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Taking Control of Sterilization Monitoring

John A. Molinari, Ph.D. and Peri Nelson, B.S. | Dental Consultants, Inc., Ann Arbor, Michigan

Sterilization is the most important component of an infection control program. The basic principle, ***"Do Not Disinfect When You Can Sterilize,"*** allows provision and assurance of the highest level of protection for patients and treatment providers alike. The difference between these two terms should not be minimized. Whereas disinfection describes the destruction of most pathogenic and other microorganisms, excluding bacterial spores, by physical or chemical means, sterilization is defined as the destruction or removal of all forms of life, with particular reference to microbial organisms. A major distinguishing feature and limiting factor for disinfection is that disinfectants do not necessarily destroy heat-resistant bacterial and mycotic spores. In short, disinfection does not ensure the margin of safety associated with sterilization processes, and is generally applied to the use of chemicals on inanimate surfaces.

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The use of heat to sterilize instruments and other items in medicine and dentistry is not a new concept. It dates back centuries to when instruments were placed in a flame until red hot, up to the current day where automated, computer chip-driven sterilizers are available with sophisticated information monitors. Infection control guidelines from all recommending health professional agencies and organizations recognize heat sterilization as the standard for reprocessing patient-care items. In dentistry, heat stable instruments are sterilized in an autoclave (i.e., steam under pressure), dry heat oven, or unsaturated chemical vapor sterilizer. Of these the autoclave is by far the most common type of sterilizer found in dental settings.

Ongoing evolution of sterilization quality control has seen the introduction and refinement of multiple types of devices. These include mechanical, chemical, and biological indicators (BI) designed to evaluate sterilizing conditions and process effectiveness. Since there are a number of possible errors that can lead to sterilization failure (Table 1), each of the monitors has an important role in ensuring the success of a sterilization cycle.

Mechanical indicators assess a cycle's temperature, pressure, and time by noting gauges or displays on the sterilizer. This control detects conditions only in the unit's chamber, and so, mechanical monitoring is not able to detect procedural problems, such as overloading the sterilizer. However, incorrect display readings can be the first indication of a problem with the cycle.

Autoclave tape has served as the historical example of a **chemical indicator**. It was used for many years as visible proof that items in the chamber had been exposed to a heat sterilization process. Unfortunately, the temperature-sensitive stripes on this tape appear long before sterilizing conditions are reached in the chamber. This external marker, therefore, is the least sensitive indicator for heat sterilization.

Internal and external chemical indicators are impregnated with heat-sensitive inks that can assess time, temperature, and pressure during the sterilization process. They are available as paper strips, labels, and steam pattern cards, which change color when certain temperature, time, and/or pressure conditions are reached during the heat cycle. Since they do not contain bacterial spores as the active agent, until recently, chemical indicators were not able to provide assurance of sterilization. Most chemical indicators and integrators are valuable by being able to detect certain malfunctions and can also help to identify procedural errors. These chemical strips are available to practitioners in five classes (Table 2),

Table 1. Representative Sterilization Process Problems.

Error	Problem
Improper instrument cleaning and potentially compromise the sterilization process	Biological and other debris can shield adherent microbes and potentially compromise the sterilization process
Improper packaging	Examples: wrong type material for method; too many items in package; excessive amounts of wrap material
Overloaded sterilizer	Can prevent thorough contact of sterilizing agent with all items in unit
Inadequate Maintenance	Critical area; example issues include worn gaskets and seals
Improper sterilization equipment	Use of non-FDA approved equipment

Table 2. Classification of Chemical Indicators/Integrators.

Class I ***(Process Indicators)***	Tapes or strips used only as external indicators to distinguish processed from unprocessed items (e.g. autoclave tape)
Class II ***(Bowie-Dick Indicators)***	Used as quality control indicators for vacuum steam (Class B) sterilizers to assess air removal during cycle
Class III ***(Temperature Specific Indicators)***	Indicate attainment of specific minimum temperature within sterilization chamber during a cycle; not sensitive to other parameters (i.e., time)
Class IV ***(Multi-Parameter Indicators)***	Provide integrated color change to the temperature, pressure, time sterilization parameters (e.g., ***Sure-Check Sterilization Pouches***, *Crosstex)*
Class V ***(Integrating Indicators)***	Strips that contain a chemical ink which reacts to all three sterilization parameters during the sterilization cycle; when the indicator bar moves left to right and enters the blue "SAFE" zone, it provides immediate notification to the user of sterilization cycle success or failure

Adapted from: Hughes CA. Sterilization Quality Assurance Process. http://www.spsmedical.com/education/articles/sterilizationquality.html

Multi-parameter indicators/integrators provide a more reliable notification that sterilization conditions have been met. By changing color when the three vital conditions have been reached, internal and external Class IV monitors on pouches, for example, can provide an early indication of a problem. The latest innovation, the Class V integrator (***STEAMPlus Sterilization Integrator***, *Crosstex)*, presents an even higher level of quality control, as it is FDA-cleared to be the closest chemical marker to biological monitoring. Multiple studies have indicated that this device offers immediate notification of the success of the sterilization cycle.

In 1993, the CDC updated earlier dental infection control recommendations, stating "proper functioning of sterilization cycles should be verified by the periodic use (at least weekly) of **biologic indicators** (i.e., spore tests)." Biological indicators containing heat resistant spores provide the best challenge for sterilization cycles. Two species are used, *Geobacillus stearothermophilus* and *Bacillus atrophaeus* (formerly *Bacillus stearothermophilus* and *Bacillus subtilis*). A spore vehicle designed for one sterilization method is not necessarily the proper modality to use for other units. Calibrated *G. stearothermophilus* spore - impregnated paper strips or glass vials are the appropriate biological monitors for autoclaves and unsaturated chemical vapor sterilizers, whereas *B. atrophaeus* preparations provide effective challenge for conditions in dry heat sterilizers and ethylene oxide units. Proof of destruction of these resistant microbial forms is used to infer that all microorganisms exposed to the same conditions have been destroyed.

By utilizing the multiple opportunities for monitoring mentioned above, *Crosstex* has created an ideal in-office sterilization monitoring system. The ***Crosstex Sterility Assurance System*** allows dental practices to have complete control of the sterilization monitoring process. The ***Sure-Check Sterilization Pouches*** with internal and external steam indicators and the ***STEAMplus Class 5 Sterilization Integrators*** are able to validate each sterilization cycle. The ultra-sensitive ***ConFirm 10 In-Office Biological Monitoring*** component yields results in just 10 hours and can be used instead of or in conjunction with a mail-in system for third party record validation in the event of an audit. In addition to chemical and biological indicators, a booklet for record keeping is included to help organize your sterilization monitoring history. When each of these components are implemented and used appropriately, they provide an easy-to-use, integrated quality control system for dental practices.