Infection Control
IN PRACTICE
Dentistry's Newsletter for Infection Control and Safety

Sterilization Monitoring

Quality control and performance assessment for sterility assurance

To guard against sterilization failures and provide the best assurance that items processed in your heat sterilizer are sterile, monitor the heat sterilization processes in your office using mechanical, chemical, and biological means.

- Mechanical monitoring includes examining the sterilizer's temperature record chart and computer printout, if available, and visually observing the unit's gauges during the cycle. Mechanically monitor each sterilization cycle.
- Chemical indicators use heat-sensitive chemicals to assess physical conditions during the cycle, for example, time, temperature, and for autoclaves, the presence of steam. Use a chemical indicator inside each instrument pack in every sterilization load. If the internal indicator is not visible from the outside of the pack, place a chemical indicator (such as autoclave tape) on the outside of each pack.
- Biological indicators (BIs, or spore tests) use high numbers of the most resistant microorganisms — bacterial endospores — to test the sterilization cycle. If the spores are killed during the cycle, then less resistant microorganisms in fewer numbers commonly found on dental instruments likely could not survive the process. Spore test your office sterilizer at least weekly.

Biological monitoring

Biological monitoring subjects highly resistant bacterial endospores to a sterilization cycle in order to test the sterilization process. Supplied as spore-impregnated strips or in self-contained vials, the spores are processed within a normal load, then cultured to determine if they survived. Spore survival (a positive culture) indicates sterilization failure; complete inactivation of spores (a negative result) suggests successful sterilization.

For quality assurance, two spore sets from the same lot are cultured: one that has been exposed to the sterilization cycle (the test), and one that has not (the control). If the sterilization process has been successful and incubation procedures have been performed correctly, the control spores should show growth when incubated; the test organisms should not. Incubating a control along with test organisms from the same lot ensures that events other than the sterilization process have not played a role in the spores' ability to grow.

Although spore tests cannot prove that all items in the load are sterile or that all were exposed to adequate sterilization conditions, it provides your best assurance that instrument processing equipment and procedures are performing — *and being performed* — as they should be. Routine spore testing establishes a pattern of performance

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OSAP Dentistry's Resource for Infection Control & Safety

Learning Objectives

- Understand the importance of the three types of sterilization monitoring
- Learn the terminology used in discussing sterilization monitoring
- Know the step-by-step procedures for monitoring heat sterilization processes

Sterilization Monitoring

continued from front cover

for sterilization equipment and offers support and assurance that items processed in a like manner are indeed sterile.

Types of spore tests. The type of spore used in sterilizer monitoring depends on the type of sterilization. Traditionally *Bacillus stearothermophilus* was used to monitor autoclaves and chemical vapor sterilizers; *Bacillus subtilis* tested dry heat units. Recently the names of these organisms have changed to *Geobacillus stearothermophilus* (for autoclaves and chemical vapor units) and *Bacillus atropaeus* (for dry heat).

Incubation. Spore tests may be incubated using in-office incubation systems or by a mail-back monitoring service, such as those offered by some private companies and dental schools. Each option has its own set of advantages and disadvantages (see below). Although postal delivery schedules can cause spore tests to arrive at the service many days after the sterilization process, mail delays have no significant influence on incubation, growth, or final test results.

Available products. Prepared as single- or dual-species indicators for monitoring autoclave, chemical vapor, and dry heat sterilization cycles, spore-impregnated paper strips measure about an inch long and come in a protective glassine envelope. Self-contained vials for spore-testing steam or ethylene-oxide sterilizers hold spore suspensions on strips or disks in a plastic vial along with an ampule of growth medium. A vented cap allows the sterilizing agent to penetrate and contact the spores.

The sterilization monitoring log

Use a log to record the results of all biologic monitoring. For each entry, include the sterilizer identification number; date; duration and temperature of sterilization cycle; a description of the general contents of the load; operator's name; results of biologic monitoring; repair and preventive maintenance measures, if warranted; and any notes, for example, citing different operators or load content other than normal.

The sterilization monitoring log documents that the sterilizer has achieved sterilization parameters (mechanical monitoring). It provides a record of performance and results of biologic monitoring, and it can simplify recall of processed instruments, if needed.

