Module F

PRINCIPLES OF DISINFECTION AND STERILIZATION IN THE DENTAL SETTING

OBJECTIVES

- State the principles of disinfection and sterilization
- List the current methods for disinfection and sterilization per CDC guideline recommendations

SPAULDING CLASSIFICATION

Spaulding Classification of Surfaces:

1. **critical** – Objects which enter normally sterile tissue or the vascular system and require sterilization
2. **semi-critical** – Objects that contact mucous membranes or non-intact skin and require high-level disinfection, which kills all but high-levels of bacterial spores
3. **non-critical** – Objects that contact intact skin but not mucous membranes, and require low-level disinfection

ORDER OF RESISTANCE OF MICROORGANISMS TO DISINFECTANTS/STERILANTS

Hardest to Kill

Easiest to Kill

Prions (Creutzfeldt-Jakob Disease (CJD), mad cow disease)

Spores (*C. difficile)*

Mycobacteria (Tb)

Non-enveloped viruses (norovirus)

Fungi (*Candida)*

Vegetative bacteria (MRSA, VRE)

Enveloped viruses (HIV, HBV)

PROCESSING CRITICAL INSTRUMENTS

- Penetrate or enter normally sterile tissue or spaces, including the vascular system
  - Surgical instruments (elevators, bone files, rongeurs, forceps, etc.)
- Must be sterilized between uses or used as single-use disposable devices
- Goal: Sterility = devoid of all microbial life

PROCESSING SEMI-CRITICAL OBJECTS

- Contact mucous membranes and non-intact skin
  - Mouth mirrors, cheek retractors, handpieces
- Must be sterilized or immersed in high-level disinfectant
- Goal: High-level disinfection = free of all microorganisms except low numbers of bacterial spores

HIGH-LEVEL DISINFECTANTS

Germicide	Concentration
Glutaraldhyde (Cidex®)	≥ 2.0%
Ortho-phthaladehyde (Cidex OPA®)	0.55%
Hydrogen Peroxide* (Sporox™)	7.5%
Hydrogen Peroxide and peracetic acid* (Peract™)	1.0% / 0.08%
Hydrogen Peroxide and peracetic acid* (Endospor™ +)	7.5% / 0.23%
Hypochlorite (free chlorine)* (Sterilox)	650-675 ppm
Accelerated hydrogen peroxide (Resert™ XL)	2.0%
Peracetic Acid (Steris 20™)	0.2%
Glutaraldehyde and Isopropanol (Aldahol III®)	3.4% / 26%
Glutaraldehyde and phenol/phenate (Sporicidin®)	1.21% / 1.93%

Exposure time ≥8 -45 min (US) and temperature 20-25°C;
*May cause cosmetic and functional damage

NON-CRITICAL INSTRUMENTS AND DEVICES

- Contact intact skin
  - BP cuffs, electrocardiogram (EKG) leads, stethoscopes
- Disinfect using a low level disinfectant
- Goal: Kill vegetative bacteria, fungi, viruses

LIQUID DISINFECTANTS

Disinfectant Agent	Use Concentration
Ethyl or isopropyl alcohol	70% - 90%
Chlorine (bleach)	100ppm
Phenolic	UD
Iodophor	UD
Quaternary ammonium compound (QUAT)	UD
Improved hydrogen peroxide	0.5%, 1.4%

Exposure time ≥ 1 minute

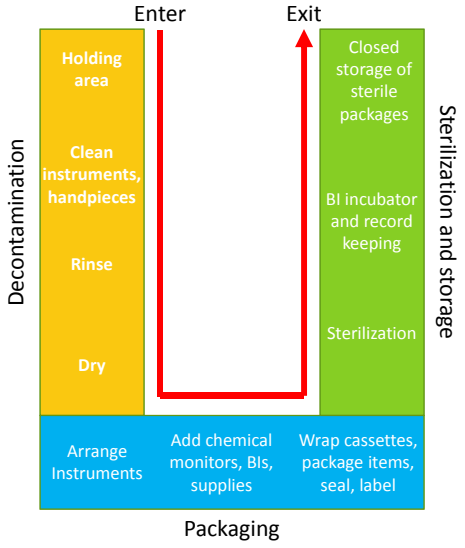
UD = Manufacturer's recommended use dilution

STERILIZATION PROCESS

FACTORS INFLUENCING THE EFFICACY OF DISINFECTION AND STERILIZATION PROCESSES

- Cleaning of the object
- Organic and inorganic load present
- Type and level of microbial contamination
- Concentration and exposure time to the disinfectant/sterilant
- Nature of the object
- Temperature, pH, and water hardness

WHERE ARE YOU PROCESSING YOUR INSTRUMENTS?



