Dental infection prevention and control is a system of policies and procedures designed to ensure the use of best practices to enhance safety and reduce the risk of transmitting potentially dangerous microbes. An effective infection prevention and control program hinges on assuring the quality of the preventive policies and procedures. This issue provides one approach to performing routine quality assurance related to packaging instruments during reprocessing. Other aspects of instrument reprocessing will be discussed in future issues.

**LEARNING OBJECTIVES**

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

- outline a quality assurance approach to an instrument reprocessing procedure.
- describe the properties of effective sterilization packaging material.
- list important steps in packaging instruments for sterilization.
- describe the type of packaging materials used for steam, unsaturated chemical vapor and dry heat sterilization.
SCENARIO: The Incident

Dr. Linn’s general dentistry practice in a small town has been active for 30 years. After the shutdown during the COVID-19 pandemic, Dr. L decided to sell the practice but specified as part of the sale that the current staff (all having been in the practice for 25 years) be retained by the new owner. As a preliminary approach to purchasing the practice, a potential buyer from out-of-state asked Dr. L to provide third-party documentation of various aspects of the practice before traveling to look over the facility. So, Dr. L hired a consultant to review the practice, interview the staff and provide a written report.

The infection prevention and control aspects of the report described several problems mostly dealing with out-of-date instrument reprocessing procedures and a poor understanding of current Centers for Disease Control and Prevention (CDC) recommendations. This part of the report included:

1. Only exam packs (explorer, probe, mirror and metal napkin chain) were packaged before autoclaving.

2. Exam packs were packaged in older style paper sterilization bags (not self-sealing). Most were closed with a paper clip so the bag could be opened without tearing and reused. Other bags were closed with a single staple. Some instruments were not adequately dried before being packaged. An internal chemical indicator was used in each bag.

3. Other instruments were autoclaved unpackaged in bulk and then placed in paper/plastic peel pouches or paper bags or arranged on metal trays subsequently wrapped with clean blue denim towels.

4. None of the processed instruments/packages were labelled.

POTENTIAL CONSEQUENCES:
It’s quite clear that there has been no quality assurance program in Dr. L’s office. Quality assurance is a systematic process involving monitoring and evaluation of procedures to ensure that a certain quality is being met. To determine the quality of a particular procedure, it’s first important to know WHAT should be done, then WHY and HOW it should be done, and, then, to determine if it is done correctly.

1. Only exam packs (explorer, probe, mirror and metal napkin chain) were packaged before autoclaving.

WHAT: The CDC indicates that before sterilization of critical or semi-critical instruments, the items are to be inspected for cleanliness, then wrapped or placed in containers designed to maintain sterility during storage. Container systems and packaging materials used are to be cleared by the Food and Drug Administration (FDA).

WHY: Proper instrument reprocessing is more than just sterilizing instruments between patients. It allows the delivery of sterile instruments to chairside for use on the next patient. To achieve this, it’s necessary to maintain the sterility of the instruments after they are processed through, and removed from, the sterilizer. Unpackaged items that are processed through a sterilizer have a zero shelf-life.

As soon as the sterilizer door is opened at the end of the cycle, there is potential for immediate recontamination of unpackaged items. They become exposed to dust, salivary spatter or aerosols in the air, by contact...
with moisture, by improper handling, or by contact with contaminated environmental surfaces. The recent COVID-19 pandemic underscored the importance of this as the SARS-CoV-2 virus has been shown to persist in aerosols for at least three hours, and on some surfaces for days under laboratory conditions.²

**HOW:** Package clean, dry, reusable, instruments using appropriate FDA-cleared packaging material prior to placing the instruments in a sterilizer. These FDA-cleared materials have been shown to maintain sterility after sterilization unless some post-sterilization event compromises the integrity of the packaging material.

2. Exam packs were packaged in older style paper bags (not self-sealing). Most were closed with a paper clip so the bag could be opened without tearing and reused. Other bags were closed with a single staple. Some instruments were not adequately dried before being packaged.

**WHAT:** Metal hand instruments, particularly those with pointed or sharp tips, may puncture or tear standard paper sterilization bags. Wet paper bags can be easily torn. Packaging sealing procedures should maintain package integrity. Follow the packaging manufacturer instructions for use (IFU).

