TEAM HUDDLE: Establishing a High Quality Instrument Processing Program:

Sterilization Monitoring

One of the most important duties of the Infection Control Coordinator (ICC) is to maintain procedures that ensure the instruments used to provide patient treatment have been adequately processed. The main goal of these procedures is to prevent the spread of potentially pathogenic microbes from contaminated instruments to patients and dental health care workers. The “Chain of Instrument Processing” (Figure 1) is similar to the “Chain of Infection”. When one (or more) link is broken the overall desired result is challenged. The sterilization monitoring link is a key step in the process to ensure sterilization of patient instruments. This directly addresses patient safety.

LEARNING OBJECTIVES

After reading this publication, the reader should be able to:

- describe how the three types of sterilization monitoring are performed.
- describe what each of the three types of sterilization monitoring indicates.
- describe what can cause sterilization failures.
SCENARIO: The Incident

Dr. Portani from Indianapolis just returned from an OSAP Annual Conference where she met April Winters, a hygienist and infection control consultant also from Indy. By the end of the conference Dr. P felt she and her staff were doing a good job with infection control, except she wasn’t sure that her instrument cleaning and sterilization system was in total compliance with the recommendations from the Centers for Disease Control and Prevention (CDC). So she contracted with April to visit the office and review the instrument processing procedures.

After the review April submitted her report and discussed the findings with Dr. P. The report indicated the following deficiencies:

- Endodontic files and diamond burs are placed in small, closed, aluminum boxes for autoclaving; gauze pads and other supply items are wrapped in aluminum foil and sealed with autoclave tape for steam sterilization; sterilization monitoring records are not kept; internal chemical indicators are not used; and there’s no evidence of mechanical or biological monitoring or testing the vacuum sterilizers for proper air removal.

Potential Consequences

Why use instruments that have been heat sterilized? For patient safety! Why monitor the sterilization process? For patient safety!

Not using appropriate sterilization monitoring and not keeping sterilization logs puts patients at unnecessary risk and creates problems should the office ever be investigated by authorities for possible disease spread. It’s no longer sufficient just to perform procedures. The performance needs to be documented.

Sterilization requires that the sterilizing agent (e.g., steam) contact the surface of an instrument for a specified time, and it’s important to use all three monitoring methods to detect this process. For example, if only external indicators (e.g., autoclave tape on the outside of packages) are used, the sterilizer could fail soon after the sterilization temperature is reached, but the autoclave tape will still show black stripes. These packages will likely not be sterile. Mechanical monitoring would have detected this sterilizer failure.

When internal indicators are not used, it’s not known if the sterilizing agent actually entered the packaging material and contacted the instruments. Chemical monitoring gives an immediate indication of exposure to sterilizing conditions. Mechanical monitoring provides an early indication that the sterilizer may not be working correctly. Biological monitoring shows if the process actually kills highly resistant microbes.

Prevention

(Also, see “Strategies” on pages 3-4 for more details)

Keep sterilization logs that include monitoring results to document patient safety efforts. Use mechanical, chemical, and biological monitoring. A Bowie-Dick test (now available for tabletop sterilizers) can determine proper air removal in vacuum type steam sterilizers.

In Dr. P’s office, the presence of internal chemical and/or biological indicators INSIDE of the supply packages would have shown that the steam cannot penetrate aluminum foil.

Some Related CDC Recommendations

- Assign responsibilities for reprocessing of dental equipment to dental healthcare personnel with appropriate training on instrument processing.
- Have manufacturers’ instructions for reprocessing reusable dental instruments/equipment readily available, ideally in or near the reprocessing area.
- Use chemical, mechanical, and biological monitors according to the manufacturer’s instructions.
- Monitor each sterilizer load with mechanical (e.g., time, temperature, pressure) and chemical indicators.
- Place a chemical indicator on the inside of each package. If the internal indicator is not visible from the outside, also place an external chemical indicator on the package.
- Place items/packages correctly and loosely in the sterilizer so as not to impede penetration of the sterilant.
- Do not use instrument packs if mechanical or chemical indicators indicate inadequate processing. Reclean, repack, and rester-
Strategies for Chemical, Mechanical, and Biological Monitoring
(additional details provided elsewhere 

It’s important to use all three sterilization monitoring methods, for they each indicate different things. The chemical and mechanical methods can immediately demonstrate that adequate processing has occurred in each load through the sterilizer. This information along with the evidence that periodic but routine biological monitoring has always shown the death of bacterial spores demonstrates that the instruments from each load are safe to use. (See Table 1, page 6 for a summary chart of Some Causes of Sterilization Failure.)

CHEMICAL MONITORING

– What is it?
Chemical Indicators (CIs) used for chemical monitoring change color or form when exposed to high temperatures or to combinations of time, temperature, and the presence of steam. Examples include autoclave tape, paper strips, tabs, special markings on bags and pouches, and tubes containing colored liquids.

According to the Association for the Advancement of Medical Instrumentation (AAMI), there are six classes of chemical indicators, but three are most commonly used in dentistry.

