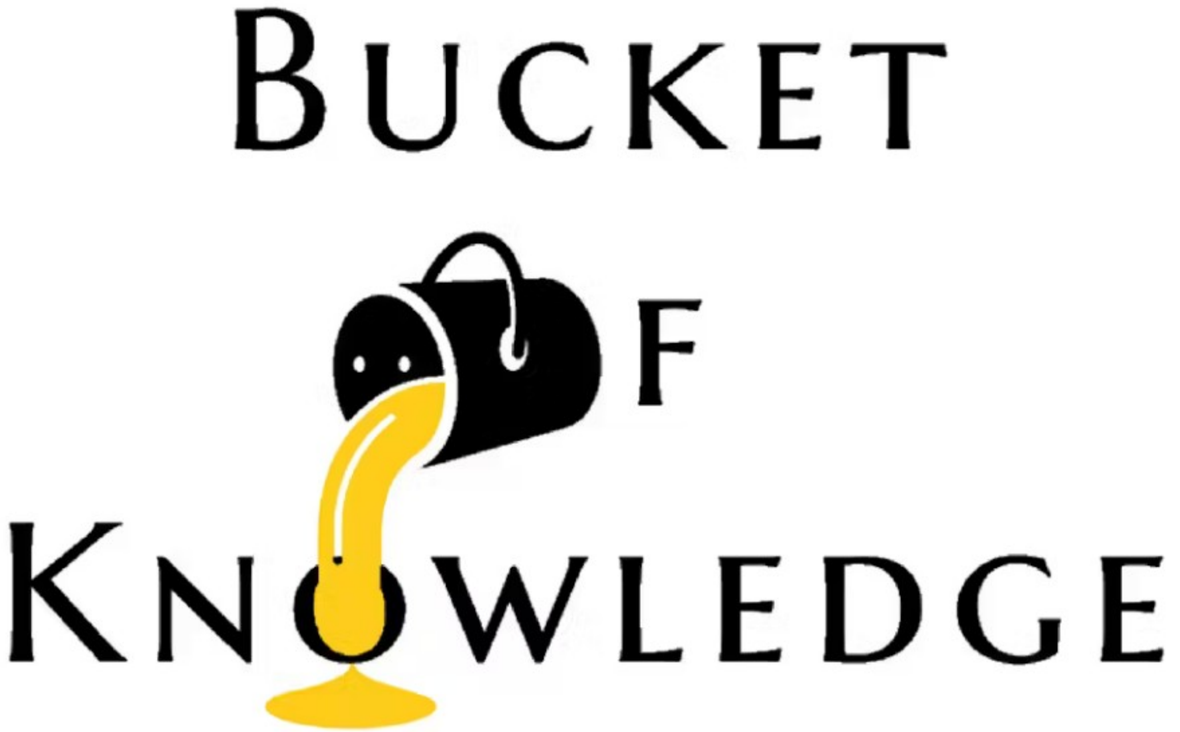
Mentimeter

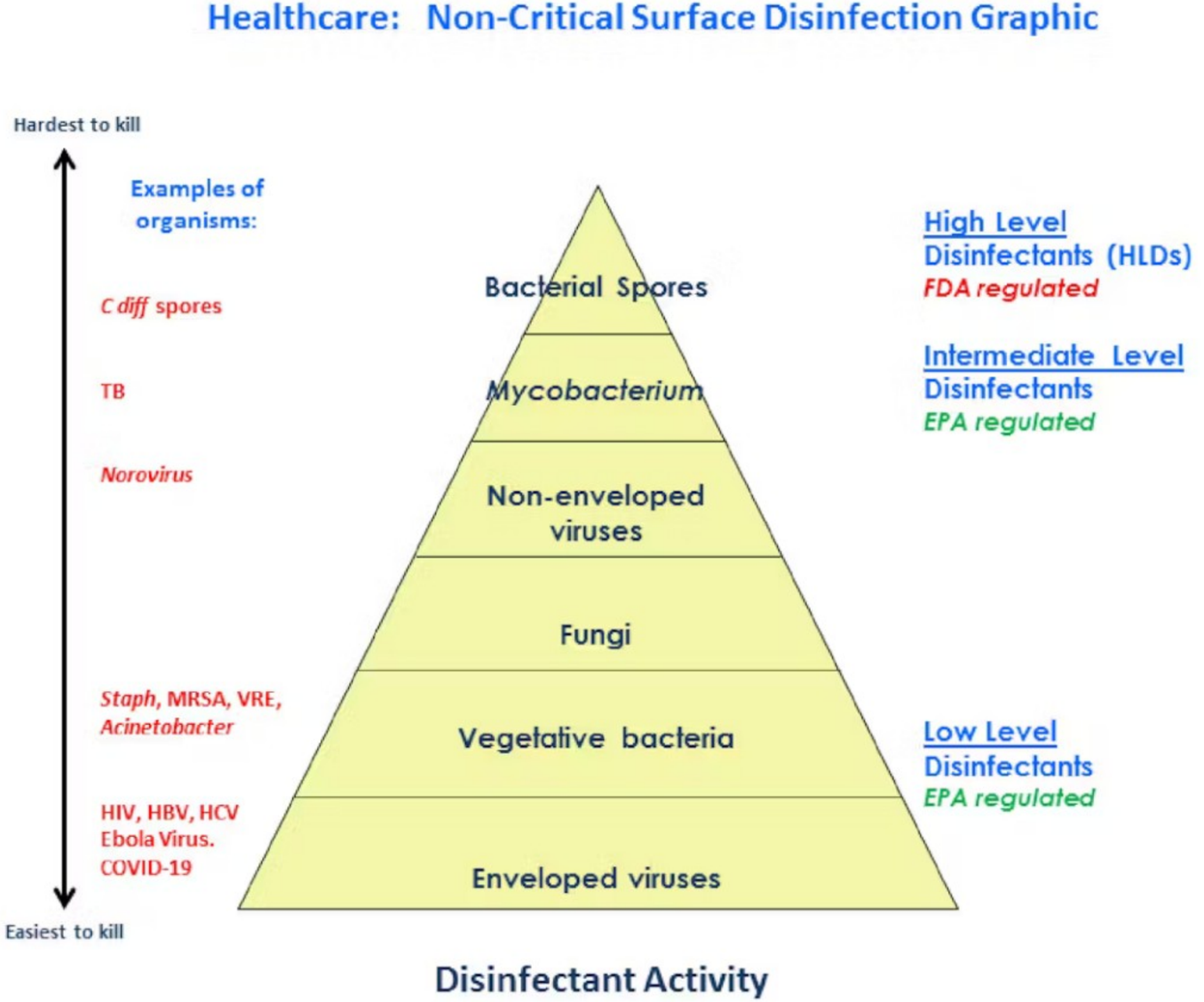
Disinfection, Sterilization, Immediate Use Sterilization and Eye Instruments!



Objectives

Upon completion, participants will be able to:

1. Describe Spaulding criteria and examples
2. Describe what immediate use sterilization is and when it is recommended to be utilized