**WHY:** If packaging material becomes punctured or torn, the contents are at risk of recontamination, and post-sterilization sterility cannot be maintained. Such packages would need to be re-cleaned, re-packaged and re-sterilized. Closing sterilization packages by stapling punctures the material. Closure with paper clips will not make a good seal. Paper bags and paper/plastic peel pouches are not reusable, but other FDA-cleared materials (e.g., special cloth) may be reusable if indicated by the manufacturer.

**HOW:** Use FDA-cleared packaging materials that can withstand the sterilization process and subsequent handling without being torn or punctured (e.g., wrapped, perforated instrument cassettes or paper/plastic peel pouches). The latter are composed of paper more sturdy than that of some paper bags.

Paper sterilization bags can be used for light-weight non-sharp items such as a bite block or film holder. Do not use safety pins, paper clips, staples or other sharp objects to close packages. Otherwise, paper sterilization bags and wrap can be sealed with sterilization/indicator tape. Paper/plastic peel pouches and some paper bags are self-sealing. Follow the manufacturer IFU.

3. Other instruments were autoclaved unpackaged in bulk and then placed in paper/plastic peel pouches or paper bags or were arranged on metal trays subsequently wrapped with clean blue denim towels.

**WHAT:** The sterility of processed instruments is to be maintained after sterilization until delivered to the point of use. Blue denim towels are not FDA-cleared sterilization materials. Never sterilize unpackaged instruments unless absolutely necessary, and then, only under certain conditions.

**WHY:** While the patient microbes on intraoral instruments have been killed by subsequent cleaning and sterilization, if unpackaged, those instruments can become recontaminated with potentially dangerous microbes from the air (dust, dental aerosols, spatter from the handling staff) and from contact with environmental surfaces.

The weave of non-FDA-cleared cloth such as blue denim towels is too loose to prevent the penetration of microbes, so they cannot be guaranteed to maintain sterility of processed items.

**HOW:** Use FDA-cleared sterilization packaging materials designed for the type of sterilizer and package contents used. For example, some paper/plastic peel pouches used for steam sterilization may come apart if processed through a dry heat sterilizer.

Non-FDA-cleared materials such as plastic bags may melt or not allow the sterilizing agent (e.g., steam, or unsaturated chemical vapor) to penetrate. Aluminum foil, closed glass jars and solid metal boxes also prevent penetration of steam or chemical vapor.

There are special solid sterilization container systems that allow for penetration and exit of steam/air through microbial filtering systems. These are more commonly used in large healthcare sterilizers than in tabletop sterilizers used in dental practices.

4. None of the processed instruments/packages were labelled.

**WHAT:** The CDC indicates that packages for sterilization should be labelled to show the sterilizer used, the cycle or load number, the date of sterilization, and if applicable, the expiration date.⁴ The latter is not needed if event-related storage is used.

**WHY:** Labels help identify and retrieve packages in the event of an instrument processing/sterilization failure. Labels can also be used to identify packages for which the contents are not visible from the outside (e.g., paper bags, wrapped items, sterilization containers).

**HOW:** Labeling information should be written on indicator tape or adhesive labels that remain securely fixed during sterilization and storage. If using a marking pen to label paper/plastic peel pouches, mark on the plastic side. Take care not to penetrate packaging material with the writing device, and don’t use marking that will fade or run during sterilization.

Autoclaving unwrapped instruments was previously known as flash sterilization where the temperature is higher and the exposure time is shorter than standard steam cycles.

This is now referred to as immediate-use steam sterilization, and it is the least satisfactory approach to patient safety for it allows for unnecessary re-contamination of the unwrapped items after sterilization.

It should not be used for routine sterilization of patient care instruments, or for reasons of convenience, as an alternative to purchasing additional instrument sets, or to save time. If used, (e.g., to sterilize an instrument urgently needed for a specific patient and that will be used promptly after removing from the sterilizer), the following conditions apply:

1) thorough cleaning and drying of instruments precedes the unwrapped sterilization cycle;
2) mechanical monitors are checked and chemical indicators are used for each cycle;
3) the sterilizer’s IFU and the device IFU for the immediate use cycle are carefully followed;
4) care is taken to avoid thermal injury to the dental workers and patients;
5) items are handled aseptically during removal from the sterilizer and transport to the point of use.

