

**CLEANING, DISINFECTION AND
STERILIZATION** | Lole Coudy, RN, BS, CIC, FAPIC



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DISCLOSURES

None

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LEARNING OUTCOMES

1. State the basic components of cleaning, disinfection and sterilization
2. Identify products and equipment used to properly clean, disinfect and sterilize instruments, devices and equipment
3. Review processing issues "in the news"
4. Evaluate potential auditing measures to ensure appropriate results from cleaning, disinfection and sterilization

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WHAT EXACTLY ARE WE ASKING?

Cleaning – To remove all visible contamination on the surface by washing, brushing or wiping. Surface level does not eliminate germs but can reduce their numbers. Usually the first step in the process

Disinfecting – To kill specific pathogens on a surface with a disinfectant. To be classified a disinfectant the agent must kill 99.999% of infectious bacteria, viruses and fungi within a 5-10 minute time frame.

Sterilizing – To completely eradicate microbes including bacterial spores, bacteria, viruses and fungi.

- Chemicals
- Steam
- Heat
- Radiation

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LEVELS OF DISINFECTION

Earle H Spalding (1968): object's level of disinfection is influenced by the object's intended use

Critical: objects which normally enter sterile tissue or the vascular/circulatory system should be sterile

Semi-critical: objects that touch mucous membranes or skin that is not intact require high level disinfection (HLD) process that kills all micro-organisms =, except high numbers of bacterial spores

Non-critical: objects that touch only intact skin require low level disinfection

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CLEAR AS MUD

Spalding is a little oversimplified

- Heat sensitive equipment
 - Arthroscopes
 - Laparoscopes
- Prions (CJD)
- Some methods too time consuming
- Optimal contact time varies or is not defined by professional organizations
- Different strategies for different semi-critical equipment

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STERILIZATION — THE “IDEAL” METHOD

- Highly effective
- Rapidly active
- Strong penetrability
- Material compatibility
- Non-toxic
- Adaptability
- Monitoring capabilities
- Cost-effective



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FDA REQUIREMENTS

The FDA requires that the manufacturer supply the user with complete and comprehensive written instructions for each device

- Handling
- Cleaning
- Disinfection
- Testing
- Packaging
- Sterilization

Health care professionals must obtain the manufacturers' most current recommendations in writing, review the recommendations and ensure that they have the necessary resources to follow the manufacturers' instructions completely

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THE PROCESS

- Meticulously clean items before disinfection or sterilization
- Remove visible organic residue and inorganic salts using an effective cleaning agent (e.g., detergent, enzymatic cleaners)
- Clean as soon as possible after use
 - Delay allows soiled material to dry
 - Dried soiled materials are difficult to remove
 - Dried soiled materials can interfere or prevent disinfection and sterilization

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PRE-CLEANING

- Enzymatics or detergents must be compatible with the instruments
- Rinse thoroughly if indicated (cleaning residual may interfere with disinfection or sterilization)
- Manual clean (friction) or mechanical clean (ultrasonic cleaner, washer-disinfector)
- Always follow manufacturers' instructions for mechanical cleaning
- Inspect for breaks in integrity; discard or repair any item that cannot be properly cleaned, disinfected or sterilized

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TJC DATA 2009-2016



"Of these, the most vulnerable locations for lapses in sterilization or HLD of equipment are ambulatory care sites (including office-based surgery facilities) and decentralized locations in hospitals"



<https://www.jointcommission.org/resources/news-and-multimedia/newsletters/newsletters/quick-safety/quick-safety-issue-33-improperly-sterilized-or-hld-equipment--a-growing-problem/improperly-sterilized-or-hld-equipment--a-growing-problem/>

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STERILIZATION

Destroys all microorganisms including bacterial spores

Critical and semi-critical items

- High temperature (e.g., steam, dry heat) – heat-tolerant critical and semi-critical items
- Low temperature (e.g., ethylene oxide gas or hydrogen peroxide gas plasma) – heat-sensitive critical or semi-critical items
- Liquid immersion (e.g., chemical sterilants: peracetic acid) – heat-sensitive critical and semi-critical items that can be immersed

