Learning Objectives:
After reading this article, the reader should be able to:
• narrow the gap between monitoring sterilizers and obtaining results;
• reduce the risk of releasing non-sterile instruments for patient care;
• identify the steps to take for managing positive monitor results.

Author’s Note:
This is an update of an article I first wrote in 2009 and updated in 2012. This subject is by far one of the most important aspects of infection prevention that I can stress to you, providing safety for your patients and staff and eliminating a risk management issue for you. If you have received continuing education credit for these on-line articles in the past, there is no reason you cannot do so again for another license renewal. It would be just the same as retaking the CPR courses and the other required education for renewal.

This latest revision was prompted by a call I received from AzDA Executive Director Kevin Earle, who had just been asked by a member what to do when an office gets a notice from their mail-in biological monitoring service that their sterilizer failed a test, a test that was performed one week before and two weeks from their last passing test. What happened in that two-week period? Was it operator error? Did it happen only once? Was the sterilizer malfunctioning? Was every load run in those two weeks a failure? Were any patients put at risk? Was there transmission of bloodborne disease? Sigh. Well, here goes a reminder that prevention is cheaper than dealing with adverse outcomes.

The Past: Varied Infection Control Standards
When we first moved to Phoenix and my husband started his dental practice, as an infection control nurse, I was curious as to how dentistry dealt with infection control. What I soon found out was that dental offices did not have the same standards as the hospitals regarding disinfection and sterilization. Over the years, the gap has narrowed quite a bit due to educational opportunities from infection control experts in the dental field and our ability to access information more readily. But the deciding factor has been government intervention and establishment of standards and guidelines. The fact remains that sterilization practices should be the same in both venues. But now the gap is widening again. Why? Because there has not been sufficient research in dentistry to support necessary change to our dental guidelines to update dental practice in sterilizer monitoring. Fortunately that is now in the works so the guidelines can be updated. In the meantime, many dentists do not want to update their monitoring unless it is mandated, but with that mindset they are compromising the risk management component of their practices.

CDC and BODEX
In 1986, the Centers for Disease Control and Prevention (CDC) first published Recommended Infection-Control Practices for Dentistry.1 These dental guidelines recommended weekly biological monitoring of sterilizers. Other than dental facilities that were government run, this was virtually unknown to dentists. Even if they did know about it, it was not an easy task to do. By 1993, new CDC dental guidelines were published2 and continued to stress the weekly biological monitoring and in addition, recommended that an external monitor should be placed on the outside of each package. It still was a non-issue in Arizona as there was no enforcement mechanism. That changed in 1994 when the Arizona State Board of Dental Examiners (BODEX) initiated their Infectious Disease Control Inspections. As part of the standard of care required by BODEX, dentists were and still are expected to follow the most current CDC guidelines and Occupational Safety & Health Administration (OSHA) regulations. In the March 2015 revised Substantial Policy, the checklist the BODEX uses includes a question, “Is the autoclave/clemiclave monitored on a weekly basis for effectiveness by using a biological monitor?”
Because of these guidelines and laws, some dental schools started offering a mail-in program to their alumni so they could meet the standard of care. That was about all one could do unless they bought an in-house monitoring program with the incubator and biological indicators and recorded their findings. This seemed like a lot of work and word was passed around that the records kept in-office would not be acceptable to government officials if inspected. That was not true, but it was widely accepted. It seemed much easier to mail in your monitors.

The Present

In my experience, the most widely used method to biologically monitor steam sterilizers in dental offices is the mail-in system. Envelopes come with monitoring strips, and the strips are run in the autoclave during sterilization cycles. The strips are then mailed to a dental school or a monitoring company for incubation and reading. A positive reading is called back to the office for prompt attention. Quarterly reports and yearly reports are provided for documentation for various government entities. A few offices only test monthly but the vast majority of the dental offices and clinics are testing weekly according to the CDC recommendations. That is great news. We have finally caught up to what we should be doing, right? Well, actually, no, not really.