⁴ Autoclaving unwrapped instruments was previously known as flash sterilization where the temperature is higher and the exposure time is shorter than standard steam cycles.
The goal of instrument packaging is to prevent recontamination of the instruments after sterilization during storage, transport and presentation at the point of use.

**PROPERTIES OF STERILIZATION PACKAGING MATERIAL**

An effective steam sterilization packaging material should, at a minimum:
- allow air to be removed and steam to penetrate and reach the items inside.
- provide a barrier to microorganisms.
- resist tearing or puncture.
- allow a method of sealing that results in a complete seal.
- allow for aseptic presentation at the point of use.
- be free of toxic materials, lint and non-fast dyes.
- be FDA-cleared.

**TYPES OF STERILIZATION PACKAGING MATERIALS FOR SMALL TABLE-TOP STERILIZERS**

The packaging material used with table-top sterilizers must be appropriate for the sterilization method used (Table 1).

Materials such as aluminum foil, freezer bags and some other plastic wraps will not allow steam or chemical vapor penetration. Most cloth materials (unless indicated as a sterilization wrap) are poor microbial barriers. Closed containers for dry heat sterilization are appropriate as long as biological indicators placed inside the container show spore death. Perforated instrument cassettes hold instrument sets during use at chairside, and during cleaning, rinsing, packaging, sterilization, storage and distribution. The cassettes must be wrapped or placed in paper/plastic pouches before sterilization. Always follow the packaging material manufacturer IFU.

Double wrapping allows for a sterile presentation of the inside package at the point of use. Only use paper/plastic peel pouches for which the manufacturer has validated the pouch for this use. If used with a tabletop steam sterilizer, be sure to confirm steam penetration to the inner package with internal biological and chemical monitoring.

**TABLE 1: Types and Uses of Sterilization Packaging Materials**

<table>
<thead>
<tr>
<th>Sterilization Method</th>
<th>Packaging Material</th>
<th>Precautions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Steam</td>
<td>• Sterilization wrap</td>
<td>• No closed containers</td>
</tr>
<tr>
<td></td>
<td>• Paper/plastic pouches</td>
<td>• Some plastics may melt</td>
</tr>
<tr>
<td></td>
<td>• Paper bags</td>
<td>• Heavy cloth may absorb too much steam</td>
</tr>
<tr>
<td></td>
<td>• Wrapped perforated cassettes</td>
<td>• Only use materials approved for steam</td>
</tr>
<tr>
<td>Chemical Vapor</td>
<td>• Paper wraps/bags</td>
<td>• No closed containers</td>
</tr>
<tr>
<td></td>
<td>• Paper/plastic pouches</td>
<td>• Some plastics may melt</td>
</tr>
<tr>
<td></td>
<td>• Wrapped perforated cassettes</td>
<td>• Heavy cloth may absorb too much chemical vapor</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Only use materials approved for chemical vapor</td>
</tr>
<tr>
<td>Dry Heat</td>
<td>• Paper wraps/bags</td>
<td>• Closed containers are OK but check with an internal spore test</td>
</tr>
<tr>
<td></td>
<td>• Polyfilm plastic tubing</td>
<td>• Some plastics may melt</td>
</tr>
<tr>
<td></td>
<td>• Wrapped perforated cassettes</td>
<td>• Some papers may char</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Only use materials approved for dry heat</td>
</tr>
</tbody>
</table>

1. Identify what regulations/recommendations apply.¹, ³, ⁴
2. Make sure the manufacturer instructions for reprocessing dental instruments and equipment are followed and posted in the reprocessing area.
3. Assure all related packaging materials are FDA cleared and comply with CDC guidelines.
4. Confirm that all dental personnel are adequately trained.

