Infection Prevention & Control
Instrument Processing and Sterility Assurance

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Disclosure

The information in this webinar is current as of January 7, 2021.

I have no financial interest in any products that may be included in this presentation. Any products included are for representative purposes only.

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Neither I nor members of my immediate family have any financial interests to disclose relating to the content of this presentation.

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Learning Objectives

- Describe the steps in instrument processing and sterility assurance
- Explain the acceptable methods of packaging and sterilizing instruments
- Identify the methods of mechanical, chemical and biologic monitoring for sterile processing.

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Sterilization and Disinfection of Patient Care Items Overview

- Works best using a systematic approach
  - Methodical approach that is repeatable and learnable through a step by step procedure.
  - Each step must be completed in the same sequence each time for the process to be successful.
  - Requires an element of quality assurance to monitor success of the process.
    - Quality assurance tools can be used to help decrease the incidence of error . Ex: monitoring, SOP's, and checklists.

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Instrument Processing and Sterility Assurance

Regulations, guidelines, and standards

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Occupational Safety and Health Administration (OSHA)

- Bloodborne Pathogens Rule
  - 29CFR 1910.1030
- Addresses issues related to employee safety while performing sterilization procedures
  - PPE
  - Labeling
  - Containers for sharps
- Information and resources at:
  www.osha.gov/SLTC/bloodbornepathogens/index.html

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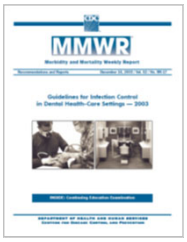
Centers for Disease Control and Prevention (CDC)

- Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008
  cdc.gov/hicpac/pdf/guidelines/Disinfection_Nov_2008.pdf
- Guidelines for Infection Control in Dental Health-Care Settings — 2003
  cdc.gov/mmwr/PDF/rr/rr5217.pdf



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AAMI/ANSI Standards

Association for the Advancement of Medical Instrumentation (AAMI)

- Develops standards related to the sterilization and disinfection of instruments and devices used in healthcare
  - Addresses processes, facilities, environment, personnel, safety, and others

American National Standards Institute (ANSI)

- Oversees the creation of thousands of norms and guidelines that directly impact businesses in nearly every sector.
- Often adopts AAMI standards rather than develop separate, overlapping standards

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Standards for Sterilization and Disinfection

- Steam Sterilization – ANSI/AAMI ST79:2017
- Chemical Indicators – ANSI/AAMI/ISO 15883: 2008/(R)2013
- Table-top Dry Heat Sterilization – ANSI/AAMI ST40:2004/(R)2010
- Chemical Sterilization and HLD – ANSI/AAMI ST58:2013
  - *Purchase standards documents or volunteer for standards development at: www.aami.org/standards*

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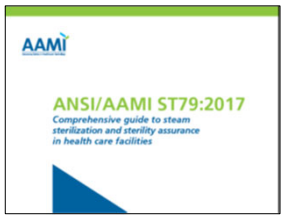
Steam Sterilization

ANSI/AAMI ST79

- Comprehensive guide to steam sterilization and sterility assurance in health care facilities
- Considered the definitive resource for sterilization, this comprehensive guide to steam sterilization in healthcare facilities covers all aspects of facility design, personnel and instrument reprocessing procedures.



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Spaulding's Classification for Patient Care Items

Category	Definition	Reprocessing	Examples
Critical	Penetrate soft tissue or bone	Sterilization	Surgical instruments, periodontal scalers
Semicritical	Contact mucous membranes or non-intact skin	Sterilization or high-level disinfection	Hand instruments, Reusable impression trays, mouth mirror
Noncritical	Contact intact (unbroken) skin	low- to intermediate-level disinfection	X-ray head/cone, Blood pressure cuff

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Issues with Spaulding's Classification

- Some semicritical instruments may not be suitable for heat sterilization or immersion in high level disinfectants
  - Dispensing "syringes"
  - Digital x-ray sensors
  - Intraoral sections of dental technology devices
    - Digital impression devices

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Semicritical Items
Special Considerations—Digital Sensors

- Follow manufacturer's instructions to safely reprocess digital radiography equipment.
- Ideally, barrier protection should be used, followed by cleaning and heat sterilization or high-level disinfection between patients.
  - If the item cannot tolerate these procedures, then at minimum, barrier protection should be used, followed by cleaning and disinfection with an intermediate-level disinfectant between patients.

