SMS

self-study course

course 2 | spring 2022

TWO CREDIT HOURS are issued for successful completion of this self-study course. These credit hours count toward your OSDB 2022-2023 biennium totals.

STERILIZATION MONITORING

about this course...

Most physical tasks that we perform produce visible results immediately, and the results give us immediate feedback on how the task was performed. For example, when you remove stain from a patient's teeth --- the patient's clean teeth are immediately visible. Or, when you enter a note in the patient's record --- the words are immediately visible. Unfortunately, immediate feedback with your sterilizer is not possible. The direct proof of your sterilizer's success is determined by the presence or absence of microbes. For this reason, sterilization monitoring is required.

The purpose of this self-study is to provide the dental professional with needed information on the why, who, what, where and how of sterilization monitoring.

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course
02
spring 2022

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COURSE
learning objectives

Upon completion of this course, the participant will be able to:

- define sterilization and disinfection
- identify what dental items must be sterilized and the preferred physical mode used for sterilization
- identify the three different types of sterilizers used in dentistry and discuss the advantages/disadvantages of each
- define a biological indicator and biological monitoring
- discuss how sterilization is confirmed
- describe a failed spore test and the possible causes
- discuss how to document a spore test failure, what remedial action is required and how to document a failed spore test
- discuss how chemical monitoring differs from biological monitoring
- list examples of how to avoid common problems with sterilization monitoring
- describe the importance of sterilization monitoring

STERILIZATION MONITORING
introduction

If the microbes were the size of marbles and bounced around when viable, you would immediately be able to see if your sterilizer was working. However, since microbes are invisible to the naked eye, there is no way to know if such organisms are living on instruments that have been processed in the sterilizer. Therefore, you need to monitor your sterilizer for proper functioning. How is this done? Through the use of a biological indicator spore strip.

WHY
use spores in monitoring?

The spores used in monitoring are difficult to kill and that is exactly why they are used. Spores are considered an exceptionally good challenge for the sterilizer.

The theory is that if the spores are killed, then the more fragile organisms like the Hepatitis B virus (HBV) or the Human Immunodeficiency virus (HIV) that may have survived on instruments after scrubbing or soaking are also killed.

WHAT
is sterilization versus disinfection?

Sterilization is the destruction of all forms of microbial life. The limiting requirement is the inactivation of bacterial spores. Proof of such destruction is the ultimate criteria for sterilization because spores are the most heat-resistant microbial forms.

Disinfection is the inhibition or killing of pathogens. Spores are not killed during disinfection.

WHAT
items must be sterilized?

Per the Centers for Disease Control and Prevention (CDC), sterilization is required for all instruments and items that are placed in the patient's mouth. If an item cannot withstand heat sterilization, a disposable (one-time use) item must be used instead.

For additional details on exactly what items require sterilization, click here for the CDC Summary of Infection Prevention Practices in Dental Settings: Basic Expectations for Safe Care.

WHAT
is used to achieve sterilization?

Heat is the most efficient and dependable physical mode of achieving sterilization of dental instruments. The heat may be moist or dry.

WHAT
types of sterilizers can be used?

The three equipment options for heat sterilization include:

- autoclave
- chemical vapor sterilizer
- dry heat oven

TYPES
of sterilizers

- **autoclave**

The use of steam heat under pressure remains the oldest, most common and most acceptable method for instrument sterilization.

Temperature | Pressure | Cycle Time

- 121°C (250°F)
- 15 psi
- 20 minutes

Advantages

- short efficient cycle time
- good penetration
- range of materials processed without destruction

Disadvantages

- corrosion of unprotected carbon steel instruments
- dulling of unprotected cutting edges
- packages may remain wet at the end of a cycle
- use of hard water may leave deposits
- possible destruction of heat-sensitive materials

- **chemical vapor sterilizer**

The chemical vapor sterilizer requires the use of organic solvents (chemicals) instead of water to produce the sterilizing vapor.