5. Identify/prepare a standard operating procedure (SOP) for instrument packaging prior to sterilization.

For example:

- Use appropriate PPE (heavy utility gloves, mask, gown and protective eyewear).
- Confirm that the packaging area is located away from sources of moisture (i.e., the sink).
- Confirm the packaging materials are stored in an area that is at room temperature, normal humidity and away from moisture.
- Confirm the integrity of the packaging material to be used.
- Review and follow the packaging manufacturer IFU.
- Use the correct type of FDA-cleared packaging for the method of sterilization (see Table 1, page 4).
- Ensure the cleaned and dried instruments are wrapped or inserted into the proper packaging.
- Insert a chemical indicator into each package and/or confirm that any paper/plastic pouch used contains its own internal chemical indicator.
- For weekly (or other) biological monitoring, insert a biological indicator into a package to be placed in the most challenging site within the sterilizer chamber according to the sterilizer manufacturer IFU.
- Ensure the packages are properly self-sealed or sealed with indicator tape.
- Check to see if the internal chemical indicator can be seen from the outside, if not, place a chemical indicator on the outside of the package.
- Label each package to show the sterilizer used, the cycle or load number, the date of sterilization, and if applicable, the expiration date.
- Confirm that the label marking used will not run or smear during sterilization.
- Confirm that the packaging has not been penetrated by any labeling device used.

(continued on page 6)
ROUTINE QUALITY ASSURANCE FOR DISEASE PREVENTION AND SAFETY: DURING INSTRUMENT PACKAGING FOR STERILIZATION

PDCA Model
Plan / Do / Check / Act

DO (MEASURE)
☐ 1. Perform the SOP.
☐ 2. Observe the performance by direct observation of all employees. Document in writing or video each step, in detail, by describing/showing what is done, what supplies/equipment are used, who is performing the SOP and when it is being performed.

CHECK (ANALYZE)
☐ 1. Receive feedback from those performing the SOP.
☐ 2. Compare the observations/measurements with the written SOP.
☐ 3. Have the office staff review the measurements and comments from the performing staff.
☐ 4. Determine any differences between the performance and the written SOP.
☐ 5. Identify problems detected.

ACT (IMPROVE)
☐ 1. Brainstorm with the team to find solutions to the detected problems.
☐ 2. Make any necessary changes in the SOP, and confirm that the SOP still provides compliance with the related regulations and recommendations.

ACT (CONTROL)
☐ 1. Institute the new SOP.
☐ 2. Observe the first performance of the new SOP to achieve quality assurance.
☐ 3. Periodically monitor performance and reassess the quality of the procedures if changes occur such as different employees or cleaning crews involved, changes in the products/equipment used or related renovations.

(continued from page 5)
Take the Micro-Learning Silent Video Challenge!

Can you identify the actions in this short video that compromise infection prevention and safety when manually cleaning dental instruments prior to sterilization? osap.org/2020-08video

Challenge your knowledge and compare to the lesson below.

The Scenario: Manual Instrument Cleaning

The Lesson: The dental healthcare personnel (DHCP) is not wearing protective eye-wear during a procedure that has potential for infectious splatter. Also, the DHCP is not wearing puncture- and chemical-resistant/heavy-duty utility gloves for instrument cleaning. Best practices for worker protection were partially adhered to with the use of protective clothing, face mask and (optional) head cover.

Coronavirus Disease (COVID-19) Updates

To help you navigate the many challenges as a result of the COVID-19 pandemic, caused by the SARS-CoV-2 virus, OSAP has assembled an informative webpage with the latest information from regulatory agencies, government, research institutes, dental associations, and health organizations. osap.org/COVID-19

The page is updated regularly and includes information on related best practices, interim guidelines, educational resources, and patient resources.
KEY TAKEAWAYS

1. A quality assurance program helps provide the Safest Dental Visit™.
2. SOPs are an important part of a quality assurance program and need to be written in detail.
3. The goal of instrument packaging is to prevent recontamination of the instruments after sterilization during storage, transport and presentation at the point of use.

Glossary

**Event-related storage**: A storage practice for sterilized packages recognizing that package contents remain sterile until some event causes a breach in the package integrity.

**Standard operating procedures**: Established methods to be followed routinely for the performance of designated tasks.

TEAM HUDDLE DISCUSSION GUIDE

1. Do your instrument packaging procedures support compliance with FDA and CDC?
2. Is your packaging SOP up-to-date?
3. Should you perform a quality assurance process on your instrument packaging procedures?