3. Describe the special precautions needed and related clinical complications that can result when improperly reprocessing eye use instruments



Cleaning, Disinfection, Sterilization

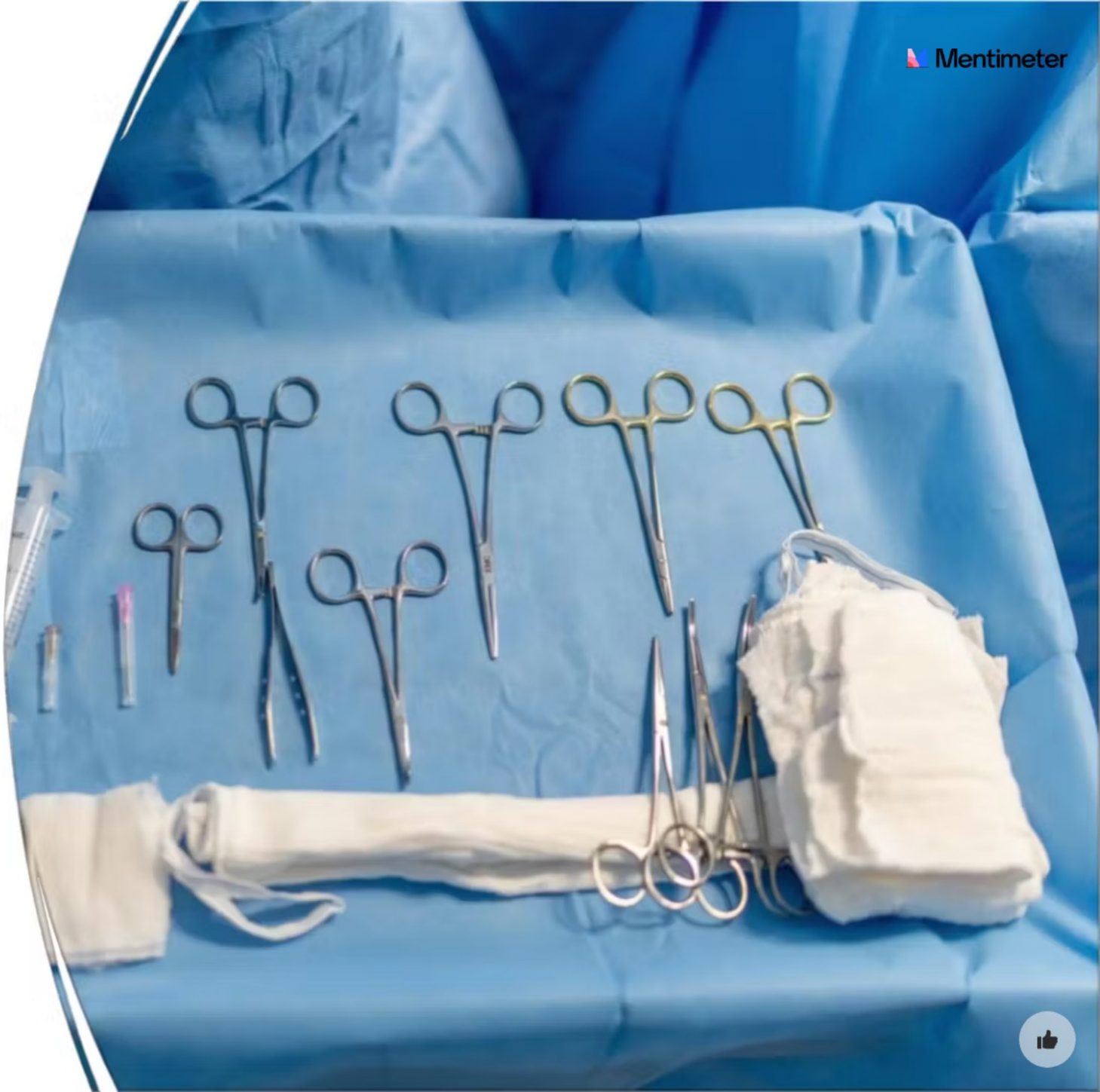
- Environmental surfaces are cleaned and disinfected using:
  - Low-level disinfectants (EPA regulated)
  - Intermediate-level disinfectants (EPA regulated)