Making the right choices

In biologic monitoring, technique counts, so it makes sense to evaluate and consider the ease or difficulty involved with each product or service. For example, although spore strips are generally less expensive, they carry an increased risk of contamination on transfer to the culture medium. Loading, storage, sterilization, and transport are as important to the monitoring process as incubation, so dental team members responsible for sterilization monitoring must be well-trained. Even the best system can be useless and costly if not properly implemented. Communicating techniques and the rationale behind them encourages understanding and compliance. **OSAP**

Spore Testing Options: Pros and Cons

	(+)	(-)
In-office monitoring	• Monitor incubation progress • May be more cost-effective • Control over process	• Results not confirmed • Technique-sensitive • Not available for dry heat
Commercial mail service	• Confirmation of results • Convenient, readily available • No equipment commitment • Outside source of information • Increased protection	• May be more costly • Receipt of spores and results (both positive and negative) not confirmed by all services • Delay between testing and receiving results

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Compliance Corner

ADA "[Chemical] indicators should be used with each load. Biological monitors should be used routinely to verify the adequacy of sterilization cycles. Weekly verification should be adequate for most dental practices."

— American Dental Association. Infection control recommendations for the dental office and the dental laboratory (May 1996)

OSAP "The use and functioning of heat sterilizers should be biologically monitored at least weekly, or more often if the practice demands it, with appropriate spore tests. Place the spore strips or vials inside a pouch, bag, pack or cassette, and include this package as part of the normal load through a normal sterilizer cycle. Always use a control spore strip or vial (not heat processed but otherwise treated identically to the test strips or vials) with each spore test performed. Additionally, chemical indicators should be used on the inside of each package during every sterilizer load. Accurate records of sterilization monitoring must be maintained. A chemical indicator from inside each pack may be initialed and dated for each day of patient care and kept in a file. The weekly spore test for each heat sterilization unit may be kept in the same file. Biologically monitor whenever there is a change in packaging, following equipment repair; retest after failure and when training new employees."

— OSAP Infection control in dentistry guidelines (September 1997)

CDC "Proper functioning of sterilization cycles should be verified by the periodic use (at least weekly) of biologic indicators (i.e., spore tests). Heat-sensitive chemical indicators (e.g., those that change color after exposure to heat) alone do not ensure adequacy of a sterilization cycle but may be used on the outside of each pack to identify packs that have been processed through the heating cycle. A simple and inexpensive method to confirm heat penetration to all instruments during each cycle is the use of a chemical indicator inside and in the center of either a load of unwrapped instruments or in each multiple instrument pack; this procedure is recommended for use in all dental practices.

— Centers for Disease Control and Prevention. Recommended infection-control practices in dentistry, 1993 (May 1993)

Glossary

Autoclave heat sterilizer using steam under pressure as the sterilizing agent

Biological indicator paper strips or vials containing bacterial endospores used to monitor heat sterilization processes; also referred to as a *spore test*

Critical instruments instruments that penetrate soft tissue or bone

Chemical indicator device that changes color or form with exposure to one or more of the physical conditions within the sterilizing chamber (e.g., temperature, steam)

Dry-heat sterilizer heat sterilizer using hot air (high tempeatures) and extended cycle times to sterilize patient care items

Endospore a spore developed within a cell

Heat sterilization the act of using a heat process to destroy all microbial life, including bacterial endospores; autoclaves, chemical-vapor sterilizers, and dry-heat sterilizers are used in dentistry for heat sterilization of patient-care items

Incubator a device that maintains the temperature and conditions required for growing cultures of microorganisms

Mechanical monitoring the process of checking sterilizer displays, readouts, and gauges for proper parameters during a sterilization cycle

Spore a highly resistant, dormant body that is formed inside some bacteria and that can survive adverse conditions, including elevated temperatures

Spore test see *biological indicator*

Infection Control In Practice is a resource prepared for clinicians by the Organization for Safety & Asepsis Procedures with the assistance and expertise of its member-contributors. OSAP is a nonprofit, independent organization providing information and education on infection control and occupational health and safety to dental care settings worldwide.

Information in this issue has been brought to you with the help of the following individuals:

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Putting It All Together

With OSAP's step-by-step instructions, sterilizer monitoring is as easy as 1-2-3.

