TECHNICAL BULLETIN

Sterilization in Dentistry

Dentists are faced with two major sterilization issues when deciding about the use of chemical indicators to monitor their sterilization processes. The first is decontamination of instruments that might have pathogenic organisms on them from a previous patient. The second is sterilization of instruments so that new patients are not infected with organisms that may be on the instruments from normal airborne sources.

The first issue, decontamination of instruments to eliminate pathogens from a previous patient, is done primarily to assure that the Dentist's office is a safe place for employees and patients. Pathogens from diseased patients must be destroyed before instruments are handled by employees who assume they are safe and clean. Liability to injury (infection) of an employee is a serious issue for any employer. In addition, nothing destroys a practice faster than publicity that a patient received an infection from the Dentist or from instruments used on another patient.

The second issue is a routine expectation of any patient about to undergo treatment that may involve penetration of the outer layer of skin. Any patient expects sterile instruments to be used whenever they are punctured, cut or abraded. Dental standards support this expectation. Tolerance is given to a few organisms that might alight on the instruments sitting on a tray, while the dental procedure is in process, but instruments should be sterilized effectively and stored in a sterile manner between patients.

The Dentist can accomplish both sterilization issues with one step-by-step procedure which takes care of one issue first, then takes care of the second issue next. First, the instruments must be effectively cleaned, then they must be effectively packaged with effective packaging, then they must be effectively sterilized, then they must be stored effectively. The use of the word *effectively* in each step is not just redundant; it is probably the most important word in the article.

Accepted sterilization procedures used in all health related endeavors are based upon one assumption; that the items being sterilized are clean. Any sterilizer exposure time is incorrect if the items have blood, proteinaceous matter or soiling of any sort on them. Make sure instruments are clean before sterilization. The cleaning solution may contain chemicals that kill microorganisms, which float off into the solution during the cleaning process.

Instruments should then be rinsed, dried and packaged carefully. Packaging materials must be used which do not interfere with penetration of steam or other sterilizing medium and which protect the instruments from re-contamination while waiting in storage for re-use. Protection from re-contamination is not too difficult provided the packages are not handled too much. Handling of packages causes air to be pumped in and out of the package, and any small crack or rip may provide a location for free, unfiltered airflow. Free, unfiltered airflow can carry microorganisms into the package and contaminate the package contents. There is an old story of a hospital that relocated its sterile processing department. When they moved a file cabinet, they found two packages of instruments wrapped with newspaper, which lay there for 20 years.

When they cultured the instruments to see if they were contaminated, they found that they were still sterile. They were un-disturbed for the 20 years and remained sterile. Contamination of sterile packages is an event related process, not time related.

After packaging the instruments, they are placed in the sterilizer to be sterilized. Sterilization is the most important step in the process. Steam does not immediately kill all microorganisms. Conditions must be correct in the sterilizer, and those conditions must be maintained for a known amount of time in order to provide sterility assurance. One interesting thing about microorganisms and living things in general, is their ability to have different characteristics. Even the same type of organism can have different characteristics. Humans are different, specific microorganisms are also different. One difference in microorganisms is their resistance to sterilization. If you have enough microorganisms, you can obtain resistance to any sterilization cycle. The concept is similar to the old adage that if you have an infinite number of monkeys playing with typewriters for an infinite amount of time, all the great novels of civilization will result.

Experts have narrowed the scope of this problem by agreeing that if the sterilization process has a one-million-to-one chance of leaving a surviving organism, the process is acceptable (this is referred to as a sterility assurance level of 10^{-6}). A sterilization cycle, which has a one-million-to-one chance of leaving a surviving microorganism, is one that is twice as long as it takes to kill a typical biological indicator. If a biological indicator takes 1.8 minutes to be killed in the sterilizer, the instruments should see conditions equal to 3.6 minutes hold time at proper temperature. If, however, the steam quality varies, it may take 1.8 minutes to kill a biological indicator on one day and 2.5 minutes on another day. In this case, if the sterilizer is set for 3.5 minutes, the correct sterility assurance of one-million-to-one is not met. An exposure time of 5 minutes would be called for.

Chemical indicators can help the Dentist monitor his sterilization process by providing information about the steam quality and the exposure time if chosen carefully. Indicators come in many shapes and sizes, and with many different capabilities. Some just provide the minimum amount of information, and some provide a wealth of information.

Two features of all indicators are their timing (when they change during the cycle) and their transition period (how abruptly they change color). Timings of three different types are available: short, medium and long. Short timing indicators are found on the outside of packages and are used to distinguish packages that have been through the sterilizer and those that have not. Medium timing indicators are placed inside of packages, next to the instruments themselves, and tell if a biological indicator would have been killed. Long timing indicators are placed inside of packages next to the instruments and tell if one-million-to-one conditions were met.

Indicator transition periods can be narrow (abrupt) or wide (gradual). Narrow transition period indicators tend to change color abruptly. When the user reads them, they tend to appear completely changed or not completely changed. The chance that the user will see an indicator that is in the middle of its color change is fairly remote since the color change occurs abruptly.

Indicators with wide transition periods change color more gradually, and therefore, the user has a greater chance of seeing an indicator that is in the middle of its color change. This can sometimes cause confusion.

Another feature of some indicators is their ability to describe steam quality. If the steam is of poor quality, the indicator will look different. Poor steam quality negatively affects the sterilization process.

All of the features mentioned above are referred to as "critical process variable" in the most recent chemical indicator standards. Those standards are based upon the ISO 11140-1 classifications. The details are as follows:

Indicator timing is referred to as Stated Value (SV). If the SV is 1.8 minutes @ 134°C, the indicator should change color at the 1.8 minute point (biological kill point) in a 134°C steam sterilization cycle. If the SV is 3.6 minutes, the indicator should change color at the 3.6 minute point (Sterility Assurance Level of 10^{-6}).

Type 1 Process Indicators are used on the outside of packages to show if they were exposed to the sterilization cycle or not.

Type 2 Specific Test Indicators are used to determine special conditions such as effectiveness of air removal in prevacuum sterilizers (Bowie-Dick test packs)

Type 3 Single Critical Process Variable Indicators are used as the most basic internal indicator that give limited single point information such as temperature only.

Type 4 Multicritical Process Variable Indicators are internal indicators with multiple points of information such as time and temp or time, temp and steam quality. The transition period is moderately wide.

Type 5 Integrating Indicators are integrating indicators with timing at the BI kill point at multiple temperatures and a very wide transition period.

Type 6 Emulating Indicators emulating indicators for cycle verification and the narrowest transition period.

Many small steam sterilizers coming on the market today have features that, in the past, were only found in hospital sterilizers. These Class B small sterilizers can pull vacuums before steam is injected. This allows the sterilizer to remove air from porous items such as gauze pads or cannulated instruments such as syringe needles. Air blocks the penetration of steam and therefore interferes with sterilization. These sterilizers solve this problem. ISO Type 2 indicators, similar to a test called Bowie-Dick, diagnose air problems in pre-vacuum sterilizers.

TECHNICAL BULLETIN

When selecting chemical indicators to incorporate into office sterilization procedures, find out what the timing is and find out what parameters the indicator measures. The more parameters it measures, the better. Do not rely on simple external process indicators to diagnose problems with sterilization, which occur inside the package.

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