Spaulding Classification Criteria

Spaulding Classification	Medical Device Contacts	Risk of Infection Transmission	Disinfection Level
Critical	Sterile tissue or the bloodstream	High	Sterilization
Semi-critical	Mucous membranes or non-intact skin	Medium	High Level Disinfection (HLD)
Non-critical	Intact skin only	Low	Intermediate level (ILD) or Low level disinfection (LLD)

Activity: Spaulding Classification

- Critical, semi-critical or non-critical?
- How should they be reprocessed?



Activity: Spaulding Classification

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- Critical, semi-critical or non-critical?

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Methods for Disinfection and Sterilization

Process	Level of Microbial Inactivation	Method	Examples (with processing times)	Health Care Application (examples)
Sterilization	Destroys all microorganisms, including bacterial spores	High temperature	Steam (~40 min), dry heat (1-6 hr depending on temperature)	Heat-tolerant critical (surgical instruments) and semicritical patient-care items
		Low temperature	Ethylene oxide gas (~15 hr), hydrogen peroxide gas plasma (28-52 min), ozone (~4 hr), hydrogen peroxide vapor (55 min)	Heat-sensitive critical and semicritical patient-care items
		Liquid immersion	Chemical sterilants include*: >2% gluteraldehyde (~10 hr); 7.35% Hydrogen Peroxide with Parecetic Acid (3 hr)	Heat-sensitive critical and semicritical patient-care items that can be immersed

APIC Text, Chapter 31: Table 31-1 Methods for Disinfection and Sterilization of Patient-Care Items and Environmental Surfaces

Methods for Disinfection and Sterilization

Process	Level of Microbial Inactivation	Method	Examples (with processing times)	Health Care Application (examples)
High-level disinfection (HLD)	Destroys all microorganisms except high numbers of bacterial spores	Heat-automated	Pasteurization (65-77°C, 30 min)	Heat-sensitive semicritical items (e.g., respiratory therapy equipment)
		Liquid immersion	Chemical sterilants/HLDs include*: >2% glut (10-90 min); 0.55% OPA (12 min); 7.35% HP with 0.23% PA (15 min); 650-675 ppm chlorine (10 min); plus others	Heat-sensitive semicritical items (e.g., GI endoscopes, bronchoscopes, endocavitary probes)

Source: APIC Text, Chapter 31: Table 31-1 Methods for Disinfection and Sterilization of Patient-Care Items and Environmental Surfaces