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FDA Statement on Dental Dispensers (5/16/2016)

- **DO:**
  - Apply disposable barrier sleeves/wraps over multiple-use dental dispensers before use with each patient.
  - Use new, uncontaminated gloves when handling.
  - Utilize dental assistants to dispense material for the dentist
  - Avoid contact of the reusable parts with the patient's mouth.
- **DO NOT:**
  - Reuse the multiple-use dental dispenser if it becomes contaminated.
  - Reprocess a contaminated multiple-use dental dispenser by using chemical wipes or disinfectants.
  - Immerse multiple-use dental dispensers in a high level chemical disinfectant.
  - Sterilize multiple-use dental dispensers.

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CDC Statement on Reprocessing Dental Handpieces – April 11, 2018

- Clean and heat sterilize handpieces and other intraoral instruments that can be removed from the air lines and waterlines of dental units.
- For handpieces that do not attach to air lines and waterlines, use FDA-cleared devices and follow the validated manufacturer's instructions for reprocessing these devices.
- If a dental handpiece cannot be heat sterilized and does not have FDA clearance with validated instructions for reprocessing, do not use that device.

CDC Statement on Reprocessing Dental Handpieces

www.cdc.gov/oralhealth/infectioncontrol/statement-on-reprocessing-dental-handpieces.htm April 11, 2018

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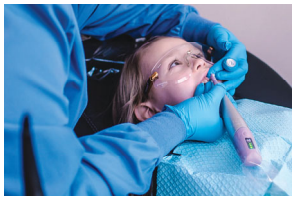
Cordless Handpieces



- Independent of air and water lines on dental unit
- Need to follow manufacturer IFU for reprocessing

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Burs and Endodontic Files -- FDA

- Can be difficult to clean
- Cleaning and heat sterilization can lead to deterioration of the cutting edge
- FDA considers all diamond-coated burs and scaler tips single-use unless their manufacturers have submitted a 510(k) for reprocessing
  - FDA maintains a searchable database for 510(k) premarket notifications, where this information would be found at www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm
- Always refer to manufacturer instructions to determine if a device is single-use
- ***If a device does not have validated reprocessing instructions, it is considered single-use***

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Manufacturer's IFU

- Device manufacturers are responsible for validating a processing IFU that includes; cleaning, packaging and sterilization procedures.
- CMS audit regulations state…"*If manufacturer's instructions are not followed, then the outcome of the sterilizer cycle is guesswork, and the practice should be citied as a violation of 42 CFR 416.44(b)(5).*"

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Single-Use (Disposable) Devices

- Intended for use on one patient during a single procedure.
- Usually not heat-tolerant.
- Cannot be reliably cleaned.
- Do **NOT** reprocess.
- Examples: syringe needles, prophylaxis cups, and plastic orthodontic brackets.

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Instrument Processing

- Follow manufacturer's instructions for reprocessing (i.e., cleaning, packaging, disinfecting, sterilizing) reusable dental instruments and equipment.
  - Maintain manufacturer's instructions (ideally) in or near the reprocessing area.
- Use FDA-cleared devices and supplies for cleaning, packaging, and heat sterilization.
- Should be assigned to DHCP with training in the required reprocessing steps.

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Instrument Processing and Sterility Assurance

Sterilization Area Workflow

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Instrument Processing Area

- Use a designated processing area to control quality and ensure safety.
- Divide processing area into work areas:
  - Receiving, decontamination, and cleaning.
  - Preparation and packaging.
  - Sterilization.
  - Storage.
- Devices and instruments should flow from high contamination areas to clean and sterile areas.