Monitoring Steam Sterilization

The steam sterilizer, or autoclave, that provides moist heat and saturated steam under pressure, is the oldest acceptable method for sterilizing instruments. Steam sterilizers are the method of choice used to render instruments sterile in the dental setting. The steam sterilizer, also known as an autoclave, is a device that is used to sterilize surgical instruments and other critical items that are reused for patient care. The gold standard for steam sterilization is achieving a temperature of 250 degrees and 15 PSI (pounds per square inch of pressure) for 30 minutes, not including the warm-up or drying cycles. These three critical parameters have been tweaked over the years by autoclave manufacturers by decreasing the chamber volume, increasing temperatures and other methods to achieve more rapid sterilization cycles. How these parameters are measured to insure sterilization has also evolved. The steam cycle is monitored by mechanical, chemical, and biological monitors.

The most recent CDC Dental Guidelines published in 2003, not only recommend weekly sterilizer biological monitoring and chemical indicators on the outside of each package but also recommend chemical indicators on the inside of each package. I have seen little of this last recommendation used in dental facilities that I have audited until recently. I have noticed that some of sterilization pouches now available have ink change markers both inside and outside of the packs. We are now in compliance with 2003 CDC guidelines. So we are in great shape, right? Well no, not exactly. There have been advancements in the field of sterilization monitoring since the 2003 dental guidelines. Between the weekly biological monitoring, there are more advanced chemical monitors that hospitals are using in sterilizer loads and in individual packaging that we can easily adapt to dental use.

Who’s Amy?

There is an organization known as the Association for the Advancement of Medical Instrumentation (AAMI, pronounced Amy). AAMI has a membership comprised of various professionals, engineers, nurses, physicians, and others who bear the responsibility for setting the standards for patient safety in the handling of patient care items, instruments, and other items that pass through the hospital sterile processing centers. This organization sets the standards for the healthcare industry in sterilization and sterilization monitoring. It has provided standards for the healthcare community for many years and is closely followed by hospital sterile processing centers. Their comprehensive guide to steam sterilization and sterility assurance in health care facilities can be intimidating to the uninitiated. I will attempt to highlight the areas that we can use for dental practice.

Types of Chemical Monitors Available Today

Class 1 (process indicators) show the package has been processed in the sterilizer. They should be placed on the outside of each package.

Class 2 (Bowie-Dick type indicators) are used for dynamic-air-removal sterilizers, such as the dental sterilizers, Lisa and Bravos, to monitor vacuum functioning.

Class 3 (single-variable indicators) only measure one critical parameter of the sterilization cycle.
Class 4 (multi-variable indicators) measure two or more critical parameters of the sterilization cycle.

Class 5 (integrating indicators) measure all of the critical parameters of the sterilization cycle and are comparable to biological indicators.

Class 6 (emulating indicators) are the newest monitors available and are used for specific sterilization cycles not widely used in dental processing due to their sophistication and ease of misuse. This may change.

Use of Chemical Monitors in Dentistry

Autoclaves usually are monitored by reading a printout that has recorded the sterilization time period at the appropriate temperature, and pressure. They are in use in hospitals and are part of their load release criteria. Many of the sterilizers used in dentistry are not electronically monitored therefore do not have the availability of the printouts for sterility assurance. So we have to rely more heavily on the use of chemical monitors for load and use release.

We are already using the class 1 in the form of tape on wrapped cassettes or on the outside of the sterilization pouches to show that the packs have been processed. If you have a dynamic-air-removal sterilizer, you should monitor with the class 2 daily at the beginning of the day. A class 4 should be placed inside each cassette or sterilization pouch so that when the pack is opened for use at chairside, it validates that the instruments are safe to use. The good news is now you may purchase, for just a few dollars per 200 packs, sterilization pouches that have the class 4s already inside. The expense is less than purchasing individual strips and is a time saver for staff. They are now also being called multi-parameter or multi-variable. If you do not look for this labeling, you are only purchasing pouches that have class 1 or 2 indicators inside.

Class 5 integrators are extremely reliable. They are widely used in hospitals to monitor all the critical parameters required. They can be used in both passive and active vacuum steam sterilizers. They are easy to read and have a very distinct pass/fail criteria. Use one Class 5 in a challenge pack for each load. A challenge pack is placing an integrator in the same type of packaging as what is being run in the sterilizer load, i.e., either sterilization pouch or cassette. Place it in the middle of the sterilizer. At the end of the cycle, open the package with the Class 5 indicator.

Use the reading of the integrator as criteria for load release. Do not release the load if the integrator fails. Record all results in a record-keeping notebook. I like to call the Class 5 “the silver bullet” as its use in every sterilization cycle prevents the release of unsterilized instruments for patient use.