Temperature | Pressure | Cycle Time

- 32°C (270°F)
- 20 psi
- 20-40 minutes

Advantages

- short cycle time
- does not rust or corrode metal instruments (including carbon steel)
- does not dull cutting edges
- suitable for orthodontic stainless wires

Disadvantages

- instruments must be completely dry before processing
- special chemical solutions must be used
- destroys heat sensitive plastics
- causes strong chemical odor in poorly ventilated areas
- cannot be used to sterilize liquids

TYPES
of sterilizers

- **dry heat oven**

The destruction of all forms of microbial life in the absence of moisture requires conditions very different from the autoclave and chemical vapor sterilizer. Dry heat sterilizes much less efficiently than moist heat. A higher temperature is required for sterilization to occur.

FDA approval is required for using any unit as a sterilizer. The use of a commercially available cooking oven is not a substitute for an FDA-approved sterilizer. The insulation and temperature criteria for a cooking oven are not as stringent as the requirements for FDA-approved medical devices.

Forced air convection ovens, or rapid heat transfer ovens are an option for dry heat sterilization. Such units use a higher temperature and a controlled internal airflow.

Temperature | Cycle Time

- 160°C (320°F) for 2 hours

  --- or ---
- 170°C (340°F) for 1 hour

Temperature | Cycle Time (Rapid Heat Transfer Oven)

- 190°C (375°F)
- 12 minutes for wrapped items
- 06 minutes for unwrapped items

Advantages

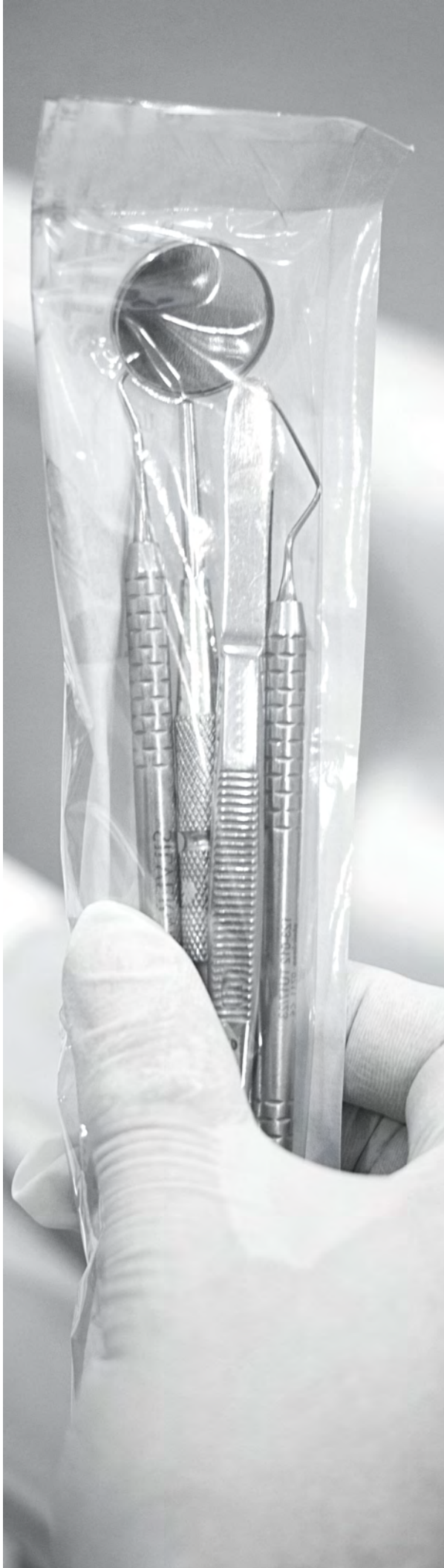
- does not dull cutting edges
- does not rust or corrode metal instruments

Disadvantages

- long cycle time
- poor penetration
- may discolor and char items
- destroys heat-labile items
- cannot sterilize liquids
- generally not suitable for handpieces

WHY
monitor sterilization equipment?

Both the CDC and ADA recommend weekly spore testing of all sterilizers. Mandated weekly testing varies from state to state. As an example, in the State of Ohio, dentists are mandated to perform weekly spore testing of all sterilizers.



HOW
do you know if a sterilizer is working?

Equipment must be monitored for proper functioning. An essential step in assessing quality control of instrument reprocessing is the monitoring of sterilization. This is done via the use of biological indicators or spore tests.

HOW
often should equipment be monitored?

Thirty-five states mandate weekly biological monitoring. In the state of Ohio, the Ohio State Dental Board (OSDB) mandates the weekly biological monitoring (spore testing) of all sterilization equipment used in the dental office. This is stated in the Ohio Administrative Code Rule 4715-20-02 Sterilization and Disinfection (effective May 2014).