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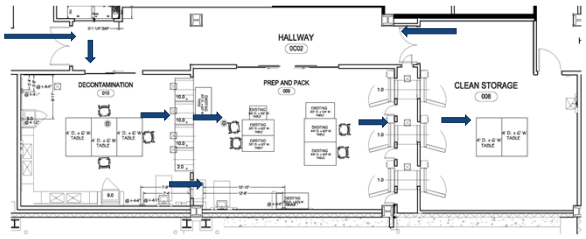
Large Facility Workflow



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Ventilation for Reprocessing Areas

- Air pressure differentials help control cross contamination
- Negative air pressure
  - Allows for air to flow into a room, but not out of a room
- Positive air pressure
  - Increase in air flow to push air out of a room, preventing the introduction of contaminants
- Soiled rooms should be negative pressure
- Clean rooms and sterile storage should be positive pressure
- Doors, pass-through windows must remain closed except during use

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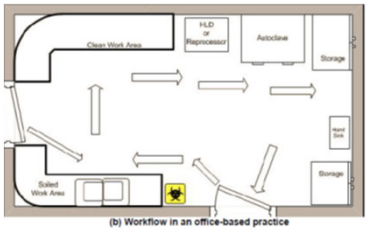
ANSI/AAMI Workflow Diagram for Office-based Sterilization



(b) Workflow in an office-based practice

Figure 2—Workflow

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Consider Workflow When Planning

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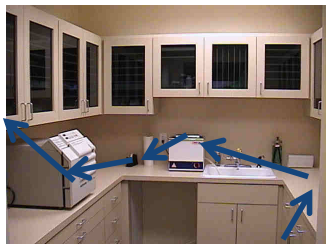
Proper Workflow Prevents Errors



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Ventilation for Non-hospital Settings

- Procedural barrier separation may be adequate
  - Work practices implemented to prevent splashing and/or aerosol contamination of clean work areas
  - Changing of PPE when personnel move from decontamination to perform clean activities, such as high level disinfection
  - Ventilation and air handling systems move air from clean to contaminated side of the room.

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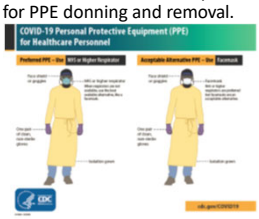
Train DHCP in use of PPE

- Follow recommended sequences for PPE donning and removal.



www.cdc.gov/coronavirus/2019-ncov/hcp/using-ppe.html

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Personal Protective Equipment (PPE)

- Protective attire should be worn to protect the personal clothing and skin from exposure to saliva, blood, aerosol, and other contaminants.
- Puncture-resistant, heavy-duty utility gloves should be worn when transporting and cleaning contaminated instruments.
- Reusable gloves should be cleaned and disinfected at least daily and discarded when they become worn.

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Transport of Contaminated Instruments AAMI/ANSI

- Prior to transportation, items contaminated with blood and other potentially infectious materials should be placed in a container that is puncture-resistant, leak-proof on the bottom and sides, labeled as biohazardous, and sealed.

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Transport of Instruments

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Transport of Instruments

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Pre-soak/Pre-spray

- Optional step in the cleaning process
  - For difficult to clean items
  - If cleaning will be delayed
  - Generally recommended by AAMI
- Follow manufacturer's IFU for mixing, storage, shelf life and disposal
  - Usually contain detergent or enzymatic cleaner

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Cleaning

- Cleaning should always occur before disinfection or sterilization.
  - Presence of soil can compromise the disinfection or sterilization process.
- Automated or manual.
- Minimize exposure potential.
- Use carrying containers to transport contaminated instruments.
- Wear personal protective equipment (e.g., heavy duty utility gloves, mask, protective eyewear and clothing).

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Ultrasonic Cleaning

- Sound waves create cavitation
  - Cavitation dislodges debris from instruments
- Follow manufacturer's instructions for use and degassing of liquids
- Change solutions regularly
- Do not overfill with instruments

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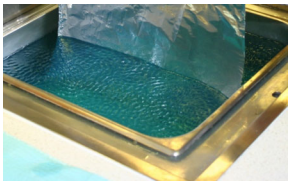
Ultrasonic Cleaner Cavitation Check



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Ultrasonic Cleaners - Additional Recommendations

- Request performance verification test methods from the ultrasonic equipment manufacturer.
- Perform cavitation testing daily whenever the equipment is in use.
- Prior to using it, degas the solution in accordance with the ultrasonic equipment manufacturer's IFU.
- Avoid placing plastics and soft metal in the ultrasonic cleaner.
- Keep the lid closed when the ultrasonic cleaner is in use unless otherwise directed by the device manufacturer's written IFU.

