Disinfection and Sterilization Guidelines – What You Need To Know

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Disinfection and Sterilization Guidelines: What You Need to Know

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Disclosure: Clorox and ASP

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Disinfection and Sterilization

- Provide overview of disinfection and sterilization recommendations
- Review significant revisions
  - Surface disinfection
  - Emerging pathogens (e.g., *C. difficile*) and prions (CJD)
  - Endoscope reprocessing
  - Semicritical equipment: endocavitary probes, applanation tonometers

disinfectionandsterilization.org

Disinfection and Sterilization in Healthcare Facilities

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

- Overview
  - Last Centers for Disease Control and Prevention guideline in 1985
  - 274 pages (>130 pages preamble, 21 pages recommendations, glossary of terms, tables/figures, >1100 references)
  - Evidence-based guideline
  - Cleared by HICPAC February 2003; delayed by FDA
  - Publication expected in late July 2007

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

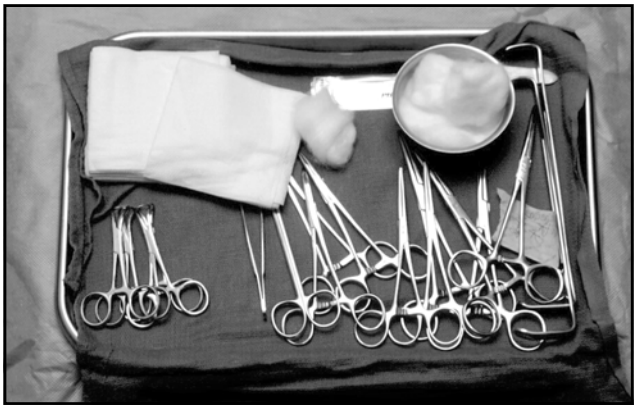
Disinfection and Sterilization

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.

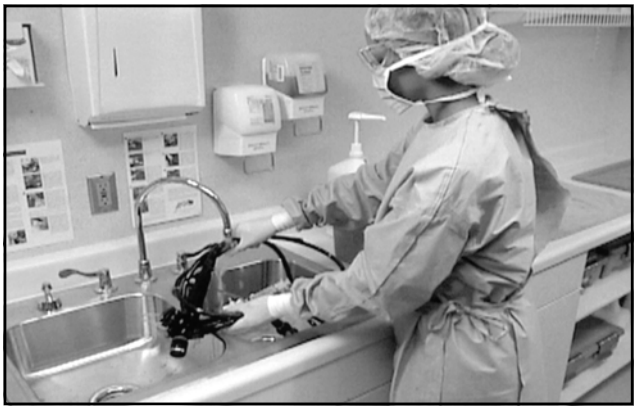
Critical Objects

- λ Surgical instruments
- λ Cardiac catheters
- λ 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%)

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, endocavitary probes, etc.
Method:	High-level disinfection

Semicritical Items

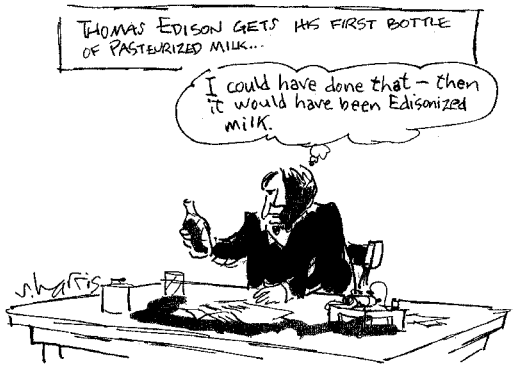
- Endoscopes
- Respiratory therapy equipment
- Anesthesia equipment
- Endocavitary probes
- Tonometers
- Diaphragm fitting rings