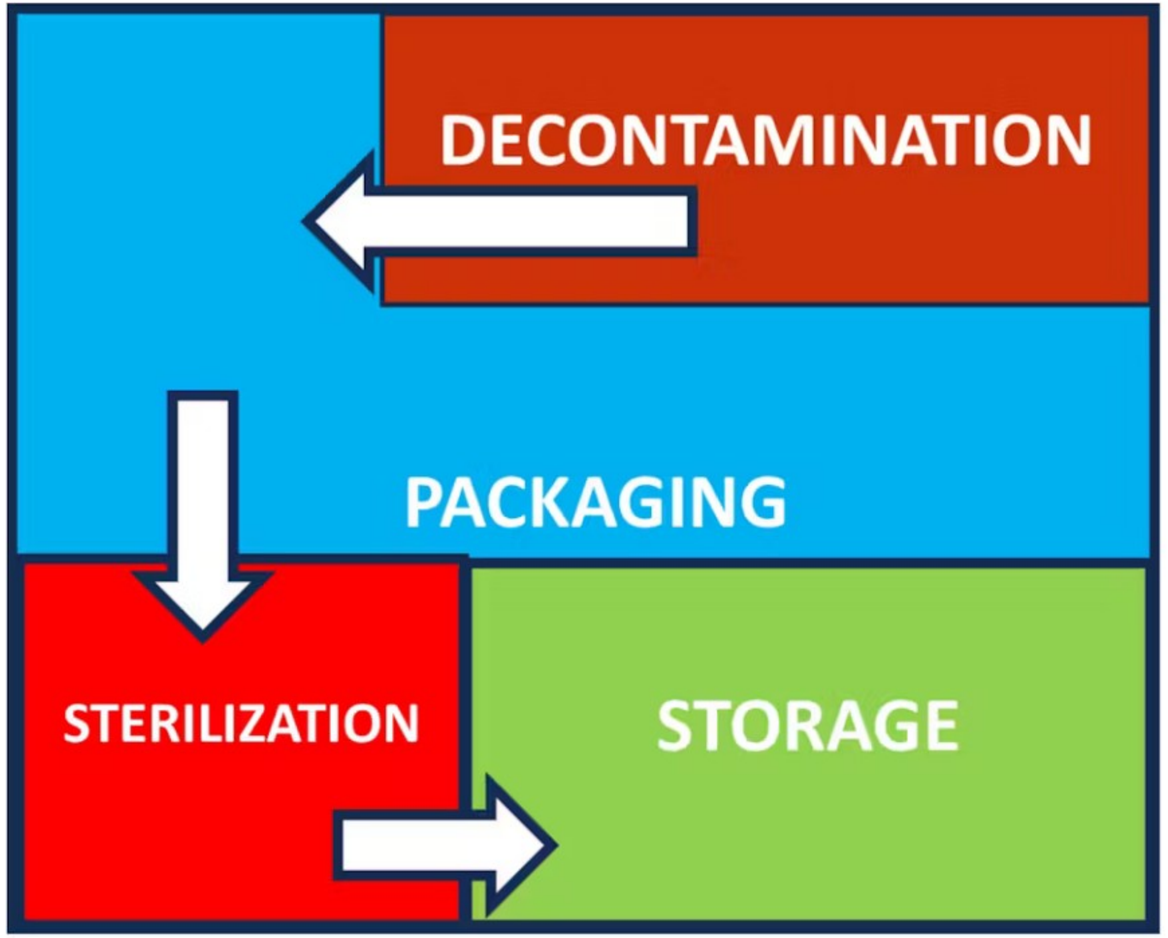
Methods for Disinfection and Sterilization

Process	Level of Microbial Inactivation	Method	Examples (with processing times)	Health Care Application (examples)
Intermediate-level disinfection	Destroys vegetative bacteria, mycobacteria, most viruses, most fungi but not bacterial spores	Liquid contact	EPA-registered hospital disinfectant with label claim regarding tuberculocidal activity (e.g., chlorine-based products, phenolics, improved hydrogen peroxide-exposure times at least 1 min)	Noncritical patient care item (blood pressure cuff) or surface with visible blood
Low-level disinfection	Destroys vegetative bacteria, some fungi and some viruses but not mycobacteria or spores	Liquid contact	EPA-registered hospital disinfectant with no tuberculocidal claim (e.g., chlorine-based products, phenolics, improved hydrogen peroxide, quaternary ammonium compounds-exposure times at least 1 min) or 70-90% alcohol	Noncritical patient care item (blood pressure cuff) or surface (bedside table) with no visible blood

Source: APIC Text, Chapter 31: Table 31-1 Methods for Disinfection and Sterilization of Patient-Care Items and Environmental Surfaces

Central Sterile Processing Department Flow

- Begin in “decontamination" where items are decontaminated and cleaned by staff wearing PPE for protection
- Watch 26-minute video by Dr. Rutala for step-by-step description of the department and equipment and indicator use (biological and chemical) for test prep
- https://Spice.unc.edu/video-library/ ("Hospital Tours: CPD")