1. Prepare instruments for heat processing in an autoclave, chemical vapor sterilizer, dry heat sterilizer, or ethylene oxide sterilizer. (See the July and August 2003 issues of *Infection Control In Practice* for instructions for holding, cleaning, preparing, and packaging patient-care items.)
2. Ensure that chemical indicators are present inside a pack and visible from the outside of each pack.
3. At least once per week, insert a test biological indicator inside one of the bags, pouches, or cassettes and complete the packaging process. Label the pack containing the spore test.
   - ❍ If using a spore strip, do not remove it from its glassine envelope.
4. Load the sterilizer as you normally would, but be sure to position the pack containing the spore test in the center of the load.
5. Run the sterilizing cycle.
6. In the sterilizer monitoring log, record the date of the test, type of sterilizer, temperature and time of the cycle, nature of the package contents containing the spore test, and name of the sterilizer operator.
7. After the cycle:
   - ❍ If using a mail-back service:
     - **a.** Retrieve the sterilized spore test.
     - **b.** Mail both the sterilized BI and the control BI to the sterilization monitoring service.
   - ❍ If monitoring in the office using spore strips:
     - **a.** Retrieve the sterilized spore test.
     - **b.** Aseptically remove the test strip from its envelope and place it in the appropriate culture medium that incorporates a pH indicator.
     - **c.** In the same manner, aseptically remove the control strip from its envelope and place it in the appropriate culture medium that incorporates a pH indicator.
     - **d.** Incubate both strips according to the manufacturer's instructions, monitoring the incubator's temperature readouts (usually 55°C for *G. stearothermophilus* and 35-37°C for *B. atropaeus*) throughout the incubation period.
   - ❍ If monitoring in the office using vials:
     - **a.** Retrieve the sterilized spore test.
     - **b.** Squeeze the test vial or depress its cap (consult the manufacturer's instructions) to break the internal ampule of growth medium, releasing and mixing it with the spores.
     - **c.** In the same manner, squeeze the control vial or depress its cap to break, release, and mix the internal ampule of growth medium with the spores.
     - **d.** Incubate both vials according to the manufacturer's instructions, monitoring the incubator's temperature readouts (usually 55°C for *G. stearothermophilus*; vials containing *B. atropaeus* are not commercially available) during the incubation period.
8. Receive results.
   - ❍ If using a mail-back service:
     - ❑ Receive a report of results by mail (successful sterilization) or by phone (usually in the case of a sterilization failure).
   - ❍ If monitored in the office:
     - ❑ Follow the spore test manufacturer's instructions for analyzing test and control BIs in the office. Cloudiness or color change in the test medium typically indicates microbial growth and failure of the sterilization cycle.
9. Record the results of both the test and control BIs in the practice setting's sterilizer monitoring log.
10. Respond to results.
    - ❍ If sterilization is successful, store or distribute instruments according to your practice's standard operating procedures.
    - ❍ If sterilization has failed, follow instructions for troubleshooting a sterilization failure (see next page).