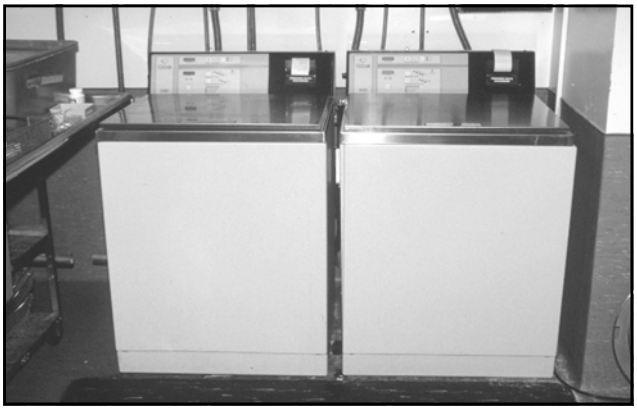
High Level Disinfection of "Semicritical Objects"

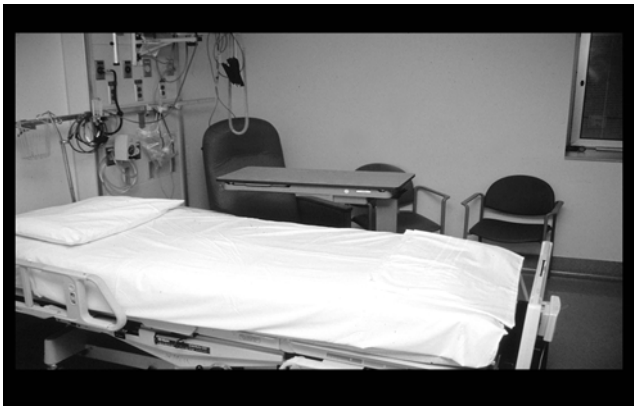
Exposure Time ≥ 12 m-30m (US), 20°C

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 for housekeeping surfaces)

Low-Level Disinfection for "Noncritical" Objects

Exposure time ≥ 1 min

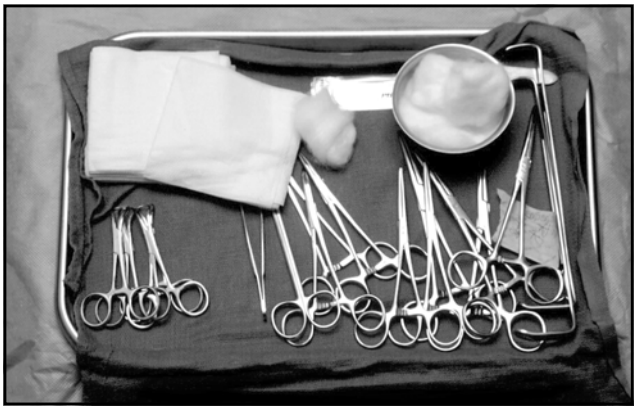
Germicide	Use Concentration
Ethyl or isopropyl alcohol	70-90%
Chlorine	100ppm (1:500 dilution)
Phenolic	UD
Iodophor	UD
Quaternary ammonium	UD

UD=Manufacturer's recommended use dilution

Methods in Sterilization

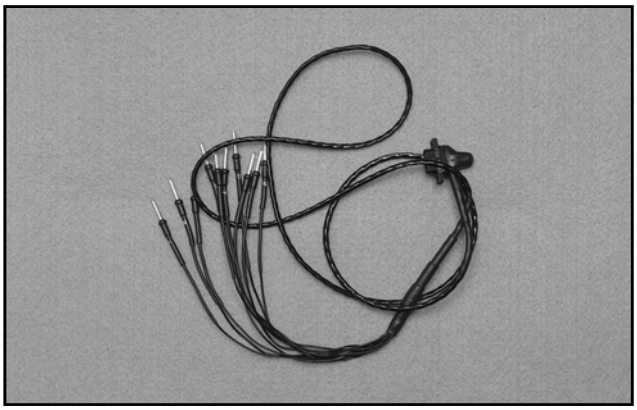
Sterilization

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

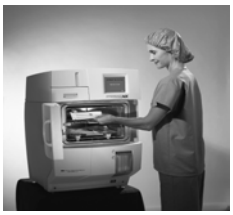


New Trends in Sterilization of Patient Equipment

- Alternatives to ETO-CFC
  ETO-CO_2, ETO-HCFC, 100% ETO
- New Low Temperature Sterilization Technology
  Hydrogen Peroxide Gas Plasma
  Peracetic Acid
  Ozone