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STEAM STERILIZATION

- Steam admitted at top or sides of chamber
- Steam is lighter than air – forces air out the bottom of the chamber through drain vent
- Proper air removal and steam quality measured with Bowie-Dick test run with first load of the day

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IUSS

ONLY used if insufficient time to process by standard method

NOT a substitute for insufficient instrument inventory

NOT for implantable devices

If no other choice for implantable device – rapid action biological and class 5 chemical integrator should be used. Implant not released until rapid action biological returns negative

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IUSS

- Must follow manufacturers' written instructions
- Item(s) must be disassembled and thoroughly cleaned
- Lumens flushed and rinsed
- Placement in sterilizer tray must allow steam contact with all parts
- Prevent contamination during transfer to sterile field
- Complete documentation and tracking of IUSS items to patient

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STEAM STERILIZATION MONITORING

Physical – printout, time, time at temperature, pressure

Chemical – inside and outside of pack

- Classes of indicators/integrators: 1-5
- Type 1 – inside and outside the package, shows the item has been sterilized
- Type 2 – specific test procedure – Bowie-Dick
- Type 3 – used to monitor the chemical sterilization process (ethylene oxide and hydrogen peroxide)
- Type 4 – monitors two or more critical parameters (time, temperature, sterilant concentration)
- Type 5 – time, temperature and steam

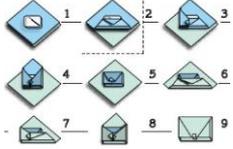
Biological – bacterial spores of *Geobacillus stearothermophilus*

- Are the spores killed in the process
- Every 7 days, every day sterilizer is used
- Always with implantable

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PACKAGING

Sequential wrapping complies with the wrap manufacturers' validation testing, FDA clearance and AAMI



PACKAGE PREPARATION FOR STERILIZATION

Sequential Wrapping - Envelope Fold



Sequential wrapping refers to the process of wrapping individual sterile items in a way that allows them to be wrapped together in a single layer of the wrap material.

1. Place the items on the table in a single layer, facing the same direction.
2. Fold the bottom flap of the wrap material over the items.
3. Fold the top flap over the bottom flap.
4. Fold the left side flap over the top flap.
5. Fold the right side flap over the left side flap.
6. Fold the left side flap over the right side flap.
7. Fold the right side flap over the left side flap.
8. Fold the top flap over the bottom flap.
9. Fold the bottom flap over the top flap.

AAMI

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DOCUMENTATION

Every sterilizer load must be completely documented so that all sterilized items can be traced back to the patient.

Documentation should include:

- Sterilizer identification
- Type of sterilizer and cycle used
- Lot control number
- Specific load contents
- Critical parameters
 - Time, temperature, pressure
- Results of the process monitors
- Operator's name, initials or identification

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ETHYLENE OXIDE

Very effective

- Penetrates medical packaging
- Compatible with most medical materials

Potential hazard to patients and staff

- Lengthy sterilization cycle
- Lengthy aeration time

Follow instrument manufacturers' guidelines

Biological indicator is made with spores of *Bacillus atrophaeus*

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ETHYLENE OXIDE

- Aeration cycle must be completed before item can be safely used
- NEVER interrupt an aeration cycle to remove items for use
 - Potential for injury to staff and patient
- Document all aeration parameters
- Program for monitoring occupational exposure to EtO

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HYDROGEN PEROXIDE GAS PLASMA

- Safe for the environment
- Safe for healthcare workers
- Cycle time 28-52 minutes
- Temperature is 50° C (122° F)
- For use with heat and moisture sensitive items
- Compatible with most medical devices

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HYDROGEN PEROXIDE PLASMA GAS

- Papers, linens and liquids cannot be processed
- Small chamber
- Restrictions on internal lumen diameter and device length
- Requires synthetic packaging (polypropylene) and special tray

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PERACETIC ACID

- Low temperature > 50°C
- Rapid cycle ~30 minutes
- 35% peracetic acid diluted to 0.2% can be disposed in ordinary sewer system
- Immersible items only
- Proper use of correct connectors
- "JUST in time" no storage of sterile instruments
- Single-use sterilant solution, no minimum effective concentration (MEC)

