# Disinfection and Sterilization in Healthcare: New CDC Guidelines

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# Disinfection and Sterilization
## New CDC Guidelines

- **Pr**ovide overview
- Discuss processes and products
- Emerging pathogens and prions
- Special instrument reprocessing issues

# Disinfection and Sterilization in Healthcare Facilities

## Rutala WA, Weber DJ and HICPAC, In press

- Overview
  - Last CDC guideline in 1985
  - 250 pages (130 pages preamble, 21 pages recommendations, glossary of terms, 15 tables, >1100 references)
  - Evidence-based guideline (search of the literature using Medline)

# Disinfection and Sterilization in Healthcare Facilities
## New Sections

- Inactivation of emerging pathogens/bioterrorist agents/antibiotic-resistant bacteria
- New sterilization processes such as hydrogen peroxide gas plasma and liquid peracetic acid
- Toxicologic, environmental and occupational concerns associated with disinfection and sterilization processes
- Disinfection of medical instruments (endoscopes, probes)
- Inactivation of Creutzfeldt-Jakob Disease Agent

# Efficacy of Disinfection/Sterilization
## Influencing Factors

Cleaning of the object

Organic and inorganic load present

Type and level of microbial contamination

Concentration of and exposure time to disinfectant/sterilant

Nature of the object

Temperature and relative humidity


DON'T YOU EVER WASH YOUR WEAPONS BEFORE YOU USE THEM?
NO, WHY?
DIK BROWNE 9-5
YOU COULD GIVE SOMEONE AN INFECTION

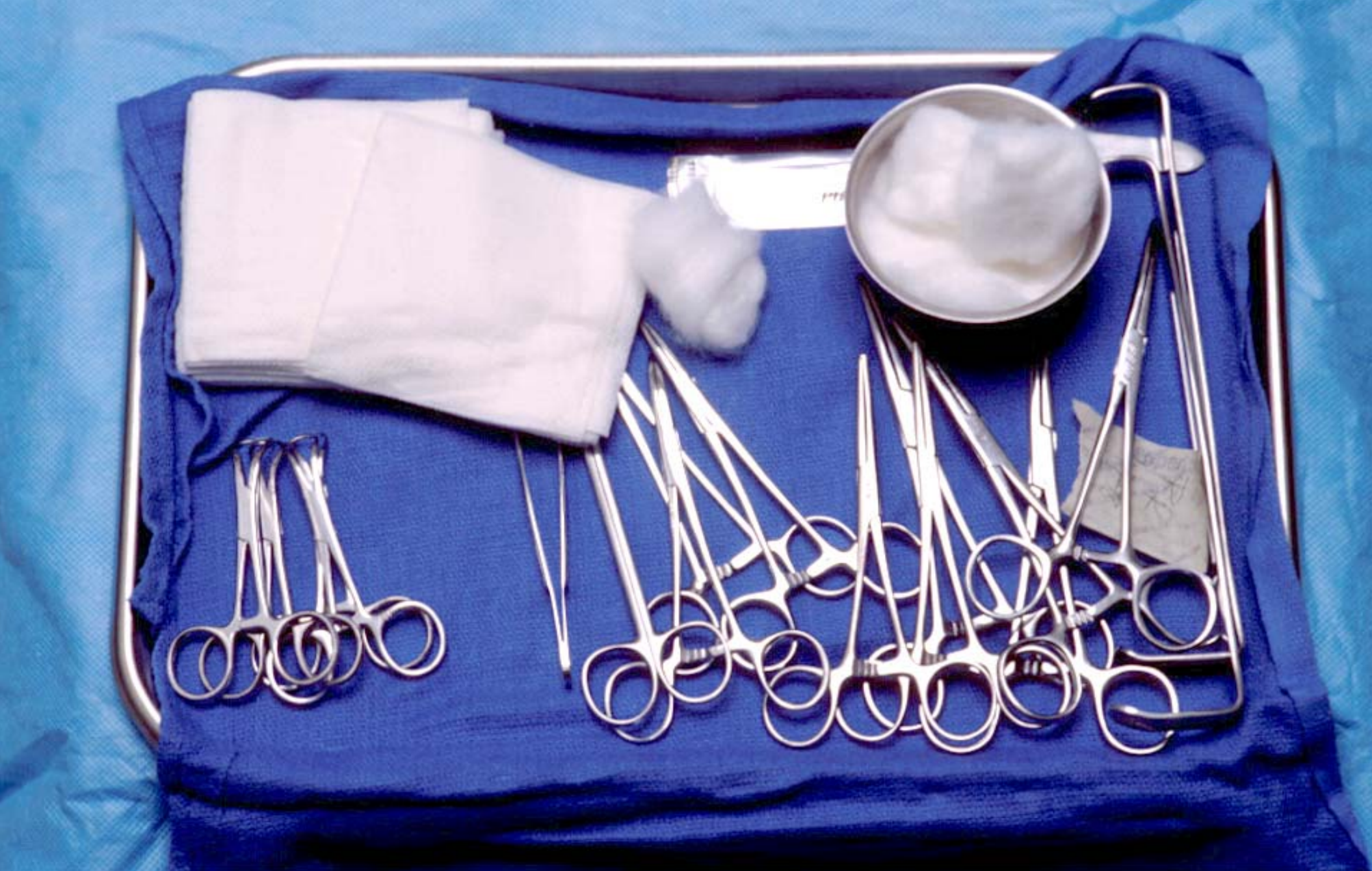
# Disinfection and Sterilization

EH Spaulding believed that how an object will be disinfected depended on the object's intended use.

CRITICAL - objects which enter normally sterile tissue or the vascular system or through which blood flows should be **sterile.**

SEMICRITICAL - objects that touch mucous membranes or skin that is not intact require a disinfection process (**high-level disinfection [HLD]**) that kills all microorganisms but high numbers of bacterial spores.

NONCRITICAL -objects that touch only intact skin require **low-level disinfection**.