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



Hydrogen Peroxide Gas Plasma Sterilization

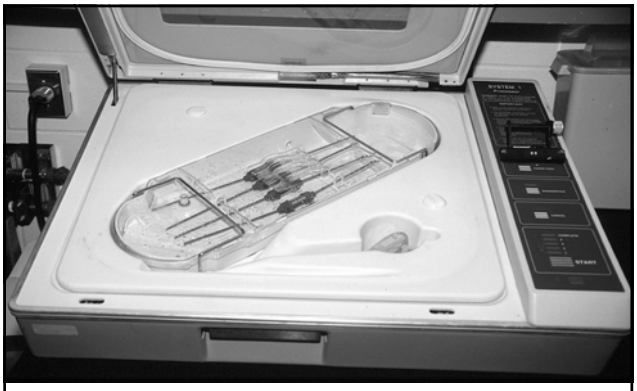
Advantages

- Safe for the environment and health care worker; it leaves no toxic residuals
- Fast - cycle time is 28-52 min and no aeration necessary
- Used for heat and moisture sensitive items since process temperature 50ºC
- 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); expanded claims with NX
- Requires synthetic packaging (polypropylene) and special container tray



Steris System Processor

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

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

Recommendations
Methods of Sterilization

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

Flash Sterilization

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

Flash Sterilization

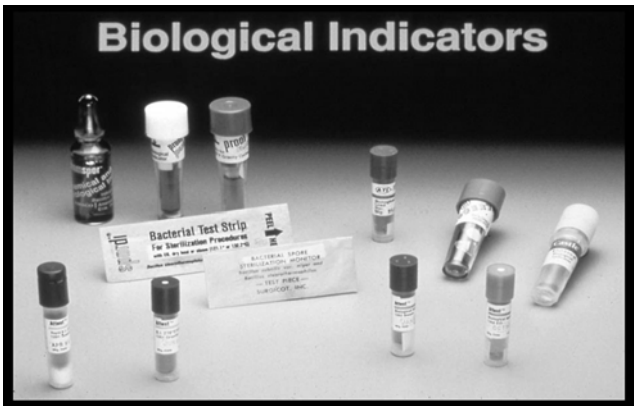
- When flash sterilization is used, certain parameters should be met: item decontaminated; exogenous contamination prevented; sterilizer function monitored by physical, chemical, and biological monitors
- Do not used flash sterilization for reasons of convenience, as an alternative to purchasing additional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

Sterilization Practices

Sterilization Monitoring

Sterilization monitored routinely by combination of physical, chemical, and biological parameters

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



Biological Monitors

- Steam - *Geobacillus stearothermophilus*
- Dry heat - *B. atrophaeus (formerly B. subtilis)*
- ETO - *B. atrophaeus*
- New low temperature sterilization technologies
  Plasma sterilization (Sterrad) - *G. stearothermophilus*
  Peracetic acid - *G. stearothermophilus*

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 used with a method other than steam, treat as non-sterile all items that have been processed in that sterilizer, dating back to last negative biological indicator.

Recommendations
Storage of Sterile Items

- Sterile storage area should be well-ventilated area that provides protection against dust, moisture, and temperature and humidity extremes.
- Sterile items should be stored so that packaging is not compromised
- Sterilized items should be labeled with a load number that indicates the sterilizer used, the cycle or load number, the date of sterilization, and the expiration date (if applicable)

Recommendations
Storage of Sterile Items

- Event-related shelf life recognizes that the product remains sterile until an event causes it to become contaminated (e.g., tear, wetness). Packages should be evaluated before use for lose of integrity.
- Time-related shelf life (less common) considers items remain sterile for varying periods depending on the type of material used to wrap the item/tray. Once the expiration date is exceeded the pack should be reprocessed.

