HIGH LEVEL DISINFECTION AND ENDOSCOPY ISSUES

Spring 2025

Nebraska Infection Control Network

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Learning Outcomes

- Discuss how Spaulding Classification System is applied to high-level disinfection
- Recognize differences between FDA approved high-level disinfectants
- Identify potential challenges with patient care equipment and HLD
- Discuss role if the infection preventionist in HLD use
- Identify resources associated with HLD and Endoscopy

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Terminology

- **High-level disinfection**
  - Process that kills all microbial pathogens but not necessarily high numbers of bacterial spores (AAMI ST58[1]; AAMI ST91[2])
- **High-level disinfectant**
  - Agent *capable* of killing bacterial spores when used in sufficient concentration under suitable conditions (AAMI ST58[1]; AAMI ST91[2])
- **Biofilm**
  - An accumulated biomass of bacteria and extracellular material that is tightly adhered to a surface and cannot be removed easily (AAMI ST58[1]; AAMI ST91[2])
- **Recognized Consensus Standards**
  - Recognition is the process whereby the FDA identifies standards to which manufacturers of medical devices may submit a declaration of conformity to demonstrate they have met relevant requirements in the Federal Food, Drug, and Cosmetic Act (FD&C Act) (FDA[3])

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Spaulding Classification System (ASGE[4])

Patient Contact	Device Classification	Examples	Reprocessing
Intact skin	**Non-critical**		Low-level disinfection; Intermediate-level disinfection
Mucous membranes; Non-intact skin	**Semi-critical**		High-level disinfection
Sterile areas of the body; Vascular system	**Critical**		Sterilization

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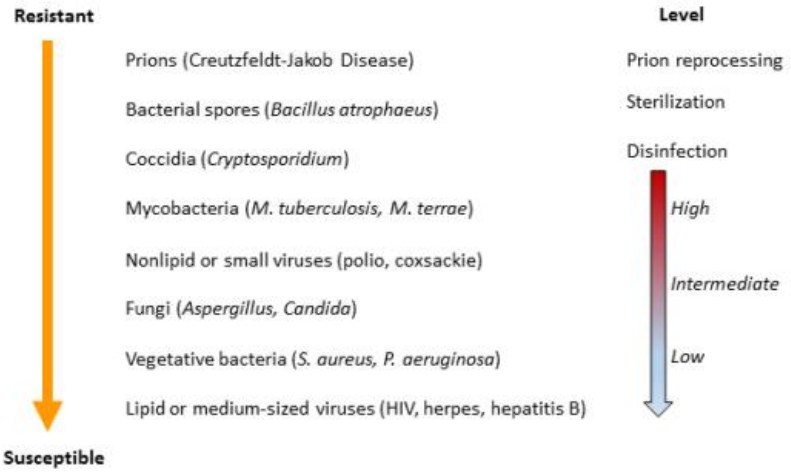
Order of resistance of microorganisms to disinfection and sterilization (CDC[5])



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Regulatory Framework (CDC[9])

- In the U.S, chemical germicides formulated as sanitizers, disinfectants, or sterilants are regulated in interstate commerce by the Antimicrobials Division, Office of Pesticides Program, EPA, under the authority of the Federal Insecticide, Fungicide, and Rodenticide Act **(FIFRA**) of 1947
- In June 1993, FDA and EPA issued a "Memorandum of Understanding" that divided responsibility for review and surveillance of chemical germicides between the two agencies. Under the agreement:
  - **FDA regulates liquid chemical sterilants used on critical and semicritical devices**
  - **EPA regulates disinfectants used on noncritical surfaces and gaseous sterilants**

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FDA-Cleared Sterilants and HLDs (CDC[5])

- Glutaraldehyde
- Hydrogen peroxide
- Ortho-phthaldehyde (OPA)
- Peracetic acid with hydrogen peroxide

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FDA-Cleared Sterilants and HLDs (FDA[6])

Information provided on website

Manufacturer

Active ingredient(s) sterilant contact conditions

HLD contact conditions

What it does not indicate

Safety

HVAC requirements

PPE

Technical information (e.g., what pathogens it kills)

Disposal requirements

Complete instructions for use (IFU)

