**How is the sterilization process monitored?**
Initial and recurrent training; staff supervision; maintenance and calibration of equipment; and recordkeeping are important elements of a sterility assurance program. Additionally, sterilization procedures are routinely monitored using a combination of mechanical (physical), chemical, and biological indicators. These indicators evaluate the sterilizing conditions and the procedure’s effectiveness.

### Sterilization Monitoring: How, When, & Why?

<table>
<thead>
<tr>
<th>How?</th>
<th>Mechanical (Physical)</th>
<th>Chemical</th>
<th>Biological (i.e., spore tests)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Assessment of cycle time, pressure, and temperature by examining the record chart/computer printout (or if not available, by visually observing the gauges).</td>
<td>Heat-sensitive inks that change color when exposed to heat, heat and time, or heat, time, &amp; steam.</td>
<td>Commercially prepared preparations containing live bacterial spores that are known to be resistant to the mode of sterilization being monitored.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>When?</th>
<th>Internal Chemical Indicator: inside every package</th>
<th>External Chemical Indicator: on the outside of the package when the internal indicator is not visible</th>
<th>At least once a week or as directed by MTF policy</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>- Incorrect readings could be the first indication of problem with the sterilizer.</td>
<td>- Indicator test results are received immediately upon completion of the sterilization cycle and could provide an early indication of a potential problem.</td>
<td>- The sterilization process is directly assessed using the most resistant microorganisms (e.g., <em>Geobacillus stearothermophilus</em> [steam or chemical vapor] or <em>Bacillus atrophaeus</em> [dry heat]); the most valid method for monitoring the effectiveness of the sterilization process and sterility of processed items.</td>
</tr>
</tbody>
</table>

| Why? | - Provides a quick, easy way to visually identify if the package was processed through a sterilizer. | - Provides a quick, easy way to visually identify if the package was processed through a sterilizer. | - Always use a matching control (i.e., biological indicator and control from same lot number)—this is not placed in the sterilizer, but is incubated along with the spore test. |

| Notes | The sterilizer gauges indicate conditions in the sterilizer chamber, not conditions within the packages being processed. | Internal or external chemical indicators do not guarantee sterility, however if either the internal or external indicator suggests inadequate processing, the item should not be used. | - Use according to manufacturer instructions (e.g., proper location in the sterilizer). |

- The indicator must be appropriate for the sterilization process being used (e.g., steam autoclave, dry heat, chemicalclave).
What is the difference between an external and internal chemical indicator?
External, or process, indicators applied to the outside of a package (e.g., chemical indicator tape or special markings on the package) change color rapidly when a certain temperature is reached. External indicators do not guarantee that sterilization has been achieved or even that a complete sterilization cycle has occurred. External indicators are primarily used to identify packages that have been processed through a heat sterilizer, thus preventing the accidental use of non-sterile items.

Internal indicators react more slowly to the sterilization parameters than external indicators and can help detect sterilizer failures that may result from incorrect packaging, improper sterilizer loading, or malfunctions of the sterilizer. Internal chemical indicators can be single parameter or multiparameter. A single parameter indicator responds to one of the critical parameters of sterilization (e.g., heat), while a multiparameter indicator is designed to react to two or more parameters (e.g., time and temperature; or time, temperature, and the presence of steam). Because multiparameter indicators provide more information about the sterilization cycle, they can provide a more reliable indication that sterilization conditions have been met. Presently, multiparameter internal indicators are available only for steam sterilizers (i.e., autoclaves). An internal chemical indicator should be placed in every package to evaluate whether the instruments were exposed to the sterilization conditions. In other words, internal chemical indicators should be used inside each package to ensure that the sterilizing agent has penetrated the packaging material and actually reached the instruments inside. In addition, an external chemical indicator (e.g., chemical indicator tape) should be used when the internal indicator cannot be seen from outside the package.

What is an air removal test (e.g., Bowie Dick test, DART)?
Prevacuum sterilizers should be tested periodically for adequate air removal, as recommended by the manufacturer. Air removal tests do not apply to gravity-displacement sterilizers. An air removal test is designed to detect inadequate air removal in prevacuum sterilizers. Air not removed from the chamber will interfere with steam contact. The test is generally conducted daily in an empty chamber, before the first processed load of instruments. Usually a short cycle is run first to properly heat the sterilizer, then the test pack is placed in the empty sterilizer chamber, near the door, over the drain, however manufacturer's instructions should be followed for the specific product being used. If a sterilizer fails the air removal test, it should not be used until inspected by sterilizer maintenance personnel and it passes the test. Air removal testing should also be performed during initial sterilizer installation, following sterilization failures (i.e., positive biological indicator), and after sterilizer relocation, malfunction or repair. A synopsis of air removal tests can be found by clicking here.