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

Disinfection and Sterilization

- Provide overview of disinfection and sterilization recommendations
- Review significant revisions
  - Surface disinfection
  - Emerging pathogens (e.g., *C. difficile*) and prions (CJD)
  - Endoscope reprocessing
  - Semicritical equipment: endocavitary probes, applanation tonometers

Surface Disinfection
Noncritical Patient Care CDC, 2007

- Disinfecting Noncritical Patient-Care Items
  - Process noncritical patient-care equipment with a EPA-registered disinfectant at the proper use dilution and a contact time of at least 1 min. *Category IB*
  - Ensure that the frequency for disinfecting noncritical patient-care surfaces be done minimally when visibly soiled and on a regular basis (such as after each patient use or once daily or once weekly). *Category IB*

Surface Disinfection
Environmental Surfaces CDC, 2007

- Disinfecting Environmental Surfaces in HCF
  - Disinfect (or clean) housekeeping surfaces (e.g., floors, tabletops) on a regular basis (e.g., daily, three times per week), when spills occur, and when these surfaces are visibly soiled. *Category IB*
  - Use disinfectant for housekeeping purposes where: uncertainty exists as to the nature of the soil on the surfaces (blood vs dirt); or where uncertainty exists regarding the presence of multi-drug resistant organisms on such surfaces. *Category II*

Clostridium difficile

Environmental Contamination
C. difficile

- 25% (117/466) of cultures positive (<10 CFU) for *C. difficile*. >90% of sites positive with incontinent patients. Samore et al. Am J Med 1996;100:32.
- 31.4% of environmental cultures positive for *C. difficile*. Kaatz et al. Am J Epid 1988;127:1289.
- 9.3% (85/910) of environmental cultures positive (floors, toilets, toilet seats) for *C. difficile*. Kim et al. J Inf Dis 1981;143:42.
- 29% (62/216) environmental samples were positive for *C. difficile*. 8% (7/88) culture-negative patient, 29% (11/38) positive cultures in rooms occupied by asymptomatic patients and 49% (44/90) in rooms with patients who had CDAD. NEJM 1989;320:204
- 10% (110/1086) environmental samples were positive for *C. difficile* in case-associated areas and 2.5% (14/489) in areas with no known cases. Fekety et al. Am J Med 1981;70:907.

Role of the Environment
C. difficile

- The presence of *C. difficile* on the hands correlated with the density of environmental contamination. Samore et al. Am J Med 1996;100:32.
  - 0-25% environmental sites positive-0% hand cultures positive
  - 26-50% environmental sites positive-8% hand cultures positive
  - >50% environmental sites positive-36% hand cultures positive
- 59% of 35 HCWs were *C. difficile* positive after direct contact with culture-positive patients.
- *C. difficile* incidence data correlated significantly with the prevalence of environmental *C. difficile*. Fawley et al. Epid Infect 2001;126:343.
- Environmental contamination does not play a major role in nosocomial CDAD in some endemic situations. Cohen et al. Clin Infect Dis 1997;24:889.

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

Control Measures
C. difficile

- Handwashing (soap and water) , contact precautions, and meticulous environmental cleaning (disinfect all surfaces) with an EPA-registered disinfectant should be effective in preventing the spread of the organism. McFarland et al. NEJM 1989;320:204.
- In units with high endemic *C. difficile* infection rates or in an outbreak setting, use dilute solutions of 5.25-6.15% sodium hypochlorite (e.g., 1:10 dilution of bleach) for routine disinfection. (Category II)
- For semicritical equipment, glutaraldehyde (20m), OPA (12m) and peracetic acid (12m) reliably kills *C. difficile* spores using normal exposure times

Adenovirus 8
A Common Cause of Epidemic Keratoconjunctivitis

Adenovirus 8

- Adenovirus is extremely hardy when deposited on environmental surfaces and may be recovered from plastic and metal surfaces for more than 30 days
- Elimination of adenovirus from inanimate surfaces and ophthalmic instruments is essential in preventing outbreaks of epidemic keratoconjunctivitis
- Unfortunately, no reports that validate CDC recommendations for disinfecting tonometer tips. CDC. MMWR 1985; 34:533.