OSAP

Spore Testing: Whens and Whys

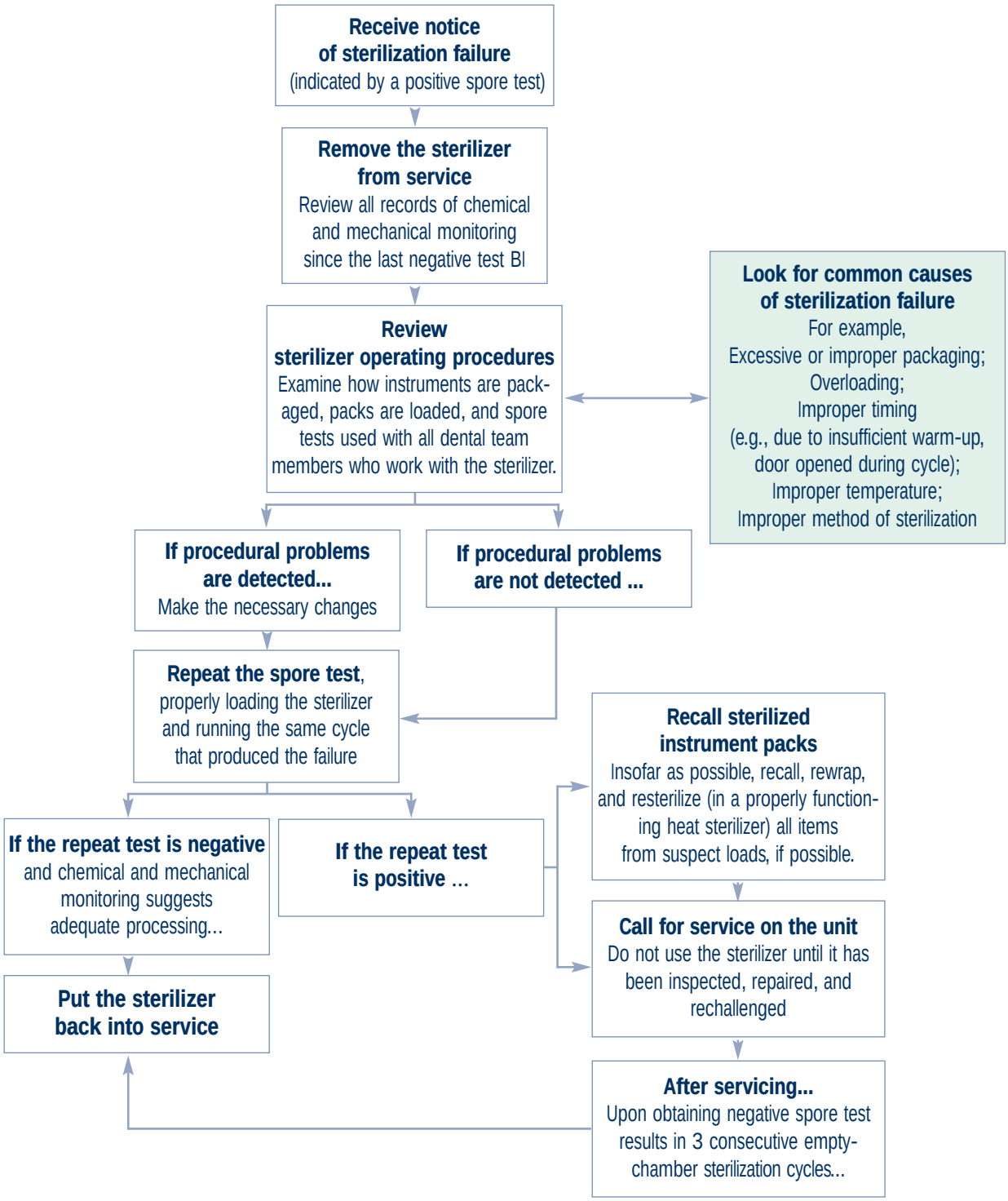
Once per week...	To routinely verify proper use and functioning of sterilization equipment	If cycle time or temperature is altered...	To ensure sterilization conditions are being reached
During initial use of a new sterilizer...	To ensure that unfamiliar operating instructions are being followed	After electrical/power source failure...	To verify proper sterilizer functioning
During the first cycle after a repair...	To verify proper functioning of the sterilizer	When door seals or gaskets are changed...	To ensure proper sealing of chamber
After training of new personnel...	To verify understanding and use of procedures and equipment	For all cycles treating implantable items*...	Added precautions are warranted for items to be implanted
With changes in packaging material...	To ensure the sterilizing agent is reaching the contents	For all cycles treating infectious waste...	To ensure that waste is not improperly discarded
With changes in loading procedure...	To ensure the sterilizing agent can reach each item	If the method of spore testing is changed...	To ensure that the spores and method of sterilization are compatible

* Note: Do not place the implant or device until sterilization has been biologically verified.

OSAP Chart & Checklist

In Case of a Sterilization Failure...

Most sterilization failures are caused by operator error, rather than equipment malfunction. If a spore test from your practice's sterilizer suggests a sterilization failure, use OSAP's flowchart to help you identify and correct problems with minimal disruption to the work schedule.



Calendar

To help practices stay on track, OSAP provides this calendar listing typical schedules for periodic maintenance, recordkeeping, and infection control activities. This schedule is intended only to serve as a guide. Proper practices, procedures, and maintenance schedules can vary according to the kinds of products used, the practice type, and patient volume. Always follow the device or equipment manufacturer's instructions for maintenance and infection control.

For a monthly dental office calendar you can customize to best meet the needs and schedules in your practice, visit osap.org/calendars/index.htm. (Adobe Acrobat Reader required.)

OCTOBER 2003

SUNDAY	MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY
			1	2	3 Monthly: update chemical inventory; discard expired supplies, drugs	4
5	6 Weekly: waterline monitoring/ maintenance; clean evacuation traps	7	8	9	10 Weekly: spore test sterilizers	11
12	13 Weekly: waterline monitoring/ maintenance; clean evacuation traps COLUMBUS DAY	14	15 Monthly: foil test ultrasonic cleaners	16	17 Weekly: spore test sterilizers	18
19	20 Weekly: waterline monitoring/ maintenance; clean evacuation traps	21	22 Monthly: check fire extinguisher operating pressure	23	24 Weekly: spore test sterilizers	25
26 DAYLIGHT SAVINGS ENDS	27 Semiannual: Change batteries in smoke detectors Weekly: waterline monitoring/ maintenance; clean evacuation traps	28	28	30	31 Weekly: spore test sterilizers HALLOWEEN	