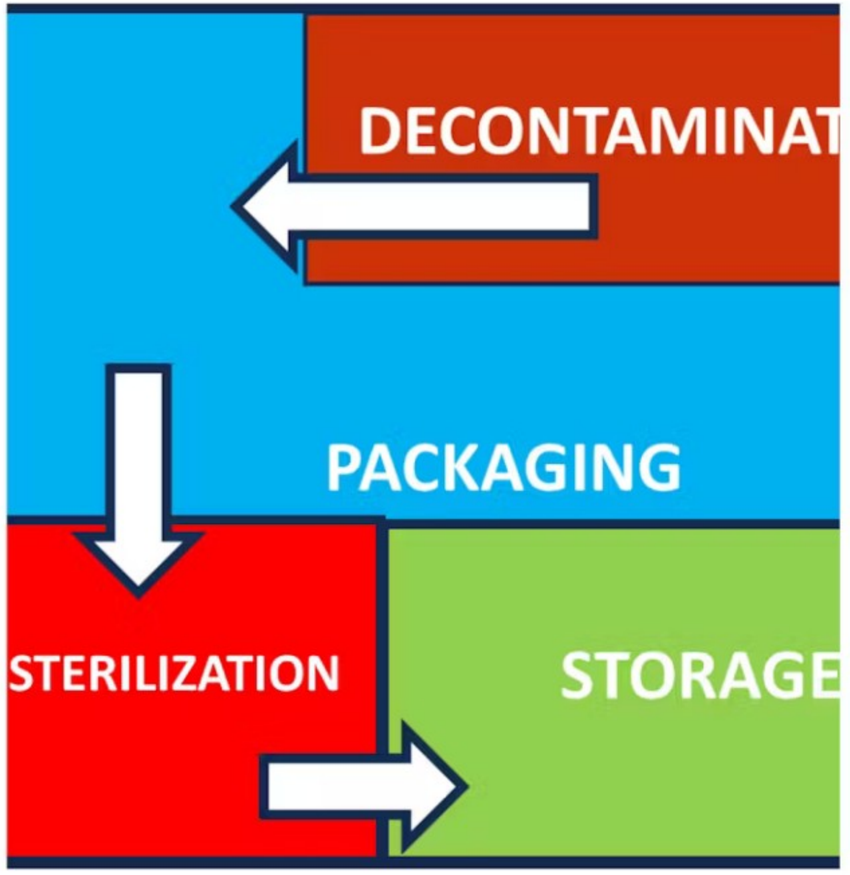


Decontamination Process

- Begins at **point of use**; gross soil and debris wiped away with gauze/water
- Transportation reminders: puncture-resistant, leakproof, sealable, biohazard label
- PPE is required to be worn by staff in this area
- Contaminated items received here and are decontaminated to make them safe for handling by performing "prewash" procedure
- Blood, visible contamination is removed during prewash using a spray and then soaking in an enzymatic solution for several minutes
- Then rinsed again and either washed by hand with detergent and friction or by an automated washer/disinfector