CDC, 1985

- Applanation tonometers-Soap and water cleaning and then disinfected by soaking them for 5 to 10 minutes in a solution containing either:
  - 5,000 chlorine (~1:10 household bleach)
  - 3% hydrogen peroxide
  - 70% ethyl alcohol
  - 70% isopropyl alcohol

Disinfectants and Antiseptics

Adeno 8 at 1 and 5 min, Rutala et al. AAC, April 2006

- Ineffective <2 $\log_{10}$ reduction
  - Bactoshield (4% CHG)
  - Vesphene (phenolic)
  - 70% isopropyl alcohol
  - 3% hydrogen peroxide
  - TBQ (0.06% QUAT)
  - Novaplus (10% povidone iodine)
  - Soft 'N Sure (0.5% triclosan)
  - Acute-Kare (1% chloroxylenol)
  - Sterilox (218 and 695 ppm chlorine)
  - Dettol (4.8% chloroxylenol)
  - Accel TB (0.5% accelerated hydrogen peroxide)
  - Microcyn (~80 ppm chlorine)

Disinfectants and Antiseptics

Adeno 8 at 1 and 5 min, Rutala et al. AAC, April 2006

- ~4 $\log_{10}$ reduction
  - Clorox, 1:10, ~6,000 ppm chlorine (but not 1:50)
  - Clorox Clean-up, ~1,910 ppm chlorine
  - Clorox disinfecting spray (65% ethanol, 0.6% Quat)
  - Steris 20 sterilant, 0.35% peracetic acid
  - Ethanol, 70%
  - Lysol disinfecting spray (79.6% ethanol, 0.1% Quat)
  - Cidex, 2.4% glutaraldehyde
  - Cidex-OPA, 0.55% OPA
  - Wavicide, 2.65% glutaraldehyde

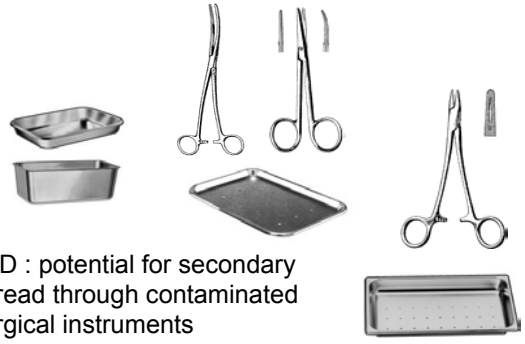
CDC Guidelines

- CDC, 1985. Applanation tonometers-soap and water cleaning and then disinfected by soaking them for 5 to 10 minutes in a solution containing either:
  - 5,000 chlorine
  - 3% hydrogen peroxide
  - 70% ethyl alcohol
  - 70% isopropyl alcohol
- CDC, 2007. Wipe clean tonometer tips and then disinfect them by immersing for 5-10 minutes in either 5000 ppm chlorine or 70% ethyl alcohol. Category II.
- These results emphasize the proper selection of disinfectants for use in disinfecting semicritical items (e.g., applanation tonometers)

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



CJD : potential for secondary spread through contaminated surgical instruments

Risk Assessment for Special Prion Reprocessing: Patient, Tissue, Device

- High-Risk 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
- High-Risk Tissue
  - Brain, spinal cord, eyes
- High-Risk Device
  - Critical or semicritical

CJD: Disinfection and Sterilization
Conclusions

- Critical/Semicritical-devices contaminated with high-risk tissue from high-risk patients requires 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)

Inactivation of Prions
Recent Studies

- Yan et al. Infect Control Hosp Epidemiol 2004;25:280.
  - Enzymatic cleaner (EC)-no effect
- Fichet et al. Lancet 2004;364:521.
  - Phenolic (Environ LpH), alkaline cleaner (AC), EC+VHP-effective
- Baier et al. J Hosp Infect 2004;57:80. AC-effective
- Lemmer et al. J Gen Virol 2004;85:3805.
  - SDS/NaOH, AC, 0.2% PA, 5% SDS-effective (in vitro)
- Jackson et al. J Gen Virol 2005;86:869. E (Pronase, PK)-effective
- Race R and Raymond G. J Virol 2004;78:2164.
  - Environ LpH-effective