CLEANING INSTRUMENTS

- Soak in enzymatic or non-enzymatic detergent
- Wear the appropriate PPE
- Keep instruments submerged in solution and use a long-handled brush when manually cleaning instruments

AUTOMATED CLEANING

- Ultrasonic cleaner
- Instrument washer
- Washer-disinfector
- Regulated by FDA
- Household dishwasher NOT recommended

PREPARATION AND PACKAGING

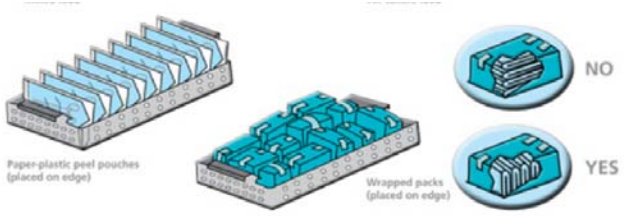
- Critical and semi-critical items that will be stored should be wrapped before heat sterilization
- Hinged instruments opened and unlocked
- Place a chemical indicator inside the pack
- Wear heavy-duty, puncture-resistant utility gloves

PACKAGING

- Peel packs
- Rigid containers
- Self seal roll stock
- Sterile wraps woven and non-woven
- Compatible with sterilization method
- Must be FDA approved

LOADING

- Place items/packages correctly and loosely into the sterilizer so as not to impede penetration of the sterilant
- Peel packs and non-perforated containers (e.g., basins) should be placed on their edge



STERILIZATION

The complete elimination or destruction of all forms of microbial life by either physical or chemical processes.

METHODS OF STERILIZATION

High Temperature Methods:

- Steam sterilization
- Dry Heat
- Steam formaldehyde (chemiclave)

Low Temperature Methods:

- Hydrogen peroxide gas plasma
- Vaporized hydrogen peroxide
- Ethylene oxide

STEAM STERILIZATION

Advantages

- Non-toxic
- Cycle easy to control and monitor
- Inexpensive
- Rapidly microbicidal
- Rapid cycle time
- Least affected by organic/inorganic soils
- Penetrates medical packing, device lumens

STEAM STERILIZATION

Disadvantages

- Deleterious for heat labile instruments
- Inappropriate for heat-sensitive instruments
- Inappropriate for moisture-sensitive instruments
  - Dulling
  - Rusting
- Potential for burns

STEAM STERILIZATION

Steam under pressure (autoclaving)

- Gravity displacement
- Pre-vacuum

PROCESS TIMES FOR PACKAGED ITEMS

Method	Time (minutes) Does not include drying time	Temperature Range, °C (°F)
Steam autoclave		
Gravity	30	121-123°C (250-254°F)
	15	132-135°C (270-275°F)
Prevacuum	4	132-135°C (270-275°F)

DRY HEAT STERILIZATION

- Transfers heat energy from air inside the oven to the instruments
- Requires higher temperatures 160-190°C (320°-375°F)
- Good for items that are likely to dull or rust in the autoclave,
- Good for powders, cellulose and ink
- Packaging must be able to withstand high temperatures

DRY HEAT STERILIZER TYPES

Static Air

- Heating coils in bottom of chamber
- Natural convection as hot air rises in chamber
- Takes 1-2 hours for sterilization at 160°C

Forced Air

- Rapid heat transfer
- Circulates heated air at high velocity throughout chamber
- Reduces time to 6-12 minutes at 190°C

UNSATURATED CHEMICAL VAPOR STERILIZATION

- Hot chemical vapors (under pressure) kill microorganisms
- Active ingredient: formaldehyde+
- Vapors extremely irritating to eyes and lungs
- Purge system and good ventilation essential
- “Harvey” sterilizer or “Chemiclave”
- No corrosion is instruments are dry
- Must use packaging designed for chemical vapor sterilizers