ANSI/AAMI ST79

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Instrument Washers

Washers

Washers/Disinfectors

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Verifying Cleaning Efficacy of Washer/Disinfectors

- At a minimum, instruments should be individually inspected and be visibly clean (CDC).
- Commercially available soil removal tests (daily and weekly)
- Consult washer manufacturer's IFU for testing frequency

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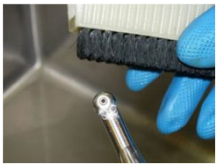
Sensitive Instruments and Devices

- Carefully remove debris with brush
- Wear utility gloves, gown and face protection
- Package and sterilize
- Also use manual cleaning for any residual debris after use of an ultrasonic or instrument washer



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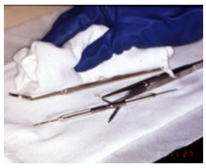
Preparing Instruments

- Dry instruments carefully
- Remove debris that was not cleaned mechanically
- Wear heavy-duty gloves and other PPE to process instruments



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Preparation and Packaging

- Wrap, package, or place instruments in containers before heat sterilization.
  - Instruments should be thoroughly dry before they are packaged, wrapped, or otherwise contained.
- Follow manufacturer's instructions.
  - For example: open hinged instruments, disassemble instruments if required, and ensure that packaging materials are compatible with the method of heat sterilization being used.

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Preparing and Packaging

- Check each instrument for proper function and lubricate as required by the instrument manufacturer.
- Hinged instruments with stiff joints may be a sign of inadequate cleaning.

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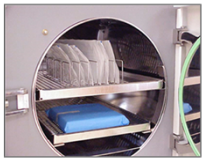
Preparing and Packaging

- Instrument packaging should be done in a clean and low contamination area, using FDA cleared products, such as sterilization pouches and/or sterilization wrap.



Special Note: Sterilization of *unwrapped* instruments is not recommended due to the risk of contamination after sterilization. Immediate-use steam sterilization (IUSS), formally known as *flash* sterilization should only be used when packaging is not possible and the instruments are used immediately upon removal from the sterilizer.

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Sterilization Pouches

- Sterilization pouches are ideal for packaging loose instruments and small, lightweight items.
- Paper/plastic pouches allow you to see the contents and come with a build in adhesive strip for sealing.
- It is important to remove all excess air, prior to sealing the sterilization pouch.

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Sterilization Wrap

- Ideal for cassettes or large trays
- Follow wrap manufacturer's instructions for use
- Avoid wrapping too tightly or too loosely
- Single vs. double wrapping
- Woven and nonwoven
- If marking, write on tape or label

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Package Labeling

- Sterilizer ID number or code
- Detailed list of the contents
- ID of person who assembled the package
- Date of sterilization
- Cycle number
- For IUSS items include patient identifier
- Expiration date, if applicable

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Package Labeling

Event-related storage
- "contents sterile unless package is opened or damaged, please check before using."
- Relies on proper storage and handling of packs
- Most commonly recommended

Time-related storage
- Expiration date
- Establishes time limit for sterile storage
  - Based on manufacturer IFU

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Instrument Processing and Sterility Assurance

Sterilization

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Sterilization Processes in Dentistry

- Steam under pressure (Autoclave)
  - Gravity
  - Dynamic air removal
- Chemical vapor
- Dry Heat (Static or convection)

Steam | Chemical vapor | Rapid Heat Transfer

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Steam Sterilization

- There are two (2) types of steam sterilizers:
- **Gravity displacement** (250°F/121°C for 30 min exposure, or 270°F/132°C for 15 min exposure, plus drying)
- **Dynamic air removal** (270°F/132°C for 4 min exposure, or 275°F/135°C for 3 min exposure, plus drying).

