

TYPES OF STERILIZER MONITORING

There are three primary methods used for monitoring the sterilization process: biological, chemical and mechanical.

Biological Monitoring

Biological indicators (BIs) are the only definitive method of demonstrating sterilization as they show if actual microbial life has been destroyed. Biological indicators are either strips or ampoules that contain a large, known quantity of the highly resistant spore *Geobacillus stearothermophilus* for steam and chemical vapor sterilization or *Bacillus atrophaeus* for dry heat and ethylene oxide sterilization. Biological monitoring of a sterilizer should be performed at least weekly. The BIs should be placed in the center of the largest, most difficult pack to be sterilized. The pack is placed horizontally in the lower front portion of the sterilizer chamber to create the greatest challenge.

After being subjected to the sterilization process, BIs must be incubated or processed according to the BI manufacturer's instructions. If a processed BI shows a positive result, the sterilizer should be retested and products should be recalled if possible. The sterilizer in question should not be used until the cause of the sterilization failure is determined, corrected, and testing has been performed to validate the sterilizer efficacy.

Chemical Monitoring

Chemical indicators show that the package has been exposed to the physical conditions within a sterilizer; they do not prove that sterilization has taken place. There are several types of chemical indicators available. Each type is meant to monitor specific parameters such as time, temperature, and/or the presence of steam or gas. There are external chemical indicators which are placed on the outside of the package and should be checked after the sterilization process. There are internal chemical indicators which are placed within the package in an area that is least accessible to the sterilant and should be checked at point-of-use. If parameters are not met, the product should NOT be considered sterile and should be reprocessed before use. A special type of chemical indicator, called a chemical integrator measures time, steam, and temperature. Chemical indicators are best when used with every load or at least once daily. Follow the chemical indicator manufacturer's instructions for interpretation of results.

Mechanical Monitoring

Mechanical monitoring includes temperature gauges, pressure gauges, and recording charts (i.e., round charts and computer driven printouts found on larger and newer sterilizing units). Checking temperature and pressure will help determine if the proper cycle parameters are being met, and will alert the operator if a malfunction occurs. Mechanical monitoring measures specific parameters at certain points in the sterilizer chamber and does not indicate that actual sterilization has taken place.

Monitoring for Quality Assurance

All three types of sterilizer monitoring are vital components of an effective infection control program. It is the responsibility of each medical and dental office to assure their staff and patients that products at point-of-use are sterile. Maintaining complete and accurate records will provide documentation should a legal dispute regarding alleged negligence occur. Use state or local regulation guidelines for retention times of documentation.