NOVEMBER 2003

SUNDAY	MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY
						1
2	3 Monthly: update chemical inventory; discard expired supplies, drugs Weekly: waterline monitoring/ maintenance; clean evacuation traps	4	5	6	7 Weekly: spore test sterilizers	8
9	10 Weekly: waterline monitoring/ maintenance; clean evacuation traps	11 VETERANS DAY	12 Monthly: foil test ultrasonic cleaners	13	14 Weekly: spore test sterilizers	15
16	17 Weekly: waterline monitoring/ maintenance; clean evacuation traps	18	18 Monthly: check fire extinguisher operating pressure	20	21 Weekly: spore test sterilizers	22
23 30	24 Weekly: waterline monitoring/ maintenance; clean evacuation traps	25	26	27 THANKSGIVING	28 Weekly: spore test sterilizers	29

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CE Unit 7/03

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1. True or False: Spore tests prove that all items in a load are sterile.
a. True **b.** False

2. Autoclave tape is an example of a _____.
a. mechanical indicator **b.** chemical indicator **c.** biological indicator **d.** cleaning indicator

3. The test spore for an autoclave is called:
a. *Bacillus atropaeus*
b. *Mycobacterium tuberculosis*
c. *Geobacillus stearothermophilus*
d. *Geobacillus subtilis*

4. A(n) _____ maintains the temperature and conditions required for microbial growth.
a. autoclave **b.** sterilant **c.** mechanical monitor **d.** incubator

5. To ensure performance of the heat sterilizer in your practice setting:
a. manually monitor unit gauges
b. use chemical indicators with each load
c. spore test the unit at least weekly
d. all of the above

6. Mechanical monitoring of heat sterilizers should be performed:
a. daily **b.** weekly **c.** monthly **d.** with every cycle

7. Cloudiness or color change in an incubated spore test indicates:
a. sterilization failure
b. improper incubation temperature
c. that the test microbes did not grow
d. improper spore type used

8. Processed instrument packs should be recalled _____.
a. after one positive spore test
b. after one negative spore test
c. after procedures have been reviewed and a second spore test suggests sterilization failure
d. any of the above

9. Daylight savings time ending is a good time to:
a. perform a spore test
b. use chemical monitors
c. change the batteries in your smoke detectors
d. try a new sterilizer monitoring service

10. True or False: Dental practices should spore test with all cycles processing an implantable device or material.
a. True **b.** False

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Practice Tip

Light handles and oral surgery

Everyone agrees: During oral surgery, the infection control stakes are higher. Dental workers use a more rigorous surgical scrub, they wear sterile gloves, and every effort is made to maintain a sterile field.

So what happens when you need to adjust the operatory light? The handle itself certainly isn't sterile. While many practices use a surface cover to protect light handles from contamination, such barriers typically are not supplied sterile and are not made to stand up to a heat sterilization process.

Dr. Tom Plamondon and the dental team at the Peterson Air Force Base dental clinic in Colorado Springs, Colorado, noticed this apparent shortcoming in their oral surgery set-ups and came up with a practical, cost-effective solution.

"Although the risk of infection from contact with a clean but non-sterile surface is decidedly slim, the nature of oral surgery procedures requires us to go above and beyond some of the standard infection control precautions we use during non-surgical procedures," explains Dr. Plamondon.

With every surgical instrument pack that goes into the sterilizer at Peterson, two precut pieces of aluminum foil are added. The foil pieces are sterilized along with the surgical instruments and any unit-dosed gauze, cotton, or other supplies needed for the procedure. When the sterile pack is opened in the operatory, the sterile foil is securely wrapped around the light handles, providing a sterile "touch surface" for any lighting adjustments that need to be made during the procedure.

"Dr. Scott Malthaner, our periodontist and infection control coordinator here at the clinic came up with this idea, and we think it's a good one," says Dr. Plamondon. "It requires almost no additional time and only the most nominal expense, but it gives us the peace of mind knowing that we're taking every precaution we can to further reduce any risk of post-surgical infection."

An OSAP member since 1995, Thomas J. Plamondon, DDS, is the Dental Flight Commander at Peterson Air Force Base in Colorado Springs, Colorado. A published researcher on dental water quality, equipment design, and percutaneous injury, he has lectured at OSAP symposia and served on several committees.

Do you have a practice tip you'd like to share with other OSAP members and subscribers? Send your suggestions for enhancing dental infection control and safety in practice to editor@osap.org. Be sure to include contact information, a photo, and a brief bio. Thanks!

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