It is important to note that, per the OSDB rule, for each week that patients are treated (regardless of how many hours or days), a spore test must be completed. The only exception would be if no patients are treated in a calendar week; in such cases, that information must be documented in the weekly spore testing log.

WHAT
is biological monitoring?

Biological monitoring involves the processing of highly resistant bacterial spores to determine if they have been killed. A biological indicator (BI) or spore strip contains the spores used in biological monitoring.

A spore strip is a small piece of paper that contains one or more types of spores – Bacillus atrophaes spores are used for testing dry heat units and Geobacillus stearothermophilus are used for testing steam and chemical vapor units. The spore strip is enclosed in a protective glassine envelope.

HOW
is sterilization confirmed?

After a spore strip is processed in a sterilizer, it is mailed to a monitoring service. In a laboratory setting, the spore strip is aseptically removed from its protective glassine envelope and placed in a test tube of culture media for 7 days. For each of the 7 days, the tube of culture media is inspected for cloudiness. If the spores are viable and have not been killed, a cloudiness is noted in the culture media. If no cloudiness is noted in the culture media, then sterilization is confirmed.

WHAT
is a failed test?

Cloudiness in the culture media indicates a failed test (spores were not killed), also known as a positive biological spore test. To rule out contamination during testing, a Gram stain is prepared to identify the bacteria in the failed test. Only when the gram-positive Bacillus organism is observed on the test slide has sterilization failed.

WHAT
causes a test to fail?

A number of conditions may cause a spore test to fail - overloading the sterilizer, inadequate temperature and/or pressure, inadequate time, or improper packaging of instruments. In the majority of cases, operator error is responsible for the failure.

WHAT
should happen after a failed test?

Per the OSDB rule, should a failure (or positive biological spore test) occur, the dentist must take immediate remedial action to ensure that heat sterilization is being accomplished.

Immediate remedial action is defined as following manufacturer guidelines and performing a second biological spore test. In the event that a second biological spore test failure occurs, the device must be removed from service until repaired. Proof of such repair must be maintained with the testing documentation.

HOW
is a sterilization monitoring documented?

Documentation must be maintained in the form of a weekly testing log reflecting the dates and person(s) conducting the testing. If the office is closed for a calendar week, such information must be documented on the weekly testing log. All weekly testing results (e.g., monthly reports from an independent testing agency such as the Sterilization Monitoring Service) must be maintained as well.

In addition, a failure log should be maintained listing the failure date, equipment type, re-test date, service call information, and action taken. Per the most recent OSDB rules, such information must be maintained for a period of at least two years. In addition, such testing documentation must be maintained in the dental facility and be made immediately available upon request by an authorized agent of the OSDB. Documentation requirements vary from state to state.

WHAT
is chemical vs. biological monitoring?

There is often confusion between biological monitoring (spore testing) and chemical monitoring.

Chemical monitoring uses heat sensitive chemicals (not spores) to assess the physical conditions during the sterilization process. Chemical monitoring involves the use of indicators that change color when exposed to certain temperatures. Examples include autoclave tape, special markings on bags and pouches, and chemical indicator strips, tabs or packets.

A color change only indicates that the sterilizer reached the proper temperature but does not indicate how long the temperature was maintained.

If a chemical indicator changes color, has sterilization taken place? Not necessarily... a chemical indicator only assesses the physical conditions (e.g., temperature) present during the cycle. When a sterilizer reaches the required temperature, it causes the chemical indicator to change color; however, it does not indicate how long the temperature was maintained or what pressure was reached and maintained. Only spore testing demonstrates microbial kill and is considered the definitive test for sterilization.

Chemical indicator use is recommended for every cycle to serve as a routine check for all items processed in the sterilizer and to provide immediate feedback concerning the critical sterilization temperature. Consequently, any sterilizer that does not reach critical sterilization temperature can be detected quickly.

WHAT
can you do to avoid sterilization monitoring problems?