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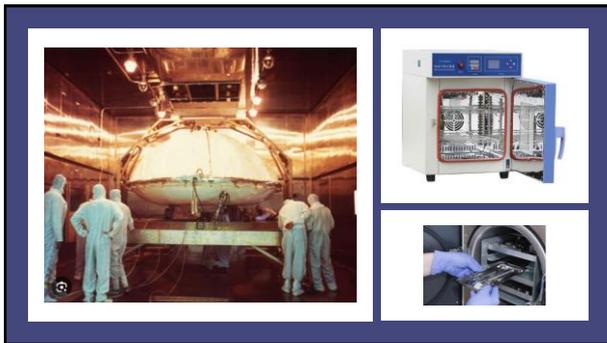


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DRY HEAT

- Mostly used in medical and dental offices
- FDA defines reliable dry sterilization as classic dry-heat processing that occurs between 160°C and 180°C (320°F and 356°F)
- Dry heat has proven effective in medical and non-medical applications
 - Prostheses
 - Implants
 - Spacecraft
 - Standard method for sterilizing spacecraft since the Viking landed in 1983

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HIGH LEVEL DISINFECTION

-  Destroys all microorganisms except high numbers of bacterial spores
-  Moderate heat
-  Liquid immersion
-  Aerosol of concentrated hydrogen peroxide

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HIGH LEVEL DISINFECTION

-  Moderate heat (pasteurization) Heat sensitive semi-critical items (respiratory therapy equipment)
-  Liquid immersion (chemical sterilants) Heat sensitive semi-critical items (flexible endoscopes)
-  Concentrated hydrogen peroxide aerosol Endocavitary probes

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MODERATE HEAT

Hot water pasteurization

- Items submerged for 30 minutes in water with constant temperature of 70°C (158°F)
- Requires no chemicals
- Eliminates high numbers of vegetative bacteria, mycobacteria and fungi
- Does not eliminate spores
- Equipment is wet after process, must be placed in hot-air drying cabinets to complete process prior to storage

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LIQUID IMMERSION

Ideal chemical HLD

- Rapid high-level disinfection (<10 minutes)
- No disinfectant residue after rinsing
- Excellent material compatibility
- Long shelf life
- Non-toxic
- No disposal issues
- Minimum effective concentration can be monitored

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LIQUID IMMERSION

FDA cleared high-level disinfectants

- 2% Glutaraldehyde
- 2.5% Glut (5 minutes at 35°C) (95°)
- 0.55% Ortho-phthalaldehyde (12 min)
- 7.5% Hydrogen peroxide
- 1.0 % HP and 0.08% Peracetic acid
- 7.5% HP and 0.23% PA (15 min)
- 650-675ppm hypochlorite
- 1.21% Glut and 1.93% phenol/phenate (20 min at 25°C) (77°F)
- 0.2% Peracetic acid (50°C)9122°F)



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LIQUID IMMERSION

- High level disinfectant minimum effective concentration (MEC)
- Dilution of solution occurs during use
- Monitor MEC with test strips
- Do not use beyond expiration, even if MEC test acceptable
- Frequency of testing based on how often solution is used
 - Used daily, test daily




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LIQUID IMMERSION

Multi-Society Guideline for Reprocessing Flexible Gastrointestinal Endoscopes, 2011

American College of Chest Physicians and American Association for Bronchoscopy



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LIQUID IMMERSION

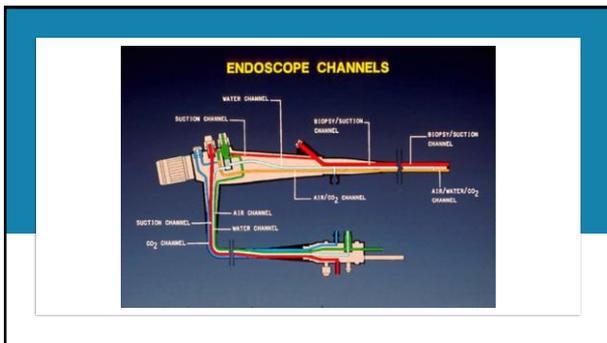
1	2	3
<p>Leak test – pressurized testing for leaks; immersion in water to rule out leaks; flexion and extension of scope under water</p>	<p>Clean – mechanically clean internal and external surfaces; brush internal channels and flush with water and enzymatic cleaner</p>	<p>Disinfect – immerse scope in high-level disinfectant, perfuse all channels, keep scope in solution at appropriate temperature and time</p>

