it has been inspected or repaired and rechallenged with BI tests in three consecutive empty-chamber sterilization cycles. When possible, items from suspect loads dating back to the last negative BI should be recalled, rewrapped, and resterilized.

Results of biological monitoring and sterilization monitoring reports should be recorded.

Common Factors Influencing the Effectiveness of Sterilization

Causes	Potential Problems
Improper cleaning of instruments.	Protein and salt debris may insulate organisms from direct contact with the sterilizing agent and interfere with the efficacy of the sterilization agent.
Improper packaging. Wrong packaging material for the method of sterilization. Excessive packaging material.	Prevents penetration of the sterilizing agent; packaging material may melt. Retards penetration of the sterilizing agent.
Improper loading of the sterilizer. Overloading. No separation between packages or cassettes even without overloading.	Increases heat-up time and will retard penetration of the sterilizing agent to the center of the sterilizer load. May prevent or retard thorough contact of the sterilizing agent with all items in the chamber.
Improper timing and temperature. Incorrect operation of the sterilizer.	Insufficient time at proper temperature to kill organisms.



Sterilization—Monitoring.

URL: http://www.cdc.gov/oralhealth/infectioncontrol/faq/sterilization_monitoring.htm [April 28]



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