What procedures are recommended if a spore test is positive?
The following are recommended in the case of a positive spore test (or as directed by Medical Treatment Facility [MTF] policy):

- Notify the dental ICO/NCOIC, medical equipment repair personnel, and MTF ICO per MTF policies.
- Take the sterilizer out of service to prevent further use.
  Why? The sterilizer should not be considered safe to use until the problem is identified and resolved.

Box 1: Sterilization Procedures To Review After a Positive Spore Test
- Past sterilization records (mechanical, chemical & biological monitoring)
- Sterilizer operating procedures including correct loading and compliance with recommendations
- Were there any changes in packaging or loading procedures?
- Were the times and temperature controls set correctly?
- Was a new staff person involved with processing instruments?
- Were the proper spore tests used and were manufacturer instructions followed (e.g., proper incubation time/temperature, same lot number, used before expiration, stored correctly)?
- Review sterilization procedures (e.g., work practices and use of mechanical [physical] and chemical indicators) to determine if operator error could be responsible. Items other than implantable devices do not necessarily need to be recalled.

Why? Many times, sterilizer failures are due to operator error and not because of a sterilizer malfunction. (Box 1)

- Retest the sterilizer by using biological, mechanical [physical], and chemical indicators after correcting any identified procedural problems.

Why? Retesting with mechanical (physical), chemical and biological indicators after correcting procedural problems will determine if the problem has been corrected or if the sterilizer has mechanically malfunctioned.

- If the repeat spore test is negative, and mechanical (physical) and chemical indicators are within normal limits, the sterilizer may be returned to service.

The following are recommended if the repeat spore test is positive:

- Do not use the sterilizer until it has been inspected or repaired or the exact reason for the positive test has been determined.

Why? The sterilizer should not be considered safe to use until the problem is identified and resolved.

- To the extent possible, recall and reprocess all items processed since the last negative spore test. Patients do not need to be notified unless a risk analysis (performed in conjunction with the MTF ICO) determines there is a need to notify patients.*

- After the cause of the sterilizer failure has been determined and corrected, rechallenge the sterilizer with biological indicator tests in three consecutive empty chamber sterilization cycles (or in three consecutive fully loaded chamber sterilization cycles if using a tabletop sterilizer) before placing the sterilizer back in service.

Why? When placed in service, a new or used sterilizer needs to be monitored for proper operation before being used to process patient care items.

*The margin of safety in steam sterilization is sufficient enough that infection risk, associated with items in a load indicating spore growth, is minimal, particularly if the item was properly cleaned and the temperature was achieved (e.g., as demonstrated by acceptable chemical indicator or temperature chart). Published studies are not available that document disease transmission through a nonretrieved surgical instrument after a steam sterilization cycle with a positive biological indicator. References: 1. CDC. Guideline for disinfection and sterilization in healthcare facilities: recommendations of CDC and the Healthcare Infection Control Practices Advisory Committee (HICPAC). MMWR (in press). 2. CDC. Guidelines for infection control in dental health-care settings – 2003. MMWR 2003; 52(No. RR-17):1–66.

What should be included in sterilization records and how long should they be maintained?

Sterilization records (i.e., mechanical [physical], chemical, and biological) should be maintained for a period dictated by local statutes and MTF policy or two years, whichever is longer. Minimum documentation includes:

- date and time of test;
- sterilizer identification number;
- sterilizing conditions
- temperature and exposure period (automated printout documentation is acceptable, if available);
- load contents (e.g., type of instrument sets [e.g., using local terminology/abbreviations such as prophylaxis, operative, surgery]);
- the individual conducting the test;
- results of the test and control; and
- nature and date of any malfunctions or repairs.
TEST YOUR KNOWLEDGE ABOUT STERILIZATION MONITORING

1. A ___________ indicator is placed inside every package to verify that the sterilant reached the instruments inside the package.
   a. mechanical (physical)
   b. chemical
   c. biological
   d. b and c

2. Before returning a malfunctioning sterilizer back to service, the sterilizer must be challenged with biological indicators (i.e., spore tests) in ___________ consecutive empty chamber sterilization cycles.
   a. two
   b. three
   c. four
   d. five

3. The following information should be included in the sterilization monitoring records:
   a. date and time of test and the individual conducting the test.
   b. sterilizer identification number.
   c. results of the test and control.
   d. nature and date of any malfunctions or repairs.
   e. all of the above

Selected References and Additional Resources:


USAF Guidelines for Infection Control in Dentistry.

Answers: 1)b; 2)b; 3)e