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LIQUID IMMERSION

Rinse	Rinse - scope and all channels thoroughly rinsed with sterile water, filtered water or tap water
Dry	Dry - rinse insertion tube and inner channels with alcohol, followed with forced air
Store	Store - hang in vertical position to promote drying and protect scope from recontamination

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LIQUID IMMERSION

- Staff to wear appropriate PPE
- Reprocessing area should be dedicated with adequate space, proper air flow and ventilation and appropriate work-flow patterns
- Re-useable accessories that break mucosal barrier need to be cleaned and sterilized between patients

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HIGH LEVEL DISINFECTION

Protocols should be equivalent to professional organizational guidelines

Scope reprocessing personnel should be specifically trained and have competency tested annually

Infection Prevention should round to ensure policy compliance

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CONCENTRATED HYDROGEN PEROXIDE

Endocavitary probes
Tropon EPR



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LOW LEVEL DISINFECTION

- Destroys vegetative bacteria, mycobacteria, most viruses, most fungi but not bacterial spores
- Liquid contact (EPA registered hospital disinfectant with label kill claim regarding tuberculocidal activity)
 - Non-critical patient care items
 - Surfaces with visible blood

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Santi-Cloth HB Wipes <ul style="list-style-type: none"> • Hard non-porous, inanimate surfaces: • Surface must be wet for 10 minutes 	Wet Task Wipes <ul style="list-style-type: none"> • Hard, inanimate, non-porous surfaces: <ul style="list-style-type: none"> • Walls • Floors • Plastic Surfaces • Surface must be wet for 10 minutes 	Super Santi-Cloth <ul style="list-style-type: none"> • Hard, inanimate, non-porous surfaces and equipment made of stainless steel, plastic, glass, or Formica • Surface must be wet for 2 minutes 	Santi-Cloth Plus <ul style="list-style-type: none"> • Hard, non-porous surfaces and equipment made of stainless steel, plastic, glass, or Formica • Surface must be wet for 3 minutes 	Santi-Cloth Bleach Wipe <ul style="list-style-type: none"> • Hard, inanimate, non-porous surfaces • Surface must be wet for 4 minutes • Safe to use on the Alaris IV pumps
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ENVIRONMENTAL CLEANING

- Patient care areas should be cleaned on a regular basis, when spills occur and when surfaces are visibly soiled
- Use a one step process and an EPA registered hospital disinfectant in patient care areas
- Follow manufacturers' instruction for use
 - Application
 - Time
 - Material compatibility
 - Dilution
 - Storage
 - Disposal
 - PPE

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ENVIRONMENTAL CLEANING

- Disinfect non-critical patient care equipment on a regular basis (after use on each patient) and when visibly soiled
- If dedicated or disposable devices is not feasible for patients on contact precautions, disinfect used devices or equipment before using on another patient

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CONTAMINATION

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9589928/>

Instrument Name	No.	Bacteria Isolate	N (%)
Gallipot	6	<i>Citrobacter freundii</i>	2 (10.5)
Dissecting forceps	5	NBG	0 (0.0)
Kocher forceps	6	<i>Bacillus cereus</i>	3 (15.7)
Ramsey's sponge holding forceps	7	NBG	0 (0.0)
Curved mosquito artery forceps	7	NBG	0 (0.0)
Kerrison forceps	8	<i>Staphylococcus aureus</i>	5 (26.3)
Metzenbaum scissors	5	NBG	0 (0.0)
Mayo's scissors	8	<i>Bacillus cereus</i>	2 (10.5)
Langenberg retractor	7	NBG	0 (0.0)
Deaver's retractor	6	<i>Citrobacter freundii</i>	4 (21.1)
Bone nibbler	5	NBG	0 (0.0)
Shunt passer	8	NBG	0 (0.0)
Stereotactic system	6	NBG	0 (0.0)
Shoulder arthroscope	9	<i>Bacillus cereus</i>	3 (15.7)