To avoid problems with sterilization monitoring, consider implementing a plan that includes the following:

- educate the staff
- assign one person
- establish a routine & use a testing calendar
- use chemical indicator strips
- mail spore tests promptly
- maintain a failure log
- review monthly reports
- review problems
- report to staff
- file & retain reports

STERILIZATION MONITORING

to do list

Educate the Staff

Make certain that your entire office staff understands the importance of weekly testing, and that weekly testing is mandated by many states including Ohio.

Assign One Person

Assign one dependable staff member to take responsibility for weekly testing. The dentist should periodically review the testing records with this staff person to ensure weekly testing is taking place, and that all testing documentation is in order.

Establish a Routine & Use a Testing Calendar

Plan to test each piece of sterilization equipment on the same day of the week, each week of the month. Pick a testing day early in the week (Monday or Tuesday), in case the assigned staff member is absent, and the normal testing day is missed. Use a calendar to keep track of weekly test dates. Indicate on the calendar the date of testing, who performed the spore test and the mail date. Also indicate on the calendar a reminder of when to re-order spore tests and chemical indicator strips.

Use Chemical Indicator Strips

For each sterilizer cycle, use a chemical indicator strip as a quick visual to determine if the minimum temperature was reached for sterilization.

Mail Tests Promptly

Always mail tests on the same day the equipment was tested.

Maintain a Failure Log

Keep a log of all test failures and document the remedial action taken.

Review Reports

It is the responsibility of the dentist to review each monthly report. If there are any discrepancies between the number of tests submitted and the number of tests processed, contact your monitoring service promptly.

Review Problems

It is the responsibility of the dentist to periodically meet with the staff person assigned to testing in order to review failures, equipment problems and staff education.

Report to Staff

Request that the staff person assigned to perform the weekly testing report on failures and the monitoring of equipment at scheduled staff meetings.

File & Retain Reports

Keep all sterilization monitoring monthly reports in one accessible file. Records requirements vary by state. In Ohio, if the office is inspected --- all pertinent information must be on the premises. In Ohio, all biological monitoring reports must be retained for at least 2 years.

resources

additional resources
available upon request

Centers for Disease Control and Prevention. Summary of Infection Prevention Practices in Dental Settings: Basic Expectations for Safe Care. Atlanta, GA: Centers for Disease Control and Prevention, US Dept of Health and Human Services; October 2016.

Guide to Infection Prevention for Outpatient Settings: Minimum Expectations for Safe Care http://www.cdc.gov/hai/settings/outpatient/outpatient-care-guidelines.html

Sterilization: Monitoring | FAQs | Infection Control | Division of Oral Health https://www.cdc.gov/oralhealth/infectioncontrol/faqs/monitoring.html

Strange, M. Chemical Indicators: a must for proper sterilization. RDH Magazine. https://www.rdhmag.com/infection-control/article/14196612/chemical-indicators-a-must-for-proper-sterilization

OSDB Infection Control Manual (2016) https://dental.ohio.gov/Enforcement/Infection-Control#728170-infection-control-manual-

Rule 4715-20-02 | Sterilization and disinfection. Ohio Administrative Code Chapter 4715-20 - Ohio Administrative Code | Ohio Laws

SMS

course
02
spring 2022

RELEASE DATE
5.2.22

DEADLINE
to complete at no cost
6.2.22

comments

your feedback is important

★ ★ ★ ★ ★

comments & suggestions are welcome

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instructions

- **READ the MATERIALS**
  read and review the course materials
- **COMPLETE the TEST**
  complete 15-questions / 12 must be correct to receive credit
- **SUBMIT your ANSWERS**
  submit answers online at http://go.osu.edu/smsce
- **CERTIFICATE of COMPLETION**
  certificate is emailed / check your email and junk/spam folders

questions

- **WHO can EARN FREE CE CREDITS?**
  EVERY dental professional in your office
- **HOW MANY CE CREDITS are EARNED?**
  two CE credits are issued for successful course completion --- credits count toward OSDB 2022-2023 biennium totals
- **WHAT if I MISS THE DEADLINE?**
  submit answers by deadline to receive credits at no charge after deadline, course can be purchased until end of biennium
- **WHEN are SMS COURSES OFFERED?**
  four times per year totaling EIGHT free CE credits
- **WHEN is the CERTIFICATE EMAILED?**
  allow two weeks for processing/emailing of the certificate
- **WHAT is my SMS NUMBER?**
  everyone in your office uses the same SMS number (office account number) - number is on back of red testing envelope