Special Note: These cycles are standard steam cycles recommended by AAMI. Dynamic air removal steam sterilizers available in pre-vacuum and steam-flush pressure pulse (SFPP) designs. In Europe, table-top, pre-vacuum steam sterilizers are referred to as "Class B" type sterilizers.

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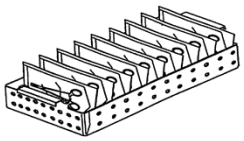
Loading the Sterilizer

- Light items on top
- Heavy items on the bottom
- Peel pouches (on edge)
- Perforated wrapped trays (flat)
- Solid wrapped trays (on edge)



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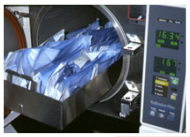
Loading the Sterilizer

- To assist sterilization and aid drying, place pouches facing each other and on edge.
- Perforated cassettes should lie flat and solid cassettes should be placed on edge
- A basket or stand may be used to keep packages upright
- Using trays…light items on top tray, heavy items on the bottom



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Unloading Sterilizers

Large volume (>2 cubic feet)

- Allow items to cool to room temperature
- Do not touch items during cooling
- Do not transfer to cold metal racks or shelves for cooling

Table-top sterilizers

- Allow items to cool before handling—follow mfg. IFU for whether or not to open the door to reduce potential condensation
- Do not transfer warm items to cold metal racks or shelves
- Do not touch packs during cooling

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Sterilization and Disinfection of Patient Care Items

High level disinfection

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Chemicals cleared for processing reusable dental devices

- Glutaraldehyde (various concentrations)
- Glutaraldehyde with phenol/phenate
- Hydrogen peroxide
- Hydrogen peroxide with paracetic acid
- Orthophthaldehyde (various concentrations)
- Glutaraldehyde with isopropanol
- Hypochlorite and Hypochlorous acid
  - Some products are for use with specific processing devices only

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Liquid Chemical Sterilant/HLD

- Only for heat-sensitive critical and semi-critical devices
- Use of glutaraldehyde is discouraged
- Heat tolerant or disposable alternatives are available
- Cannot be monitored for sterility assurance
- Some equipment manufacturers still recommend their use in equipment IFU

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Considerations for Chemical Sterilants/HLD

- Shelf life
  - Some products may be labeled single use for sterilization or multiple use for disinfection
- Temperature
- Label of immersion container
  - Compliance with Hazard Communication Standard
- Ventilation
- Disposal as a hazardous waste (varies by local regulations)

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HLD Ventilation -- OSHA

- Best Practices for Safe Use of Glutaraldehyde in Health Care (OSHA 3258-08N 2006)
  - no fewer than 10 air exchanges per hour (consistent with ANSI/AAMI), or;
  - Use of local exhaust hood, or;
  - Ductless exhaust hood, or;
  - Use of automated systems.

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Use of Sterilant/HLD

- rinsed with sterile water after removal to remove toxic or irritating residues;
- handled using sterile gloves and dried with sterile towels; and
- delivered to the point of use in an aseptic manner
- If stored before use, the instrument should not be considered sterile and should be sterilized again just before use
- sterilization process with liquid chemical sterilants cannot be verified with biological indicators
  - using heat-sensitive semicritical items that must be processed with liquid chemical germicides is discouraged

CDC

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Instrument Processing and Sterility Assurance

Quality assurance and monitoring

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Sterilization Monitoring: Types of Indicators

- Mechanical:
  - Measures time, temperature, and pressure.
- Chemical:
  - Change in color when physical parameter is reached.
- Biological (spore tests):
  - Uses biological spores to asses the sterilization process directly.
- Indicators are specific to the type of sterilization used.

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Mechanical Monitoring

- Monitor each load with mechanical (physical) indicators:
  - Time.
  - Temperature.
  - Pressure.

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Chemical Monitoring

- Use an internal chemical indicator in every package. If the internal indicator is not visible from the outside, then also use an external indicator.
  - Chemical indicators may be integrated into the package design.
- Inspect indicator(s) after sterilization and at time of use.
- If the appropriate color change did not occur, do not use the instruments.