One is a process indicator usually placed on the outside of packages that changes in the presence of high heat. Examples are autoclave tape and the markings on paper bags and paper/plastic peel pouches.

Other CIs change color or form when exposed to a combination of time and temperature or time, temperature, and the presence of steam. These are multi-parameter or integrating indicators used on the inside of packages to demonstrate if an item has been exposed to sterilizing conditions.

Another type of CI is the Bowie-Dick test, a special type of CI that determines air removal in vacuum steam sterilizers.

– Why is it used?
CIs show if the outside and the inside of packages have been exposed to one or more conditions of sterilization. This is demonstrated immediately upon removing the processed items from the sterilizer.

– How is it used?
An indicator placed on the outside of a package (external indicator) shows if the item has been processed through a heat sterilizer. This helps prevent the intermingling of processed and non-processed packages. If there is even the slightest possibility that items have not been properly processed, they need to be repackaged and resterilized.

A CI is to be placed on the inside of every package and this monitors the penetration of the sterilization agent through the packaging material to the items inside. Opening up an instrument package at chairside and seeing a CI that has changed color gives the operator confidence that the instruments have indeed been processed through the sterilizer and are safe to use (assuming the periodic spore testing has routinely shown spore kills).

Do not use the instrument packages if internal or external CIs suggest inadequate processing. Internal CIs that respond to two or more sterilizing conditions (e.g., time and temperature) provide the most information.

(Continued on page 4)
MECHANICAL MONITORING

– What is it?
Mechanical monitoring measures the physical properties of the sterilizer cycles (e.g., time, temperature, pressure). Remember, it measures the conditions in the sterilizer chamber not inside the packages.

– Why is it used?
Mechanical monitoring gives an immediate indication that certain functions of the sterilizer are or are not working properly (e.g., has the sterilizer reached the correct temperature and maintained that temperature for the proper amount of time).

– How is it used?
Mechanical monitoring gives the earliest indication of sterilizer problems that may later be confirmed by chemical and/or biological monitoring. Some sterilizers provide a printout describing the physical parameters reached for each cycle load. Otherwise the gauges and displays on the sterilizer need to be observed and the results manually recorded. Although correct readings do not guarantee sterilization, incorrect readings indicate that a problem has occurred. Do not use the processed items if mechanical monitoring suggests a sterilizer malfunction. Reclean, repackage, and resterilize the instruments after the reason for the malfunction has been corrected.

BIOLOGICAL MONITORING

– What is it?
Biological Indicators (BIs) used for biological monitoring contain highly resistant bacterial spores (Geobacillus stearothermophilus for steam and unsaturated chemical vapor sterilization or Bacillus atrophaeus for dry heat and ethylene oxide sterilization). They are packaged as small paper strips or tabs containing one or both types of the spores enclosed in protective glassine envelopes. After processing through a sterilizer the strips or tabs are cultured to determine if the spores have been killed.

Another form of BI for monitoring steam sterilization is a small self-contained vial with a vented cap and containing a spore strip or disk and an ampule of growth medium. After processing the vials are squeezed or the cap depressed to break the internal ampule and mix the spores with the growth medium. The unit is then incubated to determine if the spores have been killed. A rapid read-out BI is available. Use of a control BI (from the same lot number as the test BI) that has not been processed through the sterilizer should always show growth. This confirms that the spores used in the testing were indeed alive before being placed in the sterilizer. Spore strips are usually sent away to a sterilization monitoring service or other lab for culturing. The self-contained vials can be cultured and analyzed in the office with the purchase of an incubator.

– Why is it used?
Bacterial spores are the most difficult of all microbes to kill. So if the spores on the BIs are found to not grow (be negative) after being processed through a sterilizer and cultured, then it is assumed that all other microbes also have been killed. Thus, biological monitoring determines the lethality of the sterilization process providing the main guarantee of sterilization.

– How is it used?
For dental office (table-top) sterilizers a BI (along with a CI) needs to be placed inside of a package to be sterilized. This package is considered as the process challenge device (PCD), also referred to as the challenge test pack, and needs to be representative of each type of package being processed. For example if you are processing wrapped instrument cassettes, one of these cassettes is designated as the PCD. Follow the sterilizer manufacturer instructions for use in placement of the PCD containing the test BI and CI in the most challenging position (e.g., in the center of the load or at the bottom near the drain). When BIs are not being used in a given sterilizer cycle, a PCD containing an integrating CI can be used to monitor the process. Besides using BIs in PCDs for the routine (e.g., weekly) monitoring of the use and functioning of each sterilizer, they should also be used:

• whenever a new type of packaging material or wrapping procedure is used (verifies penetration of the sterilizing agent);
• after training of new sterilization personnel (verifies following correct procedure);
• during the initial use of a new sterilizer (verifies proper use and functioning of the sterilizer);
• during the first run of a sterilizer after being repaired (verifies proper use and functioning of the sterilizer);
• after any other change in the sterilizing procedures (verifies proper use and functioning of the sterilizer)\(^1\).
What’s Wrong With This Picture?