# Processing “Critical” Patient Care Objects

| | |
|---|---|
| Classification: | Critical objects enter normally sterile tissue or vascular system, or through which blood flows. |
| Object: | Sterility. |
| Level germicidal action: | Kill all microorganisms, including bacterial spores. |
| Examples: | Surgical instruments and devices; cardiac catheters; implants; etc. |
| Method: | Steam, gas, hydrogen peroxide plasma or chemical sterilization. |

# Critical Objects

- Surgical instruments
- Cardiac catheters
- Implants

# Chemical Sterilization of "Critical Objects"

Glutaraldehyde (≥ 2.0%)

Hydrogen peroxide-HP (7.5%)

Peracetic acid-PA (0.2%)

HP (1.0%) and PA (0.08%)

HP (7.5%) and PA (0.23%)

Glut (1.12%) and Phenol/phenate (1.93%)

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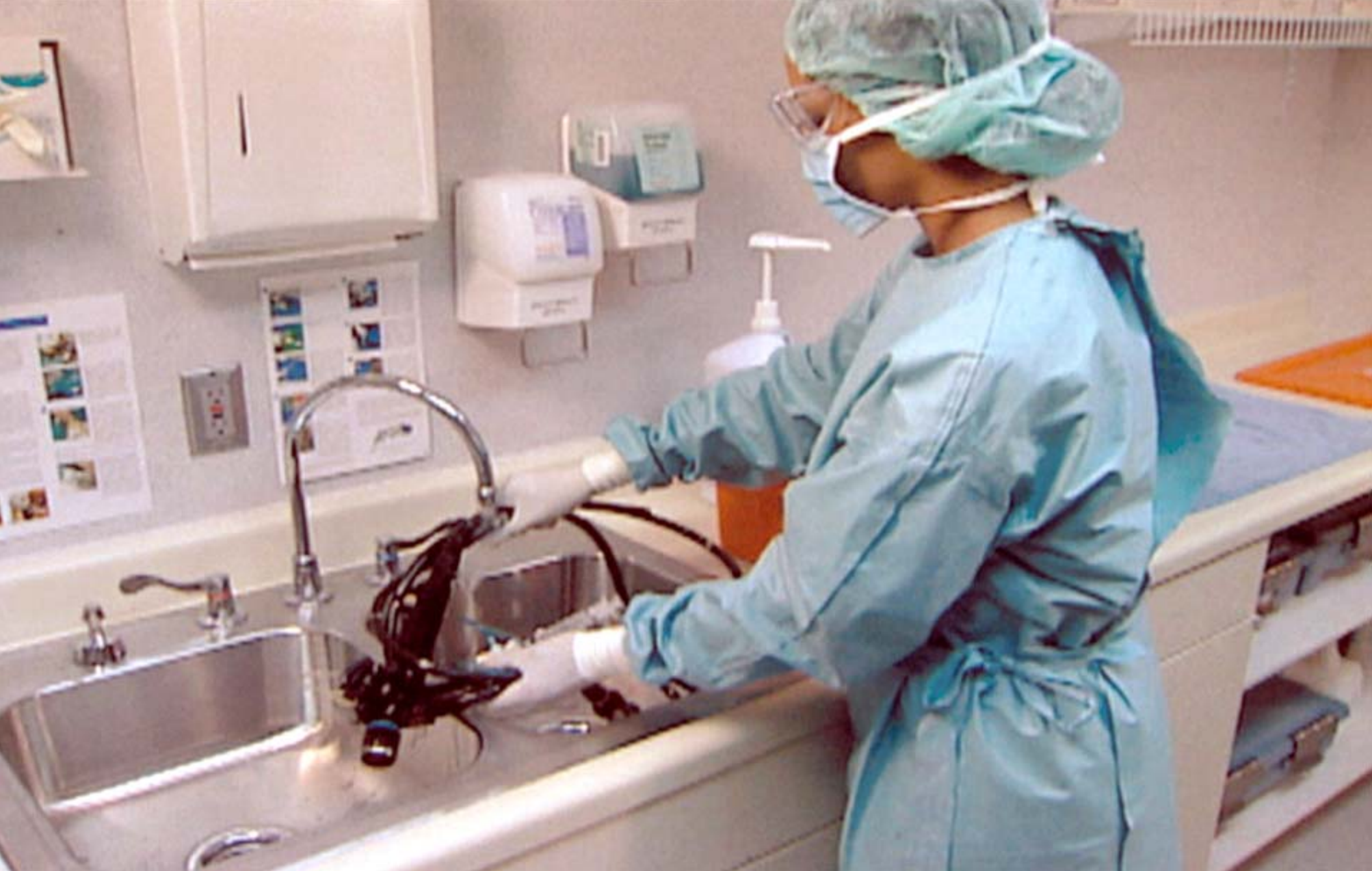
Exposure time per manufacturers' recommendations



# Processing "Semicritical" Patient Care Objects

| | |
|---|---|
| Classification: | Semicritical objects come in contact with mucous membranes or skin that is not intact. |
| Object: | Free of all microorganisms except high numbers of bacterial spores. |
| Level germicidal action: | Kills all microorganisms except high numbers of bacterial spores. |
| Examples: | Respiratory therapy and anesthesia equipment, GI endoscopes, thermometer, etc. |
| Method: | High-level disinfection |

# Semicritical Items

- Endoscopes
- Respiratory therapy equipment
- Anesthesia equipment
- Endocavitary probes
- Tonometers
- Diaphragm fitting rings

# High Level Disinfection of "Semicritical Objects"

**Exposure Time ≥ 12 m-30m, 20°C**

| Germicide | Concentration |
|---|---|
| Glutaraldehyde | ≥ 2.0% |
| Ortho-phthalaldehyde (12 m) | 0.55% |
| Hydrogen peroxide* | 7.5% |
| Hydrogen peroxide and peracetic acid* | 1.0%/0.08% |
| Hydrogen peroxide and peracetic acid* | 7.5%/0.23% |
| Hypochlorite (free chlorine)* | 650-675 ppm |
| Glut and phenol/phenate** | 1.21%/1.93% |