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Chemical Monitoring

• AAMI Standards list (6) types of chemical indicators:

• Type 1	Process indicator for use on the exterior of packages.
• Type 2	For use in specific tests procedures, *i.e. Bowie-Dick type test to* check for proper air removal of pre-vacuum steam sterilizers.
• Type 3	Single-variable indicator that reacts to one critical variable, i.e. time or temperature.
• Type 4	Multi-variable indicator that reacts to 2 or more critical variables.
• Type 5	Integrating indicator that reacts to all critical variables and is equal in performance to a biological indicator.
• Type 6	Emulating indicator that reacts to all critical variables for a specified sterilization cycle.

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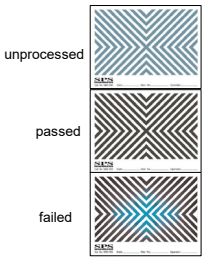
Air Removal Test (pre-vacuum sterilizers)

- Daily Test Procedure

1. Run a shortened cycle (no dry time) to heat up the sterilizer.
2. Place a Bowie-Dick type test pack in the sterilizer, flat on the lowest shelf over the drain without a load.
3. Run a 134°C/273°F for 3.5 minutes cycle with little or no dry time.
4. Remove the test pack and examine the chemical indicator sheet.

- The sterilizer passes the air removal test if the indicator sheet has a uniform color change, i.e.. the center of the sheet is the same color as the edges.



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Chemical Monitoring

- Process Challenge Device (PCD)
  - Recommended by AAMI/ANSI ST79 as optional for each load (non-implants)
  - Consist of one of the following:
    - a BI
    - a BI with a type 5 integrating indicator
    - a Type 5 integrating indicator
    - a Type 6 emulating indicator

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PCD Configuration and Placement

- Place Type 5 integrating indicator in the geometric center of a wrapped cassette or tray, or the center of a pouch of instruments.
- The test pack should be placed in the center of a load
- Upon removal of the load, check the indicator before releasing the load
- The use of a PCD does not eliminate the need to include a CI inside each pack of instruments

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Biologic Monitoring

- Biological indicators (also called spore tests) come in paper strips and in plastic vials. Sterilizers should be spore tested at least weekly and every load that contains an implant. If they can not pass the spore test, the sterilizer should be serviced and not placed back into service until 3 tests are passed.

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Sterilization Monitoring

Spore testing is considered the "gold standard" for sterility assurance when performed correctly. The type of spore used depends on the sterilizer (Steam and Chemical vapor = *Geobacillus stearothermophilus*, Dry heat = *Bacillus atropheus*). The incubation temperature varies depending on the spore (56˚C versus 37˚C) and the incubation time varies depending on the Manufacturer (10 hours to 7 days).

Most sterilizer failures are due to human error, rather than equipment malfunction. Common causes include; running the sterilizer from a cold start, over-loading the chamber, improper packaging and selecting the wrong cycle.

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Record Keeping

- Sterilization monitoring (e.g., biological, mechanical, chemical) and equipment maintenance records are important components of a dental infection prevention program.
- Ensures cycle parameters have been met and establishes accountability.
- If there is a problem with a sterilizer, documentation helps to determine if an instrument recall is necessary.

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Sterilizer Maintenance Record

Should be maintained for each sterilizer and include:

- Date of service request
- Model and serial number
- Location of equipment (larger facilities with multiple locations)
- Name of person who requested and authorized the service
- Reason for service
- Description of service provided
- Types and quantities of parts replaced
- Name of service person
- Date of work completion
- Signature of person acknowledging completion of work
- Results of any post-maintenance testing

How many Biologic Monitoring tests should be done following sterilizer service/repair?

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Sterilization and Disinfection of Patient Care Items

Storage of sterile packs

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Storage of Sterile and Clean Items and Supplies

- Store clean items in dry, closed, or covered cabinet.
- Use date- or event-related shelf-life practices.
- Examine wrapped items carefully before use.
- When packaging of sterile items is damaged, clean, repackage, and heat sterilize again.