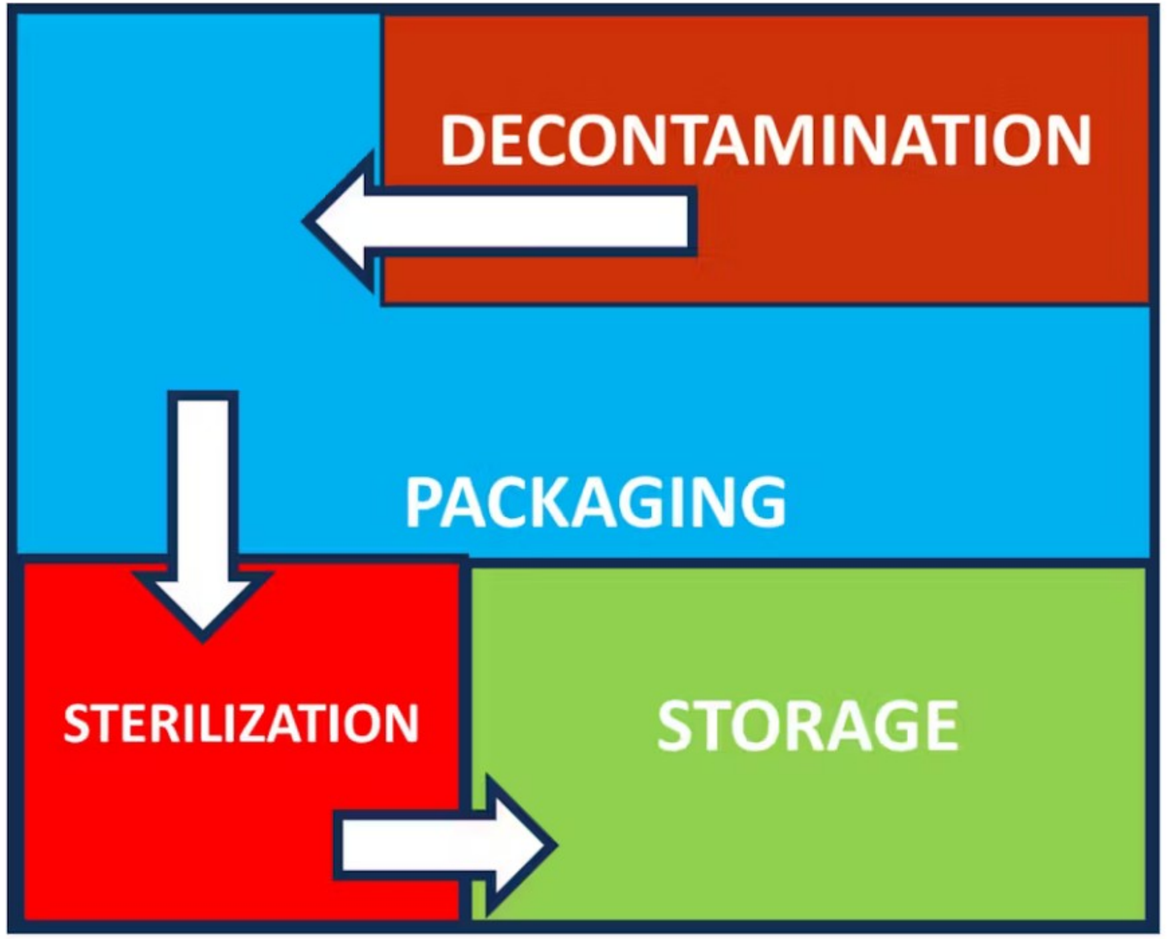
Packaging

- All these instruments have been successfully decontaminated and therefore can be handled with bare hands (no PPE required in here)
- This is where instruments are taken out of the containers and are packaged appropriately for sterilization.
- Then a chemical indicator is placed into the tray of instruments (heat sensitive) and if certain temperature is achieved, the chemical indicator will change and appear "acceptable"
- In addition to trays, a plastic type wrap may be used with chemical indicator tape on it that appears dark when it has been processed acceptably



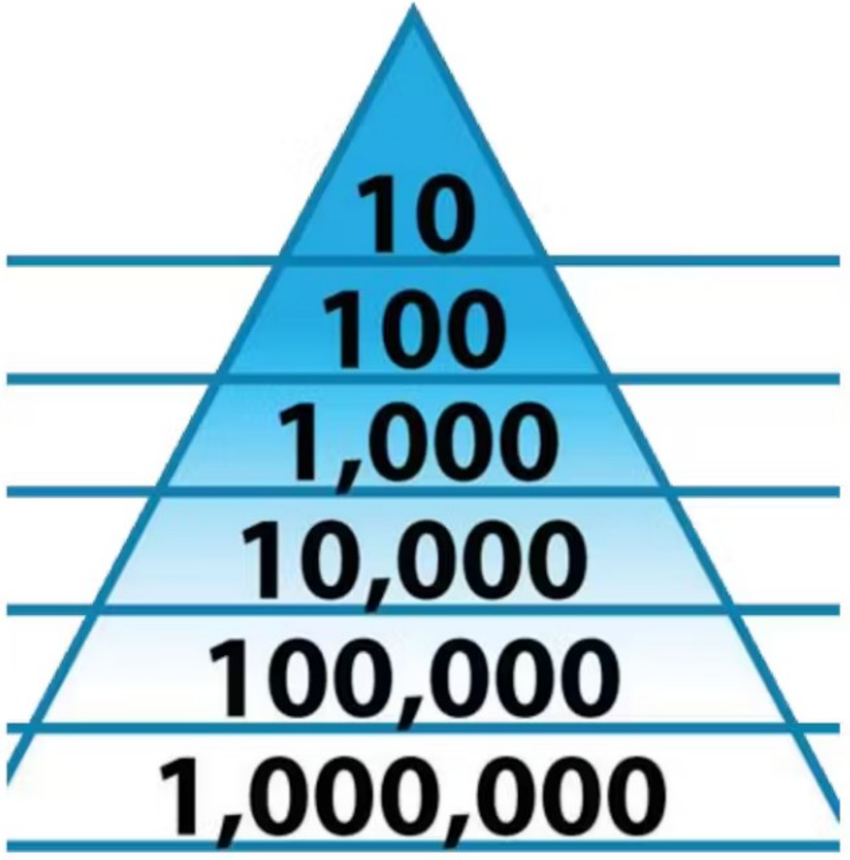
Sterilization

- Most items can be steam sterilized using a vacuum displacement sterilizer for heat resistant items. Steam sterilization under pressure is one of the oldest and most effective methods for sterilization and is the preferred method for sterilization of critical medical equipment
- For heat sensitive items, Ethylene Oxide gas (ETO) can be used
- Vaporized hydrogen peroxide sterilization is also used for heat sensitive items



Sterilization

- Sterilization is the term for the process where all microbial life, including spores, is destroyed
- Sterilization may be carried out using steam, hydrogen peroxide gas, ethylene oxide gas and liquid sterilants
- The sterility assurance level (SAL) is the probability of a microbe surviving on an item after sterilization
- A SAL of 10^{-6} means that there is, at most, a 1 in one million chance of an organism having survived
- This SAL is considered to be appropriate for critical items