Can you identify the breach(es) in infection prevention and safety procedures in this photo taken after completion of a treatment procedure? Check your answer below.

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Answer: The patient has not been given protective eyewear during a procedure that will generate spatter or risk eye injury. The dental assistant is not wearing protective eyewear. The clinician is not wearing an overgown to cover exposed forearms, clothing and microspills. The dental assistant’s overgown is not collared. The protective eyewear should have larger side shields. The clinician is not wearing an overgown to cover spatter or risk eye injury. The dental assistant is not wearing protective eyewear during a procedure that will generate spatter.
### TABLE 1: Some Causes of Sterilization Failure

<table>
<thead>
<tr>
<th>Causes</th>
<th>Potential</th>
<th>Can It Be Monitored With:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inadequate cleaning of instruments</td>
<td>Debris may insulate microbes from the sterilizing agent</td>
<td>No (Visual inspection of the instruments after cleaning helps to monitor this)</td>
</tr>
<tr>
<td>Improper packaging (e.g., excessive or wrong packaging material; closed containers in steam or Unsaturated Chemical Vapor (UCV) sterilizers)</td>
<td>Prevents or retards penetration of the sterilizing agent</td>
<td>Yes (CI, BI)</td>
</tr>
<tr>
<td>Improper loading (e.g., overloading; no separation of packages)</td>
<td>Prevents adequate contact of sterilizing agent with each package</td>
<td>Yes (CI, BI)</td>
</tr>
<tr>
<td>Improper timing of the sterilizer (e.g., operator error; sterilizer malfunction)</td>
<td>Inadequate time to achieve kill</td>
<td>Yes (MI, CI, BI)</td>
</tr>
<tr>
<td>Improper temperature (e.g., operator error; sterilizer malfunction)</td>
<td>Inadequate heat to achieve kill</td>
<td>Yes (MI, CI, BI)</td>
</tr>
</tbody>
</table>


### TEAM HUDDLE DISCUSSION GUIDE

1. Do you understand the use and meaning of all three methods of sterilization monitoring?
2. Are you keeping a log of each sterilizer load including the sterilization monitoring results?
3. Can your office’s sterilization monitoring be improved?

### Links to Resources

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KEY TAKEAWAYS

1. Sterilization monitoring procedures must be performed correctly to ensure that instruments are safe for the Safest Dental Visit™.

2. It's important that all three methods of sterilization monitoring be used.

3. Each type of sterilization monitoring provides different information.

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QUESTIONS FOR ONLINE QUIZ

1. What type of indicator is autoclave tape?
   a. Mechanical
   b. Integrated
   c. Biological
   d. Process

2. What type of sterilization monitoring provides the main guarantee for sterilization?
   a. Mechanical
   b. Biological
   c. External chemical
   d. Internal chemical

3. Where should one or more chemical indicators be placed in a sterilizer load of several paper plastic see-through pouches containing hand instruments?
   a. On the outside of every pouch
   b. On the outside of one pouch
   c. On the inside of every pouch
   d. On the inside of one pouch

4. According to the CDC, how often should a biological indicator be used at a minimum in each sterilizer?
   a. Daily
   b. Weekly
   c. Bi-weekly
   d. Monthly

5. What should be done immediately after a sterilization failure?
   a. Review the sterilizer operating instructions
   b. Take the sterilizer out of service
   c. Retest the sterilizer with a biological indicator
   d. Inform the CDC

6. Where should one or more chemical indicators be placed in a sterilizer load of several instrument cassettes each wrapped in blue sterilization wrap?
   a. On the inside and outside of every cassette
   b. On the inside and outside of one cassette
   c. On the outside of every cassette
   d. On the inside of every cassette

7. How many times should a sterilizer with an initial and repeat positive spore test be rechallenged with a biological indicator in an empty chamber after the cause of the failures has been corrected?
   a. Two
   b. Three
   c. Four
   d. Five

8. What problem cannot be detected with chemical, mechanical, or biological monitoring?
   a. Using excessive packaging material
   b. Overloading the sterilizing chamber
   c. Very low temperature in the sterilizer
   d. Inadequate cleaning of instruments

9. What method of sterilization monitoring gives the earliest indication of a sterilizer problem?
   a. Monitoring with internal chemical indicators
   b. Monitoring with external chemical indicators
   c. Mechanical monitoring
   d. Biological monitoring

10. Which of the following is true about biological monitoring?
    a. Results from mechanical and chemical monitoring of a sterilizer load are available before those of biological monitoring
    b. A control biological indicator should always show no growth of the spores
    c. The same type of spores are used to test both dry heat and steam sterilizers
    d. Fungal spores are used in this type of monitoring

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TEAM HUDDLE HIGHLIGHTS

1. When did you last evaluate your instrument processing procedures?

2. Are you confident that the instruments used on your patients are safe?

Read on!