Equipment compatibility

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Manufacturer	Active Ingredient(s)	Sterilant Contact Conditions	High Level Disinfectant Contact Conditions
	0.55% *ortho*-phthaldehyde	**No indication for device sterilization.** Passes the AOAC Sporicidal Activity Test in 32 hrs at 20°C and 25°C.	**Manual Processing** 12 min at 20°C 14 days Maximum Reuse **Automated Endoscope Reprocessor (AER)** 5 min at 25°C 14 days Maximum Reuse (For processing in an AER only with FDA-cleared capability to maintain solution temperature at 25°C.) Contact conditions established by simulated use testing with endoscopes.
	3.5% glutaraldehyde	**Indication for device sterilization.** 10 hrs at 25°C 30 days Maximum Reuse Contact conditions based on AOAC Sporicidal Activity Test only.	45 min at 25°C 30 days Maximum Reuse Contact conditions established by simulated use testing with endoscopes.
	3100-3400 ppm peracetic acid	**Indication for device sterilization** 2 hrs at 20°C 5 days Maximum Reuse Contact conditions based on AOAC Sporicidal Activity Test and by simulated use testing with endoscopes.	7 min at 20°C 5 days Maximum Reuse Contact conditions established by simulated use testing with endoscopes.

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Rigid Endoscopes

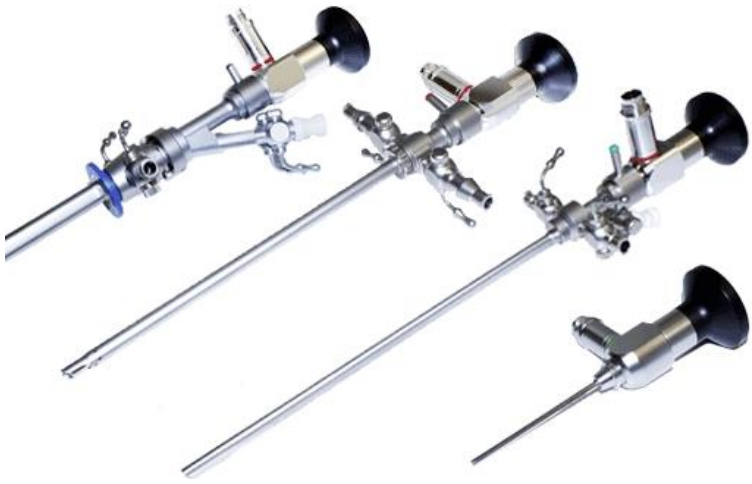

Image: Medical Resource Endoscopy

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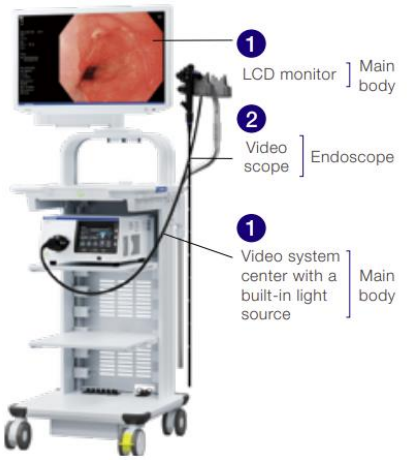
Endoscopy System



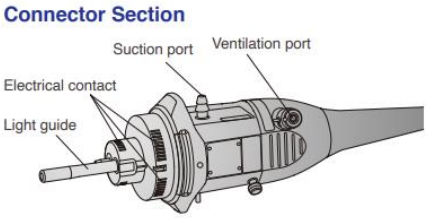


Image: Olympus

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Flexible Endoscope Anatomy

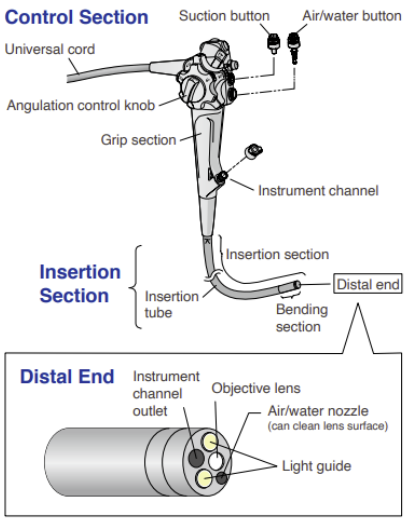

Image: Olympus

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Overview of Reprocessing Steps (HICPAC®)

- Must follow IFU for each scope brand/version
- Each phase may include numerous steps depending on scope anatomy and function
- Brands of scopes may include/omit steps
- Identify accessories used for reprocessing