Biological Monitoring

In addition to chemical monitoring, each sterilizer should be biologically monitored at least weekly. The effectiveness of steam sterilization is monitored with a biological indicator (BI) containing spores of *Geobacillus stearothermophilus* (formerly *Bacillus stearothermophilus*). Place a BI into a challenge pack and run with a full load of wrapped items. Biological monitoring is part of the load release criteria and used for recall of loads. Keep records of all biological monitoring for three years. If you are not sterilizing implants, which need each load biologically monitored, it is sufficient to run BIs once a week. However, placing a class 5 integrator in each load will safely cover the loads run between biological monitoring.

Common Factors in the Improper Use of Sterilizers

- Chamber overload
- Low temperature setting
- Inadequate exposure time
- Failure to preheat the sterilizer
- Interruption of the cycle.
In Case of Sterilizer Failure

In the past if a sterilizer had a positive reading from a biological monitor (BI), we could still use the sterilizer. We did have to retest and if the second BI test also failed, the sterilizer had to be pulled from use, repaired and retested with negative results before it could be used. That is no longer the case. Since 2006, AAMI has set the standard that if the sterilizer has a positive reading, it should be pulled from use immediately. Because this is now the standard, it is very wise to have at least two sterilizers. If one is down, you still have another to use. (I also recommend having at least two sterilizers as it increases the efficiently of processing instruments.) After evaluation of the sterilizer and review of the procedures used for processing, the sterilizer should be tested three consecutive times with negative results before it can be put back to use. If one or more of the BIs are positive, then the sterilizer needs further evaluation, repair and testing and the items pulled from the last negative BI testing must be reprocessed. In dentistry, that just does not work for us with our present technology. By the time we find out about a failure, it may be several days and all the instruments in question may already have been used again on unsuspecting patients. When the mail-in BIs are used, they can be read within 24 hours of receiving the envelope but how long does it take for the mailed envelope to reach its destination? Then to add three rounds of additional testing it would be weeks before you could put the sterilizer back in use.

Steam Sterilizer Protocol in Management of Positive Biological Indicators

- Take sterilizer out of service
- Pull all objects processed since last negative BI
- Reprocess implantable objects
- Review sterilization and monitoring procedures for correctness
- Repeat BIs in 3 consecutive sterilization cycles
- If all 3 BIs are negative, return to service
- If one or more BIs are positive, sterilizer must be submitted for further evaluation and repair if necessary

In-house Biological Monitoring

You can easily set up your in-house system. I did it in the 80s; it is not rocket science. You can get starter kits for a reasonable cost and I found BIs that run approximately $2 apiece. I found BI monitors that could be read in house in 24 hours. If you have one sterilizer, you will need two biological monitors to test, one to run in the sterilizer and one as a control that you do not run in the sterilizer. Place both in the incubator. The BI that is run in the sterilizer should not respond to incubation but the control will. If you have two sterilizers, you will only need 3 biological monitors if you run the tests for the sterilizers at the same time as you only need one control. The more sterilizers you have, the more money you will save in biological monitoring expense and that will in turn pay for the class 4s (approx. 5 cents apiece) and class 5s (approx. 50 cents apiece).

Whose Job is it?

It is the responsibility of the entire clinical staff to understand the monitor readings so packages can be pulled before use if the readings indicate an incomplete sterilization cycle.

Costs if You DO NOT Introduce New Sterilization Monitoring Methods to Your Facility

If the sterilizer fails and instruments that were processed in it were used on patents, it would be considered a bloodborne exposure incident. All patients involved, both source patients and exposed patients would have to be baseline tested for hepatitis B, hepatitis C and HIV. If not all of the source patients are willing to be tested, or if one of the source patients tests positive for any of the bloodborne diseases, all exposed patients will have to be tested at six weeks, three months and six months for signs of the bloodborne diseases. If the exposed patients are not immune to hepatitis B, they should be provided a vaccination series and then retested. If caught soon enough, the non-immune patients should be given Hepatitis B Immune Globulin in addition to the vaccination series. If any patient becomes infected with a bloodborne disease as a result of the incident, then it must be reported to the health department.
Will it cost a lot more for an exposure investigation than updating your monitoring methods? Yes. A safe estimate is tens of thousands of dollars even if caught within 48 hours, considerably more if discovered after a two-week period which represents a non-functioning sterilizer for a week and then waiting a week for results.