*May cause cosmetic and functional damage; **efficacy not verified

# Processing "Noncritical" Patient Care Objects

| | |
|---|---|
| Classification: | Noncritical objects will not come in contact with mucous membranes or skin that is not intact. |
| Object: | Can be expected to be contaminated with some microorganisms. |
| Level germicidal action: | Kill vegetative bacteria, fungi and lipid viruses. |
| Examples: | Bedpans; crutches; bed rails; EKG leads; bedside tables; walls, floors and furniture. |
| Method: | Low-level disinfection or detergent cleaning |

# Low-Level Disinfection for "Noncritical" Objects

Exposure time ≥ 1 min

| Germicide | Use Concentration |
|---|---|
| Ethyl or isopropyl alcohol | 70-90% |
| Chlorine | 100ppm (1:500 dilution) |
| Phenolic | UD |
| Iodophor | UD |
| Quaternary ammonium | UD |

UD=Manufacturer's recommended use dilution

# Disinfection and Sterilization of Emerging Pathogens

# Disinfection and Sterilization of Emerging Pathogens

- Hepatitis C virus
- *Clostridium difficile*
- *Cryptosporidium*
- *Helicobacter pylori*
- *E.coli* 0157:H7
- Antibiotic-resistant microbes (MDR-TB, VRE, MRSA)
- SARS Coronavirus, avian influenza, norovirus
- Bioterrorism agents (anthrax, plague, smallpox)

# Disinfection and Sterilization of Emerging Pathogens

Standard disinfection and sterilization procedures for patient care equipment are adequate to sterilize or disinfect instruments or devices contaminated with blood and other body fluids from persons infected with emerging pathogens

# Creutzfeldt Jakob Disease (CJD): Disinfection and Sterilization

# Decreasing Order of Resistance of Microorganisms to Disinfectants/Sterilants

Prions

Spores

Mycobacteria

Non-Enveloped Viruses

Fungi

Bacteria

Enveloped Viruses

# Risk Assessment: Patient, Tissue, Device

- Patient
  - Known or suspected CJD or other TSEs
  - Rapidly progressive dementia
  - Familial history of CJD, GSS, FFI
  - History of dura mater transplant, cadaver-derived pituitary hormone injection
- Tissue
  - High risk-brain,  spinal cord, eyes
- Device
  - Critical or semicritical

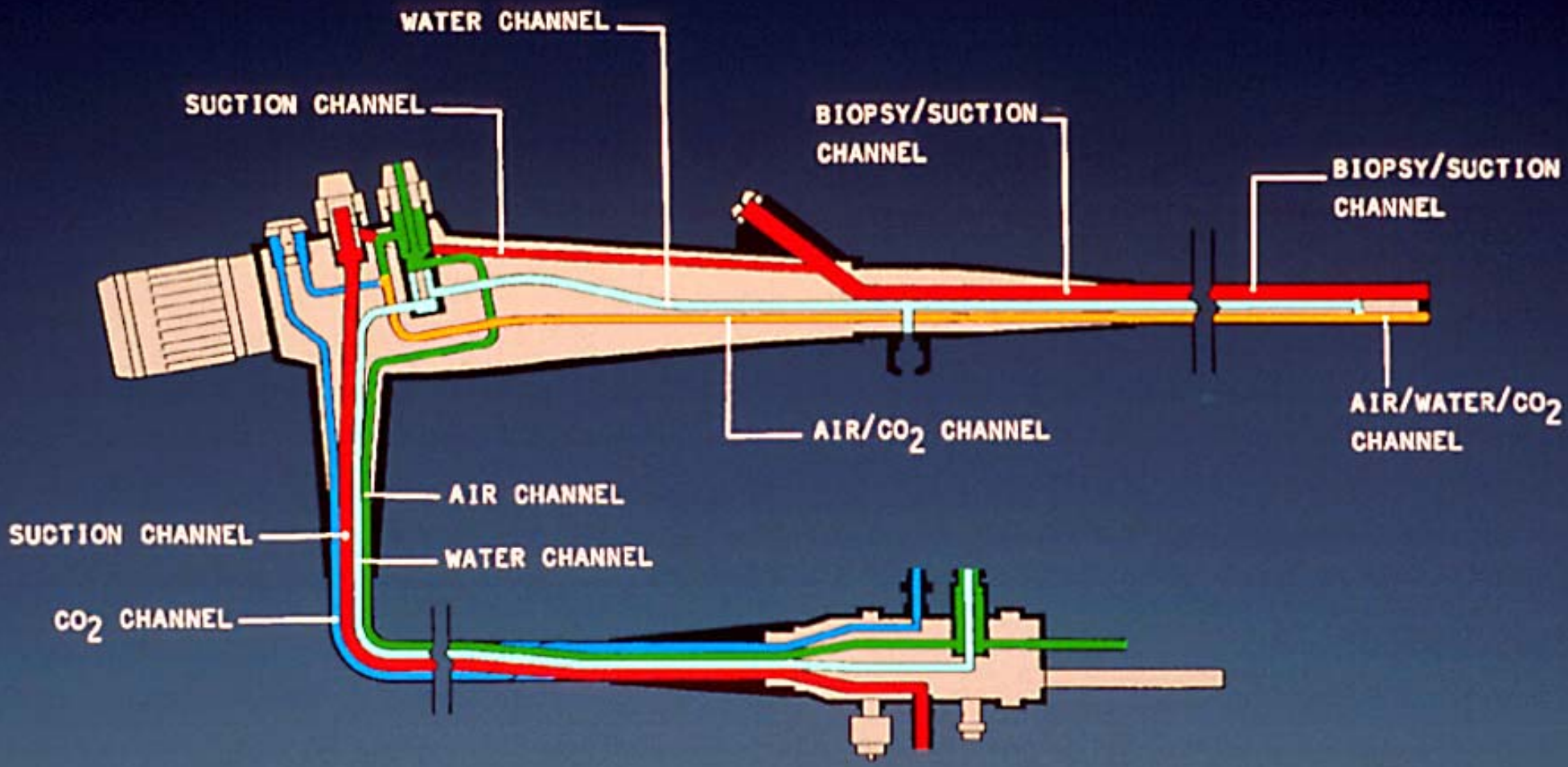
# CJD: Disinfection and Sterilization
## Conclusions