Pre-cleaning/treatment

Leak testing

Manual cleaning

Visual inspection

HLD or sterilization

Storage

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Challenges with Reprocessing Endoscopes

- Non-adherence to IFU and guidelines
  - Extensive processing requirements (100+ steps for some brands)
- Inappropriate handling/care
- Delayed reprocessing (begins at the point of use)
- Insufficient cleaning (manual, automated, rinsing channels)
- Use of damaged endoscopes (functional/cosmetic)
- Use of water-insoluble products during endoscopy
- Rinse water/water quality (AAMI ST108)
- Inadequate drying before storage
- Inadequate storage

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Potential challenges with HLD

- IP knowledge and role with the HLD process
- Identifying current HLD use in facility (in-house and off-site)
  - PPE, HVAC system, eye wash stations, spill kits…
- Identifying patient care equipment requiring HLD (minimum)
  - Existing, new/potential equipment under evaluation for purchase
- Identifying/locating equipment IFUs
  - For equipment and HLD product(s)
- Staff education and competency documentation
  - NEO, annual, new products/equipment is introduced

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Potential Challenges with HLD

- How to use HLD product:
  - PPE, HVAC, spill kit, eye wash station, workflow
  - Pre-cleaning of instrumentation/equipment (e.g., use of enzymatic)
  - Product shelf life, storage (temp), ability to use in an automatic endoscope reprocessor (AER)
  - Testing for minimum effective concentration (MEC) (test strips)
  - Daily temperature log of disinfectant before use
  - Equipment disinfection process to include rinsing (potable or sterile water based on IFUs)
  - Drying
  - Length of time before discarding (e.g., 14 days)
  - Disposal requirements (check local regulations)
  - Documentation
  - Education and competency of staff completing HLD process

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Role of IP: Endoscopy & HLD

Work with department leadership/staff/vendors

- Phase One
  - Identifying current HLD use in facility (environmental scan)
  - Identifying patient care equipment requiring HLD
  - Identifying/locating equipment IFUs
  - Staff education and competency documentation
- Phase Two
  - Shadow processes
  - Audits and feedback (can focus on one or multiple processes)
- Phase Three
  - Develop/refine policies and procedures
  - Create a repository of IFUs and resources (free and $$)
  - Staff education and competency
  - Ongoing quality improvement program

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Essential Elements of a Reprocessing Program (HICPAC®)

Administrative	Policies
Documentation	Process Failures
Inventory	
Physical setting	
Education, Training, and Competencies	
Risk Assessment and Quality Assurance	

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Key Resources for Quality Program

- ASGE Multisociety guideline on reprocessing flexible GI endoscopes: 2021 update (asge.org)
- AAMI ST58 ANSI/AAMI ST58:2024 - Chemical sterilization and high-level disinfection in health care facilities
- AAMI ST91 ANSI/AAMI ST91:2021 - Flexible and semi-rigid endoscope processing
- HICPAC Essential Elements of a Reprocessing Program for Flexible Endoscopes – Recommendations of the Healthcare Infection Control Practices Advisory Committee (cdc.gov)
- Instructions for Use/Operators Manual
  - Each brand of scope (e.g., rigid or flexible) (recent uptates?)
  - Automated Endoscope Reprocessor (AER), if applicable (recent uptates?)
  - Instructions for Use for each High-Level Disinfectant/Sterilant (recent uptates?)

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References

1. AAMI ST58 ANSI/AAMI ST58:2024 - Chemical sterilization and high-level disinfection in health care facilities
2. AAMI ST91 ANSI/AAMI ST91:2021 - Flexible and semi-rigid endoscope processing
3. FDA Standards and Conformity Assessment Program | FDA
4. ASGE Multisociety guideline on reprocessing flexible GI endoscopes: 2021 update (asge.org)
5. CDC Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008 (cdc.gov)
6. FDA FDA-Cleared Sterilants and High Level Disinfectants with General Claims for Processing Reusable Medical and Dental Devices | FDA
7. HICPAC Essential Elements of a Reprocessing Program for Flexible Endoscopes – Recommendations of the Healthcare Infection Control Practices Advisory Committee (cdc.gov)

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Additional References

- FDA Information about Automated Endoscope Reprocessors (AERs) and FDA's Evaluation | FDA
- SGNA Standards of Infection Prevention in Reprocessing Flexible Gastrointestinal Endoscopes (sgna.org)
- AJIC A Water-Soluble Alternative to Simethicone for Gastrointestinal Endoscopy: Results in a Clinical Trial

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