LIQUID CHEMICAL STERILANT/DISINFECTANTS

- Only for heat-sensitive critical and semi-critical devices
- Powerful, toxic chemicals raise safety concerns

http://www.fda.gov/cdrh/ODE/germlab.html

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ReprocessingofSingle-UseDevices/ucm133514.htm

STORAGE OF STERILE ITEMS

- Ensure the sterile storage area is a well-ventilated area that provides protection against dust, moisture, and temperature and humidity extremes.
  - 8 inches from the floor
  - 5 inches from ceiling
  - 18 inches from ceiling if sprinkler
  - 2 inches from outside walls
- Sterile items should be stored so that packaging is not compromised.
- Label sterilized items with a load number that indicates the sterilizer used, the cycle or load number, and the date of sterilization.

STORAGE OF STERILE ITEMS

- Event-related shelf life recognizes that the product remains sterile until an event causes it to become contaminated (e.g. moisture).
- Packages should be evaluated before use for loss of integrity. Repack and reprocess if compromised.

RECOMMENDATIONS METHODS OF STERILIZATION

- Cleaning removes salts and proteins and MUST precede sterilization.
- Steam is preferred for critical and semi-critical items not damaged by heat
- Follow the operating parameters recommended by the manufacturer
- Use an “FDA cleared” container, wrapping or packaging system that is compatible with the type of sterilization process used
- Use low temperature sterilization technologies for reprocessing critical and semi-critical items damaged by heat
- Immediately use critical items that have been sterilized by liquid sterilants (e.g. peracetic acid) immersion process (no long term storage).

Monitoring the effectiveness of your sterilization equipment is essential!

STERILIZATION MONITORING

- Physical - cycle time, temperature, pressure
- Chemical - heat or chemical sensitive inks that change color when germicidal-related parameters reached
- Biological - *Bacillus* spores that directly measure sterilization

MONITORING OF STERILIZERS

Internal Chemical Indicator

- Validates the sterilant penetrated the pack or tray
- Detect local problem

BIOLOGICAL MONITORS

- Steam - *Geobacillus stearothermophilus*
- Dry heat - *B. atrophaeus (formerly B. subtilis)*
- Ethylene oxide (ETO) - *B. atrophaeus*

RECOMMENDATIONS
MONITORING OF STERILIZERS

- Monitor each load with physical and chemical (internal and external) indicators.
- Use biological indicators to monitor effectiveness of sterilizers at least weekly with spores intended for the type of sterilizer.
- Use biological indicators for every load containing implantable items

RECOMMENDATIONS
MONITORING OF STERILIZERS

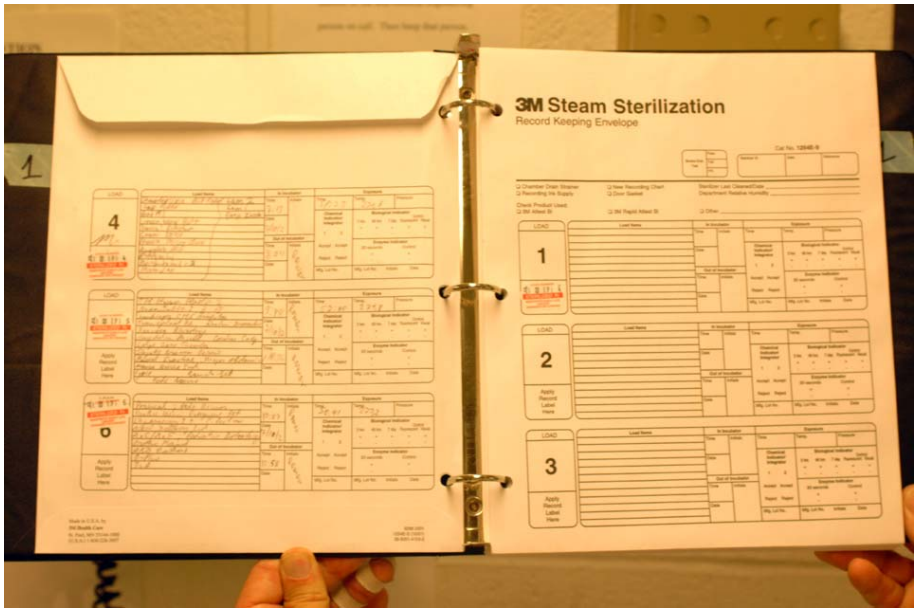
Following a single positive biological indicator from steam sterilization:

- Remove the sterilizer from service and review sterilizer instructions.
- Retest the sterilizer.
- If spore test negative, put the sterilizer back in service.
- If the spore test is positive: do not use until it has been inspected; and recall (to the extent possible) all items processed since the last negative spore test; challenge in three consecutive empty sterilization cycles.

Single positive biological indicator (BI) from other than steam sterilization (e.g., dry heat sterilization)

- Treat as non-sterile all items back to last load tested with negative indicator.
- Retrieve items and reprocess.

Record-Keeping



FAILURE TO FOLLOW DISINFECTION AND STERILIZATION PRINCIPLES

WHAT DO YOU DO?

Scenario:

Dental Office A discovered that for the past 3 days all surgical instruments were exposed to steam sterilization at 132°C for 0 minutes rather than the intended 4 minutes. A technician turned the timer to 0 minutes in error.

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Original research article

Assessing the risk of disease transmission to patients when there is a failure to follow recommended disinfection and sterilization guidelines

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STEPS IN THE EVENT OF DISINFECTION AND STERILIZATION FAILURE

1. Confirm failure of disinfection or sterilization reprocessing
2. Immediately embargo any possibly improperly disinfected/sterilized items
3. Do not use the questionable disinfection/sterilization unit (sterilizer, automated endoscope reprocessor) until proper functioning has been assured.
4. Inform key stake holders (risk management, management, lawyers)
5. Conduct a complete and thorough evaluation of the cause of the disinfection/sterilization failure
6. Prepare a line listing of potentially exposed patients
7. Assess whether the disinfection/sterilization failure increases a patient's risk for infection
8. Inform an expanded list of stakeholders of the reprocessing issue
9. Develop a hypothesis for the failure and initiate corrective actions
10. Develop a method to assess potential adverse patient events
11. Consider notification of appropriate state and federal authorities (health department, FDA)
12. Consider patient notification
13. If patients are notified, consider whether such patients require medical evaluation for possible post exposure therapy with appropriate anti-infectives, as well as follow-up and detection of infections (HIV, Hepatitis B and C) if warranted.
14. Develop a detailed plan to prevent similar failures in the future
15. Write after-action report.

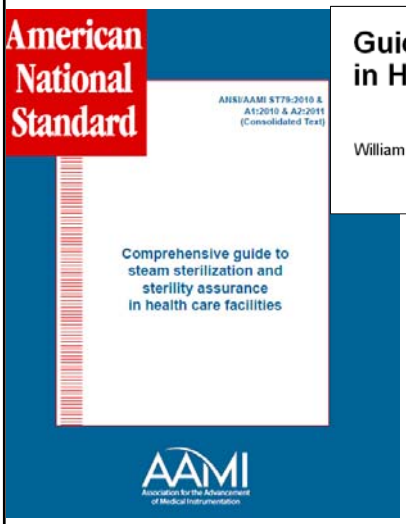
RECOMMENDATIONS FOR QUALITY CONTROL

- Provide comprehensive and intensive training for all staff assigned to reprocess medical/surgical instruments
- To achieve and maintain competency:
  - Staff receive hands-on training
  - Work with supervision until competency is documented
  - Competency testing should be conducted at commencement of employment and regularly
  - Review written reprocessing instructions to ensure compliance

RECOMMENDATIONS FOR QUALITY CONTROL

- Conduct infection control rounds periodically
- Establish a maintenance contract and record of service.
- Ensure protocols equivalent to guidelines from professional organizations
- Consult Association for the Advancement of Medical Instrumentation (AAMI) and/or manufacturer for preparation and packing of items

RESOURCES



Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008

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Infection Control Practices Advisory Committee (HICPAC)[3]

Thank You