- Critical/SC-cleaning with special prion reprocessing
  - NaOH and steam sterilization (e.g., 1N NaOH 1h, 121°C 30 m)
  - 134°C for 18m (prevacuum)
  - 132°C for 60m (gravity)
- No low temperature sterilization technology effective*
- Noncritical-four disinfectants (e.g., chlorine, Environ LpH) effective (4 log decrease in $LD_{50}$ within 1h)

*VHP reduced infectivity by 4.5 logs (Lancet 2004;364:521)

# Endoscopes/AERS

# ENDOSCOPE CHANNELS



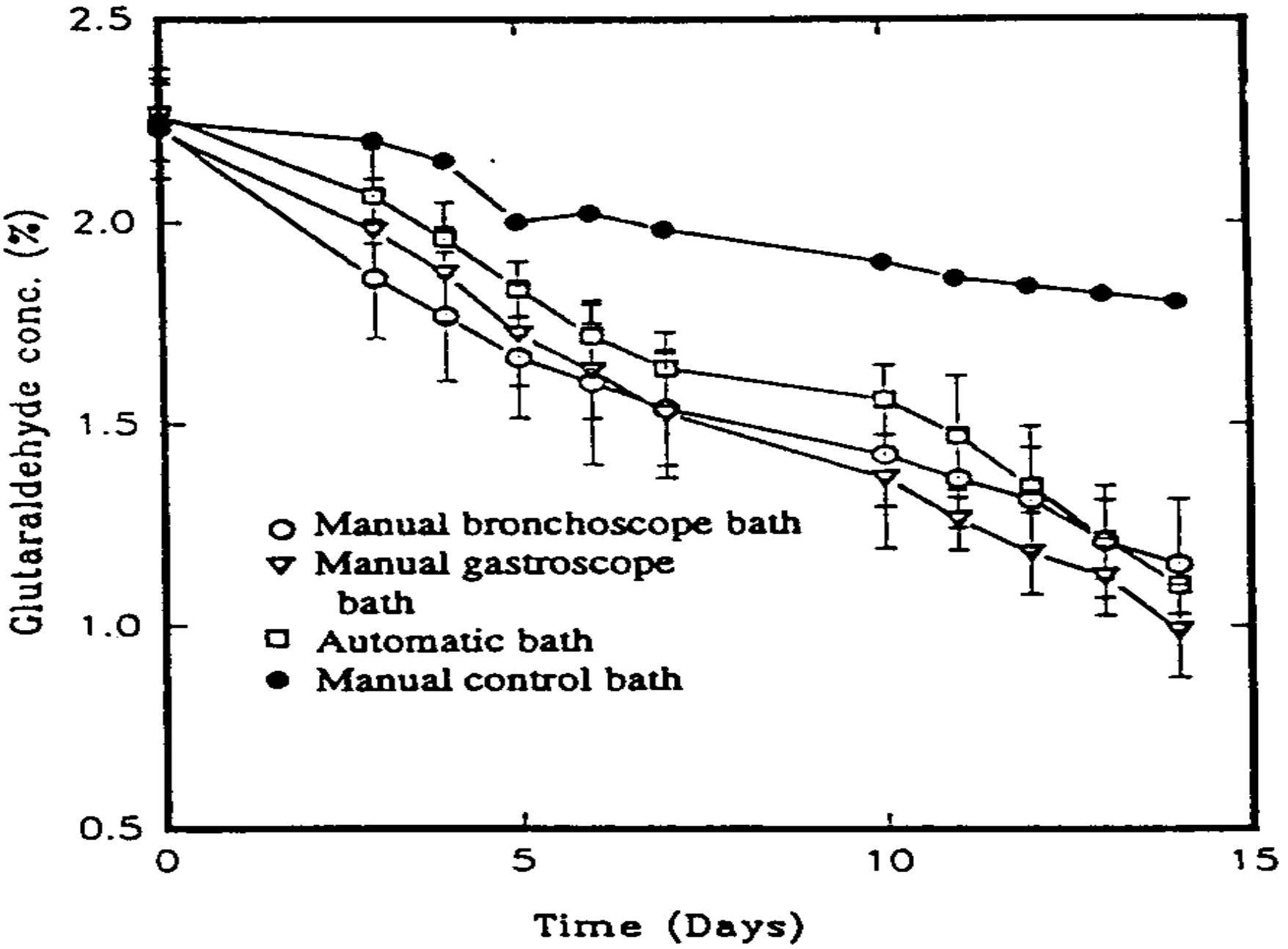
# TRANSMISSION OF INFECTION

- Gastrointestinal endoscopy
  - >300 infections transmitted
  - 70% agents *Salmonella sp.* and *P. aeruginosa*
  - Clinical spectrum ranged from colonization to death (~4%)
- Bronchoscopy
  - 90 infections transmitted
  - *M. tuberculosis*, atypical *Mycobacteria*, *P. aeruginosa*

Spach DH et al Ann Intern Med 1993: 118:117-128 and Weber DJ, Rutala WA Gastroint Dis 2002;87

# ENDOSCOPE DISINFECTION

- CLEAN-mechanically cleaned with water and enzymatic/detergent cleaner
- HLD/STERILIZE-immerse scope and perfuse HLD/sterilant through all channels for at least 12 min
- RINSE-scope and channels rinsed with sterile water, filtered water, or tap water followed by alcohol
- DRY-use forced air to dry insertion tube and channels
- STORE-prevent recontamination


2.5
2.0
1.5
1.0
0.5
Glutaraldehyde conc. (%)
0
5
10
15
Time (Days)
Manual bronchoscope bath
Manual gastroscope bath
Automatic bath
Manual control bath

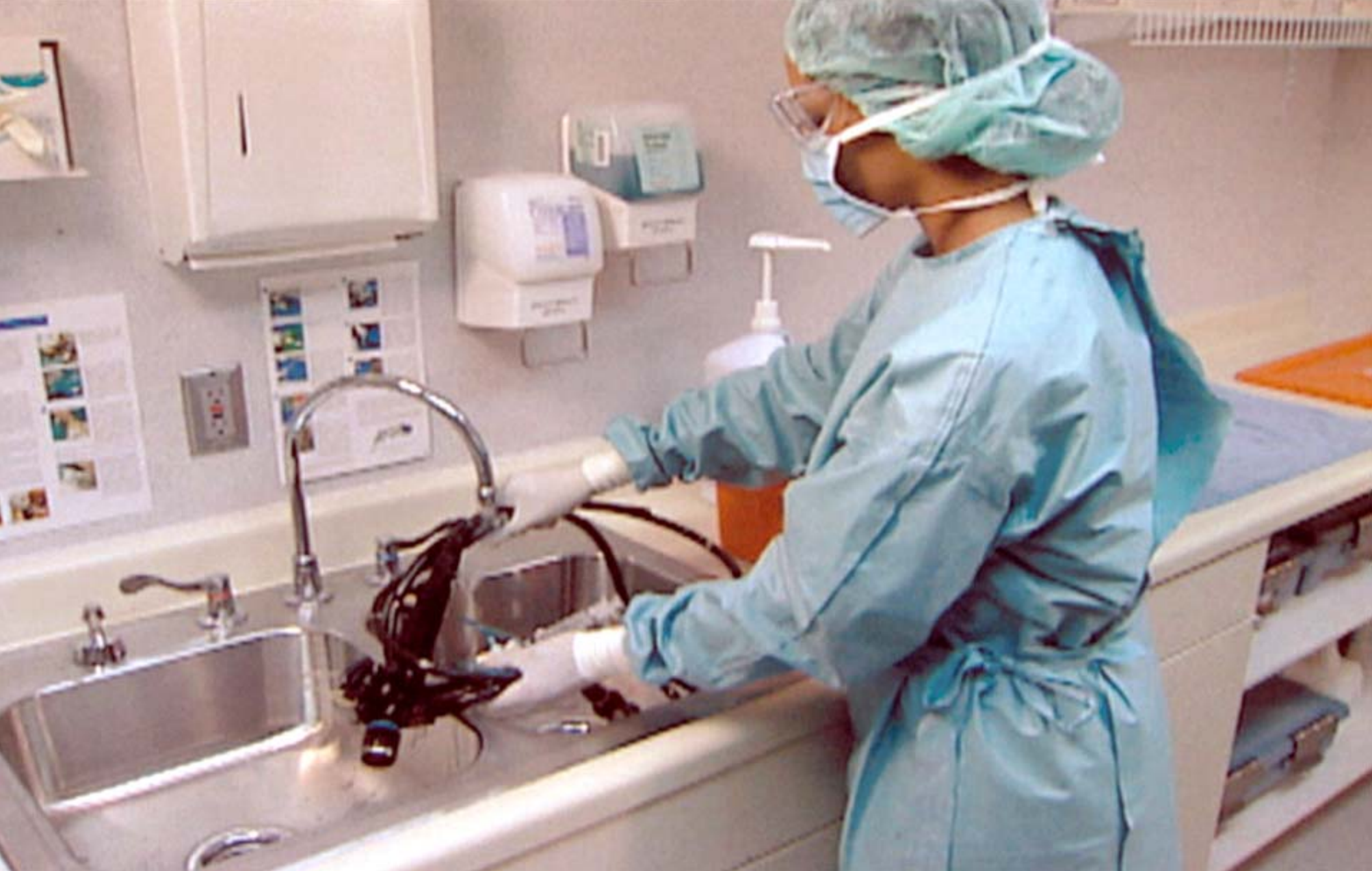
# Minimum Effective Concentration Chemical Sterilant

- Dilution of chemical sterilant occurs during use
- Test strips are available for monitoring MEC
- Test strips for glutaraldehyde monitor 1.5%
- Test strip not used to extend the use-life beyond the expiration date (date test strips when opened)
- Testing frequency based on how frequently the solutions are used (used daily, test at least daily)
- Record results

# Endoscope Safety

- Ensure policies equivalent to guidelines from professional organizations (APIC, SGNA, ASGE);

  policies = practices
- Are the staff who reprocess the endoscope specifically trained in that job?
- Are the staff competency tested at least annually?
- Conduct IC rounds to ensure compliance with policy



# Comparison of Glutaraldehyde and OPA

>2.0% Glutaraldehyde

- HLD: 45 min at 25°C
- Needs activator
- 14 day use life
- 2 year shelf life
- ACGIH ceiling limit, 0.05ppm
- Strong odor
- MEC, 1.5%
- Cost - $10/gallon

0.55% Ortho-phthalaldehyde

- HLD: 12 min at 20°C
- No activator needed
- 14 day use life
- 2 year shelf life
- No ACGIH or OSHA limit
- Weak odor
- MEC, 0.3%
- Cost - $30/gallon

# Ortho-phthalaldehyde (OPA)
## Contraindication for OPA

- Repeated exposure to OPA, following manual reprocessing of urological instruments, may have resulted in hypersensitivity in some patients with a history of bladder cancer undergoing repeated cystoscopy.
- Out of approximately 1 million urological procedures, there have been reports of 24 patients who have experience ‘anaphylaxis-like’ reactions after repeated cystoscopy (typically after 4-9 treatments).
- Risk control measures: residues of OPA minimized; and contraindicated for reprocessing of urological instruments used on patients with history of bladder cancer.

# *Clostridium difficile*

# *C. difficile*

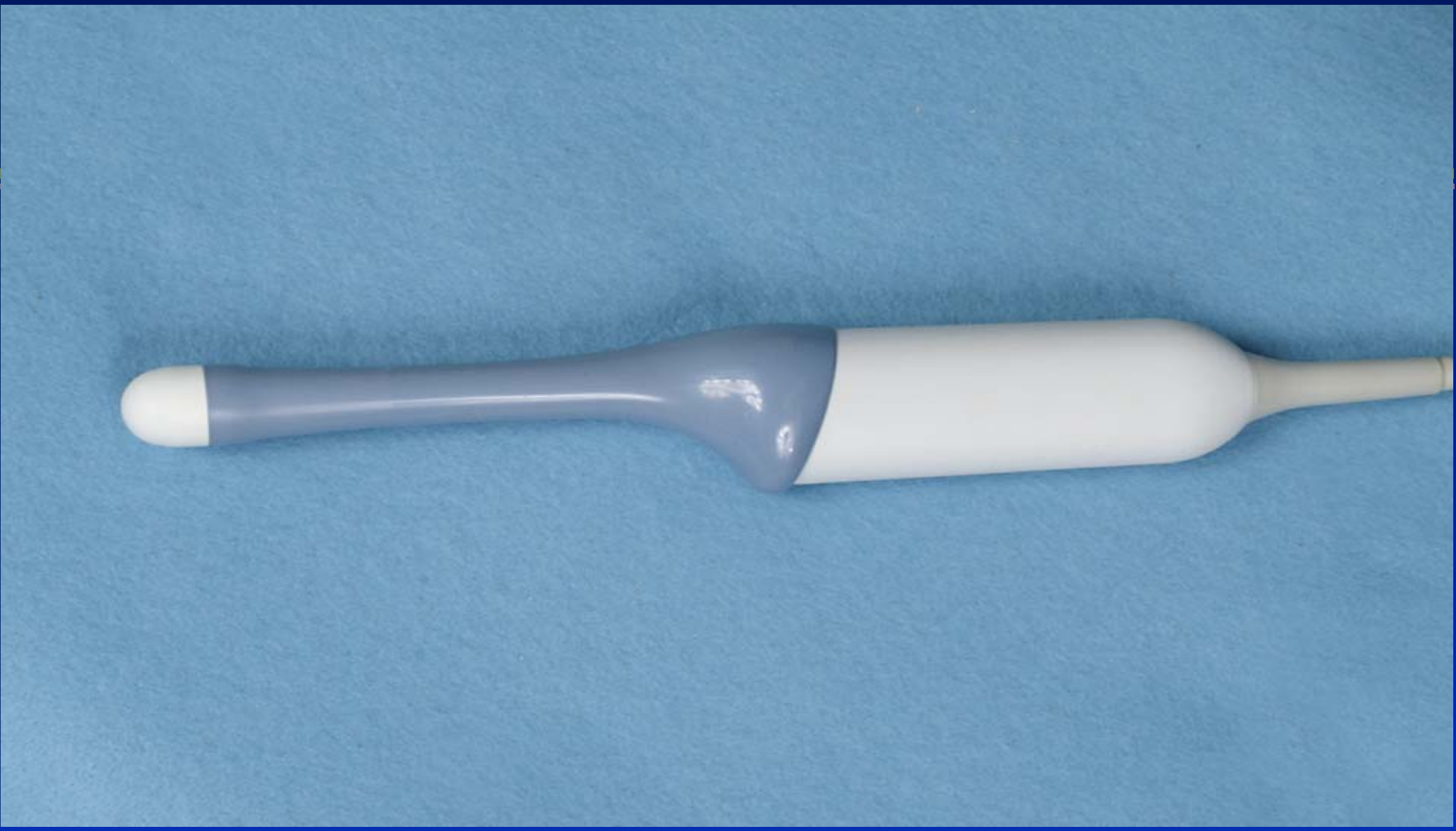
- *C. difficile* is responsible for 15-25% of cases of antibiotic-associated diarrhea and for virtually all cases of antibiotic-associated pseudomembrananous colitis.
- Costs approx $3,669 per case or $1.1 billion per year
- Overall mortality is 10-15%
- Over past 2 years, a new strain appears to be more virulent
- Patients can be contaminated from environmental surfaces, shared instrumentation, hospital personnel hands and infected roommates Clin Microbiol Infect 2001;7:405; Clin Micro Rev 2004;17:863

# Disinfectants and Antiseptics

## *C. difficile* spores at 10 and 20 min, Rutala et al, 2006

- ~4 $\log_{10}$ reduction (3 *C. difficile* strains including BI-9)
  - Clorox, 1:10, ~6,000 ppm chlorine (but not 1:50, ~1,200 ppm)
  - Clorox Clean-up, ~1,910 ppm chlorine
  - Tilex, ~25,000 ppm chlorine
  - Steris 20 sterilant, 0.35% peracetic acid
  - Cidex, 2.4% glutaraldehyde
  - Cidex-OPA, 0.55% OPA
  - Wavicide, 2.65% glutaraldehyde
  - Aldahol, 3.4% glutaraldehyde and 26% alcohol

# Special Instrument Reprocessing Issues



# Endocavitary Probes

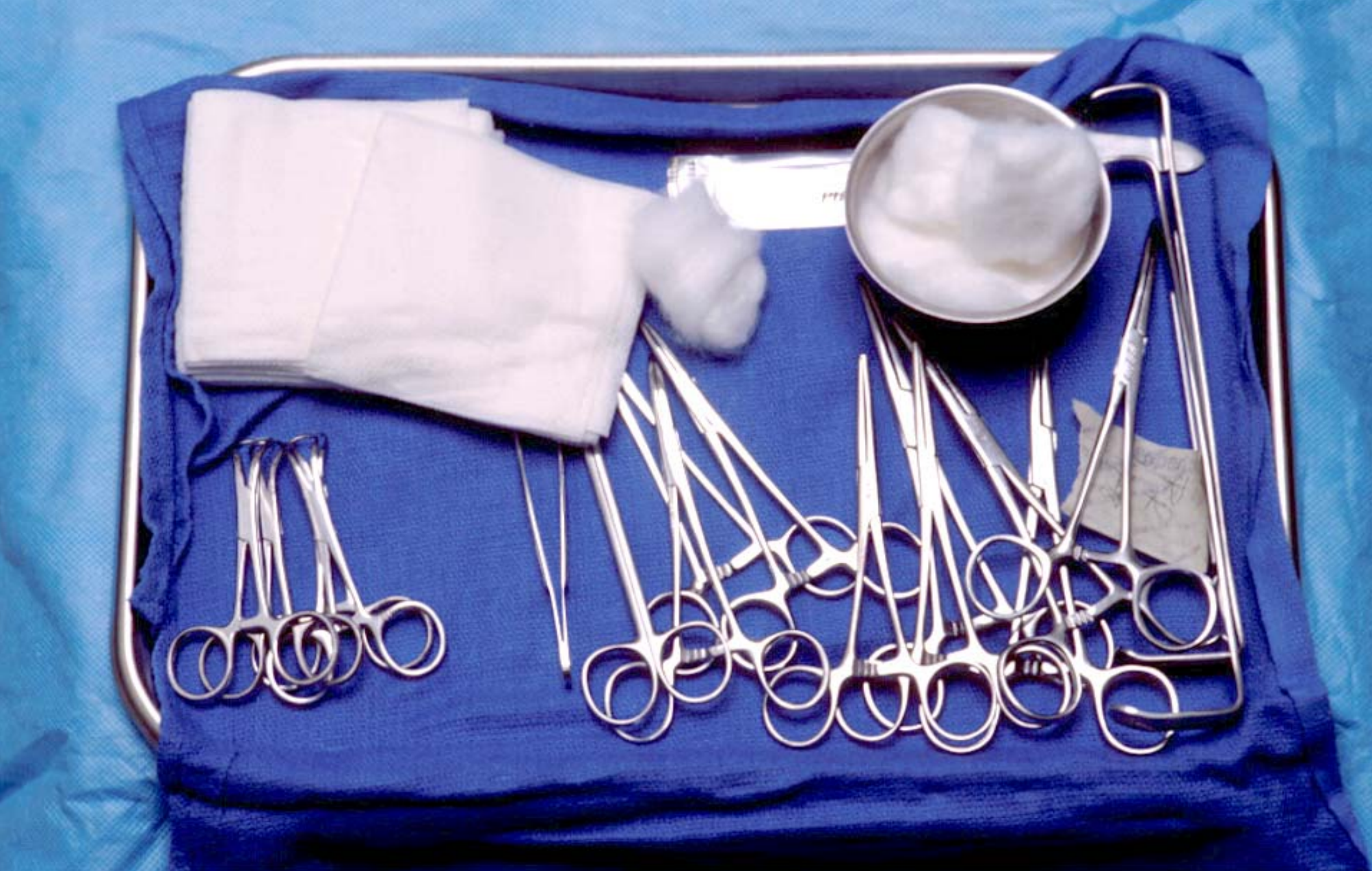
- Probes-Transesophageal echocardiography probes, vaginal/rectal probes used in sonographic scanning
- Probes with contact with mucous membranes are semicritical
- Guideline recommends that a new condom/probe cover should be used to cover the probe for each patient and since covers may fail (1-80%), HLD (semicritical probes) should be performed

# Endocavitary Probe Covers

- Sterile transvaginal probe covers had a very high rate of perforations before use (0%, 25%, 65% perforations from three suppliers)
- A very high rate of perforations in used endovaginal probe covers was found after oocyte retrieval use (75% and 81% from two suppliers) but other investigators found a lower rate of perforations after use of condoms (0.9-2.0%)
- Condoms superior to probe covers for ultrasound probe (1.7% condom, 8.3% leakage for probe covers)

# Sterilization

The complete elimination or destruction of all forms of microbial life and is accomplished in healthcare facilities by either physical or chemical processes



# Steam Sterilization

- Advantages
  - Non-toxic
  - Cycle easy to control and monitor
  - Inexpensive
  - Rapidly microbicidal
  - Least affected by organic/inorganic soils
  - Rapid cycle time
  - Penetrates medical packing, device lumens
- Disadvantages
  - Deleterious for heat labile instruments
  - Potential for burns

# Minimum Steam Sterilization Times

## Time at 132°C in Prevacuum Sterilizer

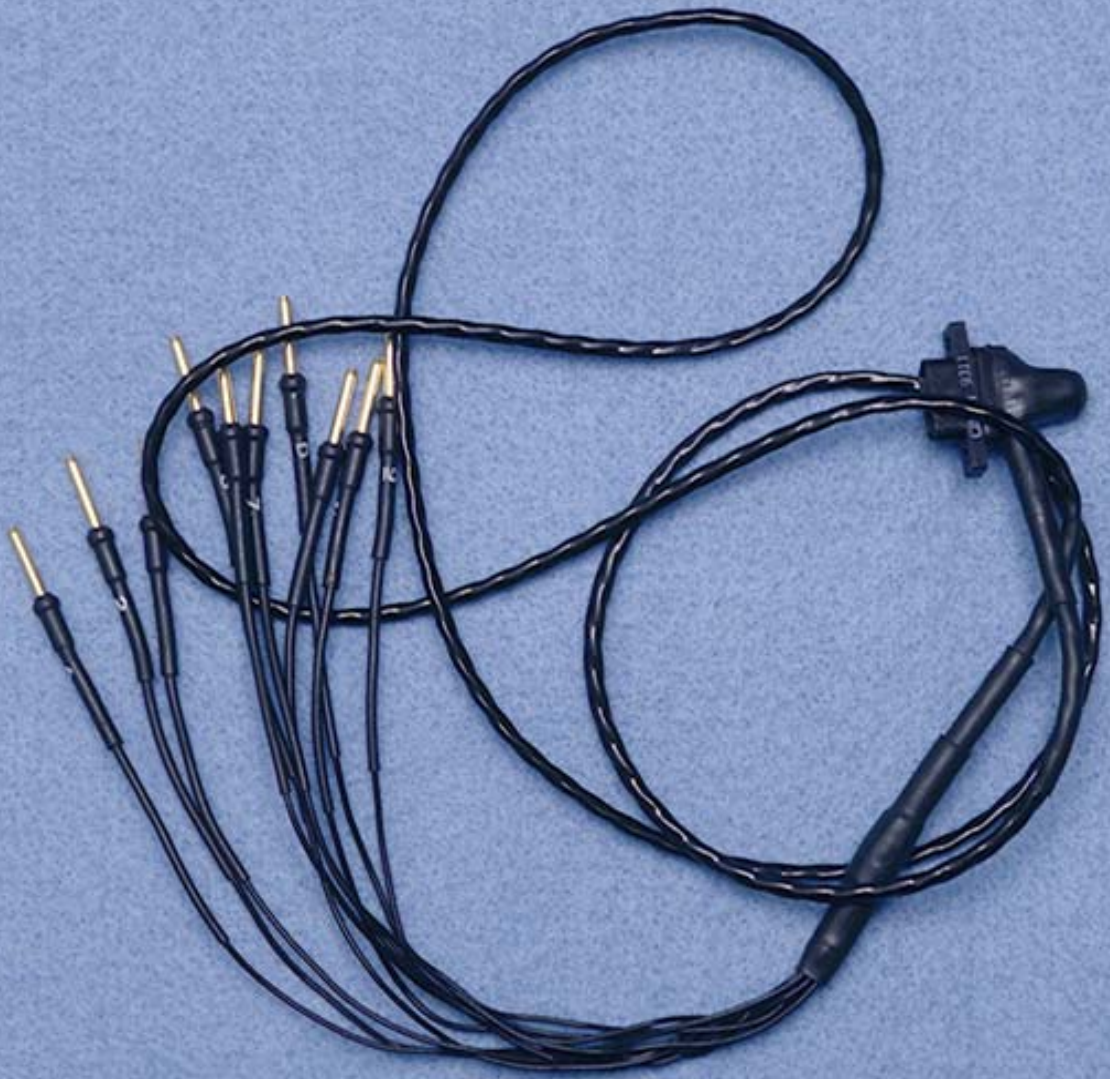
| Item | Minimum exposure | Drying time |
|---|---|---|
| Wrapped instruments | 4 min | 20-30 min |
| Textile packs | 4 min | 5-20 min |

# Flash Sterilization

- Flash originally defined as sterilization of an unwrapped object at 132$^{o}$C for 3 min at 27-28 lbs pressure in gravity
- Flash used for items that must be used immediately
- Acceptable for processing items that cannot be packaged, sterilized and stored before use
- Because of the potential for serious infections, implanted surgical devices should not be flash sterilized unless unavoidable (e.g., orthopedic screws)

# Flash Sterilization

- When flash sterilization is used, certain parameters should be met: item decontaminated; exogenous contamination prevented; sterilizer function monitored by mechanical, chemical, and biological monitors
- Do not used flash sterilization for reasons of convenience, as an alternative to purchasing additional instrument sets, or to save time



# New Trends in Sterilization of Patient Equipment

- Alternatives to ETO-CFC

  ETO-$CO_2$, ETO-HCFC, 100% ETO
- New Low Temperature Sterilization Technology

  Hydrogen Peroxide Gas Plasma

  Peracetic Acid


#7 GAS
#8 GAS

# Ethylene Oxide (ETO)

- Advantages
  - Very effective at killing microorganisms
  - Penetrates medical packaging and many plastics
  - Compatible with most medical materials
  - Cycle easy to control and monitor
- Disadvantages
  - Some states (CA, NY, TX) require ETO emission reduction of 90-99.9%
  - CFC (inert gas that eliminates explosion hazard) banned after 1995
  - Potential hazard to patients and staff
  - Lengthy cycle/aeration time


ASP
STERRAD® 50

# Hydrogen Peroxide Gas Plasma Sterilization

Advantages

- Safe for the environment and health care worker; it leaves no toxic residuals
- Fast - cycle time is 28-73 min and no aeration necessary
- Used for heat and moisture sensitive items since process temperature 50$^{o}$C
- Simple to operate, install, and monitor
- Compatible with most medical devices

# Hydrogen Peroxide Gas Plasma Sterilization

Disadvantages

- Cellulose (paper), linens and liquids cannot be processed
- Sterilization chamber is small, about $3.5ft^3$ to $7.3ft^3$
- Endoscopes or medical devices restrictions based on lumen internal diameter and length (see manufacturer's recommendations)
- Requires synthetic packaging (polypropylene) and special container tray


SYSTEM 1
Processor
START

# Steris System Processor

Advantages

- Rapid cycle time (30-45 min)
- Low temperature (50-55$^{o}$C) liquid immersion sterilization
- Environmental friendly by-products (acetic acid, $O_2$, $H_2O$)
- Fully automated
- No adverse health effects to operators
- Compatible with wide variety of materials and instruments
- Suitable for medical devices such as flexible/rigid scopes
- Simulated-use and clinical trials have demonstrated microbial killing

# Steris System Processor

Disadvantages

- Potential material incompatibility (e.g., aluminum anodized coating becomes dull)
- Used for immersible instruments only
- Biological indicator may not be suitable for routine monitoring
- One scope or a small number of instruments can be processed in a cycle
- More expensive (endoscope repairs, operating costs) than HLD
- Point-of-use system, no long-term storage

# Conclusions

- All sterilization processes effective in killing spores
- Cleaning removes salts and proteins and must precede sterilization
- Failure to clean or ensure exposure of microorganisms to sterilant (e.g. connectors) could affect effectiveness of sterilization process

# Recommendations
## Methods of Sterilization

- Steam is preferred for critical items not damaged by heat
- Follow the operating parameters recommended by the manufacturer
- Use low temperature sterilization technologies for reprocessing critical items damaged by heat
- Use immediately critical items that have been sterilized by peracetic acid immersion process (no long term storage)

# Conclusions

- When properly used, disinfection and sterilization can ensure the safe use of invasive and non-invasive medical devices.
- Method of disinfection and sterilization depends on the intended use of the medical device
- Cleaning should always precede high-level disinfection and sterilization
- Current disinfection and sterilization guidelines must be strictly followed.

# Disinfection and Sterilization
## New CDC Guidelines

- **Pr**ovide overview
- Discuss processes and products
- Emerging pathogens and prions
- Special instrument reprocessing issues

disinfectionandsterilization.org

# Thank you

# References


- Rutala WA, Weber DJ. CJD: Recommendations for disinfection and sterilization. Clin Inf Dis 2001;32:1348
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