



Sterilization monitoring with spore tests: Q&A with an infection control coordinator

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This interview with infection control expert Maria Fluent, DDS, addresses why biological indicators are the best assurance that sterilization has occurred.

According to the Centers for Disease Control and Prevention (CDC), the ability of a sterilizer to reach conditions necessary to [achieve sterilization](#) should be monitored using a combination of mechanical, chemical, and biological indicators (BI). Mechanical indicators assess the cycle time, temperature, and pressure found on displays and printouts of autoclaves. These parameters may be observed during the sterilization cycle and may serve as a first indication of any malfunction.

Chemical indicators (CI) use sensitive chemicals to assess the physical conditions during the sterilization process. Chemical indicator tapes, strips, or tabs and marking on packaging materials change color when exposed to high temperatures or combinations of time and temperature. Yet, neither of these methods guarantee sterilization—they merely detect procedural errors and equipment malfunctions. This interview addresses why BIs are the best assurance that sterilization has occurred.

Infection control coordinator (ICC): First, if mechanical and chemical indicators do not “prove” sterilization has taken place, why are these monitoring methods necessary?

Dr. Fluent (MTF): That is a great question! Both mechanical and chemical indicators are the first steps in quality assurance and should be performed for each sterilization cycle. These monitoring methods may be the first indication something has gone wrong and may differentiate between processed and unprocessed items. Using mechanical and chemical monitoring, dental personnel can rest assured that unsterilized instruments will not be used for patient care.

ICC: I have heard of “biological indicators” and “spore tests.” Are these the same?

MTF: Yes, BIs and spore tests refer to the same monitoring procedure. BIs and spore tests remain the best assurance that sterilization equipment is functioning, and instrument processing procedures are being performed correctly. This monitoring process assesses the killing of highly resistant microorganisms (e.g., *Geobacillus stearothermophilus* for autoclaves and chemical vapor units, or *Bacillus atrophaeus* for dry heat autoclaves). Inactivation of the BI strongly implies that other potential pathogens in the load have been killed. In other words, if *Geobacillus* and *Bacillus* spores are killed, all other pathogens should be killed in the sterilization cycle as well.

ICC: I have seen in-office incubation systems for spore testing and mail-in monitoring services. Which is better?

MTF: Spore testing may be incubated using in-office incubation systems, or by mail-in monitoring services provided by medical companies, universities, and dental schools. Neither choice is better than the other, however, there are several considerations to keep in mind as you select whether to perform an in-office or mail-in monitoring service. There have been some concerns that postal delays may cause spore tests to arrive at the monitoring service days after the sterilization process, however, they do not influence spore incubation or final test results.

So, there is no need to worry about inaccurate results due to delays in snail mail. For in-office spore testing, it is important to use the proper incubation temperature and time specified by the manufacturer. With either method, sterilization monitoring records (mechanical, chemical, and biological) must be maintained in accordance with state and local regulations. With mail-in services, the record keeping is done by the monitoring service, whereas recordkeeping for in-office systems must be done by dental personnel. This is an added step that requires diligence and compliance.

ICC: Can you walk me through how to perform a spore test?

MTF: Sure. First and foremost, always follow manufacturer’s instructions for use (IFU). The IFU will determine the placement and location of the test BI within the autoclave. A second control BI also has an important role in spore testing. The control BI should be from the same manufacturer and lot as the test BI, yet not processed through the sterilizer. Both the test and control BI should be incubated at the same time. The final results should show the control BI has positive results for bacterial growth, but the test BI should not. In other words, the spores from the test BI should have been killed, whereas the spores from the control BI should be alive. A passing spore test is called a negative spore test. If both the test and control BI are killed, this is an indication that something is wrong with the lot of spores and the test should be repeated with another lot. If both the test and control BI are alive, this is called a positive spore test or BI failure. This means that something has gone wrong with your sterilization process.

ICC: Now that we have a positive spore test (BI failure), now what?

MTF: First, look at your mechanical and chemical indicators. If these demonstrate that your sterilizer is functioning properly (time, temperature, and pressure), then a single positive spore test probably does not indicate a sterilizer malfunction, yet it is important to recall all items since the last negative spore test. The sterilizer should be removed from service, and all records of mechanical and chemical monitoring should be reviewed since the last negative BI test. Then, repeat the test immediately after loading the sterilizer using the same cycle that produced the failure. If the repeat test is negative (BI passing), then it is OK to place the sterilizer back into service. At this point, sterilizer operating procedures should be reviewed to determine whether operator error could be a possibility.

ICC: What if the positive spore test was due to operator error?

MTF: Most positive spore tests are due to operator error, such as overloading, lack of separation between packages, and incorrect or excessive packaging material. In such incidents, review sterilizer operating procedures (including packaging, loading, spore testing) and include all personnel involved with instrument processing. Consider inviting the manufacturer’s representative to conduct a training session and review sterilizer function and maintenance. Additionally, this is why it is a good idea to keep your IFUs for reprocessing equipment readily available, ideally in or near the reprocessing area.

ICC: How do you recall instrument packages?

MTF: The Centers for Disease Control and Prevention (CDC) recommends labeling instrument packages with sterilizer used, the cycle or load number, the date of sterilization, and if applicable,

the expiration date. If this information is written on the instrument packages, it will be easy for dental personnel to quickly identify instruments that have been processed during or after the positive spore test.

ICC: What if we have had a positive BI and a repeat failure?

MTF: If the repeat BI test is positive, and packaging, loading, and operating procedures have been performed correctly, the sterilizer should remain out of service until it has been inspected, repaired, and re-challenged with BI tests in three consecutive empty chamber sterilization cycles. It is important to determine and correct the cause of the sterilizer failure. When possible, recall instrument packages dating back to the last negative BI. These items should be re-cleaned, re-wrapped, and re-sterilized. Keep in mind that routine maintenance for sterilization equipment should be performed according to manufacturer instructions, and that maintenance records are maintained.

ICC: How often should spore testing of all sterilizers be done?

MTF: CDC recommends spore testing of all sterilizers at least weekly. Whenever possible, a biological indicator should be used for every sterilizer load that contains an implantable device and to verify results before using the implantable device. Experts also recommend spore testing when new packaging materials are used, after training new personnel, during the first run after the repair in a sterilizer, and after any other change in instrument sterilization procedures.

To conclude, sterilization monitoring should be a combination of process parameters, including mechanical, chemical, and biological, to evaluate both the sterilizing conditions and the procedure's effectiveness. Mechanical and chemical indicators are the first steps in quality assurance and should be performed for each sterilization cycle, yet biological indicators (BIs) provide the best assurance that sterilization has occurred.



Marie T. Fluent, DDS, is a graduate of the University of Michigan School of Dentistry. Her dental career spans 35 years and includes roles as an associate dentist and practice owner, infection control coordinator, office manager, and dental assistant. She has extensive experience and expertise as a dental infection control clinical instructor, educator, speaker, author, and consultant. Dr. Fluent is deeply committed to improving dental infection control and patient safety. Through her writing, webinars, and lectures, she has educated thousands of dental professionals and students nationally and internationally. Dr. Fluent has written numerous peer-reviewed articles on infection control in the dental setting, OSHA compliance, and responsible antibiotic prescribing. She serves as education consultant for the Organization for Safety, Asepsis, and Prevention (OSAP).

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