Monitoring the Effectiveness of the Sterilization Cycle to Detect Failure

1. **Physical Indicators** such as the time/temp chart on a steam sterilizer
2. **Chemical Indicators** such as those with heat or chemical sensitive that change appearance such as on tape
3. **Biological Indicators** which is a spore that is most resistant to the sterilization cycle.
   - ***Geobacillus stearothermophilus***

Bowie-Dick test: used on steam sterilizer (vacuum), it monitors for the presence of air (not wanted) in the sterilizer and the indicator turns black

About Single Use Device Reprocessing (SUD)

Safe and cost-effective

FDA regulated, published regulatory guidance in 2000

3rd party reprocessors

Reprocessing must meet requirements: decontamination, functional testing, relabeling and sterilizing

Labeled "single patient use"

Immediate Use Sterilization

(formerly known as “flash”)

Immediate Use Sterilization (IUSS) Definition:

- Modified steam sterilization for an unwrapped item placed in an open tray or special container for rapid sterilization (at 270-275° for 3-10 min)

Facts About IUSS Sterilization:

- Point-of-use processing, that occurs immediately before use and close to the patient area where the item will be used
- Associated with a higher risk of infection
- Best used for single, dropped items for which there is no replacement
- Should **not** be used for implantable items (such as screws or plates)
- Maintain record of IUSS items (log)
- Flash sterilized items cannot be stored for future use

Immediate Use Steam Sterilization (IUSS)

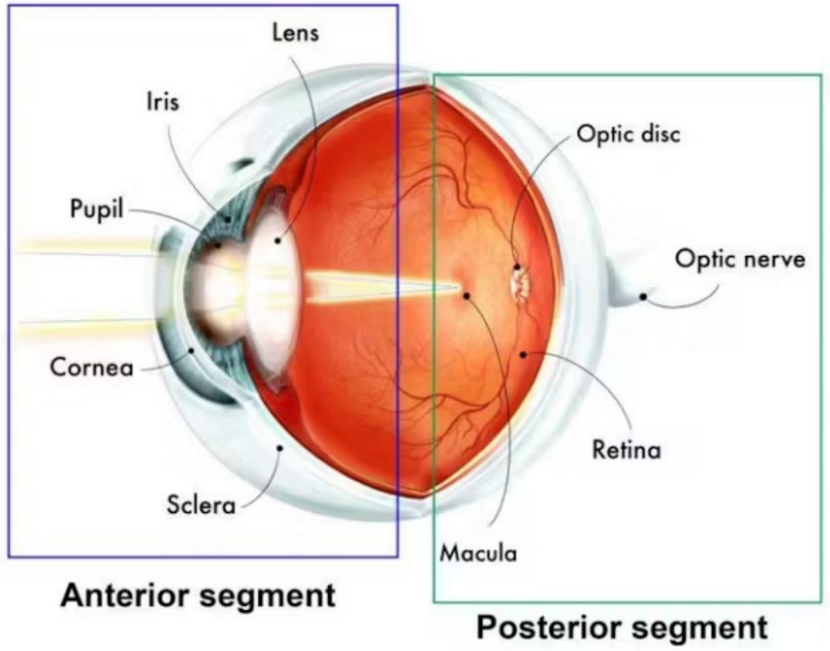
- In 2009, The Joint Commission revised its position statement on flash sterilization and emphasized that three critical steps of reprocessing must be followed to ensure sterility:
  - cleaning
  - decontamination
  - aseptic transfer
- Effective method of sterilization if it is performed according to manufacturer’s instructions
- Items that undergo immediate use steam sterilization are subject to the same cleaning and decontamination requirements that apply to preparing items for terminal sterilization, and manufacturers' instructions for use must be strictly followed.

Per CMS Memorandum

- 14-44-Hospital/CAH/ASC “Change in Terminology and Update of Survey and Certification (S&C) Memorandum 09-55 Regarding Immediate Use Steam Sterilization (IUSS) in Surgical Settings,” was released in August 2015 survey-and-cert-letter-14-44.pdf (cms.gov)

- It should be noted that IUSS is not equivalent to “short cycle” sterilization. Regardless of the cycle duration, correct use of a sterilization cycle for a wrapped/contained load that meets the device manufacturer’s instructions for use (IFU) is the equivalent of terminal sterilization and is not IUSS if it includes use of a dry time and is packaged in a wrap or rigid sterilization container intended to be stored for later use

Toxic Anterior Segment Syndrome (TASS)