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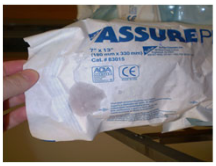
Inspect Packs After Cycle is Complete

- External indicator should have changed
- Packs should be dry
- Packs should be intact
- Packs that do not meet these criteria are considered nonsterile and should be reprocessed beginning with decontamination



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Use of fans to dry instrument packs

- According to ST79, packs should not be removed from sterilizer until drying is complete
- Wet packs can absorb contamination
- Fan may spread contamination from surrounding surfaces (floors, walls, etc.)

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Air Flow, Temperature and Humidity -- Storage

- AAMI/ANSI recommends:
  - Approximately 24°C (75°F)
  - At least 4 air exchanges per hour
  - Relative humidity not to exceed 70%

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Sterile Storage

- Sterile items should remain packaged for storage and be stored in a manner that reduces the potential for contamination or damage
- Proper storage areas include; cabinets or drawers that are clean, dry and closable.

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Event-related Storage of Sterile Instruments

- Shelf life dependent on:
  - Quality of packaging material
  - Storage conditions
  - Conditions during transport
  - Amount of handling
- Written policies and procedures
  - How shelf life is determined
  - How shelf life is indicated on packaging
- Probability of contamination increases over time and with increased handling

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Certification

IAHCSMM

- Certified Registered Central Service Technician (CRCST)
  - Preparation via online course, distance learning course, self-study preparation, work experience.

CBSPD

- Five levels of certification
  - Technician
  - Surgical instrument specialist
  - Flexible endoscope reprocessor
  - Ambulatory surgery technician
  - Management

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Summary/Takeaways

- Sterilization and disinfection of patient care items is critically important to patient safety
- Errors in process or skipping steps can result in improperly or incompletely sterilized or disinfected items
- Standard operating procedures for each step of the process, training and monitoring can reduce the chance of errors, improving patient safety

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Resources

- CDC. *Guidelines for Infection Control in Dental Health-Care Settings—2003*
- CDC. *Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008*
- CDC. *Summary of Infection Prevention Practices in Dental Settings: Basic Expectations for Safe Care*
- Resources to use in the event of a reprocessing error or failure:
  - CDC. Health Care-Associated Infections website: Outbreaks and Patient Notifications
  - Patel PR, et al. Developing a broader approach to management of infection control breaches in health care settings. *Am J Infect Control*. 2008;36:685–690.
  - Rutala WA, et al. How to assess risk of disease transmission to patients when there is a failure to follow recommended disinfection and sterilization guidelines. *Infect Control Hosp Epidemiol*. 2007;28:146–155.

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COVID-19 Toolkit & Best Practices Document

OSAP has assembled a toolkit with the latest information from regulatory agencies, government, research institutes, dental associations, and health organizations.

Visit: www.osap.org/COVID-19

OSAP/DQP Best Practices for Infection Control in Dental Clinics During the COVID-19 Pandemic

Visit: www.osap.org/covid-19-best-practices

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OSAP-DALE Foundation Dental Infection Prevention and Control Certificate Program™

Step*	Component	CE Credits
1	OSAP-DALE Foundation CDEA® module - Understanding CDC's Summary of Infection Prevention Practices in Dental Settings	2
2	OSAP-DALE Foundation Dental Infection Prevention and Control eHandbook™	10
3	OSAP-DALE Foundation eHandbook Assessment™	0

**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.*

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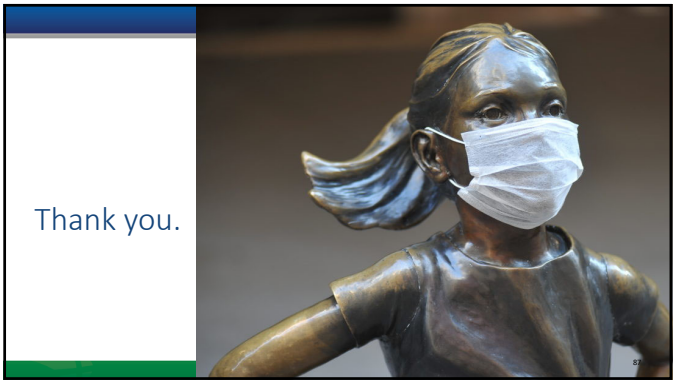

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