But WAIT, you say: “I rarely, if ever, have sterilizer failures. I do not have to worry about any of this. I do not have to do this.” I do no have to worry about any of this.3 I do not have to do this. No, you don’t have to do anything. But, what about operator error? According to one study, operator error, rather than mechanical malfunction caused 87% of sterilization failures.8 It is a common reason for sterilizer failure. Do you have temporary personnel working for you or someone new who is not sure about how to run the sterilizer and is afraid to ask? Think about that. Also know that as the updated monitoring systems are now becoming the standard of care, you have a legal and ethical responsibility to follow them to ensure that your instruments are sterilized between patient use. An experienced dental assistant should be responsible for the sterilizer monitoring and recording. In teaching the process to someone new to the procedure, demonstration and return demonstration should be employed. Do not assume that the employee understands the process completely. Constant supervision must be employed to ensure that the procedures are done correctly.

**Why do we need class 5s in each load?**

Because the number one reason for sterilization failure is operator error. It is not good enough to biologically monitor your sterilizer once a week when there can be multiple failures you are missing throughout the week, putting patients and staff at risk.

**In Summary**

The hospitals are using new technologies that narrow the gap between testing and reading the monitors. If we use our present mail-in system, it can be days before we hear anything and it can put our patients at risk. But there are other ways to monitor our sterilizers more efficiently. In the first line of monitoring, we should use class 1 chemical indicators on the outside of our packages (autoclave tape or ink change on sterilization pouches) to show that the packs have been processed in the sterilizer. Using the class 5 indicators in each load, gives us results for load release and the class 4s in each package is the final monitor to read before instrument use, protecting your patients, staff and practice. Consider in-house biological monitoring.

Step-by-step procedures for sterilizer monitoring can be found in the Infection Prevention Folder included in the 2015 IP/OSHA Toolkit Flash Drive available on the AzDA website, azda.org using search word “Toolkit.”

**References**


Kay Carl is Board Certified in Infection Control and Epidemiology renewed by examination every five years. She has worked in collaboration with AzDA since 1991 to provide continuing education in OSHA, infectious diseases and infection control. She is an active member of APIC, the national infection control association. She is married to a dentist.
1. The most common sterilization method used in dentistry today is:
   a. steam
   b. ethylene oxide
   c. glutaraldehyde
   d. chemicleave

2. What chemical monitors should you use in your sterilization processing to decrease the possibility of releasing unsterile instruments for patient use?
   a. class 1
   b. class 4
   c. class 5
   d. all of the above

3. According to BODEX, how often should you biologically monitor your sterilizer?
   a. each load
   b. once a week
   c. once a month
   d. when it acts up

4. The three critical parameters that should be monitored for steam sterilization are:
   a. time, pressure and steam.
   b. temperature, pressure, and type of instruments being processed.
   c. time, pressure, and temperature.
   d. temperature, steam and availability of resources.

5. An example of a class 1 chemical indicator is:
   a. the tape that is place on the outside of a wrapped cassette.
   b. the ink change on the outside of a sterilization pouch.
   c. a vial of Geobacillus stearothermophilus.
   d. a and b only.

6. Dynamic-air-removal sterilizers require the following monitoring:
   a. biological monitoring
   b. chemical monitoring
   c. Bowie-Dick type test
   d. all of the above

7. Class 5 chemical indicators:
   a. only measure one critical parameter of the sterilization cycle.
   b. measure two or more critical parameters of the sterilization cycle.
   c. measure all of the critical parameters of the sterilization cycle.
   d. are the newest monitors available and are only used for specific sterilization cycles.

8. What is a common cause of sterilization failure in dental facilities?
   a. loss of electricity
   b. operator error
   c. staff inexperience in sterilization monitoring
   d. b and c only

9. Whose responsibility is it to understand the indicator readings if they indicate an incomplete sterilization cycle?
   a. the dentist
   b. the assistant
   c. the hygienist
   d. all of the above

10. In case of a BI failure:
    a. retest and if the second BI test also fails, pull the sterilizer from service
    b. immediately pull the sterilizer from service
    c. test the sterilizer three consecutive times, achieving negative results, before putting it back to use.
    d. b and c only

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