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Links to Resources

What’s Wrong With This Picture?

Can you identify the breach(es) in infection prevention and safety in this photo showing use of a high-speed handpiece during a dental procedure?

**Answer:** It looks like the dental assistant is not wearing long sleeved protective outerwear. During aerosol generating procedures, high-volume evacuation and dental dams are recommended to minimize droplet spatter and aerosols. Patient use of a pre-procedural mouth rinse (PPMR) is suggested as it may reduce the level of oral microorganisms in aerosols and spatter generated during dental procedures.

Although COVID-19 was not studied, PPMRs with an antimicrobial product (chlorhexidine gluconate, essential oils, povidone-iodine or cetylpyridinium chloride) may reduce the level of oral microorganisms in aerosols and spatter generated during dental procedures.*


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**Educational Spotlight**

**The OSAP Virtual Conference**

**August 13-15, 2020**

Be part of timely education and opportunities for engagement at OSAP’s first-ever virtual conference

1. Connect with sponsors, exhibitors, and innovative thinkers in dental infection prevention, occupational health, and patient safety from across the globe.

2. You will have the ability to interact in real-time with the speakers for question/answer.

3. Daily, **live-streamed** sessions will start at 10:00 AM and end around 5:30 PM. This reimagined event celebrates our collective resilience and dedication to forging connections without boundaries.

4. Earn CE credits for participation in live-streamed sessions. With your registration, you will also have access to on-demand recordings of the sessions for one (1) year. (Note: CE credits will not be available for watching the recordings).

**There’s Still Time to Join Us!** Registration remains open!

Learn more at [osap.org/2020annualconf](http://osap.org/2020annualconf) 

**We are happy to help!** For further assistance, please contact us at office@osap.org, or 1(410) 571-0003 US & Canada: 1(800) 298-6727
GET YOUR CE CREDIT ONLINE  OSAP is recognized by the American Dental Association as a CERP provider.*

Follow the instructions below to complete the quiz to receive 1 hour of CE credit FREE to OSAP members

Step 1: Go to http://bit.ly/OSAPICIPAUG2020CE and obtain access to the CE exam through the OSAP Store. OSAP members, 1 CE credit FREE! Non-members, 1 CE credit $20.

Step 2: OSAP will send you a registration confirmation email and a separate email with the link to the online CE exam. Click on that link to access the exam.

Step 3: Complete the online exam. You have 2 attempts to pass with 7 out of 10 correct answers. When finished, you can print out or download your CE record of completion for your records. Your record of completion will also be emailed to you.

QUESTIONS FOR ONLINE QUIZ

1. What is the least desirable property of an effective steam sterilization packaging material?
   a. Being air-tight
   b. Being lint-free
   c. Being resistant to tearing
   d. Being a barrier to microorganisms

2. Why should paper bags for steam sterilization not be stapled for closure?
   a. It's too costly
   b. The staple will rust
   c. It's too time consuming
   d. It punctures the packaging material

3. What governmental agency clears sterilization packaging material to be sold in the U.S.?
   a. CDC
   b. FDA
   c. EPA
   d. OSHA

4. Which of the following dental items is best placed in paper sterilization bags?
   a. Scaler
   b. Explorer
   c. Bite block
   d. Amalgam carrier

5. What should be used to secure sterilization wrap around an instrument cassette?
   a. Indicator tape
   b. Safety pin
   c. Paper clip
   d. Staple

6. When should immediate-use steam sterilization be used?
   a. To save money on sterilization packaging material
   b. To routinely save time with the shorter cycle time
   c. To avoid purchasing additional sets of instruments
   d. To sterilize an urgently needed instrument that will be used promptly after sterilization

7. What should be used to package an instrument cassette for steam sterilization?
   a. A closed metal container
   b. Sterilization wrap
   c. Aluminum foil
   d. Freezer bags

8. What sterilization packaging material will be destroyed during dry heat sterilization?
   a. Paper/plastic peel pouches
   b. Closed metal containers
   c. Polyfilm plastic tubing
   d. Paper bags