NBG: no bacteria growth; No.: number of equipment or equipment parts examined; N: number of isolates

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CONTAMINATION



Units	Endoscope Part	No.	Bacteria Isolate	N (%)
Gastrointestinal (GI) endoscopy	Endoscope insertion tube	7	<i>Bacillus cereus</i>	2 (28.6)
			<i>Citrobacter</i> spp.	3 (42.9)
Used for the upper gastrointestinal tract	Endoscope distal tip	8	<i>Bacillus cereus</i>	2 (25.0)
			<i>Citrobacter</i> spp.	4 (50.0)
			NBQ	0 (0.0)
Used for the lower gastrointestinal tract	Endoscope insertion tube	13	<i>Citrobacter</i> spp.	4 (30.8)
			<i>Bacillus cereus</i>	2 (15.4)
	Endoscope distal tip	12	<i>Citrobacter</i> spp./ <i>Citrobacter</i> spp.	4 (33.3)
Urology endoscopy unit	Biostat (size 18-22)	4	<i>Bacillus cereus</i>	3 (75.0)
	Biostat (size 24)	8	<i>Staphylococcus aureus</i>	1 (12.5)
			<i>Bacillus cereus</i>	3 (37.5)
	Biostat (size 20-24)	5	<i>Bacillus cereus</i>	2 (40.0)
	Biostat (size 16-20)	5	NBQ	0 (0.0)
	Forceps	4	NBQ	0 (0.0)
	Sponge loading forceps	5	NBQ	0 (0.0)
	Ureteroscope	7	<i>Bacillus cereus</i>	3 (42.9)
	Cystoscope handle	5	<i>Bacillus cereus</i>	2 (40.0)
	Cystoscope obturator	8	NBQ	0 (0.0)
	Ureterotome	4	NBQ	0 (0.0)
	30° rigid Cystoscope	9	<i>Bacillus cereus</i>	3 (33.3)

NBQ: no bacteria growth; No. number of equipment or replacement parts assessed; N: number of isolates.

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC589928/>

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GLOW GERM

Can be used to check environmental cleaning

Very simple process

Shows areas that were not cleaned

Can be used for hand hygiene

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ATP TESTING

- A process that rapidly measures actively growing microorganisms through the detection of adenosine triphosphate (uses an enzyme that produces light in a firefly's tail)
- Does not detect viruses
- Can be used on environmental surfaces
- Benchmark for endoscopes is generally <200

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A HOSPITAL IN COLORADO

- 2018 revealed problems with cleaning surgical equipment
- State investigation revealed problems known in 2017. Additional investigation revealed issues since 2015
- Mostly hip and spine cases
- State documented 76 times contaminated instruments and trays were brought in the OR in 2017 and 2018
- In 2018 letters were sent to 5,800 patients, over 14,000 patients involved
- "Hundreds of severe infections, at least one death"

<https://www.denverpost.com/2019/06/16/porter-hospital-infections-surgical-sterilization-lawsuit/>

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NEW JERSEY

- Surgery Center
- Shut down by Department of Health
- 3,700 patients between 1/1 and 9/7



<https://www.nbcnews.com/health/health-news/n-j-surgery-center-possibly-exposed-thousands-hiv-had-rusty-n952971>

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TEXAS

- Orthopedic surgeries
- Inside power arthroscopic shaver
- Inside inflow/outflow cannula
- Contamination discovered with cameras
- IFUs were followed (rinse with tap water) but inadequate
- Manufacturer sued



<https://publicintegrity.org/health/filthy-surgical-instruments-the-hidden-threat-in-americas-operating-rooms/>

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VA IN FLORIDA, TENNESSEE AND GEORGIA

- Seven years of using scopes that were improperly cleaned
- Patients later tested positive for Hep B, Hep C and HIV



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REFERENCES

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THANK YOU!

Questions?

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