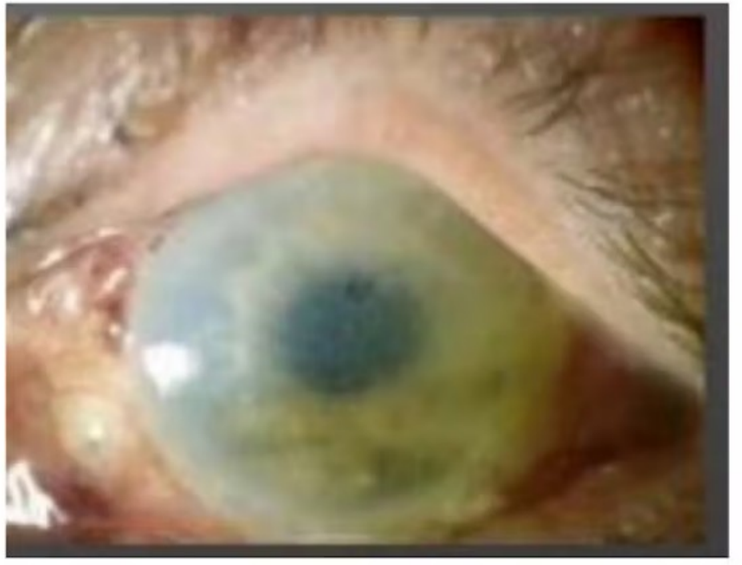
Source: Anterior segment dysgenesis (ASD): for patients - Gene Vision

Acute severe inflammatory reaction to a toxic contaminant introduced during intraocular surgery

Special Precautions for Eye Instrumentation

Toxic Anterior Segment Syndrome (TASS)

- An acute, sterile segment inflammation following generally uneventful cataract and anterior segment surgery.
- One of the main factors in differentiating TASS from an infection is the rapid onset.
- Most patients with toxic anterior segment syndrome will develop symptoms within 12 to 24 hours of the surgery.

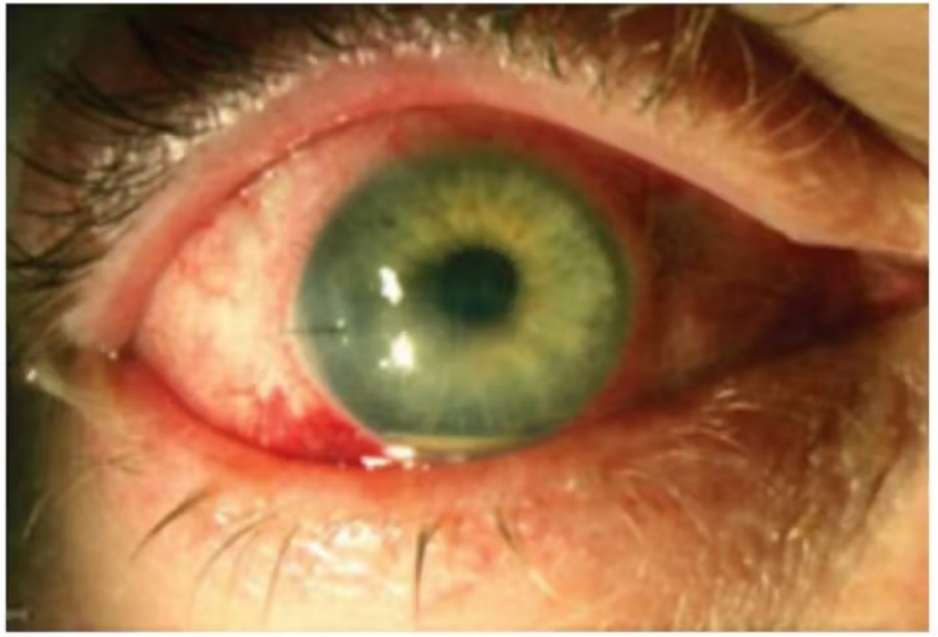


TASS...

- Eyes are high risk tissue
- Precleaning used equipment after procedure is extremely important
- Keep used instruments moist
- Eye instruments are fragile, easily damaged
- TASS is a reaction to foreign material carried into the eye; incomplete cleaning processes that leave residual residues can contribute to cases.
- Separate the decontamination process from other areas (best practice) and don’t mix decontamination process with other non-ophthalmic instruments
- Follow Manufacturer’s IFUs. Not aligning with these may represent an off-label use of the cleaning chemistry, which has patient risk and legal implications.

Endophthalmitis

- Intraoccular infection caused by microorganisms, especially gram positive bacteria
- Low incidence rate
- Causes include contaminated instruments due to failures in cleaning and sterilization processes



References and Resources:

- SPICE Video Library - Statewide Program for Infection Control & Epidemiology (unc.edu)
- Ref: S&C: 14-44-Hospital/CAH/ASC Change in Terminology and Update of Survey and Certification (S&C) Memorandum 09-55 Regarding Immediate Use Steam Sterilization (IUSS) in Surgical Settings survey-and-cert-letter-14-44.pdf (cms.gov)
- Guidelines for the Cleaning and Sterilization of Intraocular Surgical Instruments - 2018 - American Academy of Ophthalmology (aao.org)

Mentimeter

Thank You!

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