9. What step in a quality assurance process for the sterilization packaging procedure involves preparing or identifying the related SOP?
   a. Plan
   b. Do
   c. Check
   d. Act

10. What is a key step in an SOP for packaging instruments for sterilization?
    a. Use aluminum foil to package items for steam sterilization
    b. Place small items in a closed glass vial for unsaturated chemical vapor sterilization
    c. Ensure each package contains an internal chemical indicator
    d. Double staple paper bags for closure before dry heat sterilization

*ADA CERP is a service of the American Dental Association to assist dental professionals in identifying quality providers of continuing dental education. ADA CERP does not approve or endorse individual courses or instructors, nor does it imply acceptance of credit hours by boards of dentistry. Concerns or complaints about a CE provider may be directed to the CE provider or to the ADA Commission for Continuing Education Recognition Program (CERP) at ADA.org/cerp. Please email the OSAP central office at office@osap.org or call 410-571-0003 if you wish to be in contact with the course author/creator(s) with any questions or for clarification of course concepts. All participants assume individual responsibility for providing evidence of contact hours of continuing education to the appropriate authorities and for the maintenance of their individual records. Publication date: August 2020. Expiry date: August 2023.
QUICK BITES

FROM THE Editor’s Desk

BEST PRACTICES for Infection Control in Dental Practices During the COVID-19 Pandemic

As DHCP continue to navigate these uncharted waters, OSAP and DentaQuest Partnership for Oral Health Advancement (DQP), is pleased to announce a new living document to assist in implementing interim guidance.

OSAP and DQP are proud to provide this tool to assist all DHCP in making every dental visit a safe visit.

*Best Practices for Infection Control in Dental Practices During the COVID-19 Pandemic* is a checklist to assist DHCP with implementing interim guidance provided by CDC, ADA, ADHA, and OSHA.

It’s referred to as a “living” document because updates will be made as interim guidance changes. This document is made available, complimentary, for all DHCP, thanks to educational funding provided by DentaQuest Partnership for Oral Health Advancement.

The checklist was created by OSAP Board Member Karen Gregory, RN, and a team of nationally and internationally recognized dental infection prevention and safety subject matter experts. Designed as a fillable PDF, the checklist is printable and mobile-friendly.

Educational Certificate UPDATE

The OSAP-DALE Foundation Dental Infection Prevention and Control Certificate Program™ is intended for everyone on the dental team, plus educators, consultants, dental sales representatives, and state dental board investigators and inspectors.

Features of the Certificate Program:

- Based on related CDC guidelines and OSHA standards and aligned to the Master Curriculum Elements developed by ADA, AGD, AADB, AADA, ADEA, DANB, OSAP, and CDC
- Available online and can be completed within your own schedule
- Contains links to additional evidence-based sources for more advanced learning

<table>
<thead>
<tr>
<th>Step</th>
<th>Component</th>
<th>Cost</th>
<th>CE Credits</th>
</tr>
</thead>
<tbody>
<tr>
<td>1*</td>
<td>OSAP-DALE Foundation CDEA® module Understanding CDC’s Summary of Infection Prevention Practices in Dental Settings</td>
<td>$30 6-month access</td>
<td>2</td>
</tr>
<tr>
<td>2*</td>
<td>OSAP-DALE Foundation Dental Infection Prevention and Control eHandbook™</td>
<td>$225 6-month access</td>
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</tr>
<tr>
<td>3</td>
<td>OSAP-DALE Foundation eHandbook Assessment™</td>
<td>$50 60-day access</td>
<td>0</td>
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</tbody>
</table>

*Note: Steps 1 and 2 may be completed in either order. Successful completion of Steps 1 and 2 is required before Step 3 can be purchased.*

For the latest information visit: [dentalinfectioncontrol.org](http://dentalinfectioncontrol.org)

In Case You Missed This!

The Official OSAP Podcast with Michelle Lee, Executive Director of OSAP, who will be bringing you infection control tips and information with subject matter experts.

Check out the NEW home of the The Official OSAP Podcast with Michelle Lee, Executive Director of OSAP, who will be bringing you infection control tips and information with subject matter experts.

Connect to “The Official OSAP Podcast” here, on your favorite podcast platform, or from the OSAP.org home page.