Endoscopes/AERS

GI ENDOSCOPES AND BRONCHOSCOPES

- Widely used diagnostic and therapeutic procedure
- Endoscope contamination during use (GI 10^9 in/10^5 out)
- Semicritical items require high-level disinfection minimally
- Inappropriate cleaning and disinfection has lead to cross-transmission
- In the inanimate environment, although the incidence remains very low, endoscopes represent a risk of disease transmission

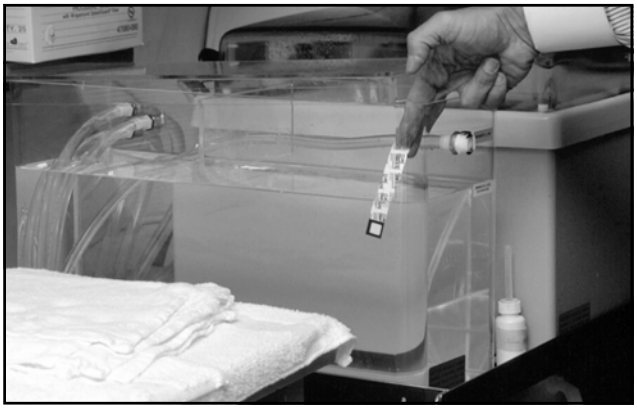
TRANSMISSION OF INFECTION

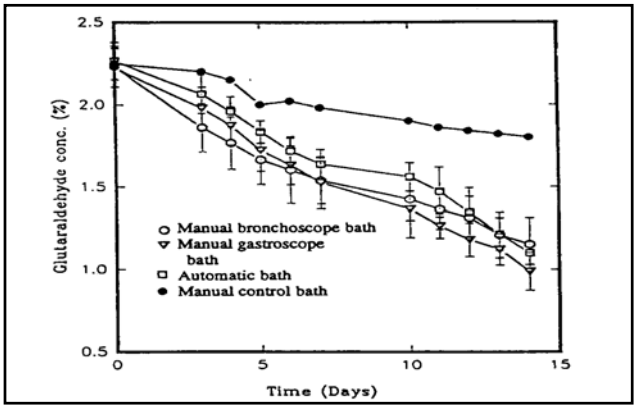
- Gastrointestinal endoscopy
  - >300 infections transmitted
  - 70% agents *Salmonella sp.* and *P. aeruginosa*
  - Clinical spectrum ranged from colonization to death (~4%)
- Bronchoscopy
  - 90 infections transmitted
  - *M. tuberculosis*, atypical *Mycobacteria*, *P. aeruginosa*

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

ENDOSCOPE DISINFECTION

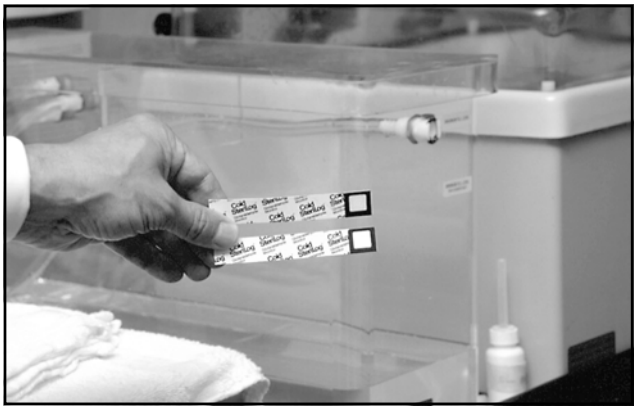
- CLEAN-mechanically cleaned with water and enzymatic cleaner
- HLD/STERILIZE-immerse scope and perfuse HLD/sterilant through all channels for at least 12 min
- RINSE-scope and channels rinsed with sterile water, filtered water, or tap water followed by alcohol
- DRY-use forced air to dry insertion tube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

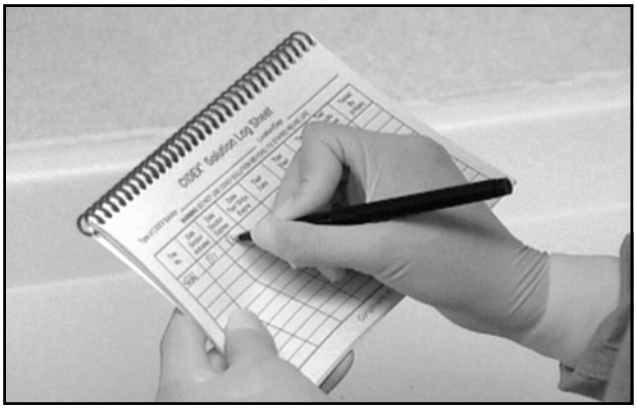




Minimum Effective Concentration Chemical Sterilant

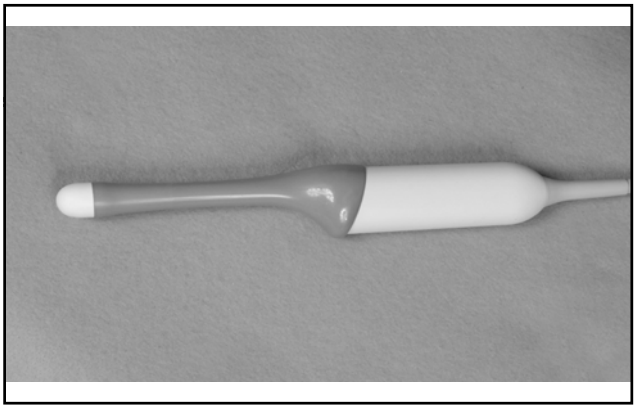
- Dilution of chemical sterilant occurs during use
- Test strips are available for monitoring MEC
- Test strips for glutaraldehyde monitor 1.5%
- Test strip not used to extend the use-life beyond the expiration date (date test strips when opened)
- Testing frequency based on how frequently the solutions are used. Check solution each day of use (or more frequently) using the appropriate indicator.
- Record results





ENDOSCOPE SAFETY

- Ensure protocols equivalent to guidelines from professional organizations (APIC, SGNA, ASGE)
- 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
- Perform microbiologic testing of the endoscope or rinse water-no recommendation (unresolved issue)



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

Rinse Recommendations for Semicritical Devices

- Use sterile water, filtered water or tapwater followed by an alcohol rinse for semicritical equipment that contact mucous membranes of the upper respiratory tract (e.g., nose pharynx, esophagus). *Category II*
- No recommendation to use sterile or filtered water rather than tapwater for rinsing semicritical equipment that will have contact with the mucous membranes of the rectum (rectal probes) or vagina (vaginal probes)

Reuse of Single Use Devices

FDA Developments

- August 2000, FDA issued final SUD Enforcement Guidance. Hospitals and TPR regulated the same as original equipment manufacturer (OEM).
- A device labeled for single-use only that is reprocessed is considered as a new device. **Hospital is considered the manufacturer.**
- **As a new device, all federal controls regarding the manufacture and marketing of the device apply.**

USA Hospital's Options

- Option 1-Comply with enforcement guidance (August 14, 2000) and continue to reprocess SUDs
- Option 2-Use Third Party Reprocessor (premarket requirements new for TPR as they have been using non-premarket requirements)
- Option 3-avoid reuse of SUDs

Recommendations
Quality Control

- Provide comprehensive and intensive training for all staff assigned to reprocess medical/surgical instruments
- To achieve and maintain competency, staff should:
  - hands-on training
  - all work supervised until competency is documented
  - competency testing should be conducted at commencement of employment and regularly
  - review written reprocessing instructions to ensure compliance
  - Conduct infection control rounds in high-risk areas (GI)

Disinfection and Sterilization

- Provide overview of disinfection and sterilization recommendations
- Review significant revisions
  - Surface disinfection
  - Emerging pathogens and prions
  - Endoscope reprocessing
  - Semicritical equipment: endocavitary probes